



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

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

**Heart Failure** *(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 – Heart failure**

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

- Based on 20 systematic reviews (248 randomised controlled trials), five broad types of self-management support intervention were identified. These focused on patient education, psychosocial and behavioural interventions, exercise interventions, home visits, and telehealth (including telemedicine and structured telephone support). Interventions such as education, prescribed 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.
- Statistically significant reductions were reported for:
  - mortality for both telehealth interventions and home visit programmes in selected patients. However, there was a lack of consistency across reviews that examined these types of interventions, with some studies reporting no effect.
  - the rate of hospital readmissions for exercise interventions, home visit programmes and telehealth interventions.
- Limited evidence was found to support the effectiveness of patient education programmes or behavioural modification interventions.
- Despite the positive results that have been reported for telemedicine and structured telephone support interventions, concerns have been raised about these being considered the standard of care for the management of heart failure patients due to inconsistent findings across studies and a lack of understanding about which specific elements of the interventions contribute to the improved outcomes.
- Based on 46 costing and cost-effectiveness studies, the economic literature was grouped into five main intervention types: education, telemedicine, multidisciplinary care, disease management and 'other' self-management support interventions. The quality of the studies was generally poor, with only four identified as high-quality studies.
- Based on randomised controlled trials that showed improvements in health-related quality of life and reductions in healthcare utilisation, the majority of telemedicine interventions reported cost savings relative to usual care, although the interventions assessed were heterogeneous.

- Based on randomised controlled trials that showed reductions in healthcare utilisation, certain disease management and education programmes were found to be cost-effective or cost saving relative to usual care.
- The reported per-patient cost of self-management interventions varied according to the intensity of the intervention, but was typically low relative to the overall cost of care of heart failure patients.

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

Telehealth and home visit interventions are associated with reductions in mortality in selected patients with heart failure although the reductions in mortality were not consistently seen across all studies.

Exercise-based interventions (including exercise-based cardiac rehabilitation), telehealth and home visit interventions can reduce rehospitalisations in selected patients with heart failure over periods of six to 12 months.

Despite the positive results reported for telehealth interventions in some studies, concern has been raised about these being considered standard of care for the management of heart failure patients due to inconsistent findings across studies and insufficient information to identify which specific elements of the interventions contribute to improving outcomes.

Economic studies suggest that telemedicine, disease management and education interventions may be cost-effective or cost saving where they achieve reductions in healthcare utilisation or improvements in health-related quality of life.

Evidence to support the clinical and cost-effectiveness of other self-management support interventions is more limited.

## Table of contents

<b>About the Health Information and Quality Authority .....</b>	<b>ii</b>
<b>Advice to the Health Service Executive (HSE) .....</b>	<b>vi</b>
<b>Advice – Heart failure .....</b>	<b>xxv</b>
<b>List of abbreviations used in this report.....</b>	<b>xlvi</b>
<b>1 Introduction.....</b>	<b>1</b>
1.1 Background to request.....	1
1.2 Terms of Reference .....	1
1.3 Overall approach.....	1
<b>2 Chronic disease self-management .....</b>	<b>3</b>
2.1 Description of self-management .....	3
2.2 Description of the interventions .....	7
2.3 Key messages.....	12
<b>3 Methodology .....</b>	<b>13</b>
3.1 Clinical-Effectiveness .....	13
3.2 Costs and Cost-Effectiveness.....	20
<b>11 Heart failure.....</b>	<b>221</b>
11.1 Description of the disease .....	221
11.2 Review of clinical effectiveness.....	221
11.3 Systematic review of cost-effectiveness.....	232
11.4 Discussion .....	246
11.5 Key points .....	250
<b>12 Discussion .....</b>	<b>252</b>
<b>Appendix A3.....</b>	<b>279</b>
<b>Appendix A11 – Heart failure .....</b>	<b>430</b>
<b>References .....</b>	<b>461</b>



## 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**

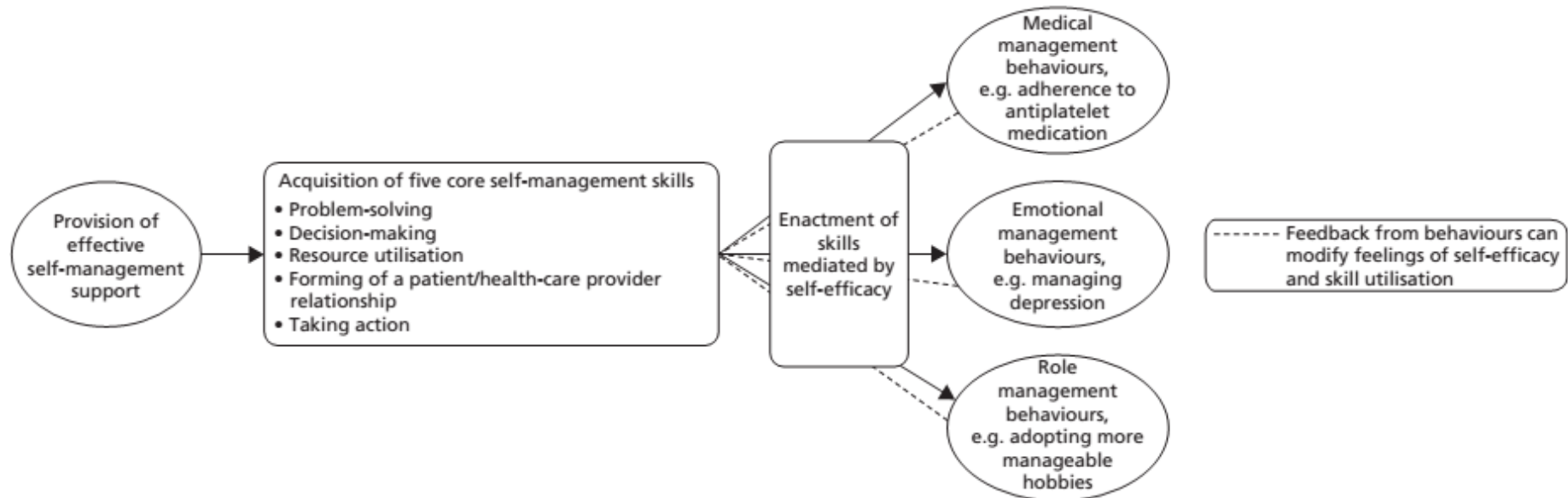
A broad range of self-management and self-management support definitions exist. For this review, the 2003 definitions agreed by the US Institute of Medicine are used:

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>

## 11 Heart failure

This Health Technology Assessment (HTA) of heart failure self-management support (SMS) is one of a series of rapid HTAs assessing SMS interventions for chronic diseases. Section 11.1 provides a brief description of heart failure followed by separate reviews of the clinical (section 11.2) and cost-effectiveness (Section 11.3) literature for SMS interventions in patients with heart failure. Brief descriptions of the background and methods used are included with full details provided in a separate document (Chapter 3). Section 11.4 includes a discussion of both the clinical and cost-effectiveness findings. The report concludes with a list of key points in relation to heart failure SMS support (section 11.5).

### 11.1 Description of the disease

Heart failure is a chronic condition characterised by an inability of the heart to pump blood effectively, due to systolic and or diastolic dysfunction. It can present as new onset heart failure in people without known cardiac dysfunction, or as acute decompensation of chronic heart failure. The condition can be caused by a range of diseases that result in damage to the heart muscle, including coronary artery disease, myocardial infarction and hypertension. Symptoms of the disease include lung congestion, fluid retention, weakness and an irregular heart rhythm. The average age at diagnosis is 76 years and the overall prevalence of heart failure in Ireland is approximately 1.1%, with a five-year mortality rate of 36%.<sup>(371-373)</sup> Prevalence is increasing due to better management of the disease and the ageing population, which has resulted in congestive heart failure becoming one of the most common reasons for emergency admission to hospitals in Ireland.<sup>(286)</sup>

### 11.2 Review of clinical effectiveness

#### 11.2.1 Background and methods

The aim of this HTA is to review the clinical effectiveness of self management support (SMS) interventions for a number of chronic conditions including heart failure. Given the large volume of literature available, it was noted that an update of an existing high quality systematic review or a review and appraisal of previously completed systematic reviews of the effectiveness of SMS interventions could be considered sufficient to inform decision-making.

Chronic heart failure was not specifically addressed in the PRISMS report. This report therefore presents a completely new review of systematic reviews rather an update of an existing report. Data extraction and quality assurance of the systematic reviews, meta-analyses and the risk of bias associated with the primary literature was undertaken as described in Chapter 3.1.3. In summary, in order to determine

the quantity, quality, strength and credibility of evidence underpinning the various SMS interventions, quality assurance of both the systematic review methodology (R-AMSTAR weighting by patient or participant trial size) and the meta-analyses (Higgins et al.'s quality assessment tool)<sup>(287)</sup> was undertaken. While the R-AMSTAR score was used to determine the quality of the systematic reviews, the scores were then weighted by patient or participant trial size, with the quality of evidence being downgraded if the review was based on fewer than 1,000 participants. The quality of the primary evidence was not evaluated directly — where reported, information on the risk of bias of the primary studies was extracted from the systematic reviews.

### **11.2.2 Description of the interventions**

A general description of self-management and typical SMS interventions is included in Chapter 2. Heart failure-specific interventions introduced in this Phase IIb report include patient education, psychosocial or behavioural therapy and exercise programmes, as well as different methods of care provision such as home visits or via telephone or the Internet.

Cardiac rehabilitation has been defined as 'a complex intervention offered to patients diagnosed with heart disease, which includes components of health education, advice on cardiovascular risk reduction, physical activity and stress management'. Cardiac rehabilitation services are defined as 'comprehensive, long-term programmes involving medical evaluation, prescribed exercise, cardiac risk factor modification, education and counselling.'<sup>(288)</sup> While cardiac rehabilitation services may differ in format and intensity, there is a consensus regarding the core components, notably: health behaviour change and education; lifestyle risk factor management (including physical activity and exercise, diet, and smoking cessation); psychosocial health; medical risk factor management; cardio-protective therapies; long-term management; and audit and evaluation.<sup>(289)</sup> Therefore, cardiac rehabilitation includes elements of self-management support, although the boundary between chronic disease self-management and what is considered 'standard' cardiac rehabilitation is often poorly defined in the literature. This is especially true for exercise-based interventions, as the terms cardiac rehabilitation and exercise-based cardiac rehabilitation are often used interchangeably. Exercise-based interventions have been included in this review in order to provide a summary of the evidence available for this particular component of cardiac rehabilitation. The cardiac rehab may involve varying degrees of self-management depending on whether the exercise training is supervised or unsupervised, or takes place in an inpatient, outpatient, community or home-based setting.



### 11.2.3 Results

The search identified 20 systematic reviews of chronic disease management programmes for people with heart failure, which were published between 2009 and 2015 (see Table 5.1). The quality of the systematic reviews (R-AMSTAR scores) ranged from 18 to 37, with 5 out of 20 achieving a score of 31 or more, indicating a high-quality systematic review. Table 11.1 shows the different types of interventions that were assessed, Table 11.2 shows the degree of overlap between reviews, while Table 11.3 summarises the quality appraisal of the included systematic reviews and meta-analyses and results for mortality and hospital admissions.

**Table 11.1 Summary of included reviews**

Review	Intervention
<b>Patient education</b>	
<b>Feltner 2014</b> <sup>(374)</sup>	Education of patient or caregiver delivered before or after discharge
<b>Wakefield 2013</b> <sup>(375)</sup>	Patient educational interventions
<b>Boyde 2011</b> <sup>(376)</sup>	Educational interventions defined as a prespecified learning activity
<b>Ditewig 2010</b> <sup>(377)</sup>	Interventions containing a self-management principle and or an education component
<b>Boren 2009</b> <sup>(378)</sup>	Heart failure self-management educational programmes
<b>Psychosocial or behavioural interventions</b>	
<b>Samartzis 2013</b> <sup>(379)</sup>	Structured non-pharmacologic intervention conducted by health professionals focused on improving the psychological and or social aspects of a patient's health
<b>Barnason 2012</b> <sup>(380)</sup>	Cognitive-behavioural interventions
<b>Exercise</b>	
<b>Rajati 2014</b> <sup>(381)</sup>	Exercise self-efficacy interventions designed to increase any type of physical activity
<b>Taylor (CR) 2014</b> <sup>(382)</sup>	Exercise-based interventions with six months' follow-up or longer compared with a no exercise control that could include usual medical care
<b>Tierney 2012</b> <sup>(383)</sup>	Specific strategies/interventions to promote or improve exercise/physical activity adherence
<b>Hwang 2009</b> <sup>(384)</sup>	Centre-based exercise training, home-based exercise training or concurrent centre and home-based exercise training

Review	Intervention
<b>Home Visits</b>	
<b>Feltner 2014<sup>(374)</sup></b>	Home-visiting programmes for heart failure patients
<b>Gorthi 2014<sup>(385)</sup></b>	In-home visits for heart failure patients
<b>Telehealth</b>	
<b>Feltner 2014<sup>(374)</sup></b>	Remote monitoring of physiologic data, with or without remote clinical visits
<b>Kotb 2015<sup>(386)</sup></b>	Telemedicine interventions in adult heart failure patients
<b>Conway 2014<sup>(387)</sup></b>	Non-invasive remote monitoring for heart failure
<b>Gorthi 2014<sup>(385)</sup></b>	Structured telephone support, non-invasive and invasive telemonitoring interventions
<b>Nakamura 2013<sup>(388)</sup></b>	Remote patient monitoring interventions in congestive heart failure patients
<b>Pandor 2013<sup>(389)</sup></b>	Home telemonitoring or structured telephone support programmes after recent discharge in patients with heart failure
<b>Giamouzis 2012<sup>(390)</sup></b>	Telemonitoring interventions in chronic HF patients
<b>Clarke 2011<sup>(391)</sup></b>	Telemonitoring on patients with congestive heart failure
<b>Inglis (CR) 2010<sup>(392)</sup></b>	Structured telephone support or telemonitoring programmes for patients with chronic heart failure
<b>Pare 2010<sup>(393)</sup></b>	Home telemonitoring in heart failure patients

Key: CR = Cochrane Review; HF = heart failure.

**Table 11.2 Study overlap**

#	Review	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1	Feltner 2014 <sup>(374)</sup>	<b>47</b>																			
2	Wakefield 2013 <sup>(375)</sup>	16	<b>35</b>																		
3	Boyde 2011 <sup>(376)</sup>	5	3	<b>19</b>																	
4	Ditewig 2010 <sup>(377)</sup>	5	7	5	<b>19</b>																
5	Boren 2009 <sup>(378)</sup>	6	12	6	9	<b>35</b>															
6	Samartizis 2013 <sup>(379)</sup>	4	7	1	3	7	<b>16</b>														
7	Barnason 2012 <sup>(380)</sup>	3	3	5	2	4	1	<b>19</b>													
8	Rajati 2014 <sup>(381)</sup>	0	0	0	0	0	0	0	<b>10</b>												
9	Hwang 2009 <sup>(384)</sup>	0	0	0	0	0	0	0	0	<b>19</b>											
10	Tierney 2012 <sup>(383)</sup>	0	0	0	0	0	0	0	2	0	<b>9</b>										
11	Taylor 2014 <sup>(382)</sup>	0	0	0	0	1	1	0	0	7	1	<b>33</b>									
12	Kotb 2015 <sup>(386)</sup>	8	11	3	7	5	1	2	0	0	0	0	<b>30</b>								
13	Conway 2014 <sup>(387)</sup>	8	8	2	7	6	3	2	0	0	0	0	16	<b>25</b>							
14	Gorthi 2014 <sup>(385)</sup>	12	16	3	5	10	4	2	0	0	0	0	15	14	<b>52</b>						
15	Nakamura 2013 <sup>(388)</sup>	2	3	0	1	0	1	0	0	0	0	0	6	5	7	<b>13</b>					
16	Pandor 2013 <sup>(389)</sup>	10	7	0	3	2	2	1	0	0	0	0	9	13	10	4	<b>21</b>				
17	Giamouzis 2012 <sup>(390)</sup>	2	1	0	1	0	0	0	0	0	0	0	6	4	7	5	3	<b>12</b>			
18	Clarke 2011 <sup>(391)</sup>	3	4	1	1	0	1	1	0	0	0	0	5	6	10	4	4	4	<b>13</b>		
19	Inglis 2010 <sup>(392)</sup>	9	8	2	7	6	3	2	0	0	0	0	21	21	14	5	12	2	5	<b>25</b>	
20	Pare 2010 <sup>(393)</sup>	3	4	0	2	0	1	0	0	0	0	0	3	3	3	0	3	0	0	3	<b>17</b>

**Table 11.3 Quality appraisal and summary of findings from meta-analyses**

Review	Quality of systematic review			Primary studies		Quality of meta-analysis	All-cause mortality	All-cause hospital admissions	HF hospital admissions
	R-AMSTAR score	Participants	Quality	N	Low-risk				
Patient education									
<b>Feltner 2014</b> <sup>(374)</sup>	31	<1,000	**	4	1	High	RR 1.20 (0.52–2.76)	RR 1.14 (0.84–1.54)	RR 0.53 (0.31–0.90)
<b>Wakefield 2013</b> <sup>(375)</sup>	23	8,071	**	35	-	Moderate	OR 0.79 (0.69-0.92)**	SMD 0.157 (0.071-0.244)	-
<b>Boyde 2011</b> <sup>(376)</sup>	22	2,686	**	19	-	N/A	-	-	-
<b>Ditewig 2010</b> <sup>(377)</sup>	31	4,162	***	19	8	N/A	-	-	-
<b>Boren 2009</b> <sup>(378)</sup>	19	7,413	**	35	-	N/A	-	-	-
Psychosocial or behavioural interventions									
<b>Samartizis 2013</b> <sup>(379)</sup>	21	2,180	**	16	-	N/A	-	-	-
<b>Barnason 2012</b> <sup>(380)</sup>	18	3,166	**	19	-	N/A	-	-	-
Exercise									
<b>Rajati 2014</b> <sup>(381)</sup>	18	800	*	10	-	N/A	-	-	-
<b>Hwang 2009</b> <sup>(384)</sup>	24	1,069	**	19	-	N/A	-	-	-
<b>Tierney 2012</b> <sup>(383)</sup>	27	3,231	**	9	-	N/A	-	-	-
<b>Taylor 2014</b> <sup>(382)</sup>	37	4,740	***	33	21	High	RR 0.93 (0.69-1.27)	RR 0.75 (0.62-0.92)	RR 0.61 (0.46-0.80)
Home visit									
<b>Feltner 2014</b> <sup>(374)</sup>	31	>1,000	***	16	1	High	RR 0.77 (0.60–0.997)	RR 0.75 (0.68–0.86)	RR 0.51 (0.31–0.82)
<b>Gorthi 2014</b> <sup>(385)</sup>	19	>1,000	**	7	-	N/A	-	-	-
Structured telephone support									
<b>Feltner 2014</b> <sup>(374)</sup>	31	>1,000	***	13	0	High	RR 0.74 (0.56–0.97)	RR 0.92 (0.77–1.10)	RR 0.74 (0.61–0.90)
<b>Kotb 2015</b> <sup>(386)</sup>	26	10,193	**	30	17	Network Meta-analysis	OR 0.80 (0.66-0.96)	OR 0.88 (0.74-1.06)	OR 0.96 (0.56-0.85)

<b>Conway 2014</b> <sup>(387)</sup>	24	>4,000	**	25	-	Moderate	RR 0.87 (0.75-1.01)	-	RR 0.77 (0.68-0.87)
<b>Inglis 2011</b> <sup>(392)</sup>	35	8,323	***	25	7	High	RR 0.88 (0.76-1.01)	RR 0.92 (0.85-0.99)	RR 0.77 (0.68-0.87)
<b>Gorthi 2014</b> <sup>(385)</sup>	19	>1,000	**	14	-	N/A	-	-	-
Structured telephone support : human –human									
<b>Pandor 2013</b> <sup>(389)</sup>	33	>1,000	***	21	10	Network Meta-analysis	HR 0.77 (0.55-1.08)	HR 0.97 (0.70-1.31)	HR 0.77 (0.62-0.96)
Structured telephone support : human-machine									
<b>Pandor 2013</b> <sup>(389)</sup>	33	>1,000	***	21	10	Network Meta-analysis	HR 0.98 (0.41-2.33)	HR 1.06 (0.44-2.53)	HR 1.03 (0.66-1.54)
Telemonitoring									
<b>Feltner 2014</b> <sup>(374)</sup>	31	<1,000	**	6	0	High	RR 0.93 (0.25–3.48)	RR 1.11 (0.87–1.42)	RR 1.70 (0.82–3.51)
<b>Kotb 2015</b> <sup>(386)</sup>	26	10,193	**	30	17	Network Meta-analysis	OR 0.53 (0.36-0.80)	OR 0.75 (0.48-1.18)	OR 0.64 (0.39-0.95)
<b>Conway 2014</b> <sup>(387)</sup>	24	>4,000	**	25	-	High	RR 0.62 (0.50-0.77)	-	RR 0.75 (0.63-0.91)
<b>Nakamura 2013</b> <sup>(388)</sup>	25	3,337	**	13	-	Low	RR 0.76 (0.62-0.93)	-	-
<b>Giamouzis 2012</b> <sup>(390)</sup>	17	3,877	**	12	-	N/A	-	-	-
<b>Clarke 2011</b> <sup>(391)</sup>	25	3,480	**	13	-	Moderate	RR 0.77 (0.61-0.97)	RR 0.99 (0.88-1.11)	RR 0.73 (0.62-0.87)
<b>Inglis 2010</b> <sup>(392)</sup>	35	8,323	***	25	-	High	RR 0.66 (0.54-0.81)	RR 0.91 (0.84-0.99)	RR 0.79 (0.67-0.94)
<b>Pare 2010</b> <sup>(393)</sup>	19	>1,000	**	17	-	N/A	-	-	-
<b>Gorthi 2014</b> <sup>(385)</sup>	19	>1,000	**	14	-	N/A	-	-	-
Telemonitoring - 24/7									
<b>Pandor 2013</b> <sup>(389)</sup>	33	>1,000	***	21	10	Network Meta-analysis	HR 0.49 (0.20-1.18)	HR 0.81 (0.33-2.00)	-
Telemonitoring - Office Hours									
<b>Pandor 2013</b> <sup>(389)</sup>	33	>1,000	***	21	10	Network Meta-analysis	HR 0.76 (0.49-1.18)	HR 0.75 (0.49-1.10)	HR 0.95 (0.70-1.34)

**Key:** **HF** – heart failure; **HR** – hazard ratio; **N/A** – not applicable; **OR** - odds ratio; **RR** - risk ratio.

\*\* Correspondence with the author indicates that what was reported as mortality was actually survival, so the value included in the above table is the reciprocal of the result reported in the article

## 11.2.4 Summary of findings

This section provides a narrative summary of the findings, relevance and applicability of the included reviews for each type of heart failure self-management support intervention. A detailed account of the data extracted from each review is provided in Appendix A11.1.

### Patient education interventions

Five reviews were identified that examined the effectiveness of patient-education interventions in chronic heart failure.<sup>(374-378)</sup> One of these were rated as high quality (R-AMSTAR greater than [ $>$ ] 30 and  $>1,000$  patients).<sup>(377)</sup> The other four were moderate quality (R-AMSTAR score less than [ $<$ ] 31 and  $>1,000$  patients or R-AMSTAR score of  $>30$  and  $<1,000$  patients).<sup>(374-376;378)</sup>

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

One high-quality review concluded that the limitations of the available evidence made it impossible to reliably estimate the effect of patient-education interventions on mortality, all-cause hospital readmissions, chronic heart failure hospitalisation rate and quality of life in patients with chronic heart failure.<sup>(377)</sup> Of the nine studies identified in this review that reported mortality outcomes, eight found no significant difference between the control and intervention groups. It also identified four studies that reported hospital admission results, two of which found no effect.

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

One moderate quality review (R-AMSTAR  $>30$  and  $<1,000$  patients) carried out a pooled analysis of educational interventions that found no significant effect on mortality or all-cause readmission rates, but did find a reduction in heart failure-specific readmission (RR 0.53, 95% CI 0.31 to 0.90).<sup>(374)</sup> Another moderate quality review (R-AMSTAR  $<31$ ,  $>1,000$  patients) reported that most heart failure self-management programmes had a teaching component, with the most frequent teaching topics being symptom recognition and management, medication review, and self-monitoring. However, it reported that individual interventions used in the programme are not described in sufficient detail to permit programme replication.<sup>(375)</sup> The final two reviews were more descriptive in nature, and characterised educational interventions as mainly involving one-to-one didactic sessions focused on symptom recognition and management.<sup>(376;378)</sup>

### **Summary statement for patient education interventions**

Based on the quantity and quality of the systematic reviews and the underpinning primary randomised controlled trials (RCTs), there is a lack of good quality evidence that patient-education programmes are associated with improvements in mortality, hospital readmissions and quality of life in patients with chronic heart failure.

### **Psychosocial or behavioural interventions**

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

Two reviews, both of moderate quality, were identified that reported results for psychosocial or behavioural interventions in chronic heart failure.<sup>(379;380)</sup>

Neither reported results for mortality or healthcare usage. One reported that psychosocial interventions improved quality of life of heart failure patients (Standardised Mean Difference [SMD] 0.46, 95% CI 0.19 to 0.72), and that face-to-face interventions showed greater improvement compared with telephone interventions.<sup>(379)</sup> The other was an integrative review, which reported that psychosocial interventions were most frequently used to improve patient's heart failure self-care, and noted that the majority of the studies reported improvements in heart failure patients' self-care maintenance and management behaviours.<sup>(380)</sup>

### **Summary statement for psychological or behavioural interventions**

Based on the quantity and quality of the systematic reviews and the underpinning primary RCTs, there is a lack of evidence that psychosocial or behavioural interventions are associated with a reduction in either mortality or healthcare usage. However, there is some evidence showing that these types of interventions, particularly when delivered face-to-face, are associated with improvements in quality of life.

### **Exercise interventions**

Four reviews that examined the impact of exercise interventions in the management of heart failure were identified in the search.<sup>(381-384)</sup>

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

One high quality Cochrane systematic review comparing exercise-based interventions (alone or in conjunction with health education and psychological interventions), with usual medical care or cardiac rehabilitation that included no exercise training, failed to find a mortality benefit at one year (RR 0.93 [95% CI 0.69 to 1.27]). However, it did report a trend toward reduced mortality in a pooled

analysis of studies with follow-up of greater than one year, though this was not statistically significant (RR 0.88 [95% CI 0.75 to 1.02]).<sup>(382)</sup> This study also reported a reduction in overall and heart failure-specific hospital admissions (RR 0.75 [95% CI 0.62 to 0.92] and RR 0.61 [95% CI 0.46 to 0.80], respectively) and improved quality of life.

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

One moderate quality review that specifically examined home exercise programmes found that these were associated with improvements in exercise duration, peak oxygen consumption and distances achieved in the six-minute walk test.<sup>(384)</sup> However, this review did not report pooled results for more relevant clinical outcomes.

A further moderate quality study focusing exclusively on ways to improve exercise adherence reported that although short-term benefits were achieved using exercise prescriptions, goal setting, feedback and problem-solving, longer-term maintenance of exercise was less successful.<sup>(383)</sup> The authors also reported that addressing self-efficacy may be a particularly useful area to consider. This was examined in the final, low-quality review, which reported a lack of evidence evaluating self-efficacy strategies to improve exercise in heart failure. It did report, however, that the most common strategies to improve patients' self-efficacy were performance accomplishments, vicarious experience, verbal persuasion, and emotional arousal.<sup>(381)</sup>

### **Summary statement for exercise interventions**

Based on the quantity and quality of the systematic reviews and the underpinning primary RCTs, there is good evidence that exercise interventions are associated with a reduced likelihood of readmission to hospital. However, no statistically significant mortality effect was observed at 12 months' follow up.

### **Home-visit interventions**

One high-quality and one moderate-quality review examining the effectiveness of home-visiting interventions for heart failure patients were identified.<sup>(374;385)</sup>

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

A high-quality 2015 review by Feltner et al. found evidence of a statistically significant effect on both mortality and hospital readmission rates at three to six months (RR 0.77 [95% CI 0.60 to 0.996] and RR 0.75 [95% CI 0.66 to 0.86], respectively).<sup>(374)</sup> This review compared a number of different types of interventions and included a total of 47 RCTs. Eight of these reported the results of home-visit



interventions and were used to calculate the pooled estimate for mortality and readmission. While the pooled estimate of effect on mortality was significant at the  $p < 0.05$  level, no individual study reported a significant effect.

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

The moderate quality review published in 2014 identified seven primary studies comparing home visits with usual care, only three of which were associated with a significant improvement in hospital readmission, while none were able to demonstrate a significant reduction in all-cause mortality.<sup>(385)</sup>

#### Summary statement for home-visit interventions

Based on the quantity and quality of the systematic reviews and the underpinning primary RCTs, there is high-quality evidence that home-visit interventions are associated with a reduction in mortality and hospital readmission rates. However, one moderate-quality review failed to replicate these findings.

### Telemedicine interventions

Ten reviews assessed the effectiveness of telehealth interventions in patients with chronic heart failure.<sup>(374;385-393)</sup> Two were rated high quality (R-AMSTAR score  $> 30$  and a combined total of  $> 1,000$  patients).<sup>(389;392)</sup> The eight remaining reviews were all rated moderate quality (R-AMSTAR score  $< 31$  and a combined total of  $> 1,000$  patients or R-AMSTAR  $> 30$  and  $< 1,000$  patients).<sup>(374;385-388;390;391;393)</sup>

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

A 2013 high-quality systematic review by Pandor et al. from the UK — examining home telemonitoring or structured telephone support programmes compared with standard care (primarily GP follow up) after recent discharge in patients with heart failure — failed to find a significant effect on mortality or hospital admission in a pooled analysis of studies with follow-up of between three and 15 months.<sup>(389)</sup> In contrast, a high-quality Cochrane review of structured telephone support and telemonitoring (also compared with standard care) in the management of patients with chronic heart failure published in 2010 found that telemonitoring was associated with a 34% mean reduction in all-cause mortality (RR 0.66 [95% CI 0.54 to 0.81]) and that structured telephone support was associated with a non-statistically significant 12% mean reduction in all-cause mortality (RR 0.88 [95% CI 0.76 to 1.01]).<sup>(392)</sup> The length of follow-up in the studies included in this review ranged from three to 18 months, with many studies reporting outcomes after 12 months. It also reported that both structured telephone support and telemonitoring significantly reduced heart failure-related hospitalisations (RR 0.77 [95% CI 0.68 to 0.87] and RR 0.79 [95% CI 0.67 to 0.94] respectively). Smaller, but still statistically

significant, reductions were also found for all-cause hospitalisations (RR 0.92 [95% CI 0.85 to 0.99] for structured telephone support and RR 0.91 [95% CI 0.84 to 0.99] for telemonitoring).<sup>(392)</sup>

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

One moderate-quality review examined remote monitoring of physiological signals with or without remote clinical consultations (such as videoconferencing) and found no significant effect in either mortality or hospital readmissions at three to six months follow-up.<sup>(374)</sup> Among the seven other moderate quality studies, there was broad agreement that telemonitoring in heart failure patients was associated with reduction in both mortality and heart failure-related hospital admissions.<sup>(385-388;390;391;393)</sup> Statistically significant estimates of the mean reduction ranged from 23% to 47% for mortality,<sup>(386;391)</sup> and 27% to 36% for heart failure-related hospital admissions.<sup>(386;387)</sup> There were a high degree of overlap between the studies included in these reviews, with 21 studies appearing in both the Inglis and Kotb studies.<sup>(386;392)</sup> There was agreement between the two moderate-quality reviews reporting a meta-analysis of structured telephone support interventions that the intervention was associated with reduced hospital admission, but while one reported a statistically significant reduction in mortality (OR 0.80 [95% CI 0.66 to 0.96]), the other found a mean decrease that was not statistically significant at the  $p=0.05$  level (RR 0.87 [95% CI 0.75 to 1.01]).

#### Summary statement for telemedicine interventions

Based on the quantity and quality of the systematic reviews and the underpinning primary RCTs, there is high-quality evidence that telemedicine interventions are associated with a significant reduction in both mortality and hospitalisation rates. However, these findings are not shared across all high-quality reviews.

### 11.3 Systematic review of cost-effectiveness

A review of the economic literature was undertaken to assess the available evidence for self-management support (SMS) interventions for adults chronic heart failure. Studies were included if they compared the costs and consequences of an SMS intervention to routine care.

#### 11.3.1 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. 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 11.4 below.

**Table 11.4 PICOS analysis for identification of relevant studies**

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

The following study types were excluded if:

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

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

### 11.3.2 Results

The initial search identified 118 potentially relevant articles. Three reviewers independently evaluated studies based on title, abstract and full text. Thirty nine studies were identified as applicable. Seven additional studies were identified following hand searching of the systematic reviews of clinical effectiveness included in Section 11.2 for primary studies that included economic outcomes, leaving a total

of 46 studies in this review, see table below. Data extraction was carried out independently by two reviewers with any disagreements resolved by discussion.

<b>Country</b>	<b>Number of studies</b>
United States	23
Spain	4
Italy	4
Australia	3
UK	3
Netherlands	3
Germany	2
Hong Kong	1
Ireland	1
Sweden	1
Taiwan	1
Total	46

The included studies were all published between 2001 and 2014. The characteristics of the included studies are given in Table 11.5.

**Table 11.5 Characteristics of the studies included**

<b>Study</b>	<b>Country</b>	<b>Intervention</b>
<b>Agren (2001)</b>	Sweden	SMS education
<b>Aguado (2010)*</b>	Spain	SMS education
<b>Anderson (2005)</b>	US	Disease management
<b>Berg (2004)</b>	US	Telemedicine
<b>Boyne (2013)</b>	Netherlands	Telemedicine
<b>Bruggink (2007)</b>	Netherlands	Heart failure clinic
<b>Chen (2010)</b>	Taiwan	Disease management
<b>Cui (2013)</b>	Canada	Telemedicine
<b>Dar (2009)</b>	UK	Telemedicine
<b>Discher (2003)</b>	US	Disease management
<b>Dunagan (2005)</b>	US	Telemedicine
<b>Giordano (2009)</b>	Italy	Telemedicine
<b>Gregory (2006)</b>	US	Disease management
<b>Hebert (2008)</b>	US	Disease management
<b>Hendricks (2014)</b>	Germany	Disease management
<b>Inglis (2006)</b>	Australia	Disease management
<b>Jerant (2001)</b>	US	Telemedicine
<b>Kasper (2002)</b>	US	Multidisciplinary care
<b>Klersy (2011)</b>	Italy	Telemedicine
<b>Koelling (2005)</b>	US	SMS education
<b>Krumholz (2002)</b>	US	SMS education
<b>Kwok (2008)</b>	Hong Kong	Disease management
<b>Laramee (2003)</b>	US	Disease management
<b>Ledwidge (2003)</b>	Ireland	Multidisciplinary care
<b>Lopez (2006)</b>	Spain	SMS education
<b>Maeng (2014)</b>	US	Telemedicine
<b>Mejia (2014)</b>	UK	Cognitive behavioural therapy

Study	Country	Intervention
<b>Miller (2009)**</b>	US	Disease management
<b>Morcillo (2005)*</b>	Spain	SMS education
<b>Murray (2007)</b>	US	Pharmacist intervention
<b>Naylor (2004)</b>	US	Disease management
<b>Pandor (2013)</b>	UK	Telemedicine
<b>Piepoli (2006)</b>	Italy	Multidisciplinary care
<b>Postmus (2011)</b>	Netherlands	Disease management
<b>Pugh (2001)</b>	US	Disease management
<b>Riegel (2004)</b>	US	SMS education
<b>Riegel (2002)</b>	US	Telemedicine
<b>Roig (2006)</b>	Spain	Disease management
<b>Scalvini (2005)</b>	Italy	Telemedicine
<b>Smith (2008)**</b>	US	Disease management
<b>Sohn (2012)</b>	Germany	Telemedicine
<b>Soran (2010)</b>	US	Telemedicine
<b>Stauffer (2011)</b>	US	Transitional care
<b>Stewart (2002)</b>	Australia	Multidisciplinary care
<b>Tsuyuki (2004)</b>	US	Disease management
<b>Wootton (2009)</b>	Australia	Telemedicine

\* The study by Aguado et al. is an update of an earlier study by Morcillo et al..

\*\* The study by Miller et al. is modelled using data from Smith et al..

The studies were classified according to the type of intervention assessed: SMS education programmes, telemedicine, disease management, multidisciplinary care and other SMS interventions. Of note, many interventions included more than one element such as case management plus telephone-based support or education plus physical activity.

This review captures all SMS interventions assessed for chronic heart failure and retrieved few conventional economic evaluations. Thirty nine of the retrieved studies gathered cost data as part of a randomised controlled trial (RCT) while data for four other studies were based on a non-randomised study designs.

Study quality was assessed using the Consensus on Health Economic Criteria (CHEC) list.<sup>(24)</sup> For studies that included an assessment of cost-utility or an economic modelling approach, applicability of the findings were evaluated using the ISPOR questionnaire.<sup>(25)</sup> The quality of the included studies was predominantly poor, and the following discussion sections will focus on the findings of studies found to be of better quality. Where possible, costs are reported in Irish euro, and were inflated to 2014 using the local consumer price index for health before transferred into Irish euro using the purchasing power parity index.

### **11.3.2.1 SMS education programmes**

Six unique studies were identified that investigated a variety of SMS education programmes (See Appendix A11.3). The studies included one cost-utility analysis and five costing studies. All of the studies were based on patient data gathered alongside a randomised controlled trial (RCT) with a follow-up ranging from three to 24 months. Study sizes ranged from 62 to 191 patients. There was one Swedish study, two from Spain and three from the US. Interventions included education programmes delivered by a healthcare specialist at home or in a primary care setting, while a US study examined a peer-support group delivered by trained mentors.

A 2013 Swedish study by Agren et al. compared a nurse-led education and psychosocial support programme with usual care for recently discharged heart failure patients and their partners. The intervention was delivered in three face-to-face sessions and included nurse-led counselling, with educational, supportive and behavioural components two, six and 12 weeks after discharge. After 12 months, significant improvements in quality of life from baseline were observed in both groups, however, the difference between groups was not significant. The total cost of the intervention including transportation was estimated to be €15,825 or €223 per patient.

The intervention, which was assessed from a societal perspective, was not found to be cost-effective for the patient alone due to increased costs and lack of utility gains. However, when the combined costs and benefits for the patient and partner or caregiver were examined, the intervention was found to be cost-effective, with a cost per QALY gained of €16,159.

The 2010 Spanish study by Aguado et al. randomly assigned patients hospitalised with systolic heart failure to either usual care or a once-off, home-based educational session by trained nursing staff one week after hospital discharge. The RCT recruited 106 patients admitted with heart failure over a 24-month period. A significant decrease in healthcare usage was reported in favour of the intervention group after 24 months of follow-up with reductions in emergency room visits (mean 0.68 (SD

0.9) versus. 2.00 (SD1.97),  $p < 0.001$ ) and unplanned readmissions (mean 0.68 (SD 1.94) versus. 1.71 (1.67)  $p < 0.003$ ); no difference in mortality was observed (46.7% versus 55.4%,  $p=0.448$ ). The mean cost of the educational intervention was €70.59, and included salary and travel costs for the nursing staff and the cost of educational material. The mean total cost per person was €898 for the intervention group and €2,879 for the control group, with a statistically significant difference of €1,982 ( $p < 0.001$ ). The authors concluded that a single educational home visit by a nurse after discharge from hospital leads to improvements in health-related quality of life (HRQoL) and has the potential to result in cost savings as a result of decreased healthcare usage.

The 2002 US study by Krumholz et al. recruited 88 heart failure patients in a prospective RCT to investigate the impact of an education and support intervention on one-year readmission rates, mortality and costs of care. After adjusting for clinical and demographic characteristics, the intervention was associated with a significantly lower risk of readmission compared with the control group (hazard ratio 0.56, 95% CI: 0.32 to 0.96,  $p=0.03$ ) as well as a decrease in the total number of readmissions (49 vs. 80,  $p=0.06$ ). A significant reduction in the relative risk of readmission or death during the 12-month follow up (RR 0.69, 95%CI 0.52-0.92,  $p=0.01$ ) was observed in favour of the intervention group. The intervention was estimated to cost USD \$530 per patient. The total costs of hospital readmissions in the control and intervention groups were \$21,935 and \$14,420, respectively resulting in an estimated net reduction in the average cost of care of \$6,985 per patient in the intervention group.

The 2006 Spanish study by Lopez et al. assessed the efficacy of a multi-factorial educational intervention by a pharmacist for patients with heart failure. Outcomes for 134 patients (mean age 75 years) with a low educational level were assessed during 12 months' follow-up. The intervention was found to reduce hospital readmissions (adjusted hazard ratio 0.56; 95%CI 0.32-0.97) and was predicted to prevent one readmission a year being prevented per every 6.5 patients with heart failure. Reductions in hospital bed days were observed at two (mean 1.7 vs. 3.5,  $p=0.034$ ), six (4.3 vs. 6.8,  $p=0.02$ ) and 12 (5.9 versus 9.6,  $p>0.05$ ) months. The cost of the intervention was €2,170 equating to a cost of €31 per patient. In terms of total costs, the intervention resulted in savings of €30,995 (€100,815- €69,820) or €578 per patient.

Koelling et al. used data from an RCT with six-month follow-up to inform a post-hoc economic evaluation of a nurse-provided education programme. The intervention group had a lower risk of hospitalisation or death, but there was no difference in the mortality rates between groups. The intervention cost €100 per subject, with the overall cost of care significantly lower in the education group €3,477.



### **11.3.2.2 Telemedicine programmes**

There were 15 studies found that evaluated telemedicine programmes (see Appendix A11.4). Of the identified studies, four were cost-utility analyses and the remaining 11 were generally costing or cost-minimisation studies. Details of the four cost-utility studies and two of the costing studies which were identified as higher quality studies are discussed.

In 2013, Boyne et al. undertook an economic evaluation of telemonitoring versus usual care for 382 heart failure patients from the Netherlands. The effectiveness of the telemonitoring programme was expressed as QALYs gained. At 12 months' follow up, no difference in HRQoL (-0.0031 QALY, 95% CI -0.0552 to 0.0578) was observed. The total cost of telemonitoring was €17,323 compared with €17,192 in the usual care group, a difference of €140 between the groups. Compared with usual care, the study reported an incremental cost-effectiveness ratio (ICER) of €41,858 per QALY gained. However, given the lack of a statistically significant difference in QALYs, presentation of an ICER would appear to be inappropriate.

A 2013 Canadian study by Cui et al. randomised 179 patients aged 40 and over with a diagnosis of chronic heart failure (levels II to IV) to one of two telemonitoring (health lines or health lines plus monitoring [HLM]) interventions or to usual care. The health lines intervention comprised standard care plus access to nurse-led telephone support that provided suggestions about the patient's daily disease management. HLM included provision of monitoring devices and instructions on how to use them in addition to the telephone support and usual care. The mean per patient cost of the intervention was €1,386 and €1,576 for health lines and HLM, respectively. When compared with usual group, the interventions were shown to result in a reduction in healthcare usage, although this finding was not significantly different between groups. The total calculated saving from averted healthcare utilisation costs through the interventions was €21,163 or €178 per patient. HRQoL, as measured by SF-6D utility scores, differed significantly between the groups ( $p=0.0247$ ). Cui et al. reported that both interventions (health lines and HLM) dominated (cost less and were more effective than) standard care and reported an ICER of €2,224/QALY for health lines relative to HLM. The study concluded that health lines had an 85.8% probability that of being cost-effective at a willingness-to-pay threshold of €37,381.

In a 2011 study by Klersy et al. undertook a cost-effectiveness analysis of a remote patient monitoring programme compared with usual care and focusing on hospitalisations as the primary outcome. The data from 21 RCTs was collected to conduct an economic analysis of a remote monitoring intervention. Remote patient monitoring was associated with significantly fewer hospitalisations for heart failure at 12 months ( $p<0.001$ ), however, there was no change in length of stay. The QALY

gain associated with the reduction in hospitalisations was estimated to be 0.04 for surviving patients and when this was added to the QALY gain of 0.02 for reduced mortality, the total QALY gain for remote patient monitoring was 0.06.

Remote patient monitoring was found to be a dominant strategy over existing treatments of heart failure as it resulted in cost saving and QALY gains. Sensitivity analysis that tested a variety of situations estimated that the difference in costs between remote patient monitoring and usual care ranged from about €300 to €1,000, with the intervention always being less costly than usual care. These cost savings were mostly driven by a reduction in the number of heart failure hospitalisations. The authors noted that an important caveat to this finding was the limited follow-up time of the studies considered in the meta-analysis, which restricted the time horizon for the cost-effectiveness assessment to one year.

Using results from a systematic review of the literature, a 2013 UK study by Pandor et al. modelled the cost-effectiveness of telemedicine strategies versus usual care for adults recently discharged (within 28 days) from acute care after an exacerbation of chronic heart failure. Interventions comprised either structured telephone support via human-to-machine (STSHM) interface; structured telephone support via human-to-human (STSHH) contact; or home telemonitoring (TM), and were compared with usual care. The average total cost per patient for the STSHM intervention over six months was estimated to be €963, equating to €160 per patient per month. The total cost per patient for the office hours' TM intervention for six months was estimated to be €1,416, equating to €233 per patient per month. STSHH intervention was estimated to cost €1448 over six months, equating to a monthly cost of €241 per patient. The expected costs over a lifetime (30-year time horizon) differed for each strategy, with STSHH having the highest costs at €12,938 followed by TM during office hours (€12,757), STSHM (€12,125) and usual care (€11,421). QALY gains were reported for all intervention groups. In terms of utilisation, TM with medical support during office hours or 24-seven was associated with 25% (HR 0.75, 95% CI 0.49 to 1.10) or 19% (HR 0.81, 95% CI 0.33 to 2.00) reduction in all-cause hospitalisations, respectively, whereas there was no major effect of STSHM (HR 1.06, 95% CI 0.44 to 2.53) or STS HH (HR 0.97, 95% CI 0.70 to 1.31). TM during office hours was identified as the most cost-effective strategy with an ICER of €12,871/QALY compared with usual care. STSHM was dominated by usual care. Limitations noted by the authors included considerable variability in what constituted remote monitoring and the absence of robust estimations of cost.

A 2014 study carried out in the US by Maeng et al investigated the cost-effectiveness of telemonitoring for disease management. The study analysed the impact of the telemonitoring programme using claims data related to changes in hospital admission and readmission rates as well as cost of care among the

insurance plan members with heart failure who had participated in the programme. The study found that members in the sample had experienced significant reductions in their odds of hospital admissions (23% lower) as well as 30-day and 90-day readmissions (44% and 38% lower, respectively) in a given month. The total cost of the programme was USD \$1,596 per member, per month while the implementation of the heart failure telemonitoring programme was associated with approximately 11% cost savings during the study period. Maeng et al estimated that the return on investment associated with the telemonitoring programme was approximately 3.3. That is, for every \$1 spent to implement the programme, there was a \$3.30 return on this investment in terms of the cost savings accrued to the insurance plan. They concluded that these findings imply that telemonitoring can be an effective add-on tool for managing elderly patients with heart failure.

A 2012 German study by Sohn et al. undertook an economic analysis to evaluate the programme 'Telemedicine for the Heart'. The programme consisted of nurse calls to motivate patients to perform regular self-measurements (blood pressure, pulse, weight) with either their own or telemedical measuring devices provided by the programme. The primary outcome of the study was healthcare utilisation and the study reported there were fewer hospital admissions in the programme group (1.02 versus 1.30 per patient per year in the intervention and control groups, respectively). Significant cost differences in favour of the study group of up to 25% in relation to the total cost could be detected. This corresponded to a reduction of €2,633 in costs per patient per year relative to the control group. The cost saving were mainly for patients with less severe heart failure and the study found that more severe heart failure patients incurred increased costs and a cost disadvantage.

Miller et al. developed a Markov model to compare a disease management programme with usual care, over a patient's lifetime. Baseline model results indicated that patients with systolic heart failure would live an average of 0.141 years (51 days) longer with disease management than those in the control group. The corresponding discounted QALY benefit was 0.111 per patient. Discounted lifetime costs per patient averaged €91,182 and €97,156 for the control and disease management groups respectively. The average (undiscounted) per-patient cost of the disease management programme was estimated at €10,576 (€303 a month for an 18-month disease management programme or €132 a month over average patient lifetime). The estimated ICER was calculated to be €53,767 per QALY saved. The authors concluded that that disease management of heart failure patients can be cost-effective in the long term, and that short-term results from a clinical trial might not reveal long-term cost-effectiveness.

### **11.3.2.3 Multidisciplinary care interventions**

Three studies were identified that examined multidisciplinary care interventions, including one cost benefit study from Ireland and one prospective randomised controlled trial each from the US and Australia (see Appendix A11.5). All studies examined the ability of multidisciplinary care to reduce rehospitalisations for recently discharged heart failure patients.

The 2003 Irish study by Ledwidge et al. aimed to determine whether multidisciplinary care can significantly reduce rates of unplanned hospitalisations. A total of 98 New York Heart Association (NYHA) class IV heart failure patients (mean age 70.8) were randomised to multidisciplinary care (n=51) or routine care (RC; n=47). Over a three-month follow up, there was an absolute reduction of 10 rehospitalisations (12 versus 2) in favour of the intervention group. The service cost was estimated at €113 (95% CI: 185–244) per patient over three months, corresponding with a cost per hospitalisation prevented of €586, and generating a net cost saving per patient treated of €729.

A 2009 US study by Kasper evaluated the effect of a multidisciplinary outpatient management programme on hospital readmissions and mortality over a six-month period. Two hundred chronic heart failure patients with a mean age of 63 years were randomised to multidisciplinary or routine care. The intervention comprised education, support and telecare from a four-member intervention team made up of a telephone nurse coordinator, the chronic heart failure nurse, the chronic heart failure cardiologist and the patient's primary physician.

There were fewer hospital admissions for any reason in the intervention group. Quality of life, measured by the Minnesota Living with Heart Failure Questionnaire, improved in both groups, but was significantly higher at six-month follow up for the intervention group (p=0.01). The intervention, including salaries and supplies, cost €1,335 per patient. The mean outpatient pharmacy cost per patient was similar in both groups: €1,998 in the intervention group and €2,075 in the non-intervention group. Mean inpatient costs for intervention group was €16,712 and €18,522 for the non-intervention group.

A 2002 study by Stewart et al compared a multidisciplinary home-based intervention (comprising structure home visits by nurse and/or pharmacist) within 7 to 14 days of discharge) with usual care. During a median of 4.2 years follow-up, home-based intervention was associated with fewer unplanned readmissions or death (0.21 versus 0.37 per patient per month, p<0.01), longer event-free survival (7 versus 3 months, p<0.01), fewer deaths (56% versus 65%, p=0.06), and a more prolonged survival (median 40 versus 22 months p<0.05). The average cost of applying the home-based intervention, taking into account both the cost of home visits and

additional cardiology, primary care, and pharmacy consultations, was €617 per patient. The authors concluded that home-based intervention is beneficial in reducing the frequency of unplanned readmissions for heart failure, that this persists in the long term and is associated with prolongation of survival, reduced levels of hospital activity and associated costs.

#### **11.3.2.4 Disease management programmes**

There were 17 studies found that evaluated disease management programmes including three cost utility analyses and 14 costing or cost-minimisation studies (see Appendix A11.6). Three cost utility studies and two of the costing studies were found to be good quality and will be examined in this section. Follow-ups ranged from three months to 10 years.

A nurse-led disease management programme was examined in the 2008 paper by Hebert et al.. The analysis focused on patients with systolic dysfunction from an ethnically diverse urban community in the US. The total cost of the intervention was €2,853 per patient with nurse and physician time accounting for the largest cost component. In terms of QALYs, the study reported a gain for the intervention group of 0.0497 QALY per person for the Health Utilities Index (HUI3, 0.6122 vs. 0.6619) and 0.0430 QALY per person for the EuroQol-5 dimension (EQ-5D, 0.6651 vs. 0.7080). The total societal cost of the intervention and usual care was €30,000 and €29,012 respectively for a total cost saving of €988 per patient. The analysis estimated an ICER of €22,994 based on the estimate of quality of life based on the EQ-5D and €19,883 for translation to HUI3. To conclude, the study found that at less than €32,768 per QALY saved, this nurse-led disease management programme was reasonably cost-effective over 12 months, especially for patients with earlier stages of heart failure.

A 2008 study carried out in the US by Smith et al. evaluated the cost-effectiveness of a telephone-based disease management programme for community dwelling heart failure patients. A total of 1,069 heart failure patients were recruited to a randomised controlled trial over an 18-month period and randomised to usual care, disease management, or augmented disease management. Subjects in the intervention arms were assigned a disease manager, a registered nurse who performed patient education and medication management with the patient's primary care provider for the full 18-month enrolment period. The mean cost of the disease management services was calculated to be €296 per patient per month. No differences were reported in clinical outcomes between the control and intervention groups. Considering all patients and all costs, the ICER was €176,762 per quality-adjusted life-year (QALY) gained, exceeding the standard of €120,353 considered the upper limit of an acceptable expenditure from a societal perspective. Subgroup analysis indicated that for patients with NYHA class III/IV symptoms and patients

with systolic heart failure, the ICERs were €81,580 and €115,203 per QALY gained, respectively. The authors concluded that telephone-based disease management did not reduce costs and was not cost-effective in community dwelling patients with heart failure, but that if programme labour costs could be reduced through technological innovation, economies of scale, or competition, carefully targeted disease management programmes may produce cost-effective improvements in heart failure outcomes.

A 2006 study carried out in Australia by Inglis et al. evaluated a home-based disease management intervention for 148 elderly patients suffering with heart failure over a 10-year follow up. The intervention was assessed in terms of the cost per life-year gained. Patients assigned to home-based intervention received the same level of care as those assigned to usual care plus the prospectively designated study intervention. Overall, the home-based intervention group accumulated more unplanned readmissions during follow-up. However, when the duration of the follow-up was adjusted; the rate of readmission was significantly lower in the home-based intervention group (intervention  $2.04 \pm 3.23$  versus control  $3.66 \pm 7.62$  admissions;  $p < 0.05$ ). The study also reported statistically fewer deaths during the follow-up period for intervention patients. The total cost to the health system of introducing the intervention was €100,138. The total cost for the intervention group and usual care group was €3,271,893 and €3,064,146, respectively, an increase of €207,460. The incremental cost effectiveness ratio of home-based intervention was estimated to be €1,731 per additional life-year gained.

The 2011 Dutch study by Postmus et al. conducted a trial-based economic evaluation of two nurse-led disease management programmes in heart failure. The intervention group received either basic or advanced disease management from a heart failure specialist nurse. This was compared with usual care (routine follow-up by a cardiologist). The study evaluated the intervention in terms of cost per QALY and per life-year gained. Postmus et al. estimated a mean quality-adjusted survival time was 287.6 days in the care-as-usual group, 296.1 days in the basic-support group, and 294.6 days in the intensive-support group. In terms of cost per life-year, basic support dominated care as usual because it generated 0.048 additional life-years while saving €79. When comparing the two disease management programmes, intensive support was found to generate 0.0022 additional life-years at an excess cost of €1,211, yielding an ICER of €547,599 per life-year. In terms of cost per quality-adjusted life-year (QALY), basic support was found to dominate both care as usual and intensive support because it generated 0.023 and 0.004 excess QALYs while saving €79 and €1,211, respectively.

A 2004 US study evaluated a two-stage multicenter disease management programme. In stage one, a pharmacist or nurse assessed each patient and made



recommendations to the physician to help treatment. In stage two, patients were randomised to usual care of a patient support programme (PSP) which involved education, telemedicine and other support. In stage one, medication adherence improved for all patients' ACE inhibitor use increasing from 58% on admission to 83% at discharge. In stage two, differences were reported in healthcare usage as cardiovascular-related emergency room visits decreased (49 versus 20,  $p=0.030$ ) as did hospitalisation days (812 versus 341,  $p=0.003$ ); adherence remained unchanged in this period. The total cost of care for cardiovascular-related events over the six-month follow-up period of this study was €3,798 for usual care patients compared with €1,684 for patient support programme patients, for a cost difference of €2,113 per patient. For all-cause events, the cost difference per patient was €2,057 (€5,139 for usual care and €3,082 for the patient support programme). It was concluded that the intervention was cost-saving relative to usual care due to a reduction in healthcare usage costs.

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

Four additional papers were identified that described a variety of other SMS interventions for heart failure (see Appendix A11.7). Two of the papers were from the US with one each from the UK and the Netherlands. All four collected cost and resource data alongside RCTs.

A cost-effectiveness analysis of a nurse-facilitated cognitive behavioural self-management programme was evaluated in a 2014 pragmatic RCT ( $n=260$ ) in the UK by Mejia et al. with follow-up at six and 12 months. The analysis reported a similar frequency of healthcare usage for both the intervention and control group. While patient-reported length of stay was lower in the self-management group, this difference was not significant (difference = 1.09, 95% CI: 1.43 to 3.61,  $p = 0.3941$ ). After controlling for baseline utility data, treatment was associated with a reduction in QALY of 0.004 and an increase in costs of €128, and consequently was dominated by usual care using cognitive behavioural therapy alone. Therefore, the study concluded that the addition of nurse facilitation to a cognitive behavioural therapy for patients with heart failure is associated with no clear effect on costs or effectiveness as measured by QALYs.

The 2007 RCT by Murray et al. examined a pharmacist intervention aimed to improve medication adherence in a cohort of heart failure patients with low health literacy and limited resources. The study recruited 314 low income patients aged 50 years of age in the US. The intervention was delivered over nine months and included assessment of patient knowledge and provision of instructions in relation to medication use. The paper estimated that the intervention cost €247 per patient and was associated with a reduction in emergency department visits (mean 2.16 versus 2.28; IRR 0.82 [0.70–0.95] and a non-significant reduction in hospital admissions

[0.78 versus 0.97]; IRR 0.81 [0.64–1.04]). No difference in disease-specific quality of life was observed at six or 12 months follow-up. While, with the exception of drugs, costs across all categories (including outpatient and inpatient costs), were lower in the intervention group, these differences were not statistically significant.

A 2007 Dutch study by Bruggink et al. evaluated a physician and nurse directed heart failure clinic. The study recruited 240 patients recently discharged heart failure patients with NYHA class III or IV for an RCT. The intervention comprised one scheduled phone call and eight scheduled patient visits to a combined, intensive physician-and-nurse-directed heart failure outpatient clinic. Verbal and written comprehensive education on topics including exercise, rest, symptoms and self-management were provided in addition to optimisation of treatment, and easy access to the clinic. During the 12-month study period, the intervention was associated with a significant reduction in admissions for worsening heart failure and, or all-cause deaths (RR 0.49 [95%CI 0.30-0.81,  $p=0.001$ ]; and a significant improvement in left ventricular ejection fraction [+2.6% vs. -3.1%,  $p=0.004$ ]). A significant improvement ( $p=0.001$ ) in health-related quality of life (HRQoL) as measured by the Minnesota Living With Heart Failure Questionnaire (MLWHFQ) was observed at three months and persisted through to 12 months' follow-up. Patients in the intervention group were hospitalised for a total of 359 days compared with 644 days for those in the usual care group (rate ratio 0.56 (95%CI 0.49 to 0.64)). The difference between the costs of hospitalisation in the intervention (€65,046) and the usual care group (€202,728) was €137,682. The total cost for the heart failure clinic programme (salaries of the heart failure nurse, heart failure physician and the dietician, and for the extra laboratory and electrocardiograms [ECGs]) was €50,246. Therefore, overall costs were €87,436 lower in the intervention group, corresponding to a difference in the overall cost of care per patient of €741.

## **11.4 Discussion**

### **11.4.1 Clinical effectiveness**

The literature in relation to the effectiveness of different self-management support interventions for patients with chronic heart failure is characterised by a high degree of inconsistency among reviews that examined the same type of intervention. The best evidence of a beneficial effect was found in studies examining telemedicine interventions that included non-invasive telemonitoring and structured telephone support, which showed statistically and clinically significant reductions in both mortality and hospital admissions in most, but not all, reviews.

There was quite a degree of heterogeneity in the way telemonitoring and telephone support interventions were provided in the individual RCTs included in the reviews. While all were based around the concept of using of technology to send data



collected about patients to healthcare professionals for the purposes of assessment and ongoing management, there were differences in the frequency with which this information was sent (for instance, daily, weekly or monthly), the sort of information gathered (such as weight, blood pressure, pulse and pulse oximetry, ECG reading, medication, symptoms) and the type of health professionals interpreting the data (for example, nurse, physician, specialist team including cardiologist).

Some positive results were also reported for home-visit programmes, but there were only two reviews of this area and the other one failed to find a significant effect. The findings of a review of exercise interventions echoed those for coronary artery disease, where a mortality reduction did not become apparent until after 12 months. However, while the review of exercise programmes for heart failure also saw an increasing effect over longer follow-up periods, the mortality reduction observed in studies with follow up of greater than 12 months was not statistically significant.

The findings of this review of systematic reviews are consistent with similar studies that have compared a number of different approaches to managing heart failure patients.<sup>(385;394)</sup> However, even in these types of broad analyses there is a degree of inconsistency. For example, a 2014 review comparing a range of different interventions concluded that telemonitoring was not associated with a reduction in mortality or admissions and that structured telephone support should be prioritised ahead of it.<sup>(374)</sup>

The application of telemedicine in the management of heart failure patients has received a lot of attention due to its potential to increase the coverage and efficiency of heart failure management programmes. This is reflected in the number of recent narrative reviews that examine not only the available evidence, but also any unresolved questions or outstanding issues in relation to these types of interventions. A 2015 overview of systematic reviews of telemedicine in heart failure that included five studies identified in this analysis<sup>(389-393)</sup> highlighted gaps in our understanding of the process by which home telemonitoring improves outcomes. It recommends that future research be directed at identifying optimal strategies and follow-up durations, as well as investigating whether there is differential effectiveness between different subgroups of heart failure patients.<sup>(395)</sup> Other overviews have also been careful to sound a note of caution about telehealth interventions being considered the standard of care for heart failure management, citing the need for more evidence given the divergent results reported to date; a lack of clarity about specific elements of the interventions that underpinned the positive outcomes; and uncertainty about how best to integrate these processes within the context of the wider health service.<sup>(396-398)</sup>

The incremental benefit of new heart failure self-management initiatives in Ireland is dependent to a large extent on the current provision of cardiac rehabilitation

services. The HSE's clinical programme for heart failure has developed a model of care for the public health service, which describes two types of programmes that can be offered:<sup>(399)</sup>

### **Model A:**

Heart failure rehabilitation programme: This model exists when there is a dedicated heart failure specialist team who coordinates and run the programme. This includes the clinical lead in heart failure, clinical nurse specialists in heart failure, physiotherapists, exercise physiologists, dieticians, psychologists, social workers, pharmacists and occupational therapists. Programmes will run for a minimum of six weeks twice weekly. Exercise will be prescribed and progressed by an exercise professional, i.e. physiotherapist or exercise physiologist. Patients should be monitored on telemetry while exercising.

### **Model B:**

This is the amalgamation of existing cardiac rehabilitation services with heart failure services. The process of referral will be through the heart failure specialists. They will work with the cardiac rehabilitation specialists in responding to symptom deterioration and acute decompensation. Heart failure patients will have undergone their self-care education as part of the model of care pathway prior to initiating the programme. AACVRP guidelines (2004) classify heart failure patients as high risk of a cardiac event during exercise (25% mortality risk). Heart failure patients may be mixed in a group with the cardiac rehabilitation patients. Staffing ratios will change according to exercise risk stratification. Programmes will run for a minimum of six weeks twice weekly. Patients should be monitored on telemetry while exercising. There should be an interplay between the heart failure and cardiac rehabilitation nursing staff in staffing the exercise component of the programme. Exercise will be prescribed and monitored by an exercise professional i.e. physiotherapist or exercise physiologist. Patients should be monitored on telemetry while exercising.<sup>(399)</sup>

Telephone support is also included in the model of care, as part of early post-discharge follow up care, which would allow heart failure patients to contact a nurse specialist for advice on weight changes, review of medication or to discuss any queries or concerns they may have.<sup>(399)</sup>

The extent to which this is in place throughout the country, and adherence levels in areas where such services are provided, was examined in a 2013 survey, which found significantly different staffing levels and resources between cardiac rehabilitation services, lengthy waiting times for some individual services and wide

variation in availability of multidisciplinary teams, which meant that not all patients receive optimal cardiac rehabilitation.<sup>(400)</sup> There is also considerable uncertainty about access to primary prevention services for patients with heart failure who have not been hospitalised following an acute cardiovascular event.

### **11.4.2 Cost-effectiveness**

Forty six studies relating to 45 unique economic evaluation studies of chronic disease self-management interventions for patients with heart failure were identified as relevant. The majority of studies evaluated disease management (n=17) with the remainder investigating telemedicine (n=15), SMS education programmes (n=6), multidisciplinary care (n=3) and other programmes (n=4). The quality of the studies was generally poor, with only four identified as high-quality reviews.

The majority of the studies had small sample sizes and collected cost data alongside RCTs. This raises inherent issues around the applicability of their cost findings to the Irish healthcare setting. In addition, most of the studies only followed participants for up to one year and it is therefore unclear how the clinical benefits and the healthcare usage would change over time. Six of the studies were limited to costing studies, a number of which did not report clear costing methodology, therefore it was difficult to determine their quality and derive the cost of different components of the interventions. The highest quality findings were reported in the study by Pandor et al. which estimated an ICER for a telemonitoring intervention compared to usual care of €12,871 per QALY gained.

The economic evaluations of SMS education programmes reported a range of results, but the majority estimated a reduction in healthcare usage and, as a result, cost savings for the intervention groups. The education programmes assessed in this analysis varied in the delivery of the programmes. A once-off post discharge education programme showed the greatest potential. A nurse-led programme in Sweden which used a societal perspective was only found to be cost-effective when combined costs and outcomes for the patient and caregiver were assessed; the study reported a cost gained per QALY of €16,159.

The best evidence was found in support of telemedicine interventions. Four cost-utility studies were identified. Studies supported the assumption that telemedicine is an effective intervention, reporting cost savings with improvements in HRQoL and reductions in healthcare usage up to 12 months' follow-up. Considerable variation in what constituted remote monitoring was noted as well as the absence of robust estimations of costs. The duration of any effect and the impact on long-term costs is uncertain.

Disease management programmes were assessed in 17 studies and were generally found to be cost-effective or cost saving relative to usual care. The role of

multidisciplinary care to reduce rehospitalisations in recently discharged heart failure patients was evaluated in three studies, the most relevant of which was a 2003 study from Ireland. It indicated that multidisciplinary care was cost saving due to reductions in rehospitalisations in a three-month follow-up period. The durability of this effect and the long-term impact on costs is not known.

In general, the cost per patient of the interventions was low, particularly relative to the overall cost of care, and the majority of the studies reported some degree of cost savings in the short-term through reduced healthcare usage. The short follow-up period and the relatively small sample sizes do raise concerns regarding the sustainability of the interventions and the applicability of the findings when applied to a larger population.

## 11.5 Key points

- Twenty systematic reviews of the clinical effectiveness of self-management support interventions in adults with chronic heart failure published between 2009 and 2015 were identified for inclusion in this overview of reviews.
- The quality of the systematic reviews varied, with five being rated as high-quality reviews, 14 being rated as moderate quality and one being rated as low quality.
- These reviews included five broad types of interventions, which were focused on: patient education, exercise, psychosocial or behavioural changes, home-based services or telehealth. Interventions such as education, prescribed 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.
- Statistically significant reductions in mortality were reported for both telehealth interventions and home-visit programmes. However, there was a lack of consistency across reviews that examined these types of interventions, with some reporting no effect.
- Statistically significant reductions in the rate of hospital readmission were reported for exercise interventions, home-visit programmes and telehealth interventions.
- There is limited evidence to demonstrate the effectiveness of patient education programmes or behavioural modification interventions.
- Despite the positive results that have been reported for telemedicine and structured telephone support interventions, concerns have been raised about these being considered the standard of care for the management of heart failure due to inconsistent findings across studies and a lack of understanding about which specific elements of the interventions contribute to the improving

outcomes.

- Forty six unique economic evaluation studies of chronic disease self-management interventions for patients with heart failure were identified as relevant.
- The interventions described by the included studies were heterogeneous and frequently comprised multiple components. The short follow-up period and the relatively small sample sizes raise concerns regarding the sustainability of the interventions and the applicability of the findings when applied to a larger population.
- Based on randomised controlled trials that showed improvements in health-related quality of life and reductions in healthcare utilisation, the majority of telemedicine interventions reported cost savings relative to usual care, although the interventions assessed were heterogeneous.
- Based on randomised controlled trials that showed reductions in healthcare utilisation, certain disease management and education programmes were found to be cost-effective or cost saving relative to usual care.
- The reported per-patient cost of self-management support interventions varied according to the intensity of the intervention, but was typically low relative to the overall cost of care of heart failure patients.
- Based on the description of the healthcare systems, the epidemiology, and the heart failure 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. The applicability of the cost-effectiveness literature to the Irish healthcare setting was considered relatively low.

## 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 A11 – Heart failure

**Table A11.1 Results of meta-analyses**

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance	ES (95% CI)
<b>Feltner 2014</b> <sup>(374)</sup>	Patient education	All cause readmission	3-6 months	200	0	RR 1.14 (0.84–1.54)
		HF-related readmission		223	+++	RR 0.53 (0.31–0.90)
		Mortality		423	0	RR 1.20 (0.52–2.76)
	Home-visiting programmes	All-cause readmission	3-6 months	1563	+++	RR 0.75 (0.68–0.86)
		HF-specific readmission		282	+++	RR 0.51 (0.31–0.82)
		Mortality		1693	++	RR 0.77 (0.60–0.997)
		All-cause readmission	30 days	418	+++	High-intensity (1 study): RR 0.34 (0.19–0.62)
					0	Medium-intensity (1 study): RR 0.89 (0.43–1.85)
		Mortality		239	0	RR 1.03 (0.15–7.16)
	Telemonitoring	All-cause readmission	30 days	168	0	RR 1.02 (0.64–1.63)
		All-cause readmission	3-6 months	434	0	RR 1.11 (0.87–1.42)
		HF-specific readmission		182	0	RR 1.70 (0.82–3.51)
		Mortality		564	0	RR 0.93 (0.25–3.48)
	Structured Telephone Support	All-cause readmission	30 days	134	0	RR 0.80 (0.38–1.65)
		HF-specific readmission		134	0	RR 0.63 (0.24–1.87)
All-cause readmission		3-6 months	2166	0	RR 0.92 (0.77–1.10)	
HF-specific readmission			1790	++	RR 0.74 (0.61–0.90)	
Mortality			2011	++	RR 0.74 (0.56–0.97)	
<b>Wakefield 2013</b> <sup>(375)</sup>	Patient educational interventions versus usual care	Mortality	Mean 204 days (SD 135)	N/A	++	OR 0.79 (0.69-0.92)**
		Readmissions		N/A	++	SMD 0.157 (0.071-0.244)
		HF-specific QoL		N/A	++	SMD 0.231 (0.064-0.399)
		Generic QoL		N/A	++	SMD 0.283 (-0.093-0.659)

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance	ES (95% CI)
		ED Visits		N/A	++	SMD 0.123 (-0.089-0.335)
<b>Taylor 2014</b>	Exercise-based interventions with six months' follow-up or longer compared with a no exercise control that could include usual medical care	All-cause mortality	Up to 12 months	1871	0	RR 0.93 [0.69, 1.27]
		Hospital admission		1328	+++	RR 0.75 [0.62, 0.92]
		All-cause mortality	More than 12 months	2845	0	RR 0.88 [0.75, 1.02]
		Hospital admission		2722	0	RR 0.92 [0.66, 1.29]
		HF-Admissions	N/A	1036	+++	RR 0.61 [0.46, 0.80]
		HRQoL		3240	--	SMD -0.46 [-0.66, -0.26]
<b>Kotb 2015<sup>(386)</sup></b>	Structured telephone support	All-cause mortality	N/A	N/A	++	OR 0.80 (0.66, 0.96)
	Telemonitoring				+++	OR 0.53 (0.36, 0.80)
	Telemonitoring and telephone support				0	OR 0.77 (0.58, 2.35)
	Video monitoring				0	OR 1.18 (0.58, 2.35)
	ECG monitoring				0	OR 0.78 (0.57, 1.06)
<b>Conway 2014<sup>(387)</sup></b>	Structured telephone support	All-cause mortality	3-18 months	5511	0	RR 0.87 (0.75, 1.01)
		HF - Hospitalisations		4269	+++	RR 0.77 (0.68, 0.87)
	Telemonitoring	All-cause mortality	3-15 months	2222	+++	RR 0.62 (0.50, 0.77)
		HF - Hospitalisations		1215	++	RR 0.75 (0.63, 0.91)
<b>Inglis 2010<sup>(392)</sup></b>	Structured telephone support	All-cause mortality	3-18 months	5563	0	RR 0.88 [0.76, 1.01]
		All-cause hospitalisations		4295	++	RR 0.92 [0.85, 0.99]
		HF hospitalisations		4269	+++	RR 0.77 [0.68, 0.87]
		All-cause mortality	>6 months	4292	0	RR 0.87 [0.74, 1.02]
		All-cause hospitalisations		2343	++	RR 0.91 [0.83, 0.99]
		HF hospitalisations		2948	+++	RR 0.76 [0.65, 0.89]
	Telemonitoring	All-cause mortality	3-18 months	2710	+++	RR 0.66 [0.54, 0.81]
		All-cause hospitalisations		2343	++	RR 0.91 [0.84, 0.99]
		HF hospitalisations		4674	+++	RR 0.77 [0.68, 0.87]
		All-cause mortality	>6 months	1994	+++	RR 0.69 [0.55, 0.86]
	All-cause hospitalisations		1748	++	RR 0.87 [0.80, 0.95]	

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance	ES (95% CI)
		HF hospitalisations		1570	++	RR 0.79 [0.67, 0.94]
<b>Pandor</b> 2013 <sup>(389)</sup>	Structured telephone support – Human to machine	All-cause mortality	N/A	N/A	0	HR 1.35 (0.78, 2.36)
		All-cause hospitalisations			0	HR 0.87 (0.54, 1.29)
		HF hospitalisations			0	HR 0.69 (0.34, 1.43)
	Structured telephone support – Human to human	All-cause mortality			0	HR 0.87 (0.69, 1.14)
		All-cause hospitalisations			0	HR 0.86 (0.62, 1.17)
		HF hospitalisations			0	HR 0.67 (0.37, 1.05)
	Home telemonitoring – Office hours	All-cause mortality			0	HR 0.85 (0.59, 1.20)
		All-cause hospitalisations			0	HR 1.17 (0.89, 1.59)
		HF hospitalisations			0	HR 0.70 (0.34, 1.50)
	Home telemonitoring – 24/7	All-cause mortality			0	HR 0.85 (0.58, 1.27)
		All-cause hospitalisations			0	HR 0.84 (0.54, 1.15)
		HF hospitalisations			0	HR 0.64 (0.34, 1.14)
<b>Nakamura</b> 2013 <sup>(388)</sup>	Remote patient monitoring interventions in congestive heart failure patients	All-cause mortality	N/A	3347	++	RR 0.76 (0.62, 0.93)
<b>Clarke</b> 2011	Telemonitoring of patients with congestive heart failure	All-cause mortality	3-15 months	2171	++	RR 0.77 (0.61, 0.97)
		All-cause hospital admissions		1951	0	RR 0.99 (0.88, 1.11)
		CHF hospital admissions		1772	+++	RR 0.73 (0.62, 0.87)
		All-cause emergency visits		907	0	RR 1.04 (0.86, 1.26)

**RR**- Relative risk; **OR** = odds ratio; **HR** = hazard rate; **N/A** = not available; **HF** = heart failure; **CHF** = congestive heart failure; **ES** = effect size; **CI** = confidence interval; **HRQoL** = health related quality of life.

\*\*Correspondence with the author indicates that what was reported as mortality was actually survival, so the value included in the above table is the reciprocal of the result reported in the article.

**Table A11.2 Summary of results from systematic reviews**

Review	Focus	Synthesis	RCTs, n; Participants, n; date range	Main results	Main conclusions (review author); important quality concerns (review author)
<b>Barnason 2012</b> <sup>(380)</sup>	Cognitive-behavioural interventions	Narrative summary	RCTs 19; Patients 3166; Dates 2000-2010	Cognitive-behavioural intervention mechanisms were most frequently used to improve patient's heart failure self-care. In the majority of the studies, the interventions demonstrated efficacy by improving heart failure patients' self-care maintenance and management behaviours. Intervention group subjects, in the majority of studies, had significantly higher levels of knowledge pertaining to heart failure and heart failure related self-care.	Based on these findings, there are improved patient outcomes when standard patient education for heart failure is augmented using cognitive-behavioural strategies that include additional evidence-based education and counselling.
<b>Boren 2009</b> <sup>(378)</sup>	Heart failure self-management education programs	Narrative summary	RCTs: 35, Patients: 7413, Dates: 1998-2007	A total of 113 unique outcomes in nine categories (satisfaction, learning, behaviour, medications, clinical status, social functioning, mortality, medical resource utilisation and cost) were measured in the studies. Sixty (53%) of the outcomes showed significant improvement in at least one study.	Educational interventions should be based on scientifically sound research evidence. The education topic list developed in this review can be used by patients and clinicians to prioritise and personalise education.
<b>Boyd 2011</b> <sup>(376)</sup>	Educational interventions defined as a prespecified learning activity	Narrative summary	RCTs: 19, Patients: 2686, Dates: 1998-2008	Studies used a variety of outcome measures to evaluate their effectiveness. Of the studies reviewed, 15 demonstrated a significant effect from their intervention in at least one of their outcome measures.	It was difficult to establish the most effective educational strategy as the educational interventions varied considerably in delivery methods and duration as well as the outcome measures that were used for the evaluation.
<b>Clarke 2011</b> <sup>(391)</sup>	Telemonitoring on patients with congestive heart failure	Meta-analysis	RCTs: 13, Patients: 3480, Dates: 2003-2009	Pooled estimate results showed that there was an overall reduction in all-cause mortality ( $P = 0.02$ ). There was no overall reduction in all-cause hospital admission ( $P = 0.84$ ), although there was a reduction in CHF hospital admission ( $P = 0.0004$ ). There was no reduction in all-cause emergency admission ( $P = 0.67$ ). There was no significant difference in length of stay in hospital, medication adherence or cost.	Telemonitoring in conjunction with nurse home visiting and specialist unit support can be effective in the clinical management of patients with CHF and help to improve their quality of life.
<b>Conway 2014</b> <sup>(387)</sup>	Non-invasive remote monitoring for heart failure	Meta-analysis	RCTs: 25, Patients: >4000, Dates: 1998-2008	Only structured telephone calls and telemonitoring were effective in reducing the risk of all-cause mortality (relative risk [RR] = 0.87; 95% confidence interval [CI], 0.75–1.01; $p = 0.06$ ; and RR = 0.62; 95% CI, 0.50–0.77; $p < 0.0001$ , respectively) and heart failure-related hospitalisations (RR = 0.77; 95% CI, 0.68–0.87; $p < 0.001$ ; and RR = 0.75; 95% CI, 0.63–0.91; $p = 0.003$ , respectively).	Structured telephone calls and telemonitoring, in which physiological data are automatically transmitted, reduced the relative risk of all-cause mortality and hospitalisations when results were combined in the meta-analyses. More research data are required to evaluate the effectiveness of videophone and interactive voice response



					technologies.
<b>Ditewig</b> 2010 <sup>(377)</sup>	Interventions containing a self-management principle and/or an education component	Meta-analysis	RCTs: 19, Patients: 4162, Dates: 1996-2009	The effectiveness of heart failure management programmes initiating self-management interventions in patients with chronic heart failure indicate a positive effect, although not always significant, on reduction of numbers of all-cause hospital readmitted patients and due to chronic heart failure, decrease in mortality and increasing quality of life.	Current available published studies show methodological shortcomings impairing validation of the effectiveness of self-management interventions on mortality, all-cause hospital readmissions, chronic heart failure hospitalisation rate and quality of life in patients with chronic heart failure.
<b>Feltner</b> 2014 <sup>(374)</sup>	Education, home-visiting programmes and remote monitoring	Meta-analysis	RCTs: 47, Patients: >1,000, Dates: 1990- 2013	At 30 days, a high intensity home-visiting programme reduced all-cause readmission and the composite end point (all-cause readmission or death; low size of effect [SOE]). Over 3 to 6 months, home-visiting programmes and multidisciplinary heart failure (MDS-HF) clinic interventions reduced all-cause readmission (high SOE). Home-visiting programmes reduced HF-specific readmission and the composite end point (moderate SOE). Structured telephone support (STS) interventions reduced HF-specific readmission (high SOE) but not all-cause readmissions (moderate SOE). Home-visiting programs, MDS-HF clinics, and STS interventions produced a mortality benefit. Neither telemonitoring nor primarily educational interventions reduced readmission or mortality rates.	Home-visiting programmes and MDS-HF clinics reduced all-cause readmission and mortality; STS reduced HF-specific readmission and mortality. These interventions should receive the greatest consideration by systems or providers seeking to implement transitional care interventions for persons with HF
<b>Giamouzis</b> 2012 <sup>(390)</sup>	Telemonitoring interventions in chronic HF patients	Narrative summary	RCTs: 12, Patients: 3877, Dates: 2007-2011	Three studies reported reduced hospitalisation rates in telemonitoring groups that reached statistical significance, and another four studies also found reductions in hospitalisation rates in favour of telemonitoring without reaching statistical significance. In four studies there were more rehospitalisations in telemonitoring groups compared to usual care groups, but statistical significance was either not reported or was not important. With regard to all-cause mortality, three studies reported statistically significant results that favoured the telemonitoring group. In two of these studies, mean age was relatively low.	Currently available trial results may seem rather ambiguous and confusing. Nevertheless, it appears that the above presented randomised controlled trials tend to be in favour of telemonitoring.
<b>Gorthi</b> 2014 <sup>(385)</sup>	Structured telephone support, telemonitoring interventions and home	Narrative summary	RCTs: 52, Patients: 19467, Dates: 1995- 2012	Structured telephone support follow-up has been shown to significantly reduce HF readmissions, but does not significantly reduce all-cause mortality or all-cause hospitalisation. A meta-analysis of 11 non-invasive telemonitoring studies demonstrated significant reductions in all-cause mortality and HF hospitalisations. Invasive telemonitoring is a potentially	Our data suggest that one approach applied to a broad spectrum of different patient types may produce an erratic impact on readmissions and clinical outcomes. HF disease management plans should include the flexibility to meet the individualised needs of specific patients.

	visits			effective means of reducing HF hospitalisations, but only one study using pulmonary artery pressure monitoring was able to demonstrate a reduction in HF hospitalisations. Other studies using invasive hemodynamic monitoring have failed to demonstrate changes in rates of readmission or mortality. The efficacy of HF DMPs is associated with inconsistent results.	
<b>Hwang</b> 2009 <sup>(384)</sup>	Centre-based exercise training, home-based exercise training or concurrent centre and home-based exercise training	Meta-analysis	RCTs: 19, Patients: 1069, Dates: 1992-2007	The mean improvement in peak oxygen consumption was 2.86 ml/kg per min [95% confidence interval (CI): 1.43–4.29]. Exercise duration increased by 1.94 min (95% CI: 0.89–2.98) and distance on the six-minute walk test was increased by 30.41m (95% CI: 6.13–54.68). Other reported benefits of home-based programmes include increased quality of life and lowered hospital admission rates.	Home-based exercise programmes have been shown to benefit people with heart failure in the short term. Further research is required to investigate the long-term effects of home exercise and to determine the optimal strategies for improving exercise adherence in patients with heart failure.
<b>Inglis</b> 2010 <sup>(392)</sup>	Structured telephone support or telemonitoring programmes for patients with chronic heart failure	Meta-analysis	RCTs: 25, Patients: 8323, Dates: 2006-2008	Of the 25 full peer-reviewed studies meta-analysed, 16 evaluated structured telephone support (5613 participants), 11 evaluated telemonitoring (2710 participants), and two tested both interventions (included in counts). Telemonitoring reduced all-cause mortality (RR 0.66, 95%CI 0.54 to 0.81, P < 0.0001) with structured telephone support demonstrating a non-significant positive effect (RR 0.88, 95% CI 0.76 to 1.01, P = 0.08). Both structured telephone support (RR 0.77, 95% CI 0.68 to 0.87, P < 0.0001) and telemonitoring (RR 0.79, 95% CI 0.67 to 0.94, P = 0.008) reduced CHF-related hospitalisations. For both interventions, several studies improved quality of life, reduced healthcare costs and were acceptable to patients. Improvements in prescribing, patient knowledge and self-care, and New York Heart Association (NYHA) functional class were observed.	Structured telephone support and telemonitoring are effective in reducing the risk of all-cause mortality and CHF-related hospitalisations in patients with CHF; they improve quality of life, reduce costs, and evidence-based prescribing.
<b>Kotb</b> 2015 <sup>(386)</sup>	Telemedicine interventions in adult heart failure patients	Network Meta-analysis	RCTs: 30, Patients: 10193, Dates: 1998-2012	Compared to usual care, structured telephone support was found to reduce the odds of mortality (Odds Ratio 0.80; 95% Credible Intervals [0.66 to 0.96]) and hospitalisations due to heart failure (0.69; [0.56 to 0.85]). Telemonitoring was also found to reduce the odds of mortality( 0.53; [0.36 to 0.80]) and reduce hospitalisations related to heart failure (0.64; [0.39 to 0.95]) compared to usual post-discharge care. Interventions that involved ECG monitoring also reduced the odds of hospitalisation due to heart failure (0.71; [0.52 to 0.98]).	Compared to usual care, structured telephone support and telemonitoring significantly reduced the odds of deaths and hospitalisation due to heart failure. Despite being the most widely studied forms of telemedicine, little has been done to directly compare these two interventions against one another. Further research into their comparative cost-effectiveness is also warranted.

<b>Nakamura</b> 2013 <sup>(388)</sup>	Remote patient monitoring interventions in congestive heart failure patients	Meta-analysis	RCTs: 13, Patients: 3337, Dates: 2003-2013	Remote patient monitoring resulted in a significantly lower mortality (risk ratio 0.76; 95% confidence interval 0.62 to 0.93) compared to usual care.	Remote patient monitoring is effective in chronic heart failure and rapid intervention was the most important factor in the remote patient monitoring model.
<b>Pandor</b> 2013 <sup>(389)</sup>	Home telemonitoring or structured telephone support programmes after recent discharge in patients with heart failure	Network Meta-analysis	RCTs: 21, Patients: >1000, Dates: 2008-2012	Compared with usual care, remote monitoring (RM) was beneficial in reducing all-cause mortality for human to human structured telephone support (STS HH) [hazard ratio (HR) 0.77, 95% credible interval (CrI) 0.55 to 1.08], Telemedicine (TM) during office hours (HR 0.76, 95% CrI 0.49 to 1.18) and TM 24/7 (HR 0.49, 95% CrI 0.20 to 1.18); however, these results were statistically inconclusive. The results for TM 24/7 should be treated with caution because of the poor methodological quality of the only included study in this network. No favourable effect on mortality was observed with human to machine structured telephone support (STS HM). Similar reductions were observed in all-cause hospitalisations for TM interventions, whereas STS interventions had no major effect.	Despite wide variation in usual care and RM strategies, cost-effectiveness analyses suggest that TM during office hours was an optimal strategy (in most costing scenarios). However, clarity was lacking among descriptions of the components of RM packages and usual care and there was a lack of robust estimation of costs.
<b>Pare</b> 2010 <sup>(393)</sup>	Home telemonitoring in heart failure patients	Narrative summary	RCTs: 17, Patients: >1000, Dates: 1996-2008	Due to the equivocal nature of current findings of home telemonitoring involving patients with heart failure, larger trials are still needed to confirm the clinical effects of this technology for these patients.	Although home telemonitoring appears to be a promising approach to patient management, designers of future studies should consider ways to make this technology more effective as well as controlling possible mediating variables.
<b>Rajati</b> 2014 <sup>(381)</sup>	Exercise self-efficacy interventions designed to increase any type of physical activity	Narrative summary	RCTs: 10, Patients: 800, Dates: 2004 to 2013	Limited published data exist evaluating the self-efficacy strategies to improve exercise in HF. Dominant strategies to improve patients' self-efficacy were performance accomplishments, vicarious experience, verbal persuasion, emotional arousal.	Findings of this study suggest that a positive relationship exists between self-efficacy and initiating and maintaining exercise in HF, especially in the short-term period.
<b>Samartizis</b> 2013 <sup>(379)</sup>	Structured non-pharmacologic intervention conducted by health professionals	Meta-analysis	RCTs: 16, Patients: 2180, Dates: 1995-2010	Psychosocial interventions improved quality of life (QoL) of CHF patients (standardized mean difference 0.46, confidence interval [CI] 0.19-0.72; P<.001). Face-to-face interventions showed greater QoL improvement compared with telephone interventions. Interventions that included caregivers did not appear to be significantly more effective. A trend was found for multidisciplinary team approaches being more effective	A significant overall QoL improvement emerged after conducting psychosocial interventions with CHF patients. Interventions based on a face-to-face approach showed greater benefit for patients' QoL compared with telephone-based approaches.

	focused on improving the psychological and/or social aspects of a patient's health			compared with non-multidisciplinary approaches.	
<b>Taylor</b> 2014 <sup>(382)</sup>	Exercise-based interventions with six months' follow-up or longer compared with a no exercise control that could include usual medical care	Meta-analysis	RCTs: 33, Patients: 4740, Dates: 2008-2013	There was no difference in outcomes of home- versus centre-based cardiac rehabilitation in mortality risk ratio (RR) was 1.31 (95% confidence interval (CI) 0.65 to 2.66), cardiac events, exercise capacity standardised mean difference (SMD) -0.11 (95%CI -0.35 to 0.13), as well as in modifiable risk factors (systolic blood pressure; diastolic blood pressure; total cholesterol; HDL-cholesterol; LDL-cholesterol) or proportion of smokers at follow-up or health-related quality of life. There was no consistent difference in the healthcare costs of the two forms of cardiac rehabilitation.	Home- and centre-based cardiac rehabilitation appear to be equally effective in improving the clinical and health-related quality of life outcomes in acute MI and revascularisation patients.
<b>Tierney</b> 2012 <sup>(383)</sup>	Specific strategies/interventions to promote or improve exercise/physical activity adherence	Narrative summary	RCTs: 9, Patients: 3231, Dates: 2003-2010	Positive outcomes occurred in the short-term from interventions using approaches such as exercise prescriptions, goal setting, feedback and problem-solving. However, longer-term maintenance of exercise was less successful. There was some support for interventions underpinned by theoretical frameworks, but more research is required to make clearer recommendations.	Motivational strategies such as goal setting, feedback and problem solving might be effective in the short-term, but how to sustain physical activity amongst those with HF remains unclear.
<b>Wakefield</b> 2013 <sup>(375)</sup>	Patient educational interventions	Meta-analysis	RCTs: 35, Patients: 8071, Dates: 1995-2008	The most commonly used interventions were patient education, symptom monitoring by study staff, symptom monitoring by patients, and medication adherence strategies. Most programmes had a teaching component with a mean (SD) of 6.4 (3.9) individual topics covered; frequent teaching topics were symptom recognition and management, medication review, and self-monitoring. Fewer than half of the 35 studies reviewed reported adequate data to be included in the meta-analysis. Some outcomes were infrequently reported, limiting statistical power to detect treatment effects.	The contribution of the individual interventions included in the multicomponent programme on patient outcomes remains unclear.

**Key:** CHF = congestive heart failure; CR = Cochrane Review; HDL = high-density lipoprotein; HRQoL = health-related quality of life; SD = standard deviation; HF = heart failure; SMD = standardised mean difference.

**Table A11.3 Summary of cost-effectiveness studies for self-management support education programmes**

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
<b>Agren</b> (2013) <sup>(403)</sup>	1) nurse-led education & psychosocial support programme for patients with heart failure (HF) & their partners 2) usual care	Recently discharged HF patients and their partners	Country: Sweden Study design: RCT economic evaluation Perspective: Healthcare Discount: Time Horizon: 12 month Costs calculated in Swedish Kronor and presented in Euros.	Patients in both the intervention group and the control group had a significantly improved QALY weight after 12 months compared with baseline. There was no significant difference between the two groups' mean improvements. The intervention, however, had positive effects on both the patient and the partner.	Total cost of the intervention including transportation was €15,825, or €223 per patient (€163 without transport). Patients in both groups had significantly improved QALY weights at 12 months. By analysing the QALY gained from the dyad, the cost gained per QALY was €16,159.	As there were no significant effects on QALY weights between the intervention group and the controls, the intervention was not found to be cost-effective for the patient alone, but was when dyad was included.
<b>Aguado</b> (2010) <sup>(404)</sup>	1) A single home-based educational intervention. (Similar to medication adherence, how to fill medication boxes appropriately) 2) Usual care	106 patients admitted with heart failure	Country: Spain Study design: RCT Perspective Healthcare Discount: Time Horizon: 24 month 2002 Spanish Euros	At 24 months of follow-up, there was a statistically significant reduction in the number hospitalisations in the intervention group. Mortality decreased by 9% in the intervention group. At 24 months, patient scores for both generic (SF-36) and specific (MLWHFQ) questionnaires, were significantly better than baseline in the intervention group.	The mean total cost per person was €671.56 (€898) for the intervention group and €2,154 (€2,879) for the control group, with a statistically significant difference of €1,482.68 (€1982) (P < .001).	For patients with systolic HF, a single educational home visit by a nursing staff member 1 week after hospital discharge reduces emergency visits and unplanned readmissions, lowers total healthcare costs, and shows a trend toward improvement in quality of life
<b>Koelling</b> (2005) <sup>(405)</sup>	One-on-one nurse-provided patient education at discharge (one hour) plus usual care compared with usual care	Patients admitted to hospital with a diagnosis of heart failure and documented left ventricular systolic dysfunction (ejection	Country: US Study design: Costing study alongside RCT (n=223) Perspective: Not stated (presume healthcare system) Discount rate: N/A Time horizon: 180 days	The number of days hospitalised or dead in the 180-day follow-up period, was lower (p=0.009) for the education group (1,554 days; mean ± SD, 14±36 days vs. 2,103 days; mean ± SD, 18±37 days). The intervention group had a lower risk of hospitalisation or death (RR	The intervention cost was estimated as \$100 (€123) per subject (total 2 hours of clinical nurse educator at \$50 (€62)/hour). The overall cost of care (including the cost of the intervention) was lower in the education group by \$2,823 (€3,477) (95%CI \$202 (€249) to \$5,644 (€6,952), p=0.035)	The authors concluded that addition of a one-hour, nurse educator-delivered teaching session at the time of hospital discharge resulted in improved clinical outcomes, increased self-care

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
		fraction ≤ 0.40)	Costs: USD 2003	0.65; 95%CI 0.45-0.93); a lower risk of rehospitalisation due to heart failure (0.49; 95%CI 0.27-0.88) and a longer time to first hospitalisation or death (p=0.012), but no difference in death rate (RR 0.94; 95%CI 0.34-2.6). The self-care measure score (sum of six self-care measures) was significantly higher for the intervention group at 30-day follow-up (p=0.001)	per subject in the 180-day follow-up period	measure adherence, and reduced cost of care in patients with systolic heart failure.
<b>Krumholz (2002)</b> <sup>(406)</sup>	Education and support intervention 2) Usual care	88 HF patients 44 controls, 44 intervention, aged ≥50	Country: US Study Design: prospective, randomised trial Perspective: Healthcare Discount rate: NA Time Horizon: 12 months  (US \$ cost year NR)	Only 12 patients (27.3%) in the intervention group compared with 21 patients (47.7%) in the control group experienced more than one readmission. The number of patients experiencing HF or other CVD readmissions or death was 22 (50.0%) in the intervention group and 35 (79.6%) in the control group	The average total estimated cost was \$530 per patient. Hospital readmission costs were higher in the control group by an average of \$7,515 per patient (\$21,935 in the control group and \$14,420 in the intervention group, After taking into consideration the average cost of \$530 per patient with intervention, the overall cost of care was \$6,985 less per patient in the intervention group.	Results suggest that all patients with HF should be offered an education and support programme that extends beyond the hospitalisation.
<b>Lopez (2006)</b> <sup>(407)</sup>	Multi factorial educational intervention carried out by a pharmacist  2) Usual care	Heart failure patients (134 patients were included, with a mean age of 75 years and a low educational level.)	Country: Spain Study Design: prospective RCT Perspective: Healthcare Discount rate: Time Horizon: 12 month (€ Spain cost year NR)	The patients in the intervention group were re-admitted less than those in the control group. One re admission a year would be prevented per every 6.5 patients with HF receiving the intervention. No significant differences between the two groups with regard to the	The cost of the intervention was €2,170. The global cost of the intervention amounted to €31 per patient. In terms of total costs the intervention resulted in savings of €30,995 (€100,815-€69,820) or €578 per patient.	In conclusion, this study demonstrates that a post discharge educational intervention in patients with heart failure, carried out by a pharmacist, in coordination with the rest of the staff,

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
				measurement of HRQoL throughout the follow-up, though satisfaction of care and the information received was greater in the patients of the intervention group		reduces hospital re admissions and the total days of hospital stay, improving treatment compliance without increasing healthcare costs.
<b>Morcillo</b> (2005) <sup>(408)</sup>	1) home-based educational intervention carried out by nursing staff 2) usual care	70 Patients hospitalised with systolic HF	Country: Spain Study Design: RCT Perspective: Healthcare Discount rate: Time Horizon: 6 month  (Spain € 2003)	At 6 months of follow-up, the educational intervention had resulted in a marked, statistically significant reduction in the number of emergency visits and hospitalisations. At 6 months, the intervention group had a significantly higher physical and mental health summary patient score, whereas scores for the control patients remained stable	The total cost per person was €314.80 (€428) ±403.30 (€549) for the intervention group and €1505.60 (€2,048) ±1391.60 (€1,893) for the control group with a statistically significant difference of €1190.90 (€1,620)	To conclude the intervention is a cost-effective health management option that improves the quality of life of patients with systolic HF.
<b>Riegel</b> (2004) <sup>(409)</sup>	Peer support (We trained 9 persons with heart failure to mentor other heart failure patients)	88 HF patients after recent exacerbation	Country: US Study Design: RCT Perspective: Healthcare Discount rate: Time Horizon: 3 month  (US \$ cost year NR)	At 90 days, self-care management self-care self-confidence, and total SCHFI scores had risen significantly more in the intervention group than in the control group. The intervention group was 46% quicker to return to the hospital than the control group.	The intervention was estimated to cost \$63 per patient in professional time required for training and oversight of the mentors. Over 90 days in patient HF costs were \$1,899 and \$2,201 for the intervention and UC respectively. All cause costs were \$2,450 and \$2,858.	The study concluded that this type of intervention is not universally appealing to hospitalised HF patients. In those who participated, it improved HF self-care and may have satisfied some social support needs, but the risk of increasing acute care resource use needs to be explored further.



**Table A11.4 Summary of cost-effectiveness studies for telemedicine**

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Cost	Authors' conclusions
<b>Berg</b> (2004) <sup>(410)</sup>	A telemedicine disease management programme  2)Usual care	Recent HF patients aged 65 and over (n=533)	Country: USA Study Design: concurrent matched-cohort study. Perspective: healthcare Discount rate: N/A Time Horizon: 1 year  (US\$ 2000)	Intervention group had significantly lower rates of acute service utilisation vs. UC including 23% fewer hospitalisations, 26% fewer inpatient bed days, 22% fewer ED visits, 44% fewer HF hospitalisations, HF inpatient bed days (34% fewer), 70% fewer 30-day readmissions & 45% fewer SNF bed days. Intervention group had 4.5% more physician office visits, which was non-significant. There were no significant differences between the 2 groups for most recommended drug classes.	The average cost was \$1,163 (€1,595) per intervention-group participant. Total cost in the intervention group, inclusive of programme fees, is \$15,535 (€21,299), compared with \$17,327 (€23,756) in the control group. Total intervention cost of \$619,902 (€849,913) generated savings of \$1,430,281 (€1,960,979), resulting in a return on investment of 2.31:1.	In summary, this community-based, concurrent trial of a commercial HF disease management intervention in the elderly demonstrated significant reductions in medical services, resulting in 10% lower cost of care.
<b>Boyne</b> (2013) <sup>(411)</sup>	Telemonitoring (TM)-supported education intervention versus usual care (UC)	382 HF patients. Mean age was 71 yrs (range 32– 93), 59% were male.	Country: Netherlands Study Design: CUA Perspective: Healthcare Discount rate: NA Time Horizon: 12 months  (€2008, Dutch)	Utility scores improved by 0.07 points for the UC and 0.1 points for the TM group, but the difference between groups was not significant. This effect correlated with the QALY-score, which also showed no difference. The difference between the groups was - .0031 QALY with 95% CI of - 0.0552 to 0.0578.	The total costs were €16,687 (€17,323) (CI 14,041–19,114) in the TM group and €16,561 (€17,192) (CI 13,635– 20,218) in the UC group. The difference between groups was €126 (€145) not a significant difference (CI - 4,374–3,763). The ICER for TM versus UC amounted to €40,321 (€41,858) per QALY gained.	At a threshold of €50,000 (€57,481) the probability of TM being cost-effective is 48%. The overall incremental cost-effectiveness analysis showed a high level of decision uncertainty. Unambiguous conclusions about the whole group cannot therefore be drawn.
<b>Cui</b> (2013) <sup>(412)</sup>	1)Standard treatment 2)health lines	179 patients aged 40 and over with a diagnosis of CHF	Country: Canada Study design: CUA Perspective: health	Patients in the control group had more all-reasons hospital in-patient days than both intervention groups, but the	Mean per patient cost of intervention was \$1,854 (€1,386) and \$2,108 (€1,576) (HL, HLM) Compared to the	We estimated the ICER for HL compared to HLM by dividing these incremental



Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Cost	Authors' conclusions
	3) health lines plus in-house monitoring	levels II to IV	system Discount: NA Time Horizon: 12 months (Can\$ 2005)	differences were not significant (p=0.4865). Hospital in-patient days for CHF were significantly higher for the intervention groups relative to the control group (p<0.05). SF-6D utility scores were higher in the intervention groups at all measurements. Results reported QALYs for HLM and HL of .063 and 0.67 respectively. Difference of 0.04QALYs (95% CI: 0.01, 0.08	control group, the total saving from averted healthcare utilisation costs through the interventions was \$28,307 (€21,163) or \$238 (€178) per capita. The total healthcare costs per patient, including intervention cost for the three study groups, were \$7,151 (€5,346) (control group), \$6,430 (€4,807) (HL) and \$6,311 (€4,718) (HLM). The mean incremental cost of HL relative to HLM was \$85 (€64) (95% CI: -\$3,088 (-€2,309), \$3,336 (€2,494)) taking into account savings from healthcare utilisation averted.	costs by incremental effectiveness. The HL was associated with an ICER of \$2,975 (€2,224) in generating additional QALYs. HL can improve care and lower costs
<b>Dar</b> (2009) <sup>(413)</sup>	1) Daily home telemonitoring of signs & symptoms (TM) 2) usual follow-up care available at each hospital from the cardiology service (UC)	182 Patients with a recent HF hospital admission.	Country: UK Study Design: a multi-centre randomised controlled Perspective: NHS Discount rate: N/A Time Horizon: 6 month (UK £ 2005)	During the 6 months of follow-up there was no difference in the median number of days alive and out of hospital in the two groups. There were significantly more emergency heart failure admissions in the UC group compared with the TM. There was no change in overall health-related quality-of-life as measured through the EQ5D over the 6 month follow-up period.	If mean direct NHS costs are considered, the incremental cost per patient for telemonitoring is statistically non-significantly higher by £1,600 (€2,290) per patient with a mean direct NHS cost for a telemonitored patient of £4,610 (€6,597) and £3,006 (€4,302) for usual care. The total median direct NHS costs per patient over the 6 month study period were £1,688 (€2,416) for the telemonitoring arm, and £1,498 (€2,144) for usual care.	Home telemonitoring in a typical elderly population of heart failure patients produces a similar outcome to 'usual' specialist care, but reduces clinic and emergency room visits and unplanned heart failure rehospitalisations at little additional cost.
<b>Dunagan</b> (2005) <sup>(414)</sup>	1)Nurse-administered, telephone-based	patients hospitalised with heart failure	Country: US Study Design: RCT	Intervention patients had longer time to encounter (HR 0.67; 95% CI 0.47–0.96;	The total overall hospital costs of the intervention were \$1,323,166 (€1,814,120) and	A nurse-administered, telephone-based disease management

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Cost	Authors' conclusions
	disease management programme 2) usual care as provided by their primary physician	n(=151)	Perspective: Healthcare Discount rate: N/A Time Horizon: 1 year (US\$ 2000)	P=.029), hospital readmission (HR 0.67; CI 0.46–0.99; P=.045) & heart failure–specific readmission (HR0.62; CI 0.38–1.03; P=.063). The number of admissions & hospital days were significantly lower during the first 6 months after intervention but not at 1 year. This was similar for physical functioning scores on both the SF-12 and the MLHF questionnaire at 6 months, but not at 12.	mean was \$17,410 (€23,870).	programme delayed subsequent health care encounters, but had minimal impact on other outcomes.
<b>Giordano (2009)</b> <sup>(415)</sup>	1)home based telemanagement (HBT) 2) Usual care	N=460 , 230 HBT, 230 UC, age 57 ±10	Country: Italy Study design: RCT Perspective: healthcare Discount rate: NA Time horizon: 12 months  (Italian € cost year NR)	During one-year follow-up, all-cause hospital readmissions occurred in 67 patients in HBT group and 96 patients in UC group (RR=0.57, 95% [CI]: 0.39–0.84; p=0.03).Fifty five patients (24%) in HBT group and 83 patients (36%) in the UC group had at least one readmission due to cardiovascular reasons (RR=0.56, 95% [CI]: 0.38, 0.82; p=0.003). One-year total mortality was 9% HBT group and 14% in UC group.	The daily cost per patient of intervention in HBT group was €0.65. The mean annual cost per patient was € 185+/- 39. Mean cost for hospital readmission was significantly lower in HBT group (€ 843 +/-1733) than in UC group (€ 1298+/-2322), (-35%, p<001). According to estimated NNT the annual cost to prevent one readmission was € 638 (95% [CI]: 850–1913).	Telemedicine holds the promise of improving access to health care and of reducing costs; home telemanagement for cardiac chronic disease could be one of the most important applications
<b>Jerant (2001)</b> <sup>(416)</sup>	1)Home telecare delivered via 2-way video-conference device with an integrated electronic	English-speaking patients 40 years of age and older with a primary hospital admission diagnosis of	Country: USA Study Design: RCT Perspective: Health system Discount rate: N/A Time Horizon: 6	Both intervention groups had significantly fewer CHF-related ED visits (P = 0.0342) & charges (P = 0.0487) than the usual care group. Trends favouring both interventions were noted for	Mean total care charges were 68% lower in the home telecare group (\$29,701) (€43,867) and 69% lower in the telephone group (\$28,888) (€42,666) than in the usual care group (\$93,686)	Substantial reductions in hospital readmissions, emergency visits, and cost of care for patients with CHF might be achieved by

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Cost	Authors' conclusions
	stethoscope 2) nurse telephone calls 3) usual outpatient care	CHF.	months (US \$ 1998)	all other utilisation outcomes.	(€138,369) The difference was not statistically significant.	widespread deployment of distance technologies. Home telecare may not offer incremental benefit beyond telephone follow-up and is more expensive.
<b>Klersy</b> (2011) <sup>(417)</sup>	1) multidisciplinary heart failure management remote patient monitoring (RPM) 2) usual care	Heart failure patients	Country: Italy Study Design: CEA CUA review Perspective: 3 <sup>rd</sup> party payer Discount rate: Time Horizon: 1 year (€ country not clear cost year NR)	RPM was associated with a significantly lower number of HF-related hospitalisations. The QALY gain due to reduction in mortality was 0.02, whereas the QALY gain due to reduced hospitalisations in surviving patients was 0.04, resulting in a total QALY gain of 0.06 for RPM.	The difference in costs between RPM and usual care ranged from about €300 to €1,000, RPM always being less costly than usual care. RPM is a 'dominant' approach over existing treatment as it is both cost saving and produces a positive QALY gain.	This novel cost-effectiveness data coupled with the demonstrated clinical efficacy of RPM compared with usual care, should encourage the acceptance of RPM amongst clinicians and consideration by third-party payers.
<b>Pandor</b> (2013) <sup>(389)</sup>	Home telemonitoring (TM) or structured telephone support (STS) Human to machine ( HM) or human to human (HH)	Adult patients recently discharged from acute care after a recent exacerbation of HF.	Country: UK Study Design: Markov model Perspective: NHS Discount rate: 3.5% Time Horizon: Lifetime (GB £ 2011)	Both TM during office hours and STS HH are similar in terms of mean HRs for mortality. STS HH showing a higher QALY gain over usual care of 0.1059 compared with an additional 0.1038 QALYs gained with TM during office hours (equivalent to an additional 37.7 and 38.6 quality-adjusted days average gain for STS HH and TM respectively).	The total cost per patient for the STS HM intervention over 6 months was estimated to be £715 (€963), that is, a monthly cost of £119 (€160) per patient. The office hours TM intervention for 6 months was estimated to be £1051 (€1,416). That is, a monthly cost of £175 (€233) per patient. The total base-case cost per patient receiving the STS HH intervention for 6 months was estimated to be £1075 (€1448), that is, a monthly cost of £179 (€241)	Comparing STS HH with usual care, the incremental cost per QALY gained is £1126 (€1,517)/0.1059 = £10,629 (€14,325), The ICER for TM during office hours compared with usual care is £992 (€1,336)/0.1038 = £9552 (€12,871). TM during office hours had an estimated

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Cost	Authors' conclusions
					per patient. The expected costs over a lifetime (30-year time horizon) differ for each strategy, with STS HH having the highest costs at £9604 (€12,938) followed by TM during office hours (£9470) (€12,757), STS HM (£9001) (€12,125) and usual care (£8478) (€11,421).	incremental cost effectiveness ratio (ICER) of £11,873 (€15,994.52) per QALY compared with usual care, whereas STS HH had an ICER of £228,035 (€307,194) per QALY compared with TM during office hours
<b>Riegel</b> (2002) <sup>(418)</sup>	Telephonic disease management	130 Patients with recent HF hospitalisation	Country: USA Study Design: RCT Perspective: Healthcare Discount rate: N/A Time Horizon: 6 months (\$ Cost year NR)	Heart failure hospitalisation rates at 3 months and 6 months were 45.7% and 47.8% lower in the intervention group than in the usual care control group respectively. Acute care utilisation was also lower.	The intervention was calculated to cost \$443 per patient if the cost of training is included. The cost saving for acute care is about \$1000 (usual care \$2,186 vs intervention \$1,192), usual care is almost double the cost of the intervention.	Intervention costs offset by savings from hospitalisations avoided.
<b>Scalvini</b> (2005) <sup>(419)</sup>	Home-based telecardiology (HBT consisted of trans-telephonic follow-up & ECG monitoring, followed by visits from the paramedical & medical team) compared with usual care	Chronic heart failure patients in stable condition. (n=426) mean age = 59 years	Country: Italy Study Design: RCT Perspective: Healthcare Discount rate: Time Horizon: 1 year (€ cost year NR)	There was an increase in quality of life in the HBT group. The mean MLQ scores were 29 in the HBT group and 24 in the usual-care group; this difference was significant. There were significant reductions in hospitalisations and instability in the HBT group relative to the usual-care group.	The total costs of intervention were €75,426. There was a reduction of 24% in the total costs after one year in the group which underwent telecardiology. The total costs were lower in the HBT group (€107,494 and €140,874, respectively).	Results suggest that a telecardiology service can detect and prevent clinical instability, reduce rehospitalisation and lower the cost of managing CHF patients.
<b>Sohn</b> (2012) <sup>(420)</sup>	Telemedicine (nurse-calls to	Patients with Chronic Heart	Country: Germany Study Design:	Participants of the "Telemedicine for the Heart"	Programme participants contributed about €2,633 less	Significant cost differences in favour

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Cost	Authors' conclusions
	motivate patients to perform regular self-measurement)	Failure	retrospective matched-pairs analysis Perspective: Health insurance Discount rate: Time Horizon: 1 year (€ German cost year NR)	group exhibited significantly higher survival than participants of the control group. Regardless of the survival status, there were fewer hospital admissions in the programme group (1.02 vs. 1.30 per patient per year in the programme and control groups, respectively).	costs than the average patient in the control group. That corresponds to a 25.0% cost reduction	of the study group of up to 25% in relation to the total cost could be detected. This corresponds to an amount of about €1,500–€2,500 (€1,591- €2,651) total costs per patient per year.
<b>Soran</b> (2010) <sup>(421)</sup>	Computer based telephonic monitoring	304 Recently hospitalised HF patients	Country: USA Study Design: RCT Perspective: Healthcare Discount rate: N/A Time Horizon: 6 months  (US \$ cost year NR)	There were no significant statistical differences between the groups in regards to 6-month cardiac mortality, rehospitalisations for heart failure, or length of hospital stay.	The 6-month mean Medicare costs were estimated to be \$17,837 and \$13,886 for the intervention and the control groups, respectively. Mean cost of the interventions were \$25 for standard care and \$804 for HFMS.	Results suggest that enhanced patient education and follow-up is as successful and less costly than a sophisticated home monitoring device with an interactive programme in elderly patients.
<b>Wootton</b> (2009) <sup>(422)</sup>	Care coordination (including intervention telephone counselling, patient support and provision of facts sheets compared with usual care	Australian veterans with a diagnosis of congestive heart failure	Country: Australia Study Design: RCT Perspective: Healthcare Discount rate: Time Horizon: 12 month  (AUS \$ 2008)	There were no significant differences between the two groups in the change from baseline to follow-up for either group.	There were no significant differences in total costs of care between the intervention and control groups.	Results from the present RCT suggest that application of care coordination to veterans with CHF was successful, but did not have advantages over usual approaches to patient management. Statistically, there were no significant differences in costs of care or in QOL measurements.

**Table A11.5 Summary of cost-effectiveness analyses for multidisciplinary care interventions**

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
<b>Ledwidge</b> (2003) <sup>(423)</sup>	Multidisciplinary care (MDC) compared with routine care (RC)	98 HF patients	Country: Ireland Study Design: CBA RCT Perspective: healthcare provider Discount rate: Time Horizon: 3 month (€ Irish cost year NR)	The number of hospitalisations in the RC and MDC groups was 12 and 2, respectively, therefore there was an absolute reduction of 10 hospitalisations as a result of the intervention.	Dividing the absolute intervention cost by the absolute reduction in hospitalisations gives a service cost of €586 per hospitalisation prevented. The absolute cost-benefit of the programme ranges from €8,634 to €65,798. In addition, to the clinical benefits produced by the intervention, there was a net cost saving of €729 per patient treated.	MDC of HF remains cost-effective and cost-beneficial when combined with optimal medical care. The cost per HF hospitalisation prevented is €586. The service cost is €113 (95% CI: 185–244) per patient over 3 months and there is a net cost saving per patient treated of €729.
<b>Kasper</b> (2002) <sup>(424)</sup>	Multidisciplinary outpatient management programme compared with usual care	Two hundred patients hospitalised with CHF	Country: US Study Design: prospective randomised trial Perspective: Healthcare Discount rate: Time Horizon: 6 months (US\$ 1998)	There were fewer hospital admissions for any reason in the intervention group. Patients in the intervention group were more likely to report stable or improved symptoms, as compared with those in the non intervention group. Quality of life, measured by the Minnesota Living With Heart Failure Questionnaire improved in both groups, but patients in the intervention group improved more	The intervention, including salaries and supplies, cost \$904 (€1,532) per patient. The mean outpatient pharmacy cost per patient was similar in both groups: \$1,353 (€2,293) in the intervention group and \$1,405 (€2,381) in the non intervention group. Mean inpatient costs for intervention group was \$11,315 (€19,175) and \$8,789 (€14,894) for the non-intervention group.	Our results indicate that a multidisciplinary approach to the management of high-risk outpatients with CHF improves quality of life, with a trend toward improvement in the primary end point of death and total number of CHF hospital admissions over a six-month intervention period.
<b>Stewart</b> (2002) <sup>(425)</sup>	Multidisciplinary home-based intervention (HBI) (comprising structure home visits by nurse ± pharmacist)	Patients aged 55 years hospitalised for HF and a history of ≥ 1 admission for acute HF.	Country: Australia Study design: Costing study alongside RCT (n=297) Perspective: Not stated (Presume healthcare payer)	During a median of 4.2 years follow-up, HBI was associated with fewer unplanned readmissions or death (0.21 vs. 0.37 per patient per month, p<0.01), longer event-free survival (7 vs. 3 months, p<0.01),	The median cost of readmissions was \$A325 (€347) (IQR 21 (€22) to 831 (€888)) versus \$A660 (€705) (IQR 74 (€79) to 1987 (€2,122)) per month per patient in the HBI and usual care groups, respectively (p<0.01). The total cost of these	The authors concluded that HBI is beneficial in reducing the frequency of unplanned readmissions for HF, that this persists in the long term and is associated with prolongation of survival, reduced levels of hospital

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
	within 7-14 days of discharge) versus usual care		Discount rate: None Time horizon: 6 years  Costs: costs from 1995 to 2001 inflated and standardised to 2000/2001 AUSD	fewer deaths (56% vs. 65%, p=0.06), and a more prolonged survival (median 40 vs 22 months p<0.05). Overall, HBI patients accumulated 16% fewer unplanned readmissions (396 versus 475) and had a lower rate of unplanned readmission (mean of 0.17 versus 0.29 readmissions per patient per month, p<0.05).	clinic visits was \$A165,579 (€176,866) versus \$A241 552 (€258,018) for the HBI and usual care groups, respectively. The average cost of applying the HBI, taking into account both the cost of home visits and additional cardiology, primary care, and pharmacy consultations, was \$A600 (€641)/patient.	activity and associated costs.



**Table A11.6 Summary of cost-effectiveness analyses for disease management programmes**

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
<b>Anderson (2005)</b>	Targeted inpatient education programme with comprehensive discharge planning & immediate outpatient reinforcement through a coordinated nurse-driven home health care programme compared with usual care	Heart failure patients over 50 years old. N=44 intervention group, n=77 UC	Country: US Study design: RCT Perspective: Healthcare Discount: Time Horizon: 6 month (U\$ 1997)	Intervention subjects had an 11.4% readmission rate within 6 months, compared with a 44.2% readmission rate in control subjects. Estimated that 14 readmissions were avoided in the intervention group	Hospital costs for programme implementation were \$6960 (€10,608) for all 44 intervention subjects (\$158 (€241) per subject). The average total 6-week cost savings for home health care for each subject in the intervention group was \$1541 (€2,349). This cost saving was a direct result of decreased utilisation. The total cost saving for all 44 intervention subjects was \$67,804 (€103,344).	These results suggest that all CHF patients should be offered comprehensive education and support that begins in the hospital and continues in the outpatient setting.
<b>Chen (2010)<sup>(426)</sup></b>	Home-based heart failure centre management programme using nursing specialist-led telephone consultations (HFC group) compared with usual care	Chinese heart failure patients. (n=550)	Country: Taiwan Study design: non concurrent, prospective design. Perspective: Healthcare Time Horizon: 6 months Costs were converted from Taiwan dollars to us dollars in 2005	The home-based intervention resulted in significantly lower all-cause admission rate/person (HFC 0.60 ± 0.77 times/person; UC 0.96 ± 0.85 times/person), shorter all-cause hospital stay (reduced by 8 days/person).	When considering all of the costs, despite having 58.9% higher out-patient care costs, the HFC home-based intervention still reduced the overall healthcare expenditure by 30.8% compared with the usual care programme. The total overall cost per month for UC and HFC were \$1,454 (€1,609) and \$1,006 (€1,113), respectively.	The 6-month, home-based intervention with nursing specialist-led telephone consultations may improve the clinical outcome and provide cost-savings for Chinese patients with heart failure.
<b>Discher (2003)<sup>(427)</sup></b>	HF algorithm & clinical pathway incorporating AHCPR criteria for CHF, physician & nurse CHF education & patient educational materials compared with usual care	Patients admitted to hospital with CHF	Country: US Study design: Before and after study Perspective: Healthcare Discount rate: Time Horizon: 1 year	Managed patients had significantly lower length of stay (3.9±2.2 vs. 6.1±2.8 days; p<0.0001) vs. unmanaged.	The average cost per managed patient was lower than that for unmanaged patients (\$4403.87±\$1989.23 (€6,284±€2,838) vs. \$6827.77±\$3346.90 (€9,742±€4,776), respectively p<0.0001). Had all 593 patients	Disease management and clinical pathways may thus provide an acceptable and effective vehicle for both implementing and further updating the continually evolving



Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
			(US\$ 1999)		been enrolled in the CHF pathway, costs would have totalled (+) \$437,693.30 ((+) 624,522) the potential loss, had all patients remained unmanaged, costs would have been \$640,979.63 (€914,581) resulting in a total hospital saving of \$1,078,672.93 (€1,539,104) for 1999.	diagnostic and therapeutic modalities for CHF, in service of further enhancing the quality and efficacy of patient care.
<b>Gregory (2006)</b> <sup>(428)</sup>	HF disease management (HFDM) programme delivered within a diverse provider network compared with usual care	Heart failure patients (n=200)	Country: US Study Design: prospective randomised assessment Perspective: Healthcare Discount rate: Time Horizon: 90 days (US\$ 2003)	Although not significant, the relative odds of at least one all-cause hospitalisation was 0.76 (95% CI 0.38-1.51) for the intervention compared with the control group.	The difference in hospitalisation cost between control & intervention groups was reduction in cost of \$375 (€913)/patient. The net effect including the costs of the programme was an increase of \$488 (€1,199)/patient for the intervention group vs. the control group. The programme would have been cost saving if HFDM costs had been 24% lower.	The intervention succeeded in reducing the rate of heart failure hospitalisations, although this effect was partially offset by an increase in non-heart failure hospitalisations. The resulting modest reduction in hospitalisation costs was exceeded by the cost of the intervention.
<b>Hebert (2008)</b> <sup>(429)</sup>	1) nurse-led disease management intervention (face-to-face encounter with nurse & regular telephone follow-up) 2) usual care	406 patients, 203 usual care, 203 nurse-led programme, mostly African American or Hispanic	Country: US Study Design: CEA alongside RCT Perspective: societal and payer Discount rate: Time Horizon: 12 months (US\$ 2001)	Patients in the nurse-managed group maintained better physical functioning throughout the 12-month intervention than did patients who received usual care. In terms of QALYs the study reported 0.0497 QALY per person for the HUI3 and 0.0430 QALY per person for the EQ-5D.	Intervention costs totalled \$2177 (€2,853) per patient. The 12-month incremental cost per QALY gained—the ICER—was \$17 543 (€22,994) for the estimate of quality of life based on translation of the SF-12 to the EQ-5D and \$15 169 (€19,883) for translation to HUI-3 From the perspective of a payer like Medicare, the incremental net cost over 12 months of implementing this programme was \$158 (€207) per patient enrolled and \$3673	At less than \$25 000 (€32,768) per QALY saved, this nurse-led disease management programme was reasonably cost-effective over 12 months, especially for patients with earlier stages of heart failure. Wider adoption of such programmes may be a sensible approach to reducing the burden of heart failure in ethnically

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
					(€4,814) and \$3176 (€4,163) per QALY for EQ-5D-derived and HUI-3-derived quality of life, respectively.	diverse, urban communities.
<b>Hendricks</b> 2014 <sup>(430)</sup>	Case management programme (CMP) compared with regular management	N=1202, 601 controls, 601 intervention	Country: Germany Study design: Non concurrent control and intervention group Perspective: Insurer Discount rate: NR Time horizon: 54months  (German € cost year NR)	The intervention group showed a lower rate of hospital admission/readmission (6.2%/18.9% versus 16.6%/36.0%; p<0.0001 / p=0.041). Mortality rates did not differ significantly (5.0% versus 6.7%; p = 0.217).	Results show no significant difference in the mean cost per heart failure-related hospital stay, with a mean of €2841.59 (95% CI: 2627.51 to 3076.12) in the intervention group and €2651.71 [95% CI: 2476.87 to 2845.63] in the control group (p= 0.205). The annual heart failure-related hospitalisation costs per patient were €222.22 (95% CI: 145.10 to 307.77) in the intervention group versus €683.88 (95% CI: 522.33 to 850.70) in the control group (p<0.0001). For every case management programme participant, the health insurer therefore achieved a mean annual saving of €461.66 when compared to a patient receiving routine care	Fewer patients in the intervention group were admitted and readmitted to hospital, and lower inpatient treatment costs were identified. The physician contact rate was higher than in the control group.
<b>Inglis</b> (2006) <sup>(392)</sup>	Nurse-led, multidisciplinary, home-based intervention (HBI) compared with usual care	Elderly patients with HF. N=149 HBI, n=148 usual care	Country: Australia Study Design: RCT Perspective: Healthcare Discount rate: Time Horizon: 10 year  (\$AUS 2002)	Overall, statistically fewer patients in the HBI group compared with UC died during this period: 114 (77%) versus 132 (89%) overall, the HBI group accumulated more unplanned readmissions during follow-up. When we adjusted for the duration of follow-up, however, the rate of readmission was significantly lower in the HBI	The cost-benefit of HBI was estimated to be \$1729 (€1,199) per additional life-year gained. The intervention cost \$100,000 (€100,138). Total healthcare costs for the HBI and UC groups were \$3,267,372 (€3,271,893) and \$3,059,912 (€3,064,146) respectively, difference \$207,460 (€207,747)	A simple cost- and time-effective nurse-led multidisciplinary intervention performed in the patient's home after hospitalisation relative to UC has the potential to extend the horizon of survival with CHF while cost-effectively reducing the frequency of recurrent

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
				group: 3.66_7.62 versus 2.04_3.23 admissions per patient per year		hospitalisation.
<b>Kwok (2008)</b> <sup>(431)</sup>	Community nurse-supported hospital discharge programme (home visits weekly x 4 then monthly; education; liaison support) versus usual care	Hospitalised patients aged ≥ 60 years with chronic heart failure and at least one admission for heart failure in the 12 months prior to the index admission	Country: Hong Kong Study design: Costing study alongside RCT (n=105) Perspective: Healthcare system / social care Discount rate: N/A Time horizon: 6 month  Costs: HKD 2000 (intervention 09/99-02/01)	At 6 months follow-up, there was no difference in re-admission rates or median number of readmissions for the intervention and control groups (46% vs. 57%, p=0.233 and 0 vs. 1 p=0.057, respectively). The intervention group had less handicap in independence (median change London Handicap Score 0 vs. 0.5, p=0.002), but there was no difference in six-minute walking distance (44m vs. 25m, p>0.05).	The median cost to the public health care system of the community nurse was HK\$2,391 per subject (median visit cost =\$385/subject). The median public health costs as a result of hospital stay and emergency care attendances were lower in the intervention group (HK\$5,229 vs. HK\$20,916, p=0.048), however the total public healthcare costs were not significantly different (HK\$10,186 vs. \$21,599, p>0.05). There was no difference in the median total personal costs (medical and social included) for the intervention and control groups (HK\$1,457 versus HK\$922, p=0.118).	The authors concluded that post-discharge visits by community nurses were not effective in reducing the change of readmission within six months, but were effective in preserving independence and were probably effective in reducing the number of unplanned admissions with no significant impact on public healthcare costs.
<b>Laramee (2003)</b> <sup>(432)</sup>	Case management (CM) (comprising early discharge planning and coordination of care, education of family and patient, 12-week telephone support and surveillance, optimisation of heart failure medication) versus usual care	Patients: admitted to hospital with primary or secondary diagnosis of CHF, LVEF <40% or radiological evidence of pulmonary oedema requiring diuresis; and who were at risk of early readmission (history of CHF or	Country: US Study design: costing study alongside RCT (n=287) Perspective: Not stated (? Healthcare provider) Discount rate: N/A Time horizon: 12 week  Costs: 2000 USD	There was no difference in 90-day readmission rates for the CM and usual care groups (37%). Patients in the CM group were more likely to be taking CHF medications at target doses (p>0.05), to be adherent with their treatment plan (p=0.40) and to be satisfied with their care (p<0.01). Subgroup analysis indicated a significant reduction in readmissions in patients initially admitted with	The intervention did not increase costs and there were no significant differences in outpatient and inpatient resource utilisation between the groups. Based on an hourly cost of USD\$34 (€48)/CM and an average time of 6.7hours/12 weeks, the average cost of the intervention was USD\$228.52 (€321) per patient. Total inpatient and outpatient median costs were lower for the	The authors concluded that compared with usual care, case management did not reduce the 90-day readmission rate (possibly due to the heterogeneous population, varied access to care and lack of a coordinated system supports), but that it significantly improved treatment plan

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
		CHF-related admission or >4 admissions in previous 5 years or living alone or documented CHF knowledge deficits OR adherence issues).		chronic renal failure or weight gain.	intervention group (USD\$15,979 (€22,675) vs \$18,662 (€26,188), p=0.14)	adherence and satisfaction in a cost-effective manner.
<b>Miller (2009)</b> <sup>(433)</sup>	Disease management programme vs. usual care  NB – modelled using data from Smith 2008 RCT	Community dwelling patients with systolic heart failure	Country: US Study design: Markov model Perspective: Health care system Discount rate: 3 % Time horizon: lifetime  Costs: 2003 USD	Baseline model results indicate that patients with systolic HF patients would live an average of 0.141 years (51 days) longer with disease management than those in the control group. The corresponding discounted QALY benefit was 0.111 per patient.	Discounted lifetime costs per patient averaged \$74,025 (€91,182) and \$78,875 (97,156) for the control and disease management groups, respectively. The average (undiscounted) per patient cost of the disease management programme was estimated at \$8,586 (€10,576) (\$246 (€303)/month for 18-month DM programme or \$107(€132)/month over average patient lifetime)	The net discounted disease management cost was \$4,850 (€5,974) per patient resulting in an ICER of \$43,650 (€53,767) per QALY saved. The authors concluded that that disease management of heart failure patients can be cost-effective in the long term, and that short terms results from a clinical trial might not reveal long term cost-effectiveness.
<b>Naylor (2004)</b> <sup>(434)</sup>	Transitional care planning by advanced nurse practitioners comprising discharge planning education, goal setting, use of evidence-based guidelines and home follow-up for 3 months compared with standard of care (which included site-	Patients aged 65 years and older hospitalised with a diagnosis of heart failure	Country: US Study design: costing study alongside RCT (n=239) Perspective: Not stated (Presume healthcare payer) Discount rate: N/A Time horizon: 52 week	Time to first readmission or death was longer in intervention patients (p=0.026). At 52 weeks, intervention group patients had lower rate of rehospitalisation or death (47.5% vs 61.2%, p=0.01), fewer readmissions (104 vs 162, p=0.047), and fewer hospital days (588 vs. 970, p=0.071). The proportion	Total and mean costs (reimbursements) per patient were lower in the intervention group than in the control group. Mean per patient 52-week total costs adjusted for unequal follow-up were significantly lower in the intervention groups were (\$7,636 versus \$12,481, p=0.002). The higher direct costs of the intervention	The authors concluded that a comprehensive transitional care intervention for elders hospitalised with heart failure increased the length of time between hospital discharge and readmission or death, reduced total number of rehospitalisations, and decreased healthcare

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
	specific HF management, discharge planning and if necessary, referral to standard home care services)		Cost year NR	patients remaining alive and with no hospital readmission was significantly lower in the control group at 30, 60, 90, 180 and 365 days post discharge. Short term improvements in overall quality of life (12 weeks, $p < 0.05$ ) and patient satisfaction (at 2 and 6 weeks, $p < 0.001$ ) for the intervention group.	(\$115,856 vs. \$64,531) resulting from the increased number of home visits compared with usual care (13.2 vs 6.3), use of APN, and greater involvement of heart failure experts were offset by reductions in other home visits, acute care visits to physicians or the ED, and hospitalisations.	costs.
<b>Piepoli (2006)</b> <sup>(435)</sup>	multidisciplinary disease management programme vs. Usual care	Patients recently hospitalised with heart failure	Country: Italy Study Design: pre and post analysis Perspective: Healthcare Discount rate: Time Horizon: 12 month (Cost year unclear 2002-2004)	Compared with the 12 months before referral, the programme intervention was accompanied by a 56.8% reduction in the hospitalisation for all causes. Significant improvement in the global score was observed: from 2.61 to 2.10 (+19.4%). In fact 63.7% (324) of the patients improved NYHA functional class,	The total estimated saving in cost because of the hospitalisation for cardiovascular diseases was €300,305. The average estimated saving in hospital admission costs was €590 per patient. The total outpatient visits were €775, with an average of 1.5 per patient during the 12-month follow-up with an average cost of €68.5 per patient.	In summary, this prospective study has shown substantial effectiveness of our HF management programme developed with the contribution of health providers from both hospital and primary care settings.
<b>Pugh (2001)</b>	Case management by a nurse case manager (comprising enhanced discharge planning, post-discharge instruction and intensive post-hospital collaboration with their providers) versus usual care	Patients aged 65 years and older hospitalised for heart failure	Country: US Study design: Costing study alongside a pilot RCT (n=58) Perspective: Healthcare Discount rate: N/A Time horizon: 6 month (Cost year not reported)	Compared with the control group, a positive effect was observed for the intervention in terms of SF-36 scores, functional status, and NYHA score; however these differences were not statistically significant.	The average monthly cost per patient was higher in the treatment group, but this difference was not significant (\$1,379.96 [SD \$1,596.35] vs. \$1,038.31 [SD \$1,263.05], $p = 0.51$ ).	The authors concluded that the delivery model was no more expensive than usual care, and provided some positive effects on functional status and quality of life.

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
<b>Postmus (2011)</b> <sup>(436)</sup>	Basic nurse-led disease management programme compared with intensive support by a nurse specialised in the management of patients with HF compared with care as usual (routine follow-up by a cardiologist)	1023 Patients with HF	Country: The Netherlands Study Design: RCT CEA COACH study Perspective: Health service Discount rate: Time Horizon: 18 month (Dutch €, 2009)	The mean quality-adjusted survival time was 287.6 days in the care-as-usual group, 296.1 days in the basic-support group, and 294.6 days in the intensive-support group.	In terms of cost per life-year, basic support dominated care as usual because it generated 0.048 additional life-years while saving €77(€79). When comparing the 2 disease management programs, intensive support was found to generate 0.0022 additional life-years at an excess cost of €1,178 (€1,211), yielding an ICER of €532,762 (€547,599) per life-year. In terms of cost per quality-adjusted life-year (QALY), basic support was found to dominate both care as usual and intensive support because it generated 0.023 and 0.004 excess QALYs while saving €77(€79) and €1,178 (€1,211), respectively.	To conclude the results provide a strong scientific case for a broader implementation of such programmes, provided that the intensity of the programme is tailored to the severity of the disease in individual patients with HF.
<b>Roig (2006)</b> <sup>(437)</sup>	Specialised care programme that includes patient education on advanced heart failure, with day-care and home care elements, and involved intravenous drug administration when necessary.	61 End stage heart failure patients	Country: Spain Study Design: before and after Observational Perspective: Healthcare Discount rate: Time Horizon: 1 year (Spanish € cost year NR)	The mean number of hospital admissions required, the days spent in the hospital, and the number of visits to the emergency room per patient decreased very significantly after inclusion in the SCP, there were a total of 308 hospital admissions, a number that was reduced to 108 during the SCP.	The mean cost of health care per patient-year was €19 175. Total hospital costs were €17,585. Thus, the application of the SCP resulted in a savings of €1,590 per patient. When, under the SCP, home care replaced the day hospital, the cost was reduced to €14,675, resulting in an even greater savings with respect to conventional care	Programmes of specialized care are of great utility in patients with end-stage HF; they reduce the numbers of readmissions and emergency room visits and, consequently, health care costs.
<b>Smith (2008)</b> <sup>(438)</sup>	Telephonic disease management (DM) compared with usual care	1069 Community dwelling CHF patients	Country: USA Study Design: RCT Perspective: Health system	Disease management produced statistically significant survival advantages among all	Analyses of direct medical and intervention costs showed no cost savings associated with the intervention. For all patients	Telephonic DM did not reduce costs and was not cost-effective in this sample. However, when

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
			Discount rate: N/A Time Horizon: 18 months (US \$ 2003)	patients (17.4 days), among patients with NYHA class III/IV symptoms at baseline (47.7 days), among patients with SHF (24.2 days), and in the combined group	and considering all-cause medical care, the ICER was \$146,870 (€176,762) per quality-adjusted life-year (QALY) gained, while for patients with NYHA class III/IV symptoms and patients with SHF, the ICERs were \$67,784 (€81,580) and \$95,721 (€115,203) per QALY gained, respectively. Costs per QALY gained were \$101,120 (€121,700) for all patients, \$72,501 (€87,257) for patients with SHF, and \$41,348 (€49,764) for patients with NYHA class III/IV symptoms. the mean cost of DM services per patient per month was \$246 (€296)	targeted properly, DM seems capable of producing life-span increases at costs that are less than \$100,000 (€120,353) per QALY gained.
<b>Tsuyuki (2004)</b> <sup>(439)</sup>	Patient support programme (PSP) (education about HF, self-monitoring, adherence aids, newsletters, telephone hotline, & follow-up at 2 weeks, then monthly for 6 months after discharge) compared with usual care including frequent contact with study coordinators	276 Hospitalised HF patients	Country: US Study Design: RCT Perspective: Health care service Discount rate: Time Horizon: 6 month  (CAN\$ 2000)	Although there were no differences in the number of all-cause physician visits, ER visits, or readmissions between treatment groups, there was a significant reduction in total length of hospital stay (627 days versus 1,082 days) and average length of hospital stay (6.6 days versus 11.0 days), between the patient support programme and usual care groups, respectively.	The total cost of care for CV-related events over the 6-month follow-up period of this study, was \$CDN 4548 (€3,798) for usual care patients compared with \$CDN 2017 (€1,684) for patient support programme patients, for a cost difference of \$CDN 2531 (€2,113) per patient. For all-cause events, the cost difference per patient was \$CDN 2463 (€2,057) (\$CDN 6154 (€5,139) for usual care and \$CDN 3691 (€3,082) for the patient support program).	A 6-month patient education and support programme for outpatients with HF had little impact on ACE inhibitor adherence however reduced utilisation of health care resources, resulting in a cost reduction of \$CDN 2531 (€2,113) per patient for CV-related events.



**Table A11.7 Summary of cost effectiveness analyses of other self-management support interventions**

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
<b>Bruggink (2007)</b> <sup>(440)</sup>	Physician-and-nurse-directed heart failure clinic vs. usual care (UC)	240 patients recently discharged HF patients with NYHA class III or IV.	Country: The Netherlands Study design: RCT Perspective: Healthcare Discount: Time Horizon: 12 months Netherlands €, cost year NR)	The incidence rate of the composite end point for the intervention and UC groups were 20.7/ 100 and 42.2/100 patient years, respectively. At 12 months, LVEF had improved in the intervention group, but deteriorated in the UC group. After 3 and 12 months, the NYHA class had significantly improved in the intervention group compared with UC. Improvements in MLWHFQ scores were greater in the intervention group at 3 months than in the UC group with the difference persisted during the remaining 9 months.	The difference between the costs of hospitalisation in the intervention group €65,046 and in the usual care group €202,728 was €137,682. The total cost for the HF clinic programme (for the salary of the HF nurse, HF physician and the dietician, and for the extra lab and ECGs) was €50,246 As a result, the positive balance for the intervention group was €87,436 and the difference in the overall cost of care per patient was €741	The intensive management programme substantially reduces hospitalisation for HF and/or all-cause mortality, while improving LVEF, NYHA class, quality of life and self-care behaviour, and achieving a reduction in costs.
<b>Mejia (2014)</b> <sup>(441)</sup>	Nurse facilitated, cognitive behavioural self-management programme compared with usual care	260 Heart failure patients with mean age 70.60	Country: UK Study Design: RCT CEA Perspective: NHS Discount rate: N/A Time Horizon: 12 months (UK £ 2008/09)	Both groups reported a similar frequency of contact with health care professionals. Patient reported length of stay was lower in the self-management group. Treatment was associated with a slight reduction in effectiveness of 0.02, but there was a large amount of uncertainty around this estimate, after using imputed data the figure changed to a reduction in QALY of 0.004	The intervention would generate an additional cost of £313.3(€435). Based on the complete case data, the intervention cost approximately £321 (€446) more than usual care when imputed data was used this changed to £69.49 (€96). Using 2011/2012 costs, the intervention would be associated with an increase in costs of £92 (€128) and thus would be dominated by usual care using CBT manual alone. The probability that the intervention is cost	In conclusion, the addition of nurse facilitation to a cognitive-behavioural therapy for patients with heart failure is associated with no clear effect on costs or effectiveness as measured by QALY.



Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
					effective is around 45%.	
<b>Murray (2007)</b> <sup>(442)</sup>	Pharmacist intervention for improving medication adherence compared with usual care	314 Low-income patients with heart failure.	Country: US Study Design: RCT Perspective: Payer Discount rate: Time Horizon: 12 month (US \$ 2003)	The intervention group had 19.4% fewer exacerbations on the combined end point of hospital admission or emergency department visit (incidence risk ratio, 0.82 (95% CI 0.73-0.93)). A significant improvement in adherence was observed in the 9-month intervention period, but dissipated in the 3-month post intervention follow-up.	The mean cost of the intervention was \$205 (€247) per patient. The mean difference in the overall cost of health care was \$3165 (€3,809) lower in the intervention group. Considering the costs of development and implementation, the intervention saved \$2960 (€3,562) per patient.	In conclusion, we found that our pharmacy-based intervention for outpatients with heart failure improved adherence to cardiovascular medications and decreased health care use.
<b>Stauffer (2011)</b> <sup>(443)</sup>	Nurse-led transitional care programme compared with usual care	Heart failure patients 65 and older.	Country: US Study Design: Prospective RCT Perspective: budget holder and health care provider Discount rate: Time Horizon: 3 month	Adjusted 30-day readmission rate was 48% lower at BMCG after the intervention than before the intervention	Before the intervention, total 60-day direct cost for an HF index admission at BMCG was \$1,251 less on average than the system average for BHCS. Although post intervention costs were less at BMCG, the difference between BMCG and the system narrowed during the intervention period owing to a significant reduction in total 60-day direct costs for BHCS facilities.	

**Table A11.8 Summary of quality appraisal of cost-effectiveness studies**

Study	Quality	Notes
<b>Agren (2013)</b>	Moderate	
<b>Aguado (2010)</b>	Moderate	
<b>Anderson (2005)</b>	Poor	Poor quality reporting and study design. Cost data is poorly described.
<b>Berg (2004)</b>	Moderate	Potential bias due to study design.
<b>Boyne (2013)</b>	High	
<b>Bruggink (2007)</b>	Poor	Cost data is poorly described.
<b>Burri (2013)</b>	Poor	Intervention and condition not relevant
<b>Calo (2013)</b>	Poor	Intervention and condition not relevant
<b>Chen (2010)</b>	Poor	Relevance is questioned as the study focuses on Taiwan population
<b>Cui (2013)</b>	High	
<b>Dar (2009)</b>	Moderate	Short follow-up period of only 6 months.
<b>Discher (2003)</b>	Poor	Physician decided which patients entered the trial, strong chance of bias.
<b>Dunagan (2005)</b>	Moderate	Only mean hospital costs presented and no description of where costs come from.
<b>Gregory (2006)</b>	Moderate	Short follow-up of 90 days. Reports perspective as societal but does not examine all relevant costs.
<b>Giordano (2009)</b>	Moderate	Only hospital costs examined
<b>Hendricks (2014)</b>	Poor	Poor study design, control and intervention group not comparable, all important costs are not considered
<b>Hebert (2008)</b>	Moderate	Population focuses on urban African Americans which may not representative of this study's population
<b>Inglis (2006)</b>	High	
<b>Jerant (2001)</b>	Poor	Short follow-up, all important costs are not considered
<b>Kasper (2002)</b>	Moderate	Short follow-up
<b>Klersy (2011)</b>	Poor	Cost data poorly described
<b>Koelling (2005)</b>	Poor	Only hospital readmission costs examined
<b>Krumholz (2002)</b>	Moderate	Only hospital costs examined
<b>Ledwidge (2003)</b>	Moderate	Cost-benefit analysis, did not consider all outcomes. Not possible to determine how outcomes were valued
<b>Kwok (2008)</b>	Moderate	Short follow-up period of only 6 months.
<b>Laramee (2003)</b>	Moderate	Short follow-up period of only 12 weeks

<b>Lopez (2006)</b>	Moderate	
<b>Maeng (2014)</b>	Poor	
<b>Mejia (2014)</b>	High	
<b>Miller (2009)</b>	Moderate	Costs not disaggregated; apportion intervention costs over lifetime of study, but unclear that this appropriate
<b>Morcillo (2005)</b>	Moderate	The study by Aguado et al. is an update of this study therefore findings should be taken from Aguado.
<b>Murray (2007)</b>	Moderate	Cost data is poorly described and reported.
<b>Naylor (2004)</b>	Moderate	Cost data presented in aggregate form only
<b>Pandor (2013)</b>	High	
<b>Piepoli (2006)</b>	Poor	Poor quality reporting and study design. Cost data is poorly described.
<b>Postmus (2011)</b>	Moderate	
<b>Pugh (2001)</b>	Poor	Costing study alongside pilot RCT (n=58) with 6-month follow-up. Cost data poorly described and reported and unclear whether all relevant costs are included.
<b>Riegel (2004)</b>	Poor	Poor quality reporting. Cost and outcome data are poorly described and it is unclear whether all relevant costs have been included.
<b>Riegel (2002)</b>	Poor	Poor quality reporting. Cost and outcome data are poorly described and it is unclear whether all relevant costs have been included.
<b>Roig (2006)</b>	Poor	Poor quality reporting. Cost and outcome data are poorly described and it is unclear whether all relevant costs have been included.
<b>Scalvini (2005)</b>	Poor	Poor quality reporting. Cost and outcome data are poorly described and it is unclear whether all relevant costs have been included.
<b>Smith (2008)</b>	Moderate	
<b>Sohn (2012)</b>	Moderate	Health insurance perspective may led to bias
<b>Soran (2010)</b>	Moderate	Poor quality reporting. Not possible to determine how clinical outcomes were measured or evaluated. It is unclear whether all relevant outcome data have been included
<b>Stauffer (2011)</b>	Poor	For profit, health insurer perspective taken
<b>Stewart (2002)</b>	Moderate	Community-based costs were not measured over the long term,
<b>Tsuyuki (2004)</b>	Moderate	Short follow-up with no incremental analysis
<b>Wootton (2009)</b>	Poor	Poor quality reporting. Cost and outcome data are poorly described and it is unclear whether all relevant costs have been included.

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