NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Evidence generation plan

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

March 2025

1 Purpose of this document

NICE's early value assessment guidance on digital front door technologies to gather information for assessments for NHS Talking Therapies recommends that more evidence on Limbic Access and Wysa Digital Referral Assistant is generated while they are being used in the NHS.

This plan outlines the evidence gaps and what data needs to be collected for a NICE review of the technologies again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. For assessing comparative treatment effects, well-conducted randomised controlled trials are the preferred source of evidence.

The companies are responsible for ensuring that data collection and analysis takes place.

NICE will withdraw the guidance if the companies do not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (3 years), the companies should submit the evidence to NICE in a form that can be used for decision making. NICE will review all the evidence and assess whether the technologies can be routinely adopted in the NHS.

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2 Evidence gaps

This section describes the evidence gaps, why they need to be addressed and their relative importance for future committee decision making.

The committee will not be able to make a positive recommendation without the essential evidence gaps (see section 2.1) being addressed. The companies can strengthen the evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. This will help the committee to make a recommendation by ensuring it has a better understanding of the patient or healthcare system benefits of the technologies.

2.1 Essential evidence for future committee decision making

Quality of data and immediate impact on clinical assessment

Evidence on the quality of the data collected by the technologies, and their impact on subsequent clinical assessment is limited. The committee decided that the quality of the data collected by the technologies could be estimated pragmatically using time-savings.

Impact of the technologies on clinical decision making and quality of life

There is limited evidence around the impact of the technologies on clinical decision making. Further evidence on the impact of changes in treatments or service use after using the technologies will support future clinical- and cost-effectiveness modelling. The potential impact could include:

- the choice of treatment prescribed
- step-ups or step-downs in medication
- changes in the service pathway followed compared with current practice
- changes in clinical outcomes, ideally measured using:
  - the Patient Health Questionnaire 9 (PHQ-9) for depression
  - Generalised Anxiety Disorder-7 (GAD-7) for anxiety
  - the Work and Social Adjustment Scale (WSAS) for the extent to which mental health problems interfere with daily life.

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Resource and service impact

More evidence is needed to determine whether the technologies offer time-savings before or during a clinical assessment. Information is also needed on whether any time-savings offered translate into more clinical assessments each day or a reduction in waiting-list times. Data on the number of self-referrals from using the technologies is needed to reduce uncertainty around the potential burden on NHS Talking Therapies services. Further information is also needed on the costs of using the technologies in the NHS to support future economic modelling.

2.2 Evidence that further supports committee decision making

User engagement and experience

Further evidence on intervention completion rates and user reported outcomes, including user preferences and acceptability, will help NICE's committee:

- assess the real-world uptake of the technologies
- identify any potential barriers to using the technologies.

There is some evidence that the technologies may improve access to mental health services for people from ethnic minority backgrounds. Further data collection on user-characteristics (for example, ethnic background) or service characteristics (for example, geographic location or service size) will support subgroup analyses to assess accessibility of the technologies in different populations.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

The external assessment group identified 4 ongoing or unpublished studies, 3 for Limbic Access and 1 for Wysa Digital Referral Assistant (DRA), that may address some of the evidence gaps.

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Evaluate treatment outcomes for AI-enabled information collection tool for clinical assessments in mental healthcare (NCT05495126)

The study aimed to collect data on treatment outcomes, clinical assessment reliability, waiting and assessment times, and assessment and referral dropout rates. The study compared the AI-supported information collection version of Limbic Access (Class 2a) with the non-AI-enabled Limbic Access version (Class 1). The study ended in December 2024, but there are no publicly available results yet.

Evaluation of a conversational information collection tool to access Talk Therapy (Essex study: NCT05678764)

This study aims to collect data on waiting times from referral to assessment, recovery rate, reliable recovery rate and drop out after referral. The estimated study end date is December 2025.

Evaluation of a conversational information collection tool to access Talk Therapy (Surrey study)

This study aims to evaluate Limbic Access in terms of clinical efficacy (including changes in treatment outcomes, diagnosis or waiting times for the people using the service), and service efficiencies (including changes in assessment times and staff wellbeing). The study will compare the Class 2 version of Limbic with the Class 1 version (without AI support). There is no published study end date available.

The benefits of using digital technology (the Wysa app and AI chatbot) to support assessments, waits for therapy and treatment within NHS Talking Therapies services for patients, clinicians, services and the wider healthcare system (ISCRTN10327977)

This trial aims to investigate the effectiveness and impact of Wysa, to evaluate user experience and to establish whether the adoption of Wysa therapeutics results in any service-related efficiencies (for example, clinical or administrative time-savings). Data on Health-Related Quality of Life, dropout rates and time taken to complete clinical assessment will be collected. The study will compare Wysa DRA with other referral methods. The anticipated study end date is July 2025.

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Table 1 Evidence gaps and ongoing studies

Evidence gap	Limbic Access	Wysa Digital Referral Assistant
Quality of data and immediate impact on clinical assessment	Limited evidence Ongoing study	Limited evidence Ongoing study
Impact of technologies on treatment and service pathways	Limited evidence Ongoing study	Limited evidence Ongoing study
Resource and service impact	Limited evidence Ongoing study	Limited evidence Ongoing study
User engagement and experience	Limited evidence	Limited evidence Ongoing study

Table 1 summarises the evidence gaps and ongoing studies that might address them. Information about evidence status is derived from the external assessment group's report. Evidence not meeting the scope and inclusion criteria is not included. The table shows the evidence available to the committee when the guidance was published.

3.2 Data sources

The NHS Talking Therapies: for anxiety and depression and Mental Health Services Data Set (MHSD) are real-world data sets that could also be used to collect information about the impact that conditions have on mental health. Most of the data needed to address the evidence gaps is already collected within the Talking Therapies services, for example:

- the number of referrals each day
- waiting lists
- treatment pathways
- the proportion of self-referrals.

New studies will be needed to collect data on measures that are more specific to using the technologies, such as:

- time taken for clinical assessments

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- impact on clinical assessments
- administrative burden
- user preferences.

NICE's real-world evidence framework provides detailed guidance on assessing the suitability of a real-world data source to answer a specific research question. The quality and coverage of real-world data collections are of key importance when used in generating evidence. Active monitoring and follow up through a central coordinating point is an effective and viable approach of ensuring good-quality data with broad coverage.

3.3 Evidence collection plan

A suggested approach to addressing the evidence gaps for Limbic Access and Wysa DRA is a mixed-methods longitudinal parallel cohort study. This approach would follow an intervention arm and a control arm, and compare their outcomes. This design would allow assessment of the clinical impact of the technologies and the resource use associated with their implementation. Qualitative data could be generated through appropriate methods such as surveys, focus-groups or interviews, as highlighted in NICE's Real World evidence framework. This could include reported outcomes (acceptability, usability and preferences) from people using the service.

The studies should enrol a representative population, that is, people who would be offered a pre-assessment, including people who have self-referred and people referred through any other method. The pre-assessment may include web- or paper-based forms, or telephone pre-assessments. The studies should compare people using digital front door technologies for pre-assessments with a similar group having standard care. Eligibility for inclusion and the point of starting follow up should be clearly defined and consistent across comparison groups to avoid selection bias. Data should be collected in all groups from the point at which a person would become eligible for standard care (referral). The data from both the intervention and comparison groups should be collected at appropriate time intervals. Data from a comparable population, but with no access to digital technologies for self-

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management, should form the comparison group. Ideally, the studies should be run across multiple centres, with the aim of recruiting centres that represent the variety of referral pathways in the NHS.

Despite consistent eligibility criteria, non-random assignment to interventions can lead to confounding bias, complicating interpretation of the treatment effect. So, approaches should be used that balance confounding factors across comparison groups, for example, using propensity score methods. To achieve this robustly, data collection will need to include prognostic factors related both to the intervention delivered and patient outcomes. These should be defined with input from clinical specialists. Incomplete records and demographically imbalanced groups can lead to bias if unaccounted for.

Data collection should follow a predefined protocol. Quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See NICE's real-world evidence framework, which provides guidance on the planning, carrying out and reporting of real-world evidence studies. This document also provides best practice principles for robust design of real-world evidence when assessing comparative treatment effects using a prospective cohort study design.

3.4 Data to be collected

Study criteria

At recruitment, eligibility criteria for the suitability of using the digital technologies and inclusion in the real-world study should be reported, and should include detailed descriptions of:

- the referral pathway
- the technologies and the specific versions.

Baseline information and patient characteristics

These should include:

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- information about individual characteristics at baseline, for example, sex, age, ethnicity, medicines and comorbidities, with other important covariates chosen with input from clinical specialists
- measures of:
  - depression (Patient Health Questionnaire 9 [PHQ-9] score)
  - anxiety (Generalised Anxiety Disorder-7 [GAD-7] score)
  - the extent to which mental health problems interfere with daily life (Work and Social Adjustment Scale [WSAS] score) should be recorded at baseline and at follow up.

Resource and system use

This should include:

- time taken for the clinical assessment (including time to review the digital front door information)
- time taken for administrative tasks
- number of clinical assessments each day
- number of people on the waiting list
- time to treatment
- number of self-referrals and service-referrals
- changes in treatment and service use
- costs of digital technologies, including:
  - licence fees
  - use and implementation of the technologies
  - healthcare professional staff and training costs
  - promotion
  - integration with NHS systems.

Reported outcomes and experience from people using the service

These should include:

- acceptability, user preferences and usability

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- access and uptake, including:
  - the number and proportion of people who were able to access the technologies (either through self-referral or referral through another service)
- pre-assessment completion rates or intervention dropout rates
- clinical assessment attendance rates
- reasons for not using the technologies (for example, accessibility issues).

Data collection should follow a predefined protocol and quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See NICE's real-world evidence framework, which provides guidance on the planning, carrying out and reporting of real-world evidence studies.

3.5 Evidence generation period

This will be 3 years to allow for setting up, implementing the test, data collection, analysis and reporting.

4 Monitoring

Companies must respond to NICE confirming:

- within 6 months of publication of this plan, that agreements are in place to generate the evidence
- annually, that the data is being collected and analysed as planned.

The companies should tell NICE as soon as possible of anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- the technology significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the companies should contact NICE to arrange an extension to the evidence generation period. NICE

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reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

5 Minimum evidence standards

There is some clinical evidence that suggests that the digital front door technologies support the pre-assessment process for accessing Talking Therapies services, and potentially offer time-savings during subsequent clinical assessments.

For new technologies, the committee has indicated that it may, in the future, be able to recommend technologies in this topic area that have evidence for:

- clinical impact of the digital front door technologies compared with standard care for the pre-assessment to Talking Therapies services without digital front door technologies
- intervention acceptance, usability, completion rates and uptake rates in different subpopulations
- cost or time-savings resulting from resource use associated with the technologies.

6 Implementation considerations

The following considerations around implementing the evidence generation process have been identified through working with system partners:

Evidence generation

- The referral pathway for mental health conditions is extremely varied in current practice. Details describing the referral pathway should be reported for future evidence generation, this will enable a better understanding of how generalisable results are

System considerations

- The technologies may offer more value to services where digital pre-assessment methods are not already in use, for example, where the pre-assessment is carried out by administrative staff

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- The technologies may need to be integrated into or linked to any existing digital infrastructure.

Equalities

- The technologies may improve accessibility to mental health services for people who are underserved, for example people from ethnic minority backgrounds.
- The technologies may not be suitable for everyone, for example, people without access to, or who cannot use, a smartphone or computer. People with cognitive impairment, problems with manual dexterity or a learning disability may need additional help from carers or advocates.
- The digital technologies could be more beneficial if it is set up to ensure that language and cultural considerations of its users are met, and the digital literacy of people using it is considered.

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