Title: **Establishing a smartphone ambulatory ECG service for patients presenting to the Emergency Department with pre-syncope and palpitations.**

Author list: Matthew J. Reed [1,2*] , Alexandra Muir [1], Julia Cullen [1,3], Ross Murphy [3], Valery Pollard [3], Goran Zangana [3], Sean Krupej [3], Sylvia Askham [3], Patricia Holdsworth [3], Lauren Davies [3]

Affiliations:

[1] Emergency Medicine Research Group Edinburgh (EMERGE), Department of Emergency Medicine, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh EH16 4SA, UK.

[2] Acute Care Group, Usher Institute of Population Health Sciences and Informatics, College of Medicine and Veterinary Medicine, University of Edinburgh, Nine Edinburgh BioQuarter, 9 Little France Road, Edinburgh EH16 4UX, UK.

[3] Acute Medicine, NHS Lothian, Edinburgh, United Kingdom

* Corresponding author

Medica Minerva article: Word count: 1938; Abstract: 283 (300); Illustrations and tables: 1 ; References: 13

Funding: MR is supported by an NHS Research Scotland Career Researcher Clinician award. The REDCap database used for this study was funded by a Royal College of Emergency Medicine grant.

Disclosures: All authors declare that they have no competing interests and no financial interest in the device used in this study. AliveCor had no involvement in the study. The Emergency Medicine Research Group Edinburgh received sponsorship for the EMERGE10 conference in 2018 from various companies including AliveCor.

 doi:10.20944/preprints202101.0315.v1

Establishing a smartphone ambulatory ECG service for patients presenting to the Emergency Department with pre-syncope and palpitations.

Abstract: 283 words (300)

Background and Objectives: The IPED study showed that a smartphone-based event recorder increased the number of patients in whom an ECG was captured during symptoms over five-fold to more than 55% at 90 days compared to standard care **[1]** and concluded that this safe, non-invasive and easy to use device should be considered part of on-going care to all patients presenting acutely with unexplained palpitations or pre-syncope. This study reports the process of establishing a smartphone palpitation and pre-syncope service.

Materials and Methods: A clinical Standard Operating Procedure (SOP) was devised, and funding was secured through a business case for the purchase of 40 AliveCor devices in the first instance. The clinic was launched on 22nd July 2019.

Results: Between 22nd July 2019 and 31st October 2019, 68 patients seen in the ED with palpitations or pre-syncope were referred to SPACC. 30 were male and 38 female and mean age was 45.8 (SD 15.1) with a range from 18 to 80 years. 50 (74%) patients underwent full investigation. 7 (11%) patients were deemed on first assessment to have non-cardiac palpitations and were not fitted with the device. All patients who underwent full investigation achieved symptomatic rhythm correlation most with sinus rhythm, ventricular ectopics or bigeminy. A symptomatic cardiac dysrhythmia was detected in 6 (8.8%) patients. 3 patients had supraventricular tachycardia; SVT (4%), 2 had atrial fibrillation (3%) and 1 atrial flutter (2%). Qualitative feedback from the SPACC team suggested several areas where improvement to the clinic could be made.

Conclusion: We believe a smartphone palpitation service based in ambulatory care is simple to implement and is effective at detecting cardiac dysrhythmia in ED palpitation patients.

Keywords: Emergency Department, Diagnosis, ECG monitoring, Cardiac dysrhythmias

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 18 January 2021 doi:10.20944/preprints202101.0315.v1

Establishing a smartphone ambulatory ECG service for patients presenting to the Emergency Department with pre-syncope and palpitations.

Introduction:

Patients with palpitations and pre-syncope commonly present to Emergency Departments (EDs), being responsible for 300,000 ED presentations a year in the United Kingdom **[2,3]** and being one of the commonest presentations to General and Family Practice (16% of presentations). **[4]**

Underlying rhythm diagnosis is difficult and is often not possible during the initial presentation. The only way to establish the underlying heart rhythm is to capture an Electrocardiogram (ECG) while the patient has symptoms. However, 12-lead ECG is of limited efficacy and conventional ambulatory monitoring such as Holter has a diagnostic yield less than 20% mainly due to the infrequency of symptoms **[5]**.

The AliveCor/Kardia mobile technology is an FDA-cleared, CE-marked single-lead rhythm strip comparable to lead I of standard ECG machines and is the most clinically-validated mobile ECG solution available worldwide. The device, when used alongside with the Kardia app, can provide an instant analysis for normal sinus rhythm, atrial fibrillation, sinus bradycardia, and sinus tachycardia in around 30 seconds **[6]**.

The IPED study **[1]** was a multi-centre open label, randomised controlled trial. Participants ≥16 years old presenting to 10 UK hospital EDs were included and were randomised to either (a) an intervention group who received standard care plus the use of a smartphone-based event recorder or (b) a control group who received standard care alone. The primary endpoint was symptomatic rhythm detection rate at 90 days. Two hundred forty-three participants were recruited over an 18-month period.

The results showed that a smartphone-based event recorder increased the number of patients in whom an ECG was captured during symptoms (symptomatic rhythm) over five-fold at 90 days (69/124; 55.6%; 95% CI 46.9–64.4% versus 11/116; 9.5%; 95% CI 4.2–14.8; RR 5.9, 95% CI 3.3–10.5; p<0.0001). Mean time to symptomatic rhythm detection in the

 doi:10.20944/preprints202101.0315.v1

intervention group was 9.5 days (SD 16.1, range 0–83) versus 42.9 days (SD 16.0, range 12–66; p<0.0001) in the control group. The commonest symptomatic rhythms detected were sinus rhythm, sinus tachycardia and ectopic beats. A symptomatic cardiac dysrhythmia was detected at 90 days in 11 (n= 124; 8.9%; 95% CI 3.9–13.9%) participants in the intervention group versus 1 (n= 116; 0.9%; 95% CI 0.0–2.5%) in the control group (RR 10.3, 95% CI 1.3–78.5; p = 0.006).

The IPED study concluded that this safe, non-invasive and easy to use device should be considered part of on-going care to all patients presenting acutely with unexplained palpitations or pre-syncope. This study reports the subsequent establishment of a Smartphone Palpitation and pre-syncope Ambulatory Care Clinic (SPACC).

Materials and Methods:

A clinical Standard Operating Procedure (SOP) was devised, and funding was secured through a business case for the purchase of 40 AliveCor devices in the first instance. From 22nd July 2019, all patients aged 16 years or older presenting to the Emergency Department (ED) or Acute Medicine Unit (AMU) of the Royal Infirmary of Edinburgh (RIE) with palpitations or pre-syncope, whose ECG was normal, who had a compatible Apple/android phone, tablet or watch and in whom an underlying cardiac dysrhythmia was possible, were offered an appointment at the SPACC, which was based in an Ambulatory Care clinic setting beside the ED. Ambulatory Care is a service which offers same or next day hospital based emergency and acute care meaning that patients are assessed, diagnosed, treated and are able to go home without being admitted into a hospital bed overnight wherever possible.

Exclusion criteria included the patient being non-ambulant, requiring hospital admission, having a prior diagnostic ECG, having multiple frequent episodes or recent acute myocardial infarction (AMI), severe heart failure or unstable angina, having associated chest pain or syncope, being unwilling or unable to use the AliveCor Heart Monitor & ECG App, having a cardiac pacemaker or other implanted electronic device or having a likely non-cardiac cause for their palpitations (e.g. anxiety, sepsis).

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 18 January 2021 doi:10.20944/preprints202101.0315.v1

The patient's phone, tablet or watch was checked for compatibility, they were asked to bring their smartphone, tablet or watch and app store password to the ambulatory appointment (and later were asked to download the Kardia app prior to coming to the clinic but not to set it up, which was done in clinic). Routine blood tests including thyroid function tests, full (complete) blood count, urea and electrolytes and magnesium levels were taken, and the patient was then discharged with a patient advice leaflet to be seen in the SPACC on the next available day. Initially only ED and AMU referrals were taken. The IPED study **[1,7]** showed that 93% of participants recording a symptomatic rhythm during the 90 days, did so in the first 28 days. It was therefore decided that patients would be reviewed at four weeks to enable efficient device usage and timely treatment. Patients without a symptomatic rhythm at four weeks could be re-reviewed if necessary.

Other components of the SPACC SOP were a list of compatible devices for the ED/AMU clinician to refer to, a patient symptom diary, a patient instruction manual, a clinic checklist and advice for the clinic clinician how to incorporate a patient ECG into the RIE Electronic Patient Record (EPR). We also sought approval from our hospital data controller (termed Caldicott Guardian) who suggested using anonymised patient information, standardised for all patients, in the Kardia application (i.e. first name 'ambulatory', last name 'care', date of birth '01/01/1980'). The study was deemed by the local ethics service to be a service evaluation and therefore ethical approval was not required. The study was registered on the RIE ED Quality Improvement Project (QIP) database. A data template was created using REDCap, a secure electronic database (http://www.project-redcap.org) for anonymised data entry. **[8,9]** which was funded by a grant from the Royal College of Emergency Medicine (RCEM).

Results: Between 22nd July 2019 and 31st October 2019, 68 patients were seen in the ED with palpitations or pre-syncope and were referred to SPACC. 30 were male and 38 female and mean age was 45.8 (SD 15.1) with a range from 18 to 80 years. **Figure 1** details the flow of patients through the SPACC. 50 (74%) patients underwent full investigation. 7 (11%) patients were deemed on first assessment to have non-cardiac palpitations and were not fitted with the device. A symptomatic cardiac dysrhythmia was detected in 6 (8.8%) patients. 3 patients had supraventricular tachycardia (SVT; 4%), 2 had atrial fibrillation (3%) and one had atrial

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 18 January 2021 doi:10.20944/preprints202101.0315.v1

flutter (2%). All other patients undergoing investigation had a non-cardiac symptomatic rhythm detected during their SPACC investigation period with sinus rhythm, ventricular ectopics and bigeminy being detected.

Difficulties addressed and improvements made:

a) *Clinic referral criteria:* Qualitative feedback from the SPACC team suggested several areas where improvement to the service could be made. Firstly, it was noted that 10% of patients referred to the clinic were deemed on first assessment to have non-cardiac palpitations and were not fitted with the device. A pre-planned sub study of the IPED study **[10]** asked the treating ED clinician to rate the likelihood of underlying cardiac dysrhythmia ranging from 1 (least likely) to 10 (most likely). An ED clinician likelihood rating of 5 or more had 92% sensitivity and 59% specificity for predicting cardiac dysrhythmia. This sub study concluded that ED clinicians are able to predict the likelihood of cardiac dysrhythmia in patients presenting to the ED with palpitation or pre-syncope with reasonable accuracy. It was therefore decided to review the SPACC referral criteria to ensure the clinic slots were prioritised for patients 'thought to be at risk of cardiac dysrhythmia'.

b) *Patients expectations:* Some patients were coming to the SPACC with an expectation that they were going to be fitted with the AliveCor device. In order to manage patients' expectations when the clinic staff might feel that the risk of cardiac dysrhythmia was not high enough to warrant AliveCor device fitting, the referral pathway was revised to ensure that patients were counselled in the ED that they were coming to the SPACC for assessment for AliveCor device fitting.

c) *Embedding of electronic ECGs into the Electronic Patient Record:* It was felt that better embedding of electronic ECGs into the EPR was required. A process and protocol for uploading ECGs into EPRs was therefore developed.

d) *ECG interpretation:* Occasionally when the recorded ECG included noise or artefact, less experienced clinic staff had difficulty interpreting the ECG and would be more likely to order additional investigations or further AliveCor wear time whereas more

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 18 January 2021 doi:10.20944/preprints202101.0315.v1

senior clinicians were comfortable interpreting these recorded ECGs as normal sinus rhythm. It was therefore encouraged for staff to seek a second opinion from the ED or on call medical consultant if required, and an ECG diagnostic algorithm was also developed.

e) *Downloading the Kardia App:* Due to poor Wi-Fi and phone reception in the SPACC location, it was decided to alter the referral pathway to ensure patients were asked to download the Kardia app prior to clinic attendance to increase clinic efficiency.

f) *Length of time between clinic appointments:* The median time patients had the device for was 28 (Q1, Q3 15.25-30 days). Although the IPED study experience deemed that this was the optimum time, the SPACC staff felt occasionally that this was too long for patients who had recorded one of more symptomatic rhythms within the first week or two of having the device. In order to optimise AliveCor device turn over and to counsel patients who had already recorded a symptomatic rhythm it was decided to bring patients back earlier at 2 weeks and if no symptomatic rhythm had been recorded, to allow them to continue use of the device until this had occurred, which for one patient was 76 days.

g) Other changes to the clinic protocol that were made included less emphasis on patient diaries which were often poorly completed, better logging of devices and a routine battery change for every device every 12 months.

Discussion:

This is the first report anywhere of an ambulatory smartphone palpitation and pre-syncope service for emergency and acute medical patients presenting with pre-syncope and palpitations. The service allows patients who present to either the ED or the AMU of the RIE with pre-syncope and palpitations to be referred to a next day assessment clinic for consideration of AliveCor/Kardia device fitting.

Our preliminary three month clinic data shows that the detection of symptomatic cardiac dysrhythmia in 8.8% patients is comparable to the 8.9% of patients who had a symptomatic

cardiac dysrhythmia detected in the IPED study **[1]** and shows that a research protocol and research finding can be successfully extrapolated and implemented in a pragmatic clinical setting.

We plan to continue to assess our service and to further evaluate the effect of the changes that were made at the three month point. Further work could include scaling up the clinic in order to allow General and Family practitioners to refer patients for investigation and also to integrate the service further with our hospital's cardiology service. We have also given support to other health boards across the United Kingdom to help them establish a similar service and contributed to NICE evaluations both in England and Wales of this service model **[6,11].**

Our service model is generalisable to a wide range of healthcare systems as well as the emergency and acute setting and could equally be applied to General and Family practitioner settings for less acute patients. The existence of an AliveCor postal service also allows hospitals to send out devices which is important during the recent COVID19 pandemic which is likely to be an ongoing concern in healthcare provision for at least the next 12 months. This remote option reduces the need for repeat face to face out-patient clinic attendances and may potentially increase the efficiency of diagnosis and definitive treatment.

Conclusions:

We believe a smartphone ambulatory ECG palpitation service is simple to implement and is effective at detecting cardiac dysrhythmia in emergency and acute palpitation and pre-syncope patients.

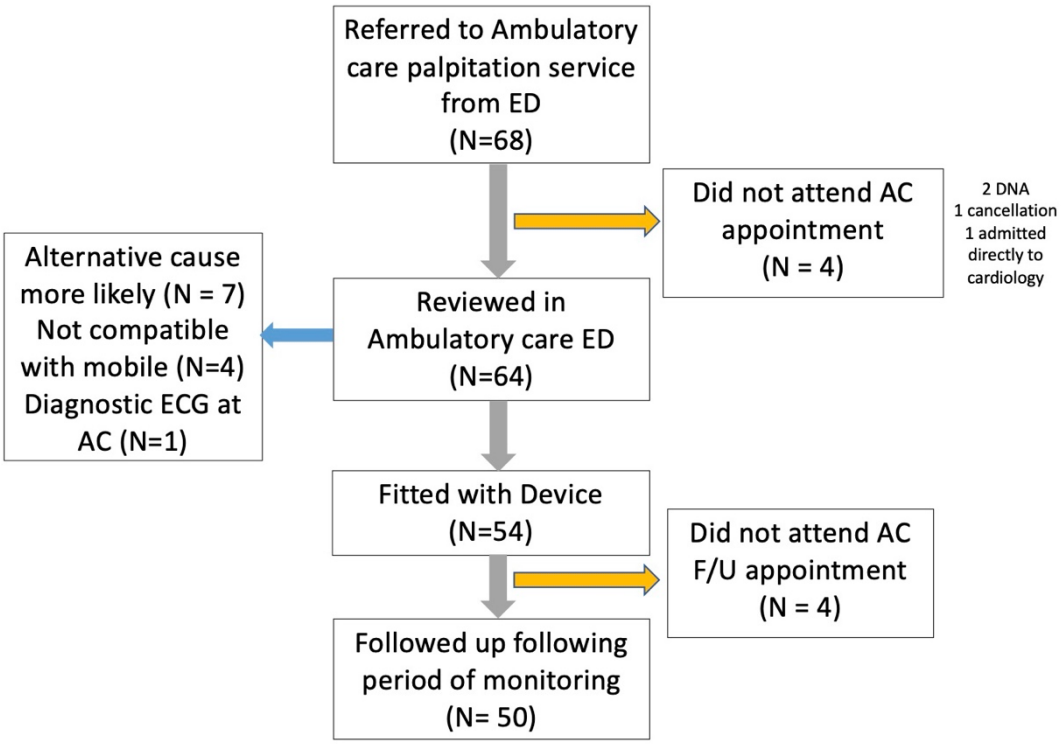
Figure and Table Legends:

Figure 1: Flowchart of patients through the SPACC.

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 18 January 2021 doi:10.20944/preprints202101.0315.v1

Figures and Tables:

Figure 1:



Abbreviations: ED=Emergency Department, ECG=Electrocardiogram, AC=Ambulatory Care, F/U= Follow-Up

Supplementary Materials: Emergency Department/ AMU RIE Smartphone Palpitation Service Clinic SOP V3 Date 13 07 2020. Revision date May 2023 **[12]**

Acknowledgments: Funding; MR is supported by an NHS Research Scotland Career Researcher Clinician award. The REDCap database used for this study was funded by a Royal College of Emergency Medicine grant.

Author Contributions: MJR conceptualised the study, AM, JC, RM, VP, GZ, SK, SA, PH and LD were responsible for acquisition of data, MJR, AM, JC were responsible for analysis of data, all authors were responsible for data interpretation of data and MJR, AM and JC drafted the work. All authors have approved the submitted version and agree to be personally accountable for their own contributions and for ensuring that questions related to the

accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and documented in the literature.

Conflicts of Interest: All authors declare that they have no competing interests and no financial interest in the device used in this study. AliveCor had no involvement in the study. The Emergency Medicine Research Group Edinburgh received sponsorship for the EMERGE10 conference in 2018 from various companies including AliveCor.

Ethics: The study was deemed by the local ethics service (South East Scotland Regional Ethics Committee to be a service evaluation project and therefore deemed that ethical approval was not required. The study was registered on the Royal Infirmary of Edinburgh Emergency Department Quality Improvement Registry. The study was conducted in accordance with the Declaration of Helsinki.

References:

1. Reed MJ, Grubb NR, Lang CC, et al. Multi-centre randomised controlled trial of a smartphone-based event recorder alongside standard care versus standard care for patients presenting to the Emergency Department with palpitations and pre-syncope: the IPED (Investigation of Palpitations in the ED) study. Lancet eClinical Medicine 2019; 8: 37–46
2. Thiruganasambandamoorthy V, Stiell IG, Wells GA, Vaidyanathan A, Mukarram M, Taljaard M. Outcomes in Presyncope Patients: A Prospective Cohort Study. Annals of Emergency Medicine 2015; 65 (3): 268-276 e6
3. Probst MA, Mower WR, Kanzaria HK, Hoffman JR, Buch EF, Sun BC. Analysis of emergency department visits for palpitations (from the National Hospital Ambulatory Medical Care Survey). Am J Cardiol 2014; 113(10): 1685-90
4. Raviele A, Giada F, Bergfeldt L, et al. Management of patients with palpitations: A position paper from the European Heart Rhythm Association. Europace 2011;13(7):920–34. doi: 10.1093/europace/eur130
5. Cheung CC1, Kerr CR, Krahn AD. Comparing 14-day adhesive patch with 24-h Holter monitoring. *Future Cardiol.* 2014; 10(3): 319-22

6. National Institute for Health and Care Excellence. AliveCor heart monitor and AliveECG app (Kardia Mobile) for detecting atrial fibrillation. NICE advice MIB35. London: NICE, 2020; https://www.nice.org.uk/advice/mib232; (accessed 03/01/2021)
7. Reed MJ, Grubb NR, Lang CC, et al. 'For how long should we monitor ED palpitation patients in the outpatient setting?' Oral presentation to RCEM ASC 2019 Gateshead; https://emj.bmj.com/cotent/36/12/787.2
8. Paul A Harris et al. (2009). "Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support". *Journal of Biomedical Informatics* 42 (2): 377–381. doi:10.1016/j.jbi.2008.08.010
9. "REDCap". https://projectredcap.org (accessed 03/01/2021)
10. Reed MJ, Grubb NR, Lang CC, et al. 'Clinician prediction of cardiac arrhythmia in patients presenting to the ED with palpitation or pre-syncope'. Oral presentation to RCEM ASC 2019 Gateshead; https://emj.bmj.com/content/36/12/783.2
11. https://www.healthtechnology.wales/reports-guidance/alivecor-kardiamobile-device/ (accessed 03/01/2021)
12. https://www.emergeresearch.org/wp-content/uploads/2015/12/Palpitation-Ambulatory-care-pathway-v3-13-07-2020-FULL-VERSION.pdf (accessed 03/01/2021)