NICE National Institute for Health and Care Excellence

HealthTech programme

HTE10055: Digital front door technologies to gather service user information for NHS Talking Therapies for anxiety and depression assessments

Draft Guidance Themed Comments

THEME: Outcomes for clinical assessment

Comment number	Name and organisation	Section number	Comment	NICE Response
1	Consultee 1 NHS England	General	The draft Guidance and Evidence Generation Plans (EGP) are disappointing as they do not assess the issues that NHS England indicated were its predominant concern. We hope the revisions will do so. If not, there will be discussion about whether the NHS will recognise the Guidance and EGP, and whether it will run webinars for NHS TT services that explain its view about how digital front doors should be used and what further evidence the NHS wishes to see collected. NHSE informed NICE and the committee that it wants digital front doors to improve the accuracy and effectiveness the initial clinical assessment in NHS TT services. Accuracy refers to whether the assessment correctly identifies the main clinical problem that requires treatment. This is important as different clinical problems require different treatments. NHS TT services use the term "problem descriptor" for the main problem that treatment will focus on. Problem descriptors are ICD-10 diagnostic codes. It is widely recognised that NHS TT services under-identify some clinical conditions (especially chronic anxiety related conditions such as OCD, panic disorder, social anxiety disorder and PTSD), often mistaking them for depression or generalised anxiety disorder. It is hoped that by collecting relevant screening information in advance of	Thank you for your comments. Section 3.10 of the guidance describes that the committee considered that digital front door technologies could enhance information gathering before assessment, helping healthcare professionals make more informed decisions during the initial clinical assessment. This could result in more accurate diagnoses and improved treatment pathway selection. Section 3.17 of the guidance states that “Also, evaluating the sensitivity and specificity of problem descriptors identified through clinical assessments would provide valuable insights into the reliability of these technologies in supporting clinical decision making.”

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			the interview, digital front doors will help NHS TT assessors to be more accurate in the problem descriptors that they identify, but there is concern that the way the information is collected and presented to assessors could have the opposite effect (i.e reduce accuracy compared to a gold standard). Sadly, the Guidance barely address this issue and the EGP doesn't even mention collecting information on problem descriptors. NHS England would expect the evidence generation plan to include information on the problem descriptors identified in clinical assessments that are, or are not, preceded by use of a digital front door, with the accuracy of the problem descriptors identified in each condition being compared to an internationally recognised gold standard assessment (the NHS E representative explained how this can be done when participating in part one of the committee meeting).	Section 3.10 of the guidance has been amended to state "The clinical experts were asked how the quality of information collected by the technologies could be estimated. They explained it could be done by comparing the problem descriptors like ICD-10 diagnostic codes identified in initial clinical assessment with those from an internationally recognised 'gold standard' assessment." The evidence generation plan has been updated to include collecting information on problem descriptors identified in clinical assessments. Please see section 2.1 and 3.4 in the evidence generation plan.
2	Consultee 1 NHS England	Draft guidance 3.10 Quality of clinical assessment for NHS Talking Therapies	The hope is that the AI-driven algorithms will present clinical assessors with information that increases the chance that the diagnoses (problem descriptors) the assessors make are correct. The fear is that the algorithms may, in certain instances, present information that makes it MORE likely that the assessor makes the wrong diagnosis. We would prefer you to spell out this POSSIBILITY, rather than just say "with unknown implications for clinical decision making".	Thank you for your comments. Section 3.10 of the guidance has been amended to "But the clinical and patient experts also raised concerns that the AI-driven algorithms in some of these technologies may selectively present information to healthcare professionals, which could, in

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				some circumstances, influence clinical decision making in ways that increase the risk of inaccurate diagnosis."
3	Consultee 1 NHS England	Draft guidance 3.10 Quality of clinical assessment for NHS Talking Therapies	It is good that the committee discussed the need to further evidence comparing clinical assessment outcomes with and without digital front door technologies, but it is unclear what that means. The absence of a requirement to collect and compare diagnoses in the Evidence Generation Plan suggests it does not include assessing the accuracy of diagnosis, a position which is unacceptable to NHS England. It is also unclear what is meant by the last sentence. Please explain/justify or delete. Is the committee thinking that if overall NHS TT outcomes improve with use of digital front doors, then diagnostic accuracy must have improved or at worst stayed the same? If so, that is an illogical and dangerous deduction. The psychotherapy research literature shows that there are numerous early interventions that can improve the average outcome of a cohort of treated patients. Enhancing patient' perception that the treatment they are about to receive is credible and likely to be effective is a well-documented example. By freeing up time in the assessment interview to talk about forthcoming interventions a digital front door might improve overall outcomes despite increasing the misdiagnosis rate of some conditions and harming their outcomes.	Thank you for your comments. Section 3.10 of the guidance has been amended to "The clinical experts were asked how the quality of information collected by the technologies could be estimated. They explained it could be done by comparing the problem descriptors like ICD-10 diagnostic codes identified in initial clinical assessment with those from an internationally recognised 'gold standard' assessment." The committee did not assume that improved average outcomes following the use of digital front doors necessarily indicate improved diagnostic accuracy of initial clinical assessment for NHS Talking Therapies. The committee acknowledged that digital front door technologies could enhance information gathering before assessment, helping healthcare professionals make more informed decisions during the

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				initial clinical assessment. Positive outcomes could result from a range of factors, including enhanced information gathering and patient engagement or expectations. There is limited evidence to suggest the potential for subgroup harms due to misdiagnosis. The committee agreed that further research in the quality of data and impact on clinical assessment by the use of digital front door technologies is needed. Please see updated section 2.1 in the evidence generation plan.
4	Consultee 1 NHS England	Draft guidance 3.17 Evidence gap review	It is not entirely clear what is meant by this statement. If it means the problem descriptors identified in clinical assessments preceded by use of a digital front door or not preceded by a digital front door will each be compared with a diagnostic gold standard, this is a very welcome/ essential statement. However, the Evidence Generation Plan does not cover this. So, a critical evidence gap has been identified but it is not being addressed in the EGP.	Thank you for your comments. Please see updated section 2.1, 3.3 and 3.4 in the evidence generation plan.
5	Consultee 2 NHS England	Draft guidance 1 What evidence generation is needed	It needs to be explicit that evidence is needed of the impact of the digital front door on the accuracy of the clinician's diagnosis/allocation of problem descriptor. The wording as it stands being 'clinical decision making' could refer to a number of clinical decisions other than that of what the person's primary problem is.	Thank you for your comments. The evidence generation plan gives detailed information on what evidence generation is needed. Please see the updates sections 2.1 and 3.3 in the evidence generation plan.

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6	Consultee 2 NHS England	Draft guidance 3.10 Quality of clinical assessment for NHS Talking Therapies	First sentence of this paragraph should specify quality and accuracy of clinical assessments for NHS Talking Therapies	Thank you for your comments. The decision was made to not use the term ‘accuracy of clinical assessments’, to avoid confusion about the purpose of digital front door technologies, which are not intended to replace clinical judgment but rather to facilitate the clinical assessments for NHS Talking Therapies. Referring more broadly to the "quality of clinical assessments" appropriately includes considerations of more accurate diagnoses and improved treatment pathway selection after the clinical assessments. Also, section 3.10 of the guidance stated that ‘digital front door technologies could enhance information gathering before assessment, helping healthcare professionals make more informed decisions during the initial clinical assessment. This could result in more accurate diagnoses and improved treatment pathway selection.’

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7	Consultee 2 NHS England	Draft guidance 3.10 Quality of clinical assessment for NHS Talking Therapies	I don't know what this means. In particular does 'quality of the data' refer to how accurate and comprehensive the information collected is, or how much it helps clinicians in their assessment? And what does 'estimated pragmatically' mean in practice?	Thank you for your comments. Please see the response to comment 1.
8	Consultee 2 NHS England	Draft guidance 3.17 Evidence gap review	should read: their potential to enhance the quality and accuracy of clinical assessments in NHS Talking Therapies.	Thank you for your comments. Please see the response to comment 6. Also, section 3.17 of the guidance states that 'Improving the quality of assessments could lead to better and more accurate treatment decisions and more effective care pathways.'

THEME: Time saved on collecting routine information

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9	Consultee 1 NHS England	General	Effectiveness includes accuracy but also covers the role of the initial assessment in effectively engaging patients in the clinical service, so they don't drop out between assessment and the start of treatment (about 10-20% of people offered treatment don't take it up) or early in treatment before they have had an adequate dose. Multiple studies in the psychotherapy literature show that patients' ratings of the credibility of treatment (Does it make sense to me? Do I think it will work?) at the start of therapy are a strong predictor of drop-out and clinical outcomes. Given this point, NHS England indicated that it did not wish	Thank you for your comments. The heading for section 3.11 of the guidance has been amended to 'time saved on collecting routine information'. Section 3.11 of the guidance now states that potential time saved on collecting routine information could allow

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			services to primarily view digital front doors as a way of reducing the time taken to do a clinical assessment. Instead, NHS England would like the advance data collection to be used to help clinicians spend time having quality conversations with patients so they can better identify problems, generate hope, and start engaging patient in treatment. Strangely, the guideline seems to have largely missed this point. It repeatedly refers to modest savings in assessment time. It suggests such savings are desirable and will allow more patients to be assessed by each clinician. The latter is a fallacious argument. Savings in the order of 12 minutes per assessment interview are cited. Services have told NHS England that they normally allocate 1.5 to 2 hours in a clinician's diary for each assessment. This covers both the direct contact with the patient and the associated within service administration (referral on, discussion with supervisor, correspondence, etc). If we take the average value (1.75 hours per assessment) a therapist would need to do at least 8 assessments (taking 14 hours excluding breaks and lunch) in a day for the digital front door to free up enough time for one more assessment that day. It goes with out saying that NHS TT clinicians do not work more than 14 hours each day.	the clinical assessor to review the distilled information when preparing for the assessment, highlight particular areas for discussion, free up appointment time for more personalised and tailored conversations, and have a more accurate and higher-quality clinical assessment. Section 3.11 of the guidance also now recognises that the information collected in advance could enable healthcare professionals to spend more time having quality conversations with people. This could mean that they would be able to better identify problems, generate hope and start engaging people in treatment. Also, time savings on collecting routine information could inform future economic modelling focused on determining the incremental cost-effectiveness of different technologies.
10	Consultee 1 NHS England	General	As I have indicated in my general comment, I do not think the recommendations are a suitable basis of guidance to the NHS. They repeatedly emphasize using digital front doors to reduce the time taken to conduct a clinical assessment whereas the NHS wants them to be used to free up time for clinicians to have broader, more incisive	Thank you for your comments. Please see the response to comment 9

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			conversations with their patients that lead to more accurate diagnosis and enhanced engagement in treatment plans. So better, rather than shorter, assessment interviews.	
11	Consultee 1 NHS England	Draft guidance 1.3 1 Recommendations	As indicated in my general comments, the NHS does not want services to see digital front doors as mainly a way to save small amounts of unrealizable assessment time. We would like to see the collection of data relevant to assessing whether digital front doors help ensure the clinical assessment interviews that they proceed are more accurate and better at engaging patients in the NHS TT service.	Thank you for your comments. Please see the response to comment 9.
12	Consultee 1 NHS England	Draft guidance 1.3 Why the committee made these recommendations	The amount of time saved is too small to allow clinicians to do another assessment in the working day (see my general comment).	Thank you for your comments. Please see the response to comment 9.
13	Consultee 1 NHS England	Draft guidance 3.11 Time savings	As pointed out in my General comments, the suggestion that modest savings in the duration of the assessment interview will allow NHS TT clinicians to do more assessments in a day is unrealistic. As the whole assessment process tends to require a 1.5 hour to 2 hour diary slot you'd need to already be doing 8 or more assessments a day to save enough time to do an extra assessment. That doesn't happen. NHS TT working days are 7.5 hours, not more than 14 hours. The last comment, about freeing up time in an assessment for more detailed discussion of people's presenting problems, is very welcome and in line with NHS England's expectation. BUT you can't have both.	Thank you for your comments. Please see the response to comment 9.
14	Consultee 2 NHS England	Draft guidance 1 What evidence generation is needed	Time saving at assessment isn't the key benefit, and time-saved here may decrease any potential benefit to accuracy of diagnosis. There could be administrative time saving, or time saved across the whole pathway (e.g. due to improved accuracy of assessment and therefore fewer changes in treatment pathway). Given “administrative burden” is	Thank you for your comments. Please see the response to comment 9.

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			already covered above, and with the addition of an explicit statement around “accuracy of assessment” as in my comment above, this line dedicated to 'time saved' is no longer be needed	
15	Consultee 2 NHS England	Draft guidance 1 Why the committee made these recommendations	I don't think we should be aiming for time-saving at assessment, and I don't think it's relevant to cost-effectiveness whether the time saving is at assessment or elsewhere in the pathway, so can we alter this to 'even if only a few minutes are saved for each referral that comes through the digital front door'	Thank you for your comments. Please see the response to comment 9.
16	Consultee 2 NHS England	Draft guidance 3.11 Time savings	This would be the case if the assessment time remained the same, but a higher proportion of the time was allocated for detailed, person-centred discussion. It can't be true that both time is saved from assessment, and that this time freed up is spent improving the quality of the assessment.	Thank you for your comments. Please see the response to comment 9.
17	Consultee 3 Limbic	Draft guidance 3.11 Time savings	Can the committee clarify whether this uncertainty extends to both products? One has provided data on time savings from peer-reviewed research, whilst the other has provided unvalidated claims on time savings. The definition of "uncertain" is not explained here and remains confusing	Thank you for your comments. Please see the response to comment 9.

THEME: Evidence on Limbic Access

Comment number	Name and organisation	Section number	Comment	NICE Response
18	Consultee 3 Limbic	Draft Guidance 1.3 What evidence generation is needed	As per initial discussions, Limbic have this data and have actively said we can provide it to the committee now as part of this evaluation if that would be helpful	Thank you for your comments. Further data suggesting potential benefits of the use of technologies would not alter the recommendations in the early

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				value assessment, which already reflect the most favourable interpretation consistent with the considered evidence. Further evidence outlined in the evidence generation plan will be considered at the end of the evidence generation period. NICE's evidence generation team will contact all manufacturers included in the final guidance following publication. There will be an opportunity to discuss further details around evidence generation then.
19	Consultee 3 Limbic	Draft guidance 1.3 Why the committee made these recommendations	There are two peer reviewed studies on Limbic Access in a combined study population of over 123,000 actual NHS Talking Therapies patients that demonstrate statistically significant benefits on: 1. Clinical assessment time savings 2. Recovery outcomes 3. Assessment accuracy and the prevention of step ups and step downs	Thank you for your comments. The EAG has considered these 2 peer reviewed studies, but recovery outcomes, assessment accuracy and prevention of step ups and step downs are outside the current NICE scope. However, the EAG included this sentence in the external assessment report: "The EAG has reported Anxiety Disorder Specific Measures (ADSM) accuracy and treatment step-ups/down data provided by Limbic for information only; the EAG considers that

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				ADSM results are outside the NICE scope." Further data suggesting potential benefits of the use of technologies would not alter the recommendations in the early value assessment, which already reflect the most favourable interpretation consistent with the considered evidence. Further evidence outlined in the evidence generation plan will be considered at the end of the evidence generation period. NICE's evidence generation team will contact all manufacturers included in the final guidance following publication. There will be an opportunity to discuss further details around evidence generation then.
20	Consultee 3 Limbic	Draft guidance 3.16 Equality considerations	Can the committee define "some evidence" in this context? There is a peer reviewed study published in Nature medicine with 129,000 NHS TTad patients that empirically shows Limbic Access improves access for underrepresented populations. What else would be required for there to be more than "some evidence" of impact? This should also state that there is clinical evidence - this isn't self-reported, this is from a bona fide clinical study	Thank you for your comments. The committee acknowledged that the study published in Nature Medicine, involving over 129,000 NHS Talking Therapies patients, represents peer-reviewed evidence supporting the impact of Limbic Access on improving

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				access for underrepresented populations. Section 3.16 of the guidance has amended 'some evidence' to 'One peer reviewed study (Habicht et al. 2024).
21	Consultee 3 Limbic	Draft guidance 3.8 Evidence	There is a third peer-reviewed study on Limbic Access relevant for this evaluation (citation at bottom of comment) that meets the objectives and outcomes noted in the scope of this evaluation, namely: - value for money - accuracy of clinical assessment Rollwage M, Habicht J, Juechems K, Carrington B, Viswanathan S, Stylianou M, Hauser TU, Harper R Using Conversational AI to Facilitate Mental Health Assessments and Improve Clinical Efficiency Within Psychotherapy Services: Real-World Observational Study JMIR AI 2023;2:e44358	Thank you for your comments. Please see the response to comment 20.
22	Consultee 3 Limbic	Draft guidance 3.8 Evidence	Why is this survey distinguished as short? Please define the cut-off in question length that distinguishes a "short online survey" from an "online survey"	Thank you for your comments. Section 3.8 of the guidance has been amended to "1 online survey of psychological wellbeing practitioners"
23	Consultee 3 Limbic	Draft guidance 3.8 Evidence	This is incorrect. The peer reviewed evidence Limbic has submitted includes results from 55 individual Talking Therapies sites and the product has been used for over 420,000 patients across England. Moreover, the ongoing Limbic observational study (referenced in a later section and evidence generation plan) further extends this investigation to multiple additional NHS Trusts and replicates the findings reported in the peer-reviewed studies.	Thank you for your comments. The EAG explained that there were 9 NHS Talking Therapies services in Rollwage 2023 and 28 NHS Talking Therapies services in Habicht 2024, of which 14 used

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			Can the committee explain why this does not meet the threshold of generalisability and indeed what this threshold is?	Limbic Access and 14 did not. It is clear from the interviews with experts that NHS Talking Therapies pre-assessment processes are heterogeneous. This means there is considerable uncertainty around the generalisability of any current digital front door technology study results.
24	Consultee 3 Limbic	Draft guidance 3.8 Evidence	Implying evidence parity between the products is dangerously misleading and misrepresents the data provided. It significantly undermines the peer-review process, which mandates the review of data by academics without any affiliation or conflicts of interest with the company. This misleading statement also does not take into account: - the publication of these peer-reviewed studies in extremely high impact journals, further validating the scientific rigor that the studies had to meet, irrespective of who ran the studies - The discrepancies in regulatory classification between the two products. Class II products require at least yearly externally auditing by a UK Approved Body. As part of these audits the clinical claims made by the company have to be substantiated. This includes the external, non-biased review of all clinical data related to claims by the UK Approved Body. Class I products do not go through this rigorous process. - One product provides no peer-reviewed or externally-reviewed data at all or any kind of powered statistical analysis for the results This misleading equivalence risks undermining patient safety and procurement integrity.	Thank you for your comments. The committee fully acknowledged that peer-reviewed studies from Limbic published in high-impact journals, such as *Nature Medicine*, represent a high standard of scientific rigor. The committee also noted the important regulatory distinctions between Class I and Class II medical devices, which was recognised in both external assessment report and the overview. However, it was noted that the overall quality of evidence assessed for both Limbic Access and Wysa DRA was considered broadly comparable. This was not a reflection of equal strength in peer-reviewed evidence, but a comment on the source of most of information available for both technologies at the time of

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				assessment. Most of the information came either directly from the companies themselves, or from published data for which most of the authors were company affiliated. This did not invalidate the findings, but it did highlight the importance of independent, externally reviewed research. But the committee acknowledged that the published data (only available for Limbic Access) was in peer-reviewed studies. Please see section 3.8 of the final guidance.
25	Consultee 3 Limbic	Draft guidance 3.10 Quality of clinical assessment for NHS Talking Therapies	Can the committee clarify whether this assessment of clinical assessment quality was made with or without the inclusion of a peer-reviewed study from 64,862 NHS TTad patients that shows statistically significant improvements in patient recovery and clinical assessment accuracy when patients refer through Limbic Access vs. other routes (webform, calls etc)?	Thank you for your comments. The peer-reviewed study from 64,862 study (Rollwage, 2024) from the systematic literature review and it was justified by the EAG because these outcomes are outside the NICE scope. The EAG included this sentence in the external assessment report: "The EAG has reported ADSM accuracy and treatment step-ups/down data provided by Limbic for information only; the EAG considers that ADSM results are outside the NICE scope.

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				The evidence generation plan highlights that relevant accuracy data may exist within studies that were outside of the current scope. Please see section 3.2 and 3.3 of the evidence generation plan.
26	Consultee 3 Limbic	Draft guidance 3.14 Limitations	Can the committee explain their reasoning on this inclusion criteria? There is a peer-reviewed study that provides economic evidence on Limbic Access: Rollwage M, Habicht J, Juechems K, Carrington B, Viswanathan S, Stylianou M, Hauser TU, Harper R Using Conversational AI to Facilitate Mental Health Assessments and Improve Clinical Efficiency Within Psychotherapy Services: Real-World Observational Study JMIR AI 2023;2:e44358	Thank you for your comments. Please see the response to comment 20.
27	Consultee 3 Limbic	Draft guidance 3.17 Evidence gap review	There are three peer-reviewed clinical studies comparing Limbic Access against traditional access routes and evaluating outcomes such as: - Accessibility - Equality in access - Recovery - Assessment quality - Assessment time savings - Cost	Thank you for your comments. Please see the response to comment 20.
28	Consultee 3 Limbic	Draft guidance 3.17 Evidence gap review	Limbic have this data on >420,000 referrals and would be happy to provide it as part of this evaluation	Thank you for your comments. Please see the response to comment 19.
29	Consultee 3 Limbic	Draft guidance 3.17 Evidence gap review	Limbic would be happy to provide exact costs on training, promotion and digital safety assurance (eg. DTAC, DCB0129 and UKCA medical device certification) from our 4 year experience in the market	Thank you for your comments. Please see the response to comment 19.

THEME: Title change

Comment number	Name and organisation	Section number	Comment	NICE Response
30	Consultee 3 Limbic	General	We note with concern the change in the evaluation title from “Digital front door technologies to pre-assess people before assessment” to “Digital front door technologies to gather information for assessments.” This shift significantly alters the framing of the evaluation, from one focused on tools that play a clinically meaningful role in pre-assessment and triage, to one that implies a more passive, administrative function. The name change also substantially deviates from the scope of the assessment with respect to sections 2.2, 2.3, 6 and 7. The original title more accurately reflected the clinical intent and regulatory positioning of certain technologies within this space - particularly those designed and approved to support triage, diagnostic data collection, and treatment allocation. Reframing the evaluation as “information gathering” risks obscuring the functional and regulatory differences between technologies included in the review. It also appears to coincide with a deprioritisation of evidence related to clinical accuracy, treatment outcomes, and economic value - despite these being closely tied to the real-world function of such tools as “information gathering” still influences clinical decision making. This change may inadvertently lower the evidentiary threshold required, allowing solutions without formal regulatory approval for clinical decision support, or without peer-reviewed outcomes data, to be considered on equal footing with those that meet higher standards of validation and oversight. In addition, this creates confusion around the Evidence Generation Plan and whether the “information-gathering” label now only refers to administrative capabilities only or full clinical decision support impact (as per the original scope of the evaluation and the evidence plan that	Thank you for your comments. The title was adjusted to better reflect the NICE scope, which focuses on digital front door technologies, defined in NHS Talking Therapies for anxiety and depression manual (2024) as “Pre-assessment digital front doors, which can collect advance screening information about possible presenting problems that will help inform and facilitate the assessment.” The manual also states, “It is important that problem descriptors are not allocated until a full clinician-led assessment has taken place.” Therefore, functions of technologies which go beyond that of a digital front door, such as providing diagnosis (assigning problem descriptors), treatment and remote monitoring will not be included in this assessment. The new wording was intended to focus on functionality of data gathering for digital front door technologies.

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			requests randomised-controlled or matched-control studies of clinical decision accuracy, downstream outcomes such as step-ups/step-downs, recovery rates and cost-per-recovery, and detailed time-saving audits to prove impact on clinician workload). By simultaneously changing the headline function to “information gathering” yet retaining triage-level evidence demands, the evaluation sends confusing and mixed signals regarding the function and regulatory status required of in-scope technologies, obscures true functional distinctions, and risks inconsistent evaluation, inclusion or exclusion of potential technologies. Therefore we ask: 1. The committee provide a justification for the change in name at such a late stage in the process. 2. The committee definitively state if digital front door devices to “gather information for assessments” specifically refers to those technologies that provide triaging and clinical decision support to downstream clinical assessments, or whether this evaluation excludes triage/clinical decision support and now solely focuses on administrative information gathering at the self-referral stage only.	
31	Consultee 3 Limbic	Draft guidance 2.1 The digital front door technologies	This definition of digital front door technologies is at odds with NICE's renaming of this evaluation from 'pre-assess' to 'gather information'	Thank you for your comments. Please see the response to comment 30.

THEME: General comments and requests for clarification

Comment number	Name and organisation	Section number	Comment	NICE Response
32	Consultee 1 NHS England	Draft guidance 3.5 Unmet need	The Five Year Forward View and the NHS Long Term Plan periods have now both elapsed. NICE should discuss with NHS England the current aspirations for the NHS TT programme. The key access number is no longer the number of people who are seen for an assessment, but rather the number who are assessed and go on to have a course of treatment. Currently, about 670,000 per year (around 13% of the community prevalence of anxiety/depression) but expected to rise substantially over the next 5 years.	Thank you for your comments. Section 3.5 of the guidance has been amended to add that "The clinical experts mentioned that the key access number is no longer the number of people seen for an assessment. Rather, it is the number of people who have an assessment and then have a course of treatment. Currently, this is about 670,000 people annually (around 13% of the community prevalence of anxiety and depression). But this number is expected to rise substantially over the next five years."
33	Consultee 1 NHS England	Draft guidance 3.10 Quality of clinical assessment for NHS Talking Therapies	Please replace "…over or under-diagnosis" with "… incorrect diagnosis". Almost everyone in NHSTT services receives a problem descriptor (diagnosis) but it is not always correct.	Thank you for your comments. Section 3.10 of the guidance has been amended to "The clinical experts explained that information collection by less experienced staff in current practice is often insufficient, leading to incorrect diagnosis."
34	Consultee 2 NHS England	Draft guidance 3.3 Referral process	This paragraph appears to confuse triage/screening and assessment. The person's presenting problems won't be known until the assessment has taken place. Screening could include a check of eligibility, and potentially consideration of likely suitability for TT from other information included in the referral and/or possibly other	Thank you for your comments. Section 3.3 of the guidance has been amended to "The referral process includes checking

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			healthcare records the service to which the service has access. The assessment includes an assessment of risk, safeguarding issues, presenting problems and medical history. Most of which is unlikely to be available prior to the assessment.	whether a person is at risk from NHS Talking Therapies, or eligibility for them. It also includes potentially considering likely suitability for NHS Talking Therapies from other information included in the referral or possibly other healthcare records to which the service has access. This is also called triage or screening." Section 3.3 of the guidance has had the following text removed: "Checking for risks and safeguarding issues, including self-harm, suicide or harm to others, is always prioritised. It is based on the person's presenting problems and medical history."
35	Consultee 2 NHS England	Draft guidance 3.9 Risks	I don't recall a discussion around prioritising risk-related information - I think this sentence is intended to distinguish between collecting information to inform clinicians' decisions around exclusion, rather than excluding them before they the assessment has taken place. Consider reviewing this section.	Thank you for your comments. Section 3.9 of the guidance has been amended to "They emphasised that the technology should prioritise collecting risk-related information to inform clinical decision-making rather than being used to exclude excluding individuals before the assessments."

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36	Consultee 2 NHS England	Draft guidance 3.10 Quality of clinical assessment for NHS Talking Therapies	I don't think it's helpful to cause alarm by saying that 'current practice is often poor' - A more precise statement which indicates that some clinical conditions, particularly some anxiety disorders, are known to be under-detected in initial NHS Talking Therapies assessments, would be more appropriate.	Thank you for your comments. Section 3.10 of the guidance has been amended to “The clinical experts explained that information collection by less experienced staff in current practice is often insufficient.”
37	Consultee 2 NHS England	Draft guidance 3.13 Survey results from people using the service	symptom management support while on the waiting list isn't necessarily recommended, so can we remove this or at least remove the 'but' so that it doesn't sound like a negative observation.	Thank you for your comments. Section 3.13 has had the following text removed: “but 77% did not have any symptom management support while on the waiting list”.
38	Consultee 2 NHS England	3.16 Equality considerations	I think this is a typo and should read ‘at increasing’	Thank you for your comments. Section 3.16 of the guidance has been amended to “One peer reviewed study (Habicht et al. 2024) showed that Limbic Access is effective at increasing referrals from people typically underrepresented in mental healthcare. This included people with diverse gender identities and people from ethnic minority backgrounds.”
39	Consultee 3 Limbic	Draft guidance 1.1 1 Recommendations	Appropriate medical device approval is also required for the legal and safe use of these products on NHS patients. Specifically when it comes to clinical decision support and triaging capabilities requiring Class II+ designation.	Thank you for your comments.

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40	Consultee 3 Limbic	Draft guidance 1.3 Why the committee made these recommendations	Typo?	Thank you for your comments. The extraneous "," has been removed from Section 1.3 of the guidance.
41	Consultee 3 Limbic	Draft guidance 2.3 Wysa Digital Referral Assistant (DRA)	Class I classification is not appropriate for devices that perform e-triage and provide reports for clinical decision support as per the classification rules 10 and 12 set out in Annex IX of Directive 93/42/EEC (the regulation used to classify medical devices in the UK), and as verified by the Psyomics Field Safety notice.	Thank you for your comments. It is each company's responsibility to provide correct regulatory status to NICE for their product. It is not in NICE's remit to determine whether or not a technology's stated regulatory status is appropriate, and no field safety notice for Wysa DRA was notified to NICE. NICE raised this comment about Wysa DRA to the MHRA. The MHRA clarified that Wysa DRA is correctly classified as a class I as per UK MDR / EU MDD and as per their UKCA certificate.
42	Consultee 3 Limbic	Draft guidance 3.9 Risks	To confirm, this is exactly how Limbic Access operates	Thank you for your comments.
43	Consultee 3 Limbic	Draft guidance 3.9 Risks	And required medical device and quality management system processes	Thank you for your comments.

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44	Consultee 3 Limbic	Draft guidance 3.9 Risks	To clarify there is no triage of individuals out of the service, ie. no assessment by the Limbic Access product that acts independently to determine whether or not the patient can access talking therapy services. Individuals are only not able to continue for the given service they are trying to access if they do not meet eligibility criteria specified by the service. This is age (17/18+ depending on the service) and location of registered GP using NHS Spine (that identifies whether the patient is in the right geographic area for the specific service they are trying to access)	Thank you for your comments.
45	Consultee 3 Limbic	Draft guidance 3.13 Survey results from people using the service	Can the committee explain why access to wait-list support is included here? This is not in the scope of the products as digital front doors	Thank you for your comments. Please see response to comment 37.
46	Consultee 4	General	I wanted to point the committee to the Improving Access to Psychological Therapies Positive Practice Guide from the Foundation for People with Learning Disabilities https://www.learningdisabilities.org.uk/learning-disabilities/publications/learning-disabilities-iapt-positive-practive-guide Whilst this guide is now 10 years old it provides a good basis for demonstrating the need for reasonable adjustments in access and diagnostics for these therapies, which need to be considered in the context of the digital front door technologies. The kind of barriers people can experience to answering these kind of questions can include language barriers, processing difficulties, difficulties with numeracy and temporal concepts, meaning individuals may need significant support to engage. There are then further barriers possible in this case to learning to use a new platform or app. Whilst some may benefit from these technologies, particularly perhaps if support from a carer or supporter is available, many others may	Thank you for your comments. The committee considered a range of access issues. Section 3.16 of the guidance highlights equality considerations.

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			really struggle. Whilst we recommend people have access to a range of options to suit their needs, we feel it is vitally important the guidance sets out safeguards in the system for how to decide if someone can use the technology reliably and safely, and ensures alternatives are available if there is a risk of someone not being able to engage, or to do so accurately.	

THEME: Evidence generation plan

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47	Consultee 1 NHS England	Evidence generation plan	The current draft Evidence Generation Plan is inadequate because it falls to address an evidence gap identified in the guidance and considered by NHS England to be its highest priority. Namely, the question of whether use of digital front doors improves or worsens the identification of a patient's correct diagnosis (problem descriptor in NHS TT terminology). To redress this shortcoming, the EGP would need to require studies in which the problem descriptors identified by services after the clinical assessment are compared between assessments where the assessor does, or does not, have access to information collected by the digital front door. Accuracy of diagnosis in both instances would need to be established by comparison to a gold standard such as an internationally recognised diagnostic interview such as the MINI. The ERP does ask the companies to collect data on treatment outcomes with and without digital front doors. This is of interest, but the ERP fails to specify the correct measures of outcome. For symptoms (as opposed to disability) it only mentions the PHQ-9 and the GAD-7. However, for panic disorder, obsessive-compulsive	Thank you for your comments. The evidence generation plan has been updated to include collection of problem descriptors to assess changes in clinical outcomes). The plan now also highlights that if the additional features, such as technology-derived problem descriptors are being used by the clinical assessor (outside of original scope), the diagnostic accuracy of these should be assessed. This is reflected in the updated section 3.3 of the evidence generation plan, that highlights a diagnostic study would be needed if the technology is used

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			disorder, social anxiety disorder, PTSD, and agoraphobia the GAD-7 is not a recommended outcome measure. It should be (and usually is) replaced by the relevant anxiety disorder specific measure (ADSM). Failure to collect ADSMs will lead to incorrect outcome assessment. Currently the EGP does not specify the collection of information on problem descriptors. This is a double difficulty. First, assessment of the accuracy of diagnoses is impossible without such information. Second, it is impossible to know whether the correct ADSM has been collected without knowing the problem descriptor. Reading the EGP one wonders whether the committee was thinking that if overall NHS TT outcomes improve with use of digital front doors, then diagnostic accuracy must have improved or at worst stayed the same? If so, that is an illogical and dangerous deduction. The psychotherapy research literature shows that there are numerous early interventions that can improve the average outcome of a cohort of treated patients. Enhancing patient' perception that the treatment they are about to receive is credible and likely to be effective is a well-documented example. By freeing up time in the assessment interview to talk about forthcoming interventions a digital front door might improve overall outcomes despite increasing the misdiagnosis rate of some conditions and harming their outcomes.	in this way. Section 3.4 has also been updated to include collection of problem descriptors, ADSMs rather than GAD, and now describes collecting diagnostic accuracy. Please see section 2.1, 3.3 and 3.4 of the evidence generation plan.
48	Consultee 1 NHS England	Evidence generation plan 2.1 Quality of data and immediate impact on clinical assessment	I assume this comment is a mistake. There is no reason to suppose that the time taken to collect data is a valid index of the quality of that data.	Thank you for your comments. That sentence has been removed, and clarification about quality of the assessment has been added. Please see section 2.1 and 3.4 of the evidence generation plan.

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49	Consultee 1 NHS England	Evidence generation plan 2.1 Impact of the technologies on clinical decision making and quality of life	Do you mean steps up and down in medication? In the context of NHS TT the critical step up/down to capture would be low versus high intensity psychological therapy.	Thank you for your comments. The intensity of the therapy has been added as an outcome to be collected in sections 2.1, 3.3 and 3.4 of the evidence generation plan.
50	Consultee 1 NHS England	Evidence generation plan 2.1 Impact of the technologies on clinical decision making and quality of life	You must also specify collection of the correct ADSM. For multiple anxiety related conditions NHS TT assesses outcome using ADSMs, not the GAD-7. To know if the correct ADSM has been collected, you also need to specify the collection of problem descriptors (currently omitted) Other variables that should be included in the evidence generation plan include: the proportion of patients who are offered treatment at the end of the assessment but don't turn up to their first or subsequent treatment appointments and the proportion of patients that start treatment but drop out early. One would hope that digital front doors would allow more time in the assessment interview for conversations that the facilitate engagement with treatment.	Thank you for your comments. Please see response to comment 47. Section 3.4 of the evidence generation plan has been updated to include: "Proportion of people who are offered treatment and complete a treatment, number of further assessment appointments and attendance rates, and attendance rates for treatment appointments".
51	Consultee 1 NHS England	Evidence generation plan 2.1 Resource and service impact	As I have pointed out in my comments on the Guideline, it is highly unlikely that the modest sayings in clinician to patient direct contact time will be enough to schedule in an extra assessment in a working day.	Thank you for your comments. This outcome has been removed from the evidence generation plan. Please see section 3.4 of the evidence generation plan.
52	Consultee 1 NHS England	Evidence generation plan 3.4 Data to be collected	For data to be collected you must also specify collection of the correct ADSM. For multiple anxiety related conditions NHS TT assesses outcome using ADSMs, not the GAD-7. To know if the correct ADSM has been collected, you also need to specify the collection of problem descriptors (currently omitted). Other variables that should be included in the evidence generation	Thank you for your comments. Please see response to comment 50.

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			plan include: the proportion of patients who are offered treatment at the end of the assessment but don't turn up to their first or subsequent treatment appointments and the proportion of patients that start treatment but drop out early. One would hope that digital front doors would allow more time in the assessment interview for conversations that the facilitate engagement with treatment.	
53	Consultee 2 NHS England	Evidence generation plan 2.1 Quality of data and immediate impact on clinical assessment	It needs to be more explicit that evidence on the digital front door's impact on the accuracy of the problem descriptor assigned at assessment is needed.	Thank you for your comments. Please see response to comment 47.
54	Consultee 2 NHS England	Evidence generation plan 2.1 Quality of data and immediate impact on clinical assessment	I don't think that that time-savings will help evaluate 'quality of data' - assessments could take the same amount of time but be better quality. Equally, time could be saved but if quality/accuracy decreases this is not desirable.	Thank you for your comments. Please see response to comment 48.
55	Consultee 2 NHS England	Evidence generation plan 2.1 Resource and service impact	I don't think it's relevant to look at time saving at the initial assessment on its own. The quality of the initial assessment will effect the likelihood that further assessment is needed further down the treatment pathway, and the efficiency of the overall treatment. Further assessment: it is not uncommon for an assessment for someone to receive more than one assessment appointment during their Talking Therapies pathway. This could be because further assessment is needed immediately after the initial assessment appointment, or because a second assessment is needed if the initial treatment is unsuccessful. It is not therefore relevant to look only at the potential time-saving of the initial assessment, if time saved here at initial assessment is due to further time is spent on further assessment further down the pathway. It is worth noting that in some services a second assessment may be more likely to be conducted by a high intensity therapist and therefore be more expensive. Efficiency of the pathway: If the digital front door improves the quality	Thank you for your comments. Section 3.4 highlights that data on changes in treatment and service use should be measured, in addition to time taken for the clinical assessment. Section 3.4 has been updated to include "Number of further assessment appointments and attendance rates" under data to be collected. Please also see response to comment 50.

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			and/or accuracy of the assessment, people may be more likely to get the right treatment first time, be well informed of what to expect from treatment, and be motivated to engage fully. This could be reflected in the clinical time spent across the whole pathway. Conversely, a negative effect of the digital front door could lead to a less efficient use of time. I therefore think it's more relevant to look at potential clinical time savings across the whole pathway from referral to discharge (including both assessment and treatment), to see whether referrals that came through the digital front door were more likely to require less clinical time overall than equivalent referrals that came via other means (obviously this would need to be carefully controlled).	
56	Consultee 2 NHS England	Evidence generation plan 2.1 Resource and service impact	I think the key thing is here the proportion of referrals that are appropriate, rather than the raw number. An increase in appropriate referrals who go on to complete a successful course of treatment would be positive, but an increase in referrals that were deemed inappropriate for treatment at assessment would be a more significant burden to services.	Thank you for your comments. The number of referrals will be required for future economic modelling to estimate potential impact of the technology. Section 2.1 and 3.4 has been updated and section 3.4 now includes “Proportion of referrals that complete a successful course of treatment”.
57	Consultee 2 NHS England	Evidence generation plan 3.2 Data sources	I would suggest altering from 'time taken for clinical assessments' to 'overall clinical time required per successful course of treatment (including assessment and treatment time)' and from 'impact on clinical assessments' to 'impact on accuracy of the problem descriptor allocated at clinical assessment (diagnosis)'	Thank you for your comments. The committee discussed that time-savings could result in system efficiencies, as well as potential improvements in patient outcomes. Additional detail has been added to section 3.4 of the

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				evidence generation plan regarding diagnostic accuracy.
58	Consultee 3 Limbic	Evidence generation plan 1 1 Purpose of this document	To note, randomised controlled trials are rarely feasible for service-level digital triage tools because clinical teams cannot be blinded when comparing digital triage tools to other referral methods. Alternatives, such as large matched-control real-world studies are the pragmatic gold standard and should be accepted for consideration	Thank you for your comments. The evidence generation plan proposes a longitudinal parallel cohort study, not a blinded randomised control trial. The plan is not intended to be a protocol and only suggests an appropriate study design. Pragmatic approaches are recognised within the constraints of the short evidence generation period.
59	Consultee 3 Limbic	Evidence generation plan 2.1 Quality of data and immediate impact on clinical assessment	Limbic has provided extensive peer-reviewed data showing a statistically significant impact on time savings at clinical assessment. Can the committee explain why this is not being included here? Additionally, beyond time-savings a proxy, Limbic has already published and provided direct accuracy metrics (93% diagnostic-match) and peer-reviewed reductions in treatment changes and drop-outs, which additionally valid measures of data quality and immediate impact on clinical assessments	Thank you for your comments. The evidence generation plan has been updated to acknowledge that data may already exist where outcomes are outside of the current scope, but where they may be useful for future assessments (section 3.3 of the evidence generation plan). A future assessment would re-scope the topic and so these data may be relevant then. Please also see response to comment 25.

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60	Consultee 3 Limbic	Evidence generation plan 2.1 Quality of data and immediate impact on clinical assessment	Two peer-reviewed studies (JMIR AI 2023 & BMJ 2024) already show statistically significant improvements in recovery rates and 45 % fewer step-ups/step-downs after assessments that used Limbic data; labelling this evidence as “limited” is factually incorrect.	Thank you for your comments. The "limited” rating reflects that whilst some evidence is available, the committee concluded that further evidence is needed to address the evidence gap. It does not necessarily indicate equivalence of quality nor quantity, where two manufacturers have the same rating. Please also see response to comments 20 and 24.
61	Consultee 3 Limbic	Evidence generation plan 2.1 Impact of the technologies on clinical decision making and quality of life	Both of these outcomes have been evaluated at scale (N = 64,862) in a peer-reviewed study of Limbic Access vs. alternative methods of referral. Would they meet the threshold of more evidence in this context?	Thank you for your comments. Please see response to comment 59.
62	Consultee 3 Limbic	Evidence generation plan 2.1 Resource and service impact	Limbic has published a matched-control study of 64,862 referrals demonstrating a mean 12.7-minute reduction in assessment duration and seven-day reduction in total wait-to-treatment; this gap has therefore been addressed. Would this meet the threshold of more evidence?	Thank you for your comments. Please see response to comment 59.
63	Consultee 3 Limbic	Evidence generation plan 2.1 Resource and service impact	What is the specific requirement here? Manufacturers can already provide data on the number of processed referrals that can be compared against the published numbers by NHS TTad.	Thank you for your comments. NICE’s evidence generation team will contact all manufacturers included in the final guidance following publication. There will be an opportunity to discuss

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				further details around evidence generation then.
64	Consultee 3 Limbic	Evidence generation plan 3.1 Evaluate treatment outcomes for AI-enabled information collection tool for clinical assessments in mental healthcare (NCT05495126)	This is a trial. If the language used for "The benefits of using digital technology ...." is trial, then the same should apply here	Thank you for your comments. Section 3.1 of the evidence generation plan has been updated accordingly
65	Consultee 3 Limbic	Evidence generation plan 3.1 Evaluation of a conversational information collection tool to access Talk Therapy (Essex study: NCT05678764)	To clarify this study is happening with multiple NHS Talking Therapy sites, not just Essex	Thank you for your comments. Section 3.1 of the evidence generation plan has been updated accordingly.
66	Consultee 3 Limbic	Evidence generation plan 3.1 The benefits of using digital technology (the Wysa app and AI chatbot) to support assessments, waits	This omits a peer-reviewed paper quantifiably demonstrating impact on clinical assessment; describing the evidence as “limited” misrepresents the published record. Can the committee provide reasoning as to why both products receive the "limited" designation when there is a difference in type, amount and quality of data that has been submitted?	Thank you for your comments.

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		for therapy and treatment within NHS Talking Therapies services for patients, clinicians, services and the wider healthcare system (ISCRTN10327977)		Please also see response to comments 20, 24 and 60.
67	Consultee 3 Limbic	Evidence generation plan 3.1 The benefits of using digital technology (the Wysa app and AI chatbot) to support assessments, waits for therapy and treatment within NHS Talking Therapies services for patients, clinicians, services and the wider healthcare system (ISCRTN10327977)	This omits a peer-reviewed paper quantifiably demonstrating impact on accuracy of service pathway allocation; describing the evidence as “limited” misrepresents the published record. Can the committee provide reasoning as to why both products receive the "limited" designation when there is a difference in type, amount and quality of data that has been submitted?	Thank you for your comments. Please see response to comment 66.
68	Consultee 3 Limbic	Evidence generation plan 3.3 3.3 Evidence collection plan	Can the committee confirm, with reasoning, if the published paper "Rollwage M, Habicht J, Juechems K, Carrington B, Viswanathan S, Stylianou M, Hauser TU, Harper R Using Conversational AI to Facilitate Mental Health Assessments and Improve Clinical Efficiency Within Psychotherapy Services: Real-World Observational Study JMIR AI 2023;2:e44358" meets the criteria for these characteristics, given it is being omitted from the current evaluation	Thank you for your comments. Please see response to comment 59

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69	Consultee 3 Limbic	Evidence generation plan 3.4 3.4 Data to be collected	Can the committee confirm, with reasoning, if the published paper "Rollwage M, Habicht J, Juechems K, Carrington B, Viswanathan S, Stylianou M, Hauser TU, Harper R Using Conversational AI to Facilitate Mental Health Assessments and Improve Clinical Efficiency Within Psychotherapy Services: Real-World Observational Study JMIR AI 2023;2:e44358" meets the criteria for measuring some of these outcomes (such as time taken for clinical assessment, time to treatment, changes in treatment), given it is being omitted from the current evaluation	Thank you for your comments. Please see response to comment 59
70	Consultee 3 Limbic	Evidence generation plan 3.4 Resource and system use	Administrative time is highly service-specific and difficult to capture prospectively; prior studies have used staff-rostering data and referral–assessment throughput as more reliable proxies.	Thank you for your comments. The plan is not intended to be a protocol and only suggests outcomes of interest. Similar outcomes of interest will be considered if future assessments.