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REVIEW

Mobile health technology in atrial fibrillation

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ABSTRACT

Introduction: Mobile health (mHealth) solutions in atrial fibrillation (AF) are becoming widespread, thanks to everyday life devices, such as smartphones. Their use is validated both in monitoring and in screening scenarios. In the published literature, the diagnostic accuracy of mHealth solutions wide differs, and their current clinical use is not well established in principal guidelines.

Areas covered: mHealth solutions have progressively built an AF-detection chain to guide patients from the device's alert signal to the health-care practitioners' (HCPs) attention. This review aims to critically evaluate the latest evidence regarding mHealth devices and the future possible patient's uses in everyday life.

Expert opinion: The patients are the first to be informed of the rhythm anomaly, leading to the urgency of increasing the patients' AF self-management. Furthermore, HCPs need to update themselves about mHealth devices use in clinical practice. Nevertheless, these are promising instruments in specific populations, such as post-stroke patients, to promote an early arrhythmia diagnosis in the post-ablation /cardioversion period, allowing checks on the efficacy of the treatment or intervention.

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Atrial fibrillation; handheld; integrated care; mobile health; photoplethysmography; telemedicine; wearables; artificial intelligence

1. Introduction

1.1. Background

Atrial fibrillation (AF) is the most common arrhythmia, currently affecting more than 37 million people worldwide, and projected to be doubled by 2030[1]. Patients with AF are at a 2-fold higher risk of death and hospitalization, and the high rate of hospital admissions have a central role in AF-related health-care costs [2,3]. Untreated AF is a significant cause of stroke (approximately 15% of all ischemic stroke cases), and AF is independently associated with heart failure, cognitive impairment, and death [4,5]. Benefits of early diagnosis of this arrhythmia include individualized modification of risk factors, appropriate characterization, and evaluation[6], and implementation of early management strategies in a holistic or integrated care manner[7]. Adherence with the latter approach has been associated with improved clinical outcomes [8,9], and is recommended in contemporary guidelines [10,11]. It is necessary to raise public awareness about the screening, early diagnosis, and holistic management of AF, leading to cost containment and improving patient outcomes.

1.2. Mobile health in atrial fibrillation

Mobile Health (mHealth) consists of 'medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.' During the last 20 years, researchers' interest in mHealth in all fields of medicine has grown (Figure 1), and it seems to increase more and more[12], also in cardiology in relation to AF detection [13,14]. This is the result of advances in device development, which has enabled clinicians to integrate the diagnostic-therapeutical process with patients' device-related information.

In guidelines, clinical (symptomatic or asymptomatic) AF diagnosis is made by 12-lead ECG or a single-lead ECG strip of 30 seconds[11]. For AF-population screening, devices connected to the world of mHealth, from apps to smartphones, play a significant role[15]. The patient becomes central in his treatment process because he is often the first to be informed of the rhythm/pulse anomaly by the device. This first event, which can lead to early AF identification, has to be succeeded by an appropriate pathway that brings him to the cardiologist's attention for the subsequent comprehensive diagnostic-therapeutical approach. As reported in recent systematic reviews [13,14,16], the amount of existing data on the clinical

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Article highlights

- mHealth solutions in atrial fibrillation (AF) are becoming widespread thanks to everyday life devices, such as smartphones, smartwatches, mobile apps, etc.
- Mobile health devices are validated both in monitoring and screening scenarios. However, few real-world clinical data are available. In addition, international AF management guidelines do not indicate different usage for different devices' subtypes.
- The accuracy of mHealth devices in AF detection varies substantially concerning the type (handheld vs wearable), the technology used (photoplethysmography, PPG-vs electrocardiogram, ECG-vs mechanocardiography, MCG-based), the monitoring time (intermittent vs. continuous), and the population target (high vs. low risk AF).
- From the authors' perspective, ECG-based devices could be helpful as a screening approach in high-risk patients, such as post-stroke patients, aiming an earlier diagnosis and appropriate therapy. On the other hand, PPG-based solutions could be more suitable in general population screening, thanks to their more accessible application, as well as in AF management, improving drug adherence, and in the post-ablation/cardioversion setting.
- Patient data flow has to be securely stored in encrypted platforms/clouds and reliable for the decision-making and monitoring process conducted by health-care practitioners.
- In wealthy countries, mHealth devices are ubiquitous, although not refundable by most health-care systems. The same devices are not provided yet in developing nations, leading to inappropriate healthcare process fragmentation in AF management.

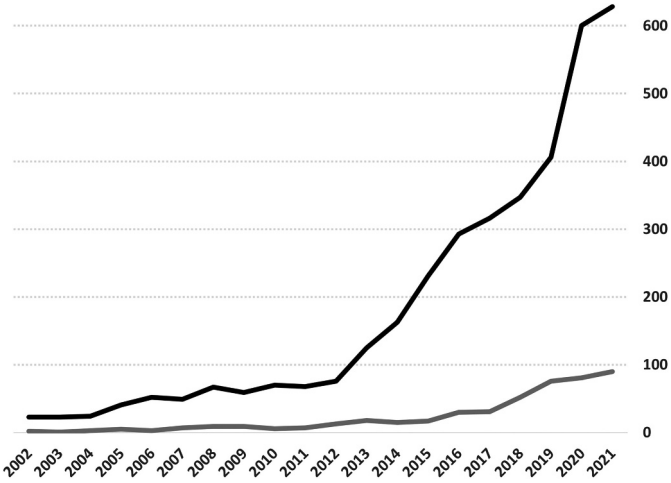

Figure 1. Number of publications per year in last 20 years about mHealth in medicine and mHealth in atrial fibrillation. (Legend: dark line: mHealth publications in medicine; gray line: mHealth publications regarding atrial fibrillation).

effectiveness of the devices is still limited, although they may be particularly useful in detecting AF (Figure 2)[17].

2. Mobile health strategies in atrial fibrillation

For the purposes of this review, only devices validated in clinical studies are presented. They have been divided into 4 categories (Figure 3): based on photoplethysmography and pulse variability (PV), based on ECG, based on mechanocardiography, and the support systems (e.g. educational programs and remote-monitoring patient platforms). The ECG-based devices are the only strategies that are diagnostic for AF themselves. On the contrary, PPG and MCG-based devices need ad ECG confirmation for the diagnosis of the arrhythmia.

In the first three categories, handled and wearables are identified depending on available devices. Handled devices work through contact with the skin of the patient and allow to detect the presence of an abnormal heart rhythm (e.g. while monitoring an abnormal rhythm causes the lighting of red light), or they send an ECG trace to a smartphone app/web platform (e.g. plate or stick technology). On the other hand, wearable devices are light devices of different sizes, capable of transmitting information about the patient's rhythm via sensors (e.g. wristwatches/bands or ECG-based devices as patches/chest belts). An ubiquitous subtype of mHealth devices is the sphygmomanometer, based on pulse-variability (PV) technology. Lastly, implantable loop recorders (ILRs) represent implantable ECG-based devices that continuously monitor heart rhythm and transmit wireless single-lead ECGs traces. The information is constantly transmitted or on-demand, depending on the type of device, especially when patients become symptomatic[18].

Patients have generally been involved in this detection chain thanks to several mobile apps and wireless connections tools: collected data are stored within encrypted platforms/clouds that allow clinicians to view and control their heart activity remotely. Moreover, the educational programs, the remote monitoring patients' systems, and the clinical decision supports, primarily via mobile apps, raise awareness of AF prevention and treatment, increasing patients and health-care practitioners' knowledge about AF, even in screening or monitoring settings[17].

2.1. PPG-/PV-based devices

The technology used by PPG devices is an optical technique: microvascular blood is lighted, and it reflects a trace of the pulse blood volume, which is detected by a sensor. Devices analyze changes in peak-to-peak intervals and the pulse morphology. In case of irregularities or variations, they alert the patients [19–21]. These devices exist as handheld and wearable ones. On the other hand, a similar methodology is the pulse variability, used by sphygmomanometers: the pulse beat-to-beat variation during blood pressure measurements on the arm-cuff (measured at least 3 times) is the trigger for the arrhythmia's alert signal. The most relevant studies are shown in Table 1.

2.1.1. Handled PPG-based devices

Given the widespread presence of smartphones, handled PPG-based devices are increasingly available systems in everyday life. They often use the smartphone camera as the emission light point for the PPG technique, which is elaborated through a mobile application on the phone. FibriCheck[22], CardioRhythm [23,24], Preventicus[25], and PULSE-SMART [26] are the only PPG-handled devices validated in prospective

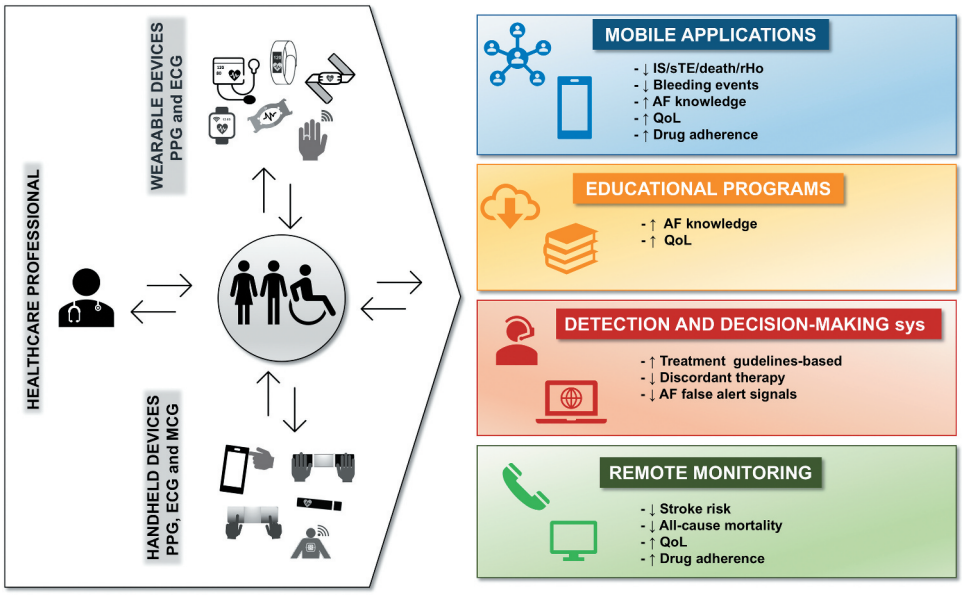

Figure 2. Mobile AF solutions patients-centered; Abbreviations: AF: atrial fibrillation; ECG: electrocardiogram; IS: ischemic stroke; MCG: mechanocardiography; PPG: photoplethysmography; rHo: re-hospitalization; sys: systems; sTE: systemic thromboembolism; QoL: quality of life.

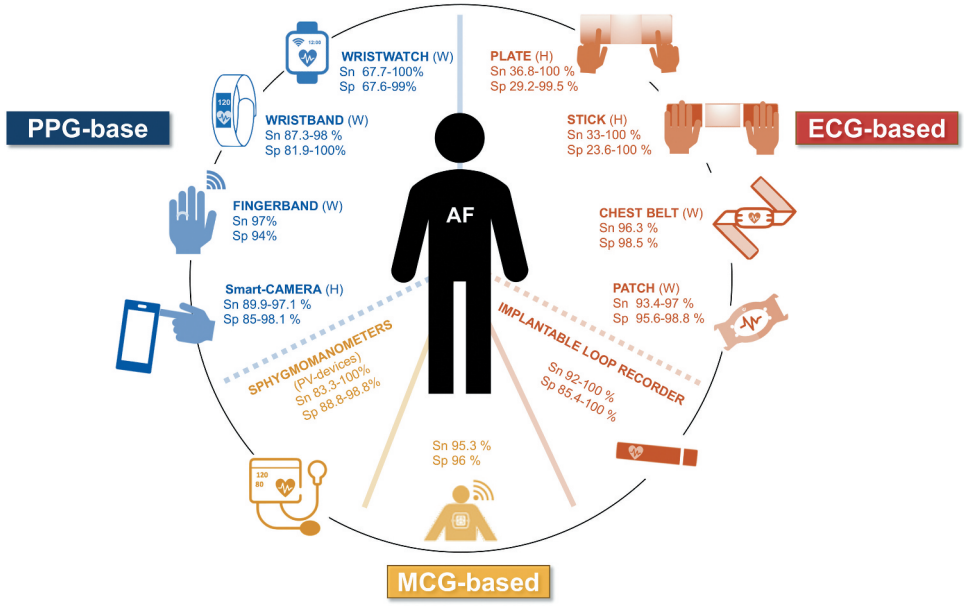

Figure 3. mHealth atrial fibrillation devices; Abbreviations: AF: atrial fibrillation; ECG: electrocardiogram; H: handheld; MCG: mechanocardiography; PPG: photoplethysmography; PV: pulse-variability; Sn: sensitivity; Sp: specificity; Smart-: smartphone; W: wearable.

studies, and only FibriCheck and Preventicus have been approved for clinical use in UE.

All these mobile-app-related devices use fingertips for the PPG signals. The mean duration for monitoring differs between the systems: 60 second-recording for FibriCheck and Preventicus, 20 seconds for CardioRhythm, and 2 or 5 minutes for PULSE-SMART. Thanks to the devices-linked app, patients can also annotate their symptoms during registration, and clinicians can evaluate remote PPG-measurements tracks to exclude errors and verify hearth rhythm. For these devices, the highest sensitivity (Sn) reported is for PULSE-SMART (97.1%), and the highest specificity (Sp) reported for Preventicus (98.1%). As shown in the table, the monitoring times do not substantially affect the overall Sn and Sp. If, on the one hand, data on long-itudinal monitoring time is still lacking with PPG devices, on the other hand, a study [27] showed no difference in Sn and Sp between 1′ vs 5′ measuring period, despite a decrease in signal quality. On the contrary, Sn and Sp vary across the reference test used (single-lead ECG vs 12 – leads-ECG with Sn: 89.9–95.4% vs 93.1–98% respectively; Sp: 85–99.6% vs 88–96.2% respectively) [17,22,25,26,28]. Sn and Sp estimates

Table 1. PPG/PV-based devices' studies – Abbreviations: AF: atrial fibrillation; Amb: ambulatory; d: days; ECV: electrical cardioversion; e.d.: expert diagnosis; f: female; Hosp: hospitalized; m: minutes; mPSA: multicenter prospective single arm; n.a.: not available; Mon.: monitoring; PSA: prospective single arm; PTA: prospective two arms; PR: prospective randomized; pts: patients; Ref.: reference; RSA: retrospective single arm; s: seconds; s-l-ECG: single-lead ECG; Sn: sensitivity; Sp: specificity; s.t.: single time; TIA: transient ischemic attack; yo: years old; 12-l-ECG: 12 leads ECG. Unless otherwise indicated, age is reported as mean years.

PPG-based

Study	Design	n°	f (%)	Age	Population	Country	Device/Technology	Mon. time	AF rate (%)	Sn (%)	Sp (%)	Ref. test
Handheld												
Yan et al[23]	PSA	217	28.6	70.3	Hosp.	CHN	CardioRhythm/ Smartphone camera	20s x 3 s.t.	34.6	95	96	12-l-ECG
Van Haelst et al[21]	PSA	190	57.7	77.3	≥65 yo	NL	FibriCheck/ Smartphone camera	1 m s.t.	48.4	98	88	12-l-ECG
Proesmans et al[22]	PSA	223	53.4	77	≥65 yo	BE	FibriCheck/ Smartphone camera	1 m x 3 s.t.	45.7	95.3	96.2	12-l-ECG
McManus et al[26]	PSA	121	19	66	Planned ECV	USA	PULSE-SAMRT/ Smartphone camera	2 m x 2 s.t.	100	97	95.5	12 -l-ECG
Chan et al[24]	PSA	1013	53.2	68.4	DM, hypertension, ≥65 yo	CHN	CardioRhythm/ Smartphone camera	20 s s.t.	2.76	92.9	97.7	e.d.
Brasier et al[25]	PSA	592	45.3	78	Hosp.	DE/CH	Preventicus/ Smartphone camera	5 m s.t.	41.9	91.5	99.6	s-l-ECG
Wearable												
Guo et al[19]	PSA	187912	13.3	34.7	Amb.	CHN	HonorBand, Huawei Watch GT/ Wristband and wristwatch	60 s every 10 m for 14 d	87	n.a.	n.a.	12-l-ECG; 24-h-Holter
Zhang et al[27]	PSA	361	49.3	50	Amb.	CHN	HonorBand, Huawei Watch GT/ Wristband and wristwatch	60–45 s every 10 m for 14 d	8.6	100	100	12-l-ECG
Tison et al[29]	mPSA	51	16	66.1	Planned ECV	USA	Apple Watch/Wristwatch	20 m	100	98	90.2	12-l-ECG
Jacobsen et al[28]	PSA	102	48	71	AF pts	DE	Eveiron/Upper armband	24 h	47	95.2	92.5	24-h-Holter
Kwon et al[32]	PSA	100	19	63.8	AF/planned ECV	KOR	CardioTracker/Fingerband	15 m	100	97	94	s-l-ECG
Bonomi et al[33]	PSA	18	44	73.1	Planned ECV	NL	CM3 gen.3/Wristband	42 h	100	97	100	s-l-ECG
Chen et al[31]	PR	401	49.1	n.a.	Hosp./Amb.	CHN	Amazfit/Wristband	3 m	37	88	96.4	12-l-ECG
Nemati et al[20]	RSA	36	n.a.	n.a.	Hosp.	USA	Samsung Simband/Wristwatch	3.5-8-5 m	33	97	94	s-l-ECG
PPV-based												
Wiesel et al[34]	PSA	405	49	73	Amb.	USA	Microlife/Sphygmomanometer	3 s.t.	23	96.8	88.8	12-l-ECG
Wiesel et al[35]	PSA	450	41	69	Amb.	USA	Omron/Sphygmomanometer	2 s.t.	12	100	91	12-l-ECG
Gandolfo et al[37]	PSA	207	50.2	77.7	Post stroke/TIA	IT	Microlife/Sphygmomanometer	3 s.t.	18.4	89.5	98.8	12-l-ECG
Marazzi et al[36]	PSA	503	45.7	67	Hypertension	IT	Microlife (1) and Omron (2)/ Sphygmomanometer	3 s.t.	20	(1) 92 (2) 100	(1) 97 (2) 94	12-l-ECG

also differ among the types of population observed (maximum Sn among elderly people, 98%, the highest Sp among hospitalized patients, 99.7%) [25,28].

2.1.2. Wearable PPG-based devices

Wearable PPG-based devices are one of the most promising mHealth strategies. They have been validated in several prospective cohort studies, focusing mainly on AF detection rather than rate-monitoring[17]. The prevalent technologies used are wristwatches (e.g.: Huawei Watch GT [19,29,30], Apple Watch [31,32], or Amazfit Health band [33]), wristbands (e.g.: Samsung Simband,[20] CM3 Generation-3), armbands [34] (e.g.: Eveiron [30]), finger-bands (e.g.: CardioTarcker [35]), and earlobe sensor devices. In addition, there is the possibility of a remote medical team evaluation to exclude error and trace disturbances in some utilities. Among the studies, the Sn and the Sp for all validated wearables PPG-devices range from 67.7 to 100% and 60.7 to 100%, respectively (Huawei Watch GT 100% Sn and CM3 Generation-3 100% Sp) [19,29,36]. These differences come from different monitoring periods and different reference tests used.

2.1.3. Pulse-variability devices

Arm cuff sphygmomanometers and wrist oscillometric blood pressure monitors represent pulse-variability devices. Compared to other methods, clinical validation studies are limited. The most studied sphygmomanometers are Microlife BP [37,38] and OMRON [37,39], with an overall Sn and Sp from 83.3 to 100% and 88.8 to 98.8%, respectively. Like the other methods, the total measurements time does not affect accuracy in detecting AF and also, between different reference tests, the Sn and Sp may differ[40], although the recording time in these devices could be probably be insufficient for accurate AF detection.

2.2. ECG-based devices

ECG-based devices are capable of monitoring and transmitting an ECG trace. These devices have an emerging role to be diagnostic: a 30 seconds single-lead ECG strip confirmed by a cardiologist allows the diagnosis of AF[11]. They can also record a single, 3, 6, or even a 12-leads ECG trace, depending on the devices used. The most relevant studies are shown in Table 2A.

2.2.1. Handled ECG-based devices

The most common and used devices are KardiaMobile [28,41–47], and MyDiagnostick [48–53]. For Zenicor and other devices, clinical data are limited. The validation studies for these devices were primarily prospective and some RCTs.

MyDiagnostick is a stick with metallic handles. Patients hold these, and the device records a single-lead ECG of 45–60 seconds. KardiaMobile records a single lead or 6-leads ECG, depending on the version of the device used. It is a metallic plate in which the patient's fingers activate electrodes. The monitoring time for an ECG strip is, in this case, 30 seconds. Both the devices, particularly MyDiagnostick, are validated in AF screening. There is also a substantial difference in the number of studies, which are 5-fold more for KardiaMobile with consequent wide Sn and Sp ranges for this device (MyDiagnostick: Sn 60.5–100%, Sp 93–97.3%; KardiaMobile: Sn 38–100%; Sp 29.2–100%)[17]. The study population and the prevalence of the arrhythmia may affect the devices' accuracy. From this point of view, the Sn and Sp estimates had the highest values among hospitalized/ward and elderly patients, respectively, both in MyDiagnostick and KardiaMobile studies. Although for most MyDiagnostick and KardiaMobile studies the reference test was 12-leads-ECG, some expert diagnosis was used as a reference test, probably impacting the Sn and Sp.

2.2.2. Wearable ECG-based devices

These devices are patches without visible electrodes, such as Zio^{XT}[54], or with short electrodes like RhythmPad [55] and Firstbeat Bodyguard[56], or they could be chest belts as Polar-H7[56]. The accuracy level of patches is comparable with chest belt devices (Sn 96.3–97%, Sp 95.6–98.2%; Sn 96.3%, Sp 98.2%, respectively).

Clinical validation studies have used prospective cohort studies (no RCTs), and in most cases, they had not used a reference test. Two studies used 12-leads-ECG as a reference test with an overall Sn ranging from 93.4 to 96.3% and Sp from 96.8 to 98.8[57]. Patches, in general, provide a single or three leads ECG. They are often attached to the upper left side of the patient chest, or they could be a multiple-sensors device, with three electrodes in both arms and one leg, which could register 6-leads ECG. Monitoring time is variable in these devices, from 10 seconds of RhythmPad to 2 weeks of ZioXT, and there are no data regarding more extended monitoring periods[57]. Each monitor solutions have a structured referral to a cloud platform in which patient's data could be stored and shared into the clinician's expert community. The study population affects the accuracy of AF detection, with the highest Sn and Sp in >65 years old and patients at high risk of AF, respectively.

Lastly, there are wireless ECG recorders, which allow clinicians to analyze immediately patient's data from an encrypted cloud without the active intervention of the patient. Recording time could be very different among different devices used (from 4 min in 24 hrs to 30 seconds twice a day for six months), and also wireless ECG could be single, 3-, 6- or 12-leads ECG. Among these, only the Medi-Trace 200 has been studied with an overall Sn of 94.6% in hospitalized patients[58].

2.2.3. Implantable loop recorders (ILRs)

ILRs are inserted subcutaneously in the chest and, after contact with the body, they automatically start to register ECG. ECGs registration could be even activated by the patient when he becomes symptomatic. This procedure allows wireless transfer of the ECG in a programmer/platform for clinical evaluation. Reveal, BioMonitor, and Confirm are the most frequently implanted ILRs, and they have been validated in several clinical studies, prospective and RCTs [17,59–61]. Although studies are shown in Table 2B included different monitoring times of follow-up, AF was diagnosed chiefly within six months after implantation [59,62–64].

Table 2A. **ECG-based devices' studies** – Abbreviations: AF: atrial fibrillation; Amb: ambulatory; e.d.: expert diagnosis; f: female; Hosp: hospitalized; m: minutes; mPSA: multicenter prospective single arm; Mon.: monitoring; n.a.: not available; PSA: prospective single arm; PTA: prospective two arms; PR: prospective randomized; Ref.: reference; s: second; s-l-ECG: single-lead ECG; Sn: sensitivity; Sp: specificity; s.t.: single time; Sn: sensitivity; Sp; specificity; yo: years old; 12-l-ECG: 12 leads ECG. Unless otherwise indicated, age is reported as mean years.

ECG-based

Study	Design	n°	f (%)	Age	Population	Country	Device/Technology	Mon. time	AF rate (%)	Sn (%)	Sp (%)	Ref. test
Handheld												
Boriani et al[45]	PSA	2814	55.5	66	General	IT	MyDiagnostick/Stick	1 m s.t.	2	98.2	23.6	12-l-ECG
Battipaglia et al[46]	PSA	855	n.a.	n.a.	General	UK	MyDiagnostik/Stick	15 s s.t.	0.8	100	100	e.d.
Desteghe et al[49]	PTA	320	43.1	67.9	Hosp.	BE	MyDiagnostick/Stick	1 m s.t.	11.9–36	60.5–89.5	93.3–96.1	12-l-ECG
Kaasenbrood et al[47]	PSA	3269	51	69.4	Vaccined	NL	MyDiagnostick/Stick	1 m s.t.	3.7	96	100	e.d.
Rivezzi et al[48]	PSA	1820	53.4	50% 65–74 yo;50% ≥75 yo	≥ 65 yo	IT	MyDiagnostick/Stick	1 m s.t.	5.5	94	100	12-l-ECG
Tavernier et al[50]	PSA	214	61.7	84	Hosp.	BE	MyDiagnostick/Stick	1 m s.t.	33	88	97	12-l-ECG
Chan et al[41]	PSA	1013	53.2	68.4	≥ 65 yo	CHN	KardiaMobile/Plate	30s s.t.	2.8	71.4	99.4	e.d.
Chan et al[43]	PSA	2052	54.2	67.8	≥ 65 yo	CHN	KardiaMobile/Plate	30s s.t.	1.2	66.7	99.5	12-l-ECG
Chan et al[40]	PTA	13122	71.5	64.7	General	CHN	KardiaMobile/Plate	30s s.t.	1.8	98	29.2	e.d.
Desteghe et al[49]	PTA	320	43.1	67.9	Hosp.	BE	KardiaMobile/Plate	30s s.t.	11.9–36	36.8–78.9	96.1–98.1	12-l-ECG
Orchard et al[38]	RCT	3103	36	75.1	≥ 65 yo	AU	KardiaMobile/Plate	30s s.t.	1.2	97	92	12-l-ECG
Lowres et al[44]	PSA	1000	56	76	≥ 65 yo	AU	KardiaMobile/Plate	30–60 s s.t.	6.7	98.5	91.4	12-l-ECG
Soni et al[42]	PSA	2074	52.2	33.7%≥66 yo	General	IND	KardiaMobile/Plate	30s 2–3 t./5 d	1.6	38	n.a.	e.d.
Van Haelst et al[21]	mPSA	190	57.4	77.3	≥ 65 yo	NL	KardiaMobile/Plate	30s s.t.	48.4	98	85	12-l-ECG
Zaprutko et al[39]	PSA	525	68.2	73.7	≥ 65 yo	PL	KardiaMobile/Plate	30s s.t.	2.4	100	98.7	e.d.
Wearable												
Lown et al[53]	mPSA	418	n.a.	n.a.	≥ 65 yo	UK	Polar-H7/Chest belt	45s	19	96.3	98.5	12-l-ECG
Sabar et al[52]	PSA	750	51	n.a.	High AF risk	UK	RhythmPad/Patch	10s	10	95.4	98.8	12-l-ECG
Lin et al[55]	PSA	30	n.a.	n.a.	Hosp.	ROC	Medi-Trace 200/Wireless record	6 m	67	94.6	n.a.	12-l-ECG
Steinhubl et al[51]	PR	2659	38.6	72.4	High AF risk	USA	Zio^{XT}/Patch	4 m	3.9	n.a.	n.a.	e.d.

ILRs Study	**Design**	**n°**	**f, (%)**	**Age**	**Population**	**Country**	**Device**	**Monitoring time**	**AF definition**	**AF rate (%)**
Haldar et al[56]	RCT	120	36	62.3	Post-AF abl.	Intern.	Reveal LINQ	22 mo. (mean)	≥30s	73
Etgen et al[62]	PSA	22	50	61.6	Crypto. stroke	DE	Reveal XT	360 d	≥ 6 m	27
Diederichsen et al[63]	PSA	597	43	76	High stroke risk	Intern.	Reveal LINQ	1200 d	≥ 6 m	35
Jorfida et al[61]	PSA	54	42.6	67.8	Crypto. stroke	IT	Reveal XT	435 d	≥ 5 m	46
Marks et al[18]	RSA	178	52	65	Crypto. stroke	USA	Reveal XT/LINQ	384.1 d (mean)	> 2 m	19.6 (30 mo)
Ritter et al[60]	PSA	60	43	63	Crypto. stroke	DE	Reveal XT	382 d (mean)	≥ 30s	17 (21 mo)
Sanna et al[65]	PR	441	36.5	61.5	Crypto. stroke	Intern.	Reveal XT	1080 d	≥ 30s	30 (36 mo)
Ziegler et al[66]	PSA	1247	47	65.3	Crypto. stroke	USA	Reveal LINQ	579 d (mean)	≥ 2 m	21.5 (24 mo)

Table 2B. **ILRs' studies** – Abbreviations: AF: atrial fibrillation; Crypto. stroke: Cryptogenic stroke; d: days; f: female; Intern.: international; m: minutes; mo.: months; n. a.: not available; OAC: oral anticoagulants; PR: prospective randomized; PSA: prospective single arm; RCT: randomized clinical trial; RSA: retrospective single arm; s: second. Unless otherwise indicated, age is reported as mean years.

ILRs

Study	Design	n°	f, (%)	Age	Population	Country	Device	Monitoring time	AF definition	AF rate (%)
Haldar et al[56]	RCT	120	36	62.3	Post-AF abl.	Intern.	Reveal LINQ	22 mo. (mean)	≥30s	73
Etgen et al[62]	PSA	22	50	61.6	Crypto. stroke	DE	Reveal XT	360 d	≥ 6 m	27
Diederichsen et al[63]	PSA	597	43	76	High stroke risk	Intern.	Reveal LINQ	1200 d	≥ 6 m	35
Jorfida et al[61]	PSA	54	42.6	67.8	Crypto. stroke	IT	Reveal XT	435 d	≥ 5 m	46
Marks et al[18]	RSA	178	52	65	Crypto. stroke	USA	Reveal XT/LINQ	384.1 d (mean)	> 2 m	19.6 (30 mo)
Ritter et al[60]	PSA	60	43	63	Crypto. stroke	DE	Reveal XT	382 d (mean)	≥ 30s	17 (21 mo)
Sanna et al[65]	PR	441	36.5	61.5	Crypto. stroke	Intern.	Reveal XT	1080 d	≥ 30s	30 (36 mo)
Ziegler et al[66]	PSA	1247	47	65.3	Crypto. stroke	USA	Reveal LINQ	579 d (mean)	≥ 2 m	21.5 (24 mo)

Most AF detected episodes were asymptomatic, and this finding underlies the importance of ILR monitoring time [65,66], as suggested by Healey et al.[67], in line with CRYSTAL-AF trial [68]: the longer the monitoring time of ILRs, the higher the AF detection rate (64% at 6 months vs 34% at one month). The majority of the validation studies have not compared IRLs to a standard monitoring technique (e.g.: Holter-ECG) to provide accuracy, except two studies [69,70] which report a very low Sn. However, routine Holter monitoring detected significantly fewer events than ILRs. Loop recorders have also been widely used as a comparative test for the accuracy of other methodic. Thanks to this, it has been possible to improve their diagnostic algorithms for AF over time: the TruRhytm algorithm of Reveal-LINQ based on P-sense detection reported Sn and Sp were 92–100% and 85.4–99%, respectively[62]. To our knowledge, comparative data between different ILRs do not exist in literature[71].

2.3. MCG (mechanocardiography) – based devices

MCG-based devices are less representative of mHealth linked to AF management compared to other technologies. They monitor mechanical cardiac activity, register heart movement, and derive cardiac activity thanks to accelerometers and gyroscopes installed in smartphones (e.g. Sony Xperia) placed on the patients' sternum. However, there are few published studies[72], with only one relevant analysis for AF detection (Table 3). Furthermore, these are only handled devices (Sn 67% and Sp 99%). Therefore, more studies are needed to improve this technology.

2.4. Support systems in AF-management

Everyday life devices, such as smartphones, have become widespread. In this perspective, mobile apps represent the future of mHealth, especially in terms of first communication between patients and clinicians. More than100000mHealth apps and 400 wearable activity monitors are present worldwide, with 500 apps explicitly dedicated to AF management[73]. Unfortunately, the major limitation of these solutions is the absence of data on their real-world effectiveness, lack in regulatory schemes and therefore, in many cases, they have not received clinical validation yet[17]. This represents an incentive to focus on clinical studies to obtain more scientific evidence in the literature about these AF-management methods. The most relevant studies are summed up in Table 4.

Significant support in AF holistic management is mobile self-care apps [15,19,74–79]. Several studies have been conducted to improve patients' self-care thanks to mobile apps, such as the Health Buddies application[78]. In a computerized app study by Magnani et al [80], the patients experienced a significantly improved quality of life measured with different scoring systems using app in AF management. The most relevant experience in this field has probably been the mobile AF application studied in mAFA-II trial[81], which best illustrates the patient-clinician interactions in AF management. In this prospective cluster randomized trial, the mAFAapp-guided approach, using a PPG-based device, was compared to usual care management associated with a significative reduction of bleeding risk (mAFA 2.1% vs usual care 4.3%), thromboembolic events, rehospitalization, and all-cause death (1.9% vs 6.0%) and an increased adherence in oral anticoagulation therapy. PPG signals via mAFA app were associated with a positive predicted value of 91.6%, an interesting result for future AF screening approach. The long-term extension cohort demonstrates high adherence (>70%) and persistence (>90%) in those using the app beyond 1 year[77]. An ancillary analysis from the mAFA-II trial shows the benefits in AF patients with multimorbidity[82], whereby it appears a promising strategy in elderly people, one of the categories most burdened by multimorbidity and the consequent polypharmacotherapy, which determine a significant complexity of patient management. Also, such app-based management applying the HAS-BLED score to mitigate modifiable bleeding risk factors and schedule high bleeding risk patients for early review and follow-up resulted in less major bleeding events at 1 year, and an

Table 3. **MCG-based devices' studies** – Abbreviations: n.a.: not available; Ref.: reference; s.t.: single time; Sn: sensitivity; Sp; specificity. Unless otherwise indicated, age is reported as mean years.

MCG-based

Study	Design	n°	f (%)	Age	Country	Device/Technology	Monitoring time	AF rate (%)	Sn (%)	Sp (%)	Ref. test
Jaakkola et al[69]	Case-control	300	44	74.8	FL	Mechanocardiography	3 m s.t.	n.a.	95.3	96	Tele-ECG

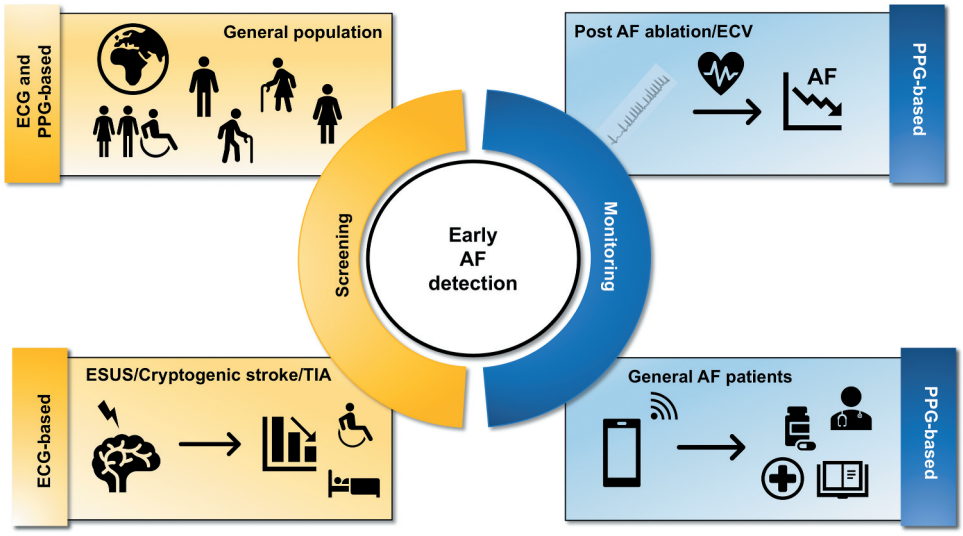

Figure 4. Different scenarios and practical devices' use proposal; Abbreviations: AF: atrial fibrillation; ECG: electrocardiogram; PPG: photoplethysmography; ESUS: embolic stroke of undetermined source; TIA: transient ischemic attack.

increase in oral anticoagulation uptake, compared to usual care (which had higher bleeding rates and a decline in OAC use)[76].

In the era of telemedicine, remote patient–management systems for AF [81,83–85] can help patients to improve their perception of disease and adherence to AF therapy and doctors to intervene more appropriately, relying on the information provided by patients. Patient-clinician contact could be by telephone or by apps. In this last modality of communication, the European Society of Cardiology introduced the Characterizing AF by Translating its Causes into Health Modifiers in the Elderly (CATCH ME) applications for patients (myAF) and clinicians (AF manager) [86]. myAF-app contributes to patients' self-education and management for better interaction with clinicians who could choose the best guidelines-guided therapy thanks to their appropriate apps. However, these have not been tested in randomized trials nor shown to make an impact on clinical outcomes.

In comprehensive AF management, educational programs [87–89] have also been studied for increasing AF knowledge about symptoms, scoring risk and therapy adherence in patients and health-care practitioners. Focusing on patients' knowledge about AF, the OCULUS educational program was formatted as a three-dimensional movie about AF stroke prevention, and it increased perceived risk and anticoagulation patients' adherence. Similarly, the EVI-COAG trial was structured as a 6-weeks Qstream spaced education platform addressed to nurses, comprising AF and anticoagulation scenarios, which improved knowledge about AF risk scores usage. Clinicians have also get involved in these educational programs through online webinars, increasing their expertise in AF-source detection on electrophysiology maps[90].

The clinical decision-making supports and AF detection systems [91–95] are often linked to ECG-based devices platforms. They have demonstrated to improve AF detection and the consequent appropriate therapy, such as Link AFinder (CareLink network). These systems support clinicians in decision-making not only in detection but also in decreasing false positive: an interesting example is AKHENATON which use artificial intelligence (AI) to limit AF alert error, reduce useless workload and preserve the safety of the patients. In an ancillary study to the Huawei Heart Study, an AI approach to predict episodes of AF has been validated[96]. Lastly, AF shared decision-making (AFSDM), Clinical decision support for AF (CDS-AF) and decision analysis in routine treatment study (DARTS) are well-studied share-decision making supports to decrease therapeutic discordances and achieve medication goals for patients' safety.

3. Conclusion

PPG-based devices are the emerging mHealth strategies. Sn and Sp for handheld devices are 91.5–98.5% and 91.4–100%, respectively. The wearables ones are represented by a heterogeneous group, with a wide accuracy range in AF detection. The most accurate are finger bands, but wristwatch studies cover the largest study population. ECG-based devices are of crescent interest due to their diagnostic role, whereby the handheld ones, especially plates devices, are the most studied and used in this category with a wide Sn and Sp range. Among wearable devices, patches, and chest belts have similar accuracy. Alternatively, ILRs use in post-neurologic acute events have proved their efficacy in AF detection, although cost-effectiveness still limits their usage in this setting. Finally, support systems in patients' data flow process have reached the outcomes of a more conscious AF knowledge about stroke risk, better medication adherence, and decreased thromboembolic events with more prolonged-monitoring periods.

Table 4. **Support system's studies** – Abbreviations: abl.: ablation; AF: atrial fibrillation; Amb: ambulatory; BP: blood pressure; BW: body weight; Crypto. stroke: Cryptogenic stroke; d: days; DM: diabetes mellitus; ECV: electrical cardioversion; e.d.: expert diagnosis; f: female; HR: heart rate; Hosp: hospitalized; h: hours; Intern.: international; IC: investigation care; IS: ischemic stroke; m: minutes; mo: months; mPSA: multicenter prospective single arm; n.a.: not available; OAC: oral anticoagulants; PAF: paroxysmal atrial fibrillation; PR: prospective randomized; PSA: prospective single arm; PTA: prospective two arms; pts: patients; QoL: quality of life; RSA: retrospective single arm; rHo: re-Hospitalization; s: second; s-l-ECG: single-lead ECG; s.t.: single time; SR: sinus rhythm; sTE/TE: systemic Thromboembolism/Thromboembolism; Sn: sensitivity; Sp; specificity; UC: usual care; y: years; yo: years old; 12-l-ECG: 12 leads ECG. Unless otherwise indicated, age is reported as mean years.

Educational programs

Study	Design	n°	f (%)	Age	Duration	Country	%AF pts	Interventions	Outcomes	Results
Desteghe et al[87]	RCT	120	35	1. 68	12 m	BE	100	1. online education	AF knowledge, QoL	1. improved AF knowledge and QoL
				2. 65				2. standard care + online		2. improved QoL
				3. 74				3. standard care		3. no improvements
Balsam et al[86]	PSA	100	38	63	12 m	PL	62	Video education	AF knowledge	Increased AF risk, drugs and OAC patients' knowledge
Ferguson et al[85]	PSA	74	82	n.a.	6 w	AU	n.a.	AF thromboprophylaxis education by different scenarios	Nurses' knowledge about OAC and AF risks	Improved nurses 'assessment of AF score risks
Mesquita et al[84]	RCT	12	50	n-a.	n.a.	Inter.	100	Electrophysiologists online training	Identification of AF driver sites	Increased AF identification sites ($p = 0.04$) and performance ($p < 0.001$) in training group
AF detection and decision-making systems										
Zoppo et al[88]	PSA	472	23	69	24 m	IT	44	AFinder web-based system: - detection AF alert signals	AF detection via web-based software	AF sensitivity enhanced; improved OAC treatment
Rosier et al[91]	RSA	60	n.a.	n.a.	9 m (mean)	FR	100	AF filter alters system	Adequate classification of AF alert	84% reduction in workload alert monitoring
Karlsson et al[90]	RCT	13379	43	n.a.	12 m	SW	100	Alert abut high-risk patients untreated	Impact of decision support on long-term outcomes	Adherence to guidelines in IC>UC ($p = 0.01$); no difference in IS/TE; IC low rate of bleeding.
Eckman et al[89]	RCT	1493	44	70	12 m	UK/USA	100	Thromboprophylaxis guidance	Decision support	Decrease in discordant therapy
Thomson et al [92]	RCT	109	44	73	3 m	UK	100	Thromboprophylaxis guidance	Decision support	Decrease in decision discordances.

4. Expert opinion

The potential benefits of ECG/PPG/MCG use in medicine is the possibility of an earlier AF detection and start of the ABC pathway[97], aiming for a decrease in morbidity and mortality. However, as proposed in recent reviews [13,14,17,98], the overall accuracy of mHealth devices has a wide range, and differs among technology used (ECG vs PPG vs MCG), the type (handheld vs wearable vs ILR), the population in the study (hospitalized vs general population), the usage setting of the mHealth systems (monitoring vs. screening) and also the AF detection time (intermittent vs continuous).

The screening scenario is the most studied situation: both ECG- and PPG-based algorithms are validated, with an overall high Sn and Sp [99,100]. As recently published in a Huawei Heart Study research[101], artificial intelligence (AI) is becoming more and more supportive in AF detection through the use of handled-PPG devices and the mobile apps on smartphones. The different machine learning systems associated with PPG devices improve Sn and Sp for AF prediction before the arrhythmia onset in this population-based screening cohort. In the future, these devices could be the most appropriate as general screening tools (Figure 4) thanks to AI improvement in their accuracy. Despite this consideration, the study involving the general population, mostly low-risk people, undermines available tests accuracy, with a caveat on future screening studies, which maybe have to focus on high-risk subjects. A recent EHRA position paper on mobile health devices in cardiac arrhythmias [102] has suggested both PPG and ECG devices can be used as screening devices in AF, although PPG devices are easier to use and more related to smartphone apps but still require an ECG confirmation for AF diagnosis. When analyzing the screening scenario from the opportunistic and the systematic screening point of view, the age categories (<65, 65–75, ≥75 years old), the number of comorbidities (0,1, ≥2), digital literacy (a continuum from limited to full), and the usage of PPG or ECG devices drives the choice between these two screening types. Thus, the screening spectrum starts from opportunistic screening in younger, limited digital literacy and less comorbid patients, in which the PPG approach is suggested; to the more systematic approach, in which ECG devices would better evaluate the elderly, fully digital skilled and more comorbid patients. In younger, non comorbid and symptomatic patients, the EHRA position paper recommends use of ECG-device-based screening. No screening, on the other hand, is required for asymptomatic, non-comorbid, younger patients.

The increasing use of ECG-based devices has been elicited by recent guidelines[11], which allow clinicians to diagnose AF from a single lead 30 seconds ECG strip. Although in the general population many arrhythmia episodes could be asymptomatic[4], ECG-based devices could be used as first screening approach in high-risk patients, such as post-stroke patients, especially ESUS and cryptogenic stroke, even stratified with scoring systems (e.g.: C_2HEST score) [103], medical history or specific biomarkers[104]. These devices used in this target population will be part of the strategy for earlier AF detection and management during patients' everyday life. However, as reported in ESC pacing and syncope guidelines [105,106], ILRs devices remain within selected usage field. Although their efficacy in AF detection is undoubted, their utility as a screening method for AF, even in selected patients, remains controversial and limited due to cost-effectiveness reasons.

Recent literature has shown that PPG technology could be as accurate as ECG [24,107], although their traces alone are not diagnostic. During the ongoing SARS-COV-2 pandemic, many PPG experiences in patients' remote monitoring solutions have occurred[108]. A particularly relevant PPG study is Telecheck-AF investigation[109], a structured stepwise practical experience to improve clinicians' control in PPG quality trace (FibriCheck algorithm). This devices category could be most helpful in post-AF-ablation/cardioversion patients, in whom monitoring intermittent longitudinal time for recurrences could be a surrogate of AF burden and density, which may represent variables of treatment efficacy[17]. Lastly, PV-devices are strictly linked to sphygmomanometers technology, and they could be an interesting screening tool for hypertensive patients.

As suggested in several trials, [15,19,74–77,81,110] particularly in the mAFA-II trial, an integrated pathway through mobile app for AF patients has reduced clinical adverse events (stroke and thromboembolism), mortality and bleeding, especially when an ABC pathway-guided approach was compared to usual care.

Mobile applications have a significant role in patients' lives nowadays, as with smartphones. Support systems could be the most effective way to reach a safer patient self-management of AF. Through apps, clinicians could collaborate faster in a patient-tailored therapeutic way. AF risks and prevention lifestyle information could be provided to patients, aiming to improve global AF knowledge.

A recent review [111] demonstrated ECG and PPG devices had similar accuracy in AF detection. Despite this, the overall limitations of these data are the reference tests used, the device monitoring modality and various non-standardized algorithms for AF, impacting Sn and Sp. Also, direct comparisons between ECG/PPG and wearable/handheld devices are few. One head-to-head comparison between PPG and ECG handheld devices by Van Haelst et al [28] found a good overall Sn and Sp, with slight differences favoring the PPG method. On the other hand, direct comparisons in computational speed between the different algorithms in AF detection are limited, and further studies are needed. In the same way, the major concern about the PPG method is the reliability of the trace, which can sometimes be burdened by errors and artifacts. Therefore, many efforts in actual ongoing studies are promoting better experiences and knowledge of these devices. The different technologies and algorithms, the different usage and monitoring periods throughout the studies, may impact the accuracy for AF detection. Artificial intelligence and machine-learning approaches for AF detection will contribute to standardizing clinical usage of mobile Health devices, especially the PPG devices, by improving arrhythmias identification. In conclusion, despite their undoubted promising role and validation in trials, wearables and handheld (both PPG and ECG) devices are still not reliable

in clinical practice, for a lack of standardization and reproducibility in AF detection. The different technologies and algorithms, the different usage and monitoring periods throughout the studies, still afflict too much the accuracy for AF detection. In this perspective, artificial intelligence thanks to machine-learning schemes for AF detection will contribute to standardizing clinical usage of mobile Health devices, especially the PPG devices, improving arrhythmias identification[112].

Both health-care practitioners and patients could have poor knowledge of the correct function of the devices and poor informatic skills. This limit could lead to the underuse of these devices in future AF management. This point highlights the necessity of a close collaboration between patients, clinicians, and the device's production companies, with the aim of a complete understanding of the potential benefits and risks of the devices used for more accurate management of AF[113]. Many attempts to emphasize the importance of health-care practitioners' education have been reported [88–90]. An inter-professional team promotion (from clinicians and nurses to the device's provider) improves digital communication and technology literacy skills. In this perspective, the evidence supports better patient comprehension, as well as technology and audit support to clinicians. Based on this model, patient involvement fits the concept of integrated care for AF management [111,112].

Data collection, storage and review by health-care practitioners is a common problem of mHealth solutions. Thanks to the wireless acquisition, collected data are quite heterogeneous and various, leading to a considerable amount of sensitive information. This raises a legal and insurance problem on their management, the reliability of the trace received, and the final decision-making process for clinicians through this data-flow. [114] However, most mHeath devices have a sensitive data-secured cloud/platform in which the holder guarantees the security and their reproducibility.

Lastly, despite their increasing uptake, mHealth solutions are burdened by several economic barriers. First, the availability of these devices is almost exclusive to the advanced financial health-care systems, thus generating a future inappropriate diversification of the management of AF. Second, the advanced health-care systems themselves generally do not provide refunds for these health-care practices. Therefore, only patients who can pay for such benefits can be involved within these systems, perhaps contributing to health-care inequalities.

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