NICE National Institute for Health and Care Excellence

NICE guidance

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

Health technology evaluation
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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.

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1 Recommendations

1.1 KardiaMobile 6L can be used in psychiatric services as an option to measure cardiac QT interval for adults having or about to have antipsychotic medication while more evidence is generated only if:

- A repeat QT interval measurement using a 12-lead electrocardiogram (ECG) device is offered to:
  - women with a corrected QT interval (QTc) longer than 470 milliseconds
  - men, trans people having hormone treatment, and intersex people who have QTc longer than 440 milliseconds
  - people who have a follow-up ECG with more than a 50-millisecond increase in QTc.

    For trans people not having hormone treatment, use the QTc threshold for their sex registered at birth.
- Training for healthcare professionals on recording an ECG, and measuring and interpreting QT interval is provided.
- 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.

1.2 The technology developers must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan) and contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.

1.3 At the end of the evidence generation period (3 years), the technology developers should submit the evidence to NICE in a form that can be used for decision making. NICE will review the evidence and assess if the technologies can be routinely adopted in the NHS.

Evidence generation

1.4 More evidence needs to be generated on:

- the accuracy of KardiaMobile 6L to measure QT interval in adults having or about to have antipsychotic medications
- how the test result affects clinical decision making
- how long the testing takes, who interprets the results and how often the test is repeated using a 12-lead device
- patient preferences
- how long it takes before antipsychotic medication is started
- how many adults who need an ECG to measure QT interval have one
- how common prolonged QT is in adults having antipsychotic medication.

Potential benefits of early access

- **Unmet need:** Detecting cardiac abnormalities such as prolonged QT interval in adults having antipsychotic medication is important because some antipsychotics can prolong the QT interval and lead to severe cardiac events. QT interval is usually measured using a 12-lead ECG device. This needs the person to partially undress and use conductive stickers or gel on the skin which can cause reluctance and distress. Therefore, QT interval is not always measured before people start having antipsychotic medication or there could be a delay starting antipsychotic medication.
- **Clinical:** Detecting prolonged QT interval can inform choice of therapy, dosing, whether to stop therapy, and potentially avoid severe cardiac events.
- **Service user preferences:** KardiaMobile 6L allows ECG recording with less need for undressing and without using conductive stickers or gel. It can be used during a routine home visit by a community health professional. This may reduce stress and anxiety.
- **Care pathway:** KardiaMobile 6L has the potential to ensure timely ECG testing is available for all which could help adults having antipsychotic medication get faster access to safe and effective antipsychotic treatment.

Managing the risk of early access

- **Accuracy:** There may be some differences in results from measuring a QT interval with KardiaMobile 6L compared with a 12-lead ECG. To reduce the potential effect of false negatives, a QT interval longer than the relevant specified threshold in section 1.1 should be verified using a 12-lead device. More evidence should be collected on the diagnostic accuracy of using KardiaMobile 6L to measure QT interval in adults having or about to have antipsychotic medications.
- **Test interpretation:** How accurate the ECG interpretation is (measuring QT length, calculating QTc, and deciding whether QT is prolonged) may differ between professionals in different settings. Training for healthcare professionals on recording an ECG and measuring and interpreting QT interval should be provided.

- **Service user preferences:** QT interval measurement should be offered to people at a place and time they can attend and in a way that they feel comfortable. Information should be offered about why QT interval measurement is important. Further evidence should be collected on service users preferences for how they have their QT interval measured.

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.

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. NICE guidelines on bipolar disorder and psychosis and schizophrenia in adults have recommendations on using antipsychotic medication. 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 stickers or 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 stickers or gel. KardiaMobile 6L ECG can be recorded during a routine home visit by a community health professional. This may reduce stress and anxiety. KardiaMobile 6L is not intended for use in children.

2.6 Further details on the technology, comparator, clinical need and care pathway are in the final scope for KardiaMobile 6L for measuring QT

interval in people having antipsychotic medication.

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 adults having antipsychotic medication

3.3 The committee considered the available evidence for using KardiaMobile 6L for measuring QT interval in adults 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 adults having or about to have antipsychotic medications and the effect of the corrected QT interval (QTc) result on clinical decision making
- how many adults 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 adults who need an ECG to measure QT interval for having antipsychotic medication have one
- how common prolonged QT is in adults having antipsychotics.

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.

5 Committee members and NICE project team

Committee members

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

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

The minutes of the diagnostics advisory committee meetings, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Specialist committee members

Additional specialist committee members took part in the discussions and provided expert advice for this topic:

Ms Katherine Barrett
Lay specialist committee member

Professor Tim Betts
Consultant cardiologist, Oxford University Hospitals NHS Foundation Trust

Dr Rudolf Cardinal
Associate professor of clinical informatics; honorary consultant liaison psychiatrist, University of Cambridge, Cambridgeshire and Peterborough NHS Foundation Trust and Cambridge University Hospitals NHS Foundation Trust

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