

**NATIONAL INSTITUTE FOR HEALTH AND CARE  
EXCELLENCE**

**DIAGNOSTICS ASSESSMENT PROGRAMME**

**Equality impact assessment – Early value guidance  
development**

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

**Consultation**

1. Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?

Potential equality issues were discussed both in the scoping workshop 2 February 2022 and in the assessment subgroup meeting 16 February 2022.

The following were identified as potential equality issues relating to the condition:

- People from minority ethnic backgrounds, particularly people of African and African-Caribbean family background living in the UK, are more likely than white British people to be diagnosed with schizophrenia. They are also more likely to be detained, given medication against their will, or given higher doses.
- Neurodiverse people (for example people with autism spectrum disorder) may be more likely to have antipsychotic medication than the general population.
- Antipsychotic medication is likely to be given to people with postpartum psychosis (ECG testing may be appropriate for this population before starting treatment).
- Women typically have a longer QT interval than men and therefore may be more susceptible to the effects of QT-prolonging medication (different QTc thresholds may be used for men and women).

The following were identified as potential equality issues relating to the assessed technology:

- KardiaMobile 6L may not be suitable for use for people with upper limb amputation or missing fingers.

- The accuracy of readings may be adversely affected if a person has a skin condition causing irritation, inflammation, or very dry skin.
- The device may not work correctly for people with a pacemaker or implantable defibrillator.
- Readings from people with tremors or those who find it challenging to sit still may be inaccurate.
- KardiaMobile 6L instructions for use specify that it has not been tested for and is not intended for paediatric use.

The following were identified as potential equality issues relating to the comparator technology:

- 12-lead devices use torso electrodes and need people to undress for the ECG.
- People may be uncomfortable with undressing for example because of culture or religion, the gender of the ECG operator, or because they have a different gender identity to their birth sex, history of trauma or sexual abuse, or they experience hyper-sensitivity, for example as part of autism spectrum disorder.
- Because of the torso electrodes, body hair may need shaving for adequate contact with the skin before the ECG.

Because KardiaMobile 6L instructions for use specify that it is not intended for use for children, the scope was restricted to adults only.

2. Have any other potential equality issues been raised in the diagnostics assessment report, and, if so, how has the committee addressed these?

No other potential equality issues were raised in the diagnostics assessment report.

3. Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?

Because antipsychotic medication has side effects, having flexibility around the time and place of the ECG appointment is important. Currently, QT interval is not always measured before people start having antipsychotic medication. 12-lead 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 preliminary recommendations say that KardiaMobile 6L that can be made more easily available at different locations (including at home during home visits) should be offered an option for the 12-lead ECG.

The preliminary recommendations use the currently used sex-specific thresholds for interpreting QT interval in recommending that a repeat QT interval measurement using a 12-lead ECG device is offered to women who have corrected QT interval (QTc) longer than 470 milliseconds and men who have QTc longer than 440 milliseconds. The thresholds for men and women differ because the risk of prolonged QT differs based on biological sex. To ensure that the preliminary recommendations are clear on a safe threshold for people who have an intersex condition or biological therapies relating to gender transition, the committee recommended that a repeat QT interval measurement should be offered when people who have an intersex condition or biological therapies relating to gender transition have a QTc longer than the lower of the sex-specific thresholds so QTc longer than 440 milliseconds.

4. Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

KardiaMobile 6L may not be suitable for use for people with upper limb amputation or missing fingers. The instructions for use specify that fingers of the left and right hand and the left ankle or knee are needed to use the device.

KardiaMobile 6L may not work correctly for people with a pacemaker or implantable defibrillator. This is noted in the instructions for use as “DO NOT use KardiaMobile6L with patients who have a cardiac pacemaker, ICDs, or other implanted electronic devices.”

12 lead ECG remains available as an option for people for whom KardiaMobile6L is not suitable.

5. Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

KardiaMobile 6L readings from people with tremors or those who find it challenging to sit still may be inaccurate. The accuracy of readings may also be adversely affected if a person has a skin condition causing irritation,

inflammation, or very dry skin. 12 lead ECG remains available as an option when KardiaMobile 6L readings are not suitable for analysis.

6. Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?

The preliminary recommendations specify that using KardiaMobile 6L should be offered as an option. To reduce the potential effect of false negatives, the recommendations also specify that a repeat QT interval measurement using a 12-lead ECG device should be offered to women who have QTc longer than 470 milliseconds, men who have QTc longer than 440 milliseconds and people who have an intersex condition or who are having biological therapies relating to gender transition and QTc longer than 440 milliseconds (see answer to question 3). And finally, people should be offered information about why the testing is done and why testing may be repeated using a 12-lead device after it has been measured using KardiaMobile 6L. By promoting the evidence generation on the technology, the early value assessment helps to provide early conditional access to the technology and aims to speed up the time to its full NICE evaluation.

7. Have the committee's considerations of equality issues been described in the early value guidance consultation document, and, if so, where?

The committee's considerations of the importance of flexibility around ECG appointments and unmet clinical need for an easily accessible and available QT interval measurement in the psychiatric service setting are described in sections 3.1 and 3.2 and considerations of the population characteristics that may affect accuracy in section 3.5. The committee's recommendations are in section 1 of the early value guidance consultation document.

**Approved by Associate Director:** Rebecca Albrow

**Date:** 14/09/2022

### **Early value guidance document**

1. Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?

No additional potential equality issues were raised during consultation. But based on the consultation it was made clearer in the early value guidance document that because KardiaMobile 6L instructions for use

specify that it has not been tested for and is not intended for paediatric use, the recommendations are for adults. Wording and composition of one of the subgroups in the recommendations (section 1.1. of the early value guidance document) has been amended to be more inclusive and in NICE's style of writing. A repeat 12-lead ECG is now recommended to be offered to intersex people and trans people who have a QTc longer than 440 milliseconds, instead of people who have an intersex condition or who are having biological therapies relating to gender transition and who have a QTc longer than 440 milliseconds.

**Commented [SH1]:** Frances, I have added this to tie the new wording in here. Does it work?

**Commented [FN2R1]:** Yes this is good - thank you

2. If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

No changes to the recommendations that would make it more difficult in practice for a specific group to access the technology were made.

3. If the recommendations have changed after consultation, is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

No.

4. If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?

N/A.

5. Have the committee's considerations of equality issues been described in the diagnostics guidance document, and, if so, where?

The committee's considerations of the importance of flexibility around ECG appointments and unmet clinical need for an easily accessible and available QT interval measurement in the psychiatric service setting are described in sections 3.1 and 3.2 and considerations of the population characteristics that may affect accuracy in section 3.5. The committee's recommendations are in section 1 of the early value guidance document.

**Approved by Associate Director (name):** Rebecca Albrow

**Date:** 14/09/2022