NICE National Institute for Health and Care Excellence

NICE guidance

Digital technologies for managing non-specific low back pain: early value assessment

Health technology evaluation
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

Can be used in the NHS with evidence generation

1.1 Five digital technologies can be used in the NHS while more evidence is generated to manage non-specific low back pain in people 16 years and over. The technologies are:

- getUBetter
- Hinge Health
- Kaia
- Pathway through Pain
- SelfBack.

These technologies can be used once they have appropriate regulatory approval and meet the standards within NHS England's Digital Technology Assessment Criteria (DTAC).

1.2 The companies must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan). They must contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance for a technology if these conditions are not met.

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

Can only be used in research

1.4 More research is needed on 5 digital technologies to manage non-specific low back pain in people 16 years and over. The technologies are:

- Ascenti Reach
- Digital Therapist
- Flok Health
- Phio Engage
- Joint Academy.

1.5 Access to the 5 technologies should be through company, research or non-core NHS funding, and clinical or financial risks should be appropriately managed. Centres already using these technologies may continue to do so but are encouraged to collect data or do further research.

Evidence generation and more research

1.6 Evidence generation and more research are needed on:

- pain and disability using the same outcome measure (Musculoskeletal Health Questionnaire)
- quality of life using the same outcome measure (EQ-5D-5L)
- patient characteristics (such as type of back pain and severity)
- time until return to normal daily activity
- treatment adherence, that is, the number of people:
  - using a technology at baseline, 30 days and between 6 months and 1 year
  - who stop using a technology and their reasons for stopping

- adverse events related to using the technology
- healthcare resource use, including:
  - GP appointments
  - physiotherapy appointments
  - emergency department visits
- how many people have self-referred for the technology and how many have been referred by a healthcare practitioner
- the position of the technology in the care pathway
- patients' views on the effects of the technologies collected using a qualitative survey or through interviews.

Potential benefits of use in the NHS with evidence generation

- **Access:**Digital technologies for managing non-specific low back pain provide access to rapid advice and offer another treatment option. They will particularly benefit anyone who needs more flexible access to treatment or prefers a digitally enabled therapy over face-to-face therapy.
- **Clinical benefit:** Clinical evidence suggests that digital technologies for managing non-specific low back pain may reduce pain and improve ability to function in everyday life.
- **Resources:** These technologies could potentially reduce waiting lists, referrals for physiotherapy, the number of physiotherapy appointments and GP visits, medication use and the need for surgery.

Considerations

- **Unmet need:** Provision of services for low back pain varies across the UK. Some people may be on a waiting list to access treatment. So, there is an opportunity to integrate digital technology to increase access and reduce waiting lists by promoting supported self-management.
- **Costs:** Early results from the economic modelling suggest that the technologies used alongside standard care may be cost effective compared with standard care alone. The potential cost effectiveness or cost saving will be affected by how they are used in the clinical pathway. This guidance will be reviewed within 3 years and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.
- **Information governance**: Local NHS hospitals and trusts should have appropriate information governance policies for using these technologies.
- **Patient outcomes**: Consistent quality-of-life measures should be used.
- **Workforce:** Local NHS hospital and trusts should verify that companies have an appropriate physiotherapy workforce available. This should have the right level of capabilities for the technologies that provide clinical support or offer physiotherapy services.

- **Equality:** Digitally enabled therapies may not be accessible to everyone. People are less likely to benefit and may prefer another treatment option if:
  - their access to equipment or an internet connection is limited
  - they are less comfortable or skilled at using digital technologies
  - English is not their first language.

Key gaps in the evidence

- It is difficult to compare technologies because a wide range of outcome measures were used. Also, some outcomes were not well-reported, such as work productivity, and patient experience and satisfaction.
- There was limited evidence on how the technologies affect psychological management, quality of life, attendance at emergency departments, and referral rates to other services such as imaging, physiotherapy or surgery.

Overall, more evidence is needed on:

- the clinical effectiveness of digital technologies for low back pain
- technology uptake and rate of adherence
- healthcare resource use.

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

2 The technologies

2.1 Digital technologies for managing low back pain (LBP) could provide:

- rapid access to specialist advice and guidance
- remote pain management support, including physical activity recommendations
- psychological therapies through web-based applications and digital platforms.

  They could offer greater flexibility because people can work through the recommendations in their own time with varying levels of support. Digital technologies for managing LBP are not homogenous and have different focuses based on the characteristics of the person with LBP. For example, some technologies are designed for acute LBP, some for chronic LBP and some for a mixture of both.

2.2 NICE has assessed 12 digital technologies for managing non-specific LBP. The assessment included technologies that offer physical, psychological or both types of LBP management. The criteria for including technologies in this assessment are in the final scope on the NICE website. The included technologies are:

- ACT for PAIN (Pain Medicine Specialist Ltd)
- Ascenti Reach (Ascenti)
- Digital Therapist (Sword Health)
- Flok Health (Flok Health Ltd)
- getUBetter (getUBetter)
- Hinge Health (Hinge Health)
- Joint Academy (Arthro Therapeutics)

- Kaia (Kaia Health)
- Pathway through Pain (Wellmind Health)
- Phio Engage (EQL)
- SelfBack (SelfBack ApS)
- SupportBack (University of Southampton).

Evidence was submitted for Physitrack (Physitrack PLC), but the committee could not make a recommendation because the technology was deemed out of NICE's scope. ACT for PAIN and Pathway through Pain only provide psychological management for chronic LBP. ACT for PAIN is not a regulated medical device, so it was deemed ineligible for inclusion in the recommendations. The regulatory status for SupportBack is unknown and the company did not respond to requests for information. Evidence was identified and assessed for SupportBack, but the technology has been excluded from the recommendations. See table 2.1 in the external assessment group (EAG) assessment report and table 2.1 in the EAG assessment report addendum for details of the technologies.

Care pathway

2.3 The target population for this assessment is people 16 years and over with non-specific LBP. The condition can either be acute (that is, lasting less than 3 months) or chronic (that is, lasting 3 months or more). NICE's guideline on low back pain and sciatica in over 16s recommends considering several non-pharmacological interventions for treating LBP. These include self-management, exercise, manual therapies, psychological therapies, combined physical and psychological programmes, and return to work programmes. It recommends that these interventions are tailored to someone's specific needs, preferences and capabilities.

2.4 Acceptance and commitment therapy (ACT) and cognitive behavioural therapy (CBT) delivered by healthcare professionals with appropriate training are recommended in NICE's guideline on chronic pain (primary and secondary) in

over 16s.

2.5 Digital technologies for managing LBP would be offered after clinical assessment and diagnosis, or through self-referral, as an addition to non-pharmacological treatment for LBP. Technologies eligible for self-referral will be those with integrated assessment and risk stratification. This is to ensure that red flags that may indicate a serious underlying cause are identified. Technologies that provide psychological support only may not be suitable for people with acute LBP because their pain has lasted less than 3 months.

The comparator

2.6 The comparator is standard care for managing non-specific LBP. Digital technologies would be used in addition to standard care. Standard care varies significantly across primary and community care.

3 Committee discussion

NICE's medical technologies advisory committee considered evidence on digital technologies to manage non-specific low back pain (LBP) in people 16 years and over from several sources. These included an early value assessment report by the external assessment group (EAG), an overview of that report and an addendum to the report by the EAG. Full details are in the project documents for this guidance on the NICE website.

Unmet need

3.1 Provision of services for musculoskeletal-related pain varies across the NHS. Most non-specific LBP is managed in primary or community care settings, which have limited workforce capacity and resources to meet the growing demand for services. The clinical experts noted that there is often a long waiting list for referral to specialist services. They added that people are likely to try to resolve pain on their own before seeing a GP.

3.2 Digital technologies for managing non-specific LBP that are suitable for self-referral would provide people with the resource they need to self-manage. One clinical expert noted that there was no evidence about people who self-referred. But, in practice, healthcare professionals will want to use digital technologies to ease the strain on resource use. The committee noted the importance of safeguards. It advised that technologies suitable for self-referral need appropriate safeguards to accurately identify and escalate potential red flags.

Implementation

3.3 Some of the technologies included in this assessment are used in the NHS. The committee stated that technologies designed to interact with GP systems ensure continuity of care by making important information accessible to healthcare professionals that need it. The companies for ACT for PAIN, getUBetter, Hinge Health and Pathway through Pain confirmed that their technologies are designed to be, or will be, able to interact with existing NHS systems.

Patient considerations

3.4 Digital technologies can provide quicker access and increase management options for people with non-specific LBP. The patient experts said that quicker access to support can lead to faster improvement in symptoms, and can reduce the possibility of acute pain developing to chronic pain. They noted that following a personalised exercise and movement plan could improve mobility, ability to manage pain and mood, and give a sense of control over the condition.

3.5 The patient experts said that reassurance is needed that personal data will be secure. There also needs to be appropriate measures in place for reporting adverse events related to using the technologies. The patient experts noted that people less comfortable or skilled at using digital technologies, or unable to read or understand health-related information (including people who cannot read English) need considering. Appropriate alternative support should be provided for them.

3.6 The patient experts advised that patient choice should be a key consideration. They added that people should have the option to remain on a waiting list for a face-to-face appointment if they agree to engage with digital technologies. The committee noted that, for some of the technologies, people will be in the care of company-employed healthcare professionals. In these instances, it will be important that there is a referral pathway back into NHS care when the technology is no longer suitable.

3.7 The committee concluded that patient choice and preferences should be taken into consideration when deciding the suitability of digital technologies for managing non-specific LBP. It also noted the importance of codesigning digital technologies with people with LBP. This is to ensure that the content and management options are appropriate and relevant for the users. The companies for ACT for PAIN, getUBetter, Hinge Health and Pathway through Pain said that they have involved people with LBP and healthcare professionals in the development phase of their technologies.

Clinical effectiveness

3.8 The EAG prioritised 17 studies for assessment:

- 5 randomised controlled trials (RCTs)
- 1 prospective single-arm trial
- 1 prospective cohort study (providing non-comparative data)
- 3 retrospective cohort studies (providing non-comparative data)
- 7 retrospective case series.

Only 5 of the studies were done in the UK and 2 other studies included UK participants. The EAG noted that there was considerable uncertainty about the generalisability of the evidence to the UK NHS setting. It stated that there was limited clinical and economic evidence for acceptance and commitment (ACT) therapy in the UK, and no studies using ACT for PAIN were identified. The EAG also stated that there was economic evidence for Pathway through Pain, but no clinical evidence was identified. The committee noted that there was no evidence of harm or safety concerns, and that access to psychological therapies for chronic LBP is limited. So, it recommended using getUBetter, Hinge Health, Kaia, Pathway through Pain and SelfBack in the NHS while more evidence is being generated. For the other technologies (Ascenti Reach, Digital Therapist, Flok Health, Phio Engage and Joint Academy), there was no or limited evidence so the committee recommended their use only in research.

3.9 The evidence from the prioritised studies reported on 47 different outcomes, including function, pain self-efficacy, intervention adherence and adverse events. The EAG suggested the evidence showed that, when compared with standard care alone, digital technologies used with standard care may be effective in terms of improving pain and physical function outcomes. But the range of outcome measures used across the trials made it difficult to compare the digital technologies. Evidence was also limited to short-term effect, with no comparative data for outcomes beyond 3 months. The committee noted that there was no evidence to suggest that any technologies were unsafe. It advised that standardised data be collected for future evaluation.

3.10 The committee noted that clinical evidence showed variability in the way adherence was measured and the reported levels of engagement. The clinical experts stated that reported adherence levels were similar to that seen in clinical practice. The committee was informed that, because of the recurrent nature of LBP, people might stop using a technology when their symptoms improve but use it again if symptoms return. One patient expert said that using digital technologies might be fairly new to people, and that they might experience some challenges. The committee acknowledged that significant effort is needed from people with LBP to complete exercise programmes. It said that the companies should ensure that nudging features are in place to prompt people to engage with the technologies. The committee concluded that more evidence is needed on short-term (30 days) and long-term (6 to 12 months) adherence rates.

3.11 During consultation, information was provided for 4 new technologies (Digital Therapist, Flok Health, Joint Academy and Physitrack) to be considered as part of the assessment. Also, further evidence was submitted for Phio Engage and SelfBack. The committee concluded that the previous evidence provided for SelfBack was enough to support the recommendation for use while further evidence is being generated. Two retrospective case series and 1 retrospective cohort study were considered as part of the assessment for Phio Engage. The committee concluded that the information was limited and there was inadequate evidence to recommend Phio Engage for use in the NHS while further evidence is generated. It suggested that further research be done through company, research or non-core NHS funding. One retrospective case series study for Joint Academy was considered relevant for the assessment by the EAG. There was no clinical evidence for Digital Therapist and Flok Health. The committee concluded that further evidence is needed for these 3 technologies.

3.12 The committee did not make a recommendation for Physitrack. It considered the technology to be out of scope for inclusion in this assessment. The clinical experts noted that Physitrack is an exercise prescription tool used in practice as a digital information leaflet, supporting the company's claim that it is not a medical device.

Equality considerations

3.13 Digital technologies for managing non-specific LBP may not be suitable for everyone, including people who:

- have limited access to devices or an internet connection
- are less comfortable or skilled at using digital technologies
- are unable to read or understand health-related information (including people who cannot read English)
- have a visual impairment
- have problems with manual dexterity.

The committee concluded that face-to-face treatment options should be available when digital technologies are not suitable, and that companies should consider providing translations.

Costs and resource use

3.14 Early economic modelling using a simple cost-utility model suggested that digital technologies for managing non-specific LBP may be cost effective when used alongside standard care. Base-case results showed the technologies alongside standard care were cost saving by an estimated £84 per person, with a quality-adjusted life year (QALY) gain of 0.01 compared with standard care alone. This was using a threshold of £20,000 per QALY gained. The analyses were done using an NHS and personal social services perspective. The base-case results were supported by sensitivity and scenario analyses. The economic model used a 1-year time horizon because of uncertainty about the long-term treatment benefits and the risk of pain relapses, particularly for people with chronic LBP.

3.15 The EAG acknowledged that, because of limited evidence, the model did not have a specific placement in the clinical pathway and that different placement may lead to different reported outcomes. The model included costs of the technologies, healthcare professional time, other health services use and

medication use. The details of the assumptions used in the model are outlined in table 8.2 of the assessment report on the NICE website. The EAG noted that the main drivers of the model were:

- the cost of the technology
- incremental utility
- proportion of people engaged with the technology
- reduction in physiotherapy referral
- number of physiotherapy appointments after referral.

The EAG excluded training and implementation costs from the model because of uncertainty in the level of resource use needed.

3.16 The committee noted that the evidence informing the cost model was limited but that there was plausibility of cost effectiveness. It concluded that it was appropriate to recommend some technologies for conditional use within the NHS while more evidence is being generated.

Evidence gap review

3.17 No clinical or economic evidence was identified by the EAG for Ascenti Reach, ACT for PAIN, Digital Therapist or Flok Health. For the remaining technologies, evidence gaps were identified in population demographics, clinical effectiveness, treatment adherence and healthcare resource use. The committee concluded that there is potential benefit and some evidence to support recommending 5 of the digital technologies for managing non-specific LBP in the NHS with evidence generation, once appropriate regulatory approval is in place. The key evidence gaps were:

- Population: the EAG noted that some clinical studies were excluded because they had an unspecified population. More evidence generation should clearly report population characteristics, particularly type of LBP (chronic or acute, specific or non-specific) and pain severity at baseline. This will ensure that data collected captures people with sciatica and back-related leg pain, so

that this data can be easily extracted and excluded from the analysis.

- Outcomes: comparative evidence identified a wide range of key outcome measures used across the trials, making comparison of the digital technologies difficult. Also, published evidence was not available for most of the outcomes in the scope of this evaluation. Evidence generation should include using consistent measures for key outcomes, such as pain score and health-related quality of life (Musculoskeletal Health Questionnaire and EQ-5D-5L) to enable comparison of different technologies.
- Adherence: studies that did report adherence varied in the definition of adherence and in the methods used to measure it, making comparisons difficult. More evidence generation should report consistent measures of adherence and reasons for stopping should be recorded.
- Referral: evidence is lacking on the referral setting (referred or self-referred) and the place of the digital technologies in the clinical pathway. It is unclear whether this affects the effectiveness of the digital technologies. There is scarce evidence on the effect of digital technologies on referral rates for other services such as imaging, physiotherapy, surgery or emergency department attendances.
- Resource use: more evidence generation is needed on healthcare resource use, including training and implementation associated with different types of digital technologies, especially those providing psychological treatment. Additional information on resource use is included in the evidence generation plan.

4 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technologies to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee meetings, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members took part in the discussions and provided expert advice for this topic:

Specialist committee members

Dr Adrian Chudyk
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NICE project team

Each early value assessment topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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Accreditation