Healthcare Improvement Scotland

evidence *note*

In response to an enquiry from Quality and Efficiency Support Team, Scottish Government

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What is the clinical effectiveness and cost effectiveness of home health monitoring devices compared with usual care for patients with hypertension?

What is an evidence note

Evidence notes are rapid reviews of published secondary clinical and cost-effectiveness evidence on health technologies under consideration by decision makers within NHSScotland. They are intended to provide information quickly to support time-sensitive decisions and are produced in a period of up to 12 months. Evidence notes are not comprehensive systematic reviews. They are based on the best evidence that Healthcare Improvement Scotland could identify and retrieve within the time available. The reports are subject to peer review. Evidence notes do not make recommendations for NHSScotland, however the Scottish Health Technologies Group (SHTG) produce an Advice Statement to accompany all evidence reviews.

Key points

- Evidence relating to home health monitoring (HHM) interventions for hypertension showed multiple differences in population characteristics, technological, organisational and clinical aspects of interventions and usual care comparators, preventing firm conclusions being drawn from this literature.
- The available evidence was consistent with a reduction in clinic systolic blood pressure (SBP) (means ranged from 2.63 to 5.64mmHg), clinic diastolic BP (DBP) (means ranged from 1.68 to 2.83mmHg), and ambulatory SBP (ASBP) (means ranged from 2.28 to 4.27mmHg) with use of HHM. In 2011, the National Institute for Health and Care Excellence (NICE) hypertension guideline development group agreed that a minimally important difference in BP was 5mmHg.
- The clinical and longer-term importance of the reductions was not clear and it was not possible to identify which aspects of the HHM intervention may be effective.
- The available evidence reported conflicting findings relating to ambulatory DBP (ADBP), medication use and primary care attendance, and it was not possible to determine whether or not HHM was beneficial for patients with hypertension. Patient satisfaction was not generally reported as an outcome measure, but a qualitative interview study conducted with 25 patients in Scotland found that most participants were positive about the intervention and perceived that it improved access to clinicians and data.
- There was insufficient evidence available to determine whether there was a significant difference in the safety of telemonitoring interventions compared with usual care.
- A United Kingdom cost utility analysis reported that HHM was likely to be cost effective in both male and female populations with incremental cost effectiveness ratios of £1,624 and £4,923 respectively. Cost-effectiveness was reliant on the short-term clinical benefits in SBP being sustained over the long run. However, there are uncertainties relating to the extrapolation of 1-year BP reduction data and technology compliance rates beyond 1-year and also relating to the appropriateness of the cost and utility estimates used in the analysis.

Definitions

Home BP monitoring: monitoring of BP at home by the patient, using a device similar to those found in clinic. Patients record measurements via paper or electronic means and take this information with them to their next in-person clinic appointment[1].

Home health monitoring (HHM): an intervention which 'supports patients to digitally receive or capture information on their condition. If required, physiological and symptom information can be relayed from the home/community setting for clinical review and remote monitoring by health and care staff'[2].

Ambulatory BP (ABP) monitoring: a portable BP monitor cuff, attached to a small device which is worn by the patient as they carry out daily activities[3].

White coat effect: a patient displays ambulatory or home BP measurements within a hypertensive range, but displays a BP measurement in clinic disproportionately greater than their average ambulatory or home BP measurements. As such, patients will require 'out of office' monitoring to provide appropriate treatment and monitor their response to treatment[4].

Systolic BP (SBP): measured pressure when the heart is beating[5].

Diastolic BP (DBP): measured pressure when the heart is resting in between beats[5].

Hypertension: a chronic condition characterised by abnormally high BP, diagnosed when BP measured on separate occasions is consistently 140/90mmHg or higher[6].

Literature search

A systematic search of the secondary literature was carried out between 9–12 June 2015 to identify systematic reviews, health technology assessments and other evidence-based reports. Medline, Medline in process, Embase, Cinahl, Web of Science databases were also searched for systematic reviews and meta-analyses.

As a developing field, it was suspected there may be a small quantity of secondary literature, therefore the primary literature was also systematically searched between 9–12 June 2015, using the following databases: Medline, Medline in process, Embase, Cinahl, Web of Science. Results were limited to English and clinical trial study type. Embase and Medline were searched from inception and Web of Science from 2009–2015. Randomised controlled trials (RCTs) (published subsequently to secondary literature) were then identified.

Key websites were searched for guidelines, policy documents, clinical summaries, economic studies and ongoing trials. Websites of organisations related to this topic, for example the British Hypertension Society, the International Society of Hypertension and Blood Pressure UK were also searched.

Concepts used in all searches included: telehealth, telemonitoring, 'HHM', telemedicine, hypertension, 'high BP'. A full list of resources searched and terms used are available on request.

Introduction

This evidence note summarises published secondary evidence, and one RCT published subsequently, relating to the clinical effectiveness, cost-effectiveness and level of patient satisfaction of HHM for the treatment of hypertension.

The growing number of people with long-term conditions, such as hypertension, is a major challenge for health and social care in Scotland[7]. In the United Kingdom (UK), over 15 million people have a long-term condition[8]. The Scottish Government has given a commitment to commission telehealth services that promote 'shifting the balance of care' towards a more preventative and anticipatory approach, with the aim of supporting people to remain safe and well for as long as possible in their own homes or in a homely setting[9]. In Scotland, HHM has been identified as one of the priority areas to support people with long-term conditions to manage their own health and care[9]. The Scottish Centre for Telehealth and Telecare reports that HHM is being used for BP in Scotland[10], and up to 7,700 people in West Central Scotland will receive HHM for diabetes, chronic obstructive pulmonary disease or heart failure between 2013–2016[2].

Health technology description

HHM does not have a universally agreed definition. The terms telecare, telehealth, telehealthcare, telemonitoring, telemedicine, telehome monitoring and HHM are often used interchangeably.

This review adopts the Scottish Centre for Telehealth and Telecare's definition of HHM as an intervention which 'supports patients to digitally receive or capture information on their condition. If required, physiological and symptom information can be relayed from the home or community setting for clinical review and remote monitoring by health and care staff'[2].

For the purposes of this review, it was assumed that the intervention included an automated BP measuring device operated by the patient, and the transfer of data via a telephone or computer network to a healthcare setting, for remote review by a nurse or doctor.

Epidemiology

Hypertension is the medical term for high BP in the arteries and is a chronic condition[11]. It is one of the main preventable causes of premature morbidity and death in the UK[4] and is a major risk factor for cardiovascular disease[5]. BP is defined as the amount of pressure applied to the walls of arteries when blood travels through them[5]. It is measured in millimetres of mercury, or mmHg, and expressed as SBP over (/) DBP[5]. Although it is essentially inaccurate to specify a threshold of BP at which hypertension exists or does not exist[4], in practice, hypertension is commonly recognised in the UK when BP readings consistently measure 140/90mmHg or higher on separate occasions[6].

The National Institute for Health and Care Excellence (NICE) classifies hypertension as stage 1 (clinic BP is 140/90mmHg or higher and subsequent ABP monitoring (ABPM) daytime average or home BP monitoring (HBPM) average BP is 135/85mmHg or higher), stage 2 (clinic BP is 160/100mmHg or higher and subsequent ABPM daytime average or HBPM average is 150/95mmHg or higher) or severe hypertension (clinic SBP is 180mmHg or clinic DBP is 110mmHg or higher)[4].

Hypertension is idiopathic in 90% of cases[12], but prevalence is strongly affected by age[13] and a number of modifiable and non-modifiable factors can increase the risk of developing the condition[5].

In 2012–2013, an estimated one-third of adults in Scotland had hypertension.Prevalence rises with age to include half of men, and more than two-thirds of women, aged over 75 years[14].

Hypertension is usually asymptomatic and therefore the measurement of BP is essential for diagnosis[6]. The current NHS advice to the general public is for adults to seek guidance from their general practitioner (GP) as to when a check should occur[5]. Therapy can include advice on lifestyle changes alone, or advice and the prescription of antihypertensive medication[3].

In 2012–2013, around 100 out of every 1,000 patients registered with a practice in Scotland consulted the GP or practice nurse at least once because of high BP[15], approximately 571,000 patients with hypertension were seen in Scotland by a GP or practice nurse[11], and there were an estimated 436,630 consultations for high BP with general practitioners and 846,910 with practice nurses[15].

Clinical effectiveness

Systematic literature searching identified a systematic review (SR) of systematic reviews, an additional systematic review of RCTs[17] not included within that overview[16,] and an additional RCT[18], published subsequently to the systematic review of RCTs. There was widespread heterogeneity in the studies included. For example, study population inclusion criteria reflected various co-morbidities and stages of hypertension, and interventions ranged widely in terms of devices used to capture data, frequency of data capture, method of data transmission, intensity of data monitoring, clinical feedback, provider and duration of intervention. Clinical settings varied from UK primary care to United States hospital outpatient settings and associated usual care comparators also ranged from United States patients with no healthcare insurance to UK patients experiencing usual care.

For this report, conventional care, control, usual care and disease management were all considered as 'usual care'. There are challenges associated with reviewing evidence on the effectiveness of HHM. In addition to the complex nature of the intervention, usual care also varies depending on the configuration and quality of care provided. This complexity affects the design, delivery and assessment of trials investigating the effectiveness of the intervention. The absence of a standard definition of HHM also posed a challenge when reviewing and reporting the evidence base. Table 1 summarises key characteristics of the included studies.

Table 1 Summary table of key characteristics of included studies

First author and study design	Hypertension stage(s) of participants	Number of studies (Number of participants)	Technological intervention components	Organisational intervention components	Clinical intervention components
Purcell[17] (SR of SRs)	Not reported (NR) in SR1; in remaining 2 SRs included stage 1 and stage 2; patients who did not meet threshold for diagnosis may also have been included.	3 SRs	NR in SR1; in remaining 2 SRs varied technology, models, and data transmission systems.	NR in SR1; in remaining 2 SRs varied frequency of data capture and transmission.	NR in SR1; in remaining 2 SRs varied intensity and timeliness of professional monitoring.
Omboni[16] (SR and meta-analysis of RCTs)	Varied; included stage 1 and stage 2.	23 RCTs	Varied technology, models, and data transmission systems.	Varied frequency of data capture and transmission.	Varied intensity and timeliness of professional monitoring.
McKinstry[18] (RCT)	Varied; included stage 1 and stage 2.	(n=401)	Electronic BP monitor (Stabil-O-Graph mobil; IEM, Stuttgart, Germany) and bluetooth enabled mobile phone transmitted BP readings to a secure website.	After an initial period, participants were asked to send readings at least weekly. Participants were able to see their data via the secure site. Optional automated texts or emails could be sent to participants every 10 readings or weekly.	Participants could contact clinicians if they wished Clinicians were able to access the participants' readings via the secure site: they were encouraged to check participants' records weekly, but were able to decide independently how frequently to log on.
Hanley[19] (Qualitative study)	Maximum variation sample from McKinstry *et al.*[18] study	(n=45) (25 patients)	As per McKinstry *et al.*[18] study	As per McKinstry *et al.*[18] study	As per McKinstry *et al.*[18] study

Outcomes

BP was the most frequently reported outcome: Table 2 summarises the reported data. High BP is a well documented risk factor for cardiovascular disease and in 2011 the NICE guideline development group decided that a minimally important difference in BP was 5mmHg (mean difference)[20]. Patient satisfaction was generally not used as an outcome measure in the included secondary literature, although quality of life was often measured. A detailed search for qualitative research relating to patient experience(s) or perceptions of HHM was beyond the remit of an evidence note, so the literature available was limited to that emerging from the clinical and cost effectiveness search.

Studies often neglected to account for factors which might potentially affect BP outcome such as levels of antihypertensive medication, lifestyle factors, and the 'white coat effect'. A flaw in many studies was that despite being acknowledged as the most accurate measure[4], ambulatory SBP (ASBP) and ambulatory DBP (ADBP) were not frequently reported in trials.

Table 2 Summary table of reported BP outcomes

First author and study design	Description of included intervention(s)	Clinic SBP	Clinic DBP	ASBP	ADBP
Purcell[17] (SR of SRs)	'Telemonitoring' and 'home BP monitoring' programmes which varied in technological, organisational and clinical aspects: some interventions had additional support or education.	Intervention group reduction difference: SR1[21]: (2.63mmHg; 95% CI 1.02 to 4.24)* SR2[22]: (5.64mmHg; 95% CI 3.36 to 7.92)† (SS*) SR3[23]: (5.19mmHg; 95% CI 2.31 to 8.07) (SS) (heterogeneity not reported for specific analyses)	Intervention group reduction difference: SR1: (1.68mmHg; 95% CI 0.79 to 2.58)* SR2: (2.78mmHg; 95% CI 1.62 to 3.93)† (SS*) SR3: (2.11mmHg; 95% CI 0.52 to 3.69) (SS) (heterogeneity not reported for specific analyses)	Intervention group reduction difference: SR2: 2.28mmHg; 95% CI 0.24 to 4.32 (SS)	Intervention group reduction difference: SR2: 1.38mmHg; 95% CI to 0.79 to 3.55
Omboni[16] (SR and meta-analysis of RCTs)	'Telemonitoring' programmes which varied in technological, organisational and clinical aspects: some interventions had additional support or education.	Intervention group reduction difference: (4.71mmHg; 95% CI 3.24 to 6.18)† (SS*)	Intervention group reduction difference: (2.45mmHg; 95% CI 1.57 to 3.33)† (SS*)	Intervention group reduction difference: (3.48mmHg; 95% CI 1.64 to 5.31) (SS)	Intervention group reduction difference: (1.43mmHg; 95% CI 0 to 2.86)
McKinstry[18] (RCT)	Self measurement of BP data, (once established, at least weekly) automated transmission to website for review by clinician (recommended at least weekly), with optional patient decision support via text or email.	Intervention group reduction difference; (4.63mmHg; 95% CI 1.74 to 7.51) (SS)	Intervention group reduction difference; (2.83mmHg; 95% CI 1.03 to 4.63) (SS)	Intervention group reduction difference; (4.27mmHg; 95% CI 2.01 to 6.53) (SS)	Intervention group reduction difference; (2.3mmHg; 95% CI 0.92 to 3.61) (SS)

CI: confidence interval
SS: statistically significant; NR: not reported
*statistically significant heterogeneity reported
†possible error in meta-analysis.

The most recent secondary evidence, a systematic review of cardiovascular disease management from 2014[17], provided an overview of three systematic reviews (SRs)[21-23] of telemonitoring and hypertension, all of which comprised a mean study duration of less than 12 months. The authors classified the strength of evidence of the first SR[21] as having no or minor methodological flaws and the other two SRs[22,23] as having major methodological flaws.

The first included SR[21] investigated 'home BP monitoring' (intervention definition not provided, but research relating to home BP monitoring' and 'tele-monitoring' was included). In an analysis of 22 RCTs (n=4,742; six RCTs in common with the second SR included in the overview), the between-group difference in mean SBP was 2.63mmHg (2.63; 95% confidence interval (CI) 1.02 to 4.24). In an analysis of 21 of the same studies, plus an additional RCT, (n=4,720, the between group difference in mean DBP was 1.68mmHg (1.68; 95% CI 0.79 to 2.58), favouring the intervention group. Substantial heterogeneity was reported for both analyses: SBP (I^2= 68.8%; p<0.0001) and DBP (I^2= 63.3%; p<0.0001).

The second SR[22] investigated 'home BP telemonitoring' (defined as the 'use of an electronic automated BP monitor storing patient values obtained at the patient's home and transferring them to a remote computer via telephone (wired or wireless), modem or internet connection (web)'). In an analysis of 10 RCTs (n=4,389; two RCTs in common with the first SR) the between-group difference in mean SBP was 5.64mmHg (5.64; 95% CI 3.36 to 7.92; p<0.0001) and 2.78mmHg in mean DBP (2.78; 95% CI 1.62 to 3.93; p<0.0001), favouring the intervention group. Substantial heterogeneity was reported for both analyses: SBP (I^2=65.8%; p<0.01) and DBP (I^2=56.6%; p<0.05). There may have been an element of double counting in these meta-analyses. In addition, an analysis of three studies (n=655) reported effect size on ASBP (2.28mmHg; 95% CI 0.24 to 4.32; p<0.05) and ADBP (1.38mmHg; 95% CI 0.79 to 3.55; p=0.21).

The third SR[23] investigated 'telecare' (intervention definition not provided, but cited Parati and Omboni (2010) 'the transmission of patient health status data to allow remote control or management of patient health'). In an analysis of eight RCTs common to the second SR, (n=2,501) the between-group difference in mean SBP was 5.19mmHg (5.19; 95% CI 2.31 to 8.07) and 2.11mmHg in mean DBP (2.11; 95% CI 0.52 to 3.69), favouring the intervention group. Heterogeneity reportedly ranged from 0.69 to 0.72 but was not reported for specific analyses.

Table 3 summarises reported medication use, primary care attendance and patient satisfaction outcomes.

Table 3 Summary table of reported medication use, primary care attendance and patient satisfaction outcomes

First author and study design	Medication use	Primary care attendance	Patient satisfaction
Purcell[17] (SR of SRs)	Inconclusive*	NR	NR
Omboni[16] (SR and meta-analysis of RCTs)	Increased number of medications used in intervention group† (SS*)	Number of office visits decreased in intervention group†	NR
McKinstry[18] (RCT)	Increased number of medications used in intervention group (SS)	Increased number of GP and nurse surgery consultations (SS) nurse telephone consulations (SS) and GP telephone consulations in intervention group	Linked qualitative study[19] found that a sample of intervention patients were mostly positive with few reports of anxiety

SS: statistically significant
NR: not reported
*statistically significant heterogeneity
†possible error in meta-analysis.

The first included SR in the overview[21] reported an analysis of 12 RCTs (n=2,248) relating to BP medication increase in participants randomised to intervention compared with the clinic BP group (relative risk (RR) 0.94; 95% CI 0.75 to 1.19), and an analysis of 10 RCTs (nine RCTs from the previous analysis) (n=1,582), relating to BP medication reduction in participants randomised to intervention compared with the clinic BP group (RR=2.02; 95% CI 1.32 to 3.11). Heterogeneity was reported as substantial (I^2=72.7%; p<0.0001) and moderate (I^2=50%; p=0.042) respectively. It was unclear why studies were included or omitted in the analyses. In an analysis of four RCTS (one of which was included in the first included SR's analysis of medication use) (n=1,991), the second SR[22] reported the between-group difference in the mean number of antihypertensive medications used by patients as 0.22 higher in the intervention group (0.22; 95% CI 0.02 to 0.43). Considerable heterogeneity was reported for this analysis (I^2=79.1%; p<0.001).

The authors of the first SR[21] attempted to test reasons for the high levels of heterogeneity observed in their meta-analyses via several a priori subgroup analyses and reported four out of ten variables to be significant: study size, use of telemonitoring, participants using dialysis, and the use of a specific medication titration protocol. The authors of the second SR[22] did not formally test reasons for high levels of heterogeneity, but suggested that it might be explained by differences in clinical settings, telemedicine technologies, timing of self-monitoring and number of readings, inclusion criteria and feature of the comparison group. The third SR[23] did not attempt to explain heterogeneity. The authors of the overview stated that further research to identify the essential components of a telemonitoring intervention and the mechanisms by which it may affect outcomes was required.

A meta-analysis from 2013[16] (by one of authors of the second included SR)[22] investigated 'home BP telemonitoring' (as previously defined). The authors classified the strength of the included evidence as of 'acceptable' quality. In an analysis of 17 RCTs (six in common with the first SR, including all of the 10 RCTs in the second SR) (n=7,037) the between-group difference in mean SBP was 4.71mmHg (4.71; 95% CI 3.24 to 6.18; p<0.001), favouring HBPT. In analysis of 15 of the same 17 studies, where DBP was reported, the between-group difference in mean DBP was 2.45mmHg (2.45; 95% CI 1.57 to 3.33; p=<0.001), in favour of the HBPT group. There was a moderately high level of heterogeneity between studies for SBP (I^2=52.2%; p=0.003) and DBP (I^2=40.4%; p=0.048) comparisons. There may have been an element of double counting in these meta-analyses. In a synthesis of five RCTs (n=935; included two RCTs from the previous comparison) where ABP was reported, the between-group difference in mean ASBP was 3.48mmHg (3.48; 95% CI 1.64 to 5.31; p<0.001), in favour of the telemonitoring group. An analysis of between-group difference in mean ADBP did not provide strong evidence that the intervention had an effect: (1.43; 95% CI 0 to 2.86; p=0.051); ASBP (I^2=20.6%; p=0.283), ADBP (I^2=28.3%; p=0.233). Seven RCTs (n=2,691) which reported on BP medication use were analysed and found to demonstrate a between-group difference in the mean number of antihypertensive medications used by patients. At study end, the number of medications used by patients was 0.40 higher in the intervention group (0.40; 95% CI 0.17 to 0.62; p<0.001). Considerable heterogeneity was reported for this finding (I^2=84.2%; p<0.001). Relating to primary care attendance, an analysis of seven RCTs, (n=3,257; including four RCTs from the medication use analysis) found there was not strong evidence of an effect of the intervention (0.18; 95% CI 0.00 to 0.37; p=0.055) (I^2=32.7%; p=0.146). The authors did not conduct subgroup analyses to explore heterogeneity but completed sensitivity analyses for outcomes by removing each study in turn. There may have been an element of double counting in these meta-analyses. The authors of the meta-analysis stated that further research should use ABPM as the BP measurement, include high-risk patients, and consider a control group design of patients using HBPM.

A pragmatic RCT[18] (n=401), published in 2013 (and not included in the 2013 systematic review of RCTs) compared 'telemonitoring' (defined as self measurement and transmission of BP data to a website for clinical review, with optional patient decision support email or text message contact) with usual care in South-east Scotland, across 20 primary care practices. The authors accounted for a 'white coat effect' by using ABP as the BP outcome measure. The between-group difference in mean ASBP was 4.27mmHg (4.27; 95%

CI 2.01, 6.53; p=0.0002) and mean ADBP was 2.3mmHg (2.3; 95% CI 0.92, 3.61; p=0.001), favouring the intervention group. Outcomes were recorded at 6 months post-randomisation, and the authors suggested that if maintained, these reductions were likely to lead to associated reductions in cardiovascular disease, but that further research should be conducted to determine longer-term BP outcomes.

The authors reported a greater increased use of medications at study end in the intervention group (75/200 (38%) intervention participants; 26/201 (13%) control participants; p<0.0001). The between-group mean difference in GP surgery consultations was around one additional consultation for the intervention group (1.06; 95% CI 0.53 to 1.61; p=0.0002), around half an additional practice nurse surgery consultation (0.58; 95% CI; 0.14 to 1.04; p=0.011) and around half an additional practice nurse telephone consultation (0.54; 95% CI 0.36 to 0.72; p<0.0001). The between-group mean difference in GP telephone consultations did not show strong evidence that the intervention had an effect (0.07; 95% CI -0.16 to 0.27; p=0.5742). The authors carried out a retrospective cluster analysis and found no evidence of between-centre heterogeneity: intraclass correlation coefficient=0.02; point estimate after adjusting for clustering was 4.06mmHg (4.06; 95% CI 1.43, 6.68; p=0.0034).

A linked qualitative analysis[19] based upon interviews with a sample of 25 patients participating in the trial, selectively sampled relating to age, sex, and associated deprivation status of their GP practice. In general, patients were positive about the telemonitoring intervention, though one patient reported that the intervention had caused them to worry about their BP. Patients perceived that the intervention improved access to clinicians and data, although a small number of patients reported a dislike of automated alerts generated by the telemonitoring system.

Safety

A meta-analysis[16] reported an analysis of reported adverse outcome data from four RCTs (n=389 of 2,925 participants). One RCT reported on all-cause mortality or non-fatal cardiovascular events, one on all-cause mortality or hospital admissions, one on death only and one on hospital admissions only. The authors reported an analysis of between-group difference in relative risk of events (RR= 1.22; 95% CI 0.86 to 1.71; p=0.263) (I^2=13.8%; p=0.326) but concluded that the studies in their review were not designed or powered to detect either a reduction or increase in adverse events. An RCT[18] conducted in Scotland (n=401) recorded 43 adverse events. The authors reported that three patients became anxious as a result of self-monitoring, but otherwise, adverse events were spread evenly across the groups. One death occurred in the intervention group and two in the usual care group, which were not considered to be related to BP. Events which may have been related to BP control were a patient who fell, and two patients who fainted. Six patients were seen in hospital with cardiovascular problems (two atrial fibrillation, two chest pain, two very high BP). In addition, one patient developed a rash hypothesised to relate to antihypertensive drug therapy and another developed hyperkalaemia (of another cause), which antihypertensive drug therapy may have exacerbated. The remaining patients were admitted to hospital with issues considered to be unrelated to the intervention or BP.

Cost effectiveness

Three economic evaluations were identified that examined the cost-effectiveness of home BP telemonitoring compared to conventional office BP monitoring for patients with hypertension. Two of the three studies – one Danish and one UK – compared the costs of the two BP monitoring strategies relative to a disease specific measure of effectiveness (mmHg). As such, although summarised below, both these studies are of limited use in determining the overall cost-effectiveness of telemonitoring relative to other technologies within the NHS.

The Danish study[24], published in 2010, found that telemonitoring was associated with lower medication costs and consultation costs compared to conventional office BP monitoring alone. However, owing to the initial cost of the technology (£92.80), telemonitoring resulted in higher total costs (£205.90 versus £135.56 respectively). It is worth noting that, for the additional cost, an improvement in systolic and diastolic ABP was experienced. After 6 months

ABP was reduced by 11.9/6.2mmHg in the telemonitoring arm and 9.6/5.4mmHg in the conventional office BP monitoring arm.

The UK study[25], published in 2013 from an NHS perspective, also found that telemonitoring of BP was more expensive than usual care. Over the 6 month study duration, telemonitoring was associated with a mean cost per patient of £290.13 versus £174.81 in the usual care arm – a mean difference of £115.32. This increase in costs is largely driven by the costs of the technology in the intervention arm (£70.77 per patient). However it should be noted that the study also found that GP surgery consultations increased in the intervention group, leading to an associated cost increase of £32.89 per patient. This finding may of course not hold in the longer-term, where BP telemonitoring would be expected to reduce the need for surgery visits.

In terms of benefits, the UK study presented data from the HITs trial[26] where systolic ABP (SABP) fell in both groups from 146.20 to 140.15mmHg in the telemonitoring arm and 146.22 to 144.50mmHg in the usual care arm. The mean difference in the mean daytime SABP at 6 months was 4.51mmHg ($p<0.001$). Based on the cost and effectiveness data, an incremental cost effectiveness ratio (ICER) was estimated of £25.60/mmHg reduced per patient. However, the disease-specific format means that this information is of limited use to cost-effectiveness decision making across the NHS. As a final point, and although not assessed within the study, the authors comment that if such clinical gains were maintained in the long-term, any additional costs associated with telemonitoring would likely be offset by a reduction in the costs of future cardiovascular events.

The study of most value to the research question is a 2014 study[26] which examined the long-term cost-effectiveness of self-management of hypertension versus usual care alone. The self-management of hypertension consisted of telemonitoring and subsequent self-titration of antihypertensive medication, whilst patients in the usual care arm received an annual hypertension review.

A cost utility analysis was undertaken, using a Markov model with a time horizon of 35 years based on patients with poorly controlled hypertension. The model consisted of a number of health states. Patients began in the 'well' health state (whereby they are stable but have poorly controlled hypertension), then based on transition probabilities, patients could remain in this health state or move to one of four acute health states, that is stroke, myocardial infarction, angina and heart failure. Those patients that survived the acute stage of the model progressed to the chronic phase, whereby they remained until death.

The clinical data used to inform the model were drawn from the TASMINH2 study[27] (a UK RCT) and published literature. Patients recruited into the TASMINH2 study were those who were willing to self-monitor, received two or fewer antihypertensive drugs, were aged 35-85 years and had BP at baseline of over 140/190mmHg. The annual probability of experiencing a cardiovascular event was estimated for both men and women, based on the mean 10-year cardiovascular risk using the Framingham equation. Age related relative risks of experiencing a cardiovascular event were also included in the model. These data were then used to extrapolate from the 12 month results seen in the TASMINH2 study where, for men, self-monitoring resulted in a reduction in BP of 17.8mmHg compared to a reduction of 11.4mmHg in the usual care arm. For women, self-monitoring resulted in a 12-month reduction in SBP of 17.2mmHg compared to 12.8mmHg in the usual care arm. It should be noted that the reduction in SBP differs from the effect size noted in the clinical effectiveness section. In addition, this reduction in SBP is considered to be a surrogate marker and therefore serves as a proxy for final patient relevant outcomes, that is stroke or myocardial infarction. Although there are uncertainties surrounding the use of surrogate outcomes, due to the short duration of the trial, this is probably reasonable.

Utility values were included in the analysis and quality of life for each health state was estimated via published literature. Patients in the 'well' health state were associated with a utility value of 0.78 while those in the acute and chronic phases experienced a lower quality of life. In relation to costs, the analysis included drug costs, the cost of inpatient and outpatient visits, primary care consultations and equipment and training. In the self-monitoring arm, telemonitoring equipment and training costs amounted to £230. These costs

intervals over the duration of the model. A discount rate of 3.5% was applied. Results were presented in the form of cost per QALY and provided for both men and women. Based on this analysis, self-management of hypertension is considered to be cost effective versus standard of care in both populations, with an ICER of £1,624 per QALY for men (based on an incremental cost of £383 and an incremental QALY gain of 0.24) and an ICER per QALY of £4,923 for women (based on an incremental cost of £576 and an incremental QALY gain of 0.12).

Various sensitivity analyses were carried out in order to gauge the impact of a declining impact of self-monitoring on BP reduction. A 20–36% reduction in the impact of the intervention on BP was tested – applied in various years of the model – and in all scenarios self-monitoring remained cost-effective. The model was also found not to be sensitive to the time horizon.

In summary, the cost utility analysis was reasonably well conducted and results are considered to be generalisable to Scotland. However there are a number of weaknesses with the analysis, indicating that the results presented within this analysis should be interpreted with some degree of caution. The primary concern relates to the extrapolation of clinical benefit over time, that is in the base case analysis it is assumed that the 12-month difference in BP between both treatment arms is maintained over the duration of the model. As clinical data are only available for up to 1 year, there is considerable uncertainty surrounding the appropriateness of this assumption. The sensitivity analysis provides some attempt to capture this uncertainty; however the decline in impact of self-monitoring appears to have been varied arbitrarily. Another potential weakness relates to the exclusion of some potentially relevant costs, that is monitoring costs associated with telemonitoring and adverse event costs. There is therefore a possibility that costs may have been understated in the analysis. Finally, it is worth noting that utility values were not derived directly from the TASMINH2 study, but instead by published literature. A number of these studies were dated (1999).

Overall, the results of the studies suggest that telemonitoring may represent a cost effective option compared to usual care. However due to uncertainty surrounding the long-term efficacy assumptions associated with telemonitoring and concerns relating to the inclusion of appropriate costs and utility values, there is considerable uncertainty surrounding these results.

Conclusion

HHM lacks a universal definition, and literature identified in relation to this evidence note included heterogeneous populations and interventions, making synthesis of the evidence challenging, and preventing definitive conclusions.

The interventions described in the evidence were complex, comprising of (at least) a measuring aspect and a monitoring aspect, and varying in clinical input and duration. In general, secondary analyses comprised of studies which did not appear to provide sufficient detail of these aspects, or consider the potential impact of implementation on clinical effectiveness, particularly where these contained additional components such as medication titration or lifestyle education.

The most frequently reported clinical outcome was BP. Hypertension increases the risk of cardiovascular disease, and overall, evidence was consistent with a reduction in clinic SBP and DBP in intervention groups. The mean reductions reported in the primary evidence and secondary pooled analyses were not consistently greater than a minimally important difference in mmHg, and the clinical importance of the reduction was not clear. Whilst reductions in BP may contribute to lower cardiovascular disease risk, absolute risk reduction would depend on the baseline cardiovascular disease risk of individuals.

Statistically significant heterogeneity was found between many studies, and despite the known 'white coat effect', ABP measurements were not commonly reported. Where reported, the intervention was found to be consistent with ASBP reductions, but not ADBP reductions, although this was not universally reported: a well-conducted Scottish RCT found reductions for both ASBP and ADBP.

The available evidence regarding the effect of HHM on medication use and primary care attendance was conflicting and it was not possible to determine the effect of the intervention on these outcomes.

In general, there was a lack of patient satisfaction outcomes reported in the included literature, most likely reflecting the scope of the search in evidence notes. A qualitative study reported that patients who participated in a telemonitoring intervention study were mostly positive about the intervention, although it was linked to anxiety in a small number of patients.

There was insufficient evidence available to determine whether there was a significant difference between the safety of telemonitoring compared with usual care.

Overall, the results of the studies relating to cost-effectiveness suggested that telemonitoring may represent a cost-effective option compared to usual care. However, due to uncertainty surrounding the long-term efficacy assumptions associated with telemonitoring and concerns relating to the inclusion of appropriate costs and utility values, there is considerable uncertainty surrounding these results.

Whilst evidence was mostly consistent with a reduction in measures of BP with HHM use, it was not possible to draw firm conclusions from the available clinical and cost- effectiveness evidence, or to determine which components of an intervention may be effective. Longer-term evaluation of the intervention was advocated in both the primary and secondary literature.

Equality and diversity

Healthcare Improvement Scotland is committed to equality and diversity in respect of the nine equality groups defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion, sex, and sexual orientation.

The process for producing evidence notes has been assessed and no adverse impact across any of these groups is expected. The completed equality and diversity checklist is available on www.healthcareimprovementscotland.org

About evidence notes

This evidence note will be considered for review 2 years post-publication, and at 2-yearly intervals thereafter. For further information about the evidence note process see http://www.healthcareimprovementscotland.org/our_work/clinical__cost_effectiveness/shtg/standard_operating_procedures.aspx

To propose a topic for an evidence note, email evidencenotes.HCIS@nhs.net

References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network http://www.knowledge.scot.nhs.uk, or by contacting your local library and information service.

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- Anna Milsom, Lead Author/Health Services Researcher
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- Members of the SHTG evidence review committee

NICE has accredited the process used by Healthcare Improvement Scotland to produce its evidence review products. Accreditation is valid for 5 years from January 2013. More information on accreditation can be viewed at www.nice.org.uk/accreditation

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