Opportunistic atrial fibrillation screening and detection in "self-service health check-up stations": a brief overview of current technology potential and possibilities

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Abstract: Up to a fifth of patients who suffer a stroke had undiagnosed atrial fibrillation (AF). About 30% of AF patients are asymptomatic and remain undiagnosed, so there are no obvious (to the patient) forewarnings. Opportunistic screening for AF applied to the above clinical situation can save lives, since the strokes that occur as a result of AF are often large, severely debilitating or fatal. Today, anyone can buy a good, FDA-approved mobile electrocardiogram (ECG) device/smartwatch for AF detection on Amazon for €100–400, but not very many asymptomatic AF patients, particularly older patients, will do so on their own. In this article, we introduce the concept and potential benefits of opportunistic AF screening and detection in a community setting using the latest generation of affordable digital ECG capture and interpretation solutions integrated into easy-to-use "self-service health check-up stations" installed in public spaces, such as supermarkets and pharmacies. A comprehensive trial of the proposed self-service health check-up stations for AF screening is needed to produce more evidence to convince decision makers to fully buy into the idea of a nation-wide screening programme using these kiosks.

Keywords: Atrial fibrillation (AF); opportunistic atrial fibrillation screening; electrocardiogram (ECG); self-service health check-up stations; digital health

Background

Atrial fibrillation (AF): a silent killer

AF is the commonest pathological arrhythmia in the world and in population-based studies is found to be present in around 3% of the world's population aged over 20 (1). When it is associated with risk factors such as age over 65, hypertension or diabetes mellitus it confers a significant increase in the risk of stroke (2). All current cardiological guidelines stress the importance of detecting AF, calculating the level of increased risk using the CHA2DS2-VASc (Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, Stroke or transient ischaemic attack (TIA), Vascular disease, Age 65 to 74 years, Sex category] score and the institution of appropriate treatment to protect from stroke and thromboembolism.

One important problem is the fact that up to around one third of AF may be asymptomatic (2), and it is possible that this accounts for a large proportion of the 20% of patients who suffer a stroke without any apparent underlying

cause. In a recent study, the presence of subclinical atrial tachyarrhythmia detected by implanted devices (pacemakers or defibrillators) was associated with a 2.5-fold increase in thromboembolic events (3). AF risk/as a risk factor for stroke risk rises sharply with age. Strokes as a result of AF are often large/severely debilitating or fatal. Between 10% and 40% of AF patients are asymptomatic or remain undiagnosed depending on the population studied, so the patient is often unaware of the risk until a stroke or thromboembolic event occurs; the risk of dementia is also increased by 30% independent of cerebrovascular thromboembolic events (4).

In recent years, the importance of pulse checks in primary care has been widely promoted. Programmes designed to increase the prevalence of such checks have proved effective but are not yet widely embraced (5). Furthermore, they are relatively imprecise, and an electrocardiogram (ECG) will always be required for the definitive diagnosis.

Opportunistic AF screening

Since 2011 when AliveCor was founded to commercialise the Kardia device (6), a wide range of wearables, smartwatches, smartphone accessories and mobile technologies capable of recording ECGs have come on the market. Most of these provide a single lead ECG, though some now produce synthesised multi-lead recordings, e.g., AliveCor KardiaMobile 6L (7). The relatively low cost, ease of use and portability of such devices, some of which were clinically validated and FDA (US Food and Drug Administration) approved, have raised great interest in opportunistic acquisition of ECGs as a screening tool or as a diagnostic tool at the time of suspected arrhythmic symptoms.

Opportunistic screening for AF has been explored in primary care and pharmacy settings (8,9). In subjects aged over 65, the prevalence of AF assessed in such a fashion is consistently between 6% and 7%. The percentage of subjects screened in this manner who are found to have newly diagnosed AF is typically 1.5%, indicating the need to screen around 70 people in this age group to detect one with newly discovered AF (10), and thus making this a cost-effective method of screening (11). As such, the KardiaMobile device has been favourably reviewed and recommended by the National Institute for Health and Care Excellence in the UK (NICE) (12). The value of such an approach has also been explored in Canada, India and Australia among other countries (8,9,13).

An important question that remains under investigation is how long a duration of continuous AF has to be present to indicate an increased thromboembolic risk. There appears to be some evidence arising from screening for subclinical AF to suggest that episodes lasting hours rather than minutes may be of greater importance (14).

Opportunistic screening with the Kardia device in populations with limited cardiological access has been tested in rural India, where it was performed by health workers. In a population of 2,100 adults, 1.6% were found to have AF (13). In this study, all Kardia-flagged abnormal (AF or unclassified) recordings were reviewed by a cardiologist in India and verified by a second one in the USA.

The advantage of cardiological (human) scrutiny of such recordings has been emphasised by a study in the Netherlands in a cardiology out-patient clinic setting, where 5,982 Kardia device recordings were reviewed by a "heart team" including cardiologists. Of all reviewed recordings, 22% were designated as "possible AF" by the Kardia device algorithm, but one fifth of these were considered not to be AF by the heart team. A further 17% of the recordings were designated "unclassifiable" by the device, but 81% of these ECG recordings were considered to be clearly readable and diagnosable by the heart team (15). This issue of the high rate of unclassified recordings was highlighted in another study performed post-direct current (DC) cardioversion in patients with previous AF. In this study, 34% of the Kardia traces were considered by the algorithm to be "unclassified", but cardiologists were able to diagnose AF correctly from the Kardia recording (compared to the 12-lead simultaneous ECG) with 100% sensitivity and 80% specificity (16). But the six-lead KardiaMobile 6L (7), with its newer algorithms, should fare better than the original KardiaMobile that was used in the above two studies.

These findings emphasise the advantage of opportunistic screening when integrated with an appropriate level of cardiological expertise in the interpretation and verification of the classification derived from mobile technology algorithms, which might be an important factor when considering the cost-effectiveness of this type of opportunistic approach, as the physician time involved could be potentially considerable. Nevertheless, ECG trace interpretation algorithms are getting better all the time with a negative predictive value for detection of AF (ruling out AF) approaching 100% (15), and are gradually proving to be generally reliable and acceptable for screening purposes when used on their own (see later below). Persons with AF (or repeatedly inconclusive results) flagged by algorithms

should in any case be referred to a cardiologist for further confirmation and management as appropriate.

Examples of current mobile ECG solutions for AF screening and detection

Here we provide a few of the most common examples of mobile clinical-grade ECG solutions on the general consumer market as of 2019, but the ultimate comparative clinical reliability, feasibility/acceptability and cost-effectiveness/affordability of the different technologies on offer today will require further investigations/trials to fully establish, which is beyond the set scope of this article.

Besides the aforementioned AliveCor offerings (6,7) (FDA-approved, with consumer prices starting around 130 Euros per unit), the Apple Watch Series 4 and Series 5 (consumer prices starting around 400 Euros per unit) features an FDA-approved ECG app with irregular heart rhythm notification function (17-19). False AF positives are rare with the Apple Watch Series 4/5 [but a heart rate over 120 BPM affects its ECG app's ability to check for AF, and the recording is reported as inconclusive in such cases (19)]. A study published in the *New England Journal of Medicine* in November 2019 and involving over 400,000 participants using the Apple Watch ECG found wearers were unlikely to receive false notifications that they have AF (20).

In 2019, Withings released their Move ECG analogue watch with a built-in medical-grade ECG to detect AF (21). According to Withings, Move ECG has been clinically-validated, with consumer prices starting around 130 Euros per unit. The company is working closely with the FDA to receive clearance (as of 2019).

The ASUS VivoWatch SP smartwatch (expected by the end of 2019 or in early 2020; price unknown at the time of writing this article, although expected to hover around 300 Euros per unit) features ECG, pulse oxygen levels and blood pressure readings, with a 2-week battery life. As the smartwatch gradually "learns" about its user, it will offer to serve her/him tailored healthy lifestyle tips from experts at Taiwan's National University Hospital. Asus revealed it has submitted an application to the FDA to certify the smartwatch's ECG functionality, and expects the application to be approved by or before January 2020 (22,23).

Fitbit (now likely to become a Google company at the time of writing this article), Bristol-Myers Squibb and Pfizer are said to be working together on a new service relying on the AF detection feature that Fitbit is still (as of Q4 2019) developing for their wearables. Once this feature has been fully tested, submitted to the FDA and approved, a digital screening programme will be launched that will also deliver patient guidance on next steps after receiving the results of AF screening (24). Meanwhile, it was announced in October 2019 that AliveCor and Xiaomi-backed Huami (China) will co-develop new medical-grade ECG wearables and put them on the market by 2020 (25).

The above commercial solutions are powered by generally reliable proprietary artificial intelligence (AI) (including machine learning/deep learning) and non-AI algorithms for mobile ECG trace interpretation; see, for example, Hannun *et al.* (26), who describe a similar algorithm trained on a deep neural network that was able to perform on par with board certified-cardiologists when annotating 12 different types of ECG rhythm classes. But, as discussed earlier, a few "human-expert-*vs.*-algorithm" studies would disagree, e.g., (15,16). In another study published in the *Lancet* in 2019, Attia *et al.* (27) conclude that "*an AI-enabled ECG acquired during normal sinus rhythm permits identification of individuals with atrial fibrillation*". Attia *et al.* used a convolutional neural network and standard 10-second, 12-lead ECG for their study (27), but it should be possible to exploit their approach and results in future generations of mobile consumer multi-lead ECG solutions, such as the six-lead KardiaMobile 6L (7) and its future successors.

It should be noted that AI is not meant to replace clinicians, including cardiologists, but to free their time to do more, to spend more time with their patients, and sometimes to be able to see more patients per session (AI can also help patients at those times when they are on their own away from conventional healthcare facilities and clinical staff). For example, in China (1.4 billion population), the national target of screening for diabetic retinopathy in all patients with diabetes would not have been possible given the relatively limited number of specialists (ophthalmologists) in the country without the help of AI (28). The US FDA has strict criteria for evaluating and approving AI products (hardware plus software or software-only) that contribute to the diagnosis and management of human disease (the so called SaMD or "software as a medical device") (29).

News is abundant with reports of lives of patients with previously undiagnosed AF being saved thanks to these devices/smartwatches, including earlier models of the Apple Watch, e.g., (30-33). For example, in 2016, the UK Arrhythmia Alliance charity reported the results of their trial involving >1,500 AliveCor Kardia pocket-size ECG

monitors. The trial successfully diagnosed many patients with an arrhythmia after years of visits to GPs (UK General Practitioner or "family doctor") who had been unable to capture any symptoms (31).

Lesser known, non-FDA-approved cheaper alternatives to KardiaMobile and Apple Watch Series 4/5 exist in the form of specialised consumer hardware/health-oriented smartwatches from little known or "no name" brands, often marketed as "ECG+PPG" (PhotoPlethysmoGraphic) because of a dedicated ECG chip inside them, such as the TI (Texas Instruments) ADS1291 and the TI AFE4900 chips [e.g., the smartwatch with ADS1291 advertised at (34)], as well as even cheaper PPG-optical-sensor-only smart bands/fitness trackers [algorithms exist for the detection of irregular pulse using these bands after filtering out unwanted activities of daily living (ADL) motion noise in their data traces, e.g., (35)].

Alternative algorithms/apps making use of modern smartphone capabilities/cameras alone (instead of using dedicated hardware sensors) are also available, e.g., smartphone camera-based PPG pulse waveform measurement to discriminate between different heart rhythms (36-38). Chan *et al.* (36) compared the accuracy and reliability of a PPG app (CARDIIO Rhythm) solely relying on the smartphone camera *vs.* AliveCor single-lead ECG, and concluded that the PPG app "*has the potential to enable population-based screening for AF*". But the wider reliability of these options has not been fully asserted. Furthermore, the performance of smartphone camera-based PPG apps depends on the qualities of a given smartphone camera and how well a user is following the correct procedure to take a measurement.

AF detection by analysing facial PPG (FPPG) signals from multiple patients concurrently without any physical contact, using a single digital camera 150 cm away and artificial intelligence (deep learning in the form of a pretrained deep convolutional neural network), is also possible (39), and might one day become a viable AF screening solution in self-service health check-up stations (see below) and in the waiting rooms of hospital outpatient clinics and GP surgeries (subject to patient consent).

The "self-service health check-up station" concept for AF screening

The cost of buying kits such as AliveCor KardiaMobile, Apple Watch Series 4/5, or Withings Move ECG watch might pose a barrier for many AF patients, particularly older patients who are not gadget enthusiasts, and patients who are asymptomatic and not perceiving a pressing need to acquire such a kit.

An alternative approach would involve a general-consumer-friendly mobile ECG acquisition and interpretation technology, based on AliveCor KardiaMobile 6L, for example, or other suitable mobile/wearable sensors, installed in free-to-use "self-service health check-up stations". These stations (or kiosks) could be located in GP clinic waiting rooms, pharmacies, such as Boots and Superdrug chains in the UK, train stations, airports, petrol stations and expressway/highway covered service areas, public parks (covered facilities), gym facilities, supermarkets and/or shopping malls [*cf.* self-service car tyre pressure gauges at petrol stations and self-service (passport) photo booths in supermarkets, post offices, etc.].

A protocol will need to be developed and adhered to for the selection of the best locations to install these stations in a given city or region based on local population/population access characteristics and other relevant factors. The stations could be promoted to attract target populations at check-out counters (e.g., in supermarkets) and through poster campaigns, etc. They need not be limited to AF screening. They can include additional sensors for measuring blood pressure, body weight, etc.

In addition to public health authorities/the NHS (National Health Service in UK) and GP clinics, pharmacies (such as Boots in UK), health insurance companies, large employers (for their employees), digital health technology companies and the likes might be interested in funding or co-funding these "self-service health check-up stations" under various possible business models. The stations' service can be offered for free to end users or for a small fee.

One can see two main approaches with these stations. Stations can be configured to offer non-tracked/anonymous screening sessions, with printed or mobile short message service (SMS) screening report and advice to user at the end of health check-up, e.g., to seek urgent or non-urgent medical attention/referral to cardiologist and/or customised, actionable lifestyle advice to achieve or maintain good health; etc. (it is also possible to have the stations send some fully anonymised stats/population summaries to the cloud for further analysis by public health authorities).

Alternatively, stations can be set up to deliver tracked sessions using some form of unique user ID to identify individual users. In this approach, the stations keep track (on the cloud) of user's data and progress, to be recalled for comparison and update the next time s/he uses a station

connected to the same cloud system. This is the approach adopted by Pursuant Health in their US network of thousands of health kiosks located within retail pharmacies and supermarkets (see later below). Printed or mobile SMS "health progress report" (compared to previous sessions, if any) and actionable advice is given to the user at the end of each health check-up session. Security and patient confidentiality/privacy issues must be carefully addressed in cloud-connected stations.

Fully anonymised comprehensive big data aggregates (age, gender, region/county, blood pressure, mobile ECG summary, etc.) pooled from "self-service health check-up stations" nationwide can help public health authorities check the "pulse of the nation" and identify good targets/areas for focused public health interventions.

Furthermore, many UK hospital outpatient clinic patients already do a self-service check-in at out-patient clinic attendance/waiting halls. It would be simple to add a 30-second ECG recording to the procedure, although achieving a high-quality recording from some of the currently available (mostly non-general-consumer-oriented) devices found in hospitals might require some practice or instruction for some patients, so a health worker able to supervise and assist at such a facility would be highly desirable.

A challenge remains to figure out how to motivate some hard-to-reach patient groups to use the installed stations while visiting their supermarket or other public spaces where these kiosks are deployed. Older people (over 65) with high-risk factors, in lower socioeconomic economic groups are often the least likely to voluntarily access screening programmes. For example, how do we get an 83-year-old socioeconomic group 5 supermarket customer in to the testing station will be important from a practical viewpoint, as these are the type of people that might not spontaneously use the station, but might maximally benefit. Merely having a station installed in a supermarket does not guarantee usage. It seems likely that not only would the kiosks need to be provided, but to reach many high-risk people in the target population who have not been checked in primary care, an incentive to staff in the screening areas to encourage and assist such subjects to use the screening stations would be necessary.

Existing commercial examples of self-service health check-up stations that can be expanded to deliver AF screening

The Pursuant Health (SoloHealth) kiosk (40-42) is an FDA-cleared interactive self-service health check-up station for preventive care and health risk assessment, suitable for installation in public spaces. It is already deployed in thousands of Walmart supermarkets, retail pharmacies and other public outlets in the USA since 2013. It offers multiple functions and sensors for checking blood pressure, weight, eyesight, and tracking lifestyle patterns, such as eating habits. It can be easily extended by adding "ECG for AF screening" to its list of functions.

Akos MD and AdviNow Medical's AI-powered telehealth kiosks, also known as the walk-in "Akos Med Clinics", are another example of a self-service health check-up station installed in public locations (43,44). As of 2019, Akos MD kiosks are available in about a dozen of Arizona and Idaho-based Safeway grocery stores in the USA. The kiosks have been described as "*similar to using the self-checkout line for groceries—only in this case, the commodity is medical care*". Akos Med Clinics use technology powered by artificial intelligence and augmented reality to gather symptoms and vital signs, and determine possible diagnoses. A computer program guides individuals in taking measurements of their health data, such as temperature, ear nose and throat images, chest sounds, blood pressure and blood oxygen content, using FDA-approved wireless devices. A virtual visit with a physician or nurse (including electronic prescriptions, if necessary) is also possible, similar to speaking with a clinician via Skype. Again, it should be feasible to have "ECG for AF screening" using KardiaMobile or equivalent added to these kiosks.

Ping An Good Doctor's One-minute Clinics are unmanned, AI-powered clinic kiosks installed in high-foot-traffic public areas across China (45-48). The self-service kiosks are intended for use by ordinary lay people to check their own health. They integrate Ping An Good Doctor's mobile healthcare and artificial intelligence technology with a variety of smart medical examination devices to provide users with medical and healthcare services, including consultation, rehabilitation guidance, medication recommendation and medicine dispensing. Each One-minute Clinic station comprises an "Independent Diagnosis Room" or booth, in which clinical examination sensors and devices are installed, and an "Intelligent Medicine Cabinet" (physically similar to a snack and drink vending machine), in which more than 100 types of common over the counter (OTC) drugs are stored at low temperatures, enabling millions of patients to seek 24/7 medical and health consultation, health management and drug purchase services anytime and anywhere these kiosks are deployed. As

of 2019, hundreds of these One-minute Clinics have been placed across 8 provinces and 80 cities in China. Adding an "ECG for AF screening" function to the kiosks should be technically possible.

Other examples of self-service health check-up stations include the OnMed Station, developed by OnMed in Florida, USA (49), and the Consult Station, developed by H4D, a French company (50). The Consult Station incorporates several diagnostic tools, including an ECG, and has been approved by the US FDA. It is currently (as of 2019) being used at several locations in France.

Are we ready for launching a national (UK) AF screening programme using these stations?

In 2014, the UK National Screening Committee refused to recommend a national AF screening programme. Four years later, in 2018, they posted an updated consultation, asking for input from individuals and organisations. The 2018 consultation still did not support setting up a national AF screening programme, despite considering it a potentially cost-effective measure (51). A meta-analysis by Petryszyn *et al.* published in 2019 (52) found that active screening for AF, including opportunistic screening, is effective beginning from 40 years of age.

It is worth noting that the aforementioned 2018 consultation did not take into account the latest FDA-approved mobile/wearable ECG sensors from AliveCor, Apple, Withings and others, which are available for anyone to buy (and use on their own), e.g., on Amazon, at affordable prices, and can be easily incorporated in self-service health check-up stations for AF screening. Single-lead ECG (e.g., the original AliveCor KardiaMobile) offered superior specificity compared with a pulse-check in a multicentre cohort study by Quinn *et al.* (53).

But it might be early days to advocate a nation-wide UK (NHS) screening programme using such stations with the evidence we have at this stage. A comprehensive trial of the proposed self-service health check-up stations for AF screening is needed to produce more evidence to convince UK decision makers to fully buy into the idea of a national AF screening programme using these kiosks [at least one related trial has been proposed in the past (54)]. Furthermore, the mobile ECG sensors/devices used in these stations need to obtain the necessary regulatory clearances from the UK Medicines and Healthcare products Regulatory Agency (MHRA, the UK equivalent of the US

FDA). Existing US FDA approvals are not sufficient for such devices to be approved for use in the UK (55).

As stated earlier, the screening stations can also spot a number of other health issues in addition to AF (they can have sensors for blood pressure, body weight, etc., and not just ECG), and this may add to their public health utility and cost-effectiveness if deployed nation-wide. Readers should note that, in this section, we discussed the situation in the UK as just one country example (the two authors' home country). But the AF screening stations could be equally useful in many other countries, including low-income countries.

Conclusions

The phenomenon of the rapid increase in availability of relatively low cost, portable (mobile or wearable), easy-to-use ECG recorders and analysers raises opportunities and challenges to healthcare systems. Given the fact that they have the opportunity to detect the commonest cardiac pathological arrhythmia, which, untreated, results in a fivefold increase in stroke and a 30% increase in dementia, the question of how best to integrate them into medical practice is important.

Although anyone can buy AliveCor KardiaMobile on Amazon for under €130 Euros, not so many asymptomatic AF patients will do so on their own, but if they find it as part of a "self-service health check-up station" booth/kiosk at their local Boots pharmacy, supermarket or GP clinic waiting room, they might try it and get diagnosed. These self-screening stations can prove particularly valuable in at-risk communities (56).

The cost of a self-service station and its installation will clearly be higher than that of a single KardiaMobile or similar unit alone (the cost per station will include the price of one AliveCor KardiaMobile unit or similar, plus the cost of any additional sensors, software, networking and other computing components, depending on station configuration/specifications). But a single station installed in one GP clinic or Boots (pharmacy) store should be able to serve very many persons, hundreds if not thousands, over time, and thus prove cost-effective in the long run. Pilot studies (to be followed by larger ones) are needed to confirm these arguments.

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Footnote

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