

Atrial fibrillation self screening, management and guideline recommended therapy (AF SELF SMART): A protocol for atrial fibrillation self-screening in general practice

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ABSTRACT

Background: Opportunistic screening for silent atrial fibrillation (AF) is recommended to reduce stroke, but screening rates are sub-optimal in general practice. We hypothesize that patient self-screening in the waiting room may improve screening and detection of AF.

Methods and analyses: This proof-of-concept study tests a purpose-designed AF self-screening station and customised software which seamlessly integrates with general practice electronic medical records and workflow. The self-screening station records a lead-1 ECG. The software automatically (1) identifies eligible patients (aged ≥ 65 years, no AF diagnosis) from the practice appointment diary; (2) sends eligible patients an automated SMS reminder prior to their appointment; (3) creates individualised QR code to scan at self-screening station; and (4) imports the ECG and result directly into the patients' electronic medical record. Between 5 and 8 general practices in New South Wales, Australia, will participate with an aim of 1500 patients undertaking self-screening. The main outcome measures will be the proportion of eligible patients that undertook self-screening, incidence of newly-diagnosed AF, and patient and staff experience of the self-screening process. De-identified data will be collected using a clinical audit tool, and qualitative interviews will determine patient and staff acceptability.

Ethics and dissemination: Ethics approval was received from the University of Sydney Human Research Ethics Committee in June 2019 (Project no: 2019/382) and the University of Notre Dame Human Research Ethics Committee (Project no: 019145S) in October 2019. Results will be disseminated through various forums, including peer-reviewed publication and conference presentations.

Trial registration number

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1. Introduction

Atrial fibrillation (AF) is the most common arrhythmia in older adults [1], and is associated with thromboembolic disease in major vascular beds [2]. Stroke is the most debilitating condition associated with AF [3]. Around one-third of strokes are caused by AF and these may be fatal, and the arrhythmia may lead to other morbidities such as heart failure, cognitive impairment and systemic embolism [1,2,4].

Approximately one-third of patients with the condition are asymptomatic; asymptomatic AF confers a similar stroke risk as

symptomatic disease [5] and unfortunately a fatal or debilitating stroke may be the first presentation of the condition [6]. As AF in older people is often silent, screening is required to reduce the ~10% of ischemic strokes related to AF which is first diagnosed at the time of stroke [16]. Current Australian and European guidelines endorse AF screening to identify asymptomatic cases; these guidelines recommend opportunistic screening by pulse palpation or ECG rhythm strip among adults aged 65 years and older [1].

General practitioners (GPs) are uniquely placed to screen and initiate management for AF. In Australia more than 90% of adults 65 years and over see their GP at least annually, and around 70% see their GP two or more times per year [7]. Pulse palpation is the simplest and cheapest way for GPs to screen for AF [8]. However, an international study found that only 10–15% of GPs regularly palpated the pulse of their patients [9]. Time is reported by

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GPs to be the greatest barrier to AF screening [10], with consultation time being increasingly challenged by complex patients and fee-for-service models.

Screening needs to have high uptake and utilise a method that is readily available at low cost to facilitate large-volume screening [11]. Furthermore, the screening needs integration into a pathway where there is timely review of the screening results, referral of abnormal screening results to 12-lead ECG or other investigations, and the commencement of anti-coagulation treatment when indicated [4]. A think tank of major stakeholders, comprising of practice managers, nurse practitioners, cardiologists, GPs and patients was convened by our group in 2018 to discuss options to achieve this. Patient self-screening at a kiosk located in an accessible area of GP practices, such as the waiting room, was raised as a potential strategy that could achieve both higher screening rates and numbers of patients screened.

1.1. Study aims and objectives

AF SELF SMART (Atrial fibrillation self-screening management and guideline-recommended therapy) is a proof-of-concept study that will develop and test a single lead electrocardiogram (ECG) self-screening station combined with automated patient prompt to screen that is integrated within practice medical software for opportunistic screening in general practice.

The specific objectives of AF SELF SMART are:

1. To increase the proportion of eligible patients undertaking opportunistic screening for AF by developing a mechanism for self-screening in general practice;
2. To assess the acceptability, competing demands, barriers, and enablers of AF self-screening in the general practice environment;
3. To examine the change in incidence of newly-diagnosed AF before and after the implementation of opportunistic patient self-screening.

2. Methods

2.1. Study design

AF SELF SMART is a cross-sectional implementation study that will take place in 5–8 general practices in New South Wales, Australia. The study will aim for a minimum of 1500 eligible patients to undertake self-screening, and implementation evaluation interviews about the self-screening process will take place with patients, doctors, and practice staff. Ethics approval was granted by the Human Research Ethics Committees of the University of Sydney (Project no: 2019/382) and the University of Notre Dame Australia (Project no: 019145S). The study protocol is registered through the Australian and New Zealand Clinical Trials Registry (ACTRN12620000233921).

2.2. Self-screening station

The self-screening station is a purpose-designed and -built table which will be placed in the practice in a highly visible and patient-accessible area, such as the patient waiting room. The self-screening station includes a mounted Kardia ECG device and an iPad (Fig. 1). The Kardia ECG device has been approved by the Therapeutic Goods Australia (TGA) as a Medical Device, Class IIa and has a validated, automated algorithm for detecting AF with 95% sensitivity and 99% specificity [12]. It is approximately the size of a credit card and comprises of two metal pads which function as ECG transducers producing a Lead I ECG. The signal is transmitted

to the mounted iPad where the Kardia software records the ECG and transfers the screening outcome and rhythm strip to the Best Practice software via Wi-Fi.

The tabletop has simple instructions for completing the screening process. Printed hands on the tabletop help guide the positioning of the patient's hands on the ECG device. The format of the tabletop and instructions were developed with input from GPs, a cardiologist, practice nurses, AF screening researchers and field tested with ten eligible patients. The station design permits easy accessibility by patients with mobility impairments by incorporating wider desk dimensions, and has customary features (e.g. rounded table edges, stability) to ensure safety when placed in a patient-accessible area of a GP practice. The design also permits easy assembly and transport and is made from easy-clean material for sanitisation.

2.3. Customised integration software (Alive2BP)

Alive2BP is customised software that has been developed for the study. This software identifies and prompts eligible patients to undertake screening and integrates the screening station with the practice electronic medical record. As detailed in Fig. 2, the software automatically:

1. Extracts data from the reception electronic appointment book to identify eligible patients for AF self-screening;
2. Sends an automated SMS text message to prompt patients to undertake self-screening, and
3. Creates a unique QR code for each patient to scan at the screening station, and
4. Imports the ECG trace and results from the screening station directly into the patient's electronic medical record.

2.4. Practice recruitment and setup

General practices will be recruited to the study by convenience sampling and advertisement through primary health networks. Primary health networks are independent organisations funded by the Australian Government that focus on health care provision in the local areas approximately corresponding with hospital districts. Participating practices need to employ at least 4 fulltime-equivalent GPs, in order to facilitate an adequate volume of patients attending the practice to test the screening procedure. Practices must also have WiFi and use the Best Practice electronic medical record software. Best Practice is one of the two major GP practice software packages in Australia. Practices must also have the PenCAT clinical auditing software installed. Licences for this software are provided to practices through the primary health networks. For each participating GP practice, written informed consent will be obtained from practice managers.

Individualised IT setup will occur at each participating practice prior to commencing patient self screening. The setup will include:

- Installation of the customised Alive2BP software on the desktops of all computers in the reception area;
- Installation of the screening station in the designated area of the practice;
- Connection of the screening station to the practice Wi-Fi; and
- Rigorous testing of the integration of the Alive2BP software and screening station with the electronic medical record.

Practices will receive a once-off study establishment fee of \$AUS1000 to cover incurred costs, including software installation and testing, staff meetings and training, and data extraction. As Australian practices operate on a fee-for-service basis, each prac-



Fig. 1. Atrial fibrillation self-screening station.

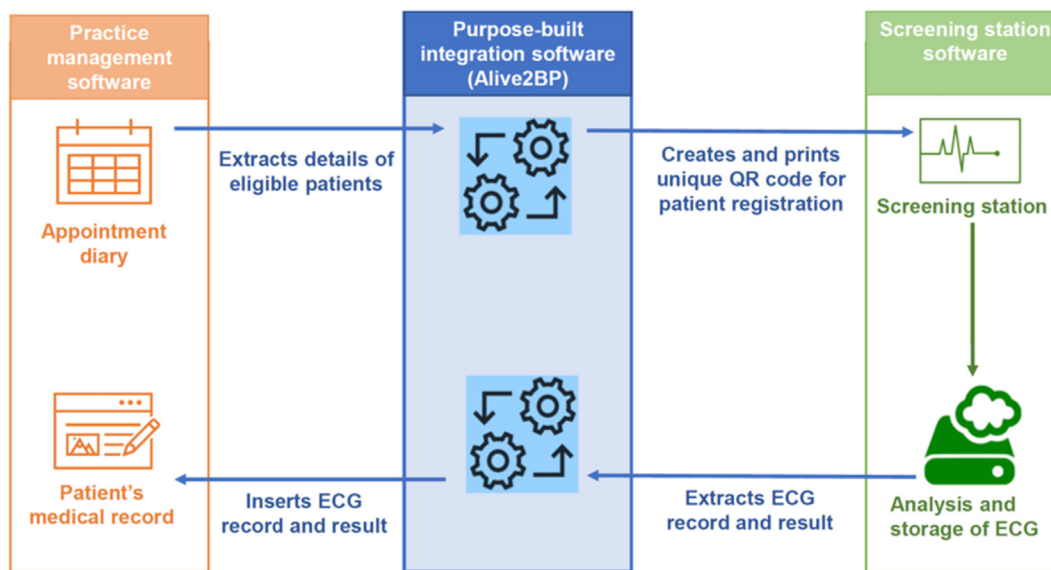


Fig. 2. Automated features of the customised integration software (Alive2BP).

tice will be remunerated for the number of patients that self-screen using a sliding scale (\$AUS500 for first 0–99 patients; \$AUS1000 for 200 patients screened; \$AUS1500 for next 100 patients; and a further \$AUS1500 for screening >300 patients). The maximum each practice will receive is \$AUS5500, inclusive of the establishment fee. The individual patients that are screened by each practice will not be paid, nor will they incur any charge for screening.

2.5. Staff training and recommendations

Once the IT setup is complete, reception staff and GPs will receive tailored training on the self-screening procedure. A user manual structured in a brochure format, will be provided to GPs and reception staff. In addition, a screening flow chart, with visual prompts of the screening procedure, will be attached to GP and reception computer monitors.

Education for GPs will be structured to be eligible for continuing medical education and quality improvement points. GPs will receive training on recent developments in the evidence-based management of AF for stroke prevention, highlighting treatment recommendations and stroke risk score thresholds from the current guidelines [1,13,14]. Current Australian guidelines advise that if AF is established, the patient's stroke risk should be calculated via the CHA₂DS₂-VA score. Oral anticoagulation (OAC) to prevent stroke and systemic embolism is recommended in patients with non-valvular AF and a CHA₂DS₂-VA score ≥ 2 , OAC should be considered in those with a score of 1 but is not recommended for patients with a CHA₂DS₂-VA score of 0 [1].

GPs will also receive training about the three possible automated diagnoses from the screening software: possible AF, uncertain, and normal. If a 'possible AF' result occurs, guidelines recommend that a 12-lead ECG is required for formal diagnosis and may also provide other valuable diagnostic information. An 'unclassified' result may occur in patients with arrhythmias such as brady/tachycardia, premature ventricular ectopic beats, Type I/IIa/IIb heart blocks or left bundle branch block. These may or may not be clinically relevant and/or been previously documented in the patient. Further investigations of the unclassified rhythm may depend on the patient history, however a 12-lead ECG would be recommended to provide more diagnostic information, and further investigations and specialist referral, if warranted. No further action is recommended in an asymptomatic patient with a 'normal' screening result. Monthly feedback will be provided to participating practices about the number of patients screened, with the numbers of possible cases of AF that have been identified.

2.6. Patient self-screening

2.6.1. Patient eligibility

As AF screening guidelines focus on opportunistic, rather than systematic screening, only patients that are attending the general practice for a GP consultation will be offered the screening. Appointments include general appointments, vaccinations, procedures (e.g. skin cancer removal, cervical screening) and chronic care assessments. Patients will be eligible for AF self-screening if they are aged ≥ 65 years and have no previous recorded diagnosis of AF.

2.6.2. Consent procedure

A patient participation information sheet will be available at the reception desk and at the self-screening station detailing the aims of the study, risks and benefits of participation and assurance of data confidentiality. Informed patient consent will be implied from their completion of the screening protocol. This method of informed consent allows self-screening to be testing in a way that more closely aligns to standard workflow and reduces the burden on both practices and patients, and is likely to maximise participation. This facilitates the testing and refinement of a screening-protocol that can be up-scaled for opportunistic general practice-based screening.

2.6.3. Self-screening procedure

The self-screening procedure and how this integrates with software and within the workflow of practice staff is summarised in Fig. 3. These steps are outlined briefly below.

Step 1: SMS text message notification. Text message notification is an effective means for GP practices to communicate with patients in the target age range, with greater than 80% of Australians aged 65 years and older using a mobile phone [15]. It is standard practice that patients register their mobile number with the GP surgery, with the option to opt out of practice text message

reminders and broadcast text messages. The customised screening station software identifies patients with booked appointments meeting the selection criteria who have consented to text message communications from the practice. A brief text message advising patients of the availability of AF self-screening is then automatically sent the day prior to their scheduled appointment. If no mobile number is registered then patients are notified of the study at reception.

Step 2: Patient attends the practice for their appointment. When an eligible patient registers their arrival at the practice reception they will be provided with a printed screening registration sheet that is automatically generated by the customised software. This sheet contains a unique QR code for the patient that is used to register their screening results at the screening station. Reception staff then direct the patient to the AF self-screening station.

Step 3: Patient undertakes self-screening. At the screening station patients scan their QR code to activate the heart rhythm recording. The iPad interface will prompt patients to touch the ECG transducer for 30 s for recording of the ECG. The self-screening is complete when the 30 s ECG trace has been recorded. The patient is notified that their doctor will discuss their results with them.

Step 4: Results are analysed and transferred to GPs results inbox. The ECG is automatically interpreted by a software algorithm that has been shown to be reliable and valid for the detection of AF [16]. The automated algorithm classifies the ECG as either 'Normal', 'Possible AF' or 'Unclassified'. The ECG rhythm trace and interpretation are instantly exported by the customised software to the GP's 'results inbox' in the patient's electronic medical record. This is the standard location for where investigation results are stored for doctor review and actioning (e.g. pathology, imaging).

Step 5: Results are reviewed by the GP. When the GP opens the patient's electronic medical record a notification appears in the patient medical record to identify that AF screening has been undertaken, thus prompting the GP to check the screening report. The GP can open and view the pdf of the 30-second lead-I ECG and the automated interpretation. Doctors will discuss the outcome of the screening with the patient during their consultation. Any further management will be entirely be at the discretion of the treating GP, including further investigations such as 12-lead ECG, blood tests, imaging, medication, or referral to a cardiologist.

2.7. Data extraction

Clinical auditing software will be configured in each practice to collect relevant de-identified data from electronic patient records, as per our previous studies [10,16–18]. These data include demographic, medication, and diagnostic information. Retrospective data extraction of patient electronic medical records for the three months prior to commencement of the project will be undertaken in each practice to enable estimation of new AF diagnoses and prescribing patterns of non-vitamin K oral anticoagulants (NOACs) prior to the intervention. Identical de-identified data will also be obtained for the three months while the intervention takes place, in order to observe differences in diagnosis and prescribing before and during the intervention.

2.8. Study outcomes

Outcomes and process measures for each practice will include:

- The total number of patients aged ≥ 65 years attending the practice for appointments during the study period;



Fig. 3. Overview of the self-screening flow.

- The proportion of eligible patients who completed self-screening for AF;
- The number identified with ECGs showing possible AF and or unclassified traces;
- The incidence of newly-diagnosed of AF in the three months prior to the intervention and during the three months of the intervention;
- Proportion of patients with newly-diagnosed AF with CHA₂DS₂-VA ≥2 commenced on guideline-recommended treatment pre- and post-intervention;
- Appropriateness of SMS text message screening prompts as per patients;
- Acceptability of the self-screening process as per patients;
- Barriers and facilitators to self-screening as per patients and practice staff;
- Issues with integration of self-screening in the practice work flow as per practice staff.

- Medications prescribed for those patients with newly diagnosed AF (i.e. warfarin/other vitamin K antagonists, aspirin, other anti-platelets, non-vitamin K antagonist oral anticoagulants [NOACS]);

Analyses of *intervention* data

- Total number of eligible patients ≥65 years actively attending the practice;
- Total number of eligible patients completing AF self-screening;
- Total number of patients identified with ECGs with 'possible AF' or 'unclassifiable';
- Total number of patients identified with AF after medical review;
- The rate of AF detection (per 1000 patients);
- CHA₂DS₂-VA score for all patients with a new diagnosis of AF;
- Medications prescribed for those patients with newly diagnosed AF (i.e. oral anti-coagulants, anti-platelet agents).

2.9. Statistical analyses

The analyses will examine pre- and post-intervention data separately, as well as time series analyses.

Analyses of *pre-intervention* data will include:

- Total number of eligible patients ≥65 years actively attending the practice;
- Total number of patients newly identified with AF in the pre-intervention period;
- The rate of AF detection (per 1000 patients);
- CHA₂DS₂-VA score for all patients with a new diagnosis of AF during the pre-intervention period;

The time-series analyses will examine trends in the diagnosis of AF over six contiguous months, comprising of the three months prior to the intervention and the three months of the intervention. Trends during the three months of the intervention will be adjusted for baseline (pre-intervention) diagnosis levels.

2.10. Process evaluation

Individual semi-structured interviews will take place with practice managers, reception staff, nurses, doctors and eligible patients. Participants who undertook self-screening will be randomly selected from each practice, and the practice manager and at least

two each of reception staff, doctors, nurses and patients will be interviewed per practice. Separate written informed consent will be obtained for all individuals participating in the process evaluation interviews. All interviews will be conducted in a private setting, and participants will be free to stop the interview or withdraw at any time without consequence in the unlikely event that a sensitive issue arose.

Interviews will focus on a detailed process evaluation of the screening procedure with an emphasis on issues for upscaling the screening for opportunistic self-screening at GP practices. Discussions with patients will focus on the appropriateness of text message prompts to screen, the acceptability of the self-screening process including the screening interface, and any barriers and facilitators patients experienced whilst undertaking self-screening. Interviews with practice staff will focus on the acceptability of the self-screening process, the integration of the screening station with the electronic medical record and into the practice workflow, and any barriers or facilitators to self-screening that they encountered.

A detailed process evaluation will be undertaken to evaluate the AF self-screening process. Transcriptions of the semi-structured interviews will be analysed thematically by several members of the research team and will focus on acceptability of the self-screening process, the barriers/enablers to screening and how the screening integrated into the workflow of the practice.

2.11. Project management

The Theory of Constraints [19], a project management model, was used to identify and plan the major steps involved in the development of each component of the self-screening process, taking resource limitations such as time and staffing into account. Exepron™ software was used to map the steps involved in the development of the self-screening station and identify the critical chain of the workflow.

2.12. Results dissemination

The results of this study will be disseminated via the usual scientific forums, including peer-reviewed publication and presentations at international conferences. Patients and staff will be able to request the results of the study. Information about obtaining the results of the study will be available on the participant information that will be available at the reception and at the screening station, and in the participant information and consent forms for the process evaluation interviews.

3. Conclusions

AF is a common arrhythmia, and the incidence is expected to rise further in the coming decade [20]. Stroke is an avoidable outcome of AF if the arrhythmia is identified and the recommended treatment commenced [21]. A patient self-screening station where AF screening is performed by patients before their GP consultations may be a practical solution to improve screening rates, and reduce the incidence of avoidable strokes.

Self-screening in GP practices has been examined in a number of studies. Most research has focussed on the screening of behavioural [22,23], mental health [24,25–26] or cardiovascular/diabetes risk [27] using questionnaires administered on a touch screen or computer tablet. Fewer studies have examined self-screening of physiological measures, such as blood pressure [28] and AF [29]. This research has shown that patient self-screening in GP practices is acceptable and evaluated positively by both patients and GPs [28–30,31]. However, major issues identified for

up-scaling have been high staff burden, and time lags between screening and the availability of results [24,31,32].

To date, interventions to improve AF screening rates have focussed on integrating screening devices during doctor consultations and have only achieved moderate increases in screening rates. Our previous research in the AF SMART study addressed low screening rates by incorporating a streamlined technology to obtain a 30 s-ECG with an automated AF detection algorithm during GP or nurse practitioner consultations [12,33]. The results of the AF SMART studies showed that this approach improved AF screening rates up to 16% of eligible patients (range 4–33%) in the metropolitan study [34] and 34% (range 9–51%) in the rural study [35] but even when incorporating this novel technology GPs and practice nurses still reported time constraints as the limiting factor for greater screening uptake [10]. In order to decrease the rates of preventable stroke, there is a need to develop a more efficient mechanism for screening of AF in older adults that circumvents the time pressures in GP practices and that can be implemented at scale for opportunistic screening.

An automated AF self-screening station whereby patients can undertake their screening prior to their GP appointment is a potentially feasible solution. Full automation of a screening system that prompts patients to undertake screening, then transfers their results into electronic medical records and is integrated within existing GP workflow is a promising advancement to increase AF screening among the population. Upscaling this system may enable the widespread implementation of the AF screening guidelines, and may achieve higher screening rates among patients, and thereby reduce the personal and economic burdens of preventable strokes.

Author statement

All Authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dr Giskes and Associate Professor Hespe have received honoraria from Pfizer. Professor Freedman has received grants, personal fees and nonfinancial support from Bayer, BMS-Pfizer, Daiichi Sankyo, AliveCor and Omron.

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