



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

| | |
|----------------------------------|--------------------------------------------------------------------------------------------------------------|
| Topic: | Remote blood pressure telemonitoring in community settings for suspected and confirmed cases of hypertension |
| Topic exploration report number: | TER216 |

Introduction and aims

Hypertension is a long-term, non-communicable medical condition wherein the blood pressure in the arteries is persistently elevated. Hypertension is the major preventable cause of cardiovascular disease and all-cause death globally. For most patients, repeat blood pressure measurements at repeat office visits have been a long-standing strategy to confirm a persistent elevation in blood pressure and classification of the hypertension status.

Remote blood pressure measurement refers to the use of either ambulatory blood pressure monitoring (ABPM) or home blood pressure monitoring (HBPM). These devices can be used to diagnose suspected cases of hypertension, as well as assess the effects of medications/treatment and monitor people with confirmed cases of hypertension.

ABPM devices provide the average of blood pressure readings over a defined period, usually 24 hours. ABPM usually consists of a cuff which wraps around the arm and is inflated by an electric recording device worn on the body. Home blood pressure monitoring (HBPM) involves self-recorded blood measurements at specific times during the day and night over a longer period of time. A smartphone application for both HBPM and ABPM provides blood pressure measurements direct to the clinician (telemonitoring). Ghennix provide a smartphone application and have partnered a clinical blood pressure device manufacturer for both HBPM and ABPM. The HBPM device is the standard table top unit, and the ABPM is a wristwatch format device.

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of ABPM and HBPM devices, with and without telemonitoring, for the diagnosis of people with suspected hypertension and the monitoring of people with confirmed hypertension.

Summary of evidence

HBPM and ABPM devices are digital health technologies and were determined to be a Tier 3b technology according to the [Evidence Standards Framework for Digital Health Technologies](#). This classification covers technologies with measurable user benefits, including tools used for treatment and diagnosis, as well as those influencing clinical management through active monitoring or calculation. For technologies of this classification, it is recommended that high-quality randomised controlled study or studies are produced to demonstrate effectiveness of the technology.

Secondary evidence

Guidance/guidelines

Guidelines produced by the European Society of Cardiology and the European Society of Hypertension (2018) support the use of HBPM and/or ABPM as alternative strategies to repeated office blood pressure measurements to confirm the diagnosis of hypertension, when these measurements are logistically and economically feasible. This approach can provide important supplementary clinical information, e.g. detecting white-coat hypertension.

The British Heart Foundation (2018) published a report specific to Wales stating that there are many undiagnosed and untreated people with hypertension. They recommend that ABPM or, when appropriate, HBPM should always be offered to people with a high blood pressure reading, in order to confirm a diagnosis of hypertension. The report states that health professionals should explore the use of remote monitoring via telehealth or blood pressure apps.

The percentage of patients with a new diagnosis of hypertension confirmed by ABPM or HBPM in the three months before entering onto the register, was made a Quality and Outcomes Framework Indicator by the National Institute for Health and Care Excellence (NICE) in 2013 (NM66).

NICE guideline 136 (2019) recommends that clinic blood pressure measurement (CBPM) alone is not an adequate method to diagnose hypertension, and that ABPM is the preferred method. If ABPM is unsuitable or the person is unable to tolerate it, HBPM should be offered to confirm the diagnosis of hypertension. NICE recommend using CBPM to monitor people with hypertension, but that HBPM should be an option. They recommend ABPM or HBPM, in addition to CBPM, for people with hypertension identified as having a white-coat effect or masked hypertension.

The evidence evaluated by NICE did not suggest that there were any benefits of adding telemonitoring to HBPM. Therefore, the committee agreed that it could not make a recommendation on telemonitoring for the diagnosis of hypertension (NICE. 2019).

NICE medical technologies guidance (MTG) recommends that WatchBP Home A should be considered for use in people with suspected hypertension and those being screened or monitored for hypertension, in primary care. WatchBP Home A is a HBPM device that also detects pulse irregularity that may be caused by atrial fibrillation. Results are stored and taken to the clinician for evaluation (NICE. 2013).

In March 2016, the Scottish Health Technologies Group (SHTG) published advice on the use of home health monitoring for the treatment of hypertension. They advised that whilst evidence was mostly consistent with a reduction in measures of blood pressure with home health monitoring use, it was not possible to draw firm conclusions from the available evidence, or to determine which components of an intervention may be effective, and that future research

should be conducted (SHTG. 2016).

Systematic reviews

Diagnostic accuracy of hypertension

One systematic review found that compared with ABPM thresholds of 135/85 millimetres of mercury (mmHg), CBPM over 140/90 mmHg had mean sensitivity and specificity of 74.6% (95% confidence interval [CI]: 60.7% to 84.8%) and 74.6% (95% CI: 47.9% to 90.4%), respectively, whereas home measurements over 135/85 mmHg had mean sensitivity and specificity of 85.7% (95% CI: 78.0% to 91.0%) and 62.4% (95% CI: 48.0% to 75.0%), respectively (Hodgkinson et al. 2011).

Reduction of stroke and heart attack incidence/mortality connected with hypertension

In a meta-analysis of eight prospective studies of HBPM (n = 17,698, mean follow up of 3.2 years), it was found that HBPM significantly predicted all-cause mortality and cardiovascular mortality, whereas results for CBPM were not significant. Moreover, both HBPM and CBPM significantly predicted cardiovascular events.

Reduction of blood pressure

SHTG advice (2016) was based on a number of studies investigating telemonitoring and hypertension: a systematic review of systematic reviews (Purcell et al. 2014), an additional systematic review and meta-analysis of randomised controlled trials (RCTs) not included in the study by Purcell et al (Omboni et al. 2013), and an additional RCT (McKinstry et al. 2013). The available evidence was consistent with a reduction in clinic systolic blood pressure and ambulatory systolic blood pressure with use of home health monitoring.

In addition to the evidence used to produce SHTG advice, we identified one systematic review investigating the use of ABPM and HBPM telemonitoring devices. Flodgren et al (2015) pooled data from four RCTs (1,170 participants) of moderate-certainty comparing telemedicine to usual care for blood pressure control: three of these studies compared ABPM with CBPM and one compared HBPM with CBPM. The systematic review found some evidence for a decrease in blood pressure with telemonitoring compared with CBPM.

Primary evidence

Organ damage due to hypertension

In a study by Gaborieau et al (2008) of 325 people with hypertension, it was found that ABPM and HBPM were correlated with organ damage more closely than CBPM was.

Quality of life/patient satisfaction

We did not identify any studies investigating quality of life/patient satisfaction as an outcome. SHTG (2016) reported a qualitative interview study conducted with 25 patients in Scotland and found that most participants were positive about the intervention and perceived that it improved access to clinicians and data (Hanley et al. 2013).

Patient adherence

A narrative review by Omboni and Ferrari (2015) investigated 13 studies (1,662 participants) examining patient adherence to HBPM telemonitoring. They found that patients showed an average adherence of 77% to telemonitoring programs. The review looked at 10 studies (1,120 participants) investigating acceptance of telemonitoring HBPM and found an average acceptance of 87% of these techniques by patients.

Cost

The estimated initial cost of indicator NM66 is £2.58 million cost in Year 1 after implementation. The report estimated that diagnosing hypertension with ABPM will mean future savings due to the cumulative effect of accurate testing and the savings of prescribing more accurately antihypertensive drugs (NICE. 2013).

In addition, an economic model used in NICE guideline 136 (2019) confirmed that ABPM is likely to be the most cost-effective method for diagnosis.

NICE MTG13 (2013) reported that 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. Cost analyses did not support the use of the device by patients in their homes.

In the report used to inform SHTG advice (2016), it was suggested that telemonitoring may represent a cost-effective option compared to usual care. A United Kingdom cost utility analysis reported that home health monitoring was likely to be cost effective in both male and female populations, with incremental cost effectiveness ratios of £1,624 and £4,923, respectively.

Areas of uncertainty

The majority of the evidence we identified investigated HBPM/ABPM devices for the control of blood pressure in people already diagnosed with hypertension. We identified limited evidence for the accuracy of HBPM/ABPM devices in the diagnosis of hypertension. This is also true of evidence we identified as being in progress. In addition, most of the evidence we found was for HBPM/ABPM devices without mention of telemonitoring capabilities. Some of the evidence with mention of telemonitoring capabilities is quite dated, and it is unclear whether this is representative of the Ghennix device mentioned in this report.

A high level of heterogeneity was found between many published studies, suggesting that well-designed, large-scale RCTs are needed to prove the clinical usefulness of HBPM/ABPM.

We identified limited evidence investigating the safety, impact on quality of life/patient satisfaction, sustainability and long-term clinical effectiveness of HBPM/ABPM telemonitoring devices. This, along with concerns relating to the inclusion of appropriate costs and utility values, also creates uncertainty surrounding the cost effectiveness.

Conclusions

Guidelines in the UK support the use of HBPM/ABPM devices, but have found limited evidence for the use of telemonitoring with these devices. There appears to be lack of evidence for the effectiveness of HBPM/ABPM devices to diagnose hypertension, to improve patient outcomes and quality of life, and on their economic value. Whilst HBPM/ABPM devices show potentially promising results for monitoring hypertension, the evidence that does exist has a high degree of heterogeneity, and it is suggested that further high-quality research would be beneficial.

Brief literature search results

| Resource | Results |
|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| HTA organisations | |
| Healthcare Improvement Scotland | SHTG Advice Statement 002-16: Home health monitoring for the treatment of hypertension. March 2016: http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/topics_assessed/shtg_002-16.aspx |
| Health Technology Assessment Group | We did not identify any evidence from this resource |
| Health Information and Quality Authority | We did not identify any evidence from this resource |
| UK guidelines and guidance | |
| SIGN | We did not identify any evidence from this resource |
| NICE | NICE guideline (NG136). Hypertension in adults: diagnosis and management. August 2019: https://www.nice.org.uk/guidance/ng136 Medical technologies guidance (MTG13). WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension. January 2013: https://www.nice.org.uk/guidance/mtg13 NM66. Quality and Outcomes Framework (QOF) Indicator Development Programme. Cost impact statement: hypertension. July 2013: https://www.nice.org.uk/standards-and-indicators/qofindicators/the-percentage-of-patients-with-a-new-diagnosis-of-hypertension-diagnosed-on-or-after-1-april-2014-which-has-been-confirmed-by-ambulatory-blood-pressure-monitoring-abpm-or-home-blood-pressure-monitoring-hbpm-in-the-three-months-before-entering-on-to-the-r |
| British Heart Foundation Cymru | High blood pressure. How can we do better? February 2018: https://www.bhf.org.uk/bp-better |
| Secondary literature and economic evaluations | |
| ECRI | We could not access any relevant evidence from this resource |
| EUnetHTA | We did not identify any evidence from this resource |
| Cochrane library | Flodgren G; Rachas A; Farmer AJ; Inzitari M; Shepperd S. 2015. Interactive telemedicine: effects on professional practice and health care outcomes. Cochrane Database of Systematic Reviews: |

| | |
|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | https://doi.org/10.1002/14651858.CD002098.pub2 |
| Medline (Ovid) | <p>Hodgkinson J, Mant J, Martin U, Guo B, Hobbs FDR, Deeks JJ, Heneghan C, Roberts N, McManus RJ. 2011. Relative effectiveness of clinic and home blood pressure monitoring compared with ambulatory blood pressure monitoring in diagnosis of hypertension: systematic review. The British Medical Journal; 342: doi: https://doi.org/10.1136/bmj.d3621</p> <p>Omboni S; Ferrari R. 2015. The role of telemedicine in hypertension management: Focus on blood pressure telemonitoring. Current Hypertension Reports, 17(4): doi:10.1007/s11906-015-0535-3 DOI: 10.1097/HJH.0000000000001867</p> |
| Ongoing primary or secondary research | |
| PROSPERO database <i>Check for recent systematic review protocols.</i> | <p>Okpechi I, Munir S, Zaidi D, Tinwala M, Braam B, Bello A. Impact of Home Telemonitoring and Management Support with Blood Pressure Control in Non-dialysis CKD: A Systematic Review and Meta-Analysis. PROSPERO 2020 CRD42020190705 Available from: https://www.crd.york.ac.uk/prospéro/display_record.php?ID=CRD42020190705 Anticipated completion: 30 June 2021</p> |
| Other | |
| <i>Evidence provided by Topic Proposer</i> | <p>Gaborieau V, Delarche N, Gosse P. 2008. Ambulatory blood pressure monitoring versus self-measurement of blood pressure at home: correlation with target organ damage. Journal of Hypertension;26:1919-1927: https://journals.lww.com/jhypertension/Fulltext/2008/10000/Increasing_plasma_fatty_acids_elevates.5.aspx</p> <p>Ward AM, Takahashi O, Stevens R, Heneghan C. 2012. Home measurement of blood pressure and cardiovascular disease: systematic review and meta-analysis of prospective studies. Journal of Hypertension; 30:449-456: https://journals.lww.com/jhypertension/Fulltext/2012/03000/Home_measurement_of_blood_pressure_and.2.aspx</p> |
| SHTG Evidence Note 59 | <p>Hanley J, Ure J, Pagliari C, Sheikh A, McKinstry B. 2013. Experiences of patients and professionals participating in the HITS home blood pressure telemonitoring trial: A qualitative study. The British Medical Journal Open; 3(5): https://bmjopen.bmj.com/content/3/5/e002671.short</p> <p>McKinstry B; Hanley J; Wild S; Pagliari C; Paterson M; Lewis S; Sheikh A; Krishan A; Stoddart A; Padfield P. 2013. Telemonitoring based service redesign for the management of uncontrolled hypertension: Multicentre randomised controlled trial. The British Medical Journal (Online); 346(7913): doi: https://doi.org/10.1136/bmj.f3030</p> <p>Omboni S; Gazzola T; Carabelli G; Parati G. 2013. Clinical usefulness and cost effectiveness of home blood pressure telemonitoring: meta-analysis of randomized controlled studies. Journal of Hypertension;31(3):455-68: doi: 10.1097/HJH.0b013e32835ca8dd</p> |

Purcell R; McInnes S; Halcomb EJ. 2014. Telemonitoring can assist in managing cardiovascular disease in primary care: a systematic review of systematic reviews. BMC Family Practice;15:43. Epub 2014/03/13.

<https://doi.org/10.1186/1471-2296-15-43>

Date of search:

July 2020

Concepts used:

Home blood pressure monitoring, HBPM, HBPT, ambulatory blood pressure monitoring, ABPM, ABPT, high blood pressure, hypertension, telemonitor, telehealth, telemedicine, diagnosis, screening