National Institute for Health and Care Excellence

Medical technologies evaluation programme

GID-HTE10021 Digital technologies for managing non-specific low back pain
Consultation comments table

There are 52 consultation comments from 13 consultees:

- 26 comments from 7 companies
- 22 comments from 5 individuals
- 4 comments from 1 professional organisation

The comments are reproduced in full, arranged in the following groups (**some comments contain multiple issues and have been split**):

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- Care pathway: comments 8 to 10
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#	Consultee ID	Role	Section	Comments
Recommendations				
1	8	Company	Are the recommendations sound	On the basis of this missing information, the evaluation and guidance is incomplete; this could be rectified by the inclusion of the additional data from Phio Engage and further evaluation. Given that over

			and a suitable basis for guidance to the NHS?	1.8 million NHS patients currently have access to this technology, it is essential that the evidence for Phio Engage should be considered in the evaluation.
2	1	Company	Are the recommendations sound and a suitable basis for guidance to the NHS?	"During the assessment of the recommendations, we have identified a few points that merit further discussion. Firstly, we have concerns regarding the choice of “standard care” as the comparator group. As the EVA authors admit themselves, “Standard care” varies significantly across primary and community care and might be perceived differently depending on regional and cultural contexts. As such, more clearly defined interventions would probably contribute to more homogeneous control groups between different trials. We suggest the inclusion of in-person physiotherapy as a comparator group since this follows previous NICE guidelines [1]. Secondly, we have come across the recommended metrics for future research as stated in the section “Evidence generation and research”, which raised some concerns specifically with the recommendation of the Musculoskeletal Health Questionnaire for disability appraisal. This metric has not been recommended in previous NICE guidelines [1], and its use has not been widely applied as other validated metrics such as Oswestry Disability Index (ODI). For the assessment of functionality in patients with LBP, a systematic review following COSMIN criteria assessed 16 questionnaires and found that the ODI and the Quebec Back Pain Disability Scale were the questionnaires most used within the scientific literature, and that showed adequate psychometric properties [2]. Furthermore, the International Consortium for Health Outcomes Measurement also recommends the use of ODI to assess this domain [3], further reinforcing its use in low back disorders. Additionally, to our knowledge, the psychometric properties of the Musculoskeletal Health Questionnaire have been predominantly assessed for arthritis conditions, whereas for LBP evidence is still scarce [4,5]. These findings would perhaps merit additional discussion on which instrument should be recommended to evaluate the outcomes of of these programs. Thirdly, we would like to suggest some modifications on the proposed time frame to study treatment adherence. Treatment adherence should be stratified for treatment and self-management interventions. In treatment interventions, since treatment duration highly depends on the specific needs of each patient, adherence analysis should follow the prescribed treatment time frame, instead of arbitrarily defined timepoints. For self-management Apps the suggested treatment adherence time points seem adequate (baseline, 30 days and between 6 months and 1 year), but we would recommend the inclusion of an additional time point between 30 days and 6 months, namely at 3 months (or 90 days). Finally, we believe the Sword Health digital care program should be considered to be used in the NHS. Below is a proposed summary for such technology: Sword Health Regulatory status: Sword Health is certified as class I in the UK, is actively pursuing DTAC certification

				Delivery: Tablet, mobile phone Target Condition: Recovery from LBP injuries, either acute or chronic (can also be used in wider MSK injuries). Supports prevention after recovery and management of recurrent episodes. Key features: Tailored digital care program to each patient needs 100% delivered by physiotherapists, real-time biofeedback and gamified exercise sessions to support and motivate patients during exercise sessions, on-demand easy access to physiotherapists through a built-in chat feature within the App, internal risk stratification matrix to assist patients transfer to other interventions when applicable. NHS staff involvement: Little staff involvement, as once referred to the program, physiotherapists and supporting clinical team of the company would be used. Pathway placement: Can be used at any point in the pathway. Option for self-referral can be included in the UK if required. Safety net to identify specific condition: Online onboarding form with key questions to identify 'red flags' and provide information that is used by the assigned physiotherapist on the 1:1 onboarding video call where the initial clinical evaluation is performed. Our safety net feature also includes on-demand bidirectional communications channels to ease the communication between each patient and their assigned physiotherapist to enable easy reporting of additional symptoms or adverse events. References: 1. National Guideline Centre (UK). Low back pain and sciatica in over 16s: assessment and management. London: National Institute for Health and Care Excellence UK (NICE). https://www.nice.org.uk/guidance/ng59/resources/lowback-pain-and-sciatica-in-over-16s-assessment-and-management-pdf- 1837521693637 (2016). 2. Wiitavaara B, Heiden M. Content and psychometric evaluations of questionnaires for assessing physical function in people with low back disorders. A systematic review of the literature. Disabil Rehabil. 2020 Jan;42(2):163-172. doi: 10.1080/09638288.2018.1495274. 3. International Consortium for Health Outcomes Measurement (ICHOM). Low back pain Data collection reference guide (version 2.0.3). https://ichom.org/files/medical-conditions/low-back-pain/low-back-pain-reference-guide.pdf (2017) (accessed on October 23, 2023). 4. Norton S, Ellis B, Santana Suárez B, Schwank S, Fitzpatrick R, Price A, Galloway J. Validation of the Musculoskeletal Health Questionnaire in inflammatory arthritis: a psychometric evaluation. Rheumatology (Oxford). 2019 Jan 1;58(1):45-51. doi: 10.1093/rheumatology/key240. 5. Arumalla N, Galloway J, Ledingham J , et al. P038 A psychometric evaluation of the Musculoskeletal Health Questionnaire (MSK-HQ): validation and sensitivity to change in inflammatory arthritis. Rheumatology. 2023 April 24;62(Supplement_2). doi: 10.1093/rheumatology/kead104.079."

3	3	Individual	1.6	Relates to my comment for 1.1 above. If you have this many questions about the evidence base, requiring more research, what is the rationale for releasing the apps for NHS consumption?
4	3	Individual	3.8	With this level of concern re the applicability of the evidence to NHS pathways etc, is it worth considering for research only at this stage? Or choosing those that have the most robust data?
5	4	Organisation	Are the recommendations sound and a suitable basis for guidance to the NHS?	Yes. The recommendation to allow these digital technologies to be used with the proviso that they collect data and allow for detailed analysis seems sound.
6	10	Individual	Are the recommendations sound and a suitable basis for guidance to the NHS?	I think there should be recommendations/ stipulations in place if other technologies want to access core NHS funding
7	11	Company	Has all of the relevant evidence been taken into account?	To the extent of my knowledge, all relevant evidence has been taken into account that is specific to the technologies included in the Draft Guidelines. It is good to see that Case Studies and Qualitative research are welcomed in these NICE guidelines. LBP is a personal and independent experience for each person and is often hard to group together in more rigorous Randomised Control Trials. This 'n=1' approach to research is refreshing and will enable the technologies to gather rich and 'real world' data to demonstrate the impact that they can have on a patient. The employment of patient focus groups specifically for LBP to help shape the direction of the features and content of the various technologies will also support this. Patient data security should remain central to the decisions made for the inclusion of technologies in these NICE guidelines and for their use in the NHS. I appreciate that Digital Technology Assessment Criteria (DTAC) status has been noted for the recommended technologies, however I also see that this is pending for some of the included companies. I believe that this should be made clearer to prospective NHS users of these technologies. Further to this, I would suggest also including the need for NHS Data Protection Toolkit (and/or Cyber Essentials), DCB-0129 compliance (including Hazard Log, Clinical Safety Report, and Clinical Risk Management Plan, with a qualified Clinical Safety Officer in post), and any additional ISO certifications (e.g. ISO 27001 & ISO 27018) so that users of these technologies can make a thorough and well informed decision. This could also extend to the recommendation that included technologies commit to providing the results of a recent Penetration Test (Non-Disclosure Agreement pending). Has it also been determined where the data is stored for the listed technologies, and specifically is the data stored in the UK (e.g. Amazon Web Servers London)?
Care pathway				
8	3	Individual	2.3	Mentioned in the Guidance Development Process - but these are aimed at people with access to and ability to use app based assistance. Evidence for low back pain (acute and chronic) is across the age spectrum, so cannot be considered in isolation as a solution to the problem... these need to be a tool used in a complete pathway, functional pain management or specialist pain management.

9	3	Individual	2.5	This statement is key. These apps cannot be used instead of appropriate pathways, at best they can be used, by people with the access and technical ability, to support ongoing self management, they need to include clear red flags that people can understand, so if their condition becomes worse, or changes, they know what to do. This level of information may be difficult to convey in a generic app, so local providers may need to have assistance to produce patient information leaflets that are specific to the app AND their own local pathways of care.
10	3	Individual	3.2	Need to be a tool used in pathways - not a solution to a capacity problem.
Clinical evidence				
11	8	Company	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	"Whilst the interpretation of the examined data appears to be reasonable, as stated in our response to question 1 (re: relevant evidence) there is additional evidence in relation to the clinical and cost effectiveness for Phio Engage, which has not been considered in this evaluation."
12	8	Company	Has all of the relevant evidence been taken into account?	"No, not all relevant evidence has been taken into account - no evidence from Phio Engage has been included. Relevant unpublished evidence, in relation to Phio Engage, is available from EQL (on request); this evidence is specific and highly relevant to Digital technologies for managing non-specific low back pain, as identified in the scope for the Early Value Assessment. In summary, evidence includes data such as adherence, clinical outcomes, chronicity and demographic data (e.g., age, ethnicity). This is presented alongside economic evaluation and safety data, which is currently missing from the evidence examined. For further context, Phio Engage is a clinically supported self-management system; the Phio system is DTAC approved and compliant with all safety requirements of DCB0129 and is a non-medical device (as such registration as a medical device is not required)."
13	4	Organisation	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	Yes. The evidence is poor in the generalisability of the findings to the UK population and there is wide variation in definitions of when pain is chronic as well as the metrics used in measuring them.
14	9	Company	3.7	SelfBack can confirm that patients from Denmark, Norway and Scotland were involved in the development phase. This is captured in our article on Intervention design, which is published in JMIR: https://www.jmir.org/2022/1/e26555/
15	9	Company	Has all of the relevant evidence been taken into account?	Stoke on Trent ICS has under the NHS England Adoption Fund carried out a project with SelfBack to evaluate the uptake and impact of providing the SelfSTart approach (SelfSTart is a new digitally supported pathway, where SelfBack and SelfBack App combined with a safety net of using STarTBack for risk stratification first) delivered by a First Contact Practitioner to people presenting with low back pain in primary care. The results are currently being prepared for publication, and a draft version of the report can be found

				using this link: [redacted] Please note: This report is at this moment submitted for peer review, but unpublished. We there kindly ask of you not to share the information, before the paper was published.
16	10	Individual		Generally, this document is good however I think it should be stressed that the clinical evidence was very weak
17	10	Individual	Has all of the relevant evidence been taken into account?	By excluding studies with patients with back related leg pain there is a risk that some relevant evidence has been missed. In clinical practice these can be very difficult to differentiate.
18	12	Individual	Has all of the relevant evidence been taken into account?	Yes, though evidence is clearly lacking. I would like to know what evidence the companies have that they have not published.
Economic evidence				
19	9	Company	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	This is a very difficult question to answer, as the costs of the interventions are the main contributor, and they have to a large degree been redacted, so it is impossible to follow through on the evidence presented to NICE, and comment on it. As for SelfBack, the price stated in your assessment report is higher than our actual price, so it may effect the overall conclusion to a smaller degree, but would certainly be something we would want to see corrected in the final version, as it effects the perception of SelfBack's cost effectiveness to have an too high cost included in the report. We have made a comment of this in the section 2.2.
20	10	Individual	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	Generally yes. However, the different technologies sit in different places in the care pathway (e.g. initial presentation, or persistent pain management) therefore by combining them in the models may not be appropriate.
21	11	Company	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	It is reassuring to see that an Early Economic Modelling process has revealed an anticipated cost saving by integrating digital technologies into healthcare. Has this taken into account the cost of licences for the NHS Trust to procure the healthcare technologies and any premium features required? I also recognise the statement made around user onboarding and training. This would be best delivered on a ‘self-serve’ and asynchronous basis to fit in with healthcare practitioner’s already stretched clinical responsibilities. The technologies UI and User Experience (Ux) for the healthcare practitioners should also be very intuitive and time efficient to ensure good uptake and engagement with the technologies from a healthcare provider’s perspective. The easier it is for the healthcare practitioner to prescribe a programme to a patient the better (e.g. through QR code, via email, or by text messaging services).
22	13	Company	Has all of the relevant evidence been taken into account?	We submitted a "2022 136 employer claims study" (n=8414) that demonstrated a per-member-per-year (PMPY) cost savings of $2,387 on overall chronic MSK cost 1 year after starting Hinge Health. The largest reductions in service utilization between the two groups were in imaging, injections, DME, and surgery. However, the study did find some evidence of reduced physiotherapy utilization and emergency

				department visits. The external assessment report suggests: "No relevant evidence identified" for Healthcare resource use, which is contrary to the evidence provided.
23	13	Company	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	The external assessment report suggests: "No relevant evidence identified" for Healthcare resource use, "Limited information available" for Adherence. We submitted comments in September 2023 in response to the "External Assessment Report" noting that several of our studies and outcomes from the studies have not been appropriately reflected in the report.
Equality considerations				
24	1	Company	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	"We believe that equality issues that merit special consideration are correctly identified in the document. However, we believe that not all relevant evidence was considered, and that, as such, the gaps in the literature on equality topics are less than what has been considered in the document. It is our opinion that the research conducted by Sword Health has allowed to shed light on several of the topics, as presented below. Sword Health is dedicated to delivering equitable access to high-quality rehabilitation for patients with musculoskeletal conditions. As part of this commitment, we have been actively researching how our digital care programs can address barriers and concerns felt by older adults, to ensure access and delivery of proper care [1]. These insights are helpful in the selection of candidates for digital care pathways and also in how to better design digital interventions to successfully provide care to this specific population. This study reports that despite the longer learning curve in engaging in digital programs, older adults, when sufficiently supported, are more compliant than their younger counterparts, being able to achieve similar recovery outcomes. Sword Health's research on healthcare inequities also focused on the impact of geographic location (rural vs urban) [2], race and ethnicities [3], and socioeconomic context [4], all studies including patients with LBP. The most recent Sword Health longitudinal study published in Nature Digital Medicine [4] (N= 12,062) was aimed at assessing the impact of this digital care program in patients with chronic MSK pain while acknowledging several social determinants of health: age, demographics, race/ethnicity, income, education, employment status, housing, transportation, rurality, proximity to healthcare facilities. Results showed that despite the worse baseline outcomes reported by patients from more socially deprived contexts, all patients regardless of their socioeconomic background, race, or even proximity to healthcare facilities, were able to achieve significant improvements in all studied outcomes (pain, analgesics intake, mental health, and productivity). In fact, patients who were identified as more socially deprived achieved better productivity outcomes than those who were not. We believe several aspects within Sword Health intervention might explain these results, namely:

				- Sword Health's clinical team includes a diverse pool of physiotherapists (69% female, 23% from race and ethnic minorities, 11% multilingual, 7% identify as LGBTQIA+) - Patients are allowed to select the physiotherapist from this diverse pool who will guide them throughout the entire program. - All Sword health physiotherapists are trained on cultural competency, as well as on unconscious bias. - WiFi hotspots sent to patients who do not have access to internet; - Additional support and resources provided to people who are less comfortable with digital technologies. Namely, phone call, built-in chat or email for immediate assistance at any stage of the intervention and for technical support. The phone call feature is particularly important for patients with 65+ years or less skilled with digital technologies who tend to prefer phone call versus chat based support. - Additional features designed to ensure inclusion of those with visual and hearing impairment, namely audio support and enlarged font for the visually impaired and closed captions for the patients with impaired hearing. In conclusion, while we believe that more research on equality issues in relation to this domain is needed, Sword Health has been addressing these issues and has indeed demonstrated, through clinical research, the potential of our digital programs in regards to mitigating them, and contributing to a more equitable access to high-quality care. References: 1. Areias AC, Janela D, Molinos M, Moulder RG, Bento V, Yanamadala V, Cohen SP, Correia FD, Costa F. Managing Musculoskeletal Pain in Older Adults Through a Digital Care Solution: Secondary Analysis of a Prospective Clinical Study. JMIR Rehabil Assist Technol. 2023 Aug 15;10:e49673. doi: 10.2196/49673. 2. Scheer J, Areias AC, Molinos M, Janela D, Moulder R, Lains J, Bento V, Yanamadala V, Dias Correia F, Costa F. Engagement and Utilization of a Complete Remote Digital Care Program for Musculoskeletal Pain Management in Urban and Rural Areas Across the United States: Longitudinal Cohort Study. JMIR Mhealth Uhealth. 2023 Mar 16;11:e44316. doi: 10.2196/44316. 3. Scheer J, Costa F, Molinos M, Areias A, Janela D, Moulder RG, Lains J, Bento V, Yanamadala V, Cohen SP, Correia FD. Racial and Ethnic Differences in Outcomes of a 12-Week Digital Rehabilitation Program for Musculoskeletal Pain: Prospective Longitudinal Cohort Study. J Med Internet Res. 2022 Oct 31;24(10):e41306. doi: 10.2196/41306. 4. Areias AC, Molinos M, Moulder RG, Janela D, Scheer JK, Bento V, Yanamadala V, Cohen SP, Correia FD, Costa F. The potential of a multimodal digital care program in addressing healthcare

				inequities in musculoskeletal pain management. NPJ Digit Med. 2023 Oct 10;6(1):188. doi: 10.1038/s41746-023-00936-2."
25	7	Company	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	For patients who have difficulty attending in person due to child care, physical access, cost of travel where digital care offers a convenient alternative. In our experience, further work is needed to improve access to those patients unable to speak English, and to support those who don't feel confident in tech but would still prefer digital as an option when recommended. Providing access to a compatible device (such as a loan) may also be considered..
26	9	Company	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	The apps have not been evaluated for supported languages. It is assumed that every user speaks English, but in reality there are citizens from countries outside Europe (for example Arab speaking part of the world) live in England who use the NHS, but can have a hard time communicating in other languages then their mother tung. Therefor it could be considered to state which languages are supported, as more languages supported would equal broader access to use of the app.
27	10	Individual	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	no
28	11	Company	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	Equality and accessibility should both be key factors in the choice of digital technologies, as highlighted in the Draft Guidance. Do all of the technologies included provide patients with a choice in how they access and consume their management programmes for LBP (e.g. via a print option, via a single web URL link, or via a full app download)? Have the technologies also been assessed for their level of accessibility against standards such as the Web Content Accessibility Guidelines (WCAG 2.1 AA standard)? It should also be determined if the content within the technologies is in itself equitable and representative of different patients (e.g. body composition, ethnicity, culture, etc). A further consideration should be made towards Social Prescribing and if the technologies included can support this. For example, if the patient has a cognitive, physical, or sensory impairment which may be a barrier to their independent use of the technology then can a caregiver assist with their programme?
Implementation				
29	3	Individual	3.12	If these were used in NHS pathways, would there be a cost to the organisations/ICS to acquire the App(s) and/or training on using them (train the trainer for example)? I cannot see the App developer(s) providing for free?
30	3	Individual	3.5	Need to understand how data is managed, stored and shared with clinical teams, if these apps are initiated in a pathway, or, if part of a self referral option, how the information is shared IF the patient feels the need to escalate their condition to a health care professional.
31	3	Individual	3.10	Agree on these points - and try to make the nudges "nice" not accusatory...

32	4	Organisation	Are there any additional implementation factors that need to be considered?	No. These digital platforms are potentially a very valuable resource for the treatment of non specific low back pain.
33	7	Company	Are the recommendations sound and a suitable basis for guidance to the NHS?	Taking patient experience into account is vital to better understand how to implement digital care, but the physiotherapist perspective should not be forgotten. How are the physiotherapists supported to deliver management to patients? In NHS settings physiotherapists are often managing big caseloads and have multiple responsibilities on multiple software. The availability of multiple software that deliver different types of care adds complexity and time to the referral pathway. Learning how to use them in addition to having the time to describe the option to patients is challenging. Developing effective processes and resources to limit the time taken in the clinic, and ensuring physiotherapists are comfortable delivering care on such platforms or working in partnership with platforms who supply their own resources is vital. It is worthwhile considering how to improve the benefits of the local team that meets with patients presenting with MSK complaints. We would recommend apps working in partnership with providers to understand how the physiotherapist can best improve access for the local population. And also how to refine the inclusion/exclusion criteria to ensure patients are supported to choose the care pathway best suited to their needs. Further research is therefore not only needed from a patient perspective, but from a physiotherapist perspective.
34	9	Company	3.3	SelfBack can confirm that we have a working EMIS integration with ICS Stoke-on-Trent, and the ability to integrate with other existing NHS Systems
Process				
35	4	Organisation	Has all of the relevant evidence been taken into account?	Having a pain consultant in the committee would have been valuable in analysing some of the pain related papers.
36	10	Individual	1.3	Why do they submit the evidence after three years. Should they not submit some of the data annually?
37	10	Individual	1.5	What if they publish research in the meantime? Can they access core NHS funding?
38	10	Individual	Are there any additional implementation factors that need to be considered?	Whose responsibility will it be to collect the information for the digital technologies? Will the NHS have to collect data, and if so is this reasonable? With the requirement to collect data - when will this be expected from? It may require a lead in time is some of the data are not collected already?
Proposed new technologies				
39	1	Company	Has all of the relevant evidence been taken into account?	"According to the inclusion criteria used to consider a digital technology for low back pain presented in ‘Early value assessment: Final scope’ - 2nd page of the document - we believe that Sword Health technology meets eligibility and should be considered in the NICE appraisal entitled ‘Digital technologies for managing non-specific low back pain’.

				The main reasons supporting the consideration of our technology are as follows: - Sword Health is certified as class I in the UK, is actively pursuing DTAC certification and will be available for use in the NHS soon, due to the advanced conversations with NHS Institutions; - Sword Health provides digital physical therapy for the management of acute and chronic musculoskeletal pain, including low back pain (LBP) and post-surgery rehabilitation. - Digital care programs provided by Sword Health were designed following the NICE guidelines [1] “NICE guideline on low back pain and sciatica in over 16s: assessment and management”, adopting the recommended biopsychosocial approach combining three main pillars: exercise, education and cognitive behavioural therapy, being managed synchronously and asynchronously by a physiotherapist. Throughout the entire program, patients are guided by a dedicated physiotherapist, who continuously provides support to patients, monitors their evolution and adjusts the intervention according to patient’s needs. - Sword Health services are accessible to individuals through a dedicated website. After filling in an initial assessment, they are assigned a physiotherapist. This physiotherapist is responsible for conducting an initial clinical assessment. In regards to LPB specifically, patients are screened for the presence of red flags (following the International Framework for Red Flags for Potential Serious Spinal Pathologies [2]) and LBP related to serious underlying conditions (such as cauda equina syndrome, spinal malignancy, vertebral fracture or spinal infection) are cleared prior to enrollment in our programs. Furthermore, the assessment includes questions designed to determine the most suitable diagnosis of LBP, in order to identify those with non-specific low back pain. All of the above are performed to guarantee the patient is a good match to the program (or if they need to be referenced to a different care pathway). - In our published evidence, we clearly define the percentage of non-specific LBP within our cohorts[3]. Impact of Sword Health’s program on LBP with possible neurological compromise was studied in a subgroup analysis, with no significant differences observed between outcomes in this subgroup and those with non-specific LBP, with both obtaining significant improvements in all outcomes measured. We are available to provide more info if needed. - Patients enrolling in our programs are assessed at baseline and at regular intervals throughout the program in several dimensions, using validated and widely used scales, namely pain (NPRS), anxiety (GAD7), depression (PHQ9), productivity (WPAI), condition-specific PROMs (in the case of LBP, the Oswestry Disability Index), together with range of motion and movement error data. This allows Sword to measure progress for each individual, providing both patient-reported and objective data that assists physiotherapists in managing patients. We also collect information around pain and fatigue after exercise sessions (continuously monitored by the physiotherapist), as well as several different on-demand

				communication channels (including an in-built secured chat) that enable each patient to timely report any concern or adverse event. - Evidence on the impact and outcomes of the Sword Health digital care program can be found in two verticals- namely randomized controlled trials and real-world investigation - following NICE suggestions presented in the 'Early value assessment: Final scope' document, 10th page. Further discussion on Sword Health's clinical publications can be found below. Additionally, evidence on economic impact can also be found for the Sword Health Digital care program. - Sword Health is the only company that actively researched health equity, representing a core value in program design. Sword Health is dedicated to delivering equitable access to high-quality rehabilitation for patients with musculoskeletal conditions from diverse backgrounds and with varying needs. As such, we have been researching the potential of Sword's digital care program to support patients regardless of age [4], race and ethnicity [5], geographic location and context (rural vs urban locations) [6] and socioeconomic context [7]. Several features have been designed to address these issues as explained in question [4]. - Sword Health has already deployed these programs at scale, with more than 8 million people covered in the United States, UK, Canada, Puerto Rico, Portugal and Australia with access to these programs, >100,000 patients treated each year, and has published numerous clinical papers (both from controlled trials and real-world data) on the engagement and outcomes of our programs - including several papers on low back pain, as further discussed below. Taken together, these points justify the consideration of the Sword Health program for implementation in the NHS, both as a standalone intervention and in combination with standard care. More information on research conducted by Sword Health will be discussed below. References: 1. National Guideline Centre (UK). Low back pain and sciatica in over 16s: assessment and management. London: National Institute for Health and Care Excellence UK (NICE). https://www.nice.org.uk/guidance/ng59/resources/lowback-pain-and-sciatica-in-over-16s-assessment-and-management-pdf- 1837521693637 (2016). 2. Finucane LM, Downie A, Mercer C, Greenhalgh SM, Boissonnault WG, Pool-Goudzwaard AL, Beneciuk JM, Leech RL, Selfe J. International Framework for Red Flags for Potential Serious Spinal Pathologies. J Orthop Sports Phys Ther. 2020 Jul;50(7):350-372. doi: 10.2519/jospt.2020.9971. 3. Cui D, Janela D, Costa F, Molinos M, Areias AC, Moulder RG, Scheer JK, Bento V, Cohen SP, Yanamadala V, Correia FD. Randomized-controlled trial assessing a digital care program versus conventional physiotherapy for chronic low back pain. NPJ Digit Med. 2023 Jul 7;6(1):121. doi: 10.1038/s41746-023-00870-3.

				4. Areias AC, Janela D, Molinos M, Moulder RG, Bento V, Yanamadala V, Cohen SP, Correia FD, Costa F. Managing Musculoskeletal Pain in Older Adults Through a Digital Care Solution: Secondary Analysis of a Prospective Clinical Study. JMIR Rehabil Assist Technol. 2023 Aug 15;10:e49673. doi: 10.2196/49673. 5. Scheer J, Costa F, Molinos M, Areias A, Janela D, Moulder RG, Lains J, Bento V, Yanamadala V, Cohen SP, Correia FD. Racial and Ethnic Differences in Outcomes of a 12-Week Digital Rehabilitation Program for Musculoskeletal Pain: Prospective Longitudinal Cohort Study. J Med Internet Res. 2022 Oct 31;24(10):e41306. doi: 10.2196/41306. 6. Scheer J, Areias AC, Molinos M, Janela D, Moulder R, Lains J, Bento V, Yanamadala V, Dias Correia F, Costa F. Engagement and Utilization of a Complete Remote Digital Care Program for Musculoskeletal Pain Management in Urban and Rural Areas Across the United States: Longitudinal Cohort Study. JMIR Mhealth Uhealth. 2023 Mar 16;11:e44316. doi: 10.2196/44316. 7. Areias AC, Molinos M, Moulder RG, Janela D, Scheer JK, Bento V, Yanamadala V, Cohen SP, Correia FD, Costa F. The potential of a multimodal digital care program in addressing healthcare inequities in musculoskeletal pain management. NPJ Digit Med. 2023 Oct 10;6(1):188. doi: 10.1038/s41746-023-00936-2."
40	1	Company	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	"We believe that summaries of Clinical and cost effectiveness would benefit from the inclusion of the evidence gathered through Sword Health studies. Our studies, as other from considered interventions, described clinical effectiveness within a population of patients with low back pain. While some considered studies have reported a non-specific LBP cohort, it is worth noting that LBP classification in these cases was based on self-reporting without any physician triage, which compromises the inclusion criteria [1]. Similarly to the included studies Geraghty et al. 2018 [2], Bailey et al. 2020 [3], Clement et al. 2018 [4] and Jain et al. 2021 [5], we have excluded all patients with serious pathology, and have identified those that presented with symptoms/signs compatible with possible neurological compromise. This allowed us to report in the Sword Health RCT (published in Nature Publishing Journals Digital Medicine) the precise proportion of sub-groups with non-specific and specific LBP [6]. Importantly, we have performed sub-group analysis that indicated no significant differences between these subgroups. In this RCT [6], in-person physiotherapy was used as a comparator group. The intervention provided in this comparator group consisted of exercise, education, manual therapy and physical modalities, adjusted according to the patient's condition. The choice of this comparator group followed NICE recommendations [7] to support better generalizability (we report intervention components as well as overall adopted protocols), and to avoid cultural/geographical variations in “standard care”. In effect, multiple evidence supports in-person physiotherapy as the standard care in the management of LBP [8]. Therefore, we believe that our results provide fair evidence of the clinical effectiveness of Sword Health’s digital care program.

				Furthermore, considering the lack of information on what constitutes standard care in the comparator group of other considered RCTs [2,9-11] we believe our study provides more transparent and useful information, and therefore should be considered as evidence. This study considered a wide range of outcome domains assessed by validated questionnaires, in line with the recommendations outlined in page 8 of the 'Final Scope' document. These included: functionality (assessed by the Oswestry Disability Index); pain intensity (assessed by the Numerical Pain Rating Scale); activation rate; treatment satisfaction; intervention adherence and completion; intervention-related adverse effects. These outcomes are described as target outcomes in the Final scope' document, 8th page. We reported that similar improvement was observed in both groups in all domains, while the digital group had a significantly lower number of drop-outs. Importantly, both groups were exposed to similar treatment dosage, which was intended by the RCT design. Alongside this RCT, two prospective longitudinal studies based on real-world context data (one focusing on acute LBP and another on chronic LBP) were published by Sword Health [12,13]. Both longitudinal studies offer insights regarding the feasibility and impact of the Sword Health digital care program, as showcased by high engagement and clinical outcomes improvement (Pain (NPRS), functionality (ODI), fear-avoidance (FABQ-PA), anxiety (GAD-7) and depression (PHQ-9)), as well as its appropriateness to promote productivity impairment (WPAI) recovery. Additionally, Sword Health has also investigated long-term effects of their programs (in cohorts which included patients with LBP) [14]. This consisted of an ad hoc analysis of a longitudinal study with a non-participant comparison group, which compared 1-year outcomes after Sword Health's digital intervention with a group of patients who enrolled in the program but never engaged in a single exercise session or partook of the educational content made available. The intervention group presented sustained and greater pain reduction until 1-year reassessment than the comparison group, reflecting greater odds ratio of achieving the minimal clinically important difference both in pain and functionality. Lower healthcare utilization in the intervention group was also observed during the 1-year follow-up. Furthermore, important research on health equity has been developed during the last year, as further detailed in question 4. Finally, Sword Health has also demonstrated the ability to provide significant cost savings. In a report published by Validation Institute, Sword Health was shown to deliver $2472 (or £2034), in savings per member per year in a cohort of US-based individuals [15]. Importantly, these savings were driven by lower spending on expensive treatments like surgery and invasive procedures, with additional savings on office visits, imaging and other forms of therapy, as also seen in the publication described previously. References:

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				11. Shebib R, Bailey JF, Smittenaar P, Perez DA, Mecklenburg G, Hunter S. Randomized controlled trial of a 12-week digital care program in improving low back pain. NPJ Digit Med. 2019 Jan 7;2:1. doi: 10.1038/s41746-018-0076-7. 12. Costa F, Janela D, Molinos M, Moulder RG, Lains J, Bento V, Scheer J, Yanamadala V, Correia FD, Cohen SP. Digital Rehabilitation for Acute Low Back Pain: A Prospective Longitudinal Cohort Study. J Pain Res. 2022 Jul 3;15:1873-1887. doi: 10.2147/JPR.S369926. 13. Areias AC, Costa F, Janela D, Molinos M, Moulder RG, Lains J, Scheer JK, Bento V, Yanamadala V, Cohen SP, Correia FD. Impact on productivity impairment of a digital care program for chronic low back pain: A prospective longitudinal cohort study. Musculoskelet Sci Pract. 2023 Feb;63:102709. doi: 10.1016/j.msksp.2022.102709. 14. Areias AC, Costa F, Janela D, Molinos M, Moulder RG, Lains J, Scheer JK, Bento V, Yanamadala V, Correia FD. Long-Term Clinical Outcomes of a Remote Digital Musculoskeletal Program: An Ad Hoc Analysis from a Longitudinal Study with a Non-Participant Comparison Group. Healthcare (Basel). 2022 Nov 23;10(12):2349. doi: 10.3390/healthcare10122349. 15. Validation Institute. 2022 Validation Report. https://validationinstitute.com/wp-content/uploads/2021/02/Sword-Health-final.pdf%20 (2022) (accessed on October 23, 2023)."
41	2	Company	Has all of the relevant evidence been taken into account?	"It is fantastic to see that NICE is carrying out an EVA to look at the use of digital technologies in NSLBP. However, there are additional digital products and services available to the NHS that meet all of the criteria within your defined scope, but have not yet been considered for evaluation. This includes our own technology, Flok Health, which launched this year and is already being used in the NHS for the digital management of back pain. Given the importance of EVA guidance, we ask that you include our technology in your evaluation and guidance following this consultation, and before any final guidance is published. We strongly believe that for the recommendations to be useful for the intended NHS audience, they must accurately reflect the market for relevant solutions. To assist with your consideration, we have summarised some of the relevant information on our technology, regulatory approvals, and NHS utilisation below. We will of course promptly provide more detailed information and supporting documents once we receive your standardised information collection forms for completion. Our technology is an app-based digital service dedicated to the management of non-specific low back pain in NHS patients, and it has been approved as a medical device (UKCA Class I) by the MHRA for use in the UK. Our system has been designed from the ground up to integrate with the NHS, for example building our electronic health record using the same SNOMED CT ontology for streamlined data integration. We have achieved CyberEssentials Plus cybersecurity certification, and are currently going through the process of DTAC clearance. We started NHS use in April 2023 after achieving regulatory clearance, and subsequently completed 3 successful pilot evaluations across 2 NHS Trusts and 1 NHS Scotland Health Board. These NHS implementations have included the successful delivery of multidisciplinary treatment to a total of >900 patients with non-specific low back pain. We receive extremely positive feedback from our patients, and are currently working towards multiple new commercial contracts in the NHS for 2024.

				Patients and HCPs have been extensively involved in the development and testing of our product throughout. The data from our pilot evaluations is not yet published as these evaluations have only recently taken place. In November we are launching a further NHS pilot with approximately 250 additional NHS patients to evaluate new features based on patient feedback and focus groups from the previous trials. We are also in the process of planning a formal study in partnership with an NHS Scotland Health Board to assess the health economic impact of introducing our solution in primary care, in particular assessing the downstream impact on capacity for existing services (MSK, GP, Neurosurgery). The results of this evaluation are intended for peer-reviewed publication and conference presentation. The care modalities delivered by our digital service include personalised physiotherapy, psychological support including mindfulness based cognitive therapy, and advice/education on pain management. We have reviewed your Evidence Generation Plan, and would strongly support your outlined approach. We sincerely hope that you allow us to participate in this EVA now that you have become aware of our technology, and look forward to hearing from you."
42	7	Company	Has all of the relevant evidence been taken into account?	Joint Academy understands from the draft document that there may still be an opportunity to be included in the review. One of the excluded studies in the scope of inclusion, non-specific LBP without spinal pathology or red flag signs and symptoms was https://rehab.jmir.org/2022/2/e38084 from Horder et al. The exclusion comment was “Population - mixed and outcomes NR separately”. We are the authors of this study that reports on 2593 patients with non-specific LBP without spinal pathology or red flag signs and symptoms that adhered to 3 months digital treatment with the Joint Academy app. The treatment program consisted of progressive video-instructed exercises, educational text lessons, and direct interaction with personal physiotherapists via chat and video functions. Inclusion criteria were as follows: Treatment age >18 years and presence of subacute or chronic LBP including nonspecific LBP. Participants without a prior clinical diagnosis of nonspecific LBP (diagnosis code ICD-10 M54.5) required a clinical diagnosis confirmed by a physiotherapist via telephone or video call. In the app, participants first need to negate recent trauma within 0 to 6 months and symptoms of cauda equina syndrome in order to be registered in the program. At the start-up consultation with the physio, further exclusion criteria were considered before eligibility: malignant disease with or without suspected metastasis, fracture or vertebral compression within 6 months, and infection. If there were uncertainties regarding diagnosis or comorbidities, candidate participants were recommended to seek face-to-face assessment before inclusion in the program. Additional relative exclusion criteria were assessed by the physio: previous or current cancer or involuntary weight loss, radiculopathy below the knee, opioid-demanding pain or pain while resting, inflammatory back pain, pregnancy or post pregnancy, and older participants (>75 years) with multiple diseases and/or structural

				deformities (eg, scoliosis). The results were in short: The mean participant age was 63 years, 74% (1915/2593) were female with a mean BMI of 26.5 kg/m2. Participants completed on average 84% of the prescribed exercises and lessons, with an adherence of ≥80% in 70% and ≥90% in 50% of the participants. Mean reduction in pain from baseline to 3 months was 95% CI –1.8 to –1.6, corresponding to a 35% relative change. MCIC was reached by 60% (1517/2593). Oswestry Disability Index decreased 4 points and MCIC was reached by 60% of the patients. An absolute improvement in back pain of ≥2 points (0-10, best to worst) or a relative improvement of 30% from baseline to 3 months was used to describe a minimal clinically important change. PASS was assessed at baseline and follow-up with the question: “Considering your lower back function, do you feel that your current state is satisfactory? With lower back function you should take into account all activities you have during your daily life, sport and recreational activities, your level of pain and other symptoms, and also your quality of life related to your lower back” (yes or no). The PASS is a treatment-response criterion developed to determine the clinical relevance of a treatment effect. Answering no is referred to as PASS(–), yes is referred to as PASS (+), and changing from no at baseline to yes at 3 months as PASS(–to+). A change from no to yes in PASS was seen in 30% (787/2593) of participants. Multivariable analysis showed positive associations between reaching an MCIC in pain and high baseline pain, adherence and motivation, while we found negative associations for wish for surgery and pain in other joints. We believe we meet the criteria as a service that delivers physiotherapy (exercise and education) to patients with symptoms of lower back pain via our smartphone app. The included non-specific LBP patients in our study “can be described as having no identifiable structural cause or pathoanatomical abnormality who are eligible for digital technology management” as defined in the” Early assessment report”. To conform with Swedish health care praxis we used ICD-10 diagnosis code M54.5. We are registered as a class 1 medical device and CE registered. We are working towards our DTAC, we have provided the necessary data and clinical governance to enable us to work in partnership to deliver care to NHS patients, and alongside other organisations such as the University of Nottingham to conduct an RCT. We are due to publish a paper shortly in collaboration with NHS Highlands and the University of Highlands and Islands. We are also ORCHA approved. Whilst the majority of our peer reviewed publications are not specific to our lower back patients, we continue to work with our NHS partners to produce the data recommended by you.

43	7	Company	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	"The evaluation focuses on LBP. We believe that studies publishing treatment of other MSK conditions but using the same app technology and type of program are useful to gain facts of clinical and cost effectiveness also for LBP treatment. The Joint Academy app has treated 150 000 patients, most of them in Sweden but also in the UK (England and Scotland), and communicated results in 20+ published studies including RCT and cohort studies. Results are published of knee, hip, back, shoulder and hand musculoskeletal chronic conditions on long-term outcomes, costing analysis, change in wishing surgeries and pain medication, as well as qualitative studies, with outcomes as good as or better than by face-to-face treatment. Jönsson T, Dell'Isola A, Lohmander LS, Wagner P, Cronström A. Comparison of Face-to-Face vs Digital Delivery of an Osteoarthritis Treatment Program for Hip or Knee Osteoarthritis. JAMA Netw Open. 2022;5(11):e2240126. doi:10.1001/jamanetworkopen.2022.40126 [https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2798148?resultClick=1]"
44	11	Company		This is a fantastic and much needed initiative led by NICE and supported by an appropriately qualified and experienced panel of experts in the field of physiotherapy and Low Back Pain (LBP). As the rate of emergence of Digital Health Technologies to support healthcare continues to grow, it is vital that the NHS is able to make well informed choices on which technologies to invest in to improve patient outcomes, increase service efficiencies, and result in cost savings for the service provider. Digital Health Technologies also provides patients with the choice in how they access and consume their healthcare, and can create a seamless and uninterrupted patient experience when moving through primary and secondary healthcare systems. Patient data security should remain central to the decisions made for the inclusion of technologies in these NICE guidelines and for their use in the NHS. I appreciate that Digital Technology Assessment Criteria (DTAC) status has been noted for the recommended technologies, however I also see that this is pending for some of the included companies. I believe that this should be made clearer to prospective NHS users of these technologies. Further to this, I would suggest also including the need for NHS Data Protection Toolkit (and/or Cyber Essentials), DCB-0129 compliance (including Hazard Log, Clinical Safety Report, and Clinical Risk Management Plan, with a qualified Clinical Safety Officer in post), and any additional ISO certifications (e.g. ISO 27001 & ISO 27018) so that users of these technologies can make a thorough and well informed decision. This could also extend to the recommendation that included technologies commit to providing the results of a recent Penetration Test (Non-Disclosure Agreement pending). Has it also been determined where the data is stored for the listed technologies, and specifically is the data stored in the UK (e.g. Amazon Web Servers London)? I believe there are a few additional considerations that should also be made regarding the Draft Guidance. Overall, it is my view that the terms 'Health Technology' and 'Digital Technology' need to be

				more clearly defined in this context. These terms are very broad and can encompass a vast range of different intended use cases, particularly in the management of LBP. For example, do these NICE guidelines intend to include advances in Artificial Intelligence (AI) within the scope of this work? As the intention is to review these recommendations in 3 years following a period of further research and data collection in line with the Unmet Needs and Evidence Gap Review there is the risk that the technologies selected at this stage may be surpassed with more advanced alternatives. The term 'self-management' should also be clearly defined in the guidelines. I note that this could be in reference to an entirely patient led and automated service, however 'self-management' can also be in response to care following face-to-face consultation, particularly in the 'self-management' of Long Term Conditions, including chronic LBP. For example, NHS Trusts may choose to use the technologies to identify which patients could be triaged to a 'remote monitoring' or 'face-to-face monitoring' pathway. This will ensure that the right patient receives the right care at the right time. It should also be considered if any clinical triage questions are provided by the healthcare technology directly, or if these can be determined by the NHS Trust and their clinical leads. The latter would offer greater choice and flexibility to suit local healthcare needs, and should include the screening of red flag conditions. The output and end result of such automated triage pathways should also include patient facing content including exercises, education, and Patient Reported Outcome Measures (PROMs) selected by the clinical team. Furthermore, 'self-management' could also be achieved by intervening at the point of referral between GP (or self-referral) to Physiotherapy services by 'triaging the waiting list' and getting patients started with the advice given through the technologies prior to their initial consultation to result in a 'waiting well' approach. This could also result in patients no longer needing their initial face-to-face contact, thus opening the appointment to a patient in need. From what I can see from the technologies included, they are predominantly designed to fit into the front end of a patient's journey. I believe consideration should also be made towards technologies used to further support patients whilst under 'standard care' and post-discharge. The definition of 'Chronic LBP' could also benefit from further clarity and context, in addition to the existing statement of 'lasting 3 months or more' (e.g. 'a condition that has an impact on a patient on a daily basis for 3 months or more'). Likewise 'specific' and 'non-specific' LBP could be further defined for full clarity of inclusion and exclusion criteria, although I note and appreciate the reference to NICE's guideline on low back pain and sciatica in over 16s to support this. I believe that these NICE guidelines should also include reference to how these technologies support the NHS Patient Initiated Follow Up (PIFU) process, particularly for patients with Chronic LBP who are likely to experience exacerbation of symptoms. This would also extend to how the technology could manage

				these requests remotely so that the patient does not return to a waiting list or take a face-to-face appointment that is not required. It is good to see that Case Studies and Qualitative research are welcomed in these NICE guidelines. LBP is a personal and independent experience for each person and is often hard to group together in more rigorous Randomised Control Trials. This 'n=1' approach to research is refreshing and will enable the technologies to gather rich and 'real world' data to demonstrate the impact that they can have on a patient. The employment of patient focus groups specifically for LBP to help shape the direction of the features and content of the various technologies will also support this. A further observation is that some of the technologies included are not currently operating in the NHS. It can take a long time for a new technology to be adopted and to build enough of a customer base in order to obtain enough meaningful data. Whilst the 3 year period is generous, it may take some technologies much longer than others to be 'up and running' in the NHS. Technologies who already have a large and loyal NHS customer base are therefore in a more advantageous position. Likewise, technologies whose existing customer base is predominately outside of the UK and the NHS should be questioned on their transferability to a different population, under a different healthcare system, and for patients with different lived experiences. I welcome the inclusion of the recommendation for uniformity in the PROMs used to monitor the clinical and patient experience outcomes in using the named technologies. The MSK-HQ and EQ-5D-5L are already widely used and respected PROMs across the NHS, and are simple and effective for patients to complete. The recommended technologies should be assessed for their capacity to include these PROMs (which may require specific licencing) or for the NHS Trust (customers) to be able to 'add their own' PROMs to the system. I appreciate that the term 'adherence' has good intentions, but this could be seen as being synonymous with the outdated term of 'compliance' in regards to patient exercise completion. I wonder if the term 'engagement' would be a more positive approach to this. I would welcome the 'Patient Experts' thoughts and opinions on this. The agreement on the metrics used to monitor 'adherence' (engagement) are also vital in defining how this will be determined. Perhaps adding 'downloaded the technology' or 'logged in at all' should be added as the first step, along with the proposed metrics of 'using a technology at baseline, 30 days and between 6 months and 1 year'. Recording and monitoring the reasons for why a patient stops using a technology is also important, as has been proposed. This will help to recognise if patients have stopped engaging as they are now recovered, or completely independent and no longer require the technology versus those who are disengaged with the technology as they are seeing no clinical value or

				otherwise. In a similar vein it might be a good idea to determine if 'adherence to rehabilitation' is always directly related to 'quality of rehabilitation'. There may be situations where patients engage very little with the technology, but when they do they get very positive outcomes, compared to those who engage a lot, but get poor outcomes. The Draft Guidance also uses the term 'Standard Care' which may be seen as the Control Group to assess the impact of digital technology against. With this in mind, it would also be useful to provide a clearer definition of 'Standard Care'. Whilst I appreciate this can vary amongst NHS Trusts, establishing a baseline of where different teams are on the Digital Healthcare maturity spectrum will enable NICE to better monitor the impact of the intervention. It is good to see that interoperability and integration with other 3rd party platforms, such as Practice Management Systems (PMS) and Electronic Medical Records (EMRs) has been taken into account in the NICE guidance. This will help to ensure a seamless and time efficient service for healthcare practitioners using the technology, and aid communication across the Multi-Disciplinary Team as well as supporting Standards of Documentation. Further to this, it would be beneficial to establish the level of integration offered by each of the technologies. For example, are Single Sign On (SSO) and webhooks to the patient's external ID used to create a patient in the technology? Is the integration 'read and write' to save a copy of what has been prescribed to the patient to their medical records? Does the technology provide an embedded Application Programming Interface (API) and User Interface (UI) into the PMS and EMR? These are questions that NHS Trusts should be prompted to ask when determining which technology to adopt in their service. Whilst these technologies being endorsed by NICE will help to improve patient's confidence when they are prescribed a programme through a 3rd party application, there is likely to still be some hesitation felt by some NHS patients. Technologies who provide a level of 'custom branding' to their application might help to increase patient trust and confidence that they are endorsed by the NHS and NICE. Do the technologies listed provide this opportunity? Equality and accessibility should both be key factors in the choice of digital technologies, as highlighted in the Draft Guidance. Do all of the technologies included provide patients with a choice in how they access and consume their management programmes for LBP (e.g. via a print option, via a single web URL link, or via a full app download)? Have the technologies also been assessed for their level of accessibility against standards such as the Web Content Accessibility Guidelines (WCAG 2.1 AA standard)? It should also be determined if the content within the technologies is in itself equitable and representative of different patients (e.g. body composition, ethnicity, culture, etc). A further consideration

				should be made towards Social Prescribing and if the technologies included can support this. For example, if the patient has a cognitive, physical, or sensory impairment which may be a barrier to their independent use of the technology then can a caregiver assist with their programme? The recognition of the need for 'nudges' in an effort to support patient engagement is very valid. It would also be worth considering if the technologies include a degree of gamification and game-based learning, and if these are based on different principles of reward and psychology. Furthermore, can these 'nudges' be determined by the patient themselves (e.g. can notifications be set at self-selected times as reminders to complete exercises, review educational materials, or complete a PROM?). It is reassuring to see that an Early Economic Modelling process has revealed an anticipated cost saving by integrating digital technologies into healthcare. Has this taken into account the cost of licences for the NHS Trust to procure the healthcare technologies and any premium features required? I also recognise the statement made around user onboarding and training. This would be best delivered on a 'self-serve' and asynchronous basis to fit in with healthcare practitioner's already stretched clinical responsibilities. The technologies UI and User Experience (Ux) for the healthcare practitioners should also be very intuitive and time efficient to ensure good uptake and engagement with the technologies from a healthcare provider's perspective. The easier it is for the healthcare practitioner to prescribe a programme to a patient the better (e.g. through QR code, via email, or by text messaging services). As a final question to the NICE Early Value Assessment medical technologies advisory committee, does the statement of 'Healthcare resource only' in the 'Key Gaps in the Evidence' section on page 6 require further explanation as it does not seem to work as a stand-alone statement? Our Physitrack Software as a Service (SaaS) product is 'tried and tested' in 60+ NHS Trusts with a wealth of positive practitioner and patient experiences, including in the management of LBP. Physitrack complies with all NHS data security requirements listed in the second paragraph of this statement, and its features support the majority of the points raised throughout my comments above. [redacted] Physitrack PLC [redacted]
The technologies				
45	9	Company	2.2	***Please correct the entry for SelfBack: App name: SelfBack

				Company name: SelfBack ApS Please amend the table 2.1 in the assessment report with the following information: Delivery: Mobile phone/Tablet Target condition: Sub-acute or Chronic low back pain, including patients with stress and/or depression. Key Features: Multi modal, personalised self-management plans that are re-tailored every week (automated progression/regression). The personalised plans include: Exercises, supported by videos and explanations, with options for the patient to skip or replace. Tailored education modules to support behaviour change (CBT). Motivational messages for compliance. Goal setting, activity monitoring and gamification elements. Additional content: Mindfulness sessions. First Aid toolkit. Sleep module. NHS Staff Involvement: Must triage patients to determine suitability. Pathway placement: Intended for use in Primary care, as self-management tool, but can be used at any point in the pathway. Option for self-referral can be included if required. Safety net: Yes. Can be optionally be used with STarT Back, or DART(https://www.researchprotocols.org/2021/5/e27205/) as a clinical decision triage tool to screen and risk stratify the patient. Current use in the NHS: yes, finalising trial with ICS Stoke-on-Trent Page 85 in the Assessment report, re. Price, the price information is not correct: Price of SelfBack: EUR 100,- for 3 months license Company website: https://selfback.dk/en Any inquiries for more information can be addressed to: [redacted]

				E-mail: [redacted] Phone: [redacted]
46	11	Company	Are the recommendations sound and a suitable basis for guidance to the NHS?	Some of the technologies included are not currently operating in the NHS. It can take a long time for a new technology to be adopted and to build enough of a customer base in order to obtain enough meaningful data. Whilst the 3 year period is generous, it may take some technologies much longer than others to be 'up and running' in the NHS. Technologies who already have a large and loyal NHS customer base are therefore in a more advantageous position. Likewise, technologies whose existing customer base is predominately outside of the UK and the NHS should be questioned on their transferability to a different population, under a different healthcare system, and for patients with different lived experiences. I believe there are a few additional considerations that should also be made regarding the Draft Guidance. Overall, it is my view that the terms 'Health Technology' and 'Digital Technology' need to be more clearly defined in this context. These terms are very broad and can encompass a vast range of different intended use cases, particularly in the management of LBP. For example, do these NICE guidelines intend to include advances in Artificial Intelligence (AI) within the scope of this work? As the intention is to review these recommendations in 3 years following a period of further research and data collection in line with the Unmet Needs and Evidence Gap Review there is the risk that the technologies selected at this stage may be surpassed with more advanced alternatives. The term 'self-management' should also be clearly defined in the guidelines. I note that this could be in reference to an entirely patient led and automated service, however 'self-management' can also be in response to care following face-to-face consultation, particularly in the 'self-management' of Long Term Conditions, including chronic LBP. For example, NHS Trusts may choose to use the technologies to identify which patients could be triaged to a 'remote monitoring' or 'face-to-face monitoring' pathway. This will ensure that the right patient receives the right care at the right time. It should also be considered if any clinical triage questions are provided by the healthcare technology directly, or if these can be determined by the NHS Trust and their clinical leads. The latter would offer greater choice and flexibility to suit local healthcare needs, and should include the screening of red flag conditions. The output and end result of such automated triage pathways should also include patient facing content including exercises, education, and Patient Reported Outcome Measures (PROMs) selected by the clinical team. Furthermore, 'self-management' could also be achieved by intervening at the point of referral between GP (or self-referral) to Physiotherapy services by 'triaging the waiting list' and getting patients started with the advice given through the technologies prior to their initial consultation to result in a 'waiting well' approach. This could also result in patients no longer needing their initial face-to-face contact, thus opening the appointment to a patient in need. From what I can see from the technologies included, they are predominantly designed to fit into the front end of a patient's journey. I believe consideration should also be made towards technologies used to further support patients whilst under 'standard care' and post-discharge.

				The definition of ‘Chronic LBP’ could also benefit from further clarity and context, in addition to the existing statement of ‘lasting 3 months or more’ (e.g. ‘a condition that has an impact on a patient on a daily basis for 3 months or more’). Likewise ‘specific’ and ‘non-specific’ LBP could be further defined for full clarity of inclusion and exclusion criteria, although I note and appreciate the reference to NICE’s guideline on low back pain and sciatica in over 16s to support this. I believe that these NICE guidelines should also include reference to how these technologies support the NHS Patient Initiated Follow Up (PIFU) process, particularly for patients with Chronic LBP who are likely to experience exacerbation of symptoms. This would also extend to how the technology could manage these requests remotely so that the patient does not return to a waiting list or take a face-to-face appointment that is not required. It is good to see that interoperability and integration with other 3rd party platforms, such as Practice Management Systems (PMS) and Electronic Medical Records (EMRs) has been taken into account in the NICE guidance. This will help to ensure a seamless and time efficient service for healthcare practitioners using the technology, and aid communication across the Multi-Disciplinary Team as well as supporting Standards of Documentation. Further to this, it would be beneficial to establish the level of integration offered by each of the technologies. For example, are Single Sign On (SSO) and webhooks to the patient’s external ID used to create a patient in the technology? Is the integration ‘read and write’ to save a copy of what has been prescribed to the patient to their medical records? Does the technology provide an embedded Application Programming Interface (API) and User Interface (UI) into the PMS and EMR? These are questions that NHS Trusts should be prompted to ask when determining which technology to adopt in their service. Equality and accessibility should both be key factors in the choice of digital technologies, as highlighted in the Draft Guidance. Do all of the technologies included provide patients with a choice in how they access and consume their management programmes for LBP (e.g. via a print option, via a single web URL link, or via a full app download)? Have the technologies also been assessed for their level of accessibility against standards such as the Web Content Accessibility Guidelines (WCAG 2.1 AA standard)? It should also be determined if the content within the technologies is in itself equitable and representative of different patients (e.g. body composition, ethnicity, culture, etc). A further consideration should be made towards Social Prescribing and if the technologies included can support this. For example, if the patient has a cognitive, physical, or sensory impairment which may be a barrier to their independent use of the technology then can a caregiver assist with their programme?
Technology - regulatory status				
47	3	Individual	1.1	If there are concerns around CE or UKCA marks not being in place, or the clinical efficacy of an app because there's currently no real basis of comparison between the outcomes experienced, why are you suggesting that the apps can be made available for use within NHS pathways?
48	5	Individual		"Thank you for this interesting report, and it’s good to see NICE evaluating digital solutions in this important clinical area. I am however concerned that the recommendations are potentially misleading to

				both patients and healthcare professionals when it comes to the regulatory status and safety of the solutions evaluated. It is my understanding that MHRA is clear that any app or software used in the treatment of a medical condition (including the delivery of rehabilitation) must legally be approved as a medical device before it can be used outside of a controlled research context in the UK. Within the list of evaluated technologies, most of them appear either not to have yet been cleared by the MHRA, or to have unknown regulatory status. While the vast majority of back pain does not involve structural pathology, there are a number of very serious conditions that can initially present as back pain. This distinction can be complex to ascertain and these patients occasionally require assessment in the Emergency department. Essential conditions not to miss include spinal fractures, malignancy, infections, and cauda equina syndrome. Left untreated these conditions can have devastating, lifelong consequences for patients, and so MHRA medical device approval is not just a legal requirement, but also a vital process to ensure that adequate safeguards and development processes have been followed. I appreciate that your guidance does say that the technologies can be used “once they have appropriate regulatory approval” however the nuance of this will be easily misinterpreted by many, including the media, who have already widely reported the list of solutions as ‘recommended by NICE for use across the NHS’. As far as I know, NICE would not generally recommend the use a list of drugs that had not received regulatory approval, and it is unclear to me why that distinction should be any different for software medical devices. NICE guidance is deservedly well respected by clinicians, and many will reasonably assume that a product recommended by NICE has already passed the relevant regulatory requirements, which in this case is not true, and may lead to the inadvertent prescribing of an app that cannot legally be prescribed for use in the UK. It would seem more appropriate to see only solutions already approved by the MHRA included in your ‘recommended’ list, and any solutions that are not currently MHRA approved should remain in the ‘research only’ bracket. Furthermore, it would be my understanding that any solution whose manufacturer claims doesn’t require MHRA clearance as a medical device cannot legally make any claims about it’s use in the treatment of back pain or any other condition, which would seem to preclude them from this evaluation."
49	9	Company	1.1	The regulatory status is: CE marked as Class 1 Medial Device (MDD) Registered in EUDAMED: B-05700002230607 Ref. no MHRA: 22315 SelfBack is currently in the process of finalising DTAC through Orcha.
50	12	Individual	1.1	How can regulatory status be unknown for some of these technologies? Surely before adoption (with evidence generation) we should know at least if companies have begun their regulatory approval process + safeguarding of the product that goes along with this?
51	12	Individual	1.6	If Pathway through pain has a CE mark as stated, they should have clinical evidence. Please request this from them before allowing adoption as part of this.

52	12	Individual	Are there any additional implementation factors that need to be considered?	Regulatory approval. Many of these products will fit under the banner of SaMD, with recent updates on regulatory processes they will likely be class 2a or 2b devices, MHRA approval will take a long time for these if the process has not already started.

"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."