NICE National Institute for Health and Care Excellence

Supporting documents for

GID-HTE10030 Digital technologies to support self-management of COPD: early value assessment

Medical Technologies Advisory Committee (MTAC)

This product was selected for early value assessment in 2023. Clinical and economic evidence has been submitted to NICE by the company, and an external assessment centre report has been completed.

This pack presents the information required for MTAC to make draft recommendations on this topic. The consultation period for these draft recommendations will take place between 23 September 2024 and 4 October 2024.

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Papers included in pack:

1. Front sheet – check which go in separately and which need to be combined into supporting docs
2. External assessment report (EAR)
3. Assessment report overview (ARO)
4. Assessment report addendum

Document cover sheet

Assessment report: Digital technologies for self-management of chronic obstructive pulmonary disease

EAG team: Hayden Holmes, Lavinia Ferrante di Ruffano, Robert Malcolm, Chris Bartlett, Rebecca Naylor, Emma Carr, Kate Lanyi, Anne Littlewood, Emma Bishop, Ben Hyde

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Economic evidence reviewer: Hayden Holmes, Robert Malcolm, Chris Bartlett, Rebecca Naylor

EAG sign-off: Hayden Holmes

Version number	Brief description of changes	Author/reviewer (e.g. J Smith)	Date (DD/MM/YY)	Date sent to NICE (if applicable)
1.0	Draft report submitted to NICE	Hayden Holmes Lavinia Ferrante di Ruffano Robert Malcolm Chris Bartlett Emma Carr Rebecca Naylor Kate Lanyi Anne Littlewood Emma Bishop Ben Hyde	21/03/2024	21/03/2024
2.0	Final report submitted to NICE	Hayden Holmes Lavinia Ferrante di Ruffano Robert Malcolm Chris Bartlett Emma Carr Rebecca Naylor Kate Lanyi	18/04/2024	18/04/2024

		Anne Littlewood Emma Bishop Ben Hyde		
3.0	Respones to company comments	Hayden Holmes Lavinia Ferrante di Ruffano Robert Malcolm Chris Bartlett Emma Carr Rebecca Naylor Kate Lanyi Anne Littlewood Emma Bishop Ben Hyde	03/05/2024	03/05/2024
4.0	Respones to company comments	Hayden Holmes Lavinia Ferrante di Ruffano Robert Malcolm Chris Bartlett Emma Carr Rebecca Naylor Kate Lanyi Anne Littlewood Emma Bishop Ben Hyde	07/05/2024	07/05/2024
5.0	Post committee meeting comments	Hayden Holmes Lavinia Ferrante di Ruffano Robert Malcolm Chris Bartlett Emma Carr Rebecca Naylor Kate Lanyi Anne Littlewood Emma Bishop Ben Hyde	24/05/2024	24/05/2024
6.0	Post consultation comments	Hayden Holmes	16/07/2024	16/07/2024

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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

[GID-HTE10030] - Digital Supported Self-Management Technologies for Adults with Chronic Obstructive Pulmonary Disease

External Assessment Group report

Produced by: York Health Economics Consortium (YHEC)

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Date completed: 24/05/2024

Contains confidential information: Yes

Number of attached appendices: 4

Purpose of the assessment report

The purpose of this External assessment group (EAG) report is to review the evidence currently available for included technologies and advise what further evidence should be collected to help inform decisions on whether the technologies should be widely adopted in the NHS. The report may also include additional analysis of the submitted evidence or new clinical and/or economic evidence. 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 early value assessment.

Declared interests of the authors

YHEC was previously involved in the MTEP evaluation of myCOPD as the external assessment group for NICE. YHEC had also produced an early NIA case study report on myCOPD prior to this.

YHEC is currently undertaking a health economic evaluation for Lenus for their digital technology in a COPD population.

The team involved in producing this assessment report has was not involved in any of the work listed above.

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.

Acknowledgements

Clinical experts provided input into the EVA:

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Rob Hallifax, Locum Consultant in Respiratory Medicine, Oxford University NHS Foundation Trust

Company representatives were contacted to clarify information related to the evidence that had been submitted:

Claire Donnelly, Chief Strategy Officer, my mhealth

Emma Chaplin, Clinical Lead, University Hospitals of Leicester NHS trust

Jeff Spitz, Director, Growth and Business Development, Wellinks

Jim McNair, Business Development Director, Lenus Health Ltd.

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Responsibility for report

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

Contents

Abbreviations

Term	Definition
AE	Adverse event
AO	Adverse outcome
AECOPD	Acute exacerbations of COPD
ANCOVA	Analysis of covariance
BCKQ	Bristol COPD Knowledge Questionnaire
BL	Baseline
CAT	COPD assessment test
CCG	Clinical commissioning group
CHF	Congestive heart failure
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
CRP	C-reactive protein
CRQ	Chronic respiratory questionnaire
CRQ-SR	Chronic respiratory disease questionnaire- self-reported
CSES	COPD self-efficacy scale
D	Deprioritised
DHT	Digital health technology
DSA	Deterministic sensitivity analysis
EAG	External assessment group
ED	Emergency department
EJP	Economically justifiable price
EMIS	Egton Medical Information Systems
EQ-5D	EuroQol- 5 dimension
EQ-5D-5L	EuroQol- 5 dimension- 5 level
EQ-VAS	EuroQol- visual analogue scale
EVA	Early value assessment
FEV	Forced expiratory volume
FEV1	Forced expiratory volume in 1 second
FTE	Full time equivalent
GBP	Great British Pounds
GOLD	Global initiative for chronic obstructive lung disease

HADS	Hospital Anxiety and Depression Scale
HCP	Health care practitioner
HR	Hazard ratio
HRQoL	Health related quality of life
HRU	Healthcare resource utilisation
ICB	Integrated care board
ICER	Incremental cost effectiveness ratio
ICS	Integrated care system
IQR	Interquartile range
ISWT	Incremental Shuttle Walk Test
ITT	Intention to treat
MCID	Minimally clinically important difference
MHRA	Medicines & Healthcare products Regulatory Agency
MLCSU	Midlands and Lancashire commissioning support unit
mMRC	Modified medical research council dyspnoea scale
MRC	Medical research council
MTAC	Medical Technologies Advisory Committee
MTEP	Medical Technologies Evaluation Programme
NA	Not applicable
NHS	National Health Service
NHS HUTH	National Health Service Hull University Trust Hospital
NICE	National Institute for Health and Care Excellence
NICE CG	NICE clinical guideline
NICE MTG	NICE medical technology guidance
NICE QS	NICE quality standard
NIV	Non-invasive ventilation
NPS	Net promoter score
NR	Not reported
P	Prioritised
PAM	Patient activation measure
PEF	Peak expiratory flow
PP	Per protocol
PR	Pulmonary rehabilitation
PRO	Patient reported outcomes
PSA	Probabilistic sensitivity analysis

PSSRU	Personal Social Services Research Unit
QALY	Quality adjusted life year
QIPP	Quality innovation productivity and prevention
QOF	Quality Outcomes Framework
QoL	Quality of life
RAG	Red amber green
RCT	Randomised controlled trial
RFI	Request for information
RR	Risk ratio
SAE	Serious adverse event
SD	Standard deviation
SE	Standard error
SGRQ	St George Respiratory Questionnaire
SPACE	Self-management program of activity, coping and education
SpO2	Saturation of peripheral oxygen
VAS	Visual analogue scale
VAT	Value added tax
VOI	Value of information
VSAQ	Veterans Specific Activity Questionnaire
VW	Virtual ward

Executive summary

Background

Chronic obstructive pulmonary disease (COPD) is the name given to a group of lung conditions that cause breathing difficulties. The target population for this assessment are adults with a confirmed diagnosis of COPD. This early value assessment summarises the clinical and economic evidence for digitally supported self-management technologies for adults with COPD, while also outlining the current evidence gaps for these technologies.

Quality and relevance of the clinical evidence

The EAG considered evidence for 9 of the 12 scoped technologies identified in a pragmatic review. The objectives and scope of the EVA process does not include exhaustive assessment of all identified evidence. The included studies were prioritised for synthesis on the basis of relevance to the decision problem and study quality. The EAG notes that the pragmatic approach means some relevant data may have been deprioritised.

Overall, the evidence base suggests that digital technologies alongside standard care may result in improvements in the COPD assessment test (CAT) score, inhaler use and admission rates from baseline in people using the technologies following discharge for an exacerbation. Evidence for the wider COPD population beyond a recent exacerbation was limited, with unclear reporting of the studied populations in most studies. Evidence for other scoped outcomes such as outpatient visits and additional medication use was mixed but indicated that technologies could plausibly have a positive effect. The EAG had concerns regarding the timepoints at which results were reported, the characteristics of the study population, and a lack of clear reporting of the content of standard care and whether this was available to participants in the intervention groups. My mhealth currently has the most evidence to suggest its product myCOPD provides benefit to the healthcare system, although other technologies had

evidence to suggest they could plausibly be effective, albeit these results were mixed in quality.

Quality and relevance of the economic evidence

A total of 5 economic costing studies and 1 early economic model were identified that report evidence in the UK, in an NHS context. The studies reported potential cost savings due to averted A&E attendance and admissions. Overall, the quality of the evidence was low. The economic analysis conducted by the EAG was a cost-comparison model designed to capture the potential benefit that could be provided from the digital technologies over a 1-year time horizon. The analysis found that the incorporation of digital technologies to support the self-management of COPD into the NHS has the potential to be cost saving. However, the results are based on limited data, primarily capturing more severe COPD populations, with a high level of uncertainty, particularly around the expected impact on healthcare resource use. Model inputs were sourced through company-provided detail, published literature and clinical advice.

Evidence gap analysis

Future evidence generation should focus on addressing the key components of the value proposition of digital technologies for the self-management of COPD. This includes:

- An improved understanding of the outcomes associated with using digital technologies for the whole COPD population, given that current evidence is based on studies with unclear population, or those who have recently had an exacerbation.
- Evidence generation on the differences in healthcare resource use from using digital technologies, with adequate power to make informed conclusions.

Studies should compare digital technologies compared with standard care alone over at least a 1-year follow up period and be conducted in a UK NHS setting, to address issues of short term follow up. Further evidence on user and staff acceptability, as well

as uptake and adherence of the technologies is also required, to ensure that benefits are fully realised.

The EAG recommends that future evaluations should not look to treat all digital technologies for managing COPD as homogenous healthcare technologies. Any future economic modelling should be designed to be flexible enough to be adapted to evaluate each of the COPD self-management digital technologies, ideally using a state transition model including different severities of CAT score.

1 Decision problem

The decision problem is described in the scope.

Table 1.1: Summary of decision problem

Decision problem	Scope	EAG comment
Population	Adults with a confirmed diagnosis of COPD. Subgroups: People that have been discharged following an acute exacerbation (non-VW use)	No change.
Intervention	Digital technologies for adults with COPD, which may include: • Active+me REMOTE • CliniTouch Vie • COPDhub • COPD Predict • Current Health • DOC@HOME • Lenus • Luscii • myCOPD • patientMpower • Space for COPD • Wellinks	Due to the volume of literature identified, this EVA was limited to evaluating the listed 12 interventions.
Comparator(s)	Standard care for COPD which could include self-management without digital support.	No change.
Healthcare setting	Community, primary or secondary care (excluding VW use).	No change.
Outcomes	As listed in the final scope: • Intermediate measures • Clinical outcomes • Patient- reported outcomes • Costs (from NHS and Person Social Services perspective)	No change.

Cost analysis	Costs will be considered from an NHS and person social services perspective. Costs for consideration may include:
	• Cost of the technologies including device, license fees and staff training
	• Cost of other resource use (e.g. associated with managing COPD, exacerbations, suspected exacerbation hospital presentations, adverse events, or complications)
	  ○ Healthcare appointments in primary, secondary and community care
	  ○ Medication use and adverse events
	  ○ Healthcare professional grade and time
	  ○ Occupied bed days
	  ○ Urgent care/ A&E attendances (for both true and suspected exacerbations that do not meet the clinical definition of a COPD exacerbation
		No change.

Time horizon	The time horizon for estimating the clinical and cost effectiveness should be sufficiently long enough to reflect any differences in costs or outcomes between the technologies being compared • 12 months (to account for seasonal variation) If data allows, a 3-month time horizon could be suitable to capture differences in resource use for the subgroup of people that have been discharged post-exacerbation.	No change.

Key: COPD – Chronic obstructive pulmonary disease, EVA – Early value assessment, VW – Virtual ward.

2 Overview of the technology

Included in this early value assessment (EVA) are digital supported self-management technologies for adults with a confirmed diagnosis of COPD who are able to use the digital technologies. COPD is defined further in Section **Error! Reference source not found.**. The digital technologies can be used by people with any severity of COPD, as the severity of an individual's COPD tends to fluctuate based on factors such as exacerbations. Digital technologies intend to support the self-management of COPD through several stages of the condition, from initial diagnosis l and assessment to supporting people who have late stages of COPD after the condition has progressed over time. This also includes people who have been discharged following an acute exacerbation, though does not include use of digital technologies as part of virtual ward care. This is because an objective of virtual ward-care is to allow people with COPD who would otherwise be admitted to hospital to receive the same level of care at home, rather than to support self management.

The digital technologies aim to improve the chronic disease management of COPD through education, guidance, improved adherence, improved self-monitoring, and early detection of exacerbations. In turn, improving self-management of COPD may prevent or lessen exacerbations, reducing primary and secondary care resource use, such as GP appointments and hospital admissions. Important features of digital technologies for supported self-management that have been identified are listed within the scope.

Technologies under consideration should ideally have support from healthcare professionals, such as consultant respiratory physicians or respiratory nurses. All included technologies should have regulatory approval or be actively working towards regulatory approval, including DTAC and CE or UKCA mark where required, and be available for use in the NHS.

2.1 Included technologies

In total, 12 digital technologies to support the self-management of adults with COPD were identified as relevant to the assessment. Details relevant to this EVA are summarised in Table 2.1. Further details on the original 12 technologies are provided in the NICE Scope. 5 companies (detailed in **Error! Reference source not found.**) were included in a previous EVA on pulmonary rehabilitation [HTE10019] which evaluated digital technologies to deliver pulmonary rehabilitation programmes. The focus of this EVA is on self-management and not pulmonary rehabilitation. Some features of these technologies are, therefore, out of scope. 6 technologies can provide a virtual ward service as part of their care delivery. A virtual ward is also out of scope of this evaluation, and only features of self-management support should be considered.

Table 2.1: Included technologies

Technology (Company)	Regulatory Status	EAG Summary
Active+me REMOTE solution (Aseptika Ltd)	The device is registered as a class 1 medical device under ISO 13485. under CE and UKCA marking. DTAC: accredited	**Delivery:** Tablet, mobile phone, or computer **Key features**: • Remote monitoring option with relevant medical devices. • Real time data feed for clinical staff. Individualised care plan created by clinicians on the technology for the person to engage with. • Educational materials including quizzes and lessons. • Exercise support through classes, videos and monitoring. • Medication tracking diary and daily symptom diary. **NHS staff involvement:** Clinician sets the care plan through the technology and can remote monitor persons vitals. NHS staff may also be involved in optimising the educational content on the technology . **Digital accessibility features:** 1-2-1 training can be provided by the company (if funded). Educational materials provided for those with poor literacy through the technology. Educational content can be uploaded by NHS trust to the technology in multiple languages. **Included in pulmonary rehabilitation EVA?** Yes

Technology (Company)	Regulatory Status	EAG Summary
		Provides virtual ward service? Yes **Current use in the NHS:** [redacted]
CliniTouch Vie (Spirit Health)	The device is registered as a class 1 medical device under CE and UKCA marking. DTAC: Accredited	**Delivery:** Tablet or mobile phone **Key features**: • Video conferencing and messaging between user and clinician. • Questions and responses to support monitoring the condition. • Educational content for people using the technology, including exercise programmes. • Remote monitoring with risk warning features for clinical staff. Some key features resemble and refer directly to a virtual ward. A virtual ward is beyond the scope of this evaluation. **NHS staff involvement:** Clinician can remote monitor persons vitals. Clinical staff encouraged to be pre-emptive and escalate care using risk stratification and submitted information by user as part of remote monitoring. **Digital accessibility features:** No description of multiple languages, or digital accessibility support provided. **Included in pulmonary rehabilitation EVA?** Yes **Provides virtual ward service?** Yes **Current use in the NHS:** [redacted]
COPDhub (The Institute of Clinical Science and Technology (ICST))	The device is registered as a class 1 medical device	**Delivery:** Tablet, mobile phone, or computer **Key features**:

Technology (Company)	Regulatory Status	EAG Summary
	under UKCA marking. DTAC: Accredited	• Digital COPD plan that can be saved on devices with or without internet access. • Diary, reminders, and log of important information relating to COPD diagnosis. • Educational materials to encourage self-management. • Live sessions with clinicians including Q&A sessions. • Ability for clinicians to sign up and support engagement with care. • Video series with tailored exercises for those with COPD **Included in pulmonary rehabilitation EVA?** No **Provides virtual ward service?** No **NHS staff involvement:** Clinical staff may be involved in interactive material such as Q&A sessions, as well as to review digital plans or diary entries. **Digital accessibility features:** Includes magnification functions, text resizing, voice overs, and functionality included for multiple languages. **Current use in the NHS:** [redacted].
COPD Predict (NEPeSMO)	The company did not provide information to NICE. Key features are summarised in Table 2.2	**Included in pulmonary rehabilitation EVA?** No
Current Health Enterprise Care-at-Home Technology Platform (Current Health)	The device is registered as a class 1 medical device (UKCA and CE marking) The device is also registered as a class 2 medical device under CE marking. No statement of UKCA mark.	**Delivery:** Tablet (provided by Current Health) **Key features**: • Remote monitoring features including wearable devices, with reading and self-management content shared through the technology with clinical staff. • Clinician dashboard accessed by clinical teams to monitor and escalate care as required. • Risk stratification and alerts.

Technology (Company)	Regulatory Status	EAG Summary
	DTAC: Accredited	• Video calling, patient reminders, nudges and education content (including customisable content). Some key features resemble and refer directly to a virtual ward. A virtual ward is beyond the scope of this evaluation. **NHS staff involvement:** Clinician can remote monitor persons vitals. Clinical staff encouraged to be pre-emptive and escalate care using risk stratification and submitted information by user as part of remote monitoring. NHS staff can customise educational content. **Digital accessibility features:** Tablet and cellular connectivity provided by company as part of service. Set up guide provided with 30 different languages available. Freephone contact provided for support with technology at all times for the user. **Included in pulmonary rehabilitation EVA?** No **Provides virtual ward service?** Yes **Current use in the NHS:** [redacted]
DOC@HOME (Docobo)	The company did not provide information to NICE. Key features are summarised in Table 2.2	**Included in pulmonary rehabilitation EVA?** No
Lenus COPD Digital Service (Lenus Health Ltd)	The device is registered as a class 1 medical device under CE and UKCA marking. DTAC: Accredited	**Delivery:** Tablet, mobile phone, or computer **Key features**: • Access to individualised care plan, symptom diary, self-management advice, and prompts for other patient reported outcome measures. • Clinician dashboard accessed by clinical teams to monitor and escalate care as required.

Technology (Company)	Regulatory Status	EAG Summary
		• Messaging service for user to contact clinical care teams. • Remote monitoring can also be included, through wearable devices which are automatically captured through to the clinical dashboard. **NHS staff involvement:** Clinician can remote monitor persons vitals. Clinical staff encouraged to be pre-emptive and escalate care using risk stratification and submitted information by user as part of remote monitoring. Data captured through platform used to support scheduled care, as well as communicate with user for any concerns. **Digital accessibility features:** Service has been developed using WCAG 2.0 Web Content Accessibility Standards (WC3 2008). Engagement with users who have low literacy levels when designing the technology. Technology can be converted to a range of languages. **Included in pulmonary rehabilitation EVA?** No **Provides virtual ward service?** Yes **Current use in the NHS:** [redacted] **Additional notes:** 'Lenus Stratify' will also be incorporated within the next year. This is an AI insights interface that provides risk stratification model scores to clinical staff. Prediction of risk may be used to further optimise self-management support.
Luscii (Luscii healthtech B.V.)	The device is registered as a class 2a medical device under CE marking. No mention of UKCA marking. DTAC: Accredited	**Delivery:** Tablet or mobile phone **Key features**: • Remote monitoring features including wearables devices, with reading and self-management content (including care plan) shared through the technology with clinical staff. • Clinician dashboard accessed by clinical teams to monitor and escalate care as required. • Risk stratification and alerts. • Video calling, patient reminders, nudges and education content (including customisable content).

Technology (Company)	Regulatory Status	EAG Summary
		• Education modules, self management advice and symptom tracking. Some key features resemble and refer directly to a virtual ward. A virtual ward is beyond the scope of this evaluation. **NHS staff involvement:** Clinician can remote monitor persons vitals. Clinical staff encouraged to be pre-emptive and escalate care using risk stratification and submitted information by user as part of remote monitoring. **Digital accessibility features:** Partnered with Apple to improve accessibility, such as text-zoom functions and text-to-voice functions and multi-language service. **Included in pulmonary rehabilitation EVA?** No **Provides virtual ward service?** Yes **Current use in the NHS:** [redacted]
myCOPD (my mhealth Ltd.)	The device is registered as a class 1 medical device under UKCA marking. DTAC: Accredited	**Delivery:** Any device with a web browser or iOS and Android application **Key features**: • Facilitates key patient-reported outcome measures, able to monitor symptoms over time through the technology and record daily activity. • Clinician dashboard accessed by clinical teams to monitor and escalate care as required, as well as contact the user of the app. • Educational resources including health literacy, lifestyle management, nudge for vaccinations and support for inhaler technique. This can be tailored by NHS clinical staff. • Exercises can be provided through the technology to support self-management. **NHS staff involvement:** Clinician involved in monitoring the user of the app, including. NHS staff may also be involved in optimising the educational content on the technology .

Technology (Company)	Regulatory Status	EAG Summary
		Digital accessibility features: Service has been developed using WCAG 2.0 Web Content Accessibility Standards (WC3 2008). Materials provided in written, visual and video formats (including subtitles), with low reading age level. Company offers 1 to 1 support for users facing digital challenges. **Included in pulmonary rehabilitation EVA?** Yes **Provides virtual ward service?** No **Current use in the NHS:** [redacted]
patientMpower (patientMpower Ltd)	The device is registered as a class 1 medical device under CE and UKCA marking. DTAC: Accredited	**Delivery:** Tablet or mobile phone **Key features**: • Facilitates key patient-reported outcome measures, able to monitor symptoms over time through the technology and record daily activity. • Educational resources including health literacy, lifestyle management, nudge for vaccinations and support for inhaler technique. • Personalised self-management support plan. • Prescriptions can be facilitated through the technology such as oxygen therapy. • Exercises can be provided through the technology to support self-management. • Remote monitoring available to clinicans. **NHS staff involvement:** Clinician can remote monitor person through the technology and respond via messaging service. NHS staff may also be involved in optimising the educational content on the technology. **Digital accessibility features:** Service to provide tablets for those without access to a tablet or mobile phone available. Technology can store measurements when offline due to intermittent internet connectivity. **Included in pulmonary rehabilitation EVA?** No **Provides virtual ward service?** Yes

Technology (Company)	Regulatory Status	EAG Summary
		Current use in the NHS: [redacted]
SPACE for COPD (UHL NHS Trust)	The device has no UKCA/CE mark. Company claim it is not required as it is classed as a self-management programme and not a medical device. DTAC: Will be sought once website is merged with 'Activate your Heart' for cardiac programmes.	**Delivery:** Hosted as website, so any computing device with an internet connection. **Key features**: • Structured programme of exercise, education and psychosocial support with self-management plan. • Clinician messaging service provided through the programme. • Clinical staff may monitor the users progress through the programme content. **NHS staff involvement:** Staff will be involved in setting the programme of exercise or support, as well as monitoring a user's progress throughout the programme. **Digital accessibility features:** No features described to support digital accessibility in current iteration. Future iteration of technology is expected to include a function for approximately 10 different languages. **Included in pulmonary rehabilitation EVA?** Yes **Provides virtual ward service?** No **Current use in the NHS:** [redacted] **Additional notes:** SPACE for COPD is currently being revamped and replaced with a new website i-IMPACT. It will be used in the same way as SPACE for COPD was, with additional features including a health tracker, expanded patient reported outcomes and guided support tools to support self-management.
Wellinks (Convexity Scientific Inc)	The company does not have a UKCA or CE mark.	**Delivery:** Tablet, mobile phone or computer **Key features**: • Access to aspects such as exercise and educational outputs to support self-management.

Technology (Company)	Regulatory Status	EAG Summary
	The company is also not DTAC accredited. This is because the company at the moment only operates in the US market.	• Health coaching function to improve self-management and support behaviour change. This is provided by allied health professionals. • Remote monitoring can also be included, through wearable devices, to support self-management, with outcomes provided through to clinical staff. **NHS staff involvement:** Stated no staff involvement, as would use their own clinical staff as part of the technology. **Included in pulmonary rehabilitation EVA?** Yes **Provides virtual ward service?** No **Current use in the NHS:** [redacted]

Key: COPD – Chronic obstructive pulmonary disease, EVA - Early value assessment, ICB - Integrated care board, SPACE - Self-management program of activity, coping and education.

Table 2.2: Feature profile of the technologies

Technology	Exercise	Education	Communication with clinical staff via technology	Symptom or other outcome tracking	Remote monitoring	Individualised self-management plan	Scoped technology in pulmonary rehabilitation EVA	Provides virtual ward service
Active+me REMOTE solution	✓	✓	✓	✓	✓	✓	✓	✓
CliniTouch Vie	✓	✓	✓		✓		✓	✓
COPDhub	✓	✓	✓	✓		✓		
COPD Predict*			✓	✓	✓			
Current Health Enterprise Care-at-Home Technology Platform		✓	✓		✓			✓
DOC@HOME*			✓	✓	✓			✓
Lenus COPD Digital Service	✓	✓	✓	✓	✓	✓		✓
Luscii		✓	✓	✓	✓	✓		✓
myCOPD	✓	✓	✓	✓	✓	✓	✓	
patientMpower	✓	✓	✓	✓	✓	✓		✓
SPACE for COPD	✓	✓	✓	✓		✓	✓	
Wellinks	✓	✓	✓	✓	✓		✓	

*The company did not provide information to NICE. This was populated with information in the public domain, so may omit relevant features (Docobo 2023, NEPeSMO 2020).

3 Clinical context

COPD is defined as a common lung condition, characterised by persistent respiratory symptoms (such as breathlessness, cough, and sputum) and airflow obstruction (usually progressive and not fully reversible (National Institute for Health and Care Excellence 2023b)). People with COPD may have episodic exacerbations where their symptoms become worse than the usual day-to-day variation (such as increased breathlessness, cough and sputum production). Supported self-management is defined as increasing the knowledge, skills and confidence a person has in managing their own health and care by putting in place interventions such as: peer support, self-management education and health coaching (NHS England 2024, National Institute for Health and Care Excellence 2023b), Supported self-management is an important tool to help mitigate the risk of exacerbations or other adverse consequences.

The target population for this assessment are adults with a confirmed diagnosis of COPD. In the UK, it is estimated that approximately 3 million people are impacted by COPD, with 2 million of these cases being undiagnosed (National Institute for Health and Care Excellence 2023a). The prevalence of COPD is expected to increase by 40% by 2030 in the UK. Furthermore, COPD is a common cause of emergency hospital admissions, accounting for 1 in 8 UK hospital admissions. Hence, this EVA will consider both adults with a confirmed diagnosis of COPD, and a subgroup of those recently discharged after an exacerbation, who may be at high risk of readmission.

Previous NICE guidelines and the NHS long-term plan both highlight the importance of self-management and suggest that self-management is a key treatment strategy for COPD. Innovative technologies that promote improved self-management of COPD have potential to reduce NHS resource use, improve people’s access to self-management resources, and improve people’s quality of life, through more effective self-management. GP appointments, hospital admissions, non-hospitalised exacerbations and inhaler usage are a non-exhaustive list of NHS resources where usage could potentially be reduced. Digital technologies to support self-management

take steps towards a healthcare user-led management of chronic conditions, which is one of NHS England's long-term goals (NHS England 2024).

The current care pathway for the management of COPD is person-specific and illustrates the heterogeneous nature of COPD. It may include:

- Personalised self-management plans to prevent worsening health outcomes.
- Recording of patient reported outcomes (PRO) to identify trends.
- Education to improve understanding of COPD and self-management.
- Medication reminders to support adherence.
- Remote monitoring during exacerbations.
- Communication functions to allow healthcare professionals to monitor/respond between exacerbations.
- Trigger identification.
- Smoking cessation.

The current care pathway paradigm necessitates the health care practitioner (HCP) to coordinate and control a person's access to care. This includes face-to-face monitoring through appointments, and self-management plans that are not digital. When people have exacerbations of their COPD symptoms, they generally present to their GP or emergency department. Waiting lists are a known issue for COPD and act as a barrier to accessing care for COPD (Locke E R et al. 2022). People who have received in-hospital care after an exacerbation are given care bundles. Digital technologies can therefore be used to support self-management of COPD, including more focused care after an exacerbation, to avoid readmission or an exacerbation recurrence. Some people or clinicians may prefer a hybrid approach to care for COPD. Hence, the technologies are likely to be used alongside standard care.

Special considerations including issues related to equality

No further equality issues have been identified since the publishing of the Scope.

4 Clinical evidence selection

4.1 Evidence search strategy and study selection

Searches were conducted to identify studies of digital technologies for the supported self-management of COPD. A single set of searches was conducted to identify both clinical and economic evidence. The searches were conducted in February 2024, in a range of resources including research published in the journal literature, conference abstracts and ongoing research.

The EAG searches retrieved a total of 2,971 records after elimination of 1,923 duplicates. Titles and abstracts were screened by 1 reviewer with the first 10% assessed by 2 reviewers independently. Due to the volume of literature identified, studies of telemonitoring or telehealth were excluded, as were studies described in abstracts as ‘telemedicine’ if they did not also report any self-management elements. Studies of digital technologies that clearly consisted of 1 component only (for example exercise websites) were also eliminated at first screen. A total of 410 full text papers were retrieved and examined by 1 reviewer (first 10% assessed by 2 reviewers) to determine those meeting the scope definition of an eligible technology. Company submissions were received from 10 companies (Aseptika, BEST BUY Health, ICST, Lenus Health Ltd, Luscii, my mhealth, patientMpower, University Hospitals of Leicester NHS Trust, Spirit Health and Wellinks) in 69 documents which were examined by the EAG. 17 relevant documents not identified by the EAG searches were added to full text screening. No evidence was identified for the following 3 companies: BEST BUY health, Docobo and patientMpower.

Full details of the search methods are provided in Appendix A.

4.2 Included and excluded studies

A total of 179 full text records were considered to meet the scope because they evaluated a digital technology with a self-management component in people with COPD. Due to this high number, the EAG agreed with NICE that further study selection in the form of prioritisation should be limited to studies of the 12 interventions listed in the final scope. In total, 32 studies (reported in 46 papers or trial records) evaluated scoped interventions.

Studies were further prioritised for extraction and synthesis based on relevance to the decision problem and quality of evidence. The distribution of prioritised and deprioritised studies is summarised in Table 4.1. 4 studies were deprioritised because they evaluated an earlier version of the digital technology that did not meet the NICE scope (telemonitoring only, 1 crossover randomised controlled trial (RCT) [Luscii] (Frerichs et al. 2023), 2 before-after studies [Luscii] (van der Burg 2020, Luscii 2022) and 1 before-after study [CliniTouch Vie] (Ghosh 2016)). 1 case series (Luscii) was deprioritised because it was conducted in a non-UK setting (Luscii 2022). 1 RCT (SPACE for COPD) was deprioritised because it included an ineligible comparator, pulmonary rehabilitation. For the remaining 26 studies, RCTs were prioritised over non-randomised comparative studies, comparative studies over non-comparative, and prospective over retrospective non-comparative studies, resulting in a final set of 14 studies prioritised for extraction and further examination, which are summarised in Table 4.2. The 18 studies of scoped interventions that were deprioritised are summarised with reasons for de-prioritisation in Table B.1, Appendix B .

A list of the 134 deprioritised studies (non-scoped interventions) and studies excluded at full text is provided in Table B.2 and Table B.3, Appendix B **Error! Reference source not found.**

Table 4.1: Evidence landscape

Technology	Status	RCTs	Cohort	Before-after	Case series
Active+me REMOTE	P	0	0	0	1 prospective (Auton KAA et al. 2024)
	D	0	0	0	0
CliniTouch Vie	P	0	0	2 prospective: (Ghosh 2018) (NHS 2022b)	0
	D	0	0	1 retrospective (Ghosh 2016)	0
COPDHub	P	0	0	0	1 retrospective (The Institute of Clinical Science and Technology 2023)
	D	0	0	0	0
COPDPredict	P	0	0	1 prospective (Patel et al. 2021)	0
	D	0	0	0	0
Lenus	P	0	1 prospective matched (Taylor et al. 2023) 1 historically controlled (Lenus Health Ltd 2024a)	0	0
	D	0	0	[redacted] (Lenus Health Ltd 2024b)	1 prospective (Cooper et al. 2023)
Luscii	P	0	0	1 retrospective (All Together Better Sunderland 2021)	1 retrospective (Luscii)
	D	1 prospective crossover RCT (Frerichs et al. 2023)	0	1 retrospective (van der Burg 2020)	1 prospective (Frerichs et al. 2021) 2 retrospective (Luscii 2021, Luscii 2022)
myCOPD	P	2 prospective	0	0	0

Technology	Status	RCTs	Cohort	Before-after	Case series
		(Crooks et al. 2020, North et al. 2020)			
	D	0	1 retrospective (Our Dorset Digital 2021)	1 prospective (Stokes and Savage 2021)	4 prospective (Cooper et al. 2022) (North M 2014) (Cooper et al. 2021) (Roberts et al. 2022) 2 retrospective (Chmiel et al. 2022) (Duckworth et al. 2023)
SPACE for COPD	P	0	1 prospective (Houchen-Wolloff 2021)	0	0
	D	1 prospective (Chaplin et al. 2017)	1 prospective (Houchen-Wolloff et al. 2021)		
Wellinks	P	0	0	1 prospective (Pierz et al. 2024)	1 prospective (Gelbman and Reed 2022)
	D	0	0	0	0

Key: D – Deprioritised, P - Prioritised.

Table 4.2: Studies selected by the EAG as the evidence base (14 studies reported in 23 records)

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Active+me REMOTE				
Auton et al. 2024 (Auton KAA et al. 2024) **Associated records:** Clinical trial registration (NCT05881590 2023) **Location**: UK **Setting**: Unclear	**Design**: Prospective case series (formally a prospective cohort study, but results for the control arm are not reported at time of writing – considered a case series for the purpose of this review) GREEN **Intervention**: Active+me REMOTE **Comparator:** None GREEN	**Participants:** Patients with COPD clinically referred for pulmonary rehabilitation, (n=69) 32/69 (46%) male, mean age 68.4 (SD 11.8) **Setting:** Patients clinically referred for pulmonary rehabilitation at the Harefield Hospital Pulmonary Rehabilitation Unit at Guy's and St Thomas' NHS Foundation Trust	• Activation/adherence • MRC • CAT • HADS • CRQ • PAM • EQ-5D-5L	No comparative data provided.
COPDHub				
The Institute of Clinical Science and Technology, 2023 (The Institute of Clinical Science and Technology 2023) **Location:** UK **Setting**: Unclear	**Design**: Retrospective case series GREEN **Intervention**: COPDHub **Comparator:** None GREEN	**Participants** All users who completed the in-App COPD Checker since its introduction in January 2022 to October 2023 Age and gender NR Subgroups: NR **Setting**: NR, all app users	• Physical activity • Inhaler use	No patient characteristics reported. No comparative data provided.
myCOPD				
Crooks et al. 2020 (Crooks et al. 2020)	**Design**: RCT GREEN	**Participants:** People with either mild–moderate COPD (defined by	• CAT score • Inhaler technique • PAM	Groups were unbalanced at baseline: myCOPD group had a higher

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Associated records: Clinical trial registration (My mhealth Ltd 2018) **Location**: UK **Setting:** Mixed	**Intervention**: myCOPD GREEN **Comparator:** Standard care; patients continued with their current NHS management in line with national and local guidelines GREEN	FEV_1/forced vital capacity) or COPD of any severity diagnosed within the past 12 months Subgroups: NR myCOPD: 29 11/29 (37.9%) male, mean age 65.9 (SD 7.3) Standard care: 31 20/31 (64.5%) male, mean age 66.4 (SD 7.0) **Setting:** Patients identified by clinical teams and recruited; patients were unable to take part if they had experienced an exacerbation in the last 4 weeks	• Self-efficacy for appropriate medication use scale score • EQ-5D-5L • QoL VAS score • Exacerbations • Hospitalisations • Daily activity • Adverse events • Adherence	symptom burden, significantly lower physical activity levels, and significantly higher exacerbation frequency than controls. This may have favoured the control Small sample size, limited power to test effectiveness. Authors report ITT analysis used but patient withdrawals after randomisation but before commencement are not included, considered per protocol
North et al. 2022 (North et al. 2020) Associated records: Clinical trial registration, (My mhealth Ltd 2015) Conference abstract, (North et al. 2018) Location: UK	**Design**: RCT GREEN I**ntervention**: myCOPD GREEN **Comparator:** HealthQuest written self-management plan, which can be individualised for the patient. It consists of a traffic light system to direct patients to	**Participants:** COPD patients recently admitted to hospital with an acute exacerbation GREEN Subgroups: NR; all patients were included from hospital for exacerbations myCOPD: 20 13/20 (65%) male, age mean 65.1 (SD 6.3)	• Adherence/activation • CAT score • Exacerbations • Inhaler technique • PAM	Study is not sufficiently powered to demonstrate effects on all measured outcomes.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Setting: AECOPD	the most appropriate action to take should their symptoms deteriorate GREEN	Standard care: 21 11/21 (52%), age mean 68.1 (SD 7.4) **Setting:** Patients discharged from hospital following acute exacerbation GREEN		
SPACE for COPD				
Houchen-Wolloff , 2021 (Houchen-Wolloff 2021) **Location**: UK **Setting**: AECOPD	**Design**: Prospective cohort study GREEN **Intervention**: SPACE for COPD website (email prompts and contact health professional function) GREEN **Comparator:** Telephone support (biweekly for 6 weeks with home exercise and education booklet) GREEN Non-digital SPACE for COPD manual (with phone calls at	**Participants:** Patients with a spirometry diagnosis of COPD (n=287, mean age 66.4 (10.2) Patient characteristics NR by arm SPACE for COPD: 11% (32*) Telephone monitoring: 67% (192*) SPACE for COPD manual: 22% (63*) Subgroup: NR **Setting:** AECOPD	• CAT • Chronic Respiratory Questionnaire	Conference abstract only, limited information Significant difference in study completion between cohorts

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	week 2 and week 4) **RED**			
Wellinks				
Gelbman et al. 2022 (Gelbman and Reed 2022) Location: USA **Setting**: Unclear	**Design**: Prospective case series (authors describe as observational, prospective pilot study) **GREEN** **Intervention**: Wellinks **GREEN** Comparator: None **GREEN**	**Participants**: Male or female patients with COPD over 30 years of age with English language literacy who were prescribed a treatment regimen that included nebulised therapy Wellinks: 19 9/19 (47%) male, mean age 79.6 (range 65 to 95) **GREEN** **Setting**: NR (participants were recruited within a clinical setting, no further information) **GREEN**	• Intervention adherence • Patient satisfaction • Adverse events	No comparative data provided.
Pierz et al. 2024 (Pierz et al. 2024) Location: USA **Setting**: Unclear	**Design**: Before-after study **GREEN** **Intervention**: Wellinks **GREEN** **Comparator:** From week 12 to 24 patients were assigned to: Arm 1: Wellinks Arm 2 Wellinks minus health coaching component	**Participants:** 141 patients over the age of 18 with a COPD diagnosis, mild and moderate severity 63/141 (44.7%) male, mean age 70 (SD 7.6) **GREEN** **Setting:** Recruited through COPD Foundation Patient-Powered Research Network, COPD360Social, and various newsletters	• QoI (CSES) • mMRC • Pulmonary function (FEV1, PEF, SpO2) • HRU	Limited information is available about the care received in the before control period.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	This is an ineligible comparator, and only the data reported at 12 weeks was extracted **RED** This was considered a single-arm study. Admissions data is reported for the 3 months prior to baseline for care prior to receiving the digital technology **AMBER**			
COPDPredict				
Patel et al. 2021 (Patel et al. 2021) Location: UK Setting: AECOPD	**Design**: Before-after study **GREEN** **Intervention**: COPDPredict **GREEN** **Comparator:** Care prior to receiving digital technology **AMBER**	**Participants**: 90 patients with non-comorbid COPD, a history of frequent exacerbations, and exacerbation free for 6 weeks. Inclusion criteria specified COPD-related hospitalisation in the past 6 months. 45 (50%) male, age range 48-91 **GREEN** **Setting**: Participants were randomised selected from University Hospitals of North Midlands NHS Trust research and outpatient clinic databases. Inclusion criteria specified minimum of 1 COPD-related hospitalisation in the preceding 6 months	• Exacerbations • Hospitalisations • Wellbeing • FEV_1	Limited information is available about the care received in the before control period.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
		GREEN		
Lenus				
Taylor et al. 2023 (Taylor et al. 2023) Associated records: Carlin et al. 2021 (Carlin et al. 2021) Taylor et al. 2022 (Taylor et al. 2022b) Taylor et al. 2021 (Taylor et al. 2021) Taylor et al. 2022 (Taylor et al. 2022a) NCT04240353 (NHS Greater Glasgow and Clyde 2018) Location: UK **Setting**: AECOPD	**Design**: Matched prospective cohort study GREEN Intervention: Lenus GREEN **Comparator:** Standard care (somewhat unclear – control arm gathered from deidentified dataset produced by the NHS GG&C Safe Haven; only intervention criteria applicable was not receiving the Lenus COPD digital service) AMBER	Participants: Lenus: Patients with severe COPD requiring hospitalisation in previous 12 months due to exacerbation and/or chronic hypercapnic respiratory failure or sleep-disordered breathing meeting established criteria for home non-invasive ventilation/continuous positive airway pressure treatment Control: Had a COPD or respiratory-related admission in the 7-days up to the onboarding date of the matched RECEIVER participant. Matched to cohort participants in a 5:1 ratio for age, sex, and not using a COPD digital service. Cohort and matched control participants had similar rates of COPD or respiratory-related admissions in the previous year. Lenus (83): 63.9 % female, mean age 64.4 (SD 9.3)	• CAT • EQ-5D • Utilisation • Admission events • Exacerbation events • Median time to COPD or respiratory related admission • Median time to COPD or respiratory related admission and death • Median time to death	Care in control arm unclear; control arm gathered from anonymised dataset produced by the NHS GG&C Safe Haven; only intervention criteria applicable was not receiving a COPD digital service Cohorts were similar at baseline for mean admissions and hospital bed days in prior 12 months (2.47 admissions in control vs 2.46 admissions in Lenus, 19.18 occupied bed days in both), indicating adequate matching of cohorts for these characteristics.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
		Control (415): 63.9% female, mean age 64.6 (SD 9.1) **GREEN** Setting: Lenus: Patients recruited opportunistically at admissions, supported discharge or outpatient review. Control: Patients selected from Safe Haven COPD dataset **GREEN**		
[redacted] (Lenus Health Ltd 2024a) Location: [redacted] **Setting**: [redacted]	**Design:** [redacted] Intervention: Lenus **GREEN** **Comparator:** [redacted]	Participants Lenus: [redacted] Control: [redacted]	[redacted]	[redacted]

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
		Setting: [redacted]		
Luscii				
All Together Better Sunderland, 2021 (All Together Better Sunderland 2021) Location: UK **Setting**: Unclear	**Design:** Before-after study GREEN Intervention: Luscii GREEN **Comparator:** Care prior to receiving digital technology AMBER	**Participants:** 30 patients with COPD onboarded to Luscii between February and November 2020 and who were users of the Luscii system for at least 7 days during that period. Gender and mean age not reported Setting: Unclear	• Admissions • ED visits • Patient satisfaction	Only included patients who used system for at least 7 days Admissions data is presented per referral, rather than per patients (130 referrals in 30 patients) Authors note the impact of the COVID-19 response will have affected the evaluation
Luscii Ltd. (unpublished) (Luscii) Location: UK **Setting**: Unclear	**Design:** Retrospective case series GREEN Intervention: Luscii GREEN Comparator: None GREEN	**Participants:** 186 patients with COPD; no participant characteristics reported Setting: Unclear	• Patient satisfaction • Adherence	Unpublished presentation No comparative data provided.
CliniTouch Vie				

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Ghosh 2018 (Ghosh 2018) Location: UK Setting: AECOPD	**Design**: Before-after study **GREEN** **Intervention**: CliniTouch Vie **GREEN** **Comparator:** Care prior to receiving digital technology **AMBER**	**Participants:** 29 Patients with COPD **Setting:** Hospital discharge	• Admissions • CAT score • Costs • Cost benefit	Study provides limited information about the participants. Limited information is available about the care received in the before control period.
NHS Chorley and South Ribble; Preston CCGs (NHS 2022b) Location: UK Setting: AECOPD	**Design**: Before-after study **GREEN** **Intervention**: CliniTouch Vie **GREEN** **Comparator:** Care prior to receiving digital technology **AMBER**	**Participants:** 29 Patients with COPD and ≥2 hospital admissions in the previous 6 months **Setting:** Hospital discharge	• CAT score • Admissions • Adherence	Patients were excluded if they did not complete onboarding, or if they were a participant in the preceding RECEIVER clinical trial. Patients who died before completion of 12 months post-baseline were not included in the analysis. Primary outcome (admissions) not reported for whole population, but for subgroups by adherence.

Key: AECOPD – Acute exacerbations of COPD, AO – Adverse outcome, BCKQ - Bristol COPD Knowledge Questionnaire, CAT – COPD assessment test, COPD - Chronic obstructive pulmonary disease, CRQ-SR - Chronic respiratory disease questionnaire- self-reported, CSES – COPD self-efficacy scale, EAG – External Assessment Group, ED – emergency department, EQ-5D-5L - EuroQol- 5 dimension- 5 level, FEV_1 – Forced expiratory volume in 1 second, HADS - Hospital Anxiety and Depression Scale, HRU – Healthcare resource utilisation, ITT – Intent to treat, MRC – Medical research council, mMRC – Modified medical research council dyspnoea scale, NHS HUTH – NHS Hull University Teaching Hospitals, NR – not reported, PAM – patient activation measure, PEF – Peak expiratory flow, PR – Pulmonary rehabilitation, QoL – Quality of life, RCT – randomised controlled trial, SD – Standard deviation, SpO_2 - Saturation of peripheral oxygen, VAS – visual analogue scale.
GREEN: Study characteristic aligns with the scope**; AMBER:** Study characteristic does not fully align with the scope**; RED:** Study characteristic does not align with the scope.

5 Clinical evidence review

5.1 Overview of methodologies of all included studies

The 14 prioritised studies assessed 9 digital health technologies listed in the NICE final scope: Active+me REMOTE (Aseptika), SPACE for COPD (SPACE for COPD/University Hospitals of Leicester NHS Trust), myCOPD (my mHealth Ltd.), COPDHub (The Institute of Clinical Science & Technology), COPDPredict (Nepesmo Ltd.), CliniTouch Vie (Spirit Digital Ltd.), Luscii (Luscii healthtech B.V.), Lenus (Lenus Health Ltd) and Wellinks (Wellinks). No evidence relevant to the scope was identified for Current Health (Current Health Ltd.), DOC@HOME (Docobo) or patientMpower (patientMpower Ltd.) in either the prioritised studies or deprioritised included studies. A summary of the evidence landscape can be found in Table 4.1.

10 studies were comparative and included 2 RCTs (Crooks et al. 2020, North et al. 2020), 2 prospective cohort studies (Taylor et al. 2023, Lenus Health Ltd 2024a, Houchen-Wolloff 2021) and 1 [redacted] (Taylor et al. 2023, Lenus Health Ltd 2024a, Houchen-Wolloff 2021) comparing digital management tools to standard care (Taylor et al. 2023, Lenus Health Ltd 2024a, Houchen-Wolloff 2021) and 5 before-after studies (Patel et al. 2021, Pierz et al. 2024, All Together Better Sunderland 2021, Ghosh 2018, NHS 2022b). Among the 5 before-after studies is 1 prospective cohort study in which all study participants received Wellinks for 12 weeks, after which 1 arm of patients continued with Wellinks minus the app's health coaching component and 1 arm continued using Wellinks in full (Pierz et al. 2024). This was considered an ineligible comparator; therefore the study was included as a before-after study (admissions data for 3 months prior to baseline was compared to 3 months post-baseline) and only the data up to 12 weeks was included.

Another study (UK, Active+me REMOTE) reported a prospective matched-cohort design, though as of the latest publication control data was not reported; the reported intervention group data was therefore extracted as a prospective case series study (Auton KAA et al. 2024). The remaining 3 studies included 1 prospective case series (Wellinks) (Gelbman and Reed 2022) and 2 retrospective case series (COPDHub and Luscii) (The Institute of Clinical Science and Technology 2023, Luscii).

Patients and settings:

The EAG considered all studies to fully meet this component of the decision scope with a red, amber, green (RAG) rating, as all included patients with COPD defined by GOLD criteria or other diagnostic tests such as spirometry or Forced Expiratory Volume (FEV), or Medical research council (MRC) dyspnoea score. 1 prospective case series included patients with COPD and other chronic lung conditions (Auton KAA et al. 2024). The EAG sought clarification from Aseptika Ltd on whether this was a mixed population study including patients with non-COPD lung diseases, and the company responded to confirm that all patients had COPD. The study was thereafter prioritised.

8 studies reported the COPD severity of included patients. 1 myCOPD RCT set out to include patients with mild or moderate COPD or patients with COPD of any severity who were newly diagnosed (within 12 months), and ultimately included only patients with mild (14/60, 23.3%) or moderate (46/60, 76.7%) COPD (Crooks et al. 2020). 1 prospective case series (Wellinks) included participants with COPD severity ranging from mild to very severe (Gelbman and Reed 2022).

7 studies included patients with severe COPD, including:

- 1 Lenus matched prospective cohort study in which all patients had severe COPD with hospitalisation in the previous 12 months and/or chronic hypercapnic respiratory failure or sleep-disordered breathing meeting established criteria for home non-invasive ventilation (NIV)/continuous positive airway pressure (CPAP) treatment (Taylor et al. 2023).
- 6 studies including 1 RCT (myCOPD) (North et al. 2020), 1 prospective cohort study (SPACE for COPD) (Houchen-Wolloff 2021), 1 [redacted] (Lenus Health Ltd 2024a) and 3 before-after studies (COPDPredict and CliniTouch Vie) (Ghosh 2018, Patel et al. 2021, NHS 2022b)) did not report severity explicitly but included patients with at least 1 COPD-related hospitalisation in the previous 6 to 12 months; an acute exacerbation within 12 months is a criterion for a “severe” GOLD rating, thus all patients in these studies would be considered to have severe COPD (GOLD 2018).
- 1 prospective cohort study (SPACE for COPD) (Houchen-Wolloff 2021) did not report severity, though during the fact check process the company clarified that the study recruited an AECOPD population (not further defined), and therefore has been considered to include patients with severe COPD.

The other 7 studies either included patients with any COPD severity or did not report severity.

A subgroup of interest in the NICE scope were patients referred to self-management following hospitalisation for acute exacerbations (AECOPD). 7 studies included this patient population exclusively:

- 1 RCT (myCOPD), included AECOPD patients within 2 weeks of discharge. (North et al. 2020)
- 1 matched prospective cohort study (Lenus), included AECOPD patients hospitalised within the previous 12 months (Taylor et al. 2023)
- 1 [redacted] (Lenus Health Ltd 2024a).
- 1 prospective cohort study (SPACE for COPD) included AECOPD patients (definition of AECOPD and duration since hospitalisation not reported) (Houchen-Wolloff 2021)
- 1 before-after study (COPDPredict), included patients with AECOPD hospitalised within the previous 6 months, though exacerbation-free for at least 6 weeks (Patel et al. 2021)
- 1 before-after study (CliniTouch Vie), included AECOPD patients hospitalised with the previous 12 months (Ghosh 2018)
- 1 before-after study (CliniTouch Vie), included AECOPD patients hospitalised with the previous 6 months (NHS 2022b)

1 RCT aimed to evaluate myCOPD in a mild or moderate COPD population, but included 1 AECOPD patient discharged following an acute exacerbation within the previous 3 months (Crooks et al. 2020). In the remaining 6 studies the setting or place in the treatment pathway of included patients was not clearly reported. These 7 studies are therefore considered to have a mixed or unclear patient setting.

Interventions

The EAG considered all studies to fully meet this component of the decision scope with a green RAG rating, as all included multicomponent self-management technologies included in the NICE scope.

9 technologies were assessed across the 14 studies. Details of the evidence landscape can be found in Table 4.1:

- SPACE for COPD: 1 prospective cohort study (Houchen-Wolloff 2021)
- myCOPD: 2 RCTs on (Crooks et al. 2020, North et al. 2020)
- COPDHub: 1 retrospective case series (The Institute of Clinical Science and Technology 2023)
- COPDPredict: 1 before-after study (Patel et al. 2021)
- CliniTouch Vie: 2 before-after studies (Ghosh 2018, NHS 2022b)
- Lenus: 1 matched prospective cohort study (Taylor et al. 2023) and 1 [redacted] (Lenus Health Ltd 2024a)
- Luscii: 1 before-after study (All Together Better Sunderland 2021) and 1 retrospective case series (Luscii)
- Wellinks: 1 before-after study (Pierz et al. 2024) and 1 prospective case series (Gelbman and Reed 2022)
- Active+me REMOTE: 1 prospective case series (Auton KAA et al. 2024)

Technologies were described in detail by 2 RCTs (Crooks et al. 2020, North et al. 2020), 1 prospective cohort study (Taylor et al. 2023, Lenus Health Ltd 2024a), 5 before-after studies (Pierz et al. 2024, Patel et al. 2021, All Together Better Sunderland 2021, Ghosh 2018, NHS 2022b) and 2 prospective case series (2017, Auton KAA et al. 2024, Gelbman and Reed 2022), each reporting multi-component devices that included at least 2 of the following components: symptom monitoring, educational content, self-management planning and healthcare practitioner contact.

In the remaining 3 studies (reported as conference abstracts) the content of the digital health technologies in the included studies was not clearly reported. 1 prospective cohort study (Houchen-Wolloff 2021) and 2 retrospective case series (The Institute of Clinical Science and Technology 2023, Luscii) reported only the technology name. These studies were prioritised because they evaluated scoped interventions, but the EAG notes that the components of these technologies may vary in terms of which components are used in different study contexts, as well as the components themselves varying across different versions of a technology. The EAG therefore considered descriptions of the interventions in these studies to be unclear. Components

as reported within each prioritised study are presented in **Error! Reference source not found.**.

Only 2 studies explicitly reported that the digital technology was administered alongside standard care, a [redacted] (Lenus Health Ltd 2024a) and a prospective case series (Active+me REMOTE) (Auton KAA et al. 2024). In the remaining studies it was not clearly reported whether participants were able to access conventional COPD management care separately from the assigned intervention during the trial. 1 before-after study (COPDPredict) reported details of concomitant medication, and reported that all participants were provided with a 5-day course of prednisolone 30mg/day plus antibiotics (doxycycline, amoxicillin, clarithromycin) (Patel et al. 2021).

Table 5.1: Key technology features described in the prioritised studies

Technology (company)	Study	Version number	Key features described
Active+ me REMOTE (Aseptika)	Auton et al., 2024 (Auton KAA et al. 2024)	Version 1.0	• Clinician approved education syllabus on cardiac, respiratory and weight management • Connection to self-monitoring devices • Medication recording • Personal care plan by a clinician • Behaviour change objectives • Exercise classes and step counter • Virtual appointments
CliniTouch Vie (Spirit Health)	Ghosh et al., 2018 (Ghosh 2018)	NR	• Monitoring of patient health at pre-determined levels to share with healthcare professionals • Educational suite with modules such as exercise guidance, dealing with breathlessness and help to stop smoking
	NHS Chorley and South Ribble; Preston CCGs, 2022 (NHS 2022b)	NR	• Virtual patient monitoring through oxygen saturation, blood pressure and questionnaires • Patient education modules
COPD Hub (ICST)	ICST, 2023 (The Institute of Clinical Science and Technology 2023)	NR	• COPD checker evaluating users' COPD control
COPDPredict (NEPeSMO)	Patel et al., 2021 (Patel et al. 2021)	NR	• Early identification of COPD exacerbations • Collection of patient reported outcomes and bio-physiological data to share with healthcare team • Personalised predictions of COPD exacerbations
Lenus (Lenus Health Ltd)	Taylor et al., 2023 (Taylor et al. 2023)	NR	• Self-management advice and resources • Messaging facilities with clinicians
	Lenus Health Ltd, 2024 (Lenus Health Ltd 2024a)	NR	• [redacted]
Luscii (Luscii)	All Together Better Sunderland, 2021 (All Together Better Sunderland 2021)	NR	• Self-monitoring • Self-management • PR
myCOPD (my m health)	Crooks et al., 2020 (Crooks et al. 2020)	NR	• Education • Self-monitoring • Self-management

Technology (company)	Study	Version number	Key features described
	North et al., 2020 (North et al. 2020)	NR	• Educational programs • 6-week online PR program • Inhaler technique videos • Environmental alerts for weather and pollution • Clinician interface
SPACE for COPD (University Hospitals of Leicester NHS trust)	Houchen-Wolloff et al., 2021 (Houchen-Wolloff 2021)	NR	• Self-management education • Home exercise program such as walking or strength exercises • Email prompts • Contact with a health professional
Wellinks (Wellinks)	Pierz et al., 2024 (Pierz et al. 2024)	NR	• Personalised health coaching • Remote PR • Respiratory therapy services • Health and wellness coaches • Individual and group-based education • Support in goal attainment • Homebased exercise guides
	Gelbman et al., 2022 (Gelbman and Reed 2022)	NR	• Recording of daily medication use and symptoms • Remote patient monitoring

Key: COPD – Chronic obstructive pulmonary disease, PR – Pulmonary rehabilitation

Comparators

Of the 10 comparative studies, the EAG considered 4 to fully meet this component of the decision scope, comparing digital interventions to various forms of standard care for COPD. This included 1 cohort study included 2 comparator arms, 1 of which was a non-digital booklet version of SPACE for COPD which the EAG considered ineligible; the other was COPD management with telephone support, which was considered eligible (Houchen-Wolloff 2021). 7 comparative studies were considered to partially meet this component of the decision scope. 2 cohort studies included comparator groups from anonymised patient data for which the only reported intervention criteria was not having received the digital intervention (Taylor et al. 2023, [redacted] and 5 before-after studies reported data from their included participants prior to beginning care with the respective digital interventions (Patel et al. 2021, All Together Better Sunderland 2021, Pierz et al. 2024, Ghosh 2018, NHS 2022b). These studies did not clearly report what previous care consisted of.

The comparative studies compared digital technologies to standard care for COPD self-management in 2 RCTs (Crooks et al. 2020, North et al. 2020), 2 prospective cohort studies (Taylor et al. 2023, Lenus Health Ltd 2024a, Houchen-Wolloff 2021), 1 [redacted] (Taylor et al. 2023, Lenus Health Ltd 2024a, Houchen-Wolloff 2021) and 5 before-after studies (Patel et al. 2021, All Together Better Sunderland 2021, Pierz et al. 2024, Ghosh 2018, NHS 2022b).

The content of standard care varied across the comparative studies:

- 1 RCT compared myCOPD to usual management according to NHS guidelines, without further detail on what this comprised (Crooks et al. 2020).
- 1 RCT compared myCOPD to the HealthQuest written self-management plan, a 1-page document which can be individualised for the patient (North et al. 2020).
- 1 matched prospective cohort study (Taylor et al. 2023) and 1 [redacted] (Lenus Health Ltd 2024a) compared a group of patients who received the Lenus technology to a cohort of patients using anonymised patient data, for whom no treatment details were reported other than that patients did not receive the Lenus technology. These treatment arms have been considered to comprise standard care in the extraction and synthesis, though the details of treatment are uncertain.
- 1 prospective cohort study compared the web version of SPACE for COPD to 2 groups: biweekly telephone support including a written home exercise and education booklet, and a non-digital version of SPACE for COPD based on a paper manual (Houchen-Wolloff 2021). The EAG considered the non-digital technology to be an ineligible comparator, therefore only the telephone support comparator arm was extracted and synthesised.
- 5 before-after studies compared to the care received prior to the introduction of the digital technologies (Patel et al. 2021, All Together Better Sunderland 2021, Pierz et al. 2024, Ghosh 2018, NHS 2022b). These treatment arms have been considered to comprise standard care in the extraction and synthesis, though the details of treatment are uncertain.

COVID-19

Studies varied in whether they preceded, overlapped with or followed the COVID-19 pandemic.

- 5 studies were completed before the COVID-19 pandemic began in March 2020 (Crooks et al. 2020, Patel et al. 2021, North et al. 2020, Ghosh 2018, NHS 2022b).
- 2 studies did not clearly report the dates between which data was collected, so the extent to which they overlapped with the pandemic period is unclear (Luscii, Auton KAA et al. 2024).
- 4 studies were conducted in the years during or immediately following the pandemic period (between 2021 and 2023) and did not discuss any effect this might have had on results (Pierz et al. 2024, The Institute of Clinical Science and Technology 2023, [redacted], Gelbman and Reed 2022).
- 2 studies began prior to COVID-19 before coinciding with the onset of the pandemic and discuss the effects this may have had on results (Taylor et al. 2023, All Together Better Sunderland 2021).
- 1 study began after March 2020 with the objective of evaluating different remote interventions to meet the needs of the pandemic period (Houchen-Wolloff 2021).

5.2 Critical appraisal of studies

As specified by the NICE EVA interim guidance no formal risk of bias assessment was conducted.

2 prioritised studies reported comparative data from RCTs (Crooks et al. 2020, North et al. 2020). Both studies are at risk of providing biased estimates of effect due to providing only per protocol (PP) analyses and/or being underpowered:

- 1 myCOPD RCT reported ITT data for primary outcomes including CAT scores, but authors noted that as a feasibility study with a small sample size (n=41) it was not powered to perform hypothesis tests for effectiveness outcomes (North et al. 2020).
- 1 myCOPD RCT reported PP (n=58) data for the primary outcomes of CAT score and inhaler error, using fewer patients than required by the power calculation (60 participants to estimate 95% confidence interval with precision of ±4.3 assuming a standard deviation (SD) of 8.4) (Crooks et al. 2020). ITT data for 60 participants was available for the rate of exacerbations. In addition, the groups differed in the

key baseline characteristic with myCOPD participants reporting a significantly higher rate of previous exacerbations and higher CAT score than standard care.

Blinding to treatment was not feasible due to the nature of the interventions. The EAG considers these trials to pose a potential risk of producing exaggerated treatment effects due to the subjective nature of the patient-reported outcomes extracted for this EVA. However, this risk cannot be avoided due to the participatory nature of these interventions.

Overall, the EAG considers the RCTs to provide low certainty evidence for the comparative effects of COPD self-management digital technologies.

The standard care comparator was not clear in 7 comparative studies, including 1 prospective cohort study (Taylor et al. 2023, Lenus Health Ltd 2024a), 1 [redacted] (Taylor et al. 2023, Lenus Health Ltd 2024a, Houchen-Wolloff 2021) and 5 before-after studies (Patel et al. 2021, All Together Better Sunderland 2021, Pierz et al. 2024, Ghosh 2018, NHS 2022b).

1 UK before-after study (CliniTouch Vie) reported admissions data for participants with high (>30 days of app use over the study) and low (<30 days) adherence separately and reported significant admissions reduction in the former population but not the latter. Removing patients with low adherence from the analysis was considered to introduce a high degree of bias to this finding (NHS 2022b).

Non-comparative studies were of lower quality, and subject to higher proportions of missing data. 1 case series that reported patient satisfaction data evaluated Luscii as part of the Airedale MyCare24 digital care hub. Patient satisfaction scores are reported for the Luscii app in particular, though because the app was received alongside wider digital services this data may not reflect satisfaction with the Luscii app alone (Luscii Undated).

The EAG had the following concerns regarding the generalisability of the 15 prioritised studies:

- Location: Evidence from the UK was available for all the technologies evaluated in the prioritised studies except Wellinks (evaluated in 1 prospective case series (Gelbman and Reed 2022) and 1 before-after study (Pierz et al. 2024) in the USA). Thus the evidence for Wellinks may be poorly generalisable to the UK NHS context.

Intervention: Eligible interventions were those named in the NICE scope which were multicomponent, and included at least 2 of the following components: symptom monitoring, educational content, self-management planning and healthcare practitioner contact. Within this scope there is range for significant heterogeneity; for example, technologies that include regular contact with healthcare professionals as a component may not be comparable to those that do not. Evidence may therefore be poorly generalisable across studies of different interventions. Components reported within each prioritised study are presented in

- Table 5.1.
- Comparator: the procedures described as standard care differed between studies, and included written self-management booklets, self-management booklets with regular telephone support and in-person pulmonary rehabilitation exercise and education. Elsewhere the content of “standard care” was not reported. Therefore, it may be difficult to understand how generalisable the findings of comparative studies are to different NHS settings.
- Impact of the COVID-19 pandemic: the prioritised studies varied in the extent to which they overlapped with the COVID-19 pandemic, and this was sometimes unclear. This introduces uncertainty to results, as the COVID pandemic is known to have impacted on people with chronic respiratory disease in numerous ways, and therefore studies conducted during the pandemic may be less generalisable to the post-pandemic NHS setting. Similarly, studies conducted prior to the pandemic may be less generalisable to current NHS practice, where remote care has become more widespread.

5.3 Results from the evidence base

Full outcome data are presented in Appendix C.

Clinical outcomes

Respiratory function

Respiratory function was measured using several different tools at various timepoints (ranging from 6 weeks to 21 months) in 8 studies, including 2 RCTs (Crooks et al. 2020, North et al. 2020), 2 prospective cohort studies (Taylor et al. 2023, [redacted], 3 before-after studies (Pierz et al. 2024, Ghosh 2018, NHS 2022b) and 1 retrospective case series (The Institute of Clinical Science and Technology 2023).

4 studies reported respiratory function outcomes for an AECOPD population, including 1 UK RCT (myCOPD), 1 prospective cohort study (Lenus) 2 UK before-after studies (CliniTouch Vie):

- Mean CAT score: A higher CAT score indicates a worse impact of COPD on health and wellbeing, thus a reduction in CAT score indicates improvement. The RCT reported mixed results. While no significant difference was found between myCOPD and standard care at 90 days in the per protocol (PP) population (mean difference -2.94, 95% CI -6.92, 1.04), a longitudinal analysis across all timepoints over 90 days in the ITT population found a statistically significant improvement compared to standard care (-4.49, 95% CI: −8.41, −0.58). (North et al. 2020). 1 prospective cohort study evaluating SPACE for COPD in the UK reported a statistically ($p<0.05$) and clinically (MCID threshold NR) significant improvement from baseline to 6 weeks in each treatment arm (-7.2 points SPACE for COPD, -2.4 telephone monitoring), but did not compare CAT scores between arms (Houchen-Wolloff 2021). 1 before-after study (UK, CliniTouch Vie) reported a significant improvement (-4.2, $p<0.001$) after a mean 222 day treatment period (Ghosh 2018).
- Median CAT score: 1 prospective study reported the median CAT scores were relatively stable over the study period for the intervention. The results were reported in a violin plot, providing a descriptive analysis of the data, rather than analysing for statistically significant differences (Taylor et al. 2023).
- Minimally clinically important difference (MCID) in CAT score: The RCT found similar proportions of patients with a MCID in CAT score (improvement of -2 or

greater) across the 2 arms at 90 days: myCOPD 18/20 (90%) vs. standard care 17/21 (81%) (no statistical comparison reported) (North et al. 2020).
- Proportion with >5% change in CAT score: 1 before-after study reported that 9/23 (39.13%) patients who recorded CAT score at the end of follow up, reported a reduction of >5% (NHS 2022b).
- modified Medical Research Council (mMRC) dyspnoea scale and St George Respiratory Questionnaire (SGRQ): The RCT reported no significant differences in scores at 90 days (mMRC: −0.0183, 95% CI −0.759, 0.796; SGRQ: −1.48, 95% CI −7.82, 4.86) (North et al. 2020).

3 studies in mixed or unclear treatment settings reported respiratory function outcomes, including 1 RCT (Crooks et al. 2020), 1 prospective case series (Auton KAA et al. 2024) and 1 retrospective case series (The Institute of Clinical Science and Technology 2023).

- Mean CAT score: 1 UK RCT (myCOPD) in a mixed treatment setting population reported no significant difference in CAT score between myCOPD and standard care in the per-protocol population at 90 days (−1.27, 95% CI −4.47, 1.92, p=0.44) (Crooks et al. 2020). 1 UK prospective case series (Active+me REMOTE) reported a statistically and clinically (MCID threshold NR) significant improvement in CAT score from baseline to 8 weeks of -2.9 (95% CI -4.2, -1.6) (Auton KAA et al. 2024).
- Mean MRC score: 1 before-after study (Wellinks, USA) reported 30/95 (31.6%) patients experienced an MRC response (defined as an improvement from baseline of 1 category or more), with most patients remaining the same (53/95, 46.8%) and a small proportion worsening (12/95, 12.6%) (Pierz et al. 2024). 1 UK prospective case series (Active+me REMOTE) reported a statistically significant mean improvement in MRC from baseline to 8 weeks of -0.05 (95% CI -0.8, -0.2) (Auton KAA et al. 2024).
- Inhaler use: 1 UK retrospective case series (COPDHub) reported an increase of 41% in the number of patients who reported not having to use an inhaler every day from baseline to 21 months (The Institute of Clinical Science and Technology 2023).

Daily activity

No studies in an AECOPD population reported daily activity outcomes.

2 UK studies reported daily activity outcomes in a mixed or unclear setting population, including 1 RCT (Crooks et al. 2020) and 1 retrospective case series (The Institute of

Clinical Science and Technology 2023). Results were either not statistically significant or were not tested for significance.

1 RCT in a mixed treatment setting population reported that there was no significant difference between myCOPD and standard care at 90 days in mean daily step count (−2252 steps, 95% CI −10, 433.8 to 5927.9) (Crooks et al. 2020, Chaplin et al. 2022).

1 retrospective case series (COPDHub) reported that among all digital technology users from January 2022 to October 2023, the proportion of users reporting regular physical activity rose by 12% (The Institute of Clinical Science and Technology 2023); statistical comparison to baseline was not reported.

Exacerbations

4 studies (2 RCTs (North et al. 2020, Crooks et al. 2020), 1 matched prospective cohort study (Taylor et al. 2023) and 1 before-after study (Patel et al. 2021)) reported exacerbations following use of interventions, and the definition of exacerbations differed between studies. 1 study distinguished between exacerbations (described as acute events characterised by a worsening of the patient's respiratory symptoms beyond normal variations leading to medication changes) and severe exacerbations (exacerbations that required hospitalisation) (Patel et al. 2021); the latter are summarised under admission outcomes. 1 matched prospective cohort study reported community-managed exacerbations, defined as any reported use of steroids or antibiotics (Taylor et al. 2023). The remaining study did not differentiate the severity of exacerbations, or state whether these led to hospitalisation (North et al. 2020).

3 UK studies in an AECOPD population found:

- No significant difference in the risk of exacerbation between patients randomised to myCOPD or standard care at 90 days (adjusted rate ratio: 0.581 favouring myCOPD, 95% CI 0.315, 1.07) (North et al. 2020).
- Most (80/90) patients in a before-after study who received COPDPredict experienced exacerbations after 6 months, with a total of 112 episodes of which 108 were mild or moderate (defined as requiring the use of steroids or antibiotics but not hospitalisation) (Patel et al. 2021). Exacerbation rate in the comparison group (period prior to baseline) was not reported.
- 1 matched prospective cohort study reported patients using Lenus experienced a median of 2 community exacerbations (those requiring antibiotics or steroids) per patient per year at 12 months; this outcome was not reported for the control group (Taylor et al. 2023).

1 UK RCT in a mixed treatment setting population reported:

- A statistically significant increase in the number of exacerbations at 90 days experienced by patients randomised to myCOPD compared to standard care in a UK RCT (incidence rate ratio 2.55, 95% CI 1.17, 5.54) (Crooks et al. 2020). However, authors note a baseline group imbalance with the myCOPD arm having a significantly higher rate of previous exacerbations and CAT score than standard care, which may overestimate the effect of standard care.

<u>Hospital admissions, readmissions or emergency admissions.</u>

Reporting of admissions varied. Some studies specifically reported COPD exacerbation-related admissions, some included all-cause admissions, and others did not specify.

6 UK studies in AECOPD populations reported rates of readmissions, including 1 RCT, 2 prospective cohort studies and 3 before-after studies. 5 of these studies reported COPD or respiratory-related admissions or emergency department (ED) visits. Only 1 study reported a significant difference between digital technologies and standard care when reporting results for all analysed patients:

- 1 RCT reported no statistically significant difference in the rate of COPD-related readmissions between myCOPD and standard care at 90 days (odds ratio 0.383, 95% CI 0.0738, 1.99) (North et al. 2020).
- A prospective matched cohort study (Lenus) reported a significant reduction in mean COPD or respiratory-related admission rates in the year following onboarding to the digital technology compared to the year prior, in both the Lenus (0.5941, p<0.0001) and standard care (0.4979, p<0.0001) groups, but did not provide an analysis of whether the reduction in admissions in the Lenus group was significantly different to that experienced in the control group. In addition, no details of the form or extent of self-management care in the year prior were reported other than that 24.1% in the Lenus group had prior pulmonary rehabilitation, so it is unclear what care the study arms are being compared against (Taylor et al. 2023). The study also reported the median time to first COPD or respiratory-related admission or death was increased in the RECEIVER cohort compared to the control cohort (335 days vs 155 days), which was statistically significant (p=0.047). A prolonged time to first COPD or respiratory-related admission was also noted in the RECEIVER cohort when considering this endpoint alone (400 days vs 255 days). However, the difference was not statistically significant between the cohorts (p = 0.241).
- 1 [redacted] reported [redacted] (Lenus Health Ltd 2024a). [redacted] (Lenus Health Ltd 2024a).
- 1 before-after study (COPDPredict) reported a statistically significant reduction in the rate of exacerbation-related ED visits (from the 3 months prior to study start vs. from baseline to after 3 months use: change (-98%, p<0.001) (Patel et al. 2021).
- 1 before-after study (CliniTouch Vie) reported a significant reduction in COPD-related admissions for a subgroup of 22/29 patients who used the app for >30 days (from the 12 months prior to the study vs. from baseline to 12 months: change in mean admission rate -1.8; p=0.0001259). The difference in admissions for the 7/29 patients who used the app for <130 days was not significant (-4 admissions compared to 12 months prior to baseline, p=0.4142) (NHS 2022b).

2 studies reported all-cause hospital admissions or ED visits in AECOPD populations, including 1 prospective cohort study that reported significantly greater reductions in digital technologies compared with standard care:

- [redacted]: 1 [redacted] (Lenus Health Ltd 2024a).
- 1 before-after study (CliniTouch Vie) reported a statistically significant reduction in the mean all-cause admission rate (-1.25 admissions, p<0.001) from the period prior to baseline compared to baseline to end of study follow up (mean 222 days) (Ghosh 2018).

3 studies reported admission data for populations in a mixed or unclear treatment setting. None reported significant differences between digital technologies and standard care.

3 studies in mixed or unclear treatment settings reported COPD or respiratory-related admissions or ED visits:

- 1 UK RCT (myCOPD) in a mixed treatment setting population reported similar numbers of exacerbation-related hospitalisations and ED visits at 90 days between patients receiving myCOPD (1 and 2 respectively) and standard care (2 hospitalisations and 1 ED) (Crooks et al. 2020).
- 1 USA before-after study (Wellinks) did not compare rates of COPD-related admissions and ED visits statistically, reporting that in the 3 months prior to baseline 132/141 (93.6%) patients had been hospitalised and 127/141 (90%) had visited the ED, while from baseline to end of follow up (24 weeks) 99 (93.4%) had been hospitalised and 95 (89.6%) had visited the ED (Pierz et al. 2024).
- 1 UK before-after study (Luscii) reported a reduction of 58% (26 to 11) in the number of respiratory-related ED visits which was not tested statistically (All Together Better Sunderland 2021).

1 study in an unclear setting reported all-cause ED visits:

- 1 UK before-after study (Luscii) reported a reduction of 16% (31 to 26) in the number of ED visits from the 9-month period prior to baseline to the 9 months following in 30 patients; the difference was not tested statistically. (All Together Better Sunderland 2021).

Outpatient clinical visits, GP visits

1 UK before-after study in an unclear treatment setting (Luscii) reported a 34% (184 to 122) reduction in the number of contacts with primary care from the 9-month period prior to baseline to 9 months in 30 patients; the difference was not tested statistically (All Together Better Sunderland 2021).

Additional medication required including steroids and antimicrobials

Requirement for additional medication was not widely reported. A UK RCT (myCOPD) in a mixed treatment setting reported on participants requiring antibiotics and/or steroids due to COPD exacerbations, but did not conduct any within-group or between-group comparisons. 3 months prior to baseline, 3/11 participants in the myCOPD group required antibiotics compared to 0/3 in the standard care group. Throughout the duration of the study, 6/13 participants in the myCOPD group and 2/8 in the standard care group required antibiotics. Steroids were required by 1/11 participants who had exacerbations in the myCOPD group and 2/3 participants who had exacerbations in the standard care group at 3 months prior to baseline. During the study 2/13 in the COPD group and 1/8 in the standard care group required steroids as a result of COPD exacerbation. Some patients required both antibiotics and steroids (3 months prior to baseline: 7/11 myCOPD participants and 1/3 standard care participants; during the study: 4/13 myCOPD participants and 6/8 standard care participants) (Crooks et al. 2020).

Optimising inhaler technique.

2 UK RCTs reported data on the optimisation of inhaler technique using the rate of critical inhaler errors.

1 RCT in an AECOPD population reported a statistically significant reduction in the rate of critical inhaler errors at 90 days in patients using myCOPD compared to those receiving standard care (adjusted risk ratio 0.377; 95% CI 0.179, 1.04) in the per protocol population (North et al. 2020).

1 RCT in a mixed treatment setting population reported no significant difference between myCOPD and standard care in the rate of critical inhaler errors (adjusted odds ratio 0.30; 95% CI 0.09, 1.06; p=0.061) or mean count of inhaler errors (adjusted incidence rate ratio 0.97; 95% CI 0.52, 1.81; p=0.93) at 90 days (Crooks et al. 2020).

Intermediate outcomes

Withdrawals and study and intervention-related adverse events are summarised in section 6.

Intervention adherence

Adherence to the digital technologies was reported by various measures at different timepoints, and only 1 study reported statistical comparisons in adherence to the digital technology with adherence to a control group (Houchen-Wolloff 2021).

4 UK studies in an AECOPD population:

- Compliance/minimum use: An RCT reported 8/20 (40%) of patients used myCOPD at the minimum recommended amount (at least once a week every week for the trial duration) (North et al. 2020). 1 matched prospective cohort study reported a mean percentage of 79.8% patients completed a CAT score entry each week in Lenus at 12 months (Taylor et al. 2023). 1 before-after study reported that 98% of 90 participants were compliant with daily wellbeing assessments for COPDPredict (supported by automatic reminder notifications) (Patel et al. 2021).
- Completion: 1 UK prospective cohort study reported that the self-management program completion rate (undefined) was significantly higher in the telephone support arm vs the SPACE for COPD arm (30% SPACE for COPD, 56% telephone support, p<0.05) (Houchen-Wolloff 2021).
- Mean days of use: 1 RCT (myCOPD) reported the mean number of days of use was 4.5 (SD 2.37) at week 1, 4.3 (SD 2.2) at week 6 and 5.6 (SD 2.13) at week 12 (North et al. 2020).

- Use for more than 30 days: 1 before-after study reported that 22/29 participants used CliniTouch Vie for at least 30 days over 9 months and 7/29 participants used it for less than 30 days (of whom 5/29 participants used the app for less than 7 days) (NHS 2022b).

4 studies in a mixed or unclear treatment setting population reported adherence using different measures:

- Compliance/minimum use: 1 USA before-after study reported that the number of patients compliant (using at least once per week) with the Wellinks app fell from 133/141 (94.3%) at week 1 to 71/144 (50.4%) at week 12. 33/141 (23.4%) were compliant for <25% of the study period and 40/141 (28.4%) were compliant for >75% of the study period (Pierz et al. 2024).
- Activation: 1 UK RCT in a mixed treatment setting population reported that 21/29 patients activated myCOPD after assignment, of whom 18/21 (86%) were using the app in the final third month of the trial (Crooks et al. 2020). 1 UK case series reported that 59/69 participants assigned Active+me REMOTE activated the app (Auton KAA et al. 2024).
- Mean days of use: 1 UK RCT (myCOPD) in a mixed treatment setting population reported that the mean days of app use at 3 months was 44 days (SD 31.6) (Crooks et al. 2020). 1 UK case series reported that the mean days of Active+me REMOTE use was 28.9 days (SD 19.5) at 8 weeks (Auton KAA et al. 2024).
- Mean weekly app entries: 1 USA prospective case series reported the mean number of weekly Wellinks app entries for medication use, oximetry and spirometry reduced by 52.3%, 54.2% and 45.4% respectively from baseline to week 8 (Gelbman and Reed 2022).

1 UK retrospective case series in an unclear treatment setting reported adherence unclearly as the number of measurements sent on the right day as 66; the meaning of this measurement was not fully described (Luscii).

Additional activation data for myCOPD was presented in the My mHealth Ltd request for information (RFI) submission document. This reports a national activation rate of [redacted] across the NHS overall, while activation rates for recent service deployments across 5 integrated care boards range from [redacted] (my mhealth Ltd 2024).

Patient-reported outcomes

Health-related quality of life

2 prospective cohort studies in an AECOPD population reported health-related quality of life (HRQoL) outcomes (Taylor et al. 2023, Houchen-Wolloff 2021). There was no comparative evidence suggesting digital technologies are superior to standard care in improving HRQoL outcomes.

- 1 UK prospective cohort study provided a descriptive analysis of EQ-5D visual analogue scale (VAS), presented in a violin boxplot. The analysis suggested that those receiving the intervention had a median VAS score between 50 to 55 across the study period. No further statistical analysis was conducted on the HRQoL data (Taylor et al. 2023).
- 1 UK prospective cohort study reported no differences in CRQ scores between SPACE for COPD and telephone monitoring arms after 6 weeks, though within-group changes from baseline were statistically ($p<0.05$) and clinically significant (MCID threshold not reported) for both groups on the CRQ dyspnoea scale (Houchen-Wolloff 2021). Emotion and fatigue domains were statistically improved in telephone monitoring patients, and the mastery domain was both clinically and statistically improved in telephone monitoring patients. Improvements considered to be clinically significant were reported in the SPACE for COPD group, but all could have been due to chance (not statistically different) (Houchen-Wolloff 2021).

3 UK studies in mixed or unclear patient treatment settings reported HRQoL data using 2 measurements at timepoints ranging from 8 weeks to 3 months.

- 2 studies reported the EQ-5D-5L, neither finding significant differences:1 RCT in a mixed treatment setting population reported a non-significant reduction in EQ-5D-5L utility and non-significant increase in visual analogue scale (VAS) scores at 90 days in myCOPD patients vs standard care (utility −0.04, 95% CI −0.12, 0.05; VAS 0.86, 95% CI −9.46 to 11.18) (Crooks et al. 2020).1 prospective case series (Active+me REMOTE) reported no difference in the EQ-5D-5L utility and VAS scores at the end of follow up (8 weeks) (Auton KAA et al. 2024).
- 1 study reported the Chronic Disease Quality (CRQ) of life scale: 1 UK prospective case series (Active+me REMOTE) reported a statistically significant mean improvement in all 4 domains of the CRQ from baseline to 8 weeks, including a clinically significant (MCID threshold NR) improvement in the dyspnoea domain (6.6, 95% CI 4.3, 8.9) (Auton KAA et al. 2024).

Patient experience, usability and acceptability

No studies in an AECOPD population reported patient satisfaction or usability.

4 studies carried out in unclear treatment settings reported patient satisfaction. 3 used a patient satisfaction survey to ascertain patient experience, usability and acceptability:

- Educational value: A US before-after study (Wellinks) reported that 74/89 (83%) participants surveyed at week 24 agreed that using Wellinks helped them to learn more about COPD (Pierz et al. 2024).
- Ease of use and overall value: 1 UK prospective case series (Wellinks) (Gelbman and Reed 2022) surveyed patients on their opinion of the app; among various questions, 15/16 (94%) of participants agreed that Wellinks was easy to use and 13/16 (81%) of participants agreed Wellinks was valuable. 1 UK before-after study surveyed 17 of 30 participants in a patient satisfaction questionnaire, of whom 13 responded; 13/13 (100%) agreed that Luscii was easy to use and effective in managing COPD and 10/13 (77%) preferred the app to their previous COPD care (3/13 had no preference) (All Together Better Sunderland 2021).
- Satisfaction: 1 UK retrospective case series (Luscii) reported a mean of 4.6 (out of 5) for overall satisfaction, 4.2/5 for reducing need to attend hospital and 4.2/5 for providing a sense of safety amongst 81 of 186 users (Luscii).

Psychological wellbeing

3 studies reported psychological wellbeing outcomes. Using different measurements and at different time points.

1 study reported psychological outcome data in an AECOPD population. This UK RCT reported no difference between myCOPD and standard care in the Hospital Anxiety and Depression Scale (HADS) (adjusted mean difference 3.08, 95% CI – 7.61, 1.45) or Patient Activation Measure (PAM) score (adjusted mean difference 5.02, 95% CI −8.28, 18.3) at 90 days (North et al. 2020).

2 studies in unclear treatment settings reported psychological health outcomes:

- 1 US before-after study (Wellinks) reported a significant improvement from baseline to week 12 in COPD Self-Efficacy Scale (CSES) score (mean change 11.1 (SE 3.1), $p<0.001$) (Pierz et al. 2024).

- 1 UK prospective case series investigating Active+me REMOTE reported significant improvement in HADs anxiety (mean change -1.1, 95% CI -2.1 to -0.2) and depression (-0.8 (95% CI -1 to -0.1) scores from baseline to 8 weeks (Auton KAA et al. 2024). There was no significant change in PAM score from baseline to week 8 (2.8,95% CI -0.5, 6.2) (Auton KAA et al. 2024).

6 Adverse events and clinical risk

6.1 Adverse events

Adverse events (AEs) were reported in 6 studies for 4 digital technologies (myCOPD, Wellinks, COPDPredict, Active+me REMOTE). The rates of reported AEs were generally low and indicate that the technologies evaluated in this EVA are plausibly safe for use. Adverse events were generally reported to be unrelated to the digital interventions.

<u>myCOPD</u>

2 studies reported AEs, though neither stated any AEs to be intervention related: 1 RCT in a mixed treatment setting compared 29 patients with COPD using myCOPD and 31 patients receiving standard care (Crooks et al. 2020) and 1 RCT in an AECOPD population compared 20 patients with COPD who used myCOPD with 21 patients who received standard care (North et al. 2020):

- Mixed treatment setting: 15 AEs were reported by 12 participants in the study. 5 of 29 patients using myCOPD reported an AE, compared to 7 AEs reported by the participants who received standard care. No serious AEs were reported. (Crooks et al. 2020). The type of AE was not reported.
- AECOPD population: 3 AEs were reported in the 20 patients who used myCOPD (number of patients experiencing an AE was not reported). 2 of these AEs were constipation and 1 was a medication side effect. There was 1 AE reported by a participant receiving standard care which was a respiratory infection (North et al. 2020).

Wellinks

2 prospective case series in unclear treatment settings reported on AEs, 1 including 19 people with COPD (Gelbman and Reed 2022) and 1 including 141 people with COPD (Pierz et al. 2024). Both studies reported no Wellinks related AEs recounted by the participants.

COPDPredict

1 prospective case series of 90 people in an AECOPD population with non-comorbid COPD received COPDPredict and reported that no AEs related to the digital technology were observed (Patel et al. 2021).

Active+me REMOTE

1 prospective case series evaluating 69 COPD patients who used Active+me REMOTE in an unclear setting reported 46 AEs and 2 serious AEs. No details of the types of AEs were provided and the serious AEs were not considered to be attributable to Active+me REMOTE (Auton KAA et al. 2024, NCT05881590 2023).

Mortality

5 studies reported on mortality. 1 matched prospective cohort study in an AECOPD discharge setting assessed participants who used Lenus against a matched group of patients from the same NHS area and reported no statistical difference in the 12-month mortality rate between Lenus and standard care, (Lenus 16.9% vs standard care 24.1%; hazard ratio: 0.743; 95%CI 0.463–1.191; p=0.215) (Taylor et al. 2023). Causes of death were not reported (Taylor et al. 2023). A [redacted] (Lenus Health Ltd 2024a). A prospective case series evaluating COPDPredict in an AECOPD population setting reported no deaths through the duration of the study (Patel et al. 2021). 1 before-after study (CliniTouch Vie) in an AECOPD population reported that 4/33 patients died during the study and were not included in the analysis (NHS 2022b). 1 prospective case series assessing Active+me REMOTE in an unclear treatment setting reported that 1 participant died

during follow up but did not report why (Auton KAA et al. 2024). No other studies reported information on mortality.

6.2 Withdrawals and discontinuations

5 studies across 4 digital technologies reported on withdrawals and discontinuations (myCOPD, Wellinks, Lenus and CliniTouch Vie).

myCOPD

1 RCT comparing myCOPD to standard care in a mixed treatment setting population reported 7 withdrawals and discontinuations. For the group receiving myCOPD (n=29) there were 3 withdrawals 1 due to being too unwell, 1 for no provided reason, and 1 with withdrew and subsequently re-entered the study. There were 2 people lost to follow up. For the standard care group (n=31), 1 person withdrew with no reason provided and 1 was lost to follow up (Crooks et al. 2020). A second RCT evaluating myCOPD (n=20) compared to standard care (n=21) in an AECOPD population setting reported 6 discontinuations, evenly distributed between study arms (North et al. 2020).

Wellinks

A cohort study in an unclear setting comparing Wellinks (n=68) and Wellinks combined with coaching (n=73), and extracted as a case series, reported data on withdrawals and discontinuations: 11 participants were lost to follow up for a range of reasons: changed their mind (n=7), worsening health status (n=2), illness of spouse (n=1), back surgery (n=1) (Pierz et al. 2024).

Lenus

A matched prospective cohort study comparing Lenus (n=83) to standard care (n=415) inn AECOPD population reported 3 withdrawals from the Lenus arm, though the reasons were not reported (Taylor et al. 2023).

Active+me REMOTE

1 prospective case series of Active+me REMOTE in 69 participants with COPD in an unclear setting reported that 23 participants were lost to follow up. Withdrawals and

discontinuations were most commonly due to not attending the end of course assessment (n=7), not completing the final assessment in the follow up period (n=2) and not being contactable for final assessment (n=2). The authors stated that non-attendance at final assessment was due to either COPD exacerbations or a comorbid musculoskeletal disorder (Auton KAA et al. 2024).

CliniTouch Vie

1 before-after study in an AECOPD population reported that 4/33 patients died during the study and were not included in the analysis (NHS 2022b).

7 Evidence synthesis

Findings across studies are discussed narratively. A meta-analysis was not feasible within the constraints of this EVA.

The evidence-base evaluated the use of self-management digital technologies in mixed-severity COPD patients, generally from mixed or general referral settings. A smaller evidence base addressed a COPD population using the technology following hospitalisation for an acute exacerbation. The EAG prioritised 14 studies, of which 10 provided comparative data. 2 UK RCTs compared myCOPD to standard care, consisting of an assigned written self-management plan in 1 RCT (North et al. 2020) and the continuation of previous usual care in the other (Crooks et al. 2020). 1 cohort study reported standard care to consist of telephone supported self-management (Houchen-Wolloff 2021); the remaining 2 cohort studies (Taylor et al. 2023, [redacted]) and 5 before-after studies (Patel et al. 2021, All Together Better Sunderland 2021, Ghosh 2018, NHS 2022b) did not report treatment details of standard care groups.

The evidence-base evaluated the use of technologies in patients with AECOPD following hospital discharge using various definitions (7 studies), and studies in which the treatment setting was mixed or unclear (7 studies). Outcomes were reported inconsistently, across a wide range of measures and with few statistically significant

differences making it difficult to interpret the data definitively. Most comparative evidence was for AECOPD populations (7 UK comparative studies) with less comparative data reported in mixed or unclear populations (1 UK RCT in a mixed population, and 1 UK study in an unclear population).

In the AECOPD population, comparative evidence for key outcomes (CAT score, exacerbations, admissions and inhaler errors) reported significant differences favoring digital technologies, or non-significant findings that were in the direction of the digital technologies. In a mixed population, 1 RCT reported non-significant differences in favour of myCOPD in CAT score and the rate of inhaler errors. Exacerbations were significantly lower in patients receiving usual care, though these patients had a significantly lower rate of prior exacerbations at baseline which may have confounded the trial's result. Evidence for impact to admissions was mixed, with 2 comparative studies finding no difference to exacerbation-related or COPD-related admissions and a third study reporting a large decrease in respiratory-related admissions and smaller decrease in ED visits, though neither were tested for statistical significance.

Adverse events (AEs) were reported in 6 studies and were generally low and not reported to be treatment-related, indicating that the technologies evaluated in this EVA are plausibly safe for use.

8 Economic evidence

8.1 Economic evidence

A single set of searches was conducted to identify both clinical and economic evidence for the scoped technologies (see Section 4.1). Search methods are reported in Appendix A and study selection criteria is summarised in Appendix D. 5 costing studies set in the UK, identified through the searches and company submitted evidence, were identified and summarised below and in Table 8.1: Narrative summary of economic studies 1 was a review article summarising the EAG report of NICE's Medical Technology Guidance 68 for a digital tool to support people to manage COPD, which included cost-comparison models. 4 studies were NHS evaluations of remote

monitoring for people with COPD in the UK. Additionally, 1 cost-effectiveness model was submitted to the EAG by Lenus.

Davies et al. (2023) (Davies H et al. 2023) assessed myCOPD in the UK. The review article summarises the EAG report to inform NICE's Medical Technology Guidance 68 to support people to manage COPD. No economic evidence was provided by the company and no studies were identified in a de novo economic literature search. De novo cost models were submitted by the company for a subgroup for self-management to support people discharged from hospital with acute exacerbation of COPD (AECOPD). The EAG updated input parameters and adjusted the company model structure. The EAG's model reported cost savings as £86,297 per clinical commissioning group (CCG) for myCOPD compared with standard care, with myCOPD predicted to be cost saving in 74% of iterations. The Medical Technologies Advisory Committee (MTAC) concluded that further evidence is required to address uncertainties in the current evidence base.

All Together Better (2021) (All Together Better Sunderland 2021) assessed a pilot study of Luscii remote monitoring in the NHS for people with COPD in Sunderland, UK. The report concluded that the pilot had improved quality of life for people with COPD and helped migrate care delivery from acute and primary care to in the community ('Recovery at Home'). It reported cost savings due to reductions in A&E attendance, emergency admissions and bed days.

3 UK studies assessed CliniTouch Vie in an NHS setting. Ghosh et al. (2016) (Ghosh 2016) was a retrospective evaluation of a combined intervention in Leicester, including an earlier version, CliniTouch, which reported savings due to averted admissions and net savings to the CCG of £2,278 per person. Ghosh et al. (2018) (Ghosh 2018) was an expansion of the 2016 study using CliniTouch Vie, which reported total savings of £2,304 per person. Chorley and South Ribble CCG / Greater Preston CCG (2022) (Chorley and South Ribble CCG / Greater Preseton CCG 2022) was an NHS report of CliniTouch Vie in COPD in Central Lancashire, UK. Analyses reported technology costs and admissions savings and claimed the pilot saved the NHS £90,128.

Lenus Health submitted an early cost-effectiveness model as part of their company submission documents. The results suggest that under base case assumptions the technology would be cost-effective, with a dominant incremental cost-effectiveness ratio (ICER). The results suggest a cost saving of £1,691 per person and a QALY gain of 0.03 per person. YHEC staff were involved in the development of this economic model. The staff involved in the development of this model were not a part of the EAG team on this EVA.

Table 8.1: Narrative summary of economic studies

Study ID and location	Title	Study type	Narrative summary
myCOPD			
Davies et al. (2023) (Davies H et al. 2023) England and Wales	myCOPD App for Managing Chronic Obstructive Pulmonary Disease: A NICE Medical Technology Guidance for a Digital Health Technology	Costing model	myCOPD was compared with standard care in COPD in cost models submitted by the company to NICE in the UK. De novo cost models were submitted for 2 subgroups: people discharged from hospital with AECOPD (where sstandard care was a written self-management plan at discharge) and people referred for PR with stable COPD (where standard care was face-to-face PR in a 6-week programme). The latter is not summarised here because there is a separate EVA dedicated to this topic (National Institute for Health and Care Excellence 2024). The EAG updated input parameters (uptake of myCOPD, number of exacerbations and readmission rate over 90 days post exacerbation for myCOPD, probability of being treated, and number of patients entering the model) and adjusted the model structures (outcomes were applied to every person discharged from hospital with an acute exacerbation, and the myCOPD uptake rate was amended down to be more realistic). The AECOPD model was a cost calculator with a 1-year time horizon using efficacy data from the RESCUE RCT. The company model base-case results reported cost savings of £204,641 per CCG. Best and worst case scenarios assessed the impact of factors including population, index admissions, uptake, GP appointments, and rate and costs of readmissions and exacerbations: best-case: £1,785,878 cost saving per CCG; worst-case: £69,530 cost increase per CCG. The EAG (York Health Economics Consortium) considered the AECOPD model structure appropriate. The EAG considered the 100% uptake rate to be optimistic and amended it to 46% to account for the proportion of people who would not agree to be registered for myCOPD. This was also varied in a sensitivity analysis. The EAG's model had cost savings reported as £86,297 per CCG for myCOPD compared with standard care with myCOPD predicted to be cost saving in 74% of iterations. The

			best-case scenario result was a £4,143,428 cost saving per CCG. The worst-case scenario result was a £58,928 cost increase per CCG. The point at which myCOPD changed from being cost saving to cost incurring was when the uptake rate was 26.2% or when the per person 90-day readmission rate was 0.30. The key driver of results for both the company and EAG models was the readmission rate over 90 days post AECOPD. The EAG conducted probabilistic sensitivity analysis on the same factors as the best and worst case scenario analysis as well as other costs and estimated myCOPD had a 73.5% probability of being cost saving. The company evidence and EAG critique was presented to the MTAC. The MTAC concluded (in 2021) that although myCOPD shows promise for self-managing COPD, further evidence was required to address uncertainties in the current evidence base. The limitations to the analysis included uncertainty over the uptake of myCOPD (evidence outcomes were short term meaning uncertainty around observed benefits and uptake), pricing and licensing (given the changes in local NHS systems structures). The trials evaluating myCOPD had small sample sizes (RESCUE and EARLY) resulting in no positive significant benefits being demonstrated for clinical outcomes, or was assessed by the EAG to have underestimated an adequately powerful sample size (TROOPER).
Luscii			
All Together Better (2021) (All Together Better Sunderland 2021) UK	Evaluation Report on the Deployment of 'Luscii' Remote Patient Monitoring for COPD Patients	Costing model	This assessment reported a pilot study of Luscii remote patient monitoring in the NHS for people with COPD in Sunderland, UK. The 2020 pilot (for 9 months) created a 'Digital Virtual Ward' to enable a more effective local care pathway that better utilised the existing 'Recovery at Home' (R@H) team. The total year 1 budget was £94,500 (including annual recurring costs of £33,000). The approach taken was a longitudinal study. The start of the project coincided with the COVID-19 pandemic, no specific benefits related to this were captured. Data on impact of acute services were taken from EMIS (for 130 referrals). Costs were modelled for A&E attendance and emergency admission. Sources of costs inputs were not further described.

			Impact on the costs to acute services as a result of the migration of care estimated 'non cashable' savings of £43,632 (equivalent to £58,176 per year) and a positive return on investment (61% versus the full first year costs or 176% versus the annual recurring costs; rising to between 222% and 625% when only assuming A&E attendances and admissions linked to a respiratory condition rather than for any admission). A&E attendance showed a 7% reduction in total cost incurred, a saving of £718 when Luscii was used (£9,701 versus £10,419). Average cost per attendance was £162 when Luscii was used versus £174 before (a 7% reduction). Emergency admissions showed a 47% reduction in total cost incurred, a saving of £42,914 when Luscii was used (£44,495 versus £87,409). Average cost per admission was £1,788 when Luscii was used versus £2,820 before (a 37% reduction). There were important limitations to this analysis. The costing methodology was not fully explained, including specific sources of costs. The authors acknowledge the study's initiation coinciding with the COVID-19 pandemic will have impacted the evaluation results. This study has not been peer-reviewed.
CliniTouch Vie			
Ghosh et al. (2016) (Ghosh 2016) UK	Combined interventions for COPD admissions within an urban setting	Costing model	A retrospective evaluation of a combined intervention: CliniTouch (an earlier version of CliniTouch Vie), clinical health coaching and specialist nurse interventions, in people with 2 or more unscheduled COPD admissions in the previous 12 months using 2013 admissions data in Leicester, UK. CliniTouch was installed in patients' homes to support self-management, which triggered intervention as necessary. The mean number of people enrolled was 54. The combined intervention provided £243,303 of overall savings (QIPP savings minus intervention costs) to Leicester City CCG over 1 year due to averted hospital admissions (per quarter the range was £46,431 to £83,491). Incremental costs were £125,753 to the CCG resulting in net savings of £117,550. The mean saving per person enrolled was £2,278 (2013).

			The limitations to the analysis included the population being enrolled being relatively high users of acute services and the evaluation being of a multifactorial intervention with it not being clear if coaching or education were delivered through CliniTouch. The authors also noted there was a 9.1% reduction in all COPD emergency admissions within the CCG for that period versus the same period 12 months prior.
Ghosh et al. (2018) (Ghosh 2018) UK	A cost saving intervention for patients with severe breathlessness	Costing model	An expansion of the 2016 study (reported above) using CliniTouch Vie, also in people with 2 or more unscheduled COPD admissions in the previous 12 months in Leicester. Patients had access to a reduced intensity of service than in the original intervention (health coaching was replaced by an educational suite within CliniTouch Vie). Data for 28 people were analysed. The costs analysis used historic admissions costs (£122,318) and total CliniTouch Vie costs (£57,799) to calculate total savings of £64,519. The mean saving per person was £2,304. The limitations to the analysis included the population being enrolled being relatively high users of acute services, and not having a control group. The study was presented as a 'comment' in a journal, not a full peer reviewed article.
Chorley and South Ribble CCG / Greater Preston CCG (2022)(Chorley and South Ribble CCG / Greater Preseton CCG 2022) UK	Central Lancashire: Respiratory – Technology Solutions	Costing model	An NHS report from 2 CCGs that share management functionality and a community COPD service provided by Lancashire and South Cumbria NHS Foundation Trust services both CCGs. CliniTouch Vie was selected to help test the use of digital technology in monitoring people using the community COPD team (who reviewed alerts), to see the impact on reducing the likelihood of exacerbation requiring hospital admission and to increase service capacity. Analysis was provided by MLCSU, as well as by Spirit Healthcare (the manufacturer). A costs analysis by Spirit Healthcare included 22 people with COPD who had greater than or equal to 2 hospital admissions from August 2018 to January 2019 and were monitored for between 1 and 6 months. The costs analysis reported a cost for CliniTouch Vie of £476 per person enrolled and savings of £2,304 per person enrolled. Mean admissions costs were reported as

			£4,118 per person prior to the use of CliniTouch Vie and £1,400 per person using CliniTouch Vie. The mean costs of CliniTouch Vie were reported as £666 per person. The reported concluded that using MLCSU analysis that 43 fewer non-elective COPD admissions had been observed, combined with the average admission cost of £2,096, it could be argued the pilot saved the NHS £90,128. There were important limitations to this analysis. The authors reported limitations of the MLCSU analysis as people being selected due to their high non-elective COPD admissions, the study not having a control group, and the possible effect of COVID-19. Furthermore, the Spirit Healthcare costing analysis methodology was not explained and 4 people were excluded who died during the course of the study, which may skew outcomes to being more favourable. This study has not been peer-reviewed.
Lenus			
York Health Economics Consortium (YHEC), 2023.	Economic evaluation of Lenus Health COPD Support Service	Early cost-effectiveness model	Lenus COPD Support Service was compared to standard of care in this early cost-effectiveness model. The population of the model was people with severe COPD. The model includes resource use (hospital admission and no admission, length of stay, time to readmission, excaberations) cost and quality of life data. The model captures ongoing and implementation costs associated with Lenus, and the clinical effectiveness is based on real world evidence. The model was provided by Lenus and submitted as company evidence. The base case results suggest that Lenus COPD Support Service may result in a cost saving of £1,691 per person, with a QALY gain of 0.03 per person. The ICER is dominant, the net health benefit is 0.11 and the net monetary benefit is £2,238. Deterministic sensitivity analysis suggested that the biggest driver of the results was the rate of exacerbation with hospital admissions per person per year in standard care, followed by that in the Lenus treatment arm, , This model was built for a population with severe COPD, so does not align completely with the scope of the evaluation. The work has not had any peer review, or a corresponding report to explain any key assumptions.

			COI: York Health Economics Consortium worked with Lenus Health to develop this early economic model. The staff involved in building this model are not a part of the current EAG group for this EVA.

Key: AECOPD - Acute exacerbation of COPD, CCG - Clinical commissioning group, COPD - Chronic obstructive pulmonary disease, EAG – External assessment group, EMIS - Egton Medical Information Systems, EVA – Early value assessment, ICER – Incremental cost-effectiveness ratio, MLCSU - Midlands and Lancashire commissioning support unit, MTAC - Medical Technologies Advisory Committee, PR – Pulmonary rehab, QALY – Quality-adjusted life year, QIPP - Quality innovation productivity and prevention, RCT – Randomised controlled trial.

8.2 Conceptual model

The primary purpose of this analysis was to assess whether it is plausible that using digital technologies for the self-management of COPD could be a cost-effective intervention for adults with a confirmed diagnosis of COPD. It is assumed that those using the digital technologies could still access standard care to support their self-management of COPD. The secondary aim of the analysis was to identify the value of future research, understand the likely key drivers of the results, and highlight the current evidence gaps.

A simple cost-comparison model was designed to capture the potential benefit that could be provided from these technologies over a 1-year time horizon. There is heterogeneity in the types of digital technologies, the features they offer to support self-management, and the other use cases they have if implemented. It is important to consider the other use cases (such as pulmonary rehabilitation or virtual wards) as these are outside of the scope of the evaluation, so it is important to identify these when considering the evidence for self-management of COPD. Some technologies do not have any data or evidence to present, while some have collected evidence, to varying degrees of quality. Hence, the evaluation is not expected to capture one base case that represents all digital technologies to support self-management of COPD. However, the model can be used to highlight the potential impact or value of digital technologies for self-management of COPD, given the current limitations of the evidence, which is collated together as part of the early modelling approach. The model can be used to conduct specific scenarios, including pricing structure or more specific elements of the technologies. The EAG considers that the cost-comparison model can provide an indication of the direction of the results, given the base case assumptions. Therefore, this should be useful for decision-makers to evaluate the potential of digital technologies to support self-management of COPD.

8.2.1 Population

The EAG considered adults with a confirmed diagnosis of COPD. This is consistent with the NICE final scope. Available evidence could not accurately disentangle the AECOPD population, and a wider COPD population, due to a lack of clarity in the

reporting of the studies which were not specifically AECOPD. However, we have conducted scenarios using data from alternative studies that explicitly reported results for AECOPD or COPD populations. Evidence which may also include pulmonary rehabilitation alongside self-management support has been considered by the EAG for the model. This is because available evidence is generally unclear in its description of what is included within self-management. The generalisability of evidence which also includes pulmonary rehabilitation (alongside self-management) in relation to solely self-management should be considered by decision-makers, while the results of the analysis should be interpreted with caution.

8.2.2 Model structure

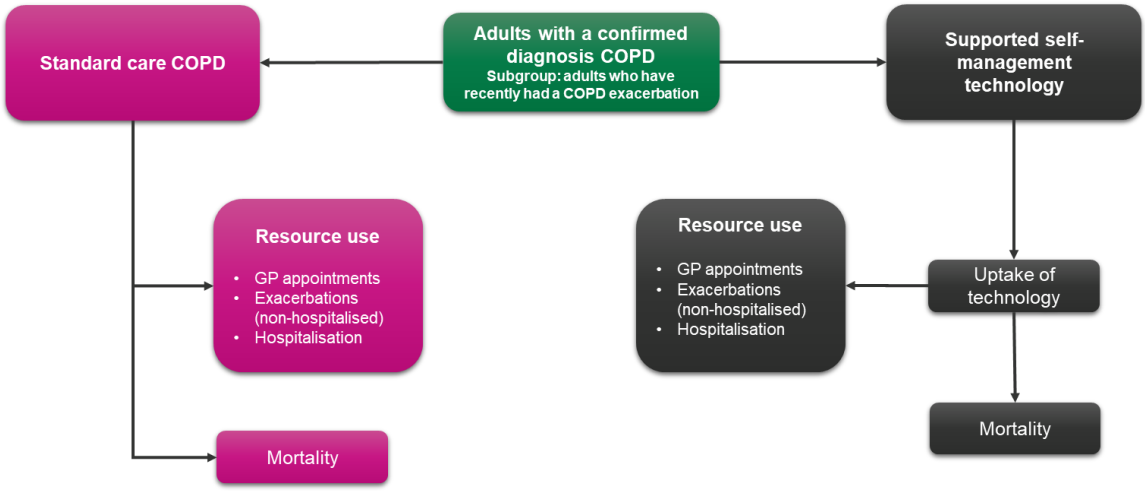
The model used by the EAG was a cost-comparison model with a 1-year time horizon. The model estimated resource use across the different treatment arms, and then applied costs to the different resource use. Mortality was captured in the model as an outcome based on the available clinical evidence. The 1-year time horizon was used because the long-term benefit of the self-management technologies was uncertain. However, it was important to consider a full year of COPD, where symptoms may fluctuate over the course of the year. Furthermore, people with COPD are at risk of exacerbations, which may correlate with certain times of the year, where future treatment is likely to be sought. Hence, the EAG believed that for this early evaluation, the time horizon should be limited to 1 year. Quality adjusted life years (QALYs) were not included in the model given the greatest impact is expected to be on resource use, and a shorter time horizon making it more suitable for cost-comparison analysis(NICE 2023). Section 8.4 discusses the potential impact of self-management technologies on quality and quantity of life, while this is also covered in sections 5 to 8 This is because it is important to determine that self-management technologies are improving (or at least not reducing) people's quality of life, even if it is not explicitly quantified in the model.

The model structure was limited by the amount and type of data available, and assumptions have been made to populate it. The model should therefore be seen as an initial exploration of the economic impact of digital technologies that provide supported-self management for the treatment of COPD.

The model captured different resource use that can be attributed to care associated with COPD. In the base case, the modelling approach took the perspective of the NHS and personal social services. The key aspect of the base case model was to capture key resource use based on the available evidence and clinical assumptions. This includes GP appointments, non-hospitalised exacerbations, hospitalisations and mortality. This resource use may not be exhaustive, especially given the heterogeneity of standard care that may be person specific, and how standard care integrates with the digital technologies to support self-management. For example, potential changes in medication use or inhaler use have not been quantified, given the limited evidence available. Hence, if the digital technologies do lead to reduction in medications and inhaler use, the model would be a conservative estimate of the potential impact. The model structure is the same for the core model. The modelling approach does not capture cycles, and while mortality is captured as an outcome, it does not impact the underlying resource use and other inputs in the model. It is assumed the average resource use inputs accounts for the fact that some people will die over the course of a year. It is assumed there is no cost associated with mortality, especially since this may lead to double counting hospitalisation costs, which may account for people who die soon after hospitalisation.

Effectiveness of the digital technologies were captured through potential reductions in resource use for people who adopted the technology to support their self-management, alongside standard care. A state-driven model is expected to be useful as more evidence is collected. This is detailed in section 10.3. The cost-comparison model diagram is presented in Figure 8.1.

Figure 8.1: Cost-comparison model structure



Outcomes from the model included incremental cost between treatment arms, breakdown in resource use, and difference in mortality. Deterministic sensitivity analysis (DSA) was conducted and represented graphically using a tornado diagram, which highlights the key drivers of the model results. Economically justifiable price (EJP) was also calculated. EJP should be interpreted with caution, given that the results of the analysis are designed to be indicative and further costs and benefits are likely to accrue beyond the 1-year time horizon. Therefore, the true value is uncertain and heterogenous across different digital technology providers.

Probabilistic sensitivity analysis (PSA) was conducted, with 1,000 simulations of the model run (enough for the results to stabilise), and the results averaged. The results consistently stabilised after 500 simulations. Where possible, confidence intervals or appropriate ranges (based on clinical experts or ranges from company evidence) were used to inform parameter uncertainty. Where no appropriate ranges could be determined, a standard error of 20% of the mean was assumed to inform parameter uncertainty, providing this appeared to capture appropriate ranges. Although this is an arbitrary variation, the EAG notes this still allows for greater understanding of the key drivers. Future modelling should look to determine appropriate confidence intervals for these inputs.

Although a probabilistic base case is preferred for health technology assessment, a deterministic value was used in the base case. The results of the deterministic and probabilistic base case are very similar, so the EAG does not expect this to impact any outcomes of the analysis. Not every input used in the economic model reported standard errors to vary in PSA. Therefore, PSA may not be useful due to the unknown uncertainty among the inputs. It is therefore more likely to be useful to view the deterministic and probabilistic values alongside each other.

8.2.3 Assumptions and limitations

A number of assumptions were required to produce the cost-comparison model using the available data. These assumptions may not completely reflect the differences in the various digital technologies. These assumptions are discussed in

Table 8.2.

Table 8.2: Assumptions and limitations of the current model

Assumption	Discussion
Costs of the technologies can be scaled down to a per person cost based on GP sizes, ICS sizes, or other metrics used for costing by digital technology companies.	As part of the model, the running cost of the digital technology are captured in the model. These costs vary between companies, with different pricing structures used by different companies. The modelling approach assumes this can be scaled using metrics like GP size or ICS size to derive a common metric per person. GP sizes are likely to vary across the country, meaning that costs may also vary when implementing the different digital technologies.
The impact of waiting time is not explicitly captured in the model	Reduced waiting time is one of the key value propositions for introducing digital technologies the treatment of COPD. However, the resource use associated with reducing waiting time is expected to be already captured within the evidence used to populate the model. By factoring in wait times directly into the model, the model may double count the potential benefits of the digital technologies. Hence, it is discussed narratively in section **Error! Reference source not found.**, while it is acknowledged some of the potential benefit of a reduced wait time is already captured.
Medical devices associated with monitoring are not captured in the base case	The exact makeup of the devices of people self-managing with COPD is likely to be heterogenous. Currently, there is no published evidence which suggests the average make up of devices required to monitor a person, and what proportion of people would require monitoring. Hence, we have assumed these are broadly equal across the intervention and comparator. Similarly, approximately half of potential companies offer devices as part of their service. If the company provided devices cost more than current supplies of monitoring devices (assuming standard care will still offer remote monitoring), this will have a negative incremental impact on the economic results. Similarly, if the devices offered by digital technology providers are cheaper than other suppliers, this will make the incremental impact less costly than the model estimates.
There may be some double counting between capturing GP appointments and non-hospitalised exacerbations	The McLaughlin and Skinner study refers to unscheduled GP appointments attributable to COPD, and not to appointments specific to exacerbations (McLaughlin K and Skinner E). This could include non-exacerbation-related appointments. The EAG 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, while these appointments may relate to more urgent requests not captured elsewhere (Jordan R et al. 2015).

Assumption	Discussion
Change in inhaler technique and usage is not explicitly captured within the model	It is likely that inhaler technique improvement will lead to reduction in exacerbations (which includes medication prescribing), hospitalisations and GP appointments. Therefore, it is likely that this is already captured within the model. However, if there is any additional healthcare resource use associated with supporting inhaler technique with standard care, this may underestimate the benefit provided by the digital technologies. Improved technique may also lead to a reduction in the number of inhalers required over the course of a year. Previous NHS documentation indicates that inhalers are likely to cost between £1.50 and £30 approximately, based on 30-200 doses(NHS 2021). Inhalers and inhaler usage are likely to be heterogenous across the COPD population. Hence, in order to not build several assumptions and uncertain evidence into the model, this has been omitted from the analysis. If improved inhaler technique leads to a reduction in prescribed inhalers, as a result of digital technologies, the model will produce a more conservative estimate of the cost impact.
Long-term outcomes of treatment are not captured. The model uses a time horizon of 1 year due to short follow up in the available clinical evidence.	People who undergo treatment may realise benefits, such as improved quality of life or reduction in healthcare resource use over time. Currently, there is limited evidence with long-term follow up, so the impact beyond 1 year is uncertain. The EAG notes that some benefits may occur after 1 year, meaning a 1-year time horizon could be considered more conservative for evaluating the potential impact of digital technologies for self-management of COPD.
Outcomes from the clinical data are scaled linearly to a 1-year time horizon	Studies used to populate the model do not have a 1 year follow up. However, the outcomes are scaled linearly to 1 year based on the follow up period provided. Depending on the data collection period of the study, or the proportion of people who recently had an exacerbation, this may overestimate the annual resource use of COPD and the impact of the digital technologies. For example, a study conducted mainly in winter is likely to find a much higher rate of resource use than 1 conducted primarily in warmer months. However, this decision was made in the absence of evidence with longer term follow up. This was not done for the hospitalisation parameters though, as this study is specifically after an exacerbation and is related to readmission, which is most likely in the first 90 days, so is likely to overestimate the true impact over the course of a year. However, a scenario is run where estimated impact on hospitalisation from the digital technology is also extrapolated over a year from alternative, statistically insignificant data.
Evidence used to populate the model may contain a mix of people post-acute exacerbation, and a wider COPD population. Some studies may also have a mix of these 2 populations	More evidence was identified for people using digital technologies to support self-management, than a wider COPD population. Furthermore, some available clinical studies did not make it explicit if the technology was used for people after an acute exacerbation, or if the study population was a mix of people who have or have not recently had an exacerbation. The modelling approach therefore does not differentiate these 2 slightly different populations. However, it may be that self-management technologies are more or less effective in people who have had a recent exacerbation.

Assumption	Discussion
The baseline resource use data used to populate the model is only available from studies where the baseline CAT score had a high or very high impact level. This may distort the number of baseline events for the general COPD population, by looking at a more severe subgroup.	If the people in the studies used to populate the model are, on average, suffering high or very high impact from their COPD, the number of baseline events may be higher than the general COPD population. The model may therefore overestimate the potential impact on people who have less severe COPD, where baseline events may be lower. COPD is expected to be cyclical, so just because someone at baseline has a high CAT score, it does not necessarily mean they will always have a high CAT score. Future evidence should look to enroll people with a range of different severities, or improve the reporting of the captured population.

Key: CAT – COPD assessment score, COPD – Chronic obstructive pulmonary disease, EAG – Evidence assessment, GP – General practitioner, ICS – Integrated care system, VW – Virtual ward.

8.2.4 Model inputs

Model inputs were derived via company evidence submissions, clinical correspondence and existing evaluations in this area (Davies H et al. 2023). A range of study data have been combined from the digital technologies, with only a subset of the technologies having suitable evidence for use in the economic analysis. Therefore, we have not produced individual models for each company, due to the available time, evidence and the early nature of the analysis. The base case is intended to represent an indicative average, rather than a definitive representation of every digital supported self-management technology for adults with COPD. Where there was a paucity of data, assumptions have been made that are explained throughout this section and, where possible, clinically verified. The range of values from the identified evidence were used as uncertainty intervals for sensitivity analyses where possible.

Set-up parameters

The model compared digital technologies with standard care. The cohort was estimated from the mean number of people registered in each Integrated care system (ICS) in England, the prevalence of COPD, and the uptake of the technologies. The uptake of technologies was estimated from various company submissions and Davies et al. (Davies H et al. 2023). Uptake of technology was found to vary, with a mean estimate applied in the base case and a range of values used as uncertainty intervals within sensitivity analysis. Set up parameters are detailed in Table 8.3.

Resource use

Resource use inputs were primarily derived from company submissions documents, such as the RESCUE study (North et al. 2020). Resource use on the number of exacerbations, GP appointments and hospitalisations for standard care is outlined in Table 8.4.

Efficacy

Efficacy inputs were derived from company evidence submissions. Reductions in resource use were applied as relative risks to standard care, to determine resource use in the intervention arm. Table 8.5 provides the relative risks associated with the intervention arm.

Costs

Costs were derived from the company evidence submissions, the Personal Social Services Research Unit (PSSRU (PSSRU 2022)), National Cost Collection (NHS England 2022) for the 2022 cost year and the British National Formulary (NICE 2024). Technology costs, primary care costs and secondary care costs are outlined in Table 8.6 Table 8.7 and

Table 8.8, respectively. Only technologies who submitted evidence to NICE have been included in the technology cost breakdown.

Mortality

Mortality was derived from company evidence submission from the RECEIVER trial. Baseline mortality in COPD was extracted from Whittaker et al. (Whittaker H et al. 2023) and converted into a probability for use in the model. Table 8.9 provides the mortality inputs and further detail on this calculation.

Set up parameters

Table 8.3: Set up parameters

Variable	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Mean number of people in each ICS (2022/23)	1,464,258	NHS England (NHS 2022a)	Calculated mean from list of populations per ICS in England.
Prevalence of COPD	1.8%	Public Health England (Office for Health Improvement and Disparities 2024)	Taken from Respiratory disease data. Period 2020/21. QOF prevalence (all ages): 1.846%
Uptake of technology	63.6%	Calculated mean from uptake data from my m health (my mhealth Ltd 2024), Taylor et al. (Taylor et al. 2023), Houchen-Wolloff et al. (Houchen-Wolloff 2021) and Davies et al. (Davies H et al. 2023).	Calculation is an average of: 76.5% from my mhealth RFI 79.8% from Taylor et al. 52% from Houchen-Wolloff et al. 46% from Davies et al.

Key: COPD – Chronic obstructive pulmonary disease, EAG – External assessment group, ICS – Integrated Care System, QOF – Quality Outcomes Framework.

Resource use

Table 8.4: Resource use

Variable	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Number of exacerbations per person	3.10 4.21 post-acute exacerbation	North et al. (North et al. 2020)	Table 1: Baseline participant characteristics. This may not necessarily reflect the severity distribution of the population of England. The post-acute exacerbation value has been used as a scenario analysis and is not used in the model base case. The high number of exacerbations per year likely reflects that the study population reflects those with more severe COPD.
Number of GP appointments per person	9.13	McLaughlin and Skinner (McLaughlin K and Skinner E)	105 appointments in 6 months. This was scaled to 1-year resource, assuming the relative resource use each month remains constant. N=23, meaning 9.13 appointments per person. The high number of GP appointments per year likely reflects that the study population reflects those with more severe COPD.
Number of hospitalisations per person	1.56	North et al. (North et al. 2020)	Table 5: Effectiveness outcome at 90 days. This value is for 90 days post-acute exacerbation but was used in absence of evidence for COPD general population. This was scaled to 1-year resource, assuming the relative resource use each month remains constant. The high number of hospitalisation per year likely reflects that the study population reflects those with more severe COPD, who have recently had a post-acute exacerbations, while scaling this up to one year may overestimate the number of hospitalisations.

Key: COPD – Chronic obstructive pulmonary disease, EAG – External assessment group.

Efficacy

Table 8.5: Efficacy parameters

Variable	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Relative risk for exacerbations	0.581	North et al. (North et al. 2020)	Table 5: Effectiveness outcome at 90 days. This value is for 90 days post-acute but was used in absence of evidence for COPD general population. Assumed that the relative risk applies over 1 year.
Relative risk for GP appointments	0.810	McLaughlin and Skinner (McLaughlin K and Skinner E)	Reported a 19% reduction in GP appointments. This was applied as a relative risk of 0.810. Assumed that the relative risk applies over 1 year.
Relative risk for hospitalisations	0.878	NICE (NICE 2021)	Supporting documentation, calculated relative risk (page 113). Value = 0.504. This value is for 90 days post-acute exacerbation but was used in absence of evidence for COPD general population, but only weighted for the first 90 days (the remainder of the year was assumed to equal a relative risk of 1). Assumed that the relative risk applies over 1 year.

Key: COPD - Chronic obstructive pulmonary disease, EAG – External assessment group, GP – General Practice.

Costs

Table 8.6: Technology costs

Parameter	Value (per person)	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Costs common to all technologies	Incorporated in listed cost for each technology	EAG assumptions, Lenus	Set up cost to NHS, assumed 7.5 hours of practice manager time per year. There are approximately 160 practices per ICS: cost of setting up licenses = £75,803 per ICS. Registration costs of technology assumed 30 mins nurse time = £26 per person (£442,067 per ICS). Training cost to NHS, elicited from email correspondence with clinician. Training should be open to all clinical staff who interact with COPD patients: 1 GP, 4 practice nurses, 1 Clinical Pharmacist and 2 HCA's. This totals £620 per practice, £99,466 per ICS. [redacted] The cost that is common to all technologies is £1,982,488 per ICS.
Active+me REMOTE	[redacted]	Aseptika	Elicited from request for information documents. Software cost [redacted] per NHS trust per month. There are approximately 5 trusts per ICS (214 trusts/42 ICS), multiplied by 12 months plus VAT = [redacted] Set up cost from company of [redacted], plus VAT (assumed set up cost is per ICS). Training cost from company of [redacted], plus VAT (assumed training cost is per ICS).
CliniTouch Vie	[redacted]	Spirit Health	Elicited from request for information documents. Software cost [redacted] per person, plus VAT. Implementation fee [redacted], plus VAT. Fee applied per set up, assumed per ICS.
COPDhub	[redacted]	Institute of Clinical Science and Technology	Elicited from request for information documents. Software cost [redacted] per ICS, plus VAT. This includes initial set up, installation and ongoing management, and annual licensing fee.
Current Health	[redacted]	Current Health	Elicited from request for information documents. Software cost [redacted] per person for high acuity, plus VAT.

			Set up cost from company elicited through email correspondence, approximately [redacted] plus VAT, applied per ICS.
Lenus	[redacted]	Lenus	Elicited from request for information documents. Software cost [redacted] for 801-2000 patients, plus VAT. Scaled up for cohort size. Set up cost from company [redacted] plus VAT, applied per ICS.
Luscii	[redacted]	Luscii	Elicited from request for information documents. Software cost [redacted] plus VAT per department, population size 750-1500K. Monthly cost, therefore scaled to an annual cost. Typical implementation cost [redacted] plus VAT.
myCOPD	[redacted]	my mhealth Ltd.	Pricing model shared by company: [redacted] in first year for cohort size. Includes software, set up, training costs.
patientMpower	[redacted]	patientMpower	Elicited from request for information documents. Software cost [redacted] scaled up to yearly cost.
Space for COPD	[redacted]	University Hospitals of Leicester NHS Trust	Elicited from request for information documents. Initial cost of [redacted] plus VAT, [redacted] plus VAT annual license fee. Software cost of [redacted] per user, plus VAT. Training costs of [redacted] per ICS, plus VAT.
Wellinks	[redacted]	Wellinks	Elicited from email correspondence with company. [redacted] per engaged member per month for 9 months. Converted to GBP at rate $1=£0.79, 27.02.24. [redacted] per month for remaining 3 months following initial 9 months, converted with same rate, and added together: £1064.79+£59.16.
Base case cost	**£283.37**		The average cost of all digital interventions (where costs were available).

Key: COPD – Chronic obstructive pulmonary disease, EAG – External assessment group, FTE – Full time equivalent, GBP – Great British Pounds, ICS – Integrated Care System, RFI – Request for Information, VAT – Value added tax.

Table 8.7: Primary care costs

Parameter	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Cost of GP face-to-face appointment	£41.00	PSSRU 2022 (PSSRU 2022)	Table 9.4.2: Unit costs for a GP. Per surgery consultation lasting 9.22 minutes (average GP consultation length). Qualification costs included.
Cost of GP practice nurse (1 hour)	£52.00	PSSRU 2022	Table 9.3.1: Costs and unit estimations for nurses working in a GP practice (Band 5). Qualification costs included.
Cost of GP practice manager (1 hour)	£63.00	PSSRU 2022	Table 9.2.1: Annual and unit costs for qualified nurses (Band 6). Qualification costs included.
Cost of HCP (1 hour)	£42.00	PSSRU 2022 NHS 2023 (NHS 2023)	HCP = band 2. Band 4 nurse from PSSRU used as a proxy as similar salary. Table 9.2.1: Annual and unit costs for qualified nurses (Band 4). Qualification costs included.
Cost of Clinical Pharmacist (1 hour)	£63.00	PSSRU 2022	Clinical Pharmacist = band 6. Band 6 burse from PSSRU used as proxy. Table 9.2.1: Annual and unit costs for qualified nurses (Band 6). Qualification costs included.
Cost of GP (1 hour)	£265.00	PSSRU 2022	Table 9.4.2: Unit costs for a GP. Hourly cost. Qualification costs included.

Key: EAG – External assessment group, GP – General Practice, HCP – Health Care Practitioner, PSSRU – Personal Social Services Research Unit.

Table 8.8: Secondary care costs

Parameter	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Cost of exacerbation without admission	£68.02	Method of costing derived from Jordan et al. (Jordan R et al. 2015) – Table 21. Cost inputs from: NHS Cost Collection (NHS England 2022): A&E PSSRU (PSSRU 2022): GP visit BNF (NICE 2024): Medications	33.3% A&E no admission: £133.46. Weighted average for all non-admitted A&E (excluded those in for dental treatment). 66.7% GP visit: £41, as above. The EAG has noted this may risk the double counting of GP appointments. Since the source was not clear how these were differentiated with routine appointments, the EAG has included it in the base case in line with Davies et al.(Davies H et al. 2023). 2 x 28 tablets x 5mg oral corticosteroids: £1.66. 15 x 500mg antibiotics (Amoxicillin): £1.23.
Cost of hospitalisation for a COPD-related event	£2,416.43	Method of costing derived from COPD Prime Tool, Chartered Society of Physiotherapy 2017 (Chartered Society of Physiotherapy 2017). Cost inputs from: NHS Cost Collection (NHS England 2022): Admission cost, A&E PSSRU (PSSRU 2022): Ambulance	Weighted average of DZ65A-K non-elective short and long stay: £1761.28 Weighted cost of all A&E costs: £242.05 (excluding those in for dental treatment). 90% Ambulance cost: £459 This cost is the sum of 'Calls' and 'See, treat and convey' from PSSRU.

Key: BNF – British National Formulary, COPD – Chronic obstructive pulmonary disease, EAG – External assessment group, GP – General Practice, PSSRU – Personal Social Services Research Unit.

Mortality

Table 8.9: Mortality parameters

Parameter	Value	Source	EAG commentary of availability, quality, reliability and relevance of the source/s
Annual mortality probability – standard care	2.15%	Whittaker et al. (Whittaker H et al. 2023). Rate converted to a probability (Jones E et al. 2017).	Table 3: Adjusted mortality rate for COPD-related. 21.7 per 1000 person years Converted into a probability: P=1-exp(-rt) = 0.0215
Hazard ratio - death	0.743	Taylor et al. (Taylor et al. 2023).	Table 2: Unadjusted hazard ratio (RECEIVER vs control).
Annual mortality probability - Intervention	1.59%	Calculation	HR applied to standard care probability.

Key: COPD – Chronic obstructive pulmonary disease, EAG – External assessment group, HR – Hazard Ratio.

8.3 Results from the economic modelling

Exploratory results from the cost-comparison model are presented in sections 8.3.1 to 8.3.3. Due to the heterogeneity across the digital technologies and limited evidence to populate the economic model, the base case is intended to represent an indicative average, rather than a definitive representation of every digital supported self-management technology for adults with COPD.

Under the base case assumptions, the deterministic base case model results indicate that digitally supported self-management for adults with COPD are potentially cost saving compared with standard care for the COPD population. The technologies are estimated to reduce health care costs, largely driven by a reduction in hospitalisations. The deterministic base case results are presented in Table 8.10. The cost breakdown in Table 8.11 suggests that the cost savings from a reduction in hospitalisations, exacerbations and GP appointments outweigh the cost of using the digital technologies.

Table 8.10: Deterministic base case results

	Digitally supported self-management for COPD	Standard care	Incremental
Cost per ICS	£69,034,599	£74,825,586	-£5,790,987
Cost per person	£4,018	£4,355	-£337
Deaths per ICS	274	369	-95

Key: COPD – Chronic obstructive pulmonary disease, ICS – Integrated care system.

Table 8.11: Cost breakdown per person

	Digitally supported self-management for COPD	Standard care	Incremental
Total cost of technology	£283	£0	£283
Cost of hospitalisations	£3,309	£3,770	-£461
Cost of non-admitted exacerbations	£123	£211	-£88
Cost of GP appointments	£303	£374	-£71
Total	£4,018	£4,355	-£337

Key: COPD – Chronic obstructive pulmonary disease, GP – General Practice.

8.3.1 Scenario analysis

Given the potential variation in digitally supported self-management for COPD, such as pricing, and the uncertainty in input values, a range of scenarios were considered. These scenarios are described, and the results reported in

Table 8.12.

Table 8.12: Scenario analyses for intervention

Scenario analyses description	EAG description	Incremental cost
EAG base case.		-£337
Highest cost of a digital technology (deterministic result).	Cost of the digital technology is set to [redacted], which is the highest total cost of the digital technologies included as part of the model in the base case.	£620
Lowest cost of a digital technology (deterministic result).	Cost of the digital technology is set to [redacted], which is the lowest total cost of the digital technologies included as part of the model in the base case.	-£503
Number of exacerbations varied to greater reflect post-acute exacerbation subgroup data.	The number of exacerbations is set to 4.21 for standard care, and 2.44 for intervention. This value is referenced in Table 8.4.	-£369
Alternative relative risk for GP appointments.	Relative risk of 0.66 applied for reduction in GP appointments. This value is from company submissions: Sunderland Luscii Evaluation Report which reported a reduction in primary care usage of 34%.	-£393
Relative risk of hospitalisation is set to 1.	Relative risk of 1 applied, meaning there is no impact of the intervention on hospitalisations.	£124
Weighted relative risk for exacerbations.	Relative risk weighted so that it is only applied to the initial 90 days. RR assumed 1 for subsequent 9 months. New calculated RR=0.895.	-£271
Alternative value for the relative risk of hospitalisations applied	Rate ratio of 0.593 applied based on unadjusted figures from the RECEIVER trial (Taylor et al. 2023). Calculated using year after hospitalisation differences across arms, using naïve relative difference. This was done pragmatically to elicit an upper bound of the potential affect on hospitalisations.	-£1,411
Alternative cost of hospitalisation used.	Cost of hospitalisation from Davies et al. (Davies H et al. 2023). of £1,721 used, based on the NHS cost collection 2019/2020. This is because the most recent NHS cost collection reflects substantially higher value than previous iterations.	-£204
No NHS staff time for monitoring with technologies.	Assumption that no NHS staff time is required for the monitoring of people with technologies.	-£417
NHS staff time doubled for monitoring with technologies.	Assumption that twice as much NHS staff time is required for the monitoring of people with technologies.	-£257

Uptake lowered for digital technologies.	Assumption that 46% (Davies et al. (Davies H et al. 2023) value) of people use the digitally supported self-management intervention. This reduces the initial cohort in the model.	-£329
Baseline event rates are halved.	This assumption is to reflect the potential impact on a milder COPD population, since available evidence is primarily focused on people with COPD suffering high or very high impact based on CAT scores.	-£27

Key: EAG – External assessment group, GP – General Practice, NHS – National Health Service.

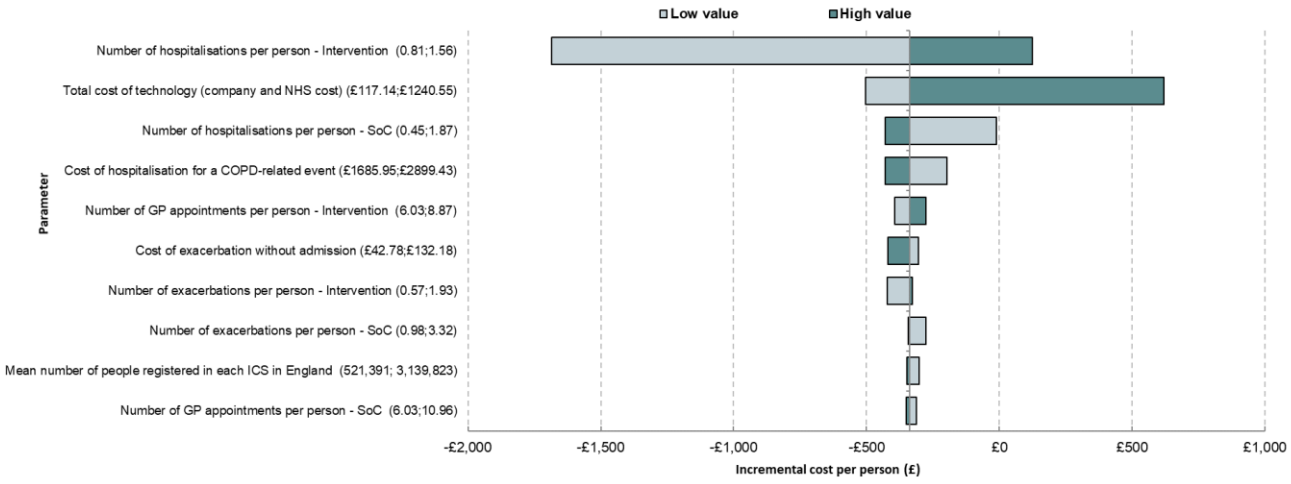
Based on the scenarios listed in Table 8.12, 2 scenarios led to cost-incurring results, using the highest technology cost and assuming no impact on hospitalisations. The remaining scenarios remained cost-saving, in line with the base case results.

8.3.2 Deterministic sensitivity analysis

One-way sensitivity analysis was conducted on all model parameters. The results of this analysis are presented in a tornado diagram in Figure 8.2. The analysis suggests the key drivers of the model results are the:

- number of hospitalisations per person in the intervention
- number of hospitalisations per person in standard care
- total cost of technology (company costs and costs to the NHS)
- cost of hospitalisation for a COPD-related event
- number of GP appointments per person

Figure 8.2: Tornado diagram



Additional DSA included EJP analysis with respect to cost-savings. In the base case, the highest price of the digital technologies while still leading to cost-savings was approximately £620 per person. The EJP should be interpreted with caution due to the early nature of the analysis but can be used as an indication of the potential benefits of digitally supported self-management technologies for COPD.

8.3.3 Probabilistic sensitivity analysis

The PSA indicated similar results to the deterministic base case. The probabilistic incremental cost per person was calculated as -£338, based on 1,000 model iterations. A graphical representation of the base case results is presented in Figure 8.3. Various scenarios on the PSA are presented in

Table 8.13.

Figure 8.3: PSA results showing cost difference on histogram

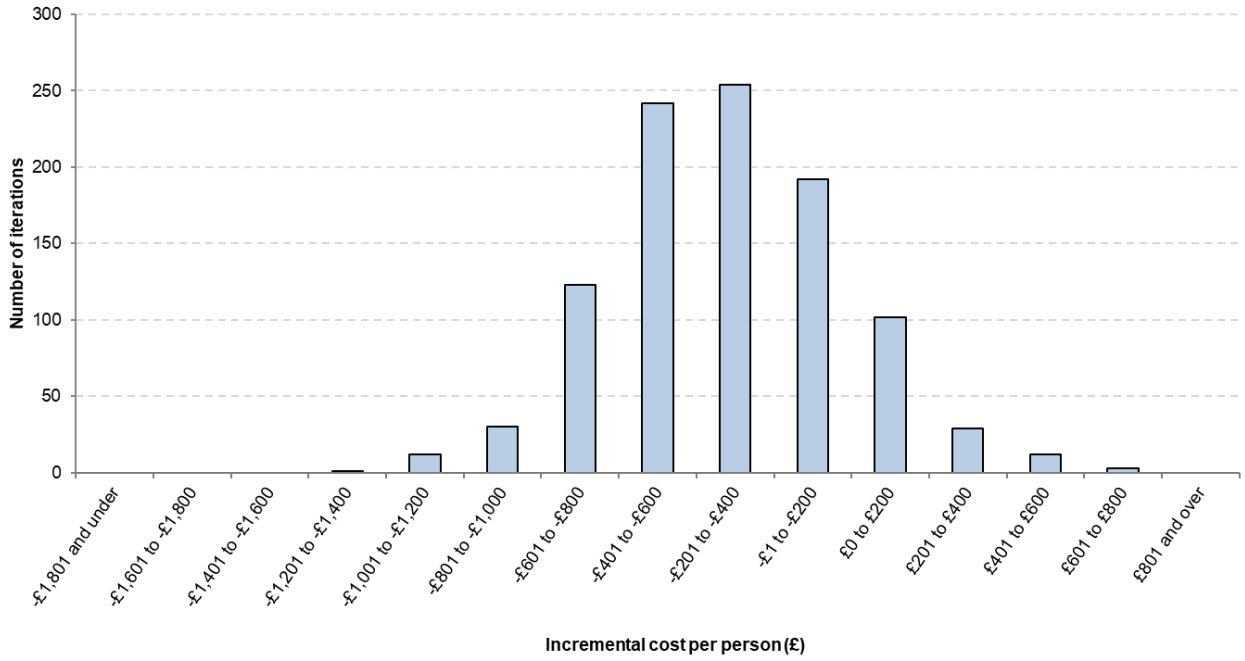


Table 8.13: Scenario analysis on PSA

Scenario analyses description	EAG description	Incremental cost	Probability of being cost saving
EAG base case.		-£338	74.4%
Highest cost of a digital technology.	Cost of the digital technology is set to [redacted], which is the highest total cost of the digital technologies included as part of the model in the base case.	£618	11.2%
Lowest cost of a digital technology (probabilistic result).	Cost of the digital technology is set to [redacted], which is the lowest total cost of the digital technologies included as part of the model in the base case.	-£500	83.5%
Weighted relative risk for exacerbations.	Relative risk weighted so that it is only applied to the initial 90 days. RR assumed 1 for subsequent 9 months. New calculated RR=0.895.	-£270	70.9%
Alternative value for the relative risk of hospitalisations applied.	Rate ratio of 0.593 applied based on unadjusted, figures from the RECEIVER trial	-£1,410	97.8%

Key: RR – Relative risk

8.4 Summary and interpretation of the economic modelling

Using the base case assumptions, it is estimated to be plausible that digital supported self-management technologies for adults with COPD are a cost saving intervention to the NHS. The estimated base case results are not intended to capture every digital technology provider perfectly but are intended to provide an indication of the potential impact from implementing these technologies.

The results of this analysis should be interpreted with caution due to the naïve and limited data available. The evidence available to populate the model is likely to represent people with more severe COPD, and less generalisable to the COPD population as a whole. Some companies have no or limited evidence for their technology or have not provided evidence as part of this evaluation, with the model making pragmatic use of the available data. Simplifying assumptions were made throughout the model to provide a useful tool for an early evaluation of digital supported self-management technologies for adults with COPD.

Key drivers of the economic results

The key drivers of the results were the number of hospitalisations per person with standard care, the total costs of the technologies to the NHS, the number of hospitalisations per person with the intervention, and the cost of hospitalisation for a COPD-related event, as demonstrated in the tornado diagram.

Current resource use data is based on limited evidence gathered from studies based on a subset of the technologies in this evaluation. Key studies used in the model were the RESCUE (North et al. 2020) and RECEIVER (Taylor et al. 2022a) trials. However, these studies are conducted in either people who have recently had an acute exacerbation, or people with severe or very severe CAT scores. Hence, the baseline events and relative impacts of the technologies may be higher, when compared with a milder population who are suffering less from their COPD. Previous clinical advice has indicated that COPD tends to lead to exacerbations, so someone with a high CAT score will not necessarily always have a high CAT score. Therefore, the relative size of the potential bias in the results in unknown, so the base case results should be interpreted with caution for the scoped population. Further evidence on the resource use and the impact of digital technologies should be captured in a wider population than those with severe or very severe CAT scores, to better reflect the impact of the digital technologies across the whole COPD population. A crude scenario was captured where the baseline events were halved, in order to reflect a potentially milder COPD population. In this case, the digital technologies remained cost-saving at the average price stated (-£27 per person) but led to materially lower cost-savings.

The cost of the technologies ranged between the companies, with the lowest identified cost of [redacted] per person and the highest identified cost of [redacted] per person. The service provided by the technologies also differs. For instance, additional features including level of clinician engagement, monitoring frequency, and the content available on the technology are different across these technologies. Therefore, these digital technologies are expected to have different levels of efficacy, so there are limitations to use a head-to-head comparison solely on price. However, based on the available evidence from the scoped interventions, it was not possible to capture the effect of

each technology individually, as some companies had no quantitative evidence on resource use. It is important to note that the EJP was approximately £620 per person based on the available evidence, which puts 1 company (with the highest identified cost) above this threshold.

The digital technologies (based on average price) remained cost saving in all but 2 scenarios, which included the highest price of the available technologies, and when there was no impact on hospitalisations.

An important scenario to highlight is related to the cost of hospitalisation for a COPD-related event. In the base case, this was estimated to be £2,416, which is substantially higher than the value calculated using NHS Cost Collection Data from previous years. This may reflect both an increase in the number of severe events in the data, and an overall increase in the cost of each of the events, particularly the severe events. In a previous MTEP evaluation, this cost was estimated to be £1,721 using NHS Cost Collection data from 2019/20. This cost was used as a scenario in Table 8.12, where the digital interventions remained cost saving compared to standard care but resulted in lower cost-savings.

Mortality

Mortality was captured in the model, through applying a hazard ratio for the intervention to annual mortality probability for people with COPD. The results suggest that digital supported self-management technologies for adults with COPD may improve mortality, through reducing the number of deaths. A high-level approach was taken to this analysis and mortality was not factored into overall costs. The available evidence indicated that across an ICS, the digital technologies may reduce mortality by 95 people per year (based on the average ICS size). However, it must be noted that the evidence used to populate mortality outcomes was statistically insignificant, so the true impact on mortality is highly uncertain.

Long-term impacts

Due to the limited available evidence, a 1-year time horizon was used in the model. Hence, potential longer-term benefits may be omitted from the analysis. For instance, if the use of these technologies supports a continued reduction in resource use, this may continue beyond 1 year, through the person having learned self-management techniques for their COPD, regardless of if they are still using the digital technology. These benefits may be realised through quality-of-life improvements, or healthcare resource use reduction which occurs after 1 year. Currently, there is very limited evidence on the long-term impact of these technologies beyond 1-year. However, since the modelling approach does not capture longer-term benefits, the model results may reflect a more conservative estimation of the impact of digital technologies to support the self-management of COPD.

Previous economic studies

Previous economic evaluations in this area have estimated a similar result to the EAG model. Davies et al. (Davies H et al. 2023). suggested the digital intervention to be cost saving and supported the case for adoption in the NHS for this population under base case parameters, although highlighting uncertainties due to the current limited evidence base. This cost saving was largely driven by the readmission rate in both the intervention and comparator arms.

Cost savings were also reported in 4 further costing studies and 1 early economic model, largely driven by reductions in hospitalisations. The findings of these previous studies and the submitted economic model were in line with the de novo economic evaluation from the EAG, as one of the key drivers for the model in the evaluations were the number of hospitalisations per person for both the intervention and standard care. It is likely that relative reductions in hospitalisation across technologies are going to drive the cost-effectiveness of digital technologies to support self-management.

9 Interpretation of the evidence

9.1 Interpretation of the clinical and economic evidence

In the context of the early value assessment, there is uncertain but plausible evidence suggesting that digital technologies alongside standard care may result in improvements in the COPD assessment test (CAT) score, inhaler use, exacerbations and admission rates from baseline in people using the technologies following discharge for an exacerbation.

Overall, evidence for the effectiveness of digital technologies to support self-management of COPD standard care is mixed and inconsistent when compared to standard care. Most outcomes of interest were not well reported or were measured using different tools, making it difficult to draw any certain conclusions across the data. Evidence from studies in a UK NHS setting was available for all technologies except Wellinks.

The EAG identified 32 relevant studies, of which 14 were prioritised for extraction and narrative synthesis because they were most relevant to the scope and presented the best quality evidence. This evidence base comprised 10 comparative studies including 2 RCTs, 3 cohort studies and 5 before-after studies.

7 studies evaluated digital technologies in the subgroup of interest, an AECOPD post-discharge population. However, study eligibility criteria varied considerably with patients recruited at widely differing times following an exacerbation-related hospitalisation, and so this evidence is likely to reflect a heterogeneous group of people with COPD.

Adherence to the digital technologies was reported at different timepoints using various measures, including mean days of use, completion, compliance with minimum recommended use and entry of user data. Comparison of adherence to standard of care COPD management was limited to 1 cohort study that reported significantly higher completion of SPACE for COPD compared to telephone support, though completion was not defined (Houchen-Wolloff 2021). It is therefore difficult to generalise findings across studies. Patient experience was reported by few prioritised studies (n=4) and using different outcome measures, including satisfaction, usability, and preference

versus usual care either as the proportion of patients agreeing with positive statements or as the mean score of a rating scale. Feedback was generally positive, though sample sizes were small and represented sub-groups of the study populations who had responded to questionnaires. The EAG notes a NICE public involvement programme summarised in the MTAC guidance for myCOPD, which also found patient's found the technology easy to use and improved their understanding and self-confidence in managing their condition. Of those using myCOPD to manage symptoms, 220/333 (66.1%) felt there had been a reduction in the number of exacerbations (NICE 2022).

AEs were reported in 6 studies including 2 RCTs (Crooks et al. 2020, North et al. 2020), 2 before-after studies (Pierz et al. 2024, Patel et al. 2021) and 2 case series (Gelbman and Reed 2022, Auton KAA et al. 2024). AE rates were generally low and not reported to be treatment-related. Mortality was very low in studies of patients in unclear treatment settings, though evidence was limited to 2 non-comparative studies. While mortality was higher in AECOPD populations, it was either significantly lower or no different in patients using digital technology when compared to standard care (evidence limited to 2 UK cohort studies and 1 before-after study). The evidence identified indicates that the technologies evaluated in this EVA are plausibly safe for use.

The EAG considers the evidence to provide potential indications that self-management digital technologies could improve clinical efficacy in both AECOPD and mixed or unclear treatment settings when compared to standard care. The evidence is limited, largely by the paucity of data from sufficiently powered comparative studies, particularly in the non-AECOPD population. Though 10 comparative studies were extracted, few provided comparative data for reported outcomes. 2 RCTs were identified that are at risk of providing biased estimates of effect due to reporting per protocol (PP) analyses for most outcomes and recruiting small numbers of patients, thus being underpowered to show differences in effect between treatment arms. The largest RCT (myCOPD) recruited 60 patients (mixed COPD population) and reported significant baseline imbalances in prior exacerbations and CAT score which undermines certainty in results (Crooks et al. 2020). 5 were before-after studies that only reported comparative data for admission rates (Patel et al. 2021, Pierz et al. 2024, All Together Better Sunderland

2021, Ghosh 2018, NHS 2022b); others tended to provide outcomes that did not compare efficacy to standard care, such as within-group changes in outcomes from baseline. Reported outcomes varied, and where multiple studies reported the same outcome, they used different methods to measure and report the outcome at different timepoints, with outcome definitions commonly differing.

Comparative evidence for key outcomes (CAT score, exacerbations, admissions and inhaler errors) in the AECOPD population reported significant differences favouring digital technologies or non-significant findings that were in the direction of the digital technologies. Evidence of an effect was less clear in mixed or unclear populations with mixed findings for admissions and other key outcomes varying from non-significant improvements in CAT score and the rate of inhaler errors following use of a digital technology, to significant increases in the exacerbation rate following digital technologies.

Comparative data for mean CAT score was reported by 3 studies with mixed results. In AECOPD populations, an RCT and before-after study both reported significant improvements in CAT score for myCOPD users compared to standard care (North et al. 2020) or after the introduction of Clinitouch Vie (Ghosh 2018), although the RCT also reported no significant difference at 90 days alone (North et al. 2020). In a mixed setting, no significant difference in CAT score at 90 days was found between myCOPD and standard care (Crooks et al. 2020). Non-comparative evidence (3 studies) found that significant improvements in respiratory function were experienced by patients after receiving either standard care and/or a digital technology (Auton KAA et al. 2024, Ghosh 2018, Houchen-Wolloff 2021).

Comparative data for inhaler technique was provided by 2 UK studies with similarly mixed results, showing a significantly greater reduction in the rate of critical inhaler errors for myCOPD users compared to standard care in an AECOPD setting (North et al. 2020), though no significant difference in the rate of errors at 90 days in a mixed population (Crooks et al. 2020).

Comparative exacerbation data (2 UK RCTs) was equally mixed, with no significant differences in the rate of exacerbations in an AECOPD population (North et al. 2020),

and a significantly lower rate of exacerbations in patients receiving standard care than myCOPD users in a mixed treatment setting; however this difference may be a consequence of selection bias (favouring standard care) with a higher rate of previous exacerbations amongst patients receiving the digital technology (Crooks et al. 2020).

Comparative data for respiratory-related hospital admissions or ED visits was reported in 8 studies, also with mixed results. 5 studies in AECOPD populations found either significant reductions in these type of admissions or non-statistically significant differences that favoured the digital technologies compared to usual care. This includes a before-after study of CliniTouch Vie that found no significant difference in COPD-related admissions in the whole study population, though reported a significant difference in this outcome when limiting to the subgroup of patients who used the technology for at least 30 days (NHS 2022b). 3 studies in mixed or unclear treatment settings reported comparative evidence on respiratory-related admissions, with 2 comparative studies reporting no difference to exacerbation-related or COPD-related admissions (Crooks et al. 2020, Pierz et al. 2024) and a third study reporting a large decrease in respiratory-related admissions and smaller decrease in ED visits, though neither were tested for statistical significance (All Together Better Sunderland 2021).

All differences in CAT score and inhaler errors that did not reach statistical significance were in the direction favouring digital technologies, although it is not possible to determine whether these differences are true treatment effects or due to chance. In AECOPD populations, this was also true for exacerbations and admissions. However, in mixed or unclear populations the evidence for these two outcomes was more mixed and without a clear direction.

The remaining 4 studies were non-comparative case series that reported statistically significant improvements in respiratory function, exacerbations and quality of life scores from baseline to end of follow up.

The EAG considers that, although this evidence provides uncertain indications of the comparative performance of digital technologies for self-management of COPD in the UK NHS setting, it does suggest that it is plausible for digital technologies to have a

positive clinical impact. Interpreting the degree or consistency of impact is prevented by the heterogeneous nature of included evidence.

Most prioritised studies were conducted recently (2017 to 2024) and in UK settings and are therefore generalisable to the NHS setting. The EAG identified the following concerns regarding the generalisability of findings:

- **Technologies and versions**: the range of different self-management components used by the scoped technologies makes comparison difficult, as it is possible that individual components may each impact on the efficacy of a technology. Features common to the 9 technologies evaluated in the 14 prioritised studies included symptom monitoring, educational content, self-management planning and healthcare practitioner contact. For example, Wellinks provides contact with health coaches and SPACE for COPD contains an 'ask the expert' feature. The features of a self-management technology also may differ across the various iterations and versions over time. Studies often did not report the content of each technology in detail. Comparing different technologies and their effectiveness is therefore difficult.
- **Setting**: 7 studies recruited AECOPD patients after a COPD-related hospital admission within the previous 12 months. The length of time since hospitalisation varied between studies from within 2 weeks, to within 12 months (with 1 study excluding patients who had been discharged within the last 6 weeks). 1 study included a mixed AECOPD and mild or moderate COPD population, and 8 studies did not report this information clearly. Clinical validation will be useful on the generalisability of this evidence to people with COPD.
- **Severity of COPD**: 7 studies included patients with severe COPD. The other 7 studies either included patients with any COPD severity or did not report details on participants' disease severity.
- **Comparator**: the procedures described as standard care differed between studies, and included written self-management booklets, self-management booklets with regular telephone support and in-person pulmonary rehabilitation exercise and education. Elsewhere the content of "standard care" was not reported. Therefore it is difficult to generalise findings across comparative studies.
- **Impact of the COVID-19 pandemic**: the prioritised studies varied in the extent to which they overlapped with the COVID-19 pandemic, and this was sometimes unclear. Therefore, it is difficult to generalise findings across studies conducted before and after the pandemic.

5 economic costing studies were identified, that all report evidence within an NHS context. The studies report potential costs savings for myCOPD, Luscii and CliniTouch Vie due to averted A&E attendance and admissions. The quality of the evidence was low. These studies were subject to biases, such as lack of peer review, having potentially non-representative samples, lack of transparency and small sample sizes.

9.2 Integration into the NHS

Of the 12 digital health technology providers included within the scope of this evaluation 9 providers submitted relevant evidence, and 9 of these are currently used within the NHS, as outlined in section 2.1. Space for COPD is currently used in the NHS, but does not have regulatory approval, such as CE or UCKA marking, with DTAC accreditation to be sought at a later date. If Space for COPD continues to be used in the NHS going forward, further clarification should be sought from the Medicines & Healthcare products Regulatory Agency (MHRA) regarding whether the technology requires these accreditations. 7 digital health technology providers who submitted evidence are noted to operate across a range of other respiratory conditions beyond COPD, outlined in 2.1. All companies should be considered by MHRA to meet regulatory requirements before any recommendations are made.

Optimal population of interest

Current evidence generated in the NHS is primarily focused on people with more severe COPD, as measure by CAT score. The EAG understands for some people this may fluctuate throughout the year based on exacerbations. However, some people may persistently suffer with more severe COPD. Therefore, the current evidence base may not be completely representative of the COPD population in England. People with milder COPD symptoms may incur different outcomes. If digital technologies to support self-management of COPD are to be used in people with milder forms of COPD, then future evidence should be generated to capture a more reflective population to the intended use case.

Training & resource use considerations

Healthcare providers are expected to undertake some training to enable the delivery of the different digital technologies. This includes training on what the technology does, how it can support care, suitable referrals to the technologies and how the technology works. Only brief details have been provided on the training requirements across company evidence, although all have stated the time required to train staff would be low. Clinical advice recommended that training should be open to all clinical staff who interact with people with COPD in practice, in the best interest of those with COPD. It was advised that this would involve, on average per GP practice, 1 lead GP, 4 practice nurses, 1 clinical pharmacist and 2 HCAs. This would entail in-house training session for an hour.

Other considerations for NHS staff time include engagement with the technologies once the person with COPD in onboarded to the technology. This is expected to vary substantially due to a range of factors including:

- if the person requires remote monitoring as part of their self-management package
- the technology used, as some technologies have more interactive features than others
- the time spent producing targeted educational content.

Hence, it is important to factor in NHS staff time into any implementation of digital technology. It is anticipated that digital technologies may ease capacity concerns surrounding COPD, such as wait lists for face-to-face care, but it is important to consider other potential capacity consequences from implementation. Submitted evidence from 1 company suggested that approximately [redacted].

Finally, it is important to consider the pricing structures of the different technologies and the impact this may have on NHS resources. The digital technologies that submitted evidence all have different pricing structures for implementation in the NHS. For instance, some technologies cost on a per engaged person for the technology, while

others cost based on number of people in an ICS which makes up the license fee. Furthermore, all technologies indicated there would be training and set up costs associated with the technology. Set up costs ranged from [redacted] per ICS across the company submissions. Although the cost is relatively small when scaled to a per person cost, any up-front charges should be considered as part of budgeting at a local level.

Clinical and management risk

Key criteria that should be considered when determining if a person is eligible for supported self-management through digital technologies include:

- cognitive impairment, learning disabilities or problems with manual dexterity
- accessibility issues, such as visual impairment or inability to understand health-related information
- potential co-morbidities and how these interact with self-management programmes
- geography of the person and any internet connectivity issues
- access to suitable devices to use the technology
- The motivation of the person to use the digital technology
- Other issues which may impact the ability of a person to self-manage (such as a person's digital literacy). Further details of other issues are detailed in the NICE scope

To mitigate some of these risks, some companies provide offline functionality, support a person being set up on the technology and the correct usage on behalf of the healthcare provider. Other risks include high professional turnover rates, which may lead to less clinical knowledge within the care teams of how to use and optimize the technologies. In these cases, regular training may have to be provided for new staff.

Other issues surrounding inequalities should also be considered where remote monitoring occurs. For example, potential inaccuracy of pulse oximeters for different ethnicities, which may be used in remote monitoring. The EAG recommends that the issues listed in the NICE scope, alongside those detailed in this section are important

considerations for implementing digital technologies to support self-management of COPD.

Attitudes of clinical staff

A further factor to consider around the implementation of digital technologies into the NHS is clinical attitudes towards using digital technologies. Provided staff have appropriate training this should not pose too much of an issue to the integration of these technologies, as healthcare is becoming increasingly digitized. However, staff may have some concerns around changing the established treatment pathways to a more hybrid model in terms of in person care. Engagement with healthcare staff to optimise the use of digital technologies in local practices will be important, in order to maximise staff adherence and potential benefits.

9.3 Ongoing studies

Studies identified through the EAG searches

The EAG searches identified 6 ongoing studies for the scoped interventions. 3 of these will provide comparative data of a digital self-management technology, including 1 full RCT and a second pilot/feasibility RCT. All details are summarised in Table 9.1. No ongoing studies were identified from company submissions.

Kaur 2023 (Kaur et al. 2023) and NCT04136418 (University of Birmingham 2020) report the same RCT which assessed the ability of COPDPredict to predict and prevent acute exacerbations of COPD. Kaur 2023 is the study protocol and NCT04136418 is the trial record for the study, with an estimated completion date of March 2023. However, the record was last updated in November 2022.

2 ongoing trial records were identified for myCOPD, NCT05086341(Umeå University 2021) and the PROPEL study (NCT05835492) (my mhealth Ltd 2023). NCT05086341 is a randomised controlled pilot and feasibility trial assessing user satisfaction and safety of myCOPD. The estimated completion date was May 2023 but has not been updated since May 2022. The PROPEL study aims to explore the implementation of myCOPD and assess its value in facilitating recovery and preventing re-admissions, as

well as investigating longevity of use and collecting subgroup data by ethnicity and rural/urban location. The study is scheduled to be completed in October 2024.

2 trial records were identified for Wellinks, NCT05330507 (Convexity Scientific Inc 2022b) and NCT05259280 (Convexity Scientific Inc 2022a). NCT05330507 was a prospective case control study looking at the impact of Wellinks on COPD hospital readmissions. It is estimated to be completed in June 2024. NCT05259280 was an observational study assessing the impact of Wellinks on HRQoL and clinical outcomes in people with COPD.

ISRCTN911338481 (University of Leicester 2020) is a single arm feasibility study that uses an technology based off the principles of SPACE for COPD and yoga to assess the self-management of COPD. The study is planned to be published in December 2024.

Studies identified through company communications

1 ongoing study was identified through company communications as part of the NICE fact check process (Luscii, received by the EAG 15th May 2024). In these comments Luscii noted that a completed evaluation of the MyCare24 COPD remote monitoring service at Airedale NHS Foundation Trust (conducted by the NHS National Innovation Collaboration for Digital Health in partnership with the National Academic Health Science Network and Health Innovation Manchester) is awaiting publication. No further information was provided on what the MyCare24 COPD remote monitoring service consists of (and therefore whether it is eligible for consideration), nor the study's design or which outcomes it has captured. Therefore the EAG considers the gaps this study fills in the evidence base to be unknown.

Table 9.1: Ongoing studies list from EAG searches

Ongoing study (EAG searches)	Alignment with scope	Outcome data for economic model	Indicated trial end date
Author (year): Kaur 2023 (Kaur et al. 2023) (protocol) **Associated:** (University of Birmingham 2020) **Study design:** RCT **Company:** Nepesmo Ltd. **Country**: UK	**Intervention**: COPDPredict and rescue medication **GREEN** **Comparator:** Standard care **GREEN** **Participants**: Patients over 18 with a diagnosis COPD, 1> acute exacerbation or hospital admission for COPD in the last 2 years and exacerbation free for 6 weeks **GREEN** **Setting**: Recruited from hospital **GREEN** **Outcomes:** AECOPD admissions, total inpatient days, number of COPD exacerbations, number of ED visits, symptom control markers, user experience of app, HRQoL, lifestyle choices, FEV_1, blood CRP, saliva CRP **GREEN**	NR	March 2023
Author (year): NCT05086341 (Umeå University 2021) **Study design:** Randomised, controlled pilot and feasibility trial **Company:** my mhealth Ltd. **Country**: Sweden	**Intervention**: my COPD **GREEN** **Comparator:** Standard care **GREEN** **Participants**: Patients with a diagnosis COPD **GREEN** **Setting**: Recruited from hospitals and primary care **GREEN** **Outcomes:** User satisfaction, physical capacity, physical activity, HRQoL, COPD symptoms (mMRC), exercise intensity, AEs, adherence, exercise progression **GREEN**	• QALY change • Health care use	May 2023

Ongoing study (EAG searches)	Alignment with scope	Outcome data for economic model	Indicated trial end date
Author (year): PROPEL study, NCT05835492 (my mhealth Ltd 2023). **Study design:** Prospective cohort study **Company:** my mhealth Ltd. **Country**: UK	**Intervention**: my COPD **GREEN** **Comparator:** myCOPD plus PR **AMBER** **Participants**: <u>Cohort 1: myCOPD</u> Patients over 18 with a diagnosis COPD, admitted to hospital with a primary diagnosis of AECOPD and assessed in a clinic or VW within 6 weeks of AECOPD **GREEN** <u>Cohort 2: myCOPD plus PR</u> Patients over 18 with a diagnosis of COPD who are suitable for a PR referral **GREEN** **Setting**: Recruited from hospitals and primary care clinics **GREEN** **Outcomes:** Hospital readmission reduction, PR uptake and completion, CAT, QoL, mMRC, ISWT, unscheduled healthcare usage, myCOPD app usage, app feedback, digital accessibility	Cost benefit analysis	June 2025
Author (year): NCT05330507 (Convexity Scientific Inc 2022b) **Study design:** Prospective case control study **Company:** Convexity Scientific Inc **Country**: US	**Intervention**: Wellinks **GREEN** **Comparator:** Matched controls, intervention NR **AMBER** **Participants**: Patients over 18 with a COPD diagnosis **GREEN** **Setting**: NR **AMBER**	NR	NR

Ongoing study (EAG searches)	Alignment with scope	Outcome data for economic model	Indicated trial end date
	Outcomes: Hospital readmission rates, QoL, exercise capacity, mMRC, Wellinks engagement (app, device and session), patient satisfaction, Wellinks feature value ranking **GREEN**		
Author (year): NCT05259280 (Convexity Scientific Inc 2022a) **Study design:** Case series **Company:** Convexity Scientific Inc **Country**: NR	**Intervention**: Wellinks **GREEN** **Comparator:** None **GREEN** **Participants**: Patients with a COPD diagnosis **GREEN** **Setting**: NR **AMBER** **Outcomes:** COPD symptoms assessment, COPD self-efficacy scale, mMRC dyspnoea scale, participant net promotor score **GREEN**	Patient-reported healthcare resource utilisation	NR
Author (year): ISRCTN911338481 (University of Leicester 2020) **Study design:** Prospective cohort study **Company:** UHL NHS Trust **Country**: India	**Intervention**: SPACE for COPD and focus groups **GREEN** **Comparator:** None **GREEN** **Participants**: Patients with stable COPD and a MRC score ≥2. Caregivers of adults with COPD **GREEN** **Setting**: NR **AMBER** **Outcomes:** Completion rates, App usefulness, adherence, compliance, app analytics, CAT, Borg scale, MRC, COPD grading and clinical history, serious AEs,	NR	March 2023

Ongoing study (EAG searches)	Alignment with scope	Outcome data for economic model	Indicated trial end date
	adaptability of SPACE for COPD for global audiences **GREEN**		

Key: AE – Adverse event, AECOPD - Acute exacerbations of chronic obstructive pulmonary disease, CAT – COPD assessment test, COPD – Chronic obstructive pulmonary disease, CRP – C-reactive protein, ED – emergency department, HRQoL – Health related quality of life, ISWT - Incremental Shuttle Walk Test, PR – Pulmonary rehabilitation, QoL – Quality of life, VW – Virtual ward, mMRC – Modified medical research council.

GREEN: Study characteristic aligns with the scope**; AMBER:** Study characteristic does not fully align with the scope**; RED:** Study characteristic does not align with the scope

10 Evidence gap analysis

Table 10.1: Evidence gap analysis

Outcomes	Active+me REMOTE	COPDHub	myCOPD	SPACE for COPD	Wellinks	COPDPredict	Lenus	Luscii	CliniTouch Vie	patientMpower	Current Health	DOC@HOME
Intermediate outcomes												
Intervention adherence	1 UK prospective case series AMBER	No studies RED	2 UK RCTs AMBER	1 UK prospective cohort study AMBER	1 US prospective case series 1 US prospective cohort study AMBER	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Rates of attrition/completion	1 UK prospective case series AMBER	No studies RED	2 UK RCTs AMBER	No studies RED	1 US prospective cohort study AMBER	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Intervention related AEs	1 UK prospective case series AMBER	No studies RED	2 UK RCTs AMBER	No studies RED	1 US prospective case series 1 US prospective cohort study AMBER	1 UK prospective case series AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED

Outcomes	Active+me REMOTE	COPDHub	myCOPD	SPACE for COPD	Wellinks	COPDPredict	Lenus	Luscii	CliniTouch Vie	patientMpower	Current Health	DOC@HOME
Inaccessibility to intervention	1 UK prospective case series AMBER	No studies RED	1 UK RCT AMBER	No studies RED	1 US prospective cohort study AMBER	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study [redacted] AMBER	1 UK before-after study AMBER	No studies RED	No studies RED	No studies RED	No studies RED
Clinical outcomes												
Respiratory function	1 UK prospective case series AMBER	1 UK retrospective case series AMBER	2 UK RCTs AMBER	1 UK prospective case series AMBER	1 US prospective cohort study	No studies RED	1 UK prospective cohort study AMBER	No studies RED	1 UK before-after study AMBER	No studies RED	No studies RED	No studies RED
Daily activity	No studies RED	1 UK retrospective case series AMBER	2 UK RCTs AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Acute COPD exacerbations	No studies RED	1 UK retrospective case series AMBER	2 UK RCTs AMBER	No studies RED	No studies RED	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED

Outcomes	Active+me REMOTE	COPDHub	myCOPD	SPACE for COPD	Wellinks	COPDPredict	Lenus	Luscii	CliniTouch Vie	patientMpower	Current Health	DOC@HOME
Hospital admissions, readmissions or emergency admissions	No studies **RED**	No studies **RED**	2 UK RCTs **AMBER**	No studies **RED**	1 US prospective cohort study **AMBER**	1 UK prospective case series **AMBER**	1 UK mixed prospective/ retrospective cohort study [redacted] **AMBER**	1 UK before-after study **AMBER**	1 UK before-after study **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**
Outpatient clinic or GP visits	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	1 US prospective cohort study **AMBER**	No studies **RED**	No studies **RED**	1 UK before-after study **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Additional medications required	No studies **RED**	No studies **RED**	1 UK RCT **AMBER**	No studies **RED**	No studies **RED**	1 UK prospective case series **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Optimising inhaler technique	No studies **RED**	No studies **RED**	2 UK RCTs **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Mortality	1 UK prospective case series **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	1 UK prospective case series **AMBER**	1 UK mixed prospective/ retrospective cohort study **AMBER**	No studies **RED**	1 UK before-after study **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**

Outcomes	Active+me REMOTE	COPDHub	myCOPD	SPACE for COPD	Wellinks	COPDPredict	Lenus	Luscii	CliniTouch Vie	patientMpower	Current Health	DOC@HOME
Patient- reported outcomes												
HRQoL	1 UK prospective case series **AMBER**	No studies **RED**	1 UK RCT **AMBER**	1 UK prospective cohort study **AMBER**	No studies **RED**	No studies **RED**	1 UK prospective cohort study **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Patient experience, usability and acceptability	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	1 US prospective case series 1 US prospective cohort study **AMBER**	No studies **RED**	1 UK mixed prospective/ retrospective cohort study **AMBER**	1 UK before-after study 1 UK retrospective case series **AMBER**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**
Psychological wellbeing	1 UK prospective case series **AMBER**	No studies **RED**	1 UK RCT **AMBER**	No studies **RED**	1 US prospective cohort study	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**	No studies **RED**

Key: AE – Adverse event, GP – General Practitioner, HRQoL – Health related quality of life, RCT – Randomised controlled trial.

RED indicates no comparative evidence for the scoped population; **AMBER** indicates weak comparative evidence for the scoped population; **GREEN** indicates robust comparative evidence for the scoped population.

Table 10.2: Evidence gap analysis for key economic outcomes

Outcomes	Gap in current evidence
Subgroups: The difference in impact of digital technologies to support self-management of COPD by those who have recently had an exacerbation and those who have not.	Current studies capture some potential impact of digital technologies, but there is limited evidence to suggest differences in impact by those who have had a recent exacerbation or not. The difference in using digital technologies to support self-management on resource use, costs, effectiveness and HRQoL depending on exacerbation history is unknown. It may be that these digital technologies are more effective in those with recent exacerbation history. **RED**
Effectiveness evidence: Long-term outcomes	It is not clear if there any long-term impacts from using digital technologies to support self-management of COPD, or if the benefits stop after use of the technology is discontinued. Follow up in the available clinical studies ranges from 3 to 9 months, other than 1 study which is 78 weeks, but was not statistically powered for a wide range of outcomes (the RECIEVER trial). **AMBER**
Effectiveness evidence: Improvement in COPD	Some evidence has been captured on improvement in COPD from digital technologies, using the CAT score. However, the follow up period is limited, and this could be used to stratify resource use and HRQoL into health states for an economic model. This would be important for designing a future model. **AMBER**
Resource use: Wider healthcare resource use impact of digital technologies for self-management of COPD	Some evidence relevant to the scope of this early value assessment was available to highlight the potential impact digital technologies which facilitate or provide self-management may have on healthcare resource use, such as reduction in healthcare appointments. However, this data was limited to a couple of companies, while this did not capture all healthcare resource (for example, differences in prescriptions for inhalers or other medications). **AMBER**
Resource use: Impact on capacity across all healthcare settings	One of the value propositions of digital technologies to support self-management is to improve capacity and reduce waiting lists associated with COPD. However, since the technologies involve some level of engagement from clinical staff, even though capacity may be improved in one part of the healthcare system, capacity may be further constrained in another. Evidence should be collected for the likely impact of the technologies across all of the health system. **AMBER**
Costs: Set up and training costs	Companies provide some evidence of the implementation or training resource use and costs to embed their technologies within the NHS, but the quality of this evidence is mixed across companies and not always clear. Further clarification should be sought on the required training, and if there are any wider implementation costs to use the technology. **AMBER**
HRQoL: Valuing HRQoL due to self-management technologies	Currently, there are some studies which capture HRQoL, using metrics such as EQ-VAS or EQ-5D. However, this is limited to a couple of smaller RCTs or prospective cohort studies and is not routinely captured by all companies. **AMBER**

Key: CAT – COPD assessment test, COPD – Chronic obstructive pulmonary disease, EAG – External assessment group, EQ-5D – EuroQol- 5 dimension, EQ-VAS – EuroQol- visual analogue scale, HRQoL – Health-related quality of life, RCT – Randomised control trial.

RED indicates no evidence for the scoped population; **AMBER** indicates weak evidence for the scoped population; **GREEN** indicates robust evidence for the scoped population

10.1 Summary and conclusions of evidence gap analysis

Clinical evidence meeting the scope was available for 9 of the 12 scoped technologies. Limited clinical evidence was available for Active+me REMOTE (Aseptika Ltd) and COPDHub (The Institute of Clinical Science & Technology), which only provided non-comparative data. No clinical evidence relevant to the scope was identified for Current Health (Current Health Ltd.), DOC@HOME (Docobo) or patientMpower (patientMpower Ltd.).

Evidence was identified for a number of key outcomes, most commonly for CAT scores, exacerbations and hospital admissions, although comparative effects were not commonly reported. Outcome definitions, measures and reported timepoints varied across the trials, making comparison across digital technologies difficult. The use of common outcome definitions and measures for key outcomes would facilitate the comparison of different technologies. Adverse events (AEs) were reported in 6 studies and were generally low and not reported to be treatment-related.

Other outcomes were not well-reported, including daily activity and psychological wellbeing. The evidence base was particularly scarce for the effect of digital technologies on the use of other healthcare resources such as outpatient/GP visits and additional medication use.

There was insufficient evidence to consider whether the variation in components used across digital technologies, such as within-app contact with healthcare professionals and symptom tracking, affected outcomes.

As noted above, the objectives and scope of the EVA process does not include exhaustive consideration of all studies identified in the review, thus the evidence gap analysis is based on the prioritised studies only. The EAG notes that the deprioritised studies may include evidence for some of the areas identified in the evidence gap analysis.

10.2 Key areas for evidence generation

Suggestions for future evidence generation are summarised in Table 10.3. Evidence generation should focus on increasing the certainty of whether digital self-management technologies consistently have a beneficial impact on key health and resource use outcomes when compared to standard care alone. The technologies evaluated in this EVA are very varied in the components they include to support self-management of COPD, and this may explain some of the inconsistency in findings. Understanding which components are of highest clinical value will be important.

Inconsistency is also due to the considerable variation in populations evaluated in prioritised studies, both reported and not reported. More detailed reporting of COPD severity and treatment setting will enable further understanding of the impact of digital technologies on the population as a whole, with most existing evidence focused on those who have recently had an acute exacerbation, or a mixed population. Investigating the effectiveness of digital self-management technologies in those who have not recently had an exacerbation requiring hospitalisation, or are experiencing milder COPD, will be important. Similarly, the consistent reporting of outcomes across technologies should be considered for any future evidence generation. For example, there was a range of definitions for admissions and hospitalisations, which varied across the studies identified, meaning comparisons of clinical evidence were limited.

Further to this, healthcare resource use associated with different types of digital technologies should be collected to observe whether digital technologies could significantly reduce resource use. Studies should compare digital technologies with standard care compared with standard care alone in a UK NHS setting for at least a 1 year follow up period. Current evidence for some technologies suggests there may be a reduction in resource use, but this evidence was either underpowered, or represents a short period of follow up, so the longer-term impact is unknown.

In order to translate favourable outcomes into clinical practice, it is essential to understand how the digital technology is being used within a study setting, namely whether people with COPD are able to access standard care in addition to the digital intervention, and if so what that standard care entails. Future trials or cohort studies

should therefore clearly report the care being received by participants in all study arms to ensure that the likely impact to health and resource use in practice can be interpreted.

There is a need for evidence from larger comparative studies, ideally controlled trials. The identified RCTs were small and underpowered, with both authors noting a need for larger, adequately-powered trials to evaluate the effectiveness of digital self-management technologies.

Finally, in order for potential benefits to be fully realised, digital technologies for the self-management of COPD need to be implemented successfully. This will require optimal staff acceptability, patient acceptability and uptake to ensure that benefits are realised across as large a proportion of the eligible COPD population as possible. Further evidence is required to establish the patient and staff acceptability of the technologies.

Table 10.3: Evidence generation recommendations

Research question	Recommended study design	Outcomes
Which components of DHTs are likely to drive differences in relevant outcomes.	Qualitative studies investigating clinical perspectives on which are the most resource saving features of DHT.	• Components of DHT to interrogate further
Patient uptake of digital technologies and facilitators of adherence and acceptability.	Mixed methods studies assessing patient adherence to DHT using different solutions to maximise uptake and adherence. This will also inform the expected cost of the technology for ICSs Conducted in the UK.	• Patient uptake and adherence • Categorisation of solutions for digital exclusion and acceptability • Facilitators and barriers of uptake
Understanding the HRQoL associated with different periods of COPD self-management, such as before, during and after acute exacerbations.	Any study should look to collect EQ-5D-3L	• HRQoL, provided for different severities of COPD based on CAT score, or the impact of acute exacerbations
Healthcare resource use associated with different types of digital technologies.	Cluster RCTs, prospective controlled cohort studies or cluster non-RCTs, comparing digital technologies with standard care compared with standard care alone over at least a 1 year follow up period. The key driver of the economic results is readmissions and hospital attendance, so the power of the study should be prioritised to this metric for resource use. This should be done for each different application. Conducted in the UK.	• Readmissions or hospital attendance • GP appointments • Inhaler usage • Medication usage • Non- hospitalised exacerbations • Other primary and secondary care attendances
What is the likely impact on health care worker capacity from implementing the technologies.	Mixed methods studies assessing the perspectives of healthcare staff using the technologies. Although some staff may see capacity benefits, others may feel further burden due to engaging with the technologies.	• Quantifiable difference in staff time. • Staff perspectives on the impact on their capacity.
What is the cost-effectiveness of different digital technologies when used alongside standard care.	Detailed in section 10.3.	• Quality of life • Resource use • Cost

Research question	Recommended study design	Outcomes
Understanding the impact that recent acute exacerbations or COPD severity has on the impact of the digital technologies.	Subgroup analysis of any impact study conducted to evaluate the evidence gaps as listed above. The study would need to power the primary outcome for differences at the subgroup level.	• Patient adherence • Quality of life • Resource use

Key: CAT – COPD Assessment Test, COPD – Chronic Obstructive Pulmonary Disorder DHT – Digital health technology, HRQoL – Health-related quality of life, ICS – Integrated care system, RCT – Randomised controlled trial.

10.3 Potential future conceptual model

When evidence is collected to inform current evidence gaps on digital health technologies for the self-management of COPD, a future model design would provide a more robust evaluation of the digital technologies. The EAG recommends a type of cohort transition model (either a semi-Markov model or a regression based-cohort model). A patient simulation model is not likely to be required, if the population is defined sufficiently, and that they are not heterogenous with respect to important outcomes.

In the state transition model, the health states could be based around different severities of CAT or global initiative for chronic obstructive lung disease (GOLD) score, a clinical tool to determine the severity of COPD at a particular point in time. For example, health states may include ‘low’, ‘medium’, ‘high’ and ‘very high’ impact (Zimlich R 2022), as well as an absorbing ‘dead’ health state. The benefit of a state-driven model based on severities of CAT or GOLD scores is that the impact of digital technologies can be extrapolated beyond the trial period by movements in these scores. This model structure would also allow for different subgroup analysis, such as those who have recently had an acute exacerbation, who are more likely to be starting at a more severe CAT score.

Using a cohort-based structure around the CAT or GOLD score would also allow the capture and extrapolation of health-related quality of life (HRQoL). Any future generated evidence could collect HRQoL information, stratified by CAT score. In line with the NICE reference case, HRQoL should be collected using the EQ-5D-3L, unless there is clear evidence that this generic measure is unsuitable or lacks sensitivity to the condition (NICE 2023).

Data from any clinical studies that recorded CAT or GOLD scores could then be used to track people by their specific health states over time, calculating transition probabilities or using a regression-based framework. The time horizon should then be expanded beyond 1 year, with results extrapolated from the trial, to estimate the evolution of people’s pain score. There is uncertainty of how much impact the digital

technology would still have if the person stopped using the technology, given there may be confounding factors. Therefore, it is likely a time horizon of 5 years is an appropriate base case, although, scenario analysis should be conducted on a range of different time horizons.

Healthcare resource use could also be captured by stratification of CAT or GOLD scores, given there is suggested correlation between the 2 (Varol Y et al. 2014, Byng D et al. 2019). Future studies should look to stratify the healthcare resource use over the follow up period based on what CAT or GOLD score was recorded at each interval. This can then be used to estimate healthcare resource use for each CAT or GOLD severity. For example, if scores are captured every 3 months for a year, and the first score recorded is representative of higher impact, those first 3 months would be used to calculate any healthcare resource use for high impact. Hence, it would be possible to estimate healthcare costs from different pain severities over time from a cohort captured in an RCT or observational study. Healthcare resource use is likely to include medication use, inhaler prescriptions, exacerbations, hospitalisations, GP appointments and other healthcare attendances.

Waiting times would not need to be included directly in the modelling approach. This is because those who wait longer at any follow up point for support with self-management in standard care may incur worse outcomes due to waiting. Therefore, this would already be reflected in the model, so to include waiting time explicitly is likely to double count the potential impact of the digital technologies. Waiting times are an important clinical consideration for self-management of COPD, even if not explicitly incorporated into the economic model.

Any future model design should be clinically validated, and adapted as appropriate in line with future evidence generation plans for individual technologies.

11 Conclusions

11.1 Conclusions from the clinical evidence

Evidence was not available for 3 of the 12 scoped technologies. 12 of the 14 prioritised studies (investigating 8 of the 9 technologies with evidence) included UK populations in a UK NHS context. Low quality comparative evidence was identified comparing digital technologies to standard care. Significantly greater improvements in CAT score, inhaler technique and hospital admissions were found in AECOPD populations. A statistically significant difference in favour of usual care in the exacerbation rate was reported in 1 RCT in a mixed treatment setting COPD population, though baseline group imbalances favouring usual care undermine the certainty of this result. Within-group comparisons in comparative and single-arm studies generally found significant improvements from baseline for both standard care and the digital technologies. Though some outcomes such as CAT score and admission rates were reported frequently across the included studies, outcome definitions and the timepoints at which results were reported varied, making comparison across digital technologies difficult. Studies did not clearly report whether the digital technology was provided alongside standard care, or instead of standard care, and clinical interpretation is needed to assess whether an assumption of additive care could be made across these studies. Evidence for other scoped outcomes, such as outpatient visits and additional medication use, was limited.

7 studies including 1 RCT specifically evaluated digital technologies in an AECOPD post-discharge population. The comparative studies provided low certainty evidence of the greater efficacy in improving CAT scores and inhaler technique in this subgroup.

The EAG concludes that digital self-management technologies for COPD are plausibly safe and effective. Some evidence of their greater effectiveness compared to standard care was found in 1 RCT. However, heterogeneity in the features of the scoped digital technologies and unclear reporting around the extent to which elements of standard care were available to people in the intervention arms make this finding difficult to generalise. My mhealth currently have the most robust evidence (2 RCTs, 1 each in AECOPD and mixed setting populations) to suggest they provide benefit to the

healthcare system, although, other technologies had evidence to suggest they could plausibly be effective, with mixed quality evidence for the other technologies.

11.2 Conclusions from the economic evidence

Previous economic evidence

A total of 5 economic costing studies and one economic model were identified that report evidence in the UK, in a NHS context. The studies and economic model report potential costs savings for myCOPD, Luscii, Lenus and CliniTouch Vie due to averted A&E attendance and admissions. The quality of the evidence was generally low and there are uncertainties in the evidence base.

Base case economic model results

The economic analysis conducted by the EAG was a simple cost-comparison model to indicate the potential benefit of digitally supported technologies for the self-management of COPD. The analysis suggests that the incorporation of digital technologies into the NHS has the potential to be cost saving, based on the limited evidence available. The base case results of the analysis suggest that there is a potential cost saving of £337 per person when using digital technologies compared with standard care. However, the results are based on uncertain data that is mixed from different companies' evidence with a high level of uncertainty. Key areas of uncertainty are the expected impact on healthcare resource use from the digital technologies (such as the impact on hospitalisations) and variations in different technology features which may impact effectiveness. Model inputs were sourced through company provided documents. Identified literature and clinical elicitation. Due to limited evidence, results for the subgroup of post-acute exacerbation could not be fully disentangled as part of the modelling. Studies used to populate the model likely represent more severe COPD populations, where the capacity to benefit may be much greater (including AECOPD populations).

Key drivers of the model results

The sensitivity analysis indicated the likely key drivers of the economic results were:

- the number of hospitalisations per person in standard care
- the total cost of technology (company costs and costs to the NHS)
- the number of hospitalisations per person in the intervention
- the cost of hospitalisation for a COPD-related event.

Future conceptual model

Limited evidence was available to model the potential impact of digitally supported technologies for the self-management of COPD for all companies. A future model could be developed to support decision-makers with:

- capturing subgroups through stratified by baseline CAT or GOLD score
- capturing HRQoL through stratified CAT or GOLD score
- capturing mortality in greater detail
- understanding the potential long-term impact of digitally supported technologies for the self-management of COPD, in terms of resource use and HRQoL.

11.3 Conclusions on the gap analysis

The primary evidence gap is the inconsistency of evidence due to the considerable variation in populations evaluated in prioritised studies. More detailed reporting of COPD severity and treatment setting will enable further understanding of the impact of digital technologies on the population as a whole, with most existing evidence focused on those who have recently had an acute exacerbation, who constitute a more severe population, or an unclear COPD population. Similarly, the consistent reporting of outcomes across technologies should be considered for any future evidence generation.

The EAG identified several ideas for further evidence generation but consider the priority to be cluster RCTs, prospective controlled cohort studies or cluster non-RCTs, comparing digital technologies as an addition to standard care with standard care

alone, and over at least a 1 year follow up period. Capturing differences in healthcare resource use will be particularly important, and in clearly defined populations of AECOPD and not AECOPD. Data on hospitalisations that is adequately powered over a longer follow up period is particularly useful for the economic case. User and staff acceptability of the technologies, alongside uptake and adherence will also need to be considered in further evidence generation.

In summary, this EAG concludes that there is currently some existing evidence to suggest that these technologies are cost saving. There was limited evidence on implementation costs and the wider healthcare resource use impact across the range of the technologies. Future evidence generation should be used to differentiate between healthcare technologies. Resource use implications need to be further understood, alongside stratifying data collection by disease severity.

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13 Appendices

Appendix A – Search methods

A MEDLINE (OvidSP) search strategy designed to identify studies of digital technologies for the supported self-management of COPD is presented below (see section A.1).

The main structure of the strategy comprised 3 concepts:

- COPD (search lines 1 to 7)
- digital technologies (search lines 8 to 34)
- self-management (search lines 35 to 54)

The concepts were combined as follows: (COPD AND digital technologies AND self-management).

In addition to the above approach, the strategy included a supplementary search strand designed to identify:

- records referring to named eligible technology platforms (and providers of the platforms) identified by the research team at project start (search lines 56 and 57)
- records that refer to COPD AND (Current Health OR Best Buy Health OR ICST OR Lenus OR Storm ID OR University of Leicester NHS Trust) (search lines 58 and 59)

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 and browsing database thesauri. Searches were not restricted by study design or outcome so were appropriate to retrieve both clinical and economic evidence.

The search terms for the digital technologies concept included the NICE search filter for health apps (Ayiku L et al. 2020) (search lines 8 to 22). After examination of records for potentially relevant studies, the NICE search filter terms were supplemented by the following additions, to enhance potential sensitivity:

- the filter was expanded by adding searches of the keyword heading word field to lines 14, 16, 18, 20 and 21
- further terms for digital technologies were added to the search strategy (search lines 23 to 34)

The strategy excluded animal studies from MEDLINE using a standard algorithm (search line 62). The strategy also excluded some ineligible publication types which were unlikely to yield relevant study reports (editorials, news items and case reports) and records with the phrase 'case report' in the title (search line 63).

Reflecting the eligibility criteria, the strategy was restricted to studies published from 2014 onwards in English (search lines 65 and 66).

Before running the search, the performance was tested using records for included studies from 2 systematic reviews. The terms for digital interventions were tested against the included studies from Janjua 2021. The terms for self-management were tested against the included studies from Schrijver 2022. The tested search concepts retrieved all the included studies. This test suggested that the strategy was reasonably robust, although it is not possible to know how representative this test set is of all studies that were eligible for this review.

The final Ovid MEDLINE strategy was peer-reviewed before execution by a second Information Specialist. Peer review considered the appropriateness of the strategy for the review scope and eligibility criteria, inclusion of key search terms, errors in spelling, syntax and line combinations, and application of exclusions.

Search limitations

The search strategy was designed to strike an appropriate balance of sensitivity and precision. A pragmatic approach was taken, which has resulted in some potential limitations to the search. The approach and limitations were discussed within the research team and agreed.

The search included the self-management concept. This approach has inherent potential limitations. Self-management can be defined in many ways and is not always well described in the title or abstracts of papers, and these papers are not always well indexed with controlled vocabulary terms applied to database records. The text word terms for the self-management concept were designed to retrieve records that explicitly referred to a range of terms that might indicate a self-management context. These included, for example, terms relating to self-management, self-education, self-monitoring, action planning. Including this concept was noted as a potential limitation but considered appropriate within project resources and time constraints. Although a potential limitation, when tested against a set of records for known, potentially relevant studies, the terms performed well (see below for details).

Some of the named interventions proved to retrieve a high proportion of many irrelevant results (for example, Current Health). Where this was the case, the named intervention was combined with terms for COPD. This is a further potential limitation on the search.

Resources searched

We conducted the literature search in the databases and information resources shown in **Error! Reference source not found.**.

Table 13.1: Databases and information sources searched

Resource	Interface / URL
Databases	
MEDLINE(R) ALL	OvidSP
Embase	OvidSP
Cochrane Database of Systematic Reviews(CDSR)	Cochrane Library/Wiley
Cochrane Central Register of Controlled Trials (CENTRAL)	Cochrane Library/Wiley
HTA Database	https://database.inahta.org/
Conference Proceedings Citation Index - Science (CPCI-S)	Web of Science
NHS Economic Evaluation Database (NHS EED)	https://www.crd.york.ac.uk/CRDWeb/HomePage.asp
EconLit	OvidSP
Trials Registers	
ClinicalTrials.gov	https://clinicaltrials.gov/
WHO International Clinical Trials Registry Platform (ICTRP)	https://trialsearch.who.int/
Other	
Reference list checking	n/a
Company submissions	n/a

The trials register sources listed above (ClinicalTrials.gov and ICTRP) were searched to identify information on studies in progress.

Records indexed as preprints were excluded from Embase search results. We limited the search for conference proceedings in Embase and CPCI-S to 2021 onwards.

We also checked included studies lists of any industry submissions to NICE as well as retrieved relevant systematic reviews published since 2021, for additional eligible studies.

Running the search strategies and downloading results

Where possible, we conducted searches using each database or resource listed above, translating the agreed Ovid MEDLINE strategy appropriately. Translation included consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The final translated database strategies were peer-reviewed by a second Information Specialist. Peer review considered the appropriateness of the translation for the database being searched, errors in syntax and line combinations, and application of exclusions.

Some pragmatic decisions were taken with the translation of the search strategy for different interfaces and databases. Some terms in the search strategy would not run in the HTA database interface, as the search will only function with terms of three or more characters. As a result, the terms m-health, e-health, e-mental, my copd, doc @ home, my mhealth, my m health and patient m power were not searched in the HTA database. As a straight translation of the MEDLINE search strategy proved to retrieve record numbers that were too high for project resources and time constraint, some appropriate compromises were made in the search translation, such as adding "chronic" or "chronically" to the COPD terms. The terms "Active+Me" and "Doc@Home" would not run in many of the interfaces. Where this was the case, Boolean AND was used instead of the characters + and @, but it is possible that this approach risked missing some potentially eligible records.

Where possible, we downloaded the results of searches in a tagged format and loaded them into bibliographic software (EndNote) (Clarivate 2021). The results were deduplicated 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.

Literature search results

The searches were conducted between 15 February 2024 and 19 February 2024 and identified 4,912 records (Table 13.2). Following deduplication, 2,970 records were assessed for relevance.

Table 13.2: Literature search results

Resource	Number of records identified
Databases	
MEDLINE	817
Embase	1370
Cochrane Database of Systematic Reviews (CDSR)	8
Cochrane Central Register of Controlled Trials (CENTRAL)	663
HTA Database	19
Conference Proceedings Citation Index - Science (CPCI-S)	82
NHS Economic Evaluation Database (NHS EED)	18
EconLit	9
Total records identified through database searching	2986
Trials Registers	
ClinicalTrials.gov.	788
WHO International Clinical Trials Registry Portal (ICTRP)	1120
Total records identified through trials register searching	1908
Other sources	
Reference list checking	0
Company evidence	18
Total additional records identified through other sources	0
Total number of records retrieved	4912
Total number of records after deduplication	2970

Search strategies

A.1: Source: MEDLINE ALL

Interface / URL: OvidSP

Database coverage dates: 1946 to 14 February 2024

Search date: 15 February 2024

Retrieved records: 817

Search strategy:

1 exp Pulmonary Disease, Chronic Obstructive/ (68693)

2 (obstruct* adj3 (airflow* or air-flow* or airway* or air-way* or lung* or pulmonary or bronchopulmonary or respirat*)).ti,ab,kf. (104782)

3 (COPD* or COAD* or COBD* or AECB*).ti,ab,kf. (80851)

4 (asthma* adj5 overlap*).ti,ab,kf. (1022)

5 (chronic* adj3 (bronchit* or bronchus or cough*)).ti,ab,kf. (17554)

6 emphysem*.ti,ab,kf. (31657)

7 or/1-6 (188128)

8 Mobile Applications/ (12201)

9 exp Internet/ (99608)

10 exp Cell Phone/ (23268)

11 exp Computers, Handheld/ (13648)

12 Medical Informatics Applications/ (2552)

13 Therapy, Computer-Assisted/ (6979)

14 (app or apps).ti,ab,kf. (47195)

15 (online or web or internet or digital*).ti. (146202)

16 ((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap*)).ab,kf. (86176)

17 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti. (28320)

18 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) adj3 (based or application* or intervention* or program* or therap*)).ab,kf. (18370)

19 (mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).ti. (9071)

20 ((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (based or application* or intervention* or program* or therap*)).ab,kf. (6541)

21 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab,kf. (24833)

22 or/8-21 (362120)

23 telemedicine/ (39044)

24 telerehabilitation/ (1108)

25 telenursing/ (268)

26 remote consultation/ (5815)

27 (telehealth* or tele health* or telecare* or tele care*).ti. (6823)

28 ((telehealth* or tele health* or telecare* or tele care* or telemedicine or tele medicine) adj3 (based or application* or intervention* or program* or therap*)).ab,kf. (5650)

29 (telemonitor* or tele monitor*).ti,ab,kf. (2781)

30 (remote adj3 monitor*).ti,ab,kf. (7157)

31 (tablet* or desktop* or handheld*).ti. (22930)

32 ((tablet* or desktop* or desk-top* or handheld* or hand-held*) adj3 (based or application* or intervention* or program* or therap*)).ab,kf. (4048)

33 ((online or web or internet or digital* or phone* or telephone* or smartphone* or cellphone* or smartwatch* or mobile* or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (platform* or dashboard* or dash-board*)).ab,kf. (13958)

34 or/22-33 (427046)

35 exp self care/ (63156)

36 self management/ (5712)

37 patient education as topic/ (88421)

38 patient participation/ (29774)

39 self efficacy/ (24751)

40 self assessment/ (13460)

41 risk reduction behavior/ (14342)

42 health plan implementation/ (6642)

43 patient generated health data/ (113)

44 diagnostic self evaluation/ (4145)

45 self examination/ (1228)

46 self directed learning as topic/ (106)

47 computer-assisted instruction/ (12639)

48 self.ti,ab,kf. (1016071)

49 ((action or manag* or care or teach* or coach* or educat* or train* or instruct*) adj2 (plan* or program*)).ti,ab,kf. (227426)

50 ((patient* or consumer* or client* or person* or individual*) adj5 (manag* or control* or track* or monitor* or care or efficac* or identif*) adj5 (symptom* or diseas* or exacerbat* or recur* or reoccur* or re-occur*or risk* or trigger* or caus*)).ti,ab,kf. (110912)

51 ((patient* or consumer* or client* or person* or individual*) adj3 (centr* or center* or focus* or educat* or complian* or participat* or behav*)).ti,ab,kf. (342851)

52 ((patient* or consumer* or client* or person* or individual*) adj3 (tailor* or goal* or objective* or target* or plan* or alert* or notif* or warn* or remind*)).ti,ab,kf. (180372)

53 (home* adj5 (base* or integrat* or rehab* or care or treat* or therap*)).ti,ab,kf. (97585)

54 or/35-53 (1934021)

55 7 and 34 and 54 (989)

56 ("active+me remote*2" or "active+meremote*2" or active me or active metm or active mer or aseptika*2 or clinitouch vie*2 or spirit health*2 or copd predict*2 or nepesmo*2 or copdpredict*2 or "doc@home*2" or "doc @ home*2" or docobo*2 or luscii*2 or mycopd*2 or my copd*2 or mymhealth*2 or my mhealth*2 or my m health*2 or patientmpower*2 or patient m power*2 or patient mpower*2 or wellinks*2).ti,ab,kf,ot. (75)

57 (copd hub*2 or copdhub*2 or current healthtm or current healthr or ibisr or ibistm or lenusr or lenustm or space for copd*2 or "institute of clinical science and technology*2" or "institute of clinical science & technology*2").ti,ab,kf,ot. (18)

58 (current health or best buy health*2 or icst*2 or lenus or storm id*2 or university of leicester nhs hospitals trust*2).ti,ab,kf,ot. (5469)

59 7 and 58 (49)

60 56 or 57 or 59 (142)

61 55 or 60 (1116)

62 exp animals/ not humans/ (5197326)

63 (news or editorial or case reports).pt. or case report.ti. (3336170)

64 61 not (62 or 63) (1101)

65 limit 64 to english language (1055)

66 limit 65 to yr="2014 -Current" (817)

A.2: Source: Embase

Interface / URL: OvidSP

Database coverage dates: 1974 to 14 February 2024

Search date: 16/02/2024

Retrieved records: 1,089 + 281 = 1,370

Search strategy:

The non-conference abstracts and conference abstracts were searched and exported separately.

Non-conference abstract search:

1 exp chronic obstructive lung disease/ (181092)

2 (obstruct* adj3 (airflow* or air-flow* or airway* or air-way* or lung* or pulmonary or bronchopulmonary or respirat*)).ti,ab,kf,dq. (155009)

3 (COPD* or COAD* or COBD* or AECB*).ti,ab,kf,dq. (139885)

4 (asthma* adj5 overlap*).ti,ab,kf,dq. (1791)

5 (chronic* adj3 (bronchit* or bronchus or cough*)).ti,ab,kf,dq. (24760)

6 emphysem*.ti,ab,kf,dq. (41582)

7 or/1-6 (324339)

8 exp mobile application/ (27366)

9 internet/ (125673)

10 exp mobile phone/ (50201)

11 text messaging/ (8073)

12 personal digital assistant/ (1865)

13 computer assisted therapy/ (4874)

14 (app or apps).ti,ab. (62370)

15 (online or web or internet or digital*).ti. (166831)

16 ((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap*)).ab. (111931)

17 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti. (33415)

18 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) adj3 (based or application* or intervention* or program* or therap*)).ab. (23773)

19 (mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).ti. (9886)

20 ((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (based or application* or intervention* or program* or therap*)).ab. (6897)

21 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab. (28459)

22 or/8-21 (460054)

23 telehealth/ (20325)

24 telemedicine/ (46860)

25 exp teleconsultation/ (16543)

26 teletherapy/ (1029)

27 telenursing/ (411)

28 telemonitoring/ (6051)

29 (telehealth* or tele health* or telecare* or tele care*).ti. (8275)

30 ((telehealth* or tele health* or telecare* or tele care* or telemedicine or tele medicine) adj3 (based or application* or intervention* or program* or therap*)).ab,kf,dq. (7592)

31 (telemonitor* or tele monitor*).ti,ab,kf,dq. (4130)

32 (remote adj3 monitor*).ti,ab,kf,dq. (10981)

33 (tablet* or desktop* or handheld*).ti. (39582)

34 ((tablet* or desktop* or desk-top* or handheld* or hand-held*) adj3 (based or application* or intervention* or program* or therap*)).ab,kf,dq. (5912)

35 ((online or web or internet or digital* or phone* or telephone* or smartphone* or cellphone* or smartwatch* or mobile* or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (platform* or dashboard* or dash-board*)).ab,kf,dq. (19384)

36 or/22-35 (574456)

37 exp self care/ (105809)

38 patient education/ (127550)

39 patient participation/ (36873)

40 self evaluation/ (38710)

41 risk reduction/ (134301)

42 self directed learning/ (1543)

43 self examination/ (3855)

44 self.ti,ab,kf,dq. (1245757)

45 ((action or manag* or care or teach* or coach* or educat* or train* or instruct*) adj2 (plan* or program*)).ti,ab,kf,dq. (309934)

46 ((patient* or consumer* or client* or person* or individual*) adj5 (manag* or control* or track* or monitor* or care or efficac* or identif*) adj5 (symptom* or diseas* or exacerbat* or recur* or reoccur* or re-occur*or risk* or trigger* or caus*)).ti,ab,kf,dq. (179278)

47 ((patient* or consumer* or client* or person* or individual*) adj3 (centr* or center* or focus* or educat* or complian* or participat* or behav*)).ti,ab,kf,dq. (542734)

48 ((patient* or consumer* or client* or person* or individual*) adj3 (tailor* or goal* or objective* or target* or plan* or alert* or notif* or warn* or remind*)).ti,ab,kf,dq. (328029)

49 (home* adj5 (base* or integrat* or rehab* or care or treat* or therap*)).ti,ab,kf,dq. (133517)

50 or/37-49 (2720289)

51 7 and 36 and 50 (2174)

52 ("active+me remote*2" or "active+meremote*2" or active me or active metm or active mer or aseptika*2 or clinitouch vie*2 or spirit health*2 or copd predict*2 or nepesmo*2 or copdpredict*2 or "doc@home*2" or "doc @ home*2" or docobo*2 or

luscii*2 or mycopd*2 or my copd*2 or mymhealth*2 or my mhealth*2 or my m health*2 or patientmpower*2 or patient m power*2 or patient mpower*2 or wellinks*2).ti,ab,kf,dq,dv,my,ot,dm. (165)

53 (copd hub*2 or copdhub*2 or current healthtm or current healthr or ibisr or ibistm or lenusr or lenustm or space for copd*2 or "institute of clinical science and technology*2" or "institute of clinical science & technology*2").ti,ab,kf,dq,dv,my,ot,dm. (44)

54 (current health or best buy health*2 or icst*2 or lenus or storm id*2 or university of leicester nhs hospitals trust*2).ti,ab,kf,dq,dv,my,ot,dm. (7029)

55 7 and 54 (89)

56 52 or 53 or 55 (295)

57 51 or 56 (2436)

58 (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ (6918200)

59 editorial.pt. or case report.ti. (1192608)

60 preprint.pt. (107257)

61 conference abstract.pt. (5047017)

62 or/58-61 (12870086)

63 57 not 62 (1491)

64 limit 63 to (english language and yr="2014 -Current") (1089)

Conference abstract search:

1 exp chronic obstructive lung disease/ (181092)

2 (obstruct* adj3 (airflow* or air-flow* or airway* or air-way* or lung* or pulmonary or bronchopulmonary or respirat*)).ti,ab,kf,dq. (155009)

3 (COPD* or COAD* or COBD* or AECB*).ti,ab,kf,dq. (139885)

4 (asthma* adj5 overlap*).ti,ab,kf,dq. (1791)

5 (chronic* adj3 (bronchit* or bronchus or cough*)).ti,ab,kf,dq. (24760)

6 emphysem*.ti,ab,kf,dq. (41582)

7 or/1-6 (324339)

8 exp mobile application/ (27366)

9 internet/ (125673)

10 exp mobile phone/ (50201)

11 text messaging/ (8073)

12 personal digital assistant/ (1865)

13 computer assisted therapy/ (4874)

14 (app or apps).ti,ab. (62370)

15 (online or web or internet or digital*).ti. (166831)

16 ((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap*)).ab. (111931)

17 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti. (33415)

18 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) adj3 (based or application* or intervention* or program* or therap*)).ab. (23773)

19 (mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).ti. (9886)

20 ((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (based or application* or intervention* or program* or therap*)).ab. (6897)

21 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab. (28459)

22 or/8-21 (460054)

23 telehealth/ (20325)

24 telemedicine/ (46860)

25 exp teleconsultation/ (16543)

26 teletherapy/ (1029)

27 telenursing/ (411)

28 telemonitoring/ (6051)

29 (telehealth* or tele health* or telecare* or tele care*).ti. (8275)

30 ((telehealth* or tele health* or telecare* or tele care* or telemedicine or tele medicine) adj3 (based or application* or intervention* or program* or therap*)).ab,kf,dq. (7592)

31 (telemonitor* or tele monitor*).ti,ab,kf,dq. (4130)

32 (remote adj3 monitor*).ti,ab,kf,dq. (10981)

33 (tablet* or desktop* or handheld*).ti. (39582)

34 ((tablet* or desktop* or desk-top* or handheld* or hand-held*) adj3 (based or application* or intervention* or program* or therap*)).ab,kf,dq. (5912)

35 ((online or web or internet or digital* or phone* or telephone* or smartphone* or cellphone* or smartwatch* or mobile* or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (platform* or dashboard* or dash-board*)).ab,kf,dq. (19384)

36 or/22-35 (574456)

37 exp self care/ (105809)

38 patient education/ (127550)

39 patient participation/ (36873)

40 self evaluation/ (38710)

41 risk reduction/ (134301)

42 self directed learning/ (1543)

43 self examination/ (3855)

44 self.ti,ab,kf,dq. (1245757)

45 ((action or manag* or care or teach* or coach* or educat* or train* or instruct*) adj2 (plan* or program*)).ti,ab,kf,dq. (309934)

46 ((patient* or consumer* or client* or person* or individual*) adj5 (manag* or control* or track* or monitor* or care or efficac* or identif*) adj5 (symptom* or diseas* or exacerbat* or recur* or reoccur* or re-occur*or risk* or trigger* or caus*)).ti,ab,kf,dq. (179278)

47 ((patient* or consumer* or client* or person* or individual*) adj3 (centr* or center* or focus* or educat* or complian* or participat* or behav*)).ti,ab,kf,dq. (542734)

48 ((patient* or consumer* or client* or person* or individual*) adj3 (tailor* or goal* or objective* or target* or plan* or alert* or notif* or warn* or remind*)).ti,ab,kf,dq. (328029)

49 (home* adj5 (base* or integrat* or rehab* or care or treat* or therap*)).ti,ab,kf,dq. (133517)

50 or/37-49 (2720289)

51 7 and 36 and 50 (2174)

52 ("active+me remote*2" or "active+meremote*2" or active me or active metm or active mer or aseptika*2 or clinitouch vie*2 or spirit health*2 or copd predict*2 or nepesmo*2 or copdpredict*2 or "doc@home*2" or "doc @ home*2" or docobo*2 or luscii*2 or mycopd*2 or my copd*2 or mymhealth*2 or my mhealth*2 or my m health*2 or patientmpower*2 or patient m power*2 or patient mpower*2 or wellinks*2).ti,ab,kf,dq,dv,my,ot,dm. (165)

53 (copd hub*2 or copdhub*2 or current healthtm or current healthr or ibisr or ibistm or lenusr or lenustm or space for copd*2 or "institute of clinical science and technology*2" or "institute of clinical science & technology*2").ti,ab,kf,dq,dv,my,ot,dm. (44)

54 (current health or best buy health*2 or icst*2 or lenus or storm id*2 or university of leicester nhs hospitals trust*2).ti,ab,kf,dq,dv,my,ot,dm. (7029)

55 7 and 54 (89)

56 52 or 53 or 55 (295)

57 51 or 56 (2436)

58 (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ (6918200)

59 editorial.pt. or case report.ti. (1192608)

60 preprint.pt. (107257)

61 or/58-60 (8161128)

62 57 not 61 (2383)

63 conference abstract.pt. (5047017)

64 62 and 63 (892)

65 limit 64 to (english language and yr="2021 -Current") (281)

A.3: Source: Cochrane Database of Systematic Reviews (CDSR)

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issue searched: Issue 2 of 12, February 2024

Search date: 16/02/2024

Retrieved records: 8 (8 reviews, 0 protocols)

Search strategy:

#1 MeSH descriptor: [Pulmonary Disease, Chronic Obstructive] explode all trees 8273

#2 (obstruct* near/3 (airflow* or air-flow* or airway* or air-way* or lung* or pulmonary or bronchopulmonary or respirat*)):ti,ab,kw 23963

#3 (COPD* or COAD* or COBD* or AECB*):ti,ab,kw 27596

#4 (asthma* near/5 overlap*):ti,ab,kw 75

#5 (chronic* near/3 (bronchit* or bronchus or cough*)):ti,ab,kw 3191

#6 emphysem*:ti,ab,kw 1795

#7 #1 or #2 or #3 or #4 or #5 or #6 40103

#8 MeSH descriptor: [Mobile Applications] this term only 1898

#9 MeSH descriptor: [Internet] explode all trees 6471

#10 MeSH descriptor: [Cell Phone] explode all trees 3421

#11 MeSH descriptor: [Computers, Handheld] explode all trees 1525

#12 MeSH descriptor: [Medical Informatics Applications] this term only 45

#13 MeSH descriptor: [Therapy, Computer-Assisted] this term only 1597

#14 (app or apps):ti,ab,kw 10673

#15 (online or web or internet or digital*):ti 18229

#16 ((online or web or internet or digital*) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 21803

#17 (phone* or telephone* or smartphone* or cellphone* or smartwatch*):ti 7244

#18 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 9976

#19 ((mobile NEXT health) or mhealth or m-health or ehealth or e-health or emental or e-mental):ti 2648

#20 (((mobile NEXT health) or mhealth or m-health or ehealth or e-health or emental or e-mental) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 2696

#21 (mobile* near/3 (based or application* or intervention* or device* or technolog*)):ti,ab,kw 8926

#22 #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 #2156156

#23 MeSH descriptor: [Telemedicine] this term only 3952

#24 MeSH descriptor: [Telerehabilitation] this term only 321

#25 MeSH descriptor: [Telenursing] this term only 45

#26 MeSH descriptor: [Remote Consultation] this term only 449

#27 (telehealth* or (tele NEXT health*) or telecare* or (tele NEXT care*)):ti 1308

#28 ((telehealth* or (tele NEXT health*) or telecare* or (tele NEXT care*) or telemedicine or (tele NEXT medicine)) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 1863

#29 (telemonitor* or (tele NEXT monitor*)):ti,ab,kw 1432

#30 (remote near/3 monitor*):ti,ab,kw 1420

#31 (tablet* or desktop* or handheld*):ti 13628

#32 ((tablet* or desktop* or desk-top* or handheld* or hand-held*) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 4152

#33 ((online or web or internet or digital* or phone* or telephone* or smartphone* or cellphone* or smartwatch* or mobile* or mhealth or m-health or ehealth or e-health or emental or e-mental) near/3 (platform* or dashboard* or dash-board*)):ab,kw 2541

#34 #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 77523

#35 MeSH descriptor: [Self Care] explode all trees 7762

#36 MeSH descriptor: [Self-Management] this term only 1216

#37 MeSH descriptor: [Patient Education as Topic] this term only 10748

#38 MeSH descriptor: [Patient Participation] this term only 2175

#39 MeSH descriptor: [Self Efficacy] this term only 4299

#40 MeSH descriptor: [Self-Assessment] this term only 914

#41 MeSH descriptor: [Risk Reduction Behavior] this term only 2375

#42 MeSH descriptor: [Health Plan Implementation] this term only 280

#43 MeSH descriptor: [Patient Generated Health Data] this term only 4

#44 MeSH descriptor: [Diagnostic Self Evaluation] this term only 291

#45 MeSH descriptor: [Self-Examination] this term only 163

#46 MeSH descriptor: [Self-Directed Learning as Topic] this term only 11

#47 MeSH descriptor: [Computer-Assisted Instruction] this term only 1480

#48 self:ti,ab,kw 142114

#49 ((action or manag* or care or teach* or coach* or educat* or train* or instruct*) near/2 (plan* or program*)):ti,ab,kw 47209

#50 ((patient* or consumer* or client* or person* or individual*) near/5 (manag* or control* or track* or monitor* or care or efficac* or identif*) near/5 (symptom* or diseas* or exacerbat* or recur* or reoccur* or re-occur*or risk* or trigger* or caus*)):ti,ab,kw 35210

#51 ((patient* or consumer* or client* or person* or individual*) near/3 (centr* or center* or focus* or educat* or complian* or participat* or behav*)):ti,ab,kw 103943

#52 ((patient* or consumer* or client* or person* or individual*) near/3 (tailor* or goal* or objective* or target* or plan* or alert* or notif* or warn* or remind*)):ti,ab,kw 41884

#53 (home* near/5 (base* or integrat* or rehab* or care or treat* or therap*)):ti,ab,kw 27523

#54 #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 323473

#55 #7 and #34 and #54 742

#56 ((active* NEXT remote*) or (active* NEXT meremote*) or aseptika* or (clinitouch NEXT vie*) or "doc@home" or "doc@hometm" or "doc@homer" or (doc near/2 home*) or (spirit NEXT health*) or (copd NEXT predict*) or nepesmo* or copdpredict* or docobo* or luscii* or mycopd* or my copd* or mymhealth* or (my NEXT mhealth*) or (my NEXT m NEXT health*) or patientmpower* or (patient NEXT m NEXT power*) or (patient NEXT mpower*) or wellinks*):ti,ab,kw 76

#57 ((copd NEXT hub*) or copdhub* or (current NEXT healthtm) or (current NEXT healthr) or ibisr or ibistm or lenusr or lenustm or (space NEXT for NEXT copd*) or (institute NEXT of NEXT clinical NEXT science)):ti,ab,kw 29

#58 ((current NEXT health) or (best NEXT buy NEXT health*) or icst* or lenus or (storm NEXT id*) or (university NEXT of NEXT leicester NEXT nhs*)):ti,ab,kw 453

#59 #7 and #58 18

#60 #56 or #57 or #59 123

#61 #55 or #60 with Cochrane Library publication date Between Jan 2014 and Feb 2024, in Cochrane Reviews, Cochrane Protocols 8

A.4: Source: Cochrane Central Register of Controlled Trials (CENTRAL)

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issue searched: Issue 2 of 12, February 2024

Search date: 16/02/2024

Retrieved records: 663

Search strategy:

#1 MeSH descriptor: [Pulmonary Disease, Chronic Obstructive] explode all trees 8273

#2 (obstruct* near/3 (airflow* or air-flow* or airway* or air-way* or lung* or pulmonary or bronchopulmonary or respirat*)) 24827

#3 (COPD* or COAD* or COBD* or AECB*)28672

#4 (asthma* near/5 overlap*) 94

#5 (chronic* near/3 (bronchit* or bronchus or cough*)) 3469

#6 emphysem* 2009

#7 #1 or #2 or #3 or #4 or #5 or #6 41708

#8 MeSH descriptor: [Mobile Applications] this term only 1898

#9 MeSH descriptor: [Internet] explode all trees 6471

#10 MeSH descriptor: [Cell Phone] explode all trees 3421

#11 MeSH descriptor: [Computers, Handheld] explode all trees 1525

#12 MeSH descriptor: [Medical Informatics Applications] this term only 45

#13 MeSH descriptor: [Therapy, Computer-Assisted] this term only 1597

#14 (app or apps)13138

#15 (online or web or internet or digital*):ti 18229

#16 ((online or web or internet or digital*) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 21803

#17 (phone* or telephone* or smartphone* or cellphone* or smartwatch*):ti 7244

#18 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 9976

#19 ((mobile NEXT health) or mhealth or m-health or ehealth or e-health or emental or e-mental):ti 2648

#20 (((mobile NEXT health) or mhealth or m-health or ehealth or e-health or emental or e-mental) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 2696

#21 (mobile* near/3 (based or application* or intervention* or device* or technolog*)) 9315

#22 #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 #2158609

#23 MeSH descriptor: [Telemedicine] this term only 3952

#24 MeSH descriptor: [Telerehabilitation] this term only 321

#25 MeSH descriptor: [Telenursing] this term only 45

#26 MeSH descriptor: [Remote Consultation] this term only 449

#27 (telehealth* or (tele NEXT health*) or telecare* or (tele NEXT care*)):ti 1308

#28 ((telehealth* or (tele NEXT health*) or telecare* or (tele NEXT care*) or telemedicine or (tele NEXT medicine)) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 1863

#29 (telemonitor* or (tele NEXT monitor*)) 1519

#30 (remote near/3 monitor*) 1483

#31 (tablet* or desktop* or handheld*):ti 13628

#32 ((tablet* or desktop* or desk-top* or handheld* or hand-held*) near/3 (based or application* or intervention* or program* or therap*)):ab,kw 4152

#33 ((online or web or internet or digital* or phone* or telephone* or smartphone* or cellphone* or smartwatch* or mobile* or mhealth or m-health or ehealth or e-health or emental or e-mental) near/3 (platform* or dashboard* or dash-board*)):ab,kw 2541

#34 #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 79997

#35 MeSH descriptor: [Self Care] explode all trees 7762

#36 MeSH descriptor: [Self-Management] this term only 1216

#37 MeSH descriptor: [Patient Education as Topic] this term only 10748

#38 MeSH descriptor: [Patient Participation] this term only 2175

#39 MeSH descriptor: [Self Efficacy] this term only 4299

#40 MeSH descriptor: [Self-Assessment] this term only 914

#41 MeSH descriptor: [Risk Reduction Behavior] this term only 2375

#42 MeSH descriptor: [Health Plan Implementation] this term only 280

#43 MeSH descriptor: [Patient Generated Health Data] this term only 4

#44 MeSH descriptor: [Diagnostic Self Evaluation] this term only 291

#45 MeSH descriptor: [Self-Examination] this term only 163

#46 MeSH descriptor: [Self-Directed Learning as Topic] this term only 11

#47 MeSH descriptor: [Computer-Assisted Instruction] this term only 1480

#48 self 146887

#49 ((action or manag* or care or teach* or coach* or educat* or train* or instruct*) near/2 (plan* or program*))50960

#50 ((patient* or consumer* or client* or person* or individual*) near/5 (manag* or control* or track* or monitor* or care or efficac* or identif*) near/5 (symptom* or diseas* or exacerbat* or recur* or reoccur* or re-occur*or risk* or trigger* or caus*)) 38872

#51 ((patient* or consumer* or client* or person* or individual*) near/3 (centr* or center* or focus* or educat* or complian* or participat* or behav*)) 111229

#52 ((patient* or consumer* or client* or person* or individual*) near/3 (tailor* or goal* or objective* or target* or plan* or alert* or notif* or warn* or remind*)) 44712

#53 (home* near/5 (base* or integrat* or rehab* or care or treat* or therap*)) 29873

#54 #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 336746

#55 #7 and #34 and #54 1011

#56 ((active* NEXT remote*) or (active* NEXT meremote*) or aseptika* or (clinitouch NEXT vie*) or "doc@home" or "doc@hometm" or "doc@homer" or (doc near/2 home*)

or (spirit NEXT health*) or (copd NEXT predict*) or nepesmo* or copdpredict* or docobo* or luscii* or mycopd* or my copd* or mymhealth* or (my NEXT mhealth*) or (my NEXT m NEXT health*) or patientmpower* or (patient NEXT m NEXT power*) or (patient NEXT mpower*) or wellinks*):ti,ab,kw 76

#57 ((copd NEXT hub*) or copdhub* or (current NEXT healthtm) or (current NEXT healthr) or ibisr or ibistm or lenusr or lenustm or (space NEXT for NEXT copd*) or (institute NEXT of NEXT clinical NEXT science)) 66

#58 ((current NEXT health) or (best NEXT buy NEXT health*) or icst* or lenus or (storm NEXT id*) or (university NEXT of NEXT leicester NEXT nhs*)) 514

#59 #7 and #58 38

#60 #56 or #57 or #59 180

#61 #55 or #60 with Publication Year from 2014 to 2024, in Trials 663

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: 16/02/2024

Retrieved records: 19

Search strategy:

Date limited: 2014 to 2024

36 #35 OR #29 19

35 #34 OR #32 OR #31 OR #30 7

34 #7 AND #33 0

33 ("current health" OR "best buy health" OR "best buy healthr" OR "best buy healthtm" OR icst* OR lenus OR "storm id" OR "storm idr" OR "storm idtm" OR "university of leicester nhs hospitals trust") 12

32 ("copd hub" OR "copd hubr" OR "copd hubtm" OR copdhub* OR "current healthtm" OR "current healthr" OR ibisr or ibistm or lenusr or lenustm or "space for copd" OR "space for copdr" OR "space for copdtm" OR "institute of clinical science") 0

31 (aseptika* OR "clinitouch vie" OR "clinitouch vier" OR "clinitouch vietm" OR "spirit health" OR copdpredict* OR "copd predict" OR "copd predictr" OR "copd predicttm" OR nepesmo* OR "doc@home" OR "doc@homer" OR "doc@hometm" OR docobo* OR luscii* OR mycopd* OR mymhealth* OR patientmpower* OR "patient mpower" OR "patient mpowerr" OR "patient mpowertm" OR wellinks*) 0

30 (active AND (remote OR remoter OR remotetm OR meremote OR meremoter OR meremotetm)) 7

29 #28 AND #7 32

28 #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 #8 899

27 (platform* OR dashboard* OR dash-board OR dash-boards) 87

26 (tablet* OR desktop* OR handheld*) 122

25 (remote AND monitor*) 47

24 (telemonitor* OR tele-monitor OR tele-monitoring OR tele-monitored OR tele-monitors OR "tele monitor" OR "tele monitoring" OR "tele monitored" OR "tele monitors") 29

23 (telehealth OR tele-health OR "tele health" OR telecare OR tele-care OR "tele care" OR telemedicine OR tele-medicine OR "tele medicine")118

22 "Remote Consultation"[mh]65

21 "Telenursing"[mh] 2

20 "Telerehabilitation"[mh] 4

19 "Telemedicine"[mh] 181

18 (mobile* AND (based OR application* OR intervention* OR device* OR technolog*)) 68

17 ("mobile health" OR mhealth OR ehealth OR emental) 17

16 (phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*) 136

15 (online OR web OR internet OR digital*) 417

14 (app OR apps) 24

13 "Therapy, Computer-Assisted"[mh] 27

12 "Medical Informatics Applications"[mh] 2

11 "Computers, Handheld"[mhe] 14

10 "Cell Phone"[mhe] 18

9 "Internet"[mhe] 59

8 "Mobile Applications"[mh] 26

7 #6 OR #5 OR #4 OR #3 OR #2 OR #1 329

6 emphysem* 36

5 (chronic* AND (bronchit* OR bronchus OR cough*)) 30

4 (asthma* AND overlap*) 1

3 (COPD* OR COAD* OR COBD* OR AECB*) 137

2 ((obstruct* AND (airflow* OR air-flow OR air-flows OR air-flowing OR air-flowed OR "air flow" OR "air flows" OR "air flowing" OR "air flowed" OR airway* OR air-way OR air-ways OR "air way" OR "air ways" OR lung* OR pulmonary OR bronchopulmonary OR respirat*))) 236

1 "Pulmonary Disease, Chronic Obstructive"[mhe] 184

A.6: Source: Conference Proceedings Citation Index – Sciences (CPCI-S)

Interface / URL: Web of Science

Database coverage dates: 1990 to 16 February 2024

Search date: 16/02/2024

Retrieved records: 82

Search strategy:

Exact search enabled. Date limit: 01/01/2021 to 16/02/2024

#29 #23 OR #28 82

#28 #24 OR #25 OR #27 7

#27 #6 AND #26 0

#26 TS=("current health" OR "best buy health*" OR icst* OR lenus OR "storm id*" OR "university of leicester nhs hospitals trust*") 51

#25 TS=("copd hub*" OR copdhub* OR "current healthtm" OR "current healthr" OR ibisr OR ibistm OR lenusr OR lenustm OR "space for copd*" OR "institute of clinical science and technology*" OR "institute of clinical science & technology*") 0

#24 TS=("active+me remote*" OR "active+meremote*" OR "active me" OR "active metm" OR "active mer" OR aseptika* OR "clinitouch vie*" OR "spirit health*" OR "copd predict*" OR nepesmo* OR copdpredict* OR "doc@home*" OR "doc @ home*" OR docobo* OR luscii* OR mycopd* OR my copd* OR mymhealth* OR my mhealth* OR "my m health*" OR patientmpower* OR "patient m power*" OR "patient mpower*" OR wellinks*) 7

#23 #6 AND #22 76

#22 #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 54,964

#21 TS=((online OR web OR internet OR digital* OR phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch* OR mobile* OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) NEAR/3 (platform* OR dashboard* OR dash-board*)) 5,344

#20 TS=((tablet* OR desktop* OR desk-top* OR handheld* OR hand-held*) NEAR/3 (based OR application* OR intervention* OR program* OR therap*)) 526

#19 TI=(tablet* OR desktop* OR handheld*) 852

#18 TS=(remote NEAR/3 monitor*) 1,746

#17 TS=(telemonitor* OR "tele monitor*") 169

#16 TS=((telehealth* OR "tele health*" OR telecare* OR "tele care*" OR telemedicine OR "tele medicine") NEAR/3 (based OR application* OR intervention* OR program* OR therap*)) 276

#15 TI=(telehealth* OR "tele health*" OR telecare* OR "tele care*") 504

#14 TS=(mobile* NEAR/3 (based OR application* OR intervention* OR device* OR technolog*)) 11,740

#13 TS=(("mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) NEAR/3 (based OR application* OR intervention* OR program* OR therap*)) 487

#12 TI=("mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) 722

#11 TS=((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*) NEAR/3 (based OR application* OR intervention* OR program* OR therap*)) 2,216

#10 TI=((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)) 2,981

#9 TS=(((online OR web OR internet OR digital*) NEAR/3 (based OR application* OR intervention* OR program* OR therap*))) 16,242

#8 TI=(online OR web OR internet OR digital*) 20,925

#7 TS=(app OR apps) 4,485

#6 #5 OR #4 OR #3 OR #2 OR #1 3,025

#5 TS=emphysem* 315

#4 TS=(chronic* NEAR/3 (bronchit* OR bronchus OR cough*)) 183

#3 TS=(asthma* NEAR/5 overlap*) 31

#2 TS=(COPD* OR COAD* OR COBD* OR AECB*) 1,853

#1 TS=(obstruct* NEAR/3 (airflow* OR air-flow* OR airway* OR air-way* OR lung* OR pulmonary OR bronchopulmonary OR respirat*)) 1029

A.7: Source: EconLit

Interface / URL: OvidSP

Database coverage dates: 1866 to 8 February 2024

Search date: 16/02/2024

Retrieved records: 9

Search strategy:

1 (obstruct* adj3 (airflow* or air-flow* or airway* or air-way* or lung* or pulmonary or bronchopulmonary or respirat*)).af. (67)

2 (COPD* or COAD* or COBD* or AECB*).af. (301)

3 (asthma* adj5 overlap*).af. (0)

4 (chronic* adj3 (bronchit* or bronchus or cough*)).af. (16)

5 emphysem*.af. (5)

6 or/1-5 (345)

7 (app or apps).af. (655)

8 (online or web or internet or digital*).af. (42415)

9 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).af. (4770)

10 (mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).af. (132)

11 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).af. (1041)

12 (telehealth* or tele health* or telecare* or tele care* or telemedicine* or tele medicine*).af. (91)

13 (telemonitor* or tele monitor*).af. (10)

14 (remote adj3 monitor*).af. (22)

15 (tablet* or desktop* or handheld*).af. (337)

16 (platform* or dashboard* or dash-board*).af. (8724)

17 or/7-16 (52341)

18 6 and 17 (11)

19 ("active+me remote*2" or "active+meremote*2" or active me or active metm or active mer or aseptika*2 or clinitouch vie*2 or spirit health*2 or copd predict*2 or nepesmo*2 or copdpredict*2 or "doc@home*2" or "doc @ home*2" or docobo*2 or luscii*2 or mycopd*2 or my copd*2 or mymhealth*2 or my mhealth*2 or my m health*2 or patientmpower*2 or patient m power*2 or patient mpower*2 or wellinks*2).af. (1)

20 (copd hub*2 or copdhub*2 or current healthtm or current healthr or ibisr or ibistm or lenusr or lenustm or space for copd*2 or "institute of clinical science and technology*2" or "institute of clinical science & technology*2").af. (0)

21 (current health or best buy health*2 or icst*2 or lenus or storm id*2 or university of leicester nhs hospitals trust*2).af. (218)

22 6 and 21 (0)

23 19 or 20 or 22 (1)

24 18 or 23 (11)

25 limit 24 to (yr="2014 -Current" and english) (9)

A.8: 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: 16/02/2024

Retrieved records: 18

Search strategy:

1 MeSH DESCRIPTOR Pulmonary Disease, Chronic Obstructive EXPLODE ALL TREES IN NHSEED 151

2 ((obstruct* AND (airflow* OR air-flow* OR airway* OR air-way* OR lung* OR pulmonary OR bronchopulmonary OR respirat*))) IN NHSEED 308

3 ((COPD* OR COAD* OR COBD* OR AECB)) IN NHSEED 153

4 ((asthma* AND overlap*)) IN NHSEED 3

5 ((chronic* AND (bronchit* OR bronchus OR cough*))) IN NHSEED 61

6 (emphysem*) IN NHSEED 21

7 #1 OR #2 OR #3 OR #4 OR #5 OR #6 373

8 (#7) IN NHSEED FROM 2014 TO 2024 18

A.9: 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). The site was made available to the public in February 2000.

Search date: 19/02/2024

Retrieved records: 788

Search strategy:

The following 5 searches were conducted separately. All search terms were entered using the Expert search interface.

The results from each search were downloaded as an individual set. The total number of records retrieved represents the sum of all searches, and includes duplicates caused by the same record being retrieved in each search.

Search 1:

AREA[ConditionSearch]((((chronic OR chronically) AND (obstruct OR obstruction OR obstructive OR obstructs OR obstructions OR obstructured OR obstructing) OR COPD OR COBD OR COAD OR AECB OR COPDs OR COBDs OR COADs OR AECBs OR ((chronic OR chronically) AND (bronchitis OR bronchial OR cough OR coughs OR coughing OR bronchus)) OR "asthma overlap" OR "asthma overlaps" OR "asthma overlapping" OR "asthmatic overlap" OR "asthmatic overlaps" OR "asthmatic overlapping" OR emphysema OR emphysemic)) AND AREA[InterventionSearch](app OR apps OR online OR web OR internet OR digital OR digitally OR phone OR phones OR telephone OR telephones OR smartphone OR smartphones OR cellphone OR cellphones OR smartwatch OR smartwatches OR "mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile OR mobiles OR telehealth OR tele-health OR "tele health" OR telehealthcare OR tele-healthcare OR "tele healthcare" OR telecare OR "tele care" OR tele-care OR telemedicine OR "tele medicine" OR tele-medicine OR telemonitor OR tele-monitor OR "tele monitor" OR telemonitors OR tele-monitors OR "tele monitors" OR telemonitored OR "tele monitored" OR tele-monitored OR telemonitoring OR tele-monitoring OR "tele monitoring" OR remote OR remotely OR tablet OR tablets OR desktop OR desk-top OR desktops OR desk-tops OR "desk top" OR "desk tops" OR handheld OR hand-held OR handhelds OR hand-helds OR "hand held" OR "hand helds" OR platform OR platforms OR dashboard OR dashboards OR dash-board OR dash-boards OR "dash board" OR "dash boards") AND AREA[InterventionSearch](self OR plan OR plans OR planning OR planner OR planners OR program OR programs OR programme OR programmes OR programming OR programing)) = 258

Search 2:

AREA[ConditionSearch](((((chronic OR chronically) AND (obstruct OR obstruction OR obstructive OR obstructs OR obstructions OR obstructured OR obstructing) OR COPD

OR COBD OR COAD OR AECB OR COPDs OR COBDs OR COADs OR AECBs OR ((chronic OR chronically) AND (bronchitis OR bronchial OR cough OR coughs OR coughing OR bronchus)) OR "asthma overlap" OR "asthma overlaps" OR "asthma overlapping" OR "asthmatic overlap" OR "asthmatic overlaps" OR "asthmatic overlapping" OR emphysema OR emphysemic)) AND AREA[InterventionSearch](app OR apps OR online OR web OR internet OR digital OR digitally OR phone OR phones OR telephone OR telephones OR smartphone OR smartphones OR cellphone OR cellphones OR smartwatch OR smartwatches OR "mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile OR mobiles OR telehealth OR tele-health OR "tele health" OR telehealthcare OR tele-healthcare OR "tele healthcare" OR telecare OR "tele care" OR tele-care OR telemedicine OR "tele medicine" OR tele-medicine OR telemonitor OR tele-monitor OR "tele monitor" OR telemonitors OR tele-monitors OR "tele monitors" OR telemonitored OR "tele monitored" OR tele-monitored OR telemonitoring OR tele-monitoring OR "tele monitoring" OR remote OR remotely OR tablet OR tablets OR desktop OR desk-top OR desktops OR desk-tops OR "desk top" OR "desk tops" OR handheld OR hand-held OR handhelds OR hand-helds OR "hand held" OR "hand helds" OR platform OR platforms OR dashboard OR dashboards OR dash-board OR dash-boards OR "dash board" OR "dash boards") AND AREA[InterventionSearch](patient OR patients OR consumer OR consumers OR client OR clients OR clientele OR person OR persons OR personal OR personally OR individual OR individuals OR individually) AND (manage OR manages OR managed OR managing OR management OR control OR controls OR controlled OR controlling OR track OR tracks OR tracked OR tracking OR monitor OR monitors OR monitored OR monitoring OR care OR efficacy OR efficacies OR identify OR identifies OR identifying OR identification OR identifications) AND (symptom OR symptoms OR disease OR diseases OR diseased OR exacerbate OR exacerbation OR exacerbates OR exacerbations OR recur OR recurring OR recurs OR recurred OR reoccurs OR reoccur OR reoccurring OR reoccurred OR re-occur OR re-occurs OR re-occuring OR re-occurred OR risk OR risks OR trigger OR triggers OR triggering OR triggered OR cause OR causing OR caused OR causes OR causation OR causations OR causative))) = 296

Search 3:

AREA[ConditionSearch](((((chronic OR chronically) AND (obstruct OR obstruction OR obstructive OR obstructs OR obstructions OR obstructured OR obstructing) OR COPD OR COBD OR COAD OR AECB OR COPDs OR COBDs OR COADs OR AECBs OR ((chronic OR chronically) AND (bronchitis OR bronchial OR cough OR coughs OR coughing OR bronchus)) OR "asthma overlap" OR "asthma overlaps" OR "asthma overlapping" OR "asthmatic overlap" OR "asthmatic overlaps" OR "asthmatic overlapping" OR emphysema OR emphysemic)) AND AREA[InterventionSearch](app OR apps OR online OR web OR internet OR digital OR digitally OR phone OR phones OR telephone OR telephones OR smartphone OR smartphones OR cellphone OR cellphones OR smartwatch OR smartwatches OR "mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile OR mobiles OR telehealth OR tele-health OR "tele health" OR telehealthcare OR tele-healthcare OR "tele healthcare" OR telecare OR "tele care" OR tele-care OR telemedicine OR "tele medicine" OR tele-medicine OR telemonitor OR tele-monitor OR "tele monitor" OR telemonitors OR tele-monitors OR "tele monitors" OR telemonitored OR "tele monitored" OR tele-monitored OR telemonitoring OR tele-monitoring OR "tele monitoring" OR remote OR remotely OR tablet OR tablets OR desktop OR desk-top OR desktops OR desk-tops OR "desk top" OR "desk tops" OR handheld OR hand-held OR handhelds OR hand-helds OR "hand held" OR "hand helds" OR platform OR platforms OR dashboard OR dashboards OR dash-board OR dash-boards OR "dash board" OR "dash boards") AREA[InterventionSearch](patient OR patients OR consumer OR consumers OR client OR clients OR clientele OR person OR persons OR personal OR personally OR individual OR individuals OR individually) AND (centre OR centred OR centring OR center OR centered OR centering OR focus OR focused OR focusing OR focussed OR focussing OR educate OR educates OR education OR educating OR educated OR compliance OR compliant OR participate OR participation OR participates OR participated OR behavior OR behaviour OR behaviors OR behaviours OR behavioural OR behavioral OR tailor OR tailors OR tailored OR tailoring OR goal OR goals OR objective OR objectives OR target OR targeting OR targets OR targeted OR alert OR alerts OR alerting OR alerted OR notify OR notifies OR notification OR notifications OR notified OR warn OR warned OR warns OR warning

OR warnings OR remind OR reminds OR reminder OR reminders OR reminded OR home OR homes))) = 173

Search 4:

("active+me remote" OR "active+me remoter" OR "active+me remotetm" OR "active + me remote" OR "active + me remoter" OR "active + me remotetm" OR aseptika OR aseptikar OR aseptikatm OR "clinitouch vie" OR "clinitouch vier" OR "clinitouch vie tm" OR "spirit health" OR "spirit healthr" OR "spirit healthtm" OR "copd predict" OR "copd predictr" OR "copd predicttm" OR copdpredict OR copdpredictr OR copdpredicttm OR nepesmo OR nepesmor OR nepesmotm OR "doc@home" OR "doc@homer" OR "doc@hometm" OR "doc @ home" OR "doc @ homer" OR "doc @ hometm" ORdocobo OR docobor OR docobotm OR luscii OR lusciir OR lusciitm OR mycopd OR mycopdr OR mycopdtm OR "my copd" OR "my copdr" OR "my copdtm" OR mymhealth OR mymhealthr OR mymhealthtm OR "my mhealth" OR "my mhealthr" OR "my mhealthtm" OR "my m health" OR "my m healthr" OR "my m healthtm" OR patientmpower OR patientmpowerr OR patientmpowertm OR "patient m power" OR "patient m powerr" OR "patient m powertm" OR "patient mpower" OR "patient mpowerr" OR "patient mpowertm" OR wellinks OR wellinksr OR wellinkstm OR "copd hub" OR "copd hubr" OR "copd hubtm" OR copdhub OR copdhubr OR copdhubtm OR "current healthr" OR "current healthtm" OR ibisr OR ibistm OR lenusr OR lenustm OR "space for copd" OR "space for copdr" OR "space for copdtm" OR "institute of clinical science and technology" OR "institute of clinical science and technologyr" OR "institute of clinical science and technologytm" OR "institute of clinical science & technology" OR "institute of clinical science & technologyr" OR institute of clinical science & technologytm) = 28

Search 5:

((((chronic OR chronically) AND (obstruct OR obstruction OR obstructive OR obstructs OR obstructions OR obstructured OR obstructing) OR COPD OR COBD OR COAD OR AECB OR COPDs OR COBDs OR COADs OR AECBs OR ((chronic OR chronically) AND (bronchitis OR bronchial OR cough OR coughs OR coughing OR bronchus)) OR "asthma overlap" OR "asthma overlaps" OR "asthma overlapping" OR "asthmatic

overlap" OR "asthmatic overlaps" OR "asthmatic overlapping" OR emphysema OR emphysemic)) AND ("current health" OR "best buy health" OR "best buy healthr" OR "best buy healthtm" OR icst OR icstr OR icsttm OR lenus OR "storm id" OR "storm idr" OR "storm idtm" OR "university of leicester nhs hospitals trust" OR "university of leicester nhs hospitals trustr" OR "university of leicester nhs hospitals trusttm")) = 33

A.10: Source: WHO International Clinical Trials Registry Portal (ICTRP)

Interface / URL: https://trialsearch.who.int/

Database coverage dates: Information not found. On the date of search, files had been imported from data providers between December 2023 and February 2024.

Search date: 19/02/2024

Retrieved records: 1,120

Search strategy:

The following 18 searches were conducted separately using the search interface at the above URL. 'Without Synonyms' was selected for all searches.

The results from each search were downloaded as an individual set. The total number of records retrieved represents the sum of all searches, and includes duplicates caused by the same record being retrieved in each search.

Search 1:

(chronic* AND obstruct* AND (app OR apps OR online OR web OR internet OR digital* OR phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch* OR "mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile* OR telehealth OR tele-health OR telecare OR tele-care OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile* OR telehealth OR tele-health OR telecare OR tele-care)) = 315

Search 2:

(chronic* AND obstruct* AND (telemedicine OR tele-medicine OR telemonitor* OR tele-monitor* OR remote* OR desktop* desk-top* OR handheld* OR hand-held* OR platform* OR dashboard* OR dash-board* OR "tablet base*")) = 146

Search 3:

(chronic* AND obstruct* AND ("current health" OR "best buy health*" or icst* or lenus or "storm id*" OR "university of leicester nhs hospitals trust*")) = 0

Search 4:

((COPD* OR COBD* OR COAD* OR AECB* OR emphysem*) AND (app OR apps OR online OR web OR internet OR digital* OR phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch* OR "mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile* OR telehealth OR tele-health OR telecare OR tele-care OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile* OR telehealth OR tele-health OR telecare OR tele-care)) = 325

Search 5:

((COPD* OR COBD* OR COAD* OR AECB* OR emphysem*) AND (telemedicine OR tele-medicine OR telemonitor* OR tele-monitor* OR remote* OR desktop* desk-top* OR handheld* OR hand-held* OR platform* OR dashboard* OR dash-board* OR "tablet base*")) = 148

Search 6:

((COPD* OR COBD* OR COAD* OR AECB* OR emphysem*) AND ("current health" OR "best buy health*" or icst* or lenus or "storm id*" OR "university of leicester nhs hospitals trust*")) = 0

Search 7:

((bronchit* OR cough* OR bronchus) AND (app OR apps OR online OR web OR internet OR digital* OR phone* OR telephone* OR smartphone* OR cellphone* OR

smartwatch* OR "mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile* OR telehealth OR tele-health OR telecare OR tele-care OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile* OR telehealth OR tele-health OR telecare OR tele-care)) = 107

Search 8:

((bronchit* OR cough* OR bronchus) AND (telemedicine OR tele-medicine OR telemonitor* OR tele-monitor* OR remote* OR desktop* desk-top* OR handheld* OR hand-held* OR platform* OR dashboard* OR dash-board* OR "tablet base*")) = 36

Search 9:

((bronchit* OR cough* OR bronchus) AND ("current health" OR "best buy health*" or icst* or lenus or "storm id*" OR "university of leicester nhs hospitals trust*")) = 0

Search 10:

(asthma* AND overlap* AND (app OR apps OR online OR web OR internet OR digital* OR phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch* OR "mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile* OR telehealth OR tele-health OR telecare OR tele-care OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile* OR telehealth OR tele-health OR telecare OR tele-care)) = 1

Search 11:

(asthma* AND overlap* AND (telemedicine OR tele-medicine OR telemonitor* OR tele-monitor* OR remote* OR desktop* desk-top* OR handheld* OR hand-held* OR platform* OR dashboard* OR dash-board* OR "tablet base*")) = 1

Search 12:

(asthma* AND overlap* AND ("current health" OR "best buy health*" or icst* or lenus or "storm id*" OR "university of leicester nhs hospitals trust*")) = 0

Search 13:

(aseptika* OR "clinitouch vie*" OR "spirit health*" OR "copd predict*" OR copdpredict* OR nepesmo* OR docobo* OR luscii* OR mycopd* OR "my copd*" OR mymhealth* OR "my mhealth*" OR "my m health*" OR patientmpower* OR "patient m power*" OR "patient mpower*" OR wellinks* OR "copd hub*" OR copdhub* OR ibisr OR ibistm OR "current healthr" OR "current healthtm" OR "space for copd*" OR "institute of clinical science*") = 35 records

Search 14:

(active AND me AND remote*) = 2

Search 15:

(activeme AND remote*) = 0

Search 16:

(active AND meremote*) = 0

Search 17:

("active mer" or "active metm" OR "active me") = 1 record

Search 18:

(doc AND home*) = 3

Appendix B – Deprioritised and excluded studies

Table B.1: Included deprioritised studies (scoped interventions) (18 in 23 reports)

Study	UK/ Non-UK	Comparative	Retrospective / prospective	Population (n)	Intervention	Comparator	Outcomes	Deprioritisation reason
Chaplin, 2017 (Chaplin et al. 2017) Associated: Physical activity outcomes (Chaplin et al. 2022) Protocol (Chaplin et al. 2015) Qualitative analysis abstract (Hewitt 2015) Nested qualitative study Bourne 2010 (Bourne 2020)	UK	Comparative	Prospective	Patients with COPD (103)	SPACE for COPD	Usual care, conventional PR at hospital or in community setting	Exercise capacity; physical activity, QoL questionnaires; mental health questionnaires; cost questionnaire	Ineligible comparator
Chimiel 2022 (Chmiel et al. 2022)	Unclear	Non-comparative	Retrospective	Patients with COPD (2374)	myCOPD	None	Exacerbations; evaluates whether data self-reported to	Not RCT

Study	UK/ Non-UK	Comparative	Retrospective / prospective	Population (n)	Intervention	Comparator	Outcomes	Deprioritisation reason
							a digital health technology can be used to predict acute exacerbation events	
Cooper 2021 (Cooper et al. 2021)	UK	Non-comparative	Prospective	Patients with COPD (129)	myCOPD	None	Activation/adherence, other clinical outcomes but only reported as "no statistically significant difference from baseline"	Not RCT
Cooper 2022 (Cooper et al. 2022)	UK	Non-comparative	Prospective	Patients with COPD (133)	myCOPD	None	Activation/adherence	Not RCT
Duckworth 2023 (Duckworth et al. 2023)	UK	Non-comparative	Retrospective	Patients with COPD (1529)	myCOPD	None	CAT score, exacerbation rate	Not RCT
Frerichs 2021 (Frerichs et al. 2021)	Non-UK (Sweden)	Non-comparative	Prospective	Patients with COPD (16)	Luscii	None	Activation/adherence	Early version of technology restricted to telemonitoring (no self-management component).
Frerichs 2023	non-UK (Sweden)	Crossover-RCT	Prospective	Patients with COPD (70)	Luscii	Usual care	Change in SF-12 physical (PCS) and	Company confirmed to be early version of technology without

Study	UK/ Non-UK	Comparative	Retrospective / prospective	Population (n)	Intervention	Comparator	Outcomes	Deprioritisation reason
(Frerichs et al. 2023)							mental component summary (MCS) as well as in CAT, mMRC, EQ5D, EG5D VAS and HADS	self-management component
Ghosh 2016 (Ghosh 2016)	UK	Comparative (before-after)	Retrospective	Patients with COPD (248)	Clinitouch Vie	Standard care (care in period prior to study)	Readmissions, costs, cost benefit, patient feedback	Early version of technology restricted to telemonitoring (no self-management component)
Houchen-Wolloff 2021 (Houchen-Wolloff et al. 2021) Associated study: ISRCTN13081008 (University Hospitals of Leicester NHS Trust 2015)	UK	Non-comparative	Prospective	Patients with COPD (100)	SPACE for COPD	None	Activation, qualitative patient satisfaction, Bristol COPD knowledge questionnaire	Not RCT
Lenus COPD evaluation (Lenus Health Ltd 2024b)	UK	Comparative (before-after)	Retrospective	Patients with COPD (354)	Lenus	Standard care (care in period prior to study)	Readmissions and more	Before-after study, cohort study evidence available

Study	UK/ Non-UK	Comparative	Retrospective / prospective	Population (n)	Intervention	Comparator	Outcomes	Deprioritisation reason
Cooper 2023 (Cooper et al. 2023)	UK	Non-comparative	Prospective	Patients with COPD (59)	Lenus	None	Readmissions, cost-effectiveness	Lenus applied as a virtual ward to promote early discharge, not to support self-management
Luscii Isala evaluation 2021 (Luscii 2021)	Non-UK (Netherlands)	Non-comparative	Retrospective	Patients with COPD (42)	Luscii	None	Patient satisfaction	Non-UK
Luscii telemonitoring steering committee (Luscii 2022)	Non-UK (Netherlands)	Non-comparative	Retrospective	Patients with COPD or another chronic lung disease (39)	Luscii	None	Readmissions and more	Early version of technology restricted to telemonitoring (no self-management component).
North 2014 (North M 2014)	UK	Non-comparative	Prospective	Patients with COPD (39)	myCOPD	None	CAT score, inhaler technique	Not RCT
Our Dorset Digital 2021 (Our Dorset Digital 2021)	UK	Non-comparative	Retrospective	Patients with COPD (1436)	myCOPD	None	Activation/adherence, CAT score percentage with worsening/improvement, qualitative patient feedback	Not RCT

Study	UK/ Non-UK	Comparative	Retrospective / prospective	Population (n)	Intervention	Comparator	Outcomes	Deprioritisation reason
Roberts 2022 (Roberts et al. 2022)	UK	Non-comparative	Prospective	Patients with COPD (26)	myCOPD	None	Activation/adherence, CAT score, patient satisfaction	Not RCT
Stokes 2021 (Stokes and Savage 2021)	UK	Non-comparative	Prospective	Patients with COPD (72)	myCOPD	None	Activation/adherence, CAT score	Not RCT
Van der Burg 2020 (van der Burg 2020)	Non-UK (Netherlands)	Comparative (before-after)	Retrospective	Patients with COPD or CHF (COPD reported separately) (83)	Luscii	Standard care (care in period prior to study)	Admissions (incidence rate ratio), costs, deaths	Early version of technology restricted to telemonitoring (no self-management component).

Key: CHF - Congestive heart failure, COPD - Chronic obstructive pulmonary disease, RCT - Randomised controlled trial.

Table B.2: Deprioritised included studies (non - scoped interventions (n=133)

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Table B.3: Excluded studies list (n=239)

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Abidi SR, Rickards T, Van Woensel W, Abidi SSR. Digital therapeutics for COPD patient self-management: Needs analysis and design study. Stud Health Technol Inform. 2024.310:209-13. doi: https://dx.doi.org/10.3233/SHTI230957.	Ineligible study design
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Alexander JT, Goyal S, Akel MJ, Hermsen M, Gupta JC, Kappel N, et al. State of evidence on effective interventions to reduce COPD readmissions: A systematic review. J Gen Intern Med. 2022.37(Suppl 2):S192. doi: https://dx.doi.org/10.1007/s11606-022-07653-8.	Ineligible SR
Ali L, Wallström S, Fors A, Barenfeld E, Fredholm E, Fu M, et al. Effects of person-centered care using a digital platform and structured telephone support for people with chronic obstructive pulmonary disease and chronic heart failure: Randomized controlled trial. J Med Internet Res. 2021; (12): e26794. Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02354401/full.	Population: mixed, COPD not reported separately
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Almeida É, Silva F, Tavares M, Ribeiro J, Silva JM, Ferreira L, da Silva FP. Telemonitoring of patients with COPD: impact beyond hospital admissions. Eur Respir J. 2023.62.	Intervention: telemonitoring
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Song CY, Liu X, Wang YQ, Cao HP, Yang Z, Ma RC, et al. Effects of home-based telehealth on the physical condition and psychological status of patients with chronic obstructive pulmonary disease: A systematic review and meta-analysis. Int J Nurs Pract. 2023.29(3):e13062. doi: https://dx.doi.org/10.1111/ijn.13062.	Eligible SR
Song X, Hallensleben C, Zhang W, Jiang Z, Shen H, Gobbens RJJ, et al. Blended self-management interventions to reduce disease burden in patients with chronic obstructive pulmonary disease and asthma: Systematic review and meta-analysis. J Med Internet Res. 2021.23(3):e24602. doi: https://dx.doi.org/10.2196/24602.	Eligible SR
Soriano JB, García-Río F, Vázquez-Espinosa E, Conforto JI, Hernando-Sanz A, López-Yepes L, et al. A multicentre, randomized controlled trial of telehealth for the management of COPD. Respir Med. 2018: 74-81. Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01651071/full.	Intervention: telemonitoring
Spielmanns M, Boeselt T, Huber S, Kaur Bollinger P, Ulm B, Peckaka-Egli AM, et al. Impact of a smartphone application (KAIA COPD app) in combination with Activity Monitoring as a maintenance prOgram following PUlmonary Rehabilitation in COPD: The protocol for the AMOPUR Study, an international, multicenter, parallel group, randomized, controlled study. Trials. 2020.21(1):636. doi: https://dx.doi.org/10.1186/s13063-020-04538-1.	Intervention: Not multi-component
Spire Inc. An exploratory, observational, non-interventional, open label, remote pilot study to assess adherence in COPD subjects. Identifier: NCT03745547. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2018. Available from https://clinicaltrials.gov/show/NCT03745547.	Intervention: telemonitoring
Spire Inc. Effect of remote physiologic monitoring (RPM) on outcomes in COPD patients. Identifier: NCT05518981. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2019. Available from https://classic.clinicaltrials.gov/show/NCT05518981.	Intervention: telemonitoring
Spirit. NICE Digital COPD EVA. Leicester: Spirit; undated.	Non-systematic review
Stenlund T, Karlsson A, Nyberg A, Liv P, Wadell K. Clinically relevant effects on physical activity with webbased self-management support in people with COPD: a randomized controlled trial. Eur Respir J. 2022.60(Suppl 66)doi: https://dx.doi.org/10.1183/13993003.congress-2022.4551.	Intervention: Not multi-component

Stenlund T, Nyberg A, Wadell K. Web-based support for self-management strategies versus usual care for people with COPD: 3 months follow up in a randomised controlled trial. Eur Respir J. 2021; (Suppl 65): Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02403866/full.	Abstract: insufficient info
Sunjaya A, Sengupta A, Martin A, Jenkins C. Efficacy of mobile applications for people with breathlessness: Systematic review. Respirology. 2022.27(Suppl 1):196. doi: https://dx.doi.org/10.1111/resp.14226.	Abstract: insufficient info
Sunjaya AP, Sengupta A, Martin A, Di Tanna GL, Jenkins C. Efficacy of self-management mobile applications for patients with breathlessness: Systematic review and quality assessment of publicly available applications. Respir Med. 2022.201:106947. doi: https://dx.doi.org/10.1016/j.rmed.2022.106947.	Eligible SR
Talboom-Kamp EPWA, Verdijk NA, Blom CMG, Harmans LM, Talboom IJSH, Numans ME, Chavannes NH. e-Vita: design of an innovative approach to COPD disease management in primary care through eHealth application. BMC Pulm Med. 2016.16(1):121. doi: https://dx.doi.org/10.1186/s12890-016-0282-5.	Ineligible study design
Tanguay P, Decary S, Martineau-Roy J, Gravel E-M, Gervais I, St-Jean P, et al. Developing a web platform to optimize the self-management of people living with a chronic respiratory disease. Physiother Can. 2021.73(2):136-44. doi: https://dx.doi.org/10.3138/ptc-2019-0110.	<9 patients
Taylor A, Manthe M, McDowell G, Lowe D, Carlin C. Provision of home high flow therapy is feasible and associated with positive patient experience and reduced admissions. Eur Respir J. 2022.60(Suppl 66)doi: https://dx.doi.org/10.1183/13993003.congress-2022.2835.	Intervention: non-digital
Tehran University of Medical Sciences. The effect of self-management on anxiety and depression of people with chronic obstructive pulmonary disease. Identifier: IRCT20160704028781N4. In: Iranian Registry of Clinical Trials (IRCT) [internet]. Tehran: Iran University of Medical Sciences (IUMS): 2020. Available from http://en.irct.ir/trial/47488.	Intervention: Not multi-component
Ter Stal S, Sloots J, Ramlal A, Op den Akker H, Lenferink A, Tabak M. An embodied conversational agent in an ehealth self-management intervention for chronic obstructive pulmonary disease and chronic heart failure: Exploratory study in a real-life setting. JMIR Hum Factors. 2021.8(4):e24110. doi: https://dx.doi.org/10.2196/24110.	Ineligible outcomes
The First Affiliated Hospital of Guangzhou Medical University. Clinical evaluation of COPD butler in patient home management. Identifier: NCT03471091. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2018. Available from https://clinicaltrials.gov/show/NCT03471091.	Intervention: telemonitoring
The George Institute for Global Health. Ambulatory monitoring and management of chronic obstructive pulmonary disease. Identifier: ACTRN12621000552886. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney: National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2021. Available from https://anzctr.org.au/ACTRN12621000552886.aspx.	Intervention: telemonitoring
Tian H, Liu S, Wu F, Zhu Y, Ran P. Home-based integrated telemedical intervention system for management of chronic obstructive pulmonary disease in Guangdong, China: Development and cluster randomised controlled study. Am J Respir Crit Care Med. 2021.203(9)doi: https://dx.doi.org/10.1164/ajrccm-conference.2021.TP103.	Abstract: insufficient info
Tistad M, Lundell S, Wiklund M, Nyberg A, Holmner A, Wadell K. Usefulness and relevance of an ehealth tool in supporting the self-management of chronic obstructive pulmonary disease: Explorative qualitative study of a cocreative	Ineligible study design

process. JMIR Hum Factors. 2018.5(4):e10801. doi: https://dx.doi.org/10.2196/10801.	
Umeå University. Feasibility and effects of KOL-webben in patients with COPD. Identifier: NCT02696187. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2016. Available from https://clinicaltrials.gov/show/NCT02696187.	Intervention: pulmonary rehab
Universidad de Granada. Tablet-assisted training in exacerbated COPD. Identifier: NCT03601403. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2017. Available from https://classic.clinicaltrials.gov/show/NCT03601403.	Intervention: Not multi-component
Universidad de Granada. Tablet-assisted training in exacerbated COPD. Identifier: NCT03601403. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2018. Available from https://clinicaltrials.gov/study/NCT03601403.	Intervention: Not multi-component
University Hospital Bispebjerg and Frederiksberg. COPD Online Rehabilitation (CORe). Identifier: NCT02667171. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2016. Available from https://classic.clinicaltrials.gov/show/NCT02667171.	Intervention: pulmonary rehab
University Hospital of North Norway. Long-term integrated telerehabilitation of COPD Patients. A multi-center trial. Identifier: NCT02258646. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2014. Available from https://clinicaltrials.gov/show/NCT02258646.	Intervention: Not multi-component
University Hospitals of Leicester. Evaluating a group-based maintenance self-management intervention for patients with COPD. Identifier: ISRCTN30110012. In: ISRCTN Registry [internet]. London: BioMed Central Limited: 2019. Available from https://trialsearch.who.int/Trial2.aspx?TrialID=ISRCTN30110012.	Non-digital SPACE for COPD
University of Alberta. Enhanced pulmonary rehabilitation with digital remote home monitoring. Identifier: NCT06077994. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2023. Available from https://clinicaltrials.gov/ct2/show/NCT06077994.	Intervention: telemonitoring
University of Alberta. The Canadian standardized pulmonary rehabilitation efficacy trial. Identifier: NCT02917915. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2016. Available from https://clinicaltrials.gov/show/NCT02917915.	Intervention: non-digital
University of Crete. Self-management in chronic obstructive pulmonary disease (COPD) patients compared to usual care. Identifier: NCT05918731. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2020. Available from https://classic.clinicaltrials.gov/show/NCT05918731.	Intervention: non-digital
University of Leicester. Usability and acceptability study of the P-STEP mobile application. Identifier: NCT05830318. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2023. Available from https://clinicaltrials.gov/ct2/show/NCT05830318.	Intervention: Not multi-component
University of Massachusetts. A mobile integrated health intervention to manage congestive health failure and chronic obstructive pulmonary disease. Identifier: NCT05540158. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2024. Available from https://classic.clinicaltrials.gov/show/NCT05540158.	Intervention: non-digital
University of Paris. Evaluating the feasibility, acceptability and pre testing the impact of a self-management and tele monitoring program for COPD patients in Lebanon. Identifier: NCT04196699. In: ClinicalTrials.gov [internet]. Bethesda: US	Intervention: telemonitoring

National Library of Medicine: 2020. Available from https://classic.clinicaltrials.gov/show/NCT04196699.	
University of South China. Application and early warning index distinguish of acute aggravation of remote management based on 'internet plus' for the chronic obstructive pulmonary disease. Identifier: ChiCTR1900026502. In: Chinese Clinical Trial Register [internet]. Chengdu: Chinese University of Hong Kong: 2019. Available from http://www.chictr.org.cn/showproj.aspx?proj=43968.	Intervention: telemonitoring
University of Southampton. Digital interventions for chronic obstructive pulmonary disease (COPD). Identifier: ISRCTN75958874. In: ISRCTN Registry [internet]. London: BioMed Central Limited: 2015. Available from http://isrctn.com/ISRCTN75958874.	Abstract: insufficient info
Uno M, O'Connor A, Farrell S, Hassan T. COVID-19 remote monitoring programme in Our Lady of Lourdes Hospital Drogheda. Ir J Med Sci. 2022.191(Suppl 5):S181. doi: https://dx.doi.org/10.1007/s11845-022-03209-1.	Ineligible patient population
VA Office of Research and Development. Developing an intervention to optimize virtual care adoption for COPD management. Identifier: NCT05986214. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2026. Available from https://classic.clinicaltrials.gov/show/NCT05986214.	Ineligible intervention
VA Office of Research and Development. The development of an integrated physical activity and mental health intervention for veterans with COPD, emotion distress, and low physical activity. Identifier: NCT04953806. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2021. Available from https://clinicaltrials.gov/show/NCT04953806.	Intervention: non-digital
VA Office of Research and Development. The effect of a technology-mediated integrated walking and tai chi intervention on physical function in veterans with COPD and chronic musculoskeletal pain. Identifier: NCT05701982. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2023. Available from https://clinicaltrials.gov/show/NCT05701982.	Ineligible intervention
van der Weegen S, Verwey R, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. It's LiFe! Mobile and web-based monitoring and feedback tool embedded in primary care increases physical activity: A cluster randomized controlled trial. J Med Internet Res. 2015.17(7):e184. doi: https://dx.doi.org/10.2196/jmir.4579.	Intervention: Not multi-component
Van Genugten L, Priori R, Barretto C, Schonenberg H, Dekker M, Klee M, Saini P. An online intervention to maintain physical activity levels in COPD patients after pulmonary rehabilitation. Bulletin of the European Health Psychology Society. 2016; (Suppl): 635. Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02148109/full.	Intervention: Not multi-component
van Zelst CM, Kasteleyn MJ, van Noort EMJ, Rutten-van Molken MPMH, Braunstahl GJ, Chavannes NH, in 't Veen JCCM. The impact of the involvement of a healthcare professional on the usage of an eHealth platform: a retrospective observational COPD study. Respir Res. 2021.22(1):88. doi: https://dx.doi.org/10.1186/s12931-021-01685-0.	Ineligible comparator
Vasilopoulou M, Papaioannou AI, Kaltsakas G, Louvaris Z, Chynkiamis N, Spetsioti S, et al. Home-based maintenance tele-rehabilitation reduces the risk for acute exacerbations of COPD, hospitalisations and emergency department visits. Eur Respir J. 2017.49(5):05. doi: https://dx.doi.org/10.1183/13993003.02129-2016.	Intervention: telemonitoring
Vastra Gotaland Region. Remote monitoring of patients with COPD. Identifier: NCT03558763. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2018. Available from https://clinicaltrials.gov/study/NCT03558763.	Intervention: telemonitoring

Velardo C, Shah SA, Gibson O, Clifford G, Heneghan C, Rutter H, et al. Digital health system for personalised COPD long-term management. BMC Med Inform Decis Mak. 2017.17(1):19. doi: https://dx.doi.org/10.1186/s12911-017-0414-8.	Intervention: telemonitoring
Verma A, Behera A, Kumar R, Gudi N, Joshi A, Islam KM. Mapping of digital health interventions for the self-management of COPD: A systematic review. Clin Epidemiol Glob Health. 2023.24:101427. doi: https://dx.doi.org/10.1016/j.cegh.2023.101427.	Eligible SR
Vilarinho R, Esteves C, Caneiras C. Effects of a home-based pulmonary rehabilitation program in patients with chronic obstructive pulmonary disease of GOLD D group. Eur Respir J. 2021.58(Suppl 65)doi: https://dx.doi.org/10.1183/13993003.congress-2021.PA613.	Intervention: non-digital
Vincent EE, Hawksley Z, Gardiner N, Houchen-Wolloff L, Singh SJ. Challenges of patient engagement to a COPD virtual ward, following an admission for an acute exacerbation of COPD. Thorax. 2023.78(Suppl 4):A264-A65. doi: https://dx.doi.org/10.1136/thorax-2023-BTSabstracts.399.	Intervention: telemonitoring
Vitacca M, Paneroni M, Grossetti F, Ambrosino N. Is there any additional effect of tele-assistance on long-term care programmes in hypercapnic COPD patients? A retrospective study. Copd. 2016; (5): 576-82. Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01444972/full.	Intervention: Not multi-component
Vivisol. Oxygen therapy remote monitoring in COPD patients. Identifier: NCT05473780. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2023. Available from https://classic.clinicaltrials.gov/show/NCT05473780.	Intervention: telemonitoring
Voncken-Brewster V, Tange H, Moser A, Nagykaldi Z, de Vries H, van der Weijden T. Integrating a tailored e-health self-management application for chronic obstructive pulmonary disease patients into primary care: a pilot study. BMC Fam Pract. 2014.15:4. doi: https://dx.doi.org/10.1186/1471-2296-15-4.	<9 patients
Vorrink S, Huisman C, Kort H, Troosters T, Lammers JW. Perceptions of patients with chronic obstructive pulmonary disease and their physiotherapists regarding the use of an ehealth intervention. JMIR Hum Factors. 2017; (3): e20. Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01425706/full.	Intervention: Not multi-component
Walker PP, Pompilio PP, Zanaboni P, Bergmo TS, Prikk K, Malinovschi A, et al. Telemonitoring in chronic obstructive pulmonary disease (CHROMED). A randomized clinical trial. Am J Respir Crit Care Med. 2018; (5): 620-28. Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01646012/full.	Intervention: telemonitoring
Wang CH, Chou PC, Joa WC, Chen LF, Sheng TF, Ho SC, et al. Mobile-phone-based home exercise training program decreases systemic inflammation in COPD: a pilot study. BMC Pulm Med. 2014; (1): Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01015297/full.	Intervention: Not multi-component
Whelan M, Biggs C, Areia C, King E, Lawson B, Newhouse N, et al. Recruiting patients to a digital self-management study whilst in hospital for a chronic obstructive pulmonary disease exacerbation: A feasibility analysis. Digit Health. 2021.7:20552076211020876. doi: https://dx.doi.org/10.1177/20552076211020876.	Ineligible study design
Whelan M, Velardo C, Rutter H, Tarassenko L, Farmer A. mHealth mood monitoring for people with COPD. Eur Respir J. 2019: Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02087029/full.	Abstract: insufficient info

Whittaker R, Dobson R, Candy S, Taylor D, Reeve J, Warren J, et al. MPR: feasibility of a mHealth pulmonary rehabilitation programme. N Z Med J. 2021.134(1542):139-40.	Abstract: insufficient info
Wootton S. Consumer feedback during the development of a mobile pulmonary rehabilitation (m-PRTM) platform. Respirology. 2022.27(Suppl 1):135. doi: https://dx.doi.org/10.1111/resp.14226.	Intervention: pulmonary rehab
Wootton SL, Dale MT, Alison JA, Brown S, Rutherford H, Chan ASL, et al. Mobile health pulmonary rehabilitation compared to a center-based program for cost-effectiveness and effects on exercise capacity, health status, and quality of life in people with chronic obstructive pulmonary disease: A protocol for a randomized controlled trial. Phys Ther. 2023.103(7):01. doi: https://dx.doi.org/10.1093/ptj/pzad044.	Intervention: pulmonary rehab
Wootton SL, Dale MT, Alison JA, Brown S, Rutherford H, Chan ASL, et al. Mobile health pulmonary rehabilitation compared to a center-based program for cost-effectiveness and effects on exercise capacity, health status, and quality of life in people with chronic obstructive pulmonary disease: A protocol for a randomized controlled trial. Phys Ther. 2023; (7): Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02559386/full.	Intervention: pulmonary rehab
Wu RC, Ginsburg S, Son T, Gershon AS. Using wearables and self-management apps in patients with COPD: a qualitative study. ERJ open res. 2019.5(3)doi: https://dx.doi.org/10.1183/23120541.00036-2019	Ineligible study design
Xiao ZX, Muszynski M, Marcinkevics R, Zimmerli L, Ivankay A, Kohlbrenner D, et al. Breathing new life into COPD assessment: Multisensory home-monitoring for predicting severity. Proceedings of the 25th International Conference on Multimodal Interaction. 2023.84-93.	Ineligible outcomes
Yonchuk JG, Mohan D, LeBrasseur NK, George AR, Singh S, Tal-Singer R. Development of respercise a digital application for standardizing home exercise in COPD clinical trials. Chronic Obstr Pulm Dis. 2021.8(2)doi: https://dx.doi.org/10.15326/JCOPDF.2020.0194.	Intervention: Not multi-component
Zanaboni P, Dinesen B, Hoaas H, Wootton R, Burge AT, Philp R, et al. Long-term telerehabilitation or unsupervised training at home for patients with chronic obstructive pulmonary disease a randomized controlled trial. Am J Respir Crit Care Med. 2023.207(7):865-75. doi: https://dx.doi.org/10.1164/rccm.202204-0643OC.	Intervention: Not multi-component
Zhang L, Maitinuer A, Lian Z, Li Y, Ding W, Wang W, et al. Home based pulmonary tele-rehabilitation under telemedicine system for COPD: a cohort study. BMC Pulm Med. 2022.22(1):284. doi: https://dx.doi.org/10.1186/s12890-022-02077-w.	Intervention: pulmonary rehab

Appendix C – Clinical effects and safety outcomes

Table C:1: Intermediate outcomes

Study name and location	Technology name	Intervention adherence	Rates of attrition (dropouts)
Active+me REMOTE			
Auton et al. 2024 (Auton KAA et al. 2024) Associated records: Clinical trial registration (NCT05881590 2023) **Location**: UK **Setting**: Unclear	**Intervention**: Active+me REMOTE (n=46)	Activation: 59/69 pof the 10 who didn't activate: 3 not onboarded due to "did not attend"; 6 withdrew from study before onboarding; 1 unknown Mean (SD) days of app use (n=59): 8 weeks: 28.9 (19.5)	Lost to follow up (n=23): Withdrew from study: 1 Unable to contact for final assessment: 2 Died during follow up: 1 Final assessment not completed within study follow up period: 2 Did not attend end of course assessment: 7 Withdrawals and non-attendance at final assessment said to be "usually due to exacerbation of their respiratory illness or comorbid musculoskeletal disorder"
COPDHub			
The Institute of Clinical Science and Technology, 2023 (The Institute of Clinical Science and Technology 2023) **Location**: UK **Setting**: Unclear	Intervention: COPDHub	NR	NR
myCOPD			

Study name and location	Technology name	Intervention adherence	Rates of attrition (dropouts)
Crooks et al. 2020 (Crooks et al. 2020) Associated records: Clinical trial registration (My mhealth Ltd 2018) **Location**: UK **Setting**: Mixed	**Intervention:** myCOPD, PP population (n=29) **Comparator:** Standard care	myCOPD: Activation of app (PP population, n=29): Did not activate: 5/29 (17.2%) Activated app: 21/29 Activated users still using app in the last month of trial: 18/21 (86%) App usage (PP population who activated app, n=21): >30 days: 12 ⩾60 days: 7 Mean days of app use (PP population who activated app, n=21): Mean: 44 days (SD 31.6 days, median 42 days, IQR 17–75 days) Standard care: NA	myCOPD: Withdrawn, no reason: 1 Withdrawn, too unwell: 1 Withdrawn and re-entered: 1 Lost to follow up: 2 Standard care: Incomplete follow up: 1 Withdrawn no reason: 1
North et al. 2022 (North et al. 2020) Associated records: Clinical trial registration, (My mhealth Ltd 2015) North et al. 2018, (North et al. 2018)	**Intervention:** myCOPD (ITT, n=20) **Comparator:** Standard care (ITT, n=21)	Patients who used app at minimum recommendation (at least once a week for full duration of trial): 8/20 (40%) Patients activating the app at least once by study week: Week 1: 17/20 (85%) Week 2: 13/20 (65%) Week 3: 12/20 (60%)	Lost to follow up: myCOPD: 3 Standard care: 3 Study completers: myCOPD: 17 Standard care: 18

Study name and location	Technology name	Intervention adherence	Rates of attrition (dropouts)
Location: UK **Setting**: AECOPD		Week 4: 10/20 (50%) Week 5: 10/20 (50%) Week 6: 11/20 (55%) Week 7: 10/20 (50%) Week 8: 10/20 (50%) Week 9: 9/20 (45%) Week 10: 8/20 (40%) Week 11: 9/20 (45%) Week 12: 8/20 (40%) Mean days of app use each study week (mean, SD): Week 2: 5 (1.83) Week 3: 4.4 (2.39) Week 4: 5.4 (1.78) Week 5: 4.9 (1.91) Week 6: 4.3 (2.20) Week 7: 4.6 (2.12) Week 8: 6 (1.33) Week 9: 5.1 (2.09) Week 10: 5.6 (1.77) Week 11: 4.4 (2.65) Week 12: 5.6 (2.13)	
SPACE for COPD			

Study name and location	Technology name	Intervention adherence	Rates of attrition (dropouts)
Houchen-Wolloff, 2021 (Houchen-Wolloff 2021) **Location**: UK **Setting**: AECOPD	**Intervention:** SPACE for COPD 11% (32*) **Comparator:** Telephone monitoring 67% (192*)	Programme completion rates: SPACE for COPD: 30% Telephone monitoring: 56% (p<0.05 vs SPACE for COPD)	NR
Wellinks			
Gelbman et al. 2022 (Gelbman and Reed 2022) **Location**: USA **Setting**: Unclear	Intervention: Wellinks	Mean app entries per week for each component: Baseline: Medication use entries: 7.8 Oximetry recording: 5.5 Spirometry recording: 3.4 8 weeks: Medication use entries: 3.7(-52.3%) Oximetry recording: 2.5 (-54.2%) Spirometry recording: 1.8 (-45.4%) Mean number of entries per week over trial: FEV1 by spirometer: 2.5 (range 1 to 7) Blood oxygenation by pulse oximeter: 4.2 (range 1 to 12) Medication use entries: 9.0 (range 1 to 25.1) Nebulizer use: 1.9 (range 0 to 11.9) Symptoms: 1.2 (range 0 to 5.6)	NR
Pierz et al. 2024 (Pierz et al. 2024)	Intervention: Wellinks	Wellinks app compliance per week: Week 1: 94.3% (n=133) Week 12: 50.4% (n=71)	Lost to follow up (11): Changed mind: 7 Worsening health status: 2

Study name and location	Technology name	Intervention adherence	Rates of attrition (dropouts)
Location: USA **Setting**: Unclear		Wellinks app compliance overall study period (12 weeks): Compliant for <25% of study period: 33/141 (23.4%) Compliance for >75% of study period: 40/141 (28.4%) Coaching compliance: 84.4% (n=119) of participants completed all 6 coaching sessions in the first 12 weeks of the study Spirometer compliance: Week 1: 82.3% (n=116) Week 12: 41.8% (n=59) Pulse oximeter compliance: Week 1: 89.4% (n=126) Week 12: 42.6% (n=60)	Illness of spouse: 1 Back surgery: 1
COPDPredict			
Patel et al. 2021 (Patel et al. 2021) **Location**: UK **Setting**: AECOPD	Intervention: COPDPredict	98% compliance with completing the daily wellbeing self-assessment	All 90 enrolled patients completed the study
Lenus			
Taylor et al. 2023 (Taylor et al. 2023)	Intervention: Lenus	Mean percentage patients completing a weekly CAT entry at 12 months: Mean weekly completion: 79.8% patients	Lenus: Withdrawn at follow up: 3 (1 subsequent death)

Study name and location	Technology name	Intervention adherence	Rates of attrition (dropouts)
Associated records: Carlin et al. 2021 (Carlin et al. 2021) Taylor et al. 2022 (Taylor et al. 2022b) Taylor et al. 2021 (Taylor et al. 2021) Taylor et al. 2022 (Taylor et al. 2022a) NCT04240353 (NHS Greater Glasgow and Clyde 2018) **Location**: UK **Setting**: AECOPD	**Comparator:** Standard care	77% of users completed at least 1 entry a week on over 50% of follow up weeks	Died: 20 Comparator: NR
NHS HUTH 2024 (Lenus Health Ltd 2024a) **Location**: UK **Setting**: AECOPD	Intervention: Lenus **Control:** Standard care	NR	NR
Luscii			
All Together Better Sunderland, 2021 (All Together Better Sunderland 2021)	Intervention: Luscii Comparator: None	NR	NR

Study name and location	Technology name	Intervention adherence	Rates of attrition (dropouts)
Location: UK **Setting**: Unclear			
Luscii Ltd. (unpublished) (Luscii) **Location**: UK **Setting**: Unclear	Intervention: Luscii Comparator: None	Number of measurements sent on the right day: 66	NR
CliniTouch Vie			
Ghosh 2018 (Ghosh 2018) **Location**: UK **Setting**: AECOPD	Intervention: CliniTouch Vie Comparator: None	NR	NR
NHS Chorlie and South Ribble; Preston CCGs (NHS 2022b) **Location**: UK **Setting**: AECOPD	**Intervention**: CliniTouch Vie **Comparator:** Standard care	On average, the 29 patients spent 150 days on CliniTouch, however, this is skewed by 7 patients who spent less than 30 days on the system, 5 of which were online less than a week.	33 patients were recruited; 4 died during onboarding. The remaining 29 were included in the analysis.

1. Fig 1 reports 9 withdrawn but listed withdrawals in same figure total 8

Key: AECOPD – Acute exacerbations of COPD, CAT – COPD assessment test, COPD - Chronic obstructive pulmonary disease, FEV1 – Forced expiratory volume in 1 second, IQR – interquartile range, ITT – intent to treat, NA – not applicable, NHS HUTH – National Health Service Hull University Trust Hospital, NR – Not reported, PP – per protocol, PR – Pulmonary rehabilitation , SD – standard deviation.

Table C.2: Intermediate outcomes 2

Study name and location	Technology name	Intervention-related adverse events	Inaccessibility to intervention (digital inequalities)
Active+me REMOTE			
Auton et al. 2024 (Auton KAA et al. 2024) Associated records: Clinical trial registration (NCT05881590 2023) **Location**: UK **Setting**: Unclear	**Intervention**: Active+me REMOTE (n=46)	Adverse events (event rate): 46 Serious adverse events (requiring acute hospitalisation, event rate): 2 None of the SAEs were considered attributable to the intervention	Recruitment rate was 30% of those approached. Despite offering a mobile phone with SIM card to provide internet access as well as the Active+me digital app for free, 58 declined to participate in the study due to digital hesitancy
COPDHub			
The Institute of Clinical Science and Technology, 2023 (The Institute of Clinical Science and Technology 2023) **Location**: UK **Setting**: Unclear	Intervention: COPDHub	NR	NR
myCOPD			
Crooks et al. 2020 (Crooks et al. 2020) Associated records: Clinical trial registration (My mhealth Ltd 2018)	**Intervention:** myCOPD (PP n=29) **Comparator:** Standard care (PP n=31)	Adverse events: myCOPD: 5/29 Standard care: 7/31 Serious adverse events: myCOPD: 0	NR

Study name and location	Technology name	Intervention-related adverse events	Inaccessibility to intervention (digital inequalities)
Location: UK **Setting**: Mixed		Standard care: 0 None stated to be intervention-related	
North et al. 2022 (North et al. 2020) Associated records: Clinical trial registration, (My mhealth Ltd 2015) North et al. 2018, (North et al. 2018) **Location**: UK **Setting**: AECOPD	**Intervention:** myCOPD (ITT, n=20) **Comparator:** Standard care (ITT, n=21)	Adverse events: myCOPD: 3 (2 constipation, 1 medication side effect) Standard care: 1 (other respiratory infections) None are reported as being related to the myCOPD app	Ability to access and use an internet enabled device was an inclusion criteria
SPACE for COPD			
Houchen-Wolloff, 2021 (Houchen-Wolloff 2021) **Location**: UK **Setting**: AECOPD	**Intervention:** SPACE for COPD 11% (32*) **Comparator:** Telephone monitoring 67% (192*)	NR	NR
Wellinks			
Gelbman et al. 2022 (Gelbman and Reed 2022)	Intervention: Wellinks	Adverse events: Wellinks: 0	NR

Study name and location	Technology name	Intervention-related adverse events	Inaccessibility to intervention (digital inequalities)
Location: USA **Setting**: Unclear			
Pierz et al. 2024 (Pierz et al. 2024) **Location**: USA **Setting**: Unclear	Intervention: Wellinks	No AEs reported by the participants during the study	Inclusion criteria required participants to have access to a home phone, a smart phone, and the internet
COPDPredict			
Patel et al. 2021 (Patel et al. 2021) **Location:** UK **Setting**: AECOPD	Intervention: COPDPredict	No AEs or deaths were reported by the participants during the study	Patients were given mobile tablets pre-installed with the COPDPredict app. Individuals with inability/unwilling to use COPDPredict™ were excluded
Lenus			
Taylor et al. 2023 (Taylor et al. 2023) Associated records: Carlin et al. 2021 (Carlin et al. 2021) Taylor et al. 2022 (Taylor et al. 2022b) Taylor et al. 2021 (Taylor et al. 2021)	Intervention: Lenus Comparator: Control	Mortality at 12 months: Lenus: 16.9% Control: 24.1% Unadjusted hazard ratio: 0.743 (95% CI; 0.463, 1.191; p=0.215)	Inclusion criteria was that patients had daily access to a smartphone, tablet or computer with internet access

Study name and location	Technology name	Intervention-related adverse events	Inaccessibility to intervention (digital inequalities)
Taylor et al. 2022 (Taylor et al. 2022a) NCT04240353 (NHS Greater Glasgow and Clyde 2018) **Location:** UK **Setting**: AECOPD			
[redacted] **Location**[redacted] **Setting**[redacted]	Intervention: [redacted] **Control:** [redacted]	[redacted]	[redacted]
Luscii			
All Together Better Sunderland, 2021 (All Together Better Sunderland 2021) **Location**: UK **Setting**: Unclear	Intervention: Luscii **Comparator:** Standard care	NR	17/30 patients selected for cohort of patients was selected from residents in areas with known health inequalities and/or socio-economic challenges as there was a concern that these patients, in particular, might find use of the technology difficult
Luscii Ltd. (unpublished) (Luscii) **Location:** UK **Setting**: Unclear	Intervention: Luscii Comparator: None	NR	NR
CliniTouch Vie			
Ghosh 2018	Intervention: CliniTouch Vie	NR	NR

Study name and location	Technology name	Intervention-related adverse events	Inaccessibility to intervention (digital inequalities)
(Ghosh 2018) **Location**: UK **Setting**: AECOPD	Comparator: Standard care		
NHS Chorlie and South Ribble; Preston CCGs (NHS 2022b) **Location**: UK **Setting**: AECOPD	**Intervention**: CliniTouch Vie Comparator: Standard care	NR	NR

Key: AECOPD – Acute exacerbations of COPD, AE – Adverse event, CI – confidence interval, COPD - Chronic obstructive pulmonary disease, ITT – intent to treat, NHS HUTH – National Health Service Hull University Trust Hospital, NR – not reported, PP – per protocol, PR – pulmonary rehabilitation, SAE – serious adverse events.

Table C.3: Clinical outcomes 1

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
Active+me REMOTE				
Auton et al. 2024 (Auton KAA et al. 2024)	**Intervention**: Active+me REMOTE (n=46)	CAT score (mean, SD): Change from BL to 8 weeks: -2.9 (95% CI -4.2, -1.6)	NR	NR

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
Associated records: Clinical trial registration (NCT05881590 2023) **Location**: UK **Setting**: Unclear		Improvement exceeded MCID (threshold NR) MRC score (mean, SD): Change from BL to 8 weeks: -0.05 (95% CI -0.8, -0.2)		
COPDHub				
The Institute of Clinical Science and Technology, 2023 (The Institute of Clinical Science and Technology 2023) **Location**: UK **Setting**: Unclear	Intervention: COPDHub	Proportion of users who reported that they didn't need to use their reliever inhaler everyday: 21 months: Increase of 41%	Proportion of users who reported that they regularly took part in physical activity: 21 months: Increase of 12%	NR
myCOPD				
Crooks et al. 2020 (Crooks et al. 2020) Associated records:	Intervention: myCOPD **Comparator:** Standard care	CAT score (mean, SD) myCOPD: Baseline: 21.5 (8.0) 90 days: 19.2 (9.0)	Mean number of steps per day: myCOPD (daily activity sub study population, n=5)	Patients experiencing exacerbations (acute events requiring change to medication, ITT, n=60): 3 months prior to baseline:

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
Clinical trial registration (My mhealth Ltd 2018) **Location**: UK **Setting**: Mixed		Unadjusted change at 90 days −1.8 (5.8) Standard care: Baseline: 19.8 (5.4) 90 days: 19.8 (7.5) Unadjusted change at 90 days −0.03 (5.5) Adjusted (adjusting for baseline CAT score, COPD severity and study centre) between-group difference in effect size at 90 days (n=58, PP) Lower in the myCOPD arm by a mean of −1.27 (95% CI −4.47, 1.92) p=0.44	Baseline: 4948.7 (SD 1667.6) 90 days (n=4): 5458.3 (SD 2266.4) Standard care(daily activity sub study population, n=9) Baseline: 9060 (SD 5135.1) 90 days: 10762 (7199.2) The adjusted mean daily step count in the myCOPD arm was −2252 steps lower at 90 days (95% CI −10 433.8 to 5927.9)	myCOPD: 11/29 Standard care: 8/31 90 days: myCOPD: 13/29 Standard care: 8/31 Exacerbations (acute events requiring change to medication, ITT n=60): 3 months prior to baseline: myCOPD: 12 Standard care: 3 90 days myCOPD: 18 Change from baseline (incidence rate ratio): 0.2 (1.28) Standard care: 11 Change from baseline (incidence rate ratio): 0.2 (0.72) Between-group incidence rate ratio: 2.55 (95% CI 1.17, 5.54)

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
				Severe exacerbations (requiring hospitalisation) during 3 month study: myCOPD: 1 Standard care: 2
North et al. 2022 (North et al. 2020) Associated records: Clinical trial registration, (My mhealth Ltd 2015) North et al. 2018, (North et al. 2018) **Location**: UK **Setting**: AECOPD	**Intervention:** myCOPD (PP, n=17) **Comparator:** Standard care (PP, n=18)	CAT score (mean SD) Baseline: myCOPD: 26.0 (8.5) Standard care: 28.0 (5.8) 90 days: myCOPD: 20.7 (7.35) Standard care: 25.1 (7.24) Adjusted between-arm difference (mean difference at 90 days from an ANCOVA model adjusted for baseline score and stratification variables (COPD severity and smoking status)): -2.94 (95% CI -6.92, 1.05) Longitudinal analysis (ITT population and all timepoints) showed the mean treatment difference for CAT score was -4.49 (95% CI: −8.41, −0.58, n = 41), favouring myCOPD Proportion of patients achieving minimally clinically significant (-2 points)	NR	Exacerbations (events, mean, SD): 3 months prior to baseline**:** myCOPD: 2.9 (1.6) Standard care: 3.2 (2.0) 90 days: myCOPD: 1.06 (0.83) Standard care: 1.88 (1.84) Adjusted between arm difference at 90 days (rate ratio): 0.581 (95% CI 0.315, 1.07)

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
		improvement in CAT score at any timepoint after baseline: myCOPD: 18/20 (90%) Standard care: 17/21 (81%) mMRC (mean, SD) Baseline myCOPD: 2.9 (1.3) Standard care: 3.1 (1.1) 90 days: myCOPD: 2.76 (1.35) Standard care: 2.78 (1.11) Adjusted between-arm difference: -0.0183* (95% CI −0.759, 0.796) St Georges respiratory questionnaire (mean, SD) Baseline: myCOPD: 66.4 (16.6) Standard care: 68.1 (13.7) 90 days myCOPD: 61.9 (14.93) Standard care: 64.1 (15.94)		

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
		Adjusted between-arm difference: −1.48 (95% CI −7.82, 4.86)		
SPACE for COPD				
Houchen-Wolloff, 2021 (Houchen-Wolloff 2021) **Location**: UK **Setting**: AECOPD	**Intervention:** SPACE for COPD 11% (32*) **Comparator:** Telephone monitoring 67% (192*)	Change in CAT score from baseline to 6 weeks: SPACE for COPD: - 7.2 Telephone monitoring: -2.4 Mean change from baseline was statistically significant ($p<0.05$) and clinically significant (threshold NR) in all treatment arms	NR	NR
Wellinks				
Gelbman et al. 2022 (Gelbman and Reed 2022) **Location**: USA **Setting**: Unclear	Intervention: Wellinks	NR	NR	NR
Pierz et al. 2024 (Pierz et al. 2024) **Location**: USA	Intervention: Wellinks Comparator: None	mMRC n (%): Baseline: I get out of breath only when I engage in strenuous exercise 13/14 9.2%)	NR	NR

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
Setting: Unclear		I get out of breath when I am hurrying or walking up a slight hill 47/141 (33.3%) I walk slower than others of my age because I am out of breath, or I have to stop often to catch my breath 38/141 (26.9%) I have to stop for breath after walking 100 yards 16/141 (11.3%) I am often too out of breath to leave the house, or I get out of breath even when I am getting dresses 27/141 (19.1%) Baseline mean: 2.0 (SD 1.26) Week 12 (n=95): Improved scores: 30/95 31.6% No change: 53/95 46.8% Worsened: 12/95 12.6% A responder was defined as a participant with an improvement from baseline of 1 category or more		
COPDPredict				

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
Patel et al. 2021 (Patel et al. 2021) **Location**: UK **Setting:** AECOPD	Intervention: COPDPredict	NR	NR	Patients experiencing exacerbations: 6 months: COPDPredict: 80/90 Patients experiencing 1 exacerbation: 52 Patients experiencing >1 exacerbation: 28 (mean 2.2, SD 0.4) Exacerbations (events): 6 months: Overall: 112 Mild/moderate 108 Severe: 4 Mild/moderate exacerbation defined as increase in respiratory symptoms for >2 consecutive days, with at least 2 major symptoms (dyspnoea, sputum purulence, sputum volume) or a major plus a minor symptom (wheeze, cold, sore throat, cough) and requiring

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
				medication by clinician decision; a severe exacerbation was an episode that also required admission.
Lenus				
Taylor et al. 2023 (Taylor et al. 2023) Associated records: Carlin et al. 2021 (Carlin et al. 2021) Taylor et al. 2022 (Taylor et al. 2022b) Taylor et al. 2021 (Taylor et al. 2021) Taylor et al. 2022 (Taylor et al. 2022a) NCT04240353 (NHS Greater Glasgow and Clyde 2018) **Location**: UK **Setting**: AECOPD	Intervention: Lenus Comparator: Control	Median CAT scores were reported in a violin plot, providing a descriptive analysis of the data, rather than analysing for statistically significant differences. The median scores were relatively stable over the study period for the intervention. Digitisation of graphically-presented data was not conducted in this EVA, thus further detail has not been extracted.	NR	Community-managed exacerbations (median per participant per year): 12 months Lenus: 2 Control: NR A community-managed exacerbation was defined as a “yes” response to the weekly PRO questionnaire question “have you taken antibiotics/steroids in the last week?”

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
[redacted] **Location**: [redacted] **Setting**: [redacted]	Intervention: [redacted] **Control:** [redacted]	[redacted]	[redacted]	[redacted]
Luscii				
All Together Better Sunderland, 2021 (All Together Better Sunderland 2021) **Location**: UK **Setting**: Unclear	Intervention: Luscii Comparator: None	NR	NR	NR
Luscii Ltd. (unpublished) (Luscii) **Location**: UK **Setting**: Unclear	Intervention: Luscii **Comparator:** Standard care	NR	NR	NR
CliniTouch Vie				
Ghosh 2018 (Ghosh 2018)	**Intervention:** CliniTouch Vie (PP n = 29)	CAT score: Mean reduction of 4.2 ($p<0.001$)	NR	NR

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
Location: UK **Setting**: AECOPD	Comparator: Standard care			
NHS Chorley and South Ribble; Preston CCGs (NHS 2022b) **Location**: UK **Setting**: AECOPD	**Intervention**: CliniTouch Vie **Comparator:** Standard care	[redacted]	NR	NR

Key: AECOPD – Acute exacerbations of COPD, ANCOVA – Analysis of covariance, BL – Baseline, CAT – COPD assessment test, CI – Confidence intervals, COPD - Chronic obstructive pulmonary disease, FEV_1 – Forced expiratory volume in one second, ITT – Intention to treat, mMRC - Modified British Medical Research Council, NHS HUTH – NHS Hull University Teaching Hospitals, NR – Not reported, PP – Per protocol, SD – Standard deviation, VSAQ - Veterans Specific Activity Questionnaire.

* Table 5 reports difference as a positive value, but endpoint values indicate the mMRC score was lower in the myCOPD arm; we have added a minus symbol to reflect this.

Table C. 4: Clinical outcomes 2

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
Active+me REMOTE					
Auton et al. 2024 (Auton KAA et al. 2024) Associated records: Clinical trial registration (NCT05881590 2023) **Location**: UK **Setting**: Unclear	**Intervention**: Active+me REMOTE (n=46)	NR	NR	NR	NR
COPDHub					
The Institute of Clinical Science and Technology, 2023	Intervention: COPDHub	NR	NR	NR	NR

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
(The Institute of Clinical Science and Technology 2023) **Location**: UK **Setting**: Unclear					
myCOPD					
Crooks et al. 2020 (Crooks et al. 2020) Associated records: Clinical trial registration (My mhealth Ltd 2018) **Location**: UK **Setting**: Mixed	**Intervention:** myCOPD (PP, n=24) **Comparator:** Standard care (PP n=30)	Exacerbation related emergency admissions (events): 90 days myCOPD: 2 Standard care: 1 Exacerbation related hospitalisations (events): 90 days myCOPD: 1 Standard care: 2	NR	Patients requiring antibiotics due to exacerbation: 3 months prior to baseline: myCOPD: 3/11 Standard care: 0/3 During study: myCOPD: 6/13	Odds of 1 or more critical inhaler errors, (PP, n=54): Change from BL to 90 days myCOPD: −0.3 (0.70) Standard care: 0.1 (0.71)

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
				Standard care: 2/8 Patients requiring steroids due to exacerbation: 3 months prior to baseline: myCOPD: 1/11 Standard care: 2/3 During study: myCOPD: 2/13 Standard care: 1/8 Patients requiring antibiotics and steroids due to exacerbation:	Adjusted odds ratio: 0.30 (95% CI 0.09, 1.06) p=0.061, favouring myCOPD Mean rate of inhaler errors (PP, n=54): Change from BL to 90 days myCOPD: −0.3 (1.61) Standard care: −0.1 (1.20) Adjusted incidence rate ratio

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
				3 months prior to baseline: myCOPD: 7/11 Standard care: 1/3 During study: myCOPD: 4/13 Standard care: 6/8	0.97 (95% CI 0.52, 1.8) p=0.928) favouring myCOPD
North et al. 2022 (North et al. 2020) Associated records: Clinical trial registration, (My mhealth Ltd 2015) North et al. 2018, (North et al. 2018) **Location**: UK	**Intervention:** myCOPD (PP, n=17) **Comparator:** Standard care (PP, n=18)	Patients who required readmissions for COPD related events 90 days: myCOPD (ITT): 18/20 (90%) Standard care (ITT): 17/21 (81%) Readmission rate for COPD related events (mean, SD) 90 days: myCOPD (PP=17): 1.08 Standard care (PP=18): 1.86 Adjusted between arm difference (odds ratio): 0.383 (95% CI 0.0738, 1.99)	NR	NR	Critical errors in inhaler rate 90 days: myCOPD (PP=17): 1.17 (1.70) Standard care (PP=18): 4.00 (4.97)

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
Setting: AECOPD					Adjusted between arm difference (rate ratio: 0.377 (0.179, 1.04)
SPACE for COPD					
Houchen-Wolloff, 2021 (Houchen-Wolloff 2021) **Location**: UK **Setting**: AECOPD	**Intervention:** SPACE for COPD 11% (32*) **Comparator:** Telephone monitoring 67% (192*)	NR	NR	NR	NR
Wellinks					
Gelbman et al. 2022 (Gelbman and Reed 2022)	Intervention: Wellinks	NR	NR	NR	NR

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
Location: USA **Setting**: Unclear					
Pierz et al. 2024 (Pierz et al. 2024) **Location**: USA **Setting**: Unclear	**Intervention**: Wellinks (PP) Comparator: None	COPD-related hospitalisations: 3 months prior to baseline: 132/141 (93.6%) 24 weeks: 99 (93.4%) COPD-related emergency department visits: 3 months prior to baseline: 127/141 (90%) 24 weeks: 95 (89.6%)	NR	NR	NR
COPDPredict					
Patel et al. 2021 (Patel et al. 2021) **Location**: UK **Setting**: AECOPD	**Intervention**: COPDPredict (n=90)	Patients with exacerbation related emergency admissions: 4/80 Total hospitalisations: 6 Months prior to baseline: 90 6 months: 2	NR	NR	NR

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
		Change from baseline: -98% (p<0.001)			
Lenus					
Taylor et al. 2023 (Taylor et al. 2023) Associated records: Carlin et al. 2021 (Carlin et al. 2021) Taylor et al. 2022 (Taylor et al. 2022b) Taylor et al. 2021 (Taylor et al. 2021) Taylor et al. 2022 (Taylor et al. 2022a) NCT04240353 (NHS Greater Glasgow and Clyde 2018)	Intervention: Lenus (69) Comparator: Control (315)	COPD or respiratory related hospital admissions (PP) Lenus: Year before: 2.29 Year after: 1.67 Change: 0.62 Wilcoxon signed-rank test effect size: 0.423 (p < 0.0001) Comparator: Year before: 2.20 Year after: 0.99 Change: 1.21 Wilcoxon signed-rank test effect size: 0.314 (p < 0.0001) COPD or respiratory related hospital admissions (ITT) Lenus: Year before (content of care NR, only 24.1% had previous pulmonary rehab): 2.46 Year after: 1.17	NR	NR	NR

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
Location: UK **Setting**: AECOPD		Change: 1.29 Wilcoxon signed-rank test effect size: 0.5941 (p < 0.0001) Comparator: Year before (content of care NR): 2.47 Year after: 1.58 Change: 0.89 Wilcoxon signed-rank test effect size: 0.4979 (p < 0.0001)			
[redacted] **Location**: [redacted] **Setting**: [redacted]	Intervention: [redacted] **Control:** [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
		[redacted]			
Luscii					
All Together Better Sunderland, 2021 (All Together Better Sunderland 2021) **Location**: UK **Setting**: Unclear	Intervention: Luscii **Comparator:** Standard care	(30 patients) ED visits (events, total) 9 months prior to baseline: 31 9 months: 26 Change: -16% ED visits (events, respiratory) Prior to Luscii: 26 9 months prior to baseline: 11 Change: -58%	(30 patients) Primary care contact (events) 9 months prior to baseline: 184 9 months: 122 Change: -34%	NR	NR

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
Luscii Ltd. (unpublished) (Luscii) **Location**: UK **Setting**: Unclear	Intervention: Luscii Comparator: None	NR	NR	NR	NR
CliniTouch Vie					
Ghosh 2018 (Ghosh 2018) **Location**: UK **Setting**: AECOPD	**Intervention:** CliniTouch Vie (n=28) Comparator: Standard care	Hospital admissions (all cause): Baseline: 55 (mean 1.96 per patient) End of follow up (mean 222 days): 20 (mean 0.71 per patient) Difference: 35 Net reduction of 1.25 admissions (63.6%), p < 0.001	NR	NR	NR
NHS Chorley and South Ribble; Preston CCGs (NHS 2022b)	**Intervention**: CliniTouch Vie	Mean COPD-related admissions (patients who used app for >1 month, n=22): Previous year: 2.4 CliniTouch Vie: 0.9	NR	NR	NR

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
Location: UK **Setting**: AECOPD	**Comparator:** Standard care	Average change in admissions: -1.8 Wilcoxon signed rank test: p=0.0001259 COPD-related admissions (events, patients who used app for <1 month): Previous year: 16 CliniTouch Vie: 4 Change in admissions: -4 Wilcoxon signed rank test: p=0.4142			

Key: AECOPD – Acute exacerbations of COPD, BL – Baseline, CI – Confidence intervals, COPD – Chronic obstructive pulmonary disease, ED – Emergency department, ITT – Intention to treat, GP – General practitioner, NHS HUTH – NHS Hull University Teaching Hospitals, NR – Not reported, PP – Per protocol, PR – Pulmonary rehabilitation.

Table C.5: Patient reported outcomes

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
Active+me REMOTE				
Auton et al. 2024 (Auton KAA et al. 2024)	**Intervention**: Active+me REMOTE (n=46)	Chronic respiratory questionnaire (mean, SD):	NR	HADS score (mean, SD): Change in HADS-A from BL to 8 weeks: -1.1 (95% CI -2.1 to -0.2)

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
Associated records: Clinical trial registration (NCT05881590 2023) **Location**: UK **Setting**: Unclear		Change CRQ-Dyspnoea from BL to 8 weeks: 6.6 (95% CI 4.3, 8.9) Improvement exceeded MCID (threshold NR) Change CRQ-Fatigue from BL to 8 weeks: 2.6 (95% CI 1.1, 4.1) Change CRQ-Emotion from BL to 8 weeks: 2.9 (95% CI 0.8, 4.9) Change CRQ-Mastery from BL to 8 weeks: 1.9 (95% CI 0.8, 3.1) EQ-5D-5L (mean, SD): Change in utility score from BL to 8 weeks: 0.03 (95% CI -0.02, 0.07) Change in VAS score from BL to 8 weeks: 2.0 (95% CI -2.9 to 6.8)		Change in HADS-D from BL to 8 weeks: -0.8 (95% CI -1.6 to -0.1) PAM score (mean, SD): Change in PAM from BL to 8 weeks: 2.8 (95% CI -0.5 to 6.2)
COPDHub				
The Institute of Clinical Science and Technology, 2023 (The Institute of Clinical Science and Technology 2023) **Location**: UK **Setting**: Unclear	Intervention: COPDHub	NR	NR	NR
myCOPD				

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
Crooks et al. 2020 (Crooks et al. 2020) Associated records: Clinical trial registration (My mhealth Ltd 2018) **Location**: UK **Setting**: Mixed	**Intervention:** myCOPD (PP, n=24) **Comparator:** Standard care (PP n=30)	Mean (SD) EQ-5D-5L utility change from baseline to 90 days: myCOPD: 0.1 (0.23) Standard care: 0.0 (0.18) The 90-day adjusted mean intervention difference at was −0.04 (95% CI −0.12, 0.05) Mean (SD) EQ-5D-5L VAS score change from baseline to 90 days: myCOPD: 62.0 (21.35) Standard care: 60.9 (19.92) The 90-day adjusted mean intervention difference was 0.86 (95% CI −9.46, 11.18).	NR	NR
North et al. 2022 (North et al. 2020) Associated records: Clinical trial registration, (My mhealth Ltd 2015) North et al. 2018, (North et al. 2018) **Location**: UK **Setting**: AECOPD	**Intervention:** myCOPD (PP, n=17) **Comparator:** Standard care (PP, n=18)	NR	NR	PAM score: Baseline: myCOPD: 59.7 (11.4) Standard care: 54.0 (11.2) 90 days: myCOPD (PP=17): 64.7 (13.46) Standard care (PP=18): 56.1 (18.49) Adjusted mean difference at 90 days difference: 5.02 (95% CI −8.28, 18.3) HAD score:

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
				Baseline: myCOPD: 18.9 (10.6) Standard care: 18.1 (6.1) 90 days: myCOPD (PP=17): 15.5 (8.88) Standard care (PP=18): 18.1 (7.78) Adjusted mean difference at 90 days: −3.08 (−7.61, 1.45)
SPACE for COPD				
Houchen-Wolloff, 2021 (Houchen-Wolloff 2021) **Location**: UK **Setting**: AECOPD	**Intervention:** SPACE for COPD 11% (32*) **Comparator:** Telephone monitoring 67% (192*)	Change in mean CRQ- Dyspnoea score from baseline to 6 weeks: SPACE for COPD: 1.1 Telephone monitoring: 0.8 Mean change from baseline was statistically significant (p<0.05) and clinically significant (threshold NR) in all treatment arms Change in mean CRQ- Fatigue score from baseline to 6 weeks: SPACE for COPD: 0.9 Telephone monitoring: 0.4 Mean change from baseline was statistically significant (p<0.05) in the telephone monitoring arm and not the SPACE for COPD arm	NR	NR

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
		Mean change from baseline was clinically significant (threshold NR) in the SPACE for COPD arm and not the telephone monitoring arm Change in mean CRQ- Emotion score from baseline to 6 weeks: SPACE for COPD: - 1.4 Telephone monitoring: 0.4 Mean change from baseline was statistically significant (p<0.05) in the telephone monitoring arm and not the SPACE for COPD arm Mean change from baseline was clinically significant (threshold NR) in the SPACE for COPD arm and not the telephone monitoring arm Change in mean CRQ- Mastery score from baseline to 6 weeks: SPACE for COPD: 0.8 Telephone monitoring: 0.6 Mean change from baseline was statistically significant (p<0.05)		

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
		and clinically significant (threshold NR) in all treatment arms Mean change from baseline was statistically significant (p<0.05) in the telephone arm and not the SPACE for COPD arm		
Wellinks				
Gelbman et al. 2022 (Gelbman and Reed 2022) **Location**: USA **Setting**: Unclear	**Intervention:** Wellinks (16 patients who took part in survey)	NR	Patient satisfaction survey: Agreed or strongly agreed that app was easy to use: 15/16 (94%) Agreed or strongly agreed that app was valuable: 13/16 (81%) Agreed or strongly agreed that it was useful to be able to take spirometry and oximetry readings at home: 15/16 (94%) Agreed or strongly agreed that symptom logging was valuable: 11 (69%) Agreed or strongly agreed that they would like to be able to contact doctor or caregiver through app: 12/16 (75%) Agreed or strongly agreed that Wellinks helped them to learn	NR

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
			more about COPD: 6/16 (38%*) Agreed or strongly agreed that Wellinks strengthened connection to doctor: 3/16 (19%*) NPS score: Wellinks: 59	
Pierz et al. 2024 (Pierz et al. 2024) **Location**: USA **Setting**: Unclear	**Intervention**: Wellinks (PP) Comparator: None	NR	Satisfaction metrics (n=89): 92.6% (n=50) of respondents in arm 1 and 68.6% (n=24) of respondents in arm 2 strongly agreed or agreed that "using the Wellinks solution has helped them learn more about COPD"	CSES (mean, SD): Baseline mean score: 103.9 (SD 28.71) Week 12 change from baseline (n=96): 11.1, SE 3.10, p < 0.001 CSES LS mean change weeks 12-24 (mean, SE): Arm 1 (continued coaching, n=38): 8.6, (4.04) p = 0.04 CSES change from baseline: All domains significantly improved from baseline in both arms (p<.001) apart from arm 2 (discontinued coaching) for negative affect (p=.006) and

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
				intense emotional arousal (p=.002)
COPDPredict				
Patel et al. 2021 (Patel et al. 2021) **Location**: UK **Setting**: AECOPD	**Intervention**: COPDPredict	NR	NR	NR
Lenus				
Taylor et al. 2023 (Taylor et al. 2023) Associated records: Carlin et al. 2021 (Carlin et al. 2021) Taylor et al. 2022 (Taylor et al. 2022b) Taylor et al. 2021 (Taylor et al. 2021) Taylor et al. 2022 (Taylor et al. 2022a) NCT04240353 (NHS Greater Glasgow and Clyde 2018) **Location**: UK **Setting**: AECOPD	**Intervention**: Lenus (69) Comparator: Control (315)	A descriptive analysis of EQ-5D visual analogue scale (VAS), presented in a violin boxplot. The analysis suggested that those receiving the intervention had a median VAS score between 50 to 55 across the study period. Digitisation of graphically-presented data was not conducted in this EVA, thus further detail has not been extracted.	NR	NR

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
[redacted] **Location**: [redacted] **Setting**: [redacted]	Intervention: [redacted] **Control:** [redacted]	[redacted]	[redacted]	[redacted]
Luscii				
All Together Better Sunderland, 2021 (All Together Better Sunderland 2021) **Location**: UK **Setting**: Unclear	Intervention: Luscii **Comparator:** Standard care	NR	COPD questionnaire 17 of the 30 included patients were offered the questionnaire; 13 responded Did you find the iPad provided easy to use? Yes: 13/13 (100%) Did the Luscii service and iPad help you manage your COPD? Yes: 13/13 (100%) Would you like to return to the old way of managing your COPD? No: 10/13 (77%); Don't mind: 3/13 (23%) Do you think that you are able to manage your health better using the iPad?	NR

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
			Yes 12/13 (92%)	
Luscii Ltd. (unpublished) (Luscii) **Location**: UK **Setting**: Unclear	Intervention: Luscii Comparator: None	NR	1 to 5 star rating scale (81 of 186 patients): Overall satisfaction 4.6/5 This type of care service means I don't have to go to the hospital as often 4.2/5 Remote monitoring with this app makes me feel safe 4.2/5	NR
CliniTouch Vie				
Ghosh 2018 (Ghosh 2018) **Location**: UK **Setting**: AECOPD	**Intervention:** CliniTouch Vie (n = 28) Comparator: Standard care	NR	NR	NR
NHS Chorley and South Ribble; Preston CCGs (NHS 2022b) **Location**: UK **Setting**: AECOPD	**Intervention**: CliniTouch Vie **Comparator:** Standard care	NR	NR	NR

Key: AECOPD – Acute exacerbations of COPD, BL – Baseline, CAT – COPD assessment test, CI – Confidence interval, COPD – Chronic obstructive pulmonary disease, CRQ - Chronic respiratory questionnaire, CSES - COPD Self-Efficacy Scale, EQ-5D-5L – EuroQol- 5 dimension- 5 level, HADS - Hospital Anxiety and Depression Scale, ITT – Intention to treat, NHS HUTH – NHS Hull University Teaching Hospitals, NPS - Net promoter score, NR – Not reported, PAM – Patient activation measure, PP – Per protocol, PR – Pulmonary rehabilitation, SD – Standard deviation, SE – Standard error, VAS – visual analogue scale.

Appendix D – Economic review study selection

Selection of economic studies was performed alongside the selection of clinical studies. Economic evaluations were considered eligible if they reported total costs, effectiveness, incremental analyses or other economic evaluation outcomes. 'Hypothetical pieces' or evidence that cannot be critiqued (due to being limited in nature) were excluded.

5 full text studies were assessed for relevance to economics outcomes and included at full text review.

GID-HTE10030 Digital Supported Self-Management Technologies for Adults with Chronic Obstructive Pulmonary Disease

EVA guidance recommendations

Medical technologies advisory committee: 16 May 2024

Introducers: Robert Hallifax, Stacey Chang-Douglass

Lay SCMs: David McLean, Rashmi Agrawal

External assessment group: Lavinia Di Ferrante, Robert Malcolm

Technical team: Aamer Jawed, Haider Shamsi, Amy Crossley

NICE National Institute for Health and Care Excellence

Unmet need and COPD self-management

- COPD is a long-term and progressive respiratory condition that causes breathlessness, persistent chesty cough, persistent wheezing and frequent chest infections. ~1.17 million people (1.9% of population) in England have diagnosed COPD, with an estimated 2 million undiagnosed. COPD prevalence is expected to increase by 40% by 2030 in the UK. Furthermore, COPD is a common cause of emergency hospital admissions, accounting for 1 in 8 UK hospital admissions.
- NICE CG115 (2019) states that self-management plans should include education and an individualised exacerbation action plan for people at risk of exacerbations. These plans should improve the confidence and knowledge for people with COPD. Treatments and plans including inhaler technique and onward referral for exercise interventions should be revisited at every review. People with COPD should be on the primary care COPD register and should attend a follow-up review in primary care at least once a year, and more often if needed.
- When people have exacerbations of COPD symptoms, they generally present to their GP or emergency department. For people that are hospitalised, there is a risk of readmission. The NACAP COPD clinical audit reports 23.9% of patients are readmitted within 30 days, and 43.2% within 90 days post-discharge, highlighting the importance of effective self-management to prevent exacerbations and readmissions.

NICE

CG: clinical guideline; COPD: chronic obstructive pulmonary disease

Digitally supported self-management technologies for COPD

- Digital technologies to support self-management will be multicomponent interventions that are tailored to the individual person's needs.
- Features may include personalised plans for preventing worsening outcomes, tracking patient reported outcomes, providing bespoke education, medication reminders for adherence, managing and monitoring exacerbations, facilitating information sharing amongst care providers, enabling communication with healthcare professionals, encouraging regular exercise, trigger identification, and smoking cessation advice.
- Digitally supported self-management technologies for COPD are intended to be an extra option for clinicians and people with COPD who are eligible. It is not intended to replace all face-to-face appointments in the care pathway completely.
- Virtual wards and pulmonary rehabilitation have not been considered as they are outside of the scope.
- NICE NG115 states that COPD care should be delivered by a multidisciplinary team. Current standard care involves in-person monitoring and non-digital self-management plans.

Decision problem

PICO	
Population	Adults with a confirmed diagnosis of COPD
Subgroups	• People that have been discharged following an acute exacerbation (non-virtual ward use)
Intervention	Digital technologies to support self-management of COPD
Comparator	Standard care for COPD which could include self-management without digital support
Key Outcomes	Intermediate measures including adherence Clinical outcomes including respiratory function, exacerbations, hospital admissions, Patient-reported outcomes including HRQoL Costs (from NHS and Person Social Services perspective)

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For full decision problem see the final scope

HRQoL: health-related quality of life

Features of included technologies

Technology	Exercise	Education	Communication with clinical staff via technology	Symptom or other outcome tracking by user	Remote monitoring	Individualised self-management plan within tech	Provides virtual ward service
Active+me REMOTE	✓	✓	✓	✓	✓	✓	✓
Clinitouch	✓	✓	✓		✓		✓
COPDhub	✓	✓	✓	✓		✓	
COPDPredict			✓	✓	✓		
Current Health		✓	✓		✓		✓
DOC@HOME			✓	✓	✓		✓
Lenus		✓	✓	✓	✓	✓	✓
Luscii		✓	✓	✓	✓	✓	✓
myCOPD	✓	✓	✓	✓	✓	✓	
patientMpower	✓	✓	✓	✓	✓	✓	✓
SPACE for COPD*	✓	✓	✓	✓		✓	
Wellinks	✓	✓	✓	✓	✓		

- All included technologies provide a different suite of features.
- DOC@HOME and COPDPredict did not provide information, the table was populated using information in the public domain.
- *SPACE for COPD is in the process of being decommissioned but will be replaced with a new website

AHP: allied health professional

COPD and supported self-management

- COPD includes chronic bronchitis and emphysema. COPD mainly affects older adults who smoke. Breathing problems tend to worsen over time and limit ability to undertake daily activities and people with COPD have a lower life expectancy. COPD is more common in areas with higher deprivation and more common in men than in women.
- Breathing problems experienced with COPD tend to get worse over time and can limit a person's ability to undertake daily activities. Treatment can help keep the condition under control and includes stopping smoking, inhalers and tablets, pulmonary rehabilitation, and surgery.
- COPD management costs NHSE £800 million per year and 1 in 8 emergency hospital admissions in the UK are attributable to COPD (NHS England).

Current management overview

- NICE NG115 states that COPD care should be delivered by a multidisciplinary team. Current standard care involves in-person monitoring and non-digital self-management plans.
- Non-digital self-management plans with education and tailored action plans for exacerbations; aims to boost patient confidence and COPD knowledge.
- Management should include regularly reviewing treatments, inhaler technique; people should get at least annual primary care reviews.
- For people who have been hospitalised after an exacerbation, care bundles are provided to prevent readmissions; however, readmission rates remain high.
- There is an emerging need for digital technologies in COPD care to enhance self-management, prevent exacerbations, reduce hospitalisations and readmissions, and increase medication adherence.

Digitally supported self-management technologies

- Digitally supported self-management technologies for COPD could improve chronic disease management by enabling self-monitoring, early detection of exacerbations, allowing the person with COPD to better distinguish between a true COPD exacerbation and a variation from their baseline health, improved medication adherence, access to educational resources, and data-driven decision-making with input from users and clinicians. Digital technologies for supported self-management have a lot of varying features.
- Digitally supported self-management technologies may be considered for use in different parts of the respiratory pathway. People may initially access the technology at the point of diagnosis, during a routine or non–routine primary care appointment, or as part of a discharge bundle.
- Offering digitally supported self-management as an option to adults with COPD could improve access, engagement and adherence to self-management plans. These technologies may reduce primary and secondary care resource use whilst optimising care for people with COPD by reducing exacerbations and hospitalisations.

Technologies must:	Technologies must not:
Be intended for adults with COPD	Be specifically for virtual ward use only
Include multicomponent, multidisciplinary interventions that are tailored to the individual person's needs	
Facilitate the delivery of a supported self-management programme	
Have appropriate regulatory and DTAC approval	

Included technologies and intended benefit

12 digital supported self-management technologies for COPD were included in the assessment:

- Active+me REMOTE
- Clinitouch
- COPDhub
- COPDPredict
- Current Health
- DOC@HOME
- Lenus
- Luscii
- myCOPD
- patientMpower
- SPACE for COPD
- Wellinks

- Submissions were received from 10 companies. COPDPredict and DOC@HOME did not respond to requests for information.

- SPACE for COPD will cease to be available but will be replaced with a new website. It has been included in this evaluation because the technology is within scope.

- All included technologies are intended to be an additional option for people with COPD who are eligible and not to replace standard care outright.

Submissions from patient and professional organisations

- No submissions were received from patient organisations or from professional organisations

Lay member views

The following 3 slides have been provided by the lay members.

Perspective of people with lived experience. What self-management of COPD involves for patients (1)

The following slides:

- Key experience and information COPD patients could benefit from support of digital technologies and
- Some examples of benefits to patients.

Some examples of key issues that are important to patients:

- Access
- Ease of Use
- Privacy and Security
- Costs (capital and recurring)
- Compatibility with other NHS systems used by patients (e.g Oximeter, BP, NHS App, etc..)

Perspective of people with lived experience (2)

- Medicines Management
- Self-monitoring access to information on medicines
- Self-education: Knowledge development
- Monitoring our environment
- Keeping active

Perspective of people with lived experience (3)

- Communication: (two way) with GPs, community services, hospitals (consultants, diagnostic services, administrators)
- Planning (daily/weekly/monthly)
- Diet management:
- Managing mental wellbeing:

Clinical evidence review

NICE National Institute for Health and Care Excellence

Clinical evidence summary

- 32 studies were identified as relevant and 14 were prioritised for inclusion in the review for 9 technologies:
  - Active+me REMOTE: 1 prospective case series
  - Clinitouch: 2 before-after studies
  - COPDhub: 1 retrospective case series
  - COPDPredict: 1 before-after study
  - Lenus: 1 prospective matched study and 1 [redacted]
  - Luscii: 2 studies, 1 before-after study and 1 retrospective case series
  - myCOPD: 2 RCTs
  - SPACE for COPD: 1 prospective cohort
  - Wellinks: 2 studies, 1 prospective case series and 1 before-after study
- No evidence relevant to the scope was identified for Current Health, DOC@HOME or patientMpower.
- Outcomes reported: Respiratory function, exacerbations, hospital admissions, ED visits, GP visits, inhaler use, patient experience, psychological wellbeing.

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Prioritised studies

Technology	RCTs	Cohort	Before-after	Case series
Active+me REMOTE	0	0	0	1 prospective (Auton KAA et al. 2024)
Clinitouch	0	0	2 prospective (Ghosh 2018; NHS 2022b)	0
COPDhub	0	0	0	1 retrospective (The Institute of Clinical Science and Technology 2023)
COPDPredict	0	0	1 prospective (Patel et al. 2021)	0
Lenus	0	1 prospective matched (Taylor et al. 2023), 1 [redacted] (Lenus Health Ltd 2024a)	0	0
Luscii	0	0	1 retrospective (All Together Better Sunderland 2021)	1 retrospective (Luscii)
myCOPD	2 prospective (Crooks et al. 2020; North et al. 2020)	0	0	0
SPACE for COPD	0	1 prospective (Houchen-Wolloff 2021)	0	0
Wellinks	0	0	1 prospective (Pierz et al. 2024)	1 prospective (Gelbman and Reed 2022)

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For further details see table 4.1 in the AR: pages 30 to 31

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Characteristics of prioritised studies (1)

	Study design, country	Population	Participants/Setting	Comparator	Key study limitations
Active+me REMOTE	Prospective cohort study but treated as case series as results not reported (Auton et al. 2024), UK	69 32/69 (46%) male Mean age 68.4 (SD 11.8)	People with COPD clinically referred for pulmonary rehabilitation	None	No comparative data provided
Clinitouch	Before-after study (Ghosh, 2018), UK	29	People with COPD, hospital discharged	Care prior to receiving digital technology	Study provides limited information about the participants. Limited information is available about the care received in the before control period
	Before-after study (NHS 2022b), UK	29	People with COPD and ≥2 hospital admissions in the previous 6 months, hospital discharged	Care prior to receiving digital technology	Patients who died before completion of 12 months post-baseline were not included in the analysis. Primary outcome (admissions) not reported for whole population, but for subgroups by adherence
COPDhub	Retrospective case series (The Institute of Clinical Science and Technology 2023), UK	Not reported	All users who completed the COPD Checker between Jan 22 to Oct 23	Usual care	No patient characteristics reported. No comparative data provided

For further details see table 4.2 in the AR: pages 32 to 41

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Characteristics of prioritised studies (2)

	Study design, country	Population	Participants/Setting	Comparator	Key study limitations
COPDPredict	Before-after study (Patel et al. 2021), UK	90 45/45 (50%) male Age range 48-91	People with COPD, a history of frequent exacerbations, at least one COPD-related hospitalisation in the preceding 6 months but clinically stable, exacerbation free for 6 weeks prior to enrolment	Care prior to receiving digital technology	Limited information is available about the care received in the before control period
Lenus	Prospective cohort study (Taylor et al. 2023), UK	478 I: 83 63.9 % female, mean age 64.4 (SD 9.3) C: 415 63.9% female, mean age 64.6 (SD 9.1)	I: People with severe COPD requiring hospitalisation in previous 12 months C: People with COPD or respiratory-related admission in the 7-days up to the onboarding date of the matched RECEIVER participant.	Care prior to receiving digital technology	Care in control arm unclear; control arm gathered from anonymised dataset; only intervention criteria applicable was not receiving a COPD digital service
	[redacted] (Lenus Health Ltd 2024a), [redacted]	[redacted]	I: [redacted] C: [redacted]	[redacted]	[redacted]

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Characteristics of prioritised studies (3)

	Study design, country	Population	Participants/Setting	Comparator	Key study limitations
Luscii	Before-after study (All Together Better Sunderland 2021), UK	30	30 people with COPD onboarded to Luscii between February and November 2020 and who were users of the Luscii system for at least 7 days during that period	Care prior to receiving digital technology	Only included patients who used system for at least 7 days Admissions data is presented per referral, rather than per patients (130 referrals in 30 patients) Authors note the impact of the COVID-19 response will have affected the evaluation
	Retrospective case series, (unpublished),UK	186	186 people with COPD	None	Unpublished presentation No comparative data provided
myCOPD	RCT (Crooks et al. 2020), UK	60 I: 29 11/29 (37.9%) male, mean age 65.9 (SD 7.3) C: 31 20/31 (64.5%) male, mean age 66.4 (SD 7.0)	People with either mild–moderate COPD (defined by FEV1/forced vital capacity) or COPD of any severity diagnosed within the past 12 months, no exacerbation in the previous 4 weeks	Standard care; patients continued with their current NHS management in line with national and local guidelines	Groups were unbalanced at baseline - myCOPD group had a higher symptom burden, significantly lower physical activity levels, and significantly higher exacerbation frequency than controls. This may have favoured the comparator. Small sample size, limited power to test effectiveness. Authors reported intention-to-treat analysis used, but patient withdrawals after randomisation but before commencement are not included, considered per protocol

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Characteristics of prioritised studies (4)

	Study design, country	Population	Participants/Setting	Comparator	Key study limitations
myCOPD	RCT (North et al. 2020), UK	41. I: 20, 13/20 (65%) male, age mean 65.1 (SD 6.3). C: 21, 11/21 (52%) male, age mean 68.1 (SD 7.4)	People with COPD recruited after being discharged from hospital following an acute exacerbation	HealthQuest written self-management plan, a 1-page document which contains a written self-management plan	Study is not sufficiently powered to demonstrate effects on all measured outcomes
SPACE for COPD	Prospective cohort (Houchen-Wolloff, 2021),UK	287. Mean age 66.4 (10.2). I: 32, C: 192	Patients with a spirometry diagnosis of COPD. AECOPD setting	Telephone support with home exercise and education booklet	Conference abstract. Significant difference in study completion between cohorts
Wellinks	Prospective case serie (Gelbman & Reed 2022), USA	19. 9/19 (47%) male, mean age 79.6 (range 65 to 95)	Over 30 years old, prescribed a regimen that included nebulisers	None	No comparative data provided
	Before-after study (Pierz et al. 2024), USA	141 63/141 (44.7%) male, mean age 70 (SD 7.6)	People with mild or moderate COPD recruited through COPD patient network and newsletters	All participants received Wellinks for 12 weeks. Week 12 to 24, participants assigned to: Arm 1: Wellinks or Arm 2: Wellinks without health coaching	Limited information is available about the care received in the before control period. This comparator was considered ineligible therefore the study was included as a before-after study. Admissions data is reported for the 3 months prior to baseline for care prior to receiving the digital technology.

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Clinical evidence: EAG critique

- 14 prioritised studies assessed 9 digital health technologies; 11 studies were comparative with 2 RCTs (for myCOPD).
- There were no included studies that compared multiple scoped technologies.
- 12 studies were UK-based apart from 2 studies for Wellinks (USA).
- Details of usual care were not generally adequately reported affecting generalisability.
- 9 studies reported COPD severity, 7 studies exclusively included AECOPD population.
- Samples were often not adequately powered in the randomised controlled trials for appropriate clinical outcome measures.
- Significant heterogeneity between the features of different technologies, so evidence may be poorly generalisable across studies of different interventions.
- The outcomes were reported inconsistently and across a wide range of measures making it difficult to draw any meaningful conclusions across the data. Where more than 1 comparative study reported the same outcome measure, no consistent differences were found across studies.
- Evidence was not available for each technology for each priority scoped outcome domain. The data was limited for quality of life, respiratory function, GP visits, exacerbation and hospitalisation outcomes.

AECOPD: Acute exacerbations of COPD

For further details see AR pages 42 to 52

Severity of COPD in included studies (1)

- All included participants had COPD - diagnosed by GOLD criteria, spirometry, forced expiratory volume, or Medical Research Council dyspnoea score.
- 9 studies reported COPD severity.
- 1 RCT (myCOPD) focused on people with mild or moderate COPD or those within 12 months of diagnosis, including 23.3% with mild and 76.7% with moderate COPD (Crooks et al. 2020).
- 1 prospective case series (Wellinks) reported a range of COPD severities, mild to very severe (Gelbman and Reed 2022).
- 7 studies included patients with severe COPD, including;
    - 1 RCT (myCOPD) by North et al. (2020), [redacted], 1 prospective cohort study (SPACE for COPD) by Houchen-Wolloff (2021) and 3 before-after studies (COPDPredict and Clinitouch) by Ghosh (2018), Patel et al. (2021), and NHS (2022b) did not explicitly report severity but included participants with at least one COPD-related hospitalisation in previous 6 to 12 months, classifying them as severe under GOLD criteria
    - 1 Lenus matched prospective cohort study, Taylor et al. (2023), involved patients with severe COPD. All participants had been hospitalised in the previous 12 months and/or exhibited chronic hypercapnic respiratory failure or sleep-disordered breathing.

GOLD: The Global Initiative for Chronic Obstructive Lung Disease

For further details see AR pages 43 to 44

Severity of COPD in included studies (2)

- People referred to self-management following hospitalisation for acute exacerbations were a subgroup of interest in the scope, with six studies exclusively including this population:
- 1 RCT (myCOPD) included AECOPD patients within 2 weeks of discharge (North et al. 2020).
- 1 matched prospective cohort study (Lenus) included people hospitalised within the previous 12 months (Taylor et al. 2023).
- [redacted] (Lenus Health Ltd 2024a).
- 1 before-after study (COPDPredict) included people hospitalised within the previous 6 months, though exacerbation-free for at least 6 weeks (Patel et al. 2021).
- 1 before-after study (Clinitouch) included people hospitalised in the previous 12 months (Ghosh 2018).
- Another before-after study (Clinitouch) included people hospitalised in the previous 6 months (NHS 2022b).
- 1 RCT aimed to evaluate myCOPD in a mild or moderate COPD population but included 1 outlier (AECOPD) who was discharged within the previous 3 months (Crooks et al. 2020).
- 1 prospective cohort study (SPACE for COPD) (Houchen-Wolloff 2021) did not report severity, but the company clarified that the study recruited an AECOPD population (not further defined), and therefore has been considered to include patients with severe COPD.
- Settings of remaining studies were not clearly reported, considered to have mixed or unclear setting.

AECOPD: Acute exacerbations of COPD

Interventions used in included studies

- Within the scope there is potential for significant heterogeneity. Technologies were described in detail which reported multi-component devices that included at least 2 of the following features:
    - Symptom monitoring, educational content, self-management planning and healthcare practitioner contact.
    - 2 RCTs (myCOPD) (Crooks et al. 2020, North et al. 2020), 3 prospective cohort studies (Active+me REMOTE, Lenus) (Auton et al. 2024, Taylor et al. 2023, Lenus Health Ltd 2024a), 5 before-after studies (Clinitouch, COPDPredict, Luscii, Wellinks) (Pierz et al. 2024, Patel et al. 2021, All Together Better Sunderland 2021, Ghosh 2018, NHS 2022b) and 1 prospective case series (Wellinks) (Gelbman and Reed 2022).
- In the remaining studies (reported as conference abstracts) the content of the digital health technologies was not clearly reported. 1 prospective cohort study (Houchen-Wolloff 2021) and 2 retrospective case series (COPDhub, Luscii) (ICST 2023, Luscii) reported only the technology name.
- The EAG noted that these technologies may vary in terms of which components are used in different study contexts, as well as the components themselves varying across different versions of a technology. Evidence may therefore be poorly generalisable across studies of different interventions.
- Only 2 studies explicitly reported that the digital technology was administered alongside standard care (Active+me REMOTE, [redacted]) (Auton et al. 2024, [redacted]).

For further details see AR pages 44 to 48

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Comparators used in included studies

- Of the 11 comparative studies, EAG considered 2 to fully meet this component of the decision scope - comparing digital interventions to various forms of standard care for COPD. These were RCTs for myCOPD, comparing myCOPD to usual NHS management guidelines (Crooks et al. 2020) and to HealthQuest written self-management plan, a plan that can be personalised (North et al. 2020).
- 2 cohort studies compared a group of patients who received the [redacted] technology with a cohort using anonymised patient data, for whom no comparative details were reported apart from not receiving [redacted] (Taylor et al. 2023, [redacted]).
- 5 before-after studies reported data from their included participants prior to beginning care with the respective digital interventions (COPDPredict, Luscii, Clinitouch, Wellinks) (Patel et al. 2021, All Together Better Sunderland 2021, Pierz et al. 2024, Ghosh 2018, NHS 2022b). These studies did not clearly report what previous care consisted of but considered to comprise standard care in the extraction and synthesis.
- Standard care (where described) differed between studies, and included written self-management booklets, self-management booklets with regular telephone support and education. Several studies did not report the content of 'standard care'. So, it may be difficult to understand how generalisable the findings of comparative studies are to different NHS settings.

For further details see AR pages 48 to 49

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Impact of COVID-19 pandemic

- Studies varied in overlap with the COVID-19 pandemic, with some having unclear timelines. The pandemic's impact on chronic respiratory patients adds uncertainty to results as it is known to have impacted on people with chronic respiratory disease in numerous ways, so studies conducted during the pandemic may be less generalisable to the post-pandemic NHS setting. Pre-pandemic studies may not reflect current NHS practice with increased remote care.
- 5 studies were completed before the start of the pandemic in March 2020 (myCOPD, Clinitouch, COPDPredict) (Crooks et al. 2020, Patel et al. 2021, North et al. 2020, Ghosh 2018, NHS 2022b).
- 2 studies did not clearly report dates between which data was collected, so the extent to which they overlapped with the pandemic period is unclear (Luscii, Auton KAA et al. 2024).
- 4 studies were conducted in the years during or immediately following the pandemic period (between 2021 and 2023) and did not discuss any effect this might have had on results (Pierz et al. 2024, The Institute of Clinical Science and Technology 2023, [redacted], Gelbman and Reed 2022).
- 2 studies that began prior to COVID-19 coincided with the onset of the pandemic. The authors discuss the effects this may have had on results (Taylor et al. 2023, All Together Better Sunderland 2021).

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Clinical evidence: clinical outcomes (1)

- Limited evidence for respiratory function, measured using different tools at different timepoints.
- 5 studies reported respiratory function outcomes; CAT (COPD assessment test), modified Medical Research Council (mMRC) dyspnoea scale and St George Respiratory Questionnaire (SGRQ) for an AECOPD population, including 1 UK RCT (myCOPD) and 2 UK before-after studies (Clinitouch), 2 cohort studies (Lenus, SPACE for COPD).
- CAT score:
    - myCOPD: No significant difference for myCOPD in the per protocol population, but longitudinal analysis across all timepoints showed statistically significant improvement for myCOPD.
    - Clinitouch: Statistically significant improvement after a mean period of 222 days.
    - Lenus: Median CAT score stable over study period.
    - SPACE for COPD: Statistical and clinically significant improvements in CAT scores in both treatment arms (telephone monitoring and SPACE for COPD) after 6 weeks.
- MCID:
    - myCOPD: Similar MCID with SOC (improvement of at least -2) at 90 days.
    - Clinitouch: 9/23 patients had a reduction of >5% at the end of follow up.
- mMRC and SGRQ: myCOPD had no significant differences in scores at 90 days.

AECOPD: Acute exacerbations of COPD, MCID: minimal clinically important difference, SOC: standard of care

For further details see AR : pages 53 to 54

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Clinical evidence: clinical outcomes (2)

- 4 studies in mixed population settings that reported respiratory function outcomes, including 1 RCT (myCOPD), 2 prospective case series (Active+me REMOTE, Wellinks) and 1 retrospective case series (COPDhub).
- CAT score:
    - myCOPD: No significant difference in CAT scores between myCOPD and SOC after 90 days.
    - Active+me REMOTE: Statistical and clinically significant improvement in CAT scores from baseline to 8 weeks.
- mMRC Score:
    - Wellinks: USA study, 31.6% of patients showed improvement in MRC scores; the majority saw no change, a minority worsened.
    - Active+me REMOTE: Statistically significant mean improvement in MRC from baseline to 8 weeks.
- Inhaler use: COPDhub reported an increase of 41% in number of patients who did not use an inhaler every day from baseline to 21 months.

CAT: COPD assessment test, mMRC: modified Medical Research Council, SOC: standard of care

For further details see AR : pages 53 to 54

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Clinical evidence: clinical outcomes (3)

- Respiratory function (Active+me REMOTE, Clinitouch, COPDhub, myCOPD, SPACE for COPD, Wellinks):
  - CAT, mMRC: statistically and clinically significant improvement for interventions and MCID. No statistically significant difference for the myCOPD CAT score in the per protocol population, but longitudinal analysis across all timepoints showed statistically significant improvement.
  - SGRQ: myCOPD reported no statistically significant differences.
  - Inhaler use: COPDhub showed an increase of people who did not require an inhaler every day.
- Daily activity (COPDhub, myCOPD):
  - Improvement in physical activity but not statistically significant.
- Exacerbations (COPDPredict, Lenus, myCOPD):
  - Majority of studies found no statistical difference between groups, some studies did not report exacerbations in the SOC group. One study showed a statistically significant increase in the number of exacerbations at 90 days experienced by patients compared to SOC in a UK RCT, but authors noted an imbalance in baseline groups which may overestimate the effect of SOC (myCOPD).

CAT: COPD assessment test, MCID: minimal clinically important difference, mMRC: modified Medical Research Council, SOC: standard of care

For further details see AR : pages 53 to 56

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Clinical evidence: clinical outcomes (4)

- Hospital admissions, readmissions or emergency admissions (Active+me REMOTE, Clinitouch, COPDPredict, Lenus, myCOPD):
  - 1 study reported a [redacted] whilst others reported no statistical difference (myCOPD, Luscii, Wellinks).
  - 1 study in unclear treatment setting reported reduction in all cause ED visits, outpatient clinical visits (GP visits) but not tested statistically.
  - In the AECOPD population, reductions seen in intervention groups. No significant difference in COPD-related readmissions at 90 days (myCOPD). [redacted] Before and after studies showed a reduction in admission/visits (COPDPredict, Clinitouch). All-cause admissions significantly reduced when using digital technology (Clinitouch, [redacted]).
- Additional medication required (myCOPD):
  - 1 RCT reported antibiotic/steroid use but, did not conduct any within-group or between-group comparison.
- Inhaler technique (myCOPD):
  - 2 UK RCTs reported data on the optimisation of inhaler technique using the rate of critical inhaler errors, 1 RCT showed a statistically significant reduction when using myCOPD compared to standard care.

NICE

AECOPD: Acute exacerbations of COPD

For further details see AR : pages 56 to 60

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Clinical evidence: clinical outcomes (5)

- Adherence (Active+me REMOTE, COPDPredict, myCOPD, SPACE for COPD, Wellinks):
  - In the mixed population, 1 study had comparator completion rate statistically significantly higher in the telephone support arm (56%) compared to the intervention (30%) (SPACE for COPD).
  - Activation rate for digital tech was 86% (Active+me REMOTE, myCOPD).
  - Daily use ranged 2.4 to 3.4 days per week (Active+me REMOTE, myCOPD).
  - Notable reduction in weekly app entries for medication, oximetry, and spirometry over 8 weeks (Wellinks).
  - 80% patients completed a COPD assessment test score entry each week at 12 months (Lenus).
  - In the AECOPD population the adherence ranged 40% to 98% (COPDPredict, Lenus, myCOPD). Usage ranged 4.3 to 5.6 days per week on average over 12 weeks (myCOPD).

AECOPD: Acute exacerbations of COPD

For further details see AR : pages 60 to 61

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Clinical evidence: patient reported outcomes

- Health-related quality of life (EQ-5D) (Active+me REMOTE, myCOPD, SPACE for COPD):
  - 1 study reported this in AECOPD population with stable VAS scores across study period (Lenus). No comparative evidence suggesting digital technologies superior to standard care in improving HRQoL outcomes (myCOPD). Statistical improvement in Chronic Respiratory Questionnaire (CRQ) from baseline to 8 weeks with clinically significant improvement in dyspnoea (Active+me REMOTE), and statistically significant improvements within groups (SPACE for COPD).
- Patient experience, useability and acceptability (Luscii, Wellinks):
  - Users overall satisfied (mean 4.6 out of 5) with digital technology (Luscii). Digital technologies easy to use (Luscii, Welllinks) and preferred over usual care (77% preferred Luscii, 23% had no preference). Users agreed (83%) that technologies helped people to learn more about COPD (Wellinks).
  - NICE public involvement programme summarised in the MTAC guidance for myCOPD, patients found the technology easy to use and improved their understanding and self-confidence in managing their condition
- Psychological wellbeing (Active+me REMOTE, myCOPD, Wellinks):
  - 1 RCT reported no difference in the Hospital Anxiety and Depression Scale (HADS) or Patient Activation Measure (PAM) score in AECOPD population (myCOPD). In the mixed setting, there was statistically significant improvement in baseline in HADS but not PAM (Active+me REMOTE). Improvement seen with digital technology for COPD Self-Efficacy Scale (Wellinks).

AECOPD: Acute exacerbations of COPD, EQ-5D: EuroQol – 5 dimension

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Clinical evidence: Adverse events, clinical risk, withdrawals and discontinuation

- myCOPD:
  - AE: In a mixed setting, n=5 in myCOPD, n=7 in SOC. In AECOPD setting, n=3 in myCOPD n=1 in SOC.
  - Withdrawals: In a mixed setting n=7 (29 participants) myCOPD, n=2 (31 participants) SOC. In AECOPD setting, n=3 (20 participants) myCOPD and n=3 SoC (21 participants).
- Active+me REMOTE:
  - AE: In a mixed setting n=46 AE n=2 SAE. Author states SAEs not due to technology. 1 participant died during follow up.
  - Withdrawals: n=23 lost to follow up (69 participants).
- Wellinks:
  - AE: 2 studies reported no AE for Wellinks (160 participants).
  - Withdrawals: n=11 lost to follow up comparing Wellinks and Wellinks with coaching (141 participants).
- Lenus:
  - AE: [redacted] In another study lower mortality rate in Lenus compared to SOC at 3 months.
  - Withdrawals: n=3 Lenus withdrawals (83 participants).
- Clinitouch: reported deaths in before/after study in AECOPD population.
- COPDPredict: no AE reported, and no deaths reported in AECOPD population (90 participants).
- No deaths are reported to be related to the intervention.

For further details see AR pages 64 to 67

AECOPD: Acute exacerbations of COPD;
AE: adverse event; SAE: serious adverse event

Clinical evidence: key results for each technology (1)

- myCOPD (2 prospective randomised controlled trials):
  - Respiratory function, health-related quality of life, admissions, exacerbations: generally comparable outcomes between groups. Changes in CAT scores met MCID (of -2 points) in intervention arm. Similar number of hospital admissions, ED visits and exacerbations between groups. 1 study had statistically significant higher exacerbations than SoC but imbalance in baseline characteristics. Improvement in inhaler technique noted in 1 RCT. The NICE public involvement programme reported that technology easy to use, improved understanding and self-confidence, and 66.1% users felt there had been a reduction in the number of exacerbations.
  - Compliance: 40% (North et al. 2020) and 4.3 – 5.6 days per week (Taylor et al. 2023).
- Active+me REMOTE (1 prospective case series):
  - Health-related quality of life, respiratory function: significant improvements in CAT, MRC, and CRQ scores over 8 weeks. No change in EQ-5D-5L.
  - Compliance: 51% (28.9 days use over 8 weeks).
- Clinitouch (2 prospective before/after):
  - Respiratory function, admissions: significant improvements in CAT scores and reduced all-cause admissions.
  - Compliance: Usage patterns varied.

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Clinical evidence: key results for each technology (2)

- COPDhub (1 retrospective case series):
  - Respiratory function, daily activity: decrease in daily inhaler use over 21 months compared to baseline and increase in regular physical activity.
- COPDPredict (1 prospective before/after):
  - Exacerbations, admissions: most users experienced mild-moderate exacerbations with a statistically significant reduction in the rate of exacerbation-related ED visits.
  - Compliance: 98% (daily assessment completed).
- Lenus (1 prospective and 1 [redacted]):
  - Admissions: significant reduction in COPD related admissions, all cause admissions/ED visits. Time to first COPD or respiratory-related admission or death was statistically significantly increased vs control.
  - Compliance: 80% (weekly assessment completed each week at 12 months).
- Luscii (1 retrospective before/after and 1 retrospective case series):
  - Admissions, GP visits, patient experience: reduction in COPD and all-cause ED visits, and primary care visits. Users satisfied with technology and preferred over usual care.
- SPACE for COPD (1 prospective cohort study):
  - Respiratory function: statistically and clinically significant improvement from baseline to 6 weeks.
  - Compliance: 30% (compliance higher in comparator telephone support arm which was 56%).

Clinical evidence: key results for each technology (3)

- Wellinks (1 prospective before/after and 1 prospective case series):
  - Respiratory function, admissions, patient experience, psychological wellbeing: majority didn't experience improved respiratory function (mMRC), rates of COPD admissions and ED visits not compared statistically.
  - Evidence from the USA so potentially poorly generalisable to the UK NHS context.
- No evidence identified for Current Health, DOC@HOME and patientMpower.

Economic evidence

A total of 5 economic costing studies and one economic model were identified that report evidence in the UK, in an NHS context. The studies and economic model report potential costs savings for myCOPD, Luscii, Lenus and Clinitouch due to averted A&E attendance and admissions. The quality of the evidence was generally low and there are uncertainties in the evidence base.

Study ID and location	Timeframe	Population Size	Study Type	Summary
myCOPD Davies et al. (2023), England and Wales	1-year horizon	Not reported	Costing model	Costs range from savings of £1,785,878 to increases of £69,530 per CCG. Key factors: readmission rates, technology uptake
Luscii All Together Better (2021), UK	9 months	130 referrals	Costing model	Savings up to £43,632 per CCG; reduced A&E and admission costs by 7% and 47%
Clinitouch Ghosh et al. (2016 & 2018), UK	Unclear	54 and 28	Costing model	2016 study saved £243,303; 2018 expansion saved £64,519 per CCG. Issues with control groups and high service users
Clinitouch Chorley and South Ribble CCG/Greater Preston CCG (2022), UK	6 months	22	Costing model	Found savings of £2,304 per person, total NHS savings of £90,128 per CCG
Lenus Health COPD Support Service YHEC (2023), UK	Not reported	Not reported	Early cost-effectiveness model	The results suggest a cost saving of £1,691 per person and a QALY gain of 0.03 per person. Hospital admission rates are a critical factor. The ICER is dominant, the net health benefit is 0.11 and the net monetary benefit is £2,238.

For further details see AR : pages 71 to 76

Conceptual model: Cost-comparison

• EAG developed a simple cost-comparison model to assess the potential benefits of digital technologies for managing COPD over a one-year period. This model focuses on estimating resource uses such as GP visits, non-hospitalised exacerbations, and hospitalisations, intentionally excluding costs for mortality to avoid double-counting.

• Effectiveness of the digital technologies is evaluated based on potential reductions in resource use. Deterministic Sensitivity Analysis was conducted using a tornado diagram to identify key drivers, while a Probabilistic Sensitivity Analysis, which stabilised after 500 of 1,000 simulations, adjusted inputs by a standard error of 20% when specific data was lacking.

• Economically Justifiable Price (EJP) was calculated, but the results are considered indicative due to uncertainties extending beyond the model's one-year focus.

• The model does not include training costs for patients, which could be significant, especially for those unfamiliar with such devices. It also omits the costs of mobile devices and internet access, essential for utilising digital technologies, and assumes uniform costs for medical devices across treatment groups, which may not reflect true cost differences.

• Set up costs to NHS include but are not limited to staff training, registration, licenses and software and monitoring costs.

For further details see AR : pages 77 to 84

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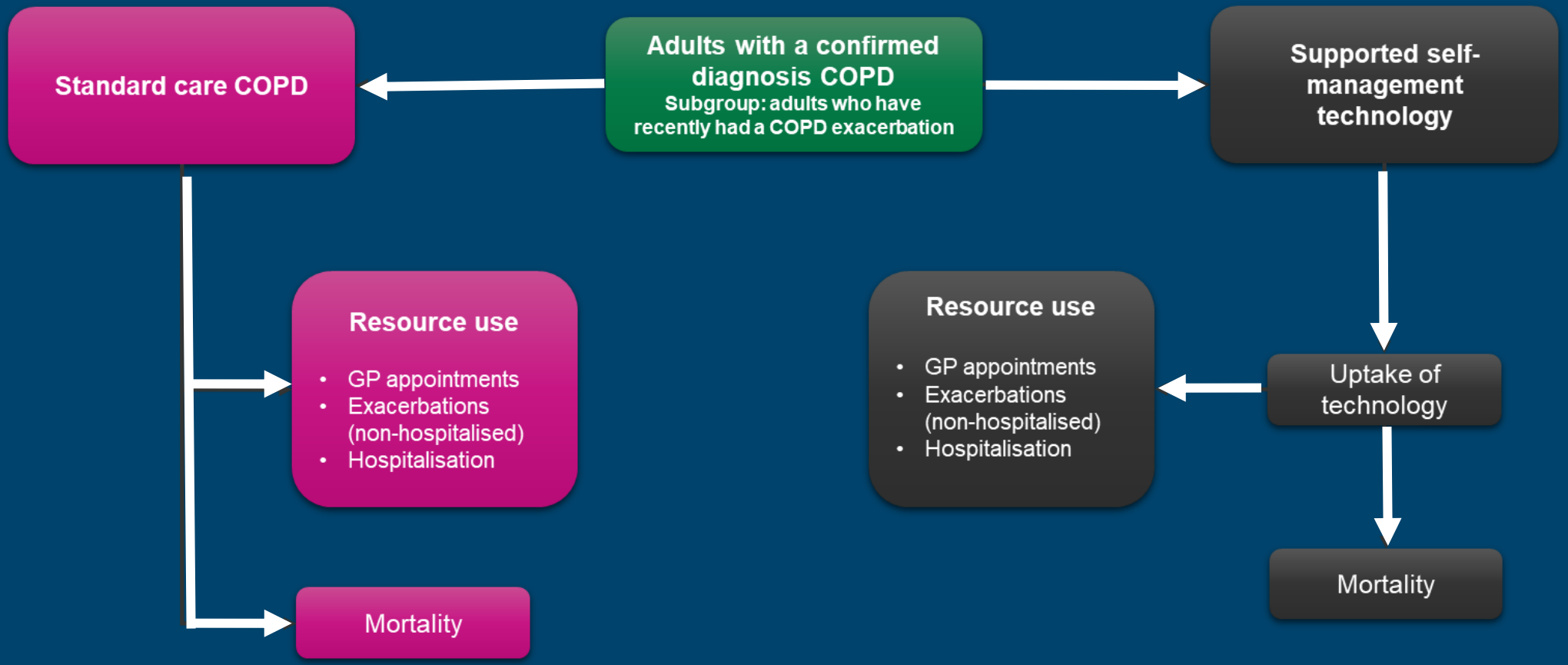
Conceptual model: Cost-comparison



Conceptual model: Assumptions and limitations (1)

Assumption	Limitation
Scaling costs	Costs for digital technologies can be scaled based on metrics like GP and ICS sizes, though variability in GP sizes could lead to cost discrepancies across regions
Waiting time impacts	While reduced waiting times are a key advantage of digital technologies, their economic benefit is not separately quantified to avoid double counting, as these are assumed to be incorporated in the resource usage data
Medical devices	Model does not account for costs and usage of medical devices associated with COPD self-management due to lack of standardisation and evidence, assuming homogeneity in intervention and comparison
Double counting resource use	Potential overlap in counting GP appointments and non-hospitalised exacerbations. Model retains existing proportions to avoid missing data on urgent care needs
Inhaler use	Improvements in inhaler technique, which might reduce need for inhalers, are not explicitly modelled. Any reductions in costs from fewer inhalers used are not captured, rendering the model conservative
Long-term outcomes	Model's 1-year time horizon does not capture long-term outcomes of treatment due to limited evidence with extended follow-up, potentially undervaluing longer-term benefits

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Conceptual model: Assumptions and limitations (2)

Assumption	Limitation
Linear Scaling of Outcomes	Clinical outcomes are linearly scaled to a 1-year horizon based on shorter follow-up periods, which may not accurately reflect annual resource use or the full impact of digital technologies
Population Differences in Studies	Evidence base includes mixed populations, with some post-acute exacerbation and others from a broader COPD cohort, which could affect applicability of results
Baseline Resource Use from Severe Cases	Baseline data derived from studies focusing on severe COPD cases may overestimate impact on general COPD population, which varies in severity

Economic evaluation: base case results

Simple cost-comparison model used to evaluate potential economic benefits of digitally supported technologies for COPD management

- Potential cost savings: Analysis indicates a potential cost saving of £337 per person when using digital technologies compared with standard care.
- Evidence base: Results derived from mixed and uncertain evidence provided by different technology companies.
- Major uncertainties:
    - Impact of digital technologies on healthcare resource use, especially hospitalisations.
    - Variations in technology features which may affect their effectiveness.
- Evidence characteristics: predominantly data from severe COPD populations, suggesting a higher potential benefit, particularly for those recently experiencing acute exacerbations.
- Limitations in subgroup analysis: due to limited evidence, specific outcomes for post-acute exacerbation subgroup could not be clearly separated in modelling.

For further details see AR : pages 95 to 101

Results from the economic modelling

	Digitally supported self-management for COPD	Standard care	Incremental
Cost per ICS	£68,316,556	£74,043,426	-£5,726,870
Cost per person	£4,018	£4,355	-£337
Deaths per ICS	271	365	-94

Table 8.10: Deterministic base-case results 1 year time horizon (from EAG report)

	Digitally supported self-management for COPD	Standard care	Incremental
Total cost of technology	£283	£0	£283
Cost of hospitalisations	£3,309	£3,770	-£461
Cost of non-admitted exacerbations	£123	£211	-£88
Cost of GP appointments	£303	£374	-£71
Total	£4,018	£4,355	-£337

Table 8.11: Cost breakdown per person per year (from EAG report)

Variable	Value	Variable	Value
Number of exacerbations per person	3.10 4.21 post-acute exacerbation	Relative risk for exacerbations	0.581
Number of GP appointments per person	9.13	Relative risk for GP appointments	0.810
Number of hospitalisations per person	1.56	Relative risk for hospitalisations	0.878

Table 8.4: Resource Use and Efficacy Parameters

ICS: Integrated Care System

Future conceptual model

Limited evidence was available to model the potential impact of digitally supported technologies for self-management of COPD for all companies. A future model could be developed to support decision-makers with:

- capturing subgroups through stratified by baseline CAT or GOLD score
- capturing HRQoL through stratified CAT or GOLD score
- capturing mortality in greater detail
- understanding the potential long-term impact of digitally supported technologies for the self-management of COPD, in terms of resource use and HRQoL.

CAT: COPD assessment test, GOLD: Global Initiative for Chronic Obstructive Lung Disease, HRQoL: Health-Related Quality of Life

For further details see AR : pages 130 to 131

Scenario analyses for intervention

Scenario description	EAG description	Incremental cost
EAG base case	-	-£337
Highest cost of a digital technology (deterministic result)	Cost of digital technology set to [redacted], which is highest total cost of the digital technologies included as part of the model in the base case.	£620
Lowest cost of a digital technology (deterministic result)	Cost of digital technology set to [redacted], which is lowest total cost of the digital technologies included as part of the model in the base case.	-£503
Number of exacerbations varied to greater reflect post-acute exacerbation subgroup data	Number of exacerbations set to 4.21 for standard care, and 2.45 for intervention. This value is referenced in Table 8.4 of the EAG report (Resource Use).	-£368
Alternative relative risk for GP appointments	Relative risk of 0.66 applied for reduction in GP appointments. This value is from company submissions: Sunderland Luscii Evaluation Report which reported a reduction in primary care usage of 34%.	-£393
Relative risk of hospitalisation set to 1	Relative risk of 1 applied, meaning there is no impact of intervention on hospitalisations.	£124
Weighted relative risk for exacerbations	Relative risk weighted so that it is only applied to initial 90 days. RR assumed 1 for subsequent 9 months. New calculated RR=0.895.	-£271
Alternative value for the relative risk of hospitalisations applied	Relative risk of 0.593 applied based on unadjusted, statistically insignificant figures from RECEIVER trial (Taylor et al. 2023).	-£1,411
Alternative cost of hospitalisation used	Cost of hospitalisation from Davies et al. (Davies H et al. 2023) £1,721 used, based on NHS cost collection 2019/2020. This is because most recent NHS cost collection reflects substantially higher value than previous iterations.	-£204
No NHS staff time for monitoring with technologies	Assumption that no NHS staff time is required for monitoring of people with technologies.	-£417
NHS staff time doubled for monitoring with technologies	Assumption that twice as much NHS staff time is required for the monitoring of people with technologies.	-£257
Uptake lowered for digital technologies	Assumption that 46% (Davies et al. (Davies H et al. 2023) value) of people use digitally supported self-management intervention. This reduces initial cohort in the model.	-£329
Baseline event rates halved	Assumption to reflect potential impact on a milder COPD population, since available evidence is primarily focused on people with COPD suffering high or very high impact based on CAT scores.	-£27

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Summary and interpretation of economic modelling (1)

- Economic model suggests that digital self-management technologies for adults with COPD might be a cost-saving intervention for the NHS. However, results:
    - are indicative and not perfectly representative of all digital technology providers
    - should be approached with caution due to the reliance on naive and limited data
    - primarily reflect outcomes for individuals with more severe COPD, making them less applicable to the broader COPD population
    - include data from some companies with little or no evidence submitted for evaluation, leading to pragmatic assumptions within the model for an assessment.

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Summary and interpretation of economic modelling (2)

- Key drivers: The key factors influencing economic outcomes are the number of hospitalisations per person under standard care and with the technologies, the cost of hospitalisation for COPD-related events, and the costs of the technologies.
- Resource use and evidence limitations: Data used is based on limited evidence primarily focusing on severe COPD cases, making results less generalisable to all people with COPD.
- Cost of technologies: Costs vary among companies, affecting assessment of efficacy when comparing technologies head-to-head based on price alone. EJP was estimated at £620 per person, with some technologies exceeding this.
- Scenarios and sensitivity: Technologies generally remained cost-saving except in scenarios with the highest costs and when there is no impact on hospitalisations. The cost of hospitalisation in the base case was significantly higher than previous estimates, impacting cost-saving potential when recalculated with lower costs.
- Mortality and long-term impacts: The model suggests potential improvements in mortality rates, though evidence is statistically insignificant. Analysis used 1-year time horizon, potentially omitting longer-term benefits such as sustained reductions in resource use or quality of life improvements beyond first year.
- Comparison with previous studies: Previous studies, including those by Davies et al. (2023), align with current model, indicating cost savings primarily driven by reduced hospitalisations.

EJP: Economically Justifiable Price

Interpretation of evidence

- Evidence Base and Quality: Evaluation gathered 31 relevant studies, prioritising 14 for detailed analysis due to their relevance and higher quality. These studies primarily assessed digital technologies in patients discharged after a COPD exacerbation and included a mix of 2 RCTs, 3 cohort studies, and 5 before-after studies
- Efficacy of Digital Technologies: Potential improvements in COPD management using digital technologies, indicated by improvements in CAT scores, inhaler use, and reductions in exacerbations and admissions. However, results are mixed and somewhat inconsistent across different patient populations and studies
- Study Populations and Generalisability: Studies largely involved patients with severe COPD symptoms following hospitalisation, limiting generalisability of findings to milder cases or broader COPD population. Different study settings and varying comparator interventions also affect generalisability of results across NHS
- Adherence and Safety: Adherence to digital technologies varied, with some studies reporting better outcomes compared to standard care. Adverse events were generally low and unrelated to treatment. Mortality was low, but evidence is limited
- Long-term and Comparative Impact: Comparative effectiveness of digital interventions is unclear, particularly in mixed or unclear treatment settings. Some studies show benefits, but others do not, reflecting the heterogeneous nature of evidence and varied methodologies used
- Economic Considerations: Five economic studies suggest potential cost savings from reduced A&E attendance and hospital admissions with digital technologies. However, these studies were generally of low quality and might be subject to various biases

Integration into the NHS

Out of 12 digital health technologies evaluated, 9 had relevant evidence submitted by their developers, and 8 of these technologies are currently being used within the NHS.

- Regulatory Considerations: 'Space for COPD', one of the technologies, is used in the NHS but lacks regulatory approvals like CE or UKCA marking. The technology developer have indicated that DTAC accreditation will be sought for an updated version. Wellinks also lacks regulatory approval and is not currently used in the NHS.
- Regulatory Advice: Further clarification from the Medicines and Healthcare Products Regulatory Agency (MHRA) on the need for these accreditations if ‘SPACE for COPD' continues to be used would be helpful.
- Provider Diversity: 7 of the technology providers that submitted evidence also offer solutions for a variety of respiratory conditions beyond COPD.

Summary of evidence gap analysis

- Limited clinical evidence was available for Active+me REMOTE, COPDhub, COPDPredict and Wellinks, which only had non-comparative data. No clinical evidence relevant to scope identified for Current Health, DOC@HOME or patientMpower.
- Evidence identified for a number of key outcomes, most commonly for CAT scores, exacerbations and hospital admissions, although comparative effects were not commonly reported. Outcome definitions, measures and reported timepoints varied across trials, making comparison across digital technologies difficult.
- Other outcomes not well-reported, including daily activity and psychological wellbeing. Evidence base was particularly scarce for effect of digital technologies on use of other healthcare resources such as outpatient/GP visits and additional medication use.
- There was insufficient evidence to consider whether variation in components used across digital technologies, such as within-app contact with healthcare professionals and symptom tracking, affected outcomes.

Gap analysis – overview

Green = clear evidence of effectiveness/non-inferiority from more than one study; amber = some evidence but unclear or inconsistent; red = no or negative evidence

Key Outcomes	Active+me REMOTE	COPDHub	myCOPD	SPACE for COPD	Wellinks	COPDPredict	Lenus	Luscii	Clinitouch
Respiratory function	1 UK prospective case series AMBER	1 UK retrospective case series AMBER	2 UK RCTs AMBER	1 UK prospective case series AMBER	1 US prospective cohort study	No studies RED	1 UK mixed prospective/ retrospective cohort study AMBER	No studies RED	1 UK prospective case series AMBER
Acute COPD exacerbations	No studies RED	1 UK retrospective case series AMBER	2 UK RCTs AMBER	No studies RED	No studies RED	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study AMBER	No studies RED	No studies RED
Hospital admissions, readmissions or emergency admissions	No studies RED	No studies RED	2 UK RCTs AMBER	No studies RED	1 US prospective cohort study AMBER	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study 1 [redacted] AMBER	1 UK before-after study AMBER	1 UK prospective case series AMBER
Health-related quality of life	1 UK prospective case series AMBER	No studies RED	1 UK RCT AMBER	1 UK prospective cohort study AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Patient experience, usability and acceptability	No studies RED	No studies RED	No studies RED	No studies RED	1 US prospective case series 1 US prospective cohort study AMBER	No studies RED	1 UK mixed prospective/ retrospective cohort study AMBER	1 UK before-after study 1 UK retrospective case series AMBER	No studies RED

- No evidence for Current Health, DOC@HOME and patientMpower.

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Gap analysis (1) – summary

Green = clear evidence of effectiveness/non-inferiority from more than one study; amber = some evidence but unclear or inconsistent; red = no or negative evidence

Outcomes	Active+me REMOTE	COPDHub	myCOPD	SPACE for COPD	Wellinks	COPDPredict	Lenus	Luscii	Clinitouch
Clinical outcomes									
Respiratory function	1 UK prospective case series AMBER	1 UK retrospective case series AMBER	2 UK RCTs AMBER	1 UK prospective case series AMBER	1 US prospective cohort study	No studies RED	1 UK mixed prospective/ retrospective cohort study AMBER	No studies RED	1 UK prospective case series AMBER
Daily activity	No studies RED	No studies RED	2 UK RCTs AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Acute COPD exacerbations	No studies RED	1 UK retrospective case series AMBER	2 UK RCTs AMBER	No studies RED	No studies RED	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study AMBER	No studies RED	No studies RED
Hospital admissions, readmissions or emergency admissions	No studies RED	No studies RED	2 UK RCTs AMBER	No studies RED	1 US prospective cohort study AMBER	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study 1 [redacted] AMBER	1 UK before-after study AMBER	1 UK prospective case series AMBER
Outpatient clinic or GP visits	No studies RED	No studies RED	No studies RED	No studies RED	1 US prospective cohort study AMBER	No studies RED	No studies RED	1 UK before-after study AMBER	No studies RED
Additional medications required	No studies RED	No studies RED	1 UK RCT AMBER	No studies RED	No studies RED	1 UK prospective case series AMBER	No studies RED	No studies RED	No studies RED
Optimising inhaler technique	No studies RED	No studies RED	2 UK RCTs GREEN	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED

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Gap analysis (2) – summary

Green = clear evidence of effectiveness/non-inferiority from more than one study; amber = some evidence but unclear or inconsistent; red = no or negative evidence

Outcomes	Active+me REMOTE	COPDhub	myCOPD	SPACE for COPD	Wellinks	COPDPredict	Lenus	Luscii	Clinitouch
Intermediate outcomes									
Intervention adherence	1 UK prospective case series AMBER	No studies RED	2 UK RCTs AMBER	1 UK prospective cohort study AMBER	1 US prospective case series 1 US prospective cohort study AMBER	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study AMBER	No studies RED	No studies RED
Rates of attrition/ completion	1 UK prospective case series AMBER	No studies RED	2 UK RCTs AMBER	No studies RED	1 US prospective cohort study AMBER	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study AMBER	No studies RED	No studies RED
Intervention related AEs	1 UK prospective case series AMBER	No studies RED	2 UK RCTs AMBER	No studies RED	1 US prospective case series 1 US prospective cohort study AMBER	1 UK prospective case series AMBER	No studies RED	No studies RED	No studies RED
Inaccessibility to intervention	1 UK prospective case series AMBER	No studies RED	1 UK RCT AMBER	No studies RED	1 US prospective cohort study AMBER	1 UK prospective case series AMBER	1 UK mixed prospective/ retrospective cohort study 1 [redacted] AMBER	1 UK before-after study AMBER	No studies RED

Gap analysis (3) – summary

Green = clear evidence of effectiveness/non-inferiority from more than one study; amber = some evidence but unclear or inconsistent; red = no or negative evidence

Outcomes	Active+me REMOTE	COPDhub	myCOPD	SPACE for COPD	Wellinks	COPDPredict	Lenus	Luscii	Clinitouch
Patient- reported outcomes									
HRQoL	1 UK prospective case series AMBER	No studies RED	1 UK RCT AMBER	1 UK prospective cohort study AMBER	No studies RED	No studies RED	No studies RED	No studies RED	No studies RED
Patient experience, usability and acceptability	No studies RED	No studies RED	No studies RED	No studies RED	1 US prospective case series 1 US prospective cohort study AMBER	No studies RED	1 UK mixed prospective/ retrospective cohort study AMBER	1 UK before-after study 1 UK retrospective case series AMBER	No studies RED
Psychological wellbeing	1 UK prospective case series AMBER	No studies RED	1 UK RCT AMBER	No studies RED	1 US prospective cohort study	No studies RED	No studies RED	No studies RED	No studies RED

- No evidence for Current Health, DOC@HOME and patientMpower.

Future evidence generation

- Confirm consistent beneficial impact of digital self-management technologies compared to standard care, identifying key effective components
- Include detailed reporting on COPD severity and treatment settings to understand impacts across various patient groups, especially those with milder COPD or not recently hospitalised
- Standardise definitions and measurements for outcome, such as hospital admissions, to facilitate data comparison across studies
- Gather data on healthcare resource use reduction by digital technologies compared with standard care, over at least a 1-year follow-up in a UK NHS setting
- Clearly document care received by participants in all study arms to understand how digital technologies integrate with and impact standard care
- Conduct larger, well-powered controlled trials to robustly evaluate effectiveness of digital self-management technologies
- Research acceptability and uptake of digital technologies among staff and patients to ensure widespread benefit realisation across COPD population

Pack only

Evidence gaps identified in EAG report

- Effectiveness of the technologies compared to standard care
- Effectiveness of the technologies for the whole population
- Effectiveness in subgroups such as those who had a recent exacerbation and those who have not and different COPD severities
- Long-term outcome measurement. e.g. 12 months, 18 months
- Impact on healthcare resource use associated with the technologies
- Clinical professional and patient acceptability and uptake rates
- Impact on quality of life

Key considerations for committee

- Unmet need in NHS, and high rates of readmission post discharge: 23.9% of patients are readmitted within 30 days, and 43.2% within 90 days post-discharge. Evaluation of early evidence base indicates digitally supported self-management technologies may be cost saving.
- Would the AECOPD population or the wider population gain the most benefit, or where in the COPD management pathway would supported self-management digital technologies have the most benefit?
- Does evidence suggest a potential benefit for the use of digitally supported self-management technologies as an option in addition to standard of care for people with COPD?

Evidence gaps and specific outcomes for data collection

Evidence gap	Question for committee
Effectiveness and outcome measurement for severity of COPD	Which outcome measure is preferred? e.g. CAT score or GOLD score
Resource use	What are the key things to collect? e.g. GP visits/ admissions for exacerbations
Long term effectiveness	What is a good time horizon to use?
Subgroup effectiveness	Which subgroups are key? e.g. disease severity, acute exacerbation
HRQoL measurement	Is there any other HRQoL tool commonly used in the NHS for COPD except the EQ-5D

Possible recommendations

Conditionally recommended for use while further evidence is generated

- Likely that the technology will solve the unmet need and it is acceptable for the technology to be used in practice while further evidence is generated

Recommended only in a research context

- Uncertain if the technology has the potential to solve the unmet need, or it is not acceptable to be widely used in practice while further evidence is generated

Not recommended for use

- Unlikely that a technology has the potential to meet the unmet need, or where there are concerns about the potential harms associated with using the technology even in a research context

Document cover sheet

Assessment report: Digital technologies for self-management of chronic obstructive pulmonary disease (addendum)

EAG team: Hayden Holmes, Lavinia Ferrante di Ruffano, Robert Malcolm, Chris Bartlett, Rebecca Naylor, Emma Carr, Kate Lanyi, Anne Littlewood, Emma Bishop, Ben Hyde

Project lead(s): Hayden Holmes and Lavinia Ferrante di Ruffano

Information specialist: Anne Littlewood

Clinical evidence reviewer: Lavinia Ferrante di Ruffano, Emma Carr, Kate Lanyi, Emma Bishop, Ben Hyde

Economic evidence reviewer: Hayden Holmes, Robert Malcolm, Chris Bartlett, Rebecca Naylor

EAG sign-off: Hayden Holmes

Version number	Brief description of changes	Author/reviewer (e.g. J Smith)	Date (DD/MM/YY)	Date sent to NICE (if applicable)
1.0	Draft addendum report submitted to NICE	Hayden Holmes Lavinia Ferrante di Ruffano Robert Malcolm Chris Bartlett Emma Carr Rebecca Naylor Kate Lanyi Anne Littlewood Emma Bishop Ben Hyde	08.08.24	08.08.24

2.0	Updates to addendum report based on NICE feedback	Hayden Holmes Lavinia Ferrante di Ruffano Robert Malcolm Chris Bartlett Emma Carr Rebecca Naylor Kate Lanyi Anne Littlewood Emma Bishop Ben Hyde	14.08.24	14.08.24
3.0	Updates to addendum report based on NICE feedback	Hayden Holmes Lavinia Ferrante di Ruffano Robert Malcolm Chris Bartlett Emma Carr Rebecca Naylor Kate Lanyi Anne Littlewood Emma Bishop Ben Hyde	15.08.24	15.08.24

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

[GID-HTE10030] - Digital Supported Self-Management Technologies for Adults with Chronic Obstructive Pulmonary Disease

External Assessment Group Report Addendum

Produced by: York Health Economics Consortium (YHEC)

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Date completed: 15.08.24

Contains confidential information: Yes

Declared interests of the authors

YHEC was previously involved in the MTEP evaluation of myCOPD as the external assessment group for NICE. YHEC has also produced an early NIA case study report on myCOPD prior to this.

YHEC is currently undertaking a health economic evaluation for Lenus for their digital technology in a COPD population.

The team involved in producing this assessment report was not involved in any of the work listed above.

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.

Acknowledgements

Company representatives were contacted to clarify information related to the evidence that had been submitted.

Responsibly for report

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

Contents

Abbreviations

Term	Definition
AE	Adverse event
AECOPD	Acute exacerbation of COPD
AI	Artificial intelligence
CAT	COPD assessment test
CE	Cost-effectiveness
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CRP	C-reactive protein
DSA	Deterministic sensitivity analysis
DTAC	Digital Technology Assessment Criteria
EAG	External Assessment Group
ED	Emergency department
EQ-5D	EuroQoL 5 Dimension
EVA	Early value assessment
EVPI	Expected value of perfect information
FEV	Forced expiratory volume
GP	General practitioner
HRQoL	Health-related quality of life
ICB	Integrated care board
ICER	Incremental cost-effectiveness ratio
ICST	Institute of Clinical Science and Technology
ITT	Intention-to-treat
MCID	Minimally clinically important difference
mMRC	Modified British Medical Research Council
MTEP	Medical Technologies Evaluation Programme
NIA	NHS Innovation Accelerator
NR	Not reported
PP	Per protocol
PSA	Probabilistic sensitivity analysis
PSS	Personal social services
QALY	Quality-adjusted life year
QoL	Quality of life

Term	Definition
RCT	Randomised controlled trial
RFI	Request for information
RR	Risk ratio
RUSAE	Related and unexpected serious adverse event
SAE	Serious adverse event
SD	Standard deviation
SE	Standard error
SF-36	Short Form 36-item
UKCA	UK Conformity Assessed
YHEC	York Health Economics Consortium

1 Background of the addendum

The NICE Final Scope for 'GID-HTE10030 Digital Supported Self-Management Technologies for Adults with Chronic Obstructive Pulmonary Disease' determined 12 technologies should be evaluated as part of the early value assessment. 2 of the 12 companies did not submit evidence to NICE, with information in the original early value assessment report limited to published evidence identified within the EAG searches (February 2024). During public consultation for the topic, 2 previously scoped companies (ICST for COPDhub and Nepesmo Ltd for COPDPredict) had additional evidence submitted for their technologies for consideration in confidence, to supplement the evidence identified previously.

Additionally, during public consultation, Doccla UK Ltd approached NICE with a relevant technology to this topic but was not originally identified as part of the evaluation. This company was advised to submit evidence.

As a result of these developments the EAG has prepared an addendum that:

- Summarises the new evidence submitted for COPDhub and COPDPredict.
- Includes the new technology Doccla, and summarising the new evidence submitted for the technology.
- Discusses how the relevant new evidence adds to the interpretation and conclusions of clinical and economic findings raised in the original assessment report.

2 Overview of the technology

This addendum assesses digital supported self-management technologies for adults with a confirmed diagnosis of COPD who are able to use the digital technologies. This is described further in the NICE Final Scope and the early value assessment report. Technologies included in the addendum are those that have been identified during the public consultation process or were included in the original assessment report but have since provided more evidence.

2.1 Included technologies

1 additional digital technology to support the self-management of adults with COPD is included within this addendum. Details relevant to COPDhub and COPDPredict were previously summarised in Table 2.1 of the original assessment report. Details relevant to the early value assessment for Doccla are summarised in Table 2.1 and Table 2.2.

Table 2.1: Included technologies

Technology (Company)	Regulatory Status	EAG Summary
Doccla (Doccla UK Ltd)	The device is registered as a class 1 medical device under UKCA marking. No mention of CE mark. [redacted] DTAC: Accredited	**Delivery:** Tablet or mobile phone, or computer. **Key features:** • Mobile and web applications for people to track their health metrics, access information about their health condition, be supported by self-management of their condition through a personalised plan and communicate with healthcare providers. • Remote patient monitoring of patient vital signs using wearable or spot check devices and sensors. • Alerts and reminders for medications and follow-up appointments. • Communicating with healthcare providers without needing to visit hospital. • Video calling via clinical dashboard. Some key features resemble and refer directly to a virtual ward. A virtual ward is beyond the scope of this evaluation. **NHS staff involvement:** Clinician can remote monitor persons vitals. Clinician can also communicate with person through secure messaging (including photos) and video consultations **Digital accessibility features:** Patient information leaflets and Doccla app translated into multiple languages. All Doccla patient-facing staff have real-time access to NHS-approved translators. A number of smart tablets provided for live contracts with the NHS.

Technology (Company)	Regulatory Status	EAG Summary
		Included in pulmonary rehabilitation EVA? No **Provides virtual ward service?** Yes **Current use in the NHS:** [redacted]

Table abbreviations: COPD, Chronic obstructive pulmonary disease; DTAC, Digital Technology Assessment Criteria; EVA, Early value assessment; ICB, Integrated care board; UKCA, UK Conformity Assessed.

Table 2.2: Feature profile of the technology

Technology	Exercise	Education	Communication with clinical staff via technology	Symptom or other outcome tracking	Remote monitoring	Individualised self-management plan	Scoped technology in pulmonary rehabilitation EVA	Provides virtual ward service
Doccla		✓	✓	✓	✓	✓		✓

3 Clinical evidence selection

3.1 Evidence search strategy and study selection

The EAG assessed evidence from company submissions and from reference checking. No further searches were conducted for this addendum report. In total, 18 documents were assessed for this addendum.

10 evidence submissions were examined for relevance (8 documents submitted by companies, 2 documents on the COPDPredict trial submitted by academic partners of Nepesmo Ltd. at the University of Birmingham):

- COPDhub: 2 reports summarising 2 new studies published after the initial EAG searches.
- COPDPredict: 2 unpublished manuscript documents (supplied as 4 files comprising the manuscripts, one figure and one supplementary material document) reporting data from the Predict and Prevent trial (NCT04136418) that had been identified in the main report as an ongoing study.
- Doccla (new scoped intervention): 6 documents submitted through the company request for information (RFI) process.

Reference checking of records listed in the submission documents and associated papers noted in included studies identified 8 documents:

- Doccla: 6 records. The Doccla RFI document referred to a Danish cluster RCT in the summary of relevant clinical evidence. This cluster RCT and 2 associated papers had been included in the main report but deprioritised due to reporting on a non-scoped intervention. The EAG identified 3 additional documents listed in the RFI that reported on this same RCT and had not been found by the original searches.
- COPDPredict: 2 records associated with the Predict and Prevent trial that were tagged as ongoing study documents in the main report.

3.2 Included and excluded studies

Of the 10 submitted documents, 5 were excluded:

- COPDhub: 1 report summarised patient satisfaction survey results for both Asthmahub and COPDhub users, without reporting results separately.

- Doccla (new scoped intervention): 4 documents comprised product information (user manual and Digital Technology Assessment Criteria report) and administrative documents relating to the RFI process (1 RFI form and 1 declaration of conformity) that did not provide data on clinical effects, safety or cost-effectiveness.

The remaining 5 submitted documents were eligible and included:

- COPDhub: 1 UK before-after study (ICST Healthhub 2024a).
- COPDPredict: 1 UK RCT (in 2 documents (Gkini E et al. 2024, Hall J et al. [unpublished]) (NCT04136418).
- Doccla: 2 UK before-after studies (Doccla Ltd 2024 [unpublished], Doccla Ltd 2024 [unpublished internal report]).

8 further eligible records were identified through reference-checking:

- COPDPredict: 2 records reporting on the same UK RCT (Predict and Prevent, NCT04136418 trial registry record and protocol) identified in the main report (University of Birmingham 2020, Kaur et al. 2023).
- Doccla: 1 cluster RCT in 6 documents (3 deprioritised in the main report (Witt Udsen et al. 2017, Udsen et al. 2017, Lilholt et al. 2016) and 3 newly identified through the company RFI (Aalborg University 2013, Udsen et al. 2014, Lilholt et al. 2017)).

In total 5 eligible studies reported across 13 documents were identified. Studies were prioritised on the basis of best-quality evidence using the same approach as followed in the main report to ensure that evidence for each digital technology was assessed consistently. Prioritisation was based on the following criteria:

- Quality of evidence: RCTs were prioritised over non-randomised comparative studies, comparative studies over non-comparative, and prospective over retrospective non-comparative studies.
- Relevance to the decision problem as described in the final scope:
    - Available UK evidence was prioritised over evidence in non-UK settings.
    - Studies comparing digital technologies to comparators other than standard care (e.g. pulmonary rehabilitation) were deprioritised.
    - Studies assessing earlier versions of scoped technologies that lacked a self-management component were deprioritised.

Accordingly, 2 UK before-after Doccla studies (Doccla Ltd 2024 [unpublished], Doccla Ltd 2024 [unpublished internal report]) were deprioritised in favour of the cluster RCT evidence(Doccla Ltd 2024 [unpublished], Doccla Ltd 2024 [unpublished internal report]). Therefore 3 studies in 11 documents were prioritised. This remainder of this report summarises these prioritised studies. These studies are summarised in Table 3.1. The excluded and deprioritised studies are summarised in Appendix A.

Table 3.1: Studies selected by the EAG as the evidence base

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
COPDhub				
ICST Healthhub, 2024a (ICST Healthhub 2024a) **Location**: UK (Wales) **Setting (AECOPD, non-AECOPD)**: Unclear	**Design:** Retrospective before-after study, comparing winter season of 2022/23 to 2023/24. GREEN **Intervention ('after'):** COPDhub GREEN **Comparator ('before' study period):** Standard care GREEN	**Participants**: COPDhub users GREEN **Setting**: People with COPD with at least 1 GP or ED visit, hospital admission, or course of Prednisolone. GREEN	• GP visit • ED visit • Steroid use	Content of standard care received prior to COPDhub is unclear. Short report, limited patient characteristics data available.
COPDPredict				
Gkini et al 2024 (Gkini E et al. 2024) **Associated records:** Cost-effectiveness analysis: Hall et al, [unpublished] (Hall J et al. [unpublished]) Trial registry record (University of Birmingham 2020)	**Design:** RCT GREEN **Intervention:** COPDPredict with rescue medication (n=45) GREEN **Comparator:** Standard care: standard self-management plan (instructing patients to recognise early signs of	**Participants**: Patients with AECOPD; inclusion criteria specify ≥1 AECOPD in any 12-month period within the last 2 years or ≥1 hospital admission for AECOPD in the previous 2 years, and exacerbation-free for at least 6 weeks. GREEN **Setting**: Mixed hospitalised and non-hospitalised.	• CAT score • ED visits • Exacerbations • EQ-5D • COPD exacerbation-related hospitalisations	Due to recruitment difficulties, the final sample size was short of target sample size of 144 patients in each arm (90 patients in each arm). [redacted] Non-ITT (complete case) analysis conducted, 10 patients with no data post-

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Protocol (Kaur et al. 2023) **Location**: UK **Setting (AECOPD, non-AECOPD)**: Mixed	exacerbation) with rescue medication (n=45) GREEN	GREEN		baseline not included in analysis. Randomisation by secure online central system provided by the Birmingham Clinical Trials Unit, with the use of minimisation to balance trial-group assignments by patient characteristics.
Doccla				
Witt Udsen et al, 2017 (Witt Udsen et al. 2017) **Associated records:** Trial registry record (Aalborg University 2013) Protocol (Udsen et al. 2014) Severity subgroup analysis (Udsen et al. 2017) HRQoL results (Lilholt et al. 2017) Technological literacy subgroup analysis (Lilholt et al. 2016) **Location**: Denmark	**Design:** Cluster RCT GREEN **Intervention:** Telehealthcare (Doccla): standard care (described below) plus telemonitoring and digital self-management (n=578) GREEN **Comparator:** Standard care: treatment and monitoring by GP with community care at regular intervals (n=647) GREEN	**Participants**: 1,225 patients with COPD across 26 municipality districts. Patients had at least two exacerbations within the past 12 months. GREEN **Setting**: Telehealthcare home monitoring GREEN	• Health-related quality of life (SF-36v2) • Admissions • ED visits • Additional medication use	The municipality districts were matched 1:1 by demographic variables. Districts were distributed randomly by a blinded volunteer by throwing a dice. Intent-to-treat analysis used for CE outcomes, per protocol for QoL outcomes.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Setting (AECOPD, non-AECOPD): Unclear				

Table abbreviations: AECOPD, acute exacerbation of COPD; CAT, COPD assessment test; CE – cost effectiveness; COPD, chronic obstructive pulmonary disease; ED, emergency department; EQ-5D, EuroQol 5 Dimension; GP, general practitioner; ICST, Institute of Clinical Science and Technology; PP, per protocol; RCT, randomised controlled trial; SF-36, Short Form 36-item.

GREEN: Study characteristic aligns with the scope

4 Clinical evidence review

4.1 Overview of methodologies of all included studies

The 3 studies were comparative and evaluated 3 technologies: COPDhub (The Institute of Clinical Science and Technology), COPDPredict (Nepesmo Ltd.) and Doccla (Doccla Ltd.):

- COPDPredict: 1 UK RCT (in 4 documents) (Gkini E et al. 2024).
- Doccla: 1 cluster RCT (in 6 documents) (Witt Udsen et al. 2017).
- COPDhub: 1 before-after study (ICST Healthhub 2024a).

All 3 studies compared digital technologies to standard care. 1 cluster RCT evaluated telemonitoring and digital self-management (Doccla) as an add-on to standard care, which comprised treatment and monitoring by a general practitioner with community care (Witt Udsen et al. 2017). 1 RCT assessed COPDPredict alone compared to standard care, consisting of a standard self-management plan with rescue medication (Kaur et al. 2023). The before-after study compared patients in Wales treated during the winter of 2023/24 (winter was defined as November 1st to end of February 2024) after the introduction of COPDhub to data from the previous winter and did not report details of what prior care comprised (ICST Healthhub 2024a).

Patients and settings

The EAG considered all studies to fully meet this component of the decision scope. 2 RCTs included patients with COPD defined by GOLD criteria, previous COPD exacerbations or other diagnostic tests such as spirometry measures, or Medical research council (MRC) dyspnoea score (Kaur et al. 2023, Witt Udsen et al. 2017). 1 before-after study did not report the diagnostic criteria for participants but included patients assigned the COPDhub app in Wales and company communications indicated that all patients had COPD (ICST Healthhub 2024a).

1 Danish cluster RCT reported that patients of any COPD severity were included, ranging from GOLD 1 to 4 and including patients for whom this information was missing (Udsen et al. 2017). 1 UK RCT included patients with GOLD state B and D, indicating

moderate-to-severe COPD (authors reported that patients generally had severe COPD) (Gkini E et al. 2024). The UK before-after study did not report details of COPD severity (ICST Healthhub 2024a).

A subgroup of interest in the NICE scope were patients referred to self-management following hospitalisation for acute exacerbations (AECOPD). All 3 studies were considered to have a mixed or unclear treatment setting population with regard to prior hospitalisation:

- 1 cluster RCT (Doccla) did not report the rate of previous COPD-related hospitalisations, but included patients with mild or moderate (GOLD rating 1 and 2) COPD so is likely to have included a mixed treatment setting population (Witt Udsen et al. 2017).
- 1 UK RCT (COPDPredict) included patients with a COPD-related hospitalisation or acute COPD exacerbation episode within the previous 2 years, therefore it was unclear whether participants were hospitalised in the previous year (Kaur et al. 2023). The unpublished manuscript reported that the mean number of hospitalisations in the previous year was 0.8 (SD 1.8) (Gkini E et al. 2024). This study was therefore considered to report a mixed treatment setting population.
- 1 UK before-after study (COPDhub) included patients with at least one unscheduled general practitioner (GP) visit, accident and emergency (A&E) admission, or course of Prednisolone in the winter of 2022/23, and so was considered to report an unclear treatment setting population (ICST Healthhub 2024a).

Interventions

The EAG considered all 3 studies to fully meet this component of the decision scope, as they included multicomponent self-management technologies included in the NICE scope.

The Danish cluster RCT reported that Doccla was received alongside standard care (Udsen et al. 2014) and the UK RCT reported that COPDPredict was received alone (with rescue medication in case of exacerbation) (Kaur et al. 2023). The COPDhub study did not report whether this technology was administered alongside any concomitant care (ICST Healthhub 2024a).

Components

Technologies were described in detail in the protocols of 2 RCTs (Kaur et al. 2023, Udsen et al. 2014), each reporting multi-component devices that included at least 2 of the following components: symptom monitoring, educational content, self-management planning and healthcare practitioner contact. Limited intervention details were reported in the UK before-after study (ICST Healthhub 2024a), though details of the COPDhub version and features used in this setting are reported on the ICST Healthhub Wales website (ICST Healthhub 2024a).

The EAG notes that the components of these technologies may vary in terms of which components are used in different study contexts, as well as the components themselves varying across different versions of a technology. The EAG therefore considered descriptions of the interventions in this study to be unclear. Components as reported within each prioritised study are presented in Table 4.1.

Table 4.1: Key technology features described in the prioritised studies

Technology (company)	Study	Version number	Key features described
COPDhub (ISCT)	ISCT Healthhub 2024 (ICST Healthhub 2024a)	NR	NR in report, Healthhub Wales website describes: • Personalised self-management plan. • Collection of patient reported outcomes and bio-physiological data to share with healthcare team. • Communication with clinician. • Educational videos on breathing exercises, inhaler techniques, etc.
COPDPredict (Nepesmo Ltd.)	Gkini et al 2024 (Gkini E et al. 2024) Features as described in trial protocol Kaur et al	NR	• Early warning decision support system uses remote monitoring of relevant data (symptoms, spirometry, biomarkers) via the app and sensor peripherals to inform AI-assisted prediction of possible exacerbations and signpost users to action plans.

Technology (company)	Study	Version number	Key features described
	2023 (Kaur et al. 2023)		• Information around COPD self-management, pulmonary rehabilitation, inhaler technique. • Clinician-facing dashboard allows for 'real-time' case management with the ability to remotely monitor patients and facilitate interaction.
Doccla (Doccla Ltd.)	Witt Udsen et al, 2017 (Witt Udsen et al. 2017)	NR	• A tablet that contains information on self-management of COPD and software that automatically instructs the patient in managing COPD during exacerbations. • Collection of relevant disease-specific data indicative of the patient's state of health (blood pressure, pulse, blood oxygen saturation and weight) through sensor equipment. • Monitoring of data by nurses with the option of contacting patients directly or GPs.

Table abbreviations: AI, artificial intelligence; COPD, chronic obstructive pulmonary disease; GP, General practitioner; ICST, Institute of Clinical Science and Technology; NR, not reported.

Comparators

All 3 comparative studies were considered to meet this component of the decision scope. Each study compared to standard care alone, which comprised different care in each trial:

- In the UK RCT (COPDPredict) standard care comprised a standard self-management plan instructing patients to recognise early signs of exacerbation and rescue medication (Kaur et al. 2023).
- In the Danish cluster RCT (Doccla) standard care comprised treatment and monitoring by a GP with community care at regular intervals (Udsen et al. 2014).
- In the UK before-after study (COPDhub) the content of standard care was not reported (ICST Healthhub 2024a).

COVID-19

Two studies were published after the COVID-19 pandemic and 1 preceded it. The Danish cluster RCT results were published prior to the pandemic in 2017 (Witt Udsen et al. 2017). The UK RCT protocol was published in 2023 (Kaur et al. 2023), though recruitment began in early 2020 and authors report that the pandemic produced recruitment difficulties which led to a smaller sample size than planned (Gkini E et al. 2024). The before-after study collected patient data from the winter of 2022/23 (ICST Healthhub 2024a).

4.2 Critical appraisal of studies

As specified by the NICE EVA interim guidance no formal risk of bias assessment was conducted.

2 studies provided comparative RCT evidence (Gkini E et al. 2024, Witt Udsen et al. 2017). The UK RCT (COPDPredict) was at risk of providing biased estimates of effect due to providing only complete case analyses (patients without at least one survey response post-baseline were excluded) and including a small sample size. The authors calculated that at least 144 patients in each arm were required to detect a difference of 1 hospital admission between groups, and planned to include 384 participants overall to account for a 25% attrition rate (Gkini E et al. 2024). The study authors reported that recruitment difficulties partly due to the COVID-19 pandemic led to a smaller final sample size of 90 patients which undermined certainty in results.

[redacted]

In the Danish cluster RCT (Doccla) the cluster centers were demographically matched municipality districts. The study conducted intent-to-treat analysis (ITT) as missing data was imputed, though there was a significant loss to follow-up for quality-of-life data, with an attrition rate of 53% (651/1,225 patients) for SF-36 data (Lilholt et al. 2017).

Blinding to treatment was not feasible due to the nature of the interventions. The EAG considers these trials to pose a potential risk of producing exaggerated treatment

effects due to the subjective nature of the patient-reported outcomes extracted for this EVA. However, this risk cannot be avoided due to the participatory nature of these interventions.

The care offered in the intervention and comparator arms of both RCTs were clearly summarised in their respective protocols, as described in Section 4.1 above.

Overall, the EAG considers the UK RCT to provide low certainty evidence for the comparative effects of COPD self-management digital technologies. The Danish cluster RCT is robust, though the primary objective was cost-effectiveness analysis and clinical efficacy data is limited to service use and SF-36 data.

The UK before-after study (COPDhub) was reported in a short online report with limited information on patient population and any attrition between the before and after study periods. The intervention characteristics of standard care received prior to COPDhub were not reported, nor were details of any concomitant care received with COPDhub.

The EAG had the following concerns regarding the generalisability of the 3 prioritised studies:

- Location: Evidence from the UK was available for all the technologies evaluated in prioritised studies in this addendum report except Doccla (evaluated in 1 Danish cluster RCT, thus it is uncertain whether these findings are generalisable to the UK NHS context (Witt Udsen et al. 2017)).
- Intervention: Eligible interventions were those named in the NICE scope which were multicomponent, and included at least 2 of the following components: symptom monitoring, educational content, self-management planning and healthcare practitioner contact. Within this scope there is range for significant heterogeneity; for example, technologies that include regular contact with healthcare professionals as a component may not be comparable to those that do not. Evidence may therefore be poorly generalisable across studies of different interventions. Components reported within each prioritised study are presented in Table 4.1.
- Comparator: the procedures described as standard care differed in each of the three studies, including standard self-management plans, standard GP and community care and unclear standard care prior to the introduction of a digital

app. Therefore, it may be difficult to understand how generalisable the findings of these studies are to different NHS settings.

- COVID-19: the prioritised studies varied in the extent to which they overlapped with the COVID-19 pandemic, and this was sometimes unclear. This introduces uncertainty to results, as the COVID pandemic is known to have impacted on people with chronic respiratory disease in numerous ways, and therefore studies conducted during the pandemic may be less generalisable to the post-pandemic NHS setting. Similarly, studies conducted prior to the pandemic may be less generalisable to current NHS practice, where remote care has become more widespread.

4.3 Results from the evidence base

Full outcome data is presented in Appendix B.

Clinical outcomes

Respiratory function

The UK RCT (COPDPredict) reported respiratory function, using the COPD assessment test score (CAT) with a minimally clinically important difference (MCID) of a reduction of 1 in the mean score (though the EAG notes that other studies use a threshold of a mean reduction of 2 points (Kon et al. 2014)). The RCT reported significant differences favouring COPDPredict over standard care at 3 and 6 months (-3.78, 95% CI -6.32 to -1.24, p=0.004 and -3.04, 95% CI -5.70 to -0.38, p=0.025 respectively), though no significant differences at 9 or 12 months (-1.76, 95% CI -4.56 to 1.03, p=0.215 and -0.82, 95% CI -3.89 to 2.24, p=0.596 respectively) (Gkini E et al. 2024).

Exacerbations

The UK RCT (COPDPredict) reported no significant difference in the adjusted risk ratio (adjusted for baseline severity and demographic characteristics) of self-defined acute exacerbations between groups at 6 and 12 months (1.08, 95% CI 0.53 to 2.22, p=0.825 and 1.029, 95% CI 0.94 to 1.11, p=0.619 respectively) (Gkini E et al. 2024). This study also reported the correlation of patient self-identified and treated exacerbations with clinician-identified exacerbations based on symptom data, and found that clinician-

identified exacerbations that were unrecognised in 24.4% of patients receiving standard self-management and 12.8% of patients using COPDPredict at 3 months (at 12 months: 7.2% and 4.7% respectively). Statistical significance was not reported.

Hospital admissions, readmissions or emergency admissions

All 3 studies reported hospitalisations or ED visits, of which 1 UK RCT (COPDPredict) reported specifically COPD-related admissions (Kaur et al. 2023).(Gkini E et al. 2024):

- Two studies reported hospital admissions. The UK RCT (COPDPredict) reported that in a complete case analysis the adjusted incident risk ratio (adjusted for baseline severity and demographic characteristics) for COPD-related admissions at 12 months was lower in the COPDPredict arm, though there was no significant difference (0.64,95% CI 0.19 to 2.17, p=0.478) (Gkini E et al. 2024). The adjusted risk ratio for admissions was also lower in the COPDPredict arm in the PP analysis, though again the difference was not significant (0.47, 95% CI 0.11 to 1.90, p=0.287).
- 1 Danish cluster RCT reported a higher mean number of admissions at 12 months in the Doccla arm than in the standard care arm, though the difference was not statistically tested (between-group difference 0.046, standardised difference 3.7%) (Witt Udsen et al. 2017).

Three studies reported ED visits:

- The UK RCT (COPDPredict) reported no significant differences in the adjusted risk ratio (adjusted for baseline severity and demographic characteristics) for ED visits at 6 or 12 months and inconsistent effect directions at different timepoints, as ED visits were slightly lower in the COPDPredict arm at 6 months and slightly higher at 12 months (0.929, 95% CI 0.26 to 3.17, p=0.889 and 1.599 95% CI 0.63 to 4.03, p=0.318 respectively) (Gkini E et al. 2024).
- The Danish cluster RCT (Doccla) reported that the mean number of outpatient or ED visits at 12 months was slightly higher in the Doccla arm than standard care arm, though the difference was not statistically tested (between-group difference 0.13, standardised difference 7.16%) (Witt Udsen et al. 2017).
- The UK before-after study (COPDhub) reported that ED visits were significantly lower using COPDhub in the winter of 2023/24 compared to standard care in the winter of 2022/23 (mean visits 1.33 vs 0.17, p=0.034) (ICST Healthhub 2024a).

Outpatient clinical visits, GP visits

Two studies reported GP visits:

- 1 Danish cluster RCT (Doccla) reported that the mean number of GP visits at 12 months was higher in the Doccla arm than standard care arm, though the difference was not statistically tested (between-group difference 0.8, standardised difference 9.35%) (Witt Udsen et al. 2017).
- The UK before-after study (COPDhub) reported that GP visits were lower using COPDhub in the winter of 2023/24 compared to standard care in the winter of 2022/23, though the difference was not significant (mean visits 2 vs 1.3, p=0.256) (ICST Healthhub 2024a).

Additional medication required including steroids and antimicrobials

Two studies reported data on additional medication. The Danish cluster RCT (Doccla) reported that both mean antibiotic use and general COPD medication use at 12 months was higher in the Doccla arm than the standard care arm (between-group difference 0.52, standardised difference 9.35%; and 1.16, 7.08% respectively), though the difference was not statistically tested (Witt Udsen et al. 2017). The UK before-after study (COPDhub) reported that the mean number of prednisolone courses was significantly lower using COPDhub in the winter of 2023/24 compared to standard care in the winter of 2022/23 (mean courses 1.71 vs 0.81, p=0.02) (ICST Healthhub 2024a).

Intermediate outcomes

Adherence

1 UK RCT reported adherence as the percentage of people in the COPDPredict arm completing >75% of symptom trackers, which was 84% at 2 weeks and 98% at 4 weeks (Gkini E et al. 2024). In the PP analysis for admissions at 12 months (excluding patients with missing data) 7/41 (17.1*%) participants in the COPDPredict arm and none of the patients in the standard care arm were reported to be non-adherent.

Patient reported outcomes

Health-related quality of life

Two studies reported health-related quality of life data using tools at different timepoints, so results are difficult to generalise across studies.

- The UK RCT reported significantly higher EQ-5D scores in patients using COPDPredict at both 3 months (incremental difference 0.073, SE 0.057 $p<0.1$; significance at $p<0.1$ was reported due to small sample size) and 6 months (incremental difference 0.097, SE 0.058, $p<0.05$) compared to standard care (Hall J et al. [unpublished]).
- The Danish cluster RCT (Doccla) reported greater improvements in SF-36 physical component and mental component scores in patients using Doccla at 12 months when adjusting for covariates and clustering, though the difference was not significant (adjusted mean difference 0.1, 95% CI -1.4 to 1.7, and 0.4, 95% CI -1.7 to 2.4 respectively) (Lilholt et al. 2017).

5 Adverse events and clinical risk

5.1 Adverse events

COPDPredict

The UK RCT (COPDPredict) reported that 13/45 (29%) people in the COPDPredict arm and 9/45 (20%) people in the standard care experienced serious adverse events at 12 months, though none were considered to be treatment-related and there was no significant difference in the rate of SAEs between groups (p=0.327) (Gkini E et al. 2024). There were three deaths in the COPDPredict arm and none in the standard care arm; authors excluded these patients from the analysis as neither intervention was considered to impact mortality. No comparison of mortality between groups was made.

Doccla

The Danish cluster RCT (Doccla) did not report adverse event rates. Mortality appeared similar between arms (50/578 people in the Doccla arm and 53/647 in the usual care arm died during the 12 month trial), but this difference was not tested for statistical significance (Lilholt et al. 2017).

5.2 Withdrawals

2 studies across 2 digital technologies reported withdrawals and discontinuations (COPDPredict and Doccla).

COPDPredict

The UK RCT (COPDPredict) reported that at 12 months 24 of 45 participants in the COPDPredict arm (7 withdrew, 3 died and for 14 data were not collected) and 17 (4 withdrew, 13 data not collected) of 45 participants in the standard care arm were lost to follow-up (Gkini E et al. 2024).

Doccla

The Danish cluster RCT (Doccla) reported that at 12 months 210 of 578 participants in the Doccla arm (50 died, 59 did not respond and 101 withdrew consent for reasons including complicated technology, concomitant health problems, lack of interest, leaving the local area, and lack of trust in the equipment) and 177 of 647 patients in the standard care arm (53 died, 63 did not respond and 61 withdrew consent for reasons including disappointment over not being assigned to Doccla, concomitant health problems, not interested and leaving the local area) (Lilholt et al. 2017).

6 Economic evidence

6.1 Economic evidence

Two eligible cost-effectiveness analyses set in the UK and Denmark were identified from the additional evidence submitted by companies for this addendum. These studies are summarised below and in **Error! Reference source not found.**Two further studies were identified for Doccla, but these specifically related to virtual wards, so were considered ineligible for this addendum report.

Hall et al. (2024) is a draft manuscript of a publication to be submitted to an academic journal. The article is an economic evaluation using RCT data captured over 6 months

follow-up as presented in Kaur et al. (2023), which was included in the clinical evidence review. Hall et al. (2024) conducted a cost-effectiveness analysis that compared COPDPredict plus standard care (standard self-management plan with rescue medication) to standard care alone in a COPD population.

[redacted]

Udsen et al. (Udsen et al. 2017) assessed the cost-effectiveness of a telehealthcare solution plus usual care compared to usual care. It was based on a Danish cluster RCT that investigated an early version of the Doccla technology. The model reported the ICER (cost per QALY gained) for the telehealthcare solution plus usual care compared with usual care alone as £47,400 (€55,327 converted from EUR to GBP using a conversion rate of 0.86, 09.08.2024). Scenario analysis tested underlying assumptions with results ranging from £17,991 (€21,000) to £38,548 (€45,000), converted to GBP as previously described. PSA was conducted and the results suggested that for a greater than 50% probability of being cost-effective, the willingness to pay threshold would have to be £47,131 [€55,000]). This is used as a reference point as Denmark does not have an explicit cost-effectiveness threshold by which it approves technologies (Shire et al. 2023).

Table 6.1: Narrative summary of economic studies

Study ID and location	Title	Study type	Narrative summary
COPDPredict			
Hall et al. (2024) UK	The cost-effectiveness of a personalised early warning decision support system (The COPDPredict system) to predict and prevent acute exacerbations of chronic obstructive pulmonary disease	Cost-effectiveness analysis, using two separate methods (a within-trial analysis and a Markov model)	[redacted]

Study ID and location	Title	Study type	Narrative summary
			[redacted]
Doccla			
Udsen et al. (Udsen et al. 2017) Denmark	Cost-effectiveness of telehealthcare to patients with chronic obstructive pulmonary disease: results from the Danish 'TeleCare North' cluster randomised trial	Cost-effectiveness analysis using a cluster RCT	Udsen assessed the cost-effectiveness of a telehealthcare solution plus usual care compared to usual care. It was based on a Danish cluster RCT that investigated an early version of the Doccla technology then not referred to by this brand name and referred to throughout the publication as "telehealthcare". Two separate linear mixed effects models were used to calculate incremental QALYs and costs. DSA were used to explore uncertainty around all-cause hospital contacts, reduced procurement prices due to large scale delivery, reduced monitoring time as well as the most optimistic scenario combining all three. PSA was also conducted. Economic outcome data included (incremental data for telehealthcare solution plus usual care compared with usual care): • Incremental cost: £1,219 • Incremental QALYs: 0.0132 • ICER (£ per QALY): £47,400* (with 50% probability of cost-effectiveness, if using a threshold of £47,131 [€55,000]). Scenario analysis tested underlying assumptions with results ranging from £17,991 (€21,000) to £38,548 (€45,000) and PSA suggested in order to

Study ID and location	Title	Study type	Narrative summary
			achieve a greater than 50% probability of cost-effectiveness, the willingness to pay threshold would have to be £47,131 (€55,000). The study had some limitations including separate modelling of costs and QALYs meaning the results are not correlated during sensitivity analysis. The intervention group in the trial included a smaller proportion of smokers than the usual care arm, though the authors estimated this had little effect on treatment effect. Implementation of the intervention may have varied across sites and time, as personnel become more efficient at delivery, which may have affected cost-effectiveness The study is also not a UK perspective, so may not be generalisable, while this study was conducted on an earlier version of Doccla. *Converted from EUR 55,327 to GBP using conversion rate of 0.86 [09.08.2024]

Table abbreviations: COPD, chronic obstructive pulmonary disease; DSA, deterministic sensitivity analysis; EVPI, expected value of perfect information; ICER, incremental cost-effectiveness ratio; PSA, probabilistic sensitivity analysis; PSS, personal social services; QALY, quality-adjusted life year; RCT, randomised controlled trial.

6.2 Implications for economic modelling

Doccla provided a cost for their technology. The technology costs were within the boundaries explored as part of the EAG economic modelling and were below the economically justifiable price determined by the EAG. The current cost-comparison model developed by the EAG is likely representative of Doccla as the technology contains similar features to that of other comparators. Assuming a similar level of effectiveness used in the EAG model, it is plausible that this digital technology may also be a cost saving intervention to the NHS. No further early economic modelling has been conducted for Doccla, while the additional evidence submitted for COPDhub and COPDPredict has not changed the conclusions of the EAG model. Details of the previous early economic modelling can be located in Section 8 of the early value assessment report.

Once evidence is collected to bridge current evidence gaps on digital health technologies to support the self-management of adults with COPD, Doccla could be evaluated using the structure suggested in Section 10.3 of the early value assessment report.

7 Interpretation of the evidence

7.1 Interpretation of the clinical and economic evidence

This addendum identified 3 additional comparative studies in mixed or unclear treatment settings (in 11 documents), including 1 RCT, 1 cluster RCT and 1 before-after study. All 3 studies compared digital technologies to standard care. The UK RCT evaluated COPDPredict alone, the Danish cluster RCT evaluated Doccla as an add-on to standard care, and the UK before-after study did not report details of any concomitant care to COPDhub. Concerns with the reliability of the RCT evidence included underpowered complete case analyses undermining the certainty of evidence in the UK RCT (Gkini E et al. 2024), while the Danish cluster RCT may not be generalisable to the UK NHS setting (Witt Udsen et al. 2017).

The main report concluded that in there is uncertain but plausible evidence suggesting that digital technologies alongside standard care may result in improvements in CAT score, inhaler use, exacerbations and admission rates from baseline in people using the technologies following discharge for an exacerbation, while the evidence for technologies in the general COPD population was unclear. The key findings from the 3 studies included in this addendum support the main report findings; no further studies in AECOPD treatment settings were identified, and the evidence in mixed or unclear treatment settings largely comprised non-significant differences and inconsistent effect directions. Further, clinical outcomes were reported with different measures at different timepoints, making it difficult to generalise findings across studies. This addendum did provide evidence not identified in the main report that digital technologies may better enable patients to self-identify exacerbations in the short-term, when compared to standard self-management.

The main report summarised 3 comparative studies in mixed or unclear populations with mixed findings for key outcomes including CAT scores, admissions and ED visits. The 3 studies identified in the addendum provide similarly mixed results with a range of significant and non-significant findings and effect directions inconsistently favouring either standard care or digital technologies. Both RCTs reported non-significant differences (or did not test differences statistically) in hospitalisations and ED visits with reported effect directions favouring both standard care and digital technologies. However, the UK before after study (COPDhub) reported significantly lower winter ED visits following use of COPDhub (details of any concomitant care unclear) compared to standard care (0.17 vs 1.33, p=0.034) (ICST Healthhub 2024a). Only 1 new study reported clinical outcomes. The UK RCT reported significantly lower CAT scores in COPDPredict users at 6 months, though no significant difference at 12 months (-3.04, 95% CI -5.70 to -0.38, p=0.025 and -0.82, 95% CI -3.89 to 2.24, p=0.596 respectively) (Gkini E et al. 2024). The study authors suggest that the diminishing treatment effect at 12 months was caused by increased missing responses in later periods, and other cofounding factors which limited the ability to identify a treatment effect (Gkini E et al. 2024).

The addendum identified additional data on use of additional healthcare services, including GP visits and additional medication use, from 2 unclear treatment setting studies, though results were not definitive. 1 finding from the before-after study suggested the digital technology (COPDhub) significantly lowered additional care (mean winter prednisolone courses) (ICST Healthhub 2024a). All other results were either not significant or not tested for significance, with the direction of effect inconsistently favouring either the digital technology or usual care.

The addendum report identified additional quality of life outcome data (from 2 RCTs) in addition to the 2 comparative studies described in the main report (1 cohort study and 1 RCT), though using different outcome measures reported at different timepoints. Findings were inconsistent: the UK RCT reported [redacted] compared to standard care (Hall J et al. [unpublished]), while the remaining studies reported that differences were either not significant or not tested for significance.

1 study reported the rate of adverse events and did not find any to be treatment related. 2 studies reported patient deaths but did not compare mortality between groups, though they appeared similar across treatment arms in both studies. Thus, the main report finding that these digital technologies are plausibly safe for treating COPD is unaffected.

The 2 cost-effectiveness analyses included in this addendum provide mixed evidence in relation to the main report's findings with respect to the cost-effectiveness of digital technologies to support the self-management of COPD. The UK study highlighted [redacted] However, this study was unpublished at the time it was submitted for this review (and so not peer-reviewed) and was [redacted]. The Danish study suggested that digital technologies are less likely to be cost-effective when offered to the whole COPD population, rather than more severe populations (such as those with a recent acute exacerbation). This study is not from an England and Wales perspective so may not be generalisable. The study did

highlight the importance of collecting additional information, as well as limitations surrounding the implementation the technology (a learning curve effect), which may have distorted the effectiveness.

If assuming a similar level of effectiveness and baseline risk of events used in the EAG model, it is plausible that Doccla may also be a cost saving intervention to the NHS. However, the Danish study highlights cost-effectiveness may be less likely where baseline risk of events are lower.

7.2 Integration into the NHS

The additional digital health technology provider included within this addendum is currently used within the NHS, as outlined in Section 2.1. Doccla is registered as a class 1 medical device under UKCA marking and has also received Digital Technology Assessment Criteria (DTAC) compliance. As outlined in the early value assessment report, there are key areas to focus on to ensure smooth integration into the NHS.

Firstly, due to a primary focus on severe cases of COPD, the current evidence base may not be completely representative of the COPD population in England. 7 of the 14 studies prioritised in the main report did not exclusively include an AECOPD population (who will have more severe COPD). However, the other 7 studies included either mixed severity populations where over half of the cases were people with severe COPD, or did not report the severity of study populations. Similarly, this addendum identified 1 RCT that included people with moderate or severe COPD but reported that most patients had severe COPD (Gkini E et al. 2024), and a cluster RCT that included a mixed-severity population (Udsen et al. 2017). Thus, the evidence base as a whole is focused on severe cases, as studies in exclusively mild to moderate COPD are few. People with milder COPD symptoms may incur different outcomes. If digital technologies to support self-management of COPD are to be used in people with milder forms of COPD, then future evidence should be generated to capture a more reflective population to the intended use case.

Secondly, there are training and resource use considerations to implement the technology successfully. For Doccla, this includes onboarding costs and training of healthcare professionals. Although the cost is relatively small when scaled to a per person cost, any up-front charges should be considered as part of budgeting at a local level.

Thirdly, there are multiple criteria that should be considered when determining if a person is eligible for supported self-management through digital technologies. These include accessibility issues, potential co-morbidities, internet connectivity, access to suitable devices, adherence rates and digital literacy. Doccla already has a number of live contracts with the NHS where smart tablets are provided to minimise digital exclusion.

Finally, a further factor to consider around the implementation of digital technologies into the NHS is clinical attitudes towards using digital technologies. Provided staff have appropriate training this should not pose too much of an issue to the integration of these technologies, as healthcare is becoming increasingly digitised. However, staff may have some concerns around changing the established treatment pathways to a more hybrid model in terms of in person care. Engagement with healthcare staff to optimise the use of digital technologies in local practices will be important, in order to maximise staff adherence and potential benefits. Furthermore, attention and care to how the technologies are deployed and enabling of specific features is important to ensure smooth integration.

7.3 Ongoing studies

Evidence for 1 RCT (COPDPredict) was provided by Nepesmo Ltd in the form of unpublished journal manuscripts (Gkini E et al. 2024, Hall J et al. [unpublished]). As the results are yet to be published, this study is considered to be ongoing and is summarised in Table 7.1**Error! Reference source not found.**.

Studies identified through company submissions

Table 7.1: Ongoing studies list from company submissions

Ongoing study (company submissions)	Alignment with scope	Outcome data for economic model	Indicated trial end date
Author (year): Kaur 2023 (Kaur et al. 2023) (protocol) **Associated:** (University of Birmingham 2020) **Study design:** RCT **Company:** Nepesmo Ltd. **Country**: UK	**Intervention**: COPDPredict and rescue medication **GREEN** **Comparator:** Standard care **GREEN** **Participants**: Patients over 18 with a diagnosis COPD, 1> acute exacerbation or hospital admission for COPD in the last 2 years and exacerbation free for 6 weeks **GREEN** **Setting**: Recruited from hospital **GREEN** **Outcomes:** AECOPD admissions, total inpatient days, number of COPD exacerbations, number of ED visits, symptom control markers, user experience of app, HRQoL, lifestyle choices, FEV_1, blood CRP, saliva CRP **GREEN**	Cost-utility and cost-effectiveness analyses	March 2023 (last updated November 2022)

Table abbreviations: AECOPD, acute exacerbation COPD; COPD, chronic obstructive pulmonary disease; CRP, c-reactive protein; ED, emergency department; FEV, forced expiratory volume; HRQoL, health-related quality of life; RCT, randomised controlled trial.

GREEN: Study characteristic aligns with the scope

8 Evidence gap analysis

The same outcomes and evidence gaps to those summarised in the original early value assessment report were also identified by the studies considered in this addendum. The EAG consider the existing summary of evidence gaps and recommendations for evidence generation reported in the EAG report to remain applicable. The new evidence submitted by ISCT (COPDhub) and Nepesmo Ltd (COPDPredict) does not affect these evidence gaps.

Doccla is likely to require further evidence generation, including the collection of healthcare resource use data. This evidence should compare Doccla with standard care compared with standard care alone in a UK NHS setting for at least a 1 year follow up period.

Table 8.1: Evidence gap analysis

Outcomes	COPDHub	COPDPredict	Doccla
Intervention adherence	No studies **RED**	1 UK prospective case series (main report) **AMBER** 1 UK RCT **AMBER**	No studies **RED**
Rates of attrition/completion	No studies **RED**	1 UK prospective case series (main report) **AMBER** 1 UK RCT **AMBER**	1 Danish cluster RTC **AMBER**
Intervention related AEs	No studies **RED**	1 UK prospective case series (main report) **AMBER** 1 UK RCT **AMBER**	No studies **RED**
Inaccessibility to intervention	No studies **RED**	1 UK prospective case series (main report) **AMBER**	No studies **RED**

Outcomes	COPDHub	COPDPredict	Doccla
Respiratory function	1 UK retrospective case series (main report) **AMBER**	1 UK RCT **AMBER**	No studies **RED**
Daily activity	1 UK retrospective case series (main report) **AMBER**	No studies **RED**	No studies **RED**
Acute COPD exacerbations	1 UK retrospective case series (main report) **AMBER**	1 UK prospective case series (main report) **AMBER** 1 UK RCT **AMBER**	No studies **RED**
Hospital admissions, readmissions or emergency admissions	1 UK before-after study **AMBER**	1 UK prospective case series (main report) **AMBER** 1 UK RCT **AMBER**	1 Danish cluster RTC **AMBER**
Outpatient clinic or GP visits	1 UK before-after study **AMBER**	No studies **RED**	1 Danish cluster RTC **AMBER**
Additional medications required	1 UK before-after study **AMBER**	1 UK prospective case series (main report) **AMBER** No studies **RED**	1 Danish cluster RTC **AMBER**
Optimising inhaler technique	No studies **RED**	No studies **RED**	No studies **RED**
Mortality	No studies **RED**	1 UK prospective case series (main report) **AMBER** 1 UK RCT **AMBER**	1 Danish cluster RTC **AMBER**
HRQoL	No studies **RED**	1 UK RCT **AMBER**	1 Danish cluster RTC **AMBER**
Patient experience, usability and acceptability	No studies **RED**	1 UK RCT **AMBER**	No studies **RED**

Outcomes	COPDHub	COPDPredict	Doccla
Psychological wellbeing	No studies **RED**	No studies **RED**	No studies **RED**

Key: **RED** indicates no comparative evidence for the scoped population; **AMBER** indicates weak comparative evidence for the scoped population; **GREEN** indicates robust comparative evidence for the scoped population.

9 Conclusions

The additional information presented to the EAG does not change the conclusions of the early value assessment report. Additional evidence was identified in mixed severity populations in treatment settings that were mixed or unclear with regard to previous COPD-related hospitalisation. The findings were similar to those identified in mixed or unclear severity population studies in the main report, with outcomes inconsistent in effect direction and generally not significant. The available clinical and economic evidence suggests that digital technology to support the self-management of adults with COPD may be beneficial to the NHS in England in people with severe COPD following exacerbation-related admission, while evidence for mild-to-moderate COPD is less clear. However, there is still a lack of comparable evidence with adequate power from a UK NHS setting for digital technologies, in particular, evidence that captures healthcare resource use. Furthermore, outcomes considering the whole COPD population, not just more severe populations are still limited. Further detail is provided in the early value assessment report.

10 References

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Doccla Ltd (2024 [unpublished]) Living Well with COPD: Results from a Clinical Review on the first 46 patients London: Doccla Ltd Available [Accessed: April]

Gkini E, Mehta R, Tearne S, et al. (2024). Use of a personalised early warning decision support system for acute exacerbations of chronic obstructive pulmonary disease: results of the 'Predict & Prevent' phase III trial.

Hall J, Turner A, Gkini E, et al. ([unpublished]). The cost-effectiveness of a personalised early warning decision support system (The COPDPredictTM system) to predict and prevent acute exacerbations of chronic obstructive pulmonary disease.

ICST Healthhub (2024a) A reduction in service use for users of Asthmahub and COPDhub. Cardiff: Icst Healthhub Available from: https://healthhub.wales/wp-content/uploads/2024/04/Service-use-ICST-Report-April-2024.pdf [Accessed: April]

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Witt Udsen F, Lilholt PH, Hejlesen O and Ehlers L. 2017. (Cost-effectiveness of telehealthcare to patients with chronic obstructive pulmonary disease: results from the Danish 'TeleCare North' cluster-randomised trial) BMJ Open [Online]. Available: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01380170/full

11 Appendices

Appendix A - List of excluded and deprioritised studies (n=3)

Table 11.1: List of excluded and deprioritised studies (n=3)

References	Exclusion reason
ICST Healthhub. Asthmahub and COPDhub: App report. Cardiff: ICST Healthhub; Feb 2024. Available from: https://healthhub.wales/wp-content/uploads/2024/04/ICST-App-Full-Report-Feb2024.pdf.	Excluded – Mixed population and outcomes not reported separately
Doccla Ltd. Living Well with COPD Service, Bristol, UK. London: Doccla Ltd; June 2024 [unpublished internal report].	Deprioritised – RCT evidence available
Doccla Ltd. Living Well with COPD: Results from a Clinical Review on the first 46 patients London: Doccla Ltd; April 2024 [unpublished].	Deprioritised – RCT evidence available

Appendix B - Clinical effects and safety outcomes

Table 11.2 Intermediate outcomes 1

Study name and location	Technology name	Intervention adherence	Rates of attrition (dropouts)
COPDHub			
ICST Healthhub, 2024a (ICST Healthhub 2024a) **Location**: UK (Wales) **Setting**: Unclear	**Design:** Before-after study, comparing winter season of 2022/23 to 2023/24. **Intervention:** COPDHub **Comparator:** Standard care	NR	NR
COPDPredict			
Gkini et al 2024 (Gkini E et al. 2024) **Associated records:** Cost-effectiveness analysis: Hall et al, [unpublished] (Hall J et al. [unpublished]) Trial registry record (University of Birmingham 2020) Protocol (Kaur et al. 2023)	**Design:** RCT **Intervention:** COPDPredict with rescue medication (n=45) **Comparator:** Standard care: standard self-management plan (instructing patients to recognise early signs of exacerbation) with	**COPDPredict adherence (>75% symptom completion in app):** 2 weeks: 84% 4 weeks: 98% **Patients described as non-adherent in the admissions PP analysis (definition NR, does not include patients with missing data):** COPDPredict: 7/41 (17.1*%) Standard care: 0/41 (0%)	**Loss to 12 month follow-up:** COPDPredict: 24 (7 withdrew, 3 died, 14 data not collected) Standard care: 17 (4 withdrew, 13 data not collected) 10 patients (6 in the COPDPredict arm and 4 in the standard care arm) did not return post-baseline survey responses and were excluded from the analysis.

Study name and location	Technology name	Intervention adherence	Rates of attrition (dropouts)
Location: UK **Setting**: Unclear	rescue medication. (n=45)		
Doccla			
Witt Udsen et al, 2017 (Witt Udsen et al. 2017) This data from HRQoL results paper: Lilholt et al, 2017 (Lilholt et al. 2017) **Location**: Denmark **Setting**: Unclear	**Design:** Cluster RCT **Intervention:** Doccla (n=578) **Comparator:** Standard care (n=647)	NR	None of the 26 cluster centres were lost to follow-up. **Doccla:** Died: 50 Did not respond: 59 Withdrew consent (reasons included complicated technology, concomitant health problems, not interested, leaving local area, does not trust equipment): 101 **Standard care:** Died: 53 Did not respond: 63 Withdrew consent (reasons included disappointment over not being assigned to Doccla, concomitant health problems, not interested, leaving local area): 61

Table abbreviations: COPD, chronic obstructive pulmonary disease; ICST, Institute of Clinical Science and Technology; PP, per protocol; RCT, randomised controlled trial. * - reviewer-calculated.

Table 11.3 Intermediate outcomes 2

Study name and location	Technology name	Intervention-related adverse events	Inaccessibility to intervention (digital inequalities)
COPDHub			
ICST Healthhub, 2024a (ICST Healthhub 2024a) **Location**: UK (Wales) **Setting**: Unclear	**Design:** Before-after study, comparing winter season of 2022/23 to 2023/24. **Intervention:** COPDHub **Comparator:** Standard care	NR	NR
COPDPredict			
Gkini et al 2024 (Gkini E et al. 2024) **Associated records:** Cost-effectiveness analysis: Hall et al, [unpublished] (Hall J et al. [unpublished]) Trial registry record (University of Birmingham 2020) Protocol (Kaur et al. 2023) **Location**: UK **Setting**: Unclear	**Design:** RCT **Intervention:** COPDPredict (Safety, n=45) **Comparator:** Standard care (Safety, n=45)	**Patients experiencing serious AE (SAE) at 12 months:** COPDPredict: 13/45 (29%) Standard care: 9/45 (20%) (p=0.327) **Patients experiencing related and Unexpected SAE (RUSAE) at 12 months:** COPDPredict: 0 Standard care: 0	NR
Doccla			
Witt Udsen et al, 2017 (Witt Udsen et al. 2017)	**Design:** Cluster RCT	AEs NR; 103/1225 (8%) patients died during the trial period (50 in	NR

Study name and location	Technology name	Intervention-related adverse events	Inaccessibility to intervention (digital inequalities)
Location: Denmark **Setting**: Unclear	**Intervention:** Doccla (n=578) **Comparator:** Standard care (n=647)	telehealthcare group; 53 in control group).	

Table abbreviations: AE, adverse event; COPD, chronic obstructive pulmonary disease; ICST, Institute of Clinical Science and Technology; NR, not reported; RCT, randomised controlled trial; RUSAE, related and unexpected SAE; SAE, serious adverse event.

Table 11.4 Clinical outcomes 1

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
COPDHub				
ICST Healthhub, 2024a (ICST Healthhub 2024a) **Location**: UK (Wales) **Setting**: Unclear	**Design:** Before-after study, comparing winter season of 2022/23 to 2023/24. **Intervention:** COPDHub **Comparator:** Standard care	NR	NR	NR

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
COPDPredict				
Gkini et al 2024 (Gkini E et al. 2024) **Associated records:** Cost-effectiveness analysis: Hall et al, [unpublished] (Hall J et al. [unpublished]) Trial registry record (University of Birmingham 2020) Protocol (Kaur et al. 2023) **Location**: UK **Setting**: Unclear	**Design:** RCT **Intervention:** COPDPredict with rescue medication (complete case, n=39) **Comparator:** Standard care: standard self-management plan (instructing patients to recognise early signs of exacerbation) with rescue medication. (complete case, n=41)	**CAT score (lower scores indicate reduced impact of COPD on daily life, MCID is reduction of >1; mean, SD):** Baseline COPDPredict: 23.8 (7.2) Standard care: 25.1 (6.4) Month 3 COPDPredict: 21.5 (8.1) Standard care: 26.1 (6.3) Adjusted mean difference: -3.78 (95% CI -6.32 to -1.24), p=0.004 Month 6 COPDPredict: 21.3 (6.5) Standard care: 25.6 (7.5) Adjusted mean difference: -3.04 (95% CI -5.70 to -0.38), p=0.025 Month 9 COPDPredict: 22.1 (7.2) Standard care: 26.1 (6.1)	NR	**Patients experiencing self-defined acute exacerbations:** 6 months: COPDPredict: 33/38 (86.8%) Standard care: 31/41 (75.6%) Adjusted risk ratio: 1.08 (95% CI 0.53 to 2.22), p=0.825 12 months: COPDPredict: 36/37 (97.3%) Standard care: 37/39 (94.9%) Adjusted risk ratio: 1.029 (95% CI 0.94 to 1.11), p=0.619 **Unreported AECOPD events (symptoms**

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
		Adjusted mean difference: -1.76 (95% CI -4.56 to 1.03), p=0.215 Month 12 COPDPredict: 22.6 (7.6) Standard care: 25.8 (5.0) Adjusted mean difference: -0.82 (95% CI -3.89 to 2.24), p=0.596		**indicated AECOPD but no action was taken):** 3 months: COPDPredict: 12.8% Standard care: 24.4% 12 months: COPDPredict: 4.7% Standard care: 7.2% Patients' ability to self-manage, as determined by whether they treated themselves when their symptoms indicated AECOPD was similar between arms, and showed little difference over time (supplementary results table S2).
Doccla				
Witt Udsen et al, 2017 (Witt Udsen et al. 2017) **Location**: Denmark	**Design:** Cluster RCT	NR	NR	NR

Study name and location	Technology name	Respiratory function (including but not limited to the COPD assessment test [CAT] score, the Modified British Medical Research Council [mMRC])	Daily activity	Acute exacerbations
Setting: Unclear	**Intervention:** Doccla (n=578) **Comparator:** Standard care (n=647)			

Table abbreviations: COPD, chronic obstructive pulmonary disease; CAT, COPD assessment test; ICST, Institute of Clinical Science and Technology; MCID, minimally clinically important difference; mMRC, Modified British Medical Research Council; NR, not reported; RCT, randomised controlled trial.

Table 11.5 Clinical outcomes 2

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
COPDHub					
ICST Healthhub, 2024a (ICST Healthhub 2024a) **Location**: UK (Wales) **Setting**: Unclear	**Design:** Before-after study, comparing winter season of 2022/23 to 2023/24. **Intervention:** COPDHub	**Mean ED visits:** COPDHub (Winter 2023/24): 0.17 Usual care (Winter 2022/23): 1.33 P= 0.033532398	**Mean GP visits:** COPDHub (Winter 2023/24): 1.3 Usual care (Winter 2022/23): 2 P=0.256	**Mean prednisolone courses:** COPDHub (Winter 2023/24): 0.81 Usual care (Winter 2022/23): 1.71 P=0.02001092	NR

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
	Comparator: Standard care				
COPDPredict					
Gkini et al 2024 (Gkini E et al. 2024) **Associated records:** Cost-effectiveness analysis: Hall et al, [unpublished] (Hall J et al. [unpublished]) Trial registry record (University of Birmingham 2020) Protocol (Kaur et al. 2023) **Location**: UK **Setting**: Unclear	**Design:** RCT **Intervention:** COPDPredict (complete case, n=39) **Comparator:** Standard care (complete case, n=41)	**Number of patients with COPD-related admissions at 12 months:** Complete case: COPDPredict: 6/39 (15.4%) Standard care: 6*/41 (14.6*%) Adjusted incident rate ratio: 0.64 (95% CI 0.19 to 2.17), p=0.478 Per protocol: COPDPredict: 4/34 (11.8%) Standard care: 6*/41 (14.6*%) Adjusted incident rate ratio: 0.47 (95% CI 0.11 to 1.90), p=0.287 **Number of patients with COPD-related admissions at 12 months (sensitivity analysis, zero-inflated negative binomial regression):** COPDPredict: 6/39 (15.4%) Standard care: 6*/41 (14.6%) Adjusted incident rate ratio: 0.67 (95% CI 0.20 to 2.29) p=0.526	NR	NR	[redacted]

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
		Number of patients with COPD-related admissions at 12 months (sensitivity analysis, imputation of PP population): COPDPredict: 6/41 (11.8%) Standard care: 6*/41 (14.6%) Adjusted incident rate ratio: 0.47 (95% CI 0.11 to 1.90), p=0.287 **Number of patients with COPD-related admissions at 12 months (sensitivity analysis, multiple imputation):** Adjusted incident rate ratio: 0.66 (95% CI 0.22 to 2.0), p=0.456 **Number of patients with at least 1 ED visit (n, %):** 6 months COPDPredict: 4/35 (11.1%) Standard care: 5/40 (12.5%) Adjusted risk ratio: 0.929 (0.26 to 3.17), p=0.889 12 months			

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
		COPDPredict: 8/23 (34.8%) Standard care: 8/31 (25.8%) Adjusted risk ratio: 1.599 (0.63 to 4.03), p=0.318 [redacted]			
Doccla					
Witt Udsen et al, 2017 (Witt Udsen et al. 2017) **Location**: Denmark **Setting**: Unclear	**Design:** Cluster RCT **Intervention:** Doccla (ITT, n=578) **Comparator:** Standard care (ITT, n=647)	**Admissions (mean, SE):** 12 months: Doccla: 0.5 (0.05) Standard care: 0.45 (0.49) Between-group difference: 0.046 (Standardised difference: difference between randomisation group averages divided by the SD of the total sample: 3.7%) **Outpatient/emergency department visits (mean, SE):** 12 months: Doccla: 0.87 (0.08) Standard care: 0.74 (0.07)	**GP visits (mean, SE)** 12 months: Doccla: 10.72 (0.35) Standard care: 9.92 (0.33) Between-group difference: 0.8 (Standardised difference: 9.35%)	**No. of antibiotic courses (mean, SE):** 12 months: Doccla: 2.41 (0.13) Standard care: 1.89 (0.11) Between-group difference: 0.52 (Standardised difference: 17.28%) **No. of R03 ATC codes (COPD medicine) at 12 months (mean, SE):** Doccla: 25.08 (0.68) Standard care: 23.92 (0.65)	NR

Study name and location	Technology name	Hospital admissions, readmissions or emergency admissions	Outpatient clinic visits, GP visits	Additional medication required including steroids, antimicrobials	Optimising inhaler technique
		Between-group difference: 0.13 (Standardised difference: 7.16%)		Between-group difference: 1.16 (Standardised difference: 7.08%)	

Table abbreviations: COPD, chronic obstructive pulmonary disease; CAT, COPD assessment test; GP, general practitioner; ICST, Institute of Clinical Science and Technology; NR, not reported; RCT, randomised controlled trial; RR, risk ratio; SD, standard deviation; SE, standard error. * - reviewer-calculated.

Table 11.6 Patient-reported outcomes

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
COPDHub				
ICST Healthhub, 2024a (ICST Healthhub 2024a) **Location**: UK (Wales) **Setting**: Unclear	**Design:** Before-after study, comparing winter season of 2022/23 to 2023/24. **Intervention:** COPDHub **Comparator:** Standard care	NR	NR	NR
COPDPredict				

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
Gkini et al 2024 (Gkini E et al. 2024) This data from cost-effectiveness paper: Hall et al [unpublished] (Hall J et al. [unpublished]) **Associated records:** Cost-effectiveness analysis: Hall et al, [unpublished] (Hall J et al. [unpublished]) Trial registry record (University of Birmingham 2020) Protocol (Kaur et al. 2023) **Location**: UK **Setting**: Unclear	**Design:** RCT **Intervention:** COPDPredict (complete case, n=39) **Comparator:** Standard care (complete case, n=41)	[redacted]	NR	NR
Doccla				
Witt Udsen et al, 2017 (Witt Udsen et al. 2017)	**Design:** Cluster RCT	**SF-36 Physical component summary (mean, SD):** Doccla: Baseline: 37.5 (9.2)	NR	NR

Study name and location	Technology name	Health-related quality of life	Patient experience, usability and acceptability	Psychological wellbeing
This data from HRQoL associated paper: Lilholt et al 2017 (Lilholt et al. 2017) **Location**: Denmark **Setting**: Unclear	**Intervention:** Doccla (ITT, n=578) **Comparator:** Standard care (ITT, n=647)	12 months: 34.6 (13.9) Mean difference: −2.6 (12.4) <u>Standard care</u>: Baseline: 37.7 (8.9) 12 months: 34.7 (13.8) Mean difference: −2.8 (11.9) Adjusted between-group difference in scores at 12 months: 0.1 (−1.4 to 1.7) **<u>SF-36 Mental component summary at 12 months (mean, SD):</u>** Doccla: Baseline: 48.5 (11.6) 12 months: 43.4 (17.2) Mean difference: - −4.7 (16.5) Standard care: Baseline: 48.9 (11.2) 12 months: 43.5 (17.3) Mean difference: −5.3 (15.5) Adjusted between-group difference in scores at 12 months: 0.4 (−1.7 to 2.4)		

Table abbreviations: COPD, chronic obstructive pulmonary disease; CAT, COPD assessment test; EQ-5D, EuroQol 5 Dimension; GP, general practitioner; ICST, Institute of Clinical Science and Technology; NR, not reported; PP, per protocol; QoL, quality of life; RCT, randomised controlled trial; SD, standard deviation; SE, standard error; SF-36, Short Form 36-item.

* Authors reported p>0.1 significance due to small sample sizes