NICE National Institute for Health and Care Excellence

Evidence generation plan for devices for remote monitoring of Parkinson's disease

Implementation support

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1 Purpose of this document

NICE's assessment of devices for remote monitoring of Parkinson's disease recommends that more evidence is generated while the technologies (Kinesia 360, KinesiaU, PDMonitor, Personal KinetiGraph and STAT-ON) are being used in the NHS.

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 are the preferred source of evidence if these are able to address the research gap and can be done well.

The companies are responsible for ensuring that data collection and analysis takes place. An approach to evidence generation is through formation of a consortium, bringing analytical partners and implementation sites together with companies.

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

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 (4 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 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.

2.1 Essential evidence for future committee decision making

Further evidence is needed to allow the committee to fully evaluate clinical and cost effectiveness, and the impact of using the technologies on carers.

Resource use

More information is needed on how using the technologies would affect resource use in the NHS and personal social services. Resource estimates should include training costs and the broader impact of the technologies on services provided by Parkinson's specialist teams and carers.

Impact on symptoms or health-related quality of life

The technologies could help management of Parkinson's disease and support better care decisions. To help understand this, evidence is needed on how much of an impact using the technologies has on symptoms or health-related quality of life for people with Parkinson's disease, and their carers. Also, it is unclear if the technologies can lead to sustained clinical benefit.

Use in the NHS

The technologies could be used in different ways in the NHS, for example:

- to indicate when non-routine review appointments are needed
- to help healthcare staff support people with symptoms that are difficult to manage

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- when people with Parkinson's disease have difficulty communicating about their symptoms.

Information is needed on how often and in what circumstances the technologies are currently used. This will help to inform evidence generation.

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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 diagnostics assessment 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

Evidence gap	Kinesia 360	KinesiaU	PDMonitor	Personal KinetiGraph	STAT-ON
Resource use	Limited evidence	Limited evidence	Limited evidence	Limited evidence	Limited evidence
Impact on symptoms or health-related quality of life	Limited evidence	No evidence	No evidence	Limited evidence Ongoing care pathway evaluation	No evidence
Use in the NHS	No evidence	No evidence	No evidence	No evidence	No evidence

In an ongoing evaluation, remote monitoring is being used to collect data every 6 months before remote review, in a supported self-management pathway (the University Hospitals Plymouth NHS trust's Parkinson's home-based care pathway). The pathway includes questionnaires on health-related quality of life; the Parkinson's disease Questionnaire (PDQ-39), a version for carers (PDQ-39-C) and the Unified Parkinson's disease rating scale (UPDRS) part 2. It also includes a non-motor symptoms questionnaire (NMSQ), and remote monitoring of motor symptoms with the Personal KinetiGraph.

3.2 Data sources

Data is likely to be needed from primary and secondary care services, as well as primary data for certain outcomes.

There are registries for Parkinson's disease, including local single-centre databases and

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national registries such as the Health Research Authority's ACCESS-PD, which may be valuable in setting up research studies.

Datasets derived from electronic health records with broader coverage (such as the Clinical Practice Research Datalink [CPRD], The Health Improvement Network [THIN], and NHS Digital's Hospital Episode Statistics [HES]) could be used to provide individual person-level data. These could be linked to cover primary and secondary care and may provide some useful information on health outcomes, resource use, and personal characteristics. Limitations of these datasets include it being challenging to know which people had used which technologies. Also, detailed data on symptoms, and on health-related quality of life using the EQ-5D, is not routinely collected and would not be included in real-world data from electronic health records.

Local or regional data collections such as the sub-national secure data environments could also be used to collect data. Secure data environments 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. The sub-national secure data environments are designed to be agile and can be modified to suit new projects, for example, facilitating quality-of-life data collection. These rich data environments may allow researchers to gain a comprehensive view of people's medical history, diagnoses, treatments, and outcomes related to management of Parkinson's disease as well as resource use.

Some data may also be generated through the technologies themselves, such as information on symptoms and some health outcomes.

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 broad coverage.

3.3 Evidence collection plan

The suggested approach to addressing the evidence gaps for the technologies is a systematic survey of their use across Parkinson's disease services over 3 months. The results could address the evidence gap on how the technologies are being used, or may be used, in the NHS. Companies could use these results to define the position of their technology in a clinical pathway. The clinical impact and resource use of using the

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technology in this way could then be investigated in a prospective parallel cohort study.

3.3.1 Survey of systematic use across Parkinson's disease services

Parkinson's disease clinical leads would be contacted to understand if and how the technologies are currently being used across the NHS. Information collected should include why the technologies are being used (for example, for people having issues with symptoms), how often they are used and in what setting (such as secondary care). The survey should also collect feedback from clinicians using the technologies on the optimal use and position of these technologies in clinical pathways.

3.3.2 Parallel cohort study

In a parallel cohort study, 2 or more groups of people are followed over time and their outcomes compared. For this study, the groups would be defined by the specific use of the technologies and a comparator group representing standard care. A parallel cohort design allows a large amount of data to be collected.

Uses of the technologies, based on discussions with clinicians and companies, could include:

- Clinical decision making for people whose Parkinson's disease is managed with oral medicines. For example, for triggering a consultation (especially relevant for people on a remote monitoring pathway) or for deciding whether to delay or start advanced treatment (such as apomorphine, duodopa, or deep brain stimulation).
- Optimally titrating medicines or adjusting stimulation settings after starting advanced treatment.
- Continuous monitoring for people with complex symptoms, dyskinesias or wearing off (when medicines are no longer working well enough).
- For people who are not able to accurately report their symptoms because of cognitive impairment or communication barriers.

The follow-up period will vary according to the use of the technology. For use with advanced treatments, evidence collection and modelling can be shorter than 4 years because clinical impact may appear sooner for people with more severe Parkinson's disease. For other uses, follow up may need to be longer, to fully capture the impact for

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people with Parkinson's disease and their carers. So, companies should consider whether enough data for the clinical use could be captured in the evidence generation period.

Data from sites using remote monitoring incorporating the technology can be collected prospectively. Ideally multiple sites should be enrolled, representative of the variety of care across the NHS. The comparator would be sites using standard care without remote monitoring. This could address the evidence gaps on clinical impact (including carer outcomes) and resource use and could provide more information on how the technologies are being used.

When more than 1 technology is in use, companies could collaborate and collect data comparing the technologies.

Incomplete records and potentially demographically imbalanced groups can lead to bias if unaccounted for. 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. 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

Data collection should address the evidence gaps, but may vary depending on the use of the technology being investigated.

When remote continuous monitoring is used, there is potential to miss clinical indicators of deterioration. Clinical outcomes should therefore be closely monitored and collected, with interim analyses and clear escalation plans specified in protocols.

Personal characteristics (to be recorded at baseline)

- Demographic information.
- A complete list of current medicines, with dosage.
- Comorbidities and medical history, including but not limited to, acute hospitalisations with diagnosis (such as hip fracture), neuropsychiatric diagnoses (such as depression,

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anxiety, delusions, hallucinations, impulse control disorder).

- Stage of Parkinson's disease.
- Current setting, for example, home or nursing home.
- Carer information.

Clinical impact

This data should be collected at baseline and over an appropriate period of follow up, which will depend on the use of the technology (for example, at 6 months and then yearly up to the end of follow up).

- Clinical benefit of the technology using validated clinical tools (Parkinson's disease specific: UPDRS, PDQ-39 or generic: EQ-5D).
- Functional disability using the Hoehn and Yahr scale.
- Cognitive impairment captured with a validated instrument (for example, the Montreal Cognitive Assessment test).
- Health-related quality of life for people with Parkinson's disease (EQ-5D or PDQ-39) and carers (PDQ-39-C).
- Incidence of falls and hip fractures.
- Acute hospital admissions, length of stay, and diagnosis (for example, hip fracture).
- Mortality and all adverse events, indicating those associated with use of the technology (for example, skin irritation).
- Estimate of clinical benefit by important subgroups, including people with communication barriers, cognitive impairment and people from ethnic minority or different socioeconomic backgrounds.

Resource use

- Number of face-to-face consultations and number of remote consultations (including specialist clinicians and nurses associated with the use of the technology, or other healthcare professional, and their NHS pay grade).

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- Number of inpatient days.
- Costs paid by people with Parkinson's disease when reimbursed by the NHS or personal social services (PSS), for example, nursing home admission and costs.
- Costs of the time used for care provided by family members, friends or a partner that might otherwise have been provided by the NHS or PSS, may be appropriate to consider, although this should be presented separately from other costs.
- Changes in medicine use associated with use of the technologies.
- All treatment used during the follow-up period including physiotherapy and exercise therapies.
- Cost of medicines.
- Nursing home placement.
- Training (for people with Parkinson's disease and healthcare professionals) and administration associated with the use of the technology (cost of failed reports will also be captured through administration cost or the recurrent costs associated with implementing these devices).
- Price of the technology (per person or per use).

Other information needed

- Information about standard care: access to more advanced treatments, type and frequency of face-to-face appointments.
- Information about the technologies: device used, the indications for use (the aim of the prescribing clinician in using the technology in the study), how often remote monitoring technologies are used (frequency of use), over what time periods (duration of use) and in which populations and settings. For example, single use or routine use, use before regularly scheduled appointments with healthcare professionals, after treatment changes to help titrate dosage, to indicate if a further review appointment with a healthcare professional is needed, or for people having issues with symptoms.
- Information should be provided on whether the technology was significantly changed or updated during the evidence generation process.

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3.5 Evidence generation period

It is likely that enough robust evidence could be generated within 4 years, depending on how the technologies are used in clinical practice.

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4 Monitoring

The companies must contact NICE:

- 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.

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5 Implementation considerations

The following considerations around implementing the evidence generation process have been identified:

- Survey results depend on comprehensive distribution across the NHS, and on the sample of respondents being representative of the target population. Data collection should be restricted to essential outcomes only and the survey widely distributed across the target population. It will be additional to existing workload and demands on staff.
- Large sample sizes may be needed to account for disease heterogeneity and capture the experiences of people from diverse socioeconomic and ethnic backgrounds or other subgroups of interest.
- A feasible study will balance the need to capture adequate data on clinical impact against the costs and complexity of a long data collection period, which may not be acceptable to people with Parkinson's disease and their families.
- Collecting more data beyond that routinely available, or extracting relevant data from electronic patient records of routine and acute care, needs dedicated research staff time. This must be factored into study budgets, plus clinical staff time for report interpretation and training.
- Clinicians need training on interpreting reports from these technologies and there will be a learning period that may need to be measured or accounted for.
- Although companies may provide training on interpreting reports, some centres have developed their own in-house protocol. For each technology, a standardised report interpretation template is necessary. A Delphi process could be run among clinical prescribers to generate a consensus statement and template before starting systematic evidence generation.
- Information governance and consent to share person-level data with the companies is variable. Local NHS governance rules stipulate different strategic level agreements and contracts. Differences in NHS trust guidelines and policies are a known barrier to delivering multisite trials. This will need to be anticipated and engaged with directly.
- The technologies perform differently for different movement parameters. Clinical

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prescribers who commented on the evidence generation plan said that remote continuous monitoring can be useful, but recognised there is a lot of variation in the way it is used. Capturing these views systematically in the survey may provide important feedback for the companies to inform product development and anticipate adoption challenges.

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