

National Institute for Health and Care Excellence Health technologies evaluation programme

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

Consultation comments table

There were 36 consultation comments from 7 consultees:

- 24 comments from 3 company representatives
- 2 comments from 1 individual consultees (academics)
- 8 comments from 2 specialist societies/organisation
- 2 comments from 1 NHS organisation

The following themes have been identified:

- Care pathway: comments 1 to 4
- The technologies: comments 5 to 14
- General comments: comments 15 to 25
- Evidence generation plan: comments 26 to 33
- Implementation: comments 34 to 36



#	Consultee ID	Role	Section	Comment [sic]	NICE response		
Ca	are pathway						
1	1	my mhealth	1.6	Self-management is, by definition, not delivered through face-to-face appointments and is not monitored—this is a function of clinical care and possibly virtual wards. This definition and use of terms are confused throughout the documents.	Chair/Lead team notes: Have removed the term 'self-management' as it mentions appointments. Thank you for your comment. To clarify, while we recognise that self-management, by definition, does not involve face-to-face appointments or direct monitoring, these are part of standard care. To address this, we have amended the guidance here to remove the term "self-		
2	4	National Respiratory Audit Programme	3.2	Thank you for referencing the role of the National Respiratory Audit Programme (NRAP) as a data source with the potential to support evidence generation for this consultation. We would like to please request you update the description of NRAP. Within the COPD secondary care audit, NRAP does not collect information about people referred from primary care, but instead about people admitted to hospital with an exacerbation of COPD. The COPD secondary care audit does not currently collect EQ-5D data. The NRAP data can be linked to other datasets, but this may require additional cost. The COPD secondary care audit does not currently require users to specify whether they are using digital technologies to support self-management, or to name a technology. If there is a formal request for us to explore the inclusion of these questions, this can be explored. However, please be aware that the COPD secondary care audit dataset is only updated annually and done so in line with our governance review process and requirement to keep the dataset streamlined.	management" from that section Chair/Lead team notes: This is related to the evidence generation plan. Thank you for your comment. Amendments made to the text to reflect these comments.		
3	7	Association of Respiratory Nurses	2.17	Mortaliy data within 30 / 90 days of hosptial admission could be added, this would add exra impact	Chair/Lead team notes: "Additionally, mortality within 30 days of index admission was 6.3%, and mortality within 90 days was 12%", added to this section.		



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					Thank you for your comment. Extra wording has been added to section 2.17 to reflect your comment.
4	7	Association of Respiratory Nurses	3.1	Reword suggested; COPD is a long-term and progressive respiratory condition that can cause breathlessness, a possible chesty cough, sometimes wheezing, and potential frequent chest infections	Chair/Lead team notes: "COPD is a long-term and progressive respiratory condition that can causes breathlessness, a possible persistent chesty cough, possible persistent wheezing, and potential frequent chest infections" – lead SCM Rob agreed the change. Thank you for your comment. The wording has been slightly amended to reflect your comment.
Tec	chnologies				
5	1	my mhealth	2.1 2	Offering digital technologies as an option for supported self-management for adults with COPD could improve access, engagement, and adherence to self-management plans. As well as: • Improve health literacy • Optimise inhaler technique • Support mental health and well-being • Encourage physical activity • Promote patient empowerment • Support positive lifestyle choices • Risk factor management	Chair/Lead team notes: have added 'optimise inhaler technique' Thank you for your comment. The wording has been slightly amended to reflect your comment.



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6	1	my mhealth	2.11	The text here does not mention that myCOPD hosts a PR course, and the symptom tracking narrative is vague (daily reporting, monthly CAT scores). it should include more detailed information regarding the self-management plan: For example, it can be personalised and updated by clinicians to guide the patient journey of recovery/health improvement post-ECOPD. It can be used as part of the respiratory discharge bundle and an annual review process supporting shared care. The other features are outlined below: Personalised Self-Management Plan: - Comprehensive, structured education covering all the BTS recommended topics - Activity diary - Breathing techniques - Communication with providers - Web-based application - Therapeutic interventions: inhaler instruction, chest clearance guidance, CBT, mindfulness exercises, advice on smoking cessation - A structured programme of exercise, education, and psychosocial support	Chair/Lead team notes: have reworded the description of myCOPD. Thank you for your comment. The wording has been slightly amended to reflect your comment.
7	1	my mhealth	3.12	myCOPD is the only technology with sufficiently robust evidence to support widespread use in the NHS.	Chair/Lead team notes: No change made to the guidance due to the limitations of the evidence base for myCOPD EAG response: Thank you for your comment. The EAG has stated our conclusions based on the available evidence in the report. The conclusion is based on the opinion of the EAG. This comment provided for myCOPD is not related to a factual inaccuracy, so no further changes have been made.
8	1	my mhealth	3.1	We are collecting data for PROPEL, looking at digital support, onboarding, and engagement. This should be changed to ongoing study. Limited evidence—should say "ongoing study" as this is being collected in PROPEL.	Chair/Lead team notes: Changes to the AR, no change to guidance EAG response: Thank you for
				Effectiveness in Different Subgroups No evidence—we are collecting data in PROPEL for ethnicity and demographics	your comment. The PROPEL

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				(rural/urban location) and including data from a previous evaluation to determine longevity	study was found in the EAG
				of use.	searches as a CT.gov record
					(NCT05835492) and is
					summarised in table 9.1. We
					have added the trial name to this
					section for clarity and added
					extra detail on the evidence this
					study will provide per your
					comment.
9	2	The Institute of Clinical Science and Technology	Has all of the relevant evidence been taken into account?	Thank you for giving us the option to comment on this document. We have already emailed NICE representatives about some evidence we feel has been missed in relation to COPDhub but I will also insert it below. I would also like to draw attention to the evidence we have gathered regarding the app's impact on reducing hospital/emergency admissions and additional medication needs. Our before-and-after study design, focusing on data collected from individuals with COPD, clearly demonstrates a substantial decrease in A&E visits and Prednisolone course use among app users. These findings, which have recently been presented at the 6th International Patient Powered Safety Symposium, show the apps efficacy in improving patient outcomes and reducing healthcare needs. Please incorporate this information into the evaluation to provide a more accurate portrayal of the app's benefits. https://healthhub.wales/wp-content/uploads/2024/04/Service-use-ICST-Report-April-2024.pdf Not only has the above findings been omitted from the report, but the results from the Nov 2022 patient survey provided to you where COPDhub app users report a decrease in service utilisation after using the apps has also not been included. Additionally, the comprehensive user testing, accessibility measures, and widespread adoption of the app were all detailed in the comments form. However, they were not adequately addressed in the evaluation. The data collection form did not explicitly state the requirement for information regarding usability or accessibility. However, we have previously provided a comprehensive app report detailing user testing conducted before and shortly after the app's launch. This report encompasses patient feedback, app usability, and the measures taken to enhance its accessibility. Additionally, it includes data on app adherence, attrition (deletion) rates, and downloads during the initial months. You	Chair/Lead team notes: Awaiting addendum EAG response: Thank you for your comment. Unfortunately neither the Feb 2024 or April 2024 documents were submitted to NICE's RFI, so the EAG could not consider them as part of the review. Due to the time constraints of conducting an EVA, it was not possible to evaluate additional unpublished evidence that was not submitted by the companies, or evidence published after the EAG searches were conducted (Feb 2024). The November 2022 report includes a mixed population of COPD patients using COPDHub and asthma patients using AsthmaHub and does not report results separately for each. Therefore this study was not



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				can access the report here: https://healthhub.wales/wp-content/uploads/2024/04/ICST-App-Full-Report-Feb2024.pdf Furthermore, the positive outcomes regarding inhaler technique confidence and the impressive independent assessment by ORCHA were also highlighted in our earlier communications. Yet, they have been omitted from the evaluation, overlooking key indicators of the app's effectiveness and quality. Lastly, the significant cost savings realised by the NHS through the app's implementation were clearly outlined in the scoping documents but were not acknowledged in the evaluation. We will continue to gather more evidence for COPDhub based on the evidence generation plan, and hopefully these will be included in future reports.	eligible for inclusion in the report. The EAG report lists digital accessibility features in section 2.2.1 which cover some key issues for the ORCHA scoring system for the committee to consider. The later sections of the report focus on key clinical and economic outcomes; thus ORCHA scores are not reported here.
					The EAG accepts that there were some brief listed figures in the request for information under the economic evidence. However, the company did not provide the necessary context for these figures (such as the source of this information), so the figures could not be appropriately critiqued. Without a formal report or model, the EAG has no ability to critique the method, accuracy or quality of the results. We have therefore not included them in the report. Thank you for stating that you are committed to continuing data collection.

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10	3	Lenus Health Ltd	Has all of the relevant evidence been taken into account?	Mostly. There was evidence provided which was not fully reviewed due to the time allocated to the supplier. Specifically Lenus Health Ltd 2024b had data relating to a general COPD population rather than an AECOPD population.	Chair/Lead team notes: No changes Thank you for your comment. This study was deprioritised by the EAG. The EAG have added a note of study prioritisation to the executive summary and evidence gap sections to clarify the pragmatic elements of this report.
11	3	Lenus Health Ltd	2.9	After app please include ",accessible via any internet connected device,"	Chair/Lead team notes: Wording has been slightly amended Thank you for your comment. The wording has been slightly amended to reflect your comment.
12	3	Lenus Health Ltd	3.13	As has previously been fed back. The evidence from Lenus Health Ltd 2024 (a) was generated from patients immediately following a AECOPD admission.	Chair/Lead team notes: Wording has been slightly amended Thank you for your comment. The wording has been slightly amended to reflect your comment.
13	5	University of Birmingham	Not specified	Yes (further evidence for COPDPredict will be available soon)	Thank you for your comment. The EAG is drafting an addendum report summarising this evidence.
14 Ger	7	Association of Respiratory Nurses	3.4	Lenus have patient advisory group feedback on usage of their technology if useful for now or future	Thank you for your comment.

Page 7 of 20



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15	1	my mhealth	1	Please see generalised feedback:	Thank you for your comment.
				Evidence: While 42 papers evaluated scoped interventions, only 14 papers were included in the review. As a result, the conclusions in this report are likely to contain significant inaccuracies, as they are based on only 30% of the real evidence base. This report, therefore, needs a strong disclaimer at the start indicating that the evidence base was not reviewed in full due to time restrictions and that there will be factual inaccuracies with respect to product features and the evidence base. Any commissioning teams should, therefore, be encouraged to conduct their own independent review of the technologies and not rely on this EVA report as the sole source of information. Health Economics: Applying a general health economics model to all companies is wrong, given the highly diverse deployment models across pure self-management and remote patient monitoring. In your feedback, you justify its inclusion on the basis that "We believe the model is still useful to support decision makers". This is a subjective response. On what statistical or practical basis do you believe this model is generalisable and useful, given the expected major heterogeneity in product costs and workforce requirements? Can you please clarify this in the report? Evidence Gap: You noted in your feedback that "the evidence gap table summarises the available evidence within the prioritised studies only". We understand this, but our position is that this table is not representative of the evidence base, and your RAG ratings are, therefore, not reasonably representative of the status of the technologies. This could lead to commissioning decisions on the basis of incorrect ratings. For example, your own independent patient.	EAG response: Thank you for your comment. We have added a note of study prioritisation to the executive summary and evidence gap sections to clarify the pragmatic elements of this report. The approach to the evaluation was agreed with NICE based on the agreed timelines. The purpose of the early modelling within the context of the EVA is to explore the plausibility of costeffectiveness and to gain an understanding of some of the key drivers of the analysis. The assessment report outlines that at this early stage, when there is limited and varying evidence across companies, the economic model should not be used to make a definitive recommendation on widescale adoption in the NHS, only to inform the plausibility of costeffectiveness. In line with NICE's statement on the EVA process, full guidance should be produced once further evidence is collected on the available technologies. We (the EAG) would suggest conducting separate models for any companies recommended during the EVA process once further evidence is collected. The early economic modelling,

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					as described in the EAR, is not designed to give a specific answer to any single technology.
16	3	Lenus Health Ltd	Are the summaries of clinical and cost effectivene ss reasonable	Yes.	Thank you for your comment.
47			interpretations of the evidence?		
17	3	Lenus Health Ltd	Are the recommend ations sound and a suitable basis for guidance to the NHS?	yes.	Thank you for your comment.
18	3	Lenus Health Ltd	Are there any equality issues that need special considerati on and are not covered in the medical technology consultatio	no.	Thank you for your comment.



#	Consultee ID	Role	Section	Comment [sic]	NICE response
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			document?		
19	3	Lenus Health Ltd	Not specified	Comments on supporting information document. As highlighted at the panel session there are a number of inaccuracies in the support documentation.	Chair/Lead team notes: no changes to guidance
				Supporting Documentation Section 2.1 Included technologies- External assessment group report (page 17). Could the NHS Staff involvement be updated to read "Clinical staff can use integrated EHR data, patient reported outcome data aggregated in the clinician dashboard to support scheduled care and can send and respond to messages from patients regarding any concerns they have." Section 2.2 Feature Profile of the Technology - External assessment group report. (Page 23). Feature profile of the technologies. If the exercise column represents videos or other features that facilitate exercise this should be ticked for Lenus, as the COPD support website includes tutorials for different exercises to improve the strength and mobility of people with severe COPD. Section 4.2 included and excluded studies - External assessment group report (Page 28) "1 prospective (Cooper et al. 2023)" in the Lenus section - Can't find a note of this abstract and the provided DOI returns no results on our side. This should be Lenus Health Ltd 2024a. Section 4.2 included and excluded studies - External assessment group report (Page 35) Could the number of baseline admissions and occupied bed days in both cohorts in the year prior to onboarding be included under "Lenus" and "Control" (2.47 admissions in control vs 2.46 admissions in Lenus, 19.18 occupied bed days in both) as this is important for showing cohort matching Section 4.2 included and excluded studies - External assessment group report (Page 35) Utilisation across users in different Scottish index of multiple deprivation groups is not included in the outcomes. Section 4.2 included and excluded studies - External assessment group report (Page 42) "1 historically controlled cohort study (Lenus) included AECOPD patients hospitalised within the previous 6 months (Lenus Health Ltd 2024a). The description of this evaluation will need to be updated. This evaluation looked at patients who had just been discharged from hospital following a severe COPD exacerbation with the index date f	Thank you for your comment. EAG response: Section 2.1 Thank you for your comment. We have reviewed this statement alongside the text drafted in the report, and believe the information provided in both sets of text is the same. Therefore, we do not consider this a factual inaccuracy, rather, differences in phrasing. We have therefore not amended the text in section 2.1. Section 2.2 The EAG has updated the exercise column in table 2.2 in the assessment report. Previous engagement had not listed videos and tutorials as a feature, only 'tracking features'. We believe the additional features listed here meet the criteria. Section 4.2: Cooper 2023 abstract- Thank you for your comment. This is a conference abstract of a Scottish study that reported recruiting patients who used the Lenus app: "Enrolled patients were moved from inpatient care to a virtual ward and onboarded to remote health



	The number of admissions and occupied bed days that were had in the previous year is	monitoring (Lenus Ap
	stated for both cohorts. Would this not fall under details of care in the year prior?	Storm ID)." The DOI is
	Section 5.3 Results from the evidence base - External assessment group report (Page	https://doi.org/10.116
	55) The text here related to the "Lenus Health Ltd 2024a" manuscript is mostly redacted,	conference.2023.207
	is it possible to see this updated information somewhere? We believe it is erroneous.	Abstracts.A4498.
	Section 6.2 Withdrawals and discontinuations - External assessment group report (Page	
	64) The number of patients included in the RECEIVER study is written as 63 here rather	Section 4.2 – Included
	than 83.	Excluded studies (pag
	Table C.5 - External assessment group report (Page 259) The patient numbers included	Thank you for your co
	for the Lenus cohort and the control cohort are for those alive at one year post-onboarding	We have added this in
	rather than the entire cohorts and there is no mention of the health-related quality of life	on cohort matching to
	data for the RECEIVER cohort	comments column of
	External assessment report collated table (Page 111) "Thank you for your comment. We	characteristics table for
	have rated the intervention adherence as amber, given that this was from a prospective	study.
	cohort study, that although has long follow up, does not compare to adherence in the	
	standard care group to self-management. Because the adherence data is not comparative	Section 4.2 – Included
	in this case, we have not rated it as green."	excluded studies (pag
	We are unsure as to how we could provide comparative evidence in the case of	Thank you for your co
	adherence. Adherence to the intervention cannot be measured in those in the standard	This was not an outco
	care cohort as they do not have access to the intervention. Could you clarify what	prioritised for this EVA
	evidence we could collect on adherence in the standard care cohort going forward?	prioritioda for time E V
	evidence we doubt on danorance in the standard dare conort going forward.	Section 4.2 Included a
		excluded studies (page
		Thank you for your co
		We have corrected th
		information in the rep
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		Section 5.3 –Results
		evidence base (page
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		Thank you for your co
		The admission rate is
		outcome of interest be

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ded and age 35) comment. information to the EAG of the study for this

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s from the je 55) comment. is the being described here. This study compares the admission rate in the study arms after 12 months against the admission rate in each arm in the 12 months prior to the study. By "no details of care in the year prior were reported" we mean to say that the content of the prior COPD



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					management care (and therefore the care compared to which the study arm interventions saw an improved admission rate) was not clear. We have edited the text for clarity.
					Section 5.3 – Results from the evidence base (page 55) Thank you for your comment. Lenus has been provided this unredacted text by NICE and noted the error (a result with a p value of 0.6 was erroneously described as statistically significant). This has been corrected in the report.
					Section 6.2 – Thank you for your comment, we have corrected this.
					Table C.5 – Thank you for your comment. The QoL data was not extracted directly because it was only presented in a box and whisker plot, and graphically presented data was not digitised from any studies due to the time constraints of the EVA process. We have summarised the information in section 5.3 and will add a concise summary of this text to the table here.
					Collated table page 111 –



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20	3	Lenus Health Ltd	3.10 Benefits of the technologie s	Lenus believe that remote monitoring, when correctly implemented, can benefit both the patients (via awareness of activity, and key physiology data such as heart rate and sleep) to support self-management, as well as to support the clinical teams awareness of the patients physiology remotely. We agree that stratification and alignment of features would be beneficial, for instance more severe patients may benefit more from remote monitoring that the general diagnosed population.	Thank you for your comment.
21	3	Lenus Health Ltd	3.13 Evidence from research studies	Lenus agrees with this comment.	Thank you for your comment.
22	5	University of Birmingham	Not specified	Research has been undertaken at the University of Birmingham (lead Professor Alice Turner, a.m.turner@bham.ac.uk), as part of an NIHR i4i grant with Nepesmo who own COPDPredict. The paper reporting the randomised controlled trial has been submitted to a journal, and the economic evaluation is about to be submitted. A qualitative paper is due to be submitted later this year. The economic evaluation reports both a trial-based analysis and a model-based analysis. Data was collected on EQ-5D-5L, all COPD-related resource use and a full costing was undertaken for the COPDPredict intervention. Furthermore, a budget impact model has also been created.	Thank you for your comment. The EAG is drafting an addendum report summarising this evidence.
23	7	Association of Respiratory Nurses	1.6 - Equality	Recommended options to resolve access to smart phones / internet needed	Chair/Lead team notes: no changes to guidance Thank you for your comment. No options to resolve have been specified here, this would be a consideration for commissioners.
24	7	Association of Respiratory Nurses	3.2	Barriers - increasing ageing population without tech knowledge, ability or access	Chair/Lead team notes: no changes to guidance Thank you for your comment. Digital literacy is mentioned in section 3.2.



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25	3	Lenus Health Ltd	3.5 Patient considerati ons	We agree with this statement	Thank you for your comment.					
Evi	dence generat	lence generation								
26	1	my mhealth	1.6 Evidence generation and more research	"Potential benefits of use in the NHS with evidence generation Access:" This is incorrect; there is robust data to show that most cases are now self-managed.	Thank you for your comment.					
27	3	Lenus Health Ltd	We would like to draw your attention to the new minimum evidence standards section (section 5). Please consider it and comment on whether it reflects sufficient criteria for future NICE recommend ations of digital technologie s for supporting selfmanagement of COPD.	Yes, it does.	Thank you for your comment.					



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28	3	Lenus Health Ltd	3.2 3 Data sources	Are these data sources to be used as additional comparator sources/ reference points for the trial cohorts?	Chair/Lead team notes: no changes to guidance, this is to do with ev generation plan. Evidence generation response: Thank you for your comment. These are potential Real-world data sources that could be used to support the evidence generation plan. Other approaches such as trials could be used to deliver the necessary evidence.
29	3	Lenus Health Ltd	3.3 Real- world prospective cohort studies	Is this a defined intervention to be compared against?	Chair/Lead team notes: no changes to guidance, this is to do with ev generation plan. Evidence generation response: Thank you for your comment. The comparator for this health technology evaluation is standard care. Standard care includes self-management of COPD without digital technologies. This may include face-to-face appointments and monitoring.



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30	3	Lenus Health Ltd	3.4 Baseline information and outcomes	How could this be achieved within an RCT context or would this require separate study?	Chair/Lead team notes: no changes to guidance, this is to do with ev generation plan. Evidence generation response: Thank you for your comment. These are the outcomes that should be collected while conducting the real-world prospective cohort study. The baseline information should be collected after recruitment of the study participants.
31	6	Health Innovation Network	Not specified	As this is a guideline about how the evaluation of digital tools should be done and what questions need to be answered, the draft looks entirely reasonable, including the evidence generation plan. As this is a guideline about how the evaluation of digital tools should be done and what questions need to be answered, the draft is entirely reasonable as it is. The key is how this is taken forward and whether the questions raised are answered by the NICE EVA call. The Health Innovation Network has significant experience in supporting the spread and adoption of MyCOPD. which will be reflected on as part of our August Respiratory Clinical Working Group meeting, that we encourage NICE colleagues to attend, and from which we may emerge with more to feed into NICE's work here. Innovations The Digital Health.London accelerator features an innovation that might meet this brief: https://patientmpower.com/copd/ We have not had time to engage with all 15 health innovation networks in real depth, to surface innovations that might meet this brief. Can an additional step be introduced into the NICE process to start this engagement earlier in the consultation process?	Chair/Lead team notes: no changes to guidance Thank you for your comment. This has been disseminated to the evidence generation team.



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32	6	Health Innovation Network	Not specified	Evidence We could encourage deeper consideration of a patient activation measure (PAMs) with regards to patient self-management element. Our experience working with innovations like MyCOPD informs that this is a huge barrier. In addition - workforce capability and training needs to be factored in to implementation approaches. Suggest that evidence generated also looks at this area.	Chair/Lead team notes: no changes to guidance Thank you for your comment. The evidence generation plan has section on "engagement with, and information about, stopping using digital technologies for supporting selfmanagement of COPD" which should capture information on patient activation. Also, the following are mentioned as part of data to be collected as part of evidence generation in the guidance in section 1.6, which includes "staff time needed to support the service, training costs" and "implementation costs".



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33	7	Association of Respiratory Nurses	1.6	I havent seen anything on data/evidence collection in differing age groups or the existing technological ability of pateint prior to the use of he technology. In addition although it mentions compliance/uptake, will this be higher in younger or working individuals.	Thank you for your comment. As this is part of the evidence generation, this data will need to be collected.
Imp	lementation				
34	3	Lenus Health Ltd	3.2 Implementa tion	We believe the risk to the burden on staff is not "the amount of information" that is shared, but how it is shared and the related service model. For example, if the data is shared in too much detail, or in an incoherent format, it will be difficult and time-consuming to interpret. How if it is shared in dashboards and graphs it can provide a useful too to support the management of the patient. In a supported self-management service model, the onus should be on the patient to seek informal advice when needed rather than the clinician being responsible for the initiation of frequent reviews. However, it is imperative that the support is available as this is key factor to reduce patient anxiety, which is an important driver in the onset of exacerbations.	Thank you for your comment. The wording has been slightly amended to reflect your comment.
35	3	Lenus Health Ltd	Are there any implementa tion considerati ons for digital technologie s for	no.	Chair/Lead team notes: no changes to guidance Thank you for your response.



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			supporting self- manageme nt of COPD that we may have missed?		
36	7	Association of Respiratory Nurses	3.8	Ensure any tech links both primary and secondary care systems for dual view	Chair/Lead team notes: no changes to guidance Thank you for your comments. The raised comments have been addressed in the relevant sections of the evidence generation plan and guidance documents.