Population Screening for AF is Important & We Have Enough Data to Advocate Screening!

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Founder and Chief Medical Officer
AliveCor
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship    Company
- Major Stock Shareholder/Equity    AliveCor, Inc.
- Ownership/Founder
- Salary & Other Financial Benefit
Population Screening for **ATRIAL fibrillation** is worthwhile …

We have enough data to advocate
AF screening

- Why .... To prevent stroke and death .... BUT
- Is undiagnosed AF common enough?
- What is the risk of undiagnosed AF and how does it respond to treatment once diagnosed?

- Does screening pick up more AF or same amount of AF as conventional care, just earlier?
- No level I evidence screening reduces stroke and hard to get – - therefore indirect evidence
- Translation to guidelines/practice of inexpensive screening at scale required for impact
AF screening

- Why screen?
  - Stroke literature
Swedish Stroke study

- Rijks Stroke study Friberg et al
- 94,000 strokes 2005 – 2010
- 33% strokes due to AF
  - 24% AF known only 1/6 on anticoagulant
  - Over half on aspirin alone, 1/3 no Rx, so 20% of all strokes could be prevented if appropriate therapy prescribed
  - 9% AF not previously known
- Need to screen
Screening to identify unknown atrial fibrillation
A systematic review

Nicole Lowres1; Lis Neubeck2; Julie Redfern2; S. Ben Freedman1
1University of Sydney, ANZAC Research Institute and Department of Cardiology, Concord Hospital, Sydney, New South Wales, Australia; 2The George Institute for Global Health, Sydney, New South Wales, Australia

Incidence 1.4% in age ≥65 ... clinic or community

Summary
Atrial fibrillation (AF) is associated with a significantly increased stroke risk which is highly preventable with appropriate oral anticoagulant therapy (OAC). However, AF may be asymptomatic and unrecongnised prior to stroke. We aimed to determine if single time-point screening for AF could identify sufficient numbers with previously undiagnosed AF, to be effective for stroke prevention. This is a systematic review of clinical trials, by searching electronic medical databases, reference lists and grey literature. Studies were included if they evaluated a general ambulant adult population, using electrocardiography or pulse palpation to identify AF. We identified 30 individual studies (n=122,571, mean age 64 years, 54% male) in nine countries. Participants were recruited either from general practitioner and outpatient clinics (12 studies) or population screening/community advertisements (18 studies). Prevalence of AF across all studies was 2.3% (95% CI, 2.2–2.4%), increasing to 4.4% (CI, 4.1–4.6%) in those ≥65 years (16 studies, n= 27,884). Overall incidence of previously unknown AF (14 studies, n=67,772) was 1.0% (CI, 0.89–1.04%), increasing to 1.4% (CI, 1.2–1.6%) in those ≥65 years (8 studies, n= 18,189) in whom screening setting did not influence incidence identified. Of those with previously unknown AF, 67% were at high risk of stroke. Screening can identify 1.4% of the population ≥65 years with previously undiagnosed AF. Many of those identified would be eligible for, and benefit from OAC to prevent stroke. Given this incidence, community AF screening strategies in at risk older age groups could potentially reduce the overall health burden associated with AF.

Keywords
Clinical studies, prevention, stroke/prevention

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Dr. S. Ben Freedman
Professor of Cardiology, Concord Hospital

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Screen-detected AF in Primary Care

- SAFE study – Fitzmaurice et al, BMJ 2007
- Either systematic screening or opportunistic screening in age ≥ 65 picks up more new AF than usual care 1.4% vs 1.0%, and probably earlier
STROKESTOP Study

- 75 year olds - 7,173 community participants
- Self-activated hand-held single lead ECG
- 3% AF in 2 weeks

Svennberg et al Circ 2015
Prognosis of screen-detected AF

- No studies
  - screen for AF
  - no anticoagulant treatment for those detected
  - shows natural history

- Reality: this study probably unethical

- Next best – cohort studies of incidentally detected silent AF, or device studies
Mayo/Olmstedt County Study

Tsang, Gersh. Abstract: Can J Cardiol 2011

- 1980 – 2000 First ECG confirmed AF
- 4618 AF, mean age 74 ± 14, half women
- Asymptomatic – 25% (older, HR↓, more persistent)
  - 3 x more ischemic stroke before AF diagnosis
  - Identical stroke and mortality rate as symptomatic after age/sex adjustment
Adverse prognosis of incidentally detected ambulatory atrial fibrillation
A cohort study

Carlos Martinez1; Anja Katholing1; Saul Benedict Freedman2
1Institute for Epidemiology, Statistics and Informatics GmbH, Frankfurt, Germany; 2Department of Cardiology Concord Hospital and Anzac Research Institute, Sydney Medical School, University of Sydney, Australia

Summary
It was the aim of this study to determine prognosis of incidentally detected ambulatory atrial fibrillation (IA-AF) and its response to antithrombotic therapy. We performed a cohort study of 5,555 patients with IA-AF (mean age 70.9 ± 10.1, 38.4% female) and 24,705 age- and gender-matched controls without AF followed three years using UK Clinical Practice Research Datallink. We measured incidence rates of stroke, all-cause mortality, myocardial infarction, major bleeding, and effect of antithrombotic therapy. Patients with IA-AF had mean CHA2DS2-VASc score 2.5 ± 1.5, 73% with score ≥2. The stroke incidence rate (IR) was 19.4 (95% confidence interval 17.1 – 21.9)/1,000 person-years vs 8.4 (7.7 – 9.1) (p<0.001) in controls, mortality 40.1 (36.8 – 43.6)/1,000 person-years vs 20.9 (19.8 – 22.0) in controls (p<0.001), and myocardial infarction 9.0 (7.5 – 10.8)/1,000 person-years vs 6.5 (5.9 – 7.2) in controls (p<0.001). IRs of all endpoints increased with age. Oral anticoagulant ± antiplatelet therapy received by 51.0% in year following IA-AF was associated with adjusted hazard ratio (HR) of 0.35 (0.17 – 0.71) for stroke, and 0.56 (0.36 – 0.85) for death compared to no therapy, while antiplatelet treatment was associated with a non-significant reduction of HR: 0.81 (0.51 – 1.29) for stroke, and 0.80 (0.55 – 1.15) for death, though both carried a similar small non-significant adjusted excess IR of major bleeding. In conclusion, asymptomatic AF detected incidentally is associated with a significant adverse effect on stroke and death, with reduction in both associated with oral anticoagulant but not antiplatelet treatment. This provides justification to assess cost-effectiveness of community screening to detect unknown AF.
Stroke and all-cause mortality
5,555 incidental ambulatory asymptomatic AF
Half treated with warfarin, quarter no RX quarter ASA
24,772 age and gender matched controls no AF
Aspirin in incidental AF?

- No significant reduction in stroke or death compared to no treatment
- Similar bleeding risk to warfarin
- Not an option for incidentally discovered AF
Screening for incidental AF

• How
Lessons from practice

All that is irregular is not AF!

And doctors don’t always take the pulse!
For those who can’t take the pulse
Think You Might Have AF? There's an App For That

Photo-plethysmography smartwatches, fitbit, etc could also do this
Devices for Atrial Fibrillation screening and prevention of cardiovascular diseases.

Microlife is a world leader in the development and production of diagnostic devices intended for both home and professional use. The blood pressure monitors with AFib technology have successfully passed the most rigorous clinical certifications and feature patented technologies allowing for the improvement of both measurement standards and patient compliance.

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- USB port
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- Suggested retail price:

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  - 3 lead
  - Handheld

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  - Patient activated handheld transmitting

- Continuous ECG
  - Holter, Patch, Wearable systems
  - Implanted loop recorder
SCREENING FOR ATRIAL FIBRILLATION
SEARCH-AF
Aims

To determine:

1. The feasibility of community screening in pharmacies using pulse palpation and single-lead iPhone ECG (iECG) for customers aged ≥ 65

2. The cost-effectiveness of screening using iECG
Feasibility and cost effectiveness of stroke prevention through community screening for atrial fibrillation using iPhone ECG in pharmacies

The SEARCH-AF study

Nicole Lowes1,2,3; Lis Neubeck4,5; Glenn Salkeld6; Ines Krass7; Andrew J. McLachlan7,8; Julie Redfern3,4; Alexandra A. Bennett7,8; Tom Briffa9; Adrian Bauman6; Carlos Martinez10; Christopher Wallenhorst10; Jerrett K. Lau1; David B. Brieger1,2,3; Raymond W. Sy1,2,3; S. Ben Freedman1,2,3

1Cardiology Department, Concord Repatriation General Hospital, University of Sydney, Sydney, New South Wales, Australia; 2Anzac Research Institute, Sydney, New South Wales, Australia; 3Sydney Medical School, University of Sydney, Sydney, New South Wales, Australia; 4The George Institute for Global Health, Sydney, New South Wales, Australia; 5Sydney Nursing School, University of Sydney, Sydney, New South Wales, Australia; 6School of Public Health, University of Sydney, Sydney, New South Wales, Australia; 7Faculty of Pharmacy, University of Sydney, Sydney, New South Wales, Australia; 8Centre for Education and Research on Aging, Concord Repatriation General Hospital, Sydney, New South Wales, Australia; 9School of Population Health, University of Western Australia, Perth, Western Australia, Australia; 10Institute for Epidemiology, Statistics and Informatics GmbH, Frankfurt, Germany

Summary

Atrial fibrillation (AF) causes a third of all strokes, but often goes undetected before stroke. Identification of unknown AF in the community and subsequent anti-thrombotic treatment could reduce stroke burden. We investigated community screening for unknown AF using an iPhone electrocardiogram (iECG) in pharmacies, and determined the cost-effectiveness of this strategy. Pharmacists performed pulse palpation and iECG recordings, with cardiologist iECG over-reading. General practitioner review/12-lead ECG was facilitated for suspected new AF. An automated AF algorithm was retrospectively applied to collected iECGs. Cost-effectiveness analysis incorporated costs of iECG screening, and treatment/outcome data from a United Kingdom cohort of 5,555 patients with incidentally detected asymptomatic AF. A total of 1,000 pharmacy customers aged ≥65 years (mean 76 ± 7 years; 44% male) were screened. Newly identified AF was found in 1.5% (95% CI, 0.8–2.5%); mean age 79 ± 6 years; all had CHA2DS2-VASC score ≥2. AF prevalence was 6.7% (67/1,000). The automated iECG algorithm showed 98.5% (CI, 92–100%) sensitivity for AF detection and 91.4% (CI, 89–93%) specificity. The incremental cost-effectiveness ratio of extending iECG screening into the community, based on 55% warfarin prescription adherence, would be $AUD5,988 (£3,142; $USD4,066) per Quality Adjusted Life Year gained and $AUD30,481 (£15,993; $USD20,695) for preventing one stroke. Sensitivity analysis indicated cost-effectiveness improved with increased treatment adherence. Screening with iECG in pharmacies with an automated algorithm is both feasible and cost-effective. The high and largely preventable stroke/thromboembolism risk of those with newly identified AF highlights the likely benefits of community AF screening. Guideline recommendation of community iECG AF screening should be considered.

Keywords
Atrial fibrillation, screening, stroke prevention, cost-effectiveness, anticoagulation

T&H June 2014; 111:1167-76
Results

- Newly identified AF found in 1.5% of 1000 customers
  - 1% no history of AF
  - 0.5% past history AF, cardioversion > 3yrs ago, no recurrence

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Age</th>
<th>Heart rate</th>
<th>CHA₂DS₂-VASc ≥ 2 (%)</th>
<th>CHA₂DS₂-VASc (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly identified AF</td>
<td>15</td>
<td>79±6</td>
<td>75±16</td>
<td>100</td>
<td>3.4±1.0</td>
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<td>52</td>
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<td>76±6</td>
<td>72±13</td>
<td>95</td>
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<tr>
<td>No history AF</td>
<td>881</td>
<td>76±7</td>
<td>74±12</td>
<td>95</td>
<td>3.3±1.1</td>
</tr>
<tr>
<td>All</td>
<td>1000</td>
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Letter to the Editor

iPhone ECG application for community screening to detect silent atrial fibrillation: A novel technology to prevent stroke

Jerrett K. Lau a, Nicole Lowres a,b, Lis Neubeck b,c,d, David B. Brieger a,c, Raymond W. Sy a, Connor D. Galloway e, David E. Albert e, Saul B. Freedman a,b,*

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b Anzac Research Institute, University of Sydney, Australia
c George Institute, Sydney, Australia
d Sydney Nursing School, University of Sydney, Australia
e AliveCor, Oklahoma City, USA

Int J Cardiol 2013; 165: 193-4
iPhone ECG screening by practice nurses and receptionists for atrial fibrillation in general practice: the GP-SEARCH qualitative pilot study

**Background**

Atrial fibrillation (AF) is often asymptomatic and substantially increases stroke risk. A single-lead iPhone electrocardiograph (ECG) with a validated AF algorithm would make it easier to screen. Atrial fibrillation (AF) is the most common heart arrhythmia and has a lifetime risk of 1 in 4 for adults.\(^1\) AF affects at least 240,000 Australians.\(^2\) Prevalence rises with age from about 1% of the whole population to their general practitioner (GP) each year, general practices are ideally placed to screen for AF. Each year 81% of adults visit their GP at least once,\(^11\) and people aged ≥65 years accounted for 30.5% of all GP encounters in 2012–2013.\(^12\)
Screening: Cost-effectiveness

Incremental cost effectiveness ratio (ICER)
Extended to all 50% of population aged 65-84 assuming 55% placed on OAC (warfarin) and cost $AUD 20

- $US 4,066 per QALY gained
- $US 20,695 per stroke avoided
- $AUD 103,566 whole of life medical costs/stroke

ICER independent of % population screened

Improved with greater treatment guideline adherence
Implications

Extend **single** screen (ages 65-84) into the community in Australia (pop 23M between Texas – Florida) …..

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<td>$37,070</td>
<td>$188,700</td>
<td>268 (cost $350)</td>
</tr>
</tbody>
</table>
Reveal LINQ Insertable Cardiac Monitor

87% Smaller* with Enhanced Capabilities

Powerfully Small

The Reveal LINQ Insertable Cardiac Monitor is a wireless and powerfully small insertable cardiac monitor ideal for patients experiencing infrequent symptoms that require long-term monitoring or ongoing management.

The Smallest, Most Powerful Insertable Cardiac Monitor
**Recommendation for screening of AF**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Level&lt;sup&gt;b&lt;/sup&gt;</th>
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<tr>
<td>Opportunistic screening for AF in patients $\geq 65$ years of age using pulse-taking followed by an ECG is recommended to allow timely detection of AF.</td>
<td>I</td>
<td>B</td>
</tr>
</tbody>
</table>
• January et al AF 2014 guideline

• No recommendation on screening
TIME TO REVISIT THE GUIDELINES ON SCREENING FOR AF
A roadmap to improve the quality of atrial fibrillation management: proceedings from the fifth Atrial Fibrillation Network/European Heart Rhythm Association consensus conference

Paulus Kirchhof\(^1,2,3\)*, Günter Breithardt\(^2,3\), Jeroen Bax\(^4\), Gerlinde Benninger\(^3\), Carina Blomstrom-Lundqvist\(^5\), Giuseppe Boriani\(^6\), Axel Brandes\(^7\), Helen Brown\(^8\), Martina Brueckmann\(^9,10\), Hugh Calkins\(^11\), Melanie Calvert\(^1\), Vincent Christoffels\(^12\), Harry Crijns\(^13\), Dobromir Dobrev\(^14\), Patrick Ellinor\(^15\), Larissa Fabritz\(^1,2\), Thomas Fetsch\(^6\), S. Ben Freedman\(^17\), Andrea Gerth\(^3,18\), Andreas Goette\(^3,19\), Eduard Guasch\(^20\), Guido Hack\(^24\), Laurent Haegeli\(^22\), Stephane Hatem\(^23\), Karl Georg Haeusler\(^3,24\), Hein Heidbüchel\(^25\), Jutta Heinrich-Nols\(^9\), Francoise Hidden-Lucet\(^26\), Gerd Hindricks\(^27\), Steen Juul-Möller\(^28\), Stefan Kääb\(^18,29\), Lukas Kappenberger\(^30\), Stefanie Kespohl\(^31\), Dipak Kotecha\(^1\), Deirdre A. Lane\(^1\), Angelika Leute\(^3\), Thorsten Lewalter\(^3,32\), Ralf Meyer\(^33\), LLuis Mont\(^20\), Felix Münzel\(^34\), Michael Nabauer\(^3,18\), Jens C. Nielsen\(^35\), Michael Oeff\(^3,36\), Jonas Oldgren\(^5,37\), Ali Oto\(^38\), Jonathan P. Piccini\(^39\), Art Pilmeyer\(^40\), Tatjana Potpara\(^41\), Ursula Ravens\(^3,42\), James Prystowsky\(^3,43\), Thomas Pueckler\(^3,44\), Irina Rostysheva\(^28\), Irene Sotilas\(^44\),
the WHO criteria for widespread screening over age 65 are now met, but the precise implementation method would need to fit with the country-specific health care system.

"We recommend the establishment of more widespread screening programmes for persistent and paroxysmal AF in those over age 65...."
Research Priority #2

"Prospective studies are needed to determine the most effective strategy for AF detection in populations and in patients at risk for AF and stroke, including the methods of detection, implementation and cost-effectiveness"
Asymptomatic Atrial Fibrillation
The Case for Screening to Prevent Stroke

Atrial fibrillation is very common, such that by age 40 years, there is a 1 in 4 lifetime risk of developing atrial fibrillation. The prevalence of atrial fibrillation increases substantially with advancing age, from 0.5% at age 40 through 50 years to 5% through 15% at age 80 years. Atrial fibrillation significantly increases the risk of mortality, heart failure, and myocardial infarction, as well as the risk of stroke, which may be severe due to a cardioembolic origin. However, treatment of patients with atrial fibrillation with oral anticoagulation is effective in reducing stroke risk by approximately two-thirds and reducing mortality by almost one-third, with a relatively smaller increased risk of major bleeding, such that the net clinical benefit favors anticoagulation for almost all patients with atrial fibrillation. European and US guidelines therefore recommend anticoagulant therapy when stroke risk, as calculated by CHA2DS2-VASc score, is 2 or higher. Such pronounced treatment effects are rarely seen in therapies for other conditions for which screening is undertaken.

Several studies have suggested that an increasing proportion of stroke events are related to atrial fibrillation. For instance, in the large Swedish Riks-Stroke survey, which included 94 083 patients with ischemic stroke, atrial fibrillation accounted for one-third of all nosed atrial fibrillation. This latter group represents a sizeable proportion of all strokes, which may have been prevented had asymptomatic atrial fibrillation been detected early by screening and appropriately treated.

Screening for Atrial Fibrillation Is Feasible
Could unknown asymptomatic atrial fibrillation be detected easily as a way to prevent stroke? In a systematic review that included 30 studies and 122 571 patients, a single time point screen using either pulse palpation or an electrocardiograph detected previously undiagnosed atrial fibrillation in 1% of patients overall, and in 1.4% of those 65 years or older. A large clinical trial of screening in primary care involving 14 802 patients in 50 practices, found that either systematic screening (sending a letter to all patients 65 years or older in the practice, requesting they visit the practice to have a 12-lead electrocardiograph) or opportunistic screening (flagging charts of patients 65 years or older during any visit to the practice to alert the general practitioner to take the pulse during the visit, and request a 12-lead electrocardiograph if the pulse was irregular) detected significantly more undiagnosed atrial fibrillation cases (149 of 9137 patients enrolled [1.63%]) than routine care (47 of 4513 patients enrolled [1.04%]).

Opportunistic and systematic screening were equally effective in detecting new atrial fibrillation cases (1.64% for opportunistic and 1.62% for systematic), but opportunistic screening was more cost-effective because of the high cost of routine 12-lead electrocardiography and low incidence of atrial fibrillation.
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- Nicole Lowres
- Lis Neubeck

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- Glenn Salkeld
- Carlos Martinez
- Christopher Wallenhorst

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- Jerrett Lau

**Design / implementation**
- Julie Redfern
- Andrew McLachlan
- Ines Krass
- Sasha Bennett
- David Brieger
- Ray Sy
- Tom Briffa
- Adrian Baumann
- Jessica Orchard

**Support: investigator-initiated grants:**
- BMS/Pfizer, Bayer, Boehringer-Ingelheim
- iECG cases and software from Alivecor
THE END
• Ischemic strokes from AF are at the most severe end of the spectrum, often severe and disabling, and highly preventable
• NEMESIS 411/1511 ischemic strokes
  – 27% due to AF at time of stroke
• ASUS 33% due to AF
AF related strokes
Adelaide Stroke Study
2013

% total AF strokes

- Unknown (must screen) 38%
- No anticoagulant 12%
- Warfarin 15%
- All CHADS$_2$ ≥ 2 35%
- 33% antiplatelet, 2% no Rx

unknown
No OAC AF known
INR <2 AF known
INR >2 AF known