# Evidence generation plan for HTG10887 Digital platforms to support preparation before and rehabilitation after primary elective hip or knee replacement surgery: early-use assessment

7 July 2026

## 1 Purpose of this document

NICE's assessment of digital platforms to support preparation before and rehabilitation after primary elective hip or knee replacement surgery recommends that the following digital platforms can be used during the evidence generation period:

- for hip or knee replacement surgery:
  - mymobility
- for hip replacement surgery:
  - GoWellHealth
- for knee replacement surgery:
  - BPMpathway
  - Physitrack.

The other technologies that were assessed can only be used in research and are not covered in this plan.

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. Evidence generated through other study approaches will also be considered. 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 take place. Support for evidence generation may be available through the National

Institute for Health and Care Research Invention for Innovation product development award. Academic support may be available through groups such the NIHR HealthTech Research Centres.

NICE will withdraw all or part of the guidance if a company does 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 format 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.

# 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 company 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 technology.

## 2.1 Essential evidence for future committee decision making

### Comparative effectiveness versus NHS current practice

To assess the effectiveness of the technologies, data comparing their clinical benefit with current practice in the NHS is needed to evaluate whether these technologies would add value.

The committee noted limited generalisability, lack of information on adverse events, and lack of sufficient comparative effectiveness evidence of the technologies and discussed that most NHS patients receive no face-to-face physiotherapy.

### Health-related quality of life

Health-related quality of life is a key driver in the economic model, but the current evidence base is limited. Current evidence is inconsistent and not measured through standard measures such as EQ-5D. Data from comparative studies done in the NHS would ideally be needed to show the long-term benefits and to quantify the cost effectiveness of these technologies

### Healthcare resource use

There is limited evidence of the impact these technologies have on healthcare resource use. The committee discussed that the current evidence base was mostly comprised of assumptions and sparse data. Further data about the impact on vital outcomes such as length of stay, length and nature of hospital appointments, length and number of physiotherapy sessions, escalation to face-to-face review, and readmissions will support a robust assessment of cost effectiveness.

## 2.2 Evidence that further supports committee decision making

### Patient engagement and adherence

Evidence on engagement and adherence is required to better understand how these technologies would be used in practice and which subgroups would be more likely to benefit from them. This information will also be useful to assess the levels of engagement with the technology and assess whether these can influence outcomes and healthcare costs.

# 3 Approach to evidence generation

## 3.1 Evidence gaps and ongoing studies

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. Information on the studies in the table can be found in the supporting documents. The table shows the evidence available to the committee when the guidance was published.

## Table 1 Evidence gaps and ongoing studies

| Evidence gap | mymobility | GoWellHealth | BPMpathway | Physitrack |
|---|---|---|---|---|
| Condition | Hip or knee replacement surgery | Hip replacement surgery | Knee replacement surgery | Knee replacement surgery |
| Comparative effectiveness versus NHS current practice | Limited evidence; ongoing study | Limited evidence | Limited evidence; ongoing study | Limited evidence |
| Adverse events | No evidence | No evidence | No evidence | No evidence |
| Health-related quality of life | Good evidence; ongoing study | Limited evidence | Limited evidence | Good evidence |
| Healthcare resource use | Good evidence; ongoing study | Limited evidence | Limited evidence | Limited evidence |
| Patient engagement and adherence | Limited evidence | Limited evidence | Limited evidence; ongoing study | No evidence |

## 3.2 Data sources

Some of the data needed for a future evaluation, particularly outcomes about engagement, is best collected as primary data through the technologies themselves.

There are several data collections that have different strengths and weaknesses that could potentially support evidence generation. 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. Potential data sources include:

- the National Joint Registry, which is useful to identify data on procedure type and long-term outcomes
- Hospital Episode Statistics, which is helpful to identify hospital admissions, length of stay, same-day discharge cases and readmissions
- primary care data sources such as the Clinical Practice Research Datalink (CPRD) and OpenSafely, which can be useful to gather information on GP appointments, prescriptions for analgesics and use of related community services
- sub-national NHS England Secure Data Environment service.

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

### Prospective real-world comparative cohort study

A prospective real-world comparative cohort study is suggested across NHS sites that offer digital platforms to support preparation before and rehabilitation after primary elective hip or knee replacement surgery compared with similar NHS sites that do not offer the digital platforms. People having surgery should be followed from the point at which they would typically enter the elective joint replacement pathway.

It is critical that the people in the cohorts are sub-grouped by either hip or knee replacement surgery. Data from the cohorts using the digital platforms should be compared with cohorts having NHS current practice, such as written information with no face-to-face physiotherapy, or face-to-face physiotherapy without access to the digital platforms. Ideally, the study should be done across multiple NHS centres to reflect variation in service delivery, rehabilitation pathways and patient demographics across the NHS.

Non-random assignment to interventions introduces a risk of confounding bias. So, appropriate methods, such as matching or adjustment (for example, propensity score methods), should be used to minimise selection bias and balance confounding factors between groups. High-quality data on patient characteristics will be essential to support these methods. The identification of key confounders should be informed by expert input during protocol development.

Data analysis should assess the relationship between digital platform use and clinical outcomes such as hospital length of stay. This will help inform whether these approaches are associated with shorter admissions and faster time to recovery, including in people who had same-day discharge.

### Qualitative survey

A qualitative study should be done to understand the experiences of people using the technologies to support rehabilitation before and after surgery, as well as the views of carers (where relevant), physiotherapists, orthopaedic teams and service managers. Evidence should be collected through semi-structured interviews, structured feedback and focus groups with a diverse sample of users across different NHS sites and type of surgical group. Advice on the conduct of qualitative studies is available in the NICE real-world evidence framework.

## 3.4 Data to be collected

When possible and appropriate, the following outcomes should be collected at baseline, 6 weeks, 3 months, 6 months and ideally 12 months.

### Study population and baseline characteristics

- age at surgery
- sex
- ethnicity
- socioeconomic deprivation index
- type of surgery (total hip replacement, hip resurfacing, total knee replacement or partial knee replacement)
- baseline digital literacy and access to smartphone or tablet
- baseline functional status
- baseline pain severity.

### Comparative effectiveness versus NHS current practice

- technology used
- start date and duration of use
- standard care in the comparable NHS site
- number and type of healthcare professional contact in each arm
- use of additional support.

### Health-related quality of life

- EQ-5D-5L score
- Oxford Knee Score (OKS)
- Oxford Hip Score (OHS)
- pain score
- functional mobility and range of motion
- return to usual activities
- complications requiring medical, surgical or escalation of rehabilitation services
- adverse events.

### Healthcare resource use

- length of stay (days)
- number of same-day discharge cases

- length and type of appointments (for example, phone call follow-up, app responses)
- number of physiotherapy sessions successfully completed
- number of face-to face reviews escalated for further support
- number of GP appointments related to rehabilitation
- number of emergency department attendances
- number of readmissions and root cause
- number of analgesic prescriptions.

### Patient engagement and adherence

- number of patients offered the technology and sign-up registrations
- number of logins per week
- number of exercises provided and number of exercises completed
- percentage of adherence to programme and reasons for engagement
- percentage of discontinuation to programme and reasons for discontinuation
- patient satisfaction with the technology
- adherence and discontinuation (presented by age, sex, deprivation status, type of surgery and digital literacy).

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, conduct, and reporting of real-world evidence studies.

## 3.5 Evidence generation period

The evidence generation period will be 3 years, to allow for enough time to set up and implement the technology, collect the necessary data, and analyse and report it.

## 3.6 Following best practice in study methodology

Following best practice in conducting studies is paramount to ensuring the reliability and validity of the research findings. Adherence to rigorous guidelines and established standards is crucial for generating credible evidence that can ultimately

improve patient care. The NICE real-world evidence framework details some key considerations.

Within the context of an early value assessment a key factor to consider as part of the informed consent process is to ensure that patients (and their carers, as appropriate) understand that data will be collected to address the evidence gaps identified in section 2. Where applicable this should take account of NICE guidance about shared decision making.

# 4 Monitoring

NICE will contact the companies:

- within 6 months of publication of this plan to confirm agreements are in place to generate the evidence
- annually to confirm 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 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

During the evidence generation period, new technologies may become available. This section summarises the minimum evidence requirements that a new technology would need to meet to be considered in the NICE evaluation after the evidence generation period.

The minimum evidence standards for this topic were informed by randomised controlled trial (RCT) evidence, company submissions, the external assessment group (EAG) report and the committee discussions. These sources provided an overview of the current clinical and economic evidence for digital platforms supporting preparation before and rehabilitation after primary elective hip or knee replacement surgery in the NHS.

The committee noted that, although evidence was available for some outcomes, including pain, joint-specific function, health-related quality of life, patient satisfaction and usability, there were important limitations in the current evidence base. Comparative evidence versus NHS current practice was limited, with many studies being single-arm or observational in design. Sample sizes were often small, follow-up periods were short, and findings were inconsistent across technologies and outcomes.

Evidence on healthcare resource use, including length of stay, physiotherapy contacts, emergency department attendance and readmissions, was limited or based on assumptions, creating uncertainty in the cost-effectiveness model. There was also limited evidence to determine which patient groups are most likely to benefit from these technologies.

Future studies should address these uncertainties by generating comparative evidence, measure health-related quality of life and quantify healthcare resource use and patient engagement in real practice. This data will support future decision making on whether these technologies should be routinely used in the NHS.

# 6 Implementation considerations

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

## Evidence generation

- The companies should provide training for staff in using the technologies, 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.

- Evidence generation should be overseen by a steering group that includes researchers, commissioners, practitioners and people with lived experience.
- The evidence generation process is most likely to succeed with dedicated research staff with sufficient expertise, to reduce the burden on NHS staff.
- Sites should be carefully selected to maximise data collection, when appropriate, and ensure that services representative of those in the NHS are included.
- Careful planning of the approach to information governance is vital. The companies should have appropriate structures and policies in place to ensure that the data is handled in a confidential and secure manner and in line with appropriate ethical and quality standards.
- Variation exists in local surgical pathways, including increasing use of ambulatory or same-day discharge surgery, when patients may receive little or no inpatient rehabilitation before discharge. This may disrupt the comparator pathway and its in-hospital physiotherapy resource use. These pathway differences should be captured and adjusted for in the analysis, particularly for the cost-effectiveness assessment.
- If there are changes in the pathway during the data collection period (for example, increase in ambulatory surgery), suitable evidence should be collected and submitted because it may influence outcomes, resource use and cost-effectiveness results.

## Equalities

- Variable levels of digital literacy and access to digital hardware or the internet, may affect the uptake and use of the technologies.

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