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Emerging Technologies for Identifying Atrial Fibrillation

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Abstract

Atrial fibrillation (AF) is a major cause of morbidity and mortality globally, and much of this is driven by challenges in its timely diagnosis and treatment. Existing and emerging mobile technologies have been used to successfully identify AF in a variety of clinical and community settings, and while these technologies offer great promise for revolutionizing AF detection and screening, several major barriers may impede their effectiveness. The unclear clinical significance of device-detected AF, potential challenges in integrating patient-generated data into existing healthcare systems and clinical workflows, harm resulting from potential false positives, and identifying the appropriate scope of population-based screening efforts are all potential concerns that warrant further investigation. It is crucial for stakeholders such as healthcare providers, researchers, funding agencies, insurers, and engineers to actively work together in fulfilling the tremendous potential of mobile technologies to improve AF identification and management on a population level.

Keywords

atrial fibrillation; mobile health; wearable technology; electrocardiography; screening; mHealth

Subject Terms:

Atrial Fibrillation; Electrocardiology

Introduction

Atrial fibrillation (AF) is a common chronic cardiac rhythm disorder that confers an increased risk for stroke, heart failure, chronic kidney disease, dementia, and death.[1] Importantly, AF is also associated with increased risk for reduced exercise capacity, depression, hospitalization, and reduced quality of life.[1,2] Ischemic stroke is the most severe outcome associated with AF and therefore a large focus of AF management. Fortunately, strokes are highly preventable with oral anticoagulation therapy if AF is appropriately

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diagnosed. However, owing to its sometimes paroxysmal nature and minimal or even absent symptoms, it is estimated that almost a million cases of AF remain undiagnosed in the US alone.[3] Unfortunately, one in five patients presenting with an ischemic stroke have a first diagnosis of AF at the time of their stroke, and up to 5% of individuals with AF present with stroke as the first manifestation of their arrhythmia.[4]

Current clinical practice guidelines offer several perspectives on the appropriateness of screening for undiagnosed AF using novel technologies. In contrast to the US Preventive Service Task Force, which concluded that there was insufficient evidence to assess the balance of benefits versus harms of electrocardiograph (ECG) based AF screening[5] and the American Heart Association/American College of Cardiology/Heart Rhythm Society guidelines,[6] which do not comment on AF screening, both the European Society of Cardiology[2] and the National Heart Foundation of Australia[7] advise opportunistic screening for AF among individuals over the age of 65 years using strategies that integrate both pulse taking and a single-lead ECG. The heterogeneity of these clinical guidelines is likely attributable to the paucity of data in establishing clear risks and benefits of mass screening. Novel technologies are, by making highly accurate AF detection possible using near-ubiquitous commercial devices, reshaping the landscape of AF identification.[8–10]

Over the last five years (since the FDA clearance of the AliveCor[11] Kardia device), several mobile health and digital health technologies that acquire and analyze pulse or electrocardiographic data have been developed and FDA-cleared for clinical use to identify of AF,[8] and large-scale clinical trials are ongoing evaluating their accuracy and outcomes associated with mobile health-facilitated AF identification.[12–15] The FDA has since also granted clearance to the AliveCor Kardia 6L, Apple Watch Series 4, and Google Study Watch devices, as well as the FibriCheck smartphone application, for AF detection. Since FDA clearance is required for US commercial distribution, no other devices or systems discussed in this manuscript are currently available for commercial use, although some have secured CE marking and are available in Europe. Further, development and implementation of industry standards (i.e. SMART on FHIR[16]) and platforms (i.e. AliveCor KardiaPro[17]) for interpretation and integration of mobile health sensor data into electronic health records systems suggest that novel technologies for AF identification may be nearing integration into clinical cardiovascular medical practice. However, although AF-detection technologies are refining our understanding of the epidemiology of undiagnosed AF globally,[12,18–21] there remain few examples of full integration of mobile health technologies across contemporary health systems.[22–24]

Despite a breakneck pace of discovery in this area, several major questions remain unanswered about technologies for AF identification. These include: 1) Can novel technologies for AF identification be effectively used by older adults at risk for AF and complications from the arrhythmia? 2) Do wearable technologies powered by pulse analysis algorithms for AF detection have sufficient accuracy in the community to warrant their “prescription” by healthcare providers? 3) Is undiagnosed AF identified by novel technologies associated with the same risk for stroke as conventionally diagnosed AF? and 4) What are the optimal steps in the subsequent evaluation and ultimate treatment of mobile or digital device-detected AF? In this manuscript, we review the present and near-future

state of mobile and digital health technologies for AF detection and monitoring, ongoing studies evaluating the accuracy and clinical impact of mobile and digital health technologies for AF detection, as well as address important remaining concerns relevant to clinical use and implementation of these devices.

Data Collection and Signal Processing Approaches

Historically, the diagnosis of paroxysmal AF has frequently required continuous electrocardiographic monitoring. Contemporary technologies used for continuous ECG monitoring include: mobile cardiac telemetry modalities, Holter monitors, external loop recorders, and implantable loop recorders.[25] Although these devices are well trusted and clinically valid, they each have significant drawbacks. External cardiac telemetry is limited in the duration of monitoring and can involve burdensome wires and adhesive electrodes that may cause skin irritation in some patients, thereby impacting adherence and patient satisfaction.[26] Implantable devices circumvent these limitations, but are invasive, costly and associated with potential complications.[27] The burden of arrhythmia required for AF detection varies across devices, further complicating clinical interpretation and management. In recent years, the advances in the accuracy, cost, and durability of biosensors and availability of valid computational signal processing approaches have expanded AF detection capabilities to mobile devices, including smartphones, smartwatches, and other wearables.

Current mobile health technologies rely on electrocardiographic (ECG) or photoplethysmographic (PPG) signal processing to detect AF (Figure 1). Many of these novel technologies analyze short segments of heart rhythm data (i.e., 30-second windows) to determine if AF is present, although automated algorithms can require several consecutive abnormal 30-second windows to classify an individual as potentially having AF.[28,29] When presenting the performance characteristics of mobile technologies for AF detection in this manuscript, we therefore consider AF to be present on the basis of the manufacturer's definition of AF (generally at least 30 seconds to 2 minutes in duration).[28–31]

ECG remains the gold standard signal used for arrhythmia detection[1] and similarly, ECG-based mobile health approaches show high accuracy for AF detection, with many ECG-based technologies demonstrating over 90% accuracy. In addition to their superior accuracy, other advantages of ECG-based technologies include their ability to detect arrhythmias other than AF (including atrial flutter), ischemia (when multiple leads are used), and they have potential applications in detection of AF drug toxicity (i.e., QT prolongation).[32] PPG approaches do not enable P wave analysis, but do have advantages over the ECG. First, camera and CPU requirements for acquisition of high-quality PPG data are present on almost every contemporary smartphone. Second, PPG analysis enables passive and near-continuous pulse signal processing using video cameras applied by many wearable devices to calculate heart rate.[15] Finally, several devices, including the Apple Watch, have both PPG and ECG sensors and are FDA-cleared to use ECG to confirm a possible pulse irregularity detected by a PPG signal.[33]

Several signal processing approaches have been deployed and FDA-cleared for AF detection. Although the algorithms used by Apple, Google, and AliveCor are not published,

signal processing methods are generally grouped into on-device (that can be programmed on a chip) or neural network/cloud-based (using artificial intelligence).[14,34] Several signal processing methods for on-device ECG and PPG analysis to identify AF have been published.[35–37] Approaches to classify AF generally incorporate motion noise detection using a device accelerometer and algorithms that analyze R-R (ECG) or peak-to-peak pulse (PPG) variability.[38] Established cut-points that discriminate AF from sinus rhythm using both PPG and ECG recordings have been published for several algorithms, either used singly or in combination, including Shannon Entropy, Time-Varying Coherence Function, Root Mean Square of Successive Differences, and Markov Models.[35,36,39–41]

Novel signal processing approaches for PPG are enabling discrimination of premature beats, bigeminy and other benign arrhythmias from AF without the need for ECG data.[14,40,42–44] Approaches that use validated cut-off thresholds for AF discrimination are generally less computationally demanding than AI approaches and can be programmed on chip (local to the device),[35,38,45] but these approaches do not "learn" a user's particular heart rate variability patterns and thus may prove less accurate. Irrespective of the signal processing approach, all methods may suffer lower accuracy if deployed in populations that differ in signal characteristics (i.e., populations with different skin tones or resting tremor), and all are vulnerable to low positive predictive values (PPVs) among populations with a low AF prevalence.[46]

Mobile and digital monitoring for intermittent AF detection

ECG-based technologies—Portable, handheld single-lead ECG devices were the first to receive FDA clearance and have the most robust evidence compared to other mobile or digital health devices with respect to their accuracy, cost-effectiveness, and the feasibility of use by patients at risk for AF in a variety of clinical environments.[34,47–50] The body of evidence showing strong performance for AF identification has increased since the FDA clearance of the AliveCor KardiaMobile device (AliveCor Inc.) in 2015 for its automated rhythm analysis using a 30-second lead I rhythm strip obtained from a single-lead ECG device paired with a smartphone (Figure 2).[28]

The approach to AF identification employed by the AliveCor system involves use of a proprietary machine learning algorithm to analyze ECG features and classifies the heart rhythm as "normal," "possible AF," or "unclassified."[34] The KardiaMobile device has been evaluated for AF screening, AF recurrence among patients after cardiac surgery, ablations or cardioversions,[51,52] AF symptom-validation, and to direct continuation of oral anticoagulation therapy (Table 1).[53–55] For example, two studies have used mobile technologies to detect AF recurrence and inform "as-needed" anticoagulation use. Both of these studies had low rates of stroke and thus were not sufficiently powered to draw meaningful clinical conclusions.[54,55]

For AF that is present at the time of the 30-second rhythm ascertainment, the KardiaMobile device has been shown to be accurate in several clinical studies, with sensitivity ranging from 67%−99.6% and specificity ranging from 91%−99% when compared to expert cardiologist review.[42,48,50,56–59] Since the prevalence of AF varies widely across AF screening studies using the AliveCor device, the PPV of the AliveCor AF detection feature

ranges from 39%−65%, whereas the negative predictive value (NPV) remains consistent close to 100%.[60,61] An important caveat to the high accuracy demonstrated is that up to 1/3 of ECG recordings are "unclassified" and thus require manual review.[48,50,57,58,62,63] Notably, a recent FDA-cleared update to the KardiaMobile's AF detection algorithm endeavored to address this issue by expanding the range of analyzable heart rates to 40 to 140 beats per minute,[64] although the effect of this update on the proportion of ECG recordings classified as uninterpretable has not been studied.

Recently, AliveCor also obtained FDA clearance for a newer, handheld 6-lead ECG device, the KardiaMobile 6L,[65] which builds upon the existing AliveCor platform by recording ECG leads I, II, III, aVR, aVF, and aVL to provide additional capabilities, including more accurate rhythm assessment and potentially detection of cardiac ischemia. This device has not undergone the extensive clinical validation that the original KardiaMobile has, but the additional information provided by having access to six leads may prove to be valuable in discriminating AF from other arrhythmias.

In addition to AliveCor's KardiaMobile device, several similar commercially available single-lead ECG devices have also been developed and validated for AF detection. These include the MyDiagnostick[66] and the Zenicor-ECG,[67] which have CE marking designation in Europe but are not cleared by the FDA for use in the US.[68] The MyDiagnostick single-lead ECG has been validated in two cohorts including 383 participants of whom 156 were in AF, and demonstrated a sensitivity of 94–100%, and a specificity of 93–96%.[66,69] The Zenicor-ECG has also been validated in 100 participants, demonstrating a 96% sensitivity and 92% specificity[67] for AF detection. Neither device manufacturer has released details regarding their signal processing algorithm, and both companies have emphasized the need for clinician over-read for confirmation in the case of suspected AF.[68] Notably, the Zenicor-ECG device developed an updated algorithm that has been tested in 3,209 individuals, of whom 84 had AF. All individuals with AF were flagged by the device as abnormal (100% sensitivity).[70]

Photoplethysmography-based technologies—Commercially available smartphones have the prerequisite hardware to enable heart rate and rhythm determination using PPG as measured through a smartphone's camera and flash, which are used to trans-illuminate capillaries in the skin for the measurement of blood flow.[40] Likely owing to high rates of smartphone use, as compared with wearable use, pulse-based smartphone applications for AF detection continue to maintain a strong following despite a shifting emphasis in literature and media to wearables, including smartwatches.

In September of 2018, one smartphone application, FibriCheck, received FDA clearance for AF detection,[71] and its heart rate measurements from PPG correlate strongly with measurements taken from the KardiaMobile device.[72] Validation in a cohort of 223 patients of whom 102 had AF showed that the smartphone application correctly identified pulse irregularity consistent with AF with 96% sensitivity and 97% specificity compared to cardiologist review of a simultaneous 12-lead ECG.[73] Given the rapidly increasing rates of smart device ownership across the globe, including among older adults,[74] development and

further refinement of mobile smart device applications using PPG analysis for AF detection will likely continue to play a large role.

Prior studies examining the performance of intermittent monitoring technologies for AF identification—As previously discussed, mobile and digital ECG technologies have been deployed successfully among patients with prevalent AF. Significant interest exists in using these technologies to facilitate the early identification of AF, particularly among populations at high risk for AF and stroke, such as patients with embolic stroke of undetermined source (or cryptogenic stroke) or among older adults with stroke risk factors.[21,49,75–77] Furthermore, the low cost of mobile and digital single-lead ECG devices and the minimal training required for use allow for scalable implementation of these technologies for AF identification across a number of community-based, low-resource, and geographically isolated settings, where the epidemiology of AF remains poorly defined.[78] This is a major strength of mobile technologies, and studies have demonstrated that guided (i.e., administered by a community health worker) or directed (i.e., telemedicine or community invitation platforms) patient use at home or in the clinic for AF screening can be successful in several contexts, including primary and urgent care, the emergency department, in pharmacies, in community centers, and as part of community outreach programs, in the US, Australia, Europe, and Asia.[21,49,50,59,79,80]

Table 1 outlines studies conducted to date and strategies used for intermittent AF screening using mobile or digital devices. The number of newly diagnosed AF cases based on these mobile health-facilitated AF screening studies varied widely due to substantial heterogeneity of the populations examined with respect to the likely prevalence of undiagnosed AF and the frequency of screening, which impacts detection of paroxysmal AF. In studies that targeted screening of older adults using a prespecified age cut-off (generally those over 65 or 75 years old), the incidence of newly detected AF was 0.9%−6.2% (Table 1). Notably, while longer periods of use may identify more cases of undiagnosed AF, adherence to mobile technologies may decrease over time, especially in older adults.[81]

A recent meta-analysis using data from published screening studies including more than 140,000 individuals showed that one new AF case can be identified for every 83 individuals aged over 65 years old screened.[82] In the five studies that screened for AF in high-risk populations, including survivors of a TIA or stroke, new AF is detected at higher rates than are seen in lower-risk populations (6% to 21%). The high variability in the number needed to screen to identify a single AF patient noted across AF screening studies to date illustrates the potential importance of age, comorbid conditions, care setting, genetics, and screening strategy (intermittent repeated vs. single time point). Further research is needed to inform risk-informed screening. In particular, among populations directly subjected to AF screening by the devices they purchase, determining how to enforce (or even recommend) screening among only those at the highest risk for AF remains a major challenge.

Mobile and digital devices for near-continuous AF detection

Despite their accuracy for single-time point or repeated use screening, currently available single-lead ECG devices do not enable continuous or near-continuous rhythm assessment.

Opportunistic screening in the clinic or community with single-lead ECG may detect persistent or permanent AF but may miss brief or paroxysmal episodes of AF, and even repeated home use of mobile or digital ECG devices may not capture clinically relevant episodes lasting minutes, hours, or days.[83] Continuous (or near-continuous) monitoring may help capture short, but potentially clinically significant episodes of AF, and quantify the burden of AF, an important factor that frequently influences prescription of anticoagulation and may increase stroke risk beyond CHA_2DS_2-VASC predicted risk.[84–87] However, it is important to note that historically, AF burden is not considered a stroke risk factor and current AF management guidelines do not recommend considering AF burden when making therapeutic decisions about anticoagulation.[1,2,7]

Wrist-worn wearables have garnered significant recent attention for AF identification. The first published demonstration that an Apple Watch could passively detect AF involved the development and training of a deep neural network fed PPG-based heart rate variability data among thousands of participants in the Health eHeart Study.[88] When tested among 51 patients undergoing cardioversion, this passive, pulse-based AF detection algorithm demonstrated 98% sensitivity and 90% specificity, although the accuracy was only modest among a separate ambulatory cohort of 1,617 different Health eHeart participants.[88]

More recently, Apple obtained FDA clearance for both PPG and ECG-based AF identification using their own algorithm.[89,90] Currently, the Apple Watch is the only commercially available wrist-based wearable with an FDA-cleared PPG algorithm for AF detection. The Apple approach includes collection of one minute of data every two hours and conducting an analysis for rhythm irregularity using the PPG signal. A proprietary algorithm based on Poincare plot dispersion analyzes for rhythm regularity and increases rhythm assessment frequency (to once every 15 minutes) if irregularity is detected. If five out of six subsequent pulse checks are detected as irregular,[89] a possible AF notification is issued to the wearer. This approach was tested in the pivotal large-scale Apple Heart Study that enrolled about 420,000 participants who owned an Apple Watch over the course of 8 months, in which participants were monitored for AF by PPG and sent a confirmatory 7-day ECG patch if they received an AF alert. Only 0.5% of participants in the study received an alert, and 34% of the subsequently deployed patches in these subjects showed AF. This low event rate is likely due to the fact that only 6% of study participants were over the age of 65. Subsequent watch-generated AF alerts in those wearing the ECG patch showed 84% positive predictive value for these alerts. It is also important to note that while over 2,000 individuals received an AF alert, only 450 ECG patches were analyzed in the study due to loss to follow up at various steps, suggesting that an opportunity exists for developing new approaches to avoid loss to follow-up from device-detected AF. Over half of these notified participants (57%) also contacted their healthcare provider outside of the study, demonstrating the potential significant downstream clinical burden imposed by use of wearables for AF identification.

In addition to the Apple Watch, several other smartwatches are capable of real-time rhythm determination based on pulse data, including the Samsung Gear Fit 2 and Simband, and the Huawei Watch GT, Honor Watch, and Honor Band 4.[91–93] The Huawei smartwatches specifically have been tested in a large pragmatic screening project, the Huawei Heart

Study,[93] which is similar in design to the Apple Heart Study. Nearly 200,000 individuals who owned the Huawei Watch GT, Honor Watch, or Honor Band 4 were monitored via PPG in the Huawei Heart Study, of whom 0.2% (n = 424) received an AF alert. Follow-up with a healthcare provider confirmed AF in 87% of the alerted participants using an in-clinic ECG or 24-hour Holter monitor. The Huawei Heart Study also examined care integration and AF management, and the study successfully routed 95% of individuals identified with AF in the study into an app-based integrated care program. An impressive 80% of participants identified as having AF and high risk for stroke were evaluated by a healthcare professional and were reported to have started anticoagulation.[93] However, both the Apple Heart Study and Huawei Heart Study used a convenience sample of existing smartwatch owners, and the shifting demographics of this population will render scientific replicability challenging. Population level changes in factors associated with smartwatch ownership (i.e., greater numbers of older smartwatch users at risk for AF) may change the performance characteristics of these technologies for AF detection.[94]

In November 2017, the FDA-cleared AliveCor's KardiaBand device for AF identification. The AliveCor KardiaBand is a watch strap for an Apple Watch that uses an embedded electrode with the thumb and wrist as contact points to obtain a 30 second single lead ECG.[95] The KardiaBand was tested in 85 participants undergoing cardioversion, and demonstrated 93% sensitivity and 84% specificity for AF identification when compared to physician ECG over-read.[96] The KardiaBand uses AliveCor's SmartRhythm technology that analyzes pulse data from the Apple Watch and alerts the user to potential irregular pulse, thus prompting them to take an ECG recording for confirmation of rhythm status. However, this product was discontinued in June of 2019, about a year after Apple incorporated a single ECG lead into the design of the Apple Watch Series 4 itself by integrating an electrode into the bevel on the side of the watch.[90]

Based on the accuracy of the Apple Watch (98.3% sensitivity and 99.6% specificity) in a validation study involving 301 patients with AF and 287 controls submitted to the FDA, the Apple Watch received FDA clearance for both generating a valid lead I ECG as well as the automated algorithm for AF detection.[31] The Study Watch (Verily, Alphabet) is also FDA-cleared for AF identification[97] using a single-lead ECG. Samsung is also seeking FDA-clearance for its newly released Galaxy Watch Active 2,[98] although at present there are no peer-reviewed publications evaluating the performance of these technologies.

Several other wearable devices are pursuing FDA clearance for AF identification using both PPG and ECG. The QardioCore chest band[99] and the Hexoskin smart shirt[100] utilize electrodes and obtain continuous ECG. Other investigational devices, including an ECG armband, are also pursuing clearance for AF identification.[101,102] Other devices, including a smart ring worn on the finger, demonstrated 100% accuracy in identifying AF from PPG signals from 119 study participants, even in presence of high PAC burden.[103] Another investigational, PPG-based technology focused on AF identification is a non-contact, facial video plethysmographic approach, which measures skin tone changes in the face to ascertain the pulse. Facial plethysmography performs equally well to conventional contact PPG when measuring heart rate, heart rate variability and irregular cardiac activity,[104] suggesting possible utility for AF detection. Non-contact plethysmography is currently being examined

in comparison to a standard ECG patch monitor to detect AF in an ongoing NIH-funded clinical trial.[105]

What is the clinical actionability of device-detected AF?

Although the clinical relevance and ideal response to AF detected by standard cardiac telemetry is becoming better understood as evidence accrues, the ideal approach to the management of brief AF episodes detected using novel technologies remains controversial since the risks versus benefits of anticoagulation therapy in this population remain unknown. We briefly review relevant evidence, but we recognize that the generalizability of available clinical trial data to wearables remains limited. The results of the ASSERT[85] and MOST[106] trials suggest that in patients with implantable devices, the shortest episode of AF that is associated with an increased risk for stroke is 5 to 6 minutes.[107] However, a subsequent study with refined stratification of the ASSERT cohort showed that participants in the top quartile of subclinical AF burden (i.e., those over 24 hours) were at significantly higher risk for stroke than were participants with lower AF burden.[84]

Furthermore, several studies have suggested that a complex interplay between AF burden along with clinical stroke risk (i.e., CHA_2DS_2-VASc scores) contribute to a patient's risk for ischemic stroke.[86,108] The TRENDS study, for example, included nearly 2,500 participants and showed that stroke risk increases only when the burden of AF is greater than 5.5 hours,[109] and the KP-RHYTHM study, which examined rates of AF and stroke among Kaiser Permanente patients prescribed a Ziopatch 2-week monitor, suggested that overall burden of AF, irrespective of duration of the longest AF episode, is the most important determinant of ischemic stroke risk.[87] Participants who spent over 11.4% of time in AF where at significantly higher risk for thromboembolic events. However, studies are needed to generate evidence from ambulatory, asymptomatic patients about the relationship between AF burden on non-invasive monitors, clinical risk factors, stroke risk, and the benefits vs. harms of anticoagulation treatment. The ongoing NOAH-AFNET 6[110] and ARTESiA[111] trials seek to evaluate the risk-benefit ratio of oral anticoagulation for patients with implantable device-detected subclinical AF lasting longer than 6 minutes.

Despite technological advances that facilitate detection of undiagnosed AF, the clinical significance of AF detected in this manner is unknown.[6] At present, the AHA guidelines do not discriminate between mobile device-detected AF and conventionally diagnosed AF, although much of the evidence for clinical actionability of brief AF episodes come from patients with implantable devices and may not be generalizable to wearable device users, who may be generally at lower overall risk for stroke. Several studies suggest that mobile device-detected AF may confer the same risk as stroke as conventionally diagnosed AF. For example, the REHEARSE-AF randomized trial of AF screening found no difference in stroke or mortality rates between older adults randomly assigned to routine care vs. twice-daily measurements with a single-lead ECG device for AF identification, though the trial was not powered to detect difference in stroke outcomes.[49]

The lack of guidelines to inform the appropriate management of device-detected AF likely contributes to heterogeneous healthcare provider opinions about the appropriate management strategy for patients with this presentation. A recent survey of 75 healthcare

providers, including cardiologists, neurologists, geriatricians, and internal medicine providers at a tertiary academic center showed that, although the vast majority were willing to recommend a smartwatch for AF detection to older patients at risk for stroke, many indicated that they would require additional confirmation with a 12-lead ECG, an in-office examination, or a patch-monitor before treating with an oral anticoagulant.[112]

Another barrier for acting on mobile device-detected AF, especially those that detect AF using PPG approaches, is the need for confirmatory testing. Although point-of-care ECG is now possible using the single-lead ECG incorporated into many mobile devices, including the Apple Watch Series 4,[33] a conventional continuous ECG monitor has been frequently prescribed for AF assessment, including in the Apple Heart Study.[14] The major advantages of a continuous ECG monitor for AF confirmation are its high accuracy and ability to quantify AF burden. However, there may be significant delays between a device-detected AF episode and when the monitor is placed. For patients with brief and infrequent episodes of AF, this strategy might not detect AF. The second option of using a point-of-care diagnostic approach with a single-lead ECG offers the option to confirm nearly contemporaneously with a PPG-detected event. However, the major drawbacks to this approach is the fact that it requires the user to actively measure an ECG reading and it does not quantify AF burden. This is a significant concern if the wearer does not notice the AF alert, such as if it occurs while the user is asleep.[113]

Finally, several studies have analyzed the cost-effectiveness of using mobile or digital single-lead ECG devices with automated AF detection for opportunistic AF screening for older adults in primary care or pharmacy settings, and studies conducted to date have concluded that AF screening with automated single-lead ECGs is very likely to be cost-effective in individuals over the age of 65.[49,50,79,83,114] It is estimated that AF screening using single lead ECG devices costs about $4.59 to $13.5 per patient screened, and the cost-effectiveness ratio of community-based screening is estimated to be between $3,602 to $4,746 USD per quality adjusted life year (QALY) gained and $7,244 to $20,695 USD for each stroke prevented.[50,114,115] Overall, this would potentially save $840 USD and increase QALY by 0.27 years per patient screened.[79] It is clear that by any estimate, the cost per QALY gained is well below the commonly used reference thresholds of $50,000 or $100,000 USD for an intervention to be deemed “cost-effective”.[116]

Ongoing Studies and Clinical Trials that Leverage Mobile and/or Digital Devices for Atrial Fibrillation Detection

VITAL-AF is an ongoing, large-scale cluster-randomized RCT of mobile-device facilitated screening for AF. VITAL-AF includes 32,000 patients over 65-year-old presenting to one of 16 primary care offices (8 clinics randomized to screen patients compared with 8 usual care clinics) within the Massachusetts General Hospital Primary Care Network.[12] This trial would be the first to show potential effectiveness of implementing opportunistic AF screening with a mobile-device at the clinic level, but it also addresses important considerations for integrating single-lead ECG devices and resulting into the workflow of routine patient care. The primary outcome of VITAL-AF is incident AF during the screening

period, and secondary outcomes include new anticoagulation prescription rates, incident ischemic stroke and incident major bleeding rates.[12]

The recently announced GUARD-AF[117] RCT aims to go further by investigating whether or not screening for undiagnosed AF impacts not only AF rates, but also rates of ischemic stroke and bleeding among individuals over 70 years of age over 12 months. The HEARTLINE study proposes to examine rates of AF detection among individuals over age 65 using an Apple Watch and clinical endpoints such as mortality, acute myocardial infarction, and ischemic stroke over a three-year follow-up.[13]

Several large screening trials are also ongoing in Europe. The Screening for Atrial Fibrillation with ECG to Reduce stroke (SAFER)[118] study is an RCT involving 300 general practices across the UK, where 100 practices are being randomized to provide patients over the age of 65 with the Zenicor-ECG. Patients will be asked to record an ECG 2 to 4 times a day for a duration of 2 to 4 weeks. The study will follow patients for 5 years and outcomes of interest include stroke, MI, death, and bleeding events. The Active Monitoring for Atrial Fibrillation (AMALFI)[119] study is an RCT that targets high risk patients, specifically those over the age of 65, and CHA_2DS_2-VASc score being ≥3 in men or ≥4 in women. This study uses the clinical Zio Patch monitor and its primary outcome is the prevalence of newly diagnosed AF after 2.5 years.

Models of data generation and research frameworks

Commercially available, FDA-approved devices for AF identification are challenging the traditional conventions of medicine and research (Figure 3). The conventional workflow of biomedical research begins with a question driven by clinical needs, which then undergoes extensive research and development well before the lay public is exposed to a given product. Promising drugs and devices move on to regulatory oversight, release into the marketplace, and ultimately influences treatment guidelines established by professional and governmental bodies. These guidelines in turn inform provider decision making, finally trickling down to the individual patient when they receive the intervention. However, this paradigm is shifted in the context of commercially available mobile health devices, in which case patients and the lay public are already interacting directly with private industry before the science is settled. Indeed, large numbers of low-risk individuals, defined by whether or not they purchased a certain Apple device with a particular feature turned on rather than by the pre-test probability they have AF, are currently undergoing AF screening. This has bypassed the usual required steps of careful research investigating clinically relevant outcomes and expert consensus. Funding and regulatory agencies as well as scientists and the health technology industry should recognize this tumultuous shift in the traditional workflow of research in order to effectively facilitate much-needed scientific progress in the field. In the interim, clinicians, researchers, and professional societies may consider expert guidelines written specifically for the lay public to help educate them regarding the appropriate use of these devices and facilitate productive patient-provider interactions.

Implementation and Usability Challenges

An important barrier to implementation of large-scale use of wearables for AF detection is their high cost. Although several insurance companies around the world offer discount plans and rewards programs for some wearable devices for members, high out-of-pocket costs for these devices act as a major barrier to use for many at-risk individuals. Affordability of devices capable of AF detection is a crucial consideration, and conversations about subsidizing their use are ongoing between patient advocacy groups, large health systems, and insurers.[120] This is compounded by the high degree of eHealth literacy required for appropriate use of wearable devices to manage atrial fibrillation. These factors selectively disadvantage vulnerable populations, such as older adults, who are particularly susceptible to AF and stroke.[121] Indeed, in many ways, the populations who might benefit most from the use of mobile health technologies for AF detection may be the least likely to afford or use them. Nevertheless, evidence suggests that should cost barriers be removed, a high proportion of older adults would be enthusiastic about smartwatch-based AF detection and management.[91]

Effective and thoughtful implementation of health technology can make the difference between meaningful improvement in health and failure. Important considerations, including existing and novel healthcare provider workflows, payment models, integration of sensor and patient reported data into the electronic health record, and privacy and security concerns, must be carefully addressed in order for AF detection technologies to be successfully implemented into clinical settings.[22,122] Rigorous studies using implementation science frameworks[123] and methods can generate valuable scientific evidence to inform successful implementation of technologies and should be employed to evaluate the best practices associated with integration of AF detection technologies into the healthcare environment.

Risk Stratification and Selective Screening

A major concern regarding the widespread use of mobile health technologies for AF identification remains the large proportion of false positive results that may occur as these AF-screening devices are used by lower risk individuals. A false positive alert may lead to anxiety, additional healthcare costs, and potentially inappropriate treatment (i.e., with an oral anticoagulant).

Existing screening efforts using mobile health technologies may provide a framework to reduce risk for false positives by enriching the screened population for AF.[83] To date, studies have used established risk for AF and stroke criteria to target higher-risk populations for AF screening, such using an age cut off (i.e., 65 years or older) or a specific health condition (i.e., ischemic stroke). Results of the STROKESTOP II study indicate that NT-proBNP is also an excellent indicator of incident AF risk and may allow for targeted mobile ECG screening and reduce the number needed to screen to identify AF. However, no mobile health-based AF screening study has leveraged more sophisticated AF predictive tools, such as the CHARGE-AF risk score,[124] to guide screening activities. Furthermore, a recent study including ECG data from 3 million adults determined that a time-varying machine learning approach for AF identification based on clinical parameters performed better than established risk prediction models, including the CHARGE-AF risk score.[125] This study

demonstrates the potential of deep learning methods to better inform AF risk stratification and screening. Furthermore, as our understanding of the genetic basis of AF expands and genetic predictors of AF are identified,[126–128] machine learning algorithms leveraging data in the electronic health record may be augmented by incorporating genetic information to identify the ideal target population for AF detection.[128]

Future Directions

Although an increasing body of evidence suggests that digital technologies are accurate for detection of undiagnosed AF among existing device users, it is not well understood whether older adults at risk for AF can adhere to mobile or digital technologies should they be prescribed to them. Studies are needed to evaluate the ideal deployment, support, and communication strategies to support long-term adherence to technologies for AF detection. Innovative trials support the notion that smart devices can be leveraged successfully across a variety of settings for AF screening if they are supported by robust data and clinical infrastructures, including telemedicine platforms. However, such systems and resources are uncommon in typical clinical practice. Scientific and professional societies, payors, software and hardware developers, patient advocacy groups, health systems, and other key stakeholders are playing an important role in driving the changes needed to optimize the care of digital technology users seeking to understand their heart rhythm. Finally, and critically, despite circumstantial evidence suggesting its relevance, undiagnosed AF detected from digital technologies is of unclear clinical significance and the ideal management strategy for this arrhythmia is unknown. Research is ongoing that will help address key knowledge gaps relevant to undiagnosed AF management. Ultimately, randomized trials with clinically relevant outcomes, such as healthcare utilization, stroke, and bleeding, will be needed to provide definitive answers that can best inform clinical practice and the lay public.

Conclusion

The recent FDA clearance of several mobile and digital technologies for AF identification has ushered in a new era of consumer driven arrhythmia detection and care. Mobile and digital technologies cleared by the FDA for AF identification offer great promise to better inform our understanding of the epidemiology of AF, identify AF prior to stroke and heart failure, and promote better and more connected cardiovascular care. However, the unknown clinical significance of mobile device-detected AF in low-risk populations, the potential harms associated with false positive alerts, the major barriers to integration of device-related data into existing clinical and electronic health record workflows, and the rudimentary nature of population-based arrhythmia care in the US remain barriers. With the increasing use of FDA-cleared mobile and digital devices by consumers at risk for AF, healthcare providers, researchers, engineers, professional societies, payers, federal agencies, and software and hardware developers, must work together to ensure that technologies for AF identification inform better care, as opposed to complicate it.

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Abbreviations:

FDA	Food and Drug Administration
ECG	electrocardiograph
PPG	photoplethysmograph
TIA	transient ischemic attack
PAC	premature atrial contractions
AHA	American Heart Association
NIH	National Institutes of Health

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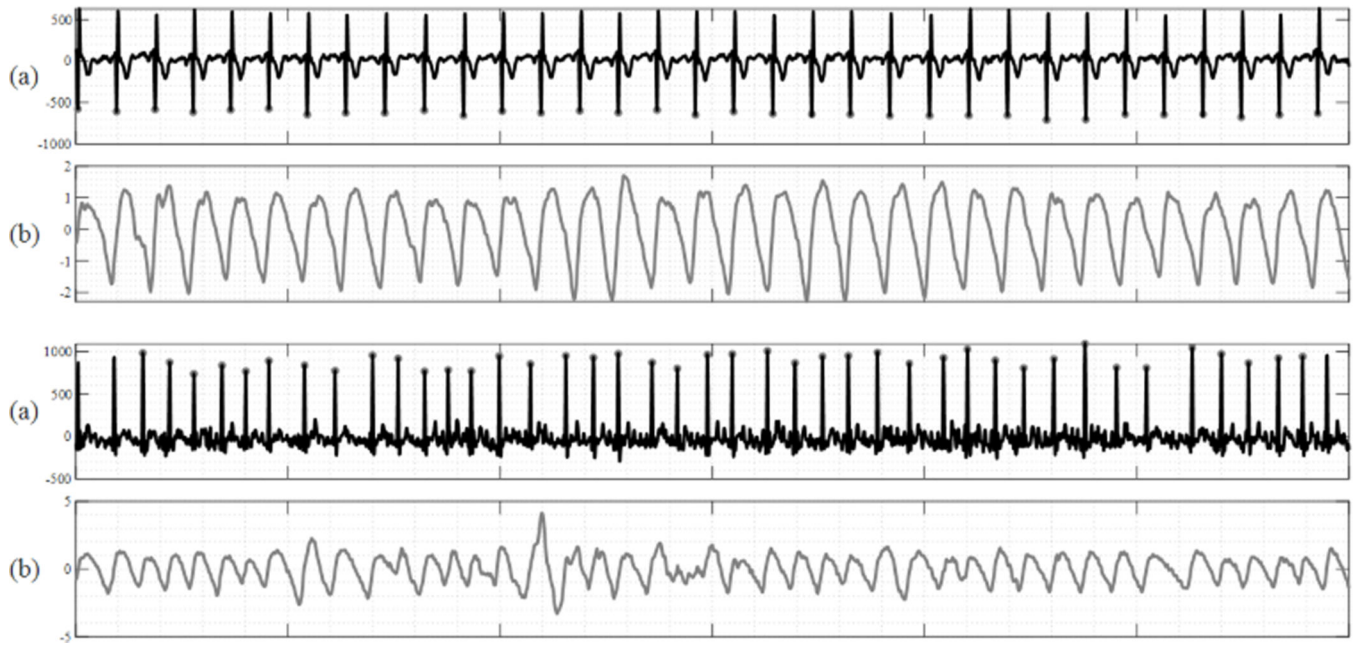

Figure 1.

Electrocardiograph (ECG, panel a) vs pulse plethysmograph (PPG, panel b) data for a patient in normal sinus rhythm (top) and a patient in AF (bottom). Figure adapted from Ding et al [91] with authors' consent.

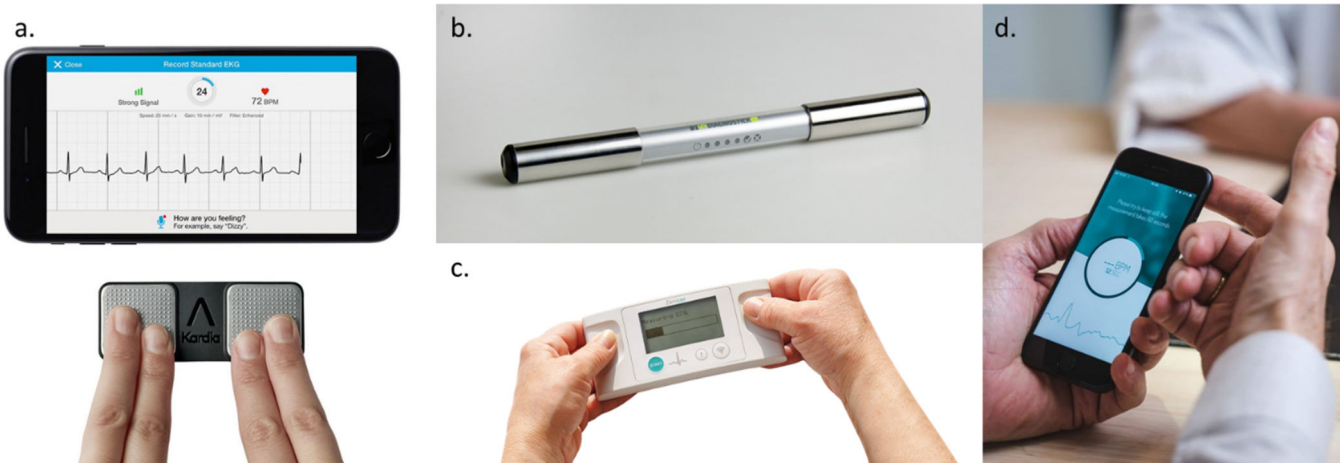

Figure 2.

Examples of intermittent AF detection tools used in clinical and research settings: KardiaMobile (a), MyDiagnostick (b), Zenicor-ECG (c), and FibriCheck (d).

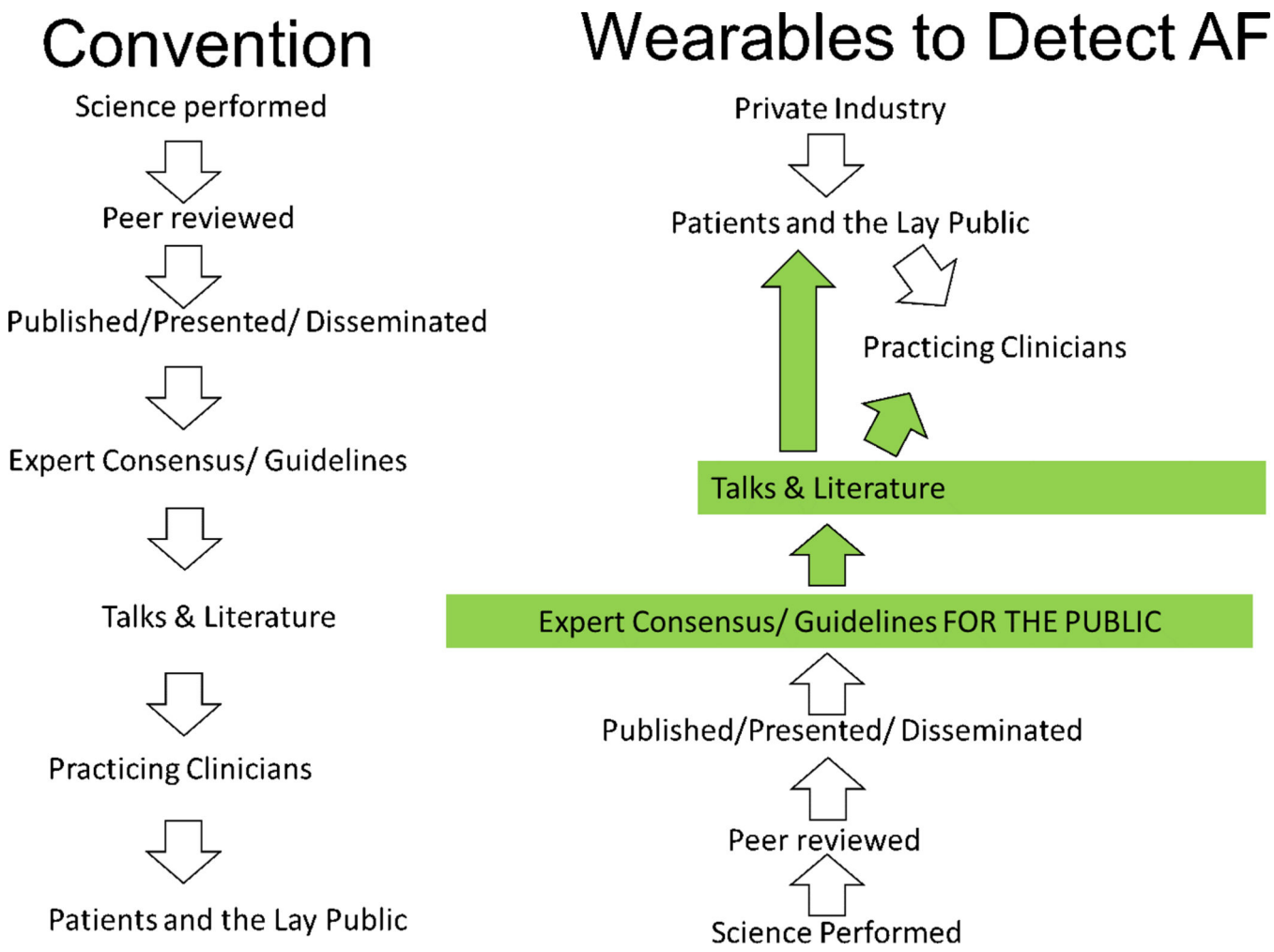

Figure 3. Changing infrastructure of biomedical research as applied to consumer-available technologies

Shown in green are suggested steps to mitigate the direct-to-consumer AF screening that is already taking place

Table 1.

New Atrial Fibrillation Diagnosed with Intermittent Rhythm Checks

Study	Setting & Population	Device Used	Mean age (SD)	Device Use	New AF cases
Ghazal et al[129]	Primary healthcare center, 290 patients 70–74 years old	Handheld ECG device	71.9 (0.1)	Twice daily for 2 weeks	16 (5.5%)
Svennberg et al[21]	7,173 people either 75 or 76 years old	Handheld ECG device	Unreported (all are 75 or 76 years old)	Twice daily for 2 weeks or when symptomatic	218 (3%)
Hendrikx et al[130]	928 out of hospital patients with $CHADS_2 \geq 1$	Handheld ECG device	69.8 (9.4)	Twice daily for 28 days or when symptomatic	35 (3.8%)
Berge et al[131]	1,510 people born in 1950	Handheld ECG device	All are 65 years old	Twice daily for 2 weeks or when symptomatic	13 (0.9%)
Engdahl et al[132]	403 people either 75 or 76 years old with $CHADS_2 \geq 2$	Handheld ECG device	Unreported (all are 75 or 76 years old)	Twice daily for 2 weeks	30 (7.4%)
Poulsen et al[133]	95 stroke/TIA patients over 65 years old	Handheld ECG device	Unreported (all over 65 years old)	Twice daily for 30 days	20 (21.0%)
Olsson et al[134]	370 stroke/TIA patients	Handheld ECG device	66 (12)	Twice daily for 2 weeks	27 (7.6%)
Orrsjö et al[135]	114 stroke/TIA patients	Handheld ECG device	70.3 (range: 41.9 – 86.6)	Twice daily for 3 weeks	13 (11.4%)
Sobocinski et al[136]	249 stroke/TIA patients	Handheld ECG device	72 (range: 39 – 91)	Twice daily for 30 days or when symptomatic	15 (6.0%)
Halcox et al[49]	500 people over 65 years old, CHADS-VASc ≥ 2	Handheld ECG device	72.6 (5.4)	Twice weekly for 12 months or when symptomatic	19 (3.8%)
Soni et al[137]	Rural India, 234 people over 50 years old	Handheld ECG device	Two-thirds over 55	Daily for 5 days	12 (5.1%)
Yan et al[138]	251 stroke/TIA in-hospital patients	Handheld ECG device	Median: 68 (IQR 57–77)	Daily until discharge	28 (11.2%)
Proesmans et al[139]	61,730 people	PPG-based smartphone application	61.9 (10.9)	Twice daily for 8 days or when symptomatic	791 (1.3%)
Verbrugge et al[140]	12,328 people	PPG-based smartphone application	49 (14)	Twice daily for 7 days	136 (1.1%)