National Institute for Health and Care Excellence

Medical technologies evaluation programme

DHT 001 myCOPD to self-manage chronic obstructive pulmonary disease

Consultation comments table

Final guidance MTAC date: 21 Jan 2022

There were 108 comments from 4 groups of consultees:

- 69 comments from 2 company representatives
- 17 comments from 2 healthcare professionals
- 21 comments from 6 members of the public
- 1 comment from a professional organisation representative

A total of 72 comments arranged in the following themes are presented in Table 1. The other 36 comments responding to the 4 consultation questions are presented in Table 2.

- Recommendations (comments 1 to 8)
- Clinical evidence (comments 9 to 16)
- Cost model (comments 17 to 23)
- Further research (comments 24 to 31)
- Patient related considerations (comments 32 to 35)
- The technology (comments 36 to 50)
- Equality considerations (comments 51 to 52)
- Clarification (wording) (comments 53 to 70)
- General (comments 71 to 72)

The company also submitted a summary document (appendix 1). The EAC summarised the clinical evidence by population groups (appendix 2) and also reviewed the power calculations for the TROOPER study (see the EAC assessment report addendum).

Table 1: individual comments from the consultees (n=72)

Comment no.	Consultee ID	Group	Section	Comments	Notes for chair/committee leads
Recommendation (n=8)					
Recommendation- 2 population groups (also see appendix 1, the issue raised by the company: myCOPD has two complimentary but distinct applications i) to support self-management ii) to enable delivery of pulmonary rehabilitation.)					
1.	1	Company	Section 1	The document completely fails to address the two key questions being asked 1. Is myCOPD an effective tool when provided on discharge from hospital following an acute exacerbation of COPD? 2. Is myCOPD a viable complementary option to support the delivery of PR? It should be explicit to the reader what the outcomes are to these questions, as that is what we were asked to present and why. Whilst additional research is always an option, the comprehensive and conservative economic analyses of myCOPD, in these indications, showed cost savings following rigorous EAC review and delivered agreed positive clinical outcomes. Further research would only seek to confirm further benefit."	Thank you for your comment. The EAC's summary of the evidence base by populations and clinical outcomes was presented to the committee (see appendix 2). The committee considered your comment carefully and discussed the evidence on using of myCOPD for self-management and pulmonary rehabilitation. The answers to the 2 questions has been clarified by more clearly distinguishing between the 2 populations throughout the guidance. The committee agreed that there were limitations in the current published studies , including the small sample sizes. It concluded that further research with a larger sample size is needed in both populations to confirm the clinical and cost benefits of the technology, as well as further real world data to inform the uptake rates in the economic modelling. I
2.	1	Company		The final draft document does not answer the questions around the use of myCOPD by patients that have been discharged following an acute exacerbation of COPD (AECOPD) or	Thank you for your comment. Please see the response to comment 1.

				whether myCOPD should be used to support the delivery PR. As such, and with the comments made regarding specific elements, we feel the the draft recommendation fails to represent the authority, responsibility and esteem NICE holds and demonstrates a lack of care with the content and language used, risking user groups drawing unfounded negative conclusions from reading the current draft. We suggest significant revisions to the current document and look forward to the outcomes from that.	
3.	2	Company	Section 1	The recommendations are incomplete and have not addressed the two case for myCOPD presented, the two economic models and the two distinct patient centre indications for use namely - self mangment and pulmonary rehabilitation. The case for pulmonary rehabilitation has not been addressed - this is the widest use case for the platform currently with over 250 00 sessions provided in the last year - its is remarkable therfore that the draft does not offer a recommendation on PR. The case for PR is distinct- it does not require evidence of long term use as it is a 6 week finite intervention, it has been unequivocally shown in a fully powered high quality RCT to be equivalent to a NICE mandated aspect of COPD care, has an	Thank you for your comment. Please see the response to comment 1. The committee considered your comment carefully and agreed to amend recommendations in section 1 to specify using myCOPD for self-management and pulmonary rehabilitation in the 2 populations. The committee also amended section 4.8 to include outcomes that should be considered in further research.

				overwhelming case for health economic benefit with 87% likelihood of cost saving even with the most conservative model. It has demonstrated a clear case to build capacity for services which are currently under resourced. The committee needs to review this glaring absence and support the PR indication - without this the many thousands of patients benefitting from this intervention will have it withdrawn.	
4.	2	Company	Section 1	This section needs to include- the recommendation for PR use. The statement that the trials were short and contained fe people is factually incorrect and must be removed. The TROOPER study was fully powered and is in fact larger than many other PR trials. The duration of the studies was appropriate for the indication beings studied- 6 weeks for PR , 3 months for hospital admission. As no claims have been made for longer term usage this statement is entirely misleading and in appropriate. The costing models have generated extremely high probabilistic models of cost saving- even when adjusted by the EAC to be most conservative. These are well above a threshold accepted by health economic experts and with over 80% likelihood of savings they could in fact not be stronger- NICE would need to	Thank you for your comment. The committee considered your comment carefully and discussed the evidence on the use of myCOPD for both self-management, and pulmonary rehabilitation. For the PR population, the committee understood that the Trooper study sample size was calculated to demonstrate non-inferiority, but it agreed that the number of people included in the study was small and had limited power to detect any change in the 2 intervention groups (see the EAC assessment report addendum). This limitation was also acknowledged by the study authors. The cost savings look likely if the assumptions driving the model are accepted. The committee concluded that further research with a larger sample size is needed to confirm the clinical and cost benefits of using the technology for people who are referred for pulmonary rehabilitation.

				stipulate what level of certainty is required - this issue will not be solved by further reserach but by NICE clearly stating what the threshold of certainty is.	
5.	1	Company		We are grateful to both groups for the opportunity to present myCOPD. There were though a limited amount of time given to this new and complex area, ultimately resulting in a draft recommendation that fails to address the use of the two models but introduces many other very positive, but tangential, elements for research in the future	Thank you for your comment. Please see the response to comment 1.
Recommedation-evidence					
6.	1	Company	1.2	myCOPD DOES have clinical benefits agreed by NICE and supported by both RCT (Trooper) and RWE, compared with standard care. Trials were representative of clinical intervention durations and Trooper was correctly powered and achieved its non-inferiority outcome, thus not small (trial power being more important than size). With regards cost savings - very conservative cost saving analyses were provided for two models of implementation. Both retained their cost savings, even after EAC alterations. Additionally, both models had a high probability of delivering these cost savings and ROI in year. thus, it is unclear how further	Thank you for your comment. Please see the responses to comments 1 and 4.

				research would develop this information.	
Recommendation – wording					
7.	1	Company	1.1	The language used is loose and raises interpretational concerns. The “good quality” data not supporting “routine adoption” will result in services discontinuing the use of myCOPD as NICE is “against” it (as evidenced by the call with NICE). This is clearly not the case but this requires finessing.	Thank you for your comment. The committee considered your comment carefully and amended section 1.1 to avoid wording that refers to not supporting ‘routine adoption’. In addition, the standard text at the beginning of all medical technologies guidance explains that a recommendation for use in research is not intended to preclude the use of the technology.
8.	2	Company	1.1	The term routine adoption needs redrafting to clarify that the decision is based on a health economic case and that more evidence for cost savings are required.	Thank you for your comment. Please see the response to comment 7.
Clinical evidence (n=8)					
Clinical evidence-non inferiority trial for PR patients					
9.	1	Company	3.3	This study was powered correctly and achieved the status of non-inferior. This is ESSENTIAL for the use of myCOPD enabling it to support the delivery of PR to a wider receivership. myCOPD can then support scaling of PR services to provide a greater proportion of the MRC≥3 group with PR or an alternative to people unable or unwilling to attend classes.	Thank you for your comment and for providing additional information about the power calculation. . The committee considered your comment carefully and understood that the TROOPER study was designed as a non-inferiority trial. The clinically important difference was used as the non-inferiority threshold for CAT scores and the 6MWT. The study authors acknowledged that the study was relatively small and recommended that a larger randomised controlled trial fully powered to demonstrate health economic benefits. The EAC reviewed the power calculation for the TROOPER study and had some concerns (see the EAC assessment report addendum). Sections 3.4 and 4.2 in the guidance have been amended to refer

					to this additional information and the committee's consideration of it.
10.	2	Company	4.1	this statement is factually incorrect. The TROOPER study was fully powered as a non-inferiority study- designed and analysed by statistical experts for Imperial College Clinical trials Unit. To state it was small- is incorrect as it was the correct size to address the question. It would be unethical to deliver larger studies than the sample size required- this statement must be changed therefor.	Thank you for your comment. Please see the response to comment 9.
Clinical evidence-patient engagement (also see appendix 1, the issue raised by the company: 2.Behaviour change and Effective Engagement)					
11.	3	Healthcare professional	3.4	Can varying levels of engagement due to ill health skew the data? Are more well patients likely to engage more ?	Thank you for your comment. The committee heard that there was no data to suggest that the level of engagement was associated with ill health.
12.	2	Company	3.5	This section demonstrates very clearly that the committee has little or know understanding of the principles by which digital health interventions or indeed behaviour change per se is delivered. The concept that sustained use is a primary goal is misguided and goes against the wide literature in this filed. The concept of effective engagement and brief interventions which is the clinical standard has been completely ignored despite it being raised by experts in the review process with the NICE team on many occasions. This section needs to be rewritten by someone who understand these concepts or removed.	Thank you for your comment. The committee considered your comment carefully and acknowledged that an understanding of the relationship between engagement with intervention and behavioural change is important. It agreed that it may be more meaningful to measure effective engagement rather than simply quantifying the level of engagement. The committee heard that the adherence data reported in the TROOPER study was correct but the wording could be clearer and it agreed to amend section 3.5. The committee also agreed that both cost models were based on a 1-year time horizon and that the potential cost savings associated with myCOPD

				The statement on the TROOPPER study is incorrect and misleading. Exercise completion was greater in the mycopd arm 3.9 sessions per week compared to only 1.6 sessions in the face to face arm. The strengthen of the online option was that patient could complete upto 5 se3ssion with 2 session being the threshold of equivalence to face to face. By the final week of the study 69% of subjects completed two session in the face to face arm and 66% in the mycopd arm. This section is entirely misleading and has raised concerns with an array of PR services using the platform in the way it has been written. It is also the case that adherence with any treatment- medication, physical therapy or digital tool declines over time. the importance is the clinical benefits depsite this. This section is non sensical therefore. Furthermore both health economic models make no claims as to longe term use requirments - and stand alone with the shorter periods of follwo up which have been tracked. It is entirely ireelvent to the health economic model to make statments about long term use.	did not depend on its long term use. The paragraph about the need for evidence of longer-term benefits has been removed.
Clinical evidence-benefits					
13.	2	Company	3.4	This section carries a number of factual errors:	Thank you for your comment.

				EARLY- groups were not matched for baseline exacerbation frequency - both groups active and control demonstrated an increase in exacerbations form baseline rate during the study - usual care 3 events increased to 11 events= a 3.67 fold rise- in mycopd the change was 11 baseline to 18 trial events a 1.63 fold change- the impact of observer bias in increasing the perception of events is well recognised and the observed result clearly favours the mycopd arm in terms of effect size. All studies have clearly demonstrated statistical and clinically importnat improvements in inhaler technique. As inhaler technique is unbiquitously poor resulting in 80% of inhaled therapies being wasted it is in no way reasonable to state that there is inconclusive data on healthcare resource use as prescription costs for inhaled medication aare the leading care cost in the primary care setting.	The committee considered your comment carefully and acknowledged that patient characteristics such as exacerbation frequency were not matched at baseline. It agreed that myCOPD has the potential to improve self-management, inhaler techniques and exercise capacity, but a larger, adequately powered trial is needed to confirm the effectiveness of myCOPD and to improve the evidence base. Sections 4.1 and 4.2 in the guidance have been amended to refer to the committee's consideration of it. The committee understand that the evidence on healthcare resource use was limited in quantity with only RESCUE reporting hospital readmissions and 2 local evaluations reporting hospital admissions (NHS Grampian and NHS Highlands). It was advised that hospital readmission rate was a key driver for the acute exacerbation COPD cost model. Therefore, the committee concluded that further data on healthcare resource use in both primary and secondary care is needed to demonstrate the clinical benefits of using myCOPD for self-management.
14.	2	Company	3.6	The evidence supplied clearly demonstrates beneficial effects on daily lives. Inhaler technique unequivocally improves in all studies- to state that gaining the ability to utilise a potential lifesaving treatment is misleading and wrong. CAT score a disease relevant measure of symptom burden and impact again impoves with use in trials and in real world usage- this	Thank you for your comment. The committee considered your comment carefully and acknowledged that the trial evidence shows that myCOPD has the potential to improve COPD symptoms and inhaler techniques. It understood that such improvements in self-management were reported in a survey done by NICE public involvement programme. However, few people commented about the impact of using myCOPD on their everyday life. The committee agreed to

				cannot be understated and undermines the patients perspective - feeling better is such a vital part of COPD care for NICE to undermine this is unacceptable.	amend section 3.6 to better reflect the results from the patient survey.
15.	1	Company	3.4	Though this is true for NHS Highland, data supplied by the Dorset CCG (using Dorset Integrated Information Service, DiiS) to NICE, did report increase healthcare service use in those using myCOPD. It also evidenced that increased use in the more deprived socioeconomic groups, challenging the statements around IT literacy, internet availability and engagement from the "hard to reach groups". This must be highlighted alongside NHS Highland findings.	Thank you for your comment. Please see the response to comment 13. The committee also heard that myCOPD has been used in people living in areas with different levels of socioeconomic deprivation. Clinical experts advised that myCOPD has been implemented as an option alongside existing services and people with COPD could choose whether or not to use myCOPD. The committee agreed to highlight this in section 4.6 of the guidance. .
16.	2	Company		THE EAC report cloncluded that there is "robust evidence from RCTs and RWE of clinical benefit of myCOPD" The 280 page report is extensive and it is remarkable that the committee has ignored the majority of its findings. It was clear in attending the committee meeting that the 'expert' panel were not aware of the findings of the report this is extremely problematic and on direct questioning in this meeting the only disease area expert present could not recall the stusies or the end points when asked directly. The committee process was clearly inadequate and the Chair should have raised this - clearly the commitee needs to reconvene.	Thank you for your comment. The committee considered your comment carefully. It considered the evidence presented in the company submission and reviewed by the EAC in the assessment report. It concluded the trial evidence shows that myCOPD has the potential to improve self-management and support the delivery of pulmonary rehabilitation, but all trials had limitations such as small sample sizes. The committee acknowledged that only one clinical expert was available at the draft guidance meeting. The role of the expert at the committee meetings is usually to comment on the care pathways and their experience of using the technology. The External Assessment Centre reviews the evidence represented and usually answers questions from the committee about the

					evidence. At the final guidance meeting the committee heard from more clinical experts who described their experience of using myCOPD in clinical practice for self-management and pulmonary rehabilitation.
Cost model (n=7)					
Cost model- cost saving figures of 2 models (also see appendix 1, the issue raised by the company:3. Health economic models					
17.	1	Company	3.7	The costing models presented in the recommendation are not clear and the subsequent paragraph only address Model 1 cost savings. Model 2 should be defined and discussed in the same way. The models are Model 1 = the CCG bought the unlimited plan, thereby being able to use myCOPD in whatever way it chooses. We modelled for the impact of providing to patients following discharge from hospital for an AECOPD. This enables patients and clinicians to access ALL elements of myCOPD including PR (which did not incur further administrative costs as they were included in the initial contract). Model 2 = This model represented the use of myCOPD by PR provider services to support their provision of PR to their service users. These are discrete organisations that provide PR. This cost was £10,000 per year to such a service.	Thank you for your comment. The committee considered your comment carefully and agreed to amend the wording in section 3.7 to clarify the cost savings in relation to both individual cost models and the licence options.

18.	1	Company	3.7	These costs are effectively additive as they arise from Model 1.	Thank you for your comment. The committee considered your comment carefully and agreed not to combine the results of the 2 cost models based on the EAC advice. The EAC considered that for the population-based licence the results from the cost models should not be combined because there is likely to be overlap between the 2 populations; that is some people discharged from hospital after an acute exacerbation would also be eligible for pulmonary rehabilitation. The EAC also noted that the extent of this overlap is expected to be fairly small (approximately 5% see the assessment report)). One clinical expert explained that using myCOPD for pulmonary rehabilitation would likely have additional benefits alongside those given from other functions of the app (see correspondence log).
19.	1	Company	4.10	This section seems to overstate the effect of the uncertainties on whether myCOPD is cost-saving or not. For example, there is no reference to the EAC's sensitivity analysis. In this, for the AECOPD model, myCOPD only becomes cost-incurring if the 90 day readmission rate in myCOPD rises above 30% or the uptake rate falls below 26%. Furthermore, the probabilistic sensitivity analysis indicates a 73% likelihood that myCOPD is cost saving in the AECOPD model. For the PR only model, myCOPD remains cost-saving after all one-way changes in parameters and there was a 87%	Thank you for your comment. The committee considered your comment carefully and understood that using myCOPD could be cost saving for self-management and pulmonary rehabilitation, but there were uncertainties of the key drivers for both models because of the availability of data sources and the limitations in the evidence. Section 4.7 has been amended to more clearly identify the key drivers of the uncertaintiy in each of the cost models.

				likelihood of myCOPD being cost-saving. It is likely, with more information and evidence provided, the cost saving would be greater and even more accurately quantified.	
Cost model-myCOPD uptake rate					
20.	1	Company	3.8	This is an assumption. It assumes RESCUE's activation rate will be mirrored in the real-world scenario, outside of research/a trial. This is clearly not necessarily the case as people respond differently in real-life as opposed to in a research environment. The current national activation rate for myCOPD is 48% (23rd November 2021; 11:17am).	Thank you for your comment. The committee considered your comment carefully and heard that the RESCUE study was considered to be the most appropriate data source for the uptake rate of using myCOPD for self-management because of a lack of real-world evidence. It understood that the uptake rate of myCOPD was a key driver of the AECOPD cost model. Thank you for sharing the recent data on activation. The EAC used this for an additional analysis and it did not change the results of the AECOPD model significantly.Section 3.8 has been amended to note this additional analysis based on the company's activation data. .
21.	2	Company	3.8	The RESCUE study uptake rate was willingness to join a randomised controlled trial- NOT the app uptake rate- this is incorrect and was identified as such to the committee but this has been ignored. Dorset CCG has provided large scale uptake rates using the most up to date app version and in the real world- these should be used.	Thank you for your comment. The committee considered your comment carefully and agreed that the uptake rate in RESCUE was the percentage of people who consented to the study, but the rate of 46% was used in the model because no other data was available specifically for the people who were discharged fromhospital after an acute exacerbation.
Cost model-parameters					

22.	1	Company	4.7	Staff time was included in the model through an extended onboarding time allocation. The information needed for onboarding a patient is name, date of birth, NHS number and email. Once those are entered, the patient is onboard. 45 minutes was allocated to this. From company experience, working many NHS organisations, this takes no more than 10-15 minutes. Additional time is spent discussing elements of COPD and it management. Additionally, engagement with the clinical team can be improved without additional cost by embedding app use into existing care: annual reviews, PR appointments, support groups and other scheduled and unscheduled COPD consultations. If patients and clinical teams understand that the data in the platform contributes meaningfully to care and outcomes, any additional engagement and use could be expected to increase patient benefit and reduce overall resource use.	Thank you for your comment. The committee considered your comment carefully and heard that staff time to register a patient was included in both cost models. Staff cost for supporting patients was also included in the pulmonary rehabilitation model. The committee decided to amend section 4.4. to note that engagement with patients can be improved through implementation plans rather than stating that improving patient engagement is likely to be an additional cost to the health service.
Cost model-evidence					
23.	2	Company	4.10	this section is is poorly written conflating clinical benefit with cost savings the EAC report and consensus is of clinical benefit - the term " robust evidence was used"	Thank you for your comment. Please see the response to comment 19.

				the costs savings are modelled by an ex[pert group- the AEC adjusted these model to be as conservative as possible and they are all still ghighly predictive of a costs saving- its completely opaque as to what is expected therefore the committee need to state this as the decision is at complete odds with NICE guidance on evidence generation for digital health tech.	
Further research (n=8)					
24.	1	Company	4.1	All comments in this section are positive and support the use of myCOPD. It would appear further research would only quantify this benefit rather than preclude the use. Additional resource impact data was supplied by Dorset CCG, adding to the above favourable evidence. It is not clear how further research would contribute more to the questions being considered, other than quantifying the benefit more clearly.	Thank you for your comment. The committee considered your comment carefully and agreed that the trial evidence shows that myCOPD has the potential to improve self-management and support the delivery of pulmonary rehabilitation, but it considered that the trials for both patient populations had limitations. Sections 4.1 and 4.2 in the guidance outline the committee conclusions about the clinical evidence. Section 4.8 describes the research the committee considers is needed to reduce the uncertainties.
25.	1	Company	4.3	This title statement is true but does not contribute to the questions being answered. The provision of myCOPD to people discharged from hospital following AECOPD had demonstrable clinical benefit in the short term. Those using myCOPD to undertake a PR course benefited equally to those who undertook a traditional class, both of which are six-week	Thank you for your comment. The committee discussed the need for evidence on the longer-term benefits of using myCOPD. It decided that although this information would be valuable information it is not necessary because the potential cost savings associated with MyCOPD do not depend on its long term use. It decided to remove the paragraph about the need for evidence on the longer term benefits of using

				interventions. All use of myCOPD was cost saving and the vast majority of qualitative data gathered supported its use. The lack of long-term data should not influence the decisions around the use of myCOPD in these two groups, it should be something we gather over time as the app is being successfully implemented.	myCODP from the guidance. The committee also amended section 4.8 to include outcomes that should be considered in further research.
26.	1	Company	4.9	myCOPD contains a range of different resources that can support patients at all stages of COPD in different ways." Part of the lack of clarity of who would benefit most is that different aspects can be used by people with different needs, severities or points on the COPD pathway. This should be seen as an advantage, as myCOPD can support throughout disease progression or changes, despite making it harder to group benefits neatly by certain patient characteristics.	Thank you for your comment. The committee considered your comment carefully and acknowledged that the evidence base suggested that myCOPD can be used by people with different COPD severity. This evaluation focussed on the 2 patient groups identified by the company in their cost modelling. The committee accepted that there are potential benefits to both these patient groups if the uncertainties in the evidence are resolved. It decided to remove the section about identifying people who are most likely to benefit.
27.	1	Company	4.10	The decision to ask for additional research is based on perceived uncertainty around the cost savings in the model. We have two key issues with this. Firstly, it needs to be explicit to the reader that the bar for DHT approval is so high and why there is a clear departure from the standard requirement of cost per QALY applied to drugs and other devices. Secondly, the conservative healtheconomic	Thank you for your comment. Please see the response for comment 19. All medical technologies guidance is developed using the same MTEP methods and process manuals. There are no special arrangements for DHTs and once a technology has been routed to MTEP the same process is followed for all medical devices. myCOPD was part of a digital pilot project that explored some adaptations of the assessment process for DHTs however these did not impact

				analyses provided, despite further conservative adjustments from the EAC, retain their cost savings and show a very high probability of delivering this. It is uncertain how these models would evolve with additional research. If the request is to deliver very large and expensive trials demonstrating impacts on mortality or length of stay, this creates issues for NICE. Firstly, there are many interventions widely used and NICE guideline endorsed that have not demonstrated these outcomes, setting a new precedent. And secondly, outcomes important to patients, such as disease control measures (CAT) and functional capacity (6MWT) that are widely accepted as clinically important and provide the basis for many NICE guidelines have been downgraded in the recommendation. The expert panel who advised the EAC in the preliminary detailed report (MIB214) was not involved in the panel discussion and there was very little COPD relevant expertise contribution to this debate - the expert panel member stating they could not remember the trial outcomes used. It is vital that the bar for DHT is not set at a level which will quash all attempts to deliver high quality, appropriately evidenced digital interventions to the NHS	the assessment of the economic evidence. Cost consequence analysis is used for the development of medical technoloiges guidance and QALYs are usually not considered. The committee considered that the additional research is needed to get more robust estimates of the clinical effectiveness of the technology in each of the targeted populations. The committee also amended section 4.8 to include outcomes that should be considered in further research.

28.	2	Company	4.2	if the healthcare models demonstrate extremely high probability of savings and the app incontrovertibly improves patient behaviours and delivers PR it is not clear why and what studies are needed.	Thank you for your comment. Please see the responses for comments 1, 4 and 19.
29.	2	Company	4.3	this is absolutely misgudied- as per previous point on effective engagement and the entire theoretical basis of behaviour change.	Thank you for your comment. Please see response to comment 12.
30.	2	Company	4.10	this section highlights a very clear gap in the committees understanding of COPD care, current outcomes and the paucity of current effective therapies to contextualise this the best prescribed therapies in wide use with NICE endorsement have never demonstrated impacts on these outcomes but costs over£1000 per year per patient it is remarkable and extremely worrying that a national body such as this is so ill informed. to suggest studies need to acheive these outcome therefore essentially removes any chance for a COPD related digital product to ever achieve NICE approval- it is ill informed and should not be allowed to be published as it will severely affect the field and patient care. Please refer to the original report which consulted widely with COPD experts and di NOT reach these conclusions.	Thank you for your comment. Please see the response for comment 19. The development of this guidance followed the standard NICE methods and process. The committee was advised by clinicans working in the NHS who are familiar with COPD care and the availability of other effective therapies.

31.	2	Company	4.11	this was provided and has been ignored	Thank you for your comment. The committee considered your comment carefully and heard that the EAC reviewed information from 2 CCGs (Coventry and W Lothian) who reported qualitative data of patients using myCOPD. The committee's conclusion was that patient experience is an important consideration when evaluating digital health technologies like myCOPD. It agreed that more patient experience such as preference and adherence would be valuable. Section 4.9 was ameneded to refer the committee consideration of it.
Patients related consideration (n=4)					
Patient related consideration-patient and clinical experts					
32.	2	Company		The committee was not quorate or representative of the COPD patient user or clinical user population. Only one patient attended- they had used an outdated version of the app and in a manner not inline with the clinical recommendation of use. In complete contrast to the overwhelming positive experience of use by the large patient user base- evidenced in this document and accepted by NICE. This patient therefore stated they could not use or were not aware of the functionality of the app and generated an entirely unrepresentative view of its usability and utility. It was remarkable that the Chair did not raise this issue nor had a more representative panel been selected. In addition there was no representation by NHS clinicians who had any recent experience of use nor	Thank you for your comment. The committee considered your comment carefully and understood that the patient expert was selected to attend the committee meeting based on the information NICE and the committee chair received about their experience of having the condition of COPD and their experience of the technology. However, information about how the technology had been referred to the patient expert, or which version of the app used was not specified. The committee acknowledged the challenge inherent to DHTs that there can be incremental changes over time that affect user experience and it understood the comments from the patient expert reflected her use of an older version. It agreed that the patient expert's experience was not representative of current users of the app. The committee also noted that alongside the patient expert advice there were the results of the patient survey which has over 300 responses from a broad range of patients.

				of its use in PR- physios, practice nurses and specialist nurses were not represented despite the faqct they represent over 90% of the NHS clinical user base-. The Dorset commissioner who could have represented the ability of the app to transform services and integrate fully with NHS systems was not present and so the main committee did not hear this evidence. the committee should reconvene with a quorate and representative group.	The committee also acknowledged that only one clinical expert was available to advise the committee at the draft guidance meeting. However at the final guidance meeting, there were a broad range of clinical experts who have used myCOPD in their local practices.
33.	1	Company	4.3	It is accepted there can always be improvements and user information is critical to this. Unfortunately, the patient expert suggested improvements that exist in the current platform and that there were issues sharing their data with their clinical team. This suggests they were using an old version of the platform and without clinical oversight. Currently, 23/22/2021, 85% of myCOPD users are using the app with clinical oversight. This means their data is shared directly with their clinical teams via the clinician dashboard and they benefit from latest functionalities, that includes notifications.	Thank you for your comment. Please see the response to comment 32.
34.	2	Company	4.4	the patient expert stated they had not used a recent version of the app nor had they been able to use any of the functions which over 83% of patient do- this was the only patient on the panel which led to a misleading and biased view of the usability and	Thank you for your comment. Please see the response to comment 32.

				expertince. We provided the process with a wide array of patient feedback- uniformly positive. this needs to be addressed	
Patients related consideration-user experience					
35.	5	Member of the public		this product is very helpfull when i see my doctor to recall exasperations better if he could view it	Thank you for your comment and sharing your experience with us.
Technology (n=15)					
Technology-clinical data					
36.	3	Healthcare professional	4.5	Is the app automatically updated with new information? What measures are in place for patients for whom the app does not update in order to ensure correct clinical information?	Thank you for your comment. The committee was advised by the company that myCOPD is a cloud-based app and it can be accessed via a smart device such as phone tablet computer. Information with the app is updated automatically. It was also understood that data input could be queried via a validatory range agreed between the clinical team and the patient. For example, the default value for FEV1 is 2 -5. However, if the patient enters a number greater than 10, then the app will raise a query with them and provide a range within which they can enter a value.
37.	3	Healthcare professional	2.1	Depending on who enters the information about prescribed medication, the information may be inaccurate. If the app has interoperability with prescribing data in primary, secondary and tertiary care this may improve accuracy and applicability. If the data is manually entered, this risks incorrect data input and thus may risk incorrectly identified conflicts or prompt incorrect management plans. How can	Thank you for your comment. Please see the response to comment 36. The committee was advised by the company that no data threat would exist or be lost if the phone was lost or stolen. If there is malicious intent to access the phone and access mymhealth (the company) dataset there are security measures. It also understood that myCOPD is a DTAC compliant app.

				accuracy be ensured? Furthermore, how can data safety be ensured if the phone is lost/stolen/hacked? Is there technological support for patients who need this?	
38.	3	Healthcare professional	2.2	Does the success and/or applicability of the app depend on how well/accurately the user inputs the information? And does it depend on the digital literacy of the health care professional reviewing the information? Digital literacy can be highly variable, how can usability be ensured?	Thank you for your comment. Please see the response to comments 36 and 37. The company also confirmed that digital health advisers have been included as a part of a contract to support the implementation of the technology and to ensure the clinical and digital support teams are fully trained.
Technology-integration with NHS software systems					
39.	2	Company	4.6	This section is incorrect and has ignoired points raised by the MMH team before and during the meeting. The mycopd platform supports a FHIR API as is fully integratable with all NHS systems. It is DTAC compliant and the Dorset reperesentative would have demonstarted fully intergation of the system with NHS systems at great scale. The onboarding is being linked to the NHS app as one of the first platforms tio acheive this. The platform is more integrated and open to integration thhan almost any other NHS system- we have provided detaqiled descriptions of this to the NICE team- the statment that better understanding can only mean these have not been reviewed nor the many use cases read. please remove this statment	Thank you for your comment. The committee considered your comment carefully and heard from clinical experts who used myCOPD in their local practice. The committee understood that myCOPD can be integrated with NHS systems, and decided to remove the section about the need of integration with NHS software systems when using myCOPD in clinical practice for remote COPD monitoring .

				and replace with an accurate representation of the connected nature of the platform. the platform is widely used in an integrated way and evidence was provided for this	
40.	1	Company	4.5	This statement needs qualifying. I am not aware that patients have fedback that myCOPD should be integrated with principal clinical systems.	Thank you for your comment. Please see the response to comment 39.
41.	3	Healthcare professional	4.6	Interoperability within primary, secondary and tertiary care is an important consideration for long term usability and value of the app.	Thank you for your comment.
42.	1	Company	4.6	This statement should be considered carefully. Integration with NHS software systems requires those software systems to integrate with myCOPD. This requires coding, language and security to be all aligned and those systems to wish to process patient reported data. Currently, our experience is this is not the case. Collaborating with NICE alongside NHSD and DTAC would be a great way to develop this need. It should not influence the decisions being made re the use for AECOPD and PR as they have already been agreed to provide clinical benefit and be cost saving.	Thank you for your comment. Please see the response to comment 39.
43.	1	Company	4.6	This statement is not a reference to myCOPD but the local awareness	Thank you for your comment.

				and utility. my mhealth provide a Digital Health Advisors who is tasked with supporting clinical teams and users to optimise their understanding and use, but failure or confusion around local awareness and the app should not be attributed to the app but to the local environment and personnel.	Please see the response to comment 39.
Technology-app feature for patient engagement (adherence)					
44.	1	Company	4.7	The patient engagement functions- nudges text messaging- are all deliverable electronically- this was explained to the committee set up time is included in the model- correction needed	Thank you for your comment. At the committee meeting clinical experts explained how current versions of the app work and how the healthcare service helped patient engagement. The committee agreed to amend section 4.4 to reflect the experts' experience in their local areas.
45.	3	Healthcare professional	3.5	Can adherence be improved by modifying the app to improve user retention? E.g. daily push notifications about weather/air quality and impact on symptoms? Or periodic automated reminders from clinicians? Can AI be used to better understand user behaviour and improve adherence/engagement with the app?	Thank you for your comment. Please see the response to comment 44. The company also heard from the company that the platform applies behaviour change theory to enhance the user's experience and engagement (for clinicians and patients), including measures such as goal setting, co-scripting of management plans and treatments and the provision of interventions. .
46.	3	Healthcare professional	4.7	Can this support be provided without the use of NHS resources e.g. provided by company or use of integrated AI?	Thank you for your comment. The company confirmed that digital health advisers have been included as a part of a contract to support the implementation of the technology and to ensure the clinical and digital support teams are fully trained. The committed understood that artificial intelligence is not used in myCOPD.

47.	1	Company	4.5	please refer to eralier section on effective engagement and interventions. The committee and the EAC are entirely misguided and misunderstand the concept of adherence in this context. Can i respectfully ask that the Chair consult an established expert in this field such as Professor Lucy Yardley before making an error such as this. As a new process the DHT panel will need to get upto speed but cant make such a glaring error as patients on myCOPD will suffer as a consequence.	Thank you for your comment. The committee considered your comment carefully and acknowledged that an understanding of the relationship between engagement with intervention and behavioural change is important. At present, there is no evidence on the relationship between engagement and clinical outcomes using myCOPD. The committee agreed to remove the paragraph about understanding why only some people using myCOPD to be important.
48.	1	Company	4.5	This section is of interest and makes good points but forms the basis for future research projects. It should not influence the decisions regarding the use of the platform in the two groups being considered. We have previously provided our Behavioural Change structure and provided reference to Professor Lucy Yardley's work which offers good insight to many of the changes seen in myCOPD usage.	Thank you for your comment. Please see the response to comment 47.
Technology-its position in the care pathway					
49.	1	Company	2.4	The care pathway is deficinet - self management is one but pulmonary rehabilitation is a second- as per the NICE guideline referenced. This needs to be addressed hear and throughout the recommendation.	Thank you for your comment. The committee agreed that both self-management and pulmonary rehabilitation are recommended in NICE clinical guideline. It agreed to amend section 2.4 to summarise the recommendations for pulmonary rehabilitation.
Technology-general					

50.	1	Company	2.3	The technology was supported by the NHS England's innovation and technology tariff in 2017 and is DTAC compliant	Thank you for sharing the information with us.
Equality considerations (n=2)					
51.	3	Healthcare professional	2.2	Does endorsing the app inadvertently increase health inequalities as not everyone is digitally literate or has access to a smartphone/other digital device or will be able to use/access this app for various reasons? How will this be addressed?	Thank you for your comment. The committee also heard that myCOPD has been used in people living in areas with different levels of digital literate and socioeconomic status. Clinical experts advised that myCOPD has been implemented as an option alongside existing services, and further evidence of myCOPD's use in a wide range of socioeconomic backgrounds, ethnicities and ages is needed to understand its effect on health inequalities. The committee agreed to highlight this in section 4.6.
52.	3	Healthcare professional	4.8	Does this exclude certain population groups and increase health inequalities?	Thank you for your comment. Please see the response to comment 51.
Clarification (wording) (n=18)					
53.	1	Company	2.1	The opening statement is not correct and different to that used in the MIB214, "the platform is designed to allow shared decision making between patient and clinician to promote self-efficacy and beliefs that the patient can self-manage effectively with the support of myCOPD." The MIB214 description is correct.	Thank you for your comment. The committee considered your comment carefully and amended section 2.1 to describe functions within the app and its intended use.
54.	1	Company	2.1	This statement should be changed as it provides an exhaustive list which is incorrect. it should read, "Among the features in myCOPD are"	Thank you for your comment. Please see the response to comment 53.
55.	1	Company	2.2	This statement is incorrect. Information is shared with healthcare	Thank you for your comment.

				professionals. Users agree to data sharing when agreeing with the Privacy Policy (under GDPR). This supports the clinical and/or shared decision making.	The committee considered your comment carefully and amended section 2.2 to describe how information can be shared between healthcare professionals and patients.
56.	1	Company	4.6	This statement is incorrect. Information is shared with the clinical team under GDPR and there are shared care programmes, from whom NICE has received a report - Dorset DiiS. It should read, "Information is shared with clinical teams, but it is unclear to what extent such data is routinely used in clinical practice."	Thank you for your comment. Please see the response for comment 55.
57.	1	Company	2.6	This statement should be changed to - The use of myCOPD could potentially minimise health service contacts and facilitate delivering care remotely.	Thank you for your comment. The sentence has been amended as suggested.
58.	1	Company	2.4	The intended use is better described in the MIB214. A more explicit explanation should be provided and used - The intended purpose of myCOPD is to create a safe, secure and supported self-help environment for patients to work with their clinical teams, tracking their symptoms, assessing their COPD and its impact, accessing a range of functions and interventions to promote self-efficacy and beliefs enabling the patient to self-manage more effectively.	Thank you for your comment. Please see the response to comment 53.

59.	1	Company	2.8	This statement is not clear. It should read - The company provides an unlimited licence plan to healthcare organisations such as clinical commissioning groups or Integrated Care Systems. myCOPD licences are available at £0.25 per year per person registered with a GP in that clinical region, with a 3-year contract. Pulmonary rehabilitation service providers using myCOPD can purchase unlimited licences to support the delivery of PR to their service users for £10,000 per year.	Thank you for your comment. The committee considered your comment carefully and amended section 2.7 to clarify the cost of the technology in relation to license options available.
60.	1	Company	3.1	This information is misleading. This "additional written support" is the self-management plan mandated by NICE for the management of patients with COPD. It was not "additional" but part of the care.	Thank you for your comment. The committee considered your comment carefully and amended to clarify the comparison of myCOPD and usual care.
61.	1	Company	3.4	This statement is incorrect and the language is very poor, the implication being myCOPD caused the exacerbation? Additionally stating the "not statistically significant" after such a statement infers an element of bias to the writing. EARLY did report more exacerbations in the myCOPD arm but the baseline was unbalanced, suggesting an issue with the randomisation - Not an intrinsic issue with myCOPD. This must be reflected in the recommendations, if the result is to be discussed.	Thank you for your comment. The committee considered your comment carefully and amended section 3.3 to summarise the evidence on using myCOPD for self-management including reported outcome on the number of exacerbations and removed the paragraph about evidence on myCOPD's effect on acute exacerbation and healthcare resource use.

62.	1	Company	3.6	Prior to this statement in the paragraph you have provided the data supporting the comments. This final statement, "had limited effect on their daily lives," requires the same level of qualification. Currently it is anecdotal and unsupported and in its current form, should not be included.	Thank you for your comment. Please see the response to comment 14.
63.	1	Company	4.1	The title and prose in this section contradict one another. Title states benefits were uncertain, the body states, "The committee noted that evidence from 4 comparative studies, including 3 randomised controlled trials, showed that myCOPD had clinical benefits. These included improved chronic obstructive pulmonary disease (COPD) assessment test scores, 6-minute walk test and inhaler technique." The title should read, "myCOPD was shown to have clinical benefits," based on the committee's discussion, as it was accepted there was clinical benefit.	Thank you for your comment. The committee considered your comment carefully and agreed to amend sections 4.1 and 4.2 to describe the current evidence base including the results and limitations of the studies.
64.	1	Company	3.9	Should be "dependant"	Thank you for your comment. This section has been amended for the clarity.
65.	1	Company	3.9	cost per person	Thank you for your comment. Please see the response to comment 64.
66.	2	Company	3.9	this section is porrly written and has a number of spelling errors	Thank you for your comment. Please see the response to comment 64.

67.	2	Company	2.6	The platform is in widespread use and is evidence to reduce face to face contacts with improvements in capacity and outcome- see real world evidence form Southend Hospital - this staent need to be redrafted.	Thank you for your comment. Please see the response to comment 57.
68.	2	Company	2.7	this is factually incorrect The intended use is two fold- 1 to support self management 2 to enable delivery of pulmonary rehabilitation	Thank you for your comment. The committee considered your comment carefully and amended section 2.1 to describe functions within the app and its intended use.
69.	2	Company	4.8	the web app runs on any device including a TV now- this was clearly explained in the meeting and in the run uop- again there is a factual inaccuracy here- this section needs to be removed or rewritten	Thank you for your comment. Section 2.2 described how people can access the app including different smart devices.
70.	1	Company	3.9	The cost savings are not clear. Model 1, following EAC review, cost savings are £109,076 (£86,297 + £22,779) Model 2, following EAC review, cost savings are £11,093. In addition to these savings and the per person svings, calculated by NICE, probability analyses of achieving these cost savings were calculated. Model 1 probability of being cost saving was 73%. Model 2 probability of being cost saving was 87%.	Thank you for your comment. Please see the response to comment 17.

				These results must be incorporated.	
General (n=2)					
71.	10	Professional organisation		Thank you for your email to the MHRA. We do not have any specific regulatory comments to feedback on this.	Thank you for your comment.
72.	2	Company		This section is unclear and does not represent the DHT process or decision suitably. It has already led to misinterpretation of draft advice by clinicians and patients. The case for adoption is predicated by the health economic case in that the technology must demonstrate cost saving in addition to clinical benefit- this is absolutely unclear from the way this is written and throughout the draft report. It is vital that this is explained clearly for patients and NHS users to understand. The term routine adoption in this context is problematic as it is being interpreted as NICE are against use of the myCOPD platform or until further research is complete. This section needs redrafting explaining the process and that the recommendation relates to health economic case.	Thank you for your comment. Please see the response to comments 7 and 27. The section at the start of the guidance is standard text which is used for all medical technologies guidance. It tries to make clear that a research recommendation does not preclude the use of the technology within the NHS. This recommendation identifies when further evidence is needed which, could support a recommendation for wider adoption..

Table 2 Comments on 4 consultation questions (n=36)

#	Consultee ID	Role	Comments

Q1: Has all of the relevant evidence been taken into account?			
	1	Company	It is not clear from the draft recommendation whether this is the case and all relevant evidence has been considered.
	2	Company	Very definitely not There is an array of evidence demonstrating positive user experience, widespread benefits to service capacity and efficiency in PR and connectivity which was provided . The evidence has been carfeully reviewed in the detailed 280 page report but almost completely ignored or misunderstood at the committee stage.
	3	Healthcare professional	Yes
	4	Healthcare professional	Yes - the consultation document describes national and local evidence to support discussion and acknowledges further areas for research
	5	The public	Yes
	6	The public	As a patient I note that the impact of Covid 19 on the availability of face to face consultation and/or pulmonary rehabilitation classes is not specifically identified. Also the integration of patient record systems needs full analysis for primary and secondary care systems.
	7	The public	Yes it was
	8	The public	As far as I can see
	9	The public	Evidence seems limited. Concerned that on-going self-management and support after an exacerbation may be treated the same. I believe post-discharge support or supporting frequent attendance and advanced COPD is different.
Q2: Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?			
	1	Company	Yes, the summaries support clinical benefit, agreed by NICE here and in MIB214 and demonstrate cost effectiveness. But, additional comments made cloud these statements which require qualification, clarity or removal.
	2	Company	Both cost models report a high probability of cost savings- despite this the recommendation of the committee is to perform studies which wont alter this finding.
	3	Healthcare professional	Yes
	4	Healthcare professional	Yes
	5	The public	I think so

	6	The public	Within the limits of the trials (duration, sample numbers etc) they appear reasonable. As suggested, further study is required eg. Records integration, combined face to face / my COPD true cost/ benefit.
	7	The public	Yes it is
	8	The public	I am not sure the costing works out correctly as surely smokers who cannot give up will evidently cost the NHS going forward due to speeding the condition up
	9	The public	Reasonable interpretation. Do not believe cost-effectiveness has been adequately measured-staff costs to respond and maintain this cannot be underestimated.
Q3: Are the recommendations sound and a suitable basis for guidance to the NHS?			
	1	Company	No, the current preliminary draft fails to offer recommendations to the two key questions asked i) is myCOPD an effective tool when provided on discharge from hospital following an acute exacerbation of COPD and ii) is myCOPD a viable complementary option to support the delivery of PR. In their current form, the draft recommendations are not suitable for guidance to the NHS.
	2	Company	Absolutely not- as written the recommendations carry a high risk of direct patient harm as they will lead to widespread withdrawal of myCOPD from the NHS- considering the enormous unmet need of this condition and how remarkable the fact that this underserved population is leading in the digital health space this will be a tragedy which would not be recoverable. This is very clearly evidenced by services who have reacted to the draft recommendation- shared with MTEP.
	3	Healthcare professional	Yes
	4	Healthcare professional	Yes
	5	The public	Yes
	6	The public	I believe so as further study is recommended. As an "end user" (patient) I find the app extremely beneficial. With further study in the areas suggested it could prove to be a significant asset in terms of cost, resource optimisation and patient benefit.
	7	The public	Yes
	8	The public	It could be used I am a long term user of the app more than 2 years and it has taught me *things* about my condition and how better to take care of myself
	9	The public	I think so

Q4: Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?			
	1	Company	A great deal has been stated about IT literacy and accessibility. It should be known the average age of the user of myCOPD is 74years old (23/11/2021) and the average reading age required is between 8 and 12, depending of the complexity of the topic being discussed. IT literacy in this context, is a healthcare perceived limitation as many people can write emails and manage video conferencing, but fail to be able to produce a powerpoint presentation. Agreed further research is needed but this should not influence the recommendation regarding the use of myCOPD, just provide further areas to look at. The Dorset data should be reviewed illustrating i) the use of myCOPD in a shared care setting ii) the increase in healthcare service use and iii) the demographic benefitting from the use.
	2	Company	Yes- the committee was entirely unrepresentative of the COPD patient user, the carer perspective and the multidisciplinary teams using the app. Having attended the committee meeting it was clear this lack of a diverse perspective has had a very significant adverse impact on the recommndation.
	3	Healthcare professional	Yes, although this product has benefits, it also has the potential to increase health inequalities in those who are unable to use it due to age, gender, ethnicity, language, socioeconomic status, visual impairment, learning disabilities etc**.**
	4	Healthcare professional	No additional comments to access to IT/ non English spoken language
	5	The public	No
	6	The public	Apart from the language issue (mentioned in the consultation) I did not see any reference to technology availability which may be a significant issue for some potential users. Access to computer, tablet , smartphone or smart TV should not be automatically assumed.
	7	The public	No
	8	The public	Not sure as the fact of english and the ability to use technology is covered but I think a lot of the older or poorer population will struggle to have equipment to engage in the app, things have changed for a lot of people in the last 2 years with Covid 19
	9	The public	Services may be scaled down in belief that telehealth a replacement.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."

Appendix 1

Additional information submitted by the company

Tuesday 23rd November 2021

DHT 001 Draft NICE Document Response to Draft Guideline- mymhealth Ltd

We are grateful for the opportunity to respond to the draft guideline for myCOPD DHT 001

Importantly we wish to highlight that the current recommendation in the form it is written will have significant adverse impacts on patients, services and clinical teams as already evidenced by concerns expressed by COPD services interpreting the draft NICE recommendation which they have interpreted as indicating that myCOPD is not suitable for NHS use.

Whilst the initial EAC report and evidence review was comprehensive, highlighting the "robust evidence" for clinical benefit and strong case for cost savings supported by the EAC, the committee review and recommendation is at distinct odds with this position. The preliminary response online is factually inaccurate in many places, the conclusions are significantly misjudged, due to lack of insights into behaviour change and digital practice, and requests for additional levels of evidence in specific areas demonstrate poor understanding of the current clinical standards of care for COPD.

The company wish to raise formally a concern about the committee process – it was not representative of patient or service users and did not include health care professionals such as physiotherapists, practice nurses or specialist respiratory practitioners who are using the myCOPD platform widely across the NHS. The single patient representative appeared not to be using a current version of the app and requested additional functionality be added to the app that has already been in place for some time. From their report, they were also using the app in isolation, something that is not aligned with the intended purpose nor NICE's statement of use, "the platform is designed to allow shared decision making between patient and clinician to promote self-efficacy and beliefs that the patient can self-manage effectively with the support of myCOPD," (page 12, Sec 2 Para 1; Medical technologies guidance [DHT001 myCOPD] External Assessment Centre report). Their individual experience was at distinct odds with the large body of patient users who feedback and their individual experience has entirely influenced the tone of the committee's report.

We respectfully request that the committee reconvene for these reasons and reconsider the position based on the following factual points:

1. myCOPD has two complimentary but distinct applications i) to support self-management ii) to enable delivery of pulmonary rehabilitation. The prolonged interaction with the NICE team required development of use cases and health economic cases for each indication - independent of each other. The committee was convened to address these two uses as technical questions. However, the preliminary draft published has failed to address the use case for Pulmonary Rehabilitation. This will lead to explicit uncertainty at a service level. At many places throughout the document the two indications are conflated and the advice provided is confusing. Importantly:
    - The evidence for clinical and cost benefit for myCOPD delivering PR is robust and validated by real world use cases

- The RCT evidence for PR was from a fully powered RCT demonstrating non-inferiority to usual care. The statement regarding small studies in this regard is inaccurate and misleading as the study was sized/powered to explore this effect in an appropriate sample population.
- Statements about requiring long term use data are not relevant to the PR indication as this is a discrete six week course and completion rates were aligned to usual care with non-inferior (numerically superior) outcomes for the 6 minute walking test and CAT score. It is not relevant to require long term platform engagement for this indication and requests for this should be qualified.
- The company has provided clear evidence for improved capacity and accessibility for delivery of PR by NHS services. This has not been acknowledged in this recommendation but was explicitly referred to in MIB214 as a potential place in therapy.
- A clear recommendation for PR is required taking into account the robust nature of the clinical trial and real world evidence and the widespread adoption of the tool across UK PR services.

2. Behaviour change and Effective Engagement:

Throughout the recommendation there are statements around the need for long term engagement or statements about use rates declining with time. It is very clear that the panel has little understanding of the principles of behaviour change underpinning the development of digital interventions or how patients engage with these tools. It would be important that this is corrected so the advice generated is relevant to patients and provides the NHS with the appropriate opportunity to use tools in the best way. There are a number of UK experts in this field – we would suggest you link with Professor Lucy Yardley who is a thought leader in this area and developed the concept of effective engagement which is the mainstay for digital tools:
https://research-information.bris.ac.uk/en/persons/lucy-yardley
Brief digital interventions can carry long term and life changing impacts.
Furthermore our health economic models for both discharge and PR are based on short term use cases - demonstrating health economic savings with minimal exposure to the platform. In reality any additional duration of use beyond 3 months is not considered in these models and would only deliver additional value.

3. Health economic models

Throughout the recommendation there is a lack of clarity regarding the indications presented for the use of myCOPD, its place in the patient pathway and the subsequent robust healtheconomic analyses provided. Consequently, the recommendation completely fails to address the two key indications for which it was convened, i) is myCOPD an effective tool when provided on discharge from hospital following an acute exacerbation of COPD and ii) is myCOPD a viable complementary option to support the delivery of PR.

Model 1, addressing i), was defined as the procurement of myCOPD by a CCG and used widely in the region on discharge from hospital and to support PR delivery. Benefits to patients and services included improved CAT scores, 6-minute walk test, inhaler technique (sec 3.3, draft doc), PR outcomes (Trooper), equivalent PR outcomes supporting a non-face-to-face alternative (sec 2.6, draft doc) and an important signal for HRQL improvement for users.

Additionally, Model 1, despite EAC alterations to its conservative economic modelling, remained cost saving, with a likelihood of 73% that the use of the platform would be cost-effective and provided an estimated ROI of 180% in year.

Model 2, addressing ii), was defined as the procurement of myCOPD to support the delivery of PR by PR service providers, enabling them to scale without the inherent staffing and infrastructural costs associated with establishing a new traditional service. Model 2 was based on a fixed capital outlay (£10,000) and its subsequent service benefit. Again, following EAC review of the costing model, the use of myCOPD remained cost saving with a likelihood of being so of 87%, returning an estimated 87.6% ROI in year.

4. Additional research requests:

The decision to ask for additional research is based on perceived uncertainty around costs savings in the model. We have two key issues with this. Firstly, it needs to be explicit to the reader that the bar for DHT approval is so high and why there is a clear departure from the standard requirement of cost per QALY applied to drugs and other devices. Secondly, the conservative healtheconomic analyses provided, despite further conservative adjustments from the EAC, retain their cost savings and show a very high probability of delivering this. It is uncertain how these models would evolve with additional research.

If the request is to deliver very large and expensive trials demonstrating impacts on mortality or length of stay, this creates issues for NICE. Firstly, there are many interventions widely used and NICE guideline endorsed that have not demonstrated these outcomes, setting a new precedent. And secondly, outcomes important to patients, such as disease control measures (CAT) and functional capacity (6MWT) that are widely accepted as clinically important and provide the basis for many NICE guidelines have been downgraded in the recommendation. The expert panel who advised the EAC in the preliminary detailed report (MIB214) was not involved in the panel discussion and there was very little COPD relevant expertise contribution to this debate - the expert panel member stating they could not remember the trial outcomes used. It is vital that the bar for DHT is not set at a level which will quash all attempts to deliver high quality, appropriately evidenced digital interventions to the NHS.

Following working with the EAC and being present in the final NICE meeting, we feel there remains ongoing misunderstanding around digital applications for health and myCOPD specifically and that these were not sufficiently well dealt with in the meeting. Additionally, there remains the unaddressed question around the two discrete indications examined- PR and hospital discharge. Unfortunately, the draft recommendation fails to represent the authority, responsibility and esteem NICE holds and demonstrates a lack of care with the content and language used , risking user groups drawing unfounded negative conclusions from reading the current draft. We suggest significant revisions to the current document and look forward to the outcomes from that.

Appendix 2

Summary of clinical evidence by population group from the EAC

Population 1: People discharged from hospital due to acute exacerbations
Population 2: People eligible for PR
CS=Clinical significance; FU=Follow up; NR=Not reported; SS=Statistical significance

Study	Design	Population	N	Comparator	Outcomes						SS	CS
					Measure	Assessment	6-7 weeks	3 months	5 months	FU NR		
Population 1												
Acute exacerbations												
RESCUE (North 2020)	RCT	1 - recruited following hospital admission with an acute exacerbation	20:21	Usual self-care	Adjusted acute exacerbations rate ratio	Not reported whether self- or staff assessed		0.58 (95% CI 0.32 to 1.07) Favours myCOPD,			N	?
Hospital admissions												
RESCUE (North 2020)	RCT	1 - recruited following hospital admission with an acute exacerbation	20:21	Usual self-care	Adjusted odds ratio for readmission	Staff assessed		0.38 (95% Cl 0.07 to 1.99) Favours myCOPD			N	?
CAT score (difference in CAT score of 2 taken as clinically significant)												
RESCUE (North 2020)	RCT	1 - recruited following hospital admission	20:21	Usual self-care	Adjusted MD in change from baseline CAT score	Not reported whether		-2.94 (95% CI -6.92 to 1.04)			N	Y

Study	Design	Population	N	Comparator	Outcomes						SS	CS
					Measure	**Assessment**	**6-7 weeks**	**3 months**	**5 months**	**FU NR**		
		with an acute exacerbation				self- or staff assessed						
Inhaler error												
RESCUE (North 2020)	RCT	1 - recruited following hospital admission with an acute exacerbation	20:21	Usual self-care	Average no. errors, adjusted RR			0.38 (95% CI 0.179 to 1.04)			N	?
Health-related quality of life												
RESCUE (North 2020)	RCT	1 - recruited following hospital admission with an acute exacerbation	20:21	Usual self-care	Hospital anxiety and depression scale adjusted MD	Not reported (normally staff assessed)		-3.08 (95% CI -7.60 to 1.45)			N	?
Population 2												
CAT score (difference in CAT score of 2 taken as clinically significant)												
Trooper (Bourne 2017)	RCT	2 – recruited from primary and secondary care	64:26	Up to 2 sessions face-to-face PR over 6 weeks	Adjusted MD in change from baseline CAT score Change from baseline CAT score	Staff assessment	−1.0 (95% CI −2.9 to 0.86, p=0.373) **Non-inferior** myCOPD: -3.2				Y	NA

Study	Design	Population	N	Comparator	Outcomes						SS	CS
					Measure	**Assessment**	**6-7 weeks**	**3 months**	**5 months**	**FU NR**		
							F2F: -1.1					
Southend CCG	RWE	2 – Patients unable to attend or waiting for a centre-based PR course	15:44:29	12 sessions face-to-face PR over 6 weeks	Mean change in CAT score		myCOPD -3.7, face-to-face + myCOPD -4.2				?	NA
6-minute walk test (difference in 6MWT of 54 m taken as clinically significant)												
TROOPER (Bourne 2017)	RCT	2 – recruited from primary and secondary care	64:26	Up to 2 sessions face-to-face PR over 6 weeks	Adjusted MD in change from baseline 6MWT score	Staff assessment	23.8m (95% CI −4.5 to 52.2, p=0.098) **Non-inferior**				Y	NA
Southend CCG	RWE	2 – Patients unable to attend or waiting for a centre-based PR course	15:44:29	12 sessions face-to-face PR over 6 weeks	Uncontrolled * change from baseline		+105 (n=15)				?	Y*
Health-related quality of life												

Study	Design	Population	N	Comparator	Outcomes						SS	CS
					Measure	**Assessment**	**6-7 weeks**	**3 months**	**5 months**	**FU NR**		
TROOPER (Bourne 2017)	RCT	2 – recruited from primary and secondary care	64:26	Up to 2 sessions face-to-face PR over 6 weeks	Hospital anxiety and depression scale adjusted MD in change score	Not reported (normally staff assessed)	-0.74 (95% CI -3.5 to 0.9, p=0.263) N**on-inferiority suggested**				?	?
TROOPER (Bourne 2017)	RCT	2 – recruited from primary and secondary care	64:26	Up to 2 sessions face-to-face PR over 6 weeks	St Georges Respiratory Questionnaire adjusted MD in change	Not reported	-3.72 (95% CI -10.7 to 3.3, p=0.291) **Non-inferiority suggested**				?	?
Other populations												
Acute exacerbations												
EARLY (Crooks 2020)	RCT	Other - Mild, moderate or recently diagnosed COPD	29:31	Usual self-care	Adjusted acute exacerbations rate ratio	Not reported whether self- or staff assessed		2.55 (95% CI 1.17 to 5.54) Favours usual self-care			?	?

Study	Design	Population	N	Comparator	Outcomes						SS	CS
					Measure	Assessment	6-7 weeks	3 months	5 months	FU NR		
NHS Grampian	RWE	Other - Patients on GPs' recruitment registers	64	None	Proportion of patients with exacerbations every other day	Self-reported			Reduced from 28% to 22%		?	?
Hospital admissions												
NHS Grampian	RWE	Other - Patients on GPs' recruitment registers	64	None	Uncontrolled change from baseline admissions	Staff assessment			6 to 0		?	?
Highlands (Cooper 2021b)	RWE	Other - Remote and rural population with COPD	120	None	Uncontrolled change from baseline admissions	Staff assessment			Insignificant change at 12 months		N	?
CAT score (difference in CAT score of 2 taken as clinically significant)												
EARLY (Crooks 2020)	RCT	Other - Mild, moderate or recently diagnosed COPD	29:31	Usual self-care	Adjusted MD in change from baseline CAT score	Not reported whether self- or staff assessed		-1.27 (95% CI -4.47 to 1.92, p=0.435)			N	N
North 2015	Observational	Other - Patients with confirmed COPD	36	Paper-based COPD self-management	Change from baseline CAT score	Staff assessed		Most myCOPD patients -4.5 compared with mean +2.4 in			?	Y

Study	Design	Population	N	Comparator	Outcomes						SS	CS
					Measure	**Assessment**	**6-7 weeks**	**3 months**	**5 months**	**FU NR**		
								control group.				
NHS Grampian	RWE	Other - Patients on GPs' recruitment registers	64	None	Uncontrolled * reduction in CAT score	Staff assessed			-2.1		?	Y*
Mid and South Essex	RWE	Other - COPD patients in contact with the respiratory team	NR	None	Uncontrolled * change in CAT score					-3.7	?	Y*
6-minute walk test (difference in 6MWT of 54 m taken as clinically significant)												
Mid and South Essex	RWE	Other - COPD patients in contact with the respiratory team	NR	None	Uncontrolled * change from baseline					+58m	?	Y*
Consultations												
NHS Grampian	RWE	Other - Patients on GPs' recruitment registers	64	None	Unscheduled GP appointments	Staff assessment			19% fewer		?	?
Inhaler error												

Study	Design	Population	N	Comparator	Outcomes						SS	CS
					Measure	Assessment	6-7 weeks	3 months	5 months	FU NR		
EARLY (Crooks 2020)	RCT	Other - Mild, moderate or recently diagnosed COPD	29:31	Usual self-care	Average number of errors, adjusted RR >1 error, adjusted OR	Staff assessed		0.97 (95% CI 0.52 to 1.8, p=0.93) 0.30 (95% CI 0.09 to 1.06, p=0.061)			N N	? ?
North 2015	Observational	Other - Patients with confirmed COPD	36	Paper-based COPD self-management	Proportion using correctly			2% at baseline, 98% at follow up			?	?
NHS Grampian	RWE	Other - Patients on GPs' recruitment registers	64	None	Proportion with good technique	Staff assessed			48% at baseline, 91% at follow up		?	?
Health-related quality of life												
EARLY (Crooks 2020)	RCT	Other - Mild, moderate or recently diagnosed COPD	29:31	Usual self-care	EQ-5D Utility Score, adjusted MD	Not reported		-0.04 (95% CI -0.12 to 0.05)			N	?