



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

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

**Generic interventions (*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 – Generic self-management support interventions**

Generic self-management support interventions are those that can be used by any individual with one or more chronic diseases and are not tailored to support management of a specific chronic disease.

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

- Based on 25 systematic reviews (362 randomised controlled trials), a wide variety of generic self-management support interventions was identified. These were broadly grouped as chronic disease self-management programmes (mainly the Stanford model), telemedicine, web-based interventions, complex interventions focussed on a single health outcome, and 'other' self-management support interventions.
- The majority of the literature retrieved for the chronic disease self-management programmes assessed the Stanford model. The evidence was of low to very low quality and was without long-term follow-up. No evidence was found of improvements in health care utilisation. Some evidence of short-term improvements in the patient-reported outcomes of self-efficacy, health behaviour (exercise) and health outcomes (pain, disability, fatigue and depression) were found for the chronic disease self-management programmes, primarily for the Stanford programme.
- Some evidence of improvements in healthcare utilisation, diet adherence, patient engagement, and self-reported health status was found in literature that assessed the impact of a range of self-management support interventions on a single health outcome; however, it is not possible to determine which types of intervention or components contributed to the positive results.
- Some evidence of improvements in outcomes was also found for other generic interventions, specifically for telephone-delivered cognitive behavioural therapy (health status), personalised care planning (depression), motivational interviewing (physical activity), and nurse-led interventions using the information-motivation-behavioural skills model (medication adherence).
- Limited evidence was found that web-based cognitive behaviour therapy can have a positive impact on psychosocial outcomes.
- Insufficient evidence was found to determine if:

- computer-based chronic disease self-management programmes are superior to usual care or standard 'face to face' versions of the Stanford chronic disease self-management programme.
- short-term improvements in activities of daily living and mobility observed with in-home care are sustained in the longer term.
- 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, is still unclear.
- Based on 25 costing and cost-effectiveness studies, the economic literature was grouped into four main intervention types: chronic disease self-management programmes, telemedicine, web-based interventions and 'other' interventions. Evidence of cost-effectiveness was generally of limited applicability to the Irish healthcare setting.
- There is limited evidence of cost-effectiveness for generic chronic disease self-management support interventions. The most consistent evidence is for chronic disease self-management programmes, but potential benefits are dependent on how efficiently the programme is run, and there is no evidence regarding longer term cost savings.
- Chronic disease self-management and telephone-based telemedicine programmes are relatively cheap to implement, but the magnitude of any cost saving in terms of reduced healthcare utilisation is unclear. The short follow-up periods used in the included studies means that it is not possible to determine if any savings are sustained.
- Where reported, the cost of the generic self-management support interventions was low. Although generally inexpensive on a per patient basis, the budget impact will be sizeable if implemented for all eligible patients with chronic disease(s).

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

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

The reported cost of generic self-management support interventions is generally low on a per-patient basis. However, given the high prevalence of chronic diseases in Ireland, the budget impact could be very substantial if implemented for all eligible patients.

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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**

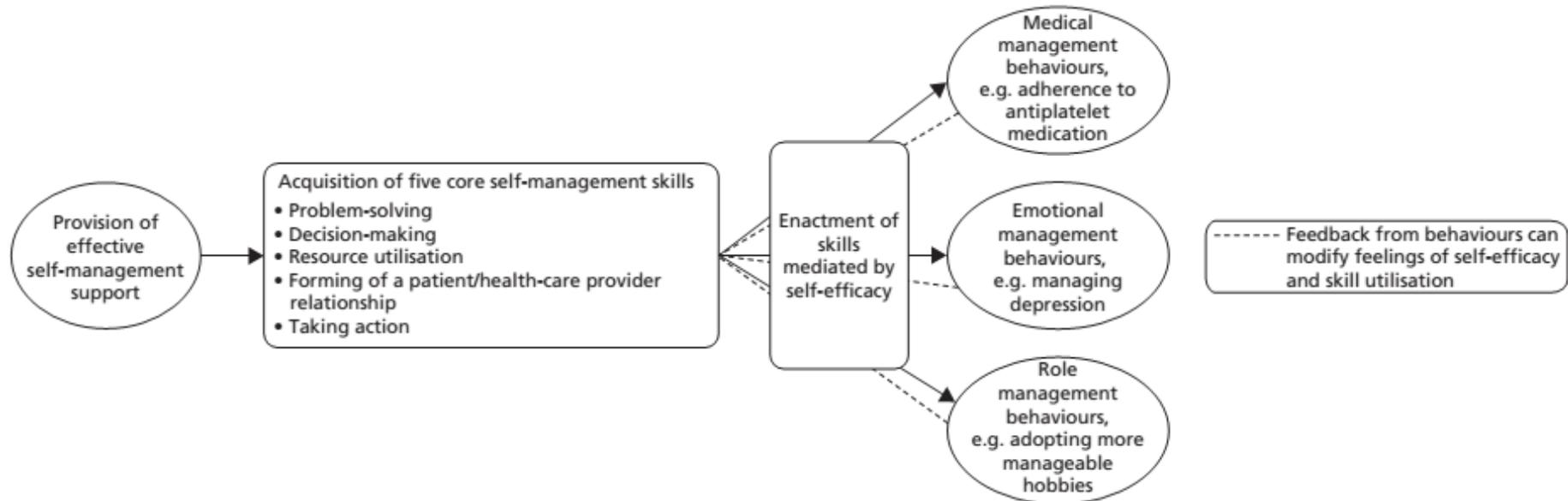
A broad range of self-management and self-management support definitions exist. For this review, the 2003 definitions agreed by the US Institute of Medicine are used:

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™ (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>

## **4 Generic self-management support for a range of chronic diseases**

This health technology assessment (HTA) of generic self-management support (SMS) for a range of chronic diseases is one of a series of rapid HTAs assessing SMS interventions for chronic diseases. Section 4.1 provides a brief description of the chronic diseases assessed followed by separate reviews of the clinical (Section 4.2) and cost-effectiveness (Section 4.3) literature for generic SMS interventions. Brief descriptions of the background and methods used are included with full details provided in Chapter 3. Section 4.4 includes a discussion of both the clinical and cost-effectiveness findings. The report concludes with a list of key points in relation to generic SMS support (Section 4.5).

### **4.1 Description of the disease**

This review assesses the clinical-effectiveness of generic self-management support (SMS) interventions which help patients manage aspects of their chronic disease through education, training and support. Reviews which assess interventions in more than one chronic disease are included per the PICOS criteria, Chapter 3 Table 3.1.

### **4.2 Review of clinical effectiveness of generic self-management support interventions**

#### **4.2.1 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. 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 in the UK. The Practical Systematic Review of Self-Management Support for long-term conditions (PRISMS) study comprised an overview of systematic reviews of randomised controlled trials (RCTs) up to 1 June 2012, and was itself undertaken according to the principles of systematic reviewing. Generic SMS interventions were not specifically addressed in the PRISMS report. This assessment therefore presents a de novo review of systematic reviews for these interventions. A search of PubMed, Embase and the Cochrane Library was undertaken to February 2015, see Appendix A3.1 for details. In accordance with the PICOS agreed with the key stakeholder, this assessment was limited to SMS interventions for adults aged 18 and over, with Phase I specifically addressing

generic interventions that could be used in a range of chronic diseases. As noted in Chapter 2, there is no universally accepted definition for self-management or SMS. This creates problems when attempting to identify, analyse and assess the available literature. However, a consistent theme is that SMS interventions are typically complex interventions that include more than one component (for example, education, information, practical support, provision of equipment, social support, lifestyle advice, prompts, financial incentives) of SMS. For this reason, 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). Further, to differentiate between SMS interventions that can be used in a range of chronic conditions and disease-specific interventions, studies that limited their inclusion criteria to a single chronic disease were excluded from the assessment of generic interventions.

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) 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; however, where reported, information on the risk of bias of the primary studies was extracted from the systematic reviews.

#### **4.2.2 Description of the interventions**

Generic SMS interventions are interventions that can be used by any individual with a chronic disease and are not specifically tailored to support management of one chronic disease. A general description of self-management and typical generic SMS interventions is included in Chapter 2.

#### **4.2.3 Results – Clinical-effectiveness**

The search identified 25 completed studies that met the inclusion criteria, see Table 4.1. Details of the total numbers of citations retrieved by the searches, numbers of duplicates, numbers of studies and reasons for excluding studies are included in Appendix A4.1.

Based on the range of SMS interventions identified, the studies were broadly categorised into one of four intervention types: chronic disease self-management

programmes, telemedicine, web-based telemedicine, 'complex SMS interventions, effect on a specific outcome' and 'other SMS interventions'. Study overlap was assessed to identify studies that added little or no additional evidence. When substantial overlap was observed between two or more systematic reviews, we based our analyses on the higher quality or more comprehensive review. While many of the systematic reviews identified also included evidence for disease-specific interventions, the summary provided here is limited to the evidence for generic interventions compared with usual care.

The following sections summarise the literature retrieved for each of the four categories and include an assessment of the efficacy of the generic SMS interventions in that category and the quality of the evidence underpinning the assessment. 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). If a meta-analysis was completed, its quality was assessed as per Chapter 3 and 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 (Chapter 3, Table 3.1).

**Table 4.1. Generic: Summary of systematic reviews retrieved, classified by intervention type**

Author (year)	Intervention
<b>Chronic disease self-management programmes</b>	
Boult (2009) <sup>(27)</sup>	Self-management focusing on the Stanford CDSMP
Franek (2013) <sup>(28)</sup>	SMS interventions – mainly Stanford CDSMP
Inouye (2011) <sup>(29)</sup>	Comprehensive care model – a component of which is chronic disease self-management which includes analysis of the Stanford CDSMP
Jonker (2009) <sup>(30)</sup>	Health behaviour change for chronic care – multiple conditions section focuses on generic models, mainly Stanford CDSMP
NZGG (2011) <sup>(7)</sup>	Self-management: cognitive behavioural therapies, health education, alternative therapies
Quinones (2014) <sup>(31)</sup>	Educational group visits for the management of chronic health conditions, mainly Stanford CDSMP

Author (year)	Intervention
<b>Telemedicine</b>	
Beratarrechea (2014) <sup>(32)</sup>	Mobile health interventions (cell phone voice communication, text messaging)
Muller (2011) <sup>(33)</sup>	Telephone-delivered CBT of varying intensities
Wootton (2012) <sup>(34)</sup>	Telemedicine (20 years)
<b>Web-based telemedicine</b>	
Bossen (2014) <sup>(35)</sup>	Self-guided web-based physical activity interventions
De Jong (2014) <sup>(36)</sup>	Internet-based asynchronous communication between health providers and patients
Eland de Kok (2011) <sup>(37)</sup>	E-health interventions (interactive websites, internet) (monitoring, treatment instructions, self-management training (coaching) and general information and web-based messaging)
Kuijpers (2013) <sup>(38)</sup>	Web-based interventions for patient empowerment and physical activity
McDermott (2013) <sup>(39)</sup>	Computers to deliver chronic disease self-management programmes
Paul (2013) <sup>(40)</sup>	Web-based approaches (CBT or information websites or access to expert advice ) impact on psychosocial health
Samoocha (2010) <sup>(41)</sup>	Web-based interventions effectiveness on patient empowerment
<b>Complex SMS interventions</b>	
Desroches (2013) <sup>(42)</sup>	Interventions to enhance adherence to dietary advice
Panagioti (2014) <sup>(43)</sup>	SMS interventions – ‘Mixed problems’ section includes the Stanford CDSMP. Remaining RCTs are not programmes or are disease-specific
Simmons (2014) <sup>(44)</sup>	Personalised health care (effect of patient engagement)
<b>Other SMS</b>	
Kivela (2014) <sup>(45)</sup>	Health coaching by health care professional
Ontario (2013) <sup>(46)</sup>	In-home care (care in the home, community, supportive housing, or long-term care facilities.)
O’Halloran (2014) <sup>(47)</sup>	Motivational interviewing
van Camp (2013) <sup>(48)</sup>	Nurse-led interventions to enhance medical adherence
Chang (2014) <sup>(49)</sup>	Information motivation behavioural skills
Coulter (2015) <sup>(11)</sup>	Personalised care planning - support behaviour change

**Key:** **CBT:** Cognitive behavioural therapy; **CDSMP:** Chronic disease self-management programme; **RCTs:** Randomised controlled trials; **SMS:** Self-management support

#### **4.2.3.1 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 A4.2. Table 4.2 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 generic SMS interventions in a range of chronic diseases.

**Table 4.2. Summary characteristics and findings for selected outcomes for included studies**

Study	Quality of Systematic Review			Primary Studies		Quality of Meta-analysis	Health care utilisation (SMD)	QoL (SMD)
	R-AMSTAR score	Partici-pants	Quality	n	low-risk <sup>a</sup>			
Chronic disease self-management programmes								
<b>Franek 2013<sup>(28)</sup></b>	28	6,074	**	10	0	Moderate	-0.03 (-0.09 to 0.04) GP visits -0.05 (-0.18 to 0.09) ED visits -0.06 (-0.13 to 0.02) H.Days -0.09 (-0.24 to 0.05) Hosp.	0.25 (0.12 to 0.39) Self-efficacy -0.24 (-0.40 to -0.07) SR health -0.20 (-0.29 to -0.12) health distress
<b>NZGG 2011<sup>(7)</sup></b>	28	>1,000	**	10	<sup>b</sup>	N/A		
Telemedicine								
<b>Beratarrechea 2014<sup>(32)</sup></b>	30	4,604	**	9	0	N/A		
<b>Muller 2011<sup>(33)</sup></b>	28	1,093	**	8	1	Low		ES: 0.225 (0.105 to 0.344) Health status
<b>Wootton 2012<sup>(34)</sup></b>	22	37,695	**	141	<sup>c</sup>	N/A		
Telemedicine web-based								
<b>Bossen 2014<sup>(35)</sup></b>	28	> 1,000	**	7	5	N/A		
<b>De Jong 2014<sup>(36)</sup></b>	29	6,067	**	15	<sup>d</sup>	N/A		
<b>Eland de Kok 2011<sup>(37)</sup></b>	24	11,203	**	12	3	N/A		
<b>Kuijpers 2013<sup>(38)</sup></b>	26	5,204	**	19	4	N/A		
<b>McDermott 2013<sup>(39)</sup></b>	26	1,506	**	11	3	N/A		
<b>Paul 2013<sup>(40)</sup></b>	28	9,814	**	11	<sup>c</sup>	N/A		
<b>Samoocha 2010<sup>(41)</sup></b>	33	3,417	***	14	2	Moderate		0.05 (-0.25 to 0.35) Self-efficacy

**Abbreviations:** ES – effect size; H.Days – hospital days; Hosp. – hospitalisations; N/A = not applicable; SMD = standard mean difference; SR health – self-rated health

**Note:** <sup>a</sup> Number of the total primary studies identified as being at low risk of bias. <sup>b</sup> One of the 24 studies was included in this review and was rated as unclear risk of bias.

<sup>c</sup> Risk of bias of primary studies not assessed. <sup>d</sup> Risk of bias not reported for individual studies.

**Table 4.2. (continued) Summary characteristics and findings for selected outcomes for included studies**

Study	Quality of Systematic Review			Primary Studies		Quality of Meta-analysis	Health care utilisation (SMD)	QoL (SMD)
	R-AMSTAR score	Participants	Quality	n	low-risk <sup>a</sup>			
Complex SMS interventions								
<b>Desroches</b> 2013 <sup>(42)</sup>	37	9,445	***	38	6	N/A		
<b>Panagiotti</b> 2012 <sup>(43)</sup>	36	4,695	***	11	3	Moderate	ES: -0.12 (-0.20 to -0.03)	0.13 (0.02 to 0.24)
<b>Simmons</b> 2014 <sup>(44)</sup>	31	3,023	***	10	4	N/A		
Other SMS								
<b>Chang</b> 2014 <sup>(49)</sup>	29	2,605	**	12	4	N/A		
<b>Coulter</b> 2015 <sup>(11)</sup>	38	10,856	***	19	6	High		-0.36 (-0.52 to -0.20) depression NS HRQoL
<b>Kivela</b> 2014 <sup>(45)</sup>	30	>1,000	**	13	<sup>c</sup>	N/A		
<b>O'Halloran</b> 2014 <sup>(47)</sup>	33	1,176	***	10	1	Moderate		
<b>Ontario</b> 2013 <sup>(46)</sup>	30	>1,000	**	12	4	Moderate		
<b>van Camp</b> 2013 <sup>(48)</sup>	29	2,587	**	10	9	Low		

**Abbreviations:** ES – effect size; HRQoL – health-related quality of life; N/A = not applicable; NS = non significant; SMD = standard mean difference.

Note: <sup>a</sup> Number of the total primary studies identified as being at low risk of bias. <sup>b</sup> Risk of bias of primary studies not reported. <sup>c</sup> Risk of bias not reported for individual studies.

**Table 4.2. (continued) Summary characteristics and findings for selected outcomes for included studies**

Study	Quality of Systematic Review			Primary Studies		Quality of Meta-analysis	Health behaviours (SMD)	Health outcomes (SMD)
	R-AMSTAR score	Participants	Quality	n	low-risk <sup>a</sup>			
Chronic disease self-management programmes								
<b>Franek 2013<sup>(28)</sup></b>	28	6,074	**	10	0	Moderate	0.16 (0.09 to 0.23) Aerobic exercise	-0.11 (-0.17 to -0.04) pain -0.14 (-0.24 to -0.05) disability -0.15 (-0.22 to -0.08) fatigue -0.15 (-0.28 to -0.03) depression
<b>NZGG 2011<sup>(7)</sup></b>	28	>1,000	**	10	<sup>b</sup>	N/A		
Telemedicine								
<b>Beratarrechea 2014<sup>(32)</sup></b>	30	4,604	**	9	0	N/A		
<b>Muller 2011<sup>(33)</sup></b>	28	1,093	**	8	1	Low		
<b>Wootton 2012<sup>(34)</sup></b>	22	37,695	**	141	<sup>c</sup>	N/A		
Telemedicine web-based								
<b>Bossen 2014<sup>(35)</sup></b>	28	> 1,000	**	7	5	N/A		
<b>De Jong 2014<sup>(36)</sup></b>	29	6,067	**	15	<sup>d</sup>	N/A		
<b>Eland de Kok 2011<sup>(37)</sup></b>	24	11,203	**	12	3	N/A		
<b>Kuijpers 2013<sup>(38)</sup></b>	26	5,204	**	19	4	N/A		
<b>McDermott 2013<sup>(39)</sup></b>	26	1,506	**	11	3	N/A		
<b>Paul 2013<sup>(40)</sup></b>	28	9,814	**	36	<sup>c</sup>	N/A		
<b>Samoocha 2010<sup>(41)</sup></b>	33	3,417	***	14	2	Moderate		

**Abbreviations:** N/A = not applicable; SMD = standard mean difference.

**Note:** <sup>a</sup> Number of the total primary studies identified as being at low risk of bias. <sup>b</sup> One of the 24 studies was included in this review and was rated as unclear risk of bias.

<sup>c</sup> Risk of bias of primary studies not assessed. <sup>d</sup> Risk of bias not reported for individual studies.

**Table 4.2. (continued) Summary characteristics and findings for selected outcomes for included studies**

Study	Quality of Systematic Review			Primary Studies		Quality of Meta-analysis	Health behaviours (SMD)	Health outcomes (SMD)
	R-AMSTAR score	Participants	Quality	n	low-risk <sup>a</sup>			
Complex SMS interventions								
<b>Desroches 2013<sup>(42)</sup></b>	37	9,445	***	38	6	N/A		
<b>Panagioti 2012<sup>(43)</sup></b>	36	4,695	***	9	3	Moderate		
<b>Simmons 2014<sup>(44)</sup></b>	31	3,023	***	10	4	N/A		
Other SMS								
<b>Chang 2014<sup>(49)</sup></b>	29	2,605	**	12	4	N/A		
<b>Coulter 2015<sup>(11)</sup></b>	38	10,856	***	19	6	High		MD: -0.24% (-0.35 to -0.14) HbA1c MD: -0.264 mmHg (-4.47 to -0.82) SBP NS SBP NS Cholesterol NS BMI
<b>Kivela 2014<sup>(45)</sup></b>	30	>1,000	**	13	<sup>c</sup>	N/A		
<b>O'Halloran 2014<sup>(47)</sup></b>	33	1,176	***	10	1	Moderate	0.19 (0.06 to 0.32) physical activity	
<b>Ontario 2013<sup>(46)</sup></b>	30	>1,000	**	12	4	Moderate	MD: -0.14 (-0.27 to -0.01) ADL MD: -0.12 (-0.29 to 0.05) Mobility MD: -0.13 (-0.29 to 0.03) IADL	MD: 0.80 (0.54 to 1.19) Mortality
<b>van Camp 2013<sup>(48)</sup></b>	29	2,587	**	10	9	Low	5.39 (1.70 to 9.07) Medication adherence (short term) 9.46 (4.68 to 14.30) Medication adherence (long term)	

**Abbreviations:** **ADL**= activities of daily living; **BMI** = body mass index; **IADL** = Instrumental activities of daily living – e.g. accessing health care; **N/A** = not applicable; **NS** = non significant; **SBP** = systolic blood pressure; **SMD** = standard mean difference.

**Note:** <sup>a</sup> Number of the total primary studies identified as being at low risk of bias. <sup>b</sup> Risk of bias of primary studies not reported. <sup>c</sup> Risk of bias not reported for individual studies.

### 4.2.3.2 Chronic disease self-management programmes

Six systematic reviews of chronic disease self-management programmes were identified for inclusion (one meta-analysis, five narrative reviews), see Appendices A4.2.1 and A4.2.2 for details.<sup>(7;27-31)</sup> The reviews were published between 2009 and 2014, and covered a range of chronic diseases such as osteoarthritis, chronic obstructive pulmonary disease (COPD), hypertension, stroke, and patients with multiple chronic diseases. Some reviews included specific populations such as 'vulnerable older people', Asian/Pacific islanders, Bangladeshi, and UK populations.

The six retrieved reviews included 25 unique randomised controlled trials (RCTs) of which there were 11 unique RCTs on the Stanford chronic disease self-management programme (CDSMP) or a variant thereof (for example, the Stanford CDSMP in varying populations and two RCTs on the UK's Expert Patient Programme [EPP]). There was considerable study overlap between the reviews as shown in Table 4.3. Other programmes that were assessed included the Flinders programme<sup>TM</sup> as described in Section 2.2.1 (n=1), 'Making the most of your healthcare' programme (n=1 RCT), 'Women Take PRIDE' programme (n=1 RCT), a fit and strong programme (n=1 RCT), a cognitive behavioural group programme (n=1 RCT) and a seven-week individual self-management and coping skills training programme (n=1 RCT).

**Table 4.3. Chronic disease self-management programmes: Study overlap between the included reviews**

Review (year)	Quinones (2014)	Franek (2013)	Jonker (2009)	Boult (2009)	Inouye (2011)	NZGG (2011)
Quinones (2014)	<b>4</b> (4 CDSMP)					
Franek (2013)	4	<b>10</b> (9 CDSMP)				
Jonker (2009)	4	7	<b>8</b> (8 CDSMP)			
Boult (2009)	2	3	3	<b>10</b> (3 CDSMP)		
Inouye (2011)	1	3	3	2	<b>3</b> (3 CDSMP)	
NZGG (2011)	4	8	7	3	3	<b>2 SR + 8 RCTs*</b> (10 CDSMP)

**Abbreviations:** CDSMP = Stanford chronic disease self-management programme or variant thereof, e.g. UK's Expert Patient Programme (EPP). **\*Note:** The NZGG included two systematic reviews and 8 additional RCTs.

A systematic review retrieved by the New Zealand Guideline Group (NZGG) included a 2007 Cochrane review and meta-analysis by Foster et al.<sup>(50)</sup> that assessed self-management education programmes by lay leaders and which they had rated as 'good quality'. This Cochrane review included seven RCTs on the Stanford CDSMP, but their meta-analysis also included five RCTs on the arthritis version of the

Stanford self-management programme and five disease-specific RCTs.<sup>(50)</sup> Two further RCTs were included in the New Zealand Guideline Group review for motivational interviewing and for a primary-care-based diet and physical activity intervention. As this section is limited to a review of the generic CDSM programmes, these results are not discussed here.

Two reviews (Franek et al. and Jonker et al.) focused on the Stanford CDSMP, while Franek et al. included one additional RCT on the 'Making the most of your healthcare' programme. The reviews summarised the evidence for 10 and eight RCTs, respectively with an overlap of seven RCTs between them.<sup>(28;30)</sup>

Substantial overlap was also found with the other published systematic reviews. To minimise duplication, only results from Franek et al. and the New Zealand Guideline Group reviews are discussed, and is limited to the relevant, non-disease-specific findings. The R-AMSTAR scores of methodological quality of the two included systematic reviews were 28 out of 44, see Table 4.2, with both rated as 'two-star' reviews based on their quality and size. The most common methodological limitations identified in the quality assessment of systematic reviews were failure to provide explicit statements that the scientific quality of the included RCTs had been assessed and evaluated; and failure to consider the quality of the scientific evidence in formulating the conclusions, see Appendix A4.2.2.

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

### Health care utilisation outcomes:

A review and meta-analysis by Franek et al. which mainly assessed the Stanford CDSMP (nine out of 10 RCTs) reported no significant difference in health care utilisation (GP visits, emergency department visits, days in hospital, hospitalisation) between the Stanford CDSMP intervention and usual care.<sup>(28)</sup> This was based on a RCT follow-up of four to 12 months (with a median of six months). Using the GRADE criteria, the authors rated the included evidence as very low quality on the basis that there was a lack of concealment allocation and blinding in the trials, a lack of appropriate intention-to-treat analysis, and because the utilisation data came from patient recall rather than administrative data, meaning that there was a high degree of uncertainty around the results. A narrative review by the New Zealand Guideline Group concurred with this finding; it reported no significant difference in outcomes in terms of health care utilisation (based on five RCTs, only n=1 additional RCT compared to Franek et al. for the UK EPP).<sup>(7)</sup>

### Patient reported outcomes (Quality of Life, patient satisfaction, self efficacy):

Franek et al. reported a small, statistically significant difference in patient-reported outcomes in favour of the Stanford CDSMP compared with usual care. More

specifically, it reported small, statistically significant improvements in self-efficacy, self-rated health, health distress, cognitive symptom management and communication with a health professional.<sup>(28)</sup> The authors rated this evidence as low quality based on the GRADE criteria.

The New Zealand Guideline Group reported no evidence of a difference in terms of quality of life for the Stanford CDSMP (n=1 RCT for the UK EPP) compared with usual care, although they noted that results from the UK's Expert Patient Programme (EPP) suggest more positive outcomes for patients with lower self-efficacy or health-related quality of life at baseline.<sup>(7)</sup>

#### Health behaviour outcomes (exercise, diet adherence):

Four reviews reported on health behaviour outcomes.<sup>(7;28-30)</sup> The meta-analysis by Franek et al. reported a small, statistically significant difference in favour of the CDSMP compared with usual care in terms of aerobic exercise. The authors assessed the evidence as being of 'low quality' using the GRADE criteria.<sup>(28)</sup>

#### Health outcomes (including biological markers of disease):

Three reviews reported on health outcomes.<sup>(28-30)</sup> The review and meta-analysis by Franek et al. reported a small, statistically significant difference in favour of the CDSMP compared with usual care in terms of pain, disability, fatigue and depression.<sup>(28)</sup> This was based on evidence rated as low quality using the GRADE criteria.<sup>(28)</sup>

### **Summary statement for chronic disease self-management programmes**

The majority of the literature retrieved assessed the Stanford chronic disease self-management programme (CDSMP). Based on evidence assessed as being of very low quality and without long-term follow-up, there is no evidence of improvements in health care utilisation. Based on RCT evidence assessed as being of low quality, there is some evidence of short-term improvements in the patient-reported outcome of self-efficacy. There is some short-term evidence of improvement in health behaviour outcomes (exercise) and health outcomes (pain, disability, fatigue and depression) for the Stanford CDSMP.

### 4.2.3.3 Telemedicine

This section summarises the evidence retrieved for a range of telemedicine solutions. Not included are systematic reviews that specifically assessed web-based support (that is to say, web-based versions of the Stanford CDSMP and other web-based interventions) - these are reported separately in Section 4.2.3.4.

Three systematic reviews of telemedicine applications for chronic disease self-management were identified for inclusion (one meta-analysis, two narrative reviews).<sup>(32-34)</sup> 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 Appendices A4.2.3 and A4.2.4. The reviews were published between 2011 and 2014, and covered a range of chronic diseases including osteoarthritis, diabetes, asthma, and cancer. The review by Wootton et al. reported on 20 years of telemedicine and retrieved a total of 141 RCTs and 22 systematic reviews.<sup>(34)</sup> The remaining two reviews reported on the impact of mobile health interventions on chronic diseases in developing countries (Beratarrechea et al.) and telephone-based cognitive based therapy (Muller et al.). A total of 156 unique RCTs were identified, with little cross-over between reviews (Table 4.4).

**Table 4.4. Telemedicine: Study overlap within the included reviews**

Review (year)	Muller (2011)	Beratarrecha (2014)	Wootton (2011)
Muller (2011)	<b>8</b>		
Beratarrechea (2014)	0	<b>9</b>	
Wootton (2012)	0	2	<b>141</b>

The R-AMSTAR scores of methodological quality of systematic reviews ranged from 22 to 30 out of 44, see Table 4.2, with all rated as 'two star' in this section. Common methodological limitations were failure to provide explicit statements that the scientific quality of the included RCTs had been assessed and evaluated; and failure to consider the quality of the scientific evidence in formulating the conclusions.

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

Patient reported outcomes (Quality of Life, patient satisfaction, self efficacy):

Two reviews presented patient-reported outcomes.<sup>(32;33)</sup> A low quality meta-analysis by Muller et al. (eight RCTs) reviewed varying intensities of telephone-delivered cognitive behavioural therapy (CBT) in people with chronic illness. It reported a significant improvement in health status following telephone-delivered CBT.<sup>(33)</sup> A

narrative review by Beratarrechea et al. reported improvements in health-related quality of life (two out of two RCTs) using mobile health interventions.<sup>(32)</sup>

Sub-group analyses were reported in the review by Muller et al. which examined the effects of amount of therapist contact, CBT focus and degree to which illness was immediately life-threatening.<sup>(33)</sup> It was noted that trials including fewer than five hours of therapist contact had a greater impact on health outcomes than trials in which participants had five or more hours of contact. Moderator analysis revealed little difference between interventions where the CBT focused mainly on emotions, compared with interventions where the CBT principles were mainly focused on the physical illness. The review also reported that telephone-delivered CBT was more effective in patients with non-life threatening illnesses.<sup>(33)</sup>

#### Health outcomes (including biological markers of disease):

A narrative review by Beratarrechea et al. reported health outcomes for telephone-delivered CBT.<sup>(32)</sup> It reported an improvement in a range of clinical outcomes using mobile health interventions in four out of five RCTs.<sup>(32)</sup>

One review reported on 20 years of telemedicine retrieving a total of 141 RCTs and 22 systematic reviews.<sup>(34)</sup> However, this review did not assess telemedicine specifically for self-management, but stated that its main roles have been in providing education (to improve self-management), in enabling information transfer (for example, telemonitoring), in facilitating contact with health professionals (for example, telephone support and follow-up) and in improving electronic records. It concluded that 73% of studies were favourable to telemedicine in chronic disease management, 26% were neutral and 1% were unfavourable. This was based on synthesising different outcomes for a range of diseases without any weighting of studies.

#### **Summary statement for telemedicine**

Based on the systematic reviews and the underpinning primary RCTs which were of limited quantity and quality, there is limited evidence that telephone-delivered cognitive behavioural therapy has a positive impact on health status.

#### **4.2.3.4 Web-based interventions**

Seven systematic reviews of web-based chronic disease self-management interventions were identified for inclusion (one meta-analysis, six narrative reviews), see Appendices A4.2.5 and A4.2.6 for details.<sup>(35-41)</sup> The reviews were published between 2010 and 2014 and cover a range of chronic diseases such as diabetes, mental health, asthma, cancer, back pain and heart failure. The reviews assessed the web-based version of the Stanford CDSMP (n=1);<sup>(39)</sup> the effects of e-health on the chronically ill (n=1);<sup>(37)</sup> the effect of web-based interventions on physical activity

(n=2);<sup>(35;38)</sup> patient empowerment (n=2);<sup>(38;41)</sup> and psychosocial health (n=1);<sup>(40)</sup> respectively in patients with chronic diseases. A final review by de Jong et al. assessed web-based asynchronous communication<sup>2</sup> between health providers and patients with chronic conditions.<sup>(36)</sup> While this review could alternatively have been included in the telemedicine section, it was included here as it was mainly focused on web-based interventions. The seven systematic reviews comprised 78 unique RCTs with limited overlap between reviews (see Table 4.5).

**Table 4.5. Web-based: Study overlap between the included reviews**

Review (year)	McDermott (2013)	Bossen (2014)	Kuijpers (2013)	de Jong (2014)	Paul (2013)	Samoocha (2010)	Eland de Kok (2011)
McDermott (2013)	<b>11</b>						
Bossen (2014)	0	<b>7</b>					
Kuijpers (2013)	0	3	<b>19</b>				
De Jong (2014)	0	0	3	<b>15</b>			
Paul (2013)	0	0	0	0	<b>11</b>		
Samoocha (2010)	0	0	3	3	0	<b>14</b>	
Elan de Kok (2011)	0	0	0	0	0	0	<b>12</b>

The R-AMSTAR scores of methodological quality of systematic reviews ranged from 24 to 33 out of 44, see Table 4.2. Broadly, the evidence assessed was of variable quality (with the quality of evidence underpinning individual conclusions generally low or not stated) and lacked long-term follow-up. The review by Samoocha et al. (2010) rated as the highest quality in this section as '*three stars*'; (the remaining were rated '*two star*'). A common methodological limitation was failure to consider the quality of the scientific evidence in formulating the conclusions.

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

Patient reported outcomes (Quality of Life, patient satisfaction, self efficacy):

A moderate quality meta-analysis by Samoocha et al. (three RCTs) reported no difference between web-based interventions and usual care in increasing general self-efficacy.<sup>(41)</sup>

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

Health care utilisation outcomes:

<sup>2</sup> Non-concurrent communication by, for example, email.

Three narrative reviews reported health care utilisation outcomes.<sup>(36;37;39)</sup> The review by de Jong et al. reported a non-significant decrease in health care utilisation based on two RCTs.<sup>(36)</sup> In contrast, the review by McDermott et al., which compared the web-based Stanford CDSMP with no self-management, reported no difference in healthcare utilisation based on one RCT.<sup>(39)</sup> Eland-de Kok et al. reported only small effects for e-health on healthcare use based on one study and no significant differences in resource use in two studies.<sup>(37)</sup>

#### Patient-reported outcomes (Quality of Life, patient satisfaction, self efficacy):

Patient-reported outcomes were assessed in three 'two-star' reviews.<sup>(36;38;40)</sup> The narrative review by de Jong et al. reported an increase in self-efficacy (one RCT), self-care (one RCT) and dyspnoea management (based on one RCT).<sup>(36)</sup> In terms of psychosocial outcomes, Paul et al. reported significant improvements in favour of the intervention in 20 out of 36 studies and no effect reported in 11 out of 36 studies.<sup>(40)</sup> Compared with usual care, Kuijpers et al. reported a significant increase in patient empowerment in four out of 13 RCTs; increases for both the intervention and the control in three out of 13 RCTs, and no difference in four out of 13 RCTs. They reported that patient satisfaction was generally high (10 RCTs).<sup>(38)</sup> Some studies noted potential usability issues when using web-based self-management.

#### Health behaviour outcomes (exercise, diet adherence):

Four narrative reviews reported health behaviour outcomes.<sup>(35;36;38;39)</sup> McDermott et al. compared the web-based Stanford CDSMP with no self-management and reported that the web-based Stanford CDSMP was more effective (11 studies), but that there was no evidence that the web-based version was better than the 'face to face' version of the Standard programme.<sup>(39)</sup> De Jong et al. reported improvements in general health behaviours in seven studies.<sup>(36)</sup> Bossen et al. reported a statistically significant improvement in physical activity in three out of seven studies, and no difference in four out of seven studies.<sup>(35)</sup> Kuijpers et al. reported improvements in physical activity in two out of 14 studies, but that physical activity increased for both the intervention and control groups in six out of 14 studies.<sup>(38)</sup> Eland-de Kok et al. reported mixed effects (improvements and no improvements) in terms of health outcomes when the intervention was used in addition to, or instead of, usual care.<sup>(37)</sup>

#### **Summary statement for web-based telemedicine**

There is insufficient evidence to determine if computer-based chronic disease self-management programmes are superior to usual care or standard 'face to face' versions of the Stanford programme. There is limited evidence that web-based cognitive behaviour therapy can have a positive impact on psychosocial outcomes.

#### 4.2.3.5 A range of self-management support interventions – effect on a specific outcome

The following section includes systematic reviews that assessed the impact of a range of SMS interventions on a specific outcome. Three systematic reviews were identified for inclusion: one meta-analysis; two narrative reviews, one of which was a Cochrane review. The reviews were published between 2013 and 2014 and covered chronic diseases such as cardiovascular diseases or hypertension, respiratory diseases and diabetes. The reviews assessed a range of SMS interventions to reduce health care utilisation,<sup>(43)</sup> improve dietary advice adherence<sup>(42)</sup> and to improve patient engagement<sup>(44)</sup> see Appendices A.4.2.7 and A4.2.8 for details.

There was no study cross-over between reviews with 57 unique RCTs identified. The review and meta-analysis by Panagioti et al. assessed the impact of several SMS interventions in populations with a range of chronic diseases to reduce health care utilisation. The meta-analysis synthesised evidence from 13 RCTs; of note four have already been commented on in the chronic disease self-management programmes section, so there is some duplication of evidence here.<sup>(43)</sup> Simmons et al. also assessed a range of SMS interventions, including chronic disease self-management programmes, internet-based programmes, self-help groups, and health coaching in one disease, with one RCT assessing the chronic disease self-management programme in several diseases. While the reviews by Panagioti et al. and Simmons et al. could alternatively have been included in section 3.2.1 on CDSMP, they are included here as Panagioti et al. combined the results of chronic disease self-management programmes and other SMS interventions in their meta-analysis and Simmons et al. based their conclusions on combining results of SMS interventions.

The R-AMSTAR scores of methodological quality of systematic reviews ranged from 26 to 37 out of 44, see Table 4.2, with all three reviews rated *'three-star'* (Desroches et al. Panagioti et al and Simmons et al.). A common methodological limitation was failure to consider the quality of the scientific evidence in formulating the conclusions.

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

##### Health care utilisation outcomes:

A moderate quality meta-analysis by Panagioti et al. of nine RCTs (four RCTs for the Stanford CDSMP) reported a small, but statistically significant reduction in hospital use.<sup>(43)</sup> However, it also reported that RCTs rated as having a high risk of bias reported greater reductions in health care utilisation. It was noted that a minority of SMS studies reported reductions in health-care utilisation in association with

decrements in health; the details of the intervention and exact numbers are not clear. The review also reported a small, but positive impact on health outcomes.<sup>(43)</sup>

#### Patient reported outcomes (Quality of Life, patient satisfaction, self efficacy):

A narrative review by Simmons et al. specifically assessed patient engagement for a range of SMS interventions.<sup>(44)</sup> It reported improvements in patient engagement (nine out of 10 studies, four of which rated as high quality) and self-reported health status (10 out of 10 studies, four of which rated as high quality).<sup>(44)</sup> It also reported improvements favouring the intervention in clinical markers of disease in five out of ten studies (four of which rated as high quality).<sup>(44)</sup>

#### Health behaviour outcomes (exercise, diet adherence):

A Cochrane review by Desroches et al. assessed a range of interventions to improve diet adherence.<sup>(42)</sup> A meta-analysis was not undertaken due to the broad range of interventions assessed. Compared with usual care, 32 of 98 dietary adherence outcomes favoured the intervention group, four favoured the control group and 62 had no significant difference between groups. Statistically significant improvements in diet adherence were found in RCTs assessing telephone follow-up, video, contract, feedback, nutritional tools and multiple tools. No statistically significant improvements in diet adherence was found in RCTs assessing the benefit of group sessions, individual sessions, reminders, restriction, and behaviour change technique interventions compared with usual care.

### **Summary statement for a range of self-management support interventions**

There is some evidence that a range of self-management support interventions can lead to small, but significant reductions in health care utilisation. However, it is not possible to identify which types of SMS interventions or components of SMS contribute to the positive results. Based on one high quality narrative review, there is some evidence of improvements in diet adherence with a range of self-management support interventions (telephone follow-up, video, contract, feedback, nutritional tools and multiple tools). There is some evidence of improvements in patient engagement and self-reported health status for a range of SMS interventions (such as chronic disease self-management programmes, internet based programmes, self-help groups, health coaching) based on one narrative review.

#### **4.2.3.6 Other SMS interventions**

The following section includes six systematic reviews of other interventions for chronic disease self-management (four meta-analyses and two narrative reviews), see Appendices A4.2.9 and A4.2.10 for details.<sup>(45-49;51)</sup> The reviews were published between 2013 and 2015, and covered a range of chronic diseases, including HIV,

obesity and heart failure. Interventions included health coaching (narrative review, n=1),<sup>(45)</sup> nurse-led interventions for medication adherence (meta-analysis, n=1),<sup>(48)</sup> motivational interviewing to increase physical activity (meta-analysis, n=1),<sup>(47)</sup> the Health Quality Ontario group on in-home care (narrative review and meta-analysis, n=1),<sup>(46)</sup> personalised care planning (meta-analysis, n=1)<sup>(51)</sup> and information-motivation-behavioural skills model (narrative review, n=1).<sup>(49)</sup> There was minimal study cross-over between reviews with 73 unique RCTs. The review by Health Quality Ontario assessed in-home care for a range of diseases with a section on 'chronic disease multimorbid patients'; it included a total of two RCTs.<sup>(46)</sup>

The R-AMSTAR scores of methodological quality of systematic reviews ranged from 29 to 38 out of 44, see Table 4.2, with two reviews rated '*three stars*' (Coulter et al., O'Halloran et al.) and the remaining rated '*two stars*' (Chang et al., Kivela et al., Ontario, van Camp et al.). A common methodological limitation was failure to consider the quality of the scientific evidence in formulating the conclusions.

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

Patient reported outcomes (Quality of Life, patient satisfaction, self efficacy):

A high quality meta-analysis (n=19 RCT) by Coulter et al. reported a small effect in favour of personalised care for depression based on moderate quality evidence.<sup>(51)</sup>

Health behaviour outcomes (exercise, diet adherence):

Based on a moderate quality meta-analysis of eight RCTs, O'Halloran et al. reported that motivational interviewing led to improvements in physical activity and, based on a further narrative review) improvements in weight loss (significantly improved results in three out of three RCTs).<sup>(47)</sup>

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

Patient reported outcomes (Quality of Life, patient satisfaction, self efficacy):

A narrative review by Kivela et al. on health coaching reported significant improvements in terms of physical health status (three out of four studies), self-efficacy (two out of three studies), satisfaction of treatment (two out of two studies) and mental health (two out of three studies) in the short term (<8 months) with non-significant improvements in the longer-term (12 to 24 months).<sup>(45)</sup>

Health behaviour outcomes (exercise, diet adherence):

Two narrative reviews (Kivela et al. on health coaching<sup>(45)</sup> and Chang et al. on information-motivation-behavioural skills model<sup>(49)</sup>) and a meta-analysis (van Camp et al. on nurse-led interventions<sup>(48)</sup>) reported on health behaviour outcomes. Kivela

et al. reported significant improvements in weight loss (three out of three RCTs) and physical activity (six out of 10 studies). The meta-analysis by van-Camp et al. reported improved medication adherence using nurse-led interventions (quality rated acceptable to high)<sup>(48)</sup> while the narrative review by Chang et al. reported improved medication adherence using the information-motivation-behavioural skills model (five out of six studies).<sup>(49)</sup> The latter review also reported significant behavioural changes at the first post intervention assessment (10 out of 12 studies) and a likely reduction in high-risk sexual behaviour for HIV patients only.<sup>(49)</sup>

#### Health outcomes (including biological markers of disease):

Three reviews on health coaching,<sup>(45)</sup> in-home care<sup>(46)</sup> and information-motivation-behavioural skills model<sup>(49)</sup> reported on a range of health outcomes. In-home care was defined as care predominantly in the patient's home that was curative, preventive or supportive in nature and aimed to enable clients to live at home. The meta-analysis by Health Quality Ontario group reported no difference between in-home care and usual care for all-cause mortality, but noted improvements in activities of daily living, instrumental activities of daily living and mobility with in-home care.<sup>(46)</sup> The narrative reviews by Kivela et al. and Chang et al. reported improvements in health outcomes in the short term (diabetes only, statistically significant in two out of four studies less than six months and not significant in a further two at six to 12 months),<sup>(45)</sup> improvements in two out of five studies<sup>(49)</sup>.

#### **Summary statement for other SMS interventions**

There is some evidence that personalised care planning and motivational interviewing can have a positive impact on depression and physical activity, respectively. There is some evidence that nurse-led interventions or using the information-motivation-behavioural skills model lead to improvements in medication adherence. There is some evidence that in-home care leads to improvements in activities of daily living, instrumental activities of daily living and mobility. Due to limited study follow-up, it is not known if the effects observed are sustained in the longer term.

## 4.3 Review of cost-effectiveness of generic self-management support interventions

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

### 4.3.1 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, fourteen systematic reviews of SMS interventions were identified through the results of the clinical effectiveness search that included cost or economic outcomes; these were used to identify additional studies.<sup>(32;34;37;52-62)</sup> 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 4.6 below.

**Table 4.6. PICOS analysis for identification of relevant studies**

<b>Population</b>	Adults $\geq$ 18 years old with at least one chronic condition.
<b>Intervention</b>	Any generic self-management support intervention that helps patients to manage aspects of their chronic disease care through 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 (RCTs), case-control studies, observational studies, economic modelling studies.

Studies were excluded if:

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

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).

### **4.3.2 Results**

The bibliographic search returned 525 studies from across the three databases, which equated to 491 unique studies after removal of duplicates (see Appendix A4.1). A further 70 studies were identified from hand searching references in previously published systematic reviews. 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. After removing irrelevant studies based on the titles and abstracts, 37 studies were identified for a full-text review. A further 12 studies were excluded based on various exclusion criteria, leaving 25 included studies.

This review retrieved few conventional economic evaluations; many of the retrieved studies gathered cost data as part of an RCT or case-control type study or completed costing studies. Results of the assessment indicate that the data available are limited in quality, see Appendix A4.3 for details.

Studies were predominantly conducted in the US (15), with five studies from the UK, two from Canada, two from Australia and one from Norway. The included studies were all published between 2000 and 2014. The characteristics of the included studies are given in Table 4.7. Costs reported in each of the studies were inflated to 2014 pricing levels using the local consumer price index and expressed in Irish Euro using the purchasing power parity index.

**Table 4.7** Included studies

Study	Country	Intervention
<b>Aanesen (2011)<sup>(63)</sup></b>	Norway	Smart house technology and video visits
<b>Ahn (2013)<sup>(64)</sup></b>	US	Chronic Disease Self-Management Programme
<b>Battersby(2007)<sup>(65)</sup></b>	Australia	Behavioural and care planning (CDSMP)*
<b>Bendixen (2009)<sup>(66)</sup></b>	US	Telerehabilitation
<b>Dimmick (2000)<sup>(67)</sup></b>	US	Rural telemedicine programme
<b>Doolittle (2000)<sup>(68)</sup></b>	US	A telehospice service providing hospice care in the home
<b>Elliott (2008)<sup>(69)</sup></b>	UK	Telephone-based pharmacy advisory service
<b>Finkelstein(2006)<sup>(70)</sup></b>	US	Telemedicine delivered home healthcare using videoconferencing and physiologic monitoring
<b>Graves (2009)<sup>(71)</sup></b>	Australia	Telephone counselling for physical activity and diet
<b>Griffiths (2005)<sup>(72)</sup></b>	UK	Culturally adapted self-management programme
<b>Henderson(2013)<sup>(73)</sup></b>	UK	Community-based telehealth intervention
<b>Jerant (2009)<sup>(74)</sup></b>	US	Home- or telephone-based peer-led chronic illness self-management support
<b>Johnston (2000)<sup>(75)</sup></b>	US	Remote video technology for home health care
<b>Katon (2012)<sup>(76)</sup></b>	US	Multi-condition collaborative treatment programme. Physician-supervised nurses collaborated with primary care physicians to provide treatment of multiple disease risk factors.
<b>Lorig (2001)<sup>(77)</sup></b>	US	Chronic Disease Self-Management Programme
<b>Moczygamba(2012)<sup>(78)</sup></b>	US	Pharmacist-provided telephone medication therapy management
<b>Noel (2000)<sup>(79)</sup></b>	US	Telemedicine integrated with nurse case management for the homebound elderly.
<b>Noel (2004)<sup>(80)</sup></b>	US	Home telehealth programme
<b>Page (2014)<sup>(81)</sup></b>	US	Six-week group education and support programme
<b>Pare (2013)<sup>(82)</sup></b>	Canada	Tele-homecare programme for elderly patients with chronic health problems
<b>Richardson (2008)<sup>(83)</sup></b>	UK	Lay-led self-care support group ("Expert Patients Programme")
<b>Schwartz (2010)<sup>(84)</sup></b>	US	Online chronic disease self-management programme
<b>Scott (2004)<sup>(85)</sup></b>	US	Group outpatient model for chronically ill, older patients
<b>Steventon (2013)<sup>(86)</sup></b>	UK	Telephone health coaching service (Birmingham OwnHealth)
<b>Tousignant (2006)<sup>(87)</sup></b>	Canada	Rehabilitation through teletreatment

\*An output of this research was the Flinders model of self-management support programme.

The studies were classified into four intervention types corresponding to those used for the assessment of clinical effectiveness: chronic disease self-management (CDSM) programmes; telemedicine; internet-based telemedicine; other SMS interventions. The following sections consider the evidence by intervention type.

#### **4.3.2.1 Chronic disease self-management programmes**

Six studies were retrieved that assessed chronic disease self-management programmes: two US studies evaluated the Stanford CDSMP,<sup>(64;77)</sup> one UK study assessed the Expert Patients Programme (a UK version of the Stanford CDSMP),<sup>(83)</sup> one UK study was based on a culturally-adapted version of the Expert Patients Programme, and one US costing study evaluated a group education and support programme.<sup>(81)</sup> The sixth study was a costing study that ran alongside four RCTs in four areas in Australia. This research subsequently led to the development of the Flinders model of SMS.<sup>(65)</sup> Five of the studies used a comparator of routine care, while the sixth was a costing study with no comparator (see Table A4.3.2). With the exception of the Lorig study,<sup>(77)</sup> which was restricted to four disease groups (heart disease, lung disease, stroke or arthritis), patient populations included those with any chronic conditions. The size of the study population was between 476 and 4,603 patients. For studies that included treatment costs, follow-up varied between four and 24 months.

Estimated costs per participant for the chronic disease self-management programmes were reported in the five studies. The most recent assessment of the Stanford CDSMP was in 2013 by Ahn et al.<sup>(64)</sup> which estimated a cost of €335 per participant (ranging between €168 and €690, depending on the number of participants per workshop and the cost of running a workshop). Based on 2005 data, Richardson et al. estimated a cost of €380 per participant for the UK version of the CSDMP, the Expert Patients Programme.<sup>(83)</sup> The culturally-adapted version of the Expert Patients Programme cost €192 per participant to deliver.<sup>(72)</sup> Finally, the education and support programme evaluated by Page et al. had an estimated cost of €172 per participant.<sup>(81)</sup>

In terms of incorporating the costs associated with treatment, four of the studies included healthcare utilisation costs.<sup>(64;65;77;83)</sup> Three studies calculated costs as part of an RCT while the fourth study used observational data. Three studies reported cost savings associated with the intervention. The two US studies reported savings of €364 over 12 months and between €511 and €682 over 24 months. The UK study estimated savings of €41 per participant over six months. The US studies therefore estimated greater savings, although these differences may relate to greater hospitalisation costs rather than improved clinical effectiveness. The authors of the Australian study noted that the trials demonstrated individual health and well-being

can be improved through patient-centred care, but was not able to demonstrate a sufficient reduction in hospital admissions to pay for the costs of coordinated care.<sup>(65)</sup>

The UK study also estimated the effect of the intervention on quality of life.<sup>(83)</sup> The study collected information on participant quality of life at baseline and six months using the EQ5D instrument (a standardised instrument for use as a measure of health outcome). The intervention was associated with an estimated quality adjusted life year (QALY) gain of 0.02 per person over six months, resulting in an incremental cost effectiveness ratio of -€2,052 per QALY.

#### 4.3.2.2 Telemedicine

Fifteen studies were identified that assessed a variety of telemedicine interventions (see Table A4.3.3). Interventions typically involved video or telephone interaction between the patient and healthcare professional in place of physical visits by the clinician or provider. The intention in most of the interventions was to increase efficiency by reducing the amount of time spent by healthcare professionals in transit to and from patients. The time saving and associated opportunity cost had to be contrasted with the cost of setting up the service, which often required capital expenditure on equipment for patients to enable telemedicine, particularly in the case of video visits.

Fourteen of the studies were based on patient data gathered either as part of an RCT, case-control study or observational study. Study sizes ranged from four to 9,977 patients; one study modelled costs based on published data.<sup>(63)</sup> Where reported, the mean age of patients was generally over 70 years, although one study had a mean age of 58 years.<sup>(71)</sup> The comparator was routine care for the particular patient population. Seven of the studies included patient populations with any of several chronic conditions.<sup>(63;66-68;70;79;86)</sup> Six studies included patients with one of a number of specified chronic conditions.<sup>(69;71;73;75;80;82)</sup> Two studies included patients eligible for medication therapy management and a prescription for physiotherapy follow-up. Patient follow-up ranged from two to 24 months.

Of the three studies that evaluated videoconference visits, two found modest cost savings per patient visit;<sup>(70;75)</sup> one of these was restricted to the costs of nurse visits, and hence it is unclear if there were any benefits in terms of other healthcare utilisation costs.<sup>(70)</sup> A modelling study of video visits found that the technology could be cost-effective if there were substantial efficiency gains for healthcare professionals (for example, through less time spend travelling to patients' homes).<sup>(63)</sup>

Two studies investigated telephone-based medicine management services.<sup>(69;78)</sup> Elliott et al. found that adherence improved in the intervention group, and estimated

a cost saving of €3,296 per additional adherent patient; however, study follow-up was limited to two months, rendering the sustainability of these effects unclear. Moczygamba et al. reported reductions in drug costs for the intervention group and increases in the same 12 month follow-up for the control group.<sup>(78)</sup> It should be noted in the latter study that the intervention participants were self-selected.

Two studies reported increased healthcare utilisation in the intervention group.<sup>(66;86)</sup> In the study by Bendixen et al. the increased utilisation was explained by increases in the areas of preventive medicine, including laboratory and radiology, and primary and geriatric patient care.<sup>(66)</sup> Meanwhile, Steventon et al. found increased emergency admissions and secondary care costs in the intervention group that could not be explained.<sup>(86)</sup>

Studies of telemedicine in a rural setting, for home hospice care and for physiotherapy follow-up all found reduced visit costs, but it was unclear how many face-to-face visits could be replaced by telephone visits.<sup>(67;68;87)</sup> Per visit savings were estimated to be €70, €41 and €74, respectively. Savings of €70 were estimated in a study that focussed on a rural population where the average distance travelled per visit was 61 miles.<sup>(67)</sup>

Two US studies of home telehealth by Noel et al. found either no difference in costs between control and intervention, or a slightly greater reduction for control than intervention.<sup>(79;80)</sup> The sample sizes were small (19 and 104 patients, respectively) and the latter study had a follow-up of no more than 12 months.

Graves et al. evaluated a telephone counselling service for patients with Type 2 diabetes or hypertension in a disadvantaged community in Australia.<sup>(71)</sup> The intervention was compared with usual care, although for ethical reasons usual care had to include the provision of literature and feedback to participants. It was also compared to the baseline data which was described as a real control. Utilities were estimated based on SF-36 responses by study participants. Compared with usual care, the intervention had an incremental cost-effectiveness ratio (ICER) of €115,352 per quality-adjusted life year (QALY), which in turn had an ICER of €17,861 per QALY relative to the real control (baseline) data. The willingness-to-pay threshold was reported as €94,000 per QALY. Although not cost-effective relative to usual care, the authors reported an ICER of €42,603 for the intervention relative to baseline data. The usual care comparator acted as a brief intervention, but there was no evidence to support it as an ongoing intervention and they concluded that the baseline data represented the true comparator.

A telehomecare programme was assessed in a Canadian study.<sup>(82)</sup> The technology was a tactile screen and an integrated modem that came programmed with a personalised monitoring protocol that monitored various health parameters, costing

an average €323 to provide per patient. Some measures of healthcare utilisation, such as nurse home visits, increased during and after the intervention. The average cost per patient was €1,058 less with the intervention compared to baseline. Patient satisfaction data were collected after four months using the system, and showed a generally high degree of satisfaction. A UK telehealth study had intervention costs of €214 for equipment and €368 for monitoring services.<sup>(73)</sup> The intervention resulted in an increased cost per patient of €268 over 12 months. The incremental cost-effectiveness ratio was estimated at €119,337 per QALY, suggesting that the intervention is unlikely to be considered cost-effective.

#### **4.3.2.3 Internet-based telemedicine**

A single study evaluating an internet-based disease management programme was found (Table A4.3.4).<sup>(84)</sup> The study used a retrospective, quasi-experimental, cohort design to compare participants and matched non-participants in the programme. Participants had a mean age of 47 and were members of a health insurance programme. The intervention was an online generic chronic disease management tool. Healthcare expenditure in participants was compared to predicted expenditure using data on non-participants. It was estimated that annual healthcare expenditure decreased by €743 per participant. It was also estimated that there was a return on investment of €10 for every Euro spent after one year using the online self-management programme. Use of a modelling approach to determine predicted expenditure introduced uncertainty into the interpretation of the results that was not clearly accounted for in the study report. The authors were employees of the company that produced and marketed the online tool being evaluated for the providing health insurer.

#### **4.3.2.4 Other SMS models**

Three studies were identified that assessed other models of self-management, both with 24 months of follow-up data (Table A4.3.5).<sup>(74;76;85)</sup>

Jerant et al. compared costs for a one-to-one home-based peer-led chronic illness self-management training programme that was delivered in home or by telephone with usual care in an RCT with 12 months follow-up involving patients aged 40 years and older with one or more of six common chronic illnesses (arthritis, asthma, COPD, heart failure, depression, diabetes). Although the in-home intervention had a limited effect on self efficacy (observed at six weeks and six months only), no effect was observed for other outcomes or for healthcare expenditures. When delivered by telephone, no significant effect was observed on any outcome.<sup>(74)</sup>

Katon et al. compared a multi-condition collaborative treatment programme with usual primary care in outpatients with depression and poorly controlled diabetes or

coronary heart disease.<sup>(76)</sup> The mean patient age was 57 years. A generic tool combining elements of interventions for depression, diabetes and chronic disease self-management was applied across the three diseases. A nurse manager was involved to enhance self-management. QALYs were estimated with improvements in biomarkers such as HbA1C and systolic blood pressure. The intervention was associated with an increase in depression-free days and increased QALYs. There was an estimated mean cost saving of €1,741 per QALY and €5 per depression-free day.

A group outpatient visit model was assessed by Scott et al.<sup>(85)</sup> Groups met with their primary care physician and a nurse every month for 90 minutes; allied health professionals would attend if necessary. Meetings included a nurse review of patient charts and blood pressure readings. Patients in the intervention group had lower healthcare utilisation and the monthly cost was €60 less per patient than for the control group. There was no evidence of effect on functional outcomes.

## 4.4 Discussion

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

### 4.4.1 Clinical-effectiveness

A vast range of generic self-management support (SMS) interventions is available and this is evident in the large body of literature retrieved as part of this review. The retrieved reviews were generally assessed to be of low to medium quality, with Cochrane reviews and meta-analyses typically being rated as having the highest quality.

Broadly, the largest body of literature was retrieved for generic chronic disease self-management programmes, mainly the Stanford CDSMP. Clinically minimal, short-term improvements in patient-reported outcomes, health behaviour, and health outcomes in favour of the Stanford CDSMP compared with usual care were noted, but the results were based on evidence of low quality. Common methodological limitations were a lack of concealment allocation and blinding in the trials, and a lack of appropriate intention-to-treat analysis, meaning that there is a high degree of uncertainty around the results. Generally, some small reductions in healthcare utilisation were reported in individual RCTs for chronic disease self-management programmes and in a review of a range of generic SMS interventions, with no evidence of a negative impact on health outcomes.

The remaining generic SMS tools comprised a heterogeneous set of interventions that have been assessed for a diverse range of chronic diseases. While there is a large quantity of evidence, it is not clear that this evidence is of sufficient quality.

There is a trend to small, clinically minimal improvements in a range of chronic diseases; the evidence is typically of low quality with a short term follow-up. It is possible that there are subgroups of people with chronic diseases that may respond better to generic SMS interventions. For example, as highlighted in the systematic review by the New Zealand Guideline Group (Section 4.2.3.2) a post-hoc subgroup analysis of the UK's Expert Patient Programme (EPP) suggested that patients with lower self-efficacy and health-related quality of life at baseline experienced greater benefits participating in the CDSMP. However, based on the available evidence, it is not possible to determine if there are subgroups of people with chronic diseases that may respond better to generic SMS interventions and which of these interventions is more effective.

As such, the optimal format of generic SMS, the diseases in which it is likely to provide benefit, and the duration of effectiveness, if any, is still unclear. Some reviews suggest that SMS should be tailored to a specific disease as patients knowledge of their own disease is believed to be an essential component of self-management. Consideration may also need to be given to patient age when tailoring generic programmes as the average age may differ considerably depending on the chronic condition under consideration. While the increasing prevalence of multimorbidity (commonly defined as the co-occurrence of two or more chronic medical conditions within an individual) has been noted as a potential limitation to the role of generic SMS interventions, it has also been highlighted that interventions that are targeted at either specific combinations of common conditions, or at specific risk factors or functional difficulties for patients with multiple conditions, may be more effective.<sup>(88)</sup> This is particularly important given the evidence that the presence of multimorbidity is predictive of future functional decline and leads to worse health outcomes with the effect being more pronounced in patients with increasing numbers of chronic disease and is linked to disease severity.<sup>(88)</sup> The need for tailored interventions is also emphasised by the fact that some multimorbid patients may be too ill to participate in some forms of SMS or may have substantial existing treatment burden, attending multiple providers for a range of complex treatments.

More research is needed to explore the long-term, 12 months and greater, effect of generic self-management interventions across all outcomes and to explore the impact of self-management on clinical outcomes.

#### **4.4.2 Cost-effectiveness**

The 25 included studies evaluated a wide range of interventions; while the six studies evaluating chronic disease self-management programmes were relatively homogeneous, the telemedicine interventions comprised a heterogeneous group.

Many of the studies gathered cost data as part of an RCT or case-control type study with relatively small sample sizes. While this approach may address questions of efficacy, it may not be readily applicable when the intervention is rolled out to a larger population. The cost per patient of delivering some of the interventions, such as the CDSM programmes, is dependent on the number of participants in each group. Economy of scale issues mean that the average cost may be higher if implemented in rural or sparsely populated areas where there may be fewer participants per group. The results for telemedicine were the converse, where the greatest savings could be achieved in areas with the longest travel times for care providers to reach patients' homes.

Follow-up tended to be short, with all but one study recording between two and 24 months of data. It is unclear whether the costs of providing the interventions or any observed changes in healthcare utilisation will be sustained beyond the study period, or even if there is a trend within the recorded data. For telemedicine interventions that replace face-to-face visits with video or telephone interaction, patient satisfaction may be high initially, but could reduce over time; however, follow-up of included studies was too short to evaluate this issue.

Few of the studies were structured as conventional economic evaluations, and hence there was frequently a lack of clarity regarding methodology. The wide variety of study settings mean that it is difficult to determine if the costs used are similar to what might accrue in an Irish context.

Two studies showed increased healthcare utilisation in the intervention group,<sup>(66;86)</sup> with one of those studies reporting that it was due to increased preventive care.<sup>(66)</sup> Most of the included studies appeared to use a payer perspective, although generally this was not clearly reported. For patients with chronic conditions in Ireland there may be substantial out-of-pocket expenses due to primary care utilisation.

In summary, there is limited evidence on the cost-effectiveness of generic chronic disease SMS interventions. The available evidence is for a heterogeneous set of interventions and comprised results from a number of RCTs with typically small sample sizes and short follow-up periods. This is in contrast to the review of the clinical effectiveness literature, which included 25 systematic reviews of 362 unique RCTs. The general finding is that chronic disease self-management programmes and telephone-based telemedicine programmes are relatively cheap to deliver per patient, but the magnitude of any cost saving in terms of reduced healthcare utilisation is unclear. Although generally inexpensive on a per-patient basis, the budget impact could be very substantial if implemented for all eligible patients.

Based on the available evidence, it is not possible to state whether implementing a generic chronic disease SMS intervention would be likely to result in cost savings, or

if such savings would be sustainable. The most consistent evidence is in regard to chronic disease self-management programmes, but the potential benefit is dependent on how efficiently the programme is run and there is no evidence of longer term cost savings.

## 4.5 Key messages

- Generic chronic disease self-management support (SMS) interventions comprise a heterogeneous group for which there is limited evidence of clinical effectiveness. Generally low or unreported quality of included studies that typically had only short term follow-up means that there is a high degree of uncertainty around the results.
- The majority of the literature retrieved assessed the Stanford chronic disease self-management programme (CDSMP). Based on RCT evidence assessed as being of low quality, there is some evidence of short-term improvements in the patient-reported outcome of self-efficacy. There is some short-term evidence of improvement in health behaviour outcomes (exercise) and health outcomes (pain, disability, fatigue and depression) for CDSMPs.
- Based on the systematic reviews and the underpinning primary RCTs which were of limited quantity and quality, there is some evidence that telephone-delivered cognitive behavioural therapy has a positive impact on health status.
- There is insufficient evidence to determine if computer-based chronic disease self-management programmes are superior to usual care or standard 'face to face' versions of the Stanford CDSMP. There is limited evidence that web-based cognitive behaviour therapy can have a positive impact on psychosocial outcomes.
- There is some evidence that a range of self-management support interventions can lead to a small, but significant reduction in health care utilisation; however, it is not possible to identify which types of SMS interventions or components of SMS contribute to the positive results. Based on one high quality narrative review, there is some evidence of improvements in diet adherence with a range of SMS interventions (telephone follow-up, video, contract, feedback, nutritional tools and multiple tools). There is some evidence of improvements in patient engagement and self-reported health status for a range of SMS interventions (such as chronic disease self-management programmes, internet based programmes, self-help groups, health coaching).
- There is some evidence that personalised care planning and motivational interviewing can have a positive impact on depression and physical activity, respectively. There is some evidence that nurse-led interventions using the information-motivation-behavioural skills model leads to improvements in

medication adherence. There is some evidence that in-home care leads to improvements in activities of daily living, instrumental activities of daily living and mobility. Due to limited study follow-up, it is not known if the effects observed are sustained in the longer term.

- 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, is still unclear.
- There is limited evidence of cost-effectiveness for generic chronic disease self-management support interventions. Studies were typically based on cost data collected alongside RCTs that used small sample sizes and short follow-up periods. The most consistent evidence is for chronic disease self-management programmes, but potential benefits are dependent on how efficiently the programme is run, with no evidence regarding longer term cost savings.
- Chronic disease self-management and telephone-based telemedicine programmes are relatively cheap to implement, but the magnitude of any cost saving in terms of reduced healthcare utilisation is unclear and it is not possible to determine if any savings are sustained.
- Where reported, the cost of the generic SMS interventions was generally low on a per-patient basis. However it is unclear if costs would be similar when programmes are rolled out to a larger population or if economies of scale might apply. Longer-term evidence would be required to determine if benefits in intervention groups are sustained, and whether costs change over time. Given the high prevalence of chronic diseases in Ireland, the budget impact would be substantial if implemented for all eligible patients.
- Based on the description of the healthcare systems, the epidemiology, and the patient populations in the included studies, and assuming that what constitutes 'usual care' is similar in Western countries, the majority of findings of this overview of clinical effectiveness are expected to be applicable to the Irish healthcare setting.

## 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 A4 – Generic self management support interventions for a range of chronic diseases**

### **Appendix A4.1 – Search details**

Clinical Effectiveness Review (see Appendix A3.1 for detailed search terms).

#### **Basic search strategy:**

Chronic disease term

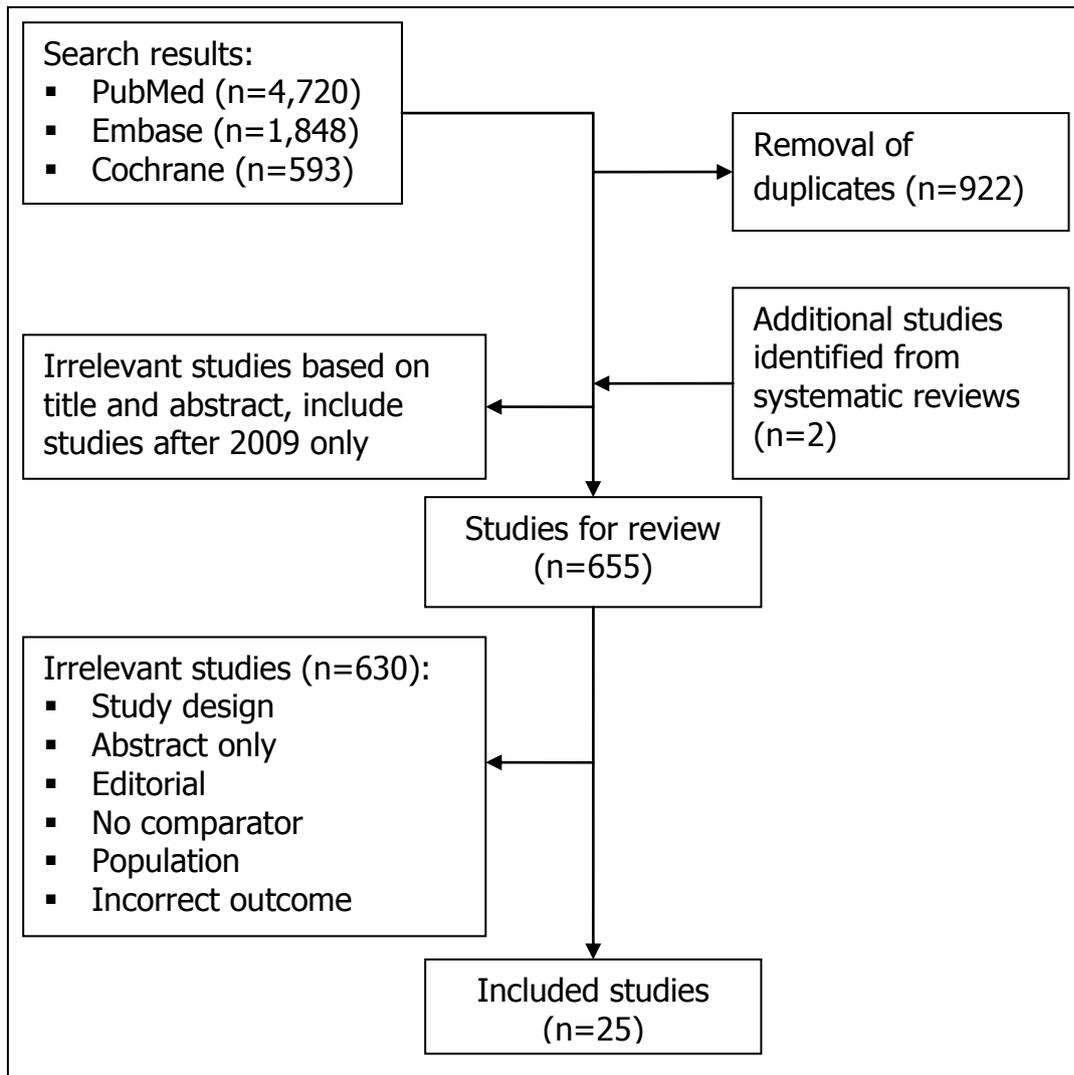
AND

Self-management term

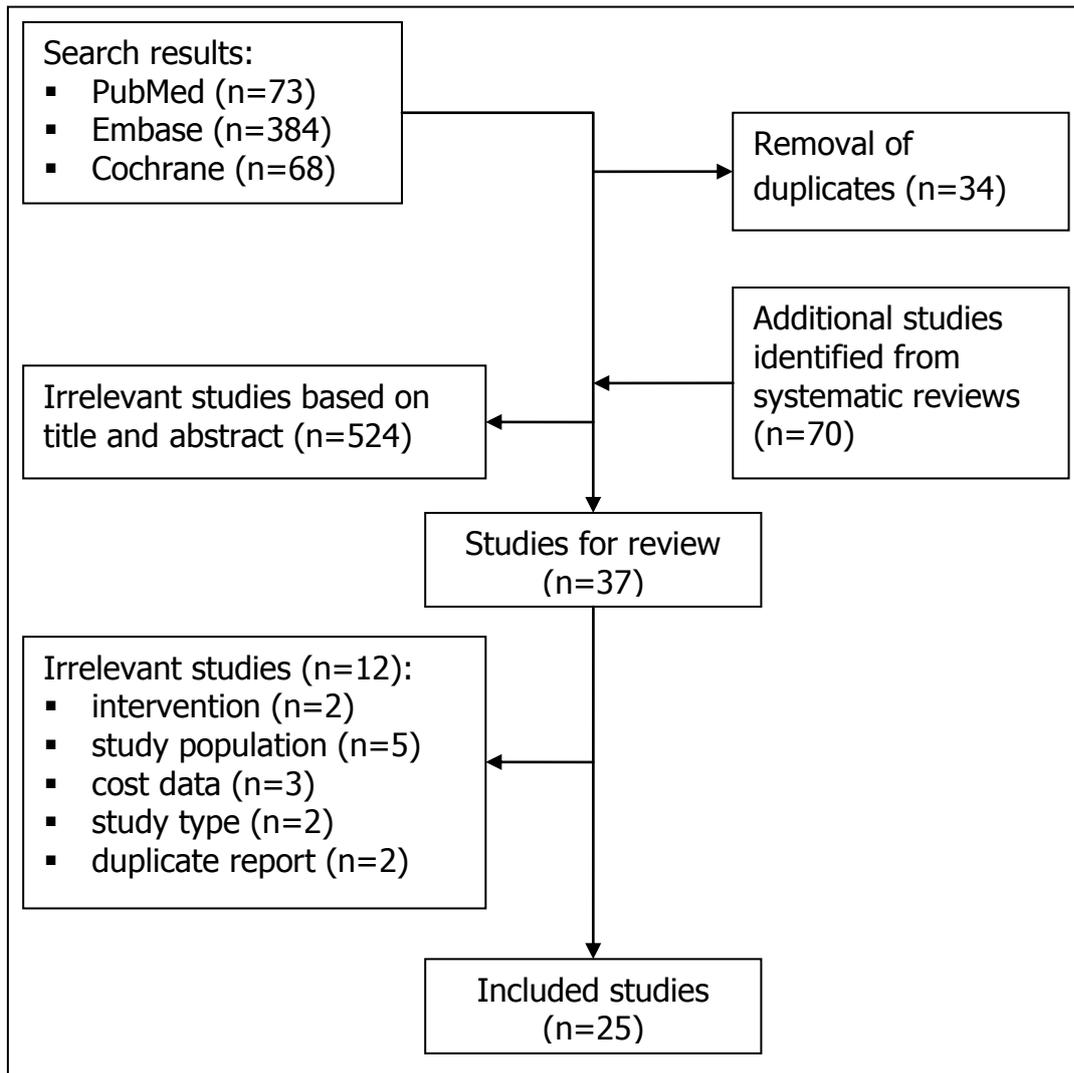
AND

systematic review term or filter.

**Figure A4.1.1 Clinical effectiveness - flowchart of included studies**



**Figure A4.1.2 Cost-effectiveness - flowchart of included studies**



## Appendix 4.2 – Evidence tables

**Table A4.2.1 CDSMPS: Summary of scope of reviews**

Review (year)	Intervention	Chronic diseases / population	Comparator	Included studies		Level of evidence from SR	Total participants	Synthesis
				SR /MA	RCTs, n (n Stanford model)			
<b>Quinones</b> (2014) <sup>(31)</sup>	Educational group visits for the management of chronic health conditions	One section on multiple chronic conditions	Usual care	-	4 (4)	Moderately strong evidence for 2 US trials.	2,593	Narrative review
<b>Franek</b> (2013) <sup>(28)</sup>	SMS interventions – mainly Stanford CDSMP	Multiple chronic conditions in some specific populations (e.g. Hispanic, Bangladeshi, UK, Netherlands)	Usual care	-	10 (9)	See below tables for each statement.	6,074	Meta-analysis
<b>NZGG</b> (2011) <sup>(7)</sup>	Health behaviour change for chronic care – multiple conditions section focuses on generic models, mainly Stanford CDSMP	DM, COPD, asthma, hypertension, stroke and multiple conditions	Range of comparators including: usual care, wait list control, exercise training, and educational material.	3	10 (6)	See below tables for each statement.	> 1,000	Narrative review
<b>Jonker</b> (2009) <sup>(30)</sup>	Self-management focusing on the CDSMP	In vulnerable older people with multiple conditions (combination of DM, asthma, CVD, lung diseases, cancer, low back pain)	Usual care	-	8 (8)	Not stated	4,284 (range: 109-954)	Narrative review
<b>Boult</b> (2009) <sup>(27)</sup>	Comprehensive care model – a component of which is CDSM which includes analysis of the Stanford CDSMP	CVD (3), multiple conditions- (6), OA(1)	Not specified	1 MA	10 (3)	Not stated	Not reported	Narrative review
<b>Inouye</b> (2011) <sup>(29)</sup>	Self-management 12 cognitive behavioural therapies, 3 health education (CDSMP), 6 alternative therapies	Asian/Pacific Islanders with chronic conditions arthritis (4), cancer (2), HIV (2), DM (6), weight loss (1), COPD (1), HF (3), comorbid section includes Stanford CDSMP (3/21 Stanford model)	Range of comparators. For example, usual care, wait list control, a course of NSAIDS, course of injections, home exercise.	-	21 (3)	11 poor quality 10 good quality	> 1,000	Narrative review

**Key:** **CBI** = Cognitive Behavioural Intervention; **COPD** = Chronic obstructive pulmonary disease; **CVD** = Cardiovascular Disease; **DM** = Diabetes Mellitus; **HF** = Heart failure; **HIV** = Human Immunodeficiency Virus; **MA** = Meta-analysis; **NR** = Narrative review; **OA** = Osteoarthritis; **SMS** = Self-management support; **SR** = Systematic-review;

**Table A4.2.2 CDSMP: Summary of results**

Review (year, synthesis)	R-AMSTAR score (/44)	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
<b>Franek</b> (2013, Meta-analysis) <sup>(28)</sup>	28	GP visits	Range 4 to 12 months	No SD between CDSMP and usual care (SMD, -0.03; 95% CI: -0.09 to 0.04; P = 0.41). [GRADE: Very Low]	6
		ED visits		No SD (SMD, -0.05; 95% CI: -0.18 to 0.09; P = 0.49). [GRADE: Very Low]	4
		Days in hospital		No SD (SMD, -0.06; 95% CI: -0.13 to 0.02; P = 0.14 / WMD, -0.27; 95% CI: -0.75 to 0.20; P = 0.26). [GRADE: Very Low]	5
		Hospitalisation		No SD (SMD, -0.09; 95% CI: -0.24 to 0.05; P = 0.20). [GRADE: Very Low]	2
		Self efficacy		Small SS increase (higher is better) in favour of CDSMP (SMD, 0.25; 95% CI: 0.12 to 0.39; P = 0.002). [GRADE: Low]	6
		Self-rated health		Small SS reduction (lower is better) in favour of CDSMP (SMD, -0.24; 95% CI: -0.40 to -0.07; P = 0.006). [GRADE: Low]	6
		HRQoL		Data on health-related quality of life were sparsely reported and difficult to interpret collectively.	N/A
		Health distress		Small SS reduction in favour of CDSMP (SMD, -0.20; 95% CI: -0.29 to -0.12; P < 0.001). [GRADE: Low]	6
		Cognitive symptom management		Small SS increase in cognitive symptom management (SMD 0.34; 95% CI: 0.20 to 0.47; p<0.001) [GRADE: Low]	3
		Communication with health professional		Small statistically significant increase in communication (SMD, 0.11; 95% CI: 0.02 to 0.21; P = 0.02) [GRADE: Low]	6
		Aerobic exercise		Small SS increase in aerobic exercise in favour of CDSMP (SMD, 0.16; 95% CI: 0.09 to 0.23; P < 0.001) [GRADE: Low]	5
		Pain		Small SS reduction in favour of CDSMP (SMD, -0.11; 95% CI: -0.17 to -0.04; P = 0.001). [GRADE: Low]	6
		Disability		Small SS reduction in favour of CDSMP (SMD, -0.14; 95% CI: -0.24 to -0.05, P = 0.004). [GRADE: Low]	4
		Fatigue		Small SS reduction in favour of CDSMP (SMD, -0.15; 95% CI: -0.22 to -0.08; P < 0.001). [GRADE: Low]	5
Dyspnoea	Non-significant trend towards reduction in shortness of breath in favour of CDSMP (SMD, -0.10; 95% CI: -0.21 to 0.01; p = 0.08). [Very Low]	4			
Depression	Small SS reduction in favour of CDSMP (SMD, -0.15; 95% CI: -0.28 to -0.03; p = 0.01). [GRADE: Low]	5			
<b>NZGG</b> (2011, Narrative)	28	Health service resource use	Authors stated majority of the included	1 SR (Foster, 2007) reported no difference between intervention and control groups (meta-analysis of 9 RCTs). This included 5 RCTs for Stanford CDSMP, 3 on the arthritis version (ASMP) and 1 disease-specific RCTs. There is no	9

Review (year, synthesis)	R-AMSTAR score (/44)	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
Review) <sup>(7)</sup>		QoL	studies had short-term (6 months) follow-up	difference for the standard programme alone.	
				No SD between groups in RCTs based on Stanford model alone (meta-analysis of 5 RCTs).	5
				1 SR (Foster, 2007) reported no difference based on 3 RCTs (WMD -0.03, 95% CI -0.09 – 0.02; NS). This is based on 1 ASMP, 2 CDSMP. No difference for CDSMP alone.	3 RCTs
		Health distress		No evidence of difference between groups for mental component of health status measure (n=1), in overall QoL measures (n=2) or in self-reported health status (n=1).	6 (Stanford or variant)
				1 SR (Foster, 2007) reported greater improvement in interventional group based on 3 RCTs for the CDSMP (SMD -0.25, 95% CI -0.34 - -0.15, P<0.00001)	3
		Self-efficacy/self-control/empowerment		Statistically significant improvement in intervention group (n=2, 6 months, 1 year), decreased health distress (n=1).	3
				1 SR (Foster, 2007) reported significant improvement in intervention group (p<0.00001) in 10/17 trials. P<0.0029 for CDSMP alone (n=5 RCTs).	10
				Statistically significant improvement at 6 months but not at 1 year follow-up (1SR).	1
		Physical activity		No difference in 2 trials, significant improvement in 2 trials, similar improvements (1 trial), significantly improved (1 trial in short term but not at 1 year). EPP reported that those at low self-efficacy at baseline were more likely to improve.	6
				1 SR (Foster, 2007) reported a small but statistically significant effect in favour of intervention group (SMD -0.20, 95% CI -0.27 to -0.12, p<0.00001). This is based on 2 ASMP, 4 CDSMP and 1 disease specific. P< 0.00001 for CDSMP alone (n=4 RCTs). [good quality based on risk of bias]	1 SR (6 RCTs)
				1SR reported not effective. [mixed quality based on risk of bias]	1 SR
				Mixed results. [mixed quality based on risk of bias]	4 RCTs
				1SR reported not effective.	1 SR
Improving diet	No difference. [mixed quality based on risk of bias]	1			
Medication adherence	No evidence of difference.	2			
Depression	1 SR (Foster, 2007) reported a small but statistically significant effect in favour of intervention group (SMD -0.16, 95% CI -0.24 to -0.07, p=0.00036). This is based on 3 ASMP, 2 CDSMP and 1 disease specific. P=0.099 for CDSMP alone	1 SR (6 RCTs)			

Review (year, synthesis)	R-AMSTAR score (/44)	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
				(n=2 RCTs). [good quality based on risk of bias] No evidence of difference.	3 RCTs
<b>Inouye</b> (2011, Narrative Review) <sup>(29)</sup>	26	Hospital stay	Baseline 4 or 6 months	Shanghai CDSMP (Fu et al.) improved hospital stay [Jadad score: 10]	1/3
		Self-efficacy		Significant increase in 2 studies [Jadad score: 9, 12] and an increase in the third [Jadad score: 10].	3
		Self-care behaviour		Significant increase in 1 study [Jadad score: 12]	1
		(Cognitive) symptom management		Significant increase in 1 study [Jadad score: 9], improved in another [Jadad score: 10]	2
		Exercise		Significant increase in 1 study [Jadad score: 9], improved duration of aerobic exercise in another [Jadad score: 10]	2
		Pain		Significantly better outcomes [Jadad score=9], improved [Jadad score: 10]	2
		Fatigue		Significantly better outcomes [Jadad score=9], improved [Jadad score: 10]	2
		Health distress		Significantly better outcomes [Jadad score=9], improved [Jadad score: 10]	2
		Energy		Significantly better outcomes [Jadad score=9]	1
		General health		Significantly better outcomes [Jadad score=9], improved [Jadad score: 10]	2
		Pain/disability/shortness of breath, social and role activity limitations		Improved outcomes [Jadad score: 10]	1
<b>Jonker</b> (2009, Narrative Review) <sup>(30)</sup>	21	Hospitalisation	<1 year	Fewer hospitalisations in 1 study (Lorig), no improvement in 2	3
		Physician/ED visits	1 year	Fewer visits in 1 study (Lorig), no improvement in 5	6
		Self-efficacy	<1 year	Improvement in 5 studies, no improvement in 2	7
		Cognitive symptom management	<6 months	Improvement in 3, no improvement in 1	4
		Mental stress management	<6 months	Improvement in 1, no improvement in 0	1
		Self-care	4-6 months	Improvement in 2, no improvement in 1	3
		General (self-rated) health	<6 months	Improvement in 4, no improvement in 3	7
		QoL	4-6 months	Improvement in 1, no improvement in 1	2
		Communication	<6 months	Improvement in 3, no improvement in 3	6
		Health distress	<1 year	Improvement in 5, no improvement in 0	5
		Anxiety	4-6 months	Improvement in 0, no improvement in 2	2
Emotional, physical & psychological well-being	4-6 months	Improvement in 2, no improvement in 1	3		

Review (year, synthesis)	R-AMSTAR score (/44)	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
		Exercise	<1 year	Improvement in 5 studies, no improvement in 1	6
		Healthy diet	4-6months	Improvement in 0, no improvement in 1	1
		Tobacco	~1 year	Improvement in 1, no improvement in 1	2
		Pain	<1 year	Improvement in 3 studies, no improvement in 5	8
		Disability/ mobility	<1 year	Improvement in 2, no improvement in 3	5
		Fatigue / energy	4-6 months	Improvement in 4, no improvement in 2	6
		Discomfort	4-6 months	Improvement in 0, no improvement in 1	1
		Shortness of breath	4-6 months	Improvement in 1, no improvement in 3	4
		Depression	4-6 months	Improvement in 1, no improvement in 3	4

**Key:** **ASMP** = Arthritis self-management programme; **CDSMP** = Chronic disease self-management programme; **ED** = Emergency Department; **ES** = Effect size; **GP** = General Practitioner; **MA** = Meta-analysis; **NR** = Narrative review; **SD** = Significant difference; **SMD** = Standardised Mean Difference; **SR** = Systematic Review; **(HR)QoL** = (Health related) Quality of Life; **SS** = Statistically Significant ; **WMD** = Weighted Mean Difference ; **SD** = Significant difference; **CI** = Confidence interval.

**Table A4.2.3 Telemedicine: Summary of scope of reviews**

Review (year)	Intervention and population	Chronic diseases / population	Comparator	Included studies			Total participants	Synthesis
				SR /MA	RCTs, n	Level of Evidence from SR		
<b>Beratarrechea</b> (2014) <sup>(32)</sup>	Mobile Health Interventions (cell phone voice communication, text messaging)	Chronic diseases in developing countries	Not specified	0	9	6 low or unclear risk of bias; 3 some risk of bias	4,604	Narrative Review
<b>Muller</b> (2011) <sup>(33)</sup>	Telephone-delivered CBT of varying intensities	SLE (1), CVD (1), End stage respiratory disease (2), RA or OA (1), MS (1), breast cancer (2). 45-61 year olds, more females	Any other intervention and/or routine care	0	8	7 unclear risk of bias; 1 low risk of bias	1,093	Meta Analysis
<b>Wootton</b> (2012) <sup>(34)</sup>	Telemedicine (20 years)	Asthma (20), COPD(11), DM (39), HF (57), hypertension (14)	Usual care	22	141	Not stated	37,695	Evidence synthesis

**Key:** CBT = Cognitive behavioural therapy; COPD = Chronic Obstructive Pulmonary Disease; CVD = Cardiovascular Disease; DM = Diabetes Mellitus; HF = Heart failure; MA = Meta-analysis; MS = Multiple Sclerosis; NR = Narrative review; OA = Osteoarthritis, SR = Systematic-review; SLE = Systemic Lupus Erythematosus; RA = Rheumatoid Arthritis.

**Table A4.2.4 Telemedicine: Summary of results**

Review (year, synthesis)	R-AMSTAR score (/44)	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
<b>Beratarrechea</b> (2014) <sup>(32)</sup>	30	HRQoL	3-6 months (1 study)	Improvements in HRQoL in 2 studies. [not stated]	2
		Asthma (expiratory volume in 1s, cough & night symptoms) HF (6 min walk test distance, physical impairment, symptoms) DM (glycaemic control)	Not specified	Improvement in 4 trials studying clinical outcomes.	5
<b>Muller</b> (2011) <sup>(33)</sup>	28	Health status	2-6 months	MA of the 8 studies revealed a significant change in health status following telephone-delivered CBT. The sample-weighted pooled effect size was $d=0.225$ (95% CI: 0.105, 0.344).	8
<b>Wootton</b> (2012) <sup>(34)</sup>	22	Asthma (n=20): Commonly healthcare utilisation, symptoms and quality of life. COPD (n=11): Commonly hospital admissions and quality of life. DM (n=39): Commonly HbA1c, QoL and self-efficacy. HF (n=61): Commonly mortality, hospital admissions, quality of life and healthcare costs. Hypertension (n=17): Commonly blood pressure and healthcare costs.		RCTs: 73% of studies were favourable to the intervention, 26% were neutral, and 1% were unfavourable. [not stated]	141
				SRs: Approximately half of the SRs provided a qualitative summary; none concluded negatively, i.e. telemedicine unhelpful in CD management. [not stated]	Approx 11/22
				SRs: 12 SRs provided 23 pooled estimates of effect, of which approximately half showed telemedicine to provide significantly better outcomes than the control condition. [not stated]	12/22
		QoL, ED visits, Hospitalisation, Mortality, HbA1c, Severe hypoglycaemia, Diabetic ketoacidosis		SRs: The other half of the pooled estimates showed telemedicine to be no better than the control condition. This emphasises the rather weak and unsatisfactory conclusions which can be drawn from the systematic reviews presently available. [not stated]	10/22

**Key:** **CVD:** Cardiovascular Disease; **CD:** Chronic Disease; **CBT:** Cognitive Behavioural Therapy; **COPD:** Chronic Obstructive Pulmonary Disease; **DM:** Diabetes Mellitus; **ES:** Effect Size; **ED:** Emergency Department; **HbA1c:** Glycated Haemoglobin; **HF:** Heart Failure; **(HR)QoL:** (Health related) Quality of Life; **MA:** Meta-analysis; **NR:** Narrative review; **SD:** Significant difference; **SR:** Systematic Review.

**Table A4.2.5 Web-based: Summary of scope of reviews**

Review (year)	Intervention	Chronic diseases / population	Comparator	Included studies			participants	Synthesis
				Total SR /MA	RCTs, n	Level of evidence		
<b>McDermott</b> (2013) <sup>(39)</sup>	Computers to deliver CDSMP	Type I or II DM (3), asthma (3), HF (2), HIV (1), TIA or minor stroke (n1), RA (1).	Equivalent 'standard' CDSMP delivered by staff, usual care or no intervention	0	11 RCTs (from 15 articles)	Variable risk of bias across studies	1,506	Narrative review
<b>Bossen</b> (2014) <sup>(35)</sup>	Self-Guided Web-Based Physical Activity Interventions	DM (11), HF (n 3), COPD (1), CVD (1), cancer (1), and mixed patient groups (CVD, lung disease, type 2 DM; n1).	No or minimal treatment	0	5 RCTs, 2 pilot RCTs	5 high-quality, 2 low quality	Ranged from 22 to 463	Narrative review
<b>Kuijpers</b> (2013) <sup>(38)</sup>	Web-Based Interventions for Patient Empowerment and Physical Activity	DM (11), HF (3), COPD (1), CVD(1), cancer(1) and CD(1)	Similar patient group (receiving another intervention or usual care)	0	18 (19 studies)		5,204	Narrative review
<b>De Jong</b> (2014) <sup>(36)</sup>	Internet-based asynchronous communication between health providers and patients	Unspecified chronic illnesses (4), chronic pain (2), DM (4), asthma (2), COPD (n=1), chronic neurological conditions (1), HF (1)	Usual care	0	15	3 high risk of bias; 12 low risk of bias	6,067	Narrative review
<b>Paul</b> (2013) <sup>(40)</sup>	Web-based approaches (CBT or information websites or access to expert advice ) impact on psychosocial health	Mental health (19), DM (7), cancer (7), CVD (1), obesity (1) and multiple chronic conditions (1)	Usual care or face-to face CBT	0	36	Not stated	9,814	Narrative review
<b>Samoocha</b> (2010) <sup>(41)</sup>	Web-based Interventions effectiveness on patient empowerment	CVD (2), mental health (3), infertility (2), COPD (1),ABI (1), arthritis(1), DM (1), CD(1),back pain (1)	Usual care or no care	0	13 RCTs, 1 quasi-RCT	6 fair quality, 7 good quality, 1 excellent quality	3,417	Meta-analysis
<b>Eland de Kok</b> (2011) <sup>(37)</sup>	E-health interventions (interactive websites, internet) (monitoring, treatment instructions, self-management training (coaching) and general information and web-based messaging)	DM (9), 1 atopic dermatitis (1), co-morbidity (1), CVD (1)	Usual care	0	12	4 low; 4 mod; 4 high	11,203	Narrative Review

**Key:** **ABI** = Acquired Brain Injury; **CD** = Chronic Disease; **COPD** = Chronic Obstructive Pulmonary Disease; **CVD** = Cardiovascular Disease; **DM** = Diabetes Mellitus; **HF** = Heart failure; **HIV** = Human Immunodeficiency Virus; **MA** = Meta-analysis; **NR** = Narrative review; **SR** = Systematic-review; **RA** = Rheumatoid arthritis; **TIA** = Transient ischemic attack.

**Table A4.2.6 Web-based: Summary of results**

Review (year, synthesis)	R-AMSTAR score (/44)	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
<b>McDermott</b> (2013) <sup>(39)</sup>	26	Behavioural (e.g. dietary habits)	0 to 6 months	Computer-based PSMP more effective when compared to no intervention or a control with no PSM element specified than when compared to standard PSMP for behavioural outcomes: 100% v 60% of studies, 77% v 25% of analyses. [not stated]	11
		Clinical (e.g. glycosylated hemoglobin)	3 to 12 months	Computer-based PSMP more effective when compared to no intervention or a control with no PSM element specified than when compared with standard PSMP for clinical outcomes: 100% v 50% of studies, 33% v 17% of analyses. [not stated]	11
<b>Bossen</b> (2014) <sup>(35)</sup>	28	Physical activity	1 to 12 months	3 [high-quality] studies reported significant increase for the intervention, 4 [2 high quality, 2 low quality] studies reported no SD. ES range from 0.13-0.56.	7
<b>Kuijpers</b> (2013) <sup>(38)</sup>	26	Patient empowerment	1 to 18 months	Increased significantly ( $p < .05$ ) in intervention group compared with usual care or observation in four studies; increase reported for both groups in 3 studies; mixed results in 2 studies; no significant change in patient empowerment in four studies. [not stated]	13
		Patient satisfaction	Not reported	High in general	10
		Physical activity	1 to 18 months	Significant improvement ( $p < .05$ ) for intervention group compared with usual care in 2 studies; increases for both groups but no difference between groups in 6 studies.	14
<b>De Jong</b> (2014) <sup>(36)</sup>	29	Health care utilisation	Not reported	Decrease, but not statistically significant. [not stated]	4
		Self-efficacy/self-management	Not reported	Increase in self-efficacy self-care managing dyspnoea found in 2 of three studies. [not stated]	3
		General health behaviour	Not reported	Improvements when using the intervention. [not stated]	7
		Health outcomes e.g. HbA1c	6 weeks in 1 study, 8 weeks in 1 study, not specified for remaining studies	Ten of the 11 studies report statistically significant improvements in one or more health outcomes.	11

Review (year, synthesis)	R-AMSTAR score (/44)	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
<b>Paul</b> (2013) <sup>(40)</sup>	28	Psychosocial outcomes	Not reported for all studies, examples include 1 month, 6 months and 12 months.	Significant positive in favour of web-based intervention found in 21 studies; mixture of positive and null findings in 4 studies; no positive effect found in 11 studies.	36
<b>Samoocha</b> (2010) <sup>(41)</sup>	33	General self-efficacy	8 weeks to one year	SMD 0.05 (95% CI - 0.25 to 0.35) no statistically SD between Web- based interventions and usual care in increasing general self-efficacy [low quality]	3 (combined n=293)
				There are improvements in mastery and self-efficacy when disease specific measurement tools or scales are used but not when general ones are used.	1
<b>Eland-de Kok</b> (2011) <sup>(37)</sup>	24	Health care use	Not reported	<i>In addition to usual care:</i> There were only small effects shown on health care use. [not stated]	1
		Resource use	Not reported	<i>In addition to usual care:</i> No SD in resource use between the intervention and control group were shown in two studies. [not stated]	2
		DM(HbA1c) CVD (cardiovascular related events)	Not specified	<i>Compared with usual care:</i> All 4 studies in patients with DM showed a greater reduction in HbA1c. 1 study showed greater improvement in clinical outcomes in patients with CVD and fewer cardiovascular-related events as measured after six months. However, not all outcomes improved in the 5 studies, and in some measures, comparable effect sizes were seen in both groups. [not stated]	5
		Physical health outcomes Primary health outcomes	Not specified	<i>In addition to usual care:</i> e-health programme resulted in significantly improving physical health outcomes with small to moderate ES on primary health outcomes of patients with DM. In two studies, e-health was not associated with improved health outcomes. [not stated]	7

**Key:** MA = Meta-analysis; NR = Narrative review; SS = Statistically Significant; SD = Significant difference; SMD = Standardised Mean Difference; ES = Effect Size; PSMP = Patient Self-Management Programme; HbA1c = Glycosolated Haemoglobin.

**Table A4.2.7 Complex SMS interventions: Summary of scope of reviews**

Review (year)	Intervention	Chronic diseases / population	Comparator	Included studies			Total participants	Synthesis
				SR /MA	RCTs, n	Level of evidence		
<b>Panagioti</b> (2014) <sup>(43)</sup>	SMS interventions – ‘Mixed problems’ section includes the Stanford CDSMP. Remaining RCTs are not programmes or are disease-specific	Arthritis = 8%, CVD= 29%, DM=6%, mental health=16%, mixed problems=7%, respiratory=24%, pain=11%	Usual care	0	9 (mixed problems)	Variable allocation concealment	4,695	Meta-analysis
<b>Desroches</b> (2013) <sup>(42)</sup>	Interventions to enhance adherence to dietary advice	CVD(9), hypertension (5), DM (6), renal (6), obesity (6), IBS (1)	No intervention (control); usual care; multiple interventions	0	38	Variable risk of bias	9,445	Narrative review (Cochrane review)
<b>Simmons</b> (2014) <sup>(44)</sup>	Personalised health care (effect of patient engagement)	DM (6),CV (1), MS (1),asthma (1), arthritis (1), bronchiectasis (1)	Usual care (60%), attention control, enhanced usual care or a wait-list control (40%).	0	10	6 low quality; 4 high quality	3,023	Narrative review

**Key:** **CD** = Chronic Disease; **COPD** = Chronic Obstructive Pulmonary Disease; **CR** = Cochrane review; **CVD** = Cardiovascular Disease; **DM** = Diabetes Mellitus; **IBS** = Irritable Bowel Syndrome; **MA** = Meta-analysis; **MS** = Multiple Sclerosis; **NR** = Narrative review; **SMS** = Self-management Support

**Table A4.2.8 Complex SMS interventions: Summary of results – Health care utilisation**

Review (year, synthesis)	R-AMSTAR score (/44)	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
<b>Panagiotti (2014)</b> <sup>(43)</sup>	36	Hospital use	5 to 12 months	Small but significant reductions in hospital use. ES= - 0.12 (- 0.20 to - 0.03). A minority of self-management support studies reported reductions in health-care utilisation in association with decrements in health.	9
		QoL	4 to 12 months	Small, but significant improvements in QoL. ES= 0.13 (0.02 to 0.24)	9
		Medication adherence	Not specified for all studies	No significant effect of pharmacist led interventions for medication reconciliation or for enhanced medication adherence.	3 MA (2, 4, 9 RCTs)
<b>Desroches (2013)</b> <sup>(42)</sup>	36	Diet adherence	<6->12 months	32/98 DA outcomes favoured the intervention group. 4 favoured the control group and 62 had no significant difference between groups.	38
<b>Simmons (2014)</b> <sup>(44)</sup>	31	Patient engagement	1 to12 months	Improvements in all components of patient engagement (knowledge, skills, confidence, and at least one behaviour). [4/10 'high' methodological quality (Jadad score≥3)]	9/10
				No changes in any component of patient engagement, and improvements in knowledge/confidence/skills but not behaviour. [4/10 'high' methodological quality (Jadad score≥3)]	1/10
		Self-reported health status	1 to 18 months	All studies reported improvements in self-reported health status.	3/3
		Clinical markers of disease	Not reported	Five studies reported reduction in clinical markers of disease (for example HbA1C). [4/10 'high' methodological quality (Jadad score≥3)]	5/10

**Key:** MA = Meta-analysis; NR = Narrative review; SD = Significant difference; HRR = Hospital readmission rates; (HR)QoL = (Health related) Quality of Life; DA = Diet adherence

**Table A4.2.9 Other SMS: Summary of scope of reviews**

Review (year)	Intervention and population	Chronic diseases / population	Comparator	Included studies			Total participants	Synthesis
				SR /MA	RCTs, n	Level of evidence		
<b>Kivela (2014)</b> <sup>(45)</sup>	Health coaching by health care professional (telephone only, internet, combination of telephone, face-to-face, internet or e-mail)	DM (3), mix conditions (3), CVD(2), overweight (2), RA (1), cancer(1)	Not specified	0	13 (11 RCTs, 2 quasi-RCTs)	All studies fair quality or above	Range 22 to 1755	Narrative review
<b>Ontario (2013)</b> <sup>(46)</sup>	In-home care (care in the home, community, supportive housing, or long-term care facilities.)	DM (1), stroke (1), COPD (1), multi-morbid (3- based on 2 RCTs), HF (6)	No home care or usual care/care received outside the home	1 HTA, 4 SRs	12 (2)	See below for each statement	Range <100 to >300 per trial	Meta-analysis & Narrative review
<b>O'Halloran (2014)</b> <sup>(47)</sup>	Motivational interviewing for increasing physical	obesity or CVD (7), MS (1), fibromyalgia (1)	Usual care	0	10	See below for each statement	1176	Meta-analysis
<b>van Camp (2013)</b> <sup>(48)</sup>	Nurse-led interventions to enhance medical adherence (mainly counseling via face-to-face, groups or electronic messages)	HIV (7), depression (1), 1 hypertension (1), arthritis(1)	Usual care		10	All studies acceptable to high quality	2,587	Meta-analysis
<b>Chang (2014)</b> <sup>(49)</sup>	Information motivation behavioural skills, for adherence to therapy or to target risky sexual behaviour	HIV (9),DM (1), CVD (1), cancer (1)	Various interventions relating to the information construct, motivation construct and behavioural skills construct. For example, instructional pamphlets, motivational interviewing techniques, instruction or role playing	0	12	All studies fair quality	2,605	Narrative review
<b>Coulter (2015)</b> <sup>(11)</sup>	Personalised care planning All studies included components intended to support behaviour change, either face-to-face or telephone support.	DM (12), mental health (3), HF (1), end stage renal disease (1), asthma (1), various conditions (1)	Usual care	0	19 (16 included in MA)	Moderate	10,856	Meta-analysis

**Key:** COPD = Chronic Obstructive Pulmonary disease; CVD = Cardiovascular disease; DM = Diabetes Mellitus; HF = Heart Failure; HIV = Human Immunodeficiency Virus; HTA = Health Technology Assessment; MA = Meta-analysis; MS = Multiple sclerosis; NR = Narrative review; SR = Systematic-review; RA = Rheumatoid Arthritis;

**Table A4.2.10 Other SMS: Summary of results**

Review (year, synthesis)	R-AMSTAR score	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
<b>Kivela (2014)<sup>(45)</sup></b>	29	Physical health status	6 weeks to 24 months	Significantly improved results reported in 3/4 studies (6 weeks, 6/8 months), non-significant outcome in 1 (at 12, 24 months).	4
		Self-efficacy	6 to 24 months	SS positive outcome in 2/3 studies (at 6 and 8 months), non-significant outcome in 1 (at 12, 24 months).	3
		Satisfaction of treatment	12 to 36 weeks	SS positive outcome in 2/2 studies.	2
		Mental health	6 weeks to 6 months	SS positive outcome in 2/3 studies, non-significant outcome in 1.	3
		Weight loss	3 to 18 months	Significantly improved results reported in 3/3 studies.	3
		Physical activity	3 weeks to 18 months	Significantly increased physical activity in 6/10 studies.	10
		HbA1c	12 weeks to 12 months	Significantly improved results reported in 2/4 studies, non-significant outcome in 1.	4
<b>Ontario (2013)<sup>(46)</sup></b>	29	Mortality	1 month to 10 years	No difference between in-home care and usual care for all-cause mortality in chronically ill multimorbid patients (Mean difference: 0.80; 95% CI: 0.54 to 1.19; $p=0.28$ ). [Moderate evidence]	1
		Activities of daily living		Mean difference -0.14 [-0.27, -0.01]. (favours home care) [Moderate evidence]	1
		Mobility		Mean difference -0.12 [-0.29, 0.05] favours home care [Moderate evidence]	1
		instrumental activities of daily living		Mean difference favours home care -0.13 [-0.29, 0.03] [Moderate evidence]	1
<b>O'Halloran (2014)<sup>(47)</sup></b>	33	Physical activity	3 to 18 months	MI increased physical activity levels for people with health conditions with a small but significant effect observed immediately following the intervention (SMD = 0.19, 95% CI 0.06 to 0.32, $p=0.004$ , $I^2=0\%$ ) [Moderate quality trials]	8
		Cardio-respiratory fitness		No effect of intervention with a SMD of -0.07 (95% CI -0.56 to 0.43, $p=0.79$ , $I^2=52\%$ ) [very low quality]	3
		Functional exercise capacity		No SD between the groups were observed (SMD 0.13, 95% CI -0.08 to 0.34, $p=0.22$ , $I^2=0\%$ ) [moderate quality]	2
<b>van Camp (2013)<sup>(48)</sup></b>	29	Medication adherence	Short term immediately post intervention	9/10 found their interventions enhanced adherence, 4 significantly. The difference in adherence in favour of the intervention group varied from +5 to 11 %.	10

Review (year, synthesis)	R-AMSTAR score	Outcomes measured	Follow-up	Results [Evidence appraisal]	Number of RCTs
			(3 to 12 months)	The pooled mean differences were +5.39 (1.70–9.07) in favour of the intervention groups (p=0.004). [Quality rates acceptable to high for all included studies]	
			Long term – after end of interventions	8/8 authors found their intervention effect was sustained in the long term and some were further increasing, 4 significantly. The pooled mean differences were +9.46 (4.68–14.30) in favour of the intervention groups (p<0.001). [Quality rates acceptable to high for all included studies]	8
<b>Chang (2014)<sup>(49)</sup></b>	29	Behavioural outcomes	3 to 12 months	10/12 reported significant behaviour changes at the first post-intervention assessment.	12
		Medication adherence	-	5/6 intervention groups showed significantly higher medication adherence than the control groups.	6
		Measured biological variables	0 to 12 months	2/5 improved results in the intervention group.	2/5
<b>Coulter (2015)<sup>(11)</sup></b>	38	Depression	1.5 to 12 months	SMD of -0.36 (95% CI -0.52 to -0.20), a small effect in favour of personalised care [moderate quality evidence]	5
		HRQoL		No effect on the physical component summary score SMD 0.16 (95% CI -0.05 to 0.38) or the mental component summary score SMD 0.07 (95% CI -0.15 to 0.28) [moderate quality evidence]	3
		Condition-specific health status		No difference between the intervention and control groups, SMD -0.01 (95% CI -0.11 to 0.10) [moderate quality evidence]	4
		HbA1c	6 to 12 months	Mean difference -0.24% (95% confidence interval (CI) -0.35 to -0.14), a small positive effect in favour of personalised care planning compared to usual care [moderate quality evidence]	9
		Systolic blood pressure	Mean difference of -2.64 mm/Hg (95% CI -4.47 to -0.82) favouring personalised care [moderate quality evidence].	6	
		Diastolic blood pressure	No significant effect, MD -0.71 mm/Hg (95% CI -2.26 to 0.84)	4	
		Cholesterol	No evidence of an effect on cholesterol (LDL-C), standardised mean difference (SMD) 0.01 (95% CI -0.09 to 0.11)	5	
		Body mass index	No evidence of an effect, MD -0.11 (95% CI -0.35 to 0.13)	4	

**Key:** ES = Effect Size; MA = Meta-analysis; NR = Narrative review; (HR)QoL = (Health related) Quality of Life; SS = Statistically Significant; MI = Motivational Interviewing; NR = Narrative review; SD = Significant difference; SMD = Standardised Mean Difference; HbA1C = Glycosolated hemoglobin.

## Appendix A4.3.1 – Appraisal of study quality for included cost-effectiveness studies

Study	Quality	Reasons for downgrading
<b>Aanesen (2011)</b>	Low	Results are dependent on the alternative to the intervention, namely living without it or the requirement to live in a nursing home. No sensitivity analyses.
<b>Ahn (2013)</b>	Low	Effectiveness based on change from baseline with no concurrent control group. No assessment of uncertainty undertaken.
<b>Bendixen (2009)</b>	Low	Retrospective, matched comparison study design. Significant variance in the results could not be attributed to the analysed variables, indicating a large error component for this study design.
<b>Battersby (2007)</b>	Low	Poorly reported cost data. No sensitivity analysis.
<b>Dimmick (2000)</b>	Low	Poorly reported study. Very small patient sample with unclear methodology regarding analysis.
<b>Doolittle (2000)</b>	Low	Poorly reported. No concurrent controls.
<b>Elliott (2008)</b>	High	
<b>Finkelstein (2006)</b>	Low	Cost data was not related to year of cost. Small study population.
<b>Graves (2009)</b>	High	
<b>Griffiths (2005)</b>	Moderate	Poor uptake of participation in underlying RCT, hence results are at risk of bias.
<b>Henderson (2013)</b>	Moderate	Data based on non-random subsample of trial population.
<b>Jerant (2009)</b>	Low	Poorly reported cost and outcome data. No sensitivity analysis.
<b>Johnston (2000)</b>	Low	Poorly reported. Unclear source of cost data. No sensitivity analysis.
<b>Katon (2012)</b>	High	
<b>Lorig (2001)</b>	Low	Waiting-list control group. The cost data are based on simplistic estimates of health care utilisation costs. The study uses a longitudinal design format, along with simple ER and hospitalisation cost multipliers, to estimate costs and cost savings.
<b>Moczygemba (2012)</b>	Low	Based on quasi-experimental study data. No sensitivity analysis.
<b>Noel (2000)</b>	Low	Based on pilot study data.
<b>Noel (2004)</b>	Moderate	Based on small RCT.
<b>Page (2014)</b>	Low	Data based on cost surveys.
<b>Pare (2013)</b>	Low	Data relating to post outcomes extrapolated from 157 to 244 days. No detail of extrapolation method given. No sensitivity analysis.
<b>Richardson (2008)</b>	High	
<b>Schwartz (2010)</b>	High	
<b>Scott (2004)</b>	High	
<b>Steventon (2013)</b>	High	
<b>Tousignant (2006)</b>	Low	Based on pilot study to establish proof of concept and a cost analysis of the intervention.

## Appendix A4.3.2. Studies investigating CDSM programmes

Study	Study design	Intervention	Comparators	Population	Findings
<b>Ahn (2013) US<sup>(64)</sup></b>	Observational study with 12 months follow-up (n=1,170).	Chronic Disease Self-Management Programme	Routine care at baseline.	Community dwelling with chronic condition (mean age 67).	Potential cost savings estimated at €335 per person. Potential savings of \$3 billion if the programme reached 5% of individuals with one or more chronic conditions.
<b>Battersby* (2007) Australia<sup>(65)</sup></b>	Costing study alongside 4 RCTs (n=4,603) in 4 regions over 2 years	SA HealthPlus generic model of chronic illness care including service coordinators and behavioural and care planning	Routine care	Patients with chronic and complex medical conditions requiring high service demand ( $\geq 8$ GP visits + $\geq 4$ ED /OPD visits $\pm \geq 1$ inpatient admission in 12mo. pre-enrolment.	The trial of coordinated care demonstrated that individual health and well being can be improved through patient-centered care. Any savings in admissions to acute care did not compensate for the coordination costs and additional community services with the intervention group showing a deficit of AUS\$4,842,898 (1998 costs) (adjusted) compared with usual care.
<b>Griffiths (2005) UK<sup>(72)</sup></b>	RCT with 4 months follow-up (n=476).	Expert patient programme	Routine care.	Bangladeshi adults with diabetes, cardiovascular disease, respiratory disease or arthritis (mean age 48.5).	The programme cost €192 per participant to deliver. The intervention group had greater improvements in self-efficacy and self-care than the control group. There were no differences between groups in terms of healthcare utilisation.
<b>Lorig (2001) US<sup>(77)</sup></b>	Longitudinal design as 2 year follow-up to a randomised trial (n=831).	Chronic Disease Self-Management Programme	Routine care at baseline.	Individuals with heart disease, lung disease, stroke or arthritis (mean age 64.9).	Two-year savings of between €511 and €682 per participant (based on health service utilisation and programme delivery costs).
<b>Page (2014) US<sup>(81)</sup></b>	Costing study (n=1,612).	Six-week group education and support programme.	None (costing study).	Individuals over the age of 60 who are living with chronic health problems in the community.	Costs for implementation per programme participant were €172.
<b>Richardson (2008) UK<sup>(83)</sup></b>	RCT with 6 months follow up (n=520).	Expert Patients Programme (EPP), a self-care group to teach self-care support skills.	Routine care.	Individuals with a (self-defined) long-term condition being treated in a community setting (mean age 55.4).	The intervention was associated with a QALY gain (0.020 [95% CI 0.007 to 0.034]) and a reduction in average cost per patient (€41 less [95% CI: €559 more to €642 less]), resulting in an ICER of -€2,0522 per QALY.

**Key:** CDSM = chronic disease self-management; ICER = incremental cost-effectiveness ratio; RCT = randomised controlled trial; QALY = quality-adjusted life year.

\* An output of this research was the Flinders' model of self-management support programme.

**Table A4.3.3 Studies investigating telemedicine interventions**

Study	Study design	Intervention	Comparators	Population	Findings
<b>Aanesen (2011) Norway<sup>(63)</sup></b>	Modelling study.	Smart house technology and video visits.	Routine care (physical visits and no smart home technology or video visits).	Elderly patients diagnosed with a chronic condition (mean age 70).	Smart home technology may be cost-effective. Video visits only cost-effective if there are significant reductions in time costs for home care providers.
<b>Bendixen (2009) US<sup>(66)</sup></b>	Observational study with 24 months follow-up (n=9,977).	Telerehabilitation.	Standard care in matched comparison group followed over 2 years.	Home dwelling elders with chronic conditions (mean age 72.4).	No significant difference in costs pre- and post-intervention. Much greater use of preventive medicine in intervention group.
<b>Dimmick (2000) US<sup>(67)</sup></b>	Case study with 12 months follow-up (n=14).	Rural telemedicine programme.	Routine care involving face to face nurse visits.	Suitable community patients with chronic disease and history of high healthcare utilisation.	The programme was associated with a reduction of 28 minutes per patient consultation and potential mileage reimbursement and drive time savings of \$49.33(€70) per visit.
<b>Doolittle (2000) US<sup>(68)</sup></b>	Costing study.	A telehospice service providing hospice care in the home.	Traditional hospice care.	Patients requiring hospice care.	The cost per traditional care visit was between \$126(€180) and \$141(€201). The average telehospice visit cost was \$29(€41).
<b>Elliott (2008) UK<sup>(69)</sup></b>	RCT with 2 months follow-up (n=500).	Telephone-based pharmacy advisory service.	Routine care control group.	Community dwelling elders suffering from stroke, cardiovascular disease, asthma, diabetes, or rheumatoid arthritis (mean age 67).	ICER of -£2.168 (-€3,296) per extra adherent patient.
<b>Finkelstein (2006) US<sup>(70)</sup></b>	RCT with 6 months follow-up (n=68).	Telemedicine delivered home healthcare using videoconferencing and physiologic monitoring.	Patients receiving traditional nursing care at home or virtual visits through video-conferencing.	Patients receiving nursing care at home.	The mean cost per visit was \$48.27(€53) for in-person visits, \$22.11 (€24) for video visits, and \$33.11(€37) for video visits with physiologic monitoring.

Table A4.3.3 continued.

Study	Study design	Intervention	Comparators	Population	Findings
<b>Graves (2009)</b> <b>Australia</b> <sup>(71)</sup>	Cluster-randomised trial with 12 months follow up (n=434).	Telephone counselling for physical activity and diet.	Usual care (provided literature and feedback) and 'real control' (baseline data).	Adults with type 2 diabetes or hypertension (mean age 58) from a disadvantaged community.	Telephone counselling vs. Usual care = \$78,489 (€115,352)/QALY. Usual care vs. real control = \$12,153(€17,861)/QALY. (Threshold = \$64k (€94,000)/QALY). No evidence to support long term effect of usual care strategy.
<b>Henderson (2013)</b> <b>UK</b> <sup>(73)</sup>	RCT with 12 months follow-up (n=965).	Telehealth monitoring system	Routine care.	Individuals with a long-term condition (heart failure, COPD, or diabetes).	The intervention cost €581 per participant to deliver. The intervention was associated with reduced healthcare utilisation costs. Overall, the intervention was associated with higher costs than usual care. The ICER for the intervention was €119,337 per QALY.
<b>Johnston (2000)</b> <b>US</b> <sup>(75)</sup>	Quasi-experimental study, unclear length of follow-up (n=212).	Remote video technology for home health care (with 24 hour access).	Routine care control group (home visits and telephone contact).	Newly referred patients with congestive heart failure, chronic obstructive pulmonary disease, cerebral vascular accident, cancer, diabetes, anxiety, or need for wound care (mean age 70).	Delivery of home care was an average \$663(€946) more in the intervention group, but hospital care costs were \$726(€1,036) lower, indicating a modest reduction in costs. Capital costs were not amortised in the calculations.
<b>Moczygemba (2012)</b> <b>US</b> <sup>(78)</sup>	Self selecting trial with 12 month follow-up (n=120)	Pharmacist-provided telephone medication therapy management	Routine care	Medicare beneficiaries who were eligible for medication therapy management (mean age 72.6)	Significant difference in the number of problems resolved (54% intervention versus 20% control) and in annual drug cost savings (drug costs decreased by \$682(€695) ± \$2,141(2,181) in the intervention group and increased by \$119(€121) ± \$1,763(€1,796) in the control group)
<b>Noel (2000)</b> <b>US</b> <sup>(79)</sup>	Costing study (n=19)	Telemedicine integrated with nurse case management for the homebound elderly.	Nurse case management	Elderly patients who were high resource users in the 6 months preceding enrolment, with at least three chronic conditions (mean age 69.4)	There were no differences in clinical outcomes and costs decreased by a comparable amount in both the intervention and treatment arms.

Table A4.3.3 continued.

Study	Study design	Intervention	Comparators	Population	Findings
<b>Noel (2004) US<sup>(80)</sup></b>	Randomised trial with 6 to 12 months follow-up (n=104).	Home telehealth programme.	Routine care (control group).	Community-dwelling participants with complex heart failure, chronic lung disease, and/or diabetes mellitus.	The mean cost per patient in the intervention group was \$8,278 (€10,364) at 6 months pre-study and \$4,849 (€6,071) at 6 months post-study. The mean cost per patient in the control group was \$12,386 (€15,507) at 6 months pre-study and \$5,832(€7,302) at 6 months post-study.
<b>Pare (2013) Canada<sup>(82)</sup></b>	Cost minimisation analysis with 9 months follow up (n=95).	Telehomecare programme for elderly patients with chronic health problems.	Routine care.	Elderly patients (mean age 70) with congestive heart failure, diabetes, COPD or hypertension.	Significant reduction in overall healthcare utilisation and costs per patient (annual cost savings of CAD\$1,557(€1,058) per patient).
<b>Steventon (2013) UK<sup>(86)</sup></b>	Cohort with matched controls with 12 months follow-up (n=5396).	Telephone health coaching service (Birmingham OwnHealth).	Routine care.	Patients from local general practices with chronic disease and a history of inpatient or outpatient hospital use (mean age 65.5).	Emergency and outpatient admissions increased more quickly among intervention participants than matched controls (0.05, 95% CI 0.00 to 0.09, P=0.046 and 0.37, 95% CI 0.16 to 0.58, P<0.001), as did secondary care costs (£175(€236), £22(€30) to £328(€443), p=0.025).
<b>Tousignant (2006) Canada<sup>(87)</sup></b>	Non-randomised study with 2 months follow-up (n=4).	Rehabilitation through teletreatment.	Homecare visits.	Community-living older adults due to be discharged with a prescription for physiotherapy follow-up.	Physiotherapy rehabilitation delivered through telemedicine cost an average of \$100 (€74) less than home visits.

**Table A4.3.4. Studies investigating internet-based telemedicine**

Study	Study design	Intervention	Comparators	Population	Findings
<b>Schwartz (2010) US<sup>(84)</sup></b>	Cohort with matched controls using 5 years of claims data (n=773).	Online chronic disease self-management programme.	Routine care.	Adult members of a US health insurance programme (mean age 47).	Health care costs per person per year were €743 (\$757) less than predicted for participants relative to matched nonparticipants, yielding a return on investment of €10 (\$9.89) for every dollar spent on the programme.

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