

Raising awareness and early detection of atrial fibrillation, an experience resorting to mobile technology centred on informed individuals



Sara Cunha^a, Eduardo Antunes^b, Sotiris Antoniou^c, Sália Tiago^d, Rui Relvas^e,
Fernando Fernandez-Llimós^f, Filipa Alves da Costa^{a,f,*}

^a Centro de Investigação Interdisciplinar Egas Moniz (CiüEM), Instituto Universitário Egas Moniz (IUEM), Campus Universitário, Quinta da Granja, Monte da Caparica, 2829-511, Caparica, Portugal

^b Serviço de Cardiologia, Hospital Santa Marta, EPE; Rua de Santa Marta, 1169-024, Lisboa, Portugal

^c Barts Health NHS Trust, St Bartholomew's Hospital, W Smithfield, London, EC1A 7BE, United Kingdom

^d Farmácia Sália, Praça do Bocage 98-99, Setúbal, Setúbal (S.Julião, N. Sra. da Anunciada e Sta. Ma da Graça), 2900-276, Setúbal, Portugal

^e Residência Sênior Egas Moniz, Avenida D. Manuel Martins, n.º 4. Maçã – Sampaio, 2970-585, Sesimbra, Portugal

^f Research Institute for Medicines (iMED.Ulisboa), Faculdade de Farmácia da Universidade de Lisboa (FFUL), Av. Prof. Gama Pinto, 1649-003, Lisboa, Portugal

ARTICLE INFO

Keywords:

Atrial fibrillation
Early diagnosis
Interprofessional relations
Portable ECG
Portugal

ABSTRACT

Background: Atrial fibrillation (AF) is a cardiac arrhythmia responsible for one third of ischemic strokes. Early detection of AF plays an important role in preventing embolic stroke.

Objectives: This study aimed to test the feasibility of an awareness event including opportunistic screening for atrial fibrillation; and to test the reliability of the innovative portable electrocardiogram (ECG) device used.

Methods: An awareness campaign was held during two weeks, where individuals consenting to participate in a pharmacist-led detection event, received a manual pulse check, were clinically evaluated and subject to a single-lead electrocardiogram using AliveCor Kardia® mobile. ECGs highlighted as possible AF were confirmed by the cardiologist and those signalled with abnormalities in cardiac rhythm were referred to their physician. Data were collected in a password protected application and analyzed using SPSS, v.24. The Kardia® mobile's sensitivity and specificity was tested against the standard 12-lead ECG.

Results: The awareness event involved 223 individuals, among which 205 were screened. Mean age was 66 years (SD = 15) and hypertension was the most frequently reported (n = 107; 52.2%). Mean CHAD₂DS₂- VASc score was 3 (SD = 1.8). Cardiac irregularities were identified in 45 individuals, 14 confirmed to be new cases of AF (6.8%) by the cardiologist. The sensitivity and specificity were 90.9% and 97.4%.

Conclusion: Data suggests this device to be potentially useful for opportunistic early detection of AF, provided interprofessional collaboration is guaranteed so that suspect cases are adequately managed and in a timely way. Fourteen new cases of AF were identified in the population studied, suggesting the pharmacist working in a multiprofessional context, may have had an important role in preventing potential ischemic-related strokes with this initiative. All healthcare professionals involved in the patient pathway should play a more active role in contributing to better health outcomes, particularly within primary care.

Introduction

According to the WHO, in 2017, cardio and cerebrovascular diseases are still the major cause of mortality globally, among which stroke individually assumes third place.^{1,2} In Portugal, the pattern is very similar, although it should be highlighted the important decrease

observed in the last years, with a standardised mortality rate for individuals below the age of 70 of 2.5 and 4.7 per 100,000 inhabitants in 2015, respectively for ischaemic and haemorrhagic stroke.³ In fact the decrease observed for ischaemic stroke in four years was 39%, exceeding the established targets. Nonetheless, deaths attributed to stroke represented 10.8% of total deaths observed in 2015.⁴ Ischaemic stroke

* Corresponding author. Centro de Investigação Interdisciplinar Egas Moniz (CiüEM), Instituto Universitário Egas Moniz (IUEM), Campus Universitário, Quinta da Granja, Monte da Caparica, 2829-511, Caparica, Portugal

E-mail addresses: sara.af.cunha@outlook.pt (S. Cunha), ejpantunes@sapo.pt (E. Antunes), sotiris.antoniou@bartshealth.nhs.uk (S. Antoniou), salia.stb@farmalink.pt (S. Tiago), rrelvas.1143@gmail.com (R. Relvas), fllimos@ff.ulisboa.pt (F. Fernandez-Llimós), alvesdacosta.f@gmail.com (F. Alves da Costa).

is frequently associated with abnormalities of cardiac rhythm, namely atrial fibrillation (AF¹). AF is a common sustained arrhythmia, often asymptomatic, which may be detected through pulse taking and subsequently verified by a 12-lead electrocardiogram (ECG²).^{5,6} When the condition is not detected by the absence of symptoms and unawareness of tests available to identify it, quite frequently the first manifestation is stroke. When AF-related stroke does occur, it is associated with more disability and worse outcomes compared to non AF-related strokes.⁷ Conversely, when detected the condition may be controlled and stroke prevented by initiating appropriate therapy, namely oral anticoagulation, which has documented economic impact.^{8,9} Aside with early treatment, early detection by the implementation of systematic or opportunistic screening has also shown to be cost-effective, predominantly in the elderly population, partly due to the ability to detect asymptomatic cases.^{10–12} The European Society of Cardiology recommends opportunistic screening for AF to be undertaken by pulse taking or ECG rhythm strip in patients over 65 as it is considered to be the best solution to reach communities, both in terms of costs and on impact on morbi-mortality.^{5,13} Previous studies have focused on the feasibility of implementing these recommendations in primary care and as such have tested the use of portable ECG devices. These studies suggest high uptake by patients and clinicians with equal reliability and success in detection rate. The community pharmacist has been identified in such studies as ideally located to have access to asymptomatic individuals, having a key role in ensuring correct referral to adequate medical care.^{14–17} However, pharmacists have also been recognised for being an untapped resource and they may practice in various settings. The community pharmacy is indeed the most common area of practice, but pharmacists also have direct patient care in hospitals and in nursing homes, both of which in Portugal are under the same career pathway, which is hospital pharmacy. There is quite a long tradition in public health interventions undertaken by pharmacists, both nationally and internationally, leading the research team to be interested in exploring the potential of engaging in Early Detection of Atrial Fibrillation (EDAF) in these three settings, while comparing the advantages and pitfalls of each of them.

Considering these international experiences, while conscious that direct extrapolation is not possible, the current study aimed to: 1) test the feasibility of actively involving pharmacists working in different settings in awareness campaigns of AF for greater outreach; 2) use awareness events as an opportunity to engage in early detection of AF; 3) to assess the sensitivity and specificity of the AliveCor Kardia® mobile, against the standard 12-lead ECG, as a convenient method to promote more frequent opportunistic screening events in primary care.

Methods

Research design

A pseudo-longitudinal study was conducted, implying various cross-sectional assessments were performed at different time points and then compared. These were undertaken in three different settings: a community pharmacy located in an urban area, a nursing home and the outpatient clinic of the cardiology unit of one of central Lisbon's main hospital centres.

Patient selection and study period

Every individual showing interest was eligible to participate in the awareness event. For the screening event, only individuals aged 40 years or older were included and those with previous diagnosis of atrial fibrillation being medicated with anticoagulants were excluded.

Individuals incapable of communicating with the researcher (either due to cognitive impairment or language barriers) were also excluded as this barrier compromised data collection. Additionally, following the indications of the device developer (AliveCor), individuals carrying pacemakers or who have had a recent bypass, i.e., within the previous 30 days and those with diseases interfering with rhythm conduction, such as Wolff-parkinson-white syndrome, were also excluded. For the Kardia® mobile validation (aim 3), we had to be certain that upon identification of any cardiac arrhythmia a subsequent 12-lead ECG was guaranteed. Hence, to meet this aim, we have only recruited individuals in the hospital setting. Across all study sites, the same researcher resorted exactly to these same screening procedures to ensure consistent, valid and comparable results.

The study lasted from May to September 2017, with recruitment extended for an entire month (May to June, as opposed to the traditional one week event organised globally by Atrial Fibrillation Association/Arrhythmia Alliance (AFA/AA), detailed ahead) enabling a 3-month period for the individuals referred for additional medical evaluation to have time to return to the pharmacist to confirm or dismiss potential diagnosis, regardless of the setting where individuals had been recruited.

Technical procedures

A portable one-lead ECG device (Kardia® mobile) was used, which works through an electrode attached to a smartphone or tablet. The device collects abnormalities of cardiac rhythm and rate and captures digitally a one-lead ECG based on the P wave, which can then be stored on a secure server, printed as a PDF file or transmitted via email to the physician. The Kardia® mobile has an algorithm system incorporated enabling quick interpretation of the signs, which are transmitted using four possible results: normal, possible AF, unreadable or unclassified. This implies other cardiac arrhythmias are not signalled by the Kardia® mobile. It is currently the most widely used portable device in the UK, as the chosen portable device by the NHS accelerator program,¹⁸ and appraised by NICE to have a sensitivity of 85% and a specificity of 90%.¹⁹ The procedure also took into account the recommendations of the producer, which state that whenever unclassified results are obtained, a new measurement should be repeated after rest. If after repetition, the situation persisted, the pharmacist evaluated the pulse using manual palpation.²⁰ The need to engage in the validation of the Kardia® mobile was merely justified by unfamiliarity of Portuguese clinicians in using this brand, although it had FDA and EMA clearance. Perhaps a certain cultural mistrust also led the research cardiologist (EA) to consider this process necessary to fully engage all team in the initiative.

Data collection

The pharmacist conducted a face-to-face in depth evaluation where demographic data, current (hypertension, heart failure, diabetes and peripheral arterial disease) and previous medical history [(stroke, transient ischaemic accident (TIA) or thromboembolism (TE) and acute myocardial infarction (AMI)], presence of symptoms (palpitations, shortness of breath, tiredness, chest pain, dizziness and irregular pulse) and therapy prescribed were collected, based on patient self-report, unless the pharmacist had access to medical charts (mainly in the hospital and nursing homes). Medication prescribed was used as a proxy measure for unknown diagnosis, mostly to discard existing and treated AF without the individual's full awareness. All this information was entered into a password protected web based app that was developed to also guide the pharmacist in the course of action to take.

Interprofessional collaboration and medical referral

The pharmacist was in charge of the screening in all three settings

¹ AF = Atrial Fibrillation.

² ECG = electrocardiogram.

but interprofessional collaboration occurred in different formats. In the pharmacy, the pharmacy technician or other pharmacists often identified the individuals and referred them to the research pharmacist who was in charge of the awareness procedures followed by the screening procedures. Whenever the pharmacist detected any abnormality in the cardiac rhythm in the community pharmacy, he would advise the individual to consult the physician. In Portugal, to consult a cardiologist in the public sector, there must be a previous referral made by the family physician. However, citizens are free to have insurance or pay out-of-pocket, and directly consult with a cardiologist in a private clinic. This decision was entirely left to the individual, assuming empowered individuals would be able to choose the best care once informed.

In the nursing home, there were nurses and psychologists involved in the identification of the individuals that met the inclusion criteria and once they consented their participation, these staff were also involved in the evaluation of the patient record in close collaboration with the pharmacist. In this setting when abnormalities were detected, the pharmacist referred directly to the physician responsible for the nursing home, either face-to-face (if physically present) or via email. In this case, depending on the status of the nursing home resident, the responsible physician would either take the decisions himself or need to refer the patient to an external treating physician (mainly for external residents, i.e., those with greater independence status).

As part of the process, a referral letter would be provided, containing the printed ECG, and a summary of the collected information. According to the data entered on the web app, the *CHAD₂DS₂-VASC* score was estimated and also used as additional information to be transmitted to the physician upon referral for confirmation of diagnosis, whenever appropriate. Upon referral, the pharmacist sought confirmation using a 12-lead ECG, based on ESC guidelines.⁵ The physician was requested to respond to the pharmacist and provide feedback on the established diagnosis, including different forms of cardiac arrhythmias. This process was used both in the community pharmacy and in the nursing home settings. In the hospital setting, a referral letter was not used as the interventions undertaken were organised in a closer interprofessional context. The process was initiated by the pharmacist's evaluation, then a technician-led 12-lead ECG conducted and immediate evaluation by the cardiologist. If AF was diagnosed, the decision on therapy to be instituted was totally left to the treating physician, as recommended by National legislation and scope of practice in Portugal. Nonetheless, pharmacists were trained with the most current treatment guidelines so they could offer advice on oral anticoagulation, if requested by the physician.

Awareness event

The AFA/AA is a charity association based in the UK which has spread worldwide and established with the main aim of helping patients and their families to understand atrial fibrillation and to obtain the best expert advice. This Association organises annual events worldwide to promote greater engagement with the condition and to raise awareness amongst the general public. In 2016, for the first time, the AFA/AA created a partnership with the International Pharmacists for Anticoagulation Care Taskforce (iPACT) with the purpose of promoting greater pharmacist involvement in such initiatives. In June 2017, as part of the Heart Rhythm Week, pharmacists worldwide collaborated in this awareness event. Posters were displayed to advertise the initiative and individual information leaflets were distributed to all the interested individuals explaining the meaning of AF, its risk factors, symptoms and transmitting the four steps for pulse check. The demonstration of the pulse check was itself a means of raising awareness. Full details of the international event and its results are available elsewhere.²¹

Data analysis

Continuous variables were expressed as mean \pm standard deviation (SD) and categorical variables as absolute values and percentages.

The sensitivity and specificity of the device was estimating using the following formulas:

- Sensitivity = $[\text{True Positives}/(\text{True Positives} + \text{False Negatives})] * 100$
- Specificity = $[\text{True Negatives}/(\text{True Negatives} + \text{False Positives})] * 100$

Where the 12-lead ECG was the standard considered for determining true or false results.

The software SPSS 24.0 (IBM SPSS, Armonk, NY) was used for the statistical analysis.

Results

Population sample

Over 223 individuals were involved in the awareness campaign implemented in three locations. This number does not take into account those in contact with the posters displayed physically and through social media. Among these, 205 were included in the early detection event as they met the predefined inclusion criteria. A sample of 101 individuals was considered for the Kardia® mobile validity testing (the 101st was a control positive AF result), some of which could also be considered for the early detection (Fig. 1).

Early detection of atrial fibrillation (EDAF)

A total of 205 individuals were included in the EDAF event. The mean age was 66 years (SD = 15), with the majority being female (n = 131; 64%). The most commonly reported symptoms were tiredness (n = 99; 48.3%), palpitations (n = 88; 42.9%) and dizziness (n = 87; 42.4%). Nearly one quarter of participants presented an irregular pulse (n = 45; 22%), among which nine were asymptomatic (20%). The mean rate observed was 73 beats per minute (SD = 15). In the overall sample, 33 presented bradycardia and eight presented tachycardia; among those with irregular pulse, nine and seven presented respectively bradycardia and tachycardia. The most commonly reported risk factor for stroke was hypertension (n = 107; 52.2%), followed by peripheral arterial disease (n = 64; 31.2%), diabetes (n = 45; 22.0%) and heart failure (n = 41; 20.0%). Around 11% of participants (n = 22) had previous history of stroke, TIA or TE and around 9% (n = 18) had history of AMI. The mean *CHAD₂DS₂-VASC* score for the overall sample was 3 (SD = 1.8). The main study indicators are presented for the overall sample and sub analysed by setting in Table 1.

Sensitivity and specificity of portable ECG

The results obtained from the sample used for the assessment of the Kardia® mobile validity, against results obtained with the 12-lead ECG, are presented in Table 2. Unclassified traces were excluded from this analysis, however carefully analysed by the cardiologist as a qualitative assessment. The total number of unclassified traces was 28 (14%), and there was one unreadable trace (0.5%).

Referral pathway

All individuals identified as having any unknown abnormality in cardiac rhythm, following confirmation from the research cardiologist of a suspected irregular ECG trace were referred to their treating physician. All individuals referred at the hospital setting had their diagnoses confirmed, as well as the majority of those at the nursing home,

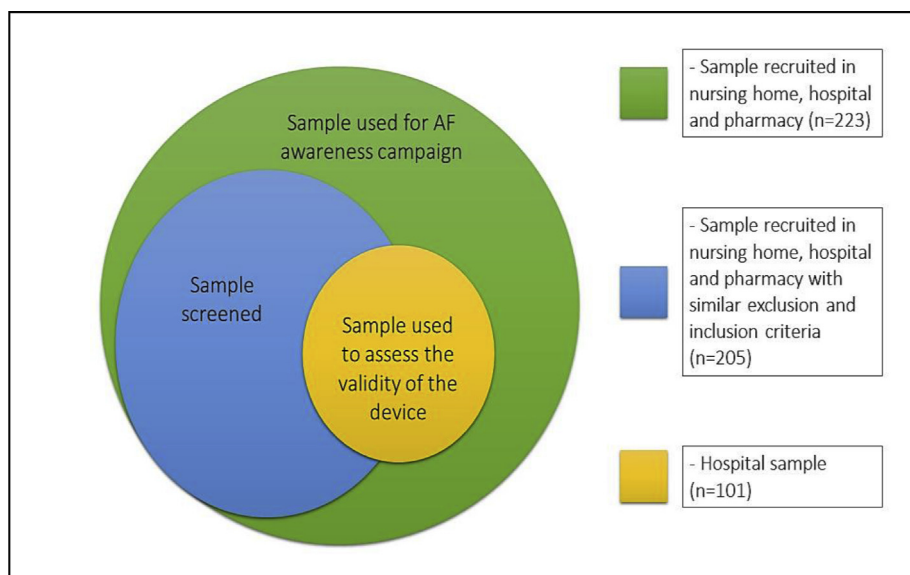


Fig. 1. Schematic representation of samples used for the different study objectives.

Table 1
Demographic and clinical characteristics of the sample included in the Early Detection of Atrial Fibrillation Event.

	Nursing Home (n = 23)	Community Pharmacy (n = 99)	Hospital (n = 83)
Age: mean (SD), years	85 (5)	62 (13)	66 (14)
Gender: female, n (%)	19 (83%)	72 (73%)	43 (52%)
Symptomatic (≥1 symptom)	14 (60.9%)	77 (77.8%)	73 (88.0%)
Irregular pulse: n (%)	8 (35%)	7 (7%)	29 (35%)
Heart Rate: mean (SD), bpm	68 (13)	72 (14)	75 (17)
Stroke Risk factors: n (%)			
Hypertension	17 (74%)	34 (34%)	56 (68%)
Peripheral Arterial disease	3 (13%)	35 (35%)	26 (31%)
Heart failure	6 (26%)	7 (7%)	28 (34%)
Diabetes	1 (4%)	12 (12%)	32 (39%)
Previous medical history: n (%)			
Stroke, TIA, TE	8 (35%)	3 (3%)	11 (13%)
AMI	2 (8%)	2 (2%)	14 (17%)
CHAD ₂ DS ₂ -VASc ≥ 2	100%	68%	90%
CHAD ₂ DS ₂ -VASc Mean (SD)	4,7 (1,42)	2,27 (1,33)	3,65 (1,93)

SD = Standard Deviation.

Table 2
Kardia® mobile Sensitivity and Specificity data indicating Atrial Fibrillation.

		Gold standard (12-lead ECG)			Specificity
		Positive	Negative	TOTAL	
Tested device (Kardia mobile)	Positive	20	2	22	[76/(76 + 2)] *100 = 97.44%
	Negative	2	76	78	
	TOTAL	22	78	100	
Sensitivity		[20/(20 + 2)]*100 = 90.91%			

whilst diagnosis was only confirmed for a few at the ambulatory setting. Table 3 presents the diagnosis obtained, by setting, assuming exclusively the confirmation from the cardiologist for the above mentioned reasons related to lack of feedback from the treating physicians.

Overall 14 new cases were identified, representing a detection rate of 6.3%. This rate was significantly different across settings, ranging

from 1% to 13%, in line with the differences reflected by the CHAD₂DS₂-VASc score, which in turn result directly from the individuals' age and number of comorbidities as presented in Table 1. Additionally, there were 11 individuals with known AF, which were considered to estimate the prevalence, but above all to identify those correctly managed with recommended pharmacotherapy and those where an intervention would be beneficial.

Discussion

The main findings of this study suggest that an important number of Portuguese citizens were reached by involving pharmacists in this awareness campaign, contributing in a visible way to increase health literacy of Portuguese citizens. The AFA has been conducting these initiatives twice a year for over 20 years, but this event was the first time where pharmacists beyond the UK have been actively involved. The contribution of pharmacists is important as they are well positioned within the local communities, enabling very efficient reach of the entire population, including those apparently healthy. This aspect is essential because the investment in disease prevention and health promotion is much more cost-effective than in treatment.

The detection rate of AF in the ambulatory setting of 1.0% was slightly lower than in other studies conducted in similar settings.²² These studies were conducted involving exclusively elders, therefore the lower detection rate is easily explained by the fact that individuals over 40 years of age were included. The main aspect to be highlighted in this setting was the inability to ensure the identified suspect consulted a physician or that the physician reported back to the research team his conclusions. Although this sample is quite small and extrapolations may not be made, this finding advises us that any future initiatives developed on a larger scale might benefit from early engagement with medical societies, carried out by the research team, and with local physicians, initiated by the local pharmacist.

The detection rate in the hospital was much higher than expected and most likely a result of a biased sample recruitment, where the setting chosen enabled the identification of individuals with previous cerebrovascular or cardiovascular conditions, hence using this specific cardiology unit. This was not a surprise, as the choice of this setting was mainly due to the need to test the validity of the Kardia® mobile, and which served very well its purposes. The referral pathway in this setting was perfect as all professionals involved discussed the case in an open and productive way, placing the patient's interest at the centre of such

Table 3
Identified cases overall and by setting.

Setting	Overall 223 (100%)	Community pharmacy 99 (100%)	Hospital outpatients 101 (100%)	Nursing home 23 (100%)
Unknown AF	14 (6.3%)	1 (1.0%)	10 (9.9%)	3 (13.0%)
Known AF and treated with OAC	9 (4.0%)	0 (0.0%)	9 (8.9%)	0 (0.0%)
Known AF but untreated with OAC	2 (0.9%)	0 (0.0%)	2 (2.0%)	0 (0.0%)
Estimated Prevalence of AF	25 (11.2%)	1 (1.0%)	21 (20.8%)	3 (13.0%)

discussions.

The nursing home setting was particularly limited in sample size, advising particular caution in any conclusions drawn. Nonetheless the detection rate of 13% was surely a reflection of age and comorbidities as indicated by the *CHAD₂DS₂-VASc* score, and in line with previous studies conducted in Europe.²³ The referral pathway in this setting worked considerably well, with the greatest difficulty being to ensure a confirmation 12-lead ECG was possible, given the location of the facility. A second aspect worth highlighting was that in some cases, the decision was that advancing age with other comorbidities meant that the risk of anticoagulation outweighed the benefits.

Involving students as partners for the implementation of new services in pharmacy practice has numerous advantages, namely the fact that they are generally motivated to contribute to better patient care and have freshly acquired knowledge. Secondly, when pharmacy directors lack the necessary staff to provide new services, students may serve as a good qualified solution and an unexpected additional resource. Previous national studies have demonstrated pharmacy students' willingness and capacity to meet such purposes in varied settings.^{24,25}

During the early detection event, 11 cases of known AF were noted, two of which were not treated with oral anticoagulation as recommended by the European Society of Cardiology (ESC) guidelines.⁵ These were situations where additional information had to be collected to identify the reason for not having the correct treatment instituted, so that room for pharmacotherapy optimisation could be identified in an interprofessional context considering the interests of the citizens as central. It may be questioned why such cases have been quantified and the reason is quite simple. Because these cases have been described as actionable AF, *i.e.*, individuals with known AF but who are not receiving optimal treatment, therefore not benefiting from the progress made through therapeutic innovation.²⁶

Finally, the validity of the Kardia® mobile was greater than expected, as reported by NICE.¹⁷ This finding suggests it could be an efficient portable solution, provided professional counselling is made available and referral pathways are in place.

Study limitations

Despite the innovative approach of this study where portable devices have been used for greater outreach and the associated inherent value, this study has limitations that need to be recognised. First, as part of an MSc project, there was no sample size estimation and geographical convenience was used to select partners for recruiting individuals. Hence, the sample is limited and restricted to a single region, implying no generalisation is possible. Self-selection bias is possible to have occurred (mostly in the busy community pharmacy environment), where probably only motivated individuals joined the event. Nonetheless, this data contributes to a larger multicentre international project, published elsewhere.²⁷ Secondly the inability to obtain confirmation from the treating physician limits the potential impact of the initiative. This is the main area where additional work must be developed to ensure efficient flow of information and interprofessional collaboration, both for the best interest of the citizen. Simultaneous top-down and bottom-up approaches need to be developed in the Portuguese context. Finally, it is worth advising caution with the high

proportion of unreadable and unclassified traces found using Kardia® mobile; this aspect should be taken into considerations in future studies and in practice. Currently in Portugal, technologies infrastructures are being developed and constantly improved so that the citizen has full right to his information and is able to access to any healthcare professional he/she believes may contribute to improved care. However, in the national electronic database, so far only physicians working in the public sector have full access to data, leading to failures in information transfer, which obviously call for more ancient methods of collaboration, including face-to-face or telephone communication.

Conclusions

This study suggests the involvement of pharmacists in awareness campaigns is important to reach a wider proportion of the population. The early detection of AF could also be an additional service delivered by pharmacists, with potential benefits in the prevention of AF-related stroke, provided information transfer is in place, citizens are empowered and interprofessional collaboration is efficiently established.

Competing interests

Sotiris Antoniou received personal fees and/or non-financial support from Bayer, Boehringer Ingelheim, Daiichi Sankyo and BMS/Pfizer related to AF anticoagulant management, outside of this work, in the previous 24 months. Filipa Alves da Costa received non-financial support from Bayer, outside of this work, in the previous 24 months. The remaining authors have no conflicts of interest to declare.

Funding

This project was financed by national funds through FCT-Foundation for Science and Technology, I.P., in the context of project UID/BIM/04585/2016.

Ethics approval and consent to participate

The project was approved by The Egas Moniz Ethics Committee (Proc. 517), by the Ethics Committee of Hospital de Santa Marta, EPE (Authorization number 4448) and notified to the National Commission for Data Protection (Ofício 15354). The authors declare that no patient data appear in this article. The authors declare that all patients included signed an informed consent, as foreseen in the ethics approval.

Acknowledgments

To all the staff in all three settings that contributed to the success of patient recruitment and evaluation.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.sapharm.2019.08.036>.

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