



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

# **Health technology assessment of chronic disease self- management support interventions**

**Hypertension (*extracted from main report*)**

**16 December 2015**

*Safer Better Care*

## About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent Authority established to drive high quality and safe care for people using our health and social care and support services in Ireland. HIQA's role is to develop standards, inspect and review health and social care and support services, and support informed decisions on how services are delivered. HIQA's ultimate aim is to safeguard people using services and improve the quality and safety of services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for health and social care and support services in Ireland.
- **Regulation** – Registering and inspecting designated centres.
- **Monitoring Children's Services** – Monitoring and inspecting children's social services.
- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** – Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information** – Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care and support services.

## **Advice to the Health Service Executive (HSE)**

This health technology assessment (HTA) examined the clinical and cost-effectiveness of non disease specific (or generic) self-management support interventions for chronic diseases and disease-specific interventions for asthma, chronic obstructive pulmonary disease (COPD), diabetes (Type 1 and Type 2) and cardiovascular disease (stroke, hypertension, coronary artery disease and heart failure).

Broadly, self-management support interventions are any interventions that help patients to manage portions of their chronic disease, or diseases, through education, training and support.

The review of clinical effectiveness was restricted to self-management support interventions evaluated through randomised controlled trials in adult populations. Given the volume of literature available, the clinical effectiveness of self-management support interventions was evaluated using an 'overview of reviews' approach where systematic reviews were reviewed rather than the primary evidence. Systematic reviews were undertaken for each disease area. In the case of asthma, COPD, Type 1 and Type 2 diabetes, stroke and hypertension, these were undertaken as updates to a recent high quality review (PRISMS report) commissioned by the UK National Institute for Health Research that was published in 2014.

The cost-effectiveness of generic and disease-specific self-management support interventions was evaluated by undertaking systematic reviews of the available literature for each area.

General findings common across all the sections of this report are presented below. Specific advice in relation to the various generic and disease-specific interventions is outlined in the dedicated advice sections.

The general findings of this HTA, which precede and inform HIQA's advice, are as follows:

- A broad range of self-management and self-management support interventions exist which impacts on the clarity of what constitutes effective self-management support. The interventions described by the included studies were heterogeneous and frequently complex, comprising numerous components.
- This HTA considered evidence from over 2,000 randomised controlled trials as presented across 160 systematic reviews of clinical effectiveness. Evidence on

the likely cost implications and cost-effectiveness of self-management support interventions was considered from 181 costing and cost-effectiveness studies.

- Evidence of the clinical-effectiveness of chronic disease self-management support interventions provides a complex picture. An overview of reviews makes use of pooled clinical effectiveness data, sometimes across a large number of primary studies, and in many cases of heterogeneous data. While the pooled estimate may show limited effect, individual studies may show more or less effect. As with any intervention, there may be subgroups of patients that experienced greater treatment effect than others.
- Randomised controlled trials typically had small sample sizes and a short duration of follow-up, limiting the applicability and validity of the findings, and potentially failing to capture long-term benefits or to demonstrate if observed benefits could be sustained.
- Most economic analyses were conducted alongside these randomised controlled trials, limiting their ability to determine if observed savings could be sustained. The costing methodology and perspective adopted differed greatly between studies making it difficult to summarise and aggregate findings. Evidence of cost-effectiveness for a wide range of self-management support interventions in patients with chronic disease was generally of limited applicability to the Irish healthcare setting.
- International evidence suggests that most self-management support interventions are relatively inexpensive to implement. Reported costs vary according to the intensity of the intervention, but are typically low relative to the overall cost of care for the chronic disease in question. In some instances, the interventions resulted in modest cost savings through reduced healthcare utilisation. However, it is unclear if costs would be similar if programmes are rolled out to a larger population or if economies of scale might apply. Longer-term evidence is required to determine if benefits are sustained and if costs change over time. Although generally inexpensive on a per patient basis, the budget impact of these interventions could be substantial due to the large number of eligible patients.
- The individuals eligible for self-management support interventions are likely to experience high levels of multimorbidity whereby they have multiple chronic conditions, a number of which may be amenable to self-management. For people with multimorbidity, a coherent evidence-based approach that acknowledges their various conditions and how they interact is essential.
- Where chronic disease self-management support interventions are provided, it is critical that the implementation and delivery of the interventions are subject to

routine and ongoing evaluation. This would help to ensure that they are delivering benefits to patients, and allow the content and format of the interventions to be refined.

Based on these findings HIQA's advice to the Health Service Executive (HSE) is as follows:

Good evidence of effectiveness was found for certain chronic disease self-management support interventions, while limited or no evidence of effectiveness was found for others. The evidence for generic and the disease-specific interventions is presented in the following advice sections.

The HSE should prioritise investment in those interventions for which there is good evidence of clinical effectiveness. Where chronic disease self-management support interventions are provided, it is critical that an agreed definition of self-management support interventions is developed and the implementation and delivery of the interventions are standardised at a national level and subject to routine and ongoing evaluation.

Most interventions are relatively inexpensive to implement relative to the costs of treating chronic disease and, in some instances, can result in modest cost savings through reductions or shifts in healthcare utilisation. However, due to the numbers of eligible patients, the budget impact of these interventions may be substantial.

## Advice – Hypertension

The key findings of this HTA in relation to self-management support interventions for adults with hypertension, which precede and inform HIQA's advice, are as follows:

- Sixteen systematic reviews (240 randomised controlled trials) of the clinical-effectiveness of self-management support interventions were identified for inclusion in this overview of reviews. A diverse range of interventions was identified with the largest volume of evidence obtained for reviews where self-monitoring of blood pressure was the main intervention. The remaining reviews assessed a range of self-management support interventions.
- Good evidence was found that self-monitoring of blood pressure alone or using a range of additional support, including telemedicine, is beneficial in lowering systolic and diastolic blood pressure. However, the clinical significance and durability of the effect are unclear. Additional support seems to enhance the blood pressure lowering effect.
- There is limited evidence of effectiveness of patient education interventions when used alone in improving medication adherence or blood pressure control, but these may form an important part of more complex interventions.
- There is some evidence that a range of complex self-management support interventions (that is involving multiple components, multiple providers and modes of delivery) lead to improvements in blood pressure control. A patient-specific approach may be the most beneficial, involving components tailored to the individual patient with hypertension.
- Some evidence was found that:
  - community pharmacist interventions which include patient education can lead to reductions in systolic and diastolic blood pressure.
  - simplification of medication regimens improves adherence although the clinical significance of this effect may be small.
- Based on 14 costing and cost-effectiveness studies, the economic literature assessed a diverse range of interventions with the largest volume of evidence obtained for reviews where self-monitoring of blood pressure was the main intervention. The remaining reviews assessed a range of self-management support interventions. The available evidence was largely for patients with uncontrolled hypertension.
- The cost-effectiveness results were inconsistent across outcomes of ambulatory blood pressure, costs, and healthcare utilisation. In some studies, the

intervention had a positive effect; in others it was negative, relative to usual care. The cost per patient of delivering the interventions was generally low.

- The context of high levels of undetected hypertension and poor blood pressure control in Ireland must be considered when evaluating the applicability of the findings of this overview. There are substantial levels of unmet need for routine care in Ireland, which may impact the estimated incremental benefits of self-management support interventions for hypertension.

Based on these findings HIQA's advice to the Health Service Executive (HSE) is as follows:

Good evidence was found that self-monitoring of blood pressure alone or using a range of additional support, including telemedicine, is beneficial in lowering systolic and diastolic blood pressure, although the clinical significance and durability of the effect is unclear.

There is some evidence that a range of complex self-management support interventions (that is involving multiple components, multiple providers and modes of delivery) lead to improvements in blood pressure control. A patient-specific approach may be the most beneficial, involving components tailored to the individual patient with hypertension.

There is some evidence that community pharmacy interventions, which include patient education, may lead to improvements in blood pressure control.

Evidence regarding the clinical and cost-effectiveness of other self-management support interventions for patients with hypertension is more limited, or conflicting.

There are substantial levels of unmet need for routine care in Ireland that may impact the applicability of these findings and the potential incremental benefits of self-management support.

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## List of abbreviations used in this report

<b>BRUCIE</b>	Better Regulation Using Carbohydrate and Insulin Education (Diabetes programme)
<b>CBT</b>	cognitive-behavioural therapy
<b>CDSMP</b>	chronic disease self-management programme – Stanford programme
<b>CODE</b>	Community Orientated Diabetes Education (Diabetes programme developed by Diabetes Ireland)
<b>DAFNE</b>	Dose Adjustment For Normal Eating
<b>DESMOND</b>	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (Diabetes Programme)
<b>ES</b>	effect size
<b>EPP</b>	Expert Patient Programme (UK programme based on Stanford model)
<b>HC</b>	health coaching
<b>HTA</b>	health technology assessment
<b>I(C)T</b>	information (and communication) technology
<b>MI</b>	motivational interviewing
<b>NIHR</b>	National Institute of Health Research
<b>PICO</b>	population - intervention - comparator – outcomes
<b>PRISMS</b>	Practical Systematic Review of Self-Management Support
<b>QoL</b>	quality of life
<b>RCT</b>	randomised controlled trial
<b>R-AMSTAR</b>	Revised Assessment of Multiple Systematic Reviews
<b>SD</b>	standard deviation
<b>SMBP</b>	self-monitoring of blood pressure
<b>SMD</b>	standard mean difference
<b>SMS</b>	self-management support

## 1 Introduction

### 1.1 Background to request

In December 2014, the Health Information and Quality Authority (HIQA) received a request from the Health Service Executive (HSE) to examine the clinical and cost-effectiveness of generic self-management support (SMS) interventions for chronic diseases and disease-specific interventions for chronic obstructive pulmonary disease (COPD), asthma, cardiovascular disease and diabetes.

### 1.2 Terms of Reference

Following an initial scoping of the technology, the terms of reference for this assessment were agreed between the Authority and the HSE:

- **Phase I:** To review the clinical and cost-effectiveness of generic chronic disease self-management support interventions.
- **Phase II:** To review the clinical and cost-effectiveness of disease-specific chronic disease self-management support interventions.
  - **Phase IIa:** The diseases include chronic obstructive pulmonary disease (COPD), asthma, and diabetes.
  - **Phase IIb:** The diseases include cardiovascular disease – stroke, hypertension, heart failure and ischaemic heart disease.
- Based on this assessment, to advise on the optimal chronic disease self-management support interventions to be implemented by the HSE.

### 1.3 Overall approach

This health technology assessment (HTA) was conducted using the general principles of HTA and employing the processes and practices used by HIQA in such projects. In summary:

- The Terms of Reference of the HTA were agreed between HIQA and the Health Service Executive.
- An Expert Advisory Group was established. The role of the Expert Advisory Group was to inform and guide the process, provide expert advice and information and to provide access to data where appropriate. The terms of reference of the Expert Advisory Group are included below. A full list of the

membership of the Expert Advisory Group is available in the acknowledgements section of this report.

- An evaluation team was appointed comprising internal HIQA staff. Additionally, Dr Fiona Cianci, a Public Health Specialist Registrar in the Health Service Executive (HSE), Shaun Walsh and Dr Mark Gouldson assisted with the systematic review and data extraction.
- Following review by the Expert Advisory Group with amendments made, as appropriate, the final draft report was submitted to the Board of the Authority for approval. The completed report was submitted to the Minister for Health and the HSE as advice and published on the Authority's website.

The Terms of Reference of the Expert Advisory Group were to:

- Contribute to the provision of high quality and considered advice by HIQA to the HSE.
- Contribute fully to the work, debate and decision-making processes of the group by providing expert guidance, as appropriate.
- Be prepared to provide expert advice on relevant issues outside of group meetings, as requested.
- Provide advice to HIQA regarding the scope of the analysis.
- Support the Evaluation Team led by HIQA during the assessment process by providing expert opinion and access to pertinent data, as appropriate.
- Review the project plan outline and advise on priorities, as required.
- Review the draft report from the Evaluation Team and recommend amendments, as appropriate.
- Contribute to HIQA's development of its approach to HTA by participating in an evaluation of the process on the conclusion of the assessment.

## 2 Chronic disease self-management

This chapter describes the general purpose of self-management support (SMS) interventions. It provides a description of the different types of SMS interventions evaluated in the following chapters and the theories that underpin them.

### 2.1 Description of self-management

A broad range of self-management and self-management support (SMS) definitions exist which may reflect the lack of clarity on what constitutes effective SMS.

For the purpose of this review, the 2003 definitions of self-management and SMS agreed by the US Institute of Medicine are used. Self-management is defined as 'the tasks that individuals must undertake to live with one or more chronic diseases. These tasks include having the confidence to deal with the medical management, role management and emotional management of their conditions'. SMS is thus defined as 'the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support.'<sup>(1;2)</sup>

Figure 2.1 (on page 6) by Taylor et al. shows the process by which SMS enables individuals to improve their medical, emotional and risk management behaviours.<sup>(2;3)</sup> This illustrates that to effect change, individuals need to acquire or develop five core self-management skills: problem-solving; decision-making; appropriate resource utilisation; forming a partnership with a health-care provider; and taking necessary actions.<sup>(2;4;5)</sup> The final step is mediated by the patient's self-efficacy which is required to enact these skills and deliver behaviour change. Self-efficacy, one of the core concepts of social cognitive theory, focuses on increasing an individual's confidence in their ability to carry out a certain task or behaviour, thereby empowering the individual to self-manage.<sup>(2)</sup> SMS interventions to enhance these five core self-management skills and to improve self-efficacy can include different components (education, training, provision of information or equipment) delivered in a variety of formats such as, education programmes, telemedicine, health coaching and motivational interviewing. A range of delivery methods also exist such as group or individual, face-to-face or remote, professional or peer-led. These interventions can be generic, that is, they can be used across a range of chronic diseases or disease-specific, that is, designed for a specific disease type.

Generic SMS is currently provided in Ireland through programmes such as those run by Arthritis Ireland, Beaumont hospital and the HSE's ('Quality of Life') SMS programme. These programmes are all based on a model developed in Stanford University (Stanford model). Disease-specific programmes are also available. For

example, there are a range of diabetes-specific programmes for both Type 1 (DAFNE and Berger programmes) and Type 2 diabetes (DESMOND, X-PERT, and the CODE programme developed by Diabetes Ireland). A wide range of education programmes and peer-support groups are also available, including those provided by voluntary organisations, such as the Asthma Society, COPD Ireland, Croí, Diabetes Ireland, and the Irish Heart Foundation. However, the efficacy of many of these programmes has not been evaluated at a national level nor an assessment made as to the optimal programme or programmes that should be implemented and to whom they should be made available.

SMS interventions may be a worthwhile adjunct to best medical care to allow patients to take control of and manage portions of their own care. The cost of the intervention is predicted to be low relative to, for example, the potential resource savings associated with a reduction in the number of general practitioner (GP) visits, emergency department visits or hospitalisations. However, at present there is uncertainty regarding the benefits of SMS interventions in the short and long term. Also there is uncertainty about the optimal format that SMS should take. Should it be programme-based and if so, what type of programme is best? Should remote solutions be implemented? What is the evidence of cost-effectiveness? While some initiatives are already available in Ireland, their implementation is not consistent and may not be adequate to meet the growing burden of chronic diseases. With co-morbidity being common in the ageing population and the rise in the number of patients with multi-morbidity, is there a need for generic SMS interventions that can be applied across a range of chronic diseases? Are generic skills sufficient to manage chronic diseases? Evidence on the general care of patients with multiple morbidities is limited, but it has been reported that interventions that focus on particular risk factors may be more effective.<sup>(6)</sup> Alternatively, is there a need for disease-specific SMS interventions to manage certain aspects of selected chronic diseases? Or can a combination of generic tools combined with disease-specific components be used to optimise care?

The uncertainty regarding the format of optimal SMS presents an obstacle to informed decision making about the provision of this intervention in the Irish public healthcare system.

## **Summary statement**

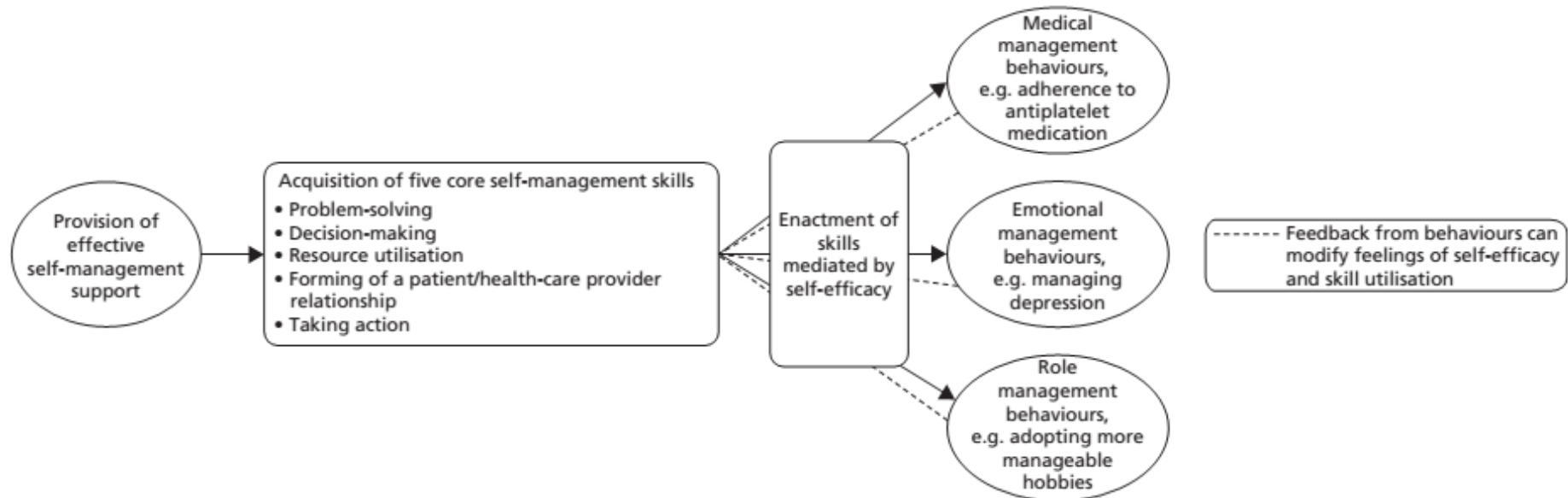
A broad range of self-management and self-management support definitions exist. For this review, the 2003 definitions agreed by the US Institute of Medicine are used:

Self-management is defined as 'the tasks that individuals must undertake to live with one or more chronic diseases. These tasks include having the confidence to deal with medical management, role management and emotional management of their conditions. '

Self-management support is defined as 'the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support.'

Self-management support interventions are any interventions that help patients to manage portions of their chronic disease or diseases through education, training and support.

**Figure 2.1** The process of adoption of self-management behaviours taken from Taylor et al. (adapted from Corbin and Strauss and Lorig and Holman).<sup>(2;3;5)</sup>



## 2.2 Description of the interventions

Phase I and Phase II of this assessment include appraisal of generic and disease-specific SMS interventions that help patients manage portions of their chronic disease through education, training and support, respectively. Included were:

- All formats and delivery methods (group or individual, face-to-face or remote, professional or peer-led).
- All studies that include a large component of SMS.

The following sections include some descriptions of well known SMS interventions. Further disease-specific interventions are discussed in the chapters on individual diseases.

### 2.2.1 Chronic disease self-management models/programmes

The following section includes a brief description of the most well-known and widely-used health behaviour change theories and health behaviour change interventions and programmes. A recent review by the New Zealand Guidelines Group included a detailed description of some of these interventions, and as such portions of these descriptions are summarised and referenced below.<sup>(7)</sup> Disease-specific programmes, where relevant, are discussed in the individual disease-specific sections of this report.

#### Health behaviour change theories

##### **Trans-Theoretical Theory<sup>(7)</sup>**

This model is based on the theory that behaviours can be modified. It is related to a person's readiness to change, the stages that they progress through to change and doing the right thing (processes) at the right time (stages). As such, tailoring interventions to match a person's readiness or stage of change is said to be essential. The model comprises emotions, cognitions and behaviours, and includes measures of self-efficacy and temptation. It has been used to modify target behaviour such as smoking cessation and stress management.

##### **Social Learning/Social Cognitive Theory<sup>(7)</sup>**

This theory proposes that behaviour change is affected by environmental influences, personal factors, and attributes of the behaviour itself. A central component of this theory is also self-efficacy. As well as belief in the behavioural change, the individual must value the outcomes they believe will occur as a result.



## **Theory of Reasoned Action and Theory of Planned Behaviour<sup>(7)</sup>**

This social cognitive theory of reasoned action states that individual performance of a target behaviour is determined by the person's intention to perform that behaviour based on their attitude toward the behaviour and the influence of their social environment or subjective norm. The shared components are behavioural beliefs and attitudes, normative beliefs, subjective norms and behavioural intentions. The Theory of Planned Behaviour adds to the Theory of Reasoned Action, the concept of perceived control over the opportunities, resources, and skills necessary to perform a behaviour. These are considered to be critical in behavioural change. This is congruent with the concept of self-efficacy.

## **Cognitive Behavioural Theory and Cognitive Behavioural Therapy (CBT)<sup>(7)</sup>**

This is a highly-structured psychotherapeutic method used to alter distorted attitudes and problem behaviours by identifying and replacing negative inaccurate thoughts and changing the rewards for behaviours. CBT attempts to help an individual make sense of overwhelming problems by breaking them down into smaller parts. CBT can take place on a one-to-one basis or with a group of people. It can be conducted from a self-help book or computer programme. The duration of the intervention can range from six weeks to six months depending on the problem and the individual; sessions usually last 30 to 60 minutes with a trained therapist.

## **Behaviour change programmes or models based on a single health behaviour change theory (including adaptations or modifications)**

### **The Chronic Care Model**

This model was developed by Wagner in the MacColl Institute in the 1990s in response to the increasing burden of chronic disease and the varying approaches of management and care (social learning/cognitive theory).<sup>(8;9)</sup> It is focused on changing a reactive system – responding mainly when a person is sick – to a more proactive system which focuses on supporting patients to self-manage. A principle part of the model is that the patient has a central role in managing their health and in particular self-efficacy. It is a high-level organisational or system level of health service provision and identifies the essential elements of a health care system that encourage high-quality care including the community, the health system, SMS, delivery system design, decision support and clinical information systems. As such, this is a higher level model than for example, the Stanford model and UK Expert Patient Programme which are discussed below, as SMS is only one component of the chronic care model.

## **Personalised care planning or 'building the house of care'**

The management and care of long-term conditions tends to be seen as the clinician's responsibility rather than a collaborative endeavour with active patient involvement and effective SMS. In the UK, the King's Fund describe the 'house of care' in 2013, a metaphor which was devised to help those working in primary care adapt the chronic care model to their own situation. It encompasses all people with long-term conditions; and assumes an active role for patients, with collaborative personalised care planning at its heart.<sup>(10)</sup> Personalised care planning is described as a collaborative process in which patients and clinicians identify and discuss problems caused by, or related to the patient's condition, and develop a plan for tackling these. It has been described as a conversation, or series of conversations, in which they agree goals and actions for managing the patient's condition.<sup>(11)</sup>

## **Stanford Programme**

This is based on the concept of self-efficacy within social learning theory. It was originally developed by Stanford University in the US. It uses peer educators to build self-efficacy in a group setting. The Stanford chronic disease self-management programme (CDSMP) is a generic programme, that is, it can be used for patients with a range of chronic diseases. It is based on the fact that people with chronic disease have similar concerns and, with specific skills and training, can effectively manage aspects of their own conditions.<sup>(12)</sup> The programme consists of two and a half hour workshops once a week for six weeks and while generally administered in community settings, is also available online.

## **UK Expert Patient Programme (EPP)**

This is a modification of the Stanford model above and was introduced into the UK in 2002 and branded the EPP.<sup>(13)</sup> Similar to Stanford's CDSMP, it uses peer educators and consists of six weekly workshops conducted in community settings; it is also available as an on-line tool. The topics discussed during the workshops are also similar to those presented in the Stanford workshops. It covers topics such as: healthy eating, exercise, pain management, relaxation, action planning and problem solving.<sup>(13)</sup> It promotes patient knowledge by teaching the skills necessary for people to effectively manage their own chronic conditions, with support from physician team members.

## **Behaviour change programmes or models based on multiple health behaviour change theories**

### **Flinders Programme™**

The Flinders programme™ is a clinician-driven, behavioural change programme (based on multiple health behaviour change theories) that emphasises the role physicians have in building patient self-efficacy and the need to actively engage patients using the principles of cognitive behavioural therapy (CBT) during patient-physician interactions (one-on-one). The programme has seven principles of self-management which allow individuals to:<sup>(14)</sup>

1. Have knowledge of their condition.
2. Follow a treatment plan (care plan) agreed with their health professionals.
3. Actively share in decision making with health professionals.
4. Monitor and manage signs and symptoms of their condition.
5. Manage the impact of the condition on their physical, emotional and social life.
6. Adopt lifestyles that promote health.
7. Have confidence, access and the ability to use support services.

### **Other programmes or models**

Other SMS interventions are based on behavioural theories such as the health belief model, the theory of reasoned action, the trans-theoretical model, the information-motivation-behavioural skills model and the theory of planned behaviour. They all specify determinants of behaviour that could potentially be changed to improve health and quality of life. The other SMS interventions that were identified as part of the systematic review of efficacy were motivational interviewing and health coaching which are similar, but distinct approaches.<sup>(15)</sup> The differences between these interventions are described briefly below.

- Motivational interviewing – based on the trans-theoretical model of behavioural change and ‘readiness to change’. It uses a brief approach such as 60 minutes of counselling and education to increase motivation and commitment to change. Once that is achieved, other approaches are pursued.
- Health coaching – based on the trans-theoretical model of behavioural change and ‘readiness to change’. It is a standalone, comprehensive intervention with a minimum of six sessions.
- Information-motivation-behavioural skills model – This is a behavioural theory which identifies constructs (including information, motivation and behaviour skills) that are needed for successful self-management or adherence.

## **2.2.2 Chronic disease self-management – Telemedicine including internet support**

Telemedicine, a term coined in the 1970s, literally means 'healing at a distance' and signifies the use of information and communication technology (ICT) to improve patient outcomes by increasing access to care and medical information.<sup>(16)</sup> However, there is no one universally accepted definition of telemedicine, so that the literature in this area describes a myriad of interventions delivered through different mechanisms for different purposes. A 2007 publication found 104 definitions of telemedicine in the peer-reviewed literature. Despite this, telemedicine was found to typically comprise four major elements: supply of medical care, use of technology, mitigation of issues of distance, and provision of benefits.<sup>(17)</sup> The World Health Organisation (WHO) has adopted the following broad description:

'The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.'<sup>(16;18)</sup>

Telemedicine is constantly evolving to incorporate new advancements in technology and to respond and adapt to changing health needs. Telemedicine applications typically have two formats; synchronous which involves real-time interaction (that is, via the telephone or videoconferencing) or asynchronous communication (not real-time, for example via text messages, email or devices that permit store-and-forward transmission of data [for example, a home glucose metre]). Asynchronous methods that use store-and-forward transmission typically forward the data to a health professional who reviews the data and uses their clinical judgement to make recommendations to the individual. Telemedicine also includes internet- or web-based support (sometimes referred to as e-health). This can include internet versions of, for example, the online version of the Stanford CDSMP described above. Internet-based support offers an alternative to face-to-face interventions which could be beneficial if resources are limited.

## 2.3 Key messages

- Self-management is defined as the tasks that individuals must undertake to live with one or more chronic diseases.
- Self-management support interventions are any interventions that help patients to manage portions of their chronic disease or diseases through education, training and support.
- Self-efficacy, one of the core concepts of social cognitive theory, focuses on increasing an individual's confidence in their ability to carry out a certain task or behaviour, thereby empowering the individual to self-manage.
- Self-management support interventions can include a variety of formats such as, education programmes, telemedicine (text messages, email, internet-based support), health coaching and motivational interviewing. A range of delivery methods also exist such as group or individual, face-to-face or remote, professional or peer-led.
- There are several behaviour change programmes which focus mainly on improving self-efficacy. These include generic programmes such as the UK Expert Patients Programme (peer-led) and the Flinders model<sup>TM</sup> (physician-led), and the generic and disease-specific Stanford programme (peer-led).

## **3 Methodology**

### **3.1 Clinical-Effectiveness**

This health technology assessment (HTA) of self-management support (SMS) interventions was undertaken as a series of rapid HTAs. As per the terms of reference, individual disease-specific assessments were prepared for asthma, chronic obstructive pulmonary disease, diabetes, cardiovascular disease (hypertension, stroke, ischaemic heart disease, and heart failure) as well as an assessment of generic SMS interventions not tailored to any one specific disease. The term 'rapid HTA' is analogous to that of a 'mini-HTA'; both terms are widely used in the international HTA setting to refer to a HTA with restricted research questions whose purpose is to inform decision making in a particular service setting or for a specific group of patients. Based on the approach used in a full HTA assessment, a rapid HTA uses a truncated research strategy with the review of published literature often restricted to a review of the secondary literature (including systematic reviews, meta-analysis, guidelines etc.) and does not include development of an independent economic model. This approach is useful when undertaking assessments that are proportionate to the needs of the decision maker.

A systematic review of chronic disease self-management support (SMS) interventions was undertaken for generic interventions and disease-specific interventions for each of the identified chronic diseases to identify, appraise and synthesise the best available evidence on their clinical effectiveness and safety.

This review included:

- development of a systematic review protocol
- appraisal and synthesis of all available evidence in line with international best practice in systematic reviews of interventions.

#### **3.1.1 Literature review**

A scoping review of the literature was carried out in preparation for this project and a large body of clinical effectiveness literature was identified. This included multiple systematic reviews of varying quality and scope that evaluated a range of SMS interventions. Based on the volume of literature available and the project timelines, an overview of reviews was considered to be the most efficient method to assess the clinical effectiveness of SMS interventions.

'Overviews of reviews' also known as, 'meta-reviews' or 'reviews of reviews' are an efficient way to gather a large body of the best available evidence in a single source to provide broad, cumulative statements that summarise the current evidence on the effectiveness of interventions. The term 'overview of reviews' is used by the

Cochrane Library and will be used in this report from this point on. An overview of reviews allows the findings of separate reviews to be compared and contrasted, thereby providing clinical decision makers with the evidence they need. The overview of reviews is limited to a summary of systematic reviews, that is reviews that are prepared using a systematic approach, and is itself done according to the principles of systematic reviewing. The disadvantage of this approach is the inability of an overview of reviews to reflect the most recent literature: following publication of a randomised controlled trial (RCT), it must first be captured in a systematic review, before subsequently being captured in an overview of reviews. This approach would therefore be less suitable for a fast-moving area where there are rapid advances in the technology. However, given their sample sizes, it is not appropriate to draw conclusions on the effect of an intervention based on a single, or a number of small RCTs. Therefore, it is unlikely that more recent RCTs not captured in an overview of reviews would be sufficient to substantially alter recommendations informing major policy decisions. As noted the scoping review identified a large body of clinical effectiveness literature. For efficiency, it was agreed that if a recent high quality review that met our inclusion criteria was retrieved, then it would be used as a starting point for this report.

### **Phase I:**

A de novo search for systematic reviews evaluating generic chronic disease SMS interventions was conducted in PubMed, Embase and the Cochrane Library (Database of Abstracts of Reviews of Effects [DARE], Cochrane Database of Systematic Reviews [CDSR] and Health Technology Assessment Database [HTA]). No language restrictions were applied. The search was limited to reviews of randomised controlled trials (RCTs) and systematic reviews of RCTs. Initially a start date of 1993 (the year in which the Cochrane Collaboration was established) was used as it marked the widespread initiation of high-quality systematic reviews. However, this was subsequently amended to 2009 due to the volume of systematic reviews retrieved. This was deemed appropriate given that the retrieved high quality reviews published after 2009 included the earlier RCT data. All searches were carried out up to 10 February 2015. A search of reference lists of relevant studies and previous review articles was also performed. The criteria used for including studies are shown in Table 3.1. Full details of the search strings used and the retrieved results are provided in Appendix A3.1.

### **Phase II:**

During scoping, the following recent high quality overview of reviews was retrieved: "A rapid synthesis of the evidence on interventions supporting self-management for people with long-term conditions: PRISMS – Practical systematic Review of Self-Management Support for long-term conditions",<sup>(2)</sup> hereafter referred to as the PRISMS report. This review was commissioned by the UK National Institute for

Health Research (NIHR) in 2012 and published in 2014. Based on a systematic search of the literature up to 1 June 2012, it summarised the best available evidence for SMS for a range of diseases including asthma, chronic obstructive pulmonary disease (COPD), Type 1 and Type 2 diabetes, stroke and hypertension.<sup>1</sup> For these diseases, this assessment therefore was limited to an update to the PRISMS report and was completed by running additional searches in PubMed, Embase and the Cochrane Library from 2012 to 1 April 2015, see Appendix A3.1. The results of the updated search as well as the original PRISMS findings are reported in the relevant chapters of this assessment with any changes to the PRISMS findings clearly documented. PRISMS also included a qualitative meta-review and implementation systematic review which assessed SMS at an organisational and professional level.<sup>(2)</sup> These sections of the PRISMS review were not updated and the results are not included here as it was beyond the immediate scope of this HTA. PRISMS did not include telehealth reviews as they deemed them to be typically about mode of delivery rather than content of what was delivered. Telehealth interventions were included in the updated review. De novo systematic reviews were undertaken for the remaining diseases included in the Terms of Reference for this project (heart failure and ischaemic heart disease) as these were not assessed in the PRISMS report. Systematic searches were run in PubMed, Embase and the Cochrane Library from 2009 to 1 April 2015, see Appendix A3.1.

**Table 3.1. PICOS criteria for study eligibility**

<b>Population</b>	<p><b>Phase I:</b> Adults <math>\geq</math> 18 years old with at least one chronic disease. This includes common physical conditions such as asthma, COPD, arthritis, diabetes and cardiovascular diseases.</p> <p><b>Phase II:</b> Adults <math>\geq</math> 18 years old with the specified disease (Type I or Type II diabetes mellitus, asthma, COPD, ischaemic heart disease, heart failure, hypertension or stroke).</p>
<b>Intervention</b>	<p><b>Phase I:</b> Any generic self-management support intervention which helps patients manage aspects of their chronic disease through education, training and support.</p> <p>All formats and delivery methods (group or individual, face-to-face or remote, professional or peer-led). All studies that include a large component of self-management support. The intervention is assessed in more than one chronic disease.</p> <p><b>Phase II:</b> Any disease-specific self-management support intervention which helps patients manage aspects of their chronic disease through education, training and support.</p>

<sup>1</sup> The dates for the searches varied for the different diseases, however, June 2012 was the earliest review.



	All formats and delivery methods (group or individual, face-to-face or remote, professional or peer-led). All studies that include a large component of self-management support. The intervention is assessed in diabetes mellitus (Type I and Type II), asthma, COPD, ischaemic heart disease, heart failure, hypertension, or stroke.
<b>Comparator</b>	Studies where self-management support plus best medical care is compared with best medical care.
<b>Outcomes</b>	<ul style="list-style-type: none"> <li>▪ Health care utilisation (including unscheduled use of healthcare services – for example, GP visits, emergency department visits, hospital (re)admissions, hospital length of stay)</li> <li>▪ Patient-centered outcomes relating to patient quality of life, patient satisfaction, self-efficacy</li> <li>▪ Health outcomes (including biological markers of disease)</li> </ul>
<b>Study design</b>	Systematic reviews of randomised controlled trials or systematic reviews (overview of reviews).

**Key:** COPD – chronic obstructive pulmonary disease; GP – general practitioner.

As noted in Section 2.1, there is no universally accepted definition for self-management or SMS. This creates problems when attempting to identify, analyse and assess the available literature. Interventions may target different recipients (for example, patients, carers, health care professionals), include different components (for example, education, information, practical support, provision of equipment, social support, lifestyle advice, prompts, financial incentives), be delivered in different formats (for example, face-to-face, remote, web-based), be provided or facilitated by different individuals including healthcare personnel and trained or untrained lay persons, as well as differing in their intensity and duration. However, a consistent theme is that SMS interventions are typically complex interventions that include more than one component of SMS. For this reason, and consistent with the PRISMS report, with the exception of education interventions, this review did not assess single component SMS (for example, simple text message appointment reminders and drug reminder packaging). Other disease-specific inclusion or exclusion criteria are included in the individual disease chapters.

Given the wide range of SMS interventions identified, where possible the SMS interventions were classified by intervention type. Categorising the interventions into groups facilitated reporting and allowed study cross-over (overlap) to be assessed per intervention type.

### 3.1.3 Data extraction and quality assurance

Preliminary screening of all returned results was carried out by a single person to eliminate studies that were clearly not relevant. Assessment of eligibility of studies and identification of multiple reports from single studies was carried out independently by two people. Any disagreements were resolved by discussion.

Data extraction was performed independently by two people, with disagreements resolved by discussion. To adequately inform decisions in relation to the quantity and quality of evidence underpinning the findings of this assessment, quality assurance of the systematic reviews and meta-analyses was undertaken. The approach adopted and the tools used are discussed below. The quality of the primary studies underpinning the systematic reviews were not directly evaluated, instead information was extracted from the systematic reviews on the quality of the primary evidence, where reported.

#### Phase I and Phase II

Assessment of the quality of included systematic reviews was performed by two people independently using the Revised Assessment of Multiple Systematic Reviews (R-AMSTAR) quality appraisal tool.<sup>(19;20)</sup> This is an 11-item tool with item scores ranging from 1 to 4, providing therefore a possible range of up to 44 for the R-AMSTAR total scores. The methodology used by the PRISMS group was adopted given the validity of their approach and to facilitate interpretation and reporting of systematic reviews. The evidence was weighted by the quality of the systematic reviews retrieved (as indicated by the R-AMSTAR score) and the size of the studies they included (total number of participants included within the systematic review) to give an overall value (range \* to \*\*\*) for each review (Table 3.2).

**Table 3.2. PRISMS quality ratings for systematic reviews<sup>(2)</sup>**

Quality of studies		
Overall Value	Quality of systematic review using R-AMSTAR	Systematic review sample size
*	Lower quality (R-AMSTAR score <31)	Smaller sample size (<1,000 participants).
**	Lower quality (R-AMSTAR score <31)	Larger sample size (≥1,000 participants)
**	Higher quality (R-AMSTAR ≥31)	Smaller sample size (<1,000 participants).
***	Higher quality (R-AMSTAR ≥31)	Larger sample size (≥1,000 participants)

**Note:** This table is taken from the PRISMS study by Taylor et al..<sup>(2)</sup>

If an included systematic review performed a quality of evidence assessment, this information was also collected during the data extraction process. Tools used included the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system criteria<sup>(21)</sup> and the Jadad Scale.<sup>(22)</sup> GRADE identifies five key elements that can be used to rate confidence in the estimates of intervention effects. The criteria are: risk of bias; inconsistency of results; indirectness of evidence; imprecision; and publication bias. Assessing and combining these components determines the quality of evidence for each outcome of interest as 'high' (further research is very unlikely to change our confidence in this estimate of effect); 'moderate' (further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate); 'low' (further research is likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate); and 'very low' (any estimate of effect is very uncertain). The Jadad scale is a validated seven-item scale that assesses the quality of RCT methods relevant to random assignment, double blinding and the accountability of all patients including withdrawals; scores range from 0 (very poor) to 5 (rigorous). An 11-item scale with a range of 0 to 13 points has also been described; scores of nine or less are considered poor quality, while scores greater than nine are considered to be of good quality.

If a meta-analysis was undertaken, the quality and strength of evidence were evaluated in order to facilitate interpretation of the findings. Each meta-analysis was reviewed using a 43-item questionnaire that evaluated the data sources used, the analysis of individual studies by meta-analysts, the conduct of the meta-analysis, and its reporting and interpretation.<sup>(23)</sup> Based on this, each meta-analysis was graded as being of low, moderate or high quality. A grading of 'low quality' referred to studies where the conclusions were at high risk of bias due to poor data collection or methods of data synthesis. The conclusions in studies identified as 'moderate quality' were at risk of bias, but were likely to be broadly accurate, while studies graded as 'high quality' were very likely to have conclusions that accurately reflected the available evidence.

Where available, data on the validity of the RCTs included in each meta-analysis were extracted to determine their risk of bias, that is, the risk that they overestimated or underestimated the true intervention effect. Biases are broadly categorised as selection bias, performance bias, detection bias, attrition bias, reporting bias and other potential sources of bias. Bias is typically assessed using a specific tool, such as the Cochrane Risk of Bias Tool. For each element the risk of bias is assessed as low, high or unclear. For each meta-analysis, the number of primary studies that were rated as being at low risk of bias (or rated as high quality) was reported relative to the total number of primary studies.

Finally, as done by the PRISMS group, a value ranging from 0 (no evidence of effect) to \*\*\* / --- very strong evidence of effect in favour of the intervention/control was assigned to each finding based on the probability of the event (Table 3.3). Effect sizes reported in the individual reviews are not just based on probabilities but include ranges of effects and confidence intervals.

**Table 3.3 PRISMS evidence of effect<sup>(2)</sup>**

Evidence of effect		
Value	Probability	Evidence of effect
0	$p > 0.05$	No evidence of effect.
+/-	$0.05 \geq p > 0.01$	Some evidence of effect in favour of intervention/control.
++/- -	$0.01 \geq p > 0.001$	Strong evidence of effect in favour of intervention/control.
+++/- - -	$p \leq 0.001$	Very strong evidence of effect in favour of intervention/control.

**Note:** This table is taken from the PRISMS study by Taylor et al..<sup>(2)</sup>

## 3.2 Costs and Cost-Effectiveness

### 3.2.1 Literature review

A review of cost-effectiveness studies was undertaken to assess the available evidence for self-management support (SMS) interventions. Studies were included if they compared the costs and consequences of a SMS intervention to routine care.

A search was carried out to identify economic analyses of SMS interventions. In tandem with the systematic review of clinical effectiveness, the search for economic evaluations was carried out in PubMed, EMBASE and the Cochrane Library. The same search terms were used with the exception of terms for systematic review and meta-analysis. In place of these, search terms and filters for economic evaluations were applied. In addition, systematic reviews of SMS interventions identified through the clinical effectiveness search that included cost or economic outcomes were used to identify additional studies. The search was carried out up until 4 March 2015.

The PICOS (Population, Intervention, Comparator, Outcomes, Study design) analysis used to formulate the search is presented in Table 3.4 below.

**Table 3.4. PICOS analysis for identification of relevant studies**

<b>Population</b>	<p><b>Phase I:</b> Adults <math>\geq</math> 18 years old with at least one chronic condition.</p> <p><b>Phase II:</b> Adults <math>\geq</math> 18 years old with the specified disease (Diabetes Type I or Type II, asthma, COPD, ischaemic heart disease, heart failure, hypertension or stroke).</p>
<b>Intervention</b>	<p><b>Phase I:</b> Any generic self-management support intervention that helps patients to manage aspects of their chronic disease care through education, training or support.</p> <p><b>Phase II:</b> Any disease-specific self-management support intervention that helps patients to manage aspects of their chronic disease care through education, training or support.</p>
<b>Comparator</b>	Routine care.
<b>Outcomes</b>	Cost or cost-effectiveness of intervention.
<b>Study design</b>	Randomised controlled trials, case-control studies, observational studies, economic modelling studies.

**Key:** COPD – chronic obstructive pulmonary disease.

Studies were excluded if:

- application of the SMS was limited to a population with a single specified chronic disease (Phase I only),
- a nursing home or non-community dwelling population was included,
- they included a paediatric population,
- cost data were not clearly reported,
- published prior to 2000 (limited relevance).

### **3.2.2 Data extraction and quality assurance**

Preliminary screening of all returned results was carried out by a single person to eliminate studies that were clearly not relevant. Assessment of eligibility of studies and identification of multiple reports from single studies was carried out independently by two people. Any disagreements were resolved by discussion.

Studies were classified into intervention types, where applicable, corresponding to the categories used for the assessment of clinical effectiveness.

In accordance with national HTA guidelines, assessment of the quality of the studies identified was performed independently by two people with the studies subsequently assessed for their transferability to the Irish healthcare setting. Any disagreements were resolved by discussion. The Consensus on Health Economic Criteria (CHEC)-list was used to assess the quality of the studies.<sup>(24)</sup> This tool is useful to evaluate economic evaluations that are being considered for inclusion in a systematic review with a view to increasing the transparency and comparability of the reviews. For studies that included an assessment of cost-utility or an economic modelling approach, assessment of the relevance of the studies to the Irish healthcare setting and their credibility was considered using a questionnaire from the International Society of Pharmacoeconomic Outcomes Research (ISPOR).<sup>(25)</sup> This tool is used and tailored towards appraising conventional economic evaluations which typically assess a set number of interventions in a specific population.

Costs reported in each of the studies were inflated to 2014 using the local consumer price index and expressed in Irish Euro using the purchasing power parity exchange rate.<sup>(26)</sup>

## 10 Hypertension

This health technology assessment (HTA) of hypertension self-management support (SMS) is one of a series of rapid HTAs assessing SMS interventions for chronic diseases. Section 10.1 provides a brief description of hypertension followed by separate reviews of the clinical (Section 10.2) and cost-effectiveness (Section 10.3) literature of SMS interventions in hypertension. Brief descriptions of the background and methods used are included with full details provided in a separate document (Chapter 3). Section 10.4 includes a discussion of both the clinical and cost-effectiveness findings. The report concludes with a list of key points in relation to hypertension SMS support (Section 10.5).

### 10.1 Description of the disease

The World Health Organization's *Health 2020* policy identifies high blood pressure or hypertension as the world's most prevalent, but preventable disease.<sup>(322)</sup> Research published in 2015 from the Irish Longitudinal Study on Ageing (TILDA) estimated that 64% of the population over 50 years of age in Ireland has high blood pressure, equivalent to 797,000 people.<sup>(323)</sup> National data suggest that there are approximately five adults aged over 45 years with undiagnosed hypertension for every three adults aged over 45 years with clinically diagnosed hypertension.<sup>(324)</sup> Hypertension is a serious medical condition that often has no symptoms, but significantly increases the risks of heart, brain, kidney and vascular disease.

In particular, the detection and management of hypertension is relevant to stroke prevention. Stroke is a leading cause of cardiovascular morbidity in Ireland — approximately 7,000 people are hospitalised following stroke each year in Ireland while in 2007 total annual stroke costs were estimated to be between €489 million and €805 million.<sup>(247)</sup> The Department of Health's National Cardiovascular Health Strategy (2010-2019) recommends that the effective management of hypertension should be prioritised in primary care and calls for guidelines on standards of assessment, management and review of patients based on best practice.<sup>(325)</sup>

Normal blood pressure is defined as <120/80 mmHg. Blood pressure is normally distributed in the population and there is no natural cut-off point above which hypertension definitively exists and below which it does not.<sup>(326)</sup> The risk associated with increasing blood pressure is continuous, with each 2 mmHg rise in systolic blood pressure associated with a 7% increased risk of mortality from ischaemic heart disease and a 10% increased risk of mortality from stroke.<sup>(326)</sup> The European Society of Hypertension and European Society of Cardiology guidelines for the management of hypertension define hypertension as having readings on separate occasions consistently showing your blood pressure to be  $\geq 140$  mmHg systolic blood pressure

(SBP) and or  $\geq 90$  mmHg diastolic blood pressure.<sup>(327)</sup> While a target blood pressure of below 130/80mmHg was typically recommended for individuals with kidney disease, diabetes or a condition that affects the heart and circulation,<sup>(328)</sup> the 2013 ESH/ESC guidelines relaxed blood pressure targets for high-risk hypertensive patients driven by a lack of commanding evidence for an aggressive approach.<sup>(327)</sup> However, this is a contentious issue and some argue that these blood pressure targets should not have dropped.<sup>(329)</sup>

The correct diagnosis of hypertension is essential to ensure adequate management. Guidelines, such as those developed by the National Institute for Health and Care Excellence (NICE) in the UK (2011), outline criteria for the appropriate measurement of blood pressure. They specify the type of conditions in which readings should be taken, the equipment that should be used, and the specific criteria for those with pulse irregularity and symptoms of postural hypotension. They also outline criteria for the diagnosis of hypertension (including criteria for multiple measurements and confirmatory ambulatory and self-monitoring blood pressure measurements).<sup>(326)</sup>

## **10.2 Review of clinical-effectiveness of self-management support interventions**

### **10.2.1 Background and methods**

Details of the background and methods for this assessment are included in Chapters 1 to 3 of this report. Briefly, an aim of this health technology assessment (HTA) is to review the clinical effectiveness of self-management support (SMS) interventions for a number of chronic conditions including hypertension. Given the large volume of literature available, it was noted that an update of an existing high quality systematic review of SMS interventions could be considered sufficient to inform decision-making.

In December 2014, a high-quality overview of reviews was published by the National Institute for Health Research (NIHR) in the UK. The Practical Systematic Review of Self-Management Support for long-term conditions (PRISMS) overview comprised an overview of systematic reviews of randomised controlled trials (RCTs) up to October 2012, and was itself undertaken according to the principles of systematic reviewing. An update to the PRISMS report was completed by running additional searches in PubMed, Embase and the Cochrane Library from 2012 to 1 April 2015, see Appendix A3.1.

In line with the PICOS (Population, Intervention, Comparator, Outcomes, Study) design agreed with the key stakeholder, this assessment is limited to SMS interventions for adults aged 18 and over. As noted in Chapter 3.1.1, SMS interventions are typically complex interventions that include more than one



component of SMS. For this reason, and consistent with the PRISMS report, with the exception of education interventions, this review did not assess single component SMS (for example, simple text message appointment reminders and drug reminder packaging). PRISMS did not include telehealth reviews as the available literature was typically about mode of delivery rather than content of what was delivered.

Telehealth interventions are included in this updated review. Relevant telehealth interventions that incorporated a significant component of SMS were also included in this updated review. Results of the updated search are reported in addition to a summary of the findings of the PRISMS report.

Data extraction and quality assurance of the systematic reviews, meta-analyses and the risk of bias associated with the primary literature was undertaken as described in Chapter 3.1.3. In summary, in order to determine the quantity, quality, strength and credibility of evidence underpinning the various SMS interventions, quality assurance of both the systematic review methodology (R-AMSTAR weighting by patient or participant trial size) and the meta-analyses (Higgins et al.'s quality assessment tool)<sup>(23)</sup> was undertaken. While the R-AMSTAR score was used to determine the quality of the systematic reviews, the scores were then weighted by patient or participant trial size, with the quality of evidence being downgraded if the review was based on fewer than 1,000 participants. The quality of the primary evidence was not evaluated directly; where reported, information on the risk of bias of the primary studies was extracted from the systematic reviews.

### **10.2.2 Description of the interventions**

A general description of self-management and typical SMS interventions is included in Chapter 2. Treatment recommendations for hypertension depend on the blood pressure level and the risk of developing a cardiovascular disease. Lifestyle changes are recommended for people with blood pressures slightly above 130/80mmHg and a low risk of cardiovascular disease. Treatment with medication and lifestyle changes is recommended for people with moderately high blood pressure (140/90mmHg or above) and a risk of cardiovascular disease in the next 10 years. Immediate treatment is recommended, possibly with further tests, if blood pressure is very high (180/110mmHg or above).<sup>(328)</sup>

Lifestyle changes can be extremely effective in reducing high blood pressure and include eating a healthy diet, reducing salt intake (to less than 5g daily), exercising regularly, stopping smoking and reducing alcohol consumption.<sup>(322)</sup> However, adherence with lifestyle modifications, especially dietary changes, is problematic and as such, improving adherence to lifestyle changes is a key target for behavioural interventions for enhancing SMS. Clinical guidelines recommend that lifestyle advice should be offered initially and then periodically to people undergoing assessment or treatment for hypertension. However, pharmacological intervention becomes

necessary in most hypertensive patients to achieve substantial, sustained blood pressure lowering.<sup>(326)</sup> Sustained reduction in blood pressure reduces the incidence of stroke, coronary artery disease, heart failure and mortality, with the potential benefit being proportional to the individual's overall cardiovascular risk. In the first year of anti-hypertensive treatment, on average only 20% of patients have sufficiently high adherence to achieve benefit.<sup>(330)</sup> This may be related to the fact that a lack of symptoms makes it a difficult disease to treat. A 2015 European study estimated that increasing adherence to anti-hypertensive therapy to 70% would save a total of €332 million (CI 95%: €319-346 million) from the national payers' perspective.<sup>(331)</sup> Measures to improve adherence include simplified dosing schedules, (for example, once-daily dosing, single pill combinations), educational interventions, telephone and computer-assisted monitoring and prompts, increased convenience of care, and involvement of community healthcare professionals (nurse and, or pharmacist).<sup>(326;332)</sup> Improving adherence is also a key target for behavioural interventions for enhancing SMS.

Self-measured or self-monitoring of blood pressure (SMBP) refers to the manual measurement of BP by a patient at home or outside of a clinic setting using a blood pressure monitor, with data recorded by the patient or electronically transmitted to a healthcare provider, using telemonitoring. Self- (also known as home) monitoring of blood pressure is indicated by clinical guidelines as an adjunctive measure in the diagnosis and or management of hypertension for certain patient cohorts.<sup>(333-335)</sup> However, despite guideline recommendations, there is a lack of clarity regarding the benefits and duration of benefits for SMBP, the best way of deploying it, and the need for additional support (for example, telemedicine, education, counselling). The validity of the data generated is dependent on the degree to which the patient adheres to recommendations in relation to SMBP, including: the use of a validated device that is calibrated at regular intervals; and the extent to which they adhere to proper measurement procedures (such as when seated with arm supported at heart level and waiting at least five minutes before the first measurement; not when rushed or uncomfortable within two hours of a large meal and so on).

Patients require adequate training in both the use of the device and the interpretation of the readings. As mentioned in Section 10.1 above, the correct diagnosis of hypertension is essential to ensure adequate management.

### **10.2.3 Results — clinical-effectiveness**

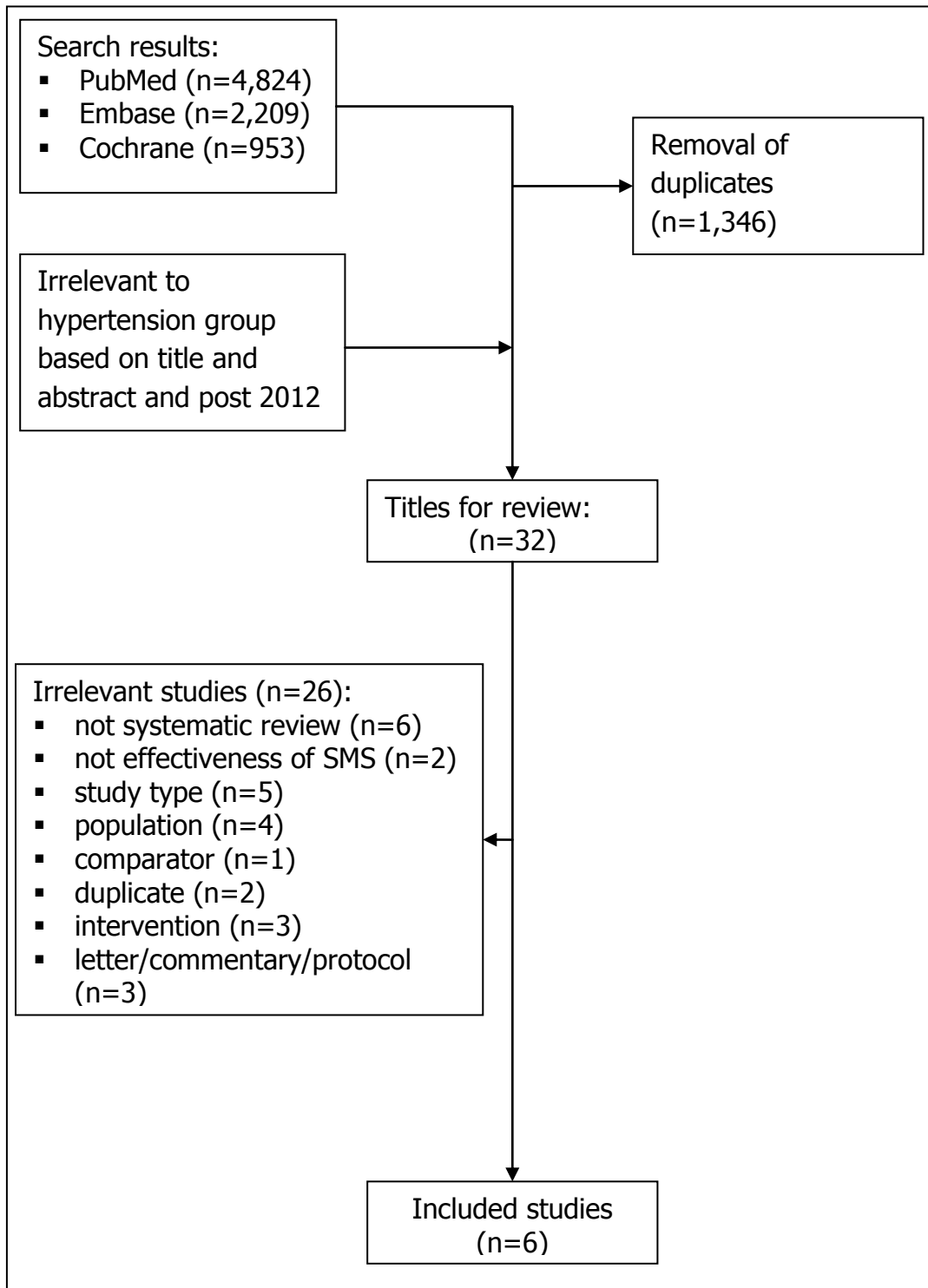
The PRISMS review retrieved a total of 10 systematic reviews of hypertension-specific SMS interventions and generic interventions used in adults with hypertension.<sup>(2)</sup> Summary details of the reviews including the intervention assessed are included in Table 10.1. The number of included RCTs ranged four<sup>(336)</sup> to 51 with the number of participants ranging from 382 to more than 87,000.<sup>(337)</sup> Study overlap

is reported in Table 10.2. The publication dates of the systematic reviews ranged from 1998 to 2011 while that of the included RCTs ranged from 1973 to 2010. Not all included systematic reviews recorded where individual RCTs had been conducted; of those that did, the greatest number was from the USA. The majority of the rest were from Europe, others were from Canada, Australia and South Africa.

The PRISMS report was updated to April 2015 using the search string in Appendix 1. A further six systematic reviews were retrieved (see Figure 10.1), details of which are included in Table 10.1. The additional six included reviews assessed a diverse range of SMS interventions for hypertension, including self-monitoring of blood pressure with or without telemedicine or additional support,<sup>(334;338;339)</sup> pharmacist-led interventions,<sup>(340)</sup> health education (in China)<sup>(341)</sup> and a range of technology interventions.<sup>(342)</sup> For the additional systematic reviews, the number of included RCTs ranged from 12 to 52 with the number of participants ranging from 2,475 to 5,400. Study overlap is reported in Table 10.2. The publication dates of the systematic reviews ranged from 2012 to 2015 while that of the included RCTs ranged from 1973 to 2014. RCT study locations were typically in Europe or North America.

The quality of the systematic reviews (R-AMSTAR scores) ranged from 12 to 33, with scores of 31 or more indicating a high-quality systematic review. When weighted according to the number of participants in the original RCTs (less than [ $<$ ] 1,000 or greater and equal to [ $\geq$ ] 1,000), four of the systematic reviews were assigned the highest quality rating (three-star \*\*\*), while one review each rated as two-star (\*\*) and one-star (\*). The identified meta-analyses were also assessed for quality; three were assessed as high quality, four as moderate quality, and four as low quality; five reviews did not include a meta-analysis. A grading of low quality referred to studies where the conclusions were at high risk of bias due to poor data collection or methods of data synthesis. The conclusions in studies identified as moderate quality were at risk of bias, but were likely to be broadly accurate, while studies graded as high quality were very likely to have conclusions that accurately reflected the available evidence. In total, 240 unique RCTs are included in the retrieved systematic reviews from the PRISMS report and updated search. The number of primary studies within each review, and the quality assessment of both the systematic reviews and the evidence underpinning them are provided in Table 10.3 on the following pages.

**Figure 10.1 Flowchart of included studies from updated search**



**Table 10.1 Hypertension: summary of systematic reviews retrieved**

Author (year)	Intervention
<b>Reviews identified in the PRISMS report</b>	
<b>SMBP (primary intervention assessed)</b>	
<b>Ebrahim (1998)<sup>(343)</sup></b>	Methods for improving adherence and control (results included for SMBP, patient / professional education)
<b>Glynn (2010)<sup>(337)</sup></b>	Model of care that improve BP control or follow-up care of patients (SMBP, patient / health professional educational interventions, health professional (nurse or pharmacist)-led care, organisational interventions aimed at improving the delivery of care, appointment reminder systems)
<b>Ogedegbe (2006)<sup>(344)</sup></b>	SMBP — Effects on adherence (2 out of 11 RCTs for SMBP alone, remaining SMBP part of complex interventions, typically education)
<b>Verberk (2011)<sup>(345)</sup></b>	SMBP — Telecare for the management of hypertension (data transfer to healthcare provider via telephone, modem, internet, mail. Many RCTs included education and behavioural training also)
<b>Other SMS interventions</b>	
<b>Bosch-Capblanch (2007)<sup>(346)</sup></b>	Contracts between practitioners and patients to improve adherence to treatment, prevention and health promotion activities
<b>Chodosh (2005)<sup>(187)</sup></b>	Self management programmes for hypertension
<b>Dickinson (2006)<sup>(347)*</sup></b>	Lifestyle interventions (Results for combinations of interventions only included e.g. improved diet, exercise, alcohol restriction, sodium restriction)
<b>Saksena (2010)<sup>(336)</sup></b>	Computer-based education for patients
<b>Schroeder (2004)<sup>(348)</sup></b>	Interventions to enhance medication adherence (education, medication regime simplification, allied health professional involvement, special monitoring such as SMBP)
<b>Takiya (2004)<sup>(349)</sup></b>	Methods to improve adherence (behavioural (to change normal behaviour or routine using e.g. telephone reminders), educational or combination of both)
<b>Reviews retrieved in updated search</b>	
<b>SMBP</b>	
<b>Fletcher (2015)<sup>(338)</sup></b>	SMBP effect on medication adherence and lifestyle factors (SMBP alone / with telemedicine / education)
<b>Omboni (2013)<sup>(334)</sup></b>	SMBP telemonitoring (alone/with support, such as education/nurse support)
<b>Uhlig (2013)<sup>(339)</sup></b>	SMBP (alone/additional support such as telemedicine, education, counselling)
<b>Other SMS interventions</b>	
<b>Cheema (2014)<sup>(340)</sup></b>	Pharmacist-led interventions
<b>Chandak 2015)<sup>(342)</sup></b>	Technology-enabled interventions
<b>Xu (2014)<sup>(341)</sup></b>	Health education in China (education on diet, nutrition, exercise, physical activity, lifestyle or social support)

**Key:** QA = quality assurance; **SMBP** = self monitoring of blood pressure; **SMS** = self-management support.

\*Lifestyle interventions include exercise, alcohol restriction and salt reduction form an integral part of hypertension care and are not considered self-management support interventions. If they were interventions to improve adherence to exercise, diet modifications and so on, then they were considered applicable.

**Table 10.2 Study overlap between the included systematic reviews (PRISMS report plus the systematic reviews from the updated search)<sup>9</sup>**

Review (year)	1	2	3	4	5	6	7	8	9	10		11	12	13	14	15	16
PRISMS reviews retrieved																	
1	Bosch-Capblanch (2007)	<b>4</b>															
2	Chodosh (2005)	1	<b>13</b>														
3	Dickinson (2006)	0	2	<b>6</b>													
4	Ebrahim (1998)	0	0	0	<b>46</b>												
5	Glynn (2010)	0	1	0	15	<b>72</b>											
6	Ogedegbe (2006)	1	0	0	1	3	<b>11</b>										
7	Saksena (2010)	0	0	0	0	0	0	<b>4</b>									
8	Schroeder (2004)	0	0	0	4	8	4	0	<b>38</b>								
9	Takiya (2004)	0	0	0	1	3	3	0	14	<b>16</b>							
10	Verberk (2011)	0	0	0	0	2	0	1	1	1	<b>9</b>						
Reviews retrieved in updated search																	
11	Cheema (2014)	0	0	0	0	0	0	0	2	0	0	<b>16</b>					
12	Chandak (2015)	0	0	0	0	0	0	0	0	0	1	0	<b>12</b>				
13	Fletcher (2015)	0	0	0	2	7	9	0	6	4	1	0	2	<b>28</b>			
14	Omboni (2014)	0	0	0	0	2	1	1	1	1	9	0	2	3	<b>23</b>		
15	Uhlig (2013)	1	1	0	6	11	7	1	6	3	9	1	3	13	15	<b>52</b>	
16	Xu (2014)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	<b>14</b>

<sup>9</sup> PRISMS review is based on a search from 1993 to October 2012. This search was updated to April 2015.

### **10.2.3.1 Summary of findings**

Detailed summaries of the systematic reviews including the intervention, outcomes assessed, duration of follow-up, sample size (number of RCTs and total number of participants) and the evidence of effect are included in Appendix A.10.1. The following are reported based on the findings from PRISMS and the additional systematic reviews retrieved in the updated search. Based on the range of SMS interventions retrieved, it was decided to classify and report the results by intervention type. The categories of systematic review include: self-monitoring of blood pressure (SMBP) and other SMS interventions. PRISMS reported their results per component of SMS and not per systematic review category. As such their results are reported by component of SMS below. In order to emphasise the relevance of the findings, results are grouped by the quality of the systematic review (using the R-AMSTAR score and size of the patient population). Table 10.3 below details the results of the quality assurance assessment of the systematic reviews and provides a summary of findings for selected outcomes from the various meta-analyses assessing the impact of SMS interventions in hypertension.

**Table 10.3 Summary characteristics and findings for selected outcomes for included studies**

Study	Quality of systematic review			Primary studies		Quality of meta-analysis	Effect on SBP mmHg (95% CI)	Effect on DBP mmHg (95% CI)
	R-AMSTAR score	Participants	Quality	n	low-risk <sup>a</sup>			
<b>Self-monitoring of blood pressure</b>								
Ebrahim 1998 <sup>(343)</sup>	28	>32,000	**	46	NR	Low	-7.6 (-8.5 to -6.7)	-4.2 (-4.6 to -3.8) (SMBP) -1.5 (-2.7 to -0.3) (patient ed.) <sup>g</sup> -1.9 (-3.3 to -0.5) (prof. ed.) <sup>h</sup>
Fletcher 2015 <sup>(338)</sup>	37	7,021	***	28	3	High		-2.02 (-2.93, -1.11)
Glynn 2010 <sup>(337)</sup>	35	>87,000	***	72	12	High	-2.5 (-3.7 to -1.3) -0.4 (-1.1 to 0.2)	-1.8 (-2.4 to -1.2) (SMBP) -0.4 (-1.1 to 0.3) (Physician ed)
Ogedegbe 2006 <sup>(344)</sup>	27	1,550	**	11		N/A		
Omboni 2014 <sup>(344)</sup>	35	7,037	***	23	NR <sup>e</sup>	Moderate	-4.71 (-6.18 to -3.24) <sup>b</sup>	-2.45 (-3.33 to -1.57) <sup>b</sup>
Uhlig 2013 <sup>(339)</sup>	33	5,400	***	52	10	Low	-3.9 <sup>c</sup>	-2.4 <sup>c</sup>
Verberk 2011 <sup>(345)</sup>	24	2,501	**	9	NR <sup>f</sup>	Low	-5.2	-2.1
<b>Other SMS interventions</b>								
Bosch-Capblanch 2007 <sup>(346)</sup>	32	382	**	4		N/A		
Chandak 2014 <sup>(342)</sup>	14	NR	*	12 <sup>d</sup>		N/A		
Cheema 2014 <sup>(340)</sup>	31	>3,032	***	16	1	Moderate	-6.13 (-8.44 to -3.81)	-2.51 (-3.46 to -1.55)
Chodosh 2005 <sup>(187)</sup>	34	1,557	***	13	NR	Moderate	-0.39 (-0.51 to -0.28)	-0.51 (-0.73 to -0.30)
Dickinson 2006 <sup>(347)</sup>	35	413	**	6		High	-5.5 (-8.8 to -2.3)	-4.5 (-6.9 to -2.0)
Saksena 2010 <sup>(336)</sup>	28	1,319	**	4		N/A		
Schroeder 2004 <sup>(348)</sup>	34	15,519	***	38		N/A		
Takiya 2004 <sup>(349)</sup>	29	2,446	**	16	NR <sup>f</sup>	Low	-	-
Xu 2014 <sup>(341)</sup>	31	2,475	***	14	1	Moderate	-19.03 (-23.26 to -14.80)	-10.33 (-13.40 to -7.26)

**Key:** \*BP = blood pressure; DBP = diastolic blood pressure; Ed = education; MD = mean difference; NR = not reported; NA = not applicable; QoI = quality of life; RR = relative risk; SBP = systolic blood pressure; SMBP = self-monitoring of blood pressure; SMS = self-management support; <sup>a</sup> Number of the total primary studies identified as being at low risk of bias. <sup>b</sup> Office SBP/DBP; <sup>c</sup> SMBP alone at six months. <sup>d</sup> Results for two of these studies are also included in the reviews by Fletcher et al., Omboni et al. and Uhlig et al. <sup>e</sup> All studies were considered to be of acceptable quality. <sup>f</sup> Risk of bias in primary studies was not assessed. <sup>g</sup> Education of patients. <sup>h</sup> Education of physicians.



**Table 10.3 (continued) Summary characteristics and findings for selected outcomes for included studies**

Study	Quality of systematic review			Primary studies		Quality of meta-analysis	Medication adherence (95% CI)	BP control, OR (95% CI)
	R-AMSTAR score	Participants	Quality	n	low-risk <sup>a</sup>			
<b>Self-monitoring of blood pressure</b>								
Ebrahim 1998 <sup>(343)</sup>	28	>32,000	**	46	NR	Low		
Fletcher 2015 <sup>(338)</sup>	37	7,021	***	28	3	High	SMD 0.21 (0.08 to 0.34)	
Glynn 2010 <sup>(337)</sup>	35	>87,000	***	72	12	High		0.83 (0.75 to 0.91) (Ed.) 0.54 (0.41 to 0.73) (appointment reminder)
Ogedegbe 2006 <sup>(344)</sup>	27	1,550	**	11		N/A		
Omboni 2014 <sup>(334)</sup>	35	7,037	***	23	NR <sup>e</sup>	Moderate		RR: 1.16 (1.04 to 1.29)
Uhlig 2013 <sup>(339)</sup>	33	5,400	***	52	10	Low		
Verberk 2011 <sup>(345)</sup>	24	2,501	**	9	NR <sup>f</sup>	Low		
<b>Other SMS interventions</b>								
Bosch-Capblanch 2007 <sup>(346)</sup>	32	382	**	4		N/A		
Chandak 2014 <sup>(342)</sup>	14	NR	*	12 <sup>d</sup>		N/A		
Cheema 2014 <sup>(340)</sup>	31	>3,032	***	16	1	Moderate	OR 12.1 (4.2 to 34.6)	
Chodosh 2005 <sup>(187)</sup>	34	1,557	***	13	NR	Moderate		
Dickinson 2006 <sup>(347)</sup>	35	413	**	6		High		
Saksena 2010 <sup>(336)</sup>	28	1,319	**	4		N/A		
Schroeder 2004 <sup>(348)</sup>	34	15,519	***	38		N/A		
Takiya 2004 <sup>(349)</sup>	29	2,446	**	16	NR <sup>f</sup>	Low	0.04 (-0.01 to 0.09)	
Xu 2014 <sup>(341)</sup>	31	2,475	***	14	1	Moderate		

Key: **BP** = blood pressure; **DBP** = diastolic blood pressure; **MD** = mean difference; **NR** = not reported; **NA** = not applicable; **QoI** = quality of life; **RR** = relative risk; **SBP** = systolic blood pressure; **SMS** = self-management support; <sup>a</sup> Number of the total primary studies identified as being at low risk of bias. <sup>b</sup> Office SBP/DBP; <sup>c</sup> SMBP alone at six months. <sup>d</sup> Results for two of these studies are also included in the reviews by Fletcher et al., Omboni et al. and Uhlig et al. <sup>e</sup> All studies were considered to be of acceptable quality. <sup>f</sup> Risk of bias in primary studies was not assessed.

To provide some context to the following results it is noted that the criteria used by the European Medicines Agency to assess the efficacy of blood pressure lowering medications include the percentage of patients with a normalisation of blood pressure (SBP less than [ $<$ ] 140 mmHg and DBP  $<$ 90mmHg) and, or reductions of SBP greater than and equal to [ $\geq$ ] 20 mmHg and/or DBP  $\geq$ 10 mmHg.<sup>(350)</sup> Clinical guidelines have used a mean change of 5mmHg as a threshold for appreciable benefits and harms when establishing the minimal important difference for blood pressure outcomes.<sup>(326)</sup> The mean reductions in blood pressure reported in Table 10.3, although statistically significant, are of a much smaller magnitude.

### 10.2.3.2 Self-management of blood pressure (SMBP)<sup>8</sup>

#### Three-star (\*\*\*) reviews

Based on one three-star (Glynn et al.)<sup>(337)</sup> and three two-star systematic reviews (Ebrahim et al., Ogedegbe et al. and Verberk et al.),<sup>(343-345)</sup> PRISMS reported that SMBP is promising, but with mixed evidence of effect, and noted that it may be more successful as part of a complex intervention. They noted that SMBP using 'telecare' had been shown to improve BP control; however, they also noted that this was based on a lower quality review (Verberk et al.).<sup>(345)</sup>

In the updated search, based on three three-star systematic reviews, good evidence was found that SMBP alone, or in combination with a range of additional support, is beneficial in lowering both SBP and DBP. The use of additional supports, such as education, seems to enhance the blood pressure lowering effect of SMBP. A 2015 meta-analysis of 28 RCTs by Fletcher et al. which assessed SMBP alone or in combination with education (face-to-face or via telemedicine) reported a small, but significant improvement in medication adherence and a significant reduction in DBP.<sup>(338)</sup>

A 2014 meta-analysis by Omboni et al. comprising 23 RCTs assessed the effect of SMBP using telemonitoring alone or with combinations of patient education, nurse support or pharmacist management and physician oversight.<sup>(334)</sup> They reported that SMBP using telemonitoring resulted in statistically significant improvements in office SBP and DBP, ambulatory blood pressure and blood pressure normalisation. A significantly higher use of antihypertensive medications was also observed, but the results for quality of life (QoL) were noted to be mixed. This report by Omboni et al. represents an update of the review by Verberk et al. identified in the PRISMS study as it included all nine RCTs identified by the Verberk report. The meta-analysis was rated of moderate quality, meaning that the conclusions were at risk of bias, but were likely to be broadly accurate.

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<sup>8</sup> For hypertension PRISMS reported their results per component of SMS and not per systematic review category.

Finally, a 2013 meta-analysis comprising 52 RCTs by Uhlig et al. assessed the effect of SMBP alone or in combination with a range of additional supports (for example, telemedicine, education or counselling).<sup>(339)</sup> They reported that SMBP, with or without additional support, lowers BP compared with usual care, but that the blood pressure effect beyond 12 months and the long-term benefits remain uncertain. They also reported that additional support enhances the blood pressure lowering effect.

#### **Summary statement for self-monitoring of blood pressure:**

Based on the quantity and quality of the systematic reviews and the underpinning primary randomised controlled trials, there is good evidence that self-measured or self-monitoring of blood pressure (SMBP) alone or in combination with a range of additional supports, including telemedicine, is beneficial in lowering systolic and diastolic blood pressure with the duration of effect being uncertain. Additional support seems to enhance the blood pressure lowering effect of SMBP. While statistically significant, the clinical effect of these interventions may be small.

#### **10.2.3.4 Other SMS interventions**

##### **Three-star (\*\*\*) reviews**

Based on two three-star (Glynn et al., Schroeder et al.)<sup>(337;348)</sup> and two two-star reviews (Ebrahim et al., Saksena et al.)<sup>(336;343)</sup> the PRISMS report concluded that there was limited evidence of effectiveness of patient educational interventions alone in improving medication adherence or blood pressure control. No additional systematic reviews on educational interventions relevant to the Irish healthcare system were identified in the updated search, for this reason the review by Xu et al. is not discussed further.<sup>(341)</sup>

Based on a single three-star review (Schroeder et al.)<sup>(348)</sup> PRISMS reported that there is some evidence that simplification of medication regimens may improve adherence, although they noted that the clinical effect of this may be small and that it was not supported by all studies.

Based mainly on three three-star reviews (Chodosh et al., Glynn et al. and Schroeder et al.)<sup>(187;337;348)</sup> and two two-star reviews (Ogedegbe et al. and Verberk et al.)<sup>(344;345)</sup> PRISMS reported that there was evidence of benefit for complex interventions (that is, including multiple components or modes of delivery of SMS in supporting self-management, with mixed results for the use of interventions led by allied health professionals. They noted that while the range of evidence available for complex interventions was too heterogeneous to be able to make definitive conclusions, a patient-specific approach may be the most beneficial, involving components tailored to the individual patient with hypertension.

The updated search identified one additional three-star systematic review evaluating other SMS interventions. The 2014 review by Cheema et al. included a meta-analysis that assessed the effectiveness of community pharmacist interventions including patient education on hypertension, identification of drug-related problems and lifestyle advice.<sup>(340)</sup> Rated as being of moderate quality, the meta-analysis reported statistically significant reductions in systolic and diastolic blood pressure and improvements in medication adherence. The authors concluded that community pharmacist-led interventions could be useful for improving clinical management of hypertension.

### **Two-star (\*\*) reviews**

Based on a single two-star systematic review (Bosch-Capblanch et al.),<sup>(346)</sup> the PRISMS report concluded that there was little evidence for the use of contracts between practitioners and patients when used alone to improve adherence in the management of hypertension. Also based on a single two-star review (Dickinson et al.),<sup>(347)</sup> PRISMS reported that lifestyle interventions may be beneficial to patients although their clinical effect may be small. Included in this review were various combinations of lifestyle interventions (for example, targeted at weight loss, alcohol or salt restriction). However, it is not clear the extent to which they included SMS.

### **One-star (\*) reviews**

A single narrative review by Chandak et al. assessing the effectiveness of technology-enabled interventions was identified.<sup>(342)</sup> The review reported results for three telemonitoring studies, however, based on an assessment of study overlap, only one is a unique RCT to this overview. The review was of poor quality and identified limited evidence of effect for a single unique RCT evaluating a telemonitoring programme.

### **Summary statement for other self-management support interventions:**

Based on the quantity and quality of the systematic reviews and the underpinning primary randomised controlled trials, there is limited evidence of effectiveness of patient education interventions when used alone in improving adherence or blood pressure control. There is some evidence that community pharmacist interventions, which include patient education, can lead to statistically significant reductions in systolic and diastolic blood pressure. There is some evidence that simplification of medication regimens may improve adherence, although the clinical effect of this improvement may be small. There is some evidence of benefit for a range of complex self-management support interventions (that is, including multiple components or modes of delivery) in improving blood pressure control. As definitive conclusions cannot be drawn based on the available evidence, a patient-specific

approach may be the most beneficial, involving components tailored to the individual patient with hypertension.

### 10.3 Review of cost-effectiveness literature of self-management support interventions

A review of cost-effectiveness studies was carried out to assess the available evidence for self-management support (SMS) interventions for people with hypertension. Studies were included if they compared the costs and consequences of a SMS intervention to routine care.

#### 10.3.1 Search strategy

A search was carried out to identify economic analyses of SMS interventions. In tandem with the systematic review of clinical effectiveness, the search for economic evaluations was carried out in MEDLINE, Embase and the Cochrane Library. The same search terms were used with the exception of terms for systematic review and meta-analysis. In place of these, search terms and filters for economic evaluations were applied. In addition, 14 systematic reviews of SMS interventions were identified through the results of the clinical effectiveness search, which included cost or economic outcomes, and were used to identify additional studies. The search was carried out up until 4 March 2015.

The PICOS (Population, Intervention, Comparator, Outcomes, Study design) analysis used to formulate the search is presented in Table 10.4 below.

**Table 10.4 PICOS analysis for identification of relevant studies**

<b>Population</b>	Adults greater than and equal to [ $\geq$ ] 18 years old with diagnosed hypertension.
<b>Intervention</b>	Any self-management support intervention incorporating education, training or support.
<b>Comparator</b>	Routine care.
<b>Outcomes</b>	Cost or cost-effectiveness of intervention.
<b>Study design</b>	Randomised controlled trials, case-control studies, observational studies, economic modelling studies.

Study types were excluded if:

- a nursing home or non-community dwelling population was included
- it included a paediatric population
- cost data were not clearly reported
- published prior to the year 2000 (due to limited relevance because of advances in technology and limited applicability of cost data).

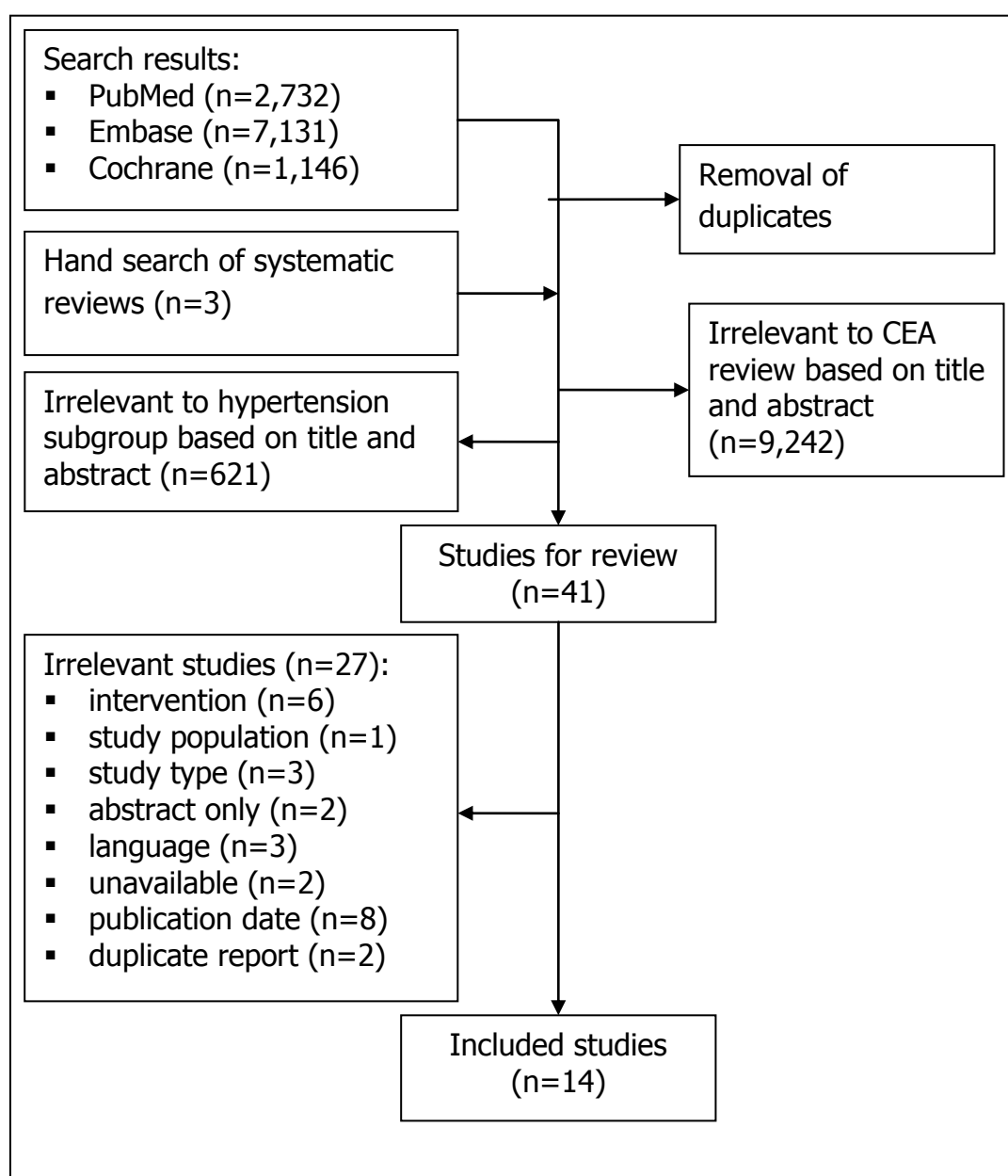
After reviewing the available studies, it was found that the majority evaluated interventions based on home-based blood pressure monitoring with or without a telemedicine component.

As outlined in Chapter 3.2.2 and in accordance with national HTA guidelines, assessment of the quality of the studies using the Consensus on Health Economic Criteria (CHEC)-list was performed independently by two people. For studies that included an assessment of cost-utility or an economic modelling approach, assessment of the relevance to the Irish healthcare setting and their credibility was considered using a questionnaire from the International Society of Pharmacoeconomics and Outcomes Research (ISPOR). Studies that were considered poor quality are not discussed below, although data from these studies are included in the evidence tables.

### **10.3.2 Results — cost-effectiveness**

The bibliographic search returned 11,009 studies from across the three databases, which equated to 9,901 unique studies after removal of duplicates (see Figure 10.2). A further three potential studies were identified after reviewing reference lists of the systematic reviews of clinical-effectiveness. After removing studies not relevant to the review of cost-effectiveness based on the titles and abstracts, 662 studies were identified that may be costing or cost-effectiveness studies. A further 621 studies were identified as not relevant to a review of hypertension interventions based on title and abstract. Finally, a further 27 were excluded based on the various exclusion criteria, leaving 14 included studies. Assessment of eligibility of studies and data extraction was carried out independently by two people, with any disagreements resolved by discussion.

Costs reported in each of the studies were inflated to 2014 using the local consumer price index and expressed in Irish Euro using the purchasing power parity index. The one exception was the 2011 study from Argentina. As reliable inflation data are not available for Argentina and the study presented figures in US dollars, the figures have been inflated using US consumer price index data. For this reason, the price data for this study are considered unreliable. In the following text, monetary data are presented in the original study currency and then in 2014 Irish Euro equivalent in brackets.

**Figure 10.2 Flowchart of included studies**

Six of the studies were based in the US, three in the UK, and one in each of Argentina, Belgium, Denmark, Italy and the Netherlands. The included studies were published between 2004 and 2014. The characteristics of the included studies are given in Table 10.5.

Two studies were excluded because full-text articles were not readily available to adequately determine their relevance. One study evaluated the feasibility of loaning self-measurement equipment to patients.<sup>(351)</sup> The study was observational in nature and was primarily concerned with accuracy of readings rather than effect on blood pressure. Another study investigated a self-management intervention based on a software application.<sup>(352)</sup> Routine care involved a telemedicine component that was

unlikely to reflect usual care in Ireland. Exclusion of these articles is unlikely to affect the findings of this review. The studies were classified into two intervention types: exercise-based and computer-based programmes.

**Table 10.5 Included studies**

Study	Country	Intervention
<b>Arrieta (2014)</b> <sup>(353)</sup>	US	Home blood pressure telemonitoring
<b>Datta (2010)</b> * <sup>(354)</sup>	US	Behavioural intervention through telemedicine
<b>Fishman (2013)</b> * <sup>(355)</sup>	US	Home blood pressure monitoring with and without pharmacist support
<b>Kaambwa (2014)</b> <sup>(356)</sup>	UK	Home blood pressure monitoring with self-titration of anti-hypertensives
<b>Maciejewski (2014)</b> * <sup>(357)</sup>	US	Nurse-led telemedicine self-management programmes
<b>Madsen (2011)</b> <sup>(358)</sup>	Denmark	Home blood pressure telemonitoring
<b>McManus (2005)</b> <sup>(359)</sup>	UK	Blood pressure self-monitoring in primary care
<b>Parati (2009)</b> * <sup>(360)</sup>	Italy	Home blood pressure telemonitoring
<b>Perman (2011)</b> <sup>(361)</sup>	Argentina	Multidisciplinary antihypertensive programme
<b>Reed (2010)</b> <sup>(362)</sup>	US	Behavioural intervention through telemedicine with blood pressure self-monitoring
<b>Staessen (2004)</b> <sup>(363)</sup>	Belgium	Home blood pressure monitoring
<b>Stoddart (2013)</b> <sup>(364)</sup>	UK	Home blood pressure telemonitoring
<b>Trogdon (2012)</b> <sup>(365)</sup>	US	Collaborative hypertension intervention including home blood pressure monitoring
<b>Verberk (2007)</b> <sup>(366)</sup>	Netherlands	Home blood pressure monitoring

\* Studies that were considered to be low quality based on the CHEC-list and ISPOR questionnaire.



### 10.3.2.1 Self-monitoring of blood pressure

Seven studies were retrieved that evaluated self-monitoring of blood pressure. See Table A10.3 in the appendices for a summary of the study details and results.

A US-based simulation study by Arrieta et al. was used to predict one-, three-, five- and 10-year returns on investment for home blood-pressure monitoring compared with usual care.<sup>(353)</sup> The data used in the model were mostly derived from health insurance claims data for beneficiaries with hypertension in a context of no home blood-pressure monitoring. Health outcomes were not reported, but were incorporated into the model in terms of costs associated with events and chronic conditions such as myocardial infarction, transient ischaemic attack, stable angina, stroke and congestive heart failure. Reductions in blood pressure associated with home monitoring were estimated from a previously published meta-analysis of RCTs. The analysis took into account attrition from plans as members migrate to other insurers. Certain costs, such as device validation and patient training, were excluded on the grounds that they would not be covered by the insurer. Depending on the insurance plan and age group, the estimated net saving of home monitoring ranged from €27 to €136 per member in the first year, and the return on investment ranged from €0.70 to €3.08 per dollar invested.

Madsen et al. evaluated home blood-pressure telemonitoring compared with usual care in a cohort of patients with poorly controlled hypertension.<sup>(358)</sup> The study was based on an RCT from Denmark that included 223 patients. Systolic and diastolic blood pressure reduced in both the intervention and control arms of the trial, and there was no statistically significant difference in blood pressure reduction between the groups. The intervention cost €166 per patient. The study reported ICERs of €32 per mm HG reduction in systolic blood pressure, and €81 per mm Hg reduction in diastolic blood pressure. Given the lack of statistically significant difference in blood pressure reductions, presentation of the ICERs would appear to be inappropriate.

A UK study by McManus et al. investigated the effect of enabling patients with uncontrolled hypertension to measure their own blood pressure at their general practitioner (GP) practice.<sup>(359)</sup> The study was based on an RCT of 441 patients. There was no statistically significant difference between the control and intervention groups at 12 months in terms of reductions in blood pressure. The intervention group had, on average, fewer GP consultations than the control group. Delivery of the intervention cost €42 per patient. The ICER for reduction in systolic blood pressure was presented as €7.94 per mm Hg, but this was in the absence of a statistically significant treatment effect. No secondary care costs were reported in the study.

An RCT by Staessen et al. with 400 participants was used to compare home-based and office-based blood pressure monitoring in patients with poorly controlled hypertension.<sup>(363)</sup> Patients were recruited at sites in Belgium and Ireland, although the majority (93%) were in Belgium. The trial ran for 12 months and at completion, the control group had achieved greater blood pressure reductions than the intervention group. However, a greater proportion of the intervention group had ceased antihypertensive drug treatment. The intervention cost €408 per 100 patients treated for one month. Total costs were lower in the intervention group: €4,317 compared with €4,750 per 100 patients per month.

A home-based blood-pressure telemonitoring intervention was compared with usual office-based monitoring in the UK in a population with uncontrolled hypertension.<sup>(364)</sup> The trial ran for six months and included 401 participants. The intervention group achieved a greater reduction in systolic blood pressure than the control group, and the difference was statistically significant. The intervention cost €92 per patient to deliver and the ICER was an estimated €33 per mm Hg drop in systolic blood pressure. The article reports different blood pressure targets for the intervention (<135/85 mm Hg) and control groups (<140/90 mm Hg). The reason given for the difference was that blood pressure measurements taken at home tend to be lower.

A Dutch RCT compared home-based blood-pressure monitoring with usual office-based monitoring in patients with uncontrolled hypertension.<sup>(366)</sup> The self-monitoring results were used to determine treatment decisions. The blood-pressure monitoring device cost €434 for 100 patients per month. Consistent with the findings of the report by Staessen et al., the control group had achieved a greater reduction in blood pressure than the intervention group at 12 months' follow-up. The intervention group used less antihypertensive medication and had lower costs. The authors concluded by suggesting that home blood-pressure monitoring could be used as an add-on to office-based monitoring rather than as an alternative, although that option was not tested as an alternative in the trial.

### **10.3.2.2 Other self-management support interventions**

Seven studies were retrieved that evaluated other types of SMS interventions. See Table A10.4 in the appendices for a summary of the study details and results.

A UK modelling study evaluated self-monitoring combined with self-titration of antihypertensives using data from a 12-month RCT.<sup>(356)</sup> The study modelled a cohort of patients with uncontrolled hypertension from age 66 years to 100 years of age. Equipment and training costs for the intervention arm were €298 per patient and annuitised over five years. The base case analysis assumed that blood pressure reductions achieved at 12 months would persist. Extensive sensitivity analyses were used to determine the impact of varying the duration of effect on blood pressure.

The ICERs for the intervention were estimated at €2,107 per QALY for men and €6,386 per QALY for women. The sensitivity analyses found that even with a relatively rapid reduction of effect, the intervention was still considered cost-effective by UK standards.

A multidisciplinary programme for middle-class elderly patients with hypertension was modelled using data from a quasi-experimental study in Argentina.<sup>(361)</sup> The programme included personal and telephone contact, support with diet and physical activity, educational material, and workshops. The intervention cost €13 per patient to deliver. The intervention resulted in an increased proportion of patients having well-controlled hypertension. The ICER for the intervention compared with usual care was €1,003 per life year gained. It was unclear if it was assumed that the effect of the programme would persist or if it was restricted to the follow up of the original study. There is a risk of bias due to the uncontrolled nature of the effectiveness data. It was also not apparent whether patients could move between risk states in the model. The study is of questionable applicability to the Irish setting.

Reed et al. estimated the cost-effectiveness of a telephonic behavioural self-management programme as part of an RCT. The trial ran for 24 months and included 636 participants. The trial had four arms: usual care; home blood pressure monitoring; a behavioural intervention; and a combined behavioural and home monitoring intervention. The study took a societal perspective. The cost per patient of delivering the intervention was €81 for home monitoring, €312 for the behavioural intervention, and €376 for the combined intervention. Only the combined intervention achieved a statistically significant reduction in systolic blood pressure compared with usual care. The two-year cost per unit reduction in systolic blood pressure for the combined intervention was €97 based on direct costs, and €268 when patient time costs were incorporated. Medicine costs were excluded from the study, which may impact on the results.

A US study used a modelling approach to simulate the effects of an education programme for patients with uncontrolled hypertension.<sup>(365)</sup> The model used data from a programme that had been rolled out to health plan members. Patients in the intervention group were given self-management kits that contained a variety of materials to educate on diet, promote exercise, and improve medication adherence. Usual care was modelled using baseline data for the cohort who had received the intervention. The lack of data for concurrent controls will have introduced a risk of bias in the study. Results were presented for one- and 10-year follow up. Scenario analysis was used to test assumptions about the effect of the intervention. Adverse events of hypertension included acute myocardial infarction, stroke, congestive heart failure, and renal failure. The total cost of delivering the programme was €114,821 for 534 patients, or €215 per patient. Based on the one-year follow-up data, the

intervention cost €719 per patient achieving controlled blood pressure, €379,635 per adverse event avoided, and €39,330 per life year gained. Given the observational and uncontrolled nature of the underlying data, the 10-year estimates are unlikely to be reliable.

## **10.4 Discussion**

This section discusses the main findings from the review of the clinical-effectiveness and cost-effectiveness literature.

### **10.4.1 Clinical effectiveness**

Sixteen systematic reviews are included in this overview of reviews of which 10 reviews were included in the PRISMS review with the additional six reviews retrieved from the updated search. A diverse range of self-management support (SMS) interventions was assessed; these differed also in the frequency, intensity and mode of delivery. Despite the heterogeneity within the intervention classes, there was a tendency for their findings to be combined, so the results of the meta-analyses should be interpreted with caution.

Compared with other chronic diseases, SMS for hypertension is not well defined within the literature. Clinical trials have shown that antihypertensive treatment can achieve blood pressure control in the majority of the patients, but that there is a gap between the treatment potential and real-life practice, possibly due to poor medication adherence. Hypertension remains a leading cause of death and cardiovascular morbidity in Ireland and elsewhere in the world. This may be related to the fact that a lack of symptoms makes it a difficult condition to treat, with hypertensive individuals being unaware of the condition or, if aware, failing to obtain or adhere to treatment. The absence of symptoms may reduce an individual's motivation to self-manage, emphasising the potential role of appropriate education and other SMS.

As noted, there was significant heterogeneity in the format and intensity of the SMS interventions, the study populations, study follow-up duration and assessed outcome measures. This makes it difficult to formulate clear recommendations regarding the most effective form and content of SMS in hypertension. The main findings from the 2014 PRISMS systematic review — and the additional findings from this updated review — indicate that SMBP with or without additional support (education, telemedicine) lowers blood pressure compared with usual care, but that the clinical significance and durability of the response remain uncertain. The main outcomes assessed in the reviews retrieved were systolic and diastolic blood pressure (SBP and DBP). In the context of criteria for efficacy used in the assessment of pharmaceuticals or the threshold for a minimal important difference (5mmHg) used

in clinical guidelines, the clinical impact of SMS support interventions appears small.<sup>(350)</sup> Results from the relevant meta-analyses indicated mean reductions in SBP ranging from 0.4 to 7.6mmHg (SMBP) and 0.4 to 4.5mmHg (lifestyle interventions) for DBP. Wide variability in changes may indicate that the evidence is not conclusive. However even small changes in blood pressure are noted to be important if there are population wide shifts. As discussed in Section 10.1, the risk associated with increasing blood pressure is continuous, with each 2 mmHg rise in systolic blood pressure associated with a 7% increased risk of mortality from ischaemic heart disease and a 10% increased risk of mortality from stroke.<sup>(326)</sup>

Complicating the picture, however, is the accuracy of the initial hypertension diagnosis and its subsequent monitoring. Data from SLÁN<sup>(367)</sup> and TILDA<sup>(368)</sup> indicate high levels of undetected hypertension and poor blood pressure control levels in Ireland. Issues include a lack of agreement on which blood pressure guidelines are to be used in the management of hypertension (European or British Hypertension Society, NICE guidelines), inability to account for white coat and masked hypertension, inaccuracy of blood pressure measuring devices and reliance on office blood pressure measurements. Further issues may include lack of a National Clinical Lead in Hypertension, funding of general practitioners and practice nurses to diagnose and manage hypertension and adequately staffed and funded blood pressure units / hypertension clinics for difficult to control or resistant hypertensive patients to be referred to. This may complicate drug treatment, leading to potential over- or under-treatment and difficulties interpreting SMBP readings.<sup>(369;370)</sup> This review assumed that patients in the primary studies had correctly diagnosed hypertension. As noted in Section 10.1, clinical guidelines outline criteria for the appropriate measurement of blood pressure and for the diagnosis of hypertension (including criteria for multiple measurements and confirmatory ambulatory and self-monitoring blood pressure measurements).<sup>(326)</sup>

The majority of the evidence should be applicable to those with diagnosed hypertension in the Irish healthcare setting based on the description of the hypertensive patient populations, epidemiology, and the healthcare systems in which the interventions were provided. A potential caveat to this assumption is the extent to which the comparator (usual care) in these RCTs is representative of usual care in Ireland. Given the increasing tendency for usual or standard of care to be determined by evidence-based clinical guidelines, and the convergence of such guidelines in Western countries, this assumption is reasonable. However, differences in healthcare systems may contribute to differences in the adherence to stated standard of care. For example, usual care for hypertension in Ireland may differ to that in the UK's NHS system where adherence to quality standards (including implementing preventive measures such as routine blood pressure checks and monitoring the proportion of patients achieving blood pressure control) is

incentivised by the quality-of-outcomes framework. The incremental benefit of new hypertension self-management initiatives in Ireland will therefore be dependent on the current adherence to stated standards of care and the level of unmet need.

Given the volume of evidence available, in the interest of efficiency this assessment of SMS interventions in adults with hypertension was undertaken in the form of an overview of reviews. As discussed in Chapter 3.4.1, a disadvantage of this approach is the inability of an overview of reviews to reflect the most recent literature.

Following publication of an RCT, it must first be captured in a systematic review, before subsequently being captured in an overview of reviews. This approach is therefore less suitable for a fast-moving area where there are rapid advances in the technology. However, given their sample sizes, it is not appropriate to draw conclusions on the effect of an intervention based on a single, or a number of small, RCTs. Therefore it is unlikely that more recent RCTs not captured in this overview of reviews would be sufficient to substantially alter recommendations informing major policy decisions.

#### **10.4.2 Cost-effectiveness**

Of the 14 costing and cost-effectiveness studies identified in this review, seven were from Europe and six from the US.

For many of the studies, the intervention was compared with usual care which involved some form of disease management by the patient's GP. Where evaluations are based on RCT evidence with six to 24 months of follow-up, most of the health service utilisation is generated in the primary care setting. The method of reimbursement in primary care varies substantially from country to country and therefore findings may not be applicable to the Irish setting. Where reduced healthcare utilisation was reported, it was in terms of reduced GP consultations. Data on reduced hospitalisations was based on longer-term simulation studies that projected adverse events related to uncontrolled or elevated blood pressure.

The majority of studies defined the study population as adults with uncontrolled hypertension. The definition of 'uncontrolled' varied from study to study and could be based on systolic or diastolic blood pressure alone, or a combination of the two. Where interventions were applied to patients with uncontrolled hypertension, it was unclear whether the intervention should continue indefinitely if the patient achieved controlled blood pressure. If the intention is that patients would continue to receive the intervention, then there would be long-term resource implications as the size of the eligible cohort would increase over time.

The relevance of the published intervention costs to Ireland is difficult to evaluate. Many of the studies included a component of home blood-pressure monitoring with or without a telemedicine component to transmit data to their GP or a centralised

management system. Many of the studies found equipment costs to be relatively low and that devices could be reused or had life spans in the region of five years. The use of independently validated devices was not always documented. The cost of training patients in how to use equipment were not always included. For home blood pressure monitoring, the monthly cost per patient ranged from €3.50 to €27.67. For other SMS interventions, the monthly cost per patient ranged from €3.38 to €17.92. The figures are not equivalent due to differing lengths of trials and need for capital investment. However, it does indicate the relatively low cost of providing the evaluated interventions.

Data on effectiveness of interventions was generally derived from RCT evidence that was based on six to 24 months of follow-up. The simulation studies relied on assumptions regarding the duration of effect, some assuming that it would be sustained to life expectancy. Where assumptions around duration of effect were tested in sensitivity analyses, a reduced duration did not change the findings. However, the sustainability of the effect may have implications for whether patients continue to receive the intervention long-term or whether it is used as a time-limited intervention.

Many studies reported cost-effectiveness as a cost per unit reduction in blood pressure. While this may facilitate comparison across the studies, it does not allow comparison with conventional willingness-to-pay thresholds. Results in terms of cost per life year gained or cost per QALY were all based on simulation studies that predicted long-term outcomes as a function of blood pressure. This is a limitation of the included studies and a feature of hypertension interventions.

The included studies have evaluated cost or cost-effectiveness based on evidence of a positive effect either in terms of blood pressure reduction or cost-reduction. Two of the studies based their estimates on RCTs that did not find a statistically significant effect, but the point estimate showed a positive effect. Thus, there is an inherent selection bias that may not be consistent with the published clinical effectiveness data. The cost and cost-effectiveness results should therefore be considered in conjunction with the clinical effectiveness review.

In summary, the review of cost-effectiveness found 14 studies where the effectiveness of interventions was generally derived from RCT evidence. This is in contrast to the review of the clinical effectiveness literature which included 17 systematic reviews of 240 unique RCTs. Half of the cost-effectiveness evaluations were of some form of blood pressure self-monitoring. The available evidence is largely for patients with uncontrolled hypertension. The results were inconsistent across outcomes of ambulatory blood pressure, costs, and healthcare utilisation. In some studies, the intervention had a positive effect; in others it was negative,

relative to usual care. The cost per patient of delivering the interventions was generally low.

## 10.5 Key points

- Sixteen systematic reviews of the clinical-effectiveness of self-management support (SMS) interventions in adults with hypertension were identified for inclusion in this overview of reviews. A diverse range of interventions was identified with the largest volume of evidence obtained for reviews where self-monitoring of blood pressure was the main intervention (n=8). The remaining reviews assessed a range of interventions.
- The quality of the systematic reviews varied, with eight rated as being higher quality reviews.
- The primary evidence underpinning the systematic reviews was found to be generally at moderate to high risk of bias, meaning that studies may have over- or under-estimated the effect size. It comprised 240 unique randomised controlled trials (RCTs) published between 1973 and 2014. These were mainly completed in Europe and North America.
- Based on the quantity and quality of the systematic reviews and the underpinning primary RCTs, there is good evidence that self-monitoring of blood pressure alone or using a range of additional support, including telemedicine, is beneficial in lowering systolic and diastolic blood pressure. However, the clinical significance and durability of the effect are unclear. Additional support seems to enhance the blood pressure lowering effect.
- There is limited evidence of effectiveness of patient education interventions when used alone in improving medication adherence or blood pressure control.
- There is some evidence that community pharmacist interventions which include patient education can lead to statistically significant reductions in systolic and diastolic blood pressure.
- There is some evidence that simplification of medication regimens improves adherence although the clinical significance of this effect may be small.
- There is some evidence that a range of complex SMS interventions (that is involving multiple components or modes of delivery) lead to improvements in blood pressure control. As definite conclusions cannot be drawn, a patient-specific approach may be the most beneficial, involving components tailored to the individual patient with hypertension.
- The review of cost-effectiveness found 14 studies where the effectiveness of interventions was generally derived from RCT evidence. Half of the evaluations were of some form of blood pressure self-monitoring, the available evidence being largely for patients with uncontrolled hypertension.



- The cost-effectiveness results were inconsistent across outcomes of ambulatory blood pressure, costs, and healthcare utilisation. In some studies, the intervention had a positive effect; in others it was negative, relative to usual care. The cost per patient of delivering the interventions was generally low.
- The context of high levels of undetected hypertension and poor blood pressure control in Ireland must be considered when evaluating the applicability of the findings of this overview. There are substantial levels of unmet need to routine care in Ireland, which may impact the estimated incremental benefits of self-management support interventions for hypertension.

## 12 Discussion

A health technology assessment (HTA) is intended to support evidence-based decision-making in regard to the optimum use of resources in healthcare services. Measured investment and disinvestment decisions are essential to ensure that overall population health gain is maximised, particularly given finite healthcare budgets and increasing demands for services provided. The purpose of this HTA was to examine the clinical and cost-effectiveness of self-management support (SMS) interventions for chronic diseases. Self-management can be broadly defined as the tasks that individuals must undertake to live with one or more chronic diseases. These can broadly be defined as interventions that help patients to manage portions of their chronic disease or diseases through education, training and support.

### 12.1 Scope of the study

This HTA examined the clinical and cost-effectiveness of generic self-management support (SMS) interventions for chronic diseases and disease-specific interventions for diabetes (Type 1 and Type 2), chronic obstructive pulmonary disease (COPD), asthma, cardiovascular disease (stroke, hypertension, ischaemic heart disease [IHD] and heart failure).

For the purpose of this review, the 2003 definitions of self-management and SMS developed by the US Institute of Medicine were used. Self-management was thus defined as: 'the tasks that individuals must undertake to live with one or more chronic diseases. These tasks include having the confidence to deal with the medical management, role management and emotional management of their conditions.' SMS was defined as: 'the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support.'

SMS interventions may: target different recipients (for example, patients, carers, healthcare professionals); include different components (for example, education, information, practical support, providing equipment, social support, lifestyle advice, prompts, financial incentives); be delivered in different formats (for example, face-to-face, remote, web-based); be delivered by different individuals (including healthcare personnel and trained or untrained lay persons); differ in their intensity and duration.

A consistent theme is that SMS interventions are typically complex interventions that include more than one component of SMS. For this reason, with the exception of education interventions, this report did not assess single component SMS (for

example, simple text message appointment reminders and drug-reminder packaging).

The review of clinical effectiveness was restricted to SMS interventions evaluated through randomised controlled trials (RCTs) in adult populations. Given the volume of literature available, the clinical effectiveness of SMS interventions was evaluated using an 'overview of reviews' approach, where systematic reviews were reviewed rather than the primary evidence. Where existing high-quality overviews were identified, these were updated rather than undertaking a de novo overview of reviews. The cost-effectiveness of generic and disease-specific SMS interventions was evaluated by undertaking systematic reviews of the available literature for each of the disease categories.

## **12.2 Previous reviews**

In December 2014, a high-quality overview of reviews was published by the National Institute for Health Research (NIHR) in the UK. The Practical Systematic Review of Self-Management Support for long-term conditions (PRISMS) study comprised an overview of systematic reviews of RCTs up to 1 June 2012, and was itself undertaken according to the principles of systematic reviewing. The PRISMS study included reviews of SMS interventions for asthma, chronic obstructive pulmonary disease, diabetes (Type 1 and Type 2), hypertension, and stroke.

In broad terms, the PRISMS study concluded that effective SMS interventions are multifaceted, disease-specific, tailored to the individual, and should be underpinned by a collaborative relationship between the patient and healthcare professional. The PRISMS study also included interventions that were applied to children, and included reviews of qualitative implementation studies. These were outside the terms of reference of this project and were not included in this report.

## **12.3 Additional evidence**

This HTA updated the PRISMS reviews to April 2015. The inclusion of the most recent evidence is particularly relevant for telemedicine and computer-based interventions given the rapid rate of technological advance. We identified an additional 47 systematic reviews for the disease areas included in the PRISMS review. PRISMS did not include telehealth reviews as they deemed these to be typically about mode of delivery rather than content of what was delivered. Relevant telehealth interventions that incorporated a significant component of self-management support were, however, included in this updated review.

The PRISMS review did not include generic SMS interventions that were not tailored for specific diseases. Chronic disease self-management programmes such as the Stanford model are designed to be used in populations with a range of chronic

conditions. Generic interventions have the benefit of being potentially applicable to a large proportion of people with one or more chronic diseases. This study evaluated the evidence for generic interventions for which 26 systematic reviews were identified.

Ischaemic heart disease (IHD) and heart failure were also not included in the PRISMS review, but were identified by the HSE as relevant to the scope of this assessment. De novo overviews of reviews were carried out as part of this assessment, identifying 14 reviews of IHD interventions and 20 reviews of heart failure interventions.

Furthermore, corresponding to the reviews of clinical effectiveness, this assessment carried out systematic reviews of the cost-effectiveness literature. These reviews provide valuable evidence on the likely cost implications and cost-effectiveness of SMS interventions. We identified and reviewed 181 costing and cost-effectiveness studies.

In total, this study considered the evidence of over 2,000 RCTs as presented across 160 systematic reviews.

## **12.4 Summary of findings**

The clinical effectiveness of self-management support interventions was reviewed in relation to each disease. A broad range of intervention types were assessed. Some intervention types were only applied to a single or small number of diseases.

### **Generic (non-disease-specific) self-management support interventions**

As noted, a de novo overview of reviews was undertaken in respect of generic self-management support (SMS) interventions. The largest volume of evidence was retrieved for the chronic disease self-management programmes, mainly the Stanford programme. There is some evidence of short-term improvements in patient-reported outcomes such as self-efficacy, health behaviour (exercise) and health outcomes (pain, disability, fatigue, depression). Short-term improvements in health status were found for telephone-delivered cognitive-based therapy. There is insufficient evidence to determine if computer-based chronic disease self-management programmes are superior to usual care or standard programmes. There is some evidence that a range of SMS interventions can lead to a small, but significant reduction in healthcare utilisation; however, it is not possible to identify which types of SMS interventions or components contribute to this positive result. Based on the available evidence, the best possible format of generic self-management support, the diseases in which it is likely to be beneficial, and the duration of its effectiveness, if any, remain unclear.

## **Asthma**

Good evidence was found that SMS interventions can improve quality of life and reduce hospital admissions and use of urgent or unscheduled healthcare in patients with asthma. While the optimal intervention format is unclear, the evidence suggests that the best asthma self-management should include education supported by a written asthma action plan, as well as improved skills training including the use of inhalers and peak flow meters. Behavioural change techniques were noted to be associated with improved medication adherence and a reduction in symptoms.

## **Chronic obstructive pulmonary disease (COPD)**

The assessment found wide variation in the interventions and patient populations, thereby making it difficult to make recommendations on the most effective content of SMS. Very good evidence was found that education is associated with a reduction in COPD-related admissions with limited evidence found that it is associated with improvements in health-related quality of life. Very good evidence was found for pulmonary rehabilitation that included exercise therapy in improving health-related quality of life (HRQoL) and functional exercise capacity of people with COPD. However, because of the substantial variation in the design of pulmonary rehabilitation programmes, the optimal format, intensity and duration of such programmes are unclear. Good evidence was found that complex SMS interventions (that is involving multiple components including education, rehabilitation, psychological therapy, and integrated disease management and or multiple professionals delivered by a variety of means) are associated with improvements in HRQoL in patients with COPD. Some evidence was found that telehealth (as part of a complex intervention) decreases healthcare utilisation while some evidence was also found of improvements in health-related quality of life for nursing outreach programmes. Given the complexity of the interventions assessed, it is difficult to identify the optimal content of a SMS intervention for COPD. Nonetheless, the inclusion of education, exercise and relaxation therapy elements have emerged as important themes.

## **Diabetes**

As the scope of this HTA was limited to adults aged 18 years and older, the majority of the evidence related to the management of Type 2 diabetes. Only two systematic reviews for SMS interventions in Type 1 diabetes were identified for inclusion in this overview of reviews. Very limited evidence was found that structured educational programmes lead to improved outcomes of quality of life and episodes of severe hypoglycaemia in adults with Type 1 diabetes. Very good evidence was found that education, including culturally-appropriate education, improves blood glucose control in the short term (less than 12 months) in adults with Type 2 diabetes, although

quality of life remains unaltered. Some evidence was found that self-management programmes are associated with small improvements in blood glucose control in the short term in Type 2 diabetes, while good evidence was found that behavioural interventions are associated with modest improvements in blood glucose control (HbA1c). Evidence of improvements in blood glucose control for a diverse range of SMS interventions — and in particular educational interventions which differ also in their frequency, intensity and mode of delivery — was also found. Given the complexity of SMS interventions assessed, it is not possible to provide clear recommendations on the optimal content and format of SMS for Type 2 diabetes, other than they should include an education component, with evidence suggesting that various models of delivery may be equally effective. Impact on resource utilisation was not assessed in any of the reviews.

## **Stroke**

There is good evidence that general rehabilitation therapy delivered in early stroke recovery has a positive impact on activities of daily living (ADL) and extended ADL for stroke survivors. There is good evidence that virtual reality-based rehabilitation (that is, using commercial gaming consoles or specifically developed consoles adopted in clinical settings) improves upper limb function and ADL when used as an adjunct to usual care. Based on the available evidence for stroke, it is not possible to draw conclusions in relation to the effectiveness of self-management programmes or a range of interventions including motivational interviewing, psychosocial or lifestyle interventions delivered to stroke survivors. There is some evidence that provision of providing information improves patients and carers' knowledge of stroke and aspects of patients' satisfaction, with small reductions (which may not be clinically significant) in patients' depression scores. Some evidence of effect was also noted for improvements in health-related quality of life for stroke liaison emphasising education and information provision.

## **Ischaemic heart disease (IHD)**

Good evidence was found that exercise programmes (including exercise-based cardiac rehabilitation) are associated with a significant reduction in mortality in suitable patient cohorts with follow-up periods greater than 12 months. Exercise-based interventions were also found to be associated with fewer rehospitalisations. Some evidence was found that patient-education interventions are associated with interim outcomes such as smoking cessation and blood pressure control. Limited evidence was found to demonstrate the effectiveness of behavioural modification interventions, although there were some reported positive effects on smoking cessation and symptom management. Limited evidence was found that home- and telehealth-based cardiac rehabilitation interventions achieve similar outcomes to centre-based cardiac rehabilitation. Interventions such as education, exercise and

behavioural changes are core components of cardiac rehabilitation, so the boundary between standard cardiac rehabilitation services and chronic disease self-management support is ill-defined.

## **Hypertension**

Good evidence was found that self-monitoring of blood pressure, alone or using a range of additional support measures including telemedicine, is beneficial in lowering systolic and diastolic blood pressure. Limited evidence of effectiveness was found for patient-education interventions when used alone to improve medication adherence or blood pressure control. Some evidence was found that community pharmacist interventions, which include patient education, can lead to statistically significant reductions in systolic and diastolic blood pressure. However, for all interventions, the clinical significance of improvements in blood pressure control and medication adherence and the durability of the effect were unclear. As with the other chronic conditions, specific recommendations in relation to the optimal format of a SMS intervention for patients with hypertension is not possible, with evidence for a range of interventions, including education, delivered in a variety of formats. Given the heterogeneity of the patient population, tailoring the components to the individual patient may be beneficial.

## **Heart failure**

Statistically significant reductions in the rate of hospital readmissions were reported for exercise interventions, telehealth interventions and home-visit programmes for patients with heart failure. Similarly, statistically significant reductions in mortality were reported for both telehealth interventions and home-visit programmes. However, despite positive results for telehealth interventions, concerns have been raised about these being the consistent standard of care for patients with heart failure due to inconsistent findings across studies and a lack of understanding about which elements of the intervention contribute to improving outcomes. Limited evidence of effect was found for patient education and behavioural modification interventions for patients with heart failure. As with ischaemic heart disease it is noted that interventions such as education, exercise and behavioural changes are core components of cardiac rehabilitation, so the boundary between standard cardiac rehabilitation services and chronic disease self-management support is ill-defined.

## **Evidence of cost-effectiveness**

Evidence of cost-effectiveness for a wide range of SMS interventions in patients with chronic disease was generally of limited applicability to the Irish healthcare setting. To be cost-effective, an intervention must first be clinically effective; given the heterogeneity of interventions assessed in the clinical effectiveness review and the

variability in the format, intensity and mode of delivery of the interventions assessed, it is difficult to generalise the evidence. A common theme identified is that SMS interventions can typically be delivered at a relatively low cost per patient, although cost is noted to vary according to the intensity of the intervention provided. Therefore, if there is evidence of clinical benefit, typically the intervention will be cost-effective or may even be cost saving (usually driven by reductions or changes in healthcare utilisation). While international evidence suggest that self-management support interventions are potentially low cost on a per-patient level, the budget impact of these interventions could be substantial due to the large numbers of eligible patients.

## **12.5 Gaps in the evidence**

One factor that may contribute to the inconsistent evidence on SMS is the lack of a clear definition of self-management across both primary studies and systematic reviews. Some of the telemedicine interventions, for example, enabled remote consultations between clinicians and patients, but the self-management aspect was a minor element of the overall intervention. The inclusion and exclusion criteria of identified systematic reviews were often based on very broad descriptions of interventions, adding to the heterogeneity of the data. A consensus on the definition of self-management would facilitate the identification of a more narrowly defined, but possibly less heterogeneous evidence-base.

With the exception of generic SMS interventions, the identified reviews related to disease-specific interventions. The included populations are likely to experience high levels of multimorbidity whereby patients have multiple chronic conditions, a number of which may be amenable to self-management. Providing a single disease-specific intervention may not be suitable for enabling successful self-management. Equally, exposure to numerous interventions may be counter-productive, placing an unsustainable burden on the individual. A systematic review of interventions for managing patients with multimorbidity found four studies that could be described as SMS interventions. The authors found that interventions that were linked to healthcare delivery or specific functional difficulties were more effective.<sup>(6)</sup> For people with multimorbidity, a coherent evidence-based approach that acknowledges their various conditions, and how they interact, is essential.

In many primary studies, interventions were implemented in addition to usual care. Because of this, many studies were structured in a manner that resulted in intervention group patients having more contact with clinical staff than the usual care group. The increased intensity of contact with health professionals may contribute to part of observed treatment effects. In some interventions, the benefit may be changing patterns of healthcare utilisation, such as the substitution of different health professionals (for instance, pharmacist support in place of general



practitioner consultations). Unfortunately, the available evidence does not support an analysis of which features of an intervention may contribute to observed effects on clinical outcomes.

Few of the included systematic reviews included outcomes of patient satisfaction. The lack of data regarding the patient experience means it was not possible to investigate the acceptability of SMS interventions to patients. As such interventions typically aim to improve or increase self-efficacy, it could be anticipated that these interventions may empower patients in their own care. However, some patients could perceive SMS negatively, for example, if they feel they have less clinician support. Further information on the patient experience would be beneficial and could give insights into why some types of SMS intervention are more effective than others.

The identified systematic reviews generally included a quality appraisal of the included primary studies, typically using the Cochrane Risk of Bias Tool or the Jadad score. These tools consider different aspects of study design such as randomisation and blinding. However, an important feature of studies is the quality of the implemented intervention, and this is not captured by the quality assessments. Poor implementation could occur in a variety of ways, such as poor quality educational material or malfunctioning equipment. Although some outcomes such as poor compliance or programme completion rates may be indicative of quality problems, they are not adequate for assessing treatment fidelity. A common audit or evaluation framework could support assessment of intervention quality, but could not be applied retrospectively. Consideration needs to be given to how the quality of intervention implementation and delivery can be evaluated.

## **12.6 Limitations**

The evidence presented in this health technology assessment (HTA), and the approach used to obtain the evidence, are subject to a number of limitations that should be taken into account when considering the findings.

The review-of-reviews approach enabled an assessment of a large quantity of evidence for a range of intervention types across a number of disease areas in a relatively short period of time. Carrying out systematic reviews would not have been feasible and would have necessitated substantial resources to identify, acquire, evaluate and summarise primary evidence where others have already done this work to an acceptable standard. However, a review of reviews places one at a remove from the primary evidence and reliant on the quality of the available reviews. More recent RCTs may not be captured in this approach. However, given their typical sample sizes, it is not possible to draw strong conclusions about effectiveness based on a single RCT, or a number of small RCTs. Therefore it is unlikely that more recent

RCTs not captured in an overview of reviews would be sufficient to substantially alter recommendations informing major policy decisions. It is clear that the quality of the identified systematic reviews was variable. Reviews are, as with the primary evidence, at risk of bias. Some reviews were optimistic in their interpretation of the available evidence and concentrated on evidence showing positive effects. By evaluating the quality of the systematic reviews using a recognised method and focusing on high-quality reviews, we have minimised the risk of bias in our review.

The majority of the trials underpinning the clinical effectiveness data had relatively short-term follow-up of participants. The majority of systematic reviews were based on RCTs with no more than 12 months of follow-up. It is unclear whether effects observed at six or 12 months might be sustained over longer time horizons. Continued beneficial effects may be contingent on ongoing exposure to the intervention, and it is unclear whether good levels of compliance are likely to be maintained over longer periods. Two reviews included trials with 10 years of follow-up data, but that does not provide enough evidence to determine the potential longer-term impact of chronic disease self-management interventions. The length of follow-up also influences the types of outcomes included in studies, with some relying on risk factors or intermediate endpoints rather than clinical endpoints. Differences in mortality, for example, may be difficult to detect over six months in trials that are powered to detect differences in relation to a more common primary outcome. Trials with longer-term follow up could provide a stronger basis to evaluate both clinical outcomes and also data on whether sustained compliance is a potential issue.

Many of the primary studies were based on small sample sizes, which were sometimes presented as pilot or feasibility studies. Small sample sizes inevitably lead to imprecise effect estimates and an inability to detect a statistically significant effect. A benefit of the systematic review approach and meta-analysis techniques is that it enables the pooling of data across studies to improve precision. While this is useful for estimates of clinical effectiveness, this is less relevant for cost-effectiveness. Due to the greater variability in cost data, studies powered to detect a clinical effect are often underpowered to generate stable cost estimates. The cost-effectiveness data was mostly generated as part of an RCT, often with a small sample population. For this reason and because of differences between RCT and real world settings, cost estimates generated by RCTs should be viewed with caution.

There was a marked lack of consistency across studies in terms of the interventions, the definition of routine care, and the outcomes reported. Within a specific disease and for a particular intervention type there could still be substantial heterogeneity. This heterogeneity poses challenges in interpreting the available evidence and forming recommendations for practice. Where possible we have evaluated the

applicability of the evidence. That is, we assessed the extent to which the available data could be used to determine what would happen if the intervention was provided to the eligible patient population in Ireland. The applicability of the evidence is contingent on it reflecting the type of intervention that would be rolled out, that it was applied to similar population, that it has been compared to an approximation of routine care in Ireland, and that the outcomes are relevant to the Irish population. Due to the inconsistency of the evidence in many instances, it is only possibly to make broad statements regarding applicability.

The studies reporting costs and cost-effectiveness were generally found to be of poor quality. In many cases the studies used data collected as part of a small RCT. There is a risk of publication bias in that studies might be more likely to publish the cost data if they either observed a clinical effect or a reduction in costs. Studies that used modelling approaches made assumptions about the sustainability of effects observed with short-term follow-up. High-quality studies tested these assumptions and used sensitivity analyses to determine the impact of effects ceasing at the end of trial follow-up. The available modelling studies often extrapolated long-term outcomes on the basis of intermediate risk factors, for example, a reduction in A1c or blood pressure, using data such as the Framingham Heart Study. The cost-effectiveness data should be viewed in conjunction with the clinical effectiveness data to reduce the risk of biased interpretation, and to ensure that cost-effectiveness is only considered where there is consistent evidence of positive clinical effect.

## **12.7 Applicability of the evidence**

### **Clinical effectiveness**

A very substantial body of literature was reviewed for this HTA, describing the clinical effectiveness of both generic and disease-specific self-management support (SMS) interventions. The applicability of the evidence is a function of the study populations, spectrum of disease, definition of routine care, health system infrastructure, and other features that impact on patient outcomes. In most cases, it was found (with caveats) that the evidence reviewed was broadly applicable to the Irish healthcare setting. A key issue was often the definition of routine care and the extent to which it corresponded to routine care as provided in Ireland.

The healthcare setting must also be considered when evaluating the applicability of the evidence. Many of the primary studies originated from the US, and due to differences in the financing and provision of healthcare, this may impact on the applicability. For example, many of the economic evaluations for SMS interventions in diabetes related to specific insurance plans, medically underserved (low income or uninsured) individuals or specific ethnic groups (for example Hispanics or Latinos), all with limited relevance to the Irish healthcare setting.

It should be borne in mind that an overview of reviews makes use of pooled clinical effectiveness data, sometimes across a large number of primary studies, and that in many cases the data were very heterogeneous. Studies were often pooled despite the fact that they implemented a variety of different interventions that were only broadly similar. In many cases the pooled estimates gave an indication of the effectiveness of a broad type of intervention rather than a specific and well-defined programme. Although the pooled estimate may show limited effect, individual studies will have shown more or less effectiveness than the average effect. Similarly, as with any healthcare intervention, within studies, some patients will have experienced a greater treatment effect than others. However, it was not possible to determine patient subgroups for which certain intervention types may be more effective. Equally it could not be stated which specific programme types might be more effective within broad intervention groupings. In the event of a policy decision to systematically provide SMS interventions, it would be advisable to consider the findings of high-quality systematic reviews and the primary evidence they included to determine what implementation might generate the greatest treatment effect.

A number of reviews included outcomes of healthcare utilisation. In some cases, studies reported either reduced utilisation or a shift in utilisation from secondary to primary care. The applicability of this evidence must be considered in conjunction with the potential for unmet need in the Irish healthcare setting. Some interventions require an element of clinician contact, for example, to carry out periodic office-based measurements. For any currently underserved patient groups, such an intervention could generate additional but appropriate utilisation. Hence, predicted reductions in service use based on international data may not translate into equivalent reductions when rolled out in Ireland.

### **Cost-effectiveness**

The data on costs and cost-effectiveness came from a wide range of settings, and were often RCT-based analyses. Estimates of cost-effectiveness or cost-utility, when reported, are probably of limited applicability. However, the per-patient cost of SMS interventions tended to be low, and this finding is anticipated to be applicable to the Irish setting. While per-patient costs are typically low, the overall budget impact could be substantial particularly for high-prevalence conditions.

## **12.8 Conclusions**

### **What did we look at?**

This HTA examined the clinical and cost-effectiveness of generic self-management support (SMS) interventions for chronic diseases and disease-specific interventions. The review of clinical effectiveness was restricted to SMS interventions evaluated through randomised controlled trials (RCTs) in adult populations. The study

considered in excess of 2,000 RCTs included across 160 systematic reviews. The quality of the primary studies underpinning those reviews was often poor. In addition, the study reviewed 181 costing studies.

### **What did we find?**

SMS interventions comprise a heterogeneous group with little clarity or consistency between studies. There is a clear need for an agreed definition of what constitutes self-management support. For the purpose of this review, the 2003 definitions of self-management and self-management support developed by the US Institute of Medicine were used. Self-management support interventions aim to help patients to manage portions of their chronic diseases through education, training and support. In theory, by improving self-efficacy, patients should be better able to manage their condition potentially leading to better health outcomes, fewer acute events, and reduced healthcare utilisation.

Evidence of the clinical-effectiveness of chronic disease self-management support interventions provides a complex picture. Certain forms of disease-specific interventions have been shown to improve outcomes over periods of six to 12 months. Longer-term outcome data are generally not collected. In particular, very good evidence was found that:

- Exercise programmes for patients with ischaemic heart disease are associated with a significant reduction in mortality in studies with greater than 12-months follow up. Exercise-based interventions are also associated with fewer rehospitalisations.
- Education is associated with a reduction in COPD-related hospital admissions.
- Pulmonary rehabilitation that includes exercise therapy improves quality of life and functional exercise capacity of people with COPD.
- Education, including culturally-appropriate education, improves blood glucose control in the short term (less than 12 months) in adults with Type 2 diabetes, although quality of life remains unaltered.
- Exercise interventions are associated with statistically significant reductions in the rate of hospital readmissions for patients with heart failure. Similar significant reductions in hospital readmission and mortality are noted for telehealth interventions and home-visits programmes. However, concerns have been raised in relation to telehealth interventions becoming the standard of care due to inconsistent findings across studies and lack of understanding about which elements of the intervention contribute to improving outcomes.

Good evidence was found that:

- Complex SMS interventions (that is involving multiple components including education, rehabilitation, psychological therapy, and integrated disease management and or multiple professionals delivered by a variety of means) are associated with improvements in health-related quality of life in patients with COPD.
- SMS interventions can reduce hospital admissions and use of urgent scheduled and unscheduled healthcare in patients with asthma. Optimal asthma SMS support should include education supported by a written action plan as well as improved skills training including the use of inhalers and peak flow meters
- General rehabilitation therapy delivered in early stroke recovery has a positive impact on activities of daily living and extended activities of daily living. Good evidence was also found that virtual reality-based rehabilitation improved upper limb function and activities of daily living when used as an add-on to usual care.
- Behavioural interventions (specifically patient activation interventions) are associated with modest improvements in blood glucose control in adults with Type 2 diabetes.
- Self-monitoring of blood pressure, alone or in conjunction with a range of additional support measures — including telemedicine — is beneficial in lowering systolic and diastolic blood pressure.

Some evidence of effect was noted that:

- Provision of information improves patients and carers' knowledge of stroke and aspects of patient satisfaction in stroke survivors
- Stroke liaison which emphasises education and information provision improves health-related quality of life in stroke survivors
- Self-management programmes are associated with small improvements in blood glucose control in the short term in Type 2 diabetes patients
- Community pharmacist interventions, which include patient education, can lead to statistically significant reductions in systolic and diastolic blood pressure in patients with hypertension.

Based on the available evidence, the optimal format of generic self-management support, the diseases in which it is likely to provide benefit, and the duration of effectiveness, if any, remain unclear.

There is limited evidence regarding the cost-effectiveness of chronic disease self-management support. With the exception of some telehealth interventions and more intensive rehabilitation programmes, most SMS interventions have a relatively low

cost per patient to implement and in some instances can result in modest cost savings through reductions or shifts in healthcare utilisation. However, budget impact is likely to be substantial if implemented for all eligible patients. Most economic analyses were conducted alongside randomised controlled trials, limiting their ability to determine if observed cost savings could be sustained. The costing methodology and perspective adopted differed greatly between studies making it difficult to summarise and aggregate findings.

### **Is it relevant?**

The data from the primary studies was very heterogeneous, reflecting the very wide range of interventions that have been implemented. Despite the many limitations of the available evidence, the findings of the clinical effectiveness are broadly applicable to the Irish healthcare setting. The extent to which the clinical effectiveness data apply to Ireland depends on the definition of routine care, the adherence to the stated standard of care, and the similarities of the healthcare systems. Evidence of cost-effectiveness for a wide range of interventions was generally of limited applicability to the Irish healthcare setting. International data suggest a relatively low cost per patient of SMS interventions, however, consideration must be given to the size of the population, particularly for high prevalence conditions, when considering the potential budget impact of implementing SMS.

### **What is the bottom line?**

SMS interventions have the potential to improve patient outcomes through improved self-efficacy. This HTA gives the evidence base for the SMS interventions that should be prioritised and for which diseases. Where chronic disease self-management support interventions are provided, it is critical that the implementation and delivery of the interventions are subject to routine and ongoing evaluation. This would help to ensure that they are delivering benefits to patients, and allow the content and format of the interventions to be refined. Evaluation will also provide a longer-term perspective not currently available in the literature and will support decisions about the optimal delivery of such interventions. The best evidence of benefit was found for the disease-specific interventions.

## Appendix A3

### Appendix A3.1 – Search details

#### Clinical Effectiveness Review Basic search terms:

<b>Chronic disease terms</b>	(Chronic disease[Mesh], chronic health/condition/ illness, long term illness/disease/ condition, diabetes[Mesh], asthma[Mesh], chronic obstructive pulmonary disease[Mesh], stroke[Mesh], hypertension[Mesh], heart failure[Mesh], coronary artery disease[Mesh], ischemic heart disease[Mesh])
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AND

<b>Self-management terms</b>	(self care[Mesh], self management, self monitor, self help, self medication, self administration, diagnostic self evaluation[Mesh], self regulation, self treat, self test, self efficacy[Mesh]) (telemedicine[Mesh], e-Health, m-Health, telecare, e-Therapy, telenursing, telemonitor, Computer-Assisted Instruction[Mesh], telephone[Mesh], Cell Phones[Mesh]), Text Messaging[Mesh]), SMS, Self help groups[Mesh], group based, Social learning theory, Behaviour change theory, Behaviour change program, Behaviour change model, motivational interview, peer led, peer support, lay led, lay support, health coach, Action plan, Care plan, Patient education as topic[Mesh], Flinders program/model, chronic care model, expert patients programme, Stanford model/program, internet[MeSH Terms], pulmonary rehab, cardiac rehab)
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AND

<b>Systematic review terms or filter</b>	(systematic review, review[Publication Type]), Meta-analysis[Publication Type], Meta-Analysis as Topic[Mesh], meta review, meta-synthesis, overview of reviews, review of reviews, cochrane review)
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#### Clinical Effectiveness Review Basic search strategy:

<b>Phase I</b>	Search from 2009 to February 2015.
<b>Phase IIa</b>	Use PRISMS results prior to 2012. New search from 2012 to April 2015.
<b>Phase IIb</b>	Stroke and hypertension: Use PRISMS results prior to 2012. New search from 2012 to April 2015. Heart failure and ischaemic heart disease: Search from 2009 to April 2015.



## Appendix A10 - Hypertension

**Table A10.1 Results of meta-analyses from PRISMS review and the systematic reviews from the updated search.**  
**Table adapted from the PRISMS review**

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance‡	ES (95% CI)
<b>PRISMS retrieved reviews</b>						
<b>Chodosh (2005)<sup>(187)</sup>***</b>	Self-management programmes for hypertension	SBP change	NR	NR	+	-0.39 (-0.51 to -0.28)
		DBP change	NR	NR	+	-0.51 (-0.73 to -0.30)
<b>Dickinson (2006)<sup>(347)</sup>**</b>	Lifestyle interventions Combinations of interventions (improved diet, exercise, alcohol restriction, sodium restriction)	Mean SBP change	NR	6 RCTs; 374 participants	+++	-5.5 (-8.8 to -2.3)
		Mean DBP change	NR	6 RCTs; 374 participants	+++	-4.5 (-6.9 to -2.0)
<b>Ebrahim (1998)<sup>(343)</sup>**</b>	Methods for improving adherence and control	Home monitoring (included effects of family monitoring): Mean DBP change	NR	NR	0	-0.5 (-0.7 to 0.7)
		Self-monitoring: Mean DBP change	NR	NR	+	-1.5 (-2.7 to -0.3)
		Patient education: Mean SBP change	NR	NR	+++	-7.6 (-8.5 to -6.7)
		Patient education: Mean DBP change	NR	NR	+++	-4.2 (-4.6 to -3.8)
		Patient education without Hypertension Detection and Follow-up Programme: Mean SBP change	NR	NR	0	-0.7 (-2.8 to 1.4)
		Patient education without Hypertension Detection and Follow-up Programme: Mean DBP change	NR	NR	0	-0.6 (-1.6 to 0.4)
		Education of Professionals: Mean DBP change	NR	NR	+	-1.9 (-3.3 to -0.5)

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance‡	ES (95% CI)
<b>Glynn (2010)</b> <sup>(337)***</sup>	Model of care that improves BP control or follow-up care of patients	Self-monitoring: Mean SBP change	NR	12 RCTs	++	-2.5 (-3.7 to -1.3)
		Mean DBP change	NR	14 RCTs	++	-1.8 (-2.4 to -1.2)
		BP control achieved	NR	6 RCTs	0	OR 0.97 (0.81 to 1.16)
		Educational interventions directed at patient: BP control achieved	NR	8 RCTs	+	OR 0.83 (95% CI 0.75 to 0.91)
		Educational interventions directed to physician: Mean SBP change	NR	NR	0	-0.4 (-1.1 to 0.2)
		Mean DBP change	NR	NR	0	-0.4 (-1.1 to 0.3)
		Appointment reminder systems: BP control achieved	NR	2 RCTs	+	OR 0.54 (0.41 to 0.73)
<b>Takiya (2004)</b> <sup>(349)**</sup>	Adherence tools and methods to improve adherence	Behavioural interventions Adherence (different measures converted to ES)	NR	NR	0	0.04 (-0.01 to 0.09)
<b>Verberk (2011)</b> <sup>(345)**</sup>	Telecare for the management of hypertension	Telecare intervention vs. control Mean SBP change	NR	NR	+++	-5.2 (p < 0.001)
		Mean DBP change	NR	NR	++	-2.1 (p < 0.01)
		Percentage meeting BP targets	NR	NR	0	2.7% (p = 0.6)
		Intervention but without antihypertensive drug modification vs. control Mean SBP change	NR	NR	0	-8.6 (no p-value provided)
		Mean DBP change	NR	NR	0	-3.6 (no p-value provided)
		Intervention with antihypertensive drug modification based on measured BP values vs. control Mean SBP change	NR	NR	0	-5.1 (p = 0.07) Mean DBP change NR NR 0 -2.2 (p = 0.22)

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance‡	ES (95% CI)
<b>Reviews retrieved in updated search</b>						
<b>Cheema (2014)<sup>(340)</sup>***</b>	Community pharmacist interventions (meta-analysis included: patient education on hypertension, identification of drug-related problems and lifestyle advice)	Effects on SBP	3 to 13 months	11 RCTs; 2,240 participants	+++	-6.13 (-8.44, -3.81) p < 0.00001; I <sup>2</sup> = 36%
		Effects on DBP		11 RCTs; 2,246 participants	+++	-2.51 (-3.46, -1.55) p < 0.00001; I <sup>2</sup> = 0%
		Effects on SBP on hypertension without cardiovascular problems		5 RCTs; 1,082 participants	++	-7.2 (95% CI -3.6 to -10.8, p = 0.004) I <sup>2</sup> = 32%
		Effects on DBP on hypertension without cardiovascular problems		5 RCTs; 1,078 participants	+++	-3.4 (95% CI -1.9 to -5.0, p < 0.00001) I <sup>2</sup> = 0%
		Effects on SBP on hypertension with cardiovascular problems		6 RCTs; 1,158 participants	+++	-5.3 (95% CI -1.7 to -8.9, P < 0.0001) I <sup>2</sup> = 46%
		Effects on SBP on hypertension with cardiovascular problems		6 RCTs; 1,168 participants	+	-1.9 (95% CI -0.7 to -3.1, P = 0.002) I <sup>2</sup> = 0%
		Medication adherence		6 RCTs; 290	+++	OR 12.1, 95% CI 4.2-34.6; P < 0.001
<b>Fletcher (2015)<sup>(338)</sup>***</b>	SMBP (includes some telemonitoring studies)	Adherence to antihypertensive medication	2 weeks to 12 months (median 6 months)	13 RCTs; 1,809	++	SMD 0.21, 95% CI 0.08, 0.34 (I <sup>2</sup> = 43%)
		Adherence to antihypertensive medication – assessed by electronic monitoring		2 RCTs;	+	SMD 0.45, 95% CI 0.10 to 0.79 (I <sup>2</sup> = 59%)
		Adherence to antihypertensive medication – pill counts		5 RCTs;	+	SMD 0.30, 95% CI 0.10 to 0.59 (I <sup>2</sup> = 42%)
		Adherence to antihypertensive medication – pharmacy fill data		2 RCTs;	0	SMD 0.12, 95% CI -0.05 to 0.29 (I <sup>2</sup> = 0%)
		Adherence to antihypertensive medication – self-report		4 RCTs;	0	SMD 0.05, 95% CI -0.13 to 0.22 (I <sup>2</sup> = 0%)
		DBP	6 months	11 RCTs; 1,798	+++	WMD -2.02, 95% CI -2.93 to -1.11, (I <sup>2</sup> = 0%).

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance‡	ES (95% CI)
<b>Omboni<sup>1</sup></b> (2013) <sup>(334)***</sup>	SMBP - telemonitoring	Office SBP	Median 24 weeks (range 8–240 weeks)	17 RCTs; 6,389 participants	+++	WMD: -4.71(95% CI: -6.18, -3.24; I <sup>2</sup> =52.2%)
		Office DBP		15 RCTs; 5,496 participants	+++	WMD: -2.45 (-3.33, -1.57) I <sup>2</sup> =40.4%.
		Ambulatory BP		5 RCTs; 935 participants	+++/0	SBP: -3.48mmHg (95% CI: -5.31 to -1.64) DBP: -1.43mmHg (95% CI: -2.86 to +0.00)
		BP normalisation		10 RCTs; 3,596 participants	+++	Improved by: RR: 1.16 (1.04, 1.29); P<0.001; I <sup>2</sup> =69%.
		Medication management: Number of medications		8 RCTs; 2,444 participants	+++	HBPT had larger prescription of antihypertensives: WMD: 0.40 (0.17, 0.62) I <sup>2</sup> =84.2%.
		Medication management: Number of office visits		7 RCTs; 2,716 participants	0	WMD: -0.18 (-0.37, 0.00), I <sup>2</sup> =32.7%.
		Quality of life (PCS)		4 RCTs; 1,104 participants	+++	WMD: 2.78 (1.15, 4.41) I <sup>2</sup> =0%.
		Quality of life (MCS)	4 RCTs; 1,104 participants	0	WMD: -0.11 (-1.65, 1.43) I <sup>2</sup> =0%.	
		Adverse events	48 weeks	4 RCTs; 2,883 participants	0	WMD: 1.22 (0.86, 1.71), I <sup>2</sup> =13.8%.
<b>Uhlig</b> (2013) <sup>(339)***</sup>	SMBP (n=52)	SBP (SMBP alone versus usual care)	6 months	9 RCTs; 2,080 participants	+++	WMD: -3.9mmHg. I <sup>2</sup> =33%.
		DBP (SMBP alone versus usual care)			+++	WMD: -2.4 mmHg. I <sup>2</sup> =44%.
		SBP (SMBP alone versus usual care)	12 months	8 RCTs; 2,290 participants	0	WMD: -1.5mmHg. I <sup>2</sup> =51%.
		DBP (SMBP alone versus usual care)			0	WMD: -0.8 mmHg. I <sup>2</sup> =77%.

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance <sup>‡</sup>	ES (95% CI)
<b>Xu</b> (2014) <sup>(341)***</sup>	Health education - China	SBP	1 month to 2 years	14 RCTs; 2,475 participants	+++	WMD: -19.03, 95% CI (-23.26, -14.80), P < 0.001
		DBP		14 RCTs; 2,475 participants	+++	WMD = -10.33, 95% CI (-13.40, -7.26), P < 0.001)

**Key:** **BP** = blood pressure; **DBP** = diastolic blood pressure; **MCS** = mental component summary; **NR** = not reported; **OR** = odds ratio; **PCS** = physical component summary; **QoL** = quality of life; **RCT** = randomised controlled trial; **SBP** = systolic blood pressure; **SMBP** = self-monitoring of blood pressure; **SMD** = standardised mean difference; **WMD** = weighted mean difference.

<sup>1</sup> Numbers of participants adjusted for double-counting.

Significance 0  $p > 0.05$ , no evidence of effect; +/-  $0.05 \geq p > 0.01$ , some evidence of effect in favour of intervention/control; ++/-  $0.01 \geq p > 0.001$ , strong evidence of effect in favour of intervention/control; +++/-  $p \leq 0.001$ , very strong evidence of effect in favour of intervention/control.

**Table A10.2 Summary of results from systematic reviews. Table extracted from PRISMS review and systematic reviews from updated search**

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n;	Main results	Main conclusions (review author); Important quality concerns (review author)
<b>PRISMS reviews retrieved</b>					
<b>Bosch-Capblanch (2007)</b> <sup>(346)**</sup>	Contracts between practitioners and patients	Narrative	4 RCTs; 382 participants	<b>BP changes:</b> 2/4 trials exploring contracts between health-care providers and patients reported on BP changes. One found no difference between groups at 1-year follow-up, and the other reporting statistically significant improvement in DBP measured over four visits. <b>Adherence outcomes:</b> 2/4 trials reported adherence outcomes. In one study the group with contracts performed worse in terms of adherence on relaxation practices. In the other study, fewer people in the contracts group discontinued treatment, compared with controls	There is not enough evidence to recommend the widespread introduction of patient contracts into health services.
<b>Chodosh (2005)</b> <sup>(187)***</sup>	Self management programmes for hypertension	Meta-analysis	13 RCTs, 1,557 participants	<b>SBP/DBP:</b> Programmes associated with a significant reduction in both SBP and DBP.	Overall pooled results from 13 studies show a statistically and clinically significant reduction in SBP and DBP. Unaccounted for heterogeneity, may be due to publication bias, pooled results must be viewed with caution.
<b>Dickinson (2006)</b> <sup>(347)**</sup>	Lifestyle interventions	Meta-analysis	6 RCTs; 413 participants	<b>SBP/DBP:</b> Combined lifestyle interventions were found to be associated with a significant reduction in SBP and a significant reduction in DBP	Despite the likelihood of achieving only a small reduction in BP, some patients with mild hypertension may wish to change their lifestyle in an effort to delay or prevent starting antihypertensive drug therapy. In people with more severe hypertension, lifestyle changes may complement the BP lowering effect of drugs and thereby reduce the number of medications needed to control BP.
<b>Ebrahim (1998)</b> <sup>(343)**</sup>	Methods for improving adherence	Meta-analysis	46 RCTs; >32,000 participants	<b>BP:</b> Home monitoring: No significant reduction in BP. <b>DBP:</b> SMBP: Statistically significant reduction in	Evidence is lacking to support any specific approaches to improving patient adherence with antihypertensive drugs or lifestyle changes.

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n;	Main results	Main conclusions (review author); Important quality concerns (review author)
	and control	Narrative synthesis		<p>DBP.</p> <p><b>SBP/DBP:</b> Patient education: Significant reductions in SBP and DBP.</p> <p><b>BP:</b> Patient education without the Hypertension Detection and Follow-up Programme (RCT): No significant reductions in BP.</p> <p><b>DBP:</b> Professional education: Significant reductions in DBP.</p> <p>No single approach to improve adherence can be recommended on the basis of the evidence reviewed.</p> <p>Complex interventions may improve adherence and control in difficult patients.</p> <p>Worksite, nurse-led, protocol-guided care may have advantages over usual care in younger men</p> <p>Educational interventions are unlikely to be effective on their own</p> <p>Changes in the location of care (e.g. worksite to home care) without use of guidelines to improve professional adherence are unlikely to yield benefits</p> <p>Simpler drug regimens are likely to improve adherence</p> <p>Simple reminder packaging does not improve adherence or control</p> <p>SMBP at home appears to have a small but significant effect on BP control. However, the pooled estimates for home monitoring included family monitoring, which was associated with a net rise in BP in one study, and thereby an insignificant reduction of BP. These studies were all conducted prior to the widespread use of ambulatory monitoring but suggest that simpler techniques of self-monitoring may be effective. The evidence base to support SMBP is small.</p> <p>Patient education produced the largest reductions in BP, but this is explained by the Hypertension</p>	Evidence to support nurse-led care compared with doctor-led care as a better option in achieving BP control is very sparse

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n;	Main results	Main conclusions (review author); Important quality concerns (review author)
				<p>Detection and Follow-up Program, which achieved major reductions in BP due to a comprehensive stepped care approach involving several elements (i.e. education, free care, specialist clinics and protocols). Consequently, it is likely that the small and statistically insignificant effects of patient education found in the remaining trials are more typical of what might be achieved without attention to other aspects of hypertensive patient care. Professional education achieved a small but statistically significant pooled effect in lowering BP. Most likely due to increased use of drug therapy in intervention groups rather than to the greater use of other non-pharmacological approaches to BP control or better adherence to treatment. Nurse-led clinics were directly compared with doctor-led care in only 1 trial, which found substantially worse BP control, (small sample size, no p-value). Another trial also compared nurse-led with doctor-led care, and this provided stronger evidence to support nurse-led clinics. The evidence to support free preventative health care comes only from the Rand Health Insurance Trial, finding that methods of financing of health care, particularly for poorer people and those with risk factors that require a preventative approach, have an impact on control.</p>	
<b>Glynn (2010)</b> <sup>(337)</sup> ***	Models of care that improve BP control or follow-up care of patients	Meta-analysis	72 RCTs; >87,000 participants	<p><b>SBP/DBP:</b> SMBP: associated with significant reductions in both SBP and DBP. No significant difference in the odds of achieving BP control targets.</p> <p><b>BP control:</b> Educational interventions directed to patients: Significant increase in odds of achieving BP control.</p> <p>Educational interventions directed to physicians: No significant reduction in BP.</p>	<p>Effective delivery of hypertension care in the community requires a rigorous approach in terms of identification, follow-up and treatment with antihypertensive drugs. This systematic review shows that such an approach is likely to translate into reductions in cardiovascular mortality and morbidity. Supplementary and alternative models of care, including self-monitoring of BP by patients, BP</p>



Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n;	Main results	Main conclusions (review author); <i>Important quality concerns (review author)</i>
		Additional narrative synthesis		<p>Appointment reminder systems: Significant increase in odds of achieving BP control.</p> <p>Educational interventions directed to patient: MD in SBP ranged from -15.7mmHg to +1.3 mmHg, and MD in DBP ranged from -8.7mmHg to +7.1mmHg</p> <p>Educational interventions directed to physicians: Control of BP produced heterogeneous results (OR ranged from 0.8 to 1.0).</p> <p>Health professional (nurse or pharmacist)-led care (12 RCTs) may be a promising way of delivering care, with the majority of RCTs associated with improved BP control. MD in SBP was reported in 10 RCTs with a range of difference in mean SBP from -13 mmHg to 0 mmHg.</p> <p>MD in DBP was reported in 11 RCTs, ranging from -8mmHg to 0 mmHg. Control of BP was reported in six RCTs and produced heterogeneous results (OR ranged from 0.1 to 0.9)</p> <p>Organisational interventions that aimed to improve the delivery of care (nine RCTs). The largest RCT, the Hypertension Detection and Follow-Up Programme produced substantial reductions in SBP and DBP. At 5-year follow-up, these reductions in BP were associated with a significant reduction in all-cause mortality (6.4% vs. 7.8%; risk difference 1.4%)</p> <p>Appointment reminder systems (eight RCTs). Pooled data from two small RCTs, gave heterogeneous results in terms of SBP and DBP</p>	<p>management by allied HCPs and computer-based clinical decision support systems require further development and evaluation.</p> <p>Educational interventions directed to either patients or health professionals alone are unlikely to produce clinically important reductions in either SBP or DBP.</p>
<b>Ogedegbe (2006)</b> <sup>(344)**</sup>	Effects of home BP monitoring on adherence	Narrative synthesis	11 RCTs; 1,550 participants	<p><b>Medication adherence:</b> Home BP monitoring reported to be associated with statistically significant improvement in medication adherence in 6 of 11 RCTs. Five of these were complex interventions which involved home BP monitoring plus additional components such as patient counselling, provision of advice and reinforcement</p>	<p>The data on the effects of home BP monitoring on patients' medication-taking behaviour are mixed, given that only a little over half of the studies reviewed reported a statistically significant improvement in medication adherence between intervention and control. The reported improvement in adherence was</p>

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n;	Main results	Main conclusions (review author); <i>Important quality concerns (review author)</i>
				of positive behaviour. All five reported similar ES. Only one of the RCTs to report positive results looked at home BP monitoring in isolation. All three RCTs conducted in primary care settings reported negative findings. Only 4 of 11 RCTs reported statistically significant improvements in both medication adherence and BP control.	greater in the trials that tested home BP monitoring along with other adherence-enhancing strategies such as patient counselling, patient reminders and the use of nurse case managers. Home BP monitoring could be considered a useful adherence-enhancing strategy in combination with other strategies such as patient counselling
<b>Saksena (2010)</b> <sup>(336)**</sup>	Effectiveness of computer-based interventions	Narrative synthesis	4 RCTs; 1,319 participants	<b>BP control:</b> Computer-based education: (n=1 RCT) No significant improvements compared with usual care. Pharmacist assistance in creating a management plan in addition to computer-based education: Significant improvement in BP control compared with either usual care or computer-based education alone.	Computer-based interventions in isolation were insufficient to change health behaviours. There is promising evidence that computer-based interventions with additional pharmacist care can improve BP control
<b>Schroeder (2004)</b> <sup>(348)***</sup>	Interventions designed to enhance medication adherence	Narrative synthesis	38 RCTs; 15,519 participants	Of all the interventions for improving adherence to treatment, 19 reported an improvement in adherence alone (13 of which reported on BP outcome). 7 RCTs found an improvement in adherence combined with a reduction in BP, and in 7 a reduction in BP occurred without an increase in adherence. Patient education seemed largely unsuccessful. Only 1/6 RCTs improved adherence with no reported effect on BP. Simplification of dosing regimens improved adherence in 7/9 RCTs. Patient motivation, support and reminders were successful in 10 / 24 RCTs, with mostly small increases in adherence. Effective interventions included daily drug reminder charts, training on self-determination, reminders and packaging, social support, nurse telephone calls, family member support, electronic medication aid cap and telephone-linked computer counselling.	Findings suggest that introducing simpler dosing regimens can be effective in improving adherence, but the effect on subsequent BP reduction has not been established and may not be clinically important. The results of various motivational and more complex interventions are promising, although there is insufficient evidence to suggest a single approach  The results of this review should be interpreted with caution due to the poor methodological quality and heterogeneity of trials included.

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n;	Main results	Main conclusions (review author); <i>Important quality concerns (review author)</i>
				Complex health and organisational interventions including interventions in combination increased adherence in 8 / 18 RCTs. Interventions were mainly complex combined interventions or structured hypertension management. Worksite care through specially trained nurses improved adherence and showed very strong evidence of a reduction in DBP compared with control. A combination of home visits, education and special dosing devices improved adherence. A strategy involving an educational leaflet, a telephone reminder, a mailed reminder and an educational newsletter was successful in both previously treated hypertensive patients and those who were newly diagnosed. There is weak evidence of an effect of a patient-centred pharmaceutical care model in which pharmacists either used a structured, brief questioning protocol to identify patients' medication-related problems and their information needs relating to hypertension and its treatment, or a combination of structured brief questioning protocol with advice, information and referral to the family practitioner	
<b>Takiya (2004)</b> <sup>(349)**</sup>	Adherence tools and methods to improve adherence	Meta-analysis	16 RCTs; 2446 participants	<b>Medication adherence:</b> Behavioural interventions were found not to be associated with any significant increase in medication adherence. No synthesised results reported for combined or educational interventions	There is no single intervention that improves adherence to antihypertensives over others; therefore a patient-specific approach should be modelled.
<b>Verberk (2011)</b> <sup>(345)**</sup>	Telecare for the management of hypertension	Meta-analysis	9 RCTs; 2501 participants	Very strong and strong evidence to support significant reduction in SBP and DBP, respectively, using telecare compared with control. No significant increase in the odds of meeting BP targets using telecare compared with control. No evidence to suggest a significant reduction in BP between those RCTs in which treatment was not adjusted during the study compared with usual	Telecare leads to a greater decrease in SBP and DBP than is obtained with usual care. Telecare may be particularly useful for increasing patients' awareness, which may lead to improved adherence to treatment and lifestyle advice

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n;	Main results	Main conclusions (review author); Important quality concerns (review author)
				care. No evidence to suggest a significant reduction in BP in those studies where drug modification was based on measured BP values compared with usual care	
<b>Reviews retrieved in updated search</b>					
<b>Chandak (2014)<sup>(342)*</sup></b>	Technology-enabled interventions	Narrative	12 RCTs;	Results reported for 3 telemonitoring studies, only 1 is a unique RCT to this overview: It showed a significant reduction in SBP for the intervention group and a significant reduction in mean DBP.	More longitudinal studies are needed where technology can be utilised to implement multifaceted interventions based on comprehensive JNC-7 guidelines. Interventions to improve BP control for SM of hypertension should be aimed at physicians and patients.
<b>Cheema (2014)<sup>(340)**</sup></b>	Community pharmacist interventions	Meta-analysis	16 RCTs; 3,032 participants	Pharmacist-led interventions were patient education on hypertension, management of prescribing and safety problems associated with medication, and advice on lifestyle. These interventions were associated with significant reductions in SBP and DBP.	Community pharmacist-led interventions can significantly reduce SBP and DBP. These interventions could be useful for improving clinical management of hypertension.
<b>Fletcher (2015)<sup>(338)***</sup></b>	SMBP effect on medication adherence and lifestyle factors	Meta-analysis	28 RCTs; 7,021 participants	Pooled analysis of adherence measures demonstrated a small but significant overall effect of SMBP.	SMBP may contribute to improvements in medication adherence in hypertensives. However, evidence for the effect of SMBP on lifestyle change and medication persistence is scarce, of poor quality, and suggests little clinically relevant benefit.
		Narrative review		Meta-analysis was not completed for lifestyle factor outcomes due to insufficient data. Dietary outcomes (8 RCTs) 1/8 showed a significant improvement in overall diet quality, 1/8 showed significant improvement in average number of fruit and vegetables consumed. Physical activity (6 RCTs): 1/6 showed an increase in mean energy expenditure.	
<b>Omboni (2013)<sup>(334)***</sup></b>	Home blood pressure telemonitoring	Meta-analysis	23 RCTs; 7,037 participants	HBPT resulted in statistically significant improvements in office SBP and DBP, ambulatory BP and BP normalisation. A significantly larger use of antihypertensive medications was observed in the HBPT than in the control group at the study end. Results for QoL were mixed.	Patients randomised to HBPT received a more intensive treatment. This might reasonably be one of the most plausible causes of the enhanced BP control achieved in the intervention group, as adherence to hypertension medications and number of office

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n;	Main results	Main conclusions (review author); Important quality concerns (review author)
					visits were both comparable between the two study arms. Given the high level of heterogeneity of studies published so far, future well designed, large-scale, prospective, controlled trials are needed to understand the long-term benefit of such technologies.
<b>Uhlig</b> (2013) <sup>(339)***</sup>	SMBP	Meta-analysis	SMBP (n=52, 5 include telemonitoring or telecounseling); 5,400 participants	SBP (SMBP alone versus usual care): SMBP was associated with statistically significant net changes in both SBP and DBP at 6 months but were no longer statistically significant at 12-months.	SMBP with or without additional support lowers BP compared with usual care, but the BP effect beyond 12 months and long-term benefits remain uncertain. Additional support enhances the BP-lowering effect.
		Narrative	25 RCTs;	SMBP plus additional support versus usual care: At 12 months: 5/25 RCTs reporting a mean net reduction in SBP or DBP. Results were mixed at 18 months. 2/25 studies found statistically significant net reductions in SBP and DBP at 24 to 60 months.	<i>The evidence base has several limitations. Many studies were quality C and were likely underpowered, even for BP outcomes. Duration of follow-up in most instances was less than 12 months. Data on clinical outcomes were lacking. Given the clinical heterogeneity stemming from the variation in the populations, interventions, outcomes, and time points examined, often only 1 or 2 studies were available for specific comparisons.</i>
<b>Xu</b> (2014) <sup>(341)***</sup>	Health education - China	Meta-analysis	14 RCTs; 2,475 participants		The effect of health education fell off as patients were followed up over a longer period. Health education plays an important role in blood pressure control in hypertensive patients, potentially reducing blood pressure by one level.

**Key:** BP = blood pressure; DBP = diastolic blood pressure; HBPT = home blood pressure telemonitoring; OR = odds ratio; QoL = quality of life; RCT = randomised controlled trial; SBP = systolic blood pressure; SMBP = self-monitoring of blood pressure; SMD = standardised mean difference; WMD = weighted mean difference.

**Table A10.3 CEA Studies investigating self-monitoring of blood pressure**

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Results
<b>Arrieta</b> (2014) <sup>(353)</sup>	Home blood pressure telemonitoring compared with usual care (clinic-based monitoring)	Employee plan members aged 20 to 44 and 45 to 64 years, and for Medicare Advantage plan members aged ≥65 years.	Country: US Study design: cost-benefit simulation model Perspective: payer Discount rate: 3% Time horizon: 10 years	None reported.	Depending on the insurance plan and age group, estimated net savings of home monitoring ranged from \$33 to \$166 per member in the first year, and from \$415 to \$1,364 over 10 years.	Estimated net saving of home monitoring ranged from \$33 (€27) to \$166 (€136) per member in the first year, and the return on investment ranged from \$0.85 (€0.70) to \$3.75 (€3.08) per dollar invested.
<b>Madsen</b> (2011) <sup>(358)</sup>	Home blood pressure telemonitoring compared with conventional office-based monitoring.	Patients (n=223) age 20-80 years with uncontrolled hypertension (>150/95mmHg or systolic BP >150mmHg and diastolic BP <90mmHg). Mean age 57 years.	Country: Denmark Study design: RCT-based costing study Perspective: payer Discount rate: NA Time horizon: 6 months	After 6 months, daytime ambulatory blood pressure was reduced by 11.9/6.2 mmHg in the intervention group and 9.6/5.4 mmHg in the control group with no significant differences between the groups.	Consultation and medication costs were lowered in the intervention group. Average intervention cost was DKK 1,343 (€166) per patient.	For systolic ambulatory blood pressure, the ICER was 256 DKK (€32) /mmHg (95% UI: -860 to 4,544). For diastolic ambulatory blood pressure, the ICER was 655 DKK (€81) /mmHg (95% UI: -674 to 69,315).
<b>McManus</b> (2005) <sup>(359)</sup>	Blood pressure self-monitoring at GP practice compared with usual care.	Patients (n=400) aged 35-75 receiving treatment for hypertension with BP in the range 140/85 mm Hg to 200/100 mm Hg. Mean age 62.6 years.	Country: UK Study design: RCT-based costing study Perspective: payer Discount rate: 3.5% (capital costs) Time horizon: 12 months	Systolic blood pressure significantly lower in the intervention group at 6 months (mean difference in change 4.3 mm Hg (95% CI: 0.8 to 7.9 mm Hg); but not at 1 year (-1.6 mm Hg (95% CI: - 5.3 to 2.2 mm Hg). No significant effect on diastolic blood pressure.	Mean cost of delivering intervention = £27 (€42) per patient.	The mean incremental cost effectiveness ratio (£/mm Hg) was 5.10 (€7.94) (95% CI: -7.2 to 19.1). Blood pressure can be controlled to the same degree with either practice based self monitoring or usual care. Self monitoring has negligible costs, reduces practice consulting rates, is acceptable to (and preferred by) patients and does not increase anxiety.

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Results
<b>Parati</b> (2009) <sup>(360)</sup>	Home blood pressure telemonitoring compared with office-based monitoring.	Patients (n=298) with uncontrolled hypertension (systolic blood pressure $\geq$ 140mm Hg or diastolic blood pressure $\geq$ 90mm Hg), aged between 18 and 75 years. Mean age 57.5 years.	Country: Italy Study design: RCT-based costing study Perspective: payer Discount rate: NA Time horizon: 6 months	Percentage patients with daytime blood pressure normalisation was higher in the intervention (62%) than in controls (50%) ( $P < 0.05$ ). Treatment changes were less frequent in the intervention group (9% vs. 14%, $P < 0.05$ ).	The overall cost of management per patient was €123 for intervention and €125 for controls.	Home blood pressure teletransmission led to a better control of ambulatory blood pressure than with usual care. There was no difference in costs.
<b>Staessen</b> (2004) <sup>(363)</sup>	Blood pressure measurement at home compared with in the physician's office.	Patients (n=400) with hypertension and a minimum age of 18 years were eligible if they were either untreated or being treated with maximum 2 different antihypertensive agents.	Country: Belgium & Ireland Study design: RCT-based costing study Perspective: payer Discount rate: NA Time horizon: 12 months	After controlling for baseline differences, the final differences between the 2 arms ranged from 4.8 to 6.8 mm Hg for systolic BP and from 2.9 to 3.5 mm Hg for diastolic BP. More intervention than control patients could permanently stop drug treatment.	The intervention cost €333 (€408) per 100 patients treated for 1 month.  The total cost per 100 patients treated for 1 month was €3,522 (€4,317) for intervention and €3,875 (€4,750) for controls.	Home BP instead of office blood pressure led to less intensive drug treatment and marginally lower medical costs but also to less long-term blood pressure control with no differences in general well-being and electrocardiographic or echocardiographic left ventricular mass.
<b>Stoddart</b> (2013) <sup>(364)</sup>	Home blood pressure telemonitoring compared with usual care.	Participants (n=401) with daytime ambulatory blood pressure averaged $\geq$ 135/85 and $<$ 210/135 mm Hg. Mean age 60.7 years.	Country: UK Study design: RCT-based CEA Perspective: payer Discount rate: NA Time horizon: 6 months	Mean daytime systolic ambulatory BP fell from 146.20 to 140.15 mm Hg for intervention and 146.22 to 144.50 mm Hg in control arm. The difference in mean daytime systolic ambulatory BP at 6 months was 4.51 mm Hg (95% CI 2.49 to 6.61; $p < 0.001$ )	The intervention cost £70.77 (€92) per patient in equipment, training and staff costs.	The ICER was £25.60 (€33) /mm Hg (95% CI £16.05 to £46.69). The intervention was significantly more effective than usual care but also significantly more costly on average lowering systolic ambulatory blood pressure by 4.51 mm Hg and raising the total cost by £115.32 (€149).

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Results
<b>Verberk (2007)</b> <sup>(366)</sup>	Self-measurement of blood pressure compared with office-based measurement.	Patients (n=430) aged 18+ years with SBP >139 mm Hg and/or DBP >89 mm Hg. Mean age 55 years.	Country: Netherlands Study design: RCT-based costing study Perspective: payer Discount rate: NA Time horizon: 12 months	24-hour ambulatory blood pressure values at the end of the trial were higher in the intervention than in the control group: 125.9 versus 123.8 mm Hg (P 0.05) for SBP and 77.2 versus 76.1 mm Hg (P 0.05) for DBP. The self-pressure group used less medication than the OP group (1.47 versus 2.48 drug steps; P<0.001).	The BP device cost \$490 (€434) for 100 patients for 1 month.  The intervention group lower costs than the control group (\$3,222 [€2,854] versus \$4,420 [€3,915] per 100 patients per month; P 0.001).	The findings support the use of self-monitoring in addition to office-based monitoring in regular clinical care to improve overall BP control and to prevent unnecessary treatment prescriptions with associated healthcare costs.

**Abbreviations:** RCT = randomised controlled trial; ICER = incremental cost-effectiveness ratio; CI = confidence interval; UI = uncertainty interval.



**Table A10.4 CEA Studies investigating other self-management support interventions**

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Results
<b>Datta</b> (2010) <sup>(354)</sup>	Behavioural intervention providing tailored information bimonthly for 2 years via telephone, compared with usual care.	Patients (n=588) with a hypertension diagnosis and had a hypertensive medication prescription filled within the last year (mean age 63 years).	Country: US Study design: RCT-based simulation study Perspective: payer Discount rate: 3% (costs only) Time horizon: life expectancy	The mean life expectancy was between 0.03 and 0.07 years greater in the intervention group, depending on patient sex and BMI.	The average annual cost per patient depended on the caseload of the nurse, and ranged between \$112 and \$224.  The average incremental cost ranged between \$2,614 and \$2,972 depending on the patient sex and BMI.	The ICER ranged between \$42,457 and \$87,300 per life year saved, depending on patient sex and BMI. If the conventional \$50,000 per life-year saved is used, the intervention can be considered cost-effective for the overweight male cohorts and normal-weight female cohorts and moderately cost-effective for the normal-weight male and overweight female cohorts.  Note: only costs were discounted so the findings are not reliable. Population 98% male.
<b>Fishman</b> (2013) <sup>(355)</sup>	Home blood pressure monitoring (with and without pharmacist care) compared with usual care (including information resources and a website to facilitate communication with healthcare providers).	Individuals with mean diastolic blood pressure between 90 and 109 mmHg or mean systolic blood pressure between 140 and 199 mmHg (mean age approx 60 years).	Country: US Study design: unclear Perspective: payer Discount rate: 3/5/7% Time horizon: 12 months follow-up, life expectancy	Controlled hypertension increased life expectancy by between 3.4 and 6.2 years for men, and between 1.6 and 4.9 years for women.	Mean cost of care per patient: usual care = \$10.56 blood pressure monitoring = \$67.36 blood pressure monitoring with pharmacist support (e-BPM) = \$400.36	Blood pressure monitoring was dominated for all but decrease in systolic blood pressure (\$23.76/mmHg drop). Cost per life year saved for e-BPM was \$1,850 for men and \$2,220 for women.  Note: the intervention was introduced to an already well-developed infrastructure. Usual care may not be applicable to Ireland.

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Results
<b>Kaambwa</b> (2013) <sup>(356)</sup>	Self-monitoring with self-titration of antihypertensives and telemonitoring of blood pressure measurements compared with usual care.	Data from trial of 527 patients aged 35-85 years with uncontrolled hypertension (>140/90 mmHg) and in receipt of treatment. Modelled from age 66 years.	Country: UK Study design: simulation model Perspective: payer Discount rate: 3.5% Time horizon: 35 years	Self-management was more effective by 0.24 and 0.12 quality QALYs gained per patient for men and women, respectively.	The mean total cost per patient of the intervention was £7,090 (€9,197) for men and £7,296 (€9,464) for women. The mean total cost per patient of usual care was £6,707 (€8,700) for men and £6,720 (€8,717) for women.	The ICER for self-management was £1,624 (€2,107) per QALY for men and £4,923 (€6,386) per QALY for women.
<b>Maciejewski</b> (2014) <sup>(357)</sup>	Three nurse-led telephone-based self-management programmes compared with usual care.	Patients (n=591) with hypertension, using antihypertensives, and with inadequate BP control (>140/90 mmHg for all patients). Mean age 64 years.	Country: US Study design: RCT-based model Perspective: payer Discount rate: not reported Time horizon: 18 months	Eighteen months after trial completion, compared with usual care the increased proportion patients with adequate BP control was statistically significant for all three interventions (ranging from 17.1% to 20.4%).	There was no statistically significant difference in costs compared with usual care.	Behavioural and medication management can generate systolic blood pressure improvements that are sustained 18 months after trial completion. Utilisation and expenditure trends were similar for patients in all 4 arms.  Note: the study population was 92% male and unlikely to be applicable to the Irish setting.
<b>Perman</b> (2011) <sup>(361)</sup>	A multidisciplinary antihypertensive programme for middle-class elderly patients compared with usual care.	Patients (n=500) aged 65 years and over with hypertension. Mean age 72.5 years.	Country: Argentina Study design: simulation model using observational data Perspective: payer Discount rate: 5% Time horizon: life expectancy	The mean life years gained was 10.78 for controls and 10.96 for the intervention arm.	Programme cost of the intervention was \$14.70 (€13) per patient.	The ICER for the intervention was \$1,124 (€1,003) per life year gained. The programme was considered highly cost-effective.

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Results
<b>Reed (2010)</b> <sup>(362)</sup>	Telephonic behavioural lifestyle intervention, patient self-monitoring, and both interventions combined compared with usual care.	Patients with (n=636) hypertension and using anti-hypertension medication. Mean age 60.5 years.	Country: US Study design: RCT-based study Perspective: societal Discount rate: 3% on costs Time horizon: 24 months	At 24 months, compared with the usual care group, mean systolic blood pressure decreased by 0.6 mm Hg (P = .69) in the home monitoring arm, increased by 0.6 mm Hg (P = .67) in the behavioural intervention arm, and decreased by 3.9 mm Hg (P = .01) in the combined intervention.	Intervention cost: home monitoring: \$90 (€81); behavioural: \$345 (€312); combined: \$416 (€376); usual care: NA	The incremental 2-year cost per 1-point reduction in systolic blood pressure was \$107 (€97) in direct medical costs and \$297 (€268) when including patient time costs. The combined intervention improved blood pressure. However, it is more expensive than usual care.
<b>Trogon (2012)</b> <sup>(365)</sup>	Collaborative hypertension intervention (including home BP monitoring, education) compared to no intervention (i.e. do nothing).	High-risk patients with uncontrolled hypertension (systolic blood pressure ≥ 140 mm Hg or diastolic blood pressure ≥ 90 mm Hg).	Country: US Study design: simulation model Perspective: payer Discount rate: 3% Time horizon: 12 months and 10 years	Number of cases brought under control = 151 of 534. Adverse events avoided: 0.29 after 1 year, 3.92 after 10 years. Life years gained: 2.77 after 1 year, 20.51 after 10 years.	Total cost of programme delivered to 534 members was \$122,403 (€114,821).  Incremental cost of intervention was \$116,154 (€108,959) after 1 year and \$38,098 (€35,735) after 10 years.	ICERs at 1 year: \$767 (€719) per person brought under control, \$404,705 (€379,635) per event avoided, or \$41,927 (€39,330) per LYG.  ICERs at 10 years: \$9,720 per event avoided and \$1,857 per LYG.

**Abbreviations:** RCT = randomised controlled trial; ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life year; LYG = life years gained; BMI = body mass index.

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