National Institute for Health and Clinical Excellence

WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension

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1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1.1 The case for adopting WatchBP Home A in the NHS, for opportunistically detecting asymptomatic atrial fibrillation during the measurement of blood pressure by primary care professionals, is supported by the evidence. The available evidence suggests that the device reliably detects atrial fibrillation and may increase the rate of detection when used in primary care. This would allow prophylactic treatment to be given to reduce the incidence of atrial fibrillation-related stroke. WatchBP Home A should be considered for use in people with suspected hypertension and those being screened or monitored for hypertension, in primary care.

1.2 People suspected of having atrial fibrillation after use of WatchBP Home A should have an electrocardiogram (ECG) in line with NICE clinical guideline 36, Atrial fibrillation.

1.3 Use of WatchBP Home A in primary care is associated with estimated overall cost savings per person measured, ranging from £2.98 for those aged between 65 and 74 years to £4.26 for those aged 75 years and over. There is uncertainty about the costs and benefits for people younger than 65, however it is plausible that using the device in this group will benefit patients and the healthcare system. Cost analyses did not support the use of the device by patients in their homes.

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2 The technology

Description of the technology

2.1 The WatchBP Home A device (Microlife) is an oscillometric blood pressure monitor. While recording blood pressure, it automatically detects pulse irregularity that may be caused by symptomatic or asymptomatic atrial fibrillation. The device measures blood pressure based on the guidelines from the European Society of Hypertension (ESH), the American Heart Association (AHA) and the British Hypertension Society (BHS). The monitor can be used for diagnosing hypertension in a clinical setting with the measurement taken under the supervision of a clinician. If hypertension is detected or suspected, the instructions for use state that the device could also be used by the person in their home for monitoring blood pressure over a longer period.

2.2 The WatchBP Home A device has an embedded algorithm that calculates the irregularity index (standard deviation divided by mean) based on interval times between heartbeats. If the irregularity index exceeds a defined threshold value, atrial fibrillation is likely to be present and an atrial fibrillation icon is displayed on the device. If atrial fibrillation is persistent, the diagnosis will be confirmed by an ECG in line with the NICE clinical guideline on atrial fibrillation. If atrial fibrillation is intermittent (paroxysmal), further ambulatory electrical monitoring tests may be needed to establish the diagnosis. To minimise the potentially misleading effect of premature beats when detecting pulse irregularity, each of the pulse beat intervals that deviates more than 25% from the average interval time is excluded from analysis.

2.3 The WatchBP Home A device can be used either in 'diagnostic' mode (4 measurements, 2 between 6 am and 9 am, and 2 between 6 pm and 9 pm, taken on 7 consecutive days) or in 'usual' mode (single measurements taken at any time). Results are stored in an internal memory or can be downloaded to a removable memory device and taken to the clinician for evaluation. In diagnostic mode, this would be after 7 days of monitoring, whereas a variable interval would be agreed with the clinician for monitoring in 'usual' mode. The device automatically displays the mean morning, evening and overall blood pressure results in a table.

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2.4 The average cost of the WatchBP Home A device stated in the sponsor's submission is £75 (excluding VAT).

2.5 The claimed benefits of WatchBP Home A in the case for adoption presented by the sponsor are:

- Provision of a convenient, portable means of measuring blood pressure while simultaneously detecting atrial fibrillation.
- Reduced risk of stroke by earlier diagnosis of atrial fibrillation, allowing the initiation of appropriate treatment to reduce thromboembolic risk.
- Reduced morbidity and mortality associated with stroke events.
- Reduced need for clinic appointments for measuring blood pressure.
- Cost savings from the reduced incidence of stroke resulting from enhanced diagnosis and treatment of atrial fibrillation.

Current management

2.6 Hypertension is diagnosed by measuring blood pressure either manually or with an automated blood pressure monitor, as outlined in NICE clinical guideline 127 on hypertension. Readings are taken initially in a clinic and can be followed by ambulatory blood pressure monitoring to confirm the diagnosis. Home blood pressure monitoring (usually using an automated monitoring device) can be undertaken for between 4 and 7 days as an alternative if ambulatory monitoring is unsuitable for the person. Treatment options for hypertension include lifestyle changes and/or antihypertensive drugs.

2.7 NICE clinical guideline 127 on hypertension recommends that blood pressure should be measured manually using direct auscultation over the brachial artery following detection of pulse irregularity.

2.8 The current care pathway for atrial fibrillation is described in the NICE clinical guideline on atrial fibrillation. Atrial fibrillation can be difficult to detect and subsequently diagnose as it is often asymptomatic and can be intermittent. The irregularity of heart rhythm caused by atrial fibrillation can be detected by

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pulse palpation. It may be present in people with symptoms such as palpitations, dizziness, blackouts and breathlessness but can also be found incidentally in people without symptoms during routine examination. The NICE clinical guideline on hypertension recommends that the pulse should be palpated before measuring blood pressure if using an automated monitor. The diagnosis of atrial fibrillation should be confirmed with an ECG when an irregular pulse is identified.

2.9 Current treatment options for atrial fibrillation are dependent on type (acute, persistent, paroxysmal or permanent), response to previous treatment and comorbidities. Treatment is focused on controlling heart rhythm or rate with antiarrhythmic drugs or electrical direct current cardioversion, and reducing the risk of thromboembolic complications with anticoagulant or antiplatelet drugs, according to an individual person's risk profile.

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3 Clinical evidence

Summary of clinical evidence

3.1 Full details of all clinical outcomes considered by the Committee are available in the assessment report overview.

3.2 The key clinical outcomes for WatchBP Home A presented in the decision problem were:

- diagnostic accuracy for hypertension
- diagnostic accuracy for atrial fibrillation
- incidence of atrial fibrillation-related stroke in people in whom atrial fibrillation is detected
- reduced mortality from atrial fibrillation-related stroke
- reduced disability from atrial fibrillation-related stroke
- device-related adverse events.

3.3 The clinical evidence for WatchBP Home A was based on 5 studies focusing mainly on the diagnostic accuracy of the WatchBP Home A algorithm to detect atrial fibrillation, compared with the recognised standard of 12-lead ECG. These included 3 cross-sectional diagnostic studies, a small case series (19 patients) with diagnostic outcomes, and an unpublished comparative diagnostic cohort study. An ongoing comparative diagnostic study was identified as relevant to the decision problem but no results were available for consideration.

3.4 The External Assessment Centre used data from 2 further studies evaluating the diagnostic accuracy of manual pulse palpation for atrial fibrillation against 12-lead ECG (Cooke et al., 2006; Hobbs et al., 2005) to make a comparison with the WatchBP Home A device.

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3.5 The study by Wiesel et al. (2004) compared the sensitivity, specificity and diagnostic accuracy of a home blood pressure monitoring device (the Omron 712C automatic sphygmomanometer), modified to detect pulse irregularity (and hence atrial fibrillation), with 12-lead ECG. The study used the same algorithm as that included in the WatchBP Home A device. The study included an initial cohort of 125 inpatients from a hospital in New York, USA, and a main cohort of 450 outpatients from a US cardiology clinic, all of whom had had 12-lead ECGs before the intervention. Of these patients, 53 inpatients and 54 outpatients had atrial fibrillation diagnosed on ECG examination. Patients with a pacemaker were excluded from the study, as were patients for whom data were not available from 2 readings. The included outpatients (n=446) had 2 successive readings taken with the modified sphygmomanometer during a scheduled clinic visit. An irregularity index, defined as the standard deviation of the time interval between beats divided by the mean of the time interval, was used to analyse ECGs from the inpatient cohort. A threshold irregularity index was selected as a value that all ECGs showing atrial fibrillation would exceed. The threshold index was then used to determine the diagnostic accuracy of the device; the rhythm was considered to be irregular if 2 successive, paired readings were greater than the threshold index. The External Assessment Centre noted that the protocol to detect atrial fibrillation in this study was defined as 2 successive positive results, as opposed to the 'usual' mode of the WatchBP Home A, which is defined as 3 successive positive readings. An analysis of 446 paired readings showed that the device had a sensitivity of 100%, a specificity of 91%, and a diagnostic accuracy of 92% for detecting atrial fibrillation. The confidence intervals and statistical significance of these results were not reported.

3.6 Wiesel et al. (2009) conducted a study on 405 cardiology outpatients visiting 2 clinics in the US, to determine the diagnostic accuracy of a Microlife oscillometric automatic home blood pressure monitor (BP3MQ1). This device used the same algorithm as that included in WatchBP Home A, to detect pulse irregularity likely to be atrial fibrillation. The study population was considered representative of people at risk of atrial fibrillation. A 12-lead ECG and 3 sequential readings with the home monitor were taken for each patient during their visit to the clinic. Two positives out of 3 readings was considered indicative of atrial fibrillation. Patients with pacemakers or defibrillators were

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excluded. The irregularity index and threshold value identified in the earlier study by Wiesel et al. (2004) were used to determine diagnostic accuracy (see section 3.5). Of the 405 patients tested, 93 (23%) patients had atrial fibrillation diagnosed by ECG readings and of these, 90 were correctly identified using the home monitor after 3 readings. For single readings, the home monitor had a sensitivity of 95% (95% confidence interval [CI] 93 to 98) and a specificity of 86% (95% CI 84 to 89). For 3 sequential readings, it had a sensitivity of 97% (95% CI 91 to 99) and a specificity of 89% (95% CI 85 to 92). Of the 64 patients with abnormal rhythms not attributable to atrial fibrillation on the ECG, the home monitor correctly classified them as non-atrial fibrillation in over 50% of cases overall. The specificity of the device for patients in sinus rhythm was 97%.

3.7 Stergiou et al. (2009) performed a study to determine the diagnostic accuracy of a Microlife oscillometric automatic home blood pressure monitor (BPA100 Plus) including the same algorithm as that in WatchBP Home A to detect atrial fibrillation. The study population was recruited from people attending an outpatient hypertension clinic or admitted to a university medical ward in Athens, Greece, and also included healthy volunteers. In total, 73 patients were recruited, including 27 with known persistent atrial fibrillation, 23 with non-atrial fibrillation arrhythmias, and 23 with sinus rhythm to act as controls. Patients with pacemakers or defibrillators were excluded. For each patient, 3 successive blood pressure readings were taken using the home monitor, while a 12-lead ECG was recorded simultaneously during each measurement. The algorithm used the irregularity index and threshold value identified in the study by Wiesel et al. (2004) (see section 3.5). The sensitivity and specificity of the home monitor for atrial fibrillation diagnosis were assessed for single, duplicate and triplicate measurements. A total of 217 simultaneous blood pressure measurements and ECG recordings were obtained from 73 patients. The sensitivity of the device was 93% (95% CI 74 to 99) and the specificity was 89% (95% CI 76 to 96) for detecting atrial fibrillation from a single measurement. If 1 positive reading from 2 taken was needed to indicate atrial fibrillation, the sensitivity was 100% (95% CI 84 to100) and specificity was 76% (95% CI 60 to 87). For triplicate measurements, if 2 positive readings were needed to detect atrial fibrillation, the sensitivity was 100% (95% CI 84 to 100) and specificity was 89% (95% CI 75 to 96). The

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authors concluded that 2 positive readings out of 3 taken was the optimal diagnostic mode for the device. Of 5 false positives observed, all showed some heartbeat irregularity during ECG measurement.

3.8 Wiesel et al. (2007) carried out a case series study to determine the efficacy of a modified home blood pressure monitor (Omron 712C automatic sphygmomanometer), with the same embedded algorithm as that included in WatchBP Home A, to detect atrial fibrillation when used by patients at home over an extended period of up to 5 months. A group of 19 patients, who were in sinus rhythm at their clinic visit, but with at least 1 previous episode of atrial fibrillation, was recruited from a hospital-based clinic in the US. The mean patient age was 74. During the study period, 6 patients were receiving antiarrhythmic medication and 11 were receiving warfarin. Patients were given the device to monitor their blood pressure once per day for up to 30 days if no irregularity was detected. If irregularity was detected, patients were asked to repeat their readings up to 3 times and in the case of 3 positive readings, to return to the clinic for an ECG. Patients were monitored for between 5 days and 5 months and an ECG was carried out at each clinic visit regardless of the home monitor readings. The monitor correctly identified recurrent atrial fibrillation in 7 patients. Throughout the study period, 9 patients had no irregular readings and in 3 patients irregular readings were identified because of sinus arrhythmia or ectopy; these were therefore false positives. One patient with atrial fibrillation had intermittently regular readings, which may have been atrial flutter.

3.9 Wiesel et al. carried out a comparative study in the USA. The Committee considered detailed findings from this study in an unpublished paper presented as academic-in-confidence (Wiesel et al., 2012). The findings have been presented as a poster (Wiesel, Saji and Messineo, 2010). The authors compared the accuracy of a Microlife home blood pressure monitor containing the WatchBP Home A algorithm with an ECG event monitor (Heartrak 2) in diagnosing atrial fibrillation in a home setting. Patients (n=160) aged 65 or over, or with hypertension, diabetes, congestive heart failure or a history of stroke, were given both devices to use at home for 30 days. The patients were instructed to follow a protocol in which home monitor and ECG readings were recorded and transmitted to the investigators. ECG recordings were used to

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determine the diagnostic accuracy of the home monitor. After a series of positive monitor readings, a second ECG was taken and used to confirm a true or false positive reading. Analysis was based on 139 patients, after considering withdrawals, exclusions and incomplete data. Of these, 16 patients had a history of previous atrial fibrillation. A total of 3896 home monitor readings were taken with corresponding ECG readings. The home monitor detected atrial fibrillation with a sensitivity of 98.5% (95% CI 92.8 to 99.9) and a specificity of 91.7% (95% CI 91.4 to 92.3). The device detected atrial fibrillation in all patients who had at least 1 atrial fibrillation-positive ECG, and in 8 patients with a history of atrial fibrillation who were diagnosed with the condition during the study period and who followed the protocol correctly. The device also detected atrial fibrillation in 2 asymptomatic patients with no history of atrial fibrillation, whose diagnosis was confirmed by ECG. The home monitor also made 7 false positive diagnoses.

3.10 An unpublished report containing interim data from a pilot study carried out in 15 GP practices in the north Hull locality group, covering a population of 54,000 (19% of the total primary care trust population) was also considered (Hancocks, M: personal communication, 2012). The GP practices used 80 WatchBP Home A devices over a 6 month period. Atrial fibrillation prevalence was compared between practices using the WatchBP Home A monitors and other localities with a broadly similar profile. Overall, 160 new cases of atrial fibrillation were identified across all Hull practices, 71 (44%) of which were made using WatchBP Home A. This equates to an increase in atrial fibrillation prevalence from 1.17% to 1.22% across all practices. Prevalence in the practices using WatchBP Home A increased by 0.8% compared with 0.4% in those not using the device.

Committee considerations

3.11 The Committee considered that the studies described above, although conducted in a hospital setting, provided evidence that the WatchBP Home A device was able to detect pulse irregularity in people having their blood pressure measured. The Committee then considered the setting in which the device would be used and concluded that the most likely benefit would be from using the WatchBP Home A device in primary care to detect asymptomatic

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atrial fibrillation during blood pressure measurement, rather than as a home monitoring device, for the reasons described in 3.12–3.15.

3.12 The Committee noted that ambulatory blood pressure monitoring is the preferred method for establishing a diagnosis of hypertension in people with raised blood pressure measured in the clinic, in line with the NICE clinical guideline 127 on hypertension. It considered that there was not enough evidence to justify using the WatchBP Home A device in place of ambulatory blood pressure monitoring for suspected hypertension.

3.13 The Committee noted that evidence that the WatchBP Home A device could detect atrial fibrillation in people having their blood pressure measured at home was limited to a small case series and an unpublished study.

3.14 The Committee concluded that because the NICE clinical guideline on hypertension recommends that home blood pressure monitoring should be undertaken twice daily for between 4 and 7 days, it would be unlikely that the device would detect asymptomatic, paroxysmal atrial fibrillation under these circumstances.

3.15 The Committee considered that the most likely benefit from using the device in primary care would be to increase the rate of detection of atrial fibrillation in people having their blood pressure measured and thereby reducing stroke incidence. Although the Committee acknowledged that there were limited data to support the clinical utility of this scenario, it was persuaded by data from the pilot study in GP practices in north Hull. This study showed that using the WatchBP Home A device may as much as double the detection rate of atrial fibrillation when used in this setting, compared with manual pulse palpation.

3.16 The Committee noted that in order to access the treatment pathway recommended in NICE clinical guideline 36 on atrial fibrillation, people with suspected atrial fibrillation detected by the WatchBP Home A device should have an ECG.

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4 NHS considerations

System impact

4.1 The sponsor claimed that using the WatchBP Home A device will reduce the number of clinic appointments for blood pressure monitoring.

Committee considerations

4.2 The Committee noted that no evidence was presented in support of the claim.

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5 Cost considerations

Cost evidence

5.1 The sponsor submitted a de novo analysis of the costs and consequences of using WatchBP Home A, compared with pulse palpation by a nurse or GP, to detect irregular pulse in people with suspected or existing hypertension or those being screened for hypertension. The model was based in primary care and used estimates of diagnostic accuracy from published evidence. Full details of all cost evidence and modelling considered by the Committee are available in the assessment report overview.

5.2 The main consequences included in the model were: referral for confirmation of atrial fibrillation with consultant-led 12-lead ECG, use of anticoagulant drugs and aspirin, adverse effects of anticoagulants and aspirin, and number of strokes prevented. The time horizon of the model was 1 year.

5.3 The key assumptions used in the model were:

- New cases of atrial fibrillation would occur at a fixed number (87,000) each year based on a published annual incidence rate.
- Each of these people would be screened for atrial fibrillation.
- Atrial fibrillation was related to an annual 4% risk of having a stroke.
- 56% of patients diagnosed with atrial fibrillation would be prescribed anticoagulants and 32% would be prescribed aspirin.
- 2.4% of all patients prescribed anticoagulants would have major bleeds and 15.8% would have minor bleeds.
- For every 5.7 patients detected as having an irregular pulse, only 1 would be confirmed as having atrial fibrillation by ECG.

5.4 The diagnostic accuracy of WatchBP Home A was estimated from Wiesel et al. (2009) (96.8% sensitivity and 88.8% specificity) and Stergiou et al. (2009) (100% sensitivity and 89% specificity). The diagnostic accuracy of pulse

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palpation was estimated from Morgan et al. (2002) (91% sensitivity and 74% specificity) and Hobbs et al. (2005) (87.2% sensitivity and 81.3% specificity). The clinical variable estimates used in the model were derived from the costing report from the NICE clinical guideline on atrial fibrillation. These were: the probability of starting anticoagulant or antiplatelet drugs, absolute risk reduction of having a stroke if on anticoagulant or antiplatelet therapy, and the probability of a minor bleed or a major bleed.

5.5 The cost of an ECG was estimated to be £36.03, taken from the costing report from the NICE clinical guideline on atrial fibrillation, adjusted for inflation (5%). The cost of pulse palpation was estimated to be £2.32, derived from Hobbs et al. (2005) and adjusted for inflation. The capital cost of the WatchBP Home A device was not included in the analysis because the sponsor assumed that GPs would need to purchase a blood pressure monitor for routine practice.

5.6 The base-case analysis showed that in primary care the WatchBP Home A device would lead to an annual saving of £9,165,000 for the NHS in England and Wales by displacing pulse palpation, based on the assumption that all people with atrial fibrillation were symptomatic and that the cost of stroke was £9906 per person. The WatchBP Home A device was associated with the prevention of 221 strokes, freeing NHS resources equivalent to £2,289,000.

5.7 A deterministic sensitivity analysis was carried out by the sponsor testing the proportion of people with atrial fibrillation who were symptomatic (100%, 65% or 50%) and varying the cost of stroke (£44,000 rather than £9906). The sensitivity analysis demonstrated that increasing the proportion of asymptomatic patients would lead to a reduced saving when using the WatchBP Home A device. If 50% of patients were assumed to be asymptomatic, using the device would incur costs. Conversely, if the more expensive estimate of stroke costs was used, using WatchBP Home A would generate further savings.

5.8 The External Assessment Centre carried out a multivariate sensitivity analysis to examine the impact of changing the following parameters:

- prevalence of atrial fibrillation in the study population

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- sensitivity and specificity of pulse palpation and the WatchBP Home A device
- including and excluding the cost of pulse palpation.

5.9 The sensitivity analyses showed that excluding the cost of time associated with pulse palpation did not make pulse palpation less costly than the WatchBP Home A in any single scenario. In addition, the worst-case sensitivity and specificity values increased costs in all cases; similarly, the best-case sensitivity and specificity values decreased costs in all cases compared with the base-case sensitivity and specificity. Total cost was highly sensitive to the prevalence of atrial fibrillation, with costs for populations with a higher prevalence higher than for those with a lower prevalence, both for the WatchBP Home A device and for pulse palpation.

5.10 The sponsor's de novo cost analysis in primary care was limited to a 1-year time horizon and did not include device costs. In its initial review of the cost analysis, the Committee requested further modelling of the longer-term impact of the device on the treatment pathway. The External Assessment Centre therefore carried out additional modelling to establish the longer-term cost impact of using WatchBP Home A in primary care for the opportunistic detection of atrial fibrillation during routine blood pressure measurement. This model also aimed to address uncertainties surrounding the costs of stroke present in the sponsor's original analysis.

5.11 In the External Assessment Centre's additional model, the comparator was defined as blood pressure measurement using a manual or automated sphygmomanometer, with manual pulse palpation to detect atrial fibrillation. A decision tree was used to model the costs associated with the diagnostic accuracy of the device and pulse palpation compared with 12-lead ECG, in terms of true or false positives or negatives. This was accompanied by a state transition model to simulate 10-year cost consequences of managing identified atrial fibrillation (true positives) in a simulated cohort of patients. Outcomes were also modelled for those with atrial fibrillation not detected by either diagnostic method (false negatives).

5.12 Patients identified as having atrial fibrillation were entered into the model in 2 cohorts according to age (65 or 75 years). Cohorts were classified according

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to stroke risk, using a clinical risk prediction scoring system of 0 to 6 ($CHADS_2$) based on cumulative risk factors (for example congestive heart failure, hypertension, age over 75 years, diabetes mellitus and previous stroke). $CHADS_2$ scores were used to stratify patients into low, moderate or high risk in order to determine the allocation of aspirin or anticoagulant therapy within the cohorts, in line with clinical guidelines. The false positive cohort was classified according to age and $CHADS_2$ score but received no management. The clinical outcomes considered in the model were the prevention of fatal and non-fatal stroke and gastrointestinal bleeding caused by prophylactic drug therapy to reduce the risk of stroke. Costs were applied to each clinical consequence and state in the model, and accumulated to form an overall cost.

5.13 Key assumptions in the model were:

- A confirmatory 12-lead ECG with 100% sensitivity and specificity would be carried out immediately after the detection of suspected atrial fibrillation.
- Patients had 1 blood pressure measurement during the 10-year period of the model.
- Patients received the same drug treatment throughout the duration of the model.
- The model considered gastrointestinal bleeding as a one-off event with no change in management and no difference in cost or clinical outcome dependent on cause.
- No treatments other than aspirin and anticoagulant therapy were considered.
- Stroke was considered in 3 clinical states: the first year after the stroke, subsequent years after the stroke, and fatality, with subsequent risk adjusted accordingly. The possibility of recurrent non-fatal strokes was not included in the model, nor was the increased likelihood of stroke occurring over the 10-year period.

5.14 The diagnostic accuracy of WatchBP Home A was estimated from Wiesel et al. (2009) (96.8% sensitivity and 88.8% specificity). The diagnostic accuracy of pulse palpation was estimated from Hobbs et al. (2005) (87.2% sensitivity and 81.3% specificity). The cohorts were allocated $CHADS_2$ scores based on a study by Gage et al. (2001), adjusted according to starting age. Other transitional variables such as stroke incidence, proportion of fatal strokes, proportion experiencing major gastrointestinal bleeding, proportion dying from

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other causes and relative risk reduction of stroke were taken from national statistics or published evidence.

5.15 Annual treatment costs and costs for major gastrointestinal bleeding were taken from the costing report from the NICE clinical guideline on atrial fibrillation, adjusted for inflation (5%). The estimates were £489 per patient for anticoagulant therapy, a negligible cost for aspirin and £2008 for a major bleed. The costs of non-fatal stroke were considered in 2 phases and were taken from a health technology assessment study by Hemingway et al. (2010) and estimated to be £12,565 for the first year and £3315 for subsequent years. The cost of fatal stroke was estimated to be £3036, taken from dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation, NICE technology appraisal 249. The cost of a 12-lead ECG was estimated to be £31, taken from Department of Health 2010/11 reference costs. The time taken for the clinical measurements was considered to be the same for either method and therefore no costs for this were included in the model. The capital outlay cost of immediate replacement of existing monitors with WatchBP Home A was not included in the model but is considered further in section 5.23.

5.16 The External Assessment Centre concluded that, given the use over the lifespan of the device (5 years), the difference in costs per use between WatchBP Home A and a standard home blood pressure monitor would be negligible.

5.17 The diagnostic cost per patient of using WatchBP Home A was calculated to be slightly less than manual pulse palpation: £2.16 in the younger cohort (65–74 years) and £1.94 in the older cohort (75–84 years).

5.18 The model established that treating patients diagnosed with atrial fibrillation by any means was likely to be cost saving in most patient groups. Treating those in the younger cohort would incur a cost of £509 over a 10-year period for those with a $CHADS_2$ score of 2, although this would become cost saving for those with a higher risk of stroke, with a potential saving of £3520 per patient for those with a $CHADS_2$ score of 5. Similarly, in the older cohort, treating those with a $CHADS_2$ score of 1 would incur a cost of £352 per patient, but for those with a score of 6, the cost saving would be £4401 per patient.

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5.19 A base-case analysis found that the overall cost saving per patient from using WatchBP Home A in place of a standard monitor and manual pulse palpation was £2.98 for the younger cohort and £4.26 for the older cohort. Limited sensitivity analyses were carried out, varying the costs of stroke and anticoagulation. Results from this indicated that using WatchBP Home A would remain cost saving despite changes in treatment costs. Raising the cost of stroke increased the potential cost saving of using the device.

5.20 The results revealed that WatchBP Home A was likely to be clinically effective, with 53–117 fatal strokes prevented, and 28–65 non-fatal strokes prevented per 100,000 patients, depending on age. This benefit is likely to be offset against an increase in gastrointestinal bleeds resulting from adverse effects of prophylactic drug therapy to reduce the risk of stroke, of 34–68 per 100,000 patients, also depending on age.

5.21 The sponsor's de novo cost analysis did not consider the cost consequences of using WatchBP Home A for home blood pressure monitoring. The External Assessment Centre was therefore asked to carry out additional analyses to estimate the costs and consequences of using the device in this setting.

5.22 The External Assessment Centre did not consider 2 identified studies carried out in a home setting (Wiesel et al., 2012 and Wiesel et al., 2007) to be suitable to provide parameters to inform the model. It therefore developed a monetised cost consequence model for patients needing home monitoring for hypertension. The population was a simulated cohort of 100,000 including some with paroxysmal atrial fibrillation and some with persistent atrial fibrillation. Each subject was randomly assigned the outcome of either atrial fibrillation detected or absence confirmed. The intervention was use of the WatchBP Home A device at home for either 4 or 7 days. The comparator was defined as an alternative home blood pressure monitoring device without an atrial fibrillation detection algorithm. The study by Wiesel et al. (2009) was used to provide a sensitivity value of 95.3% and a specificity value of 86.4% for atrial fibrillation detection from single diagnostic measurements. The number of strokes prevented was considered as a separate output.

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5.23 The External Assessment Centre included costs associated with replacing home blood pressure monitors with the WatchBP Home A device, using costs taken from the NICE clinical guideline on hypertension for use of a typical home blood pressure monitoring device (£45 annually). The External Assessment Centre considered that, other than the purchase cost of WatchBP Home A (£75), all other costs would be equivalent. Additional capital outlay for purchasing the WatchBP Home A device was estimated at around £620,000 assuming 1 device was purchased per GP practice (8245 practices in England and Wales). This would increase to around £2,700,000 if 1 device was purchased per individual GP.

5.24 The External Assessment Centre was unable to ascertain the prevalence or patterns of paroxysmal atrial fibrillation from the literature, so the following prevalence estimates were used in the model:

- 0.5%, representing the prevalence in people aged 50–59 years (from NICE clinical guideline 36 on atrial fibrillation)
- 1.28%, representing the prevalence in the general population (Majeed et al., 2001)
- 4.4%, representing the sponsor's estimate of atrial fibrillation prevalence
- 7.9%, representing the prevalence in people aged over 65 years (Hobbs et al., 2005)
- 9%, representing the prevalence in people aged 80–89 years (from NICE clinical guideline 36 on atrial fibrillation).

  Sensitivity analysis was carried out to model time spent in atrial fibrillation using varying estimates.

5.25 A base-case analysis of using WatchBP Home A for home blood pressure monitoring showed that using the device would consume NHS and personal social services resources of around £5.32 per person and prevent 22 strokes per 100,000 people screened. In all cases, use of the WatchBP Home A device incurred a cost to the NHS and personal social services. Excluding those in permanent atrial fibrillation (100%), the additional costs incurred per patient ranged from £4.44 per person (9% prevalence, 2% time in atrial fibrillation,

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7 day monitoring) to £10.30 per person (9% prevalence, 50% time in atrial fibrillation, 7 day monitoring).

Committee considerations

5.26 The sponsor's cost analysis showed that WatchBP Home A was cost saving when compared with manual pulse palpation based on the assumption that people with atrial fibrillation were symptomatic. The Committee acknowledged that there were uncertainties in the economic model presented in the sponsor's base case, mainly concerning the costs of stroke and the 1-year time horizon.

5.27 Further modelling was carried out by the External Assessment Centre to establish the longer-term cost impact of using WatchBP Home A in primary care and to provide an estimate of the cost of stroke that was as reliable as possible. From these data, the Committee accepted that the WatchBP Home A device would be cost saving compared with standard blood pressure monitors and manual pulse palpation in patients aged 65 years and older. The Committee also noted that the analyses showed that atrial fibrillation-related fatal and non-fatal strokes could be prevented.

5.28 The Committee considered advice from clinical experts, which indicated that if the device was purchased for use in primary care, it was likely to be used for blood pressure measurement across the whole GP practice population once purchased. The Committee considered 2 scenarios for purchasing WatchBP Home A for use in primary care, which were immediate wholesale replacement of existing monitors and replacement at the end of device lifespan. The Committee was advised that, as cost per use of WatchBP Home A over its 5-year lifespan would be minimal, either scenario would still lead to cost savings over a 10-year time horizon, as modelled.

5.29 The Committee acknowledged that the cost impact of using the device in a population younger than that included in the model was unknown, because there was little data on the prevalence of atrial fibrillation or associated stroke risk in this group. The Committee did consider that despite the potential for the number of false positive results to increase, incidental detection of atrial fibrillation in patients under the age of 65 years would have significant clinical benefits. Advice from clinical experts suggested that treatment for atrial

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fibrillation in younger people at low risk of stroke would be less costly than that for older people. For those at higher risk of stroke, for example with other risk factors contributing to higher $CHADS_2$ scores, use of the device would be likely to generate similar cost savings to those in older people at higher risk.

5.30 The Committee considered that although the findings from the economic modelling indicated that using WatchBP Home A for home blood pressure monitoring could potentially prevent a number of strokes, use of the device in this setting would not be cost saving.

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6 Conclusions

6.1 The Committee concluded that WatchBP Home A was cost saving and could provide significant clinical benefits when used for opportunistic atrial fibrillation detection in asymptomatic patients being screened or monitored for hypertension in primary care.

6.2 The Committee considered that use of WatchBP Home A would be particularly beneficial for older patients at higher risk of stroke.

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7 Implementation

7.1 NICE has developed tools to help organisations put this guidance into practice (listed below).

- Costing template and report to estimate the national and local savings and costs associated with implementation.

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8 Related NICE guidance

Published

- Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation. NICE technology appraisal 256 (2012).
- Dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation. NICE technology appraisal 249 (2012).
- Hypertension: clinical management of primary hypertension in adults. NICE clinical guideline 127 (2011).
- Dronedarone for the treatment of non-permanent atrial fibrillation. NICE technology appraisal 197 (2010).
- Stroke: diagnosis and initial management of acute stroke and transient ischaemic attack (TIA). NICE clinical guideline 68 (2008).
- Alteplase for the treatment of acute ischaemic stroke. NICE technology appraisal 122 (2007).
- Atrial fibrillation: the management of atrial fibrillation. NICE clinical guideline 36 (2006).

Under development

NICE is developing the following guidance:

- Stroke rehabilitation. NICE clinical guideline (expected publication date: June 2013).
- Atrial fibrillation (update). NICE clinical guideline (publication date to be confirmed).

Andrew Dillon
Chief Executive
January 2013

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Appendix A. Committee members and NICE lead team

A Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale NHS Trust

Professor Dilly Anumba
Chair of Obstetrics and Gynaecology/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Ms Susan Bennett
Lay member

Professor Bipin Bhakta
Charterhouse Professor in Rehabilitation Medicine and NHS Consultant Physician, University of Leeds

Dr Keith Blanshard
Consultant Radiologist, Leicester Royal Infirmary

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Dr Martyn Bracewell
Senior Lecturer in Neurology and Neuroscience, Bangor University

Professor Daniel Clark
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Karl Claxton
Professor of Economics, University of York

Mrs Gail Coster
Radiography Manager, Strategy, Planning and Governance, Yorkshire NHS Trust

Dr Alex Faulkner
Senior Research Fellow, Centre for Biomedicine & Society, King's College London

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Peter Gaines
Consultant Interventional Radiologist, Sheffield, Vascular Institute and Sheffield Hallam University

Mr Harry Golby
Head of Commissioning, Acute, Access and Diagnostics, Salford NHS

Mr Matthew Hill
Lay member

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Ms Catherine Leonard
Reimbursement Manager, Medtronic UK

Dr Susanne Ludgate
Clinical Director, Devices Medicines and Healthcare Products Regulatory Agency

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Mrs Jacqui Nettleton
Programme Director, Long Term Conditions, West Sussex PCT

Professor Sharon Peacock
Professor of Clinical Microbiology, University of Cambridge

Professor Brian Pollard
Professor of Anaesthesia, University of Manchester

Dr Allan Swift
Director of Quality, QIAGEN Manchester Ltd

Dr Allan Wailoo
Reader in Health Economics, School of Health and Related Research

Professor Stephen Westaby
Consultant Cardiac Surgeon, John Radcliffe Hospital, Oxford

Dr Janelle Yorke
Lecturer and Researcher in Nursing, University of Salford

B NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, expert advisers, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Joanne Higgins
Technical Analyst

Sally Doss
Technical Adviser

Professor John Cleland
Lead Expert Adviser

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Dr Neil Sulke
Lead Expert Adviser

Professor Daniel Clark
Non-Expert MTAC Member

Dr Iain Willits
External Assessment Centre Representative

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Appendix B: Sources of evidence considered by the Committee

A The External Assessment Centre report for this assessment was prepared by Newcastle and York Consortium:

- Willits I, Reay C, Keltie K et al. WatchBP Home A for diagnosing and monitoring hypertension and detecting atrial fibrillation (February 2012).

B Submissions from the following sponsor:

- Microlife (manufacturer).

C The following individuals gave their expert personal view on WatchBP Home A by providing their expert comments on the draft scope and assessment report.

- Professor John Cleland, ratified by the Royal College of Physicians (RCP) – clinical expert
- Dr Neil Sulke, nominated/ratified by the British Cardiovascular Society (BCS) – clinical expert
- Dr Ameet Bakhai, nominated/ratified by the British Cardiovascular Society (BCS) – clinical expert
- Dr Mark Hancocks, ratified by the Royal College of General Practitioners.

D The following individuals gave their expert personal view on WatchBP Home A in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Professor John Cleland, ratified by the Royal College of Physicians (RCP) – clinical expert
- Dr Neil Sulke, nominated/ratified by the British Cardiovascular Society (BCS) – clinical expert
- Dr Ameet Bakhai, nominated/ratified by the British Cardiovascular Society (BCS) – clinical expert
- Dr Mark Hancocks, ratified by the Royal College of General Practitioners – clinical expert

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- Jo Jerrome, nominated/ratified by the Atrial Fibrillation Association (AFA) – patient expert

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About this guidance

NICE medical technology guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This 'case' is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

This guidance was developed using the NICE medical technologies guidance process.

We have produced a summary of this guidance for the public. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgment. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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