

DIAGNOSTICS ASSESSMENT PROGRAMME

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

Early value guidance consultation document – Comments

THEME: Technology under assessment

Comment number	Name and organisation	Section number	Comment	NICE response
1 (10)	Nottinghamshire Healthcare NHS Foundation Trust	2.5	In practice, one frequently has to moisten the skin underneath the bottom electrode to get good contact with the KardiaMobile device. Most conveniently either using water or using alcohol "gel"	Thank you for this comment which NICE has considered. The final scope provides a more detailed description of the technology including a mention that a very dry skin can interfere with the electrodes. Using KardiaMobile 6L is briefly described in section 2.5 of the early value guidance. Section 2.6 has been added to the early value guidance to provide a link to the final scope.
2 (13)	Nottinghamshire Healthcare NHS Foundation Trust	3.5	It is noteworthy that AliveCor offer an automated QTc calculation algorithm based on machine learning that they market in the US as "InstantQT": https://www.alivecor.com/press/press_release/fda-clears-personal-ecg-device-for-measurement-of-qt-c-interval/ They published a paper on it at: https://doi.org/10.1161/CIRCULATIONAHA.120.050231 It is not as yet available in the UK	Thank you for this comment which NICE has considered. The automated QT interval analysis feature is mentioned both in the final scope and the early value assessment report by Kleijnen. But because this feature is not available to the NHS, it was not evaluated as part of this assessment and so not described in the guidance document. Section 2.6 has been added to the early value guidance to provide a link to the final scope.

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Early value guidance consultation document – Comments

THEME: Potential alternative technologies

Comment number	Name and organisation	Section number	Comment	NICE response
3 (1)	QT Medical, Inc.	General	<p>The Committee considered some criteria and needs, such as 'easily accessible' and 'less intrusive'. However, they did not do a thorough review of currently available technologies and products. If they did, they would have found that PCA 500 from QT Medical is less intrusive (anyone can use it) and easily accessible (no need to go to hospital). PCA 500 is cleared by MHRA, CE Mark and FDA for professional and laypeople (patient) use. In fact, PCA 500 has been used by thousands of patients at home, with excellent results. We strongly believe that the Committee should include other technologies and devices available and compare with KM 6L to really show the potential pros and cons of using such devices. 12-lead ECG is the medical standard since 1954, for almost 70 years. We believe that patient care should not be compromised when there are better technologies available that follows the standard of care with true 12-lead ECG.</p>	<p>Thank you for this comment which NICE has considered.</p> <p>The technology that was notified to NICE was KardiaMobile 6L which is an ECG technology. During scoping, potential alternative ECG technologies for measuring QT interval in people having or about to have antipsychotic medication, including 12-lead technologies that use chest electrodes but are more portable than traditional 12-lead ECG devices, were also explored. But because having a less intrusive QT interval measurement without the need to undress was considered a key benefit for people having antipsychotic medication, only KardiaMobile 6L was included in the final scope. Stakeholders did not identify a need to expand the scope beyond ECG based technologies. Section 2.6 has been added to the early value guidance to provide a link to the final scope.</p>

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THEME: Comparator

Comment number	Name and organisation	Section number	Comment	NICE response
4 (9)	Nottinghamshire Healthcare NHS Foundation Trust	2.4	It is very rare for 12-lead ECG to use a separate conductive gel. Instead it usually uses adhesive stickers that leave little residue.	Thank you for this comment which NICE has considered. The descriptions of using 12-lead ECG and KardiaMobile 6L in sections 2.4 and 2.5 of the early value guidance have been amended to refer to conductive stickers or gel instead of only conductive gel.

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Early value guidance consultation document – Comments

THEME: Clinical effectiveness

Comment number	Name and organisation	Section number	Comment	NICE response
5 (2)	QT Medical, Inc		<p>KardiaMobile 6L (KM 6L) is a 2-lead device. Although KM 6L claims to be 6 leads, it is actually 2 measured leads plus 4 derived leads (Lead III, aVR, aVL, and aVF are all calculated) [Giudicessi et al. 2021]. Adding Lead II in KM 6L is better than the original KM single lead device, and makes it possible to measure QT interval from Lead II, but showing the 4 derived leads essentially does not add more information that is already shown in the 2 measured leads. KM 6 L can only be used for QT measurement, not for many cardiac findings or diagnosis listed in the paper attached.</p> <p>As Dr. Robert Kleinman, cardiologist and Chief Medical Officer of ERT, points out, 6L ECG has limited usefulness in detecting [Kleiman and Rudo]: Myocardial ischemia (primarily inferior wall) Myocardial infarction (primarily inferior wall) Electrolyte abnormalities Pericarditis Cardiomyopathic processes Wolff-Parkinson-White Syndrome Early Repolarization Syndrome</p> <p>And, 6-lead ECGs have almost no ability to detect some other serious cardiac conditions:</p>	<p>Thank you for this comment which NICE has considered.</p> <p>This assessment evaluated using KardiaMobile 6L for measuring QT interval only in people having antipsychotic medication. This is specified in the final scope. Section 2.6 has been added to the early value guidance to provide a link to the final scope. The guidance does not intend for the device to be used for anything other than measuring QT interval as a screen prior to initiating QT prolonging antipsychotic medication..</p>

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THEME: Clinical effectiveness

Comment number	Name and organisation	Section number	Comment	NICE response
			<p>Hypertrophic Cardiomyopathy Left ventricular hypertrophy Right ventricular hypertrophy Anterior wall ischemia Anterior wall myocardial infarction Right ventricular myocardial infarction Brugada Syndrome Arrhythmogenic RV Dysplasia Atrial enlargement.</p> <p>References: Giudicessi JR, Schram M, Bos JM, Galloway CD, Shreibati JB, Johnson PW, Carter RE, Disrud LW, Kleiman R, Attia ZI, Noseworthy PA, Friedman PA, Albert DE, Ackerman MJ. Artificial Intelligence-Enabled Assessment of the Heart Rate Corrected QT Interval Using a Mobile Electrocardiogram Device. <i>Circulation</i>. 2021 Mar 30;143(13):1274-1286. doi: 10.1161/CIRCULATIONAHA.120.050231. Epub 2021 Feb 1. PMID: 33517677.</p> <p>Robert Kleiman, MD and Todd Rudo, MD. WHITE PAPER: USE OF “LIMITED LEAD” ECG DEVICES ECG Devices with Varying Leads: Utility and Use-Cases for Limited-Lead ECG Devices.</p>	

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THEME: Clinical effectiveness

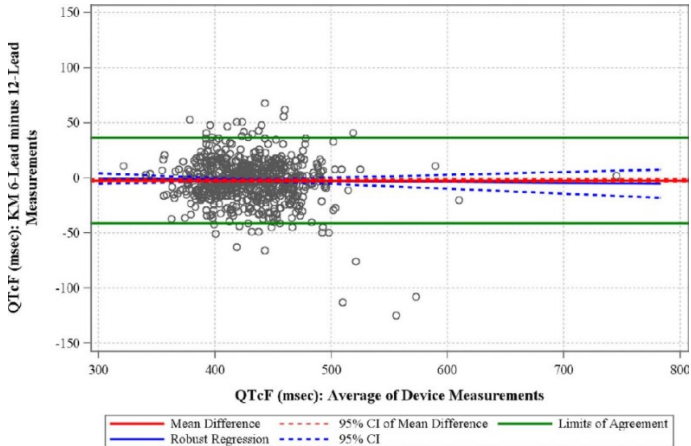
Comment number	Name and organisation	Section number	Comment	NICE response
6 (3)	QT Medical, Inc.	3.4 and 3.5	<p>KM 6L, although had some publications on QT measurement-- those are done by experts and cardiologists in a strictly controlled research setting. In the real world, when used by GPs who do not have enough training, experience and skills, there will be a lot of errors and potential harms to patients.</p> <p>The US FDA cleared KM for clinical use of measuring QTc, but that does not mean KM can replace standard 12-lead ECG for QT measurement. Although QTc can be measured from Lead II, T wave analysis requires all 12 leads, according to the latest FDA Guidance for Industry of 2017.</p> <p>In a recent study of 685 patients comparing KM 6L and standard 12-lead ECG, Kleinman et al reported that the difference in mean QTcF was 2.6 ms between KM 6L and 12-lead ECG [Kleinman et al. 2021]. While it seems encouraging that the mean QTcF values between the two are very close, the scatterplot showed that for each individual patient, the differences between 6L and 12-lead ranged very widely, and many are more than 50 ms apart. In fact, over 23% patients had their QTcF difference between 6L and 12-lead greater than 20 ms. In a thorough QT study, it is often required to have ECGs with the</p>	<p>Thank you for this comment which NICE has considered.</p> <p>The committee’s considerations of the generalisability of evidence are in section 3.5 and of the concordance data from the KardiaMobile 6L studies in section 3.4 of the early value guidance. The committee noted that none of the 8 technical validation studies on KardiaMobile 6L included people having antipsychotic medication and concluded that data from other settings may not be generalisable to the psychiatric service setting. The Kleiman et al. study was included in the early value assessment report and discussed by the committee. 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. 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. To reduce the potential effect of</p>

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			<p>sensitivity of detecting change in QTcF of 5 ms. Having a wide range of 20 ms or more in almost one in every 4 patients can create a significant risk from a regulatory standpoint.</p>  <p>Figure. “Bland–Altman and bias assessment plots for QTcF. The solid horizontal red line represents the mean difference, and the hashed red line represents the 95% confidence bounds for the measurement pairs. The horizontal green lines represent the limits of agreement” from Figure 5 in</p>	<p>false negatives, the committee decided that a QT interval longer than the relevant specified threshold in section 1.1 of the early value guidance should be verified using a 12-lead device. The evidence generation recommendations in section 4 include the effectiveness (diagnostic accuracy) of using KardiaMobile 6L to measure QT interval in people having or about to have antipsychotic medication. The committee were aware that many people may not receive an ECG to check QT interval before starting antipsychotic medication. No changes to the early value guidance were made.</p>

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THEME: Clinical effectiveness

Comment number	Name and organisation	Section number	Comment	NICE response
			<p>Comparison of electrocardiograms (ECG) waveforms and centralized ECG measurements between a simple 6-lead mobile ECG device and a standard 12-lead ECG.</p> <p>References: Kleiman R, Darpo B, Brown R, Rudo T, Chamoun S, Albert DE, Bos JM, Ackerman MJ. Comparison of electrocardiograms (ECG) waveforms and centralized ECG measurements between a simple 6-lead mobile ECG device and a standard 12-lead ECG. <i>Ann Noninvasive Electrocardiol.</i> 2021 Jul 19:e12872. doi: 10.1111/anec.12872. Epub ahead of print. PMID: 34288227.</p>	
7 (5)	QT Medical, Inc		<p>It is important to note that the sampling rate of KM 6L is 300 Hz. That is, it samples 1 ECG data every 3 to 4 ms. When measuring QT by a non-expert, the difference can often be + or – 2 data points, then it will be ± 12 ms to 16 ms. When sampling rate is 1000 Hz, the difference would be ± 2 ms. The low sampling rate of KM 6 L would have significant contribution to the wide variation in the measurements from standard 12-lead ECG.</p>	<p>Thank you for this comment which NICE has considered. Committee’s considerations of the generalisability of evidence are in section 3.5 of the early value guidance. The committee noted that in the 8 KardiaMobile 6L 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</p>

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THEME: Clinical effectiveness

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				<p>technical validation studies in other settings may not be generalisable to the psychiatric service setting. The evidence generation recommendations in section 4 of the early value guidance include the effectiveness (diagnostic accuracy) of using KardiaMobile 6L to measure QT interval in people having or about to have antipsychotic medication. No changes to the early value guidance were made.</p>
8 (7)	QT Medical, Inc		<p>The KM 6L ECG uses dry-metal electrodes. Although reusable and cheaper, dry-metal electrodes were abandoned by US hospitals 30 years ago because they are not reliable, inconsistent, and often inaccurate. Depending on the skin condition, moistness, and quality of contact, there are significant variations in ECG recording data using this type of electrode. As stated in the study of Kleinman et al, “The unfiltered 12-lead ECGs had less artifact and did not require filtering prior to performing measurements, while the unfiltered 6-lead ECGs had significantly more artifact and required filtering before IDMs could be performed.”</p>	<p>Thank you for this comment which NICE has considered.</p> <p>The committee’s considerations of the of the concordance data from the KardiaMobile 6L studies are in section 3.4 of the early value guidance. The Kleiman et al. study was included in the early value assessment report and discussed by the committee. 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. Therefore, KardiaMobile 6L is conditionally recommended for use with evidence generation in psychiatric services as</p>

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THEME: Clinical effectiveness

Comment number	Name and organisation	Section number	Comment	NICE response
				<p>an option to measure QT interval in people having antipsychotic medication. To reduce the potential effect of false negatives, the committee decided that a QT interval longer than the relevant specified threshold in section 1.1 of the early value guidance should be verified using a 12-lead device. The evidence generation recommendations in section 4 include the effectiveness (diagnostic accuracy) of using KardiaMobile 6L to measure QT interval in people having or about to have antipsychotic medications. No changes to the early value guidance were made.</p>
9 (8)	Broomwell Healthwatch		<p>Broomwell Healthwatch are the major provider of ECG interpretation services to the NHS primary care. At the centre we do some 4,500 ECGs per week and service quite a large number of Addictions Services / Substance Abuse / Mental Health Trusts</p> <p>Measuring the QT accurately can be challenging even when using a 12 lead ECG and having it interpreted by an expert. This is because the end of the QT can't always be clearly defined with significant inter-patients and inter-physicians variability.</p>	<p>Thank you for this comment which NICE has considered.</p> <p>The committee's considerations of the data from the KardiaMobile 6L technical validation studies are in section 3.4 of the early value guidance. This assessment evaluated KardiaMobile 6L used as a 6-lead ECG device. 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</p>

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			<p>Although using a 1 lead ECG to measure the QT is cheap, its validity is yet to be established. This will require a huge sample size to compare it with the 12 lead ECG (the gold standard). It is highly likely that, in cases where the end of the T wave is not well seen or when the QTc is near the upper limit of normal, a full 12 lead ECG will be required.</p>	<p>device. 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. A QT interval longer than the relevant specified threshold in section 1.1 of the early value guidance should be verified using a 12-lead device. The evidence generation recommendations in section 4 include the effectiveness (diagnostic accuracy) of using KardiaMobile 6L to measure QT interval in people having or about to have antipsychotic medications. They also include the recommendation to collect data on how often QT interval measurement is repeated using a 12-lead device after using KardiaMobile 6L and why (for example because of an abnormal QTc result on KardiaMobile 6L, or because QT interval is not measurable from KardiaMobile 6L ECG or because of a technical failure). The committee were aware that many people may not receive an ECG to check QT interval before starting antipsychotic medication. No changes to the early value guidance were made.</p>

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Early value guidance consultation document – Comments

THEME: Further pilot study data in the psychiatric service setting

Comment number	Name and organisation	Section number	Comment	NICE response
10 (11)	Nottinghamshire Healthcare NHS Foundation Trust	3.1	This was also our experience and feedback from a small pilot study on inpatient mental health wards: https://doi.org/10.1192/bjo.2021.88 ([Briley, P., & Lankappa, S. (2021). Pilot study of the use of handheld 6-lead ECG for patients on acute general adult mental health wards who refuse traditional 12-lead ECG. BJPsych Open, 7(S1), S11-S11])	Thank you for this comment which NICE has considered. This conference abstract was not identified in the external assessment group’s searches. The external assessment group notes that the abstract does not specify the hand-held ECG device used in the study. This abstract provides some further information on uptake and service user preferences in an inpatient psychiatric service setting. In summary: 13 of the 17 patients who had previously refused a 12-lead ECG, accepted examination with the hand-held ECG. Of these, 1 ECG failed due to patient agitation. When asked if they would recommend hand-held ECG to others, 90% of the 10 patients who responded stated that they would. The external assessment group consider that these results are similar to the results of the recent pilot studies included in the early value assessment report. The committee’s considerations of service user preferences are described in section 3.1 of the early value guidance. No changes to the early value guidance were made.

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THEME: Further pilot study data in the psychiatric service setting

Comment number	Name and organisation	Section number	Comment	NICE response
11 (12)	Nottinghamshire Healthcare NHS Foundation Trust	3.3	Some feedback is available in our small pilot study on this group (https://doi.org/10.1192/bjo.2021.88 [Briley, P., & Lankappa, S. (2021). Pilot study of the use of handheld 6-lead ECG for patients on acute general adult mental health wards who refuse traditional 12-lead ECG. BJPsych Open, 7(S1), S11-S11]). This too was only published in abstract form.	Thank you for this comment which NICE has considered. This conference abstract was not identified in the external assessment group's searches. This abstract provides some further information on uptake and service user preferences in an inpatient psychiatric service setting. The external assessment group consider that the results are similar to the results of the recent pilot studies included in the early value assessment report. The committee's considerations of service user preferences are described in section 3.1 of the early value guidance. No changes to the early value guidance were made.

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Early value guidance consultation document – Comments

THEME: Cost and resource use

Comment number	Name and organisation	Section number	Comment	NICE/EAG considerations
12 (4)	QT Medical, Inc		There will be a lot of education and costs associated with training both patients and providers on how to use this new, non-standard ECG.	<p>Thank you for this comment which NICE has considered.</p> <p>This assessment evaluated using KardiaMobile 6L to measure QT interval in people having antipsychotic medication by healthcare professionals in the community, primary care and psychiatric inpatient and outpatient facilities and services, not by the service users independently. The settings are specified in the final scope. The committee’s considerations of the provision of QT interval measurement in psychiatric services are described in section 3.2 and the service user preferences in section 3.1 of the early value guidance. The clinical experts noted that (regardless of the device used) to offer QT interval measurement in psychiatric services, staff training to record and interpret ECGs is essential. The committee’s recommendations in section 1.1 include training for healthcare professionals on recording an ECG, and measuring and interpreting QT interval as a condition for providing the QT interval measurement. Psychiatric service user experts explained that it is important for people to understand that the QT</p>

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THEME: Cost and resource use

Comment number	Name and organisation	Section number	Comment	NICE/EAG considerations
				interval is measured to make sure the antipsychotic medication that is offered is suitable for them. The committee’s recommendations in section 1.1 include, as a further condition for providing the QT interval measurement, offering people 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. Section 2.6 has been added to the early value guidance to provide a link to the final scope.
13 (18)	AliveCor	3.7	<p>Data sources - Both TEWV and CNTW reference faster ECG collection from KM6L than to 12L. Physical preparation alone takes longer with a 12L ECG. We are not sure how there is any debate here?</p> <p>Repeat ECG - If research demonstrated equivalence in this population of ECG validity from KM6L to 12L ECG would repeat 12L ECG be required or could a qualified physician diagnose from the KM6L ECG?</p>	<p>Thank you for this comment which NICE has considered.</p> <p>The committee’s considerations of the cost and resource parameters are in section 3.7 of the early value guidance. The data sources did suggest that it was faster to use KardiaMobile 6L than the 12-lead device. But because the times and how they were estimated varied greatly, it was not certain whether using KardiaMobile 6L would save time. It was uncertain how often the QT interval measurement from Kardimobile 6L would need repeating using a 12-lead device, and why this may be needed. The committee noted</p>

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THEME: Cost and resource use

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				<p>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.</p> <p>The committee’s evidence generation recommendations in section 4 include collecting data on how often QT interval measurement is repeated using a 12-lead device after using KardiaMobile 6L and why (for example because of an abnormal QTc result on KardiaMobile 6L, or because QT interval is not measurable from KardiaMobile 6L ECG or because of a technical failure). Further evidence on this will help determine in a future NICE assessment in which cases a repeat 12-lead ECG might be needed. No changes to the early value guidance were made.</p>

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Early value guidance consultation document – Comments

THEME: Recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
14 (6)	QT Medical, Inc	1	KM 6L is not a definitive measure, it is only used as a screening. When there are concerns, you will still have to get a 12-lead ECG. That is just one extra step with very little gain, could be a waste of time and potential resources. Also, false negative measures will be a concern-- KM 6L can easily miss ones with significantly prolonged QT interval which could not be seen without precordial leads.	Thank you for this comment which NICE has considered. The recommendations and why the committee made them are described in section 1 of the early value guidance. The committee considered that 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. To reduce the potential effect of false negatives, the committee decided that a QT interval longer than the relevant specified thresholds in section 1.1 of the early value guidance should be verified using a 12-lead device. The evidence generation recommendations in section 4 include the effectiveness (diagnostic accuracy) of using KardiaMobile 6L to measure QT interval in people having or about to have antipsychotic medications. No changes to the early value guidance were made.
15 (14)	Tees, Esk and Wear Valleys	1.1	General comment: Should baseline QT interval measurement be obtained via 12-lead ECG?	Thank you for this comment which NICE has considered.

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THEME: Recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
	NHS Foundation Trust			The committee decided that a QT interval longer than the relevant specified threshold in section 1.1. should be verified using a 12-lead device. This recommendation aims to reduce the potential effect of false negative KardiaMobile 6L results also in the baseline QT interval measurement. QTc results using KardiaMobile 6L below these thresholds would not need a repeat measurement using a 12-lead device. No changes to the early value guidance were made.
16 (15)	Tees, Esk and Wear Valleys NHS Foundation Trust	1.1	Could the guidance cover other psychotropic drugs that impact QT interval? For example, some antidepressants.	Thank you for this comment which NICE has considered. The use case notified to NICE was using KardiaMobile 6L to measure QT interval in people who are having or about to have antipsychotic medication. During the scoping, other medications that may prolong QT interval and are prescribed in the psychiatric services, including the antidepressants citalopram and escitalopram, tricyclic antidepressants, and methadone, were discussed. It was noted that the population characteristics and clinical outcomes for people having other types of medications could greatly vary from those in people having antipsychotic

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THEME: Recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
				medication. This meant that expanding the scope to other medications would likely make the assessment too broad to provide meaningful analyses. So, it was decided that the final scope included people having or about to have antipsychotics. Section 2.6 has been added to the early value guidance to provide a link to the project documents including the final scope.
17 (16)	Tees, Esk and Wear Valleys NHS Foundation Trust	1.1	<p>In National and international guidelines, an increase of 60 milliseconds from baseline would also be a cause for concern. Should this be included as another trigger point for repeating QT interval measurement using a 12-lead ECG?</p> <p>Does the guidance cover children? The boundaries of normal QTc vary with age, therefore the thresholds for repeating QT interval measurement with a 12-lead ECG might differ.</p> <p>KardiaMobil 6L would be helpful for children. It can be more challenging to obtain a standard ECG from a child, which can limit treatment choice.</p>	<p>Thank you for this comment which NICE has considered.</p> <p>NICE notes that some advice for clinical practice for example the Dorset Medicines Advisory Group guidance for mental health prescribers and Khatib et al. 2021 suggest that, if a substantial change in QTc is observed (increase of at least 60 milliseconds in Dorset Medicines Advisory Group guidance and greater than 50 milliseconds in Khatib et al.), changes in prescribing should be considered. The recommendation in section 1.1 of the early value guidance has been amended to include the condition that a repeat QT interval measurement using a 12-lead ECG device should be offered when a follow-up ECG shows more than a 50 millisecond increase in QTc.</p>

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				<p>Because KardiaMobile 6L instructions for use determine that the device has not been tested for and is not intended for paediatric use, the population in the final scope and the recommendations cover only adults. The early value guidance title and the section 1.1 of the early value guidance have been amended to specify that the recommendations cover only adults. An additional sentence about the restriction in the intended use ‘KardiaMobile 6L is not intended for use in children’ has been added to section 2.4.</p>
18 (17)	AliveCor	1.1	<p>Further evidence - is there any definition of who generates this evidence, what are the timelines and who commissions the evidence.</p> <p>People are offered information - will an example template or leaflet be made available to the public and physician use (AliveCor are happy to support with NICE the creation of this)</p>	<p>Thank you for this comment which NICE has considered.</p> <p>This topic is the first pilot using NICE’s 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.</p> <p>The process, timelines and terms of the evidence generation to follow the early value guidance are currently being developed and will be discussed</p>

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THEME: Recommendations

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				with the relevant stakeholders. No changes to the early value guidance were made.
19 (19)	AliveCor	4.1	Who generates and commissions the recommended evidence generation? what is the process and how does this take place?	<p>Thank you for this comment which NICE has considered.</p> <p>This topic is the first pilot using NICE’s 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.</p> <p>The process, timelines and terms of the evidence generation to follow the early value guidance are currently being developed and will be discussed with the relevant stakeholders.</p>