The Newcastle upon Tyne Hospitals NHS Foundation Trust





ADDITIONAL WORK SUPPLEMENT

Cost impact of the WatchBP Home A used in a primary healthcare clinic environment

Produced by NUTH and YHEC EAC

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Abbreviations

AF Atrial fibrillation
BP Blood pressure

CHADS2 Clinical risk prediction rule (Congestive heart failure,

Hypertension, Age, Diabetes, Stroke [2 points])

CI Confidence interval

EAC External Assessment Centre

ECG Electrocardiograph

FN False negative
FP False positive

GI Gastrointestinal

GP General Practitioner

HBPM Home blood pressure monitor
HTA Health technology assessment

MTAC Medical Technologies Assessment Committee

MTEP Medical Technologies Evaluation Programme

NHS National Health Service

NICE National Institute for Health and Clinical Excellence

PPI Proton-pump inhibitor
PSS Personal social services

RCT Randomised controlled trial

RR Risk reduction

TIA Transient ischaemic attack

TN True negative
TP True positive

Summary

The EAC was commissioned to produce additional economic evidence on the short and long-term cost impact of the WatchBP Home A oscillometric home blood pressure monitoring (HBPM) device in a primary care clinical setting. A two stage model was created consisting of a decision tree to simulate the diagnostic accuracy of the device, and a state transition model to simulate the long-term (10 year) cost consequences of the management of atrial fibrillation (AF). Simulated patients with AF were entered into the model according to their risk of stroke (CHADS2 scores) and starting age (65 and 75 years). The primary outcomes of the model were prevention of stroke (fatal and nonfatal) and gastrointestinal (GI) bleeding caused by the use of antiplatelet drugs and anticoagulants to reduce stroke. These consequences were monetised and the sum of all the costs was used to give the 10-year cumulative cost of AF management (with and without treatment). Short-term diagnostic costs were combined with long-term management costs to calculate overall costs to the NHS and PSS (personal social services) of the WatchBP Home A compared with manual pulse palpation.

The EAC found that the incremental cost of screening for AF (meaning the incidental detection of AF during measurement of blood pressure) using the WatchBP Home A was likely to be negligible. However, as the device has improved sensitivity and specificity compared with pulse palpation (based on indirect comparison from separate studies of 405 patients with the WatchBP Home A and 10,000 patients with pulse palpation), there was likely to be a diagnostic cost saving associated with the WatchBP Home A of around £2.16 per person screened because of resource savings from a reduction in ECGs required for AF confirmation.

The long-term model following management of patients with AF, indicated that the WatchBP Home A was cost saving in most patient groups, but the greatest cost saving was in older patients with comorbidities making them at increased risk of stroke; these patients were associated with the greatest absolute risk reduction in stroke with drug treatment. When both diagnostic costs and management costs were combined, the WatchBP Home A was associated with a mean cost saving of about £3.62 per person screened over the course of 10 years, and this saving was robust with respect to changes in assumptions regarding the cost of stroke and anticoagulation treatment. However, these results should be interpreted with some caution. Firstly, the model only allowed for screening once, which might have the effect of underestimating the saving. Secondly, the model did not include patients at low risk of AF (and very low risk of stroke), which might have had the effect of overestimating the saving. Thirdly, paroxysmal AF was not modelled due to lack of availability of data; it is uncertain what effect this might have on benefits or cost savings.

The principal patient benefit of the WatchBP Home A was the prevention of stroke following successful diagnosis and management of AF. The EAC calculated that, per 100,000 patients screened, between 53 and 117 fatal strokes, and 28 and 65 nonfatal strokes might be prevented by the device. This would be with the trade off of between 34 and 68 GI bleeds. This suggested that the WatchBP Home A was beneficial from a patient perspective.

In conclusion, the WatchBP Home A, when used in a primary care clinical setting, is likely to be cost saving to the NHS and PSS over both the short and long term in patients at relatively high risk of AF

and therefore stroke. In addition, the WatchBP Home A is likely to lead to the clinical benefit of reducing strokes in this patient group.

Rationale for additional work

As part of their economic submission to the Medical Technologies Evaluation Programme (MTEP), the sponsor (Microlife) of the WatchBP Home A oscillometric home blood pressure monitor (HBPM) produced a *de novo* economic analysis that compared the use of the device in a clinical setting with pulse palpation for the detection of atrial fibrillation (AF). This model showed that, compared with pulse palpation, the WatchBP Home A was cost saving in a population who had symptomatic AF. However, this analysis had several limitations. These included:

- The population investigated (people symptomatic of AF) was not the population specified by the scope. When the sponsor carried out sensitivity analysis in which increasing proportions of the population were asymptomatic (i.e. a population consistent with the scope), the WatchBP Home A actually cost NHS resources compared with pulse palpation.
- The *de novo* economic analysis was restricted to a one year time horizon. This meant the longer-term cost consequences of the device were not considered.
- The cost of the device itself, including capital costs relating to the device displacing standard HBPMs, was not considered in the model.

For these reasons, there remained a considerable amount of uncertainty as to whether the WatchBP Home A, used in a primary healthcare clinic setting for the incidental detection of asymptomatic AF, is likely to be cost saving for the NHS. In order to resolve some of these outstanding issues, the Newcastle/York EAC was commissioned to develop a new cost consequence model to investigate the likely cost impact associated with the use of the device to detect AF in a primary care setting. Both short-term diagnostic and longer-term management cost consequences were considered.

Description of Model

Clinical decision question

The clinical decision question the model seeks to address can be summarised as "What would be the overall cost impact of the WatchBP Home A device if it was introduced into primary healthcare offices and clinics in the NHS of England and Wales?".

The following setting has been specified:

- Population. People with suspected hypertension or those having their BP measured as
 routine screening for hypertension, in a primary healthcare setting (most likely a GP or
 nurse's office). Those with known AF or those with symptoms of possible arrhythmia (e.g.
 palpitations) are excluded.
- Intervention. Blood pressure measurement with WatchBP Home A device with the incidental detection of AF.
- Comparator. Blood pressure measurement with manual sphygmomanometer (auscultation)
 or automated device with manual pulse palpation. Manual pulse palpation for the detection
 of irregular pulse is recommended by the NICE clinical guidelines on *Hypertension* [1] in all
 people who require BP measurement.
- Outcomes. The primary outcome of interest is the total cost (cost impact) to the NHS and
 PSS of the AF detection methods in the setting described. The number of strokes prevented
 and the number of GI bleeds caused by preventative treatment is also reported, but the
 clinical benefits and disadvantages of these (for instance in terms of patient utility and life
 years gained) are not considered.
- Time horizon. From initial measurement to up to 10 years follow up of management.

Model Structure

The model is based on two phases that represent the diagnostic stage of the process (i.e. the incidental detection of AF in the clinic through the use of the WatchBP Home A or pulse palpation) and the ongoing, long-term management costs associated with treatment and consequences of AF.

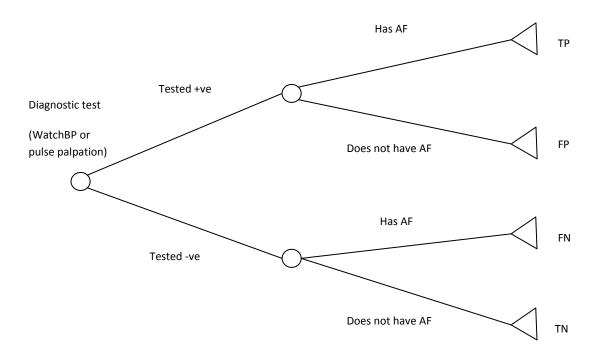
Diagnostic stage

The first stage of the model is a decision tree based on the sensitivity and specificity of the two diagnostic methods (see Figure 1) versus a gold standard. An age-dependent prevalence of AF was assumed. For each method of detection there are four possible outcomes; these are true positive (TP), true negative (TN), false positive (FP), and false negative (FN). It was assumed in the model that

a confirmatory electrocardiograph (ECG) was carried out immediately following AF detection and that this had 100% sensitivity and specificity. Thus the consequences of these states were:

- TP these are patients who have AF and are measured as having AF. These patients will
 incur an immediate one-off ECG cost and ongoing management costs as they are at
 increased risk of stroke.
- TN these patients do not have AF and are correctly excluded. They do not incur an ECG cost or ongoing management costs. As such they do not contribute a direct cost to the long-term model.
- FP these patients are falsely measured as having AF when they do not have the condition.
 They incur an ECG cost where they are assumed to be excluded from having the condition.
 Further to that they do not require ongoing management costs and do not contribute a direct cost to the long-term model.
- FN these patients have AF but have not been detected by the measurement method. They incur no ECG costs but their long-term consequences are modelled because they are at greater risk of stroke (see <u>Assumptions in the starting cohort</u>).

Figure 1. Decision tree of diagnosis of AF.



There are one-off costs associated with the diagnostic stage of the model. These include the cost of the AF detection method, as well as the cost of confirmatory ECG in TP and FP groups.

Management stage

The second phase of the model covers a time perspective of up to 10 years. This is a state transition model which simulates the potential clinical states a theoretical cohort of patients might experience. The duration of each cycle was 1 month. Annual incidence rates were changed to probabilities; these were then converted to monthly probability transitions using logarithmic correction, and half cycle correction was applied. For each Markov simulation a total starting cohort of 100,000 patients was used [2]. This large cohort reduced the standard error associated with the clinical states. Results from each Markov simulation were scaled to the size of the starting cohort applicable to each separate analysis.

Only patients who really have AF were modelled in the management stage, which included two groups. The first group is the TP group; AF has been identified in this cohort and therefore active management (with anticoagulant drugs or aspirin) can take place. The second group (FN) has AF which remains undiagnosed. They are therefore untreated and are at increased risk of stroke compared with those who do not have AF or those on active management. A schematic description of the model is illustrated in Appendix A.

True positive group

Starting immediately after diagnosis, the patients were classified into six groups according to their CHADS2 score. The CHADS2 score is a clinical risk prediction rule which uses cumulative risk factors (Congestive heart failure, Hypertension, Age [>75 years], Diabetes mellitus and previous Stroke [counts as two points]) to assess the annual risk of stroke in patients diagnosed with AF [3]. Two cohorts with different starting ages have been modelled to reflect the increasing prevalence of AF with increasing age and the increase in standard mortality rate. These reflect a starting age of 65 years for CHADS2 scores of 0 to 5, and 75 years for CHADS2 scores of 1 to 6 (see below).

The CHADS2 score also guides management in the model such that:

- Score 0 (low risk of stroke). Patient receives aspirin prophylaxis, in accordance with the NICE clinical guidelines on Atrial Fibrillation (CG36) [4]. These patients have a decreased risk of stroke compared with untreated patients but also have an increased risk of gastrointestinal (GI) bleeding. In addition, to be eligible for this cohort patients in this group are assumed to be below 75 years of age.
- Score 1 (moderate risk of stroke). Half the patients receive aspirin prophylaxis and half receive anticoagulant prophylaxis. This is considered the normal practical application of NICE guideline CG36 which recommends that clinical judgment should be used when considering antiplatelet or anticoagulation prophylaxis in patients of moderate risk of stroke. These patients are at increased risk of GI bleeds, but have a moderate risk reduction (RR) of stroke due to the protective effect of aspirin or anticoagulants.
- Score 2-4 (high risk of stroke). Patients receive anticoagulation prophylaxis. These patients have risk factors which justifies the use of anticoagulation. They have a large RR of stroke because of the protective effect of anticoagulation, but are at increased risk of GI bleeds.

• Score 5-6 (very high risk of stroke). Patients receive anticoagulation prophylaxis. These patients are at particularly high-risk of stroke because they have had a previous stroke. To be eligible for this cohort (i.e. within scope), patients are assumed only to have had a previous mild stroke or transient ischaemic attack (TIA) rather than a severe or debilitating stroke, so that they are still being managed in primary care at no additional cost compared with patients from other cohorts. Additionally, patients with a CHADS2 score of 6 are by definition aged 75 years and above.

False negative group

The FN group employs essentially the same model as the TP group, with the same clinical risk stratification assumptions (CHADS2 scores 0 to 6). However, an important difference in this group is that the patients receive neither the preventative effect of treatment nor their adverse effects (bleeding). In addition these patients do not accrue the treatment costs associated with prophylaxis. However, the model for this group is subject to some significant <u>assumptions</u>.

True negative and false positive groups

The remaining groups (TN and FP) do not have AF and as they are therefore representative of the general population, their long-term management is not considered in the model. However, the FP group will incur a one-off ECG cost.

Costing

Each clinical state has an associated monthly cost, except for GI bleeding where the cost is assumed to be incurred on entry to the state (modelled as temporary state). All costs were discounted at a standard rate of 3.5% [5]. Costs range from nil or negligible (aspirin) to significant in the case of surviving stroke. Stroke cost decreases after one year in the model, but then remains for the lifetime of the patient. This is modelled as a tunnel state. Death by stroke also has a one-off cost consequence. Deaths by other causes incur no cost to the NHS and PSS.

The costs for each relevant group were accumulated and the sum of all the clinical states in each arm (i.e. TP and FN) was calculated; this was the end outcome of the long-term cost consequence model. By repeating for both the WatchBP Home A and pulse palpation, the likely managerial cost impact of each screening method was estimated.

Assumptions made about model structure

Several assumptions were made regarding the structure of the model, which necessarily cannot reflect all the clinical and economic possibilities of every patient. The main structural assumptions are associated with the starting cohort, the subsequent management of the patient cohorts, and the effect of stroke in terms of continuing morbidity and mortality.

Assumptions in the starting cohort

The diagnostic model assumes that the person has their BP measured with either the WatchBP Home A (intervention) or pulse palpation (comparator), resulting in the incidental detection of AF. All patients who test positive for AF at the BP measurement stage immediately receive gold standard 12-lead ECG to confirm this incidental finding. However, in practice there would likely be a delay in ECG diagnosis. This could mean that a proportion of patients with paroxysmal AF remain undiagnosed at the ECG stage; that is, they have paroxysmal AF but are incorrectly diagnosed (FN group) because they are not experiencing a paroxysm at the time of confirmatory ECG.

There are several sources of uncertainty concerning the longer-term management model. These include:

- Age of starting cohort is 65 or 75 years. Although it is recognised that the WatchBP Home A device can be used to screen for hypertension (and incidentally detect AF) in adult patients of any age, it is necessary to set a starting age for the model cohort. This is because the prevalence of AF, the incidence of stroke, and the standard risk of mortality are all greatly affected by age. Two starting ages (65 and 75 years) were assumed which was a necessary simplification for this model type. The younger starting age (65 years) is generally around the age when AF first becomes a concern to clinicians. The incidence of AF also becomes significant in the 65-74 years of age cohort, and the data to support incidence, prevalence and management in this group is probably more firmly established than younger or older cohorts. However, patients aged 75 years were also modelled to reflect higher risk cohorts [6].
- Patient risk stratification according to clinical risk assessment tool (CHADS2). In the model, risk of stroke has been stratified according to their CHADS2 scores. The proportion of patients in each CHADS2 score was taken from the seminal study of Gage et al (2001) [3], which was a epidemiological study set in the United States; as such it might not be fully representative of UK primary care populations.
- The NICE clinical guidelines on Atrial Fibrillation did not explicitly use CHADS2 scores in their treatment recommendations for stroke, and instead stratified patients according to low, moderate, and high risk of stroke [4]. It has thus been necessary for the EAC to extrapolate treatment recommendations from these three groups, including the interpretation of "clinical judgment" in the CHADS2 score 1 group (50% of patients are assumed as receiving anticoagulants and 50% are assumed as receiving aspirin). Contraindications to taking drugs and poor patient adherence were not considered.

Patients are only tested once. The model assumes that patients have their initial BP measured (and incidental detection of AF) on their initial visit to the GP only; in the remaining 10 years patients are put through the model but are not rescreened. This could have a particular impact for FN patients who might be expected to be detected on subsequent screening visits, as BP measurement is recommended regularly in this group [1]. It is also possible that a person who had an initial FN result might have progressive disease, and would later become symptomatic, and thus detected. However, the nature of the progression of AF from paroxysmal AF to permanent AF is poorly understood [4] and so is difficult to model.

Assumptions in preventative treatment

The following assumptions have been made regarding the ongoing management of patients with diagnosed AF (TP group):

- The model assumes no movement between drug treatments. Patients in the model remain in the group they have been "allocated" to, allowing no movement between no treatment, anticoagulant, or aspirin arms. Additionally, polypharmacy is not allowed. This is a simplification, because in reality there are numerous reasons a patient could change their medication.
- Bleeding. The model assumes both anticoagulant and aspirin cause GI bleeding with the
 same resultant cost and clinical outcome, which might not be accurate. Additionally, in the
 model, bleeding only incurs a one-off immediate treatment cost, with the patient returning
 to the same state. In reality, bleeding can lead to permanent morbidity or mortality, and
 patients are unlikely to be returned to the same clinical management. For example, a patient
 suffering a major GI bleed whilst taking aspirin would have the options of stopping
 treatment, switching to clopidogrel or another antiplatelet drug, or taking a proton-pump
 inhibitor (PPI) concomitantly. These options would affect the preventative effectiveness of
 treatment and the cost associated with the clinical state.
- Other treatments. Only aspirin and anticoagulants (specifically warfarin) are considered as treatment options to reduce the risk of stroke. Other treatment strategies, such as cardioversion, anti-arrhythmia drugs, and newer anticoagulant options, such as heparin and dabigatran, are not considered in the model.

Assumptions concerning stroke

• Three clinical states of "stroke" have been considered; these are first year of stroke, subsequent year of stroke, and fatal stroke. Each of these states has a different cost (one-off cost for fatal stroke) and a consequence of having a nonfatal stroke is an increased future risk of death by stroke (which is different between the first and subsequent years). However, no allowance has been made for the possibility of recurrent nonfatal strokes or for subclassification of strokes (e.g. by stroke severity and stroke related disability). It has also been necessary to make assumptions concerning the cost of stroke (see Cost of strokes).

- The probability of having a first stroke is independent of time, despite the simulation having a 10 year time horizon. In reality, the likelihood of a stroke occurring might be expected to increase in this time, particularly in this high-risk (AF) population.
- The possibility of intracranial haemorrhage (i.e. haemorrhagic stroke) has not been considered. Anticoagulants are known to increase the risk of intracranial haemorrhage, with an estimated annual risk of 1.28% (95% CI 0.7 to 2.1%) in people receiving warfarin [7]. It is for this reason that the risk/benefit ratio must be considered before initiating anticoagulants, but this consideration has not informed the model.

Assumptions about model parameters

Diagnostic stage

The short-term (diagnostic) model has used sensitivity and specificity data from the same published studies that the sponsor's submission and the EAC's additional work employed; namely Wiesel *et al* (2009) [8] (WatchBP Home A) and Hobbs *et al* [6] (2005) (pulse palpation). The uncertainties surrounding these estimates (particularly the generalisability of the WatchBP Home A data) has been discussed in depth in the EAC's report on the sponsor's submission. A summary is discussed in Table 1.

Table 1. Summary of studies used to determine diagnostic accuracy of the WatchBP Home A and pulse palpation.

Study	Description	Results	Comment
Wiesel et al (2009)	405 unselected patients	96.7% sensitivity	Results for 2/3 successive
[8]	from cardiology.	88.8% specificity	readings for positive AF (not
	Intervention: WatchBP		equivalent to WatchBP Home A).
	Home A		May lack generalisability to UK
	Comparator: 12-lead ECG		primary care practice.
Hobbs et al (2005) [6]	Large HTA (10,000	87.2% sensitivity	Setting relevant to UK primary
	patients) set in UK primary	81.3% specificity	care practice.
	care.		
	Intervention: pulse		
	palpation.		
	Comparator: 12-lead ECG		

The costs considered with the short term model are restricted to the cost associated with the screening technique (which was set to zero, see Screening costs) and confirmatory ECGs. These costs are described fully in the sponsor's submission and the EAC's report on this. An assumption was made that the sensitivity and specificity of both AF detection techniques was independent on the severity of comorbidities (i.e. CHADS2 score). This may not be true because patients with more severe comorbidities (particularly previous stroke) may be subject to a more intensive clinical examination.

Management stage

Transitional probabilities

The long-term (management) model has been populated by data from a variety of sources that have been published in the literature. This is essentially a deterministic rather than a stochastic model, so the probabilistic distribution of the transitional variables has not been calculated. The transitional parameters used are summarised in Table 2. Further details are presented in Appendix A.

Table 2. Risks and probabilities (transitional variables) used in the long term model (management stage).

Parameter	Value(s)	Reference
Proportions of patients in each	CHADS2 0 – 6.9%	Study by Gage et al [3].*
CHADS2 group in 65-74 year old	CHADS2 1 – 26.8%	
cohort	CHADS2 2 – 30.3%	
	CHADS2 3 – 19.5%	
	CHADS2 4 – 12.7%	
	CHADS2 5 – 3.8%	
Proportions of patients in each	CHADS2 1 – 28.7%	Study by Gage et al [3].*
CHADS2 group in 75-84 year old	CHADS2 2 – 32.5%	
cohort	CHADS2 3 – 20.9%	
	CHADS2 4 – 13.6%	
	CHADS2 5 – 4.0%	
	CHADS2 6 – 0.3%	
Proportion with major GI	1.4% - warfarin	BAFTA study [9]
bleeding on anticoagulants or	1.6% - aspirin	
aspirin		
Proportion dying due to other	Age 69 years - 2.06%	Decennial life tables (2001 -
causes	Age 79 years – 5.93%	2002). HMO press. [10]
Baseline incidence of stroke in	CHADS2 0 – 1.9%	Study by Gage et al [3]
AF patients	CHADS2 1 – 2.8%	
	CHADS2 2 – 4.0%	
	CHADS2 3 – 5.9%	
	CHADS2 4 – 8.5%	
	CHADS2 5 – 12.5%	
	CHADS2 6 – 18.2%	
Proportion of strokes that are	33%	National audit office data [11]
fatal in first year in 65-74 year		Study by Indredavik et al [12].
old cohort		
Proportion of strokes that are	36.5%	Study by Brønnum-Hansen <i>et</i>
fatal in first year in 75-84 year		al [13]
old cohort		
Proportion of strokes that are	10%	Study by Hankey et al [14]
fatal in subsequent years		
Relative risk reductions of	Anticoagulants – 68%	Hobbs et al HTA [6]
stroke in patients with AF	Aspirin – 22%	
	only possible ages of each starting co	
not possible in under 75 years co	hart and CHADS2 scare of 0 not nos	sible in over 75 years cohort)

not possible in under 75 years cohort and CHADS2 score of 0 not possible in over 75 years cohort).

The following assumptions were made concerning the parameters:

As it was necessary to define two starting age cohorts, the data presented by Gage et al [3] had to be adjusted to account for the fact that the full age range was not possible with CHADS2 score of 0 and 6. A full breakdown of the proportion of risk factors that contribute

to the CHADS2 scores was not available. However, this is unlikely to be significant as relatively few patients belong to these extremes of risk.

- Proportion of patients with GI bleeds on aspirin or warfarin. These parameters were derived from the BAFTA (Birmingham Atrial Fibrillation Treatment of the Aged) study [9]. This was a large (n = 973) randomised controlled trial (RCT) that compared adjusted-dose warfarin with aspirin in elderly patients. People under the age of 75 years were excluded from recruitment for this study (i.e. different population from the simulated cohorts), so it has been assumed that the risk of bleed is not significantly dependent on age. However, the risk of bleeding reported in this RCT was less than that reported in some other studies. For instance, the NICE Atrial fibrillation costing report estimated that the annual rate of major bleeds was 2.4% (range 1.7–8.1%) [15]
- Proportion of patients dying from other causes. The values stated (2.06% and 5.93%) are the
 mean value of males and females aged 69 and 79 years respectively taken from decennial
 life expectancy tables [10]. This represents the midpoint of the simulated cohort (individual
 age risks were not possible with this model).
- Baseline incidence of stroke, according to CHADS2 score. These values were obtained from the study by Gage *et al* (2001) [3]. This was a validation study of a new clinical risk prediction rule which enrolled 1733 elderly patients (aged 65 to 90 years).
- Proportion of strokes that are fatal in the first year. According to the National Audit Office, approximately one third of strokes are estimated to be fatal within the first year. This value is supported by two RCTs which reported 32.8% [12] and 40% [13] mortality rates in the first year after stroke. However, in this model there is no immediate risk of death from first stroke; instead a person who has suffered a first stroke is assumed to be at significantly increased risk of fatal stroke for the following 12 months. In addition, second strokes are always fatal in this model, which is a simplification of clinical reality, where multiple strokes are possible.
- Proportion of fatal strokes in subsequent years. The risk of fatal stroke is highest in the first year. People who survive beyond this period have a smaller increased risk of stroke, which has been estimated to be about 10% in one long-term study of stroke [14]. This value is broadly reflected by CHADS2 estimates of stroke risk, which indicate that a person with previous stroke and other risk factors has an annual risk of stroke of 12.5% (at a CHADS2 score of 5) [3].
- Relative risk reduction (RR) with anticoagulants and aspirin. These RR values are widely
 accepted and were reported in the HTA study by Hobbs et al [6], which performed an
 economic analysis on a similar intervention to that of the present study (population,
 opportunistic, and targeted screening for AF).

Costing estimates

Costing estimates were taken from the published literature and, where possible, previous economic studies relating to AF. These costs are summarised in Table 3.

Table 3. Costs associated with clinical states used in the long term model.

Cost	Value(s)	Reference
Treatment costs (annual)	Anticoagulants (warfarin) -£489* Aspirin - negligible	NICE costing report on Atrial Fibrillation (2006) [15]
Adverse effects (GI bleeding – immediate cost)	Major bleed (anticoagulants) - £2,008*	NICE costing report on Atrial Fibrillation [15]
Cost of nonfatal stroke	First year – £12,565* Subsequent years - £3,315*	Hobbs <i>et al</i> HTA (1997) [16]
Cost of fatal stroke	£3,036	NICE report on Dabigatran [17]
* Adjusted for inflation (at 5%) b	y EAC	

The following assumptions were made regarding the costs of treatment and adverse effects:

- Annual treatment costs of anticoagulants and aspirin. These costs were derived from the NICE costing report on *Atrial Fibrillation* (2006) [15], and adjusted upwards for inflation (at 5% rate) by the EAC. The cost of warfarin management was estimated using a "bottom up" approach, which has been considered by some experts to be an overestimate. Because of this, the EAC performed sensitivity analysis on this cost to assess the impact of reduced anticoagulation cost on the model (see <u>Sensitivity Analyses</u>). The cost of aspirin has been estimated to be about £0.09 per day [17] which the EAC considered negligible. However, the cost of concomitant PPIs was not considered.
- Cost of GI bleeding. The cost of GI bleeding was derived from the NICE costing report on *Atrial Fibrillation* [15] and adjusted upwards for inflation (at 5% rate) by the EAC. An assumption was made that the cost of GI bleeding would be equivalent for both aspirin and warfarin, but it is unclear if this is a realistic assumption. The cost was also modelled as an immediate one-off cost. No consideration was given to future changes to treatment (e.g. addition of a PPI or switch to clopidogrel), ongoing morbidity, or mortality.

Cost of stroke

The model allowed two clinical states to represent nonfatal stroke; that of the cost of stroke in the first year and that of the cost of stroke in subsequent years. It was considered by the EAC that this biphasic approach more accurately represented stroke costs than a single cost of stroke. The value for this was derived from an HTA by Hemingway *et al* (2010) [18], and has been used in an economic analysis of the newer anticoagulant drug dabigatran etexilate [19]. The authors reported this was a mean average value from literature searches but did not report which studies it was derived from. However, the EAC considered this figure was broadly in line with other sources of stroke from an NHS and PSS perspective. For example, the NICE costing report on *Atrial Fibrillation* used the mean

of two assessments of the annual direct costs of stroke of £3,900 and £11,700 to give a figure of £7,800 (inflation adjusted £9906), which is similar to the Hemingway HTA estimates [18].

The EAC has also assumed fatal stroke has a one-off cost of £3036; this is in line with a NICE report on dabigatran etexilate [17], and reflects potential hospitalisation costs before death. However, it was unclear to the EAC from the reported data if this cost is included in the first year of stroke costs. Similarly, it is unclear whether the ongoing costs of stroke in subsequent years include management to prevent further strokes (i.e. anticoagulation). The assumption has been made that these costs are included in the stroke cost to prevent the possibility of double counting.

The individual cost of stroke is very hard to calculate because of the heterogeneous nature of the condition and the population it affects. In a 2009 report entitled *The economic burden of stroke in England* [20], used to inform a report by the National Audit Office, the authors reported on the societal burden of stroke. However the authors cited it was "impossible to interpret patient cost obtained by dividing the total costs by the patient number to produce a *meaningful* result" [EAC emphasis]. When they attempted this, their estimates were extremely wide ranging, with costs estimated at £2800, £17,500, and £135,500 depending on the level of care the patient received. Because of the uncertainties regarding the cost of stroke, the EAC performed sensitivity analyses, including threshold analysis (see <u>Cost of stroke</u>).

Results

Diagnostic stage

Using the sensitivity and specificity parameters reported in Table 1, the model simulated the following starting cohort of 100,000 patients. The number of patients (per 100,000 measured) who are TP, TN, FP, and FN for each screening method is reported in Table 4. The proportion of patients with AF who screen positive is significantly higher in the older cohort because of the higher underlying prevalence.

Table 4. Patient groups defined using diagnostic screening by WatchBP Home A and pulse palpation(screening) with confirmatory ECG (diagnosis), of 100,000 screened patients from 65-74 and 75-84 year old cohorts.

	Number of	patients	Number o	f patients
	(65-74 year o	old cohort)	(75-84 year	old cohort)
Dationt group	WatchBP Home	Pulse	WatchBP	Pulse
Patient group	A†	palpation‡	Home A†	palpation‡
True positives (TP)	2901*	2615 [*]	6963**	6275**
False negatives (FN)	99 [*]	685 [*]	237**	925**
False positives (FP)	10,864	18,129	10,393	17,344
True negatives (TN)	86,136	78,871	82,407	75,456
Total	100,000	100,000	100,000	100,000

Patient groups defined by sensitivity and specificity of † WatchBP Home A and ‡ manual pulse palpation vs. 12-lead ECG, with 3% and 7.2% prevalence of AF in 65-74 year old and 75-84 year old cohorts respectively.

Two costs are associated with the diagnostic stage of the model: these are the initial screening costs (with WatchBP Home A or pulse palpation) and the subsequent confirmatory ECG costs.

Screening costs (incidental detection of AF)

The device cost of an HBPM has been studied in the full NICE clinical guideline on Hypertension [1]. This included factors such as the cost of the unit (£42, median price from NHS Supply Chain catalogue), 5 year lifetime (discounting applied), 40 uses per year (weekly use in a *home* environment), calibration costs, service costs, and batteries. In total, the median HBPM device costs £45 annually or £1.13 per weekly use, with most of the costs being due to consumables and servicing rather than the purchase cost. The EAC considered that other than the initial purchase cost (£75 cited by sponsor for WatchBP Home A); all other costs for the device would be equivalent to a standard blood pressure device.

The EAC estimated that additional cost of using the WatchBP Home A compared to a standard HBPM over 5 years was about 0.38 pence per use, if the device gradually displaced existing HBPM monitors, and would be about 0.86 pence per use, if the device immediately replaced existing HBPM monitors. This was based on the following approximate estimates:

- Cost of new WatchBP Home A device of £75.00 (over 5 years), average cost of replacing existing devices £33.00 (cost of WatchBP Home A minus cost of standard device).
- Number of GP appointments per day 36 (based on average consultation time of 10 minutes).
- Proportion of people having their BP measured per GP visit 20% (13.5% have hypertension according to Quality Outcomes Framework [21] and additional measurement required as standard practice, for instance cardiovascular screening [22]). Thus on average seven BP measurements per day.
- Total of 8,750 uses during five year life span (7 uses per day, 5 times per week, 50 weeks per year, 5 years).

Thus, the EAC considered that given that each HBPM device is likely to be used thousands of times over the course of 5 years, the difference in costs between the WatchBP Home A and a standard HBPM is likely to negligible (less than 1 pence per use).

However, if the WatchBP Home A was introduced immediately throughout the NHS of England and Wales to displace present HBPM devices, a significant one-off capital cost of £2,700,000 might be incurred, as discussed in the EAC's report on the sponsor's submission [23], but this could not be included in the model.

In their economic submission, the sponsors of the WatchBP Home A also claimed that manual pulse palpation would incur a time cost, whereas the WatchBP Home A device would not. The EAC considered that this was unrealistic [23]. Thus this model has not included screening costs.

ECG costs

The EAC assumed that only test positive cases (i.e. TP and FP) were given an ECG to confirm diagnosis of AF. An ECG cost of £31.00 was based on those described in the Department of Health 2010-11 reference costs publication [24]. Using these assumptions and the populations of the patient groups described in Table 4, the total diagnostic costs per patient were calculated as reported in Table 5.

Table 5: Total diagnostic costs associated with WatchBP Home A and manual pulse palpation when 100,000 patients in 65-74 and 75-84 year old cohorts are initially screened.

				Diagn	ostic costs		
		True	False	False	True		Total cost
		positive	negative	positive	negative	Total cost	per
		(TP)	(FN)	(FP)	(TN)		patient
65-74	WatchBP	£89,931	£0	£336,784	£0	£426,715	£4.27
year old cohort	Pulse palpation	£81,065	£0	£561,999	£0	£643,064	£6.43
75-84	WatchBP	WatchBP £215,853		£322,183	£0	£538,036	£5.38
year old cohort	Pulse palpation	£194,525	£0	£537,664	£0	£732,189	£7.32

Assuming no screening costs for either method of measurement, the diagnostic cost per patient of the WatchBP Home A was £2.16 (34%) less expensive than manual pulse palpation in the younger

cohort and £1.94 (27%) less in the older cohort. This cost saving was solely linked to the higher specificity of the WatchBP Home A device, and thus the reduced number of false positives requiring ECG. It did not affect the costs of the 10-year management stage.

Management stage

The results from the management stage were derived using a 10 year state transition model, which simulated a theoretical cohort of patients with AF as described in <u>methods</u>. Two separate calculations were made:

- The TP cohort. This included costs and risk reductions associated with anticoagulants and aspirin, and costs and probabilities of GI bleeds associated with these therapies, as described in Tables 2 and 3.
- The FN cohort. In this group (with undetected AF), patients were assumed to be untreated
 and the costs, risk reductions and rates of GI bleed associated with aspirin and
 anticoagulants were set to zero. All other parameters were as described in Tables 2 and 3.

For each calculation, the number of strokes, number of fatal strokes, number of GI bleeds and mean management cost per patient were calculated at each cycle.

Prevention of strokes

Figure 3 illustrates the cumulative number of strokes prevented through the detection of AF (using any method) in the 65-74 year old cohort. The full data used for these figures, is reported in Appendix C. In all cases, the detection of AF has a significant impact on the prevention of stroke, and this is most apparent in people who are at higher risk of the disorder because of comorbidities (i.e. higher CHADS2 scores). In those with low CHADS2 scores (0 and 1) the relative ineffectiveness of aspirin compared with anticoagulation is also apparent. However, in the people who are at most risk of stroke (e.g. CHADS2 score) detection of AF and consequent anticoagulation reduces the number of strokes (from 65,620 in the untreated group to 29,830 in the treated group). A similar pattern is shown in the older cohort (75 to 84 years, Figure 4) but results are not directly comparable because this cohort also has a much greater chance of dying from other causes (i.e. has a higher standard mortality rate).

The high mortality rate caused by stroke in the model is broadly reflected by empirical studies published in the literature and so is plausible. For instance, a recent study by Davis *et al* reported a survival rate of 78% over a 5 year period in patients who had been diagnosed with AF [25]. This is consistent with the data presented in Appendix C.

Figure 3. Comparison of the cumulative number of strokes occurring over 10 years in patients with AF detected and undetected aged 65-74 years.

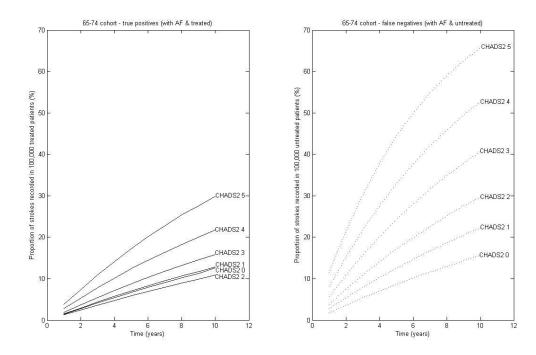
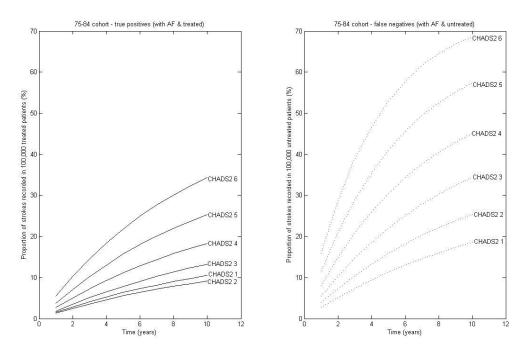


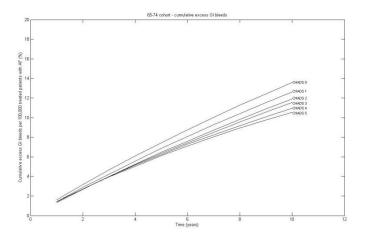
Figure 4. Comparison of the cumulative number of strokes occurring over 10 years in patients with AF detected and undetected 75-84 years.



GI bleeding

The full data set of GI bleeds, including the annual breakdown of GI bleed incidence, is presented in Appendix D and illustrated in Figure 5 (65 to 74 year old cohort only). From these results it was found that the proportion of patients at risk of GI bleed increases with advancing age regardless of the starting age of the cohort. This is due to the underlying base line risk being equivalent in all patients who receive the same drug (principally anticoagulation). The relationship is not directly linear however because with increasing age there is a cumulative risk in death by stroke and other causes.

Figure 5. Cumulative risk of GI bleeds attributable to treatment in patients with diagnosed AF aged 65 to 74 years.



The cumulative proportion of patients receiving anticoagulation or antiplatelet who experience a GI bleed after 10 years is reported in Table 6. There are fewer GI bleeds in the older cohort because these patients are more likely to die from other causes and thus be "removed" from the model.

Table 6. Cumulative excess gastrointestinal (GI) bleeds recorded per 100,000 treated patients with atrial fibrillation for each CHADS2 score, for 65-75 and 75-84 year old cohorts respectively.

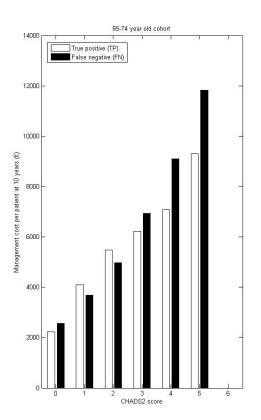
	Cumulative excess GI bleeds recorded per 100,000 treated patients							
CHADS2 score	65-74 year old cohort	75-84 year old cohort						
0	13,591	-						
1	12,610	10,503						
2	11,894	10,094						
3	11,545	9,570						
4	10,946	9,339						
5	10,532	8,765						
6	-	8,326						

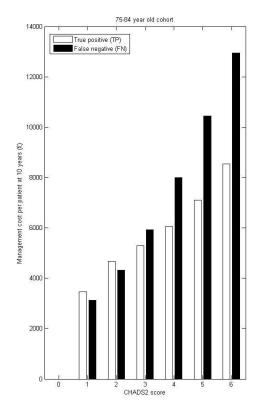
Total management costs

The total management costs (accumulated over a 10-year period) associated with the management of stroke is illustrated in Figure 6. This represents the cost per patient of those who have AF which is detected (TP) and of those who have AF but remain undetected (FN). It includes the cost of stroke; anticoagulation; and adverse effects from anticoagulation and aspirin. The full data sets used to

calculate this, including the annual total costs associated with these events and the annual number of critical events, are reported in <u>Appendix E</u> and <u>Appendix F</u> respectively.

Figure 6. Comparison of management costs in people with AF detected (TP) compared with AF undetected (FN) in people with different comorbidities and ages.





In the younger cohort (65-74 year olds) the detection of stroke (by any means) becomes cost saving in patients who have a CHADS2 score of 2 and above. Detection of AF in patients with a CHADS2 score of 0 incurs a cost saving because in this model the use of aspirin does not have a direct cost, unlike anticoagulation. Detection of AF is cost expending in patients who have CHADS2 scores of 1 and 2. For higher CHADS2 scores, detection of AF is cost saving, where the cost saved by preventing stroke is greater than the costs spent through anticoagulation treatment and its associated adverse effects. In patients who are classified with a CHADS2 score of 5 the saving is equivalent to £3,520 per patient, and in patients who are CHADS2 score 2 there is an expenditure of £509. However, it should be appreciated that these costs are associated per person in each CHADS2 cohort and not per person incidentally screened for AF, so the cost per person screened will be significantly less (as most people do not have AF), and overall costs or savings to the NHS will be highly dependent on the demographics and numbers of people having their BP measured and AF incidentally detected.

Analysis of the older cohort yields a similar effect. In the most at risk cohort (CHADS2 score 6), there was a potential cost saving of £4,401. Conversely, older patients with fewer comorbidities (CHADS2 score 1) potentially could cost the NHS £352 per patient over the 10-year period of the simulation. It is also of note that for equal CHADS2 scores, management costs are smaller in the older cohort than

the younger cohort. This is due to the effect of the older cohort having a higher standard mortality rate.

Overall these results indicate that detection of AF is more beneficial, from a cost perspective, in people who are older and who have greater comorbidities. This is because these patients have the most to gain from their absolute reduction in their stroke risk.

Combined diagnostic and management costs

The results of the cost consequence analysis performed by the EAC are reported in Table 7. The full results, including annual breakdown of cost for the WatchBP Home A and pulse palpation, are reported in Appendix G and Appendix H respectively. The consequences are presented as nonfatal strokes, strokes, and GI bleeds, and the total cost of these consequences is calculated, with the addition of limited univariate sensitivity analysis regarding stroke and anticoagulation costs. This is a pooled analysis of patients with the full range of possible comorbidities (i.e. CHADS2 scores 0 to 6) and includes the cost of diagnosis using the WatchBP Home A device or manual pulse palpation (including resources used due to false positive detection of AF), and the long-term management of AF over 10 years (including patients incorrectly diagnosed as not having AF and consequently not treated [FN patients]).

In the younger cohort (65-74 years), the WatchBP Home A was associated with a reduction of 53 nonfatal strokes and 28 fatal strokes, with the trade off of 34 excess GI bleeds which would not have otherwise occurred per 100,000 people screened. In the older cohort (75 to 84 years) this effect was more marked, with 117 nonfatal strokes prevented, 65 fatal strokes prevented, and an excess of 68 excess GI bleeds. Thus the WatchBP Home A was effective from a clinical point of view.

In terms of cost savings, the base case analysis indicated that the WatchBP Home A was associated with a cost saving of £2.98 per patient screened in the younger cohort studied, and £4.26 in the older cohort. Whilst this saving may appear modest over 10 years, it should be appreciated it is a saving that could potentially be made per each (relatively high-risk) patient having their BP measured in primary care, so in fact could be very substantial when viewed from the perspective of the NHS of England and Wales. This is especially the case when it is considered that the actual costs of detection of AF using the WatchBP Home A are quite trivial in comparison (see Screening costs).

In addition to the base case analysis, the EAC performed limited sensitivity analysis on the cost of stroke and (separately) the cost of anticoagulation. The cost of stroke is known to be the subject of considerable doubt due to the heterogeneous nature of the condition and its management (see Cost of stroke). The EAC therefore provided sensitivity analysis using realistic higher and lower values of the cost of stroke. Additionally the cost of anticoagulation is uncertain, with some experts thinking the NICE value from the Atrial Fibrillation costing report is an overestimate. The NICE document Atrial fibrillation - dabigatran etexilate: appraisal consultation [17], provided an alternative approximation of the annual cost of anticoagulant therapy to prevent stroke.

Table 7. Summary of cost consequence analysis.

		-	critical events re 2000 patients scre	•	Total cost per patient screened (£)				
		Strokes	Fatal strokes	Excess GI bleeds	Base case	Cost of stroke (£10,543.36)†	Cost of stroke (£14,586.61)‡	Cost of anticoagulation (£241.54)*	
EE 74 year old	WatchBP Home A	457	233	347	£164.87	£153.31	£175.88	£124.02	
65-74 year old cohort	Pulse Palpation	510	261	313	£167.85	£154.92	£180.25	£131.03	
	Difference	-53	-28	34	-£2.98	-£1.61	-£4.37	-£7.01	
75.04	WatchBP Home A	932	502	692	£348.47	£324.71	£371.84	£260.22	
75-84 year old cohort	Pulse Palpation	1,049	567	624	£352.80	£326.09	£379.03	£273.16	
	Difference	-117	-65	68	-£4.26	-£1.38	-£7.19	-£12.94	

[†] cost of stroke in first year and subsequent years from Pink (2011) study [19], ‡costs of stroke estimated by the EAC using the same ratio of first:later year stroke costs from Pink [19], * cost of anticoagulation therapy from NICE final appraisal determination of dabigatran etexilate study (2011) [17]

The EAC found that whilst the sensitivity analysis affected the magnitude of the cost savings, it did not affect the direction of them (i.e. the WatchBP Home A remained cost saving). In particular, the higher the estimate of stroke cost, the more cost-saving the device becomes; and the cost of stroke has been considered to be significantly underestimated, especially when societal costs are not considered [20]. Additionally, the cost of anticoagulation is likely to be an overestimate [17], meaning appropriate management of AF is likely to be more cost saving compared with the base case analysis. The EAC therefore considered that it is likely that the WatchBP Home A is cost saving compared with pulse palpation, with the cost saving being greater in higher-risk patients.

Discussion

The EAC has produced a two stage cost consequence model that has compared the WatchBP Home A with manual pulse palpation in terms of short-term diagnostic costs and longer-term management costs.

Model limitations and assumptions

Several limitations and assumptions were made when designing and implementing the model. One of the biggest limitations was that the patients were only measured for BP with the incidental detection of AF once, at the beginning of the model. This is unrealistic as in reality people in this age group would probably be measured for hypertension on a regular (usually annual) basis. This means that people who were originally detected as FN were unrealistically assumed to receive no treatment for the lifetime of the model; however, it should be remembered this is a relatively small cohort (e.g. 99 out of 100,000 patients in the younger cohort of the WatchBP Home A group), so will probably not affect the results significantly. Of greater importance is that patients who develop AF subsequent to the initial screening stage were not modelled. This is problematic, as the risk of developing AF is known to approximately double with each decade of advancing age [4], so in this respect the model probably underestimated the proportion of people with AF the device would detect.

The limitation that screening could only be undertaken once arose because of the model structure (cohort state transition model). An additional limitation was that the model had fixed ages of entry (65 and 75 years) and that very low-risk (younger) patients were not included in the model. As the *principal* function of the WatchBP Home A is the measurement of BP rather than the incidental detection of AF, the lack of modelling in very low-risk cohorts may have caused the results to significantly overestimate both clinical benefits (reduction in strokes) and cost reductions (through increased number of FP ECG results and resources used). Other assumptions that are causes of uncertainty include the limited range of treatment options, simplified stroke and GI bleeding pathways, and relatively crude transitional probability and costing values. As this was a deterministic rather than a stochastic model, the effect of these underlying uncertainties could not be adequately tested. In addition, Bayesian probabilistic analysis to assess the likelihood that the WatchBP Home A was cost expending or saving was not possible. Finally, it was not possible to simulate the consequences of paroxysmal AF with this model.

Diagnostic costs

The EAC considered the monetary cost of initial screening (i.e. AF detection) was negligible for the WatchBP Home A (probably less than 1 pence per use), because of the thousands of times the device would be used in its lifetime. This cost would be absent for manual pulse palpation. Additionally, the EAC considered that it was unlikely the WatchBP Home A would be time saving compared with pulse palpation [23]. However, the WatchBP Home A was likely to be moderately cost saving when the whole diagnostic stage was considered, saving around £2.05 per patient per 100,000 measured for BP compared with pulse palpation. This is because the device is more specific than pulse palpation, and reduces the amount of FP results, which are otherwise subsequently sent for a confirmatory ECG at cost.

Although individual screening costs are likely to be negligible, the WatchBP Home A might impose a significant one-off capital cost should it be extensively introduced to replace existing HBPM devices that do not require decommissioning, which could cause a barrier to implementation from GP consortia with limited budgets. The EAC has previously calculated this could be as much as £2,700,000 [23], but this one-off figure could not be incorporated into the present model as there is an absence of data describing the population the device would be used in.

Management costs and consequences

The EAC found that the long-term cost of treating AF (regardless of the method of detection) is likely to be cost saving in most groups of patients, with patients with the highest risk of stroke (i.e. older age, more comorbidities) being the most cost saving to treat. The costs of treating AF and preventing stroke over the course of 10 years ranged from a saving of £4,401 per patient in the highest risk group (75 years and over, CHADS2 score 6) to an expense of £509 per patient in a lower risk group (under 75 years, CHADS2 score 2). The cost saving associated with management of AF therefore generally increased with increasing age and comorbidities. This is because patients with a higher risk of stroke were associated with an increased absolute risk reduction through anticoagulation treatment.

In all cases, treatment of AF was associated with a reduction in nonfatal stroke and fatal stroke, with the tradeoff of increased risk of GI bleed. The greatest patient benefit was associated in patients who were most at risk of stroke, with patients in the highest risk group (75 years and over, CHADS2 score 6) experiencing a 55% reduction in their stroke risk (from 65,620 in the untreated group to 29,830 in the treated group). The smallest benefit was associated with those least at risk, with patients aged 65 years and under with no additional risk factors (CHADS2 score 0) experiencing a 27% risk reduction in stroke (from 15,671 in the untreated group to 12,361 in the treated group). In all cases, the clinical benefit of stroke prevention was likely to outweigh the negative effects of excess GI bleeds because of the greater morbidity and mortality that stroke causes.

Overall costs and consequences

The EAC calculated the overall costs *per patient screened* for AF which included all people having their BP measured (i.e. regardless of their AF status or stroke risk). All costs were summed including diagnostic costs (i.e. ECG costs), and costs of the consequences of stroke, anticoagulation, and GI bleeding. These results are shown in Table 7.

The results showed that the WatchBP Home A was cost saving, ranging from £2.98 per patient screened in the younger cohort studied, to £4.26 in the older cohort. This means that for each patient having their BP measured in the cohorts modelled, there might be a mean cost saving of £3.62 over the course of 10 years. Limited univariate sensitivity analysis indicated that the device would remain cost saving when realistic variations on the cost of stroke and cost of anticoagulation were applied; in fact the EAC's cost estimates were likely to be an underestimate of the true cost savings.

Regarding clinical effectiveness, the EAC's analysis showed that between 53 and 117 fatal strokes, and between 28 and 65 nonfatal strokes could be avoided per 100,000 patients screened for AF, depending on the patients age (with older patients benefitting more). This would be at the cost of 34 to 68 excess GI bleeds. Cost consequence models are not designed to evaluate cost-effectiveness, so

the clinical benefits of the device have not been fully evaluated. However, stroke is associated with a large loss of quality of life and shortened life expectancy, so its prevention is clearly a desirable outcome.

Conclusion

The EAC has produced a cost consequence model which has estimated the total cost impact of the WatchBP Home A device over a time period of up to 10 years. Using this model, the EAC found that when both diagnostic and management costs were considered, the WatchBP Home A would be expected to save approximately £3.62 per person being screened for AF compared with manual pulse palpation. This cost saving appeared to be robust concerning costing assumptions associated with stroke and anticoagulant treatment. The cost consequence analysis showed that in general, older people with more comorbidities were associated with the greatest cost savings.

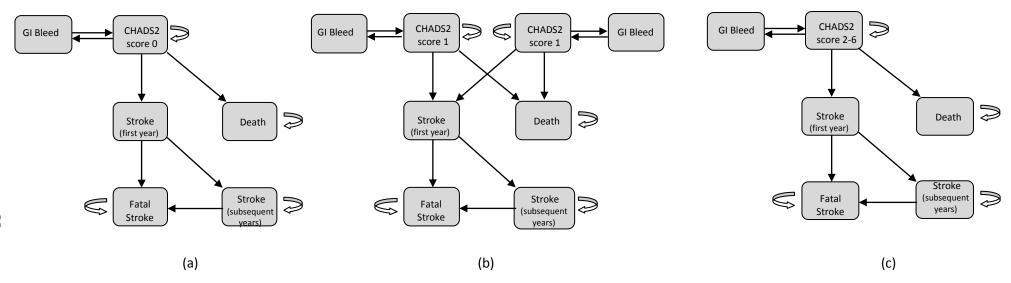
From a patient perspective, the WatchBP Home A was associated with the clinical benefit of reducing stroke in all patients treated for AF, preventing between 53 and 117 fatal strokes, and between 28 and 65 nonfatal strokes per 100,000 people screened for AF, depending on the age of the patient (with older patients benefitting more). This more than offset the incidence of GI bleeds associated with antiplatelet and anticoagulant treatment.

The model used had several assumptions and limitations. An important assumption in the model was that patients would only have their BP measured once immediately prior to the management stage. However, if more frequent BP measurement was undertaken, as seems likely, the device would be expected to detect more cases of AF and thus prevent more cases of stroke. This would likely produce additional cost savings. Another important limitation was that people with very low risk of AF (i.e. younger with a lower prevalence of AF) were not included in the model. As there are no restrictions on whom the WatchBP Home A should be used to measure BP, this could have led to an overestimate of the clinical benefits and costs savings associated with the device. Thus in the absence of reliable demographic data, the EAC was unable to draw firm conclusions on the impact of the device at the level of the NHS. Finally, paroxysmal AF was not included in this model.

In conclusion, using the assumptions made in the model, the WatchBP Home A is likely to be cost saving compared with pulse palpation with respect to its impact on NHS and PSS resources in higher-risk patients (i.e. patients aged 65 years and above). Additionally, use of the device is associated with an increased detection of AF and subsequent prevention of strokes, although the measurement sensitivity and specificity of the device is derived from only 405 patients (compared with 10,000 patients for pulse palpation). The treatment or prevention of these disorders would clearly be of significant benefit from a patient perspective. It should also be borne in mind that the NHS has an obligation to appropriately manage people with AF according to its core constitution (see www.dh.gov.uk, PDF document [26]). This is *regardless* of how AF was detected. In this context, it is the screening costs of the WatchBP Home A itself (i.e. incidental detection of AF during BP measurement) that might be considered important, and it has been shown that over the anticipated lifetime of the device, these costs are likely to be negligible.

Appendix A - Model structure

Figure A1: Model structure of management stage applied to patients with atrial fibrillation with a) CHADS2 score 0, b) CHADS2 score 1 and c) CHADS2 scores between 2 & 6 (a separate model for each score, each model with common structure).



The above models were applied to individual CHADS2 scores separately for treated and untreated patients with AF (i.e. true positive and false negative groups respectively). The process was repeated for two age groups (65-74 year old cohort and 75-84 year old cohort). The 65-74 year old cohort contained patients with CHADS2 scores between 0 and 5 and the 75-84 year old cohort contained patients with CHADS2 scores between 1 and 6.

100,000 treated patients and 100,000 untreated patients were entered into the model for each CHADS2 score. The outputs of each model represented the annual management cost per treated and untreated patient for each CHADS2 score, and also the number of critical events (i.e. strokes, fatal strokes, total deaths and major bleeds) per 100,000 treated and untreated patients.

The costs and numbers of events for each treatment model were combined with the diagnostic performance of WatchBP device and pulse palpation to compare the cost consequences of each diagnostic technique. This was carried out by combining all CHADS2 scores taking into account: 1) the sensitivity and specificity of a diagnostic screening technique (WatchBP Home A vs. manual pulse palpation), 2) the prevalence of AF within the cohort, and 3) the proportion of patients with AF within each CHADS2 score category (following the study by Gage (2001) [3]).

Appendix B - Parameters used in model

Details of parameters used to populate the long-term management model. Table B1. 65 year old cohort

		Assumed age (years)	Prevalence of AF at initial screening (%) [27]	Proportion of cohort with CHADS2 score (%) [3]	Treatment associated with CHADS2 score	Risk of major bleed (%) [9]	Risk of stroke (%) [3]	Risk of fatal first stroke (%) [11]	Risk of fatal subsequent stroke (%) [14]	Standard mortality rate* (%) [10]
a	0	65-74	3.0	6.9	Aspirin	1.6	1.9†	33.3	10.0	2.06
2 scor	1	65-74	3.0	26.8	50% aspirin, 50% anti-coagulant	1.6/1.4	2.8†‡	33.3	10.0	2.06
DS	2	65-74	3.0	30.3	Anti-coagulant	1.4	4.0‡	33.3	10.0	2.06
CHA	3	65-74	3.0	19.5	Anti-coagulant	1.4	5.9‡	33.3	10.0	2.06
	4	65-74	3.0	12.7	Anti-coagulant	1.4	8.5‡	33.3	10.0	2.06
	5	65-74	3.0	3.8	Anti-coagulant	1.4	12.5‡	33.3	10.0	2.06

†an additional 22% risk reduction associated with aspirin and ‡and additional 68% risk reduction associated with anticoagulation therapy is applied [6].

Table B2. 75 year old cohort.

		Assumed age (years)	Prevalence of AF at initial screening (%) [6]	Proportion of cohort with CHADS2 score (%) [3]	Treatment associated with CHADS2 score	Risk of major bleed (%) [9]	Risk of stroke (%) [3]	Risk of fatal first stroke (%) [13]	Risk of fatal subsequent stroke (%) [14]	Standard mortality rate** (%) [10]
S2 e	1	75-84	7.2	28.7	50% aspirin, 50% anti-coagulant	1.6/1.4	2.8†‡	36.5	10.0	5.93
CHADS2 score	2	75-84	7.2	32.5	Anti-coagulant	1.4	4.0‡	36.5	10.0	5.93
L S	3	75-84	7.2	20.9	Anti-coagulant	1.4	5.9‡	36.5	10.0	5.93
	4	75-84	7.2	13.6	Anti-coagulant	1.4	8.5‡	36.5	10.0	5.93
	5	75-84	7.2	4.0	Anti-coagulant	1.4	12.5‡	36.5	10.0	5.93
	6	75-84	7.2	0.3	Anti-coagulant	1.4	18.2‡	36.5	10.0	5.93

†additional 22% risk reduction associated with aspirin and ‡an additional 68% risk reduction associated with anticoagulation therapy is applied [6].

^{*} standard mortality rate based on mean age of cohort, 69 years old.

^{**} standard mortality rate based on mean age of cohort, 79 years old.

Appendix C - Number of strokes

Table C1: Cumulative number of strokes recorded per 100,000 patients with atrial fibrillation for each individual CHADS2 score for patients aged 65-74 years old.

			Strokes red	corded per 1	00,000 treat	ed patients		Strokes recorded per 100,000 untreated patients					
				CHADS	2 scores			CHADS2 scores					
		0	1	2	3	4	5	0	1	2	3	4	5
	1	1,480	1,527	1,267	1,881	2,749	3,837	1,816	2,788	3,782	5,634	8,054	11,469
	2	2,851	2,960	2,443	3,725	5,313	7,410	3,640	5,424	7,437	10,908	15,288	21,550
	3	4,119	4,398	3,639	5,433	7,817	10,878	5,402	7,900	10,947	15,645	21,780	30,224
	4	5,402	5,731	4,773	7,113	10,104	14,110	7,004	10,281	14,143	20,112	27,635	37,807
Year	5	6,697	7,054	5,880	8,766	12,359	17,163	8,595	12,538	17,167	24,317	32,967	44,330
Ϋ́e	6	7,929	8,307	6,936	10,305	14,420	20,105	10,170	14,657	19,924	28,018	37,764	50,014
	7	9,122	9,504	7,980	11,801	16,382	22,816	11,623	16,690	22,572	31,598	42,004	54,845
	8	10,227	10,663	8,929	13,212	18,215	25,354	12,992	18,674	25,139	34,854	45,881	58,969
	9	11,290	11,717	9,913	14,536	20,021	27,627	14,337	20,497	27,624	37,900	49,461	62,506
	10	12,361	12,809	10,960	15,852	21,785	29,830	15,672	22,209	29,801	40,730	52,543	65,620

Table C2: Cumulative number of fatal strokes recorded per 100,000 patients with atrial fibrillation for each individual CHADS2 score for patients aged 65-74 years old.

		1	Fatal strokes	recorded pe	r 100,000 <i>tre</i>	eated patient	S	Fatal strokes recorded per 100,000 untreated patients					
				CHADS	2 scores			CHADS2 scores					
		0	1	2	3	4	5	0	1	2	3	4	5
	1	214	214	196	255	362	544	255	401	548	786	1,130	1,576
	2	682	695	612	851	1,220	1,729	826	1,258	1,715	2,513	3,627	5,008
	3	1,231	1,224	1,057	1,540	2,217	3,014	1,494	2,227	3,036	4,412	6,266	8,634
	4	1,813	1,839	1,599	2,286	3,335	4,574	2,242	3,361	4,559	6,503	9,188	12,541
	5 2 6	2,453	2,528	2,163	3,131	4,486	6,209	3,079	4,531	6,262	8,724	12,268	16,559
3	<u>5</u> 6	3,133	3,263	2,781	4,023	5,717	7,914	3,962	5,791	7,894	11,109	15,441	20,549
	7	3,876	4,026	3,429	5,045	7,045	9,713	4,906	7,048	9,710	13,534	18,628	24,584
	8	4,634	4,832	4,089	6,067	8,386	11,582	5,848	8,405	11,514	16,090	21,810	28,399
	9	5,394	5,651	4,794	7,054	9,685	13,439	6,871	9,834	13,476	18,577	24,990	32,130
	10	6,201	6,516	5,525	8,107	11,109	15,360	7,950	11,307	15,417	21,042	28,092	35,756

Table C3: Cumulative number of strokes recorded per 100,000 patients with atrial fibrillation for each individual CHADS2 score for patients aged between 75-84 years old.

		Strokes recorded per 100,000 treated patients							Strokes recorded per 100,000 untreated patients						
		CHADS2 scores							CHADS2 scores						
		1	2	3	4	5	6	1	2	3	4	5	6		
	1	1,512	1,270	1,841	2,668	3,791	5,505	2,712	3,938	5,507	8,033	11,592	15,973		
	2	2,856	2,504	3,566	5,005	7,121	10,285	5,152	7,355	10,371	14,938	21,073	28,777		
	3	4,098	3,542	5,075	7,249	10,179	14,492	7,366	10,442	14,694	20,827	28,917	38,905		
	4	5,275	4,592	6,464	9,287	13,013	18,342	9,449	13,232	18,526	25,991	35,506	46,662		
Year	5	6,348	5,552	7,839	11,186	15,726	21,780	11,331	15,907	22,005	30,439	41,041	52,860		
Ye	6	7,325	6,387	9,089	12,827	18,019	24,922	13,038	18,210	25,104	34,326	45,660	57,736		
	7	8,157	7,191	10,276	14,371	20,104	27,716	14,599	20,309	27,904	37,623	49,444	61,593		
	8	9,005	7,872	11,345	15,812	21,968	30,093	15,980	22,233	30,312	40,557	52,575	64,515		
	9	9,777	8,529	12,340	17,086	23,729	32,301	17,384	23,824	32,472	42,990	55,220	66,799		
	10	10,534	9,189	13,246	18,254	25,277	34,275	18,668	25,395	34,416	45,144	57,375	68,610		

Table C4: Cumulative number of fatal strokes recorded per 100,000 patients with atrial fibrillation for each individual CHADS2 score for patients aged between 75-84 years old.

		Fatal strokes recorded per 100,000 treated patients							Fatal strokes recorded per 100,000 untreated patients						
		CHADS2 scores						CHADS2 scores							
		1	2	3	4	5	6	1	2	3	4	5	6		
Year	1	228	174	256	396	585	802	405	608	777	1,226	1,787	2,442		
	2	701	625	876	1,238	1,754	2,489	1,309	1,849	2,560	3,738	5,475	7,353		
	3	1,224	1,098	1,531	2,201	3,085	4,375	2,302	3,214	4,543	6,398	9,135	12,184		
	4	1,804	1,625	2,275	3,253	4,528	6,423	3,309	4,668	6,555	9,177	12,805	17,058		
	5	2,437	2,194	3,014	4,289	6,073	8,465	4,383	6,152	8,615	11,891	16,453	21,598		
	6	3,019	2,755	3,831	5,373	7,687	10,580	5,466	7,707	10,775	14,670	19,989	26,060		
	7	3,676	3,308	4,629	6,434	9,230	12,708	6,649	9,227	12,836	17,384	23,368	30,248		
	8	4,320	3,858	5,441	7,581	10,723	14,739	7,812	10,734	14,986	20,021	26,711	34,120		
	9	4,933	4,397	6,271	8,760	12,289	16,756	8,972	12,272	17,030	22,552	29,912	37,526		
	10	5,592	4,978	7,061	9,882	13,785	18,834	10,138	13,820	19,059	25,117	32,935	40,754		

Appendix D - GI bleeds

Table D1: Cumulative excess number of gastrointestinal (GI) bleeds recorded per 100,000 treated patients with atrial fibrillation for each CHADS2 score for patients aged 65-74 years old.

		Cumulative excess GI bleeds recorded per 100,000 treated patients									
				CHADS2 sc	ores						
		0 1 2 3 4 5									
	1	1,607	1,414	1,405	1,411	1,331	1,432				
	2	3,177	2,870	2,704	2,695	2,682	2,707				
	3	4,644	4,215	3,974	3,956	3,969	3,946				
	4	6,093	5,581	5,239	5,195	5,162	5,029				
Year	5	7,420	6,883	6,469	6,351	6,231	6,115				
Ye	6	8,737	8,082	7,587	7,427	7,301	7,104				
	7	10,027	9,259	8,705	8,496	8,228	8,027				
	8	11,267	10,407	9,820	9,564	9,166	8,945				
	9	12,427	11,548	10,877	10,578	10,083	9,745				
	10	13,591	12,610	11,895	11,545	10,946	10,532				

Table D2: Cumulative excess number of gastrointestinal (GI) bleeds recorded per 100,000 treated patients with atrial fibrillation for each CHADS2 score for patients aged between 75-84 years old.

			Cumulative exce	ss GI bleeds recorde	d per 100,000 <i>trea</i>	ted patients	
				CHADS2 so	cores		
		1	2	3	4	5	6
	1	1,421	1,363	1,302	1,377	1,345	1,306
	2	2,759	2,611	2,613	2,574	2,530	2,532
	3	4,055	3,777	3,740	3,705	3,618	3,585
	4	5,179	4,832	4,767	4,725	4,622	4,542
ar	5	6,249	5,861	5,714	5,700	5,475	5,401
Year	6	7,237	6,788	6,616	6,517	6,243	6,083
	7	8,137	7,737	7,429	7,321	6,992	6,768
	8	8,952	8,602	8,203	8,041	7,617	7,357
	9	9,744	9,370	8,930	8,713	8,209	7,854
	10	10,503	10,094	9,570	9,339	8,765	8,326

Appendix E - Management costs

Table E1: Management costs per patient with atrial fibrillation for each individual CHADS2 score for patients aged 65-74 years old

			Manage	ement costs p	er <i>treated</i> pa	tient (£)		Management costs per untreated patient (£)					
				CHADS	2 scores					CHADS	2 scores		
		0	1	2	3	4	5	0	1	2	3	4	5
	1	124.83	360.93	579.18	623.09	672.56	742.57	116.61	181.37	247.48	366.18	527.40	746.98
	2	331.14	792.98	1,194.72	1,312.82	1,455.22	1,647.39	343.40	515.43	705.56	1,041.11	1,467.87	2,092.20
	3	544.82	1,226.84	1,796.51	1,995.49	2,233.85	2,552.61	595.10	881.46	1,218.59	1,761.98	2,456.52	3,453.86
	4	771.90	1,662.18	2,382.28	2,661.04	2,999.86	3,453.96	863.48	1,267.11	1,751.18	2,514.90	3,469.89	4,819.82
Year	5	1,011.80	2,093.03	2,949.96	3,314.08	3,745.11	4,338.43	1,142.33	1,665.63	2,295.85	3,282.54	4,484.77	6,151.87
Ϋ́e	6	1,255.70	2,517.70	3,497.98	3,945.32	4,470.22	5,199.56	1,427.65	2,072.33	2,841.47	4,049.47	5,485.11	7,433.83
	7	1,504.89	2,929.67	4,023.86	4,557.24	5,167.63	6,034.67	1,717.13	2,483.10	3,388.09	4,802.16	6,449.45	8,654.46
	8	1,749.85	3,332.31	4,529.51	5,142.37	5,833.32	6,833.80	2,005.54	2,893.69	3,928.04	5,538.59	7,376.26	9,789.45
	9	1,990.10	3,719.92	5,015.90	5,698.37	6,474.90	7,590.71	2,288.60	3,295.75	4,461.82	6,249.41	8,267.91	10,847.31
	10	2,230.02	4,092.05	5,483.73	6,233.23	7,091.20	8,310.00	2,570.02	3,685.68	4,975.34	6,934.92	9,102.07	11,829.92

Table E2: Management costs per patient with atrial fibrillation for each individual CHADS2 score for patients aged between 75-84 years old.

			Manage	ment costs p	er <i>treated</i> pa	tient (£)		Management costs per untreated patient (£)					
				CHADS2	2 scores			CHADS2 scores					
		1	2	3	4	5	6	1	2	3	4	5	6
	1	354.32	569.22	604.16	660.98	726.77	836.44	173.86	254.86	358.69	527.36	759.77	1,053.27
	2	765.54	1,163.42	1,260.66	1,395.93	1,582.81	1,877.73	489.11	707.42	994.18	1,442.86	2,058.74	2,815.54
	3	1,162.34	1,714.59	1,876.67	2,101.38	2,408.15	2,877.51	821.17	1,169.16	1,658.01	2,363.71	3,307.67	4,502.41
	4	1,544.32	2,235.16	2,458.68	2,775.43	3,204.49	3,838.25	1,161.17	1,645.07	2,318.00	3,279.60	4,539.88	6,072.90
Year	5	1,909.78	2,723.42	3,006.16	3,415.24	3,968.96	4,753.25	1,507.01	2,131.47	2,980.61	4,174.86	5,705.25	7,513.57
Ϋ́	6	2,258.01	3,177.57	3,528.26	4,014.63	4,687.70	5,618.69	1,847.71	2,604.51	3,626.66	5,038.47	6,807.70	8,838.24
	7	2,584.38	3,597.36	4,013.77	4,575.86	5,357.37	6,433.63	2,188.01	3,064.64	4,245.84	5,854.04	7,833.31	10,044.26
	8	2,892.15	3,986.53	4,470.39	5,108.23	5,979.14	7,187.09	2,508.71	3,508.91	4,837.18	6,624.70	8,780.53	11,118.26
	9	3,183.53	4,344.76	4,894.24	5,599.94	6,566.11	7,890.10	2,819.15	3,928.61	5,398.73	7,341.55	9,647.69	12,077.36
	10	3,460.04	4,680.13	5,286.59	6,053.49	7,106.64	8,540.30	3,119.98	4,328.18	5,924.25	8,004.60	10,435.47	12,941.06

Appendix F - Total number of critical events

Table E1. Total number of critical events recorded in patients aged between 65-74 years old with AF after diagnostic screening with WatchBP

			-	of critical events a w up in 100,000 pa	•	Predicted number of critical events in patients with AF after 10 years			
Patient group (n)	CHADS2 score category (%)	Number of patients within each CHADS2 category	Strokes	Fatal Strokes	Excess GI Bleeds	Strokes	Fatal Strokes	Excess GI Bleeds	
	0 (6.9%)	200.2	12.36%	6.20%	13.59%	24.7	12.4	27.2	
	1 (26.8%)	778.5	12.81%	6.52%	12.61%	99.7	50.7	98.2	
TP (2,901)	2 (30.3%)	879.0	10.96%	5.53%	11.90%	96.3	48.6	104.6	
treated	3 (19.5%)	566.7	15.85%	8.11%	11.55%	89.8	45.9	65.4	
	4 (12.7%)	368.4	21.79%	11.11%	10.95%	80.3	40.9	40.3	
	5 (3.8%)	110.2	29.83%	15.36%	10.53%	32.9	16.9	11.6	
	0 (6.9%)	6.8	15.67%	7.95%	0.00%	1.1	0.5	0.0	
	1 (26.8%)	26.5	22.21%	11.31%	0.00%	5.9	3.0	0.0	
FN (99)	2 (30.3%)	30.0	29.80%	15.42%	0.00%	8.9	4.6	0.0	
untreated	3 (19.5%)	19.3	40.73%	21.04%	0.00%	7.9	4.1	0.0	
	4 (12.7%)	12.6	52.54%	28.09%	0.00%	6.6	3.5	0.0	
	5 (3.8%)	3.8	65.62%	35.76%	0.00%	2.5	1.4	0.0	
		I	Takal asses!	of outstand over 1		456.6	222.5	247.2	
			i otai number	of critical events		456.6	232.5	347.3	

Table E2. Total number of critical events recorded in patients aged between 65-74 years old with AF after diagnostic screening with Pulse Palpation

			Probability of co	ritical events after	10 years follow up	Predicted number	per of critical event	s in patients with
				in 100,000 patien	ts		AF after 10 years	
Patient group (n)	CHADS2 score category (%)	Number of patients within each CHADS2 category	Strokes	Fatal Strokes	Excess GI Bleeds	Strokes	Fatal Strokes	GI Bleeds
	0 (6.9%)	180.4	12.36%	6.20%	13.59%	22.3	11.2	24.5
	1 (26.8%)	700.8	12.81%	6.52%	12.61%	89.8	45.7	88.4
TP (2,615)	2 (30.3%)	792.3	10.96%	5.53%	11.90%	86.8	43.8	94.2
treated	3 (19.5%)	509.9	15.85%	8.11%	11.55%	80.8	41.3	58.9
	4 (12.7%)	332.1	21.79%	11.11%	10.95%	72.3	36.9	36.4
	5 (3.8%)	99.4	29.83%	15.36%	10.53%	29.7	15.3	10.5
	0 (6.9%)	26.6	15.67%	7.95%	0.00%	4.2	2.1	0.0
	1 (26.8%)	103.2	22.21%	11.31%	0.00%	22.9	11.7	0.0
FN (385)	2 (30.3%)	116.7	29.80%	15.42%	0.00%	34.8	18.0	0.0
untreated	3 (19.5%)	75.1	40.73%	21.04%	0.00%	30.6	15.8	0.0
	4 (12.7%)	48.9	52.54%	28.09%	0.00%	25.7	13.7	0.0
	5 (3.8%)	14.6	65.62%	35.76%	0.00%	9.6	5.2	0.0
			Total number of	critical events		509.5	260.7	312.9

Table E3. Total number of critical events recorded in patients aged between 75-84 years old with AF after diagnostic screening with WatchBP

			Probability of critical events after 10 years		Predicted num	ber of critical even	its in patients with	
			follow up in 100,000 patients				AF after 10 year	'S
Patient group (n)	CHADS2 score category (%)	Number of patients within each CHADS2 category	Strokes	Fatal Strokes	Excess GI Bleeds	Strokes	Fatal Strokes	GI Bleeds
	1 (28.7%)	1,998.4	10.53%	5.59%	10.50%	210.5	111.8	209.9
	3 (32.5%)	2,263.0	9.19%	4.98%	10.09%	207.9	112.7	228.4
TP (6,963)	3 (20.9%)	1,455.3	13.25%	7.06%	9.57%	192.8	102.8	139.3
treated	4 (13.6%)	947.0	18.25%	9.88%	9.34%	172.9	93.6	88.4
	5 (4.0%)	278.5	25.28%	13.79%	8.77%	70.4	38.4	24.4
	6 (0.3%)	20.9	34.28%	18.83%	8.33%	7.2	3.9	1.7
	1 (28.7%)	68.0	18.67%	10.14%	0.00%	12.7	6.9	0.0
	3 (32.5%)	77.0	25.40%	13.82%	0.00%	19.6	10.6	0.0
FN (237)	3 (20.9%)	49.5	34.42%	19.06%	0.00%	17.0	9.4	0.0
untreated	4 (13.6%)	32.2	45.14%	25.12%	0.00%	14.5	8.1	0.0
	5 (4.0%)	9.5	57.38%	32.94%	0.00%	5.5	3.1	0.0
	6 (0.3%)	0.7	68.61%	40.75%	0.00%	0.5	0.3	0.0
					·	-		
			Total number	of critical events		931.5	501.6	692.1

Table E4. Total number of critical events recorded in patients aged between 75-84 years old with AF after diagnostic screening with Pulse Palpation

			Probability of critical events after 10 years follow up			Predicted num	ber of critical event	s in patients with	
				in 100,000 patien	ts	AF after 10 years			
Patient group (n)	CHADS2 score category (%)	Number of patients within each CHADS2 category	Strokes	Fatal Strokes	Excess GI Bleeds	Strokes	Fatal Strokes	GI Bleeds	
	1 (28.7%)	1,800.9	10.53%	5.59%	10.50%	189.7	100.7	189.1	
	3 (32.5%)	2,039.4	9.19%	4.98%	10.09%	187.4	101.5	205.9	
TD (6.275)	3 (20.9%)	1,311.5	13.25%	7.06%	9.57%	173.7	92.6	125.5	
TP (6,275)	4 (13.6%)	853.4	18.25%	9.88%	9.34%	155.8	84.3	79.7	
	5 (4.0%)	251.0	25.28%	13.79%	8.77%	63.4	34.6	22.0	
	6 (0.3%)	18.8	34.28%	18.83%	8.33%	6.4	3.5	1.6	
	1 (28.7%)	265.5	18.67%	10.14%	0.00%	49.6	26.9	0.0	
	3 (32.5%)	300.6	25.40%	13.82%	0.00%	76.3	41.5	0.0	
FN (925)	3 (20.9%)	193.3	34.42%	19.06%	0.00%	66.5	36.8	0.0	
FIN (925)	4 (13.6%)	125.8	45.14%	25.12%	0.00%	56.8	31.6	0.0	
	5 (4.0%)	37.0	57.38%	32.94%	0.00%	21.2	12.2	0.0	
	6 (0.3%)	2.8	68.61% 40.75% 0.00%			1.9	1.1	0.0	
	Total number of critical events						567.3	623.8	

Appendix G - WatchBP Home A total costs

Table G1. WatchBP total costs for 100,000 modelled patients aged 65-74 years old.

	Patient group (n)	CHADS2 score category (%)	Number of patients within each CHADS2 category	10 year management cost per patient (£)	Diagnostic cost per patient*(£)	Total Cost
		0 (6.9%)	200.2	£2,230.02	£31.00	£452,656.20
		1 (26.8%)	778.5	£4,092.05	£31.00	£3,205,671.38
	TP (2,901)	2 (30.3%)	879.0	£5,483.73	£31.00	£4,847,447.67
	treated	3 (19.5%)	566.7	£6,233.23	£31.00	£3,543,674.91
		4 (12.7%)	368.4	£7,091.20	£31.00	£2,623,818.48
Patients with AF		5 (3.8%)	110.2	£8,310.00	£31.00	£919,178.20
Putients with Ar		0 (6.9%)	6.8	£2,570.02	£0.00	£17,476.14
		1 (26.8%)	26.5	£3,685.68	£0.00	£97,670.52
	FN (99)	2 (30.3%)	30.0	£4,975.34	£0.00	£149,260.20
	untreated	3 (19.5%)	19.3	£6,934.92	£0.00	£133,843.96
		4 (12.7%)	12.6	£9,102.07	£0.00	£114,686.08
		5 (3.8%)	3.8	£11,829.92	£0.00	£44,953.70
Patients without AF	FP (10,864)	-	-	£0.00	£31.00	£336,784.00
rutients without Ar	TN (86,136)	-	-	£0.00	£0.00	0
* ECG cost only	·		·		<u>'</u>	·

^{*} ECG cost only

Total	£16,487,121.43
Total cost per screened patient	£164.87

Table G2. WatchBP total costs for 100,000 patients aged between 75-84 years old.

	Patient group (n)	CHADS2 score category (%)	Number of patients within each CHADS2 category	10 year management cost per patient (£)	Diagnostic cost per patient*(£)	Total Cost
		1 (28.7%)	1,998.4	£3,460.04	£31.00	£6,976,494.34
		3 (32.5%)	2,263.0	£4,680.13	£31.00	£10,661,287.19
	TP (6,963)	3 (20.9%)	1,455.3	£5,286.59	£31.00	£7,738,688.73
	treated	4 (13.6%)	947.0	£6,053.49	£31.00	£5,762,012.03
		5 (4.0%)	278.5	£7,106.64	£31.00	£1,987,832.74
Patients with AF		6 (0.3%)	20.9	£8,540.30	£31.00	£158,240.17
Pulletius With AF		1 (28.7%)	68.0	£3,119.98	£0.00	£212,158.64
		3 (32.5%)	77.0	£4,328.18	£0.00	£333,269.86
	FN (237)	3 (20.9%)	49.5	£5,924.25	£0.00	£293,250.38
	untreated	4 (13.6%)	32.2	£8,004.60	£0.00	£257,748.12
		5 (4.0%)	9.5	£10,435.47	£0.00	£99,136.97
		6 (0.3%)	0.7	£12,941.06	£0.00	£9,058.74
Patients without AF	FP (10,393)	-	-	£0.00	£31.00	£322,183.00
rutients without Ar	TN (82,407)	-	-	£0.00	£0.00	0
* FCG cost only						

^{*} ECG cost only

Total	£34,811,360.90
Total cost per	·
screened patient	£348.11

Appendix H - Manual pulse palpation total costs

Table H1. Pulse palpation total costs for 100,000 patients aged between 65-74 years old.

	Patient group (n)	CHADS2 scores category (%)	Number of patients within each CHADS2 category	10 year management cost per patient (£)	Diagnostic cost per patient*(£)	Total Cost
Patients with AF		0 (6.9%)	180.4	£2,230.02	£31.00	£407,888.01
		1 (26.8%)	700.8	£4,092.05	£31.00	£2,889,433.44
	TP (2,615)	2 (30.3%)	792.3	£5,483.73	£31.00	£4,369,320.58
	treated	3 (19.5%)	509.9	£6,233.23	£31.00	£3,194,130.88
		4 (12.7%)	332.1	£7,091.20	£31.00	£2,365,282.62
		5 (3.8%)	99.4	£8,310.00	£31.00	£829,095.40
		0 (6.9%)	26.6	£2,570.02	£0.00	£68,362.53
		1 (26.8%)	103.2	£3,685.68	£0.00	£380,362.18
	FN (385)	2 (30.3%)	116.7	£4,975.34	£0.00	£580,622.18
	untreated	3 (19.5%)	75.1	£6,934.92	£0.00	£520,812.49
		4 (12.7%)	48.9	£9,102.07	£0.00	£445,091.22
		5 (3.8%)	14.6	£11,829.92	£0.00	£172,716.83
Patients without AF	FP (18,129)	-	-	£0.00	£31.00	£561,999.00
	TN (78,871)	-	-	£0.00	£0.00	0
* CCC anat and	•	•	•			

^{*} ECG cost only

Total	£16,785,117.36
Total cost per screened patient	£167.85

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Table H2. Pulse palpation total costs for 100,000 patients aged between 75-84 years old.

	Patient group (n)	CHADS2 score category (%)	Number of patients within each CHADS2 category	10 year management cost per patient (£)	Diagnostic cost per patient*(£)	Total Cost
Patients with AF		1 (28.7%)	1,800.9	£3,460.04	£31.00	£6,287,013.94
		3 (32.5%)	2,039.4	£4,680.13	£31.00	£9,607,878.52
	TP (6,275)	3 (20.9%)	1,311.5	£5,286.59	£31.00	£6,974,019.29
	treated	4 (13.6%)	853.4	£6,053.49	£31.00	£5,192,503.77
		5 (4.0%)	251.0	£7,106.64	£31.00	£1,791,547.64
		6 (0.3%)	18.8	£8,540.30	£31.00	£142,340.44
		1 (28.7%)	265.5	£3,119.98	£0.00	£828,354.69
		3 (32.5%)	300.6	£4,328.18	£0.00	£1,301,050.91
	FN (925)	3 (20.9%)	193.3	£5,924.25	£0.00	£1,145,157.53
	untreated	4 (13.6%)	125.8	£8,004.60	£0.00	£1,006,978.68
		5 (4.0%)	37.0	£10,435.47	£0.00	£386,112.39
		6 (0.3%)	2.8	£12,941.06	£0.00	£36,234.97
Patients without AF	FP (17,344)	-	-	£0.00	£31.00	£537,664.00
	TN (75,456)	-	-	£0.00	£0.00	0
* ECC cost only	, , ,					I

^{*} ECG cost only

Total	£35,236,856.75
Total cost per screened	
patient	£352.37

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