

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

DIAGNOSTICS ASSESSMENT PROGRAMME

Early value guidance consultation document

**KardiaMobile 6L for measuring cardiac QT
interval in people having antipsychotic
medication**

The National Institute for Health and Care Excellence (NICE) is producing early value guidance on using KardiaMobile 6L. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts. This topic is the first pilot using the new early value assessment approach. The aim of early value guidance is to provide quicker conditional recommendations from NICE on promising medical technologies while uncertainty in their evidence base is being addressed.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered and sets out the evidence generation recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read with the [evidence](#) (an early value assessment report, cost and resource use report).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been considered?
- Are the summaries of clinical effectiveness, costs and resource use reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for early value guidance to the NHS?

NICE would also welcome comments on the style and presentation of this guidance and how suitable it is for informing practitioners, commissioners and managers in the NHS.

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on people with a particular disability or disabilities.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on KardiaMobile 6L for measuring cardiac QT interval in people having antipsychotic medication. The conditional recommendations in section 1 and the accompanying points on evidence generation in section 4 may change after consultation.

After consultation, NICE will consider the comments received. The final recommendations will be the basis for NICE's early value guidance on using the technology with evidence generation.

Key dates:

Closing date for comments: 25 August 2022

1 Recommendations

1.1 KardiaMobile 6L is conditionally recommended for use in psychiatric services, as an option to measure cardiac QT interval for people having or about to have antipsychotic medication only if:

- a repeat QT interval measurement using a 12-lead electrocardiogram (ECG) device is offered to women who have corrected QT interval (QTc) longer than 470 milliseconds, men who have QTc longer than 440 milliseconds, and people who have an intersex condition or biological therapies relating to gender transition and QTc longer than 440 milliseconds,
- training for healthcare professionals on recording an ECG, and measuring and interpreting QT interval is provided
- further evidence is generated (see section 4), and
- people are offered information about why this testing is done and why testing may be repeated using a 12-lead device after it has been measured using KardiaMobile 6L.

Why the committee made these recommendations

Detecting cardiac abnormalities such as prolonged QT interval in people having antipsychotic medication is important because some antipsychotics can prolong the QT interval and lead to severe cardiac events. There is an unmet clinical need for a more easily accessible and available QT interval measurement in the psychiatric service setting. KardiaMobile 6L has the potential to improve care for service users and to help NHS services to ensure timely ECG testing is available for all while creating more efficient care pathways. In particular, the absence of physical leads may make the test more tolerable for service users.

There is a lack of evidence around how well using KardiaMobile 6L works for measuring QT interval in the psychiatric service setting. There may be differences between a psychiatry population and other populations for example in the ability to sit still or having tremor, which could affect the readings given by the device. How

accurate the ECG interpretation is (measuring QT length, calculating QTc, and deciding whether QT is prolonged) may also differ between professionals in different settings. Most evidence on KardiaMobile 6L is in cardiology services. Because of these differences in populations and in healthcare professionals' experience with ECGs, there is a need for a diagnostic accuracy study in the psychiatric service setting.

After reviewing the available evidence, the committee with its clinical experts noted that there may be some differences in the results obtained from measuring a QT interval from KardiaMobile 6L compared with a 12-lead ECG. To reduce the potential effect of false negatives, it decided that a QT interval longer than the relevant specified threshold in section 1.1. should be verified. It is expected that these people will have a 12-lead ECG in a timely manner, and that the number referred should not create an adverse effect on services.

Having early, conditional access to the technology could help people having antipsychotic medication get faster access to safe and effective antipsychotic treatment. Data should be collected so that a full assessment of the clinical and cost effectiveness of the technology can be done. Therefore, KardiaMobile 6L is conditionally recommended for use with evidence generation in psychiatric services as an option to measure QT interval in people having antipsychotic medication. It can only be used if people who need them have access to repeat 12 lead ECGs.

2 The technology

The technology

2.1 KardiaMobile 6L (AliveCor) 6-lead, handheld, electrocardiogram (ECG) device.

The comparator

2.2 12-lead ECG device.

Clinical need

- 2.3 People taking antipsychotic medication may need to have tests for cardiac abnormalities before starting treatment and at regular intervals during treatment. Detecting cardiac abnormalities such as prolonged QT interval can inform choice of therapy, dosing, whether to stop therapy, and potentially avoid severe cardiac events.
- 2.4 QT interval is usually measured using a 12-lead ECG device to record the ECG. This needs the person to partially undress and use conductive gel on the skin to create contact with the electrodes. This can cause reluctance and distress. An ECG is recorded in primary or secondary care centres.
- 2.5 The KardiaMobile 6L allows ECG recording with less need for undressing and without using conductive gel. KardiaMobile 6L ECG can be recorded during a routine home visit by a community health professional. This may reduce stress and anxiety.

3 Committee discussion

The [diagnostics advisory committee](#) considered evidence on KardiaMobile 6L for measuring QT interval from several sources, including an early value assessment report, cost and resource use report and an overview of the reports. Full details are in the [project documents for this guidance](#).

Having access to less intrusive QT interval measurement with flexibility around the time and place of the appointment is important

- 3.1 Psychiatric service user experts explained that it is important for people to have their QT interval measured and to understand that this is done to make sure the antipsychotic medication that is offered is suitable for them. This is important both in the acute phase of their condition and for ongoing monitoring. The service user experts noted that because antipsychotic medication has side effects, having flexibility around the time and place of the electrocardiogram (ECG) appointment is important. In a recent NHS

pilot in community and inpatient wards, service users found having an ECG with KardiaMobile 6L more comfortable than with a 12-lead device, said KardiaMobile 6L was easier to use, preferred it for dignity and privacy, and considered 12-lead ECG to be more intrusive than KardiaMobile 6L. The committee recognised that it is important to offer QT interval measurement to people at a place and time they can attend and in a way that they feel comfortable. It acknowledged that offering information about why QT interval is measured is important.

There is an unmet clinical need for an easily accessible and available QT interval measurement in the psychiatric service setting

3.2 Clinical experts explained that QT interval is not always measured before people start having antipsychotic medication. ECG recording or interpretation may not be available during the appointment so service users may need to travel to another place or the recording may need to be sent elsewhere for interpretation. The ECG appointment and results may not be readily available. This could delay starting antipsychotic medication, an alternative medication that is potentially less effective but has less cardiac risk may need to be offered, or the decision to offer the most suitable antipsychotic medication may need to be made without the information about the cardiac risk related to the QT interval length. The clinical experts noted that to offer QT interval measurement in psychiatric services, staff training to record and interpret ECGs is essential.

Clinical effectiveness

There is limited evidence on using KardiaMobile 6L for measuring QT interval in people having antipsychotic medication

3.3 The committee considered the available evidence for using KardiaMobile 6L for measuring QT interval in people having antipsychotic medication. It noted that the external assessment group's (EAG's) review found no published evidence in this population. The only evidence

available in this population was unpublished reports of survey data from 2 recent NHS pilot projects.

Concordance data does not provide enough information to determine how well using KardiaMobile 6L works for measuring QT interval

3.4 The EAG's review found 8 published studies that evaluated the technical performance of KardiaMobile 6L compared with a 12-lead device. Instead of diagnostic accuracy to detect prolonged QT interval, these studies reported on concordance (how closely the QT interval measurements from the 2 devices matched each other). The mean difference in corrected QT interval (QTc) between the 12-lead device and KardiaMobile 6L was generally small. But in 1 study (Azram et al. 2021), the QTc results from the 2 devices for some people differed by over 50 milliseconds. A further study (Kleiman et al. 2021) reported that the absolute difference in QTc was 40 milliseconds or more in 5% of the people. Across all the studies, the apparent direction of the difference in results suggested that on average KardiaMobile 6L slightly underestimated the QT interval length. But the committee further noted that the Bland–Altman plots from the Kleiman et al. study showed that the KardiaMobile 6L results were biased both ways. This error could be related to the ECG trace and largest in people at highest risk from medication that can prolong the QT interval. The committee concluded that the concordance data did not provide enough information to determine how well using KardiaMobile 6L to measure QT interval worked compared with using the 12-lead device.

Data from KardiaMobile 6L technical validation studies in other settings may not be generalisable to the psychiatric service setting

3.5 None of the 8 technical validation studies included people having antipsychotic medication. The committee noted that because of risk factors for prolonged QT such as advanced age, sex, heart disease and using certain medications, the prevalence and levels of normal and prolonged QT may differ in different populations. Also, there may be differences between people having antipsychotic medication and other

populations for example in the ability to sit still, having tremors and flexibility of fingers, which could result in lower quality ECG readings from the KardiaMobile 6L device. The committee further noted that how accurate the QT interval measurement depends on the accuracy of ECG interpretation (measuring QT length, calculating QTc, and deciding whether QT is prolonged) which may differ between professionals. The clinical experts explained that in many 12-lead devices this is automated but in KardiaMobile 6L it is currently done manually which can affect the accuracy. The committee noted that in the 8 technical validation studies, ECGs were interpreted by 1 or more cardiologists rather than a psychiatric nurse or a psychiatrist who is likely interpret an ECG in a psychiatric service setting. The committee concluded that data from KardiaMobile 6L technical validation studies in other settings may not be generalisable to the psychiatric service setting.

Having data on treatment decisions would allow for a linked evidence approach in future cost-effectiveness modelling

3.6 The evidence for KardiaMobile 6L did not report on treatment decisions, psychiatric or cardiac outcomes or health-related quality of life. Clinical experts explained that the association between antipsychotic medication, QT prolongation and cardiac risk was well established. The committee noted that in addition to diagnostic accuracy, it would be helpful to understand whether any differences in QTc measurements from a 12-lead device and from KardiaMobile 6L lead to differences in treatment decisions. The committee concluded that if further data on treatment decisions was collected, this could be linked to the evidence on antipsychotic medication, QT prolongation and cardiac risk in a future NICE assessment evaluating the cost effectiveness of using KardiaMobile 6L. Information about how many people who need an ECG to measure QT interval for having antipsychotic medication in current practice have one and how common prolonged QT interval is would also be useful for future health economic modelling.

Costs and resource use

Differences in the time to do the test, who interprets the ECG, and the number of repeat QT interval measurements may affect costs

3.7 Several resource use and cost parameters were identified as relevant for future economic modelling. The committee noted that the parameter values were informed by very limited data sources so they are uncertain. The committee considered that differences in 3 resource parameters between KardiaMobile 6L and a 12-lead device could particularly affect the costs associated with their use:

- Data sources suggested that it was faster to use KardiaMobile 6L than the 12-lead device. But the times and how they were estimated varied greatly, so it was not certain whether using KardiaMobile 6L would save time.
- The costs of measuring QT interval varied depending on who interpreted the ECG. It was not clear how often ECGs were interpreted by different healthcare professionals and services, and if this differed between KardiaMobile 6L and the 12-lead device.
- It was uncertain how often the QT interval measurement from KardiaMobile 6L would need repeating using a 12-lead device, and why this may be needed.

The committee noted that differences in these parameters may also affect how long it takes before antipsychotic medication is started. It concluded that more data on these parameters is needed.

4 Evidence generation recommendations

4.1 Further evidence generation is recommended on:

- the effectiveness (diagnostic accuracy) of using KardiaMobile 6L to measure QT interval in people having or about to have antipsychotic

medications and the effect of the corrected QT interval (QTc) result on clinical decision making

- how many people having antipsychotic medication choose to have their QT interval measured using KardiaMobile 6L when it is offered as an alternative to 12-lead electrocardiogram (ECG)
- how long it takes to do the test and get the QT interval result using KardiaMobile 6L and a 12-lead device (including set up, ECG recording, QT measurement and correction calculation, reporting time)
- how often are ECGs interpreted by different healthcare professionals (for example a psychiatrist or a cardiologist), and by different services (for example locally by the healthcare professional recording the ECG or making the treatment decision, or by a centralised service) when using KardiaMobile 6L and a 12-lead device
- how often is QT interval measurement repeated using a 12-lead device after using KardiaMobile 6L and why (for example because of an abnormal QTc result on KardiaMobile 6L, QT interval not measurable from KardiaMobile 6L ECG or technical failure)
- 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
- how many people who need an ECG to measure QT interval for having antipsychotic medication have one
- how common prolonged QT is in people having antipsychotics.

5 Committee members and NICE project team

Committee members

This topic was considered by the [diagnostics advisory committee](#) and [specialist committee members](#).

NICE project team

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