National Institute for Health and Care Excellence

Health technologies evaluation programme

GID-HTE10019: Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease

Consultation comments table

There were 47 consultation comments from 12 consultees:

- 17 comments from 6 company representatives
- 12 comments from 2 individual consultees (academics)
- 1 comment from 1 patient organisation
- 12 comments from 2 specialist societies
- 4 comments from NHS England

The following themes have been identified:

- Recommendations: comments 1 to 10
- The technologies: comments 11 to 20
- Implementation: comments 21 to 33
- General comments: comments 34 to 37
- Evidence generation plan: comments 38 to 47

#	Consultee ID	Role	Section	Comment [sic]	NICE response
Recommendations					
1	1	Academic	1.1	I suggest making it clear that these interventions should only be offered to people who decline face to face PR. As its currently written, the text does not make explicit that face to face PR is the gold-standard, and these interventions inferior.	Thank you for your comment. Extra wording has been added to sections 1.1 and 1.4.
2	1	Academic	1.6	I suggest adding intervention adherence rates to the outcomes section.	Thank you for your comment. 'intervention adherence rates' has been added to section 1.6
3	1	Academic	1.6	I suggest adding intervention costs to this list.	Thank you for your comment. 'resource use' covers various costs.
4	1	Academic	1.6	Would patient experience be a better choice of words? Preference implies that patients will be comparing more than one intervention.	Thank you for your comment. 'patient experience' has been added to section 1.6.
5	11	British Thoracic Society	1	Are the recommendations sound, and a suitable basis for guidance to the NHS? Although throughout the document there is reference that digital technologies to deliver pulmonary rehabilitation are not for routine adoption, this could be made clearer /defined in the recommendations e.g. "Can be used in the NHS as an alternative where face to face PR is not suitable or available while more evidence is generated" versus "Can be used in the NHS while more evidence is generated". They make reference in the benefits of technologies section that the experts recommend that digital technologies should be used to overcome barriers to participation and not to manage backlogs. This could be included in the recommendations section. Our concern is that NICE endorsement although an early value assessment will lead to widespread adoption of a quick fix.	Thank you for your comment. Extra wording has been added to sections 1.1 and 1.4 in response to the comment.
6	11	British Thoracic Society	1	2. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? Yes - i.e. robust economic analysis not possible given the data. Likely less effective than face to face	Thank you for your comment.
7	11	British Thoracic Society	1.1	• 1:1 - Recommending digital technologies to deliver PR - this current statement placement may drive digital use in the absence of evidence, and wonder if it is in the right place within the document, or should be written as 'support PR'. It almost feels as though background to PR is needed first and then onto digital technologies.	Thank you for your comment. Additional wording has been included in section 1.1.

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8	12	my mhealth	1	myCOPD has full DTAC approval- this was a criteria for eligibility for EVA - the current wording suggests the technology is not approved - this requires correction . If the other technology is not approved this needs to be stipulated clearly or will lead to confusion at sites.	Thank you for your comment. This wording is to ensure the included technologies having all relevant approval before use as the regulatory status of a technology may change over time.
9	12	my mhealth	1	these technologies should also have dtac approvall before any nhs use	Thank you for your comment. The guidance states in 1.1 that the approved technologies have to have DTAC approval in order to be used. The guidance also states that more research is needed on 5 digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD but which are not currently recommended for use in the NHS. The use of these technologies should be overseen by relevant research ethics committee.
10	11	British Thoracic Society	Potential benefits of use	• 1.6 Position in the care pathway- Add information on % eligible with respect to potential health inequalities, i.e number declined due to not having access to the technology +/- wifi etc. • Effectiveness in different groups- alongside post hospitalisation, add those who frequently exacerbate as a sub-group (e.g >/=2 exacerbations per year as per GOLD). • page 6 - third to last line - "but who are not offered it" - maybe clarify this to those who are not able to access face to face PR. • Page 6/7 – adherence is higher with digital platforms over face to face – that maybe worth adding. • Page 7- "Equality: Men aged over 50 from deprived areas are more likely to have COPD. Increasing access to pulmonary rehabilitation may have the potential to improve their clinical outcomes". – not sure this is an equitable statement – less females attend PR and have high mortality from COPD, also 8% prevalence vrs 12% (pg 12).	Thank you for your comment. 1. The requested information at a national level is not available. 2. There is a lack of effectiveness data in different subgroups and further detail can be found in the assessment report. 3. This sentence refers to unmet need in general and the target population is adults with COPD who cannot have or do not want face-to-face pulmonary rehabilitation, as detailed in the

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					guidance (e.g. sections 1.1 and 1.4). 4. Regarding 'adherence', various factors affect it and further information can be found in the assessment report. More research on intervention adherence rates is needed as mentioned in the guidance. 5. Regarding equality, extra wording has been added to the 'equality' section (p.7).
The technologies					
11	1	Academic	2.1	This sentence could be phrased more clearly. Perhaps list the different components of PR first, then what the interventions may offer.	Thank you for your comment. Additional wording has been included in section 2.1.
12	8	Aseptika	2.2	Aseptika can now present the clinical report from Harefield Hospital which indicates better outcomes based on the evaluation criteria, digital technologies used by themselves. This report, prepared independently is attached. Please note the conclusions about the improved performance compared with other digital-only solutions. We propose that the assessment is paused while these latest data are considered so as to provide patients of with a genuinely choice of solution, and so this EVA based on the latest data. If these data had been available at the start of the EVA, our view is that Active+me REMOTE for PR would have be included in the further research needed group along with myCOPD and SPACE for COPD. We therefore formally request that these latest data are considered and the publication is delayed until they are incorporated into the report. We had informed NICE that these data would be available in December from the outset. A COPY OF THE PDF WITH FIGURES AND TABLES HAS BEEN SENT SEPARATELY.	Thank you for your comment. The Harefield Hospital study has been considered and included in the evidence assessment (post consultation addendum). This is the first relevant evidence for Active+Me REMOTE. The committee felt that considerable uncertainty remains so decided not to change the recommendation ('research only').
13	12	my mhealth	2.6	myCOPD access is via an app downloaded onto any internet enabled device.	Thank you for your comment. Section 2.6 has been changed.

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14	4	Wellinks	2.9	In the document titled 'Overview of Assessment Report', slide 5 contains a table comparing features offered by the technologies. Wellinks seeks to add to this table that, in addition to the features listed, our technology includes: - In-app communication with AHP (synchronous and async in-app chat between member and clinical coaches - RRT, RN, EP, etc) - Communication external to app with AHP (telephonic and video-based communication during assessments, coaching sessions, webinars, group coaching, check-ins, etc) - Patient-reported symptom tracker (In-app, web-app, and hard-copy for offline use)	Thank you for your comment. The EAG notes that companies were not clear regarding the features of their products. The EAG compiled this table to the best of its knowledge based on information provided. The EAG is satisfied to add in-app communication with AHP, communication external to app with AHP, and patient-reported symptom tracker for Wellinks. Changes to slide 5 of the overview have also been made.
15	11	British Thoracic Society	2.10	2.10- say there maybe surgical options for some patients, rather than having it stated as 'surgery'.	Thank you for your comment. Section 2.10 describes the treatment options and the choice of treatment depends on the severity of the condition and individual's overall health.
16	10	NHS England	2.11 to 2.14	There are also some points within the draft pdf document in the section entitled Care pathway which we believe are misrepresentations of NHS England's position on PR and risk causing confusion. For ease of reference, NHS England's policy position can be found in the commissioning statements document which was published on 09th January 2024 – https://www.england.nhs.uk/long-read/pulmonary-rehabilitation-commissioning-standards/. It is entirely consistent with NICE and BTS's position which means: • PR should be offered to people with a confirmed diagnosis with COPD or other chronic respiratory conditions with a MRC breathlessness score of 3 or above (the intention may not be there but 2.12 implies that it should be offered to "all" people with a diagnosis) • we suggest the reference at 2.13 to the NHS Long Term Plan is removed; it doesn't recommend that PR should be offered to people with mild COPD and above and it was published in 2019 (not 2023).	Thank you for your comment. Section 2.12 in the draft guidance has been removed. Sections 2.13 and 2.14 in the draft guidance have been renumbered as section 2.12 and 2.13 in the final guidance, and changes have been made.

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				We therefore think it would be most helpful if references to NHS England's policy position on PR are linked to the commissioning statements . We also appreciate that there may be documents online that need to be updated in line with these commissioning statements. On 2.14, the reference regarding the proportion of people being offered PR is from 2019 and the Long Term Plan. Latest published data from the Quality and Outcomes Framework for the year 2022/23 shows that 43% of people with an MRC score of 3 or above had an offer of PR over the past 12 months. That still means there is a gap in service provision because we know actual take up will be lower and service capacity is constrained. However, we think latest data should be used - we can provide a link to the specific data if helpful.	
17	1	Academic	2.13	Conflicts somewhat with 2.12 (all people who COPD should be referred to PR)	Thank you for your comment. Section 2.12 in the draft guidance has been removed and section 2.13 has been renumbered as section 2.12 in the final guidance.
18	11	British Thoracic Society	2.14	2.14 /3.1 'less than 13%'	Thank you for your comment. Section 2.14 in the draft guidance has been renumbered as section 2.13 in the final guidance. Sections 2.13 and 3.1 have been changed.
19	1	Academic	2.15	This is a really important point but by having critical information in brackets limits the clarity of the message. Suggest rephrasing.	Thank you for your comment. Section 2.15 in the draft guidance has been renumbered as section 2.14 in the final guidance. Brackets have been removed and extra wording has been added.
20	3	Concept Health Technologies Limited	1.1	Could Pulmonary Rehabilitation in Virtual Reality (PRinVR) delivered by Concept Health Technologies be included here? Below is a paper CHT has shared with NICE already: Pulmonary Rehabilitation in Virtual Reality (PRinVR): A Comprehensive Approach to Respiratory Care	Thank you for your comment. PRinVR cannot be included in the guidance because it is out of

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				Contributor: Timothy Jung, Professor of XR, Manchester Metropolitan University Farhan Amin, CEO, Concept Health Introduction: Concept Health presents an innovative solution, the Pulmonary Rehabilitation in Virtual Reality (PRinVR) device, developed in response to the substantial healthcare challenges posed by chronic respiratory diseases. Rigorous academic evaluations, conducted by Manchester Metropolitan University (Jung et al., 2020), support this ground-breaking program, which has demonstrated transformative potential in pulmonary rehabilitation. Over two years, from February 2020 to February 2022, PRinVR has delivered advanced care to 397 individuals in North Lincolnshire, boasting an 85% compliance rate. Jung, T., Moorhouse, N., Shi, X., & Amin, M. F. (2020). A virtual reality–supported intervention for pulmonary rehabilitation of patients with chronic obstructive pulmonary disease: mixed methods study. Journal of Medical Internet Research, 22(7), e14178 Revolutionising Pulmonary Rehabilitation: PRinVR transcends traditional approaches by combining virtual reality technology with remote monitoring, empowering primary care clinicians to prescribe convenient at-home pulmonary rehabilitation. This program ensures uninterrupted access to crucial pulmonary exercises 24/7, independent of external factors such as weather conditions, transportation limitations, or pandemic-related restrictions. At its core is a user-friendly virtual reality avatar guiding patients through structured exercises, monitored remotely by the clinical team to ensure safety. Emphasising simplicity, the program offers exercises that are less strenuous than traditional alternatives, promoting frequent, light, and gentle movements to enhance pulmonary function. Device Components and Safety Measures: The PRinVR Device comprises a patient-facing software application, virtual reality components, and a pulse oximeter. Safety features, including eye-tracking and sensor data optimisation, aim to reduce the risk of dizziness. Patient user groups actively participated in the design and testing phases, validating the effectiveness of these features. The Provider Dashboard facilitates seamless communication between healthcare providers and patients, enabling personalised exercise goals and real-time monitoring. Comprehensive Core Modules: PRinVR's success is derived from its thoughtful and comprehensive approach to pulmonary rehabilitation. Structured around four core components, the program addresses specific aspects crucial for the overall well-being of individuals with COPD. These modules	scope. PRinVR is a system based on a Virtual Reality set, but it is not an app/website-based technology which is the focus of the current guidance. This difference would affect the safety and efficacy profiles of the intervention. Also, NICE being informed about PRinVR was too late, beyond the deadline for consideration of inclusion.

				include Education and Patient Activation, Personalised Exercise Programme, Psychological Therapy for Anxiety Reduction, and Predictive Analysis with an Alert Mechanism, forming an integrated approach to respiratory care. 1. Education and Patient Activation: This foundational component provides valuable insights into COPD, its management, and the importance of pulmonary rehabilitation. Virtual reality technology enhances the learning experience, making educational content engaging and accessible, empowering patients with knowledge for a deeper understanding of their condition and the role of rehabilitation in improving their quality of life. 2. Personalized Exercise Programme: At the heart of PRinVR is the dynamic Personalised Exercise Programme, guiding patients through structured exercises while seated on a sturdy chair. These exercises focus on training muscles to use less oxygen, promoting flexibility and accommodating varying levels of physical capability. Remote monitoring guarantees exercises are performed safely, providing real-time feedback to enhance patient compliance and progress. 3. Psychological Therapy for Anxiety Reduction: Recognising the interconnection of physical and mental well-being, PRinVR emphasises mental health through dedicated Psychological Therapy. This module integrates virtual reality technology to deliver immersive experiences reducing anxiety. Tailored exercises promote relaxation, mindfulness, and emotional well-being, demonstrating real-world evidence of positive outcomes in anxiety scores. 4. Predictive Analysis and Alert Mechanism: Leveraging advanced technology, this component provides a proactive approach to patient care. By analysing exercise data, PRinVR employs predictive analytics to anticipate potential clinical declines. The alert mechanism ensures prompt notifications to healthcare providers, allowing timely intervention and personalised adjustments to the rehabilitation plan. These core components work synergistically, creating a well-rounded and patient-centric approach. Addressing educational needs, providing tailored exercises, prioritising mental health, and incorporating predictive analytics, PRinVR goes beyond conventional pulmonary rehabilitation programs, empowering individuals to actively participate in their health journey. Virtual Reality in Healthcare: Virtual reality (VR) technology enables users to simulate situations or experiences within an interactive computer-generated environment using a VR headset. Its applications in medical training, such as studying human anatomy or surgical procedures, are expanding. Accredited by the Royal College of Surgeons, a VR platform provides doctors with a 'flight simulator' for total hip replacement training, incorporating visual aids and haptic feedback to simulate the feel of tissue, bone, and muscle. (*Ref: Digital Health, VR surgical simulator first to receive Royal College accreditation, April 2019*) In patient care, Oxford Health NHS Foundation Trust piloted an avatar-based virtual	

				reality-supported therapy to address common mental health issues. Particularly effective for engaging children, young people, and those with autism spectrum disorders, this therapy contributes to building resilience and supporting recovery. (*Ref: FutureNHS Collaboration Platform, Global Digital Exemplar Blueprints*) Emerging examples showcase VR technology's role in helping patients manage pain, reducing the need for opioid prescriptions. A Cedars Sinai hospital study in Los Angeles found that patients wearing VR goggles during therapeutic experiences reported a 24% drop in pain scores. Real-World Impact: Results from the North Lincolnshire CCG evaluation showcase impressive outcomes. Out of 331 onboarded patients, 140 successfully completed the program, while 134 declined, and 57 were deemed unsuitable. Physical improvements were evident, with a 77% enhancement in the 1-Minute Sit & Stand Test. Equally significant were improvements in mental well-being (anxiety and depression) scores, demonstrating positive changes (Jung et al., 2023 PrePrints). Jung, T., Cho, J., Shekawat, S., & Amin, M. F. Real-time Remotely Supervised Virtual Reality based Intelligent Pulmonary Rehabilitation for Chronic Obstructive Pulmonary Disease Patients: Quantitative Study, Journal of Medical Internet Research (2023, Preprint) Patient Testimonials: Patient feedback underscores PRinVR's success, with reported increased mobility, improved energy levels, and a return to normalcy in their lives. The program's impact on mental health, particularly in reducing anxiety and depression, is a testament to its holistic approach. Detailed case studies providing in-depth insights into individual patient experiences are attached in the appendix. Also, a study based on interviews with 56 COPD patients in Staffordshire revealed patients' positive willingness to adopt new techniques, and acceptability of VR-based PR programmes (tom Dieck et al., 2024 Preprint). tom Dieck, M. C., Cho, J., Taylor, A., Jung, T., & Amin, M. F. Service Evaluation of Pulmonary Rehabilitation in Virtual Reality for Chronic Obstructive Pulmonary Disease (COPD): Qualitative Study, Journal of Medical Internet Research (2024, Preprint) Achieving NHS Net Zero Target: VR-based interventions like PRinVR have the potential to play a significant role in contributing to the NHS's net zero target. PRinVR has demonstrated its ability to not only improve patient outcomes but also contribute to environmental sustainability. By eliminating the need for patients to travel to healthcare facilities, PRinVR has been estimated to reduce CO2 emissions by an average of 18.4 kg per patient. This translates	

				into a reduction of approximately 1,840 kg of CO2 emissions for a group of 100 patients who have engaged with the platform. Additionally, PRinVR has been shown to save patient travel costs by an average of £72 per patient, resulting in a total cost savings of £7,203 for the same group of 100 patients. (Amin and Jung, 202). Expansion and Collaborations: Building on its North Lincolnshire success, PRinVR has expanded to multiple NHS trusts, collaborating with healthcare providers in Staffordshire, Bradford, York, and CSH Surrey and Sussex ICS. This expansion provides new avenues for individuals with COPD to access this innovative pulmonary rehabilitation solution. Widespread adoption signifies growing recognition of PRinVR as a transformative tool in respiratory care, extending benefits to diverse patient populations. Collaborative efforts with NHS trusts/ICS's highlight the adaptability and scalability of PRinVR, shaping the future of pulmonary rehabilitation. By transcending geographical boundaries, PRinVR ensures individuals across the nation experience positive impacts on both physical and mental well-being. As PRinVR paves the way for a new era in respiratory care, its expansion into NHS trusts exemplifies a shared commitment to innovation, patient-centric care, and the broader mission of improving lives through advanced healthcare solutions. Conclusion: PRinVR stands as a beacon of innovation, adaptability, and patient-centric care in response to the challenges posed by chronic respiratory diseases. In a global pandemic disrupting traditional care models, PRinVR emerged as a reliable and effective alternative. High completion rates, positive patient feedback, and improved mental health outcomes solidify PRinVR's position as a transformative force in pulmonary rehabilitation. Navigating the evolving healthcare landscape, PRinVR serves as a beacon of hope, delivering care where needed most—in the homes of those battling chronic respiratory diseases. The program's success signifies not just a shift in pulmonary rehabilitation approaches but a testament to healthcare's resilience and adaptability in the face of unprecedented challenges. Summary: This scholarly exploration delves into Pulmonary Rehabilitation in Virtual Reality (PRinVR) as an innovative response to the challenges posed by chronic respiratory diseases. Rigorously evaluated over two years by Manchester Metropolitan University, PRinVR combines virtual reality technology and remote monitoring, offering a comprehensive at-home pulmonary rehabilitation solution. The program's success lies in its four core components, addressing education, personalized exercises, psychological therapy, and predictive analysis. Academic scrutiny reveals tangible improvements in physical metrics and mental health, supported by patient testimonials. PRinVR's expansion across NHS trusts signifies its transformative potential, highlighting adaptability and scalability. In conclusion, PRinVR emerges as an academically substantiated, patient-centric innovation in respiratory care, demonstrating resilience amidst global healthcare challenges.	

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				Supporting References Amin, F. & Jung, T. (2024). PRinVR Helping the NHS Deliver More Accessible, Greener, and Better Quality Care, In tom Dieck, M.C., Jung, T. and Kim, Y. (eds). XR and Metaverse, Springer International Publishing pp. (In Press). Jung, T., Moorhouse, N., Shi, X., & Amin, M. F. (2020). A virtual reality–supported intervention for pulmonary rehabilitation of patients with chronic obstructive pulmonary disease: mixed methods study. Journal of Medical Internet Research, 22(7), e14178 Jung, T., Cho, J., Shekawat, S., & Amin, M. F. Real-time Remotely Supervised Virtual Reality based Intelligent Pulmonary Rehabilitation for Chronic Obstructive Pulmonary Disease Patients: Quantitative Study, Journal of Medical Internet Research (2023, Preprint) tom Dieck, M. C., Cho, J., Taylor, A., Jung, T., & Amin, M. F. Service Evaluation of Pulmonary Rehabilitation in Virtual Reality for Chronic Obstructive Pulmonary Disease (COPD): Qualitative Study, Journal of Medical Internet Research (2024, Preprint)	
Committee discussion					
21	7	Spirit Digital	3.1	[redacted] We agree with the the committee that patients who would prefer either face-to-face or digital PR be encouraged to choose, assuming they are deemed suitable for both modalities of PR.	Thank you for your comment.
22	11	British Thoracic Society	3.1	2.14 /3.1 'less than 13%'	Thank you for your comment. Sections 2.14 and 3.1 have been changed.
23	11	British Thoracic Society	3.3	3.3– also barriers to implementation – patients having quiet space, upright chair (no wheels), patient safety	Thank you for your comment. Extra wording has been added to section 3.3
24	11	British Thoracic Society	3.4	Patient considerations - concerned re the messaging that without digital technology those dependent on oxygen are unable to participate in PR. This is not true.	Thank you for your comment. As stated in the guidance, this was the opinion from one patient expert.
25	1	Academic	3.9	We also discussed that there was no qualitative research of these interventions, therefore patient experience is not understood.	Thank you for your comment. The assessment report describes that Apps et al.

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					provide additional qualitative insights into usability and participant experiences with the technology. Due to the large number of full-text papers for this technology, the EAG does not offer a commentary on this conference abstract. Please also see response to comment 4.
26	4	Wellinks	3.10	Wellinks is appreciative of the committee's efforts to identify and review the evidence base for these technologies. We would like to draw the committee's attention to the results from the ASPIRE study, which has been recently reviewed and accepted by peer reviewers and is currently in pre-print with JMIR here: https://preprints.jmir.org/preprint/47555/accepted	Thank you for your comment. The ASPIRE study has been considered and included in the evidence assessment (post consultation addendum). The committee felt that the potential benefits of Wellinks remain uncertain, so decided not to change the recommendation ('research only').
27	4	Wellinks	3.10	Wellinks is appreciative of the committee's efforts to identify and review the evidence base for these technologies. Wellinks will provide additional data including interim analyses from ongoing studies via email as instructed. These will be marked confidential.	Thank you for your comment. NICE has not received the additional data via email as described by the consultee
28	12	my mhealth	3.11	this statement is misleading- the trials evidemnce at least for myCOPD showed that there was no difference in outcome compared to face to face PR - in a non inferirity study design, in fact the outcomes were better in the myCOPD arm numerically compared to face to face delivery. This statement should be qualified.	Thank you for your comment. The guidance states that for walking distance, the trial data suggested that digital pulmonary rehabilitation was non-inferior to face-to-face pulmonary rehabilitation. But the outcomes were compared with data from the National COPD Audit Programme, which suggested that digitally supported pulmonary rehabilitation may be

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					slightly less effective than face-to-face pulmonary rehabilitation. The rationale for the different outcomes is also explained in section 3.11.
29	7	Spirit Digital	3.12	[redacted] The committee did not highlight any potential groups who may be advantaged with digital, but focused upon those who may be potentially disadvantaged by access to digitally enabled access to pulmonary rehabilitation. The committee identified:- • people who are unfamiliar with digital technologies • people who do not have access to smart devices or the internet • people who have a visual, hearing, or cognitive impairment, • people who problems with manual dexterity, a learning disability, a mental health condition, • people who are unable to read or understand health-related information (including people who cannot read English) may need additional support to use digital technologies that support pulmonary rehabilitation, • people who would benefit from their pulmonary rehabilitation to be delivered in languages other than English • People with no fixed address or with a lack of physical space at home may find taking part in exercise aspects of digitally supported pulmonary rehabilitation difficult. Potential equalities benefits • Clinical experts highlighted that digital technologies may be an enabler to some people with language difficulties • The EAG identified that digital may be beneficial to people who live rurally. There are other groups who could be advantaged • More severe COPD itself limits people's ability to get around, so enabling access to home-based pulmonary rehabilitation may advantage people in those circumstances. • Many people with COPD have co-morbidities, it may be of value for the committee to consider those with related and also those with unrelated disabilities who may be advantaged by enabling access to digital pulmonary rehabilitation, e.g. the housebound or people who find travel difficult. • People who have caring or working responsibilities may find digital more convenient or even may enable access where they may have chosen not to otherwise access it in the past. As the committee pointed out COPD is more common in lower socio-economic groups. Enabling working is often helpful for those in reduced financial circumstances. 50% of the people who accessed the Clinitouch digital pulmonary rehabilitation intervention for COPD in Staffordshire were working.	Thank you for your comment. The committee identified people who may need additional support to promote equality of opportunity, eliminate unlawful discrimination and foster good relations between people with particular protected characteristics and others. As stated in the guidance, the committee defined the group of people who this guidance will apply to as those who cannot have or do not want face-to-face pulmonary rehabilitation (person-centred). This defined group includes all eligible people and the committee's decision was made based on the existing evidence.

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				• People without easy access to transport. • The committee advised that people with visual and hearing impairment may be disadvantaged by digital PR. However, there are people with limited visual acuity who may prefer to access their PR digitally. Smartphones are commonly used by people with severe visual impairment including blindness and have functionality that enables reading documents and much more1. For people with hearing loss, having instructions that are easily seen, read and understood on a screen may also enhance accessibility to PR services. • The committee advised that people who are unfamiliar with digital technologies or who didn't have access to a smartphone may be disadvantaged by accessing digitally based PR. The average age of a Clinitouch user is 77 years of age. 82% of people between 55 and 64 owned a smartphone in 2022, an increase of 12% from 20202. It may be that the population unfamiliar with digital technology or who don't have access to a smartphone or tablet is smaller than the committee realised. The introduction of digital pulmonary rehabilitation is potentially more convenient in a society with both a high access to smartphones and a high digital literacy. If the committee feels that face-to-face PR is first choice and only patients who had a strong preference for digitally accessed PR, should access it, the equality considerations are possibly not as relevant as they may appear because those who are unable or unwilling to access digital PR would likely choose face-to-face PR. References 1. Abraham CH, Boadi-Kusi B, Morny EKA, Agyekum P. Smartphone usage among people living with severe visual impairment and blindness. Assist Technol. 2022 Sep 3;34(5):611-618. doi: 10.1080/10400435.2021.1907485. 2. Larichia F. Statista. UK: smartphone ownership by age from 2012-2022, by age (Oct 2022) https://www.statista.com/statistics/271851/smartphone-owners-in-the-united-kingdom-uk-by-age/ accessed 24/07/23	
30	12	my mhealth	3.13	again this statement applied to myCOPD is incorrect - studies showed non inferiority or superiority	Thank you for your comment. The guidance describes that the data was used from the 2015 National COPD Audit Programme (rather than the 'usual care' arm of the trial) as the comparator. Please also see response to comment 12.

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31	7	Spirit Digital	3.14	[redacted] If 59.01 meters was the mean change in the 6-minute walking test in the 2015 NACAP audit. The Clinitouch PR patient population attained 58.92 meters in the data submitted to the committee, well within the 95% confidence interval of the NACAP audit achievement. Subsequent to that more patients have completed both the digital and face to face PR interventions and the mean digital gain in the 6-minute walking test distance was 62.3 meters. While the data is of low quantity to be able to power a comparison, there is little if any difference between the NACAP audit endpoint and the Spirit Digital, Clinitouch enabled one. It is accepted that patients who accessed the face-to-face PR intervention did better with a gain of 71.7 meters. However that achievement was substantially better than the national audit increase. However, we reject that the evidence suggests that Clinitouch mediated PR was less effective and not just in walking distance gained. the mean reduction in CAT score was -2.0. the MRC score -0.77 and QALY gain 0.05. Spirit Digital recognises the lack of patient numbers, but the dataset continues to increase apace and the effect sizes are broadly comparable to the NACAP audit data with the walking distance statistically significantly improved and comparable to that achieved in the NACAP 2015 audit whether taking the figure submitted in July of 58.92 meters or the updated 62.3meters.	Thank you for your comment. Section 3.14 is based on assessing the available evidence included in the assessment report. The committee will consider updating the guidance once further data is available.
32	11	British Thoracic Society	3.19	3.19- Include evaluation of educational component as an outcome	The intervention of interest is digital technologies for pulmonary rehabilitation so the outcomes should be relevant to the intervention rather than its individual components. While the educational component as an outcome has not been mentioned, the evidence generation plan lists engagement with and information about stopping digital technologies for pulmonary rehabilitation, including reasons for stopping as an important outcome measure.
33	5	Association of	Committee discussion	The paper has thoroughly evaluated the available evidence for digital pulmonary rehabilitation technologies and the recommendations made for use in clinical practice appear to be justified. Methods used to evaluate the evidence appear robust and the	Thank you for your comment. Specialist Committee Members

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		Respiratory Nurses		interpretation of the evidence was reasonable. A wider observation is that the additional specialist committee HCP members who took part in the discussions and provided expert advice for this topic was made up of academics and one chest physician. Our view is that the committee would have benefitted from clinicians who deliver pulmonary rehabilitation in the real world. There were 2 patient reps on the committee. One of which was noted to have raised the relevance of a 6 min walking test for anyone with advanced COPD. This was an important comment relevant to digital pulmonary rehabilitation which does not appear to have been discussed in detail. Exercise capacity is framed as the key outcome. Whilst this is the most researched outcome component of PR it may not be the most important outcome for patients. The authors discuss that the outcomes of digital PR studies may be biased as patients undertaking such studies are likely to be more enthusiastic towards a digital programme and thus have more digital literacy. However in the real world these are the very patients who would be choosing to undertake a digital programme so by default will do better than someone who would select a face to face programme. The authors point out that there is no data regarding rural areas and special needs sub-groups where access to PR is often poor. A question was raised from an ARNS member regarding patients with pulmonary fibrosis. How does that cohort fit within this guidance? They have the same access problems as COPD patients and often huge AMBOT oxygen requirements which rescript travel and time away from home.	are recruited from a wide variety of relevant experience areas to ensure a range of perspectives on varying aspects of the care pathway. For the 6-minute walk test, section 3.6 states that regarding exercise capacity measures, a patient expert questioned if using validated measures such as the 6-minute walk test was appropriate for people with advanced COPD. But there was no consensus on an alternative measure that was more appropriate for these people. 'Exercise capacity' is one of the key outcomes but not the only outcome identified. This assessment is for adults with COPD but not those with pulmonary fibrosis.
General comments					
34	2	Kaia Health		In examining the EAG report, we spotted several significant inaccuracies compared with the information submitted for the Committee's consideration on Nov 3, 2023. We believe these inaccuracies may have meaningfully impacted the assessment summarized in the report. Unfortunately the system is not allowing us to comment on the supporting documents, and as such as providing them below (in addition to the report via comment) with the hope of ensuring that Kaia COPD is accurately represented in the public record, and that accurate information is utilized to assess the solution: 1. Regulatory status: As previously communicated, Kaia COPD is in fact a Class IIa CE Mark (MDR) medical device, and not a Class I as indicated in the committee document. Given the much more rigorous safety and quality standards that Class IIa solutions are held to compared to Class I, we believe this may have significant implications in addressing any safety concerns related to the use of the solution.	Thank you for your comment. 1. The regulatory status of Kaia COPD has been changed to CE class IIa in the assessment report. The EAG did not analyse interventions differently depending on CE mark level, so this will not make a material difference to the analysis. 2. The nature and scope of an EVA necessitates prioritisation

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				2. Studies evaluating efficacy of the solution were either not accurately portrayed in line with the intended design, or appear to not have been considered at all despite all being furnished to NICE: a) Studies mentioned in supporting documents but not accurately portrayed: i) Our first RCT (https://pubmed.ncbi.nlm.nih.gov/35450945/) was designed to evaluate efficacy of Kaia COPD in a post-rehab setting (6 months following F2F rehab in both groups), and was not a head to head comparison of Kaia COPD vs F2F rehab as incorrectly indicated in the committee document. This study demonstrated that compared to standard of care, patients on Kaia COPD were able to maintain benefits of F2F PR 6 months following its conclusion- particularly when looking at CAT score and physical activity (step count)- maintaining benefits of PR in itself a significant challenge well known in the literature (https://www.atsjournals.org/doi/full/10.1164/rccm.201609-1925ED). ii) A sub-group analysis (https://www.atsjournals.org/doi/pdf/10.1164/ajrccm-conference.2022.205.1_MeetingAbstracts.A1030) highlighted that high usage subgroup within the Kaia COPD group benefitted even more via the same outcome measures b) Studies not considered: i) Our single arm, real world study (https://shorturl.at/IKL01) evaluating the impact over 3 months in non-rehab patients appears to not have been considered, despite being publicly available on the German regulatory authority listing page (having been furnished to them for the listing in Germany) and provided to the committee. This study showed a significant improvement over 3 months in disease burden (CAT score) and exercise capacity (1 minute sit to stand test). We believe the above do serve as evidence of clinical benefit via several “high priority” outcome measures (CAT score, intervention completion, adverse events) and multiple outcome measures in the “other category” (daily activity/intervention uptake) Given the significant implications of the aforementioned inaccuracies on the perception of the safety/efficacy of the solution, we kindly request that these inaccuracies in the supporting documents be addressed.	of which studies are presented and what information is presented within studies. This is made clear in the EAG report. An RCT is by design a head-to-head comparison. The comparator is standard care. SCM advice and clinical guidelines state that in the UK the standard of care is face-to-face pulmonary rehabilitation. However, it is recognised that this is not always the treatment received in reality. As described in the guidance, the comparator arms in some of the trials were suboptimal rather than ‘gold standard’ pulmonary rehabilitation.
35	9	Asthma+Lung UK		At Asthma + Lung UK (A+LUK) we are fighting for everyone's right to breathe. We're the nation's lung charity and we're here for everyone who's living with a lung condition, including those with COPD. Our recent report, Saving Your Breath, showed that current access to pulmonary rehabilitation (PR) is limited, patchy and being held back by workforce shortages. As the assessment report of this guidance states, there is a major unmet need for PR despite the	Thank you for your comment. For 'implementation and service standardisation', this is a guidance with a brief description of implementation barriers but not a detailed implementation guide or tool.

				benefits of PR to people with COPD being substantial, both to them and to the NHS. In fact, our analysis found that the expansion of PR would result in £142.6 million of direct NHS savings related to reduced exacerbations, as well as a reduction of 194,000 bed days, 66,000 of which would be saved over the winter period. Therefore, we made recommendations for the expansion of PR provision, including expanding online PR. We recognise that digital provision of PR can increase accessibility by addressing barriers identified in our own research of there not being PR services close enough to people and/or inconvenient scheduling. We also fully support the use of digital PR to increase patient choice, and subsequent expansion of the number of people able to complete a course of PR, thus we are encouraged by the progression of these upcoming guidelines to use digital technologies to deliver PR programmes. However, we have identified two key areas within this document that require further consideration. Firstly, a guideline on implementation is vital to ensure a recommendation from NICE does not lead to poor execution. An implementation guideline is necessary to address many of the issues contributing to poor PR uptake; without sufficient commissioning and implementation support digital PR will not improve outcomes or experience for people with respiratory conditions. It also brings the risk of further destabilising face to face PR provision. This guidance states that 'the digital technologies will not replace face-to-face PR'. This is essential. However this guidance makes no mention of how this is to be ensured, this should be included in an implementation guideline to prevent this technology being used to mass 'refer' patients to a link, without proper consideration of the patient's needs. A thorough implementation tool could be an opportunity to improve how healthcare professionals identify people who need PR, do a referral (including consent and promoting PR to their patient) and provide information and support to increase the likelihood of uptake and completion. As part of this there should be a choice offered including a viable local face to face option. Moreover, in order to improve uptake, eligible patients should not be offered PR but given a direct referral on an opt-out basis. The recommendation to use digital technologies to deliver PR programmes needs to include training for HCPs so they themselves can understand PR, the benefits/pitfalls of face to face and digital versions and the language needed to support their patients with the whole process. There needs to be adequate integration with local services, across primary, secondary and tertiary care. There also needs to be a process for feedback into the NHS where there are concerns about the diagnosis, treatment, symptoms and care provided.	The evidence generation plan provides further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources for myCOPD and SPACE for COPD. It includes how the evidence gaps could be resolved through real-world evidence studies. Regarding accessibility, additional support and resources may be needed for people with various needed in order to promote equity of access as stated in the guidance. The evidence generation plan provides further implementation considerations to ensure that men over 50 from deprived areas with COPD are sufficiently sampled. Extra wording has been added to 'patient considerations' to address the importance of the social aspects of pulmonary rehabilitation.

				Secondly, there appears to be a large gap in the standardisation of the service provided by these 7 different technologies. Indeed, the table in the Overview of Assessment Report clearly shows that all included technologies provide a different suite of features, and whilst it states that technologies must 'have appropriate regulatory and DTAC approval or be working towards gaining necessary regulatory or DTAC status', how can a consistent high-quality service be guaranteed through different technologies to ensure all patients receive the same standard of care? Will patients be able to try different technologies or have a choice of which one they use to select which suits them best? Any implementation guideline should consider this, and evidence on technology choice and acceptability should be gathered to help HCPs make informed choices about what service to offer to their patients. With respect to the questions on equality, we acknowledge and support that digitally provided PR has the potential benefit of reducing inequalities, particularly for those with language barriers who may benefit from being able to complete the course in their preferred language, or those who may struggle to attend fate-to-face PR. However, technology can isolate others, thus it is vital that it is not used to replace face-to-face pulmonary rehabilitation in the pathway. In fact, plenty of the benefits reported to A+LUK by people who do PR go beyond clinical indicators for their lung conditions - it's about learning about their condition, being able to meet others going through something similar, and share their experiences. The social benefits of PR need to be considered in digital solutions. Part of the assessment of these technologies should include their accessibility; this can be assessed by piloting these technologies with people who have a variety of disabilities to assess and then remove accessibility barriers, making all content visually and audibly accessible. This should apply to both patient and clinician facing information. Additionally, as men over 50 from deprived areas are more likely to have COPD, evidence specific to this population should be included in the evaluation of these technologies, considering does this cohort have sufficient and equal access to the resources required to use PR, and are these technologies acceptable to them. The acceptability of digital PR among different communities should be considered in further evidence generation. A+LUK data found that 28% of survey respondents cited co-morbidities as a challenge to accessing PR, and a lack of confidence or fitness was a major barrier, this was correlated with increasing severity of breathlessness something which must be taken into consideration for those accessing PR, digital or otherwise. We also found geographical disparities in PR provision, something which digital PR, if carefully executed, could help to reduce as an inequality. However, individual patients needs and physical abilities must be assessed before prescribing digital PR and a viable local face to face option must be	

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				offered as an alternative. To summarise, the interpretation of available evidence of clinical and cost effectiveness appears to be reasonable. We agree that these technologies should be conditionally recommended for use while further evidence is generated but NICE must establish strict guidelines that tackle the problems highlighted in this response, namely implementation and service standardisation. Note: we are happy to submit any and all data referenced in this comment.	
36	10	NHS England		Thank you for the opportunity to comment on this guidance. The work is really welcomed given the level of interest and enthusiasm in digital models of PR. We understand the EVA is a relatively new process for NICE and so some of our comments are about the approach and the evidence gathering process that is being proposed. We agree entirely that further evidence is required and wondered if either the guidance or supporting documentation could be even clearer regarding the evidence gathering process that is going to be put in place in terms of who is going to make this happen and what NICE's role is going to be? As currently drafted it suggests that further research is needed and that NICE might look at it at a future point , before further detail on a proposed process and three-year window is provided. We have provided some comments and suggestions on the evidence gathering plan to help make this clearer in terms of who is responsible for this process. We are aware of, and are anticipating given the three year-window, further digital providers to want to participate in this process and so it would be helpful to clarify if and how they might do so. It may be easier to pick these points up via a conversation and the NHS E respiratory team are due to speak with NICE's EVA team shortly.	Thank you for your comment. As described in the guidance, the evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources for myCOPD and SPACE for COPD. It includes how the evidence gaps could be resolved through real-world evidence studies. The monitoring section and implementation considerations contains some guidance on roles and responsibilities of the company or technology developer, key stakeholders and NICE that could be included in the protocol in detail. Additionally, further guidance on the monitoring requirements will be provided at a later date.

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37	11	British Thoracic Society		• General comment- there may need to be some reporting on amount of supervision offered in the programme(s) (e.g telephone calls, weekly web support etc.) • Evidence not up-to-date on myCOPD - but previously the 6 week "PR programme" was not individualised. If this is the case can we call it PR? • Who should be prescribing PR? Can any health professional give out myCOPD and therefore patients access PR unsupervised? What are the safety considerations of this? We would suggest that patients have an individual assessment prior to providing access to these digital technologies. • Will the cost of supplying equipment for accessibility be considered, particularly if all patients are to have access /equitable to digital intervention if preferred.	Thank you for your comment. 1. The evidence generation plan is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. The monitoring and implementation considerations sections contain some guidance on roles and responsibilities of the company or technology developer, key stakeholders and NICE that could be included in the protocol in detail. The amount of supervision should be discussed and documented with the NHS trust where the study is implemented. Additionally, further guidance on the monitoring requirements by NICE will be provided at a later date. 2. There is variation in the components of the pulmonary rehabilitation programme. 3. This is a guidance but not an implantation guide or tool. It should follow local process when implementing it. Please also see response to comment 34. 4. The costs considered included licensing costs for technologies, health care professional costs, and other

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					additional costs (staff training, participant training, website construction). Any additional costs are beyond the remit of this assessment and should follow local arrangements.
Evidence generation plan					
38	1	Academic	committee-discussion	We also discussed that there was no qualitative research of these interventions, therefore patient experience is not understood.	Thank you for your comment. The assessment report describes that Apps et al. provide additional qualitative insights into usability and participant experiences with the technology.
39	1	Academic	Evidence generation plan	No further comments on the suitability of the proposed data collection study	Thank you for your response.
40	1	Academic	Evidence generation plan	I added some comments to the relevant section on this point.	Thank you for your comments. The raised comments have been addressed in the relevant sections of the evidence generation plan and guidance documents.
41	6	Academic	Evidence generation plan	No further comments on the suitability of the proposed data collection study	Thank you for your response.
42	6	Academic	Evidence generation plan	No further comments on the acceptability of the suggested outcome measures to address the evidence gaps?	Thank you for your response.
43	10	NHS England	Evidence generation plan	Regarding the evidence generation plan, we feel the next steps and roles and responsibilities regarding the proposed data collection study could be clearer. It would in our view be clearer to set out the process at the outset – the fact that more evidence needs to be generated, that there is going to be a 3 year period of evidence gathering, that this document outlines the plan for that in terms of evidence gaps that needs to be filled and the real-world data that needs to be collected, that there will be support for this	Thank you for your comment. The evidence generation plan is not a study protocol but suggests an approach to generating the information

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				process, and that assuming the necessary data is collected and analysis completed, NICE will review this at the end of the 3-year period.	needed to address the evidence gaps. The monitoring section and implementation considerations contain some guidance on roles and responsibilities of the company or technology developer, key stakeholders and NICE that could be included in the protocol in detail. Additionally, further guidance on the monitoring requirements will be provided at a later date.
44	10	NHS England	Evidence generation plan	Looking at 1.6 and the section on subgroups, we wondered if attention should be given to ethnic minority groups given the recent ONS mortality analysis, cross referenced at para 2.11	Thank you for your comment. The evidence generation plan has cross referenced section 1.6 of the guideline on the subgroups in section 2.2 of the evidence generation plan. These subgroups were raised in the committee discussions. Ethnicity is an explicit outcome measure to be collected at baseline in section 3.4.2 of the evidence generation plan. In addition, the evidence generation plan provides further implementation considerations to ensure that men over 50 from deprived areas with COPD are sufficiently sampled, an equality consideration in the guidance document.
45	7	Spirit Digital	Evidence generation plan	We agree with the evidence review plan. However, it will be difficult for small to medium sized companies to generate this evidence without access to NHS funding of services	Thank you for your comment. The evidence generation plan has sign-posted that *"Support*

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					for evidence generation will be available through a competitive process facilitated by the Office for Life Sciences, pending business case approval".
46	12	my mhealth	Evidence generation plan	considering that only 13% of eligible patients receive PR using the current face to face model, the main issue of PR in the NHS is non delivery - therefore understanding overall access and completion rates enabled by digital tools is the main priority- if for example digital PR was slightly less effective thane face to face but enabled a 6 fold increase in delivery and cost savings then evaluations need to ensure these data are captured ie at a population level. The approved technologies have demonstrated non inferioroty at a patient level - the key questions are around the impact and costs of scaled implementation - the current guidance misses this direction to some degree.	Thank you for your comment. Collecting information to address these questions is included in the evidence generation plan (section 3.4).
47	12	my mhealth	Evidence generation plan – Resource use 2.1	these data do not exist for face to face PR in the real world / nhs setting - ie what are the costs savings of effectively delivering PR- this is because over 80% of patient are not receiving PR and so the great majority of costs are not impacted on- NICE need to be careful that it is not setting a bar for digital technologies that current best practice has itself not met and will never do so. The section on acute care costs is particularly vulnerable to this criticism as there is not a single PR service in the UK that could directly demonstrate the costs savings due to PR.	Thank you for your comment. The comparators recommended in the scoping and guidance documents for this early valuation assessment is face-to-face pulmonary rehabilitation or standard care (no treatment or waitlist to have face-to-face pulmonary rehabilitation). The study recommended would allow for the resources to be collected across all the interventions so that the cost effectiveness of the technologies can be calculated.