NICE National Institute for Health and Care Excellence

NICE guidance

Devices for remote monitoring of Parkinson's disease

HealthTech guidance
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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

This guidance replaces MIB258 and DG51.

1 Recommendations

1.1 Kinesia 360, KinesiaU, PDMonitor, Personal KinetiGraph (PKG) and STAT-ON are conditionally recommended as options for remote monitoring of Parkinson's disease to inform treatment if:

- further evidence is generated, including:
  - the impact on resources associated with using the technologies (for people with Parkinson's disease and their carers; see section 4.1)
  - the size of impact of using the technologies on symptoms or health-related quality of life (for people with Parkinson's disease and their carers) and how long this lasts for (see section 4.2)
  - how frequently the devices are used, and under what circumstances, in the NHS (see section 4.3), and
- cost impact is managed (see recommendation 1.2).

1.2 Commissioners should consider the available payment options for the technologies when deciding which to use (for example, pay per use, a subscription model or outright purchase). They should take into account the fact that the technologies may not be needed any more if further data shows they are not cost effective.

1.3 Clinicians should consider features of the devices and how they are used when identifying which may be most suitable for a person, particularly for people with restricted movement, missing limbs, or people who are frail or have cognitive impairment. Clinicians should also support people to set up and operate the remote monitoring devices if needed.

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.

Why the committee made these recommendations

Monitoring symptoms of Parkinson's disease is important to help clinicians make decisions about a person's care. But this can be difficult in current practice because symptoms can come and go and may be difficult to remember or describe. Review appointments may also be infrequent. Sometimes people with Parkinson's disease may struggle to accurately assess their symptoms, and how severe they think they are may differ from the view of their carer (care partner). More objective monitoring of symptoms is therefore an unmet need. Using these devices could help clinicians to better determine when changes to treatment are needed. This may help better manage symptoms of Parkinson's disease and improve quality of life for people with Parkinson's disease and their carers.

There is a lack of evidence about how much of an impact using the devices in the NHS would have on quality of life for both people with Parkinson's disease and their carers. The devices could help save NHS resources, but it is unclear by how much, and which resources. The amount of evidence for each device varies, and no studies compared 1 device against another. PKG has the most evidence, but how effective it would be when used in the NHS is not certain; this is because in the main trial, people who did and did not have the device had more check ups than they would in the NHS. The device was also used more frequently than would be expected in NHS care.

Having early conditional access to these technologies could improve management of symptoms and quality of life for people with Parkinson's disease and their carers. Data should be collected so that the clinical and cost effectiveness of the technologies can be fully assessed. So, the devices are conditionally recommended as an option to help monitor Parkinson's disease. Clinicians should take into account whether people need help to use the devices, and if 1 device is more suited to a person than others. The devices can only be used if the cost impact is managed by considering the different payment options for the technologies.

2 The tests

Clinical need and practice

Parkinson's disease

2.1 Parkinson's disease is a condition that affects the brain, resulting in a progressive loss of coordination and movement problems. It is caused by a loss of the cells in the brain that are responsible for producing dopamine, which helps to control and coordinate body movements. People with Parkinson's disease experience a range of motor symptoms, which can fluctuate in severity during the day and between days. Motor symptoms may include dyskinesia (involuntary movement), bradykinesia (slowness) and tremor; non-motor symptoms include sleep disturbances. Starting or adjusting treatment helps to control symptoms. However, these treatments can themselves cause motor-related side effects. An important consideration in decisions about treatment is the need to balance the benefits of treatment with the potential side effects.

Current care pathway

2.2 NICE's guideline on Parkinson's disease recommends that people diagnosed with Parkinson's disease are seen every 6 to 12 months to review their diagnosis. More frequent follow ups may be needed to optimise medication dosage, or for people who need more advanced treatments. Current practice for monitoring motor symptoms includes using validated questionnaires, history taking and clinical observation. It can be difficult to assess the symptoms of some people with Parkinson's disease because they can have difficulty communicating, remembering or recording their symptoms. Examination at a single point in time, for example at a clinic appointment, may over or underestimate symptom severity or incidence, given that motor fluctuations can vary over time.

Potential value of technologies

2.3 Devices that can monitor and record symptoms of Parkinson's disease could identify people who could benefit from changes to their care. By objectively measuring these symptoms over several days, the technologies may more accurately estimate a person's symptoms and help to inform medication decisions. At scoping, clinical experts highlighted that functionality to measure dyskinesia and bradykinesia was particularly important for this.

2.4 Better-informed treatment decisions could lead to improved quality of life. Improved motor symptoms could reduce falls and hip fractures. The technologies could also help improve communication between people with Parkinson's disease and clinicians when discussing symptoms and potential changes to care.

2.5 The technologies may also allow more remote monitoring of Parkinson's disease. This could help to alleviate the stress and anxiety of attending clinic appointments. Objective monitoring of symptoms could also reduce the length and number of clinic appointments, thereby freeing up NHS resources.

The interventions

2.6 The technologies all have remote monitoring capability, are automated monitors (do not require the user to perform tests), measure dyskinesia, help assess bradykinesia and can be used outside a clinical setting in the absence of a healthcare professional. The devices are intended for use together with clinical assessment. They have regulatory approval and are available to the NHS.

Kinesia 360

2.7 The Kinesia 360 motor assessment system (Great Lakes NeuroTechnologies) monitors movement to quantify motor symptoms and assess activity. The system comprises sensors worn on the wrist and ankle, a tablet, and a charge pad. Kinesia 360 measures various aspects of bradykinesia, dyskinesia and tremor. It has a 16-hour battery life, so typically someone will wear the sensors during the day and recharge the device overnight.

2.8 Algorithms are used to automatically calculate severity scores, which healthcare professionals can view through web-based reports. Data is automatically downloaded from the device and uploaded to the Kinesia Web Portal during recharging. The mobile application also includes electronic diaries for capturing patient-reported outcomes and customisable medication diaries.

2.9 Healthcare staff can be trained in Kinesia 360 in about 30 minutes. The monthly device subscription costs £224.

KinesiaU

2.10 The KinesiaU motor assessment system (Great Lakes NeuroTechnologies) comprises a smartwatch and smartphone application. Symptoms can be measured through continuous recording or through specific active tasks (which can be done while being monitored continuously). The system rates the severity of tremor, slowness and dyskinesia symptoms into good, mild, moderate and severe categories (averaged for the selected time range). The product is to be used only under the direction of a qualified clinician.

2.11 Reports can be produced throughout the day and over the course of days, weeks and months to assess response to therapy and activities. Users can view or share reports in real time using the smartphone application. Healthcare professionals can access reports remotely through the KinesiaU provider portal. The mobile application also includes customisable medication and exercise diaries, which can be added to the report.

2.12 Healthcare staff can be trained in KinesiaU in about 30 minutes. The monthly subscription costs £64 per patient.

PDMonitor

2.13 The PDMonitor system (PD Neurotechnology) consists of a SmartBox, 5 sensors and a PDMonitor mobile application. The sensors are worn on both wrists, both ankles and the waist, and acquire movement data for assessing motor symptoms. The system measures activity, posture, bradykinesia, freezing of gait, gait

disturbances, wrist tremor, leg tremor, dyskinesia and 'on' periods (when the Parkinson's disease responds to treatment and motor performance is normal) and 'off' periods (when medication becomes less effective). It also provides a summary of measured daily activity. The duration and frequency of use is decided by the healthcare professional.

2.14 The PDMonitor SmartBox is a docking station for charging the monitoring devices. It also collects, stores and processes data and uploads it to the PD Neurotechnology storage service. Healthcare professionals can access reports through the mobile application, which also includes medication, diet and self-reported symptom diaries.

2.15 The company offers training for healthcare professionals, and there is a user manual for the physician tool. The device can be purchased outright for £12,000. During consultation, the company added that an alternative pricing model is available: a yearly subscription of £350 per month, and discounts available based on volume.

Personal KinetiGraph (PKG)

2.16 The PKG Movement Recording System (Global Kinetics) is a wrist-worn PKG watch that continuously measures movement over a 6-day period. The PKG measures bradykinesia, dyskinesia, tremors, motor fluctuations, and immobility, and records when the watch is not being worn. It also monitors movement during sleep.

2.17 The PKG watch is returned by the user to the company (using a prepaid addressed envelope), which extracts the data and generates reports for users and healthcare professionals to view online. As well as providing the raw data, algorithm-generated movement scores are provided for the whole 6-day period. The report includes summary graphs showing measurements over time and a summary of results, along with a suggested target range for interpretation. The watch has medication reminders and users can record when they have taken their medication.

2.18 The company provides education and training to healthcare professionals. It

advises that healthcare professionals should review an average of 15 to 20 PKGs to be proficient, supported by an eLearning module, which takes approximately 1 to 2 hours. The device costs £225 per use per patient.

STAT-ON

2.19 The STAT-ON system (Sense4care) consists of a monitoring device, a base charger, a belt with a waist-worn inertia recorder attached, and a mobile application. The system must be configured by a healthcare professional through the mobile application. The smartphone application connects to the STAT-ON device via Bluetooth. Results are stored in its internal memory. The device measures dyskinesia, 'on' and 'off' periods, gait parameters (including bradykinesia and freezing of gait), falls, energy expenditure and posture. It does not measure tremor. The user wears the device for a minimum of 5 days (ideally for 7 days), totalling a minimum of 24 hours over the 5 days, to collect enough data. After this, a report can be generated.

2.20 The device collects data and uses algorithms to process it. It produces a report containing detailed data analyses, as well as summaries of activity and prevalence of symptoms during the monitored period. Healthcare professionals can download the report using the mobile application. The application also has medication reminders, and people can record when they have taken their medication.

2.21 Training sessions last 1.5 hours. Quick guides, videos and graphical training documents are provided for healthcare professionals to understand how the system is configured and how to interpret the report. The annual subscription cost is £1,600.

The comparator

2.22 The comparator is clinical judgement of motor and non-motor symptoms based on information including clinical history and patient diaries, which may include rating scale tools and activity trackers. The Unified Parkinson's Disease Rating Scale (UPDRS) and the Hoehn and Yahr scale can be used to describe and

assess symptoms related to Parkinson's disease.

3 Committee discussion

The diagnostics advisory committee considered evidence on Kinesia 360, KinesiaU, PDMonitor, Personal KinetiGraph (PKG), and STAT-ON for remote monitoring of Parkinson's disease from several sources, including a diagnostics assessment report and an overview of that report. Full details are in the project documents for this guidance on the NICE website.

People with Parkinson's disease could benefit from remote monitoring technologies

3.1 The external assessment group (EAG) identified 8 papers that reported patient or carer opinions on PKG, 2 papers on STAT-ON, 1 on Kinesia 360 and 1 on KinesiaU. Patient experts explained the potential benefits of easy-to-use and unobtrusive remote monitoring options for Parkinson's disease. This included contributing to a 'feeling of normality', prolonging a level of independence, acting as an urgency signal to accelerate further care, and reducing anxiety around in-person visits. It could also help with describing symptoms to healthcare professionals, which can be very difficult, particularly when trying to describe how symptoms change over time. A patient expert also explained that the reports the technologies generate can help them understand their condition. The committee noted that remote monitoring technologies could make remote care easier, so that healthcare professionals could do appointments by telephone or video call, so people did not have to travel as often to meet in person. This would reduce travel costs and could reduce how much their condition feels like a medical condition, particularly in the earlier stages. However, the patient experts said that the disease can be isolating for people with Parkinson's disease and their carers, and that face-to-face appointments can help with this. The committee also noted that the technologies may not be suitable for everyone with Parkinson's disease, for example for people who are particularly frail, use a wheelchair, are confined to bed, or have missing limbs or cognitive or sensory impairment. In some cases, additional support may be needed to help people to use the remote monitoring devices. The committee noted that the devices differ in how they work and where sensors are worn, so some may be more suited to some people than others, for example people with missing limbs or with restricted movement. It recognised

that offering face-to-face appointments is still essential, and that remote assessment would not replace this, but could offer more flexible options for care for some people. The clinical experts commented that the technologies should be considered as complementary to face-to-face appointments. The clinical experts emphasised the importance of making training and other user-support resources accessible, and making sure that they are suitable for people with hearing loss or visual impairment. The clinical experts also said that the time between review appointments can be very variable and prolonged, so having the option of using the remote monitoring devices could provide reassurance and a safety net for checking symptoms between clinic appointments. The committee concluded that devices for remote monitoring offer a range of potential benefits to people with Parkinson's disease.

Carers could benefit from remote technologies monitoring symptoms

3.2 The patient experts said that current methods of assessing symptoms can rely heavily on observations made by carers, and their ability to communicate these to clinical experts. The size of responsibility for this causes a lot of stress and anxiety, particularly as the condition progresses and if the carer is the main source of information about changes in symptoms. The person with Parkinson's disease and their carer may disagree about the extent of symptoms, which can be difficult. A technology that objectively reviews symptoms could help discussions and take pressure off the carer. The patient experts also said that if someone with Parkinson's disease does not have a carer living with them, or if their carer has cognitive issues, then the potential value of the technologies would be much greater. The committee recognised that a carer's quality of life is affected by the severity of Parkinson's symptoms, and the responsibilities of managing medication and hospital visits. The patient experts explained that caring for people with Parkinson's disease can mean that carers put off managing their own health issues, and that this can affect a carer's health-related quality of life considerably, and so increase costs to the NHS. Travel for in-person appointments can be difficult for carers who may need to take time off work, particularly if they are the only earner, so being able to use remote appointments more would help. The committee recognised that objective remote monitoring

technologies may help alleviate stress and anxiety for carers, assist in communication with healthcare professionals, and could save time at hospital appointments by providing a starting point for discussions. It concluded that it was important to consider any impact of the technologies on carers in its decision making.

The technologies could be used in many different ways in the NHS and how they would fit into the care pathway is not clear

3.3 The clinical experts explained that the technologies could be used in many different ways in the NHS. For example, 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 who are having issues with symptoms. They said that centres currently using these technologies did so in very different ways. The clinical experts noted that it was important that the technologies were integrated into care pathways, including training for clinical teams and for people with Parkinson's disease and their carers. This could mean that care pathways are changed. How the technologies would be used if adopted was not clear and could have a big impact on clinical and cost effectiveness. Studies identified by the EAG that compared the devices with standard care used the technologies in different ways: Woodrow et al. (2020) used the PKG at 5-week intervals for up to 25 weeks; Isaacson et al. (2021) used the Kinesia 360 to optimise rotigotine dosage when motor symptoms were not controlled well enough. There was little data showing the impact of the devices if they were used in ways that could be adopted by the NHS, for example to identify people who need a review appointment with a healthcare professional. The EAG explained that there was little evidence on the technologies when used in the UK. It also pointed out that how the technologies are used would affect how often they are used, and that this greatly affected cost-effectiveness estimates (see section 3.9). The committee concluded that the technologies could be used in many different ways in the NHS and how they would fit into the care pathway is not clear.

The level of care in Parkinson's disease varies and remote monitoring may become increasingly important

3.4 The clinical and patient experts explained that, although NICE's guideline on Parkinson's disease recommends that people with Parkinson's disease have a review every 6 to 12 months, this does not always happen in practice. They said the level of care varies across the NHS. The clinical experts added that the number of people with Parkinson's disease is increasing, which will place further pressure on the healthcare system. There are also backlogs for review appointments because of COVID-19 disruptions. Patient experts said the technologies could be a way for people with difficulties accessing services to have assessments. They said it was also a way to identify issues during the lengthy gaps between reviews (see section 3.1). The committee noted that the size of benefit of adopting the technologies may vary depending on current local care. It also noted that increasing pressures on NHS services may mean that the technologies are likely to become increasingly beneficial.

Clinical effectiveness

The reference standard in identified accuracy studies is imperfect and may underestimate technology performance

3.5 The EAG said that there is no clearly established reference standard for measuring Parkinson's disease symptoms, beyond clinician and patient assessment, that could be used to establish test accuracy. A potential benefit of the technologies is that they may more accurately evaluate symptoms than patient recall or clinical opinion, so a reference standard based on patient recall or clinical opinion (as used in accuracy studies identified by the EAG in its systematic review) could underestimate technology performance. The committee noted that accuracy estimates may not be the best outcome for assessing the performance of these technologies.

There is limited evidence on how much the technologies can

improve symptoms or health-related quality of life

3.6 Only 3 studies had data comparing clinical outcomes with the technologies against not using the technologies. Two of these (which assessed the Kinesia 360) were small randomised controlled trials. The largest study (which assessed the PKG and was by Woodrow et al.) reported clinical improvements in terms of statistically significant reductions in the Unified Parkinson's Disease Rating Scale (UPDRS) 3 (motor examination), UPDRS 4 (complications of therapy), total UPDRS score and PDQ-39 (Parkinson's Disease Questionnaire 39). The committee noted that the trial was not randomised. It understood that there could have been a systematic difference between the centres included in the trial and their catchment areas because people were allocated to PKG based on the centre they attended. The clinical experts also pointed out that the PKG was used every 5 weeks in the Woodrow et al. study, which would not be realistic in the NHS. Standard care in the study's comparator arms also may not represent NHS care. Because the length of follow up from the available studies was relatively short, there was also a lack of data on how long any benefit of the devices lasted once they were not used any more. Also, the EAG did not identify any data specifically on the populations who were identified in the scope as likely to have particular benefit from the technologies. These included people with communication barriers and people from black, Asian and minority ethnic family backgrounds, because symptoms can vary by family background. The committee concluded that, while the identified studies gave some indication of how the technologies could benefit people with Parkinson's disease, there was considerable uncertainty about the likely size of this benefit if the technologies were adopted in the NHS.

Most of the evidence is in people having maintenance therapy

3.7 The clinical and patient experts suggested that the technologies may be particularly useful for people who are eligible for more advanced therapies such as deep brain stimulation. But the EAG said the only evidence on the devices' comparative effectiveness was in the maintenance stage of Parkinson's disease. The committee understood that the devices may perform differently in these different populations.

How much remote monitoring devices would change decisions about care in the NHS is uncertain

3.8 The clinical experts said that, as well as changes to medication, symptoms can be managed with other changes to care like physiotherapy and exercise. Only the PKG had data on how the technologies can change decisions about care. The proportion of people who had a change in clinical management as a result of the PKG varied considerably (between 31.8% and 79%). A UK study reported that the PKG provided additional information in 45.5% of cases. In studies of clinician opinion, between 4% and 41% agreed that the PKG provided enough additional information to consider making treatment adjustments. The committee concluded that there was uncertainty about how much using remote monitoring devices would change care for people in the NHS.

Cost effectiveness

Device cost is a major driver of cost effectiveness

3.9 In the EAG's model, the intervention arm resulted in a higher cost than standard care. Device cost had the biggest impact on this. The EAG said that the device cost depended on how the devices were modelled as being used (see section 3.3) and the cost per use. The technologies have differing payment mechanisms: pay per use, a subscription model or outright purchase of the device. The committee noted that the payment options differed in terms of upfront investment and how reversible a decision to use a technology would be. The committee recalled that the technologies could be used in various ways in the NHS and noted that the EAG had modelled use at varying frequencies. This included one-time use (at baseline) and routine use (every 6 months) in its base cases, and a recurrent use scenario analysis (at 6 and 18 months in place of clinic appointments). How frequently the technologies were used substantially affected device-related costs and the cost-effectiveness estimates.

Because of the uncertainty about the devices' impact on health-related quality of life, their cost effectiveness is also uncertain

3.10 The committee recalled that there was uncertainty about the size of impact that device use would have on symptoms if used in the NHS (see section 3.6). The EAG used the Woodrow et al. trial to inform the estimates of health-related quality of life in its model. It also had to make assumptions about how long any benefit would last after using the devices. Sensitivity analyses showed that the cost-effectiveness estimates were very sensitive to this assumption. The committee concluded that the size and longevity of the benefits of device-guided decisions about care was very uncertain, and consequently so were the cost-effectiveness estimates produced by the EAG's model.

Chaudhuri et al. (2022) is likely to have overestimated how device use would affect resource use and how long any benefit would last for

3.11 Cost-effectiveness modelling reported by Chaudhuri et al. (2022) estimated that the PKG would be cost saving by £17,362, whereas in the EAG's model the PKG incurred costs. Both models compared the PKG with standard care. The committee questioned the approach used in Chaudhuri et al., which took scores with PKG use on the UPDRS from Woodrow et al. and converted them to the Hoehn and Yahr scale. They then used this to calculate resource costs. The committee noted that the EAG had been unable to verify or validate the approach used by Chaudhuri et al. It was also not clear if the symptom improvements observed from using the technologies could realistically translate into the large-scale changes in healthcare use predicted by this model. A clinical expert said that it was very unlikely that remote monitoring devices would have the effect shown on the Hoehn and Yahr scale. The EAG added that in Woodrow et al., device use did not have a statistically significant effect on the Hoehn and Yahr scores (-0.044, standard error 0.097 for adjusted data). It also said that in the Chaudhuri et al. model, the PKG's effect on symptoms was assumed to last for 5 years with only limited waning of effect after that, although there was no evidence for this. Clinical experts noted that there are no disease-modifying treatments available for Parkinson's disease that can stop progression. The committee concluded that the Chaudhuri et al. model was likely to have

overestimated how much the PKG can reduce healthcare-associated resource costs, and how long the benefit from PKG-guided care on symptoms would last for.

The broader impact of remote monitoring device use on resources is uncertain

3.12 A UK survey reported that people with Parkinson's disease interact with 18 different healthcare professions. The EAG had suggested that more data on this could identify further areas in which remote monitoring device-aided care could reduce costs. The patient experts also explained that the cost of providing care to people with Parkinson's disease can differ significantly according to whether they have a live-in carer, a paid carer or no carer at all. Costs related to social care were not included in the EAG's model because of a lack of data. Any impact of remote monitoring devices on these costs, for example delaying when someone with Parkinson's disease goes into a care home, could have been missed. The companies said that the EAG's model did not include costs related to falls and hip fractures prevented, which they said could be an uncaptured benefit if the devices did improve symptom management. The EAG explained that there was a lack of data to inform this. Also, because of a lack of data, its analysis was constrained to the management phase of Parkinson's disease. It understood that falls, hip fractures and social care costs are largely confined to the advanced stages of the disease. The committee concluded that the EAG's model may have underestimated the impact of using remote monitoring devices on some resources and associated costs. However, other costs related to implementing the devices, for example interconnectivity, may be higher in practice.

The EAG's model did not capture the potential impact of remote monitoring on carers

3.13 The committee recalled that remote monitoring devices could benefit carers (see section 3.2). But, because of a lack of data, the EAG's model did not include costs or health-related quality of life for them. The committee noted that relatively small improvements in quality-adjusted life years (QALYs) resulting from device use (perhaps related to carer benefits) could have a large impact on the cost-

effectiveness results, depending on the analysis used. The committee concluded that there was considerable uncertainty about how much the remote monitoring devices could affect carers, and noted that this had not been captured in the EAG's model.

The value of the technology may be underestimated, or was not estimated, by the EAG's model for some groups

3.14 There was not enough evidence for the EAG to be able to do subgroup analyses for people who have communication barriers, people from black, Asian and minority ethnic family backgrounds, or people from different socio-economic backgrounds. These populations were identified at scoping as being potentially likely to gain additional benefits from the technologies. The patient experts noted that remote monitoring may also benefit people who are having difficulty attending consultations, or getting care because services are at full capacity. The EAG had also not been able to model how remote monitoring devices might work for people being considered for advanced therapies such as deep brain stimulation, because there was not enough evidence.

Remote monitoring technologies have considerable promise, but more data is needed to estimate their true cost effectiveness

3.15 The committee recognised the promise that remote monitoring devices offer to people with Parkinson's disease and their carers (see section 3.1 and section 3.2). These devices could also help with increasing capacity pressures on the NHS. But their cost effectiveness is very uncertain, and to estimate it more accurately, there are several areas of uncertainty for which more data is needed (see section 4). The PKG has the most evidence, but the committee recalled that there was uncertainty about how well data from the main trial for this technology (Woodrow et al.) represents how well the device would work in the NHS (see section 3.6). The committee noted that the technologies differed in how sensors are worn (see sections 2.6 to 2.21) and the algorithms they use. Because of this, the EAG stated that clinical benefits observed for 1 technology could not be assumed for the other technologies. No identified studies compared the performance of 1 technology against another. A lot of identified data was on test accuracy. The

committee recalled its concern about the suitability of accuracy estimates for assessing the performance of these technologies (see section 3.5). It also recalled the uncertainty in how much remote monitoring devices would change decisions about care in the NHS (see section 3.8). The committee concluded that, to assess performance, further data is needed for all technologies on the size of impact of using all of the technologies on symptoms or health-related quality of life (see section 4.2).

The remote monitoring technologies can be used in the NHS while further data is collected

3.16 The committee considered the risks associated with using the technologies in the NHS while further data is collected. The clinical and patient experts said that their main concern about potentially worse patient outcomes was if use of the devices was poorly implemented. For example, if they were used to entirely replace face-to-face appointments, and were not integrated into care pathways. They also said that remote monitoring devices were already being used in some NHS centres. The committee noted that the overall cost impact of using the devices was uncertain and was largely dictated by how much the companies charged, and the different payment mechanisms (see section 3.9). The committee concluded that this was important for commissioners to consider, because the devices were likely to differ in terms of ongoing or irrecoverable costs if a later decision was made to stop using the technologies, for example if further data collection showed they did not work as well as anticipated.

Research considerations

More data collection is needed in populations that represent the potential use and benefits of the devices in the NHS

3.17 There was no or limited data for several populations who could particularly benefit from the remote monitoring technologies (see section 3.14), including people who might be helped by advanced therapies.

4 Evidence generation recommendations

More data on how much remote monitoring devices affect resource use would help decision making

4.1 There is uncertainty about how much remote monitoring devices would affect resource use in the NHS and personal social services. Some impacts may not have been included in the external assessment group's (EAG) model because of a lack of data (see section 3.12), including resource use related to carers (see section 3.13). Adopting the technologies may change how care is provided (see section 3.4) so their effect on resources is hard to estimate without direct data. So, the committee recommended collecting data on how much using the devices affects resource use, to inform cost-effectiveness estimates. Data on time dedicated to training and spent reviewing device results should also be collected. The broader impact on services provided by Parkinson's specialist teams and carers should be considered.

More data to help inform estimates of the impact on health-related quality of life would help decision making

4.2 How much using remote monitoring devices to guide decisions about care affects symptoms, and therefore health-related quality of life, is uncertain. How long after using the devices any impact would last is also uncertain. This had a sizeable influence on cost-effectiveness estimates (see section 3.10). Data on this came from studies that did not represent likely NHS practice (see section 3.6), which is itself uncertain (see section 3.3), and from assumptions made by the EAG because of lack of data. For its model, the EAG used a published algorithm from Chandler et al. (2020) to estimate quality-adjusted life years (QALYs) from the Unified Parkinson's Disease Rating Scale (UPDRS) domain scores. The clinical experts said that health-related quality of life questionnaires like the PDQ-39 are increasingly used in trials to assess health-related quality of

life for people with Parkinson's disease. The committee also recognised that the effect of the devices on the health-related quality of life of carers had not been included in the EAG's model because of a lack of data (see section 3.13).

Data should be collected on how often the remote monitoring devices are used and for what reasons

4.3 How frequently the remote monitoring devices were modelled as being used substantially affected the cost-effectiveness estimates in the EAG's model (see section 3.9). There are many ways the devices could be used in the NHS (see section 3.3) and no data was available to compare different approaches. So, it is currently not possible to highlight particular approaches that are likely to be more clinically and cost effective. Centres using the devices should therefore collect data on how often they are used and under what circumstances. For example, regularly in advance of scheduled review appointments, to indicate when such appointments are needed, or targeted to people having issues with symptoms. This will help assess the clinical and cost effectiveness of the different uses of the devices in NHS practice.

5 Implementation

NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice.

In addition, NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be considered for developing specific research study protocols as appropriate. NICE will also incorporate the recommendations for research in section 4 into its guidance research recommendations database and highlight these recommendations to public research bodies.

6 Diagnostics advisory committee members and NICE project team

Committee members

This topic was considered by the diagnostics advisory committee, which is a standing advisory committee of NICE.

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

The minutes of each committee meeting, 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 for this topic:

Specialist committee members

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NICE project team

Each diagnostics assessment is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

Vera Unwin
Topic lead

Thomas Walker
Technical adviser

Toni Gasse
Project manager

Update information

January 2024: 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.

Minor changes since publication

December 2025: Diagnostics guidance 51 has been migrated to HealthTech guidance 657. The recommendations and accompanying content remain unchanged

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