NICE National Institute for Health and Care Excellence

HealthTech Programme
Diagnostics Advisory Committee (DAC)

Supporting documents for consultation

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1. **Scope**
2. **Overview**
3. **External Assessment Report (EAR)**
4. **External Assessment Report (EAR) economic analysis**
5. **External Assessment Report (EAR) Comments with responses from External Assessment Group (EAG)**
6. **Evidence Generation feasibility report**
7. **Registers of interest**

NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies

Final scope

December 2024

1 Introduction

The topic has been identified by NICE for consideration for early value assessment (EVA). The objective of EVA for medical technologies is to identify the most promising technologies in health and social care where there is greatest need and where the evidence base is still emerging. It will provide an early indication to the system that they could be used while evidence is generated. The process will enable the technologies to be recommended for use only if further data is collected before NICE makes a final evaluation at a later date. NICE's topic selection oversight panel ratified digital front door technologies to pre-assess people before assessment for NHS Talking Therapies for anxiety and depression services (shortened to 'NHS Talking Therapies' in this document) as potentially suitable for an EVA by the HealthTech programme.

The technologies identified for this EVA are those used to digitally onboard people who need to be pre-assessed for NHS Talking Therapies. Technologies that make diagnoses or deliver talking therapies are not included in this assessment.

The purpose of this EVA is to map the evidence that is available on the technologies, assess their potential effectiveness, and identify evidence gaps to help direct data collection and further research. This EVA will inform Committee recommendations on the possible conditional use of these technologies in the NHS while further evidence is generated.

The final scope was informed by discussion at the scoping workshop on 11th November 2024. A glossary of terms and a list of abbreviations are provided in appendix A and B.

2 Description of the technologies

This section describes the properties of digital front door technologies to pre-assess people before assessment for NHS Talking Therapies. It is based on information provided to NICE from the manufacturers and information available in the public domain. NICE has not carried out an independent evaluation of this description.

2.1 Background to talking therapies services

In England, 1 in 6 people will experience a common mental health condition (like anxiety and depression) in any given week (McManus et al. 2016). NHS Talking Therapies for anxiety and depression (previously known as IAPT, Improving Access to Psychological Therapies) is a service in the UK that offers mental health support for mental health conditions specified in the NHS Talking Therapies for anxiety and depression manual (2024). In the 2022-2023 period, over 1.76 million people were referred to NHS Talking Therapies in England. The Five Year Forward View for Mental Health from 2016 set out that NHS England should increase access to evidence-based psychological therapies to reach 25% of need so that at least 600,000 more adults with common mental health conditions can access NHS Talking Therapies services each year by 2020/21 (1.5 million in total). The NHS Long Term Plan then increased this target to an additional 380,000 adults accessing NHS Talking Therapies services by 2023/24 (1.9 million in total).

2.2 Purpose of technologies

Once referred to NHS Talking Therapies, people will have a pre-assessment and then a clinical assessment to determine the most appropriate treatment. Digital front door technologies for NHS Talking Therapies are used at the pre-assessment stage. They collect information from the person referred about possible presenting concerns that will help inform and facilitate the assessment. It does not replace the assessment with a clinician but is intended to improve its efficiency and accuracy. Appointments for NHS Talking Therapies assessments are typically 30 to 45 minutes long. With manual onboarding processes, there is an administrative burden on the assessors having to manually copy and paste information either prior to, or during the assessment. The data collected during a manual pre-assessment can be of poor quality and inaccurate, leading to additional time being spent by NHS Talking Therapies clinical assessors having to recollect information during the assessment timeslot.

The potential benefit of a digital front door is improving the accuracy and quality of the data provided to the clinical assessor to reduce the administrative burden, and decrease the need to recollect data. The clinical

assessor can review the distilled information in preparation, highlighting particular areas for further discussions and freeing up appointment time for more personalised and tailored conversations.

In addition, digital front doors can potentially promote access to the service by enabling people to refer themselves for assessment at any time and capturing information at the point at which the person is seeking help. Removing the need for face-to-face interacting may promote access to those who find this a barrier (Habicht et al. 2024).

2.3 Product properties

This scope 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." Digital front door technologies can range from online referral forms, to artificial intelligence (AI) informed chatbots collecting personal details, contact information, outcome measures and information about the person's presenting difficulties, to inform and facilitate assessment.

For this EVA, NICE will consider digital front door technologies that:

- are intended for use by people over the age of 16
- collect basic information and demographics through digital tools
- further collect data by actively analysing the initial information to ask additional questions, which can facilitate the clinician's decision-making for the initial Talking Therapies assessment appointment by presenting the collected data in an efficient way
- provide relevant information (such as what NHS Talking Therapies is and involves) to the service user to prepare them for the assessment
- do not make treatment decisions or assign problem descriptors – or these functions can be decoupled from the other functions a technology can provide – this will be carried out by the clinician in the Talking Therapies assessment
- meet the standards within the digital technology assessment criteria (DTAC), including the criteria to have a CE or UKCA mark where required. Products may also be considered if they are actively working towards a required CE or UKCA mark and meet all other standards within the DTAC.

- are available for use in the NHS

Functions of technologies which go beyond that of a digital front door, such as providing diagnosis, treatment and remote monitoring will not be included in this EVA.

In total, 4 digital front door technologies for people being pre-assessed for NHS Talking Therapies are included in the final scope. The final list of included technologies may be subject to change.

AskFirst (Sensely)

AskFirst (Sensely) is an online consultation platform developed in partnership with the NHS. AskFirst is available to access at all times via an app on a smartphone or tablet, or a web version on a desktop computer or laptop. It provides a triage function with symptom checking and routing to pathways like Talking Therapies. Digital mental health assessments include Patient health questionnaire 9 item scale (PHQ-9) and Generalised anxiety disorder 7 item scale (GAD-7) questionnaires. AskFirst integrates with a number of GP IT systems, such as Egton Medical Information Systems, and 111 service providers across the country. It is free for people to use the service.

Censeo (Psyomics)

Censeo (Psyomics) is suitable for people aged 18 to 65 who are not in crisis. It is a UKCA class I web-based non-diagnostic mental health platform that supports clinician assessment. Censeo gathers pre-appointment information. Censeo guides users through a structured assessment process through an adaptive questionnaire. The gathered information helps identify potential underlying mental health concerns, such as depression and anxiety. The questions are based on:

- International Classification of Diseases 11th Revision (ICD-11) and Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) diagnostic criteria
- National Institute for Clinical Excellence guidance
- The UK Mental Health Triage Scale
- Psychological and social factors which impact on mental health
- Continuous feedback from users and clinicians

People are sent a link by their health care professional and can complete the questionnaire in their own time. The adaptive questionnaire creates a personalised question pathway. There are over 500,000 pathways with a bank

of more than 1200 questions. Censeo assembles the information into a single report. The clinical report is generated on the completion of the questionnaire.

Limbic Access (Limbic)

Limbic Access is a UKCA class IIa medical device. It is an AI chatbot for conversational referral and clinical decision support in behavioural health services by streamlining the referral and triage process. Limbic Access can be embedded on a website as an always-on referral channel for new people. People begin the referral and assessment process through a personalised and interactive conversation with the Limbic Access chatbot. Limbic Access generates a clinical report, with disorder-specific measures to aid clinician's assessment. Limbic Access also captures all activity in a dashboard with visibility into engagement, demographics, referrals, conversion rates, and staff hours saved.

WYSA

WYSA is a UKCA class I web-based AI-supported e-triage tool that collects data based on questions from the referral form for NHS Talking Therapies services. People can access the chatbot on the WYSA website. People initially submit brief demographic details because WYSA includes a built-in address and GP finder, and signposting for ineligible referrals. Demographic data will be securely transferred into electronic health records (EHR). The local NHS Talking Therapies service then reviews self-referral details and either accepts or rejects the referral. The person then completes the pre-assessment, progressing at their own pace, engaging with self-care exercises along the way supported by WYSA's chatbot. Clinical contact is created directly within the EHR, where data fields exist. This includes risk flagging and a clinical summary. A summary is provided to the clinician for their review prior to appointment.

3 Target conditions

NHS Talking Therapies primarily focuses on treating mental health conditions specified in the NHS Talking Therapies for anxiety and depression manual (2024), with a major emphasis on depression and anxiety disorders. It is recognised that many people experience more than one of these conditions. Mental health conditions treated by NHS Talking Therapies services include but are not limited to:

- Agoraphobia
- Body dysmorphic disorder
- Chronic fatigue syndrome
- Chronic pain

- Depression
- Chronic Depression
- Generalised anxiety disorder
- Health anxiety (hypochondriasis)
- Irritable bowel syndrome
- Mixed depression and anxiety
- Obsessive-compulsive disorder
- Panic disorder
- Post-traumatic stress disorder
- Social anxiety disorder
- Specific phobias

4 Care pathway

There are a range of access routes available into NHS Talking Therapies services including via community care, voluntary care, primary care, secondary care and self-referral. Once the referral is received, the person will undergo a pre-assessment and then a person-centred clinical assessment. A person-centred assessment completed by a trained clinician is a significant part of the NHS Talking Therapies pathway. It should be as efficient as possible for clinicians and as accurate as possible for people who are referred to the service to identify the primary presenting problem and appropriate treatment options. (NHS Talking Therapies for anxiety and depression manual 2024). The appropriate treatment options should be discussed after the clinical assessment appointment has taken place. Therefore, it is important to collect the right information at the pre-assessment stage to inform and facilitate the following clinical assessment.

The pre-assessment process can be divided into two stages. Stage 1 is passive data collection, where basic information and demographics are gathered through triage tools and questionnaires with the data automatically integrated into the EHR. Stage 2 is active analysis and guidance. Using the data collected in Stage 1, further questions are posed for active analysis, supporting the next steps by signposting referred people to the appropriate care path. Demographic information collected in Stage 1 does not need to be repeated.

Potential place of digital front door technologies in the care pathway

Digital front door technologies for NHS Talking Therapies are only used during the pre-assessment stage. Digital front door technologies collect advance screening information about possible presenting concerns that will help inform and facilitate the assessment. This could include:

- routine outcome measures that are part of the NHS Talking Therapies minimum dataset
- screening questions that the NHS Talking Therapies for anxiety and depression manual recommends for signalling the possible presence of different clinical conditions
- administration of the relevant NHS Talking Therapies outcome measures collection in the light of the screening questions
- broader information about the person's presenting difficulties and circumstances that may be important for getting people to the right treatment first time.

This information is collected to facilitate people's subsequent one-to-one clinical assessment with an NHS Talking Therapies clinician to identify the primary presenting problem and appropriate treatment options. It is important that problem descriptors are not allocated until the assessment has taken place. It is therefore inappropriate to offer treatment based on information collected by digital front door technologies alone.

Digital front door technologies can also provide information about NHS Talking Therapies that people may not have received pre-assessment. While waiting for an assessment, some information can be provided to inform people of what to expect from the service and help prepare for their clinical assessment. It could be appropriate to signpost to local or national digital or non-digital resources for people to access, such as free debt counselling services or NHS advice webpages.

5 Considerations and preferences of people using NHS Talking Therapies services

Digital front door technologies could be offered as an option. Alternative pre-assessment options should always be available for those who would rather use them. It should be clear to people that the information gathered is used to help them and their clinicians prepare for the clinical assessment, and that no treatment decisions are made based on the information gathered alone. They should be able to choose to provide detailed information about their problems through the digital front door or, if they prefer, to wait until their clinical assessment with a clinician. Additionally, the use of AI should be transparent to the service user.

The use of digital front door technologies could enhance people's engagement. People would be able to share information at a time that is

convenient for them, and it may help to engage them at the moment when they are seeking help.

Collecting information through a digital front door may allow some people who are not eligible for NHS Talking Therapies to be identified and signposted to other more appropriate services before having the assessment.

User-friendly interfaces and clear guidance on how to use the technology could reduce service user frustration or anxiety, ensuring a positive experience. Additionally, a system for monitoring service user feedback is desirable, allowing for adjustments based on experiences and ensuring the technology continues to meet service users' needs effectively.

6 Comparator

The comparator for this EVA is pre-assessment for NHS Talking Therapies without a digital front door technology.

7 Scope of the assessment

Table 1 Scope of the assessment

Decision question	Does the use of digital front door technologies to pre-assess people before assessment for NHS Talking Therapies have the potential to be effective and value for money for the NHS?
Population	People over the age of 16 with suspected common mental health conditions specified in NHS Talking Therapies for anxiety and depression manual (2024)
Proposed technologies	Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies, which may include: • AskFirst • Censeo • Limbic Access • WYSA
Comparator	Pre-assessment for NHS Talking Therapies without using a digital front door technology
Healthcare setting	Talking Therapies services, delivered in community care, home-based care, primary care or secondary care and virtual/remote
Outcomes	The outcome measures for consideration may include: **Accuracy and acceptability** • Quality and accuracy of the data collected by digital front door technologies • Accuracy of clinical assessment for NHS Talking Therapies

	• Completion rate of pre-assessment when using digital front door technologies • Inaccessibility to digital front door technology • Healthcare professional user acceptability of digital front door technologies **Resource and system impact** • Administrative resource impact • Time taken to review data collected by digital front door technologies • Time taken to complete clinical assessment • Time saved for the clinician during clinical assessment
	Service user reported outcomes for consideration may include: • Ease of access and usability • Information clarity and relevance • Comfort and privacy • Overall satisfaction with pre-assessment process
	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration should include: • Costs of the technologies • Initial setup and integration costs • Operational costs (if falling on the NHS rather than the technology provider) such as IT support for healthcare professionals and service users and cybersecurity • Training costs • Cost of promotion • Costs of applying digital clinical safety assurance DCB0129 – Clinical Risk Management: its Application in the Manufacture of Health IT Systems
Time horizon	The time horizon for estimating the efficacy and value for money should be until the end of the NHS Talking Therapies assessment only.

8 Other issues for consideration

Characteristics of digital technologies

- The digital technologies included in the scope may differ in terms of mode of delivery and access (mobile applications, computer, website), type of information gathering (online forms or AI chatbots), and the integration of information produced into existing NHS systems.

Need for trained clinicians for assessment

- Appropriate treatment options should be discussed after the assessment appointment has taken place. It is understood that in some areas, digital tools are being used to circumnavigate assessment, enabling people to access digitally enabled therapy treatment directly before their assessment with an NHS Talking Therapies clinician has taken place. This is not compliant with the NHS Talking Therapies manual. Everyone requires an assessment with an appropriately trained clinician to identify appropriate treatment options.

Potentially offered to people aged 16 or 17

- Some NHS Talking Therapies services provide treatment for young people aged 16 or 17. Anyone working with a child or young person should:
    - Be trained to work with under 18s
    - Understand their developmental needs and the differences in presentation between children, young people and adults
    - Be aware of relevant legislation and safeguarding
    - Use outcome measures validated for this age group
- While local practice may vary, this EVA will only look at digital front door technologies in people aged 16 and over who are being pre-assessed for NHS Talking Therapies services. Any recommendations made will be in line with individual technologies' approved age ranges.

Risk management

- When implementing digital front door technologies, it is essential to manage potential unintended consequences and risks carefully. The technologies should ensure data privacy and security, and sensitive personal information must be protected with robust protocols and regular security audits. Mental health services handle highly confidential data, and any breach could harm people's trust and compliance. There may be concerns regarding how people's data is stored, accessed, and protected, especially with third-party digital services. Digital front doors' adherence to GDPR and NHS digital security standards will be crucial. Improper handling of personal information could expose the system to legal risks. The technologies should ensure data privacy and security, and sensitive personal

information must be protected with robust protocols and regular security audits.

- To maintain the accuracy of collected information, assessment tools in the technologies should be validated and updated when required, reducing the risk of misinterpretation that could lead to inappropriate referrals.

Ongoing studies

Limbic Access

Evaluate Treatment Outcomes For AI-Enabled Information Collection Tool For Clinical Assessments In Mental Healthcare (NCT05495126)

The proposed study aims to test an AI-prototype which adaptively collects information about a person's mental health symptoms at the time of referral in order to support and facilitate the clinical assessment. The AI-system consists of a machine learning model which produces a probabilistic prediction about a person's most likely presenting problems based on standard referral information collected through Limbic Access. For this trial, the AI-model will only function as a support tool for the clinical assessment by collecting additional data ahead of time. The investigators are evaluating if the AI supported information collection improves treatment outcomes, reliability of clinical assessment, reduces waiting and assessment times as well as reduces treatment dropout rates. The location of this study is in Gosforth, UK. The estimated study completion date is 10th December 2024.

9 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Age, sex, disability, race, and religion or belief are protected characteristics under the Equality Act 2010.

National data (NHS Talking Therapies for anxiety and depression manual) indicates that the following groups tend to be under-represented in NHS Talking Therapies for anxiety and depression services:

- People who have disabilities, including people with autism and people with hearing impairments
- Lesbian, gay, and bisexual people
- Transgender people

- Men
- Older people
- People from ethnically and culturally diverse communities
- People for whom English is not their first language
- People with caring commitments
- People from deprived communities, including those who are on low incomes, unemployed or homeless
- People with learning disabilities
- People in prison or in contact with the criminal justice system
- Refugees and asylum seekers
- Serving and ex-serving armed forces personnel
- People with specific anxiety disorders such as social anxiety, specific phobias, obsessive-compulsive disorder, and PTSD
- People with long-term physical health conditions
- People with addictions, including gambling and substance misuse.

The NHS Talking Therapies Review (2023) identifies barriers in access to care, particularly for people from Black and other minority ethnic backgrounds. Compared to people from White British backgrounds, they are less likely to access services, and experience longer waits. The data also showed that poorer outcomes were experienced by people from South Asian communities, in particular from Bangladeshi backgrounds. People of mixed ethnicity, mostly White and Black Caribbean, are the least likely to access these services. The comprehensive assessment review – 'Ethnic Inequalities in Improving Access to Psychological Therapies (IAPT)' noted poor outcomes can be tackled and even disappear when access is improved, and culturally sensitive therapy is provided. People from Black African backgrounds using NHS Talking Therapies services were sometimes more likely to improve and recover in comparison with people from White British backgrounds.

Services using a digital solution had a higher referral rate, particularly among gender and minority ethnic backgrounds (Habicht et al. 2024). Personalised AI-enabled chatbots could increase self-referrals to mental health services without negatively impacting wait times or clinical assessments. -
A 39% increase was observed for Asian and Asian British individuals,

alongside a 40% increase for Black and Black British individuals in services using the chatbot. Digital front door technologies may help close the accessibility gap to mental health treatment (Meadows, 2024).

NHS Talking Therapies Positive Practice Guide: Older People (2024) stated that mental health conditions such as anxiety disorders and depression significantly impact older people's quality of life, increase healthcare costs, and strain NHS services (Frost et al. 2019). Despite making up 20% of the population, older people accounted only for 5.6% of all referrals to NHS Talking Therapies in 2021/22, although this varies across the country (NHS Digital, 2022), far below the expected 12%. Barriers include limited access to age-friendly self-referral routes and potential exclusion due to technology. Technology can be a barrier and result in exclusion; however, assuming lack of IT skills or potential in older people can also be discriminatory (Health Education England, 2020). Services should better meet the needs of older people by recognising and challenging negative attitudes and stereotypes of ageing.

Digital front door technologies are used through a mobile phone, tablet, or computer. People will need access to a device with internet access to use the technologies. Additional support and resources may therefore be needed for people who are less comfortable or skilled at using digital technologies or may not have access to appropriate equipment or internet and may prefer another treatment option.

People's ethnic, religious, and cultural background may affect their views of mental health conditions and interventions. People from disadvantaged socio-economic backgrounds may be excluded from digital services. Some people may prefer to use digital technologies due to difficulties getting to in-person appointments, for example if they do not have access to a car and have poor public transport.

People with visual, hearing, or cognitive impairment; problems with manual dexterity, a learning disability, or who are unable to read or understand health-related information (including people who cannot read English) may need additional support to use digital technologies. Some people would benefit from digital front door technologies in languages other than English. The use of language in digital front door technologies should be considered. It is essential to use words that are inclusive, respectful, and free from bias. Avoiding jargon and complex language ensures that information is accessible to people with varying literacy levels. Additionally, being mindful of cultural sensitivities and using respectful, empathetic wording fosters inclusivity, especially when discussing sensitive topics like gender, mental health or socioeconomic status.

10 Potential implementation issues

Integration with existing systems

Integrating digital front door technologies with existing EHR systems or other clinical management systems can be complex and costly. Misalignments could lead to delays in service delivery or communication errors. Some systems may not support newer digital technologies without significant updates or adaptations. Costs need to be considered when integrating with the existing systems. Streamlining information flow is also vital to prevent overwhelming clinicians with irrelevant data, which could otherwise increase their administrative burden.

Staff training

Staff training is required to use digital front door technologies to ensure smooth adoption and utilisation. The staff should be informed of updates about new features, changes to validated measures used, or improvements in the technology. Time needs to be allocated for the completion of training and staff users need a good understanding of the content available in each technology in order to appropriately use them. Further training could be around how to integrate pre-collected information from digital front doors into clinical assessment appointments. This could include more flexible questioning in the pre-assessment, more flexibility in the delivery method, and appropriate time to undertake the clinical assessment. It is important to consider whether provided staff training will have a sustained impact and remain effective in the long term.

11 Authors

Ziqi Zhou

Health Technology Assessment Analyst (topic lead)

Amy Crossley, Evan Campbell

Health Technology Assessment Adviser

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Appendix A Glossary of terms

Artificial intelligence

Artificial intelligence is the ability of a computer system to perform human cognitive functions. In the context of this topic, artificial intelligence is used to streamline access, engagement, and initial assessment for mental health services like NHS Talking Therapies.

Egton Medical Information Systems

Egton Medical Information Systems supplies electronic patient record systems and software used in primary care, acute care and community pharmacy in the United Kingdom.

Electronic health records

Electronic health records are the systematised collection of patient and population electronically stored health information in a digital format. These records can be shared across different health care settings.

Appendix B Abbreviations

AI	Artificial intelligence
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
DTAC	Digital technology assessment criteria
EHR	Electronic health records
EVA	Early value assessment
GAD	Generalised anxiety disorder
GAD-7	Generalised anxiety disorder 7 item scale
GDPR	General Data Protection Regulation

IAPT	Improving Access to Psychological Therapies
ICD-11	International Classification of Diseases 11th Revision (ICD-11) and Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
PHQ-9	Patient health questionnaire 9 item scale
RCT	Randomised controlled trial
UKCA	UK Conformity Assessed

Appendix C References

Frost R, Beattie A, Bhanu C, Walters K, Ben-Shlomo Y (2019) Management of depression and referral of older people to psychological therapies: a systematic review of qualitative studies. British Journal of General Practice 69 (680)

Habicht, J., Viswanathan, S., Carrington, B., Hauser, T. U., Harper, R., & Rollwage, M. (2024). Closing the accessibility gap to mental health treatment with a personalised self-referral Chatbot. *Nature Medicine*, 1-8.

Early value assessment

Digital front door technologies to gather information for assessments for NHS Talking Therapies

Assessment report overview

This overview summarises key information from the assessment and sets out points for discussion in the committee meeting. It should be read together with the final scope and the external assessment report. List of abbreviations used in this overview is in appendix A.

1. The technologies

NHS Talking Therapies for anxiety and depression (shortened to 'NHS Talking Therapies' in this document) is a service in the UK that offers mental health support for mental health conditions specified in the NHS Talking Therapies for anxiety and depression manual (2024). Once referred to NHS Talking Therapies, people will have a clinical assessment to determine the most appropriate treatment. Digital front door technologies for NHS Talking Therapies are used to collect information from the person referred about possible presenting concerns that will help inform and facilitate the clinical assessment for NHS Talking Therapies.

4 digital front door technologies were included and considered in the scope and external assessment report: Limbic Access (Limbic), Wysa Digital Referral Assistant (DRA) (Wysa), Censeo Digital (Psyomics) and AskFirst (Sensely). However, the Medicines and Healthcare Products Regulatory Agency (MHRA) issued a Field Safety Notice regarding Censeo Digital (Psyomics) on 22 January 2025. It was determined that Censeo Digital was incorrectly registered as a Class I medical device. Additionally, the current Clinical Evaluation Report does not provide sufficient evidence of safety and effectiveness, as required by UK MDR 2002 (as amended). As a result, the MHRA has advised that the use of Censeo Digital should be discontinued until

it has been assessed by an Approved Body or Notified Body and determined to be compliant. In accordance with established NICE processes and methods, Censeo Digital cannot be considered in the upcoming evaluation. Therefore, only Limbic Access (Limbic), Wysa Digital Referral Assistant (DRA) (Wysa), and AskFirst (Sensely) will be included in this overview. In addition, AskFirst (Sensely) did not engage with NICE team; therefore, all the information was sourced from public resources.

Table 1 presented a summary of 3 digital front door technologies included in this assessment.

Table 1 Summary of included digital front door technologies

Feature	Limbic Access (Limbic)	Wysa DRA (Wysa)	AskFirst (Sensely)
Intended use	AI-chatbot for conversational referral and clinical decision support	AI-supported e-triage tool (chatbot)	Online consultation platform developed in partnership with the NHS
CE Mark	Class IIa	Class I	Information not found

Description	• Streamlines referral and triage process (e.g. triages mild, moderate, and severe cases of depression)
	• As a minimum, information is collected relating to:
	  ○ Eligibility criteria
	  ○ Contact details
	  ○ Demographic information
	• Additional clinical information collected includes information about people presenting symptoms (MDS), such as the PHQ-9, GAD-7, WSAS and a selection of additional screening questions
	• Generates a clinical report with presenting concerns, risk levels, clinical notes, assessment scores, disorder-specific measures and diagnoses predictors to aid clinician's assessment
		• Collects data based on questions from the referral form for NHS Talking Therapies services:
		  ○ Referral: demographic questions
		  ○ Clinical: GAD-7, PHQ-9 and WSAS as default, along with all other MDS
		The referral questions are asked initially and if referral accepted, clinical questions are asked
		• Provides immediate alternative signposting to people who are not eligible for an NHS Talking Therapies clinical assessment because they do not meet the age criteria or because their GP location is not within the services' catchment area
		• Flags cases based on criteria set by the service; each case is reviewed by a clinician
			• Triage function with symptom checking and routing to pathways like NHS Talking Therapies
			• Self-assessments including PHQ-9 and GAD-7

	Captures all activity in a dashboard with visibility into engagement, demographics, referrals, conversion rates, and staff hours saved	Provides report for clinician, with summary	
Usage within NHS	Used by around 40% of NHS Talking Therapies services	Live in several NHS Talking Therapies services including Dorset, Coventry and Warwickshire, and Lancashire and South Cumbria	Information not found
NHS integration	Interoperable with any cloud-based EHR system, meaning data can be immediately accessed from or imported into the health record system	Transfers data from the Wysa referral conversation to the NHS Talking Therapies EHR system clinical contact is created directly within the EHR, where data fields exist	

AI=Artificial Intelligence; EHR=electronic health record; GAD-7=General Anxiety Disorder-7; EAG=External Assessment Group; GP=general practitioner; MDS=minimum data set; NHS=National Health Service; NICE=National Institute for Health and Care Excellence; PHQ-9=Patient Health Questionnaire-9; WSAS=Work and Social Adjustment Scale

As a Class IIa device, Limbic Access is the only product that has been externally audited by the Medicines and Healthcare products Regulatory Agency (MHRA).

Difference between CE mark Class I and Class IIa:

- As per the EU MDD, software which is used to process patient data as an aid to diagnostic would be considered as a class I as per rule 12.
- However, if the intended purpose, claims, research data or any other information used with the device, implies that the device could also be used for ‘direct diagnosis’, or if a typical user is commonly using it in this way, this would mean that it

would likely fall as class IIa as per rule 10, third indent. As per the EU MDR, software which is used to provide information to take decisions with diagnosis or therapeutic purposes is classified as class IIa,

2. The condition

The target population for NHS Talking Therapies services is people over the age of 16 years with suspected common mental health conditions as specified in the NHS Talking Therapies for anxiety and depression manual (2024). Many people may experience more than one of these conditions. Mental health conditions treated by NHS Talking Therapies services include but are not limited to:

- Agoraphobia
- Body dysmorphic disorder
- Chronic fatigue syndrome
- Chronic pain
- Depression
- Chronic depression
- Generalised anxiety disorder
- Health anxiety (hypochondriasis)
- Irritable bowel syndrome
- Mixed depression and anxiety
- Obsessive-compulsive disorder
- Panic disorder
- Post-traumatic stress disorder
- Social anxiety disorder
- Specific phobias

3. Current practice

In the NHS Talking Therapies for anxiety and depression manual (2024), the NHS Talking Therapies services pathway is divided into the following five steps: presentation, referral, pathway starts, assessment, and next step.

The external assessment group (EAG) has assumed that the pre-assessment referral practice for NHS Talking Therapies services starts with presentation and ends with assessment. The term pre-assessment refers to determining a person's risk, eligibility and/or suitability for NHS Talking Therapies; this is also known as triage or screening. The EAG consulted 8 experts (NICE Specialist Committee Members [SCMs] and stakeholders), who suggested that pre-assessment referral practice for NHS Talking Therapies in current practice varied between NHS Talking Therapies providers; 3 examples of pre-assessment practice are described in the following bullet points:

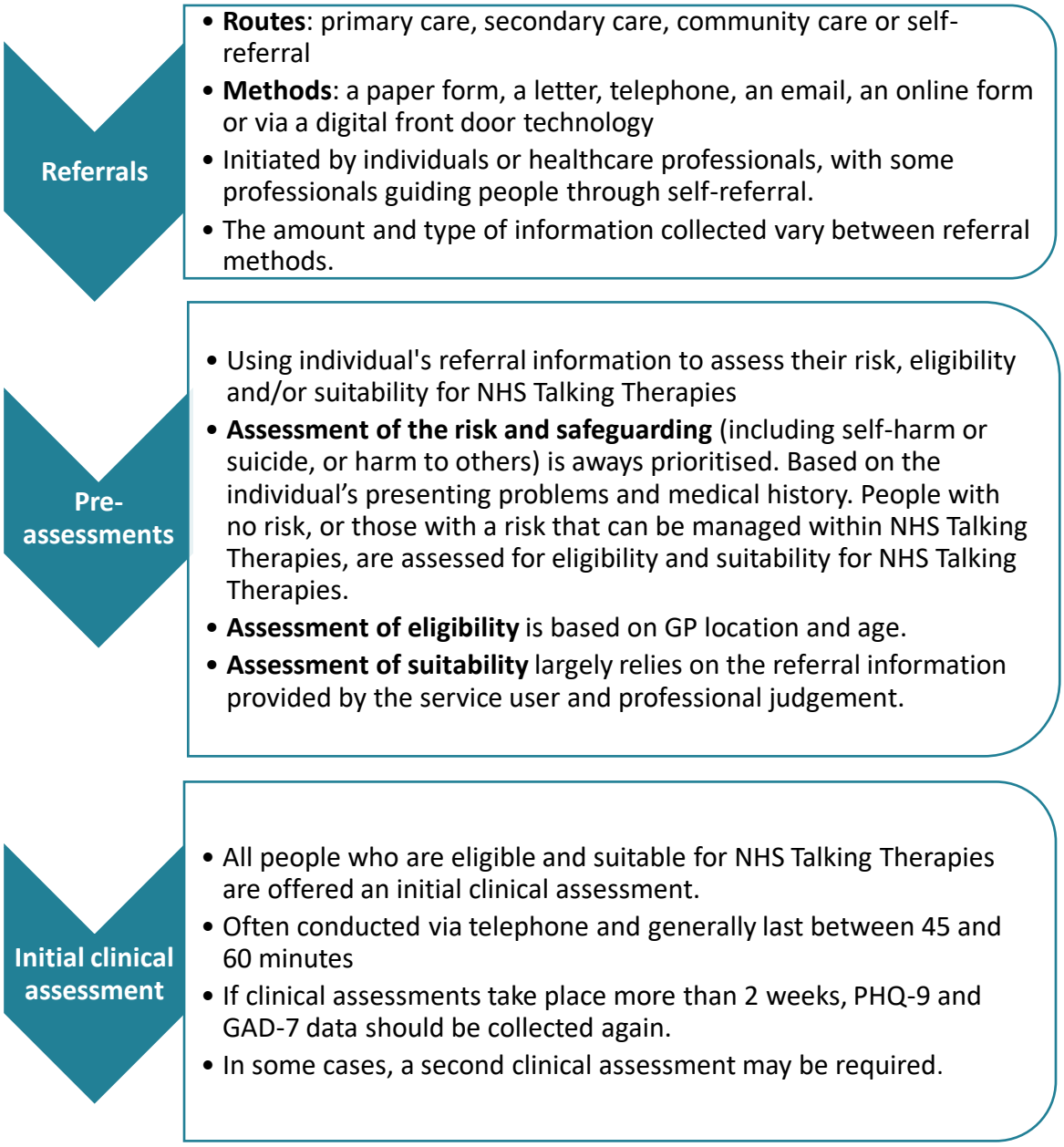
- the person is contacted and asked to book an initial clinical assessment; risk, eligibility and suitability assessments are undertaken during this initial clinical assessment

- the eligibility and suitability assessment is undertaken by an administrator who passes the referral on to a health professional if they identify any red flags (e.g. urgent care may be required), otherwise the person is contacted and asked to book an initial clinical assessment

- a health professional assesses the risk, eligibility and suitability of the person and the person is contacted to book (or not) an initial clinical assessment.

Figure 1 presented a summary of the pre-assessment referral practice for NHS Talking Therapies. Details of clinical pathway are in section 3.1 of the external assessment report (EAR).

Figure 1 - Summary of the pre-assessment referral practice for NHS Talking Therapies



4. Unmet need

In England, 1 in 6 people will experience a common mental health condition (like anxiety and depression) in any given week (McManus et al. 2016). The Five Year Forward View for Mental Health from 2016 set out that NHS England should increase access to evidence-based psychological therapies to reach 25% of need so that at least 600,000 more adults with common mental health conditions can access NHS Talking Therapies services each year by 2020/21 (1.5 million in total). The NHS Long Term Plan then increased this target to an additional 380,000 adults accessing NHS Talking Therapies services by 2023/24 (1.9 million in total).

With manual onboarding processes for NHS Talking Therapies clinical assessments, there is an administrative burden on the assessors having to manually copy and paste information prior to or during the clinical assessment. Poor-quality pre-assessment data collected before the clinical assessments often leads to additional time spent recollecting information during clinical assessments.

The potential benefit of a digital front door is improving the accuracy and quality of the data provided to the clinical assessor to reduce the administrative burden, and decrease the need to recollect data. The clinical assessors can review key information in advance, allowing more time for personalised discussions. Additionally, digital front doors may enhance accessibility by enabling self-referral at any time and reducing barriers for those who find face-to-face interactions challenging, or who have conflicting time pressures.

Further details, including descriptions of the interventions, comparator, care pathway and outcomes, are in the final scope.

5. Clinical effectiveness

The EAG did a systematic literature review with targeted literature searches including searching the electronic database, company websites and reference

lists of included studies to identify relevant published clinical evidence. In addition, Limbic and Wysa provided evidence for their respective digital front door technologies in response to NICE and EAG Requests for Information (RFIs). The company (Sensely) did not respond to NICE or EAG requests for information about AskFirst. The search and selection methods are in section 4.1.1 of the EAR.

5.1 Overview of key studies

Overall, the EAG identified 13 studies that included relevant data; 10 studies reported evidence for Limbic Access and 3 studies reported evidence for Wysa DRA. The EAG searched for information about AskFirst; no studies were identified.

Data relating to Limbic Access were available from multiple sources including two large UK-based peer-reviewed studies. However, except for some data reported in the Limbic EAG RFI response and testing data reported by Limbic Research, all data for Limbic Access relate to Class I device; Class IIa is the current version of Limbic Access used to refer people to NHS Talking Therapies services. The company reports that, in addition to the functionality of the Class I device, the more recently available Class IIa device provides artificial intelligence (AI)-driven Anxiety Disorder Specific Measure (ADSMs). Where data are available for the Class IIa device, these have been compared with Class I device data and not versus alternative methods of referral to NHS Talking Therapies. Whilst this is not a weakness of the studies, it limits the relevance of study data to this EVA.

The data provided by Wysa related to the real-world experience of Wysa DRA users; however, none of the data provided were comparative or sourced from published research studies.

Table 2 presented an overview of the study design and characteristics of the included studies. Details of the studies are in section 5.1 of the EAR. Table 3 summarises the study results. Details of the study results are in section 5.2 of the EAR.

It was not possible to synthesise the limited available clinical evidence due to heterogeneous non-comparative data.

Table 2 – Overview of the study design and characteristics of the included studies

Included studies	Study design	Intervention/ comparator	EVA outcomes addressed
Rollwage 2023	Quasi-experimental study using real-world data from patients from 9 NHS Talking Therapies services provided by Everyturn Mental Health N=64,862 Qualitative analysis with ex-patients (thematic analysis used to analyse feedback) N=32	Limbic Access (n=21,568) vs any other method of referral (n=43,294)	• RSI3: Time taken to complete clinical assessment • RSI4: Time saved for the clinician during clinical assessment • PRO1: Ease of access and usability • PRO3: Comfort and privacy
Habicht 2024	Multisite real-world retrospective observational study from 28 different NHS Talking Therapies services across England with data analysed quantitatively (referrals) and qualitatively (thematic analysis-powered natural language processing methods to analyse feedback given by patients who used Limbic Access) N=~129,400 (quantitative analysis) N= 42,332 (qualitative analysis)	Limbic Access vs other referral methods (self-referrals, GP referrals, etc) with an online webform	• AA4: Inaccessibility to digital front door technologies • PRO1: Ease of access and usability • PRO2: Information clarity and relevance • PRO3: Comfort and privacy • PRO4: Overall satisfaction with pre-assessment process
Surrey and Borders Partnership NHS Foundation Trust 2022 (Mind Matters Validation Study)	Validation study (analysis of real-world data from admin staff and PWPs working at Mind Matters and evaluation of responses from Limbic Access users, i.e. those who self-referred to NHS Talking Therapies)	Limbic Access vs benchmarked data (i.e., pre/post implementation)	• AA4: Inaccessibility to digital front door technologies • AA5: Healthcare professional acceptability of digital front door technologies • RSI1: Administrative resource impact • RSI2: Time taken to review data collected by digital front door technologies • RSI3: Time taken to complete clinical assessment

Included studies	Study design	Intervention/ comparator	EVA outcomes addressed
			• RSI4: Time saved for the clinician during clinical assessment • PRO4: Overall satisfaction with pre-assessment process
Limbic 2022 Usability Testing Formative Test Report	Formative evaluation carried out for Limbic Access (V3) to support design and development processes N=16 patients receiving therapy N=15 mental health clinicians across 10 different cities in the United Kingdom and Ireland Externally audited by the MHRA	Limbic Access (demo/ prototype)	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA4: Inaccessibility to digital front door technologies • RSI4: Time saved for the clinician during clinical assessment • PRO1: Ease of access and usability • PRO2: Information clarity and relevance • PRO3: Comfort and privacy • PRO4: Overall satisfaction with pre-assessment process
Limbic 2022 Usability Testing Summative Test Report	Summative evaluation carried out for Limbic Access (V3) to support design and development processes N=40 mental health clinicians who screen new patient referrals on a daily basis N=16 patients currently receiving therapy Externally audited by the MHRA	Limbic Access	• AA2: Accuracy of clinical assessment for NHS Talking Therapies • AA5: Healthcare professional acceptability of digital front door technologies • PRO1: Ease of access and usability • PRO2: Information clarity and relevance • PRO3: Comfort and privacy • PRO4: Overall satisfaction with pre-assessment process

Included studies	Study design	Intervention/ comparator	EVA outcomes addressed
Limbic 2024 Clinical Preparedness Study	Short online survey of PWPs from NHS services that use Limbic Access N=74	Limbic Access vs other referrals .	• AA5: Healthcare professional acceptability of digital front door technologies
Limbic 2024 Patient Feedback Report	Evaluation of feedback responses from users of Limbic Access N=17,931 Externally audited by the MHRA	Limbic Access	• PRO4: Overall satisfaction with pre-assessment process
Limbic Research 2024	Examination of the performance of Limbic Access after an algorithm that administered ADSMs had been added. Three model training studies, N=21,725: • Historical dataset, n=18,278 • Prospective dataset, n=2,557 • Live dataset, n=890 Externally audited by the MHRA	Limbic Access	• AA1: Quality and accuracy of the data collected using digital front door technologies
Limbic NICE RFI response	NICE RFI response, various sources of information including published data Not research studies	Limbic Access data compared with services not using Limbic Access	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA2: Accuracy of clinical assessment for NHS Talking Therapies • AA3: Completion rate of pre-assessment when using digital front door technologies • AA4: Inaccessibility to digital front door technologies • AA5: Healthcare professional acceptability of digital front door

Included studies	Study design	Intervention/ comparator	EVA outcomes addressed
			technologies* • RSI4: Time saved for the clinician during clinical assessment • PRO1: Ease of access and usability** • PRO4: Overall satisfaction with pre-assessment process
Limbic EAG RFI response	Additional information requested by the EAG Not research studies	Limbic Access data compared with services not using Limbic Access	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA2: Accuracy of clinical assessment for NHS Talking Therapies • AA3: Completion rate of pre-assessment when using digital front door technologies • AA5: Healthcare professional acceptability of digital front door technologies • RSI2: Time taken to review data collected by digital front door technologies • RSI3: Time taken to complete clinical assessment • RSI4: Time saved for the clinician during clinical assessment
Wysa NICE RFI response	NICE RFI response, various sources of information, none published	Wysa DRA	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA3: Completion rate of pre-

Included studies	Study design	Intervention/ comparator	EVA outcomes addressed
			assessment when using digital front door technologies • AA4: Inaccessibility to digital front door technologies • RSI4: Time saved for the clinician during clinical assessment • PRO4: Overall satisfaction with pre-assessment process
Wysa Additional Supporting Evidence	Additional information	Wysa DRA	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA3: Completion rate of pre-assessment when using digital front door technologies • AA5: Healthcare professional acceptability of digital front door technologies • RSI3: Time taken to complete clinical assessment • PRO4: Overall satisfaction with pre-assessment process
Wysa EAG RFI response	Additional information requested by the EAG	Wysa DRA	• AA1: Quality and accuracy of the data collected using digital front door technologies • RSI3: Time taken to complete clinical assessment • RSI4: Time saved for the clinician during clinical assessment • PRO4: Overall satisfaction with pre-assessment process

ADSM= Anxiety Disorder Specific Measure; DRA=Digital Referral Assistant; EAG=External Assessment Group; RFI=Request for Information; MHRA=Medicines and Healthcare products Regulatory Agency; PWP= Psychological Wellbeing Practitioners

Table 3 – Summary of the study results

Outcomes	Limbic Access	Wysa DRA (All the evidence relating to Wysa DRA was real-world data)
AA: Accuracy and acceptability		
AA1: Quality and accuracy of the data collected using digital front door technologies	• 4 studies provided information on the quality and accuracy of data collected using Limbic Access; 3 of the 4 studies highlighted the benefits to clinicians of the Anxiety Disorder Specific Measure (ADSM) information collected by Limbic Access. • Limbic data suggested that the accuracy of the Limbic Access prediction model is approximately 93% in all studies.	• The company claimed that the Wysa DRA, "…can improve the percentage of appropriate referrals." • 1 NHS Talking Services provider had used information collected by the Wysa DRA to inform the type and length of assessment appointments offered. • Results showed that 91% of initial clinical assessments for those who completed the full set of clinical questions asked by the Wysa DRA were scheduled for shorter, 30 minute appointments, instead of the service standard 60 minute appointments.
AA2: Accuracy of clinical assessment for NHS Talking Therapies	• 3 studies provided information about the accuracy of clinical assessment for NHS Talking Therapies. • The company stated that Limbic Access can provide a suggested ADSM does not appear to bias clinical decision making. • The presenting problem selected by the clinician (from Limbic Access referral output with and without ADSMs) was compared with the actual diagnosis. Comparisons were made where the machine learning presented the correct ADSM (20 cases), incorrect ADSM (20 cases) and overall (all 40 cases). • The EAG considers that ADSM results are outside the NICE scope. Treatment step-ups/down results are also	• No direct evidence of the accuracy of clinical assessment was identified. • The company state that a version of the Wysa DRA to collect clinical information after the service had received and opened a referral from a different referral route, had enabled clinicians to have access to a wider range of clinical information in over 65% of assessment appointments. However, no more information about this case study was provided. • A research protocol in place to look at how effective the data collected by the Wysa DRA is in helping the practitioner in making an accurate treatment pathway decision for people.

Outcomes	Limbic Access	Wysa DRA (All the evidence relating to Wysa DRA was real-world data)
	outside the NICE scope as the timeframe for this EVA is to the end of the initial clinical assessment only.	
AA3: Completion rate of pre-assessment when using digital front door technologies	• 2 studies provided information about pre-assessment completion rates. • Self-referral completion rates were >90%. • People who used Limbic Access were less likely to drop out during both pre-assessment and treatment than people who referred via other means. • More people using Limbic Access attended a one-to-one person-centred clinical assessment and attended NHS Talking Therapies treatment sessions than people who referred via other methods.	• The company stated that the Wysa DRA system was able to deliver a conversion rate of up to 91%". • When Wysa DRA is the only online self-referral option, the completion rate for pre-assessment demographic information was 91.2% (117,416/128,741 referrals). • When the Wysa DRA referral widget was offered on service websites alongside a static online referral form (which was stated to be the most common configuration), evidence from 3 case studies showed the completion rates ranged from 69.1% to 72.5%.
AA4: Inaccessibility to digital front door technologies	• 4 studies provided information about inaccessibility to Limbic Access. • Limbic Access led to increases in referrals versus self-referrals without Limbic Access. • Limbic Access also led to increases in accessibility for individuals from minority groups versus self-referrals without Limbic Access (Asian [increases of 39% vs 8%], Black [increases of 40% vs 4%] and non-binary [increase of 179% vs 5% decrease]) compared with self-referrals without Limbic Access. • An increase in all self-referrals, including a slight increase in out of hours self-referrals, to NHS Talking therapies since the introduction of Limbic Access. • Feedback from five individuals with physical and learning disabilities indicated that the device was usable. • Feedback on the Limbic Access referral process was consistent across all groups, including users with at least one disability and those aged ≥60 years.	• The company stated that over a third of people completed the Wysa DRA after 6pm or between 6pm to 9am. • 80% of all completed Wysa DRA referrals were completed on mobile phones. • People aged between 20 to 34 years were the largest age group that used Wysa DRA • Large numbers of older people used the Wysa DRA Compared to a matched group who self-referred using the static online form, the introduction of the Wysa DRA led to few second triage appointments and higher rates of referrals from Asian and Asian British groups.

Outcomes	Limbic Access	Wysa DRA (All the evidence relating to Wysa DRA was real-world data)
AA5: Healthcare professional acceptability of digital front door technologies	• 4 studies provided positive information about the professional acceptability of digital front door technologies. • Clinician perceptions of the useability and usefulness of Limbic Access were generally positive, and in some cases were strongly positive. • Limbic Access appeared to improve task performance during clinical assessments, reduce cognitive load of clinical assessments and improve clinician well-being.	• 1 small study suggested that 4/5 clinicians surveyed stated that they found it helpful to have the standardised questionnaire responses available via the Wysa DRA. • 2/5 clinicians reported they had more time to concentrate on the individual's problems • 1/5 stated it was helpful not to have to ask mandatory questions, to know the client's priority for treatment and that there was less needed to signpost to support.
RSI: Resource and system impact		
RSI1: Administrative resource impact	• 1 study provided some information about administrative resource impact. • 1 administrator stated that it would take 20 minutes to process a referral that had not come via Limbic Access.	• Limited available Wysa DRA resource use and impact outcome data. • The company stated that time saved during the initial clinical assessment was not always a valid or fair measure of the effectiveness or efficiency of a digital front door technology.
RSI2: Time taken to review data collected by digital front door technologies	• 2 studies provided information about the time taken to review data collected by digital front door technologies. • Some administrators considered that the information provided by Limbic Access saved time, whilst others found that it did not save time. • The time taken to review collected data was 1 minute 53 seconds (±1 minute 47 seconds). While it is not known whether this time was spent before or during the assessment.	• No data were available to address this outcome.
RSI3: Time taken to complete clinical assessment	• 3 studies provided information on the time taken to complete a clinical assessment. • The average time taken to complete an initial clinical assessment for people referred via Limbic Access was 41.6 minutes versus 54.4 minutes for people referred by other means (control); this difference was statistically	• 1 of NHS Talking Therapies services used the information collected by the Wysa DRA to inform the type and length of assessment appointments offered. • This service found that 91% of assessments for those who completed the full set of clinical

Outcomes	Limbic Access	Wysa DRA (All the evidence relating to Wysa DRA was real-world data)
	significant (p<0.001). • For people using Limbic Access, the time taken when additional clinical information was completed ahead of initial clinical assessment (40.6 minutes) versus time taken when additional clinical information was not completed (52.8 minutes); this result was also statistically significantly different (p<0.001). • Both results remained statistically significantly different after controlling for severity of mental health symptoms (p<0.001). • Around 97% people who referred via Limbic Access had completed additional clinical information • No time was spent collecting demographic data or collecting health questionnaire data/outcome measures for people referred via Limbic Access, whereas when people were referred via other methods, the time taken was approximately 3.9 minutes (demographic) or 4.6 minutes (health questionnaire). • Around 68% respondents who participated in the 2021 survey that assessments took <50 minutes, including administration time.	questions asked by the Wysa DRA were scheduled for 30-minute appointments instead of the service standard of 60 minute appointments.
RSI4: Time saved for the clinician during clinical assessment	• 5 studies provided information on time saved during a clinical assessment. • The time saved for the clinician during the clinical assessment was 12.7 minutes. • The company estimated that Limbic Access can release clinical time by making clinical assessments more efficient due to the additional clinical information collected during the referral, i.e., reducing the time taken by up to 23.4%. • Limbic Access saves approximately 8.5 minutes “through simple data collection” and 4.2 minutes “through enhanced preparation for clinicians by providing relevant	• The company stated that an average of between 16 to 21 minutes was saved for the clinician during the initial clinical assessment, depending on the length of the Wysa DRA used by the NHS Talking Therapies service.

Outcomes	Limbic Access	Wysa DRA (All the evidence relating to Wysa DRA was real-world data)
	ADSM measures and suggested primary and secondary presenting problems based on the diagnostic machine learning prediction model. • 88% of participants of a 2022 PWP staff survey agreed or partially agreed that the introduction of Limbic Access had shortened the length of time taken carry out an initial clinical assessment. The reported time saved ranged from 5 minutes to 20 minutes, with 50% answering that 10-15 minutes was saved.	
PRO: Patient reported outcomes		
PRO1: Ease of access and usability	• 5 studies provided information on ease of access and reported useability information. • Feedback from 42,332 users was largely positive and highlighted that approximately 42% of individuals found the referral process easy, fast or convenient. • No statistically significant differences between the numbers of individuals who mentioned convenience between gender identity groups (gender minority groups versus males/females) or between ethnic groups (Asian and Black ethnic groups versus White group). • Not all feedback was wholly positive: 12/32 ex-patients who considered that the list of questions asked by Limbic Access was long.	Not reported
PRO2: Information clarity and relevance	• 3 studies provided information on clarity and relevance. • After entering information into the Limbic Access system, [redacted] and • 'Self-realisation' was a theme identified by around 10% Limbic Access users. More individuals from Asian and Black ethnic groups (15.2%; 380/2499) mentioned self-	Not reported

Outcomes	Limbic Access	Wysa DRA (All the evidence relating to Wysa DRA was real-world data)
	realisation compared to White individuals (10%; 3723/37,272) (p<0.001). No statistically significant differences were found between gender identity groups (gender minority groups versus males/females).	
PRO3: Comfort and privacy	• 4 studies provided information about comfort and privacy. • Some people reported that the clinical questions were emotionally difficult to answer, and that questions sometimes felt too "heavy" to complete. [redacted]. • However, some participant views were more positive in terms of comfort and privacy. • Human-free' as a positive theme from user feedback as it removed the anxiety of talking to humans (approx. 9% of individuals). More individuals from gender minority groups (12.4%; 101/813) mentioned the human-free nature of Limbic Access compared to males/females (8.9%; 3,642/41,063) (p<0.01); there was no statistically significant difference between ethnic groups (Asian and Black ethnic groups versus White group).	Not reported
PRO4: Overall satisfaction with pre-assessment process	• 6 studies reported information on overall satisfaction with pre-assessment process. • 93% of people who have used Limbic Access (N>15,000) gave positive feedback. • 89% of the free-text feedback (N=42,332) was classified as positive, 7% neutral and 4% negative. • 94.3% of participants (N=17,931), rated the referral process as helpful, 4.9% indicated a need for more information or support and 0.8% rated the process as unhelpful, stating that they needed immediate human attention in the free-text response. • Positive evaluations of user experience across six categories (attractiveness, perspicuity, efficiency,	• Feedback from users of the Wysa DRA using either a three-point Likert scale or a five-point Likert scale. • In response to the question, 'Have I been able to help you today?', using the three-point scale, Wysa reported (data from one service) that 79.1% of users replied 'Yes', 18.5% replied 'Somewhat' and 2.3% replied 'No'. • In response to the question 'How did you find talking with me today?', using the five-point scale, Wysa reported (data from five services), approximately 60% replied 'It was really good, thanks' or 'It was engaging and helpful'.

Outcomes	Limbic Access	Wysa DRA (All the evidence relating to Wysa DRA was real-world data)
	dependability, stimulation and novelty). • Fewer individuals from gender minority groups mentioned that Limbic Access provided hope (21.5%) compared to males/females (26.9%) ($p<0.01$). Fewer individuals from Asian and Black ethnic groups (21.0%) mentioned that Limbic Access provided hope compared to the White group (27.8%); $p<0.001$.	

ADSM=Anxiety Disorder Specific Measure; DRA=Digital Referral Assistant; PWP= Psychological Wellbeing Practitioners

One of the highlighted benefits of using a digital front door technology was the potential to save time during the initial clinical assessment. Both Limbic and Wysa were confident that their digital front door technologies could save time: 12.7 minutes via Limbic Access (peer-reviewed study) and between 16 and 21 minutes via the Wysa DRA (company response). However, the EAG highlights that a shorter initial clinical assessment may mean that:

- fewer clinicians may be required to complete the same number of clinical assessments and clinicians who are no longer required to carry out initial clinical assessments could carry other duties (e.g. deliver treatment)
- any clinician time saved could be reallocated to conduct more initial clinical assessments and reduce waiting times
- any time saved may be used to discuss the patient's presenting problems and objectives in more detail which may result in a more accurate and high-quality clinical assessment

Therefore, the net time saved is not known.

5.2 Ongoing studies

Table 4 lists 5 potentially relevant ongoing studies, identified by the EAG literature searches or highlighted in Limbic RFI responses. These ongoing studies will provide data that are within the final scope.

Table 4 Ongoing studies

Ongoing study	Study design	Country	Alignment with the NICE scope	Indicated study end date
NCT05495126 Sponsor: Limbic Limited	RCT	United Kingdom	Intervention: Limbic Access Class IIa version Comparator: Limbic Access Class I version Participants: 5,030* Primary outcomes: change in depression & anxiety score after treatment, change in diagnosis, clinical assessment duration and waiting times AMBER	10/12/2024
Mind Matters (NHS Surrey and Borders Partnership) registered as NHS portfolio study Sponsor: Limbic	Observational study	United Kingdom	Intervention: Limbic Access Class IIa version Comparator: Limbic Access Class I version Participants: Not reported** Outcomes referred to in	Not reported

Ongoing study	Study design	Country	Alignment with the NICE scope	Indicated study end date
Limited			RFI EAG RFI response:[15] wait times from referral to assessment, recovery rate, reliable recovery rate, drop out post-referral AMBER	
NCT05678764 (continuation of Rollwage 2023) Sponsor: Limbic Limited	Observational study	United Kingdom	Intervention: Limbic Access Class IIa version Comparator: other self-referral methods Participants: 300,000*** Primary outcomes: change in depression & anxiety score after treatment, clinical assessment duration AMBER	30/12/2025
Study identifier: ISCRTN10327977 Sponsor: Wysa Limited	RCT	United Kingdom	Intervention: Wysa therapeutics including Wysa DRA (Part 1) Comparator: Other referral methods Participants: 100 Primary outcomes: clinical assessment duration (Part 1) AMBER	31/07/2025

* Data available from [redacted] participants presented in Limbic EAG RFI response
** Data available for 3,715 participants presented in Limbic EAG RFI response
*** Data available from [redacted] participants presented in Limbic EAG RFI response
GREEN=study characteristic aligns with the final scope; AMBER=study characteristic does not fully align with the NICE scope; RED=study characteristic does not align with the final scope
RCT=randomised controlled trial

6. Health economic evidence

The external assessment group (EAG) did a review to identify published health economic results. They did not find any published economic evidence that met the EAG systematic literature review inclusion criteria. The available economic evidence is limited, not robust and mainly relates to Limbic Access. This means that there is insufficient evidence to generate any reliable economic results for the comparison of standard NHS pre-assessment referral practice to NHS Talking Therapies with and without digital front door technologies. The EAG has therefore carried out an exploratory economic analysis to compare the benefits and costs of standard NHS pre-assessment referral practice to NHS Talking Therapies with and without digital front door technologies.

6.1 EAG exploratory analysis

For the purposes of this assessment, the EAG considers that there are two outcomes listed in the NICE scope that should be considered in an economic analysis, namely changes in:

- administration burden (RSI1)
- time taken to carry out an initial clinical assessment (RSI2)

Further details of the EAG exploratory analysis are in section 8.3 of the EAR.

Population

The population is people over the age of 16 years with suspected common mental health conditions, as specified in the NHS Talking Therapies for anxiety and depression manual (2024).

The EAG estimated that between 1 April 2023 and 31 March 2024, the average number of referrals received by an NHS Talking Therapies service was 11,801 (1,829,202 divided by 155). Current evidence suggests that the number of referrals that could be expected via a digital front door technology, for an average sized NHS Talking Therapies service, may range from 4,834 (40.96% multiplied by 11,801) to 7,435 (63% multiplied by 11,801). The EAG assumed that the proportion of referrals received via a digital front door technology is independent of the brand of digital front door technology.

Intervention

The EAG economic analysis considers 2 digital front door technologies, Limbic Access and the Wysa DRA; relevant cost and outcome data were not available for AskFirst.

Comparator

The comparator is NHS pre-assessment referral practices without digital front door technologies. The costs of digital front door technologies are in addition to all standard pre-assessment referral practices. Therefore, only purchase and implementation costs of digital front door technologies are considered, not the purchase and implementation costs of existing pre-assessment referral practices.

Perspective, time horizon and discounting

The perspective of the EAG analysis is the NHS. The time horizon is from referral (any route) until the end of the NHS Talking Therapies initial clinical assessment. As the time between referral and initial clinical assessment is always ≤12 months, costs and outcomes are not discounted.

6.2 Inputs

Costs

Technology costs

The licence cost associated with Limbic Access and Wysa DRA varies according to the number of digital front door technology referrals. Wysa charges a fixed implementation and set-up cost; this charge is only applied in Year 1. There are no fixed costs associated with Limbic Access. Table 5 presents the costs of Limbic Access and Wysa DRA. Table 6 shows the cost per digital referral for Limbic Access and Wysa DRA, estimated using a range of different numbers of digital referrals received over a 1-year period to reflect the variability in population sizes of different NHS Talking Therapies services and uncertainty around the proportion of referrals that would be received via a digital front door technology. Details of technology costs are in section 8.3.5 of the EAR.

Table 5 – Costs of Limbic Access and Wysa DRA

Number of referrals received via digital front door technology per year		Licence cost per digital referral	
Lower bound	**Upper bound**	**Without VAT**	**With VAT**
Limbic Access			
1	5,000	£5.49	£6.59
5,001	15,000	£4.99	£5.99
15,001	20,000	£4.50	£5.40
20,001	25,000	£4.00	£4.80
25,001	30,000	£3.75	£4.50
30,001	100,000	£3.50	£4.20
Wysa DRA			
1	5,000	£3.25	£3.90
5,001	10,000	£2.92	£3.50
10,001	15,000	£2.53	£3.04
15,001	20,000	£2.15	£2.58
20,001	30,000	£1.60	£1.92

Number of referrals received via digital front door technology per year		Licence cost per digital referral	
Lower bound	**Upper bound**	**Without VAT**	**With VAT**
Limbic Access			
30,001	-	£1.16	£1.39
--		**Implementation and set-up costs for Wysa DRA**	
--		£9,150	£10,180

DRA=Digital Referral Assistant; VAT=value added tax (@20%)

Table 6 – Estimated total costs per digital referral (including VAT)

Digital front door technology	Number of referrals						
	1-5,000	5,001-10,000	10,001 - 15,000	15,001-20,000	20,001 - 25,000	25,001-30,000	30,001-100,000
Limbic Access (all years)	£6.59	£5.99	£5.99	£5.40	£4.80	£4.50	£4.20
Wysa DRA (Year 1)*	£8.29	£4.97	£3.91	£3.21	£2.41	£2.32	£1.56
Wysa DRA (Year 2 onwards)	£3.90	£3.50	£3.04	£2.58	£1.92	£1.92	£1.39

*Wysa DRA implementation cost has been divided by the mid-point of the number of referrals
DRA=Digital Referral Assistant; VAT=value added tax (@20%)

Other costs

Table 8 shows a range of costs for different NHS Talking Therapies activities from the NHS Cost Collection 2023-2024. The NHS Cost Collection categories are unclear. The EAG was unable to identify any information that described the elements that were included in each cost category. For simplicity, and in line with the time horizon described in the final scope (referral to end of initial clinical assessment), the Assessment cost (01IAPT: £186) has been used in the EAG analysis.

Table 8 – Unit costs for NHS Talking Therapies: care contacts

Service description	NHS Cost Collection code	Value
Assessment	01IAPT	£186
Treatment	02IAPT	£166
Assessment and treatment	03IAPT	£158
Review only	04IAPT	£108
Review and treatment	05IAPT	£135
Follow-up appointment after treatment end	06IAPT	£130
Employment support	10IAPT	£129

Service description	NHS Cost Collection code	Value
Other (not listed)	98IAPT	£161

The EAG has calculated the cost per minute of an initial clinical assessment with durations of 45, 50, 55 and 60 minutes. Table 9 presents the estimates of the cost per minute of an initial clinical assessment.

Table 9 – Estimates of the cost per minute of an initial clinical assessment

	Possible initial clinical assessment durations*			
Time taken for assessment	45 minutes	50 minutes	55 minutes	60 minutes
Cost per minute of assessment	£4.13	£3.72	£3.38	£3.10

* Cost of an initial clinical assessment is £186 (NHS Cost Collection 2023-24)

Unknown costs

Details of unknown costs are in section 8.3.6 of the EAR. The following costs are unknown:

- Staff training and digital front door technology promotional costs
- Costs of applying digital clinical safety assurance DCB0129
- Reducing administration burden in NHS Talking Therapies services
- Time taken to review referral information
- Time taken to complete clinical assessment

6.3 Results

Exploratory analysis results

The EAG has calculated a range of estimated (notional) cost savings assuming different durations of initial clinical assessment appointments. Table 10 shows notional cost savings resulting from reduced initial clinical assessment times. Table 11 presents net cost of Limbic Access and Wysa DRA across a range of estimates of the cost per referral and notional cost savings per assessment. Details of exploratory analysis are in section 8.3.6 of the EAR.

Table 10 – Notional cost savings resulting from reduced initial clinical assessment times

Initial clinical assessment time saved	Time taken for assessment (minutes)			
	45 minutes	50 minutes	55 minutes	60 minutes

5 minutes	£20.67	£18.60	£16.91	£15.50
10 minutes	£41.33	£37.20	£33.82	£31.00
15 minutes	£62.00	£55.80	£50.73	£46.50
20 minutes	£82.67	£74.40	£67.64	£62.00
25 minutes	£103.33	£93.00	£84.55	£77.50
30 minutes	£124.00	£111.60	£101.45	£93.00

Table 11 – Net cost of Limbic Access and Wysa DRA across a range of estimates of the cost per referral and notional cost savings per assessment

		Cost per referral		
Limbic Access		**Lowest (£4.20)**	**Highest (£6.59)**	**Midpoint of highest and lowest estimates (£5.39)**
Notional cost saving per assessment	Lowest estimate (£15.50)	-£11.30	-£8.91	-£10.11
	Highest estimate (£124.00)	-£119.80	-£117.41	-£118.61
	Mid-point of high and low estimates (£69.75)	-£65.55	-£63.16	-£64.36
Wysa DRA		**Lowest (£1.56)**	**Highest (£8.29)**	**Midpoint of highest and lowest estimates (£4.93)**
Year 1				
Notional cost saving per assessment	Lowest estimate (£15.50)	-£13.94	-£7.21	-£10.57
	Highest estimate (£124.00)	-£122.44	-£115.71	-£119.07
	Mid-point of highest and lowest estimates (£69.75)	-£68.19	-£61.46	-£64.82
Year 2 onwards				
		Lowest (£1.39)	**Highest (£3.90)**	**Midpoint of highest and lowest estimates (£2.65)**
Notional cost saving per assessment	Lowest estimate (£15.50)	-£14.11	-£11.60	-£12.85
	Highest estimate (£124.00)	-£122.61	-£120.10	-£121.35
	Mid-point of highest and lowest estimates (£69.75)	-£68.36	-£65.85	-£67.10

The EAG's exploratory economic analysis results suggest that the amount of clinical assessment time saved that is required to notionally offset the Limbic Access licence cost or the Wysa DRA licence cost is small.

Threshold analysis

The EAG has undertaken a threshold analysis using the highest licence cost per referral and different durations of initial clinical assessments. Table 12 shows the results. In the worst-case scenarios, the average time savings required for Limbic Access and the Wysa DRA to deliver a (notional) cost neutral impact were less than 3 minutes. Details of the threshold analysis are in section 8.3.6 of the EAR.

Table 12 – Threshold analysis results (highest cost per referral)

Clinical assessment duration	Average time saving (minutes) required for cost neutral impact		
	Limbic Access	Wysa DRA (Year 1)	Wysa DRA (Year 2)
45	1.59	2.01	0.94
50	1.77	2.23	1.05
55	1.95	2.45	1.15
60	2.13	2.67	1.26

DRA=Digital Referral Assistant

Scenario analysis

The EAG considered a scenario where no time was saved and assessed the quality adjusted life year (QALY) gains that would need to be accrued for Limbic Access and the Wysa DRA to be considered cost effective at a willingness to pay (WTP) threshold of £20,000 per QALY gained. Table 13 presents estimated QALY gains per referral via Limbic Access and via the Wysa DRA required for these technologies to be considered cost effective at a threshold of £20,000 per QALY. Details of scenario analysis are in section 8.3.6 of the EAR.

Table 13 – Scenario analysis results

Digital front door technology	Number of referrals						
	1-5,000	5,001-10,000	10,001-15,000	15,001-20,000	20,001-25,000	25,001-30,000	30,001-100,000
Limbic Access (all years)	0.0003	0.0003	0.0003	0.0003	0.0002	0.0002	0.0002
Wysa DRA (Year 1)	0.0004	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001

Digital front door technology	Number of referrals						
	1-5,000	5,001-10,000	10,001-15,000	15,001-20,000	20,001-25,000	25,001-30,000	30,001-100,000
Wysa DRA (Year 2 onwards)	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001

The EAG's scenario analysis results show that if no time is saved, then a very small QALY gain (0.0003 QALYs per referral) would be required for Limbic Access or for the Wysa DRA to be considered cost effective at a WTP threshold of £20,000 per QALY (if only licence costs are considered).

EAG conceptual model

For the purposes of this EVA, the EAG considered it was not necessary to develop an economic model due to the short evaluation time horizon and the focus on process outcomes, for which evidence is currently limited.

7. Anecdotal evidence from experts

The EAG interviewed expert Specialist Committee Members (SCMs) and stakeholders and developed a questionnaire for experts and lay SCMs. The questionnaire was sent to 7 experts; responses were received from 5 experts (4 SCMs and 1 stakeholder) and 1 lay SCM. Table 14 presents respondent's own experience with digital front door technologies and referral pathways to NHS Talking Therapies services. Details of information provided by specialist committee members and stakeholders are in section 6 of the EAR.

Table 14 – Experts' considerations about referral pathways

Outcomes	Experts' considerations
Effects of digital front door technologies on the pre-assessment/triage stage	• 3 experts who provided responses all indicated that the effects of digital front door technologies on the pre-assessment /triage stage were positive
Time taken to review data collected by digital front door technologies	• 1 expert suggested that reviewing referral information took 3 minutes without Limbic Access and 5 minutes with Limbic Access. • 2 other experts considered that reviewing information without a digital front door technology could take at least 10 minutes, longer if there was a perceived risk
Effects of digital front door technologies on initial clinical assessment	• Most of the responses were positive • 2 respondents disagreed that a digital front door could reduce waiting times from referral or pre-

	assessment/triage to the initial clinical appointment.
Time taken to complete the NHS Talking Therapies initial clinical assessment	• It took at least 45 minutes to complete the NHS Talking Therapies initial clinical assessment without the use of a digital front door technology.
AA1: Quality and accuracy of the initial clinical assessment	• Clinical assessments were more detailed and relevant. • Increased users and clinician satisfaction.
AA4: Inaccessibility to digital front door technologies	• Barriers to digital front door technologies for whose first language was not English • Since the introduction of a digital front door technology, referrals from Black, Asian and minority ethnic groups had increased. • Potentially remove barriers to access for some harder to reach groups such as men.
Most important outcomes and other costs and benefits	Most important outcomes: • Time saving and impact on recovery • Waiting times • Access numbers for different demographics (e.g. age, ethnicity) • Qualitative data from clients, therapists and administrative staff • User experience • Quality of care • Digital clinical safety • Ease of deployment and adoption rates • Effectiveness Benefits not captured by the questionnaire: • More engaging process • Focused on efficiency • Reduced waiting times • Facilitated access • Flexibility Concerns not captured by the questionnaire • The ongoing costs and it is not offered in alternative languages • How the AI manages risky utterances from the client • The cost and investment in clinical safety cases • Legally mandated standards in the deployment of these technologies • Information governance and digital clinical safety • Digital front door technologies should not replace a one-to-one assessment and the use of clinical judgement by trained professionals • Impersonal experience

8. Public perspectives on using digital technology before assessments for NHS Talking Therapies

NICE developed a questionnaire to elicit public responses on using digital technology before clinical assessments for NHS Talking Therapies. NICE received a total of 433 responses. See details in the survey response summary report.

Characteristics of respondents

Most respondents were aged 25-59 (73%), with fewer in both younger and older age groups. Women made up 74% of the respondents. The vast majority identified as White British/English/Welsh/Scottish/Northern Irish (79%), with all other ethnic groups having significantly lower representation. Additionally, 91% of respondents reported that English is their first language. Respondents also reported whether they have long-term health conditions, impairments, or disabilities. Depression (55%) and long-term physical health conditions (48%) were the most common conditions, followed by post-traumatic stress disorder (PTSD) (34%) and generalised anxiety disorder (GAD) (30%). (Figure 2-5).

Figure 2 – Age of respondents

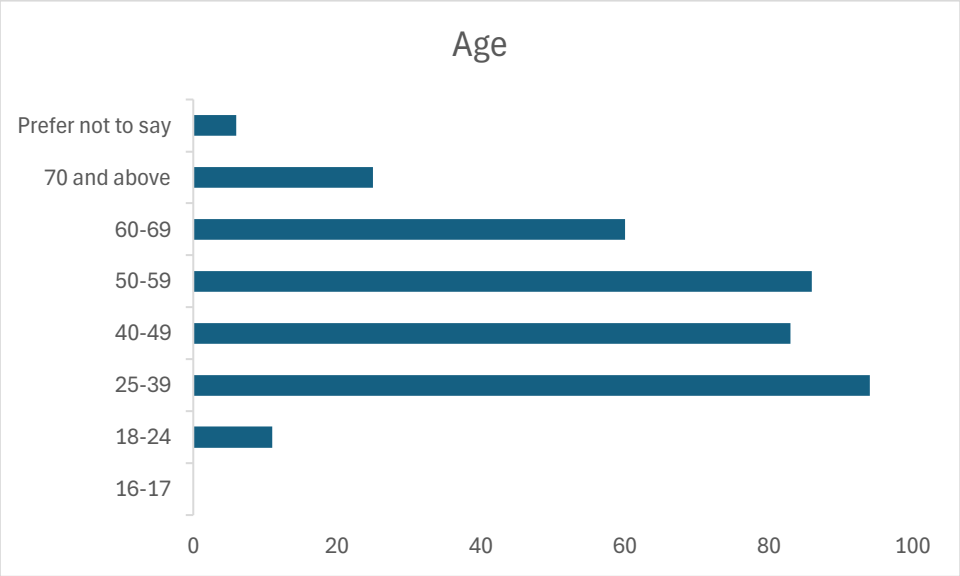


Figure 3 – Gender of respondents

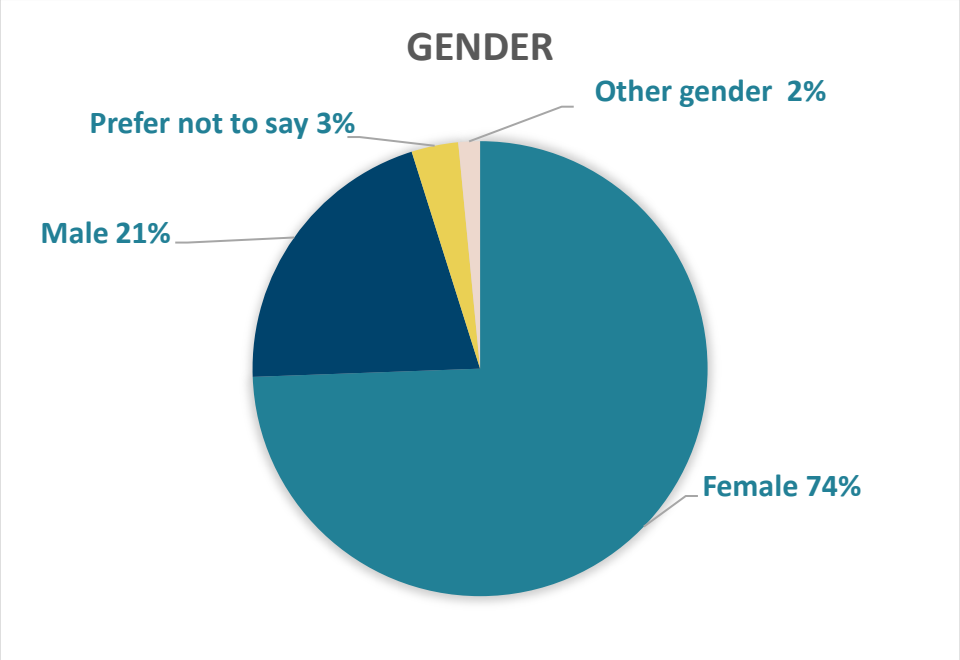


Figure 4 – Ethnicity of respondents

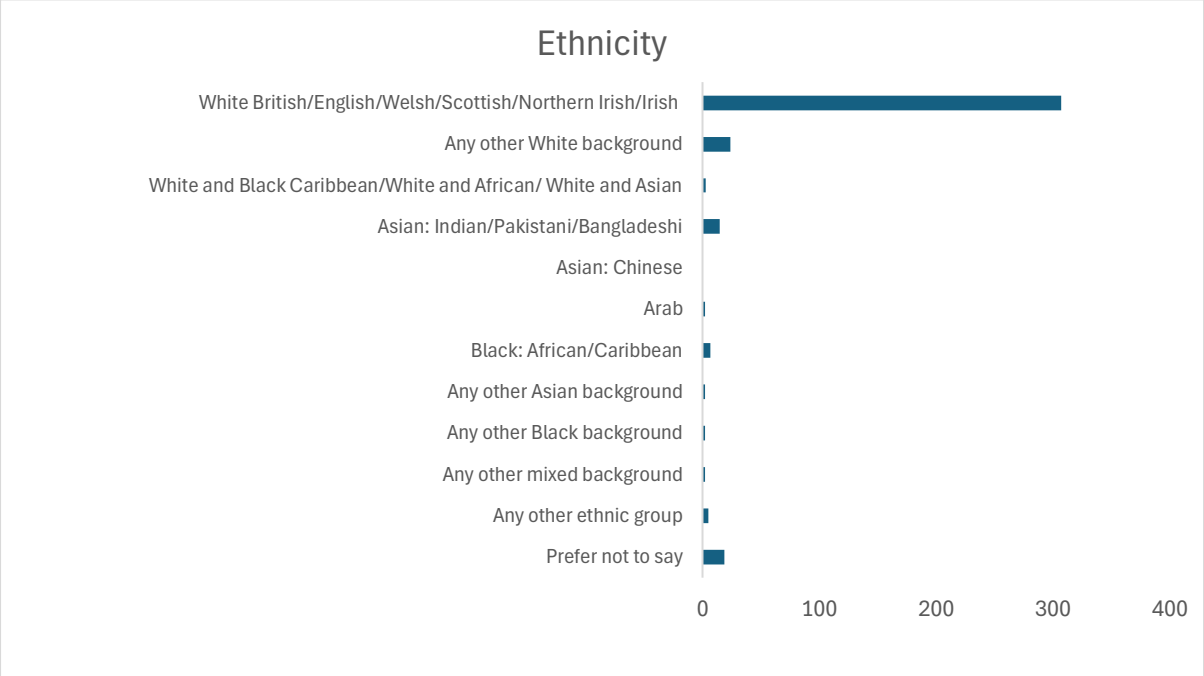
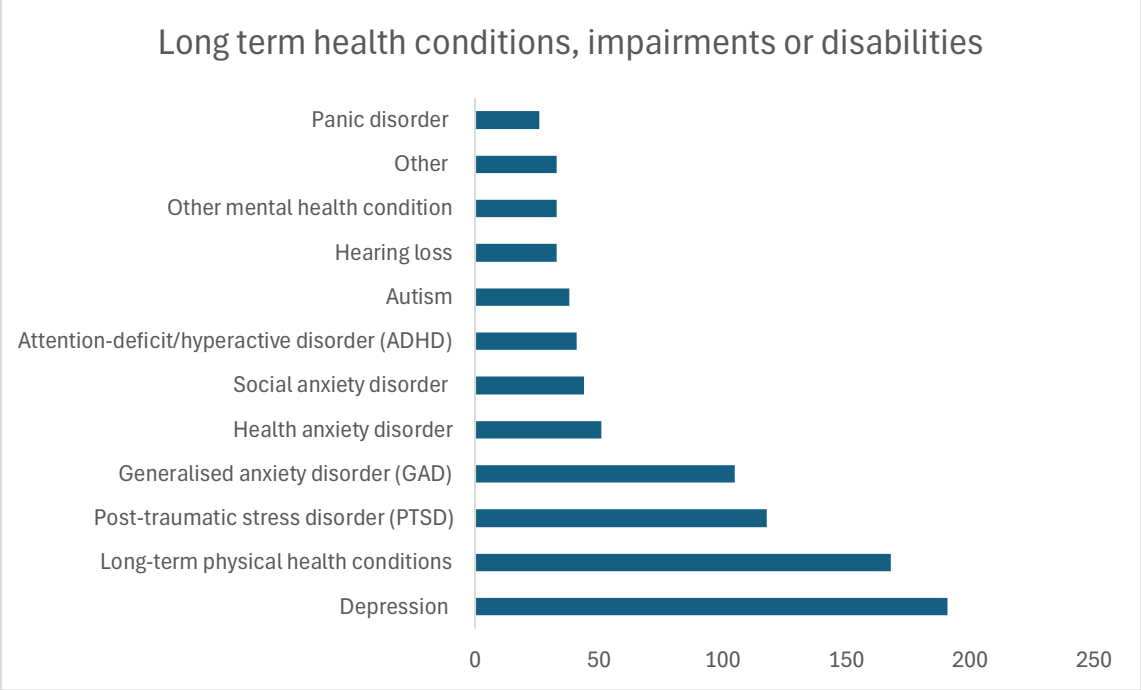


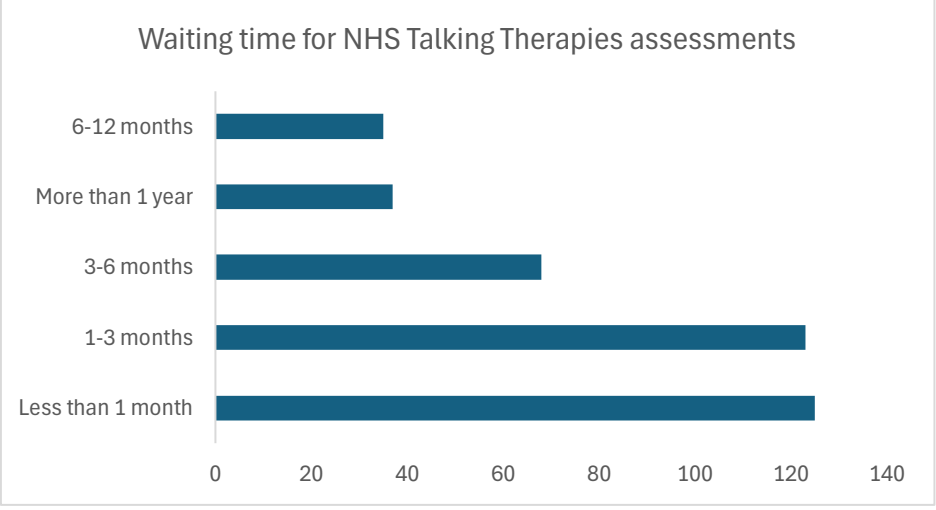
Figure 5 – Long term health conditions, impairments or disabilities of respondents



Experience of waiting before NHS Talking Therapies assessments

64% of respondents waited less than 3 months for a clinical assessment for NHS Talking Therapies. 27% of respondents waited 3-12 months, while 10% of respondents experienced waits of more than 1 year. (Figure 6)

Figure 6 – Waiting time for NHS Talking Therapies assessments



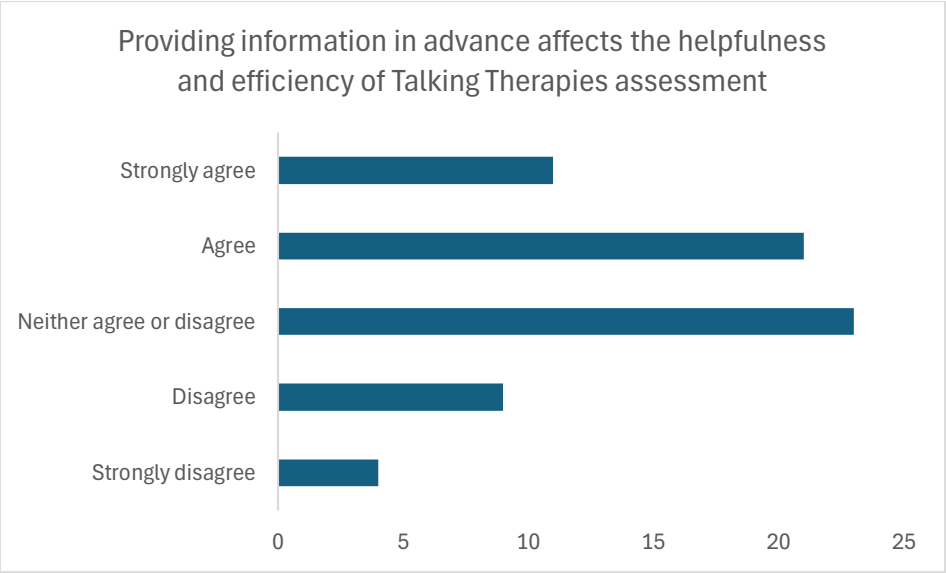
77% of respondents did not receive any support to manage their symptoms while they were on the waiting list of NHS Talking Therapies assessments. 23% of respondents received some support whilst on the waiting list, which included:

- Medication
- Support from healthcare professionals, charitable organisations
- Receiving details for further contact or action if support is needed
- Support from online content or digital technologies
- Attending workshops

Experience of information collection before NHS Talking Therapies assessments

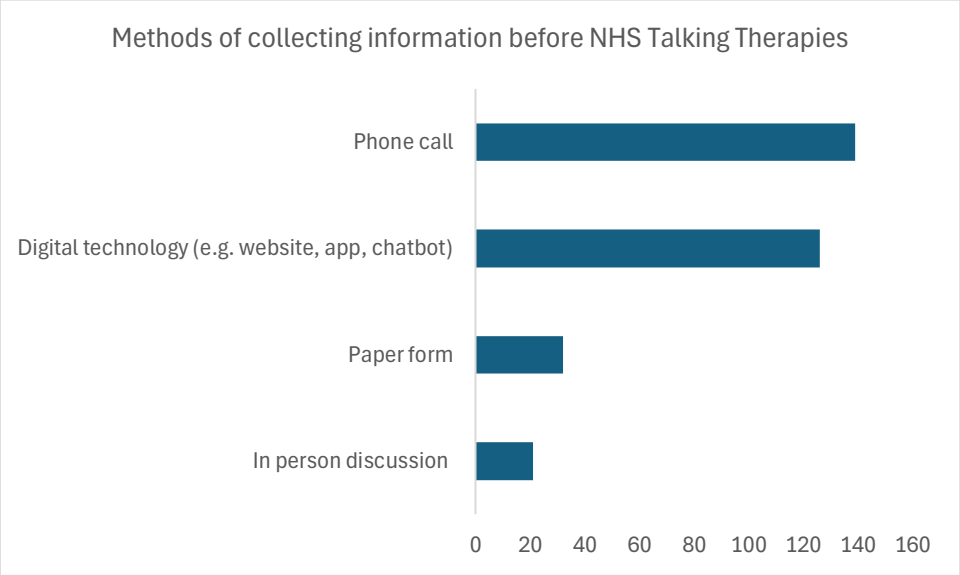
82% of respondents stated that they were asked to provide any information in advance, such as personal information, contact details, questionnaires about symptoms, and other relevant issues before the clinical assessment for NHS Talking Therapies. Over 60% of them strongly agreed or agreed that it's useful to have the chance to provide some information before the clinical assessment and would make the assessment session more efficient. (Figure 7)

Figure 7 – Providing information in advance affects the helpfulness and efficiency of Talking Therapies assessment



44% of them had their information collected by phone. 40% of them had their information collected by a digital technology, such as a website, app or chatbot. Only 17% of them used a paper form or in-person discussion. (Figure 8)

Figure 8 – Methods of collecting information before NHS Talking Therapies



The type of information collected before the assessment included:

- Personal information
- Symptoms
- Mental health questionnaire, such as PHQ-9 and GAD-7
- History of diagnosis
- Summary of why NHS Talking Therapies is needed
- Suicidal thoughts

For respondents (18%) who were not asked to provide any information before NHS Talking Therapies assessments, 47% of them strongly agreed or agreed that not having the change to provide information beforehand will affect the helpfulness or efficiency of the clinical assessment for NHS Talking Therapies.

Respondents thought the benefits of providing information before NHS Talking Therapies assessments included:

- More efficient use of clinical time
- Better understanding of people's needs
- Potential data retention to benefit further interaction
- Ensure the assessors are fully informed

- Help with triage
- Removal of duplicate information
- Data protection
- Reduce anxiety and stress
- Help people on the waitlist and potentially shorten the waitlist
- Being prepared for the assessment
- Easier to type some of the necessary information collection
- Make conversation during the assessment itself easier

Perspectives on using digital technology before NHS Talking Therapies assessments

Interestingly, 87% of respondents did not use the digital front-door technologies included in this EVA. (Figure 9) 47% of respondents were not informed of the reason they were asked to use digital technology. 49% were not offered an alternative method for submitting information if they did not want to use digital technology, while 42% were unsure whether an alternative was available. Among those who were offered an alternative (9%), the options provided were either paper forms or phone calls. 65% of respondents considered the digital technology was easy to use. (Figure 10)

Figure 9 – Digital technology that was used before

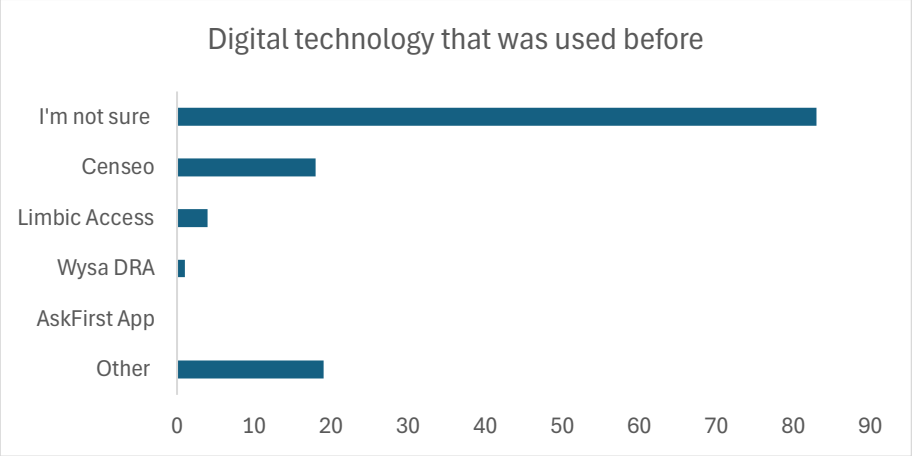
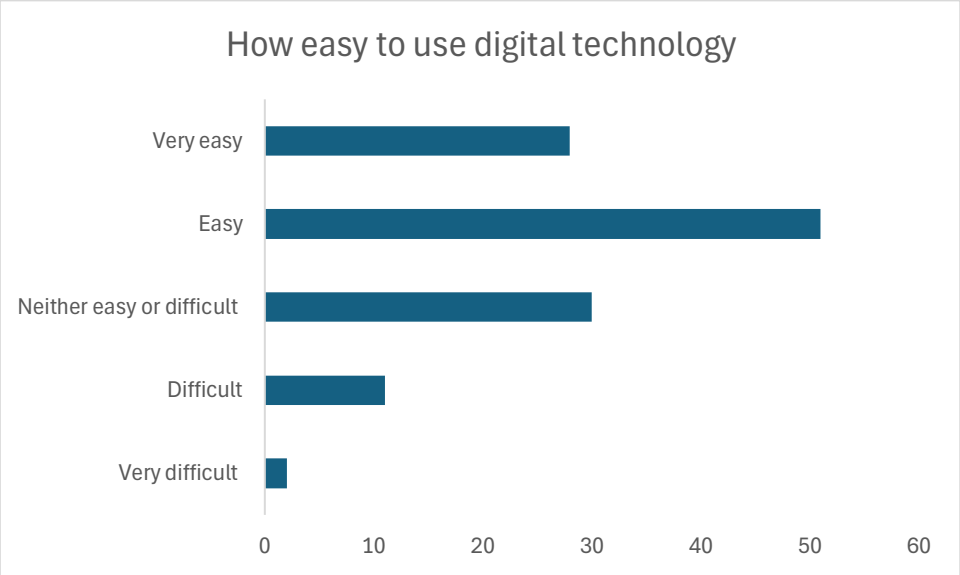
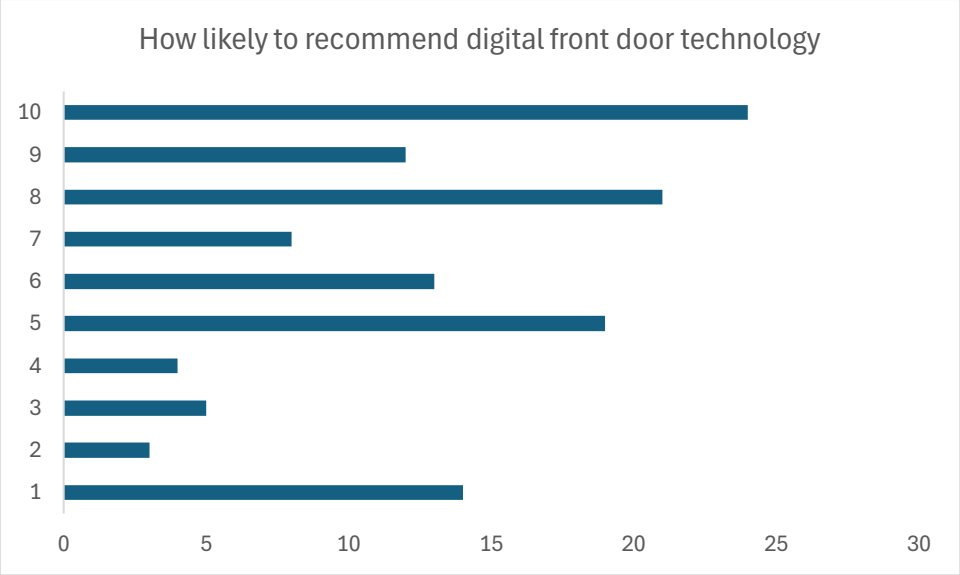


Figure 10 – How easy to use digital technology



65% of respondents who rated over 6 on a 10-point scale (1=Not at all likely, 10=very likely) believed they are likely to recommend using digital front door technology before NHS Talking Therapies assessments to others. (Figure 11)

Figure 11 – How likely to recommend using digital front door technology



82% of respondents were somewhat willing, willing or very willing to use digital technologies before NHS Talking Therapies.

Reasons that people would be willing to use digital technologies in advance included:

- Efficiency
- Easy to use
- Convenient
- Flexible time to complete the questions properly and confidentially
- Feel in control and less intrusive
- Provide information directly without other people's misinterpretation
- Better access to information
- Willing to use with extra support

Reasons that people are unwilling to use digital technologies in advance included:

- Worry about confidentiality and data protection
- Prefer in-person sessions
- Hard to determine the answers and need clarification later
- Only if the forms were discussed in session with the clinician

- Too impersonal
- Had bad experience of digital technologies
- Not comfortable at filling the information
- The same information is being asked repeatedly
- Cannot be used in blind or visually impaired people
- Only if it collects basic information
- Need extra support
- Limited access to internet and phone
- Don’t like digital technologies or AI system

9. Equality considerations

The final scope and the scoping equality impact assessment describe equality considerations for this assessment. The EAG found that Limbic and Wysa have developed technologies that are designed to be accessible to all NHS service users, including older people, people from minority groups, and those with disabilities. Some evidence shows that Limbic Access is effective at facilitating referrals from gender and ethnic minority groups that are typically underrepresented in mental healthcare.

The EAG identified additional equality issues:

- Individuals on low income who do not have access to a computer, smart phone or laptop
- People with low motivation or cognitive challenges may disengage from digital platforms before their referral is complete.
- Older adults or those with low digital literacy may face barriers to using digital front door technologies to access NHS Talking Therapies
- There may be issues for individuals from linguistically diverse backgrounds as translations may not be appropriate or content culturally relevant.

- Artificial intelligence (AI)-based chatbots may be unable to interpret information provided by individuals with different linguistic backgrounds, leading to miscommunication.
- Marginalised populations, including those experiencing domestic violence or housing insecurity, may avoid using digital services due to concerns over confidentiality.

The EAG highlights that if NHS Talking Therapies providers continue to provide multiple referral methods to access NHS Talking Therapies, it is unlikely that people attempting to access NHS Talking Therapies will be disadvantaged by the introduction of a digital front door technology.

10. Integration into the NHS

Many NHS Talking Therapies services are currently using digital front door technologies (Limbic Access and Wysa DRA). Limbic reported that over 350,000 referrals to NHS Talking Therapies had been processed via Limbic Access; Wysa reported that there had been 186,179 referrals to NHS Talking Therapies services via the Wysa DR. Although the functionality and intended purpose of the digital front door technologies varies between services, integration with current NHS software systems does not appear to have been problematic. Further guidance may be required to mitigate and manage risks, which may include:

- Training staff
- Consensus around the appropriate eligibility screening or triage criteria
- Ensuring other referral methods remain accessible
- Continuous monitoring of user experience

11. Evidence gap analysis

11.1 Evidence gaps identified by the EAG

The EAG has identified gaps between the available evidence and the evidence needed to address the outcomes listed in the final scope. Evidence gaps include population, intervention, comparator, outcome and cost effectiveness. Table 15 shows the evidence gap analysis. Details of evidence gaps are in section 10.1 of the EAR.

The EAG highlights that there is no evidence to support the use of AskFirst as a digital front door technology for NHS Talking Therapies.

Table 15 Evidence gap analysis

Outcomes	Limbic Access	Wysa DRA
Accuracy and acceptability outcomes		
AA1: Quality and accuracy of the data collected using digital front door technologies	Data provided by Limbic; unclear if definition used is relevant RED	Data provided by Wysa; unclear if definition used is relevant RED
AA2: Accuracy of the clinical assessment	Unpublished data provided by Limbic RED	No studies or data RED
AA3: Completion rate of referral for digital front door technologies	Unpublished data provided by Limbic AMBER	Unpublished data provided by Wysa AMBER
AA4: Inaccessibility to digital front door technologies	One published study, unpublished data provided by Limbic and one unpublished study GREEN	Unpublished data provided by Wysa AMBER
AA5: Healthcare professional acceptability of digital front door technologies	Unpublished data provided by Limbic and one unpublished study AMBER	Unpublished data provided by Wysa RED
Resource and system impact outcomes		
RSI1: Impact on administrative burden	One unpublished study RED	No studies or data RED
RSI2: Time taken to review data collected by digital front door technology	Unpublished data provided by Limbic and one unpublished study RED	No studies or data RED
RSI3: Time taken to complete clinical assessment	One published study, unpublished data provided by Limbic and one unpublished study AMBER	Unpublished data provided by Wysa RED
RSI4: Time saved for clinician during clinical assessment	One published study, unpublished data provided by Limbic and one unpublished study AMBER	Unpublished data provided by Wysa RED
Service user reported outcomes		
PRO1: Ease of access and usability	Two published studies and unpublished data provided by Limbic AMBER	No studies or data RED
PRO2: Information clarity and relevance	One published study and unpublished data provided by Limbic AMBER	No studies or data RED
PRO3: Comfort and privacy	Two published studies and unpublished data provided by Limbic AMBER	No studies or data RED

Outcomes	Limbic Access	Wysa DRA
PRO4: Overall satisfaction	One published study, unpublished data provided by Limbic and one unpublished study GREEN	Unpublished data provided by Wysa AMBER
Economic outcomes		
Licence costs and number of users	Unpublished data provided by Limbic GREEN	Unpublished data provided by Wysa GREEN
Initial set up and integration costs	Unpublished data provided by Limbic GREEN	Unpublished data provided by Wysa GREEN
Operational costs	Unpublished data provided by Limbic GREEN	Unpublished data provided by Wysa GREEN
Training costs	Unpublished data provided by Limbic AMBER	Unpublished data provided by Wysa AMBER
Costs of promotion	No studies or data RED	No studies or data RED
Digital safety assurance costs	No studies or data RED	No studies or data RED

GREEN=clear evidence from at least one study, AMBER=evidence is subjective and/or inconsistent; RED=no studies/sources of evidence or outcome data/definitions may not be useful, e.g. data from very small sample or outcome definition is outside of the final scope
DRA=Digital Referral Assistant

11.2 Key areas for evidence generation

The EAG considers that further evidence is required to better understand the benefits and costs of digital front door technologies for NHS Talking Therapies. Potential research questions include:

- How are referrals processed in a pathway without a digital front door?
- How should the accuracy and quality of a clinical assessment be measured?
- Do digital front door technologies improve process efficiency?
- Do digital front door technologies improve access to NHS Talking Therapies?
- What is the cost effectiveness of digital front door technologies compared to referral pathways without a digital front door or compared to a referral pathway with a different digital front door?

Details of EAG evidence generation recommendations are provided in **Error! Reference source not found.** in section 10.2 of the EAR.

12. Key points, limitations and considerations

12.1 Clinical effectiveness

Key points

- The processes and systems in place to manage people from referral to the completion of the initial clinical assessment in different trusts are heterogenous.

- The EAG considers that the evidence is generalisable to people accessing NHS services who use digital front door technologies.

- Clinicians' perceptions of the useability and usefulness of Limbic Access and Wysa DRA were positive.

- Using a digital front door technology has the potential to save time during the initial clinical assessment. However, as clinicians may spend additional

time reviewing the information prior to the initial clinical assessment; the net time saved is therefore not known.

- Unclear whether a shorter clinical assessment time could be realised in all NHS Talking Therapies services.
- Any time saved may represent an opportunity to reconsider the use of clinical or administrator time.
- The introduction of digital front door technologies could lead to better pre-referral practices and initial clinical assessments.
- None of the available clinical evidence reviewed identified any harms to clinicians or service users.
- Both static online forms and digital front door technologies offer some benefits over paper, email and telephone-based referral methods.
- Completion rates were high (approximately 91%).
- Limbic's definitions of quality and accuracy appear to rely on the ability of Limbic Access to provide diagnoses and to suggest treatment pathways, while Wysa's definitions of quality and accuracy relate to how clinicians utilise information gathered by the Wysa DRA to enhance the efficiency of the initial clinical assessment. The MHRA regulatory status differs between Limbic Access and Wysa DRA: Limbic Access is classified as Class IIa, while Wysa DRA is classified as Class I.

Limitations

- The evidence base is limited and only includes two peer-reviewed (Limbic Access) studies.
- Although real-world data have been collected by Wysa, these studies are unpublished and do not include comparative data.
- Most of the studies were non-comparative and focused mainly on the advantages and disadvantages of the digital front door technologies for

NHS Talking Therapies staff (administrative and clinical) and people accessing NHS Talking Therapies services.

- The extent to which the available clinical evidence is generalisable to all NHS Talking Therapies service providers is unclear.

- Most of the evidence from users was sourced from user responses to questions posed after the user had completed referral information collected via a digital front door technology.

- Experts who provided advice to the EAG were unable to offer clear definitions of quality or accuracy of pre-assessment practice or of initial clinical assessment.

Considerations for committee:

- Does the evidence suggest a potential benefit for the use of digital front door technologies for NHS Talking Therapies?

- Do the technologies gather relevant information to support assessments? Any potential risks?

- Do the technologies reduce clinician workload, or does it introduce additional administrative burdens?

- Will the use of digital front door technologies affect clinical decision-making?

- Will the use of digital front technologies improve the care pathway?

- How do the technologies impact service user's engagement, self-referral rates, and service uptake?

- How does the effectiveness of digital front door technologies compare to other referral and assessment methods?

- Is the evidence generalisable to all NHS Talking Therapies services?

- How do the technologies ensure data security, confidentiality, and individual's consent?

- Should any accuracy considerations be taken into account for this assessment or possible future evidence collection, and how should these outcomes be defined?

12.2 Health economic evidence

Key points:

- The amount of clinical assessment time saved that is required to notionally offset the Limbic Access licence cost or the Wysa DRA licence cost is small.

- The introduction of a digital front door technology saving time during the initial clinical assessment is not well supported by the evidence.

- If no time is saved, then a very small QALY gain (0.0003 QALYs per referral) would be required for Limbic Access or for Wysa DRA to be considered cost effective at a WTP threshold of £20,000 per QALY (if only licence costs are considered).

Limitations:

- Relevant licence costs were only provided by Limbic and Wysa.

- The specific costs associated with establishing and maintaining a digital front door technology for NHS Talking Therapies that are not covered by the licence fee are unknown. However, as it will only ever represent a small percentage of the total cost of a digital front door technology, this issue is of minor concern.

- There is an absence of quantitative data to support any claim that digital front door technologies reduce administrative burden.

- Lack of comparative data means that it has not been possible for the EAG to carry out a robust full cost effectiveness analysis for the comparison of

NHS Talking Therapies pre-assessment referral practices with and without digital front door technologies.

Considerations for committee:

- Do the results of the EAG's economic analyses demonstrate value for money of the technologies within NHS Talking Therapies?
- Are the benefits (e.g. reduced administrative burden, improved triage) sufficient to justify the costs?
- Do the technologies improve access to NHS Talking Therapies, leading to earlier interventions and potentially reducing long-term healthcare costs?
- Do the technologies shorten waiting times and improve service throughput?
- What are the long-term financial implications of adopting digital front door technologies across NHS Talking Therapies?
- Could the technologies lead to wider system efficiencies?

12.3 Evidence generation plan

Considerations for committee:

- Are there other evidence gaps?
- What outcomes should be collected, and over what time-frame should these be collected? Which is the highest priority in order to address the evidence gaps?
- Are there any existing real-world data sources that have not already been highlighted?

Appendix A Abbreviations

ADSM	Anxiety Disorder Specific Measure
AI	Artificial intelligence
DRA	Digital Referral Assistant
EAG	External assessment group
EAR	External assessment report
EHR	Electronic Health Record
GAD-7	General Anxiety Disorder-7
GP	General Practitioner
MHRA	Medicines and Healthcare Products Regulatory Agency
PHQ-9	Patient Health Questionnaire-9
PWP	Psychological Wellbeing Practitioner
QALY	Quality-adjusted life year
RFI	Request for Information
SCM	Specialist Committee Member
WSAS	Work and Social Adjustment Scale

EAG EVA final report following stakeholder comments

LIVERPOOL REVIEWS AND IMPLEMENTATION GROUP (LRiG)

Digital front door technologies for people referred to NHS Talking Therapies [HTE10055]: Early Value Assessment (EVA) final report following stakeholder comments

Confidential until published

This report was commissioned by the NIHR Evidence Synthesis Programme as project number NIHR171847

Completed 24 March 2025

Contains 'commercial in confidence' and 'academic in confidence' data

UNIVERSITY OF LIVERPOOL

LIVERPOOL REVIEWS AND IMPLEMENTATION GROUP

A MEMBER OF THE RUSSELL GROUP

Title: Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies [HTE10055]: Early Value Assessment final report following stakeholder comments

Produced by: Liverpool Reviews & Implementation Group (LRiG)

Authors: Nigel Fleeman, Senior Research Fellow (Clinical Effectiveness), LRiG, University of Liverpool

James Mahon, Director, Coldingham Analytical Services, Berwickshire

Samuel Bryning, Economic Modeller, LRiG, University of Liverpool

Sophie Beale, Director, HARE Research, North Yorkshire

Angela Boland, Director, LRiG, University of Liverpool

Janette Greenhalgh, Senior Research Fellow (Clinical Effectiveness), LRiG, University of Liverpool

Yenal Dundar, Research Fellow (Clinical Effectiveness), LRiG, University of Liverpool

Correspondence to: Liverpool Reviews & Implementation Group, University of Liverpool, Whelan Building, The Quadrangle, Brownlow Hill, Liverpool L69 3GB

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Purpose of the assessment report

The purpose of this External Assessment Group (EAG) report is to review the evidence currently available for included digital front door technologies and advise what further evidence should be collected to help inform decisions on whether the technologies should be widely adopted in the NHS. The report includes additional analysis of the submitted evidence or new clinical and/or economic evidence. The National Institute for Health and Care Excellence (NICE) has commissioned this work and provided the template for this report. The report forms part of the papers considered by the NICE Medical Technologies Advisory Committee when it is making decisions about the early value assessment.

Declared interests of the authors

None.

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Responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Any ‘commercial in confidence’ information is [redacted].

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Contributions of authors

Nigel Fleeman	Project lead, reviewed clinical effectiveness evidence, including study selection, data extraction, synthesis and interpretation of information provided by companies, Specialist Committee Members and stakeholders
James Mahon	Reviewed cost effectiveness evidence and developed the External Assessment Group exploratory economic analysis
Samuel Bryning	Reviewed the clinical and cost effectiveness evidence, including study selection and synthesis and interpretation of information provided by companies, Specialist Committee Members and stakeholders; carried out the External Assessment Group exploratory economic analysis
Sophie Beale	Critical appraisal of the clinical and economic evidence, editorial input
Angela Boland	Critical appraisal of the clinical and economic evidence, editorial input
Janette Greenhalgh	Clinical effectiveness review support, including data extraction and data checking
Yenal Dundar	Carried out literature searches and contributed to study selection

Table of contents

List of tables

List of abbreviations

ADSM	Anxiety Disorder Specific Measure
AI	artificial intelligence
DRA	Digital Referral Assistant
DTAC	Digital Technology Assessment Criteria
EAG	External Assessment Group
EPR	electronic patient record
EVA	early value assessment
GAD-7	General Anxiety Disorder-7
GP	general practitioner
iaptus	Improving Access to Psychological Therapies User System
IT	information technology
MHRA	Medicines and Healthcare products Regulatory Agency
NICE	National Institute for Health and Care Excellence
PCMIS	primary care management information system
PHQ-9	Patient Health Questionnaire-9
PWP	Psychological Wellbeing Practitioner
RFI	request for information
SLR	systematic literature review
WCAG	Web Content Accessibility Guidelines
WSAS	Work and Social Adjustment Scale

EXECUTIVE SUMMARY

The aim of this National Institute for Health and Care Excellence (NICE) Early Value Assessment (EVA) was to consider the benefits and costs of current NHS pre-assessment referral practice for NHS Talking Therapies for anxiety and depression (hereafter referred to as NHS Talking Therapies) with and without digital front door technologies (from referral [any route] to end of initial clinical assessment). Four digital front door technologies were considered: Limbic Access (Limbic), Wysa Digital Referral Assistant (DRA) (Wysa), Censeo Digital (Psyomics) and AskFirst (Sensely).

Quality and relevance of clinical evidence

Clinical evidence for referrals to NHS Talking Therapies is only available for two digital front door technologies (Limbic Access and the Wysa DRA). Only two (Limbic Access) peer-reviewed studies provided relevant data; all other information was unpublished and/or was provided by Limbic or Wysa. Most of the studies were non-comparative and focused mainly on the strengths and weaknesses of the digital front door technologies. Published evidence was not available for most of the outcomes listed in the NICE scope. In some studies, the strength of the evidence was difficult to determine due to small populations, weak methodologies and a lack of transparency in reporting.

The feedback from NHS clinicians and patients was largely positive. No evidence quantifying the potential harms of digital front door technologies was identified. It is unclear to the extent that the available clinical evidence is generalisable to all NHS Talking Therapies providers. Expert advice to the EAG is that, within NHS Talking Therapies services, the processes and systems in place to manage patients from referral to the completion of the initial clinical assessment is heterogenous. This heterogeneity will affect how the implementation of a digital front technology can impact the outcomes listed in the NICE scope.

Quality and relevance of the economic evidence

The EAG did not identify any economic evidence that met the EAG systematic literature review inclusion criteria.

Some clinical evidence suggests that Limbic Access and the Wysa DRA could potentially save time during initial assessments; data to support Limbic's claims include data derived from a peer-reviewed comparative study. Although time savings are uncertain, EAG exploratory economic analysis results suggested that only short time savings would be required to generate notional cost savings to the NHS that offset any costs incurred through the introduction of digital front door technologies.

It was not necessary to develop an economic model due to the short evaluation time horizon and the focus on process outcomes, for which evidence is currently limited.

Results of the gap analysis

The EAG has identified gaps between the available evidence and the evidence needed to address the outcomes listed in the NICE scope. The EAG highlights that there is no robust evidence to support the use of Censeo Digital and AskFirst as digital front door technologies for NHS Talking Therapies.

Study population demographic data were rarely reported; the extent to which reported differences in outcomes were driven by patient baseline characteristics was unclear. Each digital front door technology can be customised; it was not clear whether, or how, any of the assessed digital front door technologies that were described in the evidence base were customised. In addition, the EAG highlights that the two peer-reviewed Limbic Access studies relate to the Class I version of Limbic Access; this version has now been superseded by the Class IIa version. Interim analysis results from an ongoing RCT, an ongoing observational study, ongoing service evaluations and data externally audited by the Medicines and Healthcare products Regulatory Agency suggest that outcomes are at least comparable between the two versions; the EAG consider it is important that data are continuously collected to assess whether later versions of a technology deliver the same or better benefits to NHS staff and patients. Comparator data are limited and very few studies provided robust evidence for the comparison of a digital front door technology versus an individual standard referral method; more comparative data are required. Published evidence was not available for most of the outcomes listed in the NICE scope. Further research is required to confirm under what circumstances time savings may arise during initial clinical assessments, their magnitude and if there is any subsequent impact on NHS Talking Therapies service provision.

1 DECISION PROBLEM

Table 1 details the NICE scope[1] for this EVA, defined per element of assessment.

Table 1 Summary of NICE scope and decision problem addressed by the EAG

Decision problem	Final scope issued by NICE	EAG comment
Scope of the assessment	Does the use of digital front door technologies to pre-assess people before assessment for NHS Talking Therapies have the potential to be effective and offer value for money for the NHS?	As per NICE scope[1]
Population	People over the age of 16 years with suspected common mental health conditions specified in the NHS Talking Therapies for anxiety and depression manual (2024)[2]	As per NICE scope[1]
Proposed technologies	Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies, which may include: • Limbic Access (Limbic) • Wysa Digital Referral Assistant (DRA) (Wysa) • Censeo Digital (Psyomics) • AskFirst (Sensely)	Limbic Access: information provided in response to RFIs and data are publicly available from multiple sources Wysa DRA: information provided in response to RFIs Censeo Digital; RFI response indicated that live services were not currently running for NHS Talking Therapies and no data for NHS Talking Therapies are currently available AskFirst: no response to RFI and no relevant data are publicly available
Comparator	Pre-assessment for NHS Talking Therapies without using a digital front door technology	As per NICE scope[1]
Healthcare setting	NHS Talking Therapies services, delivered in community care, home-based care, primary care or secondary care and virtual/remote	As per NICE scope[1]
Outcomes	The outcome measures for consideration may include: **Accuracy and acceptability (AA)** • AA1: Quality and accuracy of the data collected by digital front door technologies • AA2: Accuracy of clinical assessment for NHS Talking Therapies • AA3: Completion rate of pre-assessment when using digital front door technologies • AA4: Inaccessibility to digital front door technology • AA5: Healthcare professional user acceptability of digital front door technologies	As per NICE scope[1] There are no universally accepted definitions of either the quality or accuracy of data collected via digital front door technologies

Decision problem	Final scope issued by NICE	EAG comment
	Resource and system impact (RSI) • RSI1: Administrative resource impact • RSI2: Time taken to review data collected by digital front door technologies • RSI3: Time taken to complete clinical assessment • RSI4: Time saved for the clinician during clinical assessment	
	Service user reported outcomes (PRO) for consideration may include: • PRO1: Ease of access and usability • PRO2: Information clarity and relevance • PRO3: Comfort and privacy • PRO4: Overall satisfaction with pre-assessment process	As per NICE scope[1]
	Costs will be considered from an NHS and Personal Social Services perspective. **Costs for consideration should include:** • Costs of the technologies • Initial setup and integration costs • Operational costs (if falling on the NHS rather than the technology provider) such as IT support for healthcare professionals and service users and cybersecurity • Training costs • Cost of promotion • Costs of applying digital clinical safety assurance DCB0129[3]	As per NICE scope[1]
Time horizon	The time horizon for estimating the efficacy and value for money should be from referral (any route) until the end of the NHS Talking Therapies assessment only	As per NICE scope[1]

DRA=Digital Referral Assistant; EAG=External Assessment Group; IT=information technology; NICE=National Institute for Health and Care Excellence; RFI=request for information

2 OVERVIEW OF THE TECHNOLOGY

A summary of the key features of Limbic Access, Wysa Digital Referral Assistant (DRA), Censeo Digital and AskFirst is presented in Table 1. As a Class IIa device, Limbic Access is the only product that has been externally audited by the Medicines and Healthcare products Regulatory Agency (MHRA). Further information about these four digital front door technologies is presented in Appendix 1 (Section 13.1).

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Table 2 Summary information about the included digital front door technologies

Feature	Limbic Access (Limbic)	Wysa DRA (Wysa)	Censeo Digital (Psyomics)	AskFirst (Sensely)
Intended use	AI-chatbot for conversational referral and clinical decision support	AI-supported e-triage tool (chatbot)	Adaptive questionnaire which creates personalised question pathway	Online consultation platform developed in partnership with the NHS
CE Mark	Class IIa	Class I	Class I	Information not found
NHS integration	Interoperable with any cloud-based EHR system, meaning data can be immediately accessed from or imported into the patient record system	Transfers data from the Wysa referral conversation to the NHS Talking Therapies EHR system, via PRISM APIs; clinical contact is created directly within the EHR, where data fields exist	Integrates with NHS systems via API to manage both GP and SPA referrals	Integrates with GP IT systems and 111 service providers
Description	• Streamlines referral and triage process (e.g., triages mild, moderate, and severe cases of depression) • As a minimum, information is collected relating to: ○ Eligibility criteria ○ Contact details ○ Demographic information • Additional clinical information collected includes information about the patient's presenting symptoms (MDS), such as the PHQ-9, GAD-7, WSAS and a selection of additional screening questions • Generates a clinical report with presenting concerns, risk levels, clinical notes, assessment scores, disorder-specific measures and diagnoses predictors to	• Collects data based on questions from the referral form for NHS Talking Therapies services: ○ Referral: demographic questions ○ Clinical: GAD-7, PHQ-9 and WSAS as default, along with all other MDS The referral questions are asked initially and if referral accepted, clinical are asked • Provides immediate alternative signposting to patients who are not eligible for an NHS Talking Therapies clinical assessment because they do not meet the age criteria or because their GP location is not within the services' catchment area • Flags cases based on	• Web-based non-diagnostic mental health platform that guides users through a structured assessment process through an adaptive questionnaire (assesses 15 common mental health conditions with a bank of >1200 questions) • Gathers pre-appointment information into a clinical report which provides: ○ Condition likelihood including severity, duration and impact on functioning across 15 condition areas (including depression, anxiety, bipolar, PTSD) ○ Triage priority: flags potentially urgent cases, facilitating rapid referral for patients in need of secondary care or	• Triage function with symptom checking and routing to pathways like NHS Talking Therapies • Self-assessments including PHQ-9 and GAD-7

Feature	Limbic Access (Limbic)	Wysa DRA (Wysa)	Censeo Digital (Psyomics)	AskFirst (Sensely)
	aid clinician's assessment • Captures all activity in a dashboard with visibility into engagement, demographics, referrals, conversion rates, and staff hours saved	criteria set by the service; each case is reviewed by a clinician • Provides report for clinician, with summary	higher-intensive services	
Risk flagging	Sends an alert to clinical staff so they can take appropriate action	Self-harm or domestic violence risk identified in free text using a combination of NLP techniques and rule-based matching to risk-related phrases	Flags urgent triage needs (e.g., suicidality, self-harm, impulsive behaviours, severe trauma)	Information not found
Additional features (beyond the scope of this EVA)	Suggests possible problem descriptors based on information collected via ADSMs	Users engage with mindful exercises as the patient completes the e-triage	Presents the likelihood of mental health conditions	Remote monitoring
Training for staff required	Training is typically run as 3 x 1-hour sessions	Requires no more than 30 minutes of training for staff	Most users can become proficient with the system after a short 30–60 minute training session	
Usage within NHS	Used by ~40% NHS Talking Therapies	Live in several NHS Talking Therapies Services including Dorset, Coventry and Warwickshire, and Lancashire and South Cumbria	Contracted with four NHS organisations; anticipated that the technology will be used in at least three NHS Talking Therapies by the end of 2025	Information not found

ADSM=Anxiety Disorder Specific Measure ; AI=artificial intelligence; API=application programming interface; CBT=cognitive behavioural therapy; EHR=electronic health record; GAD-7=General Anxiety Disorder-7; EAG=External Assessment Group; GP=general practitioner; IT=information technology; MDS=minimum data set; NHS=National Health Service; NICE=National Institute for Health and Care Excellence; NLP=natural language processing; PHQ-9=Patient Health Questionnaire-9; PTSD=post-traumatic stress disorder; RFI=requests for information; SPA=Single Point of Access; WSAS=Work and Social Adjustment Scale

Source: NICE scope,[1] NICE scoping workshop, NICE RFI responses;[4-6] company's digital front door technology websites;[7,8] Wysa online webinar;[9] Rollwage 2023[10]

3 CLINICAL CONTEXT

The target population for this assessment is people over the age of 16 years with suspected common mental health conditions, as specified in the NHS Talking Therapies for anxiety and depression manual (2024).[11]

In England, every week, 1 in 6 people experience a common mental health condition (for example, anxiety and depression).[12] The NHS Talking Therapies for anxiety and depression programme (formerly known as Improving Access to Psychological Therapies, IAPT) was developed to improve the delivery of, and access to, evidence-based, NICE recommended, psychological therapies for depression and anxiety disorders within the NHS. In this report, NHS Talking Therapies for anxiety and depression programme is referred to as NHS Talking Therapies. In 2023/24, there were 1.83 million referrals to NHS Talking Therapies (an increase of 4% from 1.76 million in 2022/23).[2] NHS Talking Therapies offer a range of interventions including cognitive-behavioural therapy (CBT), counselling for depression, and guided self-help; these are delivered in a variety of different formats.

Digital front door technologies are a new way of collecting NHS Talking Therapies referral information. The digital front door technologies automatically populate current patient management software systems (e.g., iaptus [Improving Access to Psychological Therapies User System], primary care management information system [PCMIS], or an NHS Talking Therapies provider's bespoke patient management system) with referral information.

3.1 Clinical pathway

In the NHS Talking Therapies manual,[11] the NHS Talking Therapies services pathway is divided into the following five steps:

1. presentation (person presents in community, primary or secondary care)
2. referral (referral or self-referral made to NHS Talking Therapies service)
3. pathway starts (NHS Talking Therapies services receives the referral)
4. assessment (a person-centred assessment that covers the person's health problem)
5. next steps (person starts a course of treatment or leaves the pathway)

For this EVA, the EAG has assumed that the pre-assessment referral practice for NHS Talking Therapies starts with presentation and ends with assessment (i.e., steps 1 to 4). To better understand the steps in the pathway, the EAG asked six NICE Specialist Committee Members (SCMs) and two stakeholders (i.e., eight experts) with knowledge of NHS Talking Therapiesto explain i) how referrals to NHS Talking Therapies were processed and ii) to what extent

referral pathways varied between NHS Talking Therapies service providers (Section 3.1.1 to 3.1.3).

3.1.1 Referrals

Referrals to NHS Talking Therapies may arrive via several different routes, including primary care, secondary care, community care or self-referral. Referral methods include a paper form, a letter, telephone, an email, an online form or via a digital front door technology. Referrals to NHS Talking Therapies may be initiated by a patient or a health professional. However, patient and professional referral methods may not always be distinct; in some cases, a professional may suggest that a patient self-refers and provide the patient with information about the different self-referral methods that are available. In other cases, a professional may sit with a patient and help the patient complete the self-referral process. Expert advice was that although all NHS Talking Therapies can be accessed by several different methods and all referrals include patient information, the amount and type of information collected vary between referral methods.

3.1.2 Pre-assessment: assessment of risk, eligibility and suitability

In this EAG report, the term pre-assessment refers to determining a patient's risk, eligibility and/or suitability for NHS Talking Therapies; this is also known as triage or screening. Pre-assessments are carried out using patient referral information.

Assessment of patient risk and safeguarding (including self-harm or suicide, or harm to others) is aways prioritised. The assessment of risk is based on the patient's presenting problems and medical history. If there are any concerns about the degree of patient risk, the patient is contacted by a health professional to ensure the patient's safety, to collect further information from the patient (if required) and to direct the patient to an appropriate service. Patients who are perceived to be at no risk, or those with a risk that can be managed within NHS Talking Therapies, are assessed for eligibility and suitability for NHS Talking Therapies. Patients who are perceived to be at high risk may be instructed to contact NHS crisis services.

Assessment of eligibility is based on:

- **GP location**: the patient's GP should usually be based in the region covered by the NHS Talking Therapies service, although NHS Talking Therapies are also available to patients registered with virtual GPs and/or those choosing to refer to a specific NHS Talking Therapies service
- **Age**: some services offer treatment to young people aged between 16 and 17 years old, others do not; children and young people who are not able to access adult NHS Talking Therapies are able to obtain support from their local children and young people's mental health service

The digital front door technologies can be set up to automatically signpost ineligible patients to other services based on explicitly stated criteria; for those who use static online forms, signposting information is available on NHS Talking Therapies provider websites.

Assessment of suitability is carried out to determine whether a patient is suitable for NHS Talking Therapies and largely relies on the referral information provided by the patient and professional judgement. For example, generally, an individual who is dependent on drugs or alcohol may not be suitable for NHS Talking Therapies and would be directed towards NHS drugs and alcohol support services. However, if an individual is using drugs or alcohol as a short-term strategy to deal with psychological issues, then it may be possible for NHS Talking Therapies to work with them to resolve the psychological issues. Another example could be patients receiving treatment in secondary care. These patients are generally not suitable for NHS Talking Therapies; however, a patient with a long-standing diagnosis of, for example, bipolar affective disorder, who has been receiving secondary care for several years to manage their medication and currently needs help addressing their anxiety, would be suitable for NHS Talking Therapies.

Patients who are ineligible or unsuitable for NHS Talking Therapies are not offered an initial clinical assessment; patients (and their GPs) are sent a letter explaining why the referral was not accepted. Referrals to NHS Talking Therapies may be prioritised (e.g. ex-armed forces or pre- or post-natal patients) and these patients may have their initial clinical assessments expedited.

Expert advice to the EAG was that pre-assessment varied between NHS Talking Therapies providers; three examples of pre-assessment are described in the following bullet points:

- the patient is contacted and asked to book an initial clinical assessment; risk, eligibility and suitability assessments are undertaken during this initial clinical assessment
- the eligibility and suitability assessment is undertaken by an administrator who passes the referral on to a health professional if they identify any red flags (e.g., urgent care may be required), otherwise the patient is contacted and asked to book an initial clinical assessment
- a health professional assesses the risk, eligibility and suitability of the patient and the patient is contacted to book (or not) an initial clinical assessment.

3.1.3 Initial clinical assessment

All patients who are eligible and suitable for NHS Talking Therapies are offered an initial clinical assessment. These assessments are often conducted via telephone and generally last between 45 and 60 minutes. The initial clinical assessment typically consists of the following components:

- verification of referral information
- screening questions as specified in the NHS Talking Therapies manual[11]
- collection of health questionnaire and outcome measure data (e.g., Patient Health Questionnaire-9 [PHQ-9], General Anxiety Disorder-7 [GAD-7], Anxiety Disorder Specific Measures [ADSMs]) (if not collected prior to assessment)
- discussion of presenting problem, circumstances and therapy objectives
- identification of problem descriptors, formulation of treatment and safety plan

If clinical assessments take place more than 2 weeks after receipt of any previously collected PHQ-9 and GAD-7 data, these data should be collected again. At the end of the initial clinical assessment, the health professional may review and discuss the referral with a senior colleague before deciding whether a NICE recommended NHS Talking Therapies treatment should be recommended or if the patient should be referred to an alternative service; in some cases, a second clinical assessment may be required.

3.2 Special considerations, including issues related to equality

Access to NHS Talking Therapies via a digital front door technology requires access to the internet; therefore, individuals on low income who do not have access to a computer, smart phone or laptop, those in rural areas who face connectivity issues, older adults or those with low digital literacy may face barriers to using digital front door technologies to access NHS Talking Therapies. Further, people with low motivation or cognitive challenges may disengage from digital platforms before their referral is complete.

Access to NHS Talking Therapies via digital front door technologies may be problematic for people with visual or cognitive impairment and/or whose who are unable to read or understand information presented in English (e.g., those for whom English is not their first language). There may be issues for individuals from linguistically diverse backgrounds as translations may not be appropriate or content culturally relevant. Further, artificial intelligence (AI)-based chatbots may be unable to interpret information provided by individuals with different linguistic backgrounds, leading to miscommunication.

Marginalised populations, including those experiencing domestic violence or housing insecurity, may avoid using digital services due to concerns over confidentiality.

The EAG highlights that the potential equality issues raised are not specific to digital front door technologies; all digital referral methods (static online form, email) to NHS Talking Therapies are associated with these concerns. However, if NHS Talking Therapies providers continue to provide multiple referral methods to access NHS Talking Therapies, it is unlikely that people attempting to access NHS Talking Therapies will be disadvantaged by the introduction of a digital front door technology.

4 CLINICAL EVIDENCE SELECTION

The EAG's systematic literature review (SLR) protocol[13] is registered with PROSPERO (registration number: CRD42025634844), an international database of prospectively registered systematic reviews in health and social care.[14]

4.1.1 Evidence search strategies and study selection

The EAG search strategies were those devised by NICE during the initial scoping phase, with the addition of some EAG amendments. The search strategies used relevant search terms, combining indexed keywords and free-text terms, and were adapted to the configuration of each database. No date or publication status (published, unpublished, in-press, and in-progress) limits were applied. The searches were limited to English language studies. A list of the electronic databases searched by the EAG is provided in Appendix 2 (Section 13.2) and the EAG search strategies are presented in Appendix 3 (Sections 13.3).

EAG SLR inclusion and exclusion criteria are presented in Table 3. References were identified via electronic database searches and then imported into EndNote 21. References were auto de-duplicated and any references that were clearly irrelevant were excluded by one reviewer (YD). The remaining references were then uploaded to Rayyan and, as EndNote does not always identify all duplicate references, further manual de-duplication was conducted. Evidence from other sources (Appendix 2, Table 24) were also uploaded into Rayyan and de-duplicated. The titles and abstracts of all potentially relevant references were screened by at least two reviewers (NF, SBr and YD). Discrepancies were resolved by discussion between all three reviewers.

Table 3 Inclusion and exclusion criteria

Parameter	Included	Excluded
Population	The population is people >16 years with suspected common mental health conditions as specified in the NHS Talking Therapies for anxiety and depression manual.[11]	People aged ≤16 years People without suspected common mental health conditions
Intervention	Digital front door technologies identified in the NICE scope:[1] • Limbic Access • Wysa DRA • Censeo Digital • AskFirst	Any digital front door technology not listed in the NICE scope[1]

Parameter	Included	Excluded
Comparator	Current NHS pre-assessment referral practice for NHS Talking Therapies that does not include digital front door technologies: • self-referral • community or voluntary care referral • primary care referral • secondary care referral (including both mental health and physical healthcare services)	Any other referral routes/methods
Outcomes	Outcomes that occur between referral (any route) and the end of the initial one-to-one person-centred NHS Talking Therapies clinical assessment (see Table 1)	Outcomes occurring following the end of the initial one-to-one person-centred clinical assessment
Studies	Any study type including, but not limited to: • randomised controlled trial • real-world evidence (including quasi-experimental and observation studies and benchmarking against NHS Digital published metrics) • surveys • qualitative studies • evidence based reviews • letters and opinions identifying potential benefits or harms • evidence provided by companies	Studies that only presented anecdotal evidence were excluded
Time horizon	Time period between referral (any route) until the end of the NHS Talking Therapies assessment only	Time period following the end of the initial clinical assessment

DRA=Digital Referral Assistant
Source: EAG protocol[13]

Data were extracted from included studies by one reviewer (NF) into bespoke tables, and data from at least 20% of included studies were checked by another reviewer (JG).

4.2 Overview of included and excluded studies

For simplicity, in this EAG report, all reports and publications are referred to as studies.

4.2.1 Included evidence sourced from the electronic database searches

The electronic database searches yielded 1174 results. Following initial screening by one reviewer (YD), a total of 306 records were uploaded to Rayyan and, after de-duplication, 292 unique records remained. An additional 126 records from other sources were also uploaded into Rayyan and de-duplicated. In total, titles and abstracts of 418 references were screened. Following screening, inclusion/exclusion criteria were applied to 17 full-text publications. In total, 4 studies[10,15-17] were eligible for inclusion in the EAG SLR (including 2 ongoing studies[16,17]).

4.2.2 Additional evidence (not identified by electronic database searches)

The EAG identified evidence from other sources by searching company websites and reference lists of included studies. In addition, Limbic, Wysa and Psyomics provided evidence for their respective digital front door technologies in response to NICE and EAG RFIs.[4-6,18-21] Following screening, inclusion/exclusion criteria were applied to 23 full-text publications. In total, 13 studies identified from other sources were eligible for inclusion in the EAG SLR (including 2 ongoing studies identified from the Limbic NICE RFI[4] and the Limbic EAG RFI[18]).

4.2.3 Excluded studies

Information about the 13 studies[22-34] identified via electronic databases that were excluded at the full-text stage is provided in Appendix 4 (Table 25). Information about the 10 studies[5,19,35-42] identified via other sources that were excluded at the full-text stage is also provided in Appendix 4 (Table 25). The reasons for exclusion were: wrong technology (n=11), duplicate data (n=5), anecdotal evidence (n=3), wrong outcome (n=2) and wrong population (n=2).

4.3 Landscape of the included evidence base

A summary of the landscape of the evidence base is provided in Table 4. Overall, the EAG identified 13 studies[4,6,10,15,18,20,21,43-48] that provided outcome data relevant to this EVA; 10 studies[4,10,15,18,43-48] reported Limbic Access outcome data, and 3 studies[6,20,21] reported Wysa DRA outcome data.

Table 4 includes 17 relevant studies;[4,6,10,15-18,20,21,43-50] however, 4 of these[16,17,49,50] are ongoing studies (Limbic: n=3; Wysa: n=1) and no outcome data were available for extraction. For a discussion of ongoing studies see Section 9.4; the EAG has included details of these studies as they may provide useful information in the future.

The EAG searched for information about Censeo Digital and AskFirst; no studies were identified. However, Psyomics provided information about Censeo Digital in response to NICE and EAG RFIs.[5,19] The information provided by Psyomics[5,19] relates to accessing secondary care and not to accessing NHS Talking Therapies and therefore this information has not been included in the main body of this report. However, a summary of the information provided by Psyomics is provided in Appendix 5 (Section 13.5). Sensely did not respond to NICE or EAG requests for information about AskFirst.

Table 4 Landscape of the evidence base

Source	N	Included studies
Studies with relevant outcome measures		
Electronic database searches	2	• Rollwage 2023[10,15] • Habicht 2024[9]
Other evidence sources	2	• Limbic Research 2024[44] • Surrey and Borders Partnership NHS Foundation Trust 2022 (Mind Matters Validation Study)[45]
Limbic	6	• NICE RFI response[4] • EAG RFI response[18] • Limbic 2022 useability Formative Test Report[47] • Limbic 2022 useability Summative Test Report[48] • Limbic 2024 Clinical Preparedness Study[43] • Limbic 2024 Patient Feedback Report[46]
Wysa	3	• NICE RFI response[6] • Additional information[20] • EAG RFI response[21]
Psyomics	0	• The company provided responses to NICE[5] and EAG[19] RFIs; however, all provided data related to secondary care and not to NHS Talking Therapies
AskFirst	0	• No response to NICE RFI and no studies identified by EAG searches
Total	**13**	
Ongoing studies (no data for outcome measures)		
Electronic database searches	2	• Two ongoing studies[16,17] (one[16] relating to Limbic Access and one[17] relating to Wysa DRA)*
Limbic	2	• Two ongoing studies[49,50]*
Total	**4**	

*Some data from these studies were included in the Limbic RFI responses[4,18]
EAG=External Assessment Group; NICE=National Institute for Health and Care Excellence; N=number; RFI=request for information

5 CLINICAL EVIDENCE REVIEW

The EAG identified 13 studies[4,6,10,15,18,20,21,43-48] that included relevant data; 10 studies[4,10,15,18,43,45-48] reported evidence for Limbic Access and 3 studies[6,20,21] reported evidence for Wysa DRA (Table 4). An overview of the study design and characteristics of the included studies is provided in Table 5. Information regarding the 5 ongoing studies[16,17,34,49,50] is provided in Section 9.4.

Table 5 Studies included in the EAG SLR: study design, characteristics and outcomes

Reference	Study design	Intervention/ comparator	Outcomes reported	EVA outcomes addressed	EAG comment
Rollwage 2023[10]	Quasi-experimental study using real-world data from patients from 9 NHS Talking Therapies services provided by Everyturn Mental Health N=64,862 Qualitative analysis with ex-patients (thematic analysis used to analyse feedback) N=32	Limbic Access (n=21,568) vs any other method of referral (n=43,294)	• Assessment duration • Wait time for clinical assessment • Wait time for treatment • Dropout rate • Change in allocated treatment level • Recovery rate • User reasons to provide clinical information	• RSI3: Time taken to complete clinical assessment • RSI4: Time saved for the clinician during clinical assessment • PRO1: Ease of access and usability • PRO3: Comfort and privacy	Data from November 2021 and August 2022 Patients referred via Limbic Access showed slightly lower severity (mean step of care=1.5) than those referred through other pathways (mean step of care=1.69) indicating the need to control for severity in analyses It is unclear if the ex-patients included in qualitative analysis are the same patients included in the Limbic Formative[47] and Summative[48] Test Reports
Habicht 2024[15]	Multisite real-world retrospective observational study from 28 different NHS Talking Therapies services across England with data analysed quantitatively (referrals) and qualitatively (thematic analysis-powered natural language processing methods to analyse feedback given by	Limbic Access vs other referral methods (self-referrals, GP referrals, etc) with an online webform	• Total number of referrals • Patient feedback	• AA4: Inaccessibility to digital front door technologies • PRO1: Ease of access and usability • PRO2: Information clarity and relevance • PRO3: Comfort and privacy • PRO4: Overall satisfaction with pre-assessment process	The time periods covered by the study are unclear but appear to have been between October 2020 and March 2022, depending on the service Calculated the total number of referrals for each service (with and without Limbic Access) in the pre- and post- implementation of Limbic Access. Sensitivity analyses conducted comparing Limbic Access referrals vs other self-referrals only To mitigate potential confounding factors, additional sensitivity analyses conducted matching services on the service quality (reliable recovery rates and wait

Reference	Study design	Intervention/ comparator	Outcomes reported	EVA outcomes addressed	EAG comment
	patients who used Limbic Access) N=~129,400 (quantitative analysis) N= 42,332 (qualitative analysis)				times) and demographic composition of referrals during the pre-period
Surrey and Borders Partnership NHS Foundation Trust 2022 (Mind Matters Validation Study)[45]	Validation study (analysis of real-world data from admin staff and PWPs working at Mind Matters and evaluation of responses from Limbic Access users, i.e. those who self-referred to NHS Talking Therapies)	Limbic Access vs benchmarked data (i.e., pre/post implementation)	Metrics for quantitative analysis: • Use of administration time • Out of hours access/service • Access to the service • Patient experience • Processes • Quality of work of staff • Responsiveness for early stages of risk • Auto screening in a safe way (underage to suitable providers) • Duration of assessments Metrics for qualitative analysis: • Administrative time/tasks • Save time • Out of area referrals • Unsuitable referrals • Referrals with missing	• AA4: Inaccessibility to digital front door technologies • AA5: Healthcare professional acceptability of digital front door technologies • RSI1: Administrative resource impact • RSI2: Time taken to review data collected by digital front door technologies • RSI3: Time taken to complete clinical assessment • RSI4: Time saved for the clinician during clinical assessment • PRO4: Overall satisfaction with pre-assessment process	Comparison of self-referral data from July 2020-June 2021 and July 2021-June 2022 Qualitative data from administration staff (N=3) and a PWP (N=1) working at Mind Matters (4 July 2022), quantitative data from a staff survey and evaluation of responses from Limbic Access users, i.e. those who self-referred to NHS Talking Therapies; staff surveys were conducted in 2021 (roles of participants and exact date not provided) and 22 July 2022 (one survey for administration staff and one survey for PWPs) – the number of participants included in the surveys is not reported Originally found from grey literature searching; document provided by Limbic via NICE

Reference	Study design	Intervention/ comparator	Outcomes reported	EVA outcomes addressed	EAG comment
			data • Administrative process for referrals • Comprehensiveness vs previous referral form • Helpfulness for the Admin team and Step 2 team • Time for other tasks • Sense of wellbeing		
Limbic 2022 Usability Testing Formative Test Report[47]	Formative evaluation carried out for Limbic Access (V3) to support design and development processes N=16 patients receiving therapy N=15 mental health clinicians across 10 different cities in the United Kingdom and Ireland	Limbic Access (demo/ prototype)	• User experience (patients who used Limbic Access) • Clinician experience	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA4: Inaccessibility to digital front door technologies • RSI4: Time saved for the clinician during clinical assessment • PRO1: Ease of access and usability • PRO2: Information clarity and relevance • PRO3: Comfort and privacy • PRO4: Overall satisfaction with pre-assessment process	Patients were asked to imagine the situation of self-referring themselves for mental health care treatment, to use the Limbic Access demo to accomplish this task and then asked to complete an online survey Qualitative interviews were conducted via Zoom with practising clinicians who screened and assessed new patients and treated them in mental health therapy sessions during their day-to-day work
Limbic 2022 Usability Testing	Summative evaluation carried out for Limbic Access (V3) to	Limbic Access	• Accuracy for primary presenting problem • Accuracy for differential	• AA2: Accuracy of clinical assessment for NHS Talking Therapies • AA5: Healthcare	The clinician online study examined the impact of administering ADSMs on clinician judgment and consisted of multiple stages including Limbic

Reference	Study design	Intervention/ comparator	Outcomes reported	EVA outcomes addressed	EAG comment
Summative Test Report[48]	support design and development processes N=40 mental health clinicians who screen new patient referrals on a daily basis N=16 patients currently receiving therapy		diagnoses • Clinician feedback • User experience (Patients who used Limbic Access)	professional acceptability of digital front door technologies • PRO1: Ease of access and usability • PRO2: Information clarity and relevance • PRO3: Comfort and privacy • PRO4: Overall satisfaction with pre-assessment process	Access training, familiarisation with referral output, a quiz (and further training if required), presentation of 40 example patient referrals [derived from Limbic Access (V2)] and 10 subjective questions. A key aim was to test accuracy and bias. To perform a final evaluation of the user experience, patients currently receiving therapy who had never used Limbic Access were recruited to test the finalised version of Limbic Access (V3) and answered a subsequent online survey on their experience of it
Limbic 2024 Clinical Preparedness Study[43]	Short online survey of PWPs from NHS services that use Limbic Access N=74	Limbic Access vs other referrals .	• Clinician wellbeing • Clinician emotional strain • Clinician task performance on patient assessments • Clinician cognitive load and task demands on patient assessments	• AA5: Healthcare professional acceptability of digital front door technologies	Asked clinicians about their mental state before and during patient assessments that either: 1. Did have information from Limbic Access (i.e., the patient self-referred through Limbic Access), or 2. Did not have information from Limbic Access (i.e., the patient referred via some other method)
Limbic 2024 Patient Feedback Report[46]	Evaluation of feedback responses from users of Limbic Access N=17,931	Limbic Access	• Patient feedback response (Limbic Access)	• PRO4: Overall satisfaction with pre-assessment process	Users of Limbic Access who provided feedback by rating their overall experience with the referral process The feedback was categorised as positive (indicating a helpful process), neutral (indicating a need for more information or support), or negative (indicating an unhelpful

Reference	Study design	Intervention/ comparator	Outcomes reported	EVA outcomes addressed	EAG comment
					process)
Limbic Research 2024[44]	Three model training studies, N=21,725: • Historical dataset, n=18,278 • Prospective dataset, n=2,557 • Live dataset, n=890	Limbic Access	• Accuracy of the algorithm to correctly administer the relevant ADSM for a diagnosis, if that diagnosis was present	• AA1: Quality and accuracy of the data collected using digital front door technologies	The machine model transforms inputs into a set of probabilities across a Ranked Consideration Set over 8 diagnostic categories. Limbic Access then administers additional outcome measures, known as Anxiety Disorder Specific Measures (ADSMs), corresponding to the top 2 diagnostic categories in the Ranked Consideration set. Accuracy measured by percentage of times with which the actual diagnosis is within the top two problems in Ranked Consideration Set selected and ranked by the machine learning model
Limbic NICE RFI response[4]	NICE RFI response, various sources of information including published data	Limbic Access data compared with services not using Limbic Access	• Patient experience • Completion rates • Access to services (referrals) • Wait times for assessment • Dropout rates • Reliable recovery rates • Clinician time saved • Change in treatment level • Recovery rate • Clinician preparedness • Clinician well-being • Clinician cognitive load	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA2: Accuracy of clinical assessment for NHS Talking Therapies • AA3: Completion rate of pre-assessment when using digital front door technologies • AA4: Inaccessibility to digital front door technologies • AA5: Healthcare professional acceptability of digital	Includes unpublished data and data from peer-reviewed studies included[10,15] and excluded[30] from the EAG SLR; includes data from other sources[43] included in the EAG SLR

Reference	Study design	Intervention/ comparator	Outcomes reported	EVA outcomes addressed	EAG comment
			• Clinician task performance • Costs including cost per recovery • User time taken to complete referral • Patient feedback	front door technologies* • RSI4: Time saved for the clinician during clinical assessment • PRO1: Ease of access and usability** • PRO4: Overall satisfaction with pre-assessment process	
Limbic EAG RFI response[18]	Additional information requested by the EAG	Limbic Access data compared with services not using Limbic Access	• Referral data • NHS Talking Therapies staff time • AA2: Accuracy of clinical assessment for NHS Talking Therapies • Accuracy • Costs	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA2: Accuracy of clinical assessment for NHS Talking Therapies • AA3: Completion rate of pre-assessment when using digital front door technologies • AA5: Healthcare professional acceptability of digital front door technologies • RSI2: Time taken to review data collected by digital front door technologies • RSI3: Time taken to complete clinical assessment • RSI4: Time saved for the clinician during	Includes data from peer-reviewed studies[10,15] included in the EAG SLR; also includes data from Summative Test Report[48] included in the EAG SLR as well as preliminary data from the ongoing NCT05495126 trial (N=5030),[16] observational study registered as NHS portfolio study (N=3715),[50] an unpublished clinical survey study (N=82) and data used as part of Limbic Access' Class IIa certification audit (N=46,413 and N=773)

Reference	Study design	Intervention/ comparator	Outcomes reported	EVA outcomes addressed	EAG comment
				clinical assessment	
Wysa NICE RFI response[6]	NICE RFI response, various sources of information, none published	Wysa DRA	• Referral data including completion rate • Patient satisfaction • Time saving • Costs	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA3: Completion rate of pre-assessment when using digital front door technologies • AA4: Inaccessibility to digital front door technologies • RSI4: Time saved for the clinician during clinical assessment • PRO4: Overall satisfaction with pre-assessment process	All real-world data from NHS Talking Therapies, no data from peer-reviewed published research "Data available from the 1st August 2022 to date" [17 October 2024]; includes data from N=117,769 referrals
Wysa Additional Supporting Evidence[20]	Additional information	Wysa DRA	• Quality and accuracy measured by type and length of assessment appointments • Referral completion rates • Clinician feedback • Resource and system impact • Patient feedback - Ease of access and usability • Costs	• AA1: Quality and accuracy of the data collected using digital front door technologies • AA3: Completion rate of pre-assessment when using digital front door technologies • AA5: Healthcare professional acceptability of digital front door technologies • RSI3: Time taken to complete clinical assessment	All real-world data from NHS Talking Therapies, no data from peer-reviewed published research Data available from going live up to 10 December 2024; includes referral data from N=160,691 iaptus patient records

Reference	Study design	Intervention/ comparator	Outcomes reported	EVA outcomes addressed	EAG comment
				• PRO4: Overall satisfaction with pre-assessment process	
Wysa EAG RFI response[21]	Additional information requested by the EAG	Wysa DRA	• Referral data • NHS Talking Therapies staff time • Analytics data (data from live analytics dashboard via Tableau) • Patient feedback	• AA1: Quality and accuracy of the data collected using digital front door technologies† • RSI3: Time taken to complete clinical assessment†† • RSI4: Time saved for the clinician during clinical assessment††† • PRO4: Overall satisfaction with pre-assessment process	All real-world data from NHS Talking Therapies, no data from peer-reviewed published research Data available from going live up to 31 December 2024; includes referral data from N=186,179

* Same data as reported in Limbic 2024 Clinical Preparedness Study[43]
** Same data as reported in Habicht 2024[15]
† The EAG consider this outcome is more relevant to outcome PRO4: Overall satisfaction with pre-assessment process
†† Response refers to Wysa Additional Supporting Evidence[20]
††† Same data as reported in Wysa NICE RFI response[6]
ADSM=Anxiety Disorder Specific Measure; DRA=Digital Referral Assistant; EAG=External Assessment Group; GP=general practitioner; iaptus= Improving Access to Psychological Therapies User System; NICE=National Institute for Health and Care Excellence; PWP=Psychological Wellbeing Practitioners; RFI=request for information; SLR=systematic literature review

5.1 Overview of methodologies of all included studies

An overview of the methodologies of all 13 included studies[4,6,10,15,18,20,21,43-48] providing outcome data is presented in Sections 5.1.1 to 5.1.3. All relevant studies had some methodological strengths and limitations (see Section 5.1.4).

5.1.1 Study design, intervention and comparator

Limbic Access

With the exception of some data reported in the Limbic EAG RFI response[18] and testing data reported by Limbic Research,[44] all data for Limbic Access relate to the Class I device; Class IIa is the current version of Limbic Access used to refer patients to NHS Talking Therapies. The company reports that, in addition to the functionality of the Class I device, the more recently available Class IIa device provides artificial intelligence (AI)-driven ADSMs.[18] Where data are available for the Class IIa device,[18,44] these have been compared with Class I device data and not versus alternative methods of referral to NHS Talking Therapies.

Only three Limbic Access studies,[10,15,45] including the two peer-reviewed studies,[10,15] compared Limbic Access versus alternative methods of referral to NHS Talking Therapies, i.e., versus any other referral method[10,45] or versus any other referral method via an online form.[15] Rollwage 2023[10] also made within group comparisons of outcomes between patients who completed the additional clinical information requested by Limbic Access versus those who did not complete this additional information. Analyses presented in these three studies were retrospective; one validation study,[13] one quasi-experimental[10] and one before and after study.[15] In the two peer-reviewed studies,[10,15] attempts were made to control analyses for demographic differences. Rollwage 2023[10] was only able to control for demographic details for the within group comparisons, i.e., Limbic Access patients who completed the additional clinical information, versus those who did not complete the additional information. Rollwage 2023[10] and Habicht 2024[15] controlled for severity of mental health problems and Habicht 2024[15] also controlled for service quality. It was not possible for either of the two peer-reviewed studies[10,15] to adjust for other potentially confounding factors, for example, other changes to NHS Talking Therapies that may have been implemented alongside the introduction of Limbic Access.

The Limbic Formative Test Report[47,48] elicited the views of patients (N=16) and clinicians (N=15) and the Limbic Summative Test Report[15] collected data from patients (N=16) and clinicians (N=40). In the Limbic Formative Test Report[47,48] patients were asked to imagine the situation of self-referring themselves for mental health care treatment, and to use the Limbic Access demo/prototype to accomplish this task; patients were then asked to complete an

online survey. The Limbic Formative Test Report also included a qualitative clinician survey (N=15) that was carried out to gain an in-depth understanding of current clinician workflow associated with screening and assessing new patients and to test whether the inclusion of additional ADSMs, selected by a machine-learning algorithm, helped clinicians to prepare for the initial clinical assessment. These qualitative interviews were conducted via Zoom with practising clinicians who screened and assessed new patients and treated them in mental health therapy sessions during their day-to-day work. The Limbic Summative Test Report[8] included results from a final valuation of user experience. Clinicians were involved in a variety of activities, including Limbic Access training, familiarisation with referral output, a quiz (and further training if required), presentation of 40 example patient referrals and an online survey.

One study[43] consisted of a short online survey of Psychological Wellbeing Practitioners (PWPs) who had used Limbic Access, and another study[46] reported feedback responses from Limbic Access users. One study[44] examined the performance of Limbic Access after an algorithm that administered ADSMs had been added.

Neither the Limbic NICE RFI response[4] nor the Limbic EAG RFI response[18] were research studies, rather they included data from various data sources, including some of the studies[15,43,48,50] described above.

Wysa DRA

All the evidence relating to Wysa DRA was real-world data reported in the Wysa NICE RFI response,[6] Additional Supporting Evidence[20] and the EAG RFI response.[21] No comparative evidence was available.

5.1.2 Participants and setting

Limbic Access

In addition to Limbic NICE RFI[4] and EAG RFI[18] responses, eight research studies provided real-world data from NHS Talking Therapies,[10,15,44,45] NHS Talking Therapies staff[43,47,48] and NHS Talking Therapies patients.[10,15,45-48] There was considerable variation in the numbers of participants in the studies:

- four research studies[10,15,44,46] included real-world data from >17,000 patients (range 17,931 to ~129,400)
- three studies[43,47,48] included data provided by clinicians (range: N=15 to N=74) and two of these studies[10,15] also reported patient data (N=16 in each study)
- the qualitative component of the Mind Matters Validation Study[45] study included only three participants (administrators, N=2 and PWP, N=1), whilst the numbers of participants who provided responses to the 2021 and 2022 staff surveys were not reported.

Qualitative data were also reported by Rollwage 2023[10] from a separate useability study that collected data from ex-patients (N=32); it is unclear if these patients were the same patients that provided the data presented in the Limbic Formative Test report[47] (N=16) and in the Limbic Summative Test Report[48] (N=16 in both studies).

The Limbic NICE RFI response[4] and the Limbic EAG RFI response[18] also included some real-world data collected from NHS Talking Therapies, NHS Talking Therapies staff and/or NHS Talking Therapies patients.[10,15,43,44,48] Additional data were also reported in the RFI responses[4,18] from other unpublished sources not identified by the EAG searches.

Wysa DRA

The data provided in the Wysa NICE RFI response,[6] Additional Supporting Evidence[20] and EAG RFI response[21] were sourced from real-world data collected from NHS Talking Therapies, NHS Talking Therapies staff and NHS Talking Therapies patients.

5.1.3 Outcomes

None of the included studies provided data for all outcomes included in the NICE scope,[1] however, all studies reported some outcomes (range: 1 to 7 outcomes). The reported outcome data were heterogeneous, for example, Limbic and Wysa provided different definitions of quality and accuracy of the data collected using digital front door technologies (AA1) and provided different definitions of the accuracy of clinical assessment for NHS Talking Therapies (AA2). Also, results for outcomes were reported either quantitatively and/or qualitatively, depending on the outcome and study.

5.1.4 Strengths and weaknesses of the evidence

In line with NICE PMG39[51] (Early Value Assessment interim statement), a full critical appraisal of the identified evidence was not conducted. However, the EAG has assessed the strengths and weaknesses of the evidence base (Table 6). In summary, the main strengths of the included studies were that all provided relevant real-world data relating to NHS Talking Therapies. Only two of the studies[10,15] were peer-reviewed (reporting Limbic Access data); the remaining studies[4,6,18,20,21,43-48] were unpublished Limbic Access and Wysa DRA evaluations.

Published evidence was not available for most of the outcomes listed in the NICE scope.[1] In some studies, the strength of the evidence provided by the companies was difficult to determine due to small populations, weak methodologies and a lack of transparency in reporting.

Limbic Access

Data relating to Limbic Access were available from multiple sources including two large UK-based peer-reviewed studies.[10,15] However, only limited data were available for the version of Limbic Access (Class IIa) that is currently being used to refer patients to NHS Talking Therapies; most of the data provided related to an earlier version of Limbic Access. Whilst this is not a weakness of the studies, it limits the relevance of study data to this EVA.

Wysa DRA

Wysa complied with data requests from NICE and the EAG. The data provided by Wysa[6,20,21] related to the real-world experience of Wysa DRA users; however, none of the data provided were comparative or sourced from research studies.

Table 6 Main strengths and weaknesses of the studies included in the EAG SLR

Reference	Main strengths	Main weaknesses
Rollwage 2023[10]	• Research published in a peer-reviewed journal • Provides quantitative data from a large dataset (N=64,862) from nine different NHS Talking Therapies services in different regions of England (all delivered by the same service provider: Everyturn) • Provides comparative data with other referral sources • Provides some qualitative data (N=32) • Controls for some confounding factors (severity of mental health symptoms for between arm comparisons and severity and demographics for users of Limbic Access)	• Unable to control for all likely possible confounders in quantitative analysis (e.g., differences in how services were administered and delivered with and without the digital front door technology) • Qualitative analysis was from ex-patients who tested the digital front rather than used it to refer to NHS Talking Therapies
Habicht 2024[15]	• Research published in a peer-reviewed journal • Provides comparative data with other referral sources • Provides quantitative data from a large dataset (N=~129,400) over 28 different NHS Talking Therapies services across England • Controls for some confounding factors before and after implementation of digital front door technology (severity of mental health symptoms and demographic factors) • Study authors consider staggered study design for pre-implementation and post-implementation phases across the different services should also control for seasonal variations • Provides qualitative data from a large dataset (N=42,332)	• Unable to control for all likely possible confounders in quantitative analysis (e.g., differences in how services were administered and delivered before and after implementation of the digital front door technology and/or other changes in service administration and delivery that may have accompanied the introduction of the digital front door) • Qualitative analysis was from feedback responses of text that on average had an entry length of 51 characters
Limbic studies: • Limbic NICE RFI response[4] • Limbic EAG RFI response[18]	• Data provided from multiple sources, including Rollwage 2023[10] and Habicht 2024[15] • Some data for the Limbic Access Class IIa device (from the ongoing NCT05495126[16] trial) presented	• Unclear how participants involved in the usability testing studies and in the Limbic Clinical Preparedness Study were selected (potential for selection bias) • The purpose of the usability testing studies was to test the development of the Class I device only; thus, while participant data were based on the real-world experience of participants, data were not collected from real-world users of the digital front door technology in NHS clinical practice • The useability studies did not include comparative data with referrals from other sources

Reference	Main strengths	Main weaknesses
Mind Matters 2022[45]	• Real-world case study of where Limbic Access has been employed • Presents some comparative data with referrals prior to implementing Limbic Access	• A validation study rather than an evaluation study was conducted because of a lack of baseline data (data other than the number of self-referrals were not collected prior to implementing Limbic Access) and the time available to complete the report • Number of respondents to survey data not reported
Limbic 2022 Usability Testing Formative Test Report[47]	• Externally audited by the MHRA • Provides test data for the healthcare professional acceptability of digital front door technologies as well as data for other key outcomes (N=15) • Provides patient reported outcomes (N=16); it seems likely that the data within this report relate to half of the sample of the qualitative study included in Rollwage 2023[10]	• Unclear how participants were selected (potential for selection bias) • The purpose of the study was to test the development of the Class I device only; thus, while participant data are based on the real-world experience of participants, it is not from real-world use of the digital front-door in NHS clinical practice • No comparative data with referrals from other sources • Small populations
Limbic 2022 Usability Testing Summative Test Report[48]	• Externally audited by the MHRA • Provides test data for the healthcare professional acceptability of digital front door technologies as well as data for other key outcomes in a larger sample (N=40) than in the Formative Test Report[47] • Provides patient reported outcomes; (N=16) it seems likely that the data within this report relate to half of the sample of the qualitative study included in Rollwage 2023[10]	• Unclear how participants were selected (potential for selection bias) • The purpose of the study was to test the development of the Class I device only and so while based on the real-world experience of participants, does not represent real-world use of the digital front-door • No comparative data with referrals from other sources • Small populations
Limbic 2024 Clinical Preparedness Study External Sharing [AIC][43]	• Provides real-world data for the healthcare professional acceptability of digital front door technologies as well as data for other key outcomes (N=74)	• Unclear how participants were selected (potential for selection bias) • No comparative data with referrals from other sources
Limbic 2024 Patient Feedback Report[46]	• Externally audited by the MHRA • Provides real-world data from a large sample of users of Limbic Access who provided feedback of their overall experience with the referral process (N=17,931)	• Response to one question with three response options: positive, neutral, negative • No comparative data with referrals from other sources
Limbic Research	• Externally audited by the MHRA • Provides data on the quality and accuracy of the machine-	

Reference	Main strengths	Main weaknesses
2024[44]	learning model used by Limbic Access including Live dataset with data collected after the fully certified Class II model was deployed	
Wysa studies: • NICE RFI response[6] • Additional supporting evidence[20] • Information requested by the EAG[21]	• Data provided from real-world experience of using the Wysa DRA	• No relevant data from published, peer-reviewed studies were available • Limited comparison with referrals from other sources • No control for any possible confounders • Response to one question with three response options or five response options

ADSM=Anxiety Disorder Specific Measure; DRA=Digital Referral Assistant; EAG=External Assessment Group; MHRA= Medicines and Healthcare products Regulatory Agency; NICE=National Institute for Health and Care Excellence; RFI=request for information

5.2 Results from the evidence base

The EAG has summarised the results from the evidence base in this Section, arranged by technology and by outcomes (listed in the NICE scope[1]). The data extraction tables are presented in Appendix 5, Section 13.5.

5.2.1 Limbic Access

Outcome AA: Accuracy and acceptability

AA1: Quality and accuracy of the data collected using digital front door technologies

Four studies provided information on the quality and accuracy of data collected using Limbic Access;[4,18,44,47] three[18,44,47] of the four studies highlighted the benefits to clinicians of the ADSM information collected by Limbic Access. Limbic data[4,18,44] suggested that the accuracy of the Limbic Access prediction model is approximately 93% in all studies.

Results reported in the Limbic Formative Test Report,[47] suggested that [redacted].

The EAG has reported ADSM accuracy data for information only; the EAG considers that these results are outside the NICE scope[1] (NICE scope,[1] p3 and p4).

AA2: Accuracy of clinical assessment for NHS Talking Therapies

Three studies provided information about the accuracy of clinical assessment for NHS Talking Therapies.[4,18,48]

As highlighted in the Limbic NICE RFI response[4] and the Limbic EAG RFI response,[18] the fact that Limbic Access can provide a suggested ADSM does not appear to bias clinical decision making. In the Limbic Summative Test Report,[48] to evaluate accuracy, the presenting problem selected by the clinician (from Limbic Access referral output with and without ADSMs) was compared with the patient's actual diagnosis. Comparisons were made where the machine learning presented the correct ADSM (20 cases), incorrect ADSM (20 cases) and overall (all 40 cases). Accuracy comparisons were made for i) the primary presenting problem (where all results were found to be statistically significant) and ii) two most likely differential diagnoses (no results were statistically significant).

In response to a specific question from the EAG about data to demonstrate the accuracy of clinical assessment for NHS Talking Therapies, Limbic[18] cited four studies they considered provided relevant data:

- statistically significant results (p<0.001) from an NHS clinician survey (N=82), not identified by the EAG SLR searches, that showed that clinicians found the information collected by Limbic Access helped them to prepare for the clinical assessment and helped them to complete assessments within the allocated time limit (p=0.001)
- results from the Limbic Summative Test Report (N=40)[48] (ADSM data reported above) and preliminary statistically significant (p<0.01) results from Limbic's ongoing RCT (NCT05495126;[16] N=5030) which showed that compared with the Class I device, administering ADSMs at referral led to a statistically significantly higher detection rate of specific anxiety diagnoses when using the Limbic Access Class IIa device
- statistically significant results (p<0.001) from Rollwage 2023[10] (N=64,862) which showed a 45% reduction in treatment step-ups/downs following the one-to-one clinical assessment

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[1] (NICE scope,[1] p3 and p4). Treatment step-ups/down results are also outside the NICE scope[1] as the timeframe for this EVA is to the end of the initial clinical assessment only (NICE scope,[1] p9).

AA3: Completion rate of pre-assessment when using digital front door technologies

Two studies[4,18] provided information about pre-assessment completion rates.

In the Limbic NICE RFI response,[4] it was stated that self-referral completion rates were >90% and that Limbic Access patients were less likely to drop out during both pre-assessment and treatment than patients who referred via other means.

The Limbic EAG RFI response[18] included completion rate data from four NHS Talking Therapies services that had implemented Limbic Access over the past 1.5 year; for example, results showed that more patients using Limbic Access attended a one-to-one person-centred clinical assessment and attended NHS Talking Therapies treatment sessions than patients who referred via other methods.

AA4: Inaccessibility to digital front door technologies

Four studies provided information about inaccessibility to Limbic Access.[4,15,45,47]

Results presented in a real-world study (N=129,400),[15] demonstrated that Limbic Access led to increases in referrals versus self-referrals without Limbic Access (15% vs 6%).[15] Results also demonstrated that Limbic Access led to increases in accessibility for individuals from some minority groups versus self-referrals without Limbic Access (Asian [increases of 39% vs 8%], Black [increases of 40% vs 4%] and non-binary [increase of 179% versus 5% decrease]).[15]

Results from the Mind Matters Validation Study[45] showed that there had been an increase in all self-referrals, including a slight increase in out of hours self-referrals, to NHS Talking therapies since the introduction of Limbic Access.

Results from the Limbic Formative Test report[47] (N=16), which reported feedback from five individuals with physical and learning disabilities, showed that, on the whole, the device was useable.

Limbic NICE RFI response[4] included the statement that Limbic Access was designed to be accessible to those with disabilities and reported that, "… users with physical disabilities take about 11 minutes to complete a referral, whereas those without a disability take closer to 9 minutes, indicating only very subtle differences in the usability of the product based on disability status." Feedback on the Limbic Access referral process was consistent across all groups, including users with at least one disability and those aged ≥60 years.

AA5: Healthcare professional acceptability of digital front door technologies

Four studies provided positive information about the professional acceptability of digital front door technologies.[18,43,45,48]

The Limbic Summative Test report[48] explored satisfaction across a number of areas including, referral layout, ease of use of the referral output and potential time savings. Clinician perceptions of the useability and usefulness of Limbic Access were generally positive, and in some cases were strongly positive.

The Limbic Clinician Preparedness Study[43] was carried out across four NHS Talking Therapies services. Clinician survey responses (N=74) showed that Limbic Access appeared to improve task performance during clinical assessments, reduce cognitive load of clinical assessments and improve clinician well-being. Similar (unpublished) results were reported from a clinician user study (N=80) cited in the Limbic EAG RFI response[18] in which clinicians reported improved emotional wellbeing ($p<0.001$) and reduced cognitive load ($p=0.002$).

In the Mind Matters Validation Study,[45] one administrator and a PWP stated that Limbic Access, "…makes life easier"; the PWP felt more prepared for a one-to-one assessment as a result of information collected by Limbic Access.

Outcome RSI: Resource and system impact

RSI1: Administrative resource impact

The Mind Matters Validation Study[45] provided some information about administrative resource impact. Although full details of the impact of Limbic Access on administrative resources were

not available, one administrator stated that it would take 20 minutes to process a referral that had not come via Limbic Access.

RSI2: Time taken to review data collected by digital front door technologies

Two studies provided information about the time taken to review data collected by digital front door technologies.[18,45]

Results from a 2022 staff survey of administrators (Mind Matters Validation Study[45]) were mixed; some administrators considered that the information provided by Limbic Access saved time, whilst others found that it did not save time.

Limbic (EAG RFI response[18]) provided real-world data from 38 clinicians who had interacted with the Limbic Access browser extension from November 2024 to January 2025. Study results showed that the time taken to review collected data was 1 minute 53 seconds (±1 minute 47 seconds). While it is not known whether this time was spent before or during the assessment, "…it allows us [Limbic] to infer how long clinicians spend in total on reviewing referral information collected from Limbic Access".

RSI3: Time taken to complete clinical assessment

Three studies provided information on the time taken to complete a clinical assessment.[10,18,45]

Rollwage 2023[10] found that the average time taken to complete an initial clinical assessment for patients referred via Limbic Access was 41.6 minutes versus 54.4 minutes for patients referred by other means (control); this difference was statistically significant ($p<0.001$). Rollwage 2023[10] also compared, for patients using Limbic Access, the time taken when additional clinical information was completed ahead of initial clinical assessment (40.6 minutes) versus time taken when additional clinical information was not completed (52.8 minutes); this result was also statistically significantly different ($p<0.001$) and most patients who referred via Limbic Access had completed additional clinical information (~97%). Both results remained statistically significantly different after controlling for severity of mental health symptoms ($p<0.001$).

It was stated in the Limbic RFI response[18] that no time was spent collecting demographic data or collecting health questionnaire data/outcome measures for patients referred via Limbic Access, whereas when patients were referred via other methods, the time taken was approximately 3.9 minutes (demographic) or 4.6 minutes (health questionnaire).

Approximately two-thirds of respondents (68%) who participated in the Mind Matters Validation Study[45] reported (in the 2021 survey) that assessments took <50 minutes, including administration time.

RSI4: Time saved for the clinician during clinical assessment

Five studies provided information on time saved during a clinical assessment. [4,10,18,45,47]

Rollwage 2023[10] presented quantitative data that showed that the time saved for the clinician during the clinical assessment was 12.7 minutes. Using data presented in Rollwage 2023,[10] Limbic[4] estimated that Limbic Access can release clinical time by making clinical assessments more efficient due to the additional clinical information collected during the referral, i.e., reducing the time taken by up to 23.4%. In the Limbic EAG RFI response,[18] Limbic considered it could therefore be inferred that Limbic Access saves approximately 8.5 minutes "through simple data collection" and 4.2 minutes "through enhanced preparation for clinicians by providing relevant ADSM measures and suggested primary and secondary presenting problems based on the diagnostic machine learning prediction model."

The Mind Matters Validation Study[45] presented results from a 2022 staff survey of PWPs that showed that 88% of participants agreed or partially agreed that the introduction of Limbic Access had shortened the length of time taken carry out an initial clinical assessment. The reported time saved ranged from 5 minutes to 20 minutes, with 50% answering that 10-15 minutes was saved.

Results from the Limbic Formative Test Report[47] demonstrated that clinicians considered that using Limbic Access [redacted].

Outcome PRO: Patient reported outcomes

PRO1: Ease of access and usability

Five studies provided information on ease of access and reported useability information.[4,10,15,47,48]

Habicht 2024[15] reported that feedback from 42,332 users was largely positive and highlighted that approximately 42% of individuals found the referral process easy, fast or convenient. There were no statistically significant differences between the numbers of individuals who mentioned convenience between gender identity groups (gender minority groups versus males/females) or between ethnic groups (Asian and Black ethnic groups versus White group). Positive feedback was also reported in the Limbic Formative Test Report;[47]

[redacted]. In the Limbic Summative Test Report,[48] all 16 participants mentioned easy access and the ability to get help at any time; they also agreed that the AI-chatbot user interface was intuitive, smooth and easy to follow.

However, not all feedback was wholly positive. Rollwage 2023[10] reported data collected from 12/32 ex-patients who considered that the list of questions asked by Limbic Access was long. The Limbic Formative Test Report[47] participants ([redacted]) and Limbic Summative Test Report[48] participants (3/16) also mentioned the long length of time it took to answer Limbic Access questions.

PRO2: Information clarity and relevance

Three studies provided information on clarity and relevance.[15,47,48]

It was reported in the Limbic Formative Test Report[47] and in the Limbic Summative Test Report[48] that, after entering information into the Limbic Access system, [redacted] and [redacted].

In the Habicht 2024[15] study, 'self-realisation' was a theme identified by Limbic Access users (~10%), i.e., individuals mentioned realising their need for treatment. Proportionately more individuals from Asian and Black ethnic groups (15.2%; 380/2499) mentioned self-realisation compared to White individuals (10%; 3723/37,272) ($p<0.001$). No statistically significant differences were found between gender identity groups (gender minority groups versus males/females).

PRO3: Comfort and privacy

Four studies provided information about comfort and privacy.[10,15,47,48]

Rollwage 2023[10] found that 8/32 ex-patients who tested Limbic Access reported that the clinical questions were emotionally difficult to answer, and that questions sometimes felt too "heavy" to complete. This theme was also identified in the Limbic Formative Test Report;[14] [redacted].

These negative findings were not reported in the Limbic Summative Test Report;[15] participant views were more positive, for example, "… it is confidential and easily accessible" and "It's very neutral. It's quicker than talking to an actual human. It can be used at any time."

Habicht 2024[15] identified 'human-free' as a positive theme from user feedback. Approximately 9% of individuals mentioned the human-free nature of the AI-chatbot in a positive way as it removed the anxiety of talking to humans. Proportionately more individuals from gender minority groups (12.4%; 101/813) mentioned the human-free nature of Limbic Access compared to males/females (8.9%; 3,642/41,063) (p<0.01); there was no statistically significant difference between ethnic groups (Asian and Black ethnic groups versus White group).

PRO4: Overall satisfaction with pre-assessment process

Six studies reported information on overall satisfaction with pre-assessment process.[4,15,45-48]

It is reported in the Limbic RFI response[4] that 93% of patients who have used Limbic Access (N>15,000) gave positive feedback. Habicht 2024[15] reported that overall, 89% of the free-text feedback (N=42,332) was classified as positive, 7% neutral and 4% negative. Feedback was also found to be positive from 89% of users in the Mind Matters Validation Study (N not reported).[45] In the Limbic Patient Feedback Report 2023[46] (N=17,931), 94.3% of patients rated the referral process as helpful, 4.9% indicated a need for more information or support and 0.8% rated the process as unhelpful, stating that they needed immediate human attention in the free-text response. Limbic Formative Test Report[47] patients (N=16) provided positive evaluations of user experience across six categories (attractiveness, perspicuity, efficiency, dependability, stimulation and novelty). Similar results were noted in the Limbic Summative Test Report[15] (N=16) where it was apparent that while some patients (4/16) wanted more personability from the device's prose, other patients (2/16) wanted the friendliness of the technology to be toned down.

Habicht 2024[15] stated that approximately 27% of users mentioned that self-referral via Limbic Access gave them hope to get better, or know they were not alone. Fewer individuals from gender minority groups mentioned that Limbic Access provided hope (21.5%; 175/813) compared to males/females (26.9%; 11,033/41,063) (p<0.01). Fewer individuals from Asian and Black ethnic groups (21.0%; 525/2,499) mentioned that Limbic Access provided hope compared to the White group (27.8%; 10,349/37,272); p<0.001.

5.2.2 Wysa DRA

All the evidence relating to Wysa DRA was real-world data reported in the Wysa NICE RFI response,[6] Wysa EVA Additional Supporting Evidence[20] and the Wysa EAG RFI response.[21]

Outcome AA: Accuracy and acceptability

AA1: Quality and accuracy of the data collected using digital front door technologies

Wysa stated (NICE RFI response,[6]) that the Wysa DRA, "…can improve the percentage of appropriate referrals." In their additional supporting evidence,[20] to highlight quality and accuracy of data, Wysa stated that, between October 2023 and June 2024, one NHS Talking Services provider had used information collected by the Wysa DRA to inform the type and length of assessment appointments offered. Results showed that 91% of initial clinical assessments for those who completed the full set of clinical questions asked by the Wysa DRA were scheduled for shorter, 30 minute appointments, instead of the service standard 60 minute appointments.

AA2: Accuracy of clinical assessment for NHS Talking Therapies

No direct evidence of the accuracy of clinical assessment was identified. Wysa stated (NICE RFI response[6]) that using a version of the Wysa DRA to collect clinical information after the service had received and opened a referral from a different referral route, had enabled clinicians to have access to a wider range of clinical information in over 65% of assessment appointments. However, Wysa has been unable to provide more information about this case study (for example, the number of referrals included in the study or how this affected clinical assessment). Wysa also stated in their EAG RFI response:[21] ""We have a research protocol in place with the Whittington Trust which will allow us to look at how effective the data collected by the Wysa DRA is in helping the practitioner in making an accurate treatment pathway decision for the patient."

AA3: Completion rate of pre-assessment when using digital front door technologies

Wysa (NICE RFI response[6]) considered that the Wysa DRA system was able to deliver a conversion rate of up to 91%". In NHS Talking Therapies providers where the Wysa DRA is the only online self-referral option, the completion rate for pre-assessment demographic information was 91.2% (117,416/128,741 referrals).[20] When the Wysa DRA referral widget was offered on service websites alongside a static online referral form (which was stated to be the most common configuration), evidence from three case studies showed the completion rates ranged from 69.1% to 72.5%.[20]

AA4: Inaccessibility to digital front door technologies

Wysa stated (NICE RFI response[6]) that over a third of patients completed the Wysa DRA after 6pm or between 6pm to 9am, and that 80% of all completed Wysa DRA referrals were completed on mobile phones. Patients aged between 20 to 34 years were the largest age group that used Wysa DRA; the company also reported that large numbers of older people used the Wysa DRA (Wysa NICE RFI response[6]) and that, compared to a matched group who self-referred using the static online form, preliminary data suggested that the introduction of the Wysa DRA led to few second triage appointments and higher rates of referrals from Asian and Asian British groups.

AA5: Healthcare professional acceptability of digital front door technologies

One small study, reported in Additional Supporting Evidence,[20] suggested that 4/5 clinicians surveyed stated that they found it helpful to have the standardised questionnaire responses available via the Wysa DRA. Also, 2/5 clinicians reported they had more time to concentrate on the patient's problems, 1/5 stated it was helpful not to have to ask mandatory questions, to know the client's priority for treatment and that there was less need to signpost to support.

Outcome RSI: Resource and system impact

RSI1: Administrative resource impact

Wysa reported[20] that there are limited available Wysa DRA resource use and impact outcome data. Wysa stated that time saved during the initial clinical assessment was not always a valid or fair measure of the effectiveness or efficiency of a digital front door technology.

RSI2: Time taken to review data collected by digital front door technologies

Wysa stated[21] that no data were available to address this outcome.

RSI3: Time taken to complete clinical assessment

Wysa[20] are currently working with 28 NHS Talking Therapies services, one of which used the information collected by the Wysa DRA to inform the type and length of assessment appointments offered. This service found that 91% of assessments for those who completed the full set of clinical questions asked by the Wysa DRA were scheduled for 30 minute appointments instead of the service standard of 60 minute appointments.

RSI4: Time saved for the clinician during clinical assessment

Wysa[6] stated that an average of between 16 to 21 minutes was saved for the clinician during the initial clinical assessment, depending on the length of the Wysa DRA used by the NHS Talking Therapies service.

Outcome PRO: Patient reported outcomes summary

PRO4: Overall satisfaction with pre-assessment process

The Wysa DRA collects feedback from users of the Wysa DRA using either a three-point Likert scale or a five-point Likert scale. In response to the question, 'Have I been able to help you today?', using the three-point scale, Wysa reported[21] (data from one service) that 79.1% of users replied 'Yes', 18.5% replied 'Somewhat' and 2.3% replied 'No'. In response to the question 'How did you find talking with me today?', using the five-point scale, Wysa reported[20,21] (data from five services), approximately 60% replied 'It was really good, thanks' or 'It was engaging and helpful'.

6 INFORMATION PROVIDED BY SCMS AND STAKEHOLDERS

It was anticipated that only a limited number of relevant studies would be identified for inclusion in the EAG SLR. To fill this potential data gap, the EAG interviewed expert SCMs and stakeholders and developed a questionnaire for experts and lay SCMs.

6.1 SCM and stakeholder interviews

The interviews were designed to help the EAG:

- understand current referral pathways into NHS Talking Therapies (with and without digital front door technologies)
- explore the impact that the introduction of digital front door technologies has on resources required to complete the pre-assessment and assessment process
- estimate the costs associated with implementing and operating a digital front door technology
- identify quantitative and/or qualitative data relating to accuracy of information provided for the pre-assessment and clinical assessment
- describe the equality considerations associated with adopting digital front door technologies.

6.1.1 SCM and stakeholder interview data

The EAG interviewed five SCMs and two stakeholders with experience of working within NHS Talking Therapies. All interviews were conducted via Zoom or MS Teams. Two or three members of the EAG were present. Five key topic areas were explored in a semi-structured manner (with additional questions asked as appropriate):

1. What does the referral pathway look like in your area?
2. How has the introduction of digital front door technology impacted the pre-assessment (if applicable) and initial clinical assessment?
3. Do you have data on pre-assessment completion rates for referrals via digital front door technologies?
4. Do you think the introduction of digital front door technologies leads to more accurate clinical assessments?
5. What do you think are the most important outcomes that should be considered when evaluating the effectiveness/impact of digital front door technologies?

It was highlighted to interviewees that some of the topics covered would also be covered in a follow-up questionnaire. Members of the EAG took notes during the interviews; in addition, all interviews were recorded and lasted less than 1 hour. The views and experiences shared by stakeholders (referred to as expert advice to the EAG) have been used to inform the clinical context (Section 3.1) and the EAG interpretation of the evidence (Section 9).

6.2 Questionnaire data

6.2.1 Expert questionnaire data

The EAG questionnaire was designed to elicit responses to structured questions. Copies of the expert questionnaire is provided in Appendix 6 (Section 13.6). A questionnaire was sent to seven experts; responses were received from five experts (four SCMs and one stakeholder) and one lay SCM.

6.2.2 Expert questionnaire responses

Respondents provided information about referral pathways to NHS Talking Therapies and offered insight, opinions and, in some instances, provided data relating to outcomes listed in the NICE scope[1] (Section 1). All questionnaire responses (including respondent's experience with digital front door technologies) are tabulated in Appendix 7 (Section 13.7).

Effects of digital front door technologies on the pre-assessment/triage stage

The three SCMs who provided responses all indicated that the effects of digital front door technologies on the pre-assessment /triage stage were positive (Table 7). One SCM added, "664 referrals from our go live have been signposted at the front door since go live, which has saved triage clinician from reading all those referrals, cross referencing against SystmOne, writing that many individual letters etc. For reference the total referrals since this date have been 3301."

Table 7 Effects of digital front door technologies on the pre-assessment/triage stage

Outcome	SCM1	SCM3	SCM6
Reduction in waiting times from referral to the pre-assessment/triage	5	4	4
Shorter duration of the pre-assessment/triage stage	4	4	4
Clinical assessors are more informed before the start of the pre-assessment/triage	5	5	4
More accurate data to review at the pre-assessment/triage	5	4	4
Better quality data to review at the pre-assessment/triage	4	4	4

1=strongly disagree to 5=strongly agree
SCM=Specialist Committee Member

Time taken to review data collected by digital front door technologies

Respondents had differing views about how long it took to pre-assess/triage referrals. One SCM suggested that reviewing referral information took 3 minutes without Limbic Access and 5 minutes with Limbic Access. Two other respondents considered that reviewing information without a digital front door technology could take at least 10 minutes, longer if there was a perceived risk.

Effects of digital front door technologies on initial clinical assessment

The five responses to this question were mixed (Table 8). Most of the responses were positive; however, two respondents appear to disagree with the statement that a digital front door could reduce waiting times from referral or pre-assessment/triage to the initial clinical appointment.

Table 8 Effects of digital front door technologies on initial clinical assessment

Outcome	SCM1	SCM2	SCM3	SCM6	SH1
Reduction in waiting times from referral to the one-to-one person-centred clinical assessment	4	2	4	4	2
Reduction in waiting times from pre-assessment/triage to the one-to-one person-centred clinical assessment	4	2	4	4	2
Shorter duration of the one-to-one person-centred clinical assessment	4	3	4	4	2
Clinical assessors are more informed before the start of the one-to-one person-centred clinical assessment	5	4	5	4	4
More accurate data collected prior to the one-to-one person-centred clinical assessment	5	3	4	4	4
Better quality data collected prior to the one-to-one person-centred clinical assessment	5	3	4	4	4
Clinical assessors spend more time focusing on the patient during the one-to-one person-centred clinical assessment	5	3	3	4	2
Clinical assessors spend less time on administrative tasks during the one-to-one person-centred clinical assessment	5	3	5	4	4
Better quality one-to-one person-centred clinical assessment	5	3	4	4	2
More accurate one-to-one person-centred clinical assessment	5	3	4	4	4

1=strongly disagree to 5=strongly agree
SCM=Specialist Committee Member; SH=stakeholder

Time taken to complete the NHS Talking Therapies initial clinical assessment

All five respondents agreed that it took at least 45 minutes to complete the NHS Talking Therapies initial clinical assessment without the use of a digital front door technology. One respondent estimated that the duration of the initial clinical assessment was 40 minutes for patients who referred via Limbic Access and 50 minutes for patients who referred via other methods. All respondents agreed that collecting demographic information took no more than 5 minutes irrespective of whether referrals arrived via a digital front door technology or a different method; one respondent stated that collecting demographic information for referrals via Limbic Access took 1 minute. Respondents indicated that the time taken to collect patient health questionnaire data varied between 0 and 30 minutes.

AA1: Quality and accuracy of the initial clinical assessment

Two respondents provided information about their experiences. One respondent's experience was that since the introduction of a digital front door initial clinical assessments were more

detailed and relevant. Another respondent indicated that early findings from a pilot study of digital front door technologies had shown increased patient and clinician satisfaction.

AA4: Inaccessibility to digital front door technologies

Two respondents provided information about accessibility. One respondent considered that there could be barriers to digital front door technologies for whose first language was not English, whilst another respondent highlighted that since the introduction of a digital front door technology, referrals from Black, Asian and minority ethnic groups had increased. A third respondent suggested that digital front door technologies could remove barriers to access for some harder to reach groups such as men.

Most important outcomes and other costs and benefits

The outcomes considered to be most important, as well as other costs and benefits identified by questionnaire respondents are presented in Table 9.

Table 9 Most important outcomes and other costs and benefits identified by experts

Outcome	SCM1	SCM	SCM6	SH1
Most important outcomes	Time saving and impact on recovery	Waiting times, access numbers for different demographics (e.g., age, ethnicity), qualitative data from clients, qualitative data from therapists and administrative staff	Patient experience, quality, digital clinical safety and ease of deployment and adoption rates	--
Benefits not captured by the questionnaire	The majority of feedback from patients referenced how it [the AI-chatbot] felt very human and helped them think about their problems in more depth	More engaging process for capturing demographic/ initial presenting problem information	I think there is a benefit to patients that services feel modern and focused on efficiency, so they save time. A requirement our service users have requested is the ability to book appointments and that all technology integrates with the NHS app	--
Concerns not captured by the questionnaire	The ongoing costs and it is not offered in alternative languages	How the AI manages risky utterances from the client	The cost and investment in clinical safety cases - the national training for clinical safety officers is very focused on physical health technology and so where is the support for this training need	Digital front door technologies should not replace a one to one assessment and the use of clinical judgement by

Outcome	SCM1	SCM	SCM6	SH1
			coming from? Do NHS talking therapy services understand the legally mandated standards in the deployment of these technologies and where are the guard rails regarding information governance and digital clinical safety. This should support the innovation.	trained professionals

6.2.3 Lay SCM questionnaire data

The lay questionnaire was designed to elicit responses to structured questions. Copies of the lay questionnaire is provided in Appendix 7. A questionnaire was sent to all three lay SCMs; responses were received from one lay SCM.

6.2.4 Questionnaire response: lay SCM response

The lay SCM responses are provided in Table 10.

Table 10 Lay SCM questionnaire response

Outcome	Response
Most important outcomes	• **Client reach**: Evaluate the number of individuals reached, including demographic and socioeconomic diversity, to ensure inclusivity. • **Effectiveness**: Assess whether digital pathways reduce waiting lists and improve access compared to traditional methods. • **User experience**: Measure user satisfaction, focusing on ease of use, time efficiency, and potential frustrations, such as repetitive or overly complex processes. • **Quality of care**: Determine whether patients find the digital process helpful in alleviating symptoms, or if the lack of human interaction exacerbates their distress when seeking support.
Benefits	• **Reduced waiting times:** Accelerates the referral process, enabling quicker access to mental health support. • **Facilitated access:** Allows individuals to connect with services faster and more efficiently. • **Flexibility:** Accessible for those unable to attend physical appointments for reasons such as time, mobility, health, or other constraints.
Concerns	• **Exclusion risk**: May unintentionally exclude individuals who are digitally illiterate, lack access to technology, or face additional challenges, such as those with special needs, elderly populations, homeless individuals, people from low-income backgrounds, or those who prefer human interaction, etc. • **Impersonal experience**: The process might feel automated and lack the empathy or personal touch of human interaction, which can be crucial for mental health support for some individuals.

Outcome	Response
	• **Data privacy risks**: Concerns around data protection, such as potential GDPR violations, highlighted by recent NHS data breaches.

GDPR=General Data Protection Regulation; SCM=Specialist Committee Member

7 EVIDENCE SYNTHESIS

It was not possible to synthesise the limited available clinical evidence due to heterogeneous non-comparative data.

8 ECONOMIC EVIDENCE

This section includes economic results from the EAG SLR. In addition, the EAG has carried out an exploratory economic analysis to compare the benefits and costs of standard NHS pre-assessment referral practice to NHS Talking Therapies with and without digital front door technologies.

8.1 EAG SLR results: economic data

The EAG reviewed all the results generated by the EAG SLR searches; as part of the search strategy, targeted searches of the Cost Effectiveness Analysis (CEA) Registry and EconLit databases were conducted. In addition, the EAG reviewed all the evidence provided by Limbic, Wysa and Psyomics in response to the NICE RFIs[4-6,20] and the EAG RFIs.[18,19,21] The EAG did not identify any published economic evidence that met the EAG SLR inclusion criteria.

8.2 EAG approach to economic analyses

The available economic evidence is limited, not robust and mainly relates to Limbic Access. This means that there is insufficient evidence to generate any reliable economic results for the comparison of standard NHS pre-assessment referral practice to NHS Talking Therapies with and without digital front door technologies. The EAG has therefore carried out a simple analysis of the benefits and costs associated with this comparison. For the purposes of this EVA, the EAG considers the outcomes listed in the NICE scope[1] that should be considered in an economic analysisare:

- administration burden (RSI1)
- time taken to carry out an initial clinical assessment (RSI3) / time saved for the clinician during clinical assessment (RSI4)

The limitations of the currently available data mean that results from the EAG economic analysis should only be considered exploratory.

8.3 EAG exploratory analysis

8.3.1 Population

The population is people over the age of 16 years with suspected common mental health conditions, as specified in the NHS Talking Therapies for anxiety and depression manual.[11]

The EAG estimated that, between 1 April 2023 and 31 March 2024, the average number of referrals received by an NHS Talking Therapies service was 11,801 (1,829,202/155).[2] The EAG highlights that this is the average number of referrals that an average NHS Talking Therapies provider may receive each year; however, NHS Talking Therapies provider population size does not always correlate with number of referrals received as the number of

referrals will be highly dependent on patient demographics and mental health care needs. Data relating to the proportion of referrals that each NHS Talking Therapies service receives via a digital front door technology are limited. The EAG considers that factors influencing the proportion of patients using a digital front door technology include type of digital front door technology purchased and the patient case-mix of each NHS Talking Therapies service. In a study of patient recovery rates carried out using data from four NHS Talking Therapies service providers,[30] it was estimated that 63% (27,029/42,731) of referrals were received via a digital front door technology; this proportion is higher than the estimate provided by one SCM (55%; 1399/2529) and by Limbic (40.96%; 15,371/37,572).[18] One questionnaire respondent estimated that, in their area, 46% of all self-referrals to NHS Talking Therapies were via the Wysa DRA, 22% were via a static online form and 14% were via telephone. Therefore, current evidence suggests that the number of referrals that could be expected via a digital front door technology, for an average sized NHS Talking Therapies service, may range from 4,834 (40.96% multiplied by 11,801) to 7,435 (63% multiplied by 11,801); these digital front door technology referral estimates have been generated on the assumption that the proportion of referrals received via a digital front door technology is independent of the brand of digital front door technology.

8.3.2 Intervention

Four digital front door technologies are listed in the NICE scope.[1] The EAG economic analysis considers two digital front door technologies, Limbic Access and the Wysa DRA; relevant cost and outcome data were not available for Censeo Digital and AskFirst.

8.3.3 Comparator

The comparator is NHS pre-assessment referral practices without digital front door technologies. For simplicity, the EAG has not attempted to cost standard NHS referral practices as the costs of digital front door technologies are in addition to all standard pre-assessment referral practices. Therefore, only purchase and implementation costs of digital front door technologies are considered, not the purchase and implementation costs of existing pre-assessment referral practices.

8.3.4 Perspective, time horizon and discounting

The perspective of the EAG analysis is the NHS. The time horizon is from referral (any route) until the end of the NHS Talking Therapies initial clinical assessment. As the time between referral and initial clinical assessment is always ≤12 months, costs and outcomes are not discounted.

8.3.5 Costs

The following costs were listed in the NICE scope[1] and are considered in the EAG economic analysis:

- costs of the digital front door technologies, including initial setup and implementation costs
- operational costs (if falling on the NHS rather than the technology provider), such as information technology (IT) support and cybersecurity
- training costs
- cost of promotion
- costs of applying digital clinical safety assurance DCB0129[3]

Digital front door technology costs

Pricing information provided by Limbic and Wysa are shown in Table 11 and Table 12. The EAG has included each possible licence cost in the economic analysis to reflect the variability in population sizes of different NHS Talking Therapies services and the uncertainty around the proportion of referrals that would be received via a digital front door.

Limbic Access There are no fixed costs associated with this digital front door technology and the licence cost is paid per digital front door technology referral; the price per digital referral decreases as the number of digital referrals increases (up to a threshold of 30,000 digital referrals). The EAG has assumed that IT support for NHS Talking Therapies staff and patients, and the costs of cybersecurity, are included as part of the Limbic Access licence cost.

Table 11 Cost of Limbic Access

Number of referrals received via digital front door technology per year		Licence cost per digital referral	
Lower bound	**Upper bound**	**Without VAT**	**With VAT**
1	5,000	£5.49	£6.59
5,001	15,000	£4.99	£5.99
15,001	20,000	£4.50	£5.40
20,001	25,000	£4.00	£4.80
25,001	30,000	£3.75	£4.50
30,001	100,000	£3.50	£4.20

RFI=request for information; VAT=value added tax (@20%)
Source: Limbic Access RFI[4]

The licence cost associated with the Wysa DRA varies according to the number of digital front door technology referrals; the price per digital referral decreases as the number of digital referrals increases (up to a threshold of 30,000 digital referrals). In addition to the licence cost per digital referral, Wysa charges a fixed implementation and set-up cost; this charge is only applied in Year 1.

Table 12 Cost of the Wysa DRA

Number of referrals received via digital front door technology per year		Licence cost per referral		Implementation and set-up costs
Lower bound	Upper bound	Without VAT	With VAT	
1	5,000	£3.25	£3.90	Without VAT: £9,150 With VAT: £10,180
5,001	10,000	£2.92	£3.50	
10,001	15,000	£2.53	£3.04	
15,001	20,000	£2.15	£2.58	
20,001	30,000	£1.60	£1.92	
30,001	-	£1.16	£1.39	

DRA=Digital Referral Assistant; RFI=request for information; VAT=value added tax (@20%)
Source: Wysa stakeholder comments

Table 13 shows the cost per digital referral for Limbic Access and Wysa DRA, estimated using a range of different numbers of digital referrals received over a 1-year period.

Table 13 Estimated total costs per digital referral (including VAT)

Digital front door technology	Number of referrals						
	1-5,000	5,001-10,000	10,001-15,000	15,001-20,000	20,001-25,000	25,001-30,000	30,001-100,000
Limbic Access (all years)	£6.59	£5.99	£5.99	£5.40	£4.80	£4.50	£4.20
Wysa DRA (Year 1)*	£8.29	£4.97	£3.91	£3.21	£2.41	£2.32	£1.56
Wysa DRA (Year 2 onwards)	£3.90	£3.50	£3.04	£2.58	£1.92	£1.92	£1.39

*The Wysa DRA implementation cost has been divided by the mid-point of the number of referrals
DRA=Digital Referral Assistant; EAG=External Assessment Group; VAT=value added tax (@20%)
Source: EAG calculations

8.3.6 Unknown costs

Staff training and digital front door technology promotional costs

The EAG was unable to identify any published costs of training and promotional activities associated with digital front door technologies. In the Limbic NICE RFI response,[4] Limbic stated that staff training was not required to use Limbic Access safely; however, staff training options were included within the licence cost, and it was reported that three 1 hour sessions (in person or virtually) are typically offered to NHS Talking Therapies staff. In the Wysa NICE RFI response,[6] Wysa stated that no more than 30 minutes of staff training was required. The EAG questionnaire included a question about staff training and promotional activities associated with digital front door technologies; one respondent confirmed that staff training and promotional costs were included in the Limbic Access licence. The EAG highlights that even if the company pays for staff training, there will be costs to the NHS associated with this

training that are not covered by the licence cost. For example, staff time needs to be freed up to allow staff to attend training; these costs are not covered by the company. Similarly, the promotional costs associated with introducing a digital front door technology will also be incurred by the NHS. These costs are required to ensure that all relevant local services and residents are aware of the digital front door technology and that potential users know how to access it; these costs are not covered by the companies. Additional information is required about the costs of staff training and promotional activities to help understand the true cost of implementing digital front door technologies as part of NHS Talking Therapies services.

Costs of applying digital clinical safety assurance DCB0129

The questionnaire included a question about the costs of introducing a digital front door technology that were associated with digital clinical safety assurance DCB0129 compliance.[3] One respondent stated that the cost was included in the cost of the Limbic Access licence. The cost implications of assuring digital clinical safety assurance DCB0129 compliance[3] when implementing digital front door technologies are not publicly available. Understanding these cost implications will help determine the true cost of implementing digital front door technologies as part of NHS Talking Therapies services.

Reducing administration burden in NHS Talking Therapies services

The impact that digital front door technologies have on reducing administration burden is unclear. Evidence from one questionnaire respondent was that the introduction of digital front door technologies in their area had resulted in approximately 20% of referrals being automatically triaged and signposted away from NHS Talking Therapies, thus saving NHS Talking Therapies staff from spending time on reviewing forms, checking patient data and writing letters to patients who were not eligible for NHS Talking Therapies. However, it is unclear whether any clinician triage time was saved by the introduction of a digital front door technology.

The EAG noted that three questionnaire respondents considered that the introduction of a digital front door technology had had a positive impact on the pre-assessment process. For example, reducing waiting times between referral submission and pre-assessment completion/initial clinical assessment, shorter duration of the pre-assessment process, clinical assessors being more informed before the start of the pre-assessment process, more accurate data and better quality data.

To fully understand whether the introduction of a digital front door technology can lead to a reduced administrative burden during the pre-assessment process, information is required to estimate the number of digital referrals that are automatically triaged and signposted away

from NHS Talking Therapies compared with the number of referrals that would have been signposted away had a different method of referral been used.

A digital front door technology has the functionality to automatically signpost people to alternative services, based on a number of criteria, before triage takes place. However, it is not clear whether the people who are signposted away would have submitted a referral if the digital front door technology had not been in place. If the digital front door technology increases the total number of referrals and the total number of inappropriate referrals then, even if the proportion of inappropriate referrals decreases, then the total administrative burden will have increased.

Currently there is insufficient evidence across NHS Talking Therapies services to estimate the impact of digital front door technologies on administration burden.

Time taken to review referral information

There are no published estimates of the time taken to review referral information with and without the use of a digital front door technology. However, evidence available from an unpublished study[18] suggested that clinicians using Limbic Access (N=38) spent 1 minute 53 seconds reviewing patient information; however, it is not clear whether the time taken to review patient information was spent before or during the initial clinical assessment.

Time taken to complete clinical assessment

Rollwage 2023[10] (included in the EAG SLR) estimated that the average clinical assessment time of patients referred via Limbic Access was shorter (mean time: 41.6 minutes) than the average clinical assessment time of patients who referred via other methods (mean time: 54.4 minutes; a statistically significant difference of 12.7 minutes). The EAG highlights that the impact of Limbic Access on time taken to complete any other pre- or post-assessment tasks (e.g., time taken to conduct a risk and suitability assessment or administrative time) is not known.

Rollwage 2023[10] suggests that the time saved is because the Limbic Access AI-chatbot is designed to increase patient engagement, with the goal of ensuring that a maximum number of patients provide clinically relevant information ahead of the initial clinical assessment, meaning that clinicians can spend less time during the initial clinical assessment carrying out mental health assessments. However, it is unclear whether a shorter clinical assessment time was only possible because clinicians were spending longer reviewing patient information prior to the initial clinical assessment. Questionnaire respondents agreed that the length of an initial clinical assessment, prior to the introduction of a digital front door technologies, ranged from

45 to 60 minutes. One questionnaire respondent estimated that the introduction of Limbic Access had led to a 10 minute reduction in the length of the initial clinical assessment (average length of 40 minutes for referrals via Limbic Access versus average length of 50 minutes for other referrals). However, Wysa stated (EAG RFI response[21]) that, in one area where the Wysa DRA was being used, 91% of initial clinical assessments for patients who had completed the full set of clinical questions were scheduled for 30 minute assessments instead of the standard 60 minute assessments; it is however possible that longer or additional clinical assessments took place for some of these patients.

The potential size of any initial clinical assessment time saved by the introduction of digital front door technologies is highly uncertain. Therefore, as part of an economic analysis, the EAG has monetised a range of possible time savings that reflect the available evidence on the potential time savings (5 to 30 minutes). The EAG highlights, even if time is saved, any monetary cost savings are notional, i.e., may not be realisable.

To monetise possible reductions in clinical assessment time, the cost of undertaking a clinical assessment and the time taken to complete a clinical assessment are required. The NHS Cost Collection 2023-2024[52] provides a range of costs for different NHS Talking Therapies activities (Table 14). The NHS Cost Collection categories are unclear. For example, an Assessment (01IAPT: £186) costs more than Assessment and Treatment (03IAPT: £158); the EAG was unable to identify any information that described the elements that were included in each cost category. For simplicity, and in line with the time horizon described in the NICE scope[1] (referral to end of initial clinical assessment), the Assessment cost (01IAPT: £186) has been used in the EAG analysis. A better understanding of the true cost of an initial clinical assessment and any pre-assessment activity would allow a more accurate economic analysis to be carried out in the future.

Table 14 Unit costs for NHS Talking Therapies: care contacts

Service description	NHS Cost Collection code	Value
Assessment	01IAPT	£186
Treatment	02IAPT	£166
Assessment and treatment	03IAPT	£158
Review only	04IAPT	£108
Review and treatment	05IAPT	£135
Follow-up appointment after treatment end	06IAPT	£130
Employment support	10IAPT	£129
Other (not listed)	98IAPT	£161

Source: NHS Cost Collection 2023-24[52]

To estimate the cost of possible initial clinical assessment time saved following the introduction of a digital front door technology, the EAG has assumed that the initial assessment takes 60 minutes; this allows a cost per minute of an initial clinical assessment to be estimated.

Questionnaire responses and Rollwage 2023[10] data suggest that the time taken to complete an initial clinical assessment may range from 45 to 60 minutes. The EAG has therefore calculated the cost per minute of an initial clinical assessment by assuming lengths of 45, 50, 55 and 60 minutes (Table 15).

Table 15 Estimates of the cost per minute of an initial clinical assessment

	Possible initial clinical assessment durations*			
Time taken for assessment	45 minutes	50 minutes	55 minutes	60 minutes
Cost per minute of assessment	£4.13	£3.72	£3.38	£3.10

* Cost of an initial clinical assessment is £186 (NHS Cost Collection 2023-24)[52]

The EAG has calculated a range of estimated (notional) cost savings assuming different durations of initial clinical assessment appointments (Table 16). For example, if the initial clinical assessment appointment lasts 50 minutes and the assessment time saved for a referral via a digital front door technology is 5 minutes, then the (notional) cost saving is £3.72 x 5=£18.60 per assessment.

Table 16 Notional cost savings resulting from reduced initial clinical assessment times

Initial clinical assessment time saved	**Time taken for assessment (minutes)**			
	45 minutes	**50 minutes**	**55 minutes**	**60 minutes**
5 minutes	£20.67	£18.60	£16.91	£15.50
10 minutes	£41.33	£37.20	£33.82	£31.00
15 minutes	£62.00	£55.80	£50.73	£46.50
20 minutes	£82.67	£74.40	£67.64	£62.00
25 minutes	£103.33	£93.00	£84.55	£77.50
30 minutes	£124.00	£111.60	£101.45	£93.00

Source: EAG calculations

Combining the (notional) cost savings per initial clinical assessment (Table 16) with the range of potential costs per referral (Table 13) allows estimates of the indicative net costs of Limbic Access (Table 17) and the Wysa DRA (Table 18) to be calculated. In this EAG report, when considering Limbic Access, the cost per referral relates to the licence cost, and when considering the Wysa DRA, the cost per referral relates to the licence cost and the implementation and set-up costs.

Table 17 Net cost of Limbic Access across a range of estimates of the cost per referral and notional cost savings per assessment

		Cost per referral		
		Lowest (£4.20)	**Highest (£6.59)**	**Midpoint of high and low estimates (£5.39)**
Notional cost saving per assessment	Lowest (£15.50)	-£11.30	-£8.91	-£10.11
	High estimate (£124.00)	-£119.80	-£117.41	-£118.61
	Mid-point of high and low estimates (£69.75)	-£65.55	-£63.16	-£64.36

Source: EAG calculations

Table 18 Net cost of the Wysa DRA across a range of estimates of the cost per referral and notional cost savings per assessment

		Cost per referral		
		Lowest (£1.56)	**Highest (£8.29)**	**Midpoint of high and low estimates (£4.93)**
Year 1*				
Notional cost saving per assessment	Lowest (£15.50)	-£13.94	-£7.21	-£10.57
	High estimate (£124.00)	-£122.44	-£115.71	-£119.07
	Mid-point of high and low estimates (£69.75)	-£68.19	-£61.46	-£64.82
Year 2 onwards				
		Lowest (£1.39)	**Highest (£3.90)**	**Midpoint of high and low estimates (£2.65)**
Notional cost saving per assessment	Lowest (£15.50)	-£14.11	-£11.60	-£12.85
	High estimate (£124.00)	-£122.61	-£120.10	-£121.35
	Mid-point of high and low estimates (£69.75)	-£68.36	-£65.85	-£67.10

*The Wysa DRA implementation cost has been divided by the mid-point of the number of referrals
Source: EAG calculations

EAG analysis results suggest that, for Limbic Access and the Wysa DRA, even using the lowest (notional) cost saving of £15.50 (i.e., a 5-minute saving for a 60-minute assessment) and the highest cost per referral (£6.59 and £8.29), the (notional) cost saving outweighs the costs of the technology (difference of £8.91 and £7.21). The assumption underpinning the EAG analysis is that all referrals via a digital front door technology lead to an initial clinical assessment; however, one of the perceived benefits of digital front door technologies is that they can be set up to automatically signpost people towards a service that is more appropriate for them than NHS Talking Therapies. Therefore, EAG results are likely to be over-estimates of (notional) cost savings. However, the notional cost savings are so high that even in the most

pessimistic scenario (lowest cost saving and highest cost per referral), the number of referrals via a digital front technology could be 3 to 4 times higher than the number of initial clinical assessments conducted and the (notional) cost saving per initial clinical assessment would still outweigh the cost per referral via Limbic Access or via the Wysa DRA.

To further highlight the minimal amount of initial clinical assessment time saved that would be required for Limbic Access or the Wysa DRA to be cost saving, the EAG has undertaken a threshold analysis using the highest licence cost per referral and different durations of initial clinical assessments. Results showed that, in the worst case scenarios, the average time savings required for Limbic Access and the Wysa DRA to deliver a (notional) cost neutral impact were less than 3 minutes (Table 19).

Table 19 Threshold analysis results (highest cost per referral)

Clinical assessment duration	Average time saving (minutes) required for cost neutral impact		
	Limbic Access	Wysa DRA (Year 1)	Wysa DRA (Year 2)
45	1.59	2.01	0.94
50	1.77	2.23	1.05
55	1.95	2.45	1.15
60	2.13	2.67	1.26

DRA=Digital Referral Assistant
Source: EAG calculations

The EAG emphasises that this analysis is exploratory, results are uncertain and may be of limited value to NHS decision makers. The EAG cautions that results should not be interpreted as evidence that cost savings are likely to be realisable in the NHS and/or that any cost savings would be the same for all NHS Talking Therapies services. Uncertainty will remain until more robust evidence becomes available to demonstrate the extent to which the introduction of digital front door technologies is able to reduce the time taken to conduct an initial clinical assessment and how this may generate cost savings for the NHS. Results from the EAG's simple exploratory analyses should not be used in isolation; they only form a small part of any assessment of the benefits and costs of digital front door technologies.

Given the uncertainty around initial clinical assessment time saved associated with referrals via Limbic Access and via the Wysa DRA, the EAG considered a scenario where no time was saved and assessed the quality adjusted life year (QALY) gains that would need to be accrued for Limbic Access and the Wysa DRA to be considered cost effective at a willingness to pay (WTP) threshold of £20,000 per QALY gained (Table 20).

Table 20 Estimated QALY gains per referral via Limbic Access and via the Wysa DRA required for these technologies to be considered cost effective at a threshold of £20,000 per QALY

Digital front door technology	Number of referrals						
	1-5,000	5,001-10,000	10,001-15,000	15,001-20,000	20,001-25,000	25,001-30,000	30,001-100,000
Limbic Access (all years)	0.0003	0.0003	0.0003	0.0003	0.0002	0.0002	0.0002
The Wysa DRA (Year 1)*	0.0004	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001
The Wysa DRA (Year 2 onwards)	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001

*The Wysa DRA implementation cost has been divided by the mid-point of the number of referrals
EAG=External Assessment Group; QALY=quality adjusted life year
Source: EAG calculations

8.4 EAG conceptual model

The outcomes listed in the NICE scope[1] relate to pre-assessment referral practice to NHS Talking Therapies with and without digital front door technologies. For the purposes of this EVA, it was not necessary to develop an economic model due to the short evaluation time horizon and the focus on process outcomes, for which evidence is currently limited.

When more robust evidence for the process outcomes becomes available, calculations in line with those presented in Section 8.3 could be undertaken. If outcomes outside the scope of this EVA were to be included in a future appraisal, an economic model may be required to understand the economic implications associated with the use of digital front door technologies.

9 INTERPRETATION OF THE EVIDENCE

The EAG's review of the available clinical and economic evidence is in line with two key components of the NICE scope[1] for this EVA:

- time horizon (from referral [any route] to end of initial clinical assessment)
- outcomes (quality and accuracy, resource and system impact, and patient reported outcomes)

Whilst not discussed in this report, the EAG highlights that data for outcomes beyond the NICE scope[1] for this EVA are available from Limbic (Limbic Access) and are being collected by Limbic (Limbic Access) and Wysa (Wysa DRA). These Limbic and Wysa data could be used to inform a future evaluation of pre-assessment referral methods (with and without digital front door technologies) to NHS Talking Therapies with a wider scope. All four digital front door technologies offer slightly different benefits (and limitations) and therefore evidence from one technology is unlikely to be generalisable to all other technologies.

There was limited information about NHS pre-assessment referral pathways with and without the use of digital front door technologies. Feedback from experts indicated that there is heterogeneity across NHS Talking Therapies services in terms of the quantity and nature of the referral information collected, how referrals are processed and the benefits a digital front door can offer.

Published evidence was not available for most of the outcomes listed in the NICE scope.[1] In some studies, the strength of the evidence provided by the companies was difficult to determine due to small populations, weak methodologies and a lack of transparency in reporting. The evidence for Limbic Access was more robust than the evidence for the Wysa DRA.

9.1 Interpretation of the clinical evidence

The evidence base is limited and only includes two peer-reviewed (Limbic Access) studies.[10,15] Although real-world data have been collected by Wysa, these studies are unpublished and do not include comparative data. The only available Censeo Digital data do not relate to NHS Talking Therapies and no AskFirst data are publicly available or have been provided in response to the NICE RFI[5] or EAG RFI.[19] Therefore, all EAG discussions are around the benefits and costs of Limbic Access and the Wysa DRA.

In addition to a lack of robust evidence, the extent to which the available clinical evidence is generalisable to all NHS Talking Therapies providers is unclear. Expert advice to the EAG is that, across all NHS Talking Therapies services, the processes and systems in place to manage patients from referral to the completion of the initial clinical assessment are

heterogenous. This heterogeneity will affect how the implementation of a digital front technology can impact the outcomes listed in the NICE scope.[1] However, the EAG considers that the evidence is generalisable to NHS patients who use digital front door technologies.

The available evidence focused on the advantages and disadvantages of the technologies for NHS Talking Therapies staff (administrative and clinical) and patients accessing NHS Talking Therapies. Clinicians' perceptions of the useability and usefulness of Limbic Access and the Wysa DRA were positive. Where there were data for patients accessing NHS Talking Therapies, the evidence was largely positive. However, most of the evidence was sourced from user responses to questions posed after the user had completed referral information collected via a digital front door technology and, in some studies, patients had been asked to imagine they were self-referring to NHS Talking Therapies via a digital front door. Data reported by Limbic and Wysa from individuals who started to complete the digital front door technology referral process (Limbic Access[4] and the Wysa DRA[6]) showed that completion rates were high and, generally, impressions were favourable.

Only Limbic provided direct evidence comparing outcomes for users referring via a digital front door technology (Limbic Access) versus users referring via other methods.[4,10,15,18,45] Two studies[15,45] showed that, compared to a period prior to the introduction of Limbic Access, there had been an increase in referrals to NHS Talking Therapies services. One study[10] also showed that, over the same time period, the number of referrals via Limbic Access was higher than the number of referrals via other referral methods. An important finding was that there was an increase in referrals from some minority groups, including people identifying as non-binary and those from ethnic minority groups;[15] there were no decreases in referrals from any other patient group defined by demographic characteristics.

One of the highlighted benefits of using a digital front door technology was the potential to save time during the initial clinical assessment. Both Limbic and Wysa were confident that their digital front door technologies could save time: 12.7 minutes via Limbic Access (peer-reviewed study[10]) and between 16 and 21 minutes via the Wysa DRA (unpublished data; NICE RFI response[6]). Expert advice to the EAG was mixed, ranging from estimated time savings of zero minutes (Wysa DRA) to 10 minutes (Limbic Access). Rollwage 2023[10] suggested that the time saved was because Limbic Access provided clinically relevant information ahead of the initial clinical assessment meaning that less clinician time is spent during the initial clinical assessment on assessing patient mental health. However, the EAG highlights that clinicians may spend additional time reviewing patient information prior to the initial clinical assessment; the net time saved is therefore not known. Wysa has not provided any rationale to explain why clinical assessment times may be reduced when referrals are made via the Wysa DRA and

stated that time saved during the initial clinical assessment was not always a valid or fair measure of the effectiveness or efficiency of a digital front door technology.[21] Further, it is not clear whether a shorter clinical assessment time could be realised in all NHS Talking Therapies services as time savings may depend on how each individual NHS Talking Therapies provider manages patients from referral to the end of the initial clinical assessment.

Any time saved may represent an opportunity to reconsider the use of clinical or administrator time, depending on the structure of the referral pathway and the priorities of the NHS Talking Therapies provider. For example, a shorter initial clinical assessment may mean that:

- fewer clinicians may be required to complete the same number of clinical assessments and clinicians who are no longer required to carry out initial clinical assessments could carry other duties (e.g., deliver treatment)
- any clinician time saved could be reallocated to conduct more initial clinical assessments and reduce waiting times
- any time saved may be used to discuss the patient's presenting problems and objectives in more detail which may result in a more accurate and high-quality clinical assessment

Future data collection is required to better understand under what circumstances time savings may arise, the magnitude of the time savings and how any time savings translate into changes in NHS Talking Therapies service provision.

All questionnaire respondents (N=5) were positive about the introduction of digital door technologies and considered that the introduction of this referral method would lead to better quality, more accurate pre-referral practices and initial clinical assessments. However, when asked specifically, experts who provided advice to the EAG were unable to offer clear definitions of quality or accuracy of pre-assessment practice or of initial clinical assessment. Limbic's definitions of quality and accuracy[18] appear to rely on the ability of Limbic Access to provide diagnoses (largely based on information collected via ADSMs) as well as outcomes reporting treatment step-ups/down. The EAG highlights that any definitions of quality and accuracy linked to diagnosis and treatment are outside of the NICE scope.[1] Wysa stated[21] that their focus was on providing continuous and accessible support to patients (via their app, Every Day Mental Health) and that they have a research protocol in place to explore how data collected by the Wysa DRA may help clinicians to make an accurate treatment decision for the patient; this is also outside of the NICE scope.[1]

None of the available clinical evidence reviewed identified any harms to clinicians or patients. However, expert advice to the EAG was that whilst some patients may prefer referring via digital front door technologies, others may prefer more traditional referral methods; therefore, it is important that all currently available referral methods remain available to patients. Further,

static online forms that link EPRs appear to deliver many of the benefits offered by digital front door technologies. Both static online forms and digital front door technologies offer some benefits over paper, email and telephone-based referral methods.

9.2 Interpretation of the economic evidence

The economic evidence currently available to support the use of digital front door technologies to pre-assess people before NHS Talking Therapies clinical assessments is minimal.

Most of the costs associated with the introduction of a digital front door technology to access NHS Talking Therapies appear to be licence costs; relevant licence costs were only provided by Limbic[4,18] and Wysa.[6,20] The specific costs associated with establishing and maintaining a digital front door technology for NHS Talking Therapies that are not covered by the licence fee are unknown. However, the EAG considers that, as the non-licence fee costs will only ever represent a small percentage of the total cost of a digital front door technology, this issue is of minor concern.

Evidence from a published study,[10] Limbic NICE RFI response,[4] Wysa RFI response,[6] and expert advice to the EAG is that the adoption of Limbic Access or the Wysa DRA may reduce the time taken to complete a clinical assessment. The EAG's exploratory economic analysis results suggest that the amount of clinical assessment time saved that is required to notionally offset the Limbic Access licence cost or the Wysa DRA licence cost is small. However, whether the introduction of a digital front door technology saves time during the initial clinical assessment is not well supported by the evidence. If no time is saved, then a very small QALY gain (0.0003 QALYs per referral) would be required for Limbic Access or for the Wysa DRA to be considered cost effective at a WTP threshold of £20,000 per QALY (if only licence costs are considered).

There is an absence of quantitative data to support any claim that digital front door technologies reduce administrative burden.

9.3 Integration into the NHS

Information provided by Limbic, Wysa and experts confirmed that many NHS Talking Therapies services are currently using digital front door technologies (Limbic Access and the Wysa DRA). Limbic reported in their NICE RFI response[4] that over 350,000 referrals to NHS Talking Therapies had been processed via Limbic Access; Wysa reported that there had been 186,179 referrals to NHS Talking Therapies services via the Wysa DRA.[21] Although the functionality and intended purpose of the digital front door technologies varied between services, integration with current NHS software systems does not appear to have been

problematic. Further guidance may be required to mitigate and manage risks, which may include:

- **Training staff** to interpret and use the output from the digital front door technologies; it is important to ensure that clinicians are not unduly influenced by any AI-suggested problem descriptors and suggested treatment pathway
- **Consensus around the appropriate eligibility screening/triage criteria** so that digital front door technologies do not exclude patients who may benefit from NHS Talking Therapies
- **Ensuring other referral methods remain accessible** so that digital front door technologies do not reduce access to NHS Talking Therapies for individuals who are more likely to refer via other methods (e.g., online static form, email, telephone)
- **Continuous monitoring of user experience** to ensure that digital front door technologies provide optimal patient experience and collect appropriate data

9.4 Ongoing studies

A list of relevant ongoing studies, identified by the EAG literature searches or highlighted in Limbic RFI responses,[4,18] is presented in Table 21; these ongoing studies will provide data that are within the NICE scope.[1] Psyomics advised that Censeo Digital (EAG RFI response[19]) is expected to be adopted by NHS Talking Therapies in 2025 (Q2 and Q3).

Table 21 Ongoing studies

Ongoing study	Alignment with the NICE scope	Outcome data	Indicated study end date
Study identifier: NCT05495126[16] Study design: RCT Sponsor: Limbic Limited Country: United Kingdom	Intervention: Limbic Access Class IIa version Comparator: Limbic Access Class I version Participants: 5,030* Primary outcomes: change in depression & anxiety score after treatment, change in diagnosis, clinical assessment duration and waiting times AMBER	• Time taken to complete clinical assessment • Referral dropout rates • Assessment dropout rate	10/12/2024
Mind Matters (NHS Surrey and Borders Partnership) observational study registered as NHS portfolio study[50] Sponsor: Limbic Limited Country: United Kingdom	Intervention: Limbic Access Class IIa version Comparator: Limbic Access Class I version Participants: Not reported** Outcomes referred to in RFI EAG RFI response:[18] wait times from referral to assessment, recovery rate, reliable recovery	• Wait times from referral to assessment	Not reported

Ongoing study	Alignment with the NICE scope	Outcome data	Indicated study end date
	rate, drop out post-referral AMBER		
Study identifier: NCT05678764[49] Study design: Observational study (continuation of Rollwage 2023[10]) Sponsor: Limbic Limited Country: United Kingdom	Intervention: Limbic Access Class IIa version Comparator: other self-referral methods Participants: 300,000*** Primary outcomes: change in depression & anxiety score after treatment, clinical assessment duration AMBER	• Time taken to complete assessment • Referral dropout rates • Assessment dropout rate	30/12/2025
Study identifier: ISCRTN10327977[17] Study design: RCT Sponsor: Wysa Limited Country: United Kingdom	Intervention: Wysa therapeutics including the Wysa DRA (Part 1) Comparator: Other referral methods Participants: 100 Primary outcomes: clinical assessment duration (Part 1) AMBER	• HRQoL data • Dropout rates • Time taken to complete clinical assessment	31/07/2025

* Data available from [redacted] participants presented in Limbic EAG RFI response[18]
** Data available for 3,715 participants presented in Limbic EAG RFI response[18]
*** Data available from [redacted] participants presented in Limbic EAG RFI response[18]
GREEN=study characteristic aligns with the NICE scope;[1] AMBER=study characteristic does not fully align with the NICE scope;[1] RED=study characteristic does not align with the NICE scope[1]
HRQoL=health-related quality of life; RCT=randomised controlled trial

10 EVIDENCE GAP ANALYSIS

The EAG considers that further evidence is required to better understand the benefits and costs of digital front door technologies for NHS Talking Therapies. The EAG has identified gaps between the available evidence and the evidence needed to address the outcomes listed in the NICE scope.[51] The EAG highlights that there is no evidence to support the use of Censeo Digital and AskFirst as digital front door technologies for NHS Talking Therapies.

Each of the components listed in the NICE scope[51] is associated with evidence gaps; these are described narratively in Section 10.1. A summary of the Limbic Access and the Wysa DRA evidence gaps, identified by the EAG SLR, is presented in Table 22

10.1 Evidence gaps identified by the EAG

Population gaps

- Study population demographic data were rarely reported; the extent to which reported differences in outcomes were driven by patient baseline characteristics was unclear.

Intervention gaps

- Each digital front door technology can be customised (e.g., eligibility screening criteria, content and ordering of the AI-chatbot questions, recommended treatment pathway) in line with NHS Talking Therapies provider preferences; it was not clear whether, or how, any of the assessed technologies were customised.
- Two peer-reviewed Limbic Access studies[10,15] provided information relating to the Class I version of Limbic Access; this version has now been superseded by the Class IIa version of Limbic Access. The Class IIa version includes the additional functionality to select ADSMs (using a machine learning algorithm) during referral. Interim analysis results from an ongoing RCT,[16] an ongoing observational study,[50] ongoing service evaluations (all data from the Limbic EAG RFI response[18]) and data externally audited by the MHRA[43,44,47,48] suggest that outcomes are at least comparable between the two versions; the EAG consider that it is important that data are continuously collected to assess whether later versions of a technology deliver the same or better benefits to NHS staff and patients.
- There is no relevant evidence from NHS Talking Therapies available for the use of Censeo Digital and AskFirst as digital front door technologies for NHS Talking Therapies.

Comparator gaps

- There was often limited information reported in studies about the referral methods or services being compared with digital front door technologies; for example, what specific information was collected as part of the referral process; this made it difficult to assess the generalisability of study results.
- Very few studies provided robust evidence for the comparison of a digital front door technology versus an individual standard referral method.

Outcome gaps

- Published evidence was not available for most of the outcomes listed in the NICE scope.[1] In some studies, the strength of the evidence provided by the companies was difficult to determine due to small populations, weak methodologies and a lack of transparency in reporting.
- Outcome data were rarely reported by demographic group, (e.g., males, ethnic minorities); therefore, it is uncertain if, and to what to extent, the benefits of digital front door technologies varied across patient subgroups.
- Lack of relevant data to measure the impact of digital front door technologies on the accuracy of clinical assessment for NHS Talking Therapies (AA2).
- All the different referral methods are associated with different benefits and costs and therefore only comparing digital front door technologies versus all standard referral methods may lead to results that are not helpful.

Cost effectiveness gaps

- Further research is required to confirm under what circumstances time savings may arise during initial clinical assessments, their magnitude and if there is any subsequent impact on NHS Talking Therapies service provision.
- There are some uncertainties around the cost to the NHS of training, promotion and digital safety assurance associated with the use of digital front door technologies. Although NHS Talking Therapies cost data are currently collected (and reported in NHS Cost Collection), costs are not currently reported for referrals and/or any pre-assessment activity.

Table 22 Evidence gap analysis

Outcomes	Limbic Access	The Wysa DRA
Accuracy and acceptability outcomes		
AA1: Quality and accuracy of the data collected using digital front door technologies	Data provided by Limbic; unclear if definition used is relevant RED	Data provided by Wysa; unclear if definition used is relevant RED
AA2: Accuracy of the clinical assessment	Unpublished data provided by Limbic RED	No studies or data RED
AA3: Completion rate of referral for digital front door technologies	Unpublished data provided by Limbic AMBER	Unpublished data provided by Wysa AMBER
AA4: Inaccessibility to digital front door technologies	One published study, unpublished data provided by Limbic and one unpublished study GREEN	Unpublished data provided by Wysa AMBER
AA5: Healthcare professional acceptability of digital front door technologies	Unpublished data provided by Limbic and one unpublished study AMBER	Unpublished data provided by Wysa RED
Resource and system impact outcomes		
RSI1: Impact on administrative burden	One unpublished study RED	No studies or data RED
RSI2: Time taken to review data collected by digital front door technology	Unpublished data provided by Limbic and one unpublished study RED	No studies or data RED
RSI3: Time taken to complete clinical assessment	One published study, unpublished data provided by Limbic and one unpublished study AMBER	Unpublished data provided by Wysa RED
RSI4: Time saved for clinician during clinical assessment	One published study, unpublished data provided by Limbic and one unpublished study AMBER	Unpublished data provided by Wysa RED
Service user reported outcomes		
PRO1: Ease of access and usability	Two published studies and unpublished data provided by Limbic AMBER	No studies or data RED
PRO2: Information clarity and relevance	One published study and unpublished data provided by Limbic AMBER	No studies or data RED
PRO3: Comfort and privacy	Two published studies and unpublished data provided by Limbic AMBER	No studies or data RED
PRO4: Overall satisfaction	One published study, unpublished data provided by Limbic and one unpublished study GREEN	Unpublished data provided by Wysa AMBER

Outcomes	Limbic Access	The Wysa DRA
Economic outcomes		
Licence costs and number of users	Unpublished data provided by Limbic GREEN	Unpublished data provided by Wysa GREEN
Initial set up and integration costs	Unpublished data provided by Limbic GREEN	Unpublished data provided by Wysa GREEN
Operational costs	Unpublished data provided by Limbic GREEN	Unpublished data provided by Wysa GREEN
Training costs	Unpublished data provided by Limbic AMBER	Unpublished data provided by Wysa AMBER
Costs of promotion	No studies or data RED	No studies or data RED
Digital safety assurance costs	No studies or data RED	No studies or data RED

GREEN=clear evidence from at least one study; AMBER=evidence is subjective and/or inconsistent; RED=no studies/sources of evidence or outcome data/definitions may not be useful, e.g., data from very small sample or outcome definition is outside of NICE scope[1]
DRA=Digital Referral Assistant

10.2 Key areas for evidence generation

The EAG considers that future research should build on the real-world evidence that has already been collected from clinicians and patients who have used Limbic Access and the Wysa DRA. EAG evidence generation recommendations are provided in Table 23. Effectiveness data from these studies will help inform future cost effectiveness analyses.

Table 23 Digital front door technologies: EAG evidence generation recommendations

Research question	Possible study design	Outcomes
1. How are referrals processed in a pathway without a digital front door?	Delphi method or other consensus methods	• A standard NHS Talking Therapies referral pathway or a set of referral pathways
2. Does the digital front door technology improve the accuracy and quality of the data collected?	Delphi method or other consensus methods to define quality and accuracy followed by comparative study of individuals referred via digital front door technology vs those referred by other route(s)*	• Quality and accuracy of data collected by digital front door and comparator(s) using clearly defined measure(s) from Delphi method
3. Do digital front door technologies improve the accuracy of clinical assessment for NHS Talking Therapies	Comparative study of individuals referred via digital front door technology vs those referred by other route(s)	• Sensitivity/specificity of problem descriptor identified by clinical assessment versus problem descriptor identified by 'gold standard' reference standard

4. Do digital front door technologies improve process efficiency?	Comparative study of individuals referred via digital front door technology vs those referred by other route(s)*	• Clinical and/or administrative burden including:
		  ○ Time taken to complete pre-assessment
		  ○ Time taken to complete clinical assessment (including any clinician time reviewing referral information prior to assessment)
		• Healthcare professional acceptability of digital front door technology

5. Do digital front door technologies improve access to NHS Talking Therapies?	Comparative study of individuals referred via digital front door technology vs those referred by other route(s)*	• Number of referrals • Number of referrals signposted or referred to other services • Number of referrals offered a clinical assessment • Number of referrals completing assessment • Number of referrals recommended NHS Talking Therapies treatment • Population subgroup analyses (defined a priori) • Patient user views of digital front door technology including ease of access and usability, information relevance and

Research question	Possible study design	Outcomes
		clarity, comfort and privacy and overall satisfaction
6. What is the cost effectiveness of digital front door technologies compared to referral pathways without a digital front door or compared to a referral pathway with a different digital front door?	Comparative study of individuals referred via digital front door technology vs those referred by other route(s)*	• Training, promotion and digital safety assurance costs of digital front doors • Resource use estimates at each stage of the referral pathway • EQ-5D data (for patients and healthcare professionals)

* Cluster RCT (by service provider) or, if not feasible, a before and after cohort study with matching control services (similar to Habicht 2024[15])
EAG=External Assessment Group; EQ-5D=EuroQol-5 Dimensions; RCT=randomised controlled trial

11 CONCLUSIONS

11.1 Clinical evidence

Evidence is only available for two digital front door technologies (Limbic Access and the Wysa DRA) for pre-assessment referrals to NHS Talking Therapies. Only two peer-reviewed studies[10,15] provided relevant data (Limbic Access); all other information was unpublished and/or was provided by Limbic and Wysa. Available clinical data were sourced from NHS clinicians and patients and their feedback was largely positive. However, most of the studies were non-comparative and focused mainly on the strengths and weaknesses of the digital front door technologies. Limbic and Wysa have developed technologies that are designed to be accessible to all NHS patients, including older people, minority groups, and those with disabilities. Some evidence has been provided to show that Limbic Access is effective at facilitating referrals from gender and ethnic minority groups that are typically underrepresented in mental healthcare. No evidence quantifying the potential harms of digital front door technologies was identified by the EAG SLR.

There was no consensus amongst experts as to how the quality and accuracy of collected data and the accuracy of the initial clinical assessment should be defined or measured. Limbic focused discussions of accuracy around the ability of the technology to accurately identify problem descriptors/diagnoses (these outcomes are outside the NICE scope[1] for this EVA).

11.2 Economic evidence

The evidence provided by Limbic and Wysa suggested that there was the potential for Limbic Access and the Wysa DRA to save time during initial clinical assessments. Further research is required to confirm under what circumstances time savings may arise, their magnitude and if there is any subsequent impact on NHS Talking Therapies service provision. The EAG highlights that although time savings are uncertain, EAG exploratory economic analysis results suggested that only short time savings would be required to generate notional cost savings to the NHS and offset any costs incurred through the introduction of digital front door technologies. Only short time savings would be required as the only costs included in the EAG analyses were licence costs, which were modest. There may be other cost savings that could be realised during the referral process (e.g., reduced pre-assessment process administrative burden); however, data are not currently available to support any other cost saving assumptions.

The EAG has been able to map the available digital front door technology evidence, assess potential benefits and costs and identify evidence gaps to help direct future data collection and further research. However, lack of comparative data means that it has not been possible for

the EAG to carry out a robust full cost effectiveness analysis for the comparison of NHS Talking Therapies pre-assessment referral practices with and without digital front door technologies.

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13 APPENDICES

13.1 Appendix 1: Information about the digital front door technologies

13.1.1 Limbic Access

All information in this section is derived from the Limbic RFI response.[4]

Limbic is the company that has developed Limbic Access. Limbic Access has completed a Digital Technology Assessment Criteria (DTAC) and is a UK Conformity Assessed class IIa medical device which is currently used in the NHS for NHS Talking Therapies. Limbic Access is the most widely used digital front door in NHS mental health pathways having processed over 350,000 referrals into NHS Talking Therapies services.

Limbic Access is compliant with all NHS digital and data protection standards including the General Data Protection Regulation (GDPR). As a class IIa medical device and certified to ISO 13485, initial development, and ongoing assessment, of Limbic Access' risk profile includes designed mitigations against security risks. Limbic Access is compliant to Web Content Accessibility Guidelines (WCAG) web accessibility standards to support ease of viewing and individuals with visual impairments.

Limbic Access (medical device) software is a cloud-based conversational AI-chatbot integrated into an NHS Talking Therapies service's website that determines whether the individual who uses the tool is eligible for NHS Talking Therapies. Users may be self-referrals or directed to use it by other health professionals (e.g., GPs). Limbic Access can refer users not eligible for NHS Talking therapies (based on age, GP location and risk/crisis) to a more appropriate service.

Limbic Access has native usability on desktop and mobile. Limbic Access:

- collects required contact and demographic information
- collects additional clinical information about the patient's presenting symptoms, e.g., PHQ-9, GAD-7 and Work and Social Adjustment Scale [WSAS]; it should be noted that for a referral to be complete, it is not necessary for the user to complete the additional clinical information.
- leverages AI to predict diagnosis by adaptively tailoring the collection of clinically relevant information, e.g. Anxiety Disorder Specific Measures (ADSMs).

All the information collected by the AI self-referral tool is then attached to the referral record within the NHS Talking Therapies service. Limbic Access integrates directly (via API) with all major patient management systems (e.g., iaptus and PCMIS). Where users have completed clinical information, the output will include an indication of most likely diagnoses (depression, generalised anxiety, panic disorder, PTSD, OCD, eating disorders, health anxiety, specific

phobia, social phobia). While Limbic Access can provide predicted diagnoses, it is only designed to support and augment clinician-led assessments, not replace them.

The Limbic Access output is presented to clinicians in the following ways:

- directly in the patient's record in the patient management system
- via the Limbic Access browser extension
- via email or PDF reports (typically this is only used for non-NHS use cases of Limbic Access - eg. private insurance / employer models).

Limbic Access outputs are configured to contain the following sections:

- Tags. Phrases used to provide key information about the referral. Typically, information used by the service to prioritise patients, e.g., "high/low risk", "veteran", "substances", "diabetes" (Long Term Conditions - LTCs).
- Risk. Reaffirming risk level, providing PHQ-9 Q9 score, whether or not words/phrases were detected in free text (with the actual words/phrases if present), whether or not the patient said they could keep themself safe.
- Potential diagnoses. Potential diagnoses with logic on why (e.g., scored above X on Y ADSM)
- Minimum Data Set scores. Scores to the PHQ-9, GAD-7, WSAS and phobia scales (individual and cumulative)
- ADSM scores. List of all potential ADSMs that could have been asked, with total scores for those administered and a status of "not administered" for those not asked to the patient
- Patient information. All answers to demographic questions (e.g., gender, race), contact information, consents given etc.
- Social/Medical history. All answers to questions asked about contextual medical or social history, for example alcohol use, drug use, medication, employment, LTCs etc. The above configuration of the Limbic Access output.

The Limbic Access browser overlays the cloud-based PMS in the native browser (e.g., Google Chrome, Microsoft Edge or Mozilla Firefox). It allows clinicians to view a record of a patient (referred via Limbic Access) in a more presentable and actionable format (e.g., data visualisation).

There is no training requirement for Limbic Access to be used safely by patients. However, for it to be used effectively by NHS staff, training (typically three 1 hour sessions) is required for administrative staff and clinicians. Training is provided by Limbic as part of the implementation of the product with additional training provided free as when needed (e.g., when a new PWP is employed by the service). Limbic has a staffed team who can be contacted and feedback channels are available via the browser extension part of the product.

Prior to becoming a class II device in January 2023, Limbic Access was previously available as class I medical device. The class I device did not contain any machine learning and served

as a digital collection of intake information for NHS Talking Therapies, as well as encompassing additional clinical questions (pre-set) to be collected from patients.

13.1.2 Wysa Digital Referral Assistant

Except where stated, all information in this section has been extracted from the Wysa NICE RFI response.[6]

Wysa Ltd is the company that has developed the Wysa DRA (registered name of the product: the Wysa e-triage). The Wysa DRA has completed a DTAC and is live in several NHS Talking Therapies Services including Dorset, Coventry and Warwickshire, and Lancashire and South Cumbria.

The Wysa DRA is compliant with all NHS digital and data protection standards including GDPR. The Wysa DRA aligns to WCAG 2.1 guidelines to ensure that the user interface is accessible to people with varying abilities or disabilities.

The Wysa DRA is a web-based conversational tool embedded within an NHS Talking Therapy's service website. It is designed to facilitate people who feel they have a mental health difficulty to access Talking Therapies services. The Wysa DRA is for self referrals only. The software is also designed to support those who are not eligible for NHS Talking Therapies services by directing them to an alternative appropriate service. Eligibility is defined by age and GP location, only. All other referrals are accepted by NHS Talking Therapies.

The web widget works across windows, iOS and Android on desktop, laptops, mobile and tablet. The Wysa DRA:

- collects required contact and demographic information
- collects additional clinical information about the patient's presenting symptoms, including GAD-7, PHQ-9 and WSAS as default, along with all other minimum data set questions
- identifies risk to self (self-harm) or risk from others (domestic violence) via free text using a combination of natural language processing (NLP) techniques and rule-based matching to risk-related phrases.

As highlighted in the Wysa EAG RFI response,[6] the questions included within the Wysa DRA can also be customised in relation to both content and ordering, as can the prioritisation flags that are created and transferred into the iaptus electronic patient record (EPR) system. The technology is not intended to replace a clinical review. It is intended to provide, in an easy to read and understand format, a range of demographic and clinical information that services can use to inform the type of assessment that is most appropriate for the patient and that clinicians

can use to inform their one-to-one clinical assessment. All referrals are reviewed by healthcare professionals.

On submission of the completed questions, the product transfers information directly into iaptus and all patients are offered instant access to the Everyday Mental Health by Wysa App for 12 months. This app provides an AI coach, contains a wide range of meditation and relaxation exercises, CBT based self help conversational exercises, problem solving and thought reframing. As highlighted in the Wysa EAG RFI response,[21] access to the tools and conversational support within the Everyday Mental Health by Wysa App is optional for both the service and the individual. The Wysa app can be customised with local signposting support options for each service, and the onboarding conversation is bespoke and agreed with the service prior to go-live. The features of this app are beyond the scope of this EVA and are not being evaluated within this EAG report.

The Wysa DRA requires no more than 30 minutes of training for staff. Wysa also provides a staff user guide, and an email address in the case of any queries, questions or concerns.

The Wysa DRA software is regularly updated on an iterative basis according to service needs and continuous improvement cycles.

13.1.3 Censeo Digital

Except where stated, all information in this section is derived from the Psyomics RFI response.[5] It should be noted that in January 2025, following discussions with the MHRA, the MHRA determined that Censeo Digital was incorrectly registered as a Class I medical device and the current Clinical Evaluation Report (CER) does not demonstrate adequate evidence of safety and effectiveness as required by UK medical device regulation 2002 (as amended).

Psyomics Ltd is the company that has developed Censeo Digital (often referred to as Censeo). The product was built by NHS clinicians with the NHS system and pathways in mind. Censeo is currently contracted for use with four NHS organisations but is not currently used for referrals to NHS Talking Therapies. As stated in the EAG RFI response,[19] all current and future provider partners could use Censeo at any point. Psyomics are aware that one client will be going live with Talking Therapies in April 2025 and expect at least two others will go live between May and September 2025.

Censeo is fully compliant with NHS digital and data protection standards, including GDPR. For users of Censeo with literacy challenges or certain disabilities (e.g., visual impairment), additional support may be required. Censeo is an online questionnaire. It is an adaptive

questionnaire meaning questions are skipped or added based on patient responses to ensure relevance and reducing unnecessary questions.

Censeo is a cloud based software, accessible on mobile, tablet, and desktop platforms. Censeo's algorithm uses self-reported patient data, including:

- mental health history
- symptom severity across 15 conditions
- psychosocial factors such as housing and employment status
- priority indicators, such as suicidality, self-harm, and impulsive behaviours.

Censeo integrates with NHS systems via API to manage both GP and Single Points of Access (SPA) referrals. Once a referral is made and classified as non-urgent, the system automatically sends a link for the patient to complete the Censeo questionnaire. Censeo uses rule-based algorithms and adaptive questioning to analyse the patient-reported data. It generates a detailed report that categorises conditions by likelihood (e.g., 'Possible', 'Probable', 'Highly Likely') and flags urgent triage needs such as suicidality or severe trauma. Clinicians can access this data through a secure web platform integrated into the EPR and an email notification is sent to the assessing team if the triage priority is high or very high, flagging potentially urgent cases. Censeo does not provide diagnoses. It presents the likelihood of mental health conditions based on patient-reported data and categorises cases by urgency, helping clinicians prioritise cases for review. However, the final diagnostic and treatment decisions are always made by trained professionals. Censeo reports are designed to be interpreted by professionals who are already trained in mental health triage and familiar with DSM-5 and ICD-11 conditions. Therefore, users must be competent in making autonomous clinical decisions based on these diagnostic frameworks. The Censeo output supports clinicians in guiding those patients to other relevant services based on their needs.

Minimal training is required for NHS staff who can become proficient with the system after a short 30 to 60 minute training session, which covers the key functionalities of the platform, report interpretation, and its integration into clinical workflows. Psyomics offers ongoing support and supplementary materials, such as user guides, video tutorials, and FAQs. A helpdesk service is also available to address any technical or operational queries.

Censeo has undergone iterative improvements since its initial release. The key changes made across versions have focused on enhancing user experience, improving the accuracy of condition likelihood estimates, and refining the triage prioritisation system. New updates are planned for in the next 18 months that will further refine the user interface, enhance integration with Electronic Health Records (EHR) systems, and potentially introduce screening for ADHD

and expand the age range to under 18s. There are also plans to improve accessibility features, such as screen reader compatibility, to ensure the platform is more inclusive.

13.1.4 AskFirst

Sensely is the company that has developed AskFirst in partnership with the NHS. Sensely have not provided an RFI response for this EVA. Therefore, the limited information available about this digital front door is taken from the final NICE scope.[1]

AskFirst is an online consultation platform accessible on mobile, tablet, and desktop platforms. It provides a triage function with symptom checking and routing to pathways, including NHS Talking Therapies. Digital mental health assessments include PHQ-9 and GAD-7 questionnaires. AskFirst integrates with GP IT systems and 111 service providers.

13.2 Appendix 2: Data sources searched by the EAG

Table 24 Data sources searched by the EAG

Source	Date range	Date of search
MEDLINE	1946 to December 06, 2024	08.12.2024
EMBASE	1974 to 2024 December 05	08.12.2024
APA PsycInfo	1806 - current	10.12.2024
Cochrane Library: CENTRAL	Issue 11 of 12	08.12.2024
Cochrane Library: Cochrane Database of Systematic Reviews	Issue 12 of 12	08.12.2024
EconLit	1886 - current	10.12.2024
Cost-Effectiveness Analysis (CEA) Registry	n/a	11.12.2024
WHO International Clinical Trials Registry Platform (ICTRP)	n/a	13.12.2024
United States National Library of Medicine registry of clinical trials (ClinicalTrials.gov)	n/a	12.12.2024
Google Scholar	n/a	11.12.2024
Lens.org	n/a	12.12.2024
Web pages supported by companies	n/a	06.11.2024 to 12.12.2024
RFIs requested by NICE and the EAG	n/a	
Reference lists of included studies	n/a	13.12.2024

EAG=External Assessment Group; n/a=not applicable; RFI=request for information

13.3 Appendix 3: EAG search strategies

Database: Embase <1974 to 2024 December 05>

ID	Search Strategy	Hits
1	limbic.af. and (mental health* and (app or ai or artificial intelligence or chatbot* or etriag* or e triag* or talking therap*)).tw.	8
2	(censeo or psyomics).af.	29
3	WYSA.af.	12
4	(((askfirst or ask first) and nhs) or ask nhs or mediktor or sensely or "sense.ly").af.	10
5	or/1-4	59
6	mental health*.tw.	304434
7	IAPT.af.	485
8	(counselling or counseling or cbt or cognitive behavio?r therapy or psychotherap* or psychological therapy or psychological therapies or talking therapy or talking therapies).tw.	278862
9	or/6-8	565252
10	((triage or triaging or symptom checker*) and (app or apps or ai or "artificial intelligence" or chatbot* or chat bot* or digital or machine learning or online or electronic or technology)).tw.	7297
11	(etriage or e triage or auto triage or autotriage or automated triage or smart triage or intelligent triage).tw.	117
12	digital front door*.tw.	12
13	or/10-12	7357
14	9 and 13	291
15	5 or 14	346
16	limit 15 to english language	341
17	16 not (nonhuman/ not (human/ and nonhuman/))	336

Database: Ovid MEDLINE(R) ALL <1946 to December 06, 2024>

ID	Search Strategy	Hits
1	limbic.af. and (mental health* and (app or ai or artificial intelligence or chatbot* or etriag* or e triag* or talking therap*)).tw.	5
2	(censeo or psyomics).af.	39
3	WYSA.af.	30
4	(((askfirst or ask first) and nhs) or ask nhs or mediktor or sensely or "sense.ly").af.	9
5	or/1-4	83
6	mental health*.tw.	246536
7	IAPT.af.	386
8	(counselling or counseling or cbt or cognitive behavio?r therapy or psychotherap* or psychological therapy or psychological therapies or talking therapy or talking therapies).tw.	193988
9	or/6-8	427368
10	((triage or triaging or symptom checker*) and (app or apps or ai or "artificial intelligence" or chatbot* or chat bot* or digital or machine learning or online or electronic or technology)).tw.	4322
11	(etriage or e triage or auto triage or autotriage or automated triage or smart triage or intelligent triage).tw.	93
12	digital front door*.tw.	11
13	or/10-12	4371
14	9 and 13	170
15	5 or 14	249
16	limit 15 to english language	246
17	16 not (animals/ not humans/) (245)	

Search Name: Cochrane

Date Run: 08/12/2024 05:34:51

ID	Search	Hits
#1	(mental next health*)	42216
#2	IAPT	122
#3	(counselling or counseling or cbt or cognitive behavior therapy or cognitive behaviour therapy or psychotherap* or psychological therapy or psychological therapies or talking therapy or talking therapies)	97335
#4	{OR #1-#3}	126662
#5	((triage or triaging or symptom checker*) and (app or apps or ai or "artificial intelligence" or chatbot* or "chat bot" or "chat bots" or digital or "machine learning" or online or electronic or technology))	736
#6	(etriage or "e triage" or "auto triage" or autotriage or "automated triage" or "smart triage" or "intelligent triage")	5
#7	"digital front door"	0
#8	{OR #5-#7}	738
#9	#4 and #8	158
#10	((limbic and mental and (app or ai or "artificial intelligence" or chatbot* or etriag* or (e next triag*) or (talking next therap*))) or (censeo or psyomics) or WYSA or (askfirst or "ask first" or "ask nhs" or mediktor or sensely or "sense.ly"))	24
#11	#9 or #10	182

1. Cochrane Central Register of Controlled Trials
   Issue 11 of 12, November 2024
   94 (Cochrane reviews: 77 plus Cochrane Protocols: 17)

2. Cochrane Database of Systematic Reviews
   Issue 12 of 12, December 2024
   86

(Special collections 1 Clinical answers 1)

Search Strategy APA PsycInfo (1806 - current)

Searched via EBSCOhost

#	Query	Results
S11	S6 OR S10	402
S10	S7 OR S8 OR S9	69
S9	(askfirst or "ask first" or "ask nhs" or mediktor or sensely)	30
S8	(censeo or psyomics or WYSA)	13
S7	(limbic and mental and (app or ai or "artificial intelligence" or chatbot* or etriag* or (e next triag*) or (talking next therap*)))	26
S6	S1 AND S5	333
S5	S2 OR S3 OR S4	707
S4	digital front door	5
S3	(etriage or e triage or auto triage or autotriage or automated triage or smart triage or intelligent triage)	373
S2	((triage or triaging or symptom checker*) and (app or apps or ai or "artificial intelligence" or chatbot* or chat bot* or digital or machine learning or online or electronic or technology))	425
S1	("mental health" or "mental healthcare" or IAPT or counselling or counseling or cbt or "cognitive behavior therapy" or "cognitive behaviour therapies" or psychotherap* or "psychological therapy" or "psychological therapies" or "talking therapy" or "talking therapies")	1,151,122

Economics searches – Econ Lit
Searched via EBSCOhost

#	Query	Results
S11	S6 OR S10	11
S10	S7 OR S8 OR S9	10
S9	(askfirst or "ask first" or "ask nhs" or mediktor or sensely)	10
S8	(censeo or psyomics or WYSA)	0
S7	(limbic and mental and (app or ai or "artificial intelligence" or chatbot* or etriag* or (e next triag*) or (talking next therap*)))	0
S6	S1 AND S5	1
S5	S2 OR S3 OR S4	29
S4	digital front door	0
S3	(etriage or e triage or auto triage or autotriage or automated triage or smart triage or intelligent triage)	11
S2	((triage or triaging or symptom checker*) and (app or apps or ai or "artificial intelligence" or chatbot* or chat bot* or digital or machine learning or online or electronic or technology))	21
S1	("mental health" or "mental healthcare" or IAPT or counselling or counseling or cbt or "cognitive behavior therapy" or "cognitive behaviour therapies" or psychotherap* or "psychological therapy" or "psychological therapies" or "talking therapy" or "talking therapies")	4,710

TOTAL: 1174

Duplicate references: 170

Total (duplicates removed electronically): **961**

Total references after irrelevant references excluded: 306

Company websites

WYSA
https://www.wysa.com/clinical-evidence

askfirst
https://sensely.com/askfirst/

Mediktor
https://www.mediktor.com/en/resources/reports

Psyomics
https://www.psyomics.com/clinicians

Sensely
https://sensely.com/customer/#providers

ICTRP (via Cochrane) (15)

#1	(limbic and (mental NEXT health* and (app or ai or "artificial intelligence" or chatbot* or etriag* or e NEXT triag* or talking NEXT therap*))):ti,ab,kw
#2	(censeo or psyomics):ti,ab,kw
#3	(WYSA):ti,ab,kw
#4	((((askfirst or "ask first") and nhs) or "ask nhs" or mediktor or sensely or "sense.ly")):ti,ab,kw
#5	{OR #1-#4}
#6	mental NEXT health*
#7	(IAPT):ti,ab,kw
#8	(counselling or counseling or cbt or "cognitive behavior therapy" or "cognitive behaviour therapy" or psychotherap* or "psychological therapy" or "psychological therapies" or "talking therapy" or "talking therapies"):ti,ab,kw
#9	{OR #6-#8}
#10	(((triage or triaging or symptom NEXT checker*) and (app or apps or ai or "artificial intelligence" or chatbot* or chat bot* or digital or "machine learning" or online or electronic or technology))):ti,ab,kw
#11	((etriage or "e triage" or "auto triage" or autotriage or "automated triage" or "smart triage" or "intelligent triage")):ti,ab,kw
#12	digital NEXT front NEXT door*
#13	{OR #10-#12}
#14	#9 AND #13
#15	#5 OR #14

ClinicalTrials.gov 40

limbic AND "mental health" AND (app OR ai OR "artificial intelligence" OR chatbot OR chatbots OR etriage OR "e triage" OR "talking therapy" OR "talking therapies")
(censeo OR psyomics OR WYSA OR askfirst OR mediktor OR sensely OR "sense.ly")
"mental health" AND ((triage OR triaging OR "symptom checker") AND (app OR apps OR ai OR "artificial intelligence" OR chatbot OR chatbots OR "chat bot" OR "chat bot" OR digital OR "machine learning" OR online OR electronic OR technology))
(IAPT OR counselling OR counseling OR cbt OR "cognitive behavior therapy" OR "cognitive behaviour therapy" OR psychotherapy OR psychotherapies OR "psychological therapy" OR "psychological therapies" OR "talking therapy" OR "talking therapies") AND ((triage OR triaging OR "symptom checker") AND (app OR apps OR ai OR "artificial intelligence" OR chatbot OR chatbots OR "chat bot" OR "chat bot" OR digital OR "machine learning" OR online OR electronic OR technology))
"mental health" AND (etriage OR "e triage" OR "auto triage" OR autotriage OR "automated triage" OR "smart triage" OR "intelligent triage" OR "digital front door")
(IAPT OR counselling OR counseling OR cbt OR "cognitive behavior therapy" OR "cognitive behaviour therapy" OR psychotherapy OR psychotherapies OR "psychological therapy" OR "psychological therapies" OR "talking therapy" OR "talking therapies") AND (etriage OR "e triage" OR "auto triage" OR autotriage OR "automated triage" OR "smart triage" OR "intelligent triage" OR "digital front door")

LENS.org (Targeted Searches) 23

Title: ("mental health" OR "mental well-being") AND Title: (limbic)
Title: (WYSA)
Title: (AskFirst)
Title: mediktor
Title:(sensely NOT (sense OR senses OR sensing))
Title:(sense.ly NOT (sense OR senses OR sensing))
NHS AND apps AND ("mental health" OR "mental well being") AND "AskFirst"
NHS AND app AND ("mental health" OR "mental well being") AND "AskFirst"
(censeo OR psyomics) AND ("mental health" OR "mental well-being")
("mental health" OR "mental well being") AND "digital front door"

Google Scholar (Targeted Searches) 100

allintitle: limbic "mental health" OR "mental well-being"
allintitle: WYSA
allintitle: AskFirst
allintitle: mediktor OR sensely OR sense.ly
NHS apps "mental health" OR "mental well being" "AskFirst"
NHS app "mental health" OR "mental well being" "AskFirst"
allintitle: censeo OR psyomics
NHS censeo "mental health" OR "mental well-being"
"mental health" OR "mental well being" "digital front door"

CEA Registry 21

WYSA OR limbic OR AskFirst OR censeo OR psyomics OR mediktor OR sensely OR sense.ly OR digital front door OR etriage OR e triage OR auto triage OR autotriage OR automated triage OR smart triage OR intelligent triage
app AND (mental health)
app AND (mental well-being)

apps AND (mental health)
apps AND (mental well-being)
ai AND (mental health)
ai AND (mental well-being)
(artificial intelligence) AND (mental health)
(artificial intelligence) AND (mental well-being)
chatbot AND (mental health)
chatbot AND (mental well-being)
chatbots AND (mental health)
chatbots AND (mental well-being)
(chat bot) AND (mental health)
(chat bot) AND (mental well-being)
(chat bots) AND (mental health)
(chat bots) AND (mental well-being)
Digital AND (mental health)
Digital AND (mental well-being)
(machine learning) AND (mental health)
(machine learning) AND (mental well-being)
Online AND (mental health)
Online AND (mental well-being)
Electronic AND (mental health)
Electronic AND (mental well-being)
Technology AND (mental health)
technology AND (mental well-being)

13.4 Appendix 4: Excluded studies

Table 25 Studies excluded from the EAG SLR at the full-text stage

Reference	Intervention + comparator	Study type	Reason for exclusion
Studies found from electronic databases			
Chaudhry 2024[22]	Wysa app	Qualitative study based on 159 reviews of the Wysa app left on the Google Play store	Wrong technology – not a digital front door technology of interest
Funnell 2022[23]	A "newly developed digital mental health assessment"	Qualitative study of user perspectives (N=1304)	Wrong technology – not a digital front door technology of interest
Funnell 2022[24]	Mental health screening and diagnostic apps	Review of 92 publicly available apps	Wrong technology – not a digital front door technology of interest
Funnell 2024[25]	Mental health apps, "with a specific focus on apps designed for self-assessment and triage"	Qualitative study based on semi structured interviews (N=16) conducted over Zoom (n=14), Microsoft Teams (n=1) or telephone (n=1)	Wrong technology – not a digital front door technology
Gao 2024[26]	Wysa app	Tutorial discussion on intelligent AI test modelling chat systems including basic concepts, validation process, testing scopes, approaches, and needs	Wrong technology – not a digital front door technology of interest
Gutierrez 2024[27]	AI applications including triage, psychotherapy delivery, treatment monitoring, therapy engagement support, identification of effective therapy features, and prediction of treatment response, dropout, and adherence	Review of 29 studies utilising a mixed-methods approach encompassing meta-analysis and network meta-analysis	Wrong technology – not a digital front door technology of interest
Habicht 2023[28]	Limbic Access vs other referral methods (self-referrals, GP referrals, etc) with an online webform	Multisite real-world retrospective before- and after-observational study	Duplicate - Pre-print, subsequently published as Habicht 2024[15] and used for primary source for data in the

Reference	Intervention + comparator	Study type	Reason for exclusion
			EAG SLR
Martin-Key 2022[29]	Question-and-answer–based digital tools for diagnosing and screening psychiatric conditions in adults	Review of 28 studies	Wrong technology – not a digital front door technology of interest
NCT05943418[33]	Wysa for Worry Program vs weekly delivery of psychoeducational resources	RCT	Wrong technology – not a digital front door technology of interest
NCT05533190 (ISRCTN14644939)[34]	Wysa AI-chatbot mental health app vs standard care (no intervention)	RCT	Wrong technology – not a digital front door technology of interest
Rollwage 2022[31]	Limbic Access vs other sources of referral to NHS Talking Therapies	Real-world before and after study	Duplicate report of study – pre-print of Rollwage 2024[30]
Rollwage 2024[30]	Limbic Access vs other sources of referral to NHS Talking Therapies	Real-world before and after study	Wrong outcome – reports recovery rates and economic analysis based on this outcome (which are beyond the scope of this EVA)
Sin 2024[32]	Limbic Access vs other referral methods with an online webform	Commentary (in a peer-reviewed journal)	Wrong outcome – no new data available regarding benefits and harms (Commentary on Habicht 2024[15] included in the EAG SLR)
Studies found from other sources (provided by companies and other grey literature identified from website searches)			
Limbic website: Bradford case study[38]	Limbic Access vs other referrals	Online case study	Anecdotal evidence
Limbic website: Essex case study[36]	Limbic Access vs other referrals	Online case study	Anecdotal evidence
Limbic website: Everyturn case study[37]	Limbic Access vs other referrals	Online case study	Anecdotal evidence
Limbic website: Habicht 2024[35]	Limbic Care vs matched control group of patients who did not use the therapy support tool	Multisite real-world study	Wrong technology – not a digital front door technology of interest

Reference	Intervention + comparator	Study type	Reason for exclusion
	during treatment		
Limbic website: Mind Matters[39]	Limbic Access vs benchmarked data (i.e., pre/post implementation)	Validation study (analysis of real-world data)	Duplicate - Summary information (full report[45] subsequently provided by Limbic and included in the EAG SLR
Limbic website: Limbic Research 2024[40]	Limbic Care vs matched control group of patients who did not use the therapy support tool during treatment	Pilot study, with an observational real-world design	Wrong technology – not a digital front door technology of interest
NHS England Transformation Directorate[41]	Limbic Access vs benchmarked data (i.e., pre/post implementation)	Validation study (analysis of real-world data)	Duplicate - Summary information (full report[45] subsequently provided by Limbic and included in the EAG SLR
Surrey and Borders Partnership NHS Foundation Trust[42]	Limbic Access vs benchmarked data (i.e., pre/post implementation)	Validation study (analysis of real-world data)	Duplicate - Summary information (full report[45] subsequently provided by Limbic and included in the EAG SLR
Psyomics RFI response[5]	Censeo Digital	RFI response, various sources of information	Wrong population – data and services relate to primary and secondary care
Psyomics response to EAG[19]	Censeo Digital	Additional information requested by the EAG	Wrong population – data and services relate to primary and secondary care

13.5 Appendix 5: Data extraction of information relating to outcomes relevant to the EVA

Table 26 Accuracy and acceptability outcomes – Limbic Access

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
Rollwage 2023[10]	--	--	--	--	--
Habicht 2024[15]	--	--	--	Increase in referrals with Limbic Access vs control services (15% vs 6%; p< 0.0001) and increased accessibility for underrepresented minority groups: i. 39% vs 8% increase in referrals from Asian individuals ii. 40% vs 4% increase in referrals from Black individuals iii. 179% increase vs 5% decrease in referrals from non-binary individuals" "Additionally, Limbic Access was built to be compliant to WCAG web accessibility standards to support ease of viewing and individuals with visual impairments."	--

Surrey and Borders Partnership NHS Foundation Trust 2022 (Mind Matters Validation Study)[45]	--	--	--	Quantitative data "Limbic data shows that the majority of individuals refer themselves via a mobile device. The data from Mayden (the developer of iaptus) data shows that 76% of self-referrals come via Limbic. As Limbic is the primary form and the only online method to refer into the service via the mobile device, this supports the findings. On average 75.5 % of self-referrers completed the Limbic form up until the MDS Assessment." "There has been a slight increase of Out of Hours referrals into the service since Limbic form is being used, with referrals between the hours of 5pm-9am equating to 42% in 21/22 compared to 38% in 20/21" Overall: "88% of Limbic referrals come in between 9am and start to drop off after 11pm"	Qualitative findings One administrator said "Limbic makes life easier" "… the PWP said that Limbic "makes life easier" as the available information dictates how to frame assessments. The PWP as a result feels more prepared"
Limbic 2022 Usability Testing Formative	[redacted]	--	--	As part of the 16 primary user participants who took part in the study, we	--

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
Test Report[47]	[redacted]			made sure to include individuals who have physical and learning disabilities (n=5) to ensure the device is catering for needs of the full diversity of the target patient population … On the whole this [evaluation] provides good evidence to show that the device is usable by a variety of potential primary users with learning and physical needs	
Limbic 2022 Usability Testing Summative Test Report[48]	--	To evaluate accuracy, the presenting problem as selected by the clinician (from Limbic Access referral output with and without ADSMs) was compared with the patient's actual diagnosis. Results: 1. Overall mean improvement in accuracy due to ADSM= +4.4%, std=8.7%; p=0.021 Correct ML ASDM	--	--	Clinician's perceptions on the useability and usefulness of Limbic Access were generally positive (and in some cases were strongly positive). • referral layout (28/40) • usefulness of the collected referral information (40/40) • ease of use of the referral output (35/40) • comprehensibility of the referral output (31/40)

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
		mean improvement due to ADSM= +9.1%, std=14.8%; p=0.0004 Incorrect ML ADSM mean difference due to ADSM= -2.2%, std=11.5%; p=0.23 2. Overall mean improvement in accuracy due to ADSM= +1.8%, std=12.3%; p=0.37 Correct ML ASDM mean improvement due to ADSM= +3.5%, std=17.9%; p=026 Incorrect ML ADSM mean improvement due to ADSM= +0.5%, std 11.5%; p=0.87 Results indicate that "…even when a wrong ADSM was administered, this did not negatively affect the clinical judgement. This shows that the inclusion of additional ADSM			• perceived potential for time savings based on this output (33/40) • likelihood that clinicians would use Limbic Access in the future (25/40). • usefulness of Limbic Access to prepare a clinical assessment/ screening (40/40).

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
		information is not biassing clinicians even when the algorithm is incorrect"			
Limbic 2024 Clinical Preparedness Study[43]	--	--	--	--	It was found Limbic Access: • Improves wellbeing • Reduces emotional strain • Improves specific task performance on patient assessments • Reduces cognitive load and task demands on patient assessments
Limbic 2024 Patient Feedback Report[46]	--	--	--	--	--
Limbic Research 2024[44]	Algorithm diagnosis accuracy (ADSMs): • Historical data: the model achieved an overall accuracy of 93.5% • Prospective evaluation: overall accuracy of 94.2% • Live data: Limbic Access correctly detected 92.47%	--	--	--	--

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
	of diagnoses				
Limbic NICE RFI response[4]	<u>Quality</u> RFI Q8: • "… the emphasis of the clinical assessments moves away from data collection "Hi Joe, nice to meet you, what's brought you here today?". Instead clinicians are able to dive into hypotheses testing, differential diagnosis exploration, capsule summaries and formulation. **This requires behavioural change in how clinicians run their assessments in order to make them as efficient and high quality as possible**" <u>Accuracy</u> LRFI Q13: • "Making triaging assessments more accurate (as measured by a reduction in subsequent changes in treatment pathway)	RFI Q6: • More reliable diagnosis RFI Q8: • Does not negatively bias clinical decision making	RFI Q6: • Self-referral completion rates of >90% • Limbic Access patients are less likely to drop out pre-assessment and throughout treatment	Data presented from Habicht 2024[15] In addition, RFI Q10: • "Limbic Access was designed to be accessible to those with disabilities with 15% of users indicating the presence of at least one disability—such as ADHD (6%)" • "Limbic Access has proven to be accessible by an older demographic typically not as literate in technology usage with 7.5% of referrals coming from the 60+ age range, representing over 26,000 referrals, and 19% of referrals coming from ages 46 - 60 (~65,000 referrals)" • "Additionally, Limbic Access was built to	Data presented from Limbic 2024 Clinical Preparedness Study[43]

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
	• Enabling assessments to be conducted in a shorter time period without compromising on quality (as demonstrated in the above bullet)" Limbic RFI, response to Q15: • Algorithm is >93% accurate Limbic (1) RFI response Q9: • "… the overall performance of the diagnostic prediction model was 93.2%"			be compliant to WCAG web accessibility standards to support ease of viewing and individuals with visual impairments. As part of this the product includes contrast and enlarged text modes" Limbic (1) RFI response Q9: • "In depth analyses indicated that the machine learning performance was consistent across all demographic groups related to age, gender, ethnicity & disability/health status. While the overall performance of the diagnostic prediction model was 93.2%, the range for specific groups was	

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
				between 91.04% and 93.88% indicating no substantial differences in performance for different subgroups" RFI Q10: "… users with physical disabilities take about 11 minutes to complete a referral, whereas those without a disability take closer to 9 minutes, indicating only very subtle differences in the usability of the product based on disability status."	
Limbic EAG RFI response[18]	"The quality and accuracy of the collected data is particularly relevant with respect to the administration of ADSMs…" "Our ML-model demonstrated strong diagnostic capabilities across the nine most common mental health	Four sources of evidence presented to support this: Large-scale Clinical Observational Study (N=64,862)[10] "Using treatment step-ups and step-downs as indicators of initial assessment accuracy (where changes in	Data from four NHS Talking Therapies services implementing Limbic Access over the past 1.5 years Number of referrals to NHS Talking Therapies 15,371 Limbic Access 22,156 Other	--	Clinical Survey Study (N=82) "Limbic Access … significantly improved emotional wellbeing ($p<0.001$) and reduced cognitive load, as measured with the NASA Task Index ($p=0.002$)."

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
	conditions in NHS Talking Therapy services [N=46,413 patient data points], achieving an overall accuracy of 92.5% (CI=92.2% to 92.7%) in 10-fold cross-validation. Note: since we have to this date run a multitude of different validation studies with different data sets, the accuracy numbers will naturally slightly vary between studies and data sets, however they vary in the narrow range between accuracies of 92.5% to 93.7%. The accuracy claim listed for our product has been verified at medical device assessment by our UK Approved Body." "After training our ML-model, we conducted an additional evaluation study using a prospective dataset of 773 newly collected patients. We then compared this prediction against the clinicians' diagnoses both at clinical assessment and their final "ground truth"	treatment step suggest initial misallocation), we demonstrated that Limbic Access referrals showed a 45% reduction in step-ups/downs" (p<0.0001) Clinician User Study (N=40)[48] "Results demonstrated improved accuracy in selecting both primary presenting problems and differential diagnoses when clinicians had access to Limbic Access data." Clinical Survey Study (N=82) "Results showed highly significant positive effects of Limbic Access in supporting assessment preparation (p<0.001) and the ability to complete assessments within the allocated time limit (p=0.001)." Ongoing Randomised Controlled Trial	Number of referrals re-directed to services other than NHS Talking Therapies 1,549 (10.08%) Limbic Access 2,640 (11.91%) Other Patients who referred using Limbic Access were 1.21 times less likely to be referred on to other services (10.08%, n=1,549) than those who referred via any other means (11.9%, n=2,640; X^2=30.734, p<0.001): • Limbic referrals were 1.24 times less likely to be referred to other services than those who self-referred without Limbic Access (X^2=34.728, p<0.001) • Limbic referrals were 1.14 times less likely to be referred to other services than those who did not self-refer (X^2=8.572,		

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
	diagnosis after treatment completion. In these prospective data, the ML-model's predictions aligned with the final diagnoses in 93.7% of cases. By contrast, the initial human clinical assessments aligned with the final diagnoses only 85.1% of the time. Statistical analysis demonstrated that the model's diagnostic reliability significantly surpassed that of the clinicians at the initial assessment stage (Odds-ratio=2.08, [CI=1.57 to 2.77], X^2=25.96, p<0.001)." "Moreover, additional data has been collected since then with larger sample sizes (N>46,000) confirming these accuracies in a similar range (92.5%)"	(N=5,030)[16] "Preliminary analysis … shows that ADSM administration at referral leads to a significantly higher detection rate of specific anxiety diagnoses when the Limbic Access Class IIa is utilised (p<0.01), suggesting more accurate clinical assessments informed by this output."	p=0.003) Number who start to complete the referral but do not submit the referral 3,833 (24.94%) Limbic Access ~8,089 (36.51%) Other Note: "Importantly, up to 9.62% of these [Limbic Access referrals] were ineligible for the service and thus were successfully signposted out – hence, this attrition had a positive impact on the services, as reflected by the increased assessment and treatment rates for Limbic" Number who submit a partially completed referral 2,539 (16.52%) Limbic Access ~22,156 (100%) Other Number who submit a complete referral		

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
			12,832 (83.48%) Limbic Access ~0 (0%) Other (see note) Note: "Given that other referral methods are, to our knowledge, unable to administer the relevant ADSMs, then by definition all 22,156 were partial submissions and 0 were complete submissions" Number who attend an NHS Talking Therapies one-to-one person-centred clinical assessment 9,753 (63.45%) 10,838 (48.92%) Note: "Patients referring through Limbic were 1.81 times more likely to attend an assessment (63.45%, n = 9,753) than patients referring through any other means (48.92%, n = 10,838; X^2=773.540, p<0.001)." Number who attend an NHS Talking Therapies		

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
			treatment session 5,620 (36.56%) 6,185 (26.92%) Note: "Similarly, patients referring through Limbic were 1.49 times more likely to attend a treatment session (36.56%, n = 5,620) than patients referring through any other means (27.92%, n = 6,185; X^2=314.276, p<0.001).		

ADSM=Anxiety Disorder Specific Measure ; CI=confidence interval; EAG=External Assessment Group; iaptus= Improving Access to Psychological Therapies User System; MDS=minimum data set; ML=machine learning; NICE=National Institute for Health and Care Excellence; PWP=Psychological Wellbeing Practitioners; RFI=request for information; WCAG=Web Content Accessibility Guidelines

Table 27 Resource and system impact – Limbic Access

Source	RSI1: Administrative resource impact	RSI2: Time taken to review data collected by digital front door technologies	RSI3: Time taken to complete clinical assessment	RSI4: Time saved for the clinician during clinical assessment
Rollwage 2023[10]	--	--	Limbic Access vs other referrals Mean time: Limbic Access=41.6 mins Control=54.4 mins p<0.001 With clinical information completed in Limbic Access vs without: With=40.6 mins Without=52.8 mins p<0.001 The effect remained statistically significant after controlling for severity (p<0.001)	Limbic Access vs other referrals: 12.7 mins saved
Habicht 2024[15]	--	--	--	--
Surrey and Borders Partnership NHS Foundation Trust 2022 (Mind Matters Validation Study)[45]	"Both members of the administrative team commented on how it saves them time and provides more details to aid with assessments" "One member of the administrative team said a non-Limbic referral would've taken 20 minutes more than a Limbic referral to process"	<u>2022 staff survey: administrator quotes</u> "The limbic form will be better once it can be fully integrated into iaputus and once we have the new form with the information in the correct order" "Very useful for filtering out those who are not within out catchment area/not suitable. Form still needs to be more admin friendly regarding the layout. This will save some time	<u>Qualitative findings: quotes</u> "The length of the assessment is based on the individual need of the person who uses our services – one assessment observed took 60 minutes to complete due to the nature of the call <u>2021 staff feedback survey: quote</u> "During a survey conducted in 2021, 68% of staff said their	<u>2021 staff feedback survey: quotes</u> "Currently I feel Limbic is not making a difference due to having to still ask all the same questions I would have to ask in a normal assessment because of client waiting time" "Info from the Limbic is great because I can just review it with clients and move on" "It did save me time and felt like I could focus more on the main

Source	RSI1: Administrative resource impact	RSI2: Time taken to review data collected by digital front door technologies	RSI3: Time taken to complete clinical assessment	RSI4: Time saved for the clinician during clinical assessment
	For PWPs: "Assessments still take 30 to 60 minutes dependent on the assessment, though there is a sense of feeling more prepared and finding the process easier. There is more information to shape questions and opportunity to ask closed questions in some instances to confirm whether certain information is still correct. This includes checking who their GP is, marital status or if incorrect information has been provided e.g. if prior medication has been included to long term conditions box. The individual feels they can make informed questions based on the data that they now have available."	filtering through the information which is not relevant to admin."	assessments took them less than 50 minutes, including admin time"	problem with the client" "It feels like the current questions asked in advance shave off seconds more than minutes of time" "Limbic identified a number of areas risk, recreational drug use and carer responsibilities. which is helpful. However, did not save me time as I then needed to assess this. I think Limbic saves time if it highlights the absence of risk, alcohol use etc." "Limbic was pretty useless on this occasion and hindered rather than helped." <u>2022 staff survey: PWPs</u> Information gathered via the form supports with assessments and allows them to focus on the issues 88% of participants agreed or partially agreed that the Limbic referral form has shortened the length of time taken to do the assessment Time saved ranged from 5 mins to 20 mins with 50% answering that 10-15 minutes was saved Illustrative quotes: "Screening questions are

Source	RSI1: Administrative resource impact	RSI2: Time taken to review data collected by digital front door technologies	RSI3: Time taken to complete clinical assessment	RSI4: Time saved for the clinician during clinical assessment
				covered by limbic and if no concerns with the response, then there isn't the need to ask those additional questions” “Less focus on unnecessary questions and more focus on keeping to time and to the point so that we can focus on treatment” “I don’t have to ask so many questions anymore, unless the information in Limbic is not complete” “It give you a brief idea of what the client wants and you can focus on those details that need clarifying instead of asking everything”
Limbic 2022 Usability Testing Formative Test Report[47]	--	--	--	[redacted]
Limbic 2022 Usability Testing Summative Test Report[48]	--	--	--	--
Limbic 2024	--	--	--	--

Source	RSI1: Administrative resource impact	RSI2: Time taken to review data collected by digital front door technologies	RSI3: Time taken to complete clinical assessment	RSI4: Time saved for the clinician during clinical assessment
Clinical Preparedness Study[43]				
Limbic 2024 Patient Feedback Report[46]	--	--	--	--
Limbic Research 2024[44]	--	--	--	--
Limbic NICE RFI response[4]	--	--	--	RFI Q6: Limbic Access can release clinical time by making clinical assessments more efficient due to the additional clinical information collected during the referral, reducing the time taken in these appointments by up to 23.4%.
Limbic EAG RFI response[18]		In a sample of 38 clinicians who interacted with the browser extension from 7 Nov 2024 to 6 Jan 2025, we found that referrals were reviewed on average for 1 min 53 seconds (±1 min 47 seconds) in the browser extension. While it is not possible to identify whether this is done before or during the assessment, it allows us to infer how long clinicians spend in total on reviewing referral information collected from	"Based on timestamps that are collected throughout the Limbic Access chatbot as users move through each "section" of the referral (e.g., demographic section, NHS mandatory questionnaires section, ADSM section) we can estimate how long it takes to collect different types of data that would otherwise be collected during assessments. Based on the average length of completing these sections, without this digital front door, we estimate	"Our peer-reviewed publication in JMIR [Rollwage 2023[10]] showed that clinical assessments are 12.7 minutes faster for Limbic-referred patients. Therefore, we can infer that Limbic saves ~8.5 minutes through simple data collection, and a further 4.2 minutes through enhanced preparation for clinicians by providing relevant ADSM measures and suggested primary and secondary presenting problems based on the diagnostic ML

Source	RSI1: Administrative resource impact	RSI2: Time taken to review data collected by digital front door technologies	RSI3: Time taken to complete clinical assessment	RSI4: Time saved for the clinician during clinical assessment
		Limbic Access”	that demographic data collection would take ~3.9 minutes on average (±2.7 minutes) and mental health questionnaire collection would take ~4.6 minutes on average (±2.3 minutes) during the clinical assessment.”	prediction model.”

EAG=External Assessment Group; JMIR=Journal of Medical Internet Research; ML=machine learning; NICE=National Institute for Health and Care Excellence; PWP=Psychological Wellbeing Practitioners; RFI=request for information

Table 28 Patient reported outcomes in NICE scope – Limbic Access

Source	PRO1: Ease of access and usability	PRO2: Information clarity and relevance	PRO3: Comfort and privacy	PRO4: Overall satisfaction with pre-assessment process
Rollwage 2023[10]	"38% (12/32) of the patients reported that the number of questions was perceived as long and potentially overwhelming." Ex-patients included in qualitative analysis may be the same patients included in Formative[47] and Summative[48] Test Reports	--	"25% (8/32) of the patients reported that the nature of the clinical questions was emotionally difficult and could feel too heavy to complete." Ex-patients included in qualitative analysis may be the same patients included in Formative[47] and Summative[48] Test Reports	--
Habicht 2024[15]	Positive theme identified: Convenient (~42%) Individuals mentioned that the referral process was easy, fast or convenient (for example, they could fill the referral at their own pace at any time) No statistically significant differences between gender identity groups (gender minority groups [39.1%] versus males/females [42.0%]) or between ethnic groups (Asian and Black ethnic groups [41.2%] versus White group [41.8%])	Positive theme identified: Self-realisation (~10%) Individuals mentioned that the referral provided a self-realisation of their current situation, such as a realisation of suffering from a mental health condition or a need for treatment More individuals from Asian and Black ethnic groups (15.2%) mentioned the theme around self-realisation compared to White individuals (10.0%); p<0.001; no statistically significant differences between gender identity groups (gender minority groups [9.5%] versus males/females [10.4%]) "When investigating ethnic minorities, we found that individuals from Asian and Black ethnic groups mentioned the	Positive theme identified: Human-free (~9%) Individuals mentioned the human-free nature of the chatbot in a positive way and removing the anxiety of talking to humans Individuals from gender minority groups (12.4%) mentioned the tool's human-free nature more compared to males/females (8.9%); p<0.01; no statistically significant differences between ethnic groups (Asian and Black ethnic groups [8.0%] versus White group [8.9%]) "Individuals from gender minority groups mentioned the absence of human involvement as a positive more frequently than females and males (p= 0.0099)" The personalised self-referral chatbot, "…could resolve an	"Overall, 89% of the free-text feedback was classified as positive, 7% neutral and 4% negative." Positive theme identified: Provided hope (~27%) Individuals mentioned that the referral gave them hope to get better or know they were not alone Fewer individuals from gender minority groups (21.5%) mentioned the tool as providing hope compared to males/females (26.9%); p<0.05 Fewer individuals from Asian and Black ethnic groups (21.0%) mentioned the tool as providing hope compared to the White group (27.8%); p<0.001

Source	PRO1: Ease of access and usability	PRO2: Information clarity and relevance	PRO3: Comfort and privacy	PRO4: Overall satisfaction with pre-assessment process
		self-realisation about the need for treatment theme more than White individuals ($\chi2(1)=68.3$, $p<0.0001$). This reflects an increased awareness from the individual that they might suffer from a mental health condition which may benefit from treatment, whereby this awareness is linked to the referral process. This may reflect how the chatbot could reduce the stigma faced by ethnic minority groups in seeking mental health support. In addition, Asian and Black ethnic minority groups mentioned the hopeful nature of the chatbot less than White individuals ($\chi2(1)=53.5$, $p<0.001$).”	important barrier for this group by being human-free and indicates the mechanism for why we observed increased referrals from this minority group might be a reduction in stigma and judgment during this AI-enabled self-referral process.”	Neutral theme identified: Needed specific support (~4%) Individuals mentioned that they needed to talk about specific illnesses or other mental disorders More individuals from Asian and Black ethnic groups (5.5%) mentioned needing more specific support compared to White individuals (3.8%); $p<0.001$; no statistically significant differences between gender identity groups (gender minority groups [5.8%] versus males/females [3.9%]) Other neutral feedback: Individuals mentioned any other neutral feedback, such as that they would have preferred to speak to a human for the referral or wanted to provide more information (~4%) No statistically significant differences between gender identity groups (gender minority groups versus males/females) or between ethnic groups (Asian and Black ethnic groups versus White group) Negative theme identified: Expected support sooner Individuals mentioned that they

Source	PRO1: Ease of access and usability	PRO2: Information clarity and relevance	PRO3: Comfort and privacy	PRO4: Overall satisfaction with pre-assessment process
				expected to start therapy faster (~1.5%) No statistically significant differences between gender identity groups (gender minority groups versus males/females) or between ethnic groups (Asian and Black ethnic groups versus White group) Negative theme identified: Wanted urgent support Individuals mentioned that they felt that they needed immediate attention (~1.5%) No statistically significant differences between gender identity groups (gender minority groups versus males/females) or between ethnic groups (Asian and Black ethnic groups versus White group) Other negative feedback: Individuals mentioned any other negative feedback (~1%) No statistically significant differences between gender identity groups or between ethnic groups

Source	PRO1: Ease of access and usability	PRO2: Information clarity and relevance	PRO3: Comfort and privacy	PRO4: Overall satisfaction with pre-assessment process
Surrey and Borders Partnership NHS Foundation Trust 2022 (Mind Matters Validation Study)[45]	--	--	--	89% of patients going through the referral process agreed that using Limbic Access had been helpful
Limbic 2022 Usability Testing Formative Test Report[47]	[redacted]	[redacted]	[redacted]	• Results (N=16) suggest that users' attractiveness towards the product and their understanding of it scored excellent on the scale of -3 (horribly bad) and +3 (extremely good). Overall, Limbic Access received a highly positive evaluation of user experience in all six categories measured by the UEQ.
Limbic 2022 Usability Testing Summative Test Report[48]	16/16 participants mentioned themes around easy access to get help by oneself at anytime 16/16 patient testers found the	100% of patients (16/16) gained a good comprehension of how Limbic Access worked. 100% of patients (16/16) were	"That it is confidential and easily accessible." "There's no pressure talking to an actual human, so its good for	Contrastingly, some users (4/16) wanted more personability from the device's prose, whilst a few (2/16) wanted the friendliness of the device to be toned down:

Source	PRO1: Ease of access and usability	PRO2: Information clarity and relevance	PRO3: Comfort and privacy	PRO4: Overall satisfaction with pre-assessment process
	chatbot user interface intuitive, smooth and easy to follow, guiding them through the referral process Some users (3/16) found the referral process took too long	clear about the events following their successful referral via Limbic Access.	anxiety. It's very neutral. It's quicker than talking to an actual human. It can be used at any time."	UEQ scores achieved in the summative testing, received a highly positive evaluation of user experience in all six categories
Limbic 2024 Clinical Preparedness Study[43]	--	--	--	--
Limbic 2024 Patient Feedback Report[46]	--	--	--	94.3% of patients rated referral process as helpful 4.9% indicated a need for more information or support 0.8% rated the process as unhelpful, stating they needed immediate human attention in the free-text response
Limbic Research 2024[44]	--	--	--	--
Limbic NICE RFI response[4]	Data presented from Habicht 2024[15]	--	--	RFI Q6: • 93% of patients (N>15,000) had positive feedback
Limbic EAG RFI response[18]	--	--	--	--

EAG=External Assessment Group; NICE=National Institute for Health and Care Excellence; RFI=request for information; UEQ=User Experience Questionnaire

Table 29 Economic outcomes (costs) – Limbic Access

<table>
<tr><th>Source</th><th>Costs of the technologies</th><th>Initial setup and integration costs</th><th>Operational costs (if falling on the NHS rather than the technology provider)</th><th>Training costs</th><th>Cost of promotion</th><th>Costs of applying digital clinical safety assurance DCB0129</th><th>Other</th></tr>
<tr><td>Limbic NICE RFI response[4]</td><td>Limbic RFI, response to Q23:
“Limbic Access is priced using an annual software license fee, calculated based on the estimated total annualised referrals covered by the solution.”</td><td colspan="5">Limbic RFI, response to Q23:
Limbic Access is priced using an annual software license fee, calculated based on the estimated total annualised referrals covered by the solution. This pricing structure encourages full deployment of the platform, optimising service delivery and reducing unit costs. By adopting this platform-based pricing model, we are able to bundle all new features into the core solution at no additional cost, with no implementation fees. This approach ensures both parties share the utilisation risk and provides cash flow certainty.

Pricing Table (ex VAT)<table><tr><td colspan="2">Limbic Access Patients</td><td>Price</td></tr><tr><td>1</td><td>5,000</td><td>£5.49</td></tr><tr><td>5,001</td><td>15,000</td><td>£4.99</td></tr><tr><td>15,001</td><td>20,000</td><td>£4.50</td></tr><tr><td>20,001</td><td>25,000</td><td>£4.00</td></tr><tr><td>25,001</td><td>30,000</td><td>£3.75</td></tr><tr><td>30,001</td><td>100,000</td><td>£3.50</td></tr></table>RFI Q24:
“… fees for consumables, maintenance, enablement/training etc are bundled into the annual license fee.”</td><td>RFI Q6:
“… cost per recovery through Limbic Access was 90% cheaper compared to other digital tools [Rollwage 2024[30]] excluded from this review”</td></tr>
</table>

NICE=National Institute for Health and Care Excellence; RFI=request for information

Table 30 Accuracy and acceptability outcomes – Wysa DRA

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
Wysa NICE RFI response[6]	RFI Q6: "…the Wysa Referral Assistant can improve the percentage of appropriate referrals"	RFI Q6: Wider range of clinical information in over 65% of assessment appointments	RFI Q6: Our triage methodology is configured to support access targets and together we are able to deliver a conversion rate of up to 91%"	RFI Q6: Over 1/3 of patients complete DRA after 6pm or between 6-9am 80% complete their referrals on their phones "Those aged between 20-34 are the highest users of the DRA, however we also have large numbers of older people using the assistant, including over 2000 who are over retirement age." "We have preliminary data from one of our contracts showing trends for higher rates of referral submissions via Wysa compared with other referral routes for Asian and Asian British groups, and for fewer second triage appointments for those who submit their referral information using Wysa (compared to a matched group	--

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
				who self referred using the static Mayden form). "To ensure that our user interface is accessible to people with varying abilities or disabilities, we align to WCAG 2.1 guidelines"	
Wysa EVA Additional Supporting Evidence[20]	"We currently work with 28 NHS Talking Therapies services, nine of which are provided by Vita Health Group (VHG). Between October 2023 and June 2024, one of these services ([redacted]) used the information collected by the Wysa DRA to inform the type and length of assessment appointments offered. 91% of assessments for those who completed the full set of clinical questions asked by the DRA were scheduled for shorter, 30 minute appointments instead	--	Where the Wysa DRA is the only online self referral option, the completion rate for pre-assessment demographic information is 91.2% from 128,741 referrals. Where the Wysa DRA referral widget is offered on service websites alongside a static online referral form, which is the most common configuration, the completion rates for the two services for which data are presented, ranges from 69.1% (of 7130 referrals) to 72.5%.(of 3095 referrals)	--	"Kensington & Chelsea Talking Therapies: Clinician Survey (N=5): More time to concentrate on problems: 2 Helpful not to have to ask mandatory questions: 1 Helpful to have standardised questionnaires already completed: 4 Knowing the client's priority for treatment: 1 Less need to signpost to support: 1 Less need for follow up appointments: 0 "..it takes lots of

Source	AA1: Quality and accuracy of the data collected using digital front door technologies	AA2: Accuracy of clinical assessment for NHS Talking Therapies	AA3: Completion rate of pre-assessment when using digital front door technologies	AA4: Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
	of the service standard 60 minute appointments.		Completion rates for the additional pre-assessment clinical information vary from 85.3% (of 4173 referrals) to 90.2% (of 2776 referrals) in the case studies presented.		pressure off when I'm doing triages" "patients who have used it find it helpful 'nice to have someone to talk to and are excited to see AI technologies being used in the NHS" "It's easy to use and gives a sense of personalisation in approaching mental health services."
Wysa EAG RFI response[21]	Refers to Wysa EVA Additional Supporting Evidence[20]	"We have a research protocol in place with the Whittington Trust which will allow us to look at how effective the data collected by the Wysa DRA is in helping the practitioner in making an accurate treatment pathway decision for the patient"	--	Numbers of patients available for: • Age group by referral • Gender • Sexuality • LTC • Ethnicity • Time of the day	--

DRA=Digital Referral Assistant; EAG=External Assessment Group; EVA=early value assessment; NICE=National Institute for Health and Care Excellence; RFI=request for information; WCAG=Web Content Accessibility Guidelines

Table 31 Resource and system impact – Wysa DRA

Source	RSI1: Administrative resource impact	RSI2: Time taken to review data collected by digital front door technologies	RSI3: Time taken to complete clinical assessment	RSI4: Time saved for the clinician during clinical assessment
Wysa NICE RFI response[6]	--	--	--	RFI Q6: 16 to 21 minutes saved depending on the length of the DRA used by the service
Wysa EVA Additional Supporting Evidence[20]	"… the majority of our services are choosing not to outcome the effectiveness of the DRA in terms of the time taken to complete an assessment appointment. Instead they are focussing on using the quality and quantity of clinical information provided by the Wysa DRA to allow clinicians to ask further questions around particular areas of concerns and/or to begin working with the patient on goals, problem statement summaries and/or providing psychoeducation in relation to the patient's identified provisional complaint. For these services, the metric of time taken to complete a first attended assessment or assessment and treatment appointment would not be a valid or fair measure of the effectiveness or efficiency of the use of a pre-assessment	--	"We currently work with 28 NHS Talking Therapies services, nine of which are provided by Vita Health Group (VHG). Between October 2023 and June 2024, one of these services ([redacted]) used the information collected by the Wysa DRA to inform the type and length of assessment appointments offered. 91% of assessments for those who completed the full set of clinical questions asked by the DRA were scheduled for shorter, 30 minute appointments instead of the service standard 60 minute appointments… the majority of our services are choosing not to outcome the effectiveness of the DRA in terms of the time taken to complete an assessment appointment. Instead, they are focussing on using the	--

Source	RSI1: Administrative resource impact	RSI2: Time taken to review data collected by digital front door technologies	RSI3: Time taken to complete clinical assessment	RSI4: Time saved for the clinician during clinical assessment
	DRA."		quality and quantity of clinical information provided by the Wysa DRA to allow clinicians to ask further questions around particular areas of concerns and/or to begin working with the patient on goals, problem statement summaries and/or providing psychoeducation in relation to the patient's identified provisional complaint. For these services, the metric of time taken to complete a first attended assessment or assessment and treatment appointment would not be a valid or fair measure of the effectiveness or efficiency of the use of a pre-assessment DRA."	
Wysa EAG RFI response[21]	--	--	Refers to Wysa EVA Additional Supporting Evidence[20]	Data presented from Wysa NICE RFI response[6]

DRA=Digital Referral Assistant; EAG=External Assessment Group; EVA=early value assessment; NICE=National Institute for Health and Care Excellence; RFI=request for information

Table 32 Patient reported outcomes – Wysa DRA

Source	PRO1: Ease of access and usability	PRO2: Information clarity and relevance	PRO3: Comfort and privacy	PRO4: Overall satisfaction with pre-assessment process
Wysa NICE RFI response[6]	--	--	--	RFI Q6: 98% of patients are satisfied with the Wysa DRA and said that it helped them to refer into the service
Wysa EVA Additional Supporting Evidence[20]	See PRO4: Overall satisfaction with pre-assessment process	--	--	Feedback from users See Table 33 below
Wysa EAG RFI response[21]	--	--	--	Feedback from users See Table 34 and Table 35 below

DRA=Digital Referral Assistant; EAG=External Assessment Group; EVA=early value assessment; NICE=National Institute for Health and Care Excellence; RFI=request for information

Additional tables that did not fit in the cells above

The Wysa DRA collects feedback from users of the Wysa on either a five point scale or a three point scale, depending on service choice.

Table 33 Feedback using the five point scale presented in the Wysa EVA Additional Supporting Evidence

Value	Lancs & South Cumbria TT	Milton Keynes TT	Coventry & Warwickshire TT	Kensington & Chelsea TT	All
N	4037	932	2663	555	**8187**
It was really good, thanks!	33.0%	29.2%	32.1%	31.2%	**32.1%**
It was engaging and helpful	27.0%	24.1%	27.9%	26.1%	**26.9%**
It was fine	21.5%	28.0%	23.5%	24.9%	**23.1%**
It was a little challenging	13.5%	12.9%	12.4%	11.5%	**13.0%**
It was very difficult	5.0%	5.8%	4.2%	6.3%	**4.9%**

TT=Talking Therapies

Table 34 Feedback using the five point scale presented in the Wysa EAG RFI response

How did you find talking with me today?	Total*	%
It was really good, thanks!	1171	31.6%
It was engaging and helpful	1026	27.7%
It was fine	882	23.8%
It was a little challenging	452	12.2%
It was very difficult	179	4.8%

*3710 responses

EAG=External Assessment Group

Table 35 Feedback using the three point scale presented in the Wysa EAG RFI response

Have I been able to help you today?	Total*	%
Yes	17,900	79.1%
Somewhat	4190	18.5%
No	530	2.3%

*22,610 responses
EAG=External Assessment Group

Table 36 Economic outcomes (costs) – Wysa DRA

Source	Costs of the technologies	Initial setup and integration costs	Operational costs (if falling on the NHS rather than the technology provider)	Training costs	Cost of promotion	Costs of applying digital clinical safety assurance DCB0129	Other
Wysa NICE RFI response[6]	Wysa, RFI response, Q24: "There is an additional one off … plus VAT implementation cost, per service. Each service is allocated a specific number of customisation person-days, depending on the size of the contract, with additional customisations completed on request and at additional cost" [Updated cost provided in Additional Supporting Evidence[20]]						
Wysa EVA Additional Supporting Evidence[20]	<u>Costs of the technologies</u> Wysa offers a capitated pricing model based on license fees for the number of annual referrals expected to be processed. This model is published on GCloud14. The fees in the table below are annual fees with a minimum contract length of 12 months. Annual license fees are inclusive of: - Regular updates and scheduled maintenance - End-user access to the Wysa help-desk through the app - Service access to the Wysa help-desk through Zendesk - Standard communications collateral - Access to, and unlimited usage of, EMH by Wysa for all NHS Talking Therapies patients - Customisation days (calculated at 10% of the contract value and represented as person-days at £100 per hour for a 7.5 hour day) Annual license fees are exclusive of: - Development costs associated with a change of EPR system or significant adaptations to the EPR system which would impact on the functionality of the software - Hardcopy/printed communication materials - License fees associated with the use of any additional clinical questionnaires not already licensed by Wysa or by the NHS Digital Copyright Licensing Service - Software development/customisations requested outside of the standard customisations listed once the contractual customisation days have been used. - Additional customisations will be mutually agreed in a Statement of Works and calculated at £100 per person-hour to complete. - Additional training sessions requested after the allowance is used from the implementation fee calculated at £100 per person-hour to complete						

<table>
<tr><th>Source</th><th>Costs of the technologies</th><th>Initial setup and integration costs</th><th>Operational costs (if falling on the NHS rather than the technology provider)</th><th>Training costs</th><th>Cost of promotion</th><th>Costs of applying digital clinical safety assurance DCB0129</th><th>Other</th></tr>
<tr><td></td><td colspan="7">
<table>
<tr><th colspan="2">Capitated referral numbers processed</th><th>Fee per referral</th></tr>
<tr><td>1</td><td>5,000</td><td>£3.54</td></tr>
<tr><td>5,001</td><td>10,000</td><td>£3.28</td></tr>
<tr><td>10,001</td><td>15,000</td><td>£2.76</td></tr>
<tr><td>15,001</td><td>20,000</td><td>£2.16</td></tr>
<tr><td>20,001</td><td>30,000</td><td>£1.74</td></tr>
<tr><td>30,001</td><td>upwards</td><td>£1.26</td></tr>
</table>

Fees in the table above do not include VAT at the relevant rate.

<u>Initial setup and integration costs</u>
A one-off implementation fee of £9,150+VAT is charged to cover set-up, customisation and onboarding. This is payable from the Effective Date of the contract and cover:
- Support with standard customisations of the question flow
- Co-branding, integrating local signposting and helplines
- Up to 5, 30 minute staff training sessions
- Communications collateral
- Establishment of local clinical safety and information governance documentation
- Build of service’s analytics dashboard
- Staff training sessions
</td></tr>
</table>

DRA=Digital Referral Assistant; EMH=online resources for mental health care; EPR=electronic patient record; EVA=early value assessment; NICE=National Institute for Health and Care Excellence; RFI=request for information; VAT=value added tax

Table 37 Accuracy and acceptability outcomes – Censeo Digital

Source	Quality and accuracy of the data collected using digital front door technologies	Accuracy of clinical assessment for NHS Talking Therapies	Completion rate of pre-assessment when using digital front door technologies	Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
Psyomics RFI response[5]	From safety and performance data reported in figure in RFI response Q6, condition algorithms, comparison was between psychiatrist ratings and the Censeo system across 15 mental health conditions (N=160): • 87% match rate • Overall AUC–ROC: 0.86 • Overall sensitivity: 0.90 • Overall specificity: 0.81 • Most conditions show good to excellent performance (AUC > 0.80) The ratings were on an ordinal scale of condition likelihood scores (Unlikely, Possible, Probable, and Highly Likely) For binary classification metrics, positive cases were considered as Possible, Probable, and	--	From safety and performance data reported in figure in RFI response Q6: • 65% completion rate for referred to patients	RFI response Q10: Censeo has been designed with an intuitive user interface, minimizing technological complexity. It is accessible on mobile, tablet, and desktop platforms. However, for those with significant digital literacy challenges or certain disabilities (e.g., visual impairment), additional support may be required. We are exploring further options, such as screen reader compatibility. RFI response Q9: Censeo is not designed for patients with neurocognitive disorders, severe learning disabilities, or those in immediate crisis. It also may not be as effective for patients without basic digital literacy or access to internet-enabled devices.	--

Source	Quality and accuracy of the data collected using digital front door technologies	Accuracy of clinical assessment for NHS Talking Therapies	Completion rate of pre-assessment when using digital front door technologies	Inaccessibility to digital front door technologies	AA5: Healthcare professional acceptability of digital front door technologies
	Highly Likely, while negative cases were Unlikely Data was collected from real clinical cases from mental health services				
Psyomics EAG RFI response[19]	"MPFT recently reported that of 23 referrals which went through censeo, only 2 required reassessment vs. 25 referrals without censeo where 19 required reassessment. This was not in a TT setting. This data is held by our clients and therefore I can only share an example that was shared with us. It would require a scoped piece of work to answer this question fully."	"No current data"	--	--	--

AUC=area under the curve; EAG=External Assessment Group; MPFT=Midlands Partnership University NHS Foundation Trust; NICE=National Institute for Health and Care Excellence; RFI=request for information; ROC=Receiver Operating Characteristic; TT=Talking Therapies

Table 38 Resource and system impact – Censeo Digital

Source	Administrative resource impact	Time taken to review data collected by digital front door technologies	Time taken to complete clinical assessment	Time saved for the clinician during clinical assessment
Psyomics RFI response[5]	• 80% of professionals found the reports saved a moderate to large amount of time in clinical workflow	--	--	--
Psyomics EAG RFI response[19]	--	--	--	--

Table 39 Patient reported outcomes in NICE scope – Censeo

Source	Ease of access and usability	Information clarity and relevance	Comfort and privacy	Overall satisfaction with pre-assessment process
Psyomics RFI response[5]	From safety and performance data reported in figure in RFI response Q6, User acceptance/ engagement: • 70.71% patients found it easy to complete • More likely to engage and receive onward referral (77% vs 69%)	From safety and performance data reported in figure in RFI response Q6, User acceptance/ engagement: • 78.1% of patients found questions relevant • 86.6% found Censeo Digital comprehensive	RFI response Q6: Improved Preparedness and Comfort: The adaptive, patient-completed questionnaire allows patients to consider their responses thoughtfully, completing the process at their own pace. This helps them prepare for triage and assessment, making their appointments more efficient and less anxiety-inducing"	RFI response Q27: Being measured in future studies
Psyomics EAG RFI response[19]	Note on data in rows above • Based on documentation showing over 1000+ service user feedback responses • Completion rate definition: 41% of users who start the assessment complete all questions (60% interact with referral, 50% start questions, 41% complete) • The "more likely to engage and receive onward referral" comparison (77% vs 69%) appears to be from MPFT internal evaluation • Baseline patient characteristics would need to be provided from current implementation sites		--	--

EAG=External Assessment Group; MPFT=Midlands Partnership University NHS Foundation Trust; NICE=National Institute for Health and Care Excellence; RFI=request for information

Table 40 Economic outcomes (costs) – Censeo Digital

Source	Costs of the technologies	Initial setup and integration costs	Operational costs (if falling on the NHS rather than the technology provider)	Training costs	Cost of promotion	Costs of applying digital clinical safety assurance DCB0129	Other
Psyomics NICE RFI response[5]	RFI response Q23: [redacted] RFI response Q24: [redacted]						

API=application programming interface; NICE=National Institute for Health and Care Excellence; RFI=request for information

13.6 Appendix 6: Questionnaire for NHS Talking Therapies SCMs and stakeholders

Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies Early Value Assessment (EVA)

Your details

1. Name

2. Please specify your role in this EVA (please bold your response):
    - Specialist committee member
    - Stakeholder
    - Other

3. Please tell us your job title

Digital front door technologies

4. Please tell us about any experience you have had of digital front door technologies for NHS Talking Therapies

5. Have any of the following digital front door technologies been introduced in your area? Please bold all that apply:
    - AskFirst
    - Censeo Digital
    - Limbic Access
    - Wysa Digital Referral Assistant

6. How do people know whether a digital front door technology is available in their area? If a digital front door technology is available, how can people find out how to access it?

NHS Talking Therapies referral pathway

7. Please describe the current referral pathways to NHS Talking Therapies. If relevant, please describe how the following three stages are linked (i) self-referral, (ii) pre-assessment/triage and (iii) one-to-one in-person clinical assessment, and the NHS personnel who are involved at each stage.

8. If relevant, please describe how current referral pathways have been affected by the introduction of digital front door technologies?

9. If a digital front door technology is used in your area, which eligibility criteria does the digital front door technology automatically use to divert people away from local NHS Talking Therapies. Please **bold** all that apply.
   - Age
   - GP location
   - Currently receiving mental health care (secondary care setting)
   - None
   - Other (Please specify in the box below)

10. Are all patients who are not eligible for NHS Talking Therapies automatically signposted to other services? If not, what is the process (with and without digital front door technologies)?

11. Over the last 12 months, in your area, approximately what proportions of patients were referred to NHS Talking Therapies via the following routes?

Referral route	**Areas without a digital front door technology (%)**	**Areas with a digital front door technology**	
		Before a digital front door technology was introduced (%)	**After a digital front door technology was introduced (%)**
Self-referrals			
Primary care referrals			
Community or voluntary care referrals			
Secondary care referrals (mental health services)			
Secondary care referrals (physical healthcare services)			
Other			
Please use this box to expand on any of your responses.			

12. Are any national or local data on referral routes into NHS Talking Therapies routinely collected? If yes, please provide these data, or the source of these data.

Information collected at referral

13. Which of the following data are typically collected from patients at the referral stage? (Please tick all that apply)

Information	With a digital front door technology	Without a digital front door technology	Don't know
Demographic and contact information			
Brief free-text description of problem(s)			
Patient Health Questionnaire – 9 items (PHQ-9)			
Generalised Anxiety Disorder scale – 7 items (GAD-7)			
Risk factors such as self-harm, suicidal intent, post-partum, pregnancy, drug/alcohol misuse			

14. What other tools are frequently used to collect physical and mental health information/ outcome measures from patients at the referral stage? (Please tick all that apply)

Questionnaire	With a digital front door technology	Without a digital front door technology	Don't know
Work and Social Adjustment Scale (WSAS)			
Social Phobia Inventory (SPIN)			
Mobility inventory for agoraphobia			
Obsessive-Compulsive Inventory (OCI)			
Panic Disorder Severity Scale (PDSS)			
PTSD Checklist for DSM-5 (PCL-5)			
Body Image Questionnaire Weekly			
Patient Health Questionnaire (Physical symptoms, PHQ-15)			
Francis Irritable Bowel Scale (IBS-SSS)			
Health Anxiety Inventory (HAI)			
Chalder Fatigue Questionnaire (CFQ)			
Assessment PEQ			
Treatment PEQ			
None of the above			

15. Please provide details of any other data typically collected from patients at the referral stage.

Pre-assessment/triage

16. Is any of the following (risk and suitability) information typically reviewed at the pre-assessment/triage stage? (Please tick all that apply)

Information	With a digital front door technology	Without a digital front door technology	Don't know
Demographic and contact information			
Brief free-text description of problem(s)			
Patient Health Questionnaire – 9 items (PHQ-9)			
Generalised Anxiety Disorder scale – 7 items (GAD-7)			
Risk factors such as self-harm, suicidal intent, post-partum, pregnancy, drug/alcohol misuse			
None of the above			
Other			

17. Please answer the following questions about pre-assessment/triage.

	Without a digital front door technology	With a digital front door technology
Is the person who conducts the pre-assessment/triage the same person who carries out the one-to-one person-centred clinical assessment?		
Typically, how long does it take to complete a pre-assessment/triage (minutes)?		
During a pre-assessment/triage, how much time is spent reviewing demographic data (minutes)?		
During a pre-assessment/triage, how much time is spent reviewing health questionnaire data (minutes)?		
What is the next step for patients who are not considered suitable for a one-to-one person-centred clinical assessment?		
Please use this box to expand on any of your responses.		

18. To what extent do you agree that the introduction of digital front door technologies has the following effects on the pre-assessment/triage stage? (Please tick)

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Reduction in waiting times from referral to the pre-assessment/triage					
Shorter duration of the pre-assessment/triage stage					
Clinical assessors are more informed before the start of the pre-assessment/triage					
More accurate data to review at the pre-assessment/triage					
Better quality data to review at the pre-assessment/triage					

19. If you are aware of any data to support your response to Q18 please provide these data, or sources of data.

NHS Talking Therapies one-to-one person-centred clinical assessment

20. Are one-to-one person-centred clinical assessments carried out using a standard protocol? If yes, does the standard protocol differ depending on referral route?

21. Please answer the following questions about an NHS Talking Therapies one-to-one person-centred clinical assessments

	Without a digital front door technology	With a digital front door technology
Typically, how long is a one-to-one person-centred clinical assessment (minutes)?		
During a one-to-one person-centred clinical assessment, how much time is spent collecting demographic data (minutes)?		
During a one-to-one person-centred clinical assessment, how much time is spent collecting health questionnaire data/outcome measures (minutes)?		
Please use this box to expand on any of your responses.		

22. If you are aware of any data to support your responses to Q21, please provide these data, or sources of these data.

23. To what extent do you agree that the introduction of digital front door technologies could have the following effects on the one-to-one person-centred clinical assessment? (Please tick)

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Reduction in waiting times from referral to the one-to-one person-centred clinical assessment					
Reduction in waiting times from pre-assessment/triage to the one-to-one person-centred clinical assessment					
Shorter duration of the one-to-one person-centred clinical assessment					
Clinical assessors are more informed before the start of the one-to-one person-centred clinical assessment					
More accurate data collected prior to the one-to-one person-centred clinical assessment					
Better quality data collected prior to the one-to-one person-centred clinical assessment					
Clinical assessors spend more time focusing on the patient during the one-to-one person-centred clinical assessment					
Clinical assessors spend less time on administrative tasks during the one-to-one person-centred clinical assessment					
Better quality one-to-one person-centred clinical assessment					
More accurate one-to-one person-centred clinical assessment					

24. If you are aware of any data to support your responses to Q23, please provide these data, or sources of data.

Quality and accuracy of the one-to-one person-centred clinical assessment

25. If you think the introduction of digital front door technologies has led to a better quality one-to-one person-centred clinical assessment, please explain what you mean by better quality and suggest how quality can be measured.

26. If you think the introduction of digital front door technologies has led to a more accurate one-to-one person-centred clinical assessment, please explain what you mean by the term 'more accurate' and suggest how accuracy can be measured.

Costs

27. Please provide any information that might help us to assess the costs associated with implementing and operating a digital front door technology.

	Cost	Source/references/other person to contact
Costs of the digital front door technologies		
Initial setup and integration costs		
Operational costs (if falling on the NHS rather than the technology provider) such as IT support for healthcare professionals and patients and cybersecurity		
Training costs		
Cost of promotion		
Costs of applying digital clinical safety assurance DCB0129 (Clinical Risk Management: its Application in the Manufacture of Health IT Systems)		
Other		
Please use this box to expand on any of your responses.		

Other

28. Has the introduction of digital door technologies made any groups of people more likely/less likely to access NHS Talking Therapies?

29. Are there any benefits of digital front door technologies that have not been captured in this questionnaire?

30. Do you have any concerns about digital front door technologies that have not been captured in this questionnaire?

31. If available, please provide conversion rate data for the following stages in the referral process

	Without a digital front door technology	**With a digital front door technology**
Referral to one-to-one person-centred clinical assessment		
Referral to pre-assessment/triage		
Pre-assessment/triage to one-to-one person-centred clinical assessment		
Referral to first treatment session		
One-to-one person-centred clinical assessment to first-treatment session		

32. If you are aware of any data to support your responses to Q31, please provide these data, or sources of data.

33. Please provide any other information that will help us assess the costs and benefits of digital front door technologies for NHS Talking Therapies

34. What do you think are the most important outcomes that should be considered when evaluating the effectiveness/impact of digital front door technologies?

35. Please suggest anyone else that you think would be interested in completing this questionnaire or talking to us about referrals to NHS Talking Therapies

Thank you for taking the time to complete this questionnaire

13.7 Appendix 7: Questionnaire responses

Table 41 Digital front door technologies

Question	SCM1	SCM2	SCM3	SCM6	SH1
Q4.Please tell us about any experience you have had of digital front door technologies for NHS Talking Therapies	The trust I work in are using both WYSA and Limbic. The service I work in is using Limbic. I was involved in the set up of Limbic in the service.	Discussed in meeting [experience of Limbic Access and Wysa DRA]	Familiar with Wysa and Limbic but no direct experience	I led two NHS Talking Therapies services […] between 2009 and 2019. In both services I mobilised front door technologies for referral and triage of NHS Talking Therapies referrals alongside other mental health referral routes and worked closely with primary care colleagues to improve the productivity of mental health front doors. I have held a strategic role in digital for a mental health and learning disabilities tryst since 2019. I have led the procurement and deployment of front door technologies as part of this role in both primary and secondary mental health. I am a clinical safety officer and have completed clinical safety cases on front door technologies	We don't use any of the digital front doors listed below, we use the Mayden version linked to iaptus
Q5. Digital front	Limbic Access	Discussed in meeting	See above	Censeo Digital	None

Question	SCM1	SCM2	SCM3	SCM6	SH1
door technology used?	Wysa DRA	[currently using the Wysa DRA]			
Q6. How do people know whether a digital front door technology is available in their area? If a digital front door technology is available, how can people find out how to access it?	Both Wysa and Limbic are available when accessing the talking therapies websites. A small pop up loads the moment you access the website	Discussed in meeting	--	Via websites, social media, GP websites and ICB information sources. It could also be via the patient portal (NHS app) for a specific area	--

Table 42 NHS Talking Therapies referral pathway (Q7 to Q10)

Question	SCM1	SCM2	SCM3	SCM6	SH1
Q7. Please describe the current referral pathways to NHS Talking Therapies. If relevant, please describe how the following three stages are linked (i) self-referral, (ii) pre-assessment/triage and (iii) one-to-one in-person clinical assessment, and the NHS personnel who are involved at each stage	Patient completes a self referral (telephone, online static form (mayden hosted) or AI assisted (limbic). Next the referral is uploaded to iaptus via our admin team, they also check whether the patient is known on other systems, such as SystmOne. Once it has been processed, the referral is added to the duty screening folder on iaptus. The referral is then paper triaged by a clinician. If the patient is suitable, it will then be decided who will assess and then admin will offer the patient an assessment	Discussed in meeting	Self referral (Via phone, email, professional) -> admin to input onto clinical system -> clinician (pwp/CBT therapist) reviews and carries out triage (routine and expediated if risk identified) -> decision made to either go through to assessment or be signposted out. -> referred for assessment by either PWP/ CBT depending on presenting information in self-referral and/or triage – -> following assessment decision made for what part of step care they may benefit or signposted out. -> Some assessments may need a further assessment depending on risk/complexity/ accessibility/ modality or other factors (e.g trauma presentation identified at assessment, further assessed by EMDR	Self referral is open to all residents […] via web based forms which then are integrated into the electronic patient record where they are triaged. There may be a pre-assessment phone call with the person referring to establish any missing details or more information. If they meet the criteria of NHS talking therapies they will be offered an assessment usually from a psychological wellbeing practitioner. There are additional offers at this point from primary care practitioner (non NHS talking therapies) or a direct referral into secondary care if the presenting problem is considered to be related to a severe and enduring mental health difficulty or if there is a immediate risk that cannot be managed within NHS talking therapies.	Referral/self referral-ITA (1:1 initial telephone assessment completed by PWP/HIT)

Question	SCM1	SCM2	SCM3	SCM6	SH1
			therapist to determine suitability)		
Q8. If relevant, please describe how current referral pathways have been affected by the introduction of digital front door technologies?	The digital front door will enable the paper triage to be quicker, as it will have collected more information in order to make a decision on whether they are suitable and what step is best to assess. This enables our triaging clinicians to triage quicker. It has also reduced the number of inappropriate patients getting to the paper triage stage	Discussed in meeting	n/a	We have introduced front door technology into secondary care pathway in one area […] NHS talking therapies is using web based form but no decision support technology for pre-assessment.	The Mayden online referral option populated straight into iaptus which reduced admin time and reduces the risk of error/referral getting lost/missed. Also give the patient/referrer the opportunity to give some referral information before they are seen by the service.
Q9. If a digital front door technology is used in your area, which eligibility criteria does the digital front door technology automatically use to divert people away from local NHS Talking Therapies.	Age Other: Immediate crisis	None	Age GP/location Other: On occasions due to presentation e.g if referral indicates eating disorder or Psychosis they may be directly signposted to secondary care even if they are not currently open to them	Age GP location Currently receiving mental health care (secondary care setting) Other: We have a small pilot which is situated in secondary care not NHS talking therapies. NHS talking therapies are using a web based self referral but I do not think this meets the criteria	Age GP location Other: Risk and the need for urgent care
10. Are all patients who are not eligible for NHS Talking Therapies automatically	Yes, all are signposted out. We ask all the eligible questions but we do not allow the AI bot to signpost all, only age	--	If local services are available that meets clients needs then yes otherwise redirected	Yes and the referral is sent between services - the person does not have to re-refer to	Signposting is done as part of the ITA

Question	SCM1	SCM2	SCM3	SCM6	SH1
signposted to other services? If not, what is the process (with and without digital front door technologies)?	and risk. All the others we still review and devise personalised signposting options		back to care of GP.	secondary care.	
Question asked one SCM in email: From your experience, do you have an idea of how many referrals to NHS Talking Therapies require two (or more?) one-to-one clinical assessments (in general and with and without a digital front door technology)? Just a guestimate would do. I think when we chatted, you said this may vary by geographical area depending on the needs of that area (so would be more where ethe needs are more complex like a lot of trauma and PTSD)?	--	--	In my last service, we had modality assessments so for example every client that was identified as appropriate for EMDR was put forward for another assessment to assess suitability by a EMDR therapist. (If the initial assessment was done by somebody trained in EMDR then a second assessment was not necessary). In terms of 2nd assessments due to complexity or risk I would guesstimate a small percentage approx 1 or 2 out of every 20 assessments. So if a service was assessing 200 a week, approx 10 may require a further assessment. Hope that's helpful.	--	--

Table 43 Proportions referred (Q11) and referral routes (Q12)

Type/question	SCM1		SCM2	SCM3	SCM6	SH1	
Information provided	Before vs after Limbic Access		With Wysa	--	--	--	--
Q11. Self-referrals	72%	75%	46% digital triage 22% online form (Mayden) 14% telephone	--	--	--	--
Primary care referrals	22%	18%	9%	--	--	--	--
Community or voluntary care referrals	2%	3%	1%	--	--	--	--
Secondary care referrals (mental health services)	4%	4%	1%	--	--	--	--
Secondary care referrals (physical healthcare services)	<1%	<1%	1%	--	--	--	--
Other	--	--	6%	--	--	--	--
Q12. Are any national or local data on referral routes into NHS Talking Therapies routinely collected? If yes, please provide these data, or the source of these data	Yes, Admin record where the referral has come from when creating the patient referral, this is then accessible via the Mayden Dashboard on iaptus		NHS Digital – Futures website https://tabanalytics.data.england.nhs.uk/views/TTAD_ProgrammeDevelopmentTool/Front?%3Aembed=y&%3AshowVizHome=n&%3Ajsdebug=y&%3Atabs=y&%3Atoolbar=y&customViews=true&%3AapiID=host0#navType=1&navSrc=Parse&1	National available data can be found here: https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/improving-access-to-psychological-therapies-data-set/improving-access-to-psychological-therapies-data-set-reports	This forms part of the MHSDS Mental Health Services Data Set (MHSDS) - NHS England Digital	--	--

Table 44 Information collected at referral (Q13)

Type	SCM1		SCM2		SCM3		SCM6		SH1	
Information provided	With Limbic Access vs without		With the Wysa DRA vs without		Without digital front door		Without digital front door		Without digital front door	
Demographic and contact information	X	X	X	X	--	x	--	X	--	x
Brief free-text description of problem(s)	X	X	X	X	--	x	--	X	--	x
Patient Health Questionnaire – 9 items (PHQ-9)	X	--	X	X	--	x	--	X	--	--
Generalised Anxiety Disorder scale – 7 items (GAD-7)	X	--	X	X	--	x	--	X	--	--
Risk factors such as self-harm, suicidal intent, post-partum, pregnancy, drug/alcohol misuse	X	--	X	X	--	x	--	X	--	--

Table 45 Other tools (Q14+Q15)

Type	SCM1		SCM2		SCM3		SCM6		SH1	
Information provided	With Limbic Access vs without		With the Wysa DRA vs without		In built tools on clinical management system e.g. PCMIS – links sent to complete questionnaires Online referral forms that link into clinical systems		Without digital front door		Without digital front door	
Work and Social Adjustment Scale (WSAS)	X	--	X	--	--	x	--	--	--	--
Social Phobia Inventory (SPIN)	X	--	X	--	--	x	--	--	--	--
Mobility inventory for agoraphobia	X	--	X	--	--	x	--	--	--	--
Obsessive-Compulsive Inventory (OCI)	X	--	X	--	--	x	--	--	--	--
Panic Disorder Severity Scale (PDSS)	X	--	X	--	--	x	--	--	--	--
PTSD Checklist for DSM-5 (PCL-5)	X	--	X	--	--	x	--	--	--	--
Body Image Questionnaire Weekly	X	--	X	--	--	x	--	--	--	--
Patient Health Questionnaire (Physical symptoms, PHQ-15)	--	--	X	--	--	Don't know	--	--	--	--
Francis Irritable Bowel Scale (IBS-SSS)	--	--	X	--	--	x	--	--	--	--
Health Anxiety Inventory (HAI)	X	--	X	--	--	x	--	--	--	--

Type	SCM1		SCM2		SCM3		SCM6		SH1	
Chalder Fatigue Questionnaire (CFQ)	--	--	X	--	--	x	--	--	--	--
Assessment PEQ	--	--	--	--	--	x	--	X	--	--
Treatment PEQ	--	--	--	--	--	x	--	X	--	--
None of the above	--	X	--	--	--	--	--	--	--	--
Other	Previous mental health/history, medication, children under the age of 18yrs under their care, sexual orientation, language, pronouns, alcohol and drugs, physical health issues, adhd/austim diagnosis		--		Equality and diversity monitoring forms Physical health conditions questionnaire		--		Any co-morbidities (physical or mental health), next of kin details, other demographic information eg ethnicity etc. Any preferences for gender of therapist	

Table 46 Information reviewed at pre-assessment/triage (Q16)

Type	SCM1		SCM2		SCM3		SCM6		SH1	
Information provided	With Limbic Access vs without Limbic Access		--		Without digital front door		Without digital front door		--	
Demographic and contact information	X	X	--	--	--	x	--	X	--	--
Brief free-text description of problem(s)	x	X	--	--	--	x	--	X	--	--
Patient Health Questionnaire – 9 items (PHQ-9)	X	--	--	--	--	x	--	X	--	--
Generalised Anxiety Disorder scale – 7 items (GAD-7)	X	--	--	--	--	x	--	X	--	--
Risk factors such as self-harm, suicidal intent, post-partum, pregnancy, drug/alcohol misuse	X	--	--	--	--	x	--	X	--	--
None of the above	--	--	--	--	--	--	--	--	--	--
Other	--	--	--	--	--	--	--	--	--	--

Table 47 Time taken and next steps at pre-assessment/triage (Q17)

Question	SCM1		SCM2		SCM3		SCM6		SH1	
Information provided	Without vs with Limbic Access		Without vs with the Wysa DRA		Without digital front door		Without digital front door		--	
Is the person who conducts the pre-assessment/triage the same person who carries out the one-to-one person-centred clinical assessment?	No	No	No	No	No	n/a	No	--	--	--
Typically, how long does it take to complete a pre-assessment/triage (minutes)?	3mins	5mins	varies	Varies	Differs, varies from 10-15 minutes. Some longer if there is risk.	--	10 minutes	--	--	--
During a pre-assessment/triage, how much time is spent reviewing demographic data (minutes)?	30secs	30secs	minimal	minimal	Brief, most is gathered at assessment stage.	--	5 minutes	--	--	--
During a pre-assessment/triage, how much time is spent reviewing health questionnaire data (minutes)?	1mins	NA	2mins	2mins	Brief.	--	5 minutes	--	--	--

Question	SCM1		SCM2		SCM3		SCM6		SH1	
What is the next step for patients who are not considered suitable for a one-to-one person-centred clinical assessment?	They are written to with an explanation as to why, provided alternative services or directly referred to secondary care services	They are written to with an explanation as to why, provided alternative services or directly referred to secondary care services	Discharge to GP (usually)	Discharge to GP (usually)	Signposted or liaising with other professionals. Occasionally sent for assessment to gather more information to ensure appropriate signposting.	--	They are signposted to another service	--	--	--

Table 48 Effects of digital front door technologies on the pre-assessment/triage stage (Q18+Q19)

1=strongly disagree to 5= strongly agree

Outcome	SCM1	SCM2	SCM3	SCM6	SH1
Reduction in waiting times from referral to the pre-assessment/triage	5	--	4	4	--
Shorter duration of the pre-assessment/triage stage	4	--	4	4	--
Clinical assessors are more informed before the start of the pre-assessment/triage	5	--	5	4	--
More accurate data to review at the pre-assessment/triage	5	--	4	4	--
Better quality data to review at the pre-assessment/triage	4	--	4	4	--
Supporting data	664 referrals from our go live have been signposted at the front door since go live, which has saved triage clinician from reading all those referrals, cross referencing against SystmOne, writing that many individual letters etc. For reference the total referral since this date have been 3301.	--	--	--	--

Table 49 One-to-one person-centred clinical assessment (Q20 to Q22)

Question	SCM1		SCM2		SCM3		SCM6		SH1	
Q20. Are one-to-one person-centred clinical assessments carried out using a standard protocol? If yes, does the standard protocol differ depending on referral route?	Yes, the template is shorter for Limbic Access referrals		--		Differs dependant on service but usually contains demographic info, presenting problem, history taking, risk, goals, plan and questionnaires		Yes, the protocol differs depending on if it is NHS Talking therapies or non-NHS talking therapies - other primary or secondary care mental health offer		No, the protocol is the same no matter the referral route	
Q21. Information provided	Without vs with Limbic Access		Without vs with the Wysa DRA		Without digital front door		Without digital front door		Without digital front door	
Typically, how long is a one-to-one person-centred clinical assessment (minutes)?	50mins	40mins	45mins-60mins	45mins-60mins	45 minutes to an hour	--	45 minutes	--	45 minutes	--
During a one-to-one person-centred clinical assessment, how much time is spent collecting demographic data (minutes)?	5mins	1min (confirm details are correct)	Minimal – usually would be checked at referral/booking stage by admin	Minimal – usually would be checked at referral/booking stage by admin	5 mins	--	The info is already there - verifying 2 min's	--	Don't know	--
During a one-to-one person-centred clinical assessment, how much time is spent collecting health questionnaire data/outcome measures (minutes)?	10mins	0-10mins (depending on if a patient has submitted it when referring as its options)	Minimal – usually completed via Mayden form sent 24-48hrs before assessment.	None if completed during digital triage. If not then can take approx. 15mins	Differs depending on patient. Some 5 minutes others I have spent nearly 30 minutes e.g those	--	The info is already there - verifying 2 mins.	--	Don't know	--

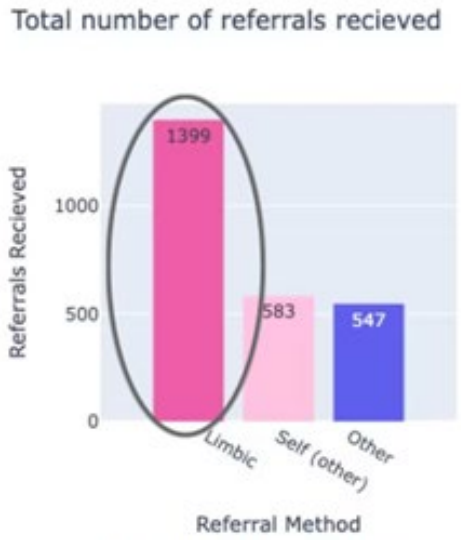
Question	SCM1	SCM2	SCM3	SCM6	SH1
			to wish to expand on the answer or there are language difficulties.		
Please use this box to expand on any of your responses	--	--	--	--	--
Q22. If you are aware of any data to support your responses to Q21, please provide these data, or sources of these data	--	--	--	Internal productivity calculations	--

Table 50 Effects of digital front door technologies on one-to-one person-centred clinical assessment (Q23)

1=strongly disagree to 5= strongly agree

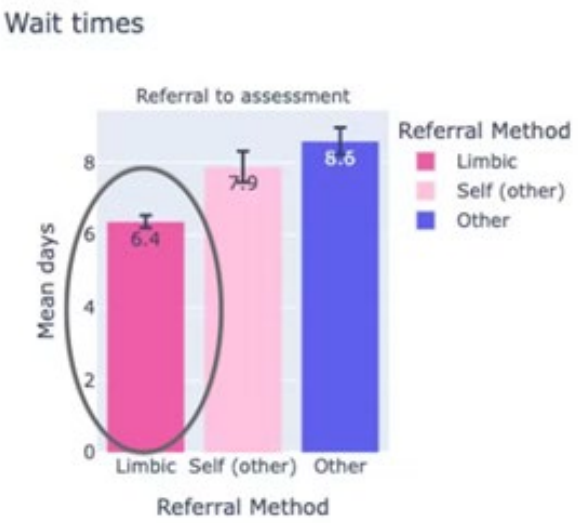
Outcome	SCM1	SCM2	SCM3	SCM6	SH1
Reduction in waiting times from referral to the one-to-one person-centred clinical assessment	4	2	4	4	2
Reduction in waiting times from pre-assessment/triage to the one-to-one person-centred clinical assessment	4	2	4	4	2
Shorter duration of the one-to-one person-centred clinical assessment	4	3	4	4	2
Clinical assessors are more informed before the start of the one-to-one person-centred clinical assessment	5	4	5	4	4
More accurate data collected prior to the one-to-one person-centred clinical assessment	5	3	4	4	4
Better quality data collected prior to the one-to-one person-centred clinical assessment	5	3	4	4	4
Clinical assessors spend more time focusing on the patient during the one-to-one person-centred clinical assessment	5	3	3	4	2
Clinical assessors spend less time on administrative tasks during the one-to-one person-centred clinical assessment	5	3	5	4	4
Better quality one-to-one person-centred clinical assessment	5	3	4	4	2
More accurate one-to-one person-centred clinical assessment	5	3	4	4	4
Supporting data	Preliminary findings after 3 months - see below	--	--	--	--

Preliminary findings after 3 months (SCM1):



Significant differences found between all variables

Significant differences found between all variables



No significant difference between Self (other) and Other (p=0.213)
Significant difference between Self (other) and Limbic: p=0.001
Significant difference between Other and Limbic: p=0.000

Table 51 Quality and accuracy of the one-to-one person-centred clinical assessment (Q25 to Q26)

Question	SCM1	SCM2	SCM3	SCM6	SH1
Q25. If you think the introduction of digital front door technologies has led to a better quality one-to-one person-centred clinical assessment, please explain what you mean by better quality and suggest how quality can be measured	Staff are collecting more information on the main problem as the assessment starts focused on what they described in the referral and what matches with the clinical measures (MDS + ADSMs). So less time is spent up trying to figure it out and therefore we are finding assessments are more detailed and relevant.	--	--	Early findings from our pilot have shown increased patient and clinician satisfaction due to preparedness	--
Q26. If you think the introduction of digital front door technologies has led to a more accurate one-to-one person-centred clinical assessment, please explain what you mean by the term ‘more accurate’ and suggest how accuracy can be measured	The assessments appear to be resulting in patients ending up at the right pathway for assessment and treatment. We are seeing less need for further assessments.	--	--	The decision support focuses both the service user and the clinician	--

Table 52 Costs (Q27)

Outcome	SCM1		SCM2		SCM3		SCM6		SH1	
	Cost	Source	Cost	Source	Cost	Source	Cost	Source	Cost	Source
Costs of the digital front door technologies	60K for 2yrs	--	--	--	--	--	£270000 over three year contract	Censeo contract internal to trust	--	--
Initial setup and integration costs	Included in the above	--	--	--	--	--	--	--	--	--
Operational costs (if falling on the NHS rather than the technology provider) such as IT support for healthcare professionals and patients and cybersecurity	None	--	--	--	--	--	--	--	--	--
Training costs	Included	--	--	--	--	--	1 day per clinician/admin colleague using the tool	--	--	--
Cost of promotion	Included	--	--	--	--	--	--	--	--	--
Costs of applying digital clinical safety assurance DCB0129 (Clinical Risk Management: its Application in the Manufacture of Health IT Systems)	Included	--	--	--	--	--	Implementation and deployment took 15 days of CSO time but the ongoing updates	Internal Clinical Safety Officer	--	--

Outcome	SCM1		SCM2		SCM3		SCM6		SH1	
							need factoring			
Other	--	--	--	--	--	--	--	--	--	--
Please use this box to expand on any of your responses	--		--		--		It is hard to calculate costs to the NHS - I can price the pilot and the business case for whole trust roll out if that is of use			

Table 53 Other (Q28 to Q35)

Question	SCM1	SCM2	SCM3	SCM6	SH1
Q28. Has the introduction of digital front door technologies made any groups of people more likely/less likely to access NHS Talking Therapies?	Our BAME referrals are increase. No decrease in groups have been significant	--	Language barriers -less likely to people who's first language is not English	Not known	Perhaps some harder to reach groups such as men.
Q29. Are there any benefits of digital front door technologies that have not been captured in this questionnaire?	The majority of feedback from patients references how it felt very human and helped them think about their problem more in depth	--	More engaging process for capturing demographic/ initial presenting problem information	I think there is a benefit to patients that services feel modern and focused on efficiency so they save time. A requirement our service users have requested is the ability to book appointments and that all technology integrates with the NHS app.	--
Q30. Do you have any concerns about digital front door technologies that have not been captured in this questionnaire?	The ongoing costs and it is not offered in alternative languages	--	How the ai manages risky utterances from the client	The cost and investment in clinical safety cases - the national training for Clinical safety officers if very focused on physical health technology and so where is the support for this training need	Digital front door technologies should not replace one to one assessments and the use of clinical judgements by trained professionals.

Question	SCM1	SCM2	SCM3	SCM6	SH1
				coming from? Do NHS talking therapy services understand the legally mandated standards in the deployment of these technologies and where are the guard rails regarding information governance and digital clinical safety. This should support the innovation.	
Q31. If available, please provide conversion rate data for the following stages in the referral process	See below	--	--	--	--
Q32. If you are aware of any data to support your responses to, please provide these data, or sources of data	As provided in bar chart above	--	--	--	--
Q33. Please provide any other information that will help us assess the costs and benefits of digital front door technologies for NHS Talking Therapies	--	--	--	--	--
Q34. What do you think are the most important outcomes that should be considered when evaluating the effectiveness/impact of digital front door technologies?	Time saving and impact on recovery	--	Waiting times. Access numbers for different demographics (e.g., age, ethnicity) Qualitative data from clients in terms whether it	Patient experience, quality, digital clinical safety and ease of deployment and adoption rates	--

Question	SCM1	SCM2	SCM3	SCM6	SH1
			helps access or hinders. Qualitative data from therapists and administrative staff		
Q35. Please suggest anyone else that you think would be interested in completing this questionnaire or talking to us about referrals to NHS Talking Therapies	--	--	--	You are very welcome to connect with [our] Talking therapy teams.	--

13.8 Appendix 8: Questionnaire for lay SCMs

Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies Early Value Assessment (EVA)

1. Your name

2. Have you ever accessed NHS Talking Therapies? If yes, how did you access NHS Talking Therapies and what were the main challenges you faced that could have been overcome if you had used a digital front door technology?

3. If you have ever accessed NHS Talking Therapies using a digital front door technology, which of the following digital front door technologies did you use? **(Please bold all that apply)**:
    - AskFirst
    - Censeo Digital
    - Limbic Access
    - Wysa Digital Referral Assistant
    - None
    - Other (please specify below)

4. What do you consider are the main benefits of using digital front door technologies to access NHS Talking Therapies?

5. Do you have any concerns about the use of digital front door technologies to access NHS Talking Therapies?

6. What do you think are the most important outcomes that need to be measured to evaluate the cost and benefits of digital front door technologies used to access NHS Talking Therapies?

7. If you haven't personally accessed NHS Talking Therapies using a digital front door technology, is there anything you can tell us about friends' or family members' experiences?

Thank you for taking the time to complete this questionnaire

Cohort size

Data source: Proportion of referrals received via a DFD: Rollwage et al. (2023)

	Value	Source
Average number of referrals received per annum by a NHS TT provider	11,801	See "NHS TT Data 2023-24.xls" file. Calculated using data from NHS Talking Therapies Annual Report 2023-2024
Proportion of referrals received via a DFD	63.25%	Rollwage et al. (2022) Conversational AI facilitates mental health assessments and is associated with improved recovery ratesmedRxiv 2022.11.03.22281887; doi: https://doi.org/10.1101/2022.11.03.22281887l
Number of referrals received via DFD	7,465	Calculation

Intervention costs

	Number of users		Fee per referral (excl. VAT)	Active value	Implementation/set-up costs	Maintenance/support costs	Source
	Lower Bound	Upper Bound					
Limbic Access	1	5000	£5.49	£4.99	-	-	Company RFI
	5001	15000	£4.99				
	15001	20000	£4.50				
	20001	25000	£4.00				
	25001	30000	£3.75				
	30001	100000	£3.50				

	Number of users		Fee per referral (excl. VAT)	Active value	Implementation/set-up costs (excl. VAT)	Maintenance/support costs	Source
	Lower Bound	Upper Bound					
Wysa	1	5000	£3.25	£2.92	£9,150.00	-	Company RFI
	5001	10000	£2.92				
	10001	15000	£2.53				
	15001	20000	£2.15				
	20001	30000	£1.60				
	30001	-	£1.16				

Digital front door technology	License cost	Implementation/set-up costs	Maintenance/support costs	Cost per referral (Year 1) inc.VAT	Cost per referral (Year 2) inc. VAT
Limbic Access	£37,249	-	-	£5.99	-
Wysa	£21,797	£9,150	-	£4.97	£3.50

Digital front door technology	Number of referrals received via digital front door per year						
	1-5,000	5,001-10,000	10,001-15,000	15,001-20,000	20,001-25,000	25,001-30,000	30,001-100,000
Limbic Access	£6.59	£5.99	£5.99	£5.40	£4.80	£4.50	£4.20
Wysa DRA (Year 1)	£8.29	£4.97	£3.91	£3.21	£2.41	£2.32	£1.56
Wysa DRA (Year 2)	£3.90	£3.50	£3.04	£2.58	£1.92	£1.92	£1.39

Midpoint	Median	Max	Min
£5.39	£5.40	£6.59	£4.20
£4.93	£3.21	£8.29	£1.56
£2.65	£2.58	£3.90	£1.39

NHS Talking Therapies costs

	Value	Source
NHS Talking Therapies clinical assessment unit cost	£186.00	NHS Cost Collection 2023-2024 Assessment 01APT

Clinical assessment duration	Cost per minute
45	£4.13
50	£3.72
55	£3.38
60	£3.10

	Time taken to complete clinical assessment			
Assessment time saved by DFD	45	50	55	60
5	£20.67	£18.60	£16.91	£15.50
10	£41.33	£37.20	£33.82	£31.00
15	£62.00	£55.80	£50.73	£46.50
20	£82.67	£74.40	£67.64	£62.00
25	£103.33	£93.00	£84.55	£77.50
30	£124.00	£111.60	£101.45	£93.00

Midpoint	Median
£69.75	£62.00

Limbic Access

Notional cost saving per assessment	Cost per referral		
	Lowest	Highest	Midpoint of high and low estimates
Lowest	-£11.30	-£8.91	-£10.11
High estimate	-£119.80	-£117.41	-£118.61
Midpoint of high and low estimates	-£65.55	-£63.16	-£64.36

Wysa DRA (Year 1)

Notional cost saving per assessment	Cost per referral		
	Lowest	Highest	Midpoint
Lowest	-£13.94	-£7.21	-£10.57
High estimate	-£122.44	-£115.71	-£119.07
Midpoint of high and low estimates	-£68.19	-£61.46	-£64.82

Wysa DRA (Year 2)

Notional cost saving per assessment	Cost per referral		
	Lowest	Highest	Midpoint of high and low estimates
Lowest	-£14.11	-£11.60	-£12.85
High estimate	-£122.61	-£120.10	-£121.35
Midpoint of high and low estimates	-£68.36	-£65.85	-£67.10

Threshold analysis

Clinical assessment duration	Limbic Access	Wysa DRA (Year 1)	Wysa DRA (Year 2)
45	1.59	2.01	0.94
50	1.77	2.23	1.05
55	1.95	2.45	1.15
60	2.13	2.67	1.26

QALY analysis

WTP threshold	£20,000

Digital front door technology	Number of referrals received via digital front door per year						
	1-5,000	5,001-10,000	10,001-15,000	15,001-20,000	20,001-25,000	25,001-30,000	30,001-100,000
Limbic Access	0.0003	0.0003	0.0003	0.0003	0.0002	0.0002	0.0002
Wysa DRA (Year 1)	0.0004	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001
Wysa DRA (Year 2)	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001

Health Tech Programme

HTE 10055 Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies

External Assessment Report - Comments collated table

Any confidential sections of the information provided should be underlined and highlighted. Please underline all confidential information, and separately highlight information that is 'commercial in confidence' in blue and all that is 'academic in confidence' in yellow

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
1	Rachel Heggart NHSE	16	3	"NHS Talking Therapies offer a range of interventions including cognitive-behavioural therapy (CBT), counselling, and self-guided help; these are delivered in a variety of different formats" – this should say 'counselling for depression and guided self-help'	The EAG has amended the wording in the EAR as suggested.
2	Rachel Heggart NHSE	17	3.1.2	"Preassessments are carried out using patient referral information." I don't think this always happens to all referrals, so I would amend to 'sometimes carried out….' I don't think the 'assessment of patient risk and safeguarding' wording seems correct – risk is assessed 1:1 between clinician and patient. Suggest reviewing this wording with a clinical expert. It wouldn't usually be possible to assess risk pre-assessment	No changes have been made to the EAR. Please see descriptions of the different approaches to pre-assessment practices that are reported at the end of Section 3.1.2 in the EAR.
3	Rachel Heggart NHSE	19	3.1.3	I think it would be better to use the national targets around waiting times for assessment and treatment.	The EAG is unaware of any national targets for waiting time for assessment. From NHS manual (Section 6.4): "… of the referrals that have a course of treatment (two or more clinical sessions), 75% should have their first session within six weeks, and 95% within 18 weeks."

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
4	Rachel Heggart NHSE	52	6.2.2	I think the description of reduction in waiting times from referral to assessment and assessment to treatment gives the impression that somehow people could skip the queue if they used a digital front door, which would not be acceptable. I can see that generally improved efficiencies in the use of clinical team could overall lead to a reduced waiting time for all, but I think wording around this is important.	The EAG has deleted a sentence from the EAR (Section 3.1.3), that stated: "Ideally, clinical assessments are scheduled to take place within 10 days of receipt of the referral".
5	Rachel Heggart NHSE	60-67	8.3.6	The economic evaluation doesn't consider the potential economic benefit of improving the accuracy of the assessment and therefore getting the right treatment first time and reducing wastage associated with delivering inappropriate treatments first/symptoms worsening while they get the wrong treatment first.	The accuracy of assessment using outcomes that are measured following the initial clinical assessment are beyond the NICE scope. See EAG response to Comment 6. No changes have been made to the EAR.
6	Limbic	9	Section not delineated on this page	Under the section "Quality and relevance of clinical evidence" the second sentence of the first paragraph states "Only two (Limbic Access) peer-reviewed studies provided relevant data…" This is incorrect. Limbic has published three studies with relevant data for the scope of this EVA programme: 1. Rollwage M, Habicht J, Juchems K, Carrington B, Hauser TU, Harper R. Conversational AI facilitates mental health assessments and is associated with improved recovery rates. BMJ Innov. 2024; 10:4. 2. Rollwage M, Habicht J, Juechems K, Carrington B, Stylianou M, Hauser TU, Harper R. Using Conversational AI to Facilitate Mental Health Assessments and Improve Clinical Efficiency Within Psychotherapy Services:	It is stated in the NICE scope that: "The time horizon for estimating the efficacy and value for money should be until the end of the NHS Talking Therapies assessment only". Therefore, the exclusion of Rollwage 2024 from the systematic literature review was justified. No changes have been made to the EAR.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				Real-World Observational Study. JMIR AI. 2023; 2:e44358. 3. Habicht J, Viswanathan S, Carrington B, Hauser TU, Harper R, Rollwage M. Closing the accessibility gap to mental health treatment with a personalized self-referral chatbot. Nat Med. 2024 Feb;30(2):595-602. doi: 10.1038/s41591-023-02766-x. Epub 2024 Feb 5. PMID: 38317020. The report suggests that Rollwage (2024, BMJ) is not relevant to the considered outcomes. This is factually incorrect as this manuscript includes data and results relevant to judgments about the quality of assessment and cost efficiency. The reasons provided for excluding this paper (the only peer-reviewed study submitted to this evaluation that attempts to evaluate clinical assessment quality and economic impact) are completely inconsistent with the rest of the report, namely: ● The official scope of this programme does not categorically specify outcome measures to be evaluated but yet the paper is excluded for not addressing the outcome measures of the scope ● The report talks to the fact there is no agreed definition of clinical assessment quality then disqualifies this study baselessly despite the fact it addresses scientifically relevant measures of potential clinical assessment quality - namely changes in treatment allocation and the downstream impact on recovery metrics This point is further addressed in the table below.	

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
7	Limbic	9	Section not delineated on this page	Under the section "Quality and relevance of the economic evidence" the first sentence of the second paragraph states "*Some clinical evidence suggests that Limbic Access and the Wysa DRA could potentially save time during initial assessments. "* No clinical evidence exists for time saving during initial assessment for the Wysa DRA solution. The manufacturer only provided internally reported information that cannot be verified. This statement is therefore misleading and completely conflates peer-reviewed evidence and a manufacturer's "word"	The EAG has added the following sentence (EAR, p9) to the text, "…data to support Limbic's claims are derived from a peer-reviewed comparative study".
8	Limbic	10	Section not delineated on this page	In the section "Results of the gap analysis", sentence two in paragraph two states *"Each digital front door technology can be customised; it was not clear whether, or how, any of the assessed digital front door technologies that were described in the evidence base were customised".* Limbic would be happy to provide information on how the product is customised if requested by the evaluation committee given that this point is used to negatively assess the strength of evidence provided later on in the report (see "Intervention Gaps" on page 74)	No changes have been made to the EAR.
9	Limbic	10	Section not delineated on this page	In the section "Results of the gap analysis" sentences three and four in paragraph two state *"In addition, the EAG highlights that the two peer-reviewed Limbic Access studies relate to the Class I version of Limbic Access; this version has now been superseded by the Class IIa version. It is important that data are continuously collected to assess whether later versions of a technology deliver the same or better benefits to NHS staff and patients."*	The EAG has amended the text in the summary to: "Interim analysis results from an ongoing RCT, an ongoing observational study, ongoing service evaluations and data externally audited by the Medicines and Healthcare products Regulatory Agency suggest that outcomes are at least comparable between the two versions; the EAG

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				Whilst this statement correctly identifies that ongoing work should be done to collect evidence on the Class IIa product (as noted in further sections on ongoing studies) it fails to highlight the fact that Limbic's **UK approved body have deemed the two products** (Class I and IIa) **technically and clinically equivalent under UK MDR 2002 (as amended)**. This is factually important because under medical device law it acknowledges that the benefits seen in the Class I are applicable to the Class IIa product.	consider it is important that data are continuously collected to assess whether later versions of a technology deliver the same or better benefits to NHS staff and patients". The EAG has amended the text in Section 10.1 to match that in the executive summary.
10	Limbic	14	Table 2	Wysa DRA, Censeo Digital and AskFirst under the "intended use" and "description" rows claim the ability to triage, with Wysa DRA and Censeo claiming features that recommend to secondary care. A recent Field Safety Notice has shown that MHRA have ruled that Censeo is unlawfully being marketed as a Class I product given its claimed feature set and lack of evidence base (see "Psyomics FSN - 22 Jan 2025" attachment in this submission"). This is in keeping with Limbic's experience of being required to upregulate our product in order to provide triaging information to support clinician assessment, which as per UK MDR classification rules, and confirmed by our UK Approved Body and this MHRA ruling, requires devices to be Class II+. This suggests that other devices with intended use of triage functionality need to be Class II+ raising potential concerns that these other devices might break medical device regulations with their current certification class. No information is provided in this table - or anywhere else in this report - to specifically highlight whether or not these products are appropriately classified under	The EAG has added the following sentence (EAR, p13) "As a Class IIa device, Limbic Access is the only product that has been externally auditedby the Medicines and Healthcare products Regulatory Agency (MHRA)".

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				the UK medical device regulation. It is in the interest of NHS services that this report in no uncertain terms highlights that only legally regulated devices with appropriate classification for their intended use should be used to protect the safety of patients. We believe this report should include a dedicated section on medical device classification and the appropriateness of the classification of each product based on their reported intended use. In addition, it should be made clear that Limbic Access and its evidence base is the only product that is externally audited by an independent third party regulator.	
11	Limbic	24	Table 4	Row “Electronic database searches” notes two ongoing studies for Wysa DRA, references 27 and 30. It is unclear why these studies have been included in this report. A review of these studies shows that whilst “triage and assessment” is mentioned, these studies also focus on the use of an app for waitlist treatment support. As per the consultation discussions on setting the scope for this EVA programme (including the consultation on 11th November 2024) it was confirmed by all parties that the evaluation of treatment and waitlist support would be removed from the scope of this EVA. As such, it is unclear why these studies are included in the evaluation given that in section 4.3.1 shows that studies have been excluded from this report for “wrong technology”	Reference 30 (ISCRTN10327977) appears to include an evaluation of the Wysa DRA. The EAG has excluded reference 27 (NCT05533190 / ISRCTN14644939) and has edited the EAR text as appropriate. Note: These references are now numbered 17 (ISCRTN10327977) and 30 (NCT05533190 / ISRCTN14644939)
12	Limbic	34	5.1.1	As per comment 004 above section 5.1.1 fails to adequately address that the evaluation of the benefits of the Class I product extend to the Class IIa product due to the external evaluation of the two products by a UK Approved Body under the UK MDR 2002 (as amended).	The EAG has deleted the point made by the company from the weaknesses column (EAR, Table 6). The EAG has added the following text to the EAR (p36): “Whilst this is not a

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				This is crucial information to enable the accurate representation and interpretation of the evidence base for the product.	weakness of the studies, it limits the relevance of study data to this EVA." The EAG has included studies externally audited by the MHRA as a strength for these studies in EAR Table 6.
13	Limbic	37	5.1.4	As in the above comment 005 the section "Limb Access" again fails to acknowledge the legal applicability of the Class I peer-reviewed evidence to the Class IIa product.	See EAG response to Comment 10.
14	Limbic	38	Table 6	In the row *"Habicht 2024[20]"* please provide justification as to why the sentence *"(which is shorter than the length of this text in these parentheses)"* is included in the weaknesses column. The column already states the average length of characters as a supposed weakness. The inclusion of this statement is quite clearly superfluous and clearly designed to add emphasis and sentiment. It is alarming to see the inclusion of such comments given that this report is supposed to strictly use impartial language. Limbic note that no such statements are included for the Wysa DRA product.	This text was included in earlier drafts for the benefit of the EAG team for illustrative purposes only. The text in parentheses has been deleted from the EAR (EAR, Table 6).
15	Limbic	40	Table 6	The penultimate row *"Limbic Research 2024"* (reference 21) notes a weakness as *"narrow focus - ADSM only"*. This weakness lacks contextual grounding. Specifically, the study referenced was a narrow study designed to answer one specific research question: is the AI model accurate. The study achieves this aim. We therefore dispute that this is a weakness of the study. In fact, it is the only study of any product	The EAG has deleted this text from the EAR (EAR, Table 6).

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				reviewed that aims to address the accuracy of the machine learning used in the product. For example, there is no study evaluating the accuracy of the NLP model(s) used to identify risk patients in Wysa DRA as described in "risk flagging" section of Table 2	
16	Limbic	40	Table 6	In the last row (*"Wysa studies"*) please provide clarification as to why weaknesses described for the Limbic studies are not explored for the Wysa studies (references 6, 17 and 18), namely: ● Whether comparative data with referrals from other sources was provided ● Whether these studies were able to control for all likely possible confounders in quantitative analysis ● Why the use of a three point scale for feedback collection (detailed in section 5.2.2 PRO4 on page 49) is not listed as a weakness given the feedback for Limbic's patient satisfaction study is *"Response to one question with three response options: positive, neutral, negative"*	The EAG considers that the text in the first bullet point has already been included by the text in the following bullet point: • Limited comparison with referrals from other sources The following bullet points have been added to the EAR (EAR, Table 6): • No control for any possible confounders • Response to one question with three response options or five response options
17	Limbic	41	5.2.1 AA1	Evidence is missing that supports the accuracy and acceptability of data collected by Limbic Access: ● Rollwage (2023, JMIR AI) shows that the clinical information collected in Limbic Access is associated with improved recovery rates and reduced assessment times (***P*-values<0.001, N=21,546**). This strongly suggests that the data collected through Limbic Access was of high quality and accuracy, to both support clinical efficacies and efficiencies. ● Similarly, in the Limbic Summative Test Report it was shown that the data provided by Limbic Access is accurate as it improves the quality of diagnostic decision making.	The EAG disagrees that relevant evidence is missing. Regarding each of Limbic's bullet points: • Improved recovery rate is an outcome outside the NICE scope for this EVA and reduced clinical assessment time is addressed by outcome RSI4. • The Limbic Summative Test Report result was included as a source of evidence for outcome AA2. • Information provided by Limbic that multiple different studies

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				● Finally, multiple different studies showcased the accuracy of the ML prediction model for selecting the correct clinical information including tens of thousands of patients in these studies. These studies have been reviewed and certified by a certified body as part of Limbic medical device class IIa certification. Since the NICE EAG did not provide a consensus of how to measure quality and accuracy of data, we would urge them to consider the evidence we provided as we believe it is strong evidence for the quality and accuracy of our data. **Revised Rating Recommendation: GREEN** instead of **RED**, based on the robust real-world and peer-reviewed evidence supporting improved assessment accuracy. Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	showcased the accuracy of the ML prediction model is included in EAR, Appendix 5, Table 26 (outcome AA1). These results are outside the NICE scope and have been presented for information only. For clarity, the EAG has added the sentence (EAR, p40): "The EAG has reported ADSM accuracy data for information only; the EAG considers that these results are outside the NICE scope (NICE scope, p3 and p4)." Diagnoses/problem descriptors are currently outside of the NICE scope; however, a future evaluation may adopt a broader framework. No other changes have been made to the EAR.
18	Limbic	41	5.2.1 AA2	Evidence is missing that supports Limbic Access' role in improving the accuracy of clinical assessments: ● A large-scale real-world study demonstrates a strong and highly **significant reduction in treatment changes after clinical assessment** (i.e. step-ups and step-downs) associated with the use of Limbic Access (***P*<0.001, N=64,862**). This indicates that Limbic Access supports more accurate	The EAG disagrees that relevant evidence is missing. These outcomes are outside the NICE scope – see EAG response to Comment 6. For clarity, the EAG has added the sentence (EAR, p41): "The EAG has reported ADSM accuracy and treatment step-ups/down data provided by Limbic for information only; the EAG considers

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				assignment of patients to the correct treatment pathway during the clinical assessment, i.e. increases the accuracy in clinical assessments (Rollwage et al., JMIR AI, 2023). This study provides direct, clear and very strong evidence for Limbic Access improving the quality of clinical assessments. ● Two peer-reviewed studies (Rollwage et al., JMIR AI, 2023; BMJ Innov, 2024) provide **statistically significant improvements in recovery rates (*P-values*<.001)**, for assessments conducted with Limbic Access. This suggests that patients receiving an assessment with information provided by Limbic Access are more likely to recover after these assessments. This is likely to be driven by more accurate assessments leading to better treatment allocation and thus better recovery rates. Importantly, in Rollwage (2023) it was further shown that this is driven by the clinical evidence provided through the Limbic Access referral, providing support for this mechanistic interpretation. While recovery is an indirect measure of clinical assessment accuracy, it is ultimately the measure of interest and thus should be incorporated as relevant evidence for improved clinical accuracy. ● Several unpublished studies further support these claims, adding **nuanced insights** rather than serving as the primary evidence base. **Revised Rating Recommendation: GREEN** instead of **RED**, based on the robust real-world and peer-	that ADSM results are outside the NICE scope (NICE scope, p3 and p4). Treatment step-ups/down results are also outside the NICE scope as the timeframe for this EVA is to the end of the initial clinical assessment only (NICE scope, p9)." Diagnoses/problem descriptors are currently outside of the NICE scope; however, a future evaluation may adopt a broader framework. No other changes have been made to the EAR.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				reviewed evidence supporting improved assessment accuracy. Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	
19	Limbic	42	5.2.1 AA3	Evidence is missing that supports pre-assessment completion rates: ● Data shows lower drop-out rates from referral to assessment **with Limbic Access,** indicating higher completion rates (21.9% probability to dropout for Limbic Access compared to 26.7% in the standard referral pathway, ($t_{33,269}$=9.03; P<.001). ● Supported by Rollwage et al. (JMIR AI, 2023). **Revised Rating Recommendation: GREEN** instead of **AMBER**, reflecting strong completion rate data and direct impact on assessment adherence.	The EAG disagrees that relevant evidence is missing. It is stated in the cited publication that: "We determined whether the use of the AI self-referral tool would reduce the likelihood of patients dropping out of the service at **any point during the care pathway**. Dropouts were defined as those patients who cancelled an appointment and did not rebook a new appointment. The dropout rate was measured as the percentage of patients who dropped out of the treatment." [emphasis added]

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	This outcome is outside the NICE scope – see EAG response to Comment 6. No changes have been made to the EAR.
20	Limbic	42	5.2.1 AA4	Evidence is missing that supports Limbic Access' role in improving accessibility: ● **Habicht 2024** demonstrates not only increased accessibility for minority groups but also a **general increase in accessibility** across all users (15% increase in accessibility in services using Limbic Access compared to 6% in matched services, $\chi 2(1) = 86.3$, $p<.001$). ● Additional user testing studies support more nuanced evaluations of the accessibility of the product for different sub-groups. **Revised Rating Recommendation: GREEN** instead of **AMBER**, given the strong methodological rigor and large-scale real-world data supporting accessibility improvements. Habicht 2024, was published by a high impact journal (Nature Medicine) and went through a rigorous peer-review process. For the analysis of accessibility the study design is optimal and importantly, the design is even mentioned as gold standard in section "*10.2 Key areas for evidence generation"* and thus it is surprising that such strong evidence is given an Amber rating. Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	The EAG has changed the outcome AA4 rating from AMBER to GREEN (EAR, Table 22).

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
21	Limbic	45	5.2.1 PRO1	Evidence is missing that supports Limbic Access' ease of use and usability: ● **In a large sample (N=42,332) in a peer-reviewed study, 89% of user feedback was positive, with the most frequently mentioned advantage of Limbic Access being its convenience** (Habicht et al, 2024), showing broad usability acceptance. **Revised Rating Recommendation: GREEN** instead of **AMBER**, based on consistently strong user satisfaction data. Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	The EAG considers that relevant evidence is not missing from the EAR. The EAG highlights that most of the available useability feedback is presented by Habicht 2024 and this relates to the Class I device. The burden of the additional data collected from service users required by the Class IIa device may affect service user reported outcomes. Therefore, the EAG has made no change to the rating. No changes have been made to the EAR. However, as there is evidence from both the Class I and Class IIa devices for PRO4, the EAG has amended the rating for this outcome to GREEN.
22	Limbic	46	5.2.1 PRO2	Evidence is missing that supports the clarity and relevance of information: ● Reports from **early user testing versions** should be excluded from this analysis (i.e. formative user testing) as these are by definition earlier versions of the product, whereby the aim of these user tests is to optimise the product based on these insights for real-world usage. ● Only **summative study data** reflecting the live product should be considered.	The EAG considers that relevant evidence is not missing from the EAR. See EAG response to Comment 21. No changes have been made to the EAR.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				Revised Rating Recommendation: GREEN instead of **AMBER**. Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	
23	Limbic	47	5.2.2 AA1	There are inconsistencies in the stated strength of evidence for the accuracy and acceptability of the Wysa DRA tool: ● Wysa's only stated benefit is that it assigns more users to shorter assessments, which does not equate to improved efficiency or accuracy as it is unclear whether these shorter assessments need to be redone if too short. ● **No comparative data, no statistics, and no peer-reviewed studies** support this claim. Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	The EAG has added the following sentence (EAR, p46): "All the evidence relating to Wysa DRA was real-world data reported in the Wysa NICE RFI response,[6] Additional Supporting Evidence[17] and the EAG RFI response.[18]"
24	Limbic	48	5.2.2 AA4	There are inconsistencies in the stated strength of evidence for the accessibility of the Wysa DRA tool: ● Wysa's data **fails to robustly support increased accessibility**, particularly with minimal comparative metrics. **Revised Rating Recommendation: RED** instead of **AMBER**.	As stated in response to Comment 20, the EAG has changed the outcome AA4 rating for Limbic Access from AMBER to GREEN (EAR, Table 22). The EAG has made no change to the outcome AA4 rating for the Wysa DRA.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	
25	Limbic	51	6.2.2	In the section "Time taken to review data collected by digital front door technologies" it states *"One SCM suggested that reviewing referral information took 3 minutes without Limbic Access and 5 minutes with Limbic Access."* Can the committee clarify why anecdotal information from the SCM interviews is able to be included in the report but several Limbic publications (eg. references 44, 45 and 46) in Table 25 have been excluded for being "anecdotal evidence"? We found it difficult to understand the criteria the committee is applying for inclusion or exclusion of data in the report.	The EAG made the decision to exclude these case studies since their purpose is to promote Limbic Access and therefore the data reported may be selectively reported. The Mind Matters case study was included because it was linked to the Surrey and Borders Partnership NHS Foundation Trust report. The EAG considers that the SCM views are impartial/important and should be included in the EAR. No changes have been made to the EAR.
26	Limbic	50 - 55	6	There are multiple references to Limbic Access throughout this section but not any of the other products under evaluation. It is unclear why this is the case. This section could benefit from specifying why other products under evaluation are not mentioned in name. The user remains unclear in the current format for this decision and the report would benefit from explicitly explaining this (e.g. Limbic Access being the most widely used product)	This is a reflection of the experiences of interviewed SCMs. Details of experts' experience of digital front door technologies is provided in Appendix 7, Table 41 (pp149-150). No changes have been made to the EAR.
27	Limbic	52	6.2.2	In section "Time taken to complete the NHS Talking Therapies initial clinical assessment" it states: *"All five respondents agreed that it took at least 45 minutes to complete the NHS Talking Therapies initial clinical assessment without the use of a digital front door technology. One respondent estimated that the*	Section 6.2.2 is a descriptive section that reports expert responses to the questionnaire. In Section 8 (economics) and Section 9 (interpretation of the evidence), the EAG has cited the time saving of 12.7 minutes. The EAG agrees that a time saving of 12.7 minutes is a

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				duration of the initial clinical assessment was 40 minutes for patients who referred via Limbic Access and 50 minutes for patients who referred via other methods" The inclusion of this anecdotal evidence implicitly provides a comparison to the stated assessment time savings reported in Limbic's peer reviewed large scale study. Contextual clarifiers should be included to uphold consistency in evaluating the veracity of claims being made, namely: 1. That the claim of 10 minute time savings is from one individual and represents anecdotal evidence. This is a data point that holds significantly less scientific veracity compared to the time savings documented in the large-scale peer reviewed publication (Rollwage et al 2023, JMIR AI) 2. This section should explicitly state that the claims made by Wysa DRA are from anecdotal evidence and could not be verified or confirmed through the SCM and stakeholder questionnaire process	more robust estimate than the time saving of 10 minutes mentioned by one questionnaire respondent. No changes have been made to the EAR.
28	Limbic	57	8.2	There is an economic evaluation of Limbic that is appropriate and has been published in a peer-reviewed journal (Rollwage et al 2024, BMJ). The analysis from this study is legitimate, within scope and therefore should be included in this section.	As stated in Table 25 of the EAR, this study was excluded for the following reason, "Wrong outcome – reports recovery rates and economic analysis based on this outcome (which are beyond the scope of this EVA)". See EAG response to Comment 6.
29	Limbic	62	8.3.6	In the section "Time taken to complete clinical assessment" it states:	The EAG has deleted the bullet point as suggested (EAR, p61).

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				"the reported time saving of 12.7 minutes does not account for differences in the severity of mental health problems between patients who accessed the service via a digital front door technology or by standard referral methods. Study authors reported that the time saving remained statistically significant after adjusting for severity; the adjusted value was not reported" This statement is written to influence sentiment and is factually incorrect. As correctly mentioned in the statement, the same results on time savings were found when controlling for severity in the analysis. If the NICE committee requested, we would have been happy to provide the adjusted value. The adjusted value when controlling for severity is a time saving of 12.65 minutes, i.e. a time saving which remains highly significant (P<.001) and equivalent in effect size as reported in Rollwage 2023. Therefore, we urge the NICE committee to delete this comment. In general we would like to mention a concern about the committee not clarifying these questions with Limbic and including such conclusions in the report as it could be perceived as conclusions are being drawn without evidence which could have been provided and does exist.	
30	Limbic	63	8.3.6	In the section "Time taken to complete clinical assessment" it is stated: *"Wysa stated (EAG RFI response18) that, in one area where the Wysa DRA was being used, 91% of initial clinical assessments for patients who had completed the full set of clinical questions were scheduled for 30 minute assessments instead of the standard 60 minute assessments; it is however possible that*	No changes have been made to the EAR.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				longer or additional clinical assessments took place for some of these patients." There should be contextual clarifications for these claims to highlight the quality and appropriateness of this supposed evidence, namely: 1. That the claim from Wysa is internally reported data, no peer-reviewed or externally audited data exists to back up this claim and the EAG committee could not verify the accuracy of these time saving claims 2. This analysis conflates two things: the specific *duration* of assessments (used to analyse Limbic) and the length of *scheduled appointment slots* (used to analyse Wysa DRA). This is not a like for like comparison. Furthermore the length of a scheduled appointment slot is not an accurate proxy for the actual observed assessment time (see below bullet point). This discrepancy should be stated. 3. The statement *"it is however possible that longer or additional clinical assessments took place for some of these patients."* should also state that Wysa DRA have been unable to verify the 91% triaging accuracy to "shortened assessments". Due to these limitations, it should be considered whether this statement holds any meaningful information for the duration of clinical assessments or should be removed completely as it is anecdotal and does not allow a conclusion about the outcome of interest.	

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
31	Limbic	9	Executive Summary	At multiple points throughout this report it states *"Two peer-reviewed studies for Limbic Access."* This is factually incorrect. There are three peer-reviewed studies supporting its clinical assessment benefits (Rollwage et al., 2023; Rollwage et al., 2024; Habicht et al., 2024) and we strongly believe Rollwage et al., 2024 should be included as it is relevant for the section "AA2: Accuracy of clinical assessment" (as noted above).	See EAG response to Comment 6.
		68	9.1		
		74	10.1		
		79	11.1		
32	Limbic	68	9	This summarised level of the interpretation of clinical data provided on the Wysa DRA product lacks any clarification regarding the quality of the data, which is alarming given that all claims to the product rely solely on internal reports. This section should explicitly state that Wysa DRA studies: 1. Are unpublished 2. Lack comparative data 3. Do not include any statistical evidence or analysis of significance 4. Cannot and have not been verified through the EVA programme Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	The EAG has amended the text as follows, "The evidence for Limbic Access was more robust than the evidence for the Wysa DRA" (EAR, p66).
33	Limbic	68	9.1	The first sentence of the second paragraph states *"In addition to a lack of robust evidence, the extent to which the available clinical evidence is generalisable to all NHS Talking Therapies providers is unclear"*	There were 9 NHS Talking Therapies services in Rollwage 2023 and 28 NHS Talking Therapies services in Habicht 2024, of which 14 used Limbic Access and 14 did not.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				This is incorrect for Limbic Access. Limbic studies include multiple NHS Talking Therapies providers across England, demonstrating broad applicability. The reported peer-reviewed studies alone include data from 55 NHS Talking Therapy services which is clearly stated in the manuscripts. Moreover, the ongoing study "Habicht J. NCT05678764: Evaluation of a Conversational Information Collection Tool to Access Talk Therapy." further extends this investigation to multiple additional NHS Trusts and replicates the findings reported in the peer-reviewed studies. While we agree that the generalisability is a clear limitation for the other solutions, it should be clearly stated that this is not applicable to Limbic.	It is evident 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. No changes have been made to the EAR.
34	Limbic	69	9.1	The final sentence in paragraph two states *"However, as some of the study periods overlapped with the start of the Covid-19 pandemic, it is not possible to draw firm conclusions about how digital front door technologies affected the number of referrals from any group."* This is factually incorrect. Peer reviewed studies on Limbic Access used a matched control group, isolating time effects.	This sentence has been deleted from the EAR.
35	Limbic	69 -70	9.1	This section compares the presented time savings for Limbic Access and Wysa DRA. There is no clarification that the reported time savings presented by Wysa DRA cannot be verified or relied upon. Merely stating that the 16 - 21 minute time savings are from the *"(NICE RFI response[6])"* is a complete misrepresentation of the gulf in scientific rigour with which these statistics have been collected and	The EAG has amended the text as follows, '(unpublished data; NICE RFI response)" (EAR, p68).

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				presented, and the gulf in reliability of the statistics themselves. Given the scope of this EVA programme calls out time savings at assessment as an outcome measure we expect NICE to provide more scientific rigour and clarification around this important point.	
36	Limbic	70	9.1	The first sentence in the final paragraph on this page states *"None of the available clinical evidence reviewed identified any harms to clinicians or patients"*. This section should be taken further to explain that these tools can reduce harms to clinicians and patients. This is empirically evidenced in Limbic's summative clinician study and Rollwage et al. (2023), which shows a reduced risk of misdiagnosis and improved treatment allocation with Limbic Access.	The point made in the EAR is factually accurate. No changes have been made to the EAR.
37	Limbic	71	9.2	The first sentence of the first paragraph states *"The economic evidence currently available to support the use of digital front door technologies to pre-assess people before NHS Talking Therapies clinical assessments is minimal."* This is incorrect and should state that there is data from a peer-reviewed study on the economic analysis and benefits of Limbic Access in a real-world setting (Rollwage, 2024, BMJ).	See EAG response to Comment 6.
38	Limbic	71	9.3	The first paragraph in this section explains that it has been confirmed that both technologies are used in the NHS TTad. However it fails to highlight the extent to which both tools are used, including the extent of procurement across NHS TTad and the number of referrals processed by each tool. This information was	This information has been added.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				requested as part of RFI responses. Why is it not included in this section?	
39	Limbic	74	10.1	As flagged at multiple times throughout this response, the section “Intervention Gaps” fails to appropriately acknowledge that the clinical benefits seen for the Class I are applicable to the Class IIa product, as independently reviewed and evaluated by a UK Approved Body.	See response to Comment 10.
40	Limbic	74	10.1	The section “Outcome Gaps” fails to acknowledge that there is peer-reviewed evidence demonstrating that Limbic Access positively impacts recovery outcomes and the quality of assessment as published in Rollwage et al 2023. As discussed below the scope of this evaluation does not specify the exclusion of such outcomes.	See EAG response to Comment 6.
41	Limbic	76 - 77	Table 22	The quality weighting for many of these comparisons are completely off given the size, scope, quality and publication profile of the studies in question. The following changes should be made for Limbic Access given the benchmarking for the RAG status of comparable Wysa DRA studies: **Should be GREEN:** ● AA1: Quality and accuracy of data (3 peer-reviewed studies, plus additional real-world study supporting improved recovery rates). ● AA2: Accuracy of Clinical Assessment (2 peer-reviewed studies, plus additional real-world study supporting improved recovery rates). ● AA3: Completion rate of referral (1 peer-reviewed study, ~65k referrals) ● AA4: Inaccessibility to Digital Front Door Technologies (5 studies, 240,844 patients,	In response to Limbic comments, the EAG has revised the rating for AA4 (from AMBER to GREEN) and PRO4 (from AMBER to GREEN).

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				including peer-reviewed large-scale real-world data). ● AA5: Healthcare Professional Acceptability (4 studies, 212 clinicians). ● RSI3: Time to Complete Clinical Assessment (3 supporting studies, including peer-reviewed studies). ● RSI4: Time Saved for Clinician (5 supporting studies, including peer-reviewed studies). ● PRO1: Ease of Access and Usability (4 supporting studies, including peer-reviewed studies). ● PRO2: Information Clarity and Relevance (3 supporting studies, including peer-reviewed studies). ● PRO3: Comfort and Privacy (4 supporting studies, including peer-reviewed studies). ● PRO4: Overall Satisfaction (5 supporting studies, including peer-reviewed studies). **Should be AMBER:** ● RSI2: Time Taken to Review Data (2 studies, providing relevant insights). As noted through this response and the covering letter, we are concerned that the report fails to appropriately delineate between quality and appropriateness of the studies and evidence provided by providers throughout this report. The world looks to NICE to be the arbiter of scientific rigour and excellence and we believe the way studies within this report are weighted fails to meet this high standard.	

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				Please refer to attached documents *"Appendix A: Response to Clinical Evidence Weighting"* and *"Appendix B: Response to Clinical Evidence Ratings"* for full details.	
42	Limbic	87-88	13.1.2 13.1.3	As mentioned in comment 005 the description of the Wysa DRA and Censeo products should include: ● That these are self-certification only devices that have not undergone independent audit by MHRA or UK Approved bodies ● That tools that support clinical assessments (clinical decision support) and provide triaging support (eg. prioritisation) require classification as Class II medical devices ● For Censeo, it should explicitly mention that the product has been requested to be removed from the market by MHRA because of a breach of the UK medical device regulation	See EAG response to Comment 10. The EAG has also added the following text to Appendix 1, Section 13.1.3: "It should be noted that in January 2025, following discussions with the MHRA, the MHRA determined that Censeo Digital was incorrectly registered as a Class I medical device and the current Clinical Evaluation Report (CER) does not demonstrate adequate evidence of safety and effectiveness as required by UK medical device regulation 2002 (as amended)."
43	Limbic	101	Table 25	Row 4 Table 25 on page 101 "Rollwage 2024[39]" indicates that the peer-reviewed, large-scale real-world evidence study published in the British Medical Journal (reference 39) has been excluded from consideration because it *"reports recovery rates and economic analysis based on this outcome (which are beyond the scope of this EVA)"*. We strongly argue that this decision should be re-evaluated for the following reasons: 1. It reinforces a worrying precedent for this report that internally reported evidence is given similar weighting to peer-reviewed publications. In this particular case the dichotomy of excluding a large-scale peer reviewed study for one product, whilst reviewing other products based entirely on	Regarding the first bullet point, the EAG has not given internally reported evidence similar weighting to peer-reviewed publications (as evident by constant reference in the EAG report to where peer reviewed evidence is available). Regarding the second and third bullet points, see EAG response to Comment 6.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				internally provided evidence only is in complete contradiction to NICE's principles of upholding the highest standards of evidence generation 2. The scope of this EVA aims to explicitly address whether these products provide "value for money for the NHS" whilst simultaneously leaving out the only robust economic analysis of the products evaluated 3. Whilst recovery rates are not explicitly mentioned, the scope does not categorically define the outcomes that will be included for review. Specifically the published scoping document uses the language "The outcome measures for consideration **may** include" and thus does not exclude the review of recovery data. The BMJ study evaluates recovery rates that are a direct measure of assessment quality, which is an explicit outcome of the scope of this EVA programme. It is difficult to reason how large-scale, real-world evidence generated on the quality of assessments that directly address the impact for patients could be excluded from this programme. Please refer to the attached document *"Appendix A: Response to Clinical Evidence Weighting"* for full details.	
44	Limbic	101	Table 25	Rows 7 (reference 46), 8 (reference 44) and 9 (reference 45) are excluded on the basis of being *"anecdotal evidence"*.	See EAG response to Comment 25.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				Please provide clarification on how “anecdotal evidence” is distinguished from information provided in the RFI and EAG responses.	
45	Wysa	14	Table 2	Table states that data is simultaneously transferred to EHRs and to local TT services - but these are one in the same. The data transfer is from the Wysa referral conversation to the Talking Therapies EHR system, via PRISM APIs. Table states that Wysa recommends secondary care for complex cases - this is incorrect. Wysa will flag cases as complex based on criteria set by the service, but each case is reviewed by a clinician and it is the clinician's decision whether or not to refer a case into a secondary care or specialist service.	The EAG has amended the text as suggested (EAR, Table 2).
46	Wysa	49 and 70	RSI1	Can the below be qualified? ie time saved during initial clinical assessment is not **always/necessarily** a fair measure of the effectiveness or efficiency of a digital front door technology (because some services will want this as an outcome, but others will be looking for alternative outcomes such as quality of information provided) **RSI1: Administrative resource impact** *Wysa reported[17] that there are limited available Wysa DRA resource use and impact outcome data. Wysa stated that time saved during the initial clinical assessment was not a valid or fair measure of the effectiveness or efficiency of a digital front door technology.*	The EAG has amended the text as suggested (EAR p48 and EAR p68).
47	Wysa	60	Table 12	The Wysa costs now that we are on gcloud are slightly lower than the stated costs provided on earlier RFI responses. New costs are as follows:	Costs and associated calculations have been updated (EAR, Section 8).

<table>
<tr><th>Comment no.</th><th>Stakeholder</th><th>Page no.</th><th>Section no.</th><th>Comment</th><th>EAG Response</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><th>Capitated referral numbers processed</th><th></th><th>Price/referral</th></tr>
<tr><td>1</td><td>5000</td><td>£3.25</td></tr>
<tr><td>5001</td><td>10000</td><td>£2.92</td></tr>
<tr><td>10001</td><td>15000</td><td>£2.53</td></tr>
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<tr><td>20001</td><td>30000</td><td>£1.60</td></tr>
<tr><td>30001</td><td>Upwards</td><td>£1.16</td></tr>
</table>

There is no change to the implementation fee and we are aware that you have already completed calculations based on our earlier pricing schedule that may not be able to be changed, so this is more for information and transparency.</td><td></td></tr>
<tr><td>48</td><td>Wysa</td><td>76</td><td>Table 22</td><td>Healthcare acceptability: Wysa is marked as red yet we provided this data - see evidence on table on page 32 (EVA outcome AA5).

Please could you provide us with what outcomes/evidence fall into 'comfort and privacy' (PRO3) and 'information clarity and relevance' (PRO2)? Apologies if these were missed, but Wysa has a very strong privacy record so unsure why we are marked as red?</td><td>The study included only 5 clinicians and was marked red for the following reason: RED=no studies/sources of evidence or outcome data/definitions may not be useful, e.g., data from very small sample or outcome definition is outside of NICE scope

Outcomes/evidence for PRO2 and PRO3 could be derived from questions asked of users of the digital front door, e.g., specific question(s) within the technology itself or evidence from research/evaluations specifically asking</td></tr>
</table>

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
					users about these outcomes (e.g., qualitative research or surveys).
49	David Clark NHSE	Page 11	Table 1	The main purpose a digital front door is the improve the accuracy of the NHS TT initial assessment so the correct problem descriptor is identified, and patients get to the right NICE recommended treatment for their clinical condition first time. It is surprising to see the comment that "there is no universally accepted definitions of ….the accuracy of data collected by digital front door technologies". In NHS TT the problem descriptors are aligned to ICD-10 diagnostic codes and there are universally accepted definitions of the accuracy of a diagnosis. It does seem that none of the digital front doors have assessed whether they improve (or worsen) diagnostic accuracy, which is a major problem. However, it is wrong to imply that there are no agreed methodologies for doing so.	This statement in the EAR relates to the quality and accuracy of the data collected by digital front door technologies, not the accuracy of the clinical assessment. Table amended to clarify this by inclusion of "(AA1)".
50	David Clark NHSE	Page 14	Table 2	There are problems with some of the listed features for Limbic Access or Wysa that need to be considered by the NICE EAG. WYSA DRA is said to flag cases as "too complex" for NHS TT. As there is no NHS E approved definition of "too complex for NHS TT" this is a step too far. Limbic and Wysa both claim to do risk assessment and flag risk to services. The EAG needs to consider whether this is appropriate given the recent NICE guidance on risk assessment which discourages the use of risk assessments simply based on the information available to Limbic/ Wysa. Is there a danger that the flagging of risk by the digital front doors will lull NHS TT assessors into a false sense of security so they will not conduct a full risk assessment in people flagged as "low risk"? Sadly, we know that many people who kill themselves fall into that category (see recent NICE guideline).	Text in EAR, Table 2 has been edited. Please see EAG response to Comment 45.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				Finally, it is incorrectly asserted that the Limbic function of "suggesting possible problem descriptors based in information collected via in ADSMs" is "beyond the scope of the EVA". As the main function of a digital front door is to ensure NHS TT assessors are more accurate in identifying of problem descriptors, that Limbic function could be a help. We'd expect the NHS TT assessors to come to their own judgement after their assessment interview but the flagging of candidate problem descriptors by Limbic might help that decision process (to be tested).	Diagnoses/problem descriptors are currently outside of the NICE scope; however, a future evaluation may adopt a broader framework.
51	David Clark NHSE	Page 19	3.1.3	This section, and the preceding section (3.1.2), are based on discussions with a very small number of individuals and are not fully accurate. The statement that "Ideally, clinical assessments are scheduled to take place within 10 days of receipt of referral" seems to be a personal view. The average time between referral and initial assessment is 20 days. Similarly, it is quite right to say that initial clinical assessments are "usually" conducted via telephone. That is true in some services, but other services have a substantial proportion of in-person assessments, depending on the referral information. I suggest you change "usually" to "often".	The sentence, "Ideally, clinical assessments are scheduled to take place within 10 days of receipt of referral" has been deleted from the EAR (EAR, p19). The EAR text has been amended from 'usually' to 'often' (EAR, p19)
52	David Clark NHSE	Pages 41 & 42	AA2	None of the four studies cited in this section answer the question of whether Limbic improves, does not change, or worsens the accuracy of the problem descriptors (diagnoses) identified in the NHS TT clinical assessment (step 4 in the pathway). This is because none involve a gold standard for diagnosis (for example structured interviews using the MINI) so it is impossible to know whether the clinical assessment is more or less accurate when informed by Limbic. The findings that Limbic highlight do not answer the "exam question".	The EAG agrees that this question has not been answered because diagnoses/problem descriptors are currently outside of the NICE scope; however, a future evaluation may adopt a broader framework. See response to Comment 17

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
53	David Clark NHSE	Page 61		It is commented that "Evidence from one questionnaire respondent was that introduction of digital technologies in their area had resulted in approximately 20% of referrals being automatically triaged and signposted away from NHS Talking Therapies…". N of one is not impressive. It is also not clear that the automatic triage was a good thing. National guidance is that all referrals should be clinically reviewed. No evidence is presented to show it was appropriate for the digital front door to automatically signpost 20% of referrals elsewhere or whether the chosen "elsewhere" was correct. There is also no information from patients about whether they were happy to be automatically rejected by NHS TT services without a clinician being involved.	The EAG considers that the SCM experience is valid and should be included in the EAR. The EAR includes the existing bullet point (EAR, p71), "Consensus around the appropriate eligibility screening/triage criteria so that digital front door technologies do not exclude patients who may benefit from NHS Talking Therapies". No changes have been made to the EAR.
54	David Clark NHSE	Page 64		The Rollwage (2023) study and the EAR analyses seem to assume that NHSTT patients only have a single assessment session. While that is often true, for a significant subgroup of patients assessment extends into a second session after further questions are raised by the initial assessor's supervisor. Not taking this into account means that estimates of the % of time saved by a digital front door may be overoptimistic.	The EAG agrees with the comment; however, EAG economic analyses are exploratory and are based on assumptions. No changes have been made to the EAR.
55	David Clark NHSE	Page 64 & 65		It is not clear to me whether the estimates of saved time include admin after the clinical interview. Assessors need to ensure that all the relevant information collected in the assessment interview, including that collected by the digital front door, is entered into IAPTus or PC-MIS. Has that been considered? My understanding, which may be out of date, is that integration with IAPTus / PC-MIS is not seamless, so some time-consuming manual transfer of information from Limbic /WYSA may be required. This should be checked.	The EAG agrees with the comment. The following revised text is included in the report, "The EAG highlights that the impact of Limbic Access on time taken to complete any other pre- or post-assessment tasks (e.g., time taken to conduct a risk and suitability assessment or administrative time) is not known" (EAR, p61).

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
56	David Clark NHSE	Page 74	10.1	The section on “Evidence gaps identified by the EAG” omits the most important evidence gap, at least as far as NHS England is concerned. We have encouraged the use of digital front doors because we know that initial assessments in NHS TT can be wrong. Patients’ main mental health problem (termed “problem descriptor”) is sometimes missed and, consequently, they start with the wrong treatment. At best this means patients must wait until the “wrong treatment” fails before they are switched to the right treatment. At worst, patients become dissatisfied and drop out before getting the correct treatment. No evidence is presented to indicate whether the digital front doors improve, don’t change, or worsen problem descriptor identification. This needs to be highlighted as a major evidence gap. Widescale adoption of digital front doors is difficult to support without evidence that they improve the accuracy of the initial clinical assessment. Worryingly, the absence of an evaluation of accuracy means it has not been possible to rule out the proposition that the way the products collect, and present pre-assessment information may mislead assessors and mean that their clinical assessment ends up being less accurate. At the least NHS England would like to see NICE produce an evidence-generation plan that makes it clear that, going forwards, providers of digital front doors should be collecting and reporting evidence on diagnostic accuracy	This has been added as an outcome gap in the EAR (p74).
57	David Clark NHSE	Page 78	10.2	Table 23 includes possible study designs for collecting further evidence. Under Research Question 2 (“How should the accuracy and quality of a clinical assessment be measured”) it is suggested that a “Dephi method or other consensus methods” should be used. What does this mean? Better guidance	Thank you for this suggestion. The EAG has amended Table 23 by including a suggested study design to address how the accuracy of clinical assessment for NHS Talking Therapies (AA2) could be measured.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
				needs to be provided. As mentioned above, there are well established good standard methods (such as internationally accepted semi-structured interviews delivered by trained interviewers) for establishing ICD-10 diagnoses / problem descriptors. The most obvious research design would involve diagnoses established this way being compared with diagnoses / problem descriptors identified in a standard NHSTT clinical assessment that is, or is not, preceded by data collection with a digital front door.	
58	David Clark NHSE	Page 78	10.2	Table 23 Research Questions 3-5. It is not clear to me that cluster (by service) randomization is preferable to patient level (within service) randomization to answer questions 3 to 5. Elsewhere in the EAR it is correctly stated that processing practices vary a great deal between services. This point means that many services will be needed for an adequate cluster randomized design. By contrast, within service randomization (which is perfectly possible) is not complicated by processing variance, though several services would be desirable to establish generalizability. If the EAG is convinced cluster randomization is the best method, it should explain its thinking because there will be researchers who take a different view.	EAR, Table 23, Research Questions 3 to 5, text has been amended to, “RCT (by service provider or within service)…” (EAR, p78; information now in the footnote to Table 23).

Overview

Explanation

This page outlines the Early Value Assessment Team's comprehensive evaluation of whether a technology could be suitable for Early Value Assessment and if data collection is feasible. The assessment does not provide any guidance on whether a medicine technology is a cost-effective, or plausibly cost-effective, use of NHS resources . This document should be read in conjunction with other critical documents, particularly the company's evidence submission and External Assessment Group (EAG) report. Additional details for each consideration are available within the separate tabs.
While a rationale is provided, in general, the ratings for each area are:
- **Green** - No key issues identified
- **Amber** - Either outstanding issues that the Early Value Assessment team is working to resolve, and/or subjective judgments are required from the committee/stakeholders (see key questions)
- **Red** - The Early Value Assessment team does not consider this topic suitable for an early value recommendation.

Topic name:
Topic ID: HTE10055 Talking therapies
Technology name[s]: AskFirst (Sensely), Censeo Digital (Psyomics), Limbic Access (Limbic), WYSA DRA (Wysa)
Early Value Assessment Lead: Guidance team: Ziqi Zhou, Amy Crossley EvGen Team: Vera Unwin, Thomas Lawrence
Date of assessment(s): 05/02/2025

Is Early Value Assessment appropriate - Overall rating	Comments / Rationale
Data collection could potentially resolve evidence gaps depending on committee decision	

Area	Rating (Responses for rating: Yes, No, Unclear, Not applicable)	Comments / Rationale
Are any technologies in the topic currently being used in the NHS?	Yes	Limbic is "used by 40% of NHS talking therapies". WYSA is in Dorset, Coventry and Lancashire and S.Cumbria. Censeo is in 4 trusts, but not specifically being used for Talking therapies services.
Is it feasible to collect data that could sufficiently resolve the key evidence gaps outlined in the EAG report?	Yes	Evidence gaps are very short-term outcomes that would be quick to collect within the EVA timeframe
Can data collection be completed without undue resource burden on patients or the NHS?	No	Healthprofessionals and service users will need to dedicate time towards data collection
Are there any other substantive issues that are barriers to EVA?	No	Only a relatively small number of outcomes are needed for data collection, follow-up is immediate and the time horizon is short. No potential safety issues as the technology accompanies current care.

Key questions for committee if Early Value Assessment is considered	
1. Which evidence gaps does the committee consider to be essential?	
2. What follow-up period is most appropriate to collect data for these outcomes?	

NICE National Institute for Health and Care Excellence

Diagnostics Advisory Committee Interests Register

Topic: Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies: early value assessment

NICE's declaration of interest policy can be accessed here

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Brian Shine	Standing committee member	None	-	-	-	-	-
Alex Novak	Standing committee member	None	-	-	-	-	-
Anne Scott	Standing committee member	None	-	-	-	-	-
Diane Davies	Standing committee member	None	-	-	-	-	-
Farai Goromonzi	Standing committee member	Financial	Previously an employee at Medtronic	-	April 2024	July 2023	*Declare and Participate*
Ghada Ahmed	Standing committee member	None	-	-	-	-	-
John Cairns	Standing committee member	Financial	Participation in meeting advising on economic modelling of treatments for Dravey Syndrome and Lennox Gastaut Syndrome funded by Maple Health Group	February 2024	May 2024	March 2024	*Declare and Participate*
John Cairns	Standing committee member	Financial	Advice to Pierre Fabre advising on economic modelling of a treatment for non-small-cell lung cancer.	May 2024	September 2024	June 2024	*Declare and Participate*

John Cairns	Standing committee member	Financial	Advice to Johnson & Johnson on economic modelling of a treatment for urothelial carcinoma.	June 2024	September 2024	June 2024	*Declare and Participate*
John Cairns	Standing committee member	Financial	Advice to Johnson & Johnson on economic modelling of a treatment for non-small-cell lung cancer.	July 2024	September 2024	August 2024	*Declare and Participate*
Jonathan Weir-McCall	Standing committee member	None	-	-	-	-	-
Joy Allen	Standing committee member	Financial	Employee of Roche Diagnostics	31 August 2021	May 2024	Ongoing	*Declare and Participate*
Keith Abrams	Standing committee member	Financial	Director of a company providing HTA consultancy services to pharmaceutical companies. The company has not provided any services related to any companies or the technologies being assessed.		February 2024	Ongoing	*Declare and Participate*
Matt Stevenson	Standing committee member	None	-	-	-	-	-
Michael Morton	Standing committee member	None	-	-	-	-	-
Neil Hawkins	Standing committee member	Financial	I am a director of a company providing consultant services related to HTA to pharmaceutical companies. No services have been provided to any companies named as stakeholders or in relation to the technologies being assessed.		February 2024	Ongoing	*Declare and Participate*
Patrick McGinley	Standing committee member	Non-financial professional and personal interest	I provide advice on NHS Finance to MTECHAccess	January 2019	March 2024	Ongoing	*Declare and Participate*

Patrick McGinley	Standing committee member	Financial	I am Hon treasurer to Association for Study of Obesity	October 2020	November 2023	Ongoing	*Declare and Participate*
Patrick McGinley	Standing committee member	Non-financial professional and personal interest	Member of the strategic Committee of APPG on Obesity	November 2019	March 2024	Ongoing	*Declare and Participate*
Rashmi Kumar	Standing committee member	None	-	-	-	-	-
Rebecca Allcock	Standing committee member	None	-	-	-	-	-
Sam Creavin	Standing committee member	None	-	-	-	-	-

NICE National Institute for Health and Care Excellence

Diagnostics Advisory Committee Interests Register

Topic: Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies: early value assessment

NICE's declaration of interest policy can be accessed here

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Elizabeth Kingdom	Specialist Committee Member	Non-financial professional and personal interests	The Trust I work for has contracts with both Wysa and Limbic		January 2024	Ongoing	*Declare and Participate*
Emran Hussain	Specialist Committee Member	None	-	-	-	-	-
Jagdeep Ghundoo	Specialist Committee Member	None	-	-	-	-	-
Jane Lam	Specialist Committee Member	Financial	Member of staff with West Sussex Talking Therapies, Sussex Community NHS Foundation Trust.	2014	September 2024	Ongoing	*Declare and Participate*
Joycee Rebelo	Specialist Committee Member	Non-financial professional and personal interests	Volunteering, supporting the mental health of young people at No5, a charity in Reading	September 2024	September 2024	Ongoing	*Declare and Participate*
Joycee Rebelo	Specialist Committee Member	Indirect	British Association of Dental Nurses Education Committee Member	2021	September 2024	Ongoing	*Declare and Participate*
Joycee Rebelo	Specialist Committee Member	Indirect	Orthodontic National Group Lay Committee Member	2023	September 2024	Ongoing	*Declare and Participate*
Katy James	Specialist Committee Member	Indirect	In my employed role I work at Vita Health Group that delivers a number of NHS Talking Therapies services.		September 2024	Ongoing	*Declare and Participate*

			These services use either Wysa or Limbic digital triage products, though their contract with Wysa is coming to an end next year. In my role I am not a decision maker in terms of the specific product that is chosen/purchased for digital triage use, however I am consulted in relation to the clinical viability/risks of any product that is being considered.				
Rosie Hill	Specialist Committee Member	None	-	-	-	-	-
Samantha Russell	Specialist Committee Member	Financial	Patient and public contributor for NIHR, local service user groups and research projects, representing patient and carer experiences and views and providing feedback on research proposals. Honoraria and expenses are often included	2020	September 2024	Ongoing	*Declare and Participate*
Samantha Russell	Specialist Committee Member	Financial	Self-employed physiotherapist	2020	September 2024	Ongoing	*Declare and Participate*
Samantha Russell	Specialist Committee Member	Financial	NHS England Patient & Public Voice (PPV) Partner	2024	September 2024	Ongoing	*Declare and Participate*

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Diagnostics Advisory Committee Interests Register

Topic: Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies: early value assessment

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Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
David M Clark	Expert	Financial	Non-Executive Director of Oxford Health NHS Foundation Trust	July 2024	September 2024	Ongoing	*Part One only*
David M Clark	Expert	Financial	NHS England's Clinical and Informatics Advisor for the NHS Talking Therapies programme		September 2024	Ongoing	*Part One only*
Joanna Hillier	Expert	Non-financial professional and personal interests	I have spoken with suppliers Psyomics and Wysa as part of my role as CCIO of a mental health trust. I am subject matter expert for digital health and provide information and opinions to the Trust's decision-makers. I have no role in day-to-day decisions about the technologies in use within the Trust. I have attended conferences and NHS Confederation events where Psyomics are present and have sponsored elements of the events.		January 2025	Ongoing	*Declare and Participate*
Joanna Hillier	Expert	Indirect	As a trust we are in contract with Psyomics to deliver digital services and we have an intention to work with Psyomics as a Trust to develop a triage tool for children and young people. The chief investigator is within our research and development team and any evaluation data will be shared with the teams deploying the technology and the project manager working with Psyomics. Funding has		January 2025	Ongoing	*Part One only*

			been applied for via the Wellcome Trust via Psyomics on behalf of 4 Trusts - I am CCIO for one of these Trusts. Sussex Partnership would receive funding to pay for project leadership, digital clinical leadership, and clinical safety assessment of the product.				
Joanna Hillier	Expert	Non-financial professional and personal interests	I am related by marriage to a NICE Non-Executive Director		September 2024	Ongoing	*Declare and Participate*
Rachel Heggart	Expert	None	-	-	-	-	*Part One only*