NICE National Institute for Health and Care Excellence

Evidence generation plan for digital technologies for managing non-specific low back pain

Implementation support

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1 Purpose of this document

NICE's early value assessment of digital technologies for managing low back pain (that is, getUBetter, Hinge Health, Kaia, Pathway through Pain and selfBack) recommends that they can be used in the NHS while more evidence is generated. Ascenti Reach, Digital Therapist, Flok Health, Phio Engage and Joint Academy can only be used in research and are not covered in this plan.

This plan outlines the evidence gaps and what real-world 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, randomised controlled trials remain the preferred source of evidence when these are viable to address the research gap and can be well conducted.

The companies are responsible for ensuring that data collection and analysis takes place. Support for evidence generation will be available through a competitive process facilitated by the Office for Life Sciences, pending business-case approval. This will be in the form of funding for evidence generation consortia, which will bring analytical partners and implementation sites together with companies for evidence generation.

Guidance on commissioning and procurement of the technologies will be provided by NHS England. It is developing a digital health technology policy framework to further outline commissioning pathways.

NICE will withdraw the guidance if the technology companies do not meet the conditions about monitoring evidence generation in section 4.

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

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 following essential evidence gaps being addressed.

2.1 Essential evidence for future committee decision making

Musculoskeletal disability and quality of life

A standardised score of musculoskeletal-specific symptoms and quality of life is needed to measure the clinical and cost effectiveness of digital technologies in managing low back pain. The Musculoskeletal Health Questionnaire (MSK-HQ) was identified by the NICE committee as its preferred measure to collect this information.

Additionally, the committee asked for more information about health-related quality of life, ideally collected through the EQ-5D-5L questionnaire. This measures how changes in a person's health state relate to their perceived quality of life. Quality of life is an important driver of health-economic evaluation. The EQ-5D-5L questionnaire can be more easily incorporated into health-economic evaluations than quality of life captured through the MSK-HQ.

The committee also wanted to know whether the interventions help people return to their normal activities of daily living.

Adherence

More evidence is needed on how people engage with the technologies and whether approaches to support people using them are effective. Measures of engagement should include information about enrolment, starting treatment, and continued engagement at 30 days, and 6 and 12 months. Ideally, reasons for stopping treatment should also be collected.

Qualitative evidence from people with low back pain using the technologies can complement this information. This should focus on perceived treatment effectiveness, acceptability, and the rationale for continuing or stopping treatment.

Healthcare resource use

Healthcare resource use is a key factor in calculating cost effectiveness. It should consider overall costs, and the burden placed on people with low back pain and the broader healthcare system.

The committee identified 3 key outcomes that will help to address this evidence gap:

- GP appointments: GPs are usually the first point of contact for people with low back pain and will also manage care over time.
- Physiotherapist appointments: physiotherapy plays a critical role in managing the condition and its rehabilitation.
- Emergency department visits: low back pain may lead to acute exacerbations that need emergency medical care.

Besides these outcomes, additional data collection may focus on healthcare resources in areas in which the technologies are expected to have the most benefit (see section 3.4).

Outcomes in people with different types of low back pain

The committee wanted to understand how the impact of the technologies differs between people with acute or chronic types of low back pain. This included for musculoskeletal symptoms, quality of life, resource use, adherence and engagement.

Placement of technology in the clinical pathway

Further information is needed to understand how the technologies are likely to be used in practice, including:

- about how people are referred to the technology
- at what point in their clinical pathway.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

Some technologies have ongoing studies that may address the evidence gaps. Wellmind Health, SelfBack and getUBetter are doing comparative studies, which will complete within the evidence generation period.

Table 1 summarises the evidence gaps and the existing evidence for each technology. Information about evidence status is derived from the external assessment group's report. Evidence not meeting the scope and inclusion criteria is not included.

Table 1 Summary of the evidence gaps and ongoing studies

Technology	Musculoskeletal disability and quality of life	Adherence	Healthcare resource use	Placement of technology in the clinical pathway
getUBetter (getUbetter)	No relevant evidence identified Ongoing study	No relevant evidence identified Ongoing study	No relevant evidence identified Ongoing study	No relevant evidence identified
Hinge Health (Hinge Health)	Limited information available	Limited information available	No relevant evidence identified	No relevant evidence identified
Kaia (Kaia Health)	Limited information available	Limited information available	Limited information available	No relevant evidence identified
Pathway through Pain (Wellmind Health)	No relevant evidence identified	No relevant evidence identified Ongoing study	No relevant evidence identified Ongoing study	No relevant evidence identified
SelfBack (SelfBack Consortium)	Limited information available	Limited information available	No relevant evidence identified Ongoing study	Limited information available

3.2 Data sources

This topic is likely to need primary data collection for certain outcomes. Information is also needed from primary and secondary care services. Data collection can be supported using routinely collected data.

Local or regional data collections, such as the subnational secure data environments (SDEs), could be used to collect data to address the evidence gaps. SDEs are data storage and access platforms that bring together many sources of data, such as from primary and secondary care, to enable research and analysis. Subnational SDEs are designed to be agile. They can be modified to suit the needs of new projects, for example, helping to collect pain scores and quality-of-life data. The data environment of an SDE supports linkage. Also, it may allow researchers a more comprehensive view of medical history, diagnoses, treatments and outcomes related to low back pain, as well as resource use. The West Midlands subnational SDE specialises in collecting data about musculoskeletal health and may be particularly well suited.

It is possible that some data may be generated through the technologies themselves, such as starting treatment and engagement outcomes. This data can be integrated with other data collected.

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

3.3 Evidence collection plan

A mixed methods approach is suggested to address the evidence gaps, for example, a prospective cohort or a before and after study in combination with a qualitative survey. Such a study should include people with low back pain who would be expected to be offered one of the technologies in the real world. It should compare the use of the technologies alongside standard care with standard care alone and include an embedded qualitative study.

The technologies may be applied at different points in the care pathway, for example, primary care or alongside specialist services such as physiotherapy. Depending on the

setting, different experimental designs may offer greater robustness:

- When there is limited variation and well-defined standard care across services, a prospective comparative cohort study is suggested.
- When there is considerable variation between services, a before and after study is suggested.

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, conduct and reporting of real-world evidence studies. This document also provides best practice principles for robustly design real-world evidence when assessing comparative treatment effects.

Prospective comparative cohort study

In this type of study, data should be collected from healthcare services where the technology is offered for low back pain. It should be compared with other similar services where the technology is not offered. It is important that people in both services are included and followed up from the point at which they would be offered the technology. This should be in line with the intended use of the technology in the clinical pathway.

High-quality data on patient characteristics is needed to correct for any important differences between comparison groups, for example, using propensity score methods. Important confounding factors should be identified with input from clinical experts during protocol development.

Before and after study

In a before and after study, data should be collected and compared before and after implementing the intervention in the same setting. This is to ensure that service performance and configuration are accounted for in the final outcomes and to reduce the risk of bias.

In this study design, after an enrolment period, data should be collected for people in the period after implementing the technology. The data collection period should be long enough to ensure that there is sufficient follow-up data for the standard care group. The digital technology should then be implemented in the service. Data should then be

collected from people having care through the technologies.

Companies should provide clear descriptions of the services and settings in which the study is done. Such a study could be done at a single centre or ideally, replicated across multiple centres. This would show how the technology can be implemented across a range of services and so be representative of the variety in the NHS. Outcomes may reflect other changes that occur over time in the population, unrelated to the interventions. Additional robustness could be achieved by collecting data in a centre that has not implemented the technology but is as similar as possible (in terms of clinical practice and patient characteristics) to a site in which the technology is being used. This could control for changes over time that might have occurred anyway as described above, it is important that participants are followed up from the point at which they would be offered the technology. High-quality data on patient characteristics is also needed to correct for any important differences between comparison groups

Qualitative survey

Feedback should be collected through a survey or structured interviews with people who have low back pain using the technologies.

The robustness of survey results depends on:

- comprehensive distribution across people who are eligible
- the sample of respondents being representative of the population of potential users.

3.4 Data to be collected

Prospective comparative cohort or before and after study

The following information should be collected:

- eligibility criteria (for example, the indication for referral) and point of starting follow up, which should be consistent between comparison groups
- type of low back pain at baseline and how this was defined (that is, acute or chronic. for example, chronic back pain may be defined as symptoms for 3 months or longer)

- type of healthcare professional referring the person with back pain to the technology
- MSK-HQ at baseline, 30 days, and 6 and 12 months
- ideally, EQ-5D-5L at baseline, 30 days, and 6 and 12 months
- use of the technology including:
  - number of people offered the technology
  - number and proportion referred
  - number and proportion who started using the technology
  - engagement at 30 days and over time
  - number and proportion who stopped by 30 days and over time
  - reasons why people stopped using the technologies (for example, whether engagement stopped because of improvements in symptoms, lack of improvement or other reasons)
- information on healthcare resource use, collected at 30 days, and 6 and 12 months:
  - number of GP appointments per patient
  - number of physiotherapist appointments per patient
  - number of visits to the emergency department per patient
- additional prespecified resource use outcomes, which could focus on areas in which the technologies are expected to have the most benefit, for example:
  - number of occupational therapist appointments
  - number of cognitive behavioural therapy (CBT) or acceptance and commitment therapy (ACT) sessions
  - number of secondary care appointments
  - number of people starting or stopping pharmacological treatment
  - number of people with imaging referrals
  - surgical referrals or surgical intent

- patient characteristics at baseline, including:
  - important confounders such as age, sex, comorbidities and concomitant interventions
  - other characteristics that may be related to likelihood of choosing to access the technology, for example, socioeconomic status, language or ethnicity
- the number and type of adverse event presented using the technology.

Qualitative survey study

Outcomes to be collected from people with the condition:

- Perceptions from people with back pain about whether the technologies help alleviate pain and help them to return to normal daily activity
- Satisfaction, engagement and accessibility of the technology, including barriers encountered by people using and continuing to use the technologies

Information about the technologies:

- Information about how the technologies were developed
- Information about how people are referred to the technology and at what point in their clinical pathway
- Information about any updates to the technologies

See the NICE evidence standards framework for digital health technologies.

3.5 Evidence generation period

This will be about 3 years to allow for setting up, implementation, data collection, analysis and reporting.

4 Monitoring

Companies are required to contact NICE:

- within 6 months of the evidence generation plan's publication to confirm that agreements are in place to generate the evidence specified
- annually to confirm that the data is being collected and analysed as planned.

Companies should inform NICE at the earliest opportunity of anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- significant changes to the technology that affect 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 reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

5 Implementation considerations

Companies should work with providers and central NHS England teams to begin evidence generation. Planning for a period for the setup of the technology is advised. The following considerations around implementing the evidence generation process have been identified through working with system partners:

- Companies should provide training for staff in using the technology, when support is needed. The training and implementation period should be before the data collection period and be sufficient to account for potential learning effects.
- Focus should be on people with back pain who are referred to the technologies as part of the clinical pathway rather than self-referring.
- The company may improve their chance of securing funding by also collecting data on outcomes relevant to other national organisations, for example, work and productivity outcomes.
- The evidence generation process is most likely to succeed with dedicated research staff to reduce the burden on NHS staff.
- Sites should be carefully selected to, when appropriate, maximise data collection and ensure services representative of those in the NHS are included.
- Evidence generation should be overseen by a steering group including researchers, commissioners, practitioners and representatives with lived experience of lower back pain.
- Careful planning of approaches to information governance is vital.

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

- the availability of research funds for data collection, analysis and reporting, as well as NHS funding to cover the costs of implementing the technologies in clinical practice
- lack of expertise and staff to collect data
- burden on clinical staff, such as the need to have training before implementation, data collection and follow up

- variable levels of technological literacy affecting uptake and use of the technologies
- careful consideration by companies about the point at which the technologies are offered in the clinical pathway because this may affect the technology uptake and observed outcomes
- support for languages other than English in the technologies affecting their uptake and use.

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