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Implementation of AliveCor KardiaMobile Electrocardiogram (ECG) 6-Lead in an Early Intervention Psychosis (EIP) Service: A Mixed-Methods Evaluation of Completed ECGs Outcomes and Feedback from Patients and Staff

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Abstract

Background: Clinical guidance recommends that people with psychotic disorders are assessed for cardiovascular issues at least annually, at the start of antipsychotic medication and following medication changes such as dose changes and switching of antipsychotic medication. The AliveCor KardiaMobile 6-lead electrocardiogram (ECG) is a small, battery operated, hand-held portable ECG which has comparable accuracy to a 12-lead device and may be suitable, in particular for QTc monitoring, where it is not practical or preferable to use a 12-lead device. Purpose/Aim: To obtain patient and staff feedback on KardiaMobile and to quantify ECG completions within an early intervention in psychosis (EIP) service. Methods: A mixed-methods evaluation was undertaken, using patient and staff surveys, alongside data collection and analysis to report ECG completion. Results: The use of the KardiaMobile 6-lead in EIP was associated with improved ECG completion rates, enhanced compliance with antipsychotic monitoring guidance, and reduced patient refusal. Patient and staff feedback indicated that the KardiaMobile 6-lead was portable, accessible, easy and simple to use and was quicker, less intrusive, and more efficient than a standard 12-lead device. Conclusion: The findings support use of KardiaMobile 6-lead for better healthcare guidance compliance, safer prescribing, and better patient outcomes. By addressing the practical, emotional, and cultural barriers often associated with traditional portable ECGs, KardiaMobile fosters greater patient engagement and staff efficiency. A

12-lead device may be required in some cases and should be obtained at baseline if possible as it provides more comprehensive information and rules out pre-existing abnormalities, it is also indicated in specific clinical guidance. The addition of the KardiaMobile 6-lead offers flexibility and enhanced compliance with guidelines. It is essential that heart functioning assessment is undertaken to maximise compliance with guidelines, safety, and best patient outcomes, and that appropriate ECG assessment remains a priority of mental health services.

Keywords

AliveCor, KardiaMobile, ECG, 6-Lead, Psychosis, Antipsychotics, EIP, Heart

1. Introduction

Early intervention in psychosis (EIP) services are multidisciplinary, community-based mental health teams that aim to assess and treat people within two weeks of referral for a first episode of psychosis; they provide assessment, monitoring, and support, alongside a full range of pharmacological, psychological, social, occupational, and educational interventions for up to three years [1]. EIP services seek to address both the *negative* symptoms of psychosis (including emotional apathy, lack of drive, poverty of speech, social withdrawal, and self-neglect) and *positive* symptoms (hallucinations, delusions, and disorganised thinking or behaviour). In addition, they provide regular physical health checks and monitoring [2]. United Kingdom (UK) National Health Service (NHS) standards for EIP services require physical health monitoring and interventions, in line with Lester Positive Cardiometabolic Health Resource for those with psychosis and schizophrenia, with monitoring frequency at the start of treatment (baseline), three months, then annually (six monthly for patients under age 18 years) [3]. This is required more frequently if there is a physical health abnormality and when antipsychotic treatment is changed in dosage or to an alternative antipsychotic medication [2]. As per The National Institute for Health and Care Excellence (NICE) guidance for physical health monitoring in those with psychosis and schizophrenia, an electrocardiography (ECG) should form part of this assessment [4].

Prolongation of the QT interval is a clinically important cardiovascular risk associated with some antipsychotic medications. The QT interval represents the total time from ventricular depolarisation to complete repolarisation and is typically reported as the corrected QT interval (QTc) on an ECG. Antipsychotic medications vary in their effects on QTc duration [5]. Some antipsychotic medications are associated with prolonged ventricular repolarisation, potentially giving rise to QT prolongation, which may lead to arrhythmias such as polymorphic ventricular tachycardia (including torsades de pointes). This can cause hypotension with symptoms such as dizziness, fainting, and convulsions, and can progress to ventricular fibrillation and risk of sudden cardiac death [6]. Current UK NICE guid-

ance recommends that an ECG is offered prior to starting antipsychotic medication when specified in the drug's summary of product characteristics, or a physical examination has identified specific cardiovascular risk, or there is a family history of cardiovascular disease, or other cardiovascular risk factors such as arrhythmia, or if the service user is being admitted as an inpatient [7].

The Royal College of Psychiatrists' (RCPsych) National Clinical Audit of Psychosis (NCAP) recommends that people with psychotic disorders are assessed for risk of cardiovascular disease at least annually, using the QRISK tool [8]. The choice of antipsychotic medication, the starting dose and/or the increase in frequency of monitoring should then be influenced by the presence of any cardiovascular disease history, as well as other factors such as poor nutrition or liver disease [6]. Identification of cardiovascular risk factors should initiate a more detailed cardiac assessment including an ECG, which should be examined for evidence of prolonged QTc, ischaemic heart disease, left ventricular hypertrophy, and repolarisation abnormalities [6].

Widely used portable ECG equipment is bulky (approximately 50 cm × 50 cm × 20 cm), heavy to carry, with multiple accessories including a stand, charging cable, 12 electrical leads, and adhesive electrode pads. These devices are not battery operated and therefore require proximity to a main power supply, as well as sufficient physical spacer for operation. It is a time consuming process to set up and use, which requires application and removal of sticky electrode pads and the patient has to remove upper body clothing to attach the electrode pads. Difficulties in providing appropriately trained same-sex clinical staff can create additional challenges, as assessments may require two members of staff, including a same-sex chaperone. Some patients refuse to go through this procedure, and some are not well enough to do so [9]. Various issues can prevent assessment, as recognised in the wider healthcare literature; including factors associated with a person's culture or religion, having a different gender to the ECG operator, having a different gender identity to their birth sex, experiencing hyper-sensitivity (for example due to autism spectrum disorder [ASD]), or having a history of trauma or sexual abuse (which may make clinical procedures distressing or re-traumatizing) [7] [10]-[13]. Practical challenges may also arise in environments where privacy is difficult such as a person living in a shared house or where no private room is available [7].

Flexible and timely access to ECG monitoring is essential within EIP services. Given the characteristics of the patient population, such as psychotic symptoms not wishing to engage with others, and difficulties tolerating clinical or prolonged procedures [14], sustained engagement and responsiveness to individual preferences and needs are central to service delivery. As a result, physical health monitoring requires adaptation to a range of settings, including patients' homes and other non-clinical places. In addition, medication changes are frequent necessitating repeated ECG monitoring in order to meet guidelines, and the safe delivery of high-quality care and treatment.

Smaller, battery-operated portable ECG technologies offer a potential supplementary solution by providing accurate QTc assessments in a more convenient and accessible format [15]. The KardiaMobile 6L is such a device; it is a hand-held battery powered portable 6-lead ECG device (manufactured by AliveCor). The KardiaMobile has several advantages over existing widely used portable 12-lead ECG equipment. It is smaller, easier to transport/carry, more easily used in a patient's home, and results are sent directly to clinical team digitally via portable document format (PDF) document. It allows for real-time ECG monitoring and reading (reducing delays for additional appointments, removing a need for additional clinical space, and reducing delays for medication changes that are reliant on ECG to being done and then checked by appropriate clinicians). This results in more efficient clinical care (quicker initiation and change of medication). Maintenance of dignity and acceptability is also improved, as patients do not need to remove clothing for the ECG to be completed [16] and therefore do not require a same-sex chaperone. This approach is paperless and with effective digital communication of results, reduces waste and carbon footprint and risks of data loss and security or confidentiality breaches. It works with smartphones or suitable computers/tablets, Apple and Android. There is also the option to use this approach for the assessment and monitoring of atrial fibrillation (AF) including the evaluation of stroke or transient ischaemic attack risk.

Evaluations of KardiaMobile have been undertaken across a range of settings. A prospective study involving 674 patients compared standard 12-lead ECGs with KardiaMobile 6-lead ECGs obtained sequentially during the same visit, with recordings digitally transferred to a centralised core laboratory and analysed by cardiologists who were blinded to subject identifiers, treatment, and study details [17]. Comparisons demonstrated consistency in interval duration measurements (IDMs), with no evidence of systematic measurement bias at either high or low values, supporting the utility of KardiaMobile in providing rapid, high-quality ECG recordings for the assessment of cardiac rate and rhythm, atrioventricular conduction, and standard IDMs (PR, QRS, QT/QTc) [17]. The authors noted that the absence of precordial leads limits the detection of some conditions, including unstable angina, anterior wall ischaemia or infarction, and repolarisation syndromes that predominantly manifest in the chest [17]. Complementing this evidence, Tees, Esk and Wear Valleys NHS Foundation Trust evaluated the adoption of KardiaMobile for monitoring patients prescribed antipsychotic medication, reporting positive feedback from both patients and staff, an average saving of 17.5 minutes per ECG, and associated cost savings for community mental health teams [18]. More recently, a systematic review assessing whether KardiaMobile 6L provides an effective and safe alternative to 12-lead ECGs found that mean differences in corrected QT interval between devices were generally small (≤10 ms) [19]. Evidence relating specifically to QT-based cardiac risk assessment in service users prescribed antipsychotic medication, drawn from two pilot project reports of retrospective staff and service-user surveys, indicated that use of KardiaMobile may

reduce the time required to complete ECGs and associated costs, and was preferred by the majority of respondents [19]. However, the review highlighted the need for further evaluation, including technical validation studies in psychosis populations, assessment of service-user and healthcare professional preferences, comparison of time required to complete ECGs using KardiaMobile 6L versus standard 12-lead ECGs, evaluation of impacts on ECG uptake and acceptability, and assessment of associated costs [19].

This study addresses some of these outstanding questions by examining the implementation of KardiaMobile within an EIP service. Specifically, the study aimed to: (1) gather feedback from patients and clinicians on the acceptability and usability of KardiaMobile; (2) quantify ECG uptake and the time required to complete ECG monitoring; and (3) assess whether the use of KardiaMobile improves accessibility to ECG monitoring and increases the proportion of ECGs completed, with secondary exploratory analyses examining documentation processes and downstream clinical actions.

2. Methods

2.1. Design

A mixed-methods approach was used comprising patient and staff feedback collected via surveys, with data collection and analysis on ECG completions and time taken to perform ECGs.

2.2. Approval

The project was undertaken from 11/03/2024 to 10/03/2025. Approval for the study was gained from the EIP service lead and NHS healthcare trust in which the service was based (reference for approval: KARDIAMOBILMH2024). The study was undertaken in accordance with the Declaration of Helsinki.

2.3. AliveCor KardiaMobile ECG 6-Lead

The KardiaMobile is a portable 6L ECG manufactured by AliveCor. It uses three electrodes to record a person's ECG and wirelessly transmits the data to a compatible smartphone or computer via Bluetooth. The KardiaMobile software application allows the ECG data to be converted into a portable document format (PDF). This can then be sent via e-mail to health service staff; the results of the test are shared with an appropriate clinician for analysis and if any abnormalities are highlighted the patients' clinical team can provide the required intervention. User data are stored on a General Data Protection Regulation (GDPR) compliant cloud-based system hosted in Frankfurt, Germany. The KardiaMobile is powered by a single coin-cell battery. There are two electrodes on the top of the KardiaMobile for use with the fingers of the left and right hands (positioned separately on either end of the device), and one on the bottom of the KardiaMobile for use with the bare skin of the left knee or inside of ankle. The service user is usually seated for the test. In two-channel mode, KardiaMobile records a 6L ECG. It's a small

device, with dimensions being, 9.0 cm × 3.0 cm × 0.72 cm and a weight of 24 grams.

2.4. Setting

The EIP service comprises a multidisciplinary mental health team that provides specialist, recovery-focused treatment and care to people aged 14 to 65 years old, experiencing a first episode of psychosis or those at high risk of psychosis. The service is community-based, aiming to offer support in the least restrictive setting, often through outpatient contacts, home visits, and outreach in familiar environments to patients, such as schools, colleges, or workplaces. EIP teams include psychiatrists, psychologists, nurses, occupational therapists, social workers, and support workers, who work collaboratively with service users and their families. The service is designed to be accessible, patient-centred, youth-friendly for under 18s, and non-stigmatising, with a focus on early detection, prompt support and treatment, and holistic support that addresses mental health, physical health, personal, and social needs.

The sample was purposefully recruited from people under the care of the EIP service within the UK's NHS. Patients with EIP are referred to the service by inpatient settings, crisis services, GPs, and other healthcare provisions. Patients are comprehensively assessed for psychotic illness before being accepted onto the caseload and offered EIP provided support, treatment, and interventions. These services regularly initiate and manage antipsychotic treatment, which requires ECG monitoring in line with NICE [7] guidance. In this service every person is offered a NICE concordant package of care and treatment as per national standards, which includes a multi-disciplinary team (MDT) model of care [2]. Goals of the service related to key performance indicators (KPIs) include reducing weight gain; improving wellbeing; reducing symptoms of psychosis and impact of those symptoms; improving physical activity; and enabling better self-management and healthier lifestyles.

2.5. Training

Training was provided by the project lead to all EIP staff (embedding new practice across the service) on the use, data management and sharing of results, results interpretation, charging, cleaning, and how to calculate QTc. Training was influenced by NHS Health Innovation organisation's "User Guidance for The Tees Remote ECG Pathway" [20]. Training was also provided on the project evaluation procedure and data collection.

Training for staff on the use and implementation of the KardiaMobile was delivered through a structured and multi-modal approach to ensure consistency and confidence across the team. Initial face-to-face teaching sessions were delivered using a PowerPoint presentation, covering the rationale for ECG monitoring, the role of the KardiaMobile, and its integration within the service. Staff were provided with a written guidebook and access to the relevant Standard Operating Procedure (SOP) for reference, alongside practical demonstrations of the Kardi-

aMobile. These sessions included guidance on KardiaMobile set-up, patient preparation, correct use of the KardiaMobile, troubleshooting common issues, use of the accompanying app, and the process for securely sending PDF results to interpreting professionals. To reinforce learning, refresher teaching was offered on a 1:1 basis, allowing staff to practice in a supported environment. Additional specialist training was delivered to medics and advanced practitioners, focusing on ECG interpretation, QTc interval calculation using the MDCalc resource, and correct documentation within the clinical system.

2.6. Inclusion/Exclusion Criteria

2.6.1. EIP Service Eligibility

EIP service inclusion criteria are individuals presenting with clear or emerging psychotic symptoms, such as hallucinations, delusions, disordered thinking, or marked changes in perception and behaviour. The service may also work with those considered at high risk of psychosis or who are showing attenuated symptoms, in order to offer early assessment and intervention before the development of a full psychotic episode. Diagnoses commonly supported include schizophrenia spectrum disorders, affective psychosis, and other psychotic illnesses where timely intervention can improve outcomes.

Individuals are not usually accepted if their primary difficulties are linked to non-psychotic conditions such as anxiety, depression, or personality disorder without psychotic features. Similarly, people whose psychotic symptoms are considered to be secondary to an organic condition, such as dementia, neurological illness, or head injury, fall outside the scope of the service. Those with longstanding or chronic psychotic disorders who have already been under the care of secondary mental health teams are not eligible, as their needs are better met by other specialist teams. In addition, individuals who are younger than the lower age threshold (under 14 years old) are supported by Child and Adolescent Mental Health Services (CAMHS), while those above the upper limit (65 years old and over) are supported by older adults' mental health services.

2.6.2. Study Inclusion Criteria

For the purposes of this evaluation, participants were eligible if they were under the care of the EIP service and had commenced on antipsychotic medication, were receiving ongoing antipsychotic treatment requiring ECG monitoring, or experienced a change in antipsychotic treatment during the project period. Participants continued with any prescribed medication and existing psychological interventions as part of routine clinical care.

2.7. Procedure

Implementation of KardiaMobile was undertaken as part of routine antipsychotic monitoring within the EIP service. Baseline data were collected from up to six months prior to the introduction of the KardiaMobile, allowing for comparison with subsequent readings. Prior to each ECG, verbal consent was obtained from

the patient, and the purpose and procedure of the investigation were explained in accessible terms to ensure understanding and engagement.

The KardiaMobile was introduced within existing physical health clinics as an alternative to the standard 12-lead ECG, provided that a 12-lead recording had previously been completed for baseline assessment. Recordings were also performed opportunistically during routine medication reviews with doctors and non-medical prescribers (NMPs), particularly at the point of initiating, adjusting, or titrating antipsychotic medication. This ensured integration of cardiac monitoring into established clinical pathways.

Prior to the project commencing, feedback was gathered from staff regarding anticipated benefits and potential challenges of implementing the KardiaMobile. Patient feedback was sought following their completion of a KardiaMobile ECG, focusing on acceptability, comfort, and perceived usefulness. At the conclusion of the project, staff feedback was collected again to evaluate usability, integration into practice, and perceived impact on monitoring processes.

An opportunistic non-probability sampling method was employed, as all eligible patients within the EIP caseload were offered the intervention. The project was not restricted by age, sex, or ethnicity. This approach allowed for the broadest possible evaluation of feasibility and acceptability in a real-world service setting.

2.8. Measures

A brief patient feedback questionnaire was administered at point of use. The questionnaire included the following items: 1) Was KardiaMobile easy to use? Yes/No - If yes what did you like about using it? 2) Were there any issues/problems? Yes/No - If yes what issues/problems? 3) How does it compare to having 12 leads and contact points attached to upper body? 4) Any other comments about using KardiaMobile? Staff feedback was collected using an interview questionnaire that included questions related to changes to resources and time required for taking, sharing, monitoring, assessing, and actions taken following assessment. The length of time required to complete the ECGs was evaluated using a timer measuring the duration from start to finish for both standard 12-lead ECGs and KardiaMobile recordings.

2.9. Analysis

2.9.1. Quantitative Analysis

Prior to analysis, the dataset was screened for duplicate entries using IBM's Statistical Package for the Social Sciences (SPSS) software. Duplicate ECG records were defined as repeated ECGs occurring within the same study period (either pre-pilot or pilot) for the same participant. To preserve the clinical relevance of repeated ECGs across different phases of the study, only duplicates within the same phase were removed.

Duplicate identification was conducted using the Identify Duplicate Cases procedure in SPSS. Matching was defined using the unique NHS number and the study period (*i.e.*, pre-pilot or pilot). Within each matched group, records were

sorted by the date of ECG completion. Within each matched group, records were sorted by the date of ECG completion, and an indicator variable (KeepFirst) was used to retain only the first ECG per patient per phase.

The data cleaning procedure did not distinguish between different ECG types (e.g., 6-lead vs. 12-lead). If a participant had multiple ECGs within the same phase, only the first ECG was retained regardless of type. This approach avoided over-representation of individuals with repeated ECGs within a single phase but may underrepresent within-phase variation in ECG type usage.

Following data cleaning, descriptive statistics were generated to assess the frequency of ECG completions. A contingency table was constructed to examine the association between study period (pre-pilot vs. pilot) and ECG completion status (completed vs. not completed). A total of 209 ECG records remained after data cleaning. Some patients appeared in both the pre-pilot and pilot phases, while others were recorded in only one phase. This means the unit of analysis was ECG cases, not unique individuals, which was important to consider in interpretation.

ECG completion was specified a priori as the primary quantitative outcome. Because some patients contributed observations in both study phases, generalised estimating equations (GEE) with a binomial distribution and logit link were used to analyse ECG completion, clustering on patient (NHS number) and using robust (sandwich) standard errors to account for within-patient correlation. Study phase (pre-pilot vs. pilot) was included as the primary predictor. Secondary outcomes, including documentation of results, referral, repeat ECG requests, and upload of ECGs to the SystmOne clinical records system were examined using unadjusted analyses to provide descriptive context.

2.9.2. Qualitative Analysis

Free-text responses from the surveys were analysed using a content analysis approach to identify key themes related to the acceptability, comfort, usability, and clinical utility. Content analysis was chosen for its suitability in summarising textual data and highlighting patterns in responses to open-ended questions [21]. Responses were read multiple times to ensure familiarisation with the data, and initial codes were generated to capture recurring ideas. These codes were then grouped into broader thematic categories aligned with the study's domains of interest.

The approach was primarily descriptive and inductive, allowing themes to be developed from the data while remaining guided by our predefined focus areas. To enhance trustworthiness and credibility, coding decisions and emerging themes were discussed among members of the study team [22]. This process supported consistency and reduced the influence of individual bias in theme development.

3. Results

3.1. Quantitative

Generalized estimating equations (GEE) were used to analyse the primary out-

come of ECG completion in order to account for repeated observations within patients across study phases. Secondary outcomes were examined using unadjusted analyses to describe patterns across the pre-pilot and pilot periods.

ECG completion:

Using generalized estimating equations with a binomial distribution and logit link, clustering on patient (NHS number) with robust standard errors, ECG completion differed significantly by study phase (Wald $\chi^2(1) = 18.63$, $p < 0.001$). Compared with the pre-pilot phase, the odds of ECG non-completion were substantially lower during the pilot phase (OR = 0.06, 95% CI 0.02 - 0.21), indicating that ECGs were significantly more likely to be completed during the pilot period.

Referrals:

In unadjusted analyses, referral rates did not differ meaningfully between the pre-pilot and pilot phases ($\chi^2(1, N = 209) = 1.28$, $p = 0.258$), with referrals remaining low across both periods.

Repeat ECG requested:

Unadjusted comparisons indicated no clear difference in the proportion of ECGs requiring repeat testing between study phases ($\chi^2(1, N = 209) = 0.47$, $p = 0.494$). Although repeat ECG requests were slightly more frequent during the pilot phase (12.8%) compared with the pre-pilot phase (9.8%), this difference was not statistically significant.

Result documentation:

In unadjusted analyses, documentation of ECG results appeared more frequent during the pilot phase than during the pre-pilot phase ($\chi^2(1, N = 209) = 4.45$, $p = 0.035$), increasing from 80.4% to 90.6%.

Upload to SystmOne clinical records system:

There was no clear difference in the proportion of ECGs uploaded to the SystmOne clinical records system between the two phases in unadjusted analyses ($\chi^2(1, N = 209) = 1.76$, $p = 0.185$).

Overall, ECG completion was significantly more likely during the pilot phase. Secondary outcomes provide descriptive context and should be interpreted cautiously, as they were assessed using unadjusted analyses and some patients contributed data in both study phases. A visual representation of ECG completion across the two phases is shown in **Figure 1**.

3.2. Patients' and Staff Feedback: Experience of Using the KardiaMobile

Easy and simple to use

Of the 27 patients who gave feedback (27 out of 209 [response rate 13%]), 100% reported that the KardiaMobile was easy to use. Participants noted that the KardiaMobile was "*Simple and easy*" [P5]; "*Simple to use*" [P8]; "*User friendly*" [P24] and "*Easy to use*" [P13, P19]. One of the participants expressed the simplicity of using the KardiaMobile:

P10: *It's easy to use in terms of just needs to be put on your knee and properly*

held. It's convenient.

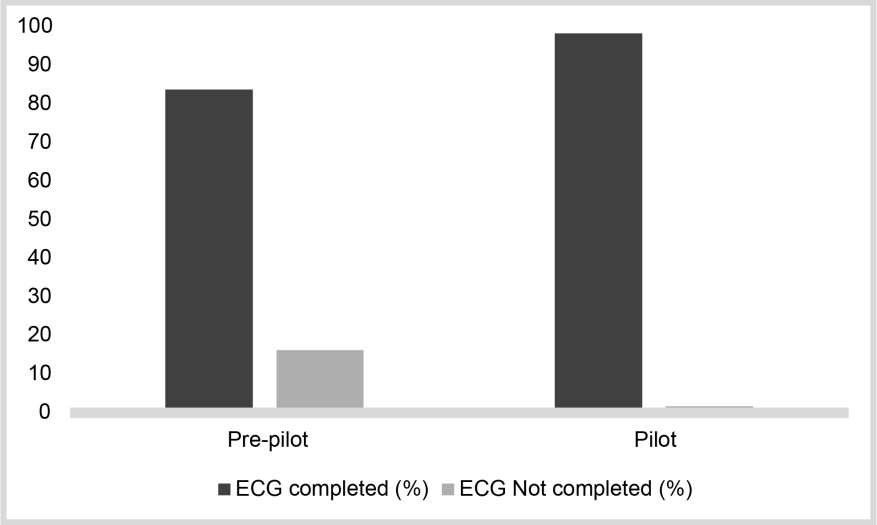

Figure 1. Bar chart comparing ECG completion status across pre-pilot and pilot periods.

Other reasons for the KardiaMobile being easy to use were that it was comfortable, a small device, and it was simpler than "*The process of lying down, potentially being waxed and plugged in*" [P1].

The staff also identified that the KardiaMobile was simple and easy to use: "*It's easier and more convenient to use*" [S1]; and "*Service user friendly. Easy*" [S5]. It was noted that this ease and convenience meant that the experience for the patient is improved.

S3: *It has made for a better physical health check appointment experience, due to its ease and convenience of use.*

Quicker and less time consuming

The patients noted that the KardiaMobile was quicker to use compared to the 12-lead ECG: "*It's much quicker to use than the* 12*-lead*" [P22]; "*Takes less time in comparison*" [P10]; "*Less time consuming than the other option*" [P19]. They also commented that the results and process was quicker:

P17: *Quick and easy - didn't have to get undressed.*
P22: *Less stickers. Quicker. Didn't need to undress.*

When staff estimated how much time was required to use KardiaMobile they reported it was less than the 12-lead (depending on prep required e.g., undressing, shaving), staff and patients liked this. By being quicker staff had more time for other tasks, and more ECGs could be completed.

S1: *It has been quicker to use in the physical health check appointments. It has resulted in more ECG's being completed.*

Staff noted time saving in relation to passing on the findings and getting inter-

pretations:

S3: *Paperless has made it easier for report to be passed to interpreting professionals with reduced delay.*
S5: *Interpretation of ECG quicker as sent via email.*

Less intrusive and invasive process

A benefit of the KardiaMobile in comparison with the 12-lead ECG was patients do not have to get undressed meaning they felt the process was more acceptable:

P27: *Not intrusive, don't have to take anything off.*
P19: *More relaxed and feel less exposed.*

Professionals also highlighted that in comparison with the 12-lead, the KardiaMobile caused less embarrassment and afforded more privacy for the patients. Staff described the KardiaMobile as "*less intrusive*" [S1, S2]; and "*less invasive*" [S3, S4, S5]. This meant patients previously having refused ECGs, now agreed to having one.

S5: *People have declined* 12*-lead ECG due to reasons, whether part of their illness/previous trauma, but have agreed to have a* 6*-lead ECG, as less invasive.*
S1: *It saves patients having to get undressed for this and potentially feeling embarrassed.*

This can be particularly useful to overcome religious and cultural reasons for refusal of a 12-lead ECG.

S3: *A young Muslim lady has previously refused to have* 12*L as uncomfortable removing or adjusting her Burka agreed to have* 6*L ECG as could complete without having to do this. She has had two ECGs since the* 6*L introduced.*

Overcomes negative issues associated with useability of* 12*-lead ECG

Both patients and staff reported that a benefit of the KardiaMobile was that it negated certain issues and problems associated with the useability and acceptability of the 12-lead ECG. For example, they felt it was a benefit not having to have sticky pads placed on the body which did not always stick well:

*P*16: *No stickers on my chest previously not stuck well due to hairy chest.*
*S*3: *The stickers often do not stick very well.*

that the sticky pads could be painful when being removed:

P2: *Leaves glue, worried when I have* 12*-lead ECG it's going to pull my hair out or hurt.*
S1: *It saves sticky pads being placed on male chests, that may pull hair off when removed*

patients didn't need to be shaved:

P23: *Don't have to shave my chest* [*for KardiaMobile*].
S2: *May have to shave chest for* 12*-lead.*

there were no cables:

P20: *So much better than to be strapped up to all those cables.*

it is more comfortable:

P21: *KardiaMobile is more comfortable than sticky pads.*

Portable and accessible

A key advantage raised by the staff was that the KardiaMobile was, especially compared to the 12-lead ECG, a very portable device, that can be used in the community and taken to the patient. This means professionals can use it on home visits and fit in assessments around the patient needs.

S1: *I used in place of a* 12*-lead, during a home visit, where the KardiaMobile device was portable to take with me.*
S2: *Have used when meeting a patient during their lunch break from work.*

This portability element of the KardiaMobile offers a great advantage that staff can still get the reading that they need when patients are unable or unwilling to attend appointments or come to clinics.

S3: *Portable to take on home visits for patients that can't attend clinics for various reasons or miss appointments.*
S4: *In a patient's home when increasing medication, the patient was refusing to come to base for a* 12*-lead.*

This portability of the KardiaMobile also means it is readily accessible and therefore can be used as and when needed, and not something that needs to be pre-planned, organised and pre-booked.

S3: *Being more mobile has made it easier and more convenient to carry around when out in the community, more readily available when seeing patients.*
S5: *During medication reviews in non-clinic space, unplanned situations where was not expecting to see a patient and being responsive to change in treatment plan and having it to hand when medication changes occur.*

More effective and efficient patient care and treatment

The staff identified various areas where they felt that using the KardiaMobile promoted a more effective and efficient service for their patients. Due to ease and convenience, portability, less invasive, and not having some of the negative aspects associated with the 12-lead, professionals reported that patient assessment and treatment was enhanced in that the KardiaMobile encouraged a greater uptake of ECGs. This resulted in patients having their required assessment and monitoring more frequently.

S1: *Increases uptake of ECG recording and better health monitoring.*

Using the KardiaMobile meant it was more likely that individuals would get an ECG, this can reduce negative health outcomes:

S5: *It makes ECG recording more likely, to monitor this whilst they are on medication, reducing the risk of adverse effects and health outcomes, through enabling certain health interventions to be identified;*

making it safer for patients and more responsive to their needs:

S3: *ECG monitoring has increased ensuring that antipsychotic prescribing is safer and cardiac risks are monitored. It has allowed for team to be more responsive to patient needs.*

KardiaMobile increased the number of ECGs being done. Some staff were not trained and therefore were not able to do a 12-lead ECG, however all staff were trained to use the KardiaMobile.

S4: *Previously it was only a couple of staff members that were trained and able to complete ECGs whereas the wider team are trained and able to use the device, increasing accessibility and quantity of ECGs being completed.*

A greater number of ECGs can be done because the KardiaMobile is quicker, it can be offered to those who can't attend clinic, and those have previously declined a 12-lead.

S2: *It increased number of ECG's taken for those that may not attend clinic or decline a* 12*-lead ECG, it is ensuring these patients don't miss out on identification of any potential health issues.*

KardiaMobile has enabled staff to meet NICE guidelines in relation to assessment, monitoring and treatment:

S1: *Better NICE compliance by increasing the number of ECG's completed, which is an important element of medication monitoring.*

Preferred option taken by patients

Patient participants suggested that they would rather use the KardiaMobile than the 12-lead ECG, suggesting it was "*much better*" [P7, P11, P12, P13, P15, P16, P17] "*much preferred*" [P1, P2] and "*much better than the other one*" [P21].

Staff all said that they felt their patients preferred to use the KardiaMobile.

S4: *Is it much preferred by service user group. People have refused the* 12*-lead ECG but have agreed to have a* 6*-lead ECG.*

Issues associated with KardiaMobile use

Staff flagged up that a 12-lead may still be required on some occasions, particularly for baseline readings.

S3: 12*-lead is gold standard and required as baseline.*

Of the 27 patient participants, the majority ($n = 25$, 93%) reported that they had

no issues or problems with the KardiaMobile. Two reported issues, both minor and resolved:

P1: *Slight issue getting the left ankle to work [positioning of sensor], moved to knee instead.*
P8: *It didn't work the first time; it did work the second time.*

The staff also reported a couple of technical issues that they experienced, one with the software app and having to delay sending information, and another reporting the fact that it is recorded in real time and if not aware of this, some may interpret abnormalities that are benign (movement, connectivity, etc). The main technical problem was if there were issues with connectivity and wi-fi internet signals, this could affect usage; however, this was not common.

S1: *Occasionally a signal wasn't strong enough and resulting in an inadequate reading.*

The staff identified the need for more KardiaMobiles.

S4: *More devices are needed.*

4. Discussion

This mixed-methods evaluation examined the impact of implementing the KardiaMobile 6-lead ECG within an EIP service, integrating quantitative outcomes with patient and clinician feedback. Overall, the findings indicate that the introduction of the KardiaMobile was associated with improved ECG accessibility, increased uptake, enhanced workflow efficiency, and a more acceptable patient experience. These improvements have important implications for improving antipsychotic monitoring, NICE compliance, and overall patient safety and health within EIP services.

Quantitative analysis demonstrated a significant improvement in ECG completion during the pilot phase, indicating that the introduction of a small, battery powered, and minimally invasive ECG solution supported greater engagement with physical health monitoring. This finding suggests that reducing practical and procedural barriers can meaningfully improve completion of recommended cardiac monitoring in routine care. Improvements in documentation rates were also observed, indicating that the streamlined digital workflow may support more consistent clinical recording. These findings are consistent with wider evidence that digital health technologies can improve uptake, efficiency, and documentation in in frontline services [23].

Changes in ECG modality also reflected the intended effect of implementation. While KardiaMobile ECGs were not used prior to the pilot, their subsequent uptake (28% of ECGs) indicates that KardiaMobile and standard 12-lead ECGs were used in combination during the pilot phase. Referral rates and repeat ECGs remained stable across phases, suggesting that improvements in completion rates did not simply reflect increased clinical burden elsewhere. Taken together, these

findings indicate that KardiaMobile improved accessibility and operational performance in a population where monitoring can be challenging due to fluctuating engagement, symptom severity, and logistical barriers.

EIP services aim to deliver rapid, holistic, and preventative treatment and care to improve long-term outcomes following first-episode psychosis. Cardiometabolic monitoring is essential due to the increased physical health risks associated with antipsychotic medications [7]. The flexibility offered by KardiaMobile aligns closely with the EIP model, which prioritises community-based and responsive care. Staff reported being able to conduct ECGs during home visits, opportunistically during medication reviews, and in non-clinical settings. This adaptability reflects national priorities to improve physical health care within community based mental health services [24] and supports more equitable access for individuals who may struggle to attend clinic-based appointments.

Patient feedback highlighted the high acceptability of the KardiaMobile, with all patients reporting the KardiaMobile as easy to use. This finding aligns with existing evidence that user-centred and minimally intrusive technologies can improve engagement with physical healthcare among people with serious mental illness [23]. Not needing sticky pads, shaving, undressing, or cables eliminated many distressing components associated with traditional 12-lead ECGs. This is particularly important given the known influence of psychotic symptoms, trauma histories and cultural considerations on ECG avoidance. This study's findings align with trauma-informed care guidance, which emphasises minimising unnecessary intrusiveness to support patient trust and engagement [25]. The KardiaMobile offers both clinical and relational advantages for people with experience of psychosis.

Clinicians identified time savings. Faster interpretation through digital transmission further enhanced decision-making. Similar work-flow efficiencies have been reported in cardiology and emergency settings where smartphone-based ECGs improve workflow efficiency [26] [27]. These efficiency benefits have potential cost implications, including: reduced clinical time per ECG, greater capacity within EIP service and physical health clinics, reduction in missed ECGs due to refusal, and decreased need for separate 12-lead ECG appointments. Although a formal economic evaluation was beyond the scope of this study, these findings suggest that KardiaMobile may support more cost-effective service delivery.

Improved ECG uptake enables closer adherence to NICE recommendations for cardiac monitoring in patients prescribed antipsychotics [7]. Clinicians reported that the KardiaMobile enabled more consistent ECG completion, including in patients who historically refused or avoided 12-lead ECGs. This has direct implications for safety, given the importance of detecting QTc prolongation and arrhythmias in this population. Previous research has shown that the KardiaMobile has acceptable accuracy for rhythm analysis and QT measurement in community and clinical settings [28]. However, it does not replace the full diagnostic capability of a 12-lead ECG, and staff appropriately identified that a 12-lead remains the gold

standard for baseline assessment and some specific diagnostic use.

The integration of KardiaMobile within EIP services highlights several opportunities for service development. First, the positive impacts observed in this evaluation suggest that the model has potential scalability across other EIP teams, wider community mental health services, and mental health inpatient settings. Second, increased availability of ECG monitoring is facilitated by enabling a broader range of staff to undertake ECGs, reducing historical reliance on a small number of trained clinicians. Third, the reduced invasiveness of the technology may support more equitable access to ECG monitoring, particularly for individuals from culturally, ethnically, or religiously diverse backgrounds, as well as for those with histories of trauma or sexual abuse. In addition, integration with electronic health record systems offers opportunities for digital optimisation, strengthening clinical documentation, auditability, and governance. Finally, improved frequency and success of ECG monitoring may support earlier detection of cardiac abnormalities, safer antipsychotic prescribing, and potential improvements in physical health outcomes and overall wellbeing.

4.1. Limitations

The evaluation was undertaken within a single NHS EIP service, which restricts generalisability. Despite all NHS EIP services being based on same commissioning requirements, local differences in service design, clinician skill-mix, organisational culture, and local operational demands and priorities may influence KardiaMobile implementation outcomes and user experience. As a result, this study's improvements in ECG completion, workflow efficiency, and patient satisfaction may not be directly transferable to other settings.

The evaluation drew on routine clinical records, which, while reflective of real-world practice, are subject to variability in documentation quality and completeness. The qualitative component involved a relatively small group of patients and clinicians, which introduces a risk of response bias. Participants with particularly strong views, either positive or negative, may have been more inclined to engage, potentially skewing the thematic findings. The evaluation relied heavily on self-reported perceptions of ease of use, confidence, and efficiency.

The absence of long-term follow-up restricts understanding of whether improvements seen were sustained over time. The study did not examine long-term KardiaMobile adoption, staff skill retention, or whether enhanced cardiometabolic monitoring was maintained beyond the initial implementation period.

4.2. Further Study

Given these limitations, several directions for further study are warranted. Large-scale, multi-site evaluations would help determine whether the benefits observed in this service are consistent across different EIP teams, population groups, and clinical environments. Such studies would enhance the external validity of the findings and support the development of national implementation guidance.

Further studies should also include comparative diagnostic studies assessing the quality and accuracy of KardiaMobile 6L ECGs against conventional 12-lead ECGs in routine EIP practice. Establishing equivalence or identifying limitations in specific clinical scenarios would strengthen the evidence base for safe prescribing and cardiometabolic monitoring, particularly for antipsychotic medication management.

Mixed-methods evaluation incorporating objective workflow metrics would provide a robust evaluation of clinical efficiency. This could include measuring time to ECG completion, the proportion of repeat attempts required, task-switching patterns among clinicians, and the impact on appointment duration. Economic evaluation, including cost-effectiveness and cost-benefit analysis, would further inform NHS decision-making regarding the scalability.

Longitudinal studies are needed to explore how KardiaMobile use can influence practice over extended periods. Areas of interest include whether earlier and more frequent ECG access contributes to improved detection of cardiometabolic abnormalities, enhances medication safety, or reduces long-standing physical health disparities experienced by people with psychosis.

Further studies should aim to capture a broader and more diverse range of patient experiences, including individuals with language or communication needs, or more complex mental health presentations. This would help ensure that implementation strategies support equitable access. Understanding barriers and facilitators across diverse patient groups will be essential for embedding cardiometabolic monitoring technologies in a way that is both clinically effective and inclusive.

5. Conclusions

This evaluation demonstrates that the KardiaMobile 6-lead ECG can be successfully integrated within an EIP service and can meaningfully enhance physical health monitoring in routine clinical practice. The findings support the use of KardiaMobile 6L as a pragmatic adjunct to standard care, associated with improved compliance with clinical guidance, safer antipsychotic prescribing, increased patient engagement, and greater staff efficiency. By reducing practical, emotional, trauma experience, and cultural barriers commonly associated with traditional 12-lead ECGs, the KardiaMobile facilitates higher uptake of cardiac monitoring among individuals with psychosis, a population in whom engagement can be particularly challenging.

Importantly, while the KardiaMobile offers clear advantages in accessibility and acceptability, it does not replace the diagnostic role of a standard 12-lead ECG. A 12-lead ECG remains essential in certain clinical contexts, including baseline assessment, detection of pre-existing abnormalities, and where specific guidance indicates its use. Rather than functioning as a substitute, the KardiaMobile should be viewed as a complementary tool that enables more consistent and timely cardiac monitoring and where traditional ECGs are difficult to obtain.

Ensuring effective assessment of cardiac function in people receiving antipsychotic medication is fundamental to safe, guideline compliant treatment and care. This study highlights the potential for digitally-enabled patient-centred approaches to strengthen physical healthcare delivery within mental health services. Wider adoption of KardiaMobile may support improved equity of access, enhanced patient experience, cost savings, and better clinical outcomes, and should be considered a priority for service development within EIP and wider mental health settings.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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