In response to an enquiry from Quality and Efficiency Support Team, Scottish Government
Number 60 March 2016

What is the clinical effectiveness, cost effectiveness and safety of home health monitoring compared with usual care for patients with moderate to severe chronic obstructive pulmonary disease?

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.

Definitions
Chronic obstructive pulmonary disease: is a lung disease characterised by chronic airflow obstruction that is not fully reversible and usually progressive.\(^1\)

Exacerbation: characterised by the rapid and sustained worsening of respiratory symptoms beyond normal daily variations.\(^1\)

Bronchitis: inflammation that narrows the bronchi (the tubes carrying air to and from the lungs) and causes chronic bronchial secretions.\(^2\)

Emphysema: permanent destructive enlargement of the airspaces within the lung without any accompanying fibrosis of the lung tissue.\(^2\)

Airflow obstruction: when the ratio between forced expiratory volume in 1 second (FEV\(_1\)) and forced vital capacity (FVC) is less than 0.7.\(^1\)

Forced vital capacity: volume of air forcibly exhaled from the point of maximal inspiration.\(^3\)

Key points
- The available evidence is conflicting and thus it is not possible to draw firm conclusions regarding the clinical effectiveness of home health monitoring (HHM) for patients with moderate to severe chronic obstructive pulmonary disease (COPD).
- Based on the evidence reviewed, there was no statistically significant difference in mortality rates between patients receiving HHM interventions (HHM alone and HHM plus usual care) and those receiving usual care.
- In studies variously comparing HHM plus usual care with usual care, and HHM alone with usual care, the intervention reduces hospitalisation rates, and improves the time free of hospitalisation and other healthcare services.
- Evidence regarding the effect of HHM on respiratory exacerbations, health-related quality of life (HRQOL), emergency department (ED) visits and length of hospital stay is inconsistent.
- Cost effectiveness analyses, with time horizons ≤1 year, indicate that HHM plus usual care compared with usual care alone is not cost-effective in patients with moderate to severe COPD.
- Patients were generally satisfied with HHM.
- No evidence relating to the long-term effects and safety (adverse events caused by HHM) of the technology was identified.
- Further research is needed to examine the long-term effects, safety and characteristics of patients most likely to benefit from this intervention.
Literature search

A systematic search of the secondary literature was carried out between 16–18 June 2015 to identify systematic reviews, health technology assessments (HTAs) and other evidence based reports. Medline, Medline in process, Embase, Cinahl, Web of Science databases were also searched for systematic reviews and meta-analyses. Results were limited to review articles published in English language between 2009–2015.

The primary literature was systematically searched between 16–18 June 2015 using the following databases: Medline, Medline in process, Embase, Cinahl, Web of Science. The search was carried out to identify any relevant randomised controlled trials (RCTs) published after the secondary literature. Results were limited to English language, 2009–2015 and clinical trial study type.

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 Thoracic Society (BTS) and the Primary Care Respiratory Society UK, were also searched.

Concepts used in all searches included: telehealth, telemonitoring, ‘home health monitoring’, telemedicine, COPD and chronic obstructive pulmonary disease. A full list of resources searched and terms used is available on request.

Introduction

The growing number of people with long-term conditions is a major challenge for health and social care. In the United Kingdom (UK), over 15 million people have a long-term medical condition. Home health monitoring (HHM) has been viewed as one of the priority areas in addressing this health challenge.

The Scottish Government has given a commitment to commission services that promote ‘shifting the balance of care’ towards a more preventative and anticipatory approach. This approach is aimed at supporting people, particularly those with long-term conditions, to remain safe and well, for as long as possible, in their own homes or in a homely setting.

Through several initiatives, about £20 million has been invested in telecare between 2006–2011. Some of these initiatives include supporting partnerships to provide HHM services for patients with chronic health conditions.

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’.

The main objective of HHM is to support people to have a more central role in managing their health, with the aim of improving access to care and clinical outcomes while reducing hospital readmissions and complications.

The Medical Research Council defines complex interventions as those comprising ‘a number of components which usually include behaviours, parameters of behaviours, and methods of organising and delivering those behaviours’. Based on this definition, HHM can be regarded as a ‘complex intervention’ as it involves several components that are influenced by personal, psychological and organisational issues.

For the purposes of this review, it was assumed that the intervention included direct transfer of data from a home setting to a healthcare setting in a timely manner, and also involved:

1. periodic measurement of physiological indicators and/or recording of vital signs or symptoms in a standardised format, and

2. a clinical review and action, if the data crossed a predefined threshold.

Physiological and symptom information can be relayed through any of the following:

- telephone or videophone
- mobile network that allows data to be entered either manually or via direct connection (Bluetooth or wired) to measuring devices
personal computer with a HHM programme (some programmes may include touch screens and voice prompts) and peripheral connections.

Data can be monitored either in real time or can be stored and reviewed at a later time.

The Scottish Centre for Telehealth and Telecare reports that, through the United4Health project, about 7,700 people in West Central Scotland will receive HHM, between 2013 and 2016.

**Epidemiology**

COPD is a broad term for long-term lung diseases (chronic obstructive airways disease, emphysema and chronic bronchitis) involving chronic airflow obstruction.

Symptoms include: phlegm production, cough, breathlessness, chest congestion and wheezing. These symptoms are caused by inflammation and lead to decreased elasticity of the lungs, increased mucus production and thickening of the airways. Lung damage is irreversible.

COPD is associated with several co-morbidities and systemic effects such as skeletal muscle dysfunction, nutritional disturbances and weight loss.

Cigarette smoking is the main risk factor. Other risk factors include: environmental pollution, genetic susceptibility and exposure to dusts, chemicals and fumes. Treatment involves alleviating symptoms and promoting lifestyle changes.

COPD is a major cause of mortality and morbidity. Over the last 25 years, COPD has accounted for between 25,000–30,000 deaths every year, in the UK. Because a large number of patients remain undiagnosed, it is generally acknowledged that the true burden of COPD is underestimated. It has been estimated that about 100,000 people have COPD in Scotland. In 2012/2013, Practice Team Information data indicated that the national prevalence of COPD in primary care was 18.3 per 1,000 patients for men and 19.8 per 1,000 patients for women. This was based on patients consulting a general practitioner (GP) or practice nurse at least once due to COPD. In the UK as a whole, COPD accounts for 1.4 million GP consultations and over 1 million hospital bed-days, annually. This represents a cost of approximately £982 million per year, to the health service.

There are several ways of categorising COPD based on its severity. The most common method of categorising COPD is based on airflow limitation. Table 1 shows the National Institute for Health and Care Excellence (NICE) and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification of COPD by severity.

COPD can lead to acute respiratory exacerbations that often require hospital admissions. Patients with moderate to severe COPD have an average of one to two exacerbations per year. About 30% of patients, discharged from hospital after an acute exacerbation, will require readmission within 3 months.

**Table 1 COPD classification by severity**

<table>
<thead>
<tr>
<th>Severity</th>
<th>NICE</th>
<th>GOLD</th>
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<tbody>
<tr>
<td>Mild</td>
<td>&gt;80%*</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>Moderate</td>
<td>50%-79%</td>
<td>≥50%-&lt;80%</td>
</tr>
<tr>
<td>Severe</td>
<td>30%-49%</td>
<td>≥30%-&lt;50%</td>
</tr>
<tr>
<td>Very severe</td>
<td>&lt;30% **</td>
<td>&lt;30%</td>
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</table>

* symptoms should be present to diagnose COPD in people with mild airflow obstruction

** or FEV1 <50% with respiratory failure
Clinical effectiveness

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.

The search identified six papers3,12,17,20-22 that were considered relevant for inclusion. Of these, three were systematic reviews of primary studies12,17,20 (one review12 was part of an HTA and two reviews17,20 incorporated meta-analysis), one was a review of reviews21 and two were evidence-based reports3,22 published by the BTS22 and GOLD3. The reviews were good quality, while the reports were of moderate quality.

The papers assessed the impact of HHM interventions (HHM alone and HHM plus usual care), on healthcare utilisation and health-related outcomes, in patients with moderate to very severe COPD. They were published between 2012–2014 from the UK21,22, Belgium3, Portugal17, Canada12 and Japan20. The papers did not always specify if HHM was carried out alone or in addition to usual care. The papers variously compared HHM plus usual care with usual care and HHM alone with usual care.

Three reviews12,17,20, including the reviews17,20 with a meta-analysis, focused specifically on patients with COPD. One review20 evaluated the impact of HHM plus nursing support. Two reviews12,20 carried out subgroup analyses, based on duration of intervention and COPD severity.

The first review17 included nine studies of 587 patients (seven RCTs and two non-randomised controlled clinical trials (CCTs)). The studies compared HHM plus usual care with usual care. Based on the Hailey et al.23 scoring system, designed to evaluate telemedicine research, the studies included were regarded as being of good to high quality.

The second review20 included nine papers reporting seven studies (five RCTs and two CCTs) of 593 patients. The seven studies were reported as being of good to high quality, based on the Hailey et al.23 assessment scale. Of the nine papers, six papers compared HHM plus nursing support with usual care and three papers compared disease management or respiratory ambulatory care services with HHM plus nursing support.

The third review12 included six papers, which reported five trials (three RCTs and two CCTs) of 310 patients. The evidence was considered to be of low quality according to the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) criteria. However, this review assessed certain healthcare utilisation outcomes (time free of hospitalisation and time free of other healthcare services) that were not reported in other reviews.

Some of the primary studies included in these reviews overlap. The reviews highlighted some issues relating to the methodological quality of the primary studies such as lack of blinding and potential lack of power.

One review of reviews21 and one evidence-based report22 involving patients with several diagnoses were also included, because results for COPD patients were evaluated or reported separately. These papers assessed the effectiveness of HHM in patients with long-term conditions. The review21 identified three systematic reviews on COPD patients.

The components of HHM interventions varied across studies but mainly included: the use of a HHM technology to measure, monitor and transmit physiological data routinely; training on how to use the technology; education on self-care and management of symptoms; access to and a response from (where required) a designated healthcare team. The main differences observed were related to the design and implementation of the intervention, such as the: type of HHM technology used; number and type of co-interventions; parameters monitored; frequency of data transmission to the clinical team; length of follow-up and; number of healthcare practitioners involved in the intervention. The level of support provided during the intervention varied, depending on COPD severity.
The components of usual care also varied across studies. Patients received either primary care treatment alone or basic education and support from the healthcare team (without routine transfer and monitoring of data), in addition to primary care treatment.

The duration of intervention ranged from 1–12 months. The majority of interventions commenced during or immediately after hospital admission, while others began after a pulmonary rehabilitation program or during outpatient clinics. In most of the studies, data transmission was carried out daily and led to immediate action from the monitoring team if readings went outside pre-specified levels. The most common parameters collected were: oxygen saturation, medication use, spirometric parameters (FEV₁), heart rate, weight and body temperature.

Where reported, patients’ compliance with data transmission ranged from 40–98%, while drop out rates were generally above 20%¹⁷,²². The majority of patients included in the studies were aged over 60 years.

**Results**

The evidence-based reports³,²² did not provide results for specific outcomes. They provided overall conclusions regarding the use of HMM for COPD patients.

Based on evidence from three studies, including one Scottish-based RCT²⁴, the GOLD report concluded that HMM interventions did not result in benefits to patients with COPD and should not be recommended for use³. The BTS report concluded that the overall benefits of HMM for COPD patients were uncertain²².

A wide range of outcomes, relating to health and healthcare utilisation, was assessed and reported across the four systematic reviews identified.

**Effect on health-related outcomes**

**Mortality rates**

Four reviews¹²,¹⁷,²⁰,²¹ reported on mortality. The majority of studies included in the analyses measured all-cause mortality.

All four reviews reported that there was no statistically significant difference in mortality rates between patients, with moderate to severe COPD, receiving HMM interventions (HMM alone and HMM plus usual care) compared with those receiving usual care.

The confidence intervals were wide in the two reviews¹⁷,²⁰ that carried out a meta-analysis. The first review¹⁷ combined data from four studies with 294 patients (Relative Risk (RR)=1.43; 95% Confidence Interval (CI) 0.40 to 5.03; p=0.582; I²=0%) and the second review²⁰ combined data from five RCTs, including one RCT of 40 patients included in the first review¹⁷ (RR=1.36; 95% CI 0.77 to 2.41; I²=0%; n=374 patients).

<table>
<thead>
<tr>
<th>Outcomes/studies</th>
<th>Cruz et al.¹⁷</th>
<th>Kamei et al.²⁰</th>
<th>Brettle et al.²¹</th>
<th>Ontario HTA¹²</th>
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<tbody>
<tr>
<td>Health-related outcomes</td>
<td>NS</td>
<td>NS</td>
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<td>NS</td>
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<tr>
<td>Mortality rates</td>
<td>NS</td>
<td>SSD</td>
<td>-</td>
<td>NS</td>
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<tr>
<td>Respiratory exacerbations</td>
<td>NS</td>
<td>SSD</td>
<td>-</td>
<td>IR</td>
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<td>HRQoL</td>
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<tr>
<td>Healthcare utilisation</td>
<td>SSD</td>
<td>SSD</td>
<td>SSD</td>
<td>IR</td>
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<tr>
<td>Hospitalisation rates</td>
<td>NS</td>
<td>SSD</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Mean number of hospitalisations</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>SSD</td>
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<tr>
<td>Time free of hospitalisations</td>
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<td>Time free of other healthcare services</td>
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<tr>
<td>ED visits</td>
<td>NS</td>
<td>SSD</td>
<td>-</td>
<td>IR</td>
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<tr>
<td>Length of hospital stay</td>
<td>NS</td>
<td>SSD</td>
<td>NR</td>
<td>NS</td>
</tr>
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</table>

NS: no statistically significant difference between HMM and usual care
SSD: statistically significant difference in outcome measured in favour of HMM
IR: inconsistent results found
**Respiratory exacerbations**

Results, from three reviews\(^\text{12,17,20}\) that analysed data on respiratory exacerbations, were inconsistent.

Results from two reviews\(^\text{17,20}\) showed that the rates of COPD exacerbation were lower in the intervention group than the usual care group.

The first review\(^\text{20}\) combined data from two RCTs in a meta-analysis, and found that the HHM group had statistically significant lower rates of COPD exacerbation, after 3 months (\(RR=0.57; 95\% \text{ CI } =0.41 \text{ to } 0.79; I^2=0\%\); \(n=138\) patients).

The second review\(^\text{17}\) reported data from one RCT and one CCT. Although the control group had a higher incidence of respiratory events in the RCT (\(n=99\) patients), the difference between both groups was not statistically significant (\(p=0.152\)).

It was unclear from the review if this RCT was adequately powered for this outcome. The CCT (\(n=165\) patients) found a statistically significant difference in the mean number of exacerbations in favour of HHM (\(p=0.004\)).

The third review\(^\text{12}\) reported data from one CCT that examined respiratory exacerbations as a secondary outcome and found no significant difference in number of exacerbations between study groups (\(p>0.05\)).

**Health-related quality of life (HRQOL)**

Three reviews\(^\text{12,17,20}\) examined data on HRQOL. Not all studies assessed HRQOL as a primary outcome. The tools used to measure HRQOL also varied across studies. Some of the measurement tools used included: St. George’s Respiratory Questionnaire (SGRQ), EuroQol 5-D (EQ-5D), Clinical COPD Questionnaire and the Hospital Anxiety and Depression Scale (HADS). Based on the SGRQ scale, a decrease greater than 4 SGRQ units is considered a clinically significant improvement in QOL\(^\text{20}\).

Inconsistent results regarding the impact of HHM interventions on HRQOL were reported across the three reviews.

The first review\(^\text{17}\) found that overall, there were no significant differences between the intervention and control groups in the seven studies that assessed HRQOL. The review combined results from two RCTs that measured the mean change in the total SGRQ scores. Results suggest that patients had a statistically significant greater HRQOL after receiving HHM (standardised mean difference (SMD) in total SGRQ score=0.53; 95\% CI -0.97 to -0.09; \(p=0.019; I^2=17.74\%\)). Both groups achieved clinically significant changes in the total SGRQ score in one RCT, while only the intervention group achieved a clinically significant change in total SGRQ score, in the second RCT.

Based on data from three RCTs that utilised the SGRQ scale, the second review\(^\text{20}\) reported that HHM interventions lasting more than 6 months improve HRQOL in patients with severe and very severe COPD.

The third review\(^\text{12}\) reported data from two RCTs that could not be pooled. One RCT reported statistically and clinically significant improvements in the mean change in total SGRQ score in the intervention group compared with usual care (\(p=0.018\)). The other RCT, which was not powered to assess HRQOL, did not find any significant differences in the change in EQ-5D (\(p=0.64\)), hospital anxiety score (\(p=0.83\)) and SGRQ scores between the groups (\(p=0.83\)).

A subsequently published RCT\(^\text{16}\) carried out in the UK was identified by the literature search. The study randomised 110 patients with moderate to severe COPD to receive HHM plus usual care or usual care for 6 months. The primary outcome measure of the study was the effect of HHM on QOL, measured by SGRQ. There was a statistically and clinically significant improvement in the total SGRQ scores in the intervention group compared with the control group (mean difference (MD)=5.75; 95\% CI 2.32 to 9.18; \(p=0.001\)). It should be noted that the assessors in this study were not blind to the different groups. It is also worth noting that there may be more subsequently published RCTs that have not been covered in this review.

**Effect on healthcare utilisation**

**Hospitalisation**

Hospitalisation was reported differently across studies that assessed this outcome. Four reviews\(^\text{12,17,20,21}\) reported on ‘hospitalisation rates’ while two reviews\(^\text{17,20}\) reported on ‘mean number of hospitalisations’. In addition, hospitalisation rates were defined and measured differently across the primary studies included in the reviews. One RCT that assessed COPD-specific hospitalisations was reported across three of the reviews\(^\text{12,17,20}\).
Of the reviews that measured hospitalisation rates, three reviews\textsuperscript{17,20,21} reported that HHM was effective in reducing hospital admissions in COPD patients. Two meta-analyses\textsuperscript{17,20} found that patients receiving HHM interventions (HHM alone and HHM plus usual care) had a significantly lower risk of hospitalisation than those receiving usual care. The first meta-analysis\textsuperscript{17} combined data from six RCTs and two CCTs including 486 patients (RR=0.72; 95% CI 0.53 to 0.98; p=0.034; \(I^2=4.73\%\)). The second meta-analysis\textsuperscript{20} combined data from four RCTs and two CCTs, involving 550 patients (RR=0.80; 95% CI 0.68 to 0.94; p=0.007; \(I^2=0\%\)).

Pre-specified subgroup analyses by COPD severity and duration of intervention were carried out in one of the reviews\textsuperscript{20}. In a study of 100 patients with moderate COPD, there was no significant difference in hospitalisation rates between the intervention and control groups (RR=0.55; 95% CI 0.22 to 1.36; p=0.19). Results from a subgroup of 450 patients with severe and very severe COPD showed that the rates of hospitalisation were significantly reduced in the intervention group compared with usual care (RR=0.81; 95% CI 0.69 to 0.95; p=0.01; n=5 studies).

There was no statistically significant difference in hospitalisation rates between patients that received an intervention or usual care for: 3 months or less (RR=0.64; 95% CI 0.31 to 1.33; p=0.23; n=137 patients); 6 months (RR=0.78; 95% CI 0.50 to 1.20; p=0.25; n=155 patients); and 12 months (RR=0.80; 95% CI 0.64 to 1.01; p=0.06; n=258 patients).

Conflicting results were reported in the fourth review\textsuperscript{12}. Of the studies included in this review\textsuperscript{12}, three studies (two RCTs and one CCT) found no significant difference in hospitalisation rates between both groups, while two studies (one RCT and one CCT) found significant reductions in favour of the intervention. The RCT which assessed COPD-specific hospitalisations as a primary outcome did not find any significant difference between groups over 6 months (p=0.16). The evidence base was considered to be of very low quality according to GRADE.

Results of the two reviews\textsuperscript{17,20} that reported on mean number of hospitalisations were inconsistent. The first review\textsuperscript{17} combined data from four studies including 244 patients, and found no significant difference in the mean number of hospitalisations per patient between patients that received HHM plus usual care and those that received usual care alone (SMD=-0.06; 95% CI -0.32 to 0.19; p=0.617; \(I^2=16.42\%\)).

The second review\textsuperscript{20} reported that overall, there was a significantly lower mean number of hospitalisations in the intervention group than in the usual care group, in patients with severe and very severe COPD (MD=-0.14; 95% CI -0.19 to -0.09; n=490 patients). This finding was based on a meta-analysis of six studies, including one CCT reported in the first review\textsuperscript{17}. There was no statistical heterogeneity observed between studies (\(I^2=0\%\)). A subgroup analysis with five studies, including 453 patients with severe COPD patients, found that the mean number of hospitalisations in the intervention group was lower than that in the usual care group. One RCT of 37 very severe COPD patients found no significant difference in the mean number of hospitalisations between study groups (p=1.0).

### Time free of hospitalisations

One review\textsuperscript{12} reported that HHM improves the time free of hospitalisations compared with usual care. The review examined two studies (one RCT and one CCT) that investigated time free of hospitalisations in patients with severe COPD as a secondary outcome. The RCT found that the intervention group (HHM alone) had a longer time until first hospitalisation compared with the usual care group (p<0.0012). The CCT found that the intervention group were less likely to experience early hospitalisation (p<0.05). The quality of the evidence base was considered low according to GRADE.

### Time free of other healthcare services

One review\textsuperscript{12} reported results from one RCT of 101 COPD patients. Results showed that patients receiving HHM were more likely to have a longer time until first urgent GP call (p=0.013), first exacerbation (p<0.001) and first ED visit (p=0.0003). The quality of the evidence base was considered low according to GRADE.

### Emergency department visits

Results were inconsistent in the three reviews\textsuperscript{12,17,20} that examined ED visits.
The first review combined data from four RCTs with 194 COPD patients, and found no evidence of a significant effect of HHM plus usual care on ED visit rates compared with usual care (RR = 0.68; 95% CI 0.38 to 1.18; p = 0.179; I² = 22.53%).

The review also combined data from one RCT and one CCT that assessed the effect of HHM on the mean number of ED visits. The studies compared HHM plus usual care with usual care, over 4–6 months, in 160 patients with severe to very severe COPD. Results showed that the number of ED visits was not significantly different between groups (SMD = 0.20; 95% CI -0.49 to 0.88; p = 0.576). There was substantial heterogeneity (I² = 74.81%).

An analysis based upon study design was conducted to explore the heterogeneity observed between the two studies. A significantly lower mean number of ED visits in favour of the intervention was reported in the CCT (SMD = 0.51; 95% CI 0.14 to 0.88; p = 0.007). The RCT did not find any significant difference between groups (SMD = -0.19; 95% CI -0.78 to 0.39; p = 0.515). The authors noted that due to the nature of its study design, the significant effect observed in the CCT should be interpreted with caution.

The second review examined four RCTs, including 335 patients with severe and very severe COPD. Overall, meta-analysis showed that the intervention group had a significantly lower rate of ED visits than the control group (RR = 0.52; 95% CI 0.41 to 0.65; p < 0.00001; I² = 0%).

A pre-specified subgroup analysis by duration of intervention was carried out. The study reported that there was a significant reduction in the number of ED visits in patients who received an intervention for 3 months or less (RR = 0.38; 95% CI 0.14 to 1.01; p = 0.05; n = 37 patients) and 12 months (RR = 0.54; 95% CI 0.36 to 0.79; p = 0.002; n = 258 patients) compared with patients who received usual care for the same time period. There was a moderate statistical heterogeneity between the two studies that provided data at 12 months (I² = 60%). The review noted that the heterogeneity observed could have been due to differences in healthcare systems across countries.

There was no significant difference in the number of ED visits in patients receiving either the intervention or usual care after 6 months (RR = 0.50; 95% CI 0.10 to 2.43; p = 0.39; n = 40 patients).

The third review investigated two RCTs that analysed ED visits as a secondary outcome. The RCTs found no significant difference in the median number of ED visits per patient or total ED visits between HHM and usual care.

**Length of hospital stay**

There were inconsistent results reported in the four reviews that investigated length of hospital stay.

Three reviews reported that there was no significant difference in the length of time spent in hospital between the HHM and usual care groups.

The fourth review combined data from three studies (one RCT (n = 40 patients) and two CCTs (n = 215 patients)) in a meta-analysis. Results showed that overall, the mean number of bed days of care per patient was significantly lower in the intervention group than in the control group in moderate to very severe COPD patients (MD = -0.76; 95% CI -0.79 to -0.73; I² = 0%). The RCT found that the intervention group had a longer duration of bed days than the control group, while the CCTs found that the intervention group had shorter duration of bed days when compared with the control group.

**Patient views**

The literature search did not set out to identify papers on patient views. However, the general search identified five papers examining patient views with regards to HHM. Of these, there were: three reviews including one review primarily aimed at exploring patients’ satisfaction and adherence with the use of HHM systems; one evidence-based report; and one Scottish-based qualitative study nested in an RCT. Results from two of the papers identified were not specific to COPD patients.

The review primarily aimed at exploring patients’ satisfaction included 12 studies (five RCTs, four uncontrolled before and after studies and three CCTs) reported in 17 papers. The majority of the studies were considered to be of good to high quality. The second review reported evidence from 11 studies (six systematic reviews and five qualitative studies). The third review assessed five studies investigating patients’ experience with HMM. Of the five studies, two studies focused exclusively on patients with COPD while three studies included
patients with other conditions as well as COPD. Two of the five studies were also reported in the review\textsuperscript{25} aimed at exploring patients’ satisfaction.

Generally, the studies were heterogeneous with regards to the type of technology used, the study population and the method of assessing patient satisfaction. Data was gathered irrespective of healthcare use and clinical outcome.

Overall, patients were generally satisfied with HHM\textsuperscript{12,21,22,25}. However, it was difficult to determine the relationship between patient satisfaction and improvements in health outcomes and healthcare utilisation.

One review\textsuperscript{25} reported that overall, patients found the systems easy to use and felt safer or more secure as a result of using HHM. Patients reported that the systems helped in improving healthcare provision and their understanding of the condition, its associated symptoms and ways of controlling them. Patients also reported having an increased feeling of reassurance and security knowing that their condition was being monitored and action taken if their condition deteriorated.

Another review\textsuperscript{12} found that HHM had the potential to reduce the need to travel for care, with the associated stress that it brings, by improving self-management, feelings of security and independence in certain patients. However, another report noted that instead of facilitating autonomy, there was a potential for some patients to become passive, dependent and anxious as a result of using HHM\textsuperscript{22}.

Difficulties relating to using the technology\textsuperscript{12,25} and decreased compliance\textsuperscript{22,25} were also reported. Some of the difficulties encountered included: keeping up with the technological advancement of systems; small push buttons; display screen with words too small to read; difficulties associated with using touch-screen equipment due to poor sensation and fine motor control; length of time taken to charge batteries and over sensitivity of the emergency call button\textsuperscript{25}.

Some of the reasons for withdrawal and low compliance during the intervention period included: frequency of data transmission; usability and technical problems with the system; deteriorating physical condition and relocation\textsuperscript{25}.

The papers identified noted that there is limited evidence examining the characteristics of patients that are likely to stick with the intervention. It was also noted that current practice tends to miss a group of patients that may benefit from the service such as patients who are at an earlier stage of the disease and those who do not speak English\textsuperscript{12}. In addition, the optimal frequency and time of data collection and transmission are yet to be determined\textsuperscript{25}.

The papers highlighted the importance of addressing these issues before widespread adoption of the technology. They recommended that future studies need to ensure that more meaningful patient outcomes are measured by exploring the characteristics of patients most likely to benefit from this intervention\textsuperscript{21}. Additionally, systems need to be designed with due consideration of the needs of and acceptability to the patients\textsuperscript{25}.

In a Scottish-based primary study\textsuperscript{26} researchers carried out semi-structured interviews with 38 COPD patients to examine patient views 6 months after receiving a HHM intervention. Results showed that the opportunity to use HHM was embraced enthusiastically by many patients. Overall, patients felt that compared with usual care, HMM helped them to accept more responsibility for their health by: improving their understanding of their condition; providing a feeling of reassurance; increasing access to healthcare professionals; and offering additional rationale to adjust treatment or seek expert advice. Patients generally found the technology easy to use. They also noted that because information was collected over time, HHM helped them to use trends in the data to determine their state of health and make decisions regarding their daily activities. The study concluded that, with support from healthcare professionals, HHM offers patients an increased responsibility in managing their health. The study also highlighted the importance of minimising the risk of increased dependence on practitioner support due to HHM.

Safety

No evidence relating to the effect of HHM technology on safety (adverse events caused by HHM) was identified in the papers\textsuperscript{12,22} that set out to assess this outcome.
Some sources of potential environmental hazards such as limited space in patients' homes to accommodate equipment and appropriate placement of equipment were highlighted as important factors to consider for patient safety.

Cost effectiveness

Six studies were identified in the literature search. Three were excluded due to non-generalisability and/or lack of cost-effectiveness results. Three studies were considered relevant for review. It is worth noting at this point that the intervention in all three studies was HHM in addition to usual care.

The first study, Stoddart et al.27, compared the cost-effectiveness of HHM plus usual care versus usual care in patients with COPD. A cost utility analysis was conducted assuming a one year time horizon with the results presented in the format of cost per quality-adjusted life year (QALY). The clinical data in the economic evaluation was taken from an RCT24, whereby patients received HHM plus usual care or usual care alone. In relation to costs, direct costs associated with HHM were included in the analysis and accounted for equipment, patient training, installation and weekly monitoring of data. Secondary costs pertaining to hospitalisations (such as length of stay and number of intensive care and high dependency unit bed days) were also included. The source of the direct costs (installation and maintenance as well as patient training) was based on communication with NHS Lothian and face to face contact with nurse staff, while costs associated with weekly monitoring of data was based on Personal Social Services Research Unit estimates. In terms of secondary care costs, this information was taken from patients' secondary care records. Overall the sources seemed reasonable.

When it came to capturing health benefits, QALYs were used. Based on EQ-5D responses, there was no statistically significant difference in QALYs between the HHM and usual care treatment arms, although QALY gain point estimates of 0.42 and 0.43 per patient in the HHM and usual care arms respectively were presented. The results of the analysis estimated an incremental cost effectiveness ratio (ICER) of £137,727 per QALY, based on an incremental cost of £2,293 and an incremental QALY gain of 0.01, indicating that HHM was not considered to be cost-effective versus usual care.

Overall, the study appears to be well conducted and results are considered to be generalisable to Scotland. However, a number of weaknesses were identified with the analysis, including uncertainty surrounding the health benefit associated with HHM within this patient group. There was a negligible difference in QALYs versus usual care alone, suggesting that there was no additional quality of life benefit with HHM over usual care. It should be noted that the results of this analysis are based on one study. Based on the results of this analysis, HHM plus usual care is not cost-effective versus usual care in patients with COPD. In order to establish more robust results, long-term clinical and cost-effectiveness data would be required.

A second study by McDowell et al.16 conducted a cost utility analysis comparing HHM in addition to usual care with usual care alone. The time horizon used in the analysis was 6 months and the clinical data used in the study was derived from an RCT conducted in Northern Ireland which included patients with moderate to severe COPD. The primary outcome in the analysis was patients’ quality of life. This was measured using the SGRQ questionnaire. However, it should be noted that a number of alternative measures were used to capture quality of life including EQ-5D and the HADS anxiety score. In order to elicit utility values for the economic evaluation the change in EQ-VAS scores were used. The costs included in the analysis were not transparent and no unit costs have been provided. Resource use relating to GP contacts, ED visits and hospitalisations were included. The results of the study estimated a base case ICER of £203,900 per QALY, based on an incremental cost of £2,039 and an incremental QALY gain of 0.01. The results indicated that HHM in addition to usual care was not cost-effective versus usual care alone. The study appears to be appropriate and the results are generalisable to Scotland.

There are some additional weaknesses worth considering. For instance, the time horizon in the analysis was 6 months. As COPD is considered to be a chronic condition, the length does not appear appropriate to capture all the necessary costs and benefits associated with the condition. Furthermore, there is considerable uncertainty around the EQ-VAS scores used to estimate the
utility values in the analysis. The EQ-5D measure is considered to be the most appropriate means of eliciting patient preferences, and an adequate explanation for the use of EQ-VAS outcome measure was not provided.

Finally, Henderson et al.28 examined the cost effectiveness of HHM in addition to standard support and treatment versus standard support and treatment alone. A 1-year cost utility analysis was conducted, whereby the primary outcome was cost per QALY. The clinical data used in the analysis was taken from the Whole System Demonstrator telehealth trial, which used routinely collected administrative datasets to examine the effect of HHM on primary and secondary healthcare and social care use by individuals with long-term conditions. It is worth noting that the study presented the pooled results of patients with long-term conditions (COPD, heart failure and diabetes) rather than just COPD. Based on this analysis, HHM in addition to standard care resulted in an ICER of £92,000 versus standard care alone. Probabilistic sensitivity analysis indicated an 11% chance of being cost-effective at a willingness to pay threshold of £30,00028. The primary concern with the analysis is the lack of stratified subgroup results, specifically, a subgroup of COPD patients. Therefore the results should be interpreted with caution, as they are not reflective of solely COPD patients.

To conclude, HHM (with or without standard care) does not seem to be cost-effective when compared to usual care alone. The results which are reported in all the studies indicate a base case cost per QALY that far exceeds the UK conventional willingness to pay thresholds of £20,000 to £30,000 per QALY. Furthermore there are a number of concerns within each study, which limits the validity of the results. As a general concern, all studies were relatively short (less than 1 year), as such the time horizon used in the economic analyses was not sufficient to capture the necessary costs and benefits associated with the chronic nature of the condition. One study did not present the results for the COPD population, which is the population of interest. Thus HHM (with or without standard care) is not a cost-effective treatment option for NHSScotland.

**Ongoing research**

A large-scale pilot study of 3,500 COPD patients from six regions in Europe is currently ongoing (January 2013–December 2015). This study is being planned by the United4Health consortium, whose coordinating body is based in Scotland29.

The study is aimed at assessing the effectiveness and organisational aspects of the telehealth service model. A telemonitoring package, consisting of videoconferencing with a pulse oximeter, will be provided to patients recently discharged from the hospital after admission due to respiratory exacerbation. Data will be collected frequently and a medical action will be taken if required. Patients will be followed up for up to 12 months29.

**Discussion**

As shown in Table 2, inconsistent results regarding the impact of HHM were reported for most of the outcomes assessed for patients with moderate to severe COPD.

Overall, evidence suggests that:

- HHM interventions (HHM plus usual care and HHM alone) compared with usual care appear to have a positive impact in reducing hospitalisation rates as well as improving the time free of hospitalisation and other healthcare services.

- There is no significant difference in mortality rates between patients receiving HHM interventions (provided alone or in addition to usual care) from those receiving usual care.

- There is inconsistent evidence regarding the effect of HHM interventions (HHM plus usual care and HHM alone) on respiratory exacerbations, HRQOL, ED visits and length of hospital stay.

- HHM plus usual care compared with usual care alone is not cost-effective.

For hospitalisation rates, subgroup analysis by severity and duration of intervention highlighted the importance of COPD severity in HHM management. The duration of the intervention did not have a significant effect on hospitalisation rates. However, the rates were significantly reduced in patients with severe and very severe COPD.
It was not always clear if healthcare utilisation was specifically as a result of respiratory exacerbations. As a result, it was difficult to ascertain any decrease in COPD-related healthcare utilisation.

As all-cause mortality was measured in most studies, it was also difficult to ascertain the true impact of HHM interventions on mortality.

No evidence was found relating to the long-term effects and safety of the technology.

Variations in compliance and dropout rates suggest that HHM may not be appropriate for all patients. These may have contributed to failures in detecting health deterioration.

Most reviews noted that although a number of RCTs were included in their analysis, there were a number of concerns relating to the quality of the evidence base. They include: short duration of intervention; small size of studies; inappropriate blinding; inconsistencies in data collection and reporting of outcome measures; use of poor and varied measurement instruments; and a lack of patient and economic perspectives.

In addition, the components, application and duration of intervention as well as the level of support provided to the intervention and usual care groups varied considerably between studies. Outcomes were also defined and measured differently across the trials.

These factors need to be considered when interpreting the evidence and conclusions of this report as they limit the generalisability of results.

The papers included in this report highlighted that results need to be confirmed by high quality studies. They advocate that future research should be carefully designed to identify the population of patients that will benefit most from and accept the intervention. This should help in reducing risks and improving optimal use of the technology. In addition, future studies should aim to investigate the most important components of the intervention and address methodological issues so that the long-term effects of HHM on healthcare utilisation and health-related outcomes particularly mortality and safety can be determined. Studies assessing the effectiveness of the technology also need to apply and adhere to a set of common indicators for health outcomes.

The BTS advise that HHM should not act as separate interventions but be fully integrated with existing services, with due consideration of individual patient condition as well as any existing co-morbidity.

**Conclusion**

There is growing interest and commitment to support the use of HHM interventions. HHM is a complex intervention, involving multiple technological and healthcare components.

Based on the evidence reviewed, there were inconsistent results for most of the outcomes reported. The literature identified consisted of heterogeneous technologies and usual care comparators. This makes it difficult to draw firm conclusions regarding the effectiveness, safety and cost effectiveness of HHM on healthcare utilisation and health-related outcomes, for patients with moderate to severe COPD.

Future research needs to be carefully designed to identify the most important components of the HHM intervention, its long-term effects, as well as the characteristics of patients most likely to benefit from its use.

**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
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References


References continued


