NICE National Institute for Health and Care Excellence

Evidence generation plan for KardiaMobile 6L for measuring cardiac QT interval in adults having antipsychotic medication

Implementation support

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1 Purpose of this document

NICE's assessment of KardiaMobile 6L recommends that further evidence is generated while it is 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 technology again in the future. It is not a study protocol.

The technology developer is responsible for ensuring that data collection and data analysis takes place. Support for evidence generation will be available through a competitive process facilitated by the Office for Life Sciences, pending business case approval. This will be in the form of funding for evidence generation consortia, bringing analytical partners and implementation sites together with developers for evidence generation.

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

NICE will withdraw the guidance if the technology developer does not meet the conditions in section 4 on monitoring.

After the evidence generation period (3 years), the developer 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 technology 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 their evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. Addressing these will help the committee to make a recommendation by better understanding the patient or healthcare system benefits of the technology.

2.1 Essential evidence for future committee decision making

Testing and interpretation

Addressing these evidence gaps is necessary to understand the resource use impact:

- how long it takes to do the test and get the QT interval result using KardiaMobile 6L and a 12-lead electrocardiogram (ECG) device
- how often ECGs are interpreted by different healthcare professionals, and by different services, when using KardiaMobile 6L and a 12-lead ECG device
- how often QT interval measurement is repeated using a 12-lead ECG device after using KardiaMobile 6L and why.

Diagnostic accuracy

This evidence is needed to ensure that KardiaMobile 6L is effective in measuring QT interval in adults having or about to have antipsychotic medication.

Time to antipsychotic medication and impact of ECG result

Evidence is needed on how long it takes before antipsychotic medication is started,

whether having an ECG delays this, and whether any treatment changes are made after the ECG result. Differences in how long it takes to do the test, who interprets the ECG, and the number of repeat tests (see the section on testing and interpretation) may also affect the time to antipsychotic medication.

In addition to diagnostic accuracy (see the section on diagnostic accuracy), evidence is needed on whether QTc measurements from a 12-lead ECG device and from KardiaMobile 6L lead to different treatment decisions.

2.2 Evidence that further supports committee decision making

Uptake of KardiaMobile 6L

To understand the impact on resource use, evidence is needed on how many people having antipsychotic medication choose to have their QT interval measured using KardiaMobile 6L. This information may also be useful for future health economic modelling.

Prolonged QT interval and ECG uptake

For future health economic modelling, it would be useful to know:

- how common prolonged QT is in people having antipsychotic medication
- how many people who need an ECG to measure QT interval for having antipsychotic medication have one.

3 Approach to evidence generation

3.1 Ongoing studies

There are 4 ongoing studies assessing KardiaMobile 6L in cardiology settings. The generalisability of these to a psychiatric setting, in people having or about to have antipsychotic medication, is limited. No further ongoing studies that could address the evidence gaps for this evaluation have been identified.

3.2 Real-world data collections

Local or regional data collections, such as the sub-national secure data environments, which measure outcomes specified in the evidence generation plan, could be used to collect data that addresses the evidence gaps. 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 NHS Mental Health Services Data Set (MHSDS) is a mandated national data collection that could potentially collect the necessary data. But it may not routinely collect all the outcome measures identified in the early value assessment. Also, there are potential issues with data quality and whether data on all people who are eligible are included. NHS England has suggested that modification of MHSDS may take up to 2 years, so it is unlikely that it could be modified in time to support data collection.

The evidence base for this evaluation included information from 2 Academic Health Science Network pilots that implemented this technology in 2 mental health trusts. Real-world data from local electronic health records of trusts implementing the technology, collected retrospectively, could provide information to supplement the clinical and economic evidence generated.

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 generation plan

Diagnostic accuracy study

This could be done as a diagnostic cross-sectional study in people having or about to have antipsychotic medication in a psychiatric setting. The study should attempt to enrol a representative population, that is, people who would be expected to be offered the test in the real world.

The study would compare agreement between KardiaMobile 6L and 12-lead electrocardiogram (ECG) device results (the reference standard). When both tests are successfully done, it would be possible to report measures of accuracy for diagnosis of prolonged QT (including sensitivity, specificity, negative predictive values and positive predictive values) and concordance for QT length and QTc measurements. Test results should be interpreted without knowledge of the results of the other test (for both KardiaMobile 6L and 12-lead ECG device) and reflect use and interpretation by specialities or healthcare professionals in a real-world setting. Information should be provided on whether results were calculated manually or generated by the device.

A user preference survey embedded in the study could assess the preferences and acceptability of KardiaMobile 6L.

Real-world implementation study

This study could compare impact on services before and after implementing KardiaMobile 6L. Prospective data collection in the period before and after implementation of KardiaMobile 6L may be required to ensure sufficient data quality. Baseline characteristics should be reported for all people included in this study.

To adequately assess impact, it is important that the context and clinical pathway within which the technology is evaluated in the study reflects how it will be used in routine practice.

3.4 Data to be collected

The following information should be collected in the suggested studies:

- time to complete the test and get the QT interval result (including set up, ECG recording, QT measurement and correction calculation, reporting time)
- grade of NHS professional and different services involved in doing and interpreting the ECG when using KardiaMobile 6L and 12-lead ECG device
- accuracy of the technology for diagnosing prolonged QT interval
- concordance for QT length and QTc measurements between KardiaMobile 6L and 12-lead ECG device
- number and proportion of technical failures (how often results were insufficient for decision making or needed to be repeated for both KardiaMobile 6L and 12-lead ECG device)
- number and proportion of people who refused either test or for whom it was not possible to do the tests
- number and proportion of people eligible for an ECG test (for example, having antipsychotic medication) who have one
- number and proportion of people who have KardiaMobile 6L compared with 12-lead ECG device in the first instance
- number of times the ECG was repeated using a 12-lead ECG device after using KardiaMobile 6L
- among those who have not yet started treatment, time from initial referral for either test to antipsychotic prescription
- treatment decision (to start medication, stop medication, reduce dose, switch antipsychotic medication or continue medication) after ECG result
- training and implementation costs
- information on baseline factors such as age, sex, medications, conditions needing antipsychotic medication, and comorbidities including any previously known cardiac abnormalities or heart disease; it should be clear whether the person has already started antipsychotic medication prior to ECG testing
- specific antipsychotic medications should be reported; this could allow for subgroup analysis, for example, for medications that have a greater risk of QT prolongation

- overall prevalence of prolonged QT in people having antipsychotic medication.

3.5 Evidence generation period

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

4 Safety and monitoring

4.1 Safety

NICE's patient safety oversight group recommends that time to antipsychotic medication and impact of electrocardiogram (ECG) result are monitored as safety indicators.

NICE and the Medicines and Healthcare products Regulatory Agency (MHRA) should be notified of any data collected that could indicate a safety concern, and the proposed response.

4.2 Monitoring

Technology developers 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.

Technology developers 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
- significant changes to the technology that affect the evidence generation process.

If data collection is expected to end later than planned, the technology developers should contact NICE to arrange an extension to the evidence generation period. NICE will withdraw the guidance if data collection is delayed without reasonable justification, or it is unlikely to resolve the evidence gaps.

5 Implementation considerations

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

General

- Developers should provide training for staff to support use of the technology.
- The evidence generation process is most likely to succeed with dedicated research staff to reduce the burden on NHS staff, and by using a suitable real-world data source to collect information when possible.
- Evidence generation should be overseen by a steering group including researchers, commissioners, practitioners and representatives with experience working with or caring for people with psychosis or taking antipsychotic medication.
- Evidence generation should ideally be across multiple centres. Contributing services or centres should be chosen to maximise the generalisability of evidence generated, or to improve data collection for any relevant subgroups.
- Careful planning of approaches to information governance is vital.

Topic specific

- It will not be possible to collect data for people having antipsychotic medication who are unable to give informed consent.
- KardiaMobile 6L needs to connect to the internet to transmit electrocardiogram (ECG) data to healthcare professionals. This may not be possible for some home visits.
- Saving and sending information could be a risk to data protection and information governance if not done correctly and with encrypted NHS mobile devices.
- Calculations from 12-lead ECG devices could vary, for example, because of different machine calibrations. Quality assurance could be provided by verifying a sample of QTc results from a 12-lead ECG device with manual calculation.

- Currently, QTc is measured manually by healthcare professionals when using KardiaMobile 6L. Availability of validated software for automatic QTc measurement can reduce time for testing and reporting.

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