NICE National Institute for Health and Care Excellence

Evidence generation plan for digital platforms to support cardiac rehabilitation: early value assessment

Implementation support

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Contents

1 Purpose of this document

NICE's early value assessment of digital platforms to support cardiac rehabilitation recommends that more evidence is generated while the following technologies are being used in the NHS:

- Activate Your Heart
- D REACH-HF
- Digital Heart Manual
- Gro Health HeartBuddy
- KiActiv
- myHeart
- Pumping Marvellous Cardiac Rehab Platform.

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.

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 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

Clinical effectiveness

The impact of the technologies on intermediate and longer-term clinical outcomes in comparison with conventional care is uncertain. Further evidence is needed to assess clinical effectiveness of the technologies both when they are used alongside conventional cardiac rehabilitation, and when used alone in place of conventional cardiac rehabilitation. The impact on clinical effectiveness of changing from paper to digital manuals is also uncertain.

Evidence on intermediate clinical outcomes should include:

- patient-reported outcomes
- health-related quality of life
- exercise capacity or performance
- cardiovascular risk profile
- psychological wellbeing
- nutrition status

- medication adherence
- behaviour change.

Further evidence is needed on the longer-term clinical effects (for example secondary cardiac events, hospital readmissions, referrals to specialist services and clinic visits). Information on the longevity of any clinical benefits will provide a clearer indication of the accumulated benefits over time and support cost-effectiveness modelling. Length of follow up should cover the duration of the cardiac rehabilitation program (which is technology specific) and an additional 12 months or more, but ideally 18 months.

The committee noted significant variation in the measurements of outcomes, and highlighted that these should ideally be standardised. Suggested measurements for the clinical outcomes are detailed in section 3.4.

Resource and service impact

Early cost-effectiveness modelling was driven by cost savings from a reduction in face-to-face cardiac rehabilitation sessions. Further evidence is needed to support these analyses, particularly around the resource costs and system impacts of using the technologies compared with conventional care. This should include overall costs and the broader resource impact that cardiac rehabilitation has on the healthcare system during its use and at least 12 months afterwards, ideally up to 18 months.

Key areas that will help to address this evidence gap are:

- healthcare resource use associated with the technologies and NHS standard care, for example:
  - community, primary and secondary care appointments
  - hospital visits, admissions and readmissions related to cardiac events
- implementation costs, for example, set up and training costs, and staff time needed to support the service
- technology costs including licence costs.

Engagement and acceptability

More evidence on intervention uptake, adherence, completion and attrition rates (including reasons for stopping therapy) will support future cost-effectiveness modelling and help the committee assess the real-world uptake of the technologies. Evidence on user-reported outcomes including user preferences, usability and acceptability will also help assess how acceptable the technologies are for people who use them.

2.2 Evidence that further supports committee decision making

Uptake in different subgroups

The impact of the technologies on uptake of cardiac rehabilitation in different subgroups is unknown. Evidence is needed for user subgroups who may benefit from the remote and digital delivery of cardiac rehabilitation programs. These may include:

- people who may not be able to attend daytime in-person cardiac rehabilitation sessions (for example, people with work or caring responsibilities or people living in rural communities with long travel times to clinics)
- subgroups in which current uptake of cardiac rehabilitation is low (for example women, people under 65 years, people from deprived areas, people with psychological comorbidities, people whose first language is not English, and people from Black, Asian and other ethnic minority groups).

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; 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.

Table 1 Evidence gaps and ongoing studies

Technology	Clinical effectiveness	Resource and service impact	Engagement and acceptability	Uptake in different subgroups
Activate Your Heart	Limited evidence	Limited evidence	Limited evidence	No evidence
D REACH-HF	Limited evidence	Limited evidence	No evidence	No evidence Ongoing study
Digital Heart Manual	No evidence	Limited evidence	Limited evidence	No evidence
Gro Health HeartBuddy	Limited evidence Ongoing study	Limited evidence	Limited evidence	No evidence
KiActiv	Limited evidence Ongoing study	Limited evidence	Limited evidence Ongoing study	No evidence
myHeart	Limited evidence Ongoing study	Limited evidence	Limited evidence	No evidence
Pumping Marvellous Cardiac Rehab Platform	No evidence	No evidence	No evidence	Limited evidence

3.2 Data sources

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.

The National Audit of Cardiac Rehabilitation (NACR) is the data source that is most likely to be able to collect the real-world data necessary to address the essential evidence gaps. The audit collects data to support the monitoring and improvement of cardiovascular prevention and rehabilitation services. Currently, data is collected at the start and end of a cardiac rehabilitation program. The audit currently indicates if cardiac rehabilitation has included Activate Your Heart, or the manual or digital version of D REACH-HF or Heart manual. There are future plans to link patient-level data to other datasets such as the Hospital Episode Statistics and Office for National Statistics for collection of longer-term outcomes. Additional data collection is planned around the mode of delivery of cardiac rehabilitation as part of the audit.

Other useful sources of data are the National Institute for Cardiovascular Outcomes Research and the National Cardiac Audit Programme.

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.

Ongoing studies

There are 2 highly relevant, ongoing studies that may address some of the clinical effectiveness, resource-impact and service-impact evidence gaps. Both are due to end in 2025.

3.3 Evidence collection plan

The suggested approach to addressing the evidence gaps for the technologies is a real-world historical control study with propensity score methods. The study would compare outcomes before and after implementation of the technologies. Quantitative data for the

historical control arm is likely to exist in the NACR dataset. This dataset includes patient-level data such as components of cardiovascular risk profiles; exercise capacity; health-related quality of life; psychological wellbeing; and nutrition. The dataset also details service-user characteristics such as age, sex, ethnicity, geographical location and employment status, which will enable subgroup analyses. These baseline cohort differences may affect clinical outcomes and should be adjusted for in future analyses. In 2024, there were 40 services collecting 12-month assessment period data.

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 technologies.

Despite consistent eligibility criteria, non-random assignment to interventions can lead to confounding bias, complicating interpretation of the intervention effect. To minimise bias and identify a suitable control group, appropriate statistical approaches that balance confounding factors across comparison groups should be used, for example, propensity score matching. The comparator group of primary interest is cardiac rehabilitation face-to-face sessions, or a hybrid programme of in-person group-based and home-based programmes (including paper manuals, live online classes, home visits or telehealth) without digital cardiac rehabilitation technologies. NICE's real-world evidence framework provides further detailed guidance on the planning, conduct and reporting of real-world evidence studies assessing comparative effects.

3.4 Data to be collected

Study criteria

At recruitment, eligibility criteria for the suitability of the digital technologies for the participant and inclusion in the real-world study should be reported. This should include the referral pathway for participants. There should be detailed descriptions of each technology, including its training requirements, digital-safety assurance and its specific version.

Service-user characteristics and clinical outcomes

These should include:

- Information about individual characteristics at baseline, for example, sex, age, ethnicity, first language, medicines, diagnosis, comorbidities, socioeconomic status, and location, with other important covariates chosen with input from clinical specialists. Characteristics should include those needed for adjustment to address confounding, and for subgroup analysis.
- Measures recorded at baseline and follow up (at least 12 months later, ideally up to 18 months) of:
  - exercise capacity (for example the shuttle walk test)
  - cardiovascular risk profile (including blood pressure, weight, height, and cholesterol)
  - psychological wellbeing (Patient Health Questionnaire-9, Generalised Anxiety Disorder-7 or Hospital Anxiety and Depression Scale, Cardiac Distress Inventory-Short Form)
  - health-related quality of life (EQ-5D or Dartmouth COOP)
  - nutrition status (Mediterranean Diet Score tool)
  - medication adherence.
- Adverse events.

Resource and system use

This should include:

- time from post-discharge referral to start of core cardiac rehabilitation programme
- number and cost of face-to-face cardiac rehabilitation sessions (and details about the health professional including the banding of staff leading or supporting the sessions)
- referrals to other specialist services
- number of appointments in primary, secondary and community care
- costs of digital technologies for supporting cardiac rehabilitation, including:
  - licence fees

  - healthcare professional staff time, staff banding, and training costs to support the service
  - integration with digital NHS systems
  - implementation costs
- other technology costs.

Engagement and acceptability

This should include:

- usability and acceptability of the technologies
- intervention adherence, uptake, completion and attrition rates (including reasons for not using the technology).

It is also important to report and specify if any optional features of the technologies are being used (for example additional artificial intelligence modules) during evidence generation.

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

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

3.6 Following best practice in study methodology

It is important to follow best practice in conducting studies to ensure 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.

In the context of an early value assessment, a key factor to consider as part of the informed consent process is making sure 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's 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 period of evidence generation 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 committee heard that the digital platforms have comparable clinical effectiveness to conventional cardiac rehabilitation and that the technologies could increase access to cardiac rehabilitation in some populations. But the evidence for this is uncertain.

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

- non-inferiority of the digital platforms compared with conventional cardiac rehabilitation in terms of clinical effectiveness
- user engagement with the technology, including intervention acceptance, usability and completion rates
- cost savings resulting from resource use associated with the technologies.

Companies can strengthen the evidence base by also having evidence for uptake rates in different subpopulations.

6 Implementation considerations

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

System requirements

- Conventional cardiac rehabilitation may be offered by various healthcare professionals and involve multiple allied healthcare professionals. The mode of delivery of conventional cardiac rehab should be reported during evidence generation to minimise risk of bias and accurately assess costs for cost comparisons.

Evidence generation

- Data collection should ideally link to existing NHS infrastructure and to the NACR to avoid duplication and promote data standardisation.
- Issues with data quality may impact analysis. Clear reporting about data quality is important and approaches such as multiple imputation could be used to address issues.
- Trusts should take into account the costs of the digital technologies used in this assessment when implementing the technologies. When negotiating with companies, trusts should also consider the upfront costs for implementing a technology, staff and user training, integration with NHS systems and providing smart devices that need an internet connection.

Equalities

- Face-to-face cardiac rehabilitation sessions should be available for people with conditions that are not indicated for use with the digital technologies, or who decline using the technologies. Continued support from cardiac rehabilitation teams should still be offered to people who accept the technology.
- People who are eligible to use a technology in line with its intended use but who are excluded for any other reasons should be described in the reporting of future

evidence.

- There is a risk that using digital technologies could widen the gap in access to cardiac rehabilitation. Support and resources may be needed for people:
  - unfamiliar with digital technologies
  - without access to smart devices or the internet
  - with visual, hearing, or cognitive impairment, problems with manual dexterity or a learning disability
  - with a mental health condition
  - with a lower reading ability (including people who do not have English as a first language)
  - experiencing homelessness
  - living in a house in multiple occupation
  - having residential care.

Adverse events

- Reporting intervention-related adverse events is essential to assess any risk associated with the use of the technologies in the NHS.

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