Horizon Scan Report 0032 **16 July 2013**

Diagnostic Technology: Hand-held ECG monitors for the detection of atrial fibrillation (AF) in primary care.

Clinical Questions:

1. In primary care settings, how accurate are wireless handheld ECG monitors for detecting AF in symptomatic patients who use the device as an event recorder?
2. In primary care settings, how accurate are wireless handheld ECG monitors for detecting AF in asymptomatic patients as part of a screening programme for AF, compared to routine practice?
3. Are wireless handheld ECG monitors feasible to use to monitor the effectiveness of anti-arrhythmic treatments?

Current Practice and Advantages over Existing Technology:

a) Event-based and daily recordings for patients who may have paroxysmal arrhythmias:
Existing Technology: Continuous Holter monitoring over 24 hours or more, with analysis involving linked software. For longer periods of analysis, implantable devices can be used.
Benefits of handheld devices: Wireless, electrode-free and portable nature of device means fewer lifestyle restrictions on patient. The devices are easy to use; it has been reported that four-year-old children were able to use such a device (2). Patients can bring the device directly to their general practitioner who can "review" the recorded ECGs and analyse them directly.

b) Tools for opportunistic screening of AF:
Current Practice: Pulse palpation by general practitioners; if an irregular pulse is detected patients undergo a 12-lead ECG.
Benefits of handheld devices: – pulse palpation has a low sensitivity of 70-77% (1) and using the device saves a separate ECG appointment, the results of which will then need following up. Devices which analyse the heart trace could be used in clinics by nursing or auxiliary staff for screening purposes.

c) Assessing efficacy of anti-arrhythmic treatments:
Current Practice: Rate control can be assessed by palpation, but success of conversion to sinus rhythm requires a 12-lead ECG usually involving a nurse appointment
Benefits of handheld devices: ECGs can be done on-the-spot, by general practitioners, during a patient's medical review, to assess both rate and rhythm control, rather than organising a separate ECG appointment.

Details of Technology:

The table in Appendix 1 provides an overview of the 14 portable, wireless devices identified.

Handheld ECG devices allow electrocardiogram readings to be stored on a portable device, for review at a later time, either by transferring the data to a PC, "playing back" the ECG on the device screen, or transmitting the reading via "telemedicine". Unlike 12 lead ECGs, which require electrodes to be placed on the patient and connected to the ECG, the handheld devices have integral electrodes so the only actions required to activate it are placing the patient's thumbs, fingers or palms on the device, and, in some cases, holding the device against the chest. The devices are battery powered and can store multiple ECG tracings. Some devices have an analysis function whereby they instantly alert the user if a trace indicates an arrthymia.

Devices which show the ECG trace would likely be the most useful in primary care as they can be used very quickly for screening or in acutely unwell patients, as well as a monitoring device over a period of time. The models which include this function are: InstantCheck™, Omron Heartscan™, MD 100, Easy ECG PC-80, Prince 180 and Miniscope™.
The Merlin wristwatch is the most compact and portable device, and therefore may be ideal to use as an event recorder by patients at home.
Memory capacity is important for devices used as event recorders at home. Devices which have capacity for storing approximately 100 readings of thirty seconds include InstantCheck™, Omron Heartscan™, Prince 180b and Miniscope™.

Devices which are independent from a telemedicine system so can be purchased and will operate on a stand-alone basis. These include the InstantCheck™, Omron Heartscan™, ReadMyHeart™, Merlin wristwatch, MD 100, Easy ECG, Prince 180 and Miniscope. Devices which have an analysis function to identify when a patient is in AF would be valuable for nurse-led or GP-led opportunistic screening for AF.

In addition to those shown on the table there is a new device, the "Cardiobip™" (NewCardio) which is yet to be available commercially (http://www.newcardio.com/products-cardio-bip.php). It uses telemedicine and is operated by holding the device against the chest and touching two integral finger electrodes.

Devices mostly come with any cables and software needed for data transfer and a padded carrying pouch.

Patient Group and Use:

a) Screening for AF in patients at higher risk of AF due to increased age or known co-morbidities - this could include nurse-led screening, particularly with devices which include waveform analysis functions.
b) Diagnosis in unwell patients on home visits, nursing home visits, or at the practice.
c) Event recording at home for patients with palpitations.
d) Monitoring the effectiveness of anti-arrhythmic drugs or other treatment of AF, for example radiofrequency ablation.
e) Monitoring of patients who have had a stroke or TIA to detect undiagnosed asymptomatic paroxysmal AF.
f) Detection of acute coronary events in patients presenting with chest pain.

Importance:

The prevalence of atrial fibrillation increases with age, with a British study demonstrating a prevalence of 4.7% in the population aged 65 years or over (3). AF is an independent risk factor for TIA or stroke (4) and heart failure (5). Detection of AF allows management of AF and its associated risks, notably either by pharmaceutical treatments, where anti-arrhythmic drugs as well as anticoagulants are used, or invasive procedures. Treating AF early after its onset has been shown to confer survival benefit (6), and there is evidence that new-onset AF carries a higher imminent stroke risk than long-established AF (7).

Routine screening for AF is not currently recommended in primary care although it meets many of the Wilson-Jungner criteria for screening (8) and there is evidence to demonstrate that opportunistic screening for AF may be of benefit (9). One study demonstrated that nurse-led screening for AF in primary care is both feasible and effective (10) Paroxysmal AF carries an independent risk of stroke and there is evidence that paroxysmal AF commonly converts to continuous AF (11).

For patients with palpitations, event monitoring is more effective than continuous Holter monitoring in detecting supraventricular arrthymias (12). However, only approximately one in twelve episodes of paroxysms of AF is symptomatic (13) and some groups (European Heart Rhythm Association) recommend using daily monitoring and well as patient-initiated event monitoring (14). The patient-activated portable ECG devices allow both regular and event-led monitoring without lifestyle restrictions or inconvenience posed by electrodes.

Previous Research:

Accuracy compared to existing technology:

The Omron Heartscan™ device has been evaluated in three studies conducted in secondary care clinics. A small US study of 18 patients with palpitations compared the recording of symptomatic episodes with both the device and a standard patient-activated event monitor (15). There was 100% patient compliance with the Heartscan™ device, and 78% compliance with the standard event monitor ($p = 0.1$). No difference was seen between the diagnostic yield of the Heartscan™ and the standard event recorder, and the study concluded that both high patient concordance and high-quality ECGs were seen when using the Heartscan™.

A German study of 508 patients with a clinical indication for an ECG used the Heartscan™ device. The Heartscan™ had 99% sensitivity and 96% specificity for detecting AF. The detection rate of the device for a normal ECG was 91% sensitive and 95% specific (16). A further Belgian study of 30 patients found that the Heartscan™ device was easy to use in children as young as 4 years (2).

The Cardiobip™ device has been used in two studies to monitor AF recurrence following antiarrhythmic treatments. One study set in Serbia of 18 patients following cardioversion found that the device was not inferior to a 12-lead ECG for detecting AF, with an insignificant difference in the rate of AF between the Cardiobip™ and a 12-lead ECG (p=0.31) (17). Another study by the same group, of 25 patients following radioablation found that the device was more sensitive than a Holter monitor for detecting recurrence of AF. AF was detected using the Cardiobip™ device in 84% of patients during a two month monitoring period following ablation, compared to 32% using two 24-hour periods of Holter monitoring at the end of each of the first and second months ($p < 0.01$) (18).

Impact compared to existing technology:

One three-part study set in Sweden (19) used the Zenicor™ device to evaluate the feasibility of using such devices for screening. In the first part, 100 patients with known AF recruited from a cardiology outpatient clinic, had Zenicor™ ECG readings immediately followed by a twelve-lead ECG, and a cardiologist compared the paired tracings. This demonstrated a sensitivity of 96% and a specificity of 92% for AF. In the second part of the study, twelve patients following cardioversion (age range 43-87 years), recorded twice-daily readings using the device for one month. The device successfully detected four recurrences. ECG quality improved over the month as patients became more familiar with the device. Eleven of the twelve patients found the device "very easy" to use, (the eldest, aged 87, did not) and patients felt comforted that they were being monitored regularly. In the third part of the study, 606 individuals of all ages used the device once (recording length 32 seconds) to mimic screening, of which 12 (2%) showed AF, half of whom were not previously known to have AF.

The Instromedix device was evaluated in two studies. In one, 98 stroke patients on a French Stroke Unit with negative 24-hour Holter studies, recorded one reading a day for a month and any time when they had palpitations, chest pain or dyspnoea. AF was detected in nine patients (20). In a Welsh study, 80 symptomatic patients with normal resting ECGs used the device to record symptomatic events for one month, of which 11 had an arrthymia detected (AF in 2 other supraventricular tachycardias in 9). However, diagnoses were not confirmed with a twelve-lead ECG, and the study did not compare the device to a continuous monitor (21).

The Miniscope™ device was used in a study of 43 patients referred for Holter monitoring who were randomly allocated to either the Miniscope™ device to use an event recorder, or a 48-hour Holter study. The Minscope™ device was twice as likely to produce a diagnostic rhythm strip during symptoms, although of the 8 arrhythmias it detected only 2 were AF or atrial flutter (22).
A study is in progress currently in Guildford, England, (23) which aims to assess the accuracy of the Omron Heartscan™ device in diagnosing AF compared to an implantable continuous monitoring device, and data from this study will be relevant to this report.

Guidelines and Recommendations:

The current NICE guidelines for management of AF (24) recommends patient-activated event recording to detect AF, if the AF is symptomatic and episodes last longer than 24 hours. A consensus from a European Heart Rhythm Association conference concluded that daily plus symptom-activated trans-telephonic ECG monitoring are equally accurate at detecting paroxysmal AF. It concluded that as well as symptom-activated use of event monitors, additional regular ECG readings are vital, whether by a scheduled 24hour period with a Holter monitor, or whether with a daily 30-60 second ECG recording (14).
There are no references in existing guidelines about the use of electrode-free handheld patient-activated ECG devices.

Research Questions:

1. Assess feasibility and detection rate of handheld wireless ECG monitors for daily and event-recording, compared to continuous monitoring in primary care settings.
2. Assess the cost:benefit ratio of using handheld ECG devices for opportunistic screening for AF in primary care settings.

Suggested next step:

1. Validation of AF detection for more of the devices named here, by performing simultaneous 12-lead ECGs when using the devices and comparing accuracy for detecting AF.
2. Comparisons between utility of specific devices to guide purchasing for primary care practices.
3. Long-term studies to assess changes in morbidity associated with use of handheld ECG devices in primary care to detect previously undiagnosed AF.
4. Systematic review of accuracy studies for these devices, when there are sufficient studies available
5. Cost-effectiveness study of screening for undiagnosed AF (in all patients, and those at high risk or with comorbidities), and for diagnosis of patients with palpitations compared to existing technologies
6. Feasibility of integrating this technology into smartphones for wider applicability in clinical and home settings (25).

Expected outcomes:

If proven to be accurate and cost-effective in the primary care setting, these devices could improve the detection and management of AF, thus reducing the well-known risks of stroke, TIAs or heart failure in these patients. The ease-of-use, convenience and portable nature of these devices means implementation could see a better rate of patient compliance when compared to a Holter monitor, in patients who use the device for home recordings.

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Appendix 1: Table of available devices

Device (company)	Electrode use	Display ECG trace?	Storage capacity	Instant ECG Analysis?	Data transfer	Size (mm) Height x Width x Depth	Weight (grams)	Display	Quoted price	Batteries, lifespan	CE certified?
InstantCheck (DailyCare Biomedical)	Two thumbs or fingers	Yes	100x 30sec	Yes	To PC via USB cable	23x124x78	180	Backlit screen 41x72mm	£380	2 x AAA, unspecified capacity	Yes
Omron Heartscan	One finger, hold against chest	Yes	300 ECGs	Yes	To PC via cardreader	24x121x67	140	Backlit 44x52mm	£215	2 x AAA, lasts 400 measurements.	Yes
ReadmyHeart (DailyCare Biomedical)	Two thumbs	No	30x25sec	No	To PC via USB Cable	12x85x22	134	Not backlit.	Unknown	2xAAA	Yes
Merlin ECG (Meditech)	Wristwatch – place palm on watchface	No	15mins total, ECGs 5sec – 5mins	No	To PC via optical serial cable	13x35x43 (plus leather strap)	36	Not backlit	£599	2x 3V lithium coin cells, last approx. 6months	Yes
AfibAlert ™ (Lechnologies)	Two thumbs	No	5x45sec	Yes	Telemedicine	150x70x28	Unknown	Unknown	Unknown	2xAAA, last 27 recordings	Unknown. TUV certified.
MD100 a/b/e (Choice Medical)	One thumb, hold against chest	Yes	A: 100x30sec B: 200x30sec E: 2000.	No	To PC	A:unknown B:136x84x21 E:140x75x26	A: unknown B:120 C:125	Backlit. B: 136x84x21 mm	unknown	2xAAA , >500 measurements	Yes
Easy ECG PC-80 (Shenzhen Creative)	Two palms (or use chest/leg)	Yes	24x30sec	Yes	To PC	112x55x17	100	Backlit. 49x25mm	unknown	2xAAA, >500 measurements	Yes
Prince 180a/b ECG (Heal Force)	Two thumbs	Yes	A:24x30sec B:300x30sec	Yes	To PC	A: 115x58x18 B:125x70x22	A: 76 B: 106	A: 49x25mm B:58x40mm backlit	unknown	2xAAA	Yes
CardioCall (Advanced Biosystems, Inc)	Hold against chest	No	20x60sec	No	Telemedicine or via PC	30x56x71	91	Indicator LEDS only	£550	1xAA, lasts approx. 6months.	Yes
Zenicor EKG (Zenicor)	Two thumbs	No (?)	Unknown capacity	No	Telemedicine (bluetooth)	145x65x25	135	unknown	unknown	3xAA	Yes
Miniscope M3 (Schiller)	Hold against chest	Yes	30mins total	No	To PC	77x126x20	250	unknown	£715	unknown	Yes
Beam® ECG (IEM)	Hold against chest	No	128x15sec	No	Telemedicine (bluetooth)	unknown	102	unknown	unknown	Two batteries, unknown size	Yes
CardGuard AG CG-2206 (Lifewatch)*	Hold against chest	No	6x32 sec or 3x60sec	No	Telemedicine	105x55x10	42	No display	unknown	2x lithium 3V CR3032, >2000 measurements	Unknown
ECG@home ™ (Health Frontier)	Two thumbs	unknown	10sec readings, unknown no.	No	Telemedicine	104x81x15	100	LCD	£395	2xAAA, unknown capacity	Unknown