National Institute for Health and Care Excellence

Medical technologies evaluation programme

Digitally enabled therapies for adults with depression: early value assessment

Consultation comments table

There were 29 comments from 7 groups:

- 3 comments from 1 manufacturer
- 3 comments from 3 members of the public
- 22 comments from 2 NHS England representatives
- 1 comment from an NHS Provider

Some of the comments have been split because they represented multiple themes. The following themes have been identified:

- Recommendations: comment 1
- Patient Considerations: comments 2 to 4
- Technology – regulatory status: comment 5
- Clinical evidence: comments 6 to 9
- Review Period: comments 10 to 15
- General comment: comment 16
- Wording: comments 17 to 29

Comment no.	Consultee ID	Group	Section	Comments	NICE response
Recommendations (n= 1)					
1.	1	NHS England	General	ignificant concerns with inconsistency across the adult products vs CYP products, in particular when guidance could have market shaping impacts. The underlying objective of this work was to be able to more clearly articulate what evidence levels industry needs to meet and support NHS in making good commissioning decisions. This flexible and subjective approach does not support these core objectives. Different evidence levels will be required by different product types based on risk, but there needs to be a consistent approach to determining risk level of use case and what this means for evidence level required for a conditional recommendation through NICE, given the market shaping impacts EVA guidance could have. This approach also risks significant implications on markets and wider NHS programmes that have not been fully considered within NICE's methodology. Whilst we are very much supportive of a clear expectation being set for digital health technologies and acknowledge that this will likely result in negative outcomes for some products, it is also critical that the implications of the guidance on markets, NHS and impact on innovation are considered in the design of methodologies. We are further concerned by the rationale that NICE have put forward for the intentional inconsistency: Determination of greater unmet need for children and young people than adults, despite larger demand gap	Thank you for your comment. The Medical Technologies Advisory Committee (MTAC) is an independent committee that considers evidence on the clinical and cost effectiveness of medical technologies and makes recommendations for their use in the NHS. Each early value assessment topic is assessed and considered separately with recommendations made by the committee based on these specific assessments and committee discussions. The committee's considerations vary across topics and these have been outlined in the draft guidance. While NICE has sought to explain the committee's considerations, it does not influence the committee's recommendations. Evidence and any uncertainty is considered in the context of which a technology will be used, including financial and clinical risk, as well as factors relevant and important to the user. For example, the two mental health topics differ in clinical pathway and service provision, different unmet need, multiple indications and different range of technologies. Guidance recommendations are therefore focussed on the use of a technology in specific scenarios to address an unmet need of the NHS or patients, and may differ across or within disease areas and conditions. Evidence generation plans are also specific to the use of technology in context and so inform industry and the NHS on the evidence needed for that specific use to demonstrate the benefits to patients and the NHS

				in adult populations and very similar mode of action across pathways. Comparison in CYP to alternative waitlist interventions is incorrect as the recommendation by NICE includes assessment by clinician and guidance, meaning it should not be cons Expert advice that CYP evidence generalisable, but Adult evidence not generalisable, however this advice was given by different people without an explicit comparison made across the topics Assumption that a small number of products recommended in adult space could successfully meet user need, despite clear feedback with NHS that range of products and a positive market to drive innovation needed to support adoptions	and ensure clinical and financial risk is managed appropriately. NICE can review guidance when new evidence that could materially affect the recommendations is produced so this guidance approach should not prevent innovation but provide an approach to managing value for money while benefits are assessed during the lifecycle of a new technology.
Patient Considerations (n= 3)					
2.	3	Member of the public	General	It is important that even though this is a digital technology that the patient feels they are being treated as an individual with feedback from the Therapist showing this and not just a cut and paste exercise. The requirement to say what you actually mean rather what is what you want the therapist or computer to hear is far more important than thinking that that if you answer correctly the emotion will automatically follow.	Thank you for your comment. The committee considered the experiences of people with depression and the importance of patient choice and empowerment. It also highlighted the importance of capturing patient experiences during further evidence generation. This will be considered by the NICE data and analytics team who is developing an evidence generation plan based on the guidance.
3.	4	NHS England/ Patient representative	General	These comments are submitted on behalf of a Patient and Public Voice representative who sits on the NHS England Talking Therapies Expert Advisory Group: Digital Enabled Therapies for Adults with Depression. Once again my first thoughts were that this is long overdue for those for whom it is suitable as obviously, as we all know ‘one size doesn’t fit all’ and not everyone is IT Literate. Also, again I had concerns around Digital Technologies actually exacerbating the condition it would be used to help. This would be around the	Thank you for your comment. The guidance states treatment options should be discussed by healthcare professionals, the person considering treatment and (when appropriate) carers. Clinical assessment, the person’s preferences and needs, and the level of support needed should be considered. These technologies should be considered as an option for treatment, rather than an alternative to a waitlist. They would be supported by appropriately trained NHS Talking Therapies clinicians.

				flexibility of the Technology as from past experience, you can sometimes be taken down unwanted paths just to move on and of course the level of Therapist Support and this being tailored to individuals. Although it is being researched as a positive, wait time saving tool, It could also have a negative impact on the already negative mindset that comes with Depression, such as feeling *pawned off to an on-line service to save money or feeling not worthy of an actual therapists time for sessions not just occasional support. There is a paragraph entitled 'Clinical Benefit', that claims that Digitally Enabled Therapies may benefit Depression by reducing symptoms, better management of the condition and aid Treatment choices. How? As this document is for Public Consultation I I felt this should be clarified. The paragraph below this entitled Resources, for me echoes back to my earlier point's* above. Again I see the language of 'less severe', 'more severe' and more severe episodes of Depression and I feel the need to say that any Mental Health Condition is as severe as the effect it has on the sufferer. However, not just for Depression, but Anxiety too, I don't see reference to lengths of episodes? Evidence Gap Overview – under this section is included the fact that some evidence was collected out with the UK. Personally, I see this as a positive as we generally talk about data collection across the country, but we can also learn a lot if we ditch the boxes we can sometimes find ourselves in and go further afield. It can be a two way path and a lot of otherwise overlooked knowledge learned.	The clinical benefit and resource paragraphs found in section 1 of the guidance provides a very brief overview of the guidance, with further details relating to clinical benefit and resource use discussed in more detail in sections 3.1 to 3.5, and 3.12. The use of the terms less and more severe depression are based on terminology used in NICE's clinical guideline on adults with depression. It relates to severity rating scales, to aid clinical decision making. It is not intended as to reflect how the patient feels about their depression. The recommendations are not limited by the length of episodes and so episode length is not discussed as part of this evaluation. The evaluation considered clinical and economic evidence from any country. If further evidence were collected by companies outside the UK, this would also be considered by NICE. However, as the evidence generation programme is designed specifically to benefit use of the technologies within the NHS, this recommendation is limited to the UK. Section 3.13 of the guidance acknowledges that co-morbidity of depression and anxiety is high, meaning evidence on mixed population was not a major limitation when considering the clinical evidence.

				Anxiety and Depression are very often 'Partners in Crime' and I think that my reviews, in the main could equally apply to each other. Personally, I support Early Value Assessments, before these already complex conditions can become embedded in the Individual and even more complex and difficult to process. I feel without any doubt that we are still striving for Parity of Esteem and truly hope this project proves to be another step towards this.	
4.	5	Member of the public	General	I have been reading about the conditional recommendation by NICE of digital therapies for adults with depression and anxiety. I'm in my late 40's & have received 3 separate blocks of NHS talking therapies during my life so far. I'm hearing impaired and use hearing aids to access speech. I find virtual communication much harder than face to face where I can benefit from body language and facial expression clues. I have been extremely grateful that my last block of talking therapy in 2021 was able to be face to face despite being after the pandemic. I know it's difficult to talk about feelings and emotions that are overwhelming and I would have not been able to do this digitally. My worry is that should I need further support of this type in the future and these digitally enabled therapies have been launched it will be expected that I participate in them. I really hope that NICE recommendations will explicitly state that patients that are deaf / have hearing loss and rely on hearing technology should be offered face to face support and not ushered down these digital routes. I worry that once an offer of virtual therapy has been made, if a deaf patients requests to wait for a face to face appointment which they can access, it will	Thank you for your comment. The recommendations state that these technologies are an option for treatment, alongside a range of other treatments recommended within NICE's clinical guideline on adults with depression. The guidance states that choice of treatment should consider the person's needs and preferences, meaning that if face-to-face treatment would be more appropriate, it should be offered instead of a digitally enabled therapy. Both clinical and patient experts agreed that personal choice should be a key when considering treatment options.

				be recorded as declining treatment on their notes and jeopardise the their ability to access further services. Thank you for taking these concerns into consideration.	
Technology – regulatory status (n = 1 comment)					
5.	2	Member of the public	General	Please consider clarifying regulatory requirements: These products are all medical devices and require appropriate CE / UKCA marking in order to be legally allowed on market. Therefore NICE should absolutely mention this as a requirement, and state their risk class and intended use. While DTAC is required, it does not mean a device is legally on market, so by omitting mention of CE marking this recommendation could make it appear as if DTAC is all that is required, which is not the case. Of note - CE marking is mentioned in the press release but not in the guidance. Perhaps this is an oversight? Following on from this clarification - it would be good practice for the NICE team in future to check if the products they are reviewing are actually legally allowed on the UK market by checking if they are registered with the MHRA, and reviewing their certificates. At the time of writing, several of the recommended devices are not registered appropriately nor have the correct risk class CE certification, which makes it appear as if NICE is recommending medical devices that are illegally on market. Simple communication with the MHRA, especially to determine correct risk class and registration would suffice.	Thank you for your comment. Regulatory statuses of the technologies have been considered alongside this evaluation. NICE has worked with the MHRA to confirm the regulatory statuses of the recommended technologies. Technologies must achieve regulatory approval prior to their NHS use. These technologies must also have Digital Technology Assessment Criteria (DTAC) approval and an NHS Talking Therapies for anxiety and depression digitally enabled therapies assessment from NHS England prior to use in the NHS.

Clinical evidence (n = 3 comments)					
6.	1	NHS England	Section 3.8	Section 3.8: Based on details in assessment report, I believe it is incorrect to group the three products together as limited or no evidence as in the following statement "There was limited or no evidence within the scope of this assessment for Minddistrict, Iona Mind and Wysa." This section should make clear the differences in the evidence that Wysa and Minddistrict have compared to Iona Mind, and specify in more detail where the evidence gaps are for these specific products that will get a 'negative' outcome.	Thank you for your comment. The text has been amended to 'There was limited evidence for Wysa and no evidence for Minddistrict and Iona Mind within the scope of this assessment'. Section 3.11 links to the assessment report where further information on the evidence can be found.
7.	1	NHS England	Section 3.8	Section 3.8: Could this statement "But, there was not enough evidence for Minddistrict, Iona Mind and Wysa to make a recommendation for use." be expanded on i.e. in acknowledgement of the fact that in order to generate evidence, the product will need to be used in controlled research settings, for example?	Thank you for your comment. Text has been added to section 3.11 to clarify that further research is needed in formal research settings.
8.	1	NHS England	Section 3.8	Section 3.8: Exclusion of international research should be reviewed. If population demographics, care pathways or conditions are substantially different then this may be required, but if comparable populations are identified with appropriate methodologies used and outcomes measured, I do not believe international research should be considered less than equivalent research in UK. Focus should be on whether research in looking at a comparable use case to determine whether in scope.	Thank you for your comment. Evidence from outside of the UK was considered within the evaluation process and used in the decision making. The external assessment group questioned the generalisability as the technologies were not used within a set up equivalent to that of an NHS Talking Therapies service. This was considered a limitation of the evidence but did not prevent the inclusion of the evidence.
9.	6	Company	General	With regard to the consultation question 'has all the relevant evidence been considered', we understand the position the committee took in only considering research data and RCTs occurring within the UK, as NICE is recommending products for use within the UK. As a global company with the app in use in tens of countries, we feel the evidence base we are	Thank you for your comment. The assessment and committee considerations were not limited to research data and randomised controlled trials in the UK as shown in Table 2 of the external assessment report which includes a range of study designs and locations.

				generating across multiple different countries would add to the evidence base locally in terms of our ability to serve different communities and equality cohorts across the UK. We have submitted similar evidence to the MHRA which has been accepted. We would ask for future reviews of evidence for NICE to consider evidence generated in the USA or elsewhere in settings where the academic rigour around the studies is of a high enough standard to be acceptable for institutions such as the FDA etc.	The external assessment group (EAG) were asked to reply to this comment. They stated that the evidence included in the EAG report, comprising one mixed methods study (Beatty et al, 2022) and two qualitative studies (Inkster et al, 2018; Malik et al, 2022). Reasons for exclusion for each excluded study are provided in Appendix D, Table 27, of the EAG report. Certain studies on the technology were excluded because they did not meet the inclusion criteria. Ingelsias et al (2022) used the Return to Work version, which the paper states is 'not available commercially', hence not eligible for this appraisal. Three AIC papers by [redacted] were excluded on grounds of population [redacted]). The EAG did not consider evidence on depression secondary to other health and medical conditions, partly to make the scope of work manageable and partly because these types of depression can be quite different in nature than primary depression.
Review Period (n = 4 comments)					
10.	1	NHS England	General	The three year review window does not seem appropriate for pace of product development and research, especially if there is not a consistent approach and clear expectation for review. With guidance that is potentially limiting for some products in the market, it is even more important that we get this right first time, as the current approach specifies a 3 year period for evidence review. A number of the products reviewed have live RCT studies, which will not be considered until the end of the three years, creating potentially substantial barriers to being commissioned for what is a very extended period for companies of this nature. Alternatively a rolling research review could be considered to allow updates to research to be made.	Thank you for your comment. The EVA interim statement states that evidence generation should be for the shortest time necessary to collect the data needed to sufficiently resolve uncertainties in the evidence. The 3-year evidence generation period aims to provide enough time for all companies in the assessment to generate relevant evidence before the topic is considered for multiple technology guidance.

11.	1	NHS England	Section 1	Box with managing the risks, costs bullet 4 years seems like a long period to continue using the products without clear understanding of cost effectiveness – what is the rationale for this and could it be reduced to e.g. 2 years? Also this is different to the 3 year window referenced elsewhere in the document – how do these relate?	Thank you for your comment. As this is a pilot process a 4-year time frame for a full review was given. The 3 years refers to the period of evidence collection. The times given within the guidance are maximum periods. NICE's interim process and methods for early value assessment acknowledges that evidence generation should be for the shortest time necessary to collect the data needed to sufficiently resolve uncertainties in the evidence.
12.	1	NHS England	Section 1.3	para 1.3 Are Iona Mind, Minddistrict and Wysa currently in use anywhere in the NHS and have we considered the impact on the market of issuing a research only recommendation? Especially if reassessment doesn't occur for 3 years? I am concerned about potentially shutting these products out of the market.	Thank you for your comment. Minddistrict and Wysa are used in the NHS with Iona Mind planned on being piloted. A research recommendation does not prevent use of these technologies in the NHS but use should be within a research context.
13.	1	NHS England	Section 4	Section 4 This section should acknowledge that some products recommended only for research may develop more within the next year, in advance of the next NICE review. Any additional evidence may want to be considered alongside the NICE guidance by NHS organisations making commissioning decisions.	Thank you for your comment. We encourage further research and new evidence on digitally enabled therapies. The research only recommendations made by NICE do not prevent the use of these technologies in the NHS but use should be within a research context.
14.	6	Company	General	We would like to understand the offer of ongoing support from NICE following the recommendations and to ask whether NICE would consider broadening that scope. Our understanding is that only the products recommended for treatment will enjoy NICE's further support in evidence generation. However, we would argue that products that haven't already reached that threshold, but have been recommended for research might benefit the market more if they were also supported by NICE to generate the requisite evidence to become a product recommended for therapy. Could this support offer be reconsidered?	Thank you for your comment. A research only recommendation is made when the committee are uncertain if the technology has the potential to solve the unmet need. In this instance a research only recommendation was made as the committee felt that there was not currently enough clinical evidence on the indicated population to determine if the technology would provide benefit. The external assessment report provides an overview of the evidence gaps to help with further evidence generation for all the technologies.

					Please see the interim process and methods for Early Value Assessment for further information
15.	6	Company	General	It is our understanding from the feedback EVA session that the recommendations won't be re-reviewed for a minimum period of 3 years. We would strongly urge NICE to consider a different review mechanism than temporal (every 3 years) for the EVA review and instead set the burden of evidence for a quantitatively assessed review threshold. When we entered into the EVA process, to the best of our understanding and from the documents shared with us at the time, we were not aware of a 3 year review cycle. The market will struggle to operate like this as it disincentives companies from accepting to undertake EVA, as they enter effectively an additional 3 year evidence gathering cycle which wasn't in place before. It is our expectation that in advance of 3 years, we will have generated enough evidence from research that NICE would possibly consider us a recommended therapy. We currently have multiple RCTs which are due to end in 2023/24 in the UK as an example. If companies remain labelled as a status of 'for research only for 3 years', as an SME, revenue generation will be difficult as effectively the recommendation could act as an inhibitor to trade and revenue generation. We ask that NICE reconsider this periodic review and offer an earlier review period in order that businesses are profitable enough to go the distance. As an example, the EVA recommended for therapy products have been trading in the UK for many years prior to the introduction of the NICE EVA. Their trade has not been restricted by the NICE EVA process or their status. We would ask to be treated with the same opportunities as these predecessor products	Thank you for your comment. The EVA interim statement states that evidence generation should be for the shortest time necessary to collect the data needed to sufficiently resolve uncertainties in the evidence. The 3-year evidence generation period aims to provide enough time for all companies in the assessment to generate relevant evidence before the topic is considered for multiple technology guidance. The external assessment group (EAG) were asked to reply to this comment. They state that the EAG has provided a list of ongoing studies in Section 13.4 (p. 114 onwards) and has included all studies that the company mentioned in its submission. The relevance of evidence can only be confirmed once a full manuscript is available. UK RCTs would be highly relevant, provided the populations are appropriate to the decision problem. UK studies are generally the most relevant due to differences in health care pathways.
General comment (n = 1 comment)					
16.	7	NHS Provider	General	**Draft guidance Adult Depression DET EVA – Comments from** [redacted]	Thank you for your comment. Thank you for providing information in support of the early value assessment on digitally enabled therapies

				About us: [redacted] is a provider of psychological therapy services to the NHS in England and Scotland. We provide primary care treatments for common mental health conditions in adults using a digital text-based interface where a therapist has a 1:1 typed conversation with a patient. Learning from our decade of experience as a digital health provider, we are currently building out digital therapeutics to treat a variety of indications. **Overview** We welcome the publication of the draft NICE Early Value Assessment (EVA) guidance on digitally enabled therapies (DET) for adults with depression. It represents a key step towards (1) making evidence-based treatment more readily available to patients, (2) reducing costs while ensuring valued-based care for more people in need, and (3) making the NHS an attractive location for innovators by enabling national commissioning of DET for depression and supporting an integrated marketplace instead of fragmented arrangements within individual ICSs. Based on research conducted by [redacted], there is good reason to believe that providing better access to people in need of psychological therapy will lead to (1) better mental health outcomes (Catarino et al., 2018 https://doi.org/10.1192/bjo.2018.57), (2) lower healthcare costs (Catarino et al., under review), and (3) broader economic savings resulting from keeping people in employment (Layard et al., 2007 https://doi.org/10.1177/0027950107086171). **Comments to the committee questions** This draft EVA guidance on digitally enabled therapies for adults with depression is informed by a robust analysis on the 6 digital health technologies under scrutiny.	for adults with depression and confirming that relevant evidence has been considered, based on the published scope. NICE acknowledges that the considerations of evidence on mental health and long-term health conditions was not considered in this evaluation. This was because this is a large topic area and so an evaluation of a population of people with long term health conditions would be more suited to a separate evaluation. The committee and clinical experts acknowledged that there are long wait times for treatment in NHS Talking Therapy programmes. Evidence with waitlist comparators were considered as part of the evaluation. For future research it was considered to be more appropriate to have other care options as comparators instead of waitlists as digitally enabled therapies should be considered as a care option rather than an alternative to a waitlist. Please see the interim process and methods for Early Value Assessment (EVA) for further information on the EVA process. Where existing NICE publications are relevant, such as the NICE clinical guideline on adults with depression, we make ensure that recommendations align where appropriate. NICE acknowledged that the sub-categorisation of depression was a limitation in the evaluation of the evidence for this early value assessment. The recommendations suggest that evidence generation includes information of base line characteristics, which includes symptom severity, based on widely used scoring systems. This would not limit evidence collection to set categories. The categorisation used for a medical technology guidance would be based on a clinical guideline, where relevant. We have passed

				The relevant evidence has been considered based on the scope of the evaluation and its interpretations are reasonable. As such, the recommendations are a suitable basis for EVA guidance to the NHS. Moreover, equality issues have been adequately considered. **A real-world approach** Although a rigorous analysis has been conducted within the boundaries of the selected search terms, we consider the scope of the evaluation to be too restrictive with regards to population and comparators. ***An integrated approach to physical and mental health to improve outcomes and reduce economic burden*** As highlighted in the external assessment group report for DETs for adults with depression (see pg. 21 of the Supporting Documentation), there is an overlap between depression and long-term health conditions. People living with long-term physical health conditions are more likely than the general population to experience mental ill-health. For example, in diabetes, prevalence rates are 25% for comorbid depression (Grigsby et al, 2020 https://doi.org/10.1007/s13300-015-0118- y) and 40% for comorbid anxiety (Ascher-Svanum et al., 2015 https://doi.org/10.1007/s13300-015-0118-y). As well as direct effects on emotional wellbeing, depression can negatively impact a person's ability to manage their physical health condition by adhering to treatment and engaging in self-care behaviours. The consequences are poorer physical health outcomes, poorer quality of life, and higher healthcare costs. Targeting mental health needs can improve physical health outcomes. For example, [redacted] recently showed that digital psychological therapy can be effective in reducing mental health symptoms in people with diabetes and comorbid depression and/or	on this information the clinical guideline surveillance team for consideration.

				anxiety (https://www.businesswire.com/news/home/20220606005191/en/ieso-AnnouncesResults-Showing-Novel-Form-of-Online-Cognitive-Behavioral-Therapy-Improves-PatientOutcomes-in-Type-2-Diabetes). This increased patients' engagement in managing their condition, improved quality of life and alleviated diabetes-related distress for up to six months. Increasing early access to mental health treatment with DETs in the context of long-term conditions would enable the application of a holistic and integrated approach to physical and mental healthcare, addressing the need to improve personalisation of treatment to achieve better health outcomes in real world settings. DETs should be an integral part of the plans to achieve parity of esteem between mental and physical health, which is not currently achieved through current healthcare provision models (as indicated by the National Audit Office 2023 report 'Progress in improving mental health services in England'). The forthcoming Major Conditions Strategy offers the opportunity to address this gap by integrating actions to tackle mental health conditions alongside physical health ones. ***The cost of waiting*** The scope of the evaluation focuses on standard care according to NICE's clinical guidelines on depression as an appropriate comparator in this EVA. However, as highlighted in the external assessment group report for DETs for adults with depression (see pg. 10 of the Supporting Documentation), patients often face a waiting time for treatment in real life. Waiting times have reached a record high (Royal College of Psychiatry survey, 2022) and have considerable impact in cost-effectiveness evaluation.	

				At [redacted], we have demonstrated that faster access to treatment is associated with better mental health outcomes (Catarino et al., 2018 https://doi.org/10.1192/bjo.2018.57) and lower healthcare costs (Catarino et al., under review), owing to a reduction in background medical costs (e.g., GP and A&E visits) that are caused by treatment delays and typically outweigh the cost of mental health treatment itself. Moreover, waiting list controls are considered appropriate in the NHS Assessment Criteria for Digitally Enabled Therapies (a key step to for DETs to obtain the final NICE recommendation). Therefore there is an opportunity to include waiting list controls in future EVA scopes for DETs, to better evaluate the impact of waiting in outcomes and cost effectiveness, representing more accurately what patients experience in accessing mental healthcare. **EVA: challenges and opportunities for innovators** The NICE EVA framework reduces the barriers for innovators to gather real-world evidence at scale. However, the tight relationship between EVA and NICE clinical guidelines raises the question of whether the current system is future-proofed to enable innovation at speed. The NICE EVA recommendations are conditional on obtaining the NHS Talking Therapies digitally enabled therapies assessment from NHS England. The clinical component of this assessment is based on the very rigorous NICE clinical guidelines, that are scheduled for review every three years. NICE clinical guidelines for depression were updated in 2022 with new classification categories. According to current NICE clinical guidelines, 'less severe depression' now includes the traditional categories of subthreshold symptoms and mild depression, while 'more severe depression' includes the traditional categories of moderate and severe depression. This	

				means that evidence generation efforts before 2022 are already (to a certain extent) diverging from NICE guidelines. This exemplifies the need for a timely bidirectional relationship between EVA and NICE clinical guidelines. The NICE EVA process offers the opportunity to integrate new evidence generated by these programmes into NICE guidelines, offering alternative and innovating treatment pathways, evidenced safely and responsibly in real-world settings. For example, by interrogating [redacted] treatment dataset, we identified a reliable and reproducible set of depression subtypes (Catarino et al., 2022 https://doi.org/10.1017/S0033291720002032 ; Simmonds-Buckley et al., 2022 https://doi.org/10.1002/da.23161) that respond preferentially to different elements of psychological therapy. Data-driven insights into condition subtypes, and their response to treatment, could be integrated into future NICE guidelines, offering an important route to personalised treatment and improved patient recovery rates.	
Wording (n = 13 comments)					
17.	1	NHS England	General	Please can we refer to 'NHS Talking Therapies for anxiety and depression' rather than 'NHS Talking Therapies' throughout.	Thank you for your comment. The text has been amended in response to this comment.
18.	1	NHS England	Section 1.1 (Recommendations). Page 3, Line 5	The "NHS Talking Therapies digitally enabled therapies assessment from NHS England " is mentioned. Please add the weblink so readers of the EVA can access it. The weblink is: https://www.england.nhs.uk/mental-health/adults/nhs-talking-therapies/digital/assessment-criteria/	Thank you for your comment. The link has been added in response to this comment.
19.	1	NHS England	1.2	Would recommend also including rates of reliable deterioration and average number of treatment sessions at step 2, step 3 and both (with and without DET)	Thank you for your comment. The text has been amended in response to this comment.

20.	1	NHS England	Section 1.2 (Recommendations). Page 4, line 1	Please insert “and symptom severity” after “baseline data including demographics…” It is essential that any report on outcomes for DETs includes data on the severity of the sample that received the DET. Without this information, it will be impossible to benchmark outcomes against those normally obtained with non-digital therapy in NHS Talking Therapies for Anxiety and Depression services. There is a strong correlation between baseline severity and the probability of a patient recovering and that relationship needs to be taken into account in any benchmarking.	Thank you for your comment. Symptom severity has been added to section 1.2.
21.	1	NHS England	Section 1	Box on the benefits and risks of DETs (page 5) Please change the two high level titles for this box. We suggest changing “Potential benefits of early access” to “Potential benefits of digitally enabled therapies” and changing “Managing the risk of early access” to “Managing the risk of digitally enabled therapies”. The text below the titles does not need to be changed. The change of titles is required because treatment with DETs will NOT start earlier than the equivalent non-digital treatment. DETs may require less therapist time and therefore could help services see more people with a given workforce. This is likely to reduce overall wait times for the service. However, patients will still have to wait for a free therapist slot to start with a DET, just as they do with telephone, video, or in-person therapy delivery. Services are not going to tell their therapists to allocate therapy slots, so people get seen quicker if they opt for digital delivery and slower if they opt for some other modality of treatment delivery. That would be discriminatory and would deprive patients of genuine choice about the modality of their treatment. NHS England is concerned that the EVA panel have	Thank you for your comment. The use of ‘early access’ in the draft guidance reflects the aim of early value assessment to get promising technologies into the NHS quicker than full guidance. The wording has been amended to ‘early value assessment’ to prevent misinterpretation.

				not understood this point. While observing the public section of the 17th February Panel Meeting we noted that several panel members seemed to incorrectly assume that opting for a DET would result in earlier treatment. When speaking about DETs on [redacted] a panel member [redacted]) incorrectly stated that patients would be given the choice between being treated quickly with a DET or having to wait longer for a non-digital therapy. It is essential that the final NICE document does contain any such suggestion.	
22.	1	NHS England	Section 1	Box with managing the risks, access bullet Can we be more specific with workforce – instead of "supported by psychological wellbeing practitioners of therapists" can we replace with "supported by appropriately trained NHS Talking Therapies Clinicians, including Psychological Wellbeing Practitioners."	Thank you for your comment. The text has been amended in response to this comment.
23.	1	NHS England	Section 1	Box with managing the risks, resources bullet "This could reduce demand on some mental health services…" implies people with DETs won't be treated by the services, which isn't the intention. Could we amend to "This could free up resources that could be allocated elsewhere in the services to increase access or reduce waiting times."	Thank you for your comment. The text has been amended in response to this comment.
24.	1	NHS England	Section 1	Box with managing the risks, care pathway bullet 'This guidance focuses on using digitally enabled therapies for treating depression in adults who have been referred to NHS Talking Therapies.' Can we say 'This guidance focuses on using digitally enabled therapies for treating depression in adults accessing NHS Talking Therapies.' This then covers self-referral.	Thank you for your comment. The text has been amended in response to this comment.
25.	1	NHS England	Section 2.1	Also add overview per product or as an overview other use cases and functionalities for products not considered in this guidance.	Thank you for your comment.

					The guidance provides a brief summary of the included technologies. A full description of the technologies can be found in the scope.
26.	1	NHS England	Section 2.1	2.1 Technologies 'They are delivered with support from a trained practitioner in NHS Talking Therapies Services who facilitates the self-help intervention, encourages completion, and reviews progress and outcomes'. Can we add 'recommends complementary material' (or similar) after 'encourages completion so it reads: They are delivered with support from a trained practitioner in NHS Talking Therapies Services who facilitates the self-help intervention, encourages completion, recommends complementary material, and reviews progress and outcomes'.	Thank you for your comment. The text has been amended in response to this comment.
27.	1	NHS England	Section 3.1 and 3.2	3.1 and 3.2 Unmet need This reads as if DET is a way of reducing treatment waits and system pressures rather than a way of delivering therapy via methods that may be more suited to certain patients. I don't think this will help clinician 'buy in' to the effectiveness of DET. 3.2 also refers to those who need more 'personalised' care which suggests that application of DET isn't personalised (which shouldn't be the case). Again, I'm unsure this will enhance clinician buy in (many see DET as a bronze treatment offer). Please can we reframe to better reflect the impact on access and waits and position benefits around being a more appropriate therapy option for some people.	Thank you for your comment. The text in 3.1 has been amended to remove reference to long wait times and the text in 3.2 has removed 'personalised' from face-to-face care.
28.	1	NHS England	Section 3.11	Section 3.11: Costs and resource use Could more be said about what cost and resource implications were considered in the analysis for the digital and for the comparator treatments? For example license costs and therapist time. Aware this is detailed further in the evidence reports but this	Thank you for your comment. Further information has been added to section 3.12 in relation to the cost and resource use. Alongside this published guidance a resource impact tool is published to aid commissioning decisions.

				section will often be read without reference to that and costs are important considerations for commissioners.	
29.	1	NHS England	Section 4.2	Section 4.2 Is there a reason that the equivalent section in the anxiety topic is so different? Suggest making them more similar to one another with as much info to support evidence generation as possible.	Thank you for your comment. The evidence generation sections both provided the same information, but with slightly different formatting. The text and formatting has been amended for consistency.