Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health technology assessment of chronic disease self-management support interventions

Ischaemic Heart Disease *(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 – Ischaemic heart disease

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

- Based on 14 systematic reviews (244 randomised controlled trials), five broad types of self-management support intervention were identified for patients with ischaemic heart disease. These focused on patient education, exercise, psychosocial or behavioural changes, home-based services or telehealth. 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.
- Good evidence of a statistically significant reduction in mortality was found for exercise programmes (including exercise-based cardiac rehabilitation) in suitable patient cohorts from studies with follow-up periods greater than 12 months. Exercise –based interventions are also associated with fewer rehospitalisations but inconsistent results have been reported for myocardial infarction rates.
- Some evidence was found that patient education programmes are associated with an improvement in interim outcomes such as smoking cessation and reduced blood pressure, but there is uncertainty about how long any such effect persists.
- Limited evidence was found:
    - to demonstrate the effectiveness of behavioural modification interventions, although some have reported positive effects on smoking cessation and symptom management.
    - that comparable home- and telehealth-based cardiac rehabilitation interventions achieve similar outcomes to centre-based interventions.
- Based on 15 costing and cost-effectiveness studies, the economic literature was broadly grouped into four main intervention types: cardiac rehabilitation, case management, telemedicine, and 'other interventions'.
- Compared with no rehabilitation, there is evidence that cardiac rehabilitation can create cost savings as a result of reductions in health care utilisation.
- It is not possible to draw conclusions in relation to the cost-effectiveness of telemedicine-delivered self-management support interventions and nurse-led case management programmes due to the heterogeneity of the interventions assessed and equivocal findings.

- 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 these patients.

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

Exercise-based interventions (including exercise-based cardiac rehabilitation) can reduce mortality and rehospitalisations in selected patients with ischaemic heart disease. The optimal format of these interventions and the duration of effectiveness are still unclear. These interventions can result in modest cost savings through reductions or shifts in healthcare utilisation.

Some evidence was also found that patient education programmes are associated with an improvement in interim outcomes such as smoking cessation and reduced blood pressure. Evidence regarding the clinical and cost-effectiveness of other self-management support interventions for patients with ischaemic heart disease is more limited, or conflicting.

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List of abbreviations used in this report

BRUCIE	Better Regulation Using Carbohydrate and Insulin Education (Diabetes programme)
CBT	cognitive-behavioural therapy
CDSMP	chronic disease self-management programme – Stanford programme
CODE	Community Orientated Diabetes Education (Diabetes programme developed by Diabetes Ireland)
DAFNE	Dose Adjustment For Normal Eating
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (Diabetes Programme)
ES	effect size
EPP	Expert Patient Programme (UK programme based on Stanford model)
HC	health coaching
HTA	health technology assessment
I(C)T	information (and communication) technology
MI	motivational interviewing
NIHR	National Institute of Health Research
PICO	population - intervention - comparator – outcomes
PRISMS	Practical Systematic Review of Self-Management Support
QoL	quality of life
RCT	randomised controlled trial
R-AMSTAR	Revised Assessment of Multiple Systematic Reviews
SD	standard deviation
SMBP	self-monitoring of blood pressure
SMD	standard mean difference
SMS	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.'[1;2]

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.[2;3] 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.[2;4;5] 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.[2] 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.[6] 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

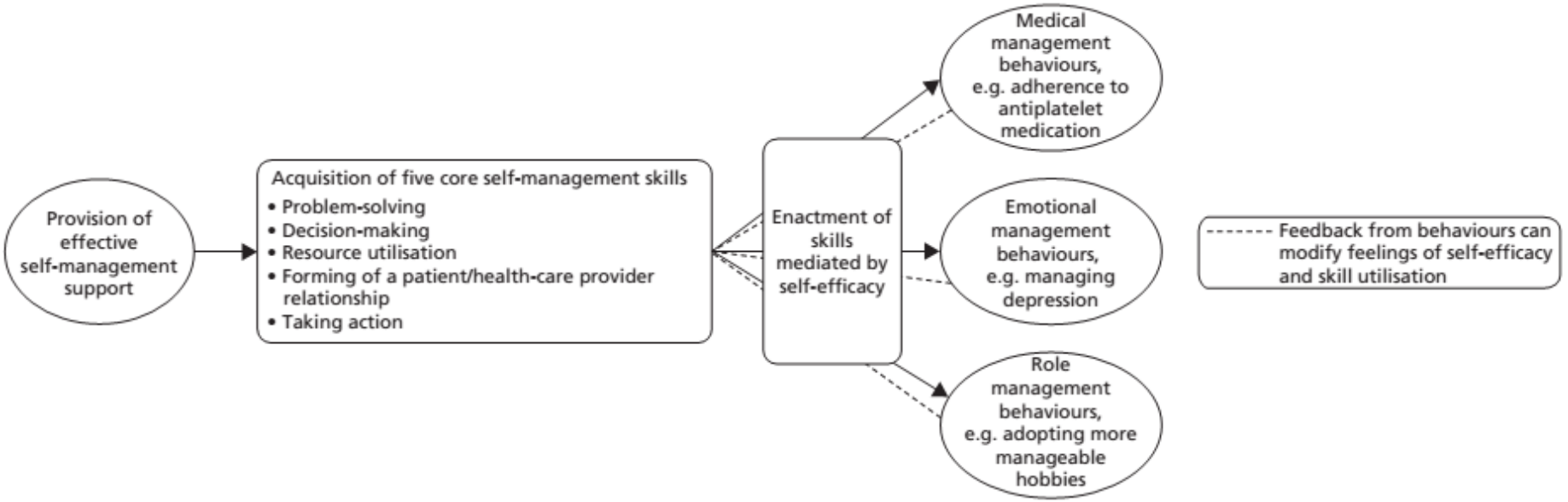
A broad range of self-management and self-management support definitions exist. For this review, the 2003 definitions agreed by the US Institute of Medicine are used:

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).[2;3;5]



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.[7] Disease-specific programmes, where relevant, are discussed in the individual disease-specific sections of this report.

Health behaviour change theories

Trans-Theoretical Theory[7]

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[7]

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[7]

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)[7]

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).[8;9] 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.[(10)] 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.[(11)]

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.[(12)] 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.[(13)] 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.[(13)] 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:[14]

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.[15] 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.[16] 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.[17] 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.'[16;18]

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, cardiovasculuar 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",[(2)] 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.1 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.[(2)] 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

Population	**Phase I:** Adults ≥ 18 years old with at least one chronic disease. This includes common physical conditions such as asthma, COPD, arthritis, diabetes and cardiovascular diseases. **Phase II:** Adults ≥ 18 years old with the specified disease (Type I or Type II diabetes mellitus, asthma, COPD, ischaemic heart disease, heart failure, hypertension or stroke).
Intervention	**Phase I:** Any generic self-management support intervention which helps patients manage aspects of their chronic disease through education, training and support. 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. **Phase II:** Any disease-specific self-management support intervention which helps patients manage aspects of their chronic disease through education, training and support.

[1] 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.
Comparator	Studies where self-management support plus best medical care is compared with best medical care.
Outcomes	▪ Health care utilisation (including unscheduled use of healthcare services – for example, GP visits, emergency department visits, hospital (re)admissions, hospital length of stay) ▪ Patient-centered outcomes relating to patient quality of life, patient satisfaction, self-efficacy ▪ Health outcomes (including biological markers of disease)
Study design	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.[19;20] 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 indicted 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[2]

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..[2]

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[21] and the Jadad Scale.[22] 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.[23] 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[2]

Evidence of effect		
Value	**Probability**	**Evidence of effect**
0	p>0.05	No evidence of effect.
+/–	0.05≥p>0.01	Some evidence of effect in favour of intervention/control.
++/– –	0.01≥p>0.001	Strong evidence of effect in favour of intervention/control.
+++/– – –	p≤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..[2]

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

Population	**Phase I:** Adults ≥ 18 years old with at least one chronic condition. **Phase II:** Adults ≥ 18 years old with the specified disease (Diabetes Type I or Type II, asthma, COPD, ischaemic heart disease, heart failure, hypertension or stroke).
Intervention	**Phase I:** Any generic self-management support intervention that helps patients to manage aspects of their chronic disease care through education, training or support. **Phase II:** Any disease-specific self-management support intervention that helps patients to manage aspects of their chronic disease care through education, training or support.
Comparator	Routine care.
Outcomes	Cost or cost-effectiveness of intervention.
Study design	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.[24] 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).[25] 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.[26]

9 Ischaemic heart disease

This health technology assessment (HTA) of ischaemic heart disease self-management support (SMS) is one of a series of rapid HTAs assessing SMS interventions for chronic diseases. Section 9.1 provides a brief description of ischaemic heart disease followed by separate reviews of the clinical (Section 9.2) and cost-effectiveness (Section 9.3) literature on such interventions for ischaemic heart disease. Brief descriptions of the background and methods used are included with full details provided in a separate document (Chapter 3). Section 9.4 includes a discussion of both the clinical and cost-effectiveness findings. The report concludes with a list of key points in relation to ischaemic heart disease SMS support (Section 9.5).

9.1 Description of the disease

Ischaemic heart disease (IHD) is a chronic condition characterised by narrowing and hardening of the arteries that supply blood to the heart muscle. This occurs as a result of the build up of cholesterol and other materials on the interior wall of the artery, through a process called atherosclerosis. Restriction of blood supply to the heart can result in angina or myocardial infarction. IHD claims around 5,000 lives annually in Ireland, which represents approximately half of all cardiovascular deaths.[286] As well as being associated with significant mortality, it can also weaken the heart muscle over time, which can lead to the development of heart failure and cardiac arrhythmias.

9.2 Review of clinical-effectiveness of self-management support interventions

9.2.1 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 ischaemic heart disease (IHD). 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.

IHD was not specifically addressed in the PRISMS report, and no other existing review of reviews was identified for the disease. This report therefore presents a de novo 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)[287] 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. In addition, while the quality of the primary evidence was not evaluated directly, where reported, information on the risk of bias in the primary studies was extracted from the systematic reviews.

9.2.2 Description of the interventions

A general description of self-management and typical self-management support (SMS) interventions is included in Chapter 2. Interventions specific to IHD introduced in this Phase IIb report include patient education, psychosocial or behavioural therapy and exercise programmes (including exercise based cardiac rehabilitation), 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.'[288] While cardiac rehabilitation services may differ in format and intensity, there is 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.[289] Therefore, cardiac rehabilitation includes elements of self-management support and 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, which may involve varying degrees of self-management depending on whether the exercise training is

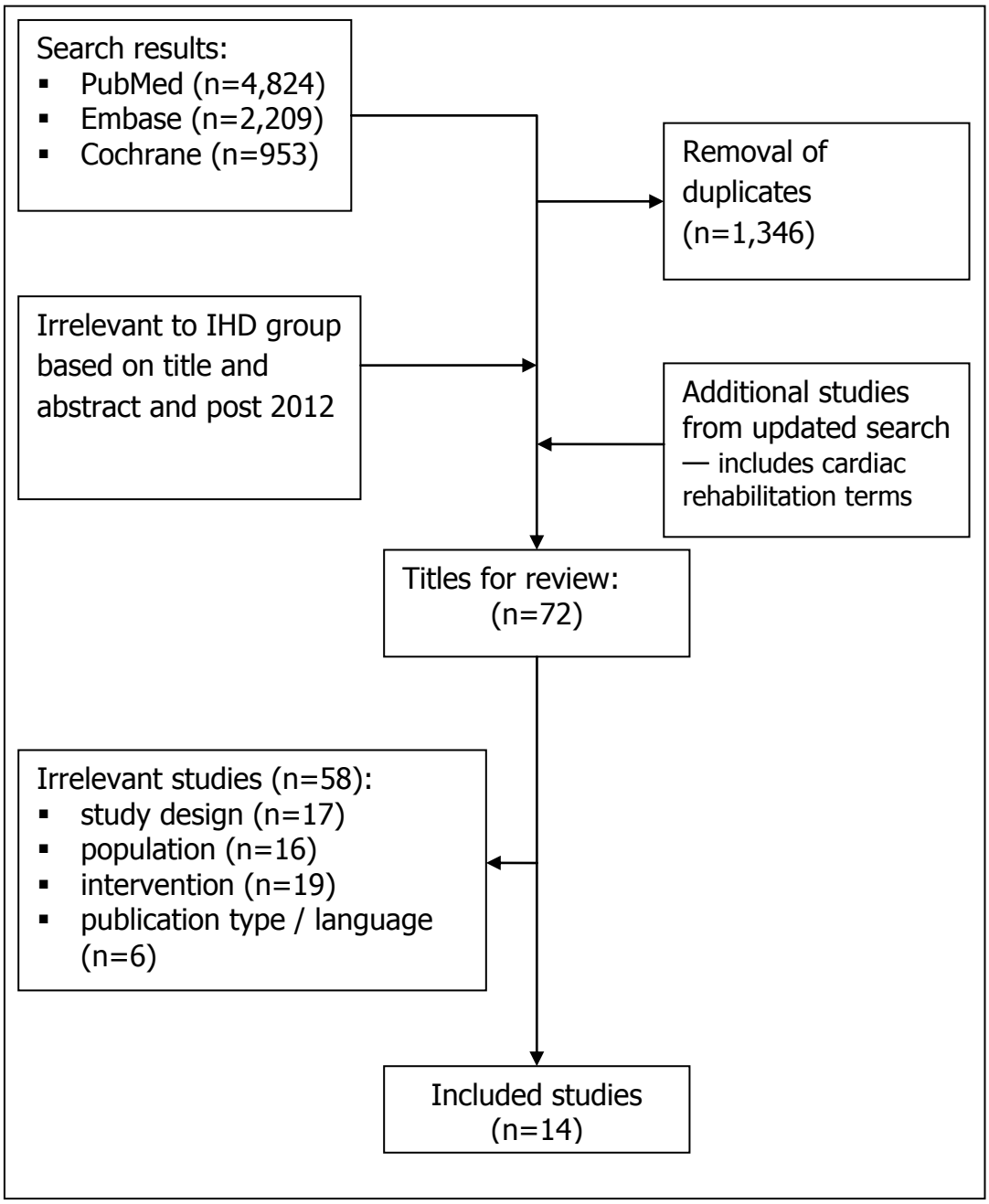
supervised or unsupervised, or takes place in an inpatient, outpatient, community or home-based setting.

9.2.3 Clinical effectiveness results

The search identified 14 systematic reviews of chronic disease self-management support (SMS) interventions for people with ischaemic heart disease (IHD), which were published between 2009 and 2015 and were based on randomised controlled trials (RCTs) published between 1974 and 2012 (see Figure 9.1). The quality of the systematic reviews (R-AMSTAR scores) ranged from 18 to 38 out of a maximum score of 44, with 5 out of 12 achieving a score of 31 or more, indicating a high-quality systematic review.

The identified meta-analyses were also assessed for quality with all assessed as high quality, meaning that they were very likely to have conclusions that accurately reflected the available evidence. Table 9.1 shows the different types of interventions that were assessed. Table 9.2 shows the degree of overlap between reviews and Table 9.3 summarises the results for mortality and hospital admissions.

Figure 9.1 Flowchart of included studies from updated search



Key: IHD = ischaemic heart disease

Table 9.1 Summary of included reviews

Author (year)	Intervention
Patient Education	
Ghisi (2014)[290]	Patient-education interventions
Brown (2013)[291]	Patient-education interventions
Brown (2011) CR[292]	Patient-education interventions
Psychosocial or behavioural interventions	
Barth (2015) CR[293]	Behavioural therapeutic changes with telephone support and self-help material
McGillion (2014)[294]	Supportive coaching, anxiety and stress management or counselling, exercise, nutrition planning, medication review, relaxation training and energy conservation
Whalley (2014)[295]	Psychological intervention
Exercise	
Heran (2011) CR[296]	Exercise plus educational or psychological management (or both) and exercise only
Lawler (2011)[297]	Supervised or unsupervised cardiac rehabilitation programmes that may have included other interventions, which took place in an outpatient, community or inpatient setting.
Home Visit	
Clark (2010)[298]	Home-based interventions, relating to prevention, rehabilitation and support services
Taylor (2010) CR[299]	Home-based cardiac rehabilitation programme
Telehealth	
Huang (2015)[300]	Telehealth delivered cardiac rehabilitation
Kotb (2014)[301]	Telephone support
Neubeck (2009)[302]	Telephone, videoconference or web-based interventions
Combined Interventions	
Cole (2011)[303]	Interventions that involved dietary changes, exercise, education, psychological or organisational changes.

Key: **CR** = Cochrane review

Table 9.2 Study overlap between the included systematic reviews

	Review (year)	1	2	3	4	5	6	7	8	9	10	11	12	13
1	Barth (2015)	**40**												
2	Brown (2011, 2013)	2	**13**											
3	Clark (2010)	0	2	**36**										
4	Ghisi (2014)	7	1	0	**42**									
5	Heran (2011)	1	0	5	0	**47**								
6	Huang (2015)	0	0	5	0	1	**9**							
7	Kotb (2014)	5	1	6	1	0	0	**26**						
8	McGillion (2014)	0	0	1	0	0	0	0	**9**					
9	Neubeck (2009)	2	2	4	0	1	0	5	0	**11**				
10	Taylor (2010)	0	0	7	0	2	4	1	0	0	**12**			
11	Whalley (2014)	1	0	0	1	1	0	2	1	0	0	**24**		
12	Lawler (2011)	3	1	3	0	15	1	0	0	1	2	**1**	**34**	
13	Cole (2011)	2	3	3	2	2	0	1	1	1	0	0	2	**21**

Table 9.3 Quality appraisal and summary of findings from meta-analyses

Review	Quality of systematic review			Primary studies		Quality of meta-analysis	All-cause mortality	Disease-specific mortality	Hospital admissions
	R-AMSTAR Score	Participants	Quality	N =	Low-risk				
Patient education									
Brown (2011, 2013)[291;292]	34	68,556	***	13	2	High	RR 0.79 (0.55 to 1.13)	-	RR 0.83 (0.65 to 1.07)
Ghisi (2014)[290]	18	16,079	**	42	-	N/A	-	-	-
Psychosocial or behavioural interventions									
Barth (2015)[293]	33	7,682	***	40	-	N/A	-	-	-
McGillion (2014)[294]	25	1,282	**	9	-	N/A	-	-	-
Whalley (2014)[295]	26	9,296	**	24	5	High	RR 0.89 (0.75 to 1.05)	RR 0.80 (0.64 to 1.00)	-
Exercise									
Heran (2011)[296]	33	10,794	***	47	4	High	RR 0.87 (0.75 to 0.99)	RR 0.74 (0.63 to 0.87)	RR 0.69 (0.51 to 0.93)
Lawler (2011)[297]	28	6,111	**	34	-	High	OR 0.74 (0.58 to 0.95)	OR 0.64 (0.46 to 0.88)	-
Home visit									
Clark (2010)[298]	24	8,297	**	36	0	High	RR 1.08 (0.73 to 1.60)	-	-
Taylor (2010)[299]	38	1,938	***	12	1	High	RR 1.31 (0.65 to 2.66)	-	-

Telehealth									
Huang (2015)[300]	26	1,546	**	9	2	High	RR 1.15 (0.61 to 2.19)	-	-
Kotb (2014)[301]	23	4,081	**	26	14	High	OR 1.12 (0.71 to 1.77)	-	OR 0.62 (0.40 to 0.97)
Neubeck (2009)[302]	27	3,145	**	11	Not reported	Moderate	RR 0.70 (0.45 to 1.10)	-	-
Combined interventions									
Cole (2011)[303]	29	10,972	**	21	-	Low	RR 0.75 (0.65 to 0.87)	RR 0.63 (0.47 to 0.84)	-

Abbreviations: **OR** = odds ratio; **RR** = risk ratio.

9.2.3.1 Summary of findings

This section provides a narrative summary of the findings, relevance and applicability of the included reviews for each type of IHD self-management intervention. A detailed account of the data extracted from each review is provided in Appendix A9.1.

9.2.3.2 Patient education interventions

Three reviews of patient education interventions were identified, all of which had combined sample sizes of over 1,000 patients.[290-292] Two reviews that had R-AMSTAR scores of 31 or more (indicating a high-quality review), were found to be duplicate reports of the same evidence.[291;292]

Three star (***) reviews

A 2011 Cochrane review (13 RCTs [n=68,556 patients]) of patient education in the management of coronary heart disease reported no significant effect on all-cause mortality, myocardial infarction, revascularisation rates or hospitalisation rates. While the review did find increased quality of life scores in some domains, there was no consistent evidence of superiority.[291;292]

Two star (**) reviews

A 2014 qualitative review (42 RCT, n=16,079 patients) examined the effect of patient education on a range of intermediate outcomes such as patient knowledge, physical activity, dietary habits and smoking cessation rates.[290] This review included observational studies as well as RCTs. Of the six RCTs that assessed patient knowledge: four reported a statistically significant positive effect compared with controls, one reported a beneficial effect at four months that had disappeared at one year, and one reported no difference in effect.

Patient-education interventions were found to be associated with a significant beneficial effect in: 77% of all studies that reported physical activity outcomes, 84% of all studies reporting dietary habits, and 65% of all studies reporting smoking cessation rates.

Summary statement for patient education interventions

Based on the quantity and quality of the systematic reviews and the underpinning primary randomised controlled trials, there is short-term evidence that patient-education interventions are associated with an improvement in interim outcomes such as physical activity, dietary habits and smoking cessation.

9.2.3.3 Psychosocial or behavioural interventions

Three reviews examined the impact of psychosocial or behavioural interventions in ischaemic heart disease .[293-295] The total sample size in each of these was greater than 1,000. However, only one had an R-AMSTAR score of 31 or more.

Three star (***) reviews

A 2015 Cochrane review specifically examined psychosocial interventions for smoking cessation. Based on 40 randomised controlled trials (RCTs) (n=7,682 participants), it reported a positive effect of interventions on abstinence after 6 to 12 months, with a relative risk (RR of 1.22 [95% CI 1.13 to 1.32]).[293]

Two star (**) reviews

Two reviews examined the effect of psychosocial or behavioural interventions on ischaemic heart disease symptoms, quality of life and psychological outcomes. One narrative review based on nine RCTs (n=1,282) found a significant improvement in the frequency of angina symptoms, a reduction in the use of sublingual nitrates, as well as improvements in physical limitation and depression scores.[294] This review reported no effect on angina stability, disease perception, or treatment satisfaction. The other review — published the same year, 2014 — and comprising 24 RCTs (n=9,296) reported no strong evidence that psychological intervention reduced total deaths, risk of revascularisation, or non-fatal infarction.[295] However, it noted psychological intervention did result in small to moderate improvements in depression and anxiety, and there was a small effect for cardiac mortality.

Summary statement for psychosocial or behavioural interventions

Based on the quantity and quality of the systematic reviews and the underpinning primary randomised controlled trials, there is limited evidence to demonstrate the effectiveness of behavioural modification interventions, although some have reported positive effects on smoking cessation and symptom management.

9.2.3.4 Exercise interventions

Two reviews examined clinical outcomes associated with exercise programmes. As outlined earlier (in section 9.2.3.1), exercise interventions are nowadays considered a central component of 'standard' cardiac rehabilitation programmes.

Three star (***) reviews

One high-quality Cochrane systematic review of exercise interventions for ischaemic heart disease was identified. The intervention arm in the studies included exercise

training alone or exercise training in addition to psychosocial and or educational interventions (that is, comprehensive cardiac rehabilitation) and could be supervised or unsupervised. The intervention arm could also be delivered in a variety of settings (inpatient, outpatient, community or home-based) and be of varying intensity.

The control arm included standard medical care such as drug therapy, but did not receive any form of structured exercise training or advice. Pooled analysis from studies with follow-up periods of greater that 12 months showed that compared with no structured exercise training or advice, exercise-based interventions reduced overall mortality and cardiovascular mortality (RR 0.87 [95% CI 0.75 to 0.99] and RR 0.74 [95% CI 0.63 to 0.87] respectively).[296]

A positive effect on hospital admissions was evident from studies with a follow-up period of less than 12 months (RR 0.69 [95% CI 0.51 to 0.93]). Exercise-based interventions did not reduce the risk of total myocardial infarction, coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA). In seven out of 10 trials reporting health-related quality of life using validated measures, there was evidence of a significantly higher level of quality of life with exercise-based interventions than with usual care.[296]

Two star (**) reviews

One other systematic review was identified that assessed exercise-based cardiac rehabilitation post-myocardial infarction. This review was judged by the HTA reviewers to be of lower quality. The intervention arm in the RCTs included: exercise-only cardiac rehabilitation, exercise-based cardiac rehabilitation as part of a comprehensive secondary prevention programme or both in two independent intervention arms, and had a minimum intervention duration of two weeks and a minimum follow up of 12 weeks.

All trials included a non-exercising control arm. This review also found evidence of a reduction in mortality associated with exercise-based programmes (OR 0.74, 95% CI 0.58 to 0.95).[297] A subgroup analysis found that this reduction was only evident in studies with a follow-up period of greater than one year. This analysis also reported statistically significant reductions in disease-specific mortality (OR 0.64, 95% CI 0.46 to 0.88) and re-infarction rates (OR 0.54, 95% CI 0.38 to 0.76).

Summary statement for exercise interventions

There is good evidence from studies with follow-up periods of greater than 12 months of a statistically significant reduction in mortality for exercise programmes in suitable patient cohorts. Exercise-based interventions are also associated with fewer hospitalisations, but inconsistent results have been reported in myocardial infarction rates.

9.2.3.5 Home visit interventions

Two reviews of home-based interventions for the management of ischaemic heart disease were identified.[298;299] The combined sample size of each of these exceeded 1,000 patients, but only one had an R-AMSTAR score over 30.[299]

Three star (***) reviews

A 2010 Cochrane review found no difference in outcomes of home versus centre-based cardiac rehabilitation on mortality, cardiac events, exercise capacity or non-modifiable risk factors (blood pressure, cholesterol) or proportion of smokers at follow-up or health-related quality of life.[299] Neither was there a consistent difference in healthcare costs.

Two star (**) reviews

A separate systematic review of RCTs published in 2010 also found no statistically significant effect of home-based programmes on mortality or the rate of cardiovascular events.[298] However, compared with usual care, home-based interventions significantly improved quality of life, systolic blood pressure, smoking cessation and total cholesterol. Home-based secondary prevention interventions are formalised interventions for the secondary prevention of coronary heart disease (CHD) with predominant or exclusive home-based components, which can be provided in a range of ways including paper, face-to-face, electronic, or telephone-based methods.[298] Usual care was defined as normal healthcare and or risk factor management at the time the trial was undertaken without supplementary secondary prevention intervention. Cardiac rehabilitation was defined as dedicated secondary prevention programmes provided by healthcare professionals in an acute (hospital) or community care provider setting.[298] The authors reported that comparisons between home-based interventions and cardiac rehabilitation could not be made because of the small number of trials and high levels of heterogeneity.

Summary statement for home visit interventions

There is limited evidence that home-based and centre-based interventions have comparable outcomes.

9.2.3.6 Telemedicine interventions

Three reviews of telemedicine interventions in ischaemic heart disease were identified in the search, all of which included studies with a combined total of more

than 1,000 patients. However, none had an R-AMSTAR score of greater than 31.[300-302] Two studies compared telehealth interventions to usual care and one compared telehealth interventions to supervised, centre-based programmes.

Two star (**) reviews

Of the two with the usual care comparator, one only included telephone-based interventions and found no difference in mortality or cholesterol levels. However, it did report fewer hospitalisations (OR 0.62 [95% CI 0.40 to 0.97]), better smoking cessation rates (OR 1.32 [95% CI 1.07 to 1.62]), reduced blood pressure and lower depression and anxiety scores (standardised mean difference (SMD) 20.10 [20.21 to 20.00] and SMD 20.14 [20.24, 20.04], respectively).[301] The other review compared any telehealth intervention (telephone, Internet, and videoconferencing) to usual care, also finding no statistically significant difference in mortality (RR 0.70 [95% CI 0.45 to 1.1]), but beneficial effects on total cholesterol levels (weighted mean difference (WMD) 0.37 mmol/l [95% CI 0.19 to 0.56]), systolic blood pressure (WMD 4.69 mmHg [95% CI 2.91–6.47]) and smoking cessation (RR 0.84 [95% CI 0.65 to 0.98]).[302]

The final review compared cardiac rehabilitation provided using telehealth to centre-based cardiac rehabilitation. This review found no statistically significant difference in any of the outcomes examined, which included mortality, blood pressure, lipid profile, smoking, exercise capacity, weight and quality of life.[300] Non-inferiority of telehealth outcomes would be advantageous if the cost of this type of intervention was lower than supervised, centre-based cardiac rehabilitation. However, the review found that although the evidence was limited, the costs of both type of intervention appear to be similar.

Summary statement for telemedicine interventions

There is limited evidence that telemedicine and centre-based interventions have comparable outcomes.

9.2.3.7 Combined interventions

Two star (**) reviews

One systematic review that examined the clinical effectiveness of interventions that included dietary advice, exercise, psychological or educational interventions, and organisational improvements reported statistically significant improvements in all cause and cardiovascular mortality (RR 0.75 [95% CI 0.65 to 0.87] and RR 0.63 [95% CI 0.47 to 0.84] respectively). It also reported a reduction in non-fatal cardiac events such as myocardial infarction or revascularisation procedures (RR 0.68 [95% CI 0.55 to 0.84]).[303] However, a limitation of these multifactorial interventions is an

inability to determine the relative contribution of each of the different elements of the interventions to the improved outcomes reported.

Summary statement for combined interventions

There is moderate quality evidence that interventions that combine multiple types of chronic disease self-management interventions are associated with improved outcomes. However, the relative impact of each component of these interventions is unclear.

9.3 Review of cost-effectiveness of SMS interventions

A review of cost-effectiveness studies was undertaken to assess the available evidence for self-management support interventions for patients with ischaemic heart disease . Studies were included if they compared the costs and consequences of an SMS intervention with routine care.

9.3.1 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 undertaken up until 4 March 2015.

The PICOS (Population, Intervention, Comparator, Outcomes, Study design) analysis used to formulate the search is presented in Table 9.4 below.

Table 9.4 PICOS analysis for identification of relevant studies

Population	Adults greater than or equal to [≥] 18 years old that had ischaemic heart disease .
Intervention	Any self-management support intervention that helps patients with ischaemic heart disease through education, training or support.
Comparator	Routine care.
Outcomes	Cost or cost-effectiveness of the intervention.
Study design	Randomised controlled trials, case-control studies, observational studies, economic modelling studies.

Study types were excluded if:

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

9.3.2 Cost-effectiveness results

The initial screening retrieved 41 papers relating to ischaemic heart disease. Of these, fifteen studies were identified for full text review, with the remaining 27 excluded as irrelevant or unsuitable based on screening of abstract or full text. There were three studies from the US, four from the UK, two from Australia, and one from Denmark, Netherlands, Belgium, Italy and Germany. The included studies were all published between 2003 and 2015. The characteristics of the included studies are given in Table 9.5.

Table 9.5. Characteristics of the included studies

Study	Country	Intervention
Ballegaard (2004)[304]	Denmark	Cardiac rehabilitation
Barley (2014)[305]	UK	Case management
Berndt (2015)[306]	Netherlands	Telemedicine
Briffa (2005)[307]	Australia	Cardiac rehabilitation
Dendale (2008)[308]	Belgium	Cardiac rehabilitation
Furze (2012)[309]	UK	Lay-facilitated angina management
Ito (2012)[310]	US	Multiple interventions
Jolly (2007)[311]	UK	Cardiac rehabilitation
Ladapo (2011)[312]	US	Smoking cessation
Marchionni (2003)	Italy	Cardiac rehabilitation
Reid (2005)[313]	US	Cardiac rehabilitation
Seidl (2014)[314]	Germany	Case management
Taylor (2007)[315]	UK	Cardiac rehabilitation
Turkstra (2013)[316]	Australia	Telemedicine
Raftery (2005)[317]	UK	Nurse-led secondary prevention programme

The studies were classified according to the type of intervention assessed: cardiac rehabilitation, case management, telemedicine, and 'other' interventions (including complex interventions, and nurse-led, pharmacist-led and lay-led education interventions). Some studies combined elements of different intervention types.

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. Cost effectiveness results from each included study reported in this section were converted to 2015 euro.

9.3.2.1 Cardiac rehabilitation

Seven studies were retrieved that evaluated cardiac rehabilitation. See Table A9.3 in the appendices for a summary of the study details and results. One was a cost-utility analysis, while the remaining six were costing or cost-minimisation studies. Two of the studies were from the UK with one each from the US, Australia, Italy, Belgium and Denmark. In three studies, the comparator was no cardiac rehabilitation (routine care), while for the other four studies, the comparator was different modes of delivery of cardiac rehabilitation (home- versus hospital-based rehabilitation [n=3], and intensive versus dispersed rehabilitation [n=1]). Study follow-up ranged from nine months to 13 years.

A 2005 study carried out in Australia by Briffa et al.[307] compared an 18-session comprehensive exercise-based outpatient cardiac rehabilitation programme with conventional care (no cardiac rehabilitation) in 113 patients with ischaemic heart disease aged 41–75 years who had experienced an acute coronary syndrome. Patients allocated to rehabilitation were offered a six-week package of sessions three times a week, each comprising 60–90 minutes of supervised exercise, combined with 45 minutes of education (12 occasions) and 45 minutes of psychosocial counselling (six occasions).

Sessions were conducted in groups (maximum of 15 people) and, if necessary, additional one-to-one counselling was provided. Non-exercise sessions addressed symptom management, pharmacological treatment, healthy eating, psychosocial counselling and stress management delivered by a clinical nurse consultant, physiotherapist, clinical psychologist, dietician, social worker or pharmacist. Rehabilitation costs of €647 per patient were offset by a reduction in follow-up costs of €242, resulting in a non-significant (p=0.75) increase in costs of €405 per patient compared with the control group. Gains in utility scores from baseline were observed for both the intervention and control groups at 6 and 12 months. While the estimated improvement in utility was higher in rehabilitation patients at 12 months, the difference between improvements in the conventional and rehabilitation groups was not significant (p = 0.38). The estimated gain in QALYs was 9.289 per 1,000 patients up to 12 months for the intervention group, providing an incremental cost-effectiveness ratio (ICER) of €43,589 per QALY saved. The intervention was suggested to be an effective treatment and although non-significant advantages were reported in terms of quality of life, the cost of delivering rehabilitation was low.

A 2008 Belgian study by Dendale et al.[308] compared a cardiac rehabilitation programme for patients' post-percutaneous coronary intervention (PCI) with standard care (no cardiac rehabilitation). The intervention comprised a three-month rehabilitation programme comprising 24 one-hour supervised exercise training sessions, dietary and psychological counselling as well as counselling to participate in an eight-week smoking cessation programme where applicable. The study took the perspective of the healthcare provider and evaluated patients over a 4.5 year follow-up period. The study estimated that the cost of one cardiac rehabilitation session to be €27 per patient.

The cardiac rehabilitation programme resulted in a significant reduction in hospitalisations for angina (75% versus 45%, p<0.05) and coronary revascularisations (17% versus 7%, p<0.05). However, a significant (p<0.05) increase in non-fatal myocardial infarction was reported (2.5% versus 7.5%). Overall, the intervention resulted in a lower incidence of cardiac events with an incidence rate of 0.93 compared with 1.52 for the control group. The total cost for

the intervention and control groups were €5,655 per patient and €6,395 per patient, respectively, a difference of €636, with the difference in cost being attributed to reduced hospitalisations for angina and repeat PCI in the intervention group.

A home-based cardiac rehabilitation programme using a 'Heart Manual' was compared with conventional centre-based cardiac rehabilitation in the 2007 UK study by Jolly et al.[311]. The study recruited patients who had experienced an MI or coronary revascularisation within the previous 12 weeks from four hospitals in predominantly inner-city, multi-ethnic, socio-economically deprived areas for a randomised controlled trial with a 24-month follow-up period. The mean cost per home-based cardiac rehabilitation patient was €337, approximately 25% above that of the hospital arm of €267. No differences in primary or secondary clinical outcomes were reported during the trial period. Incremental QALYs reported after the 24-month period for home-based and centre-based care were 0.731 and 0.753, respectively, a difference of 0.022. Discounting of costs or benefits was not reported. The study reported costs from both a societal and health service perspective.

From a National Health Service (NHS) perspective, the home-based arm was more costly than the hospital-based arm. From a societal perspective, however, the inclusion of patient travel costs and travel time increased the mean cost of the hospital-based arm to €308. The study concluded that for low to moderate risk patients with ischaemic heart disease , a home-based cardiac rehabilitation programme does not produce inferior outcomes compared with the traditional centre-based programmes. With the level of home visiting in this trial, the home-based programme was more costly to the health service, because costs associated with the centre-based programmes were borne by the patients who incurred substantial out-of-pocket travel costs.

Additionally, a cost-effectiveness analysis was undertaken in the 2007 UK study by Taylor et al.[315] to evaluate home- versus hospital-based cardiac rehabilitation. Using the perspective of the healthcare system, the study compared the costs and consequences for 104 patients with an uncomplicated acute myocardial infarction and without major co-morbidity randomised to home-based ('Heart Manual') or hospital-based rehabilitation over a nine-month follow-up period. The cost of the home and hospital-based rehabilitation interventions were €279 and 328 per patient, respectively. Therefore, home-based cardiac rehabilitation was €51 per patient less than for the hospital-based group. Mean utility values for the home and hospital groups were comparable at baseline (0.76 vs. 0.74), and nine months (0.74 vs. 0.78), with no significant difference between the groups (p=0.06). Overall healthcare costs for the home and hospital-based groups did not differ significantly.

Although the evidence presented seems to favour hospital-based cardiac rehabilitation, the authors noted that the findings were not conclusive due to the small sample size, short duration of follow up and high variability in healthcare costs between patients. Further sensitivity analysis found that simulations included all four-quadrants of the cost-effectiveness plane and ranged from a small QALY gain and lower cost in favour of hospital-based rehabilitation to a small QALY gain and lower cost in favour of home-based rehabilitation.

The 2005 US study by Reid et al.[313] aimed to determine the most efficient delivery of cardiac rehabilitation. To achieve this, the study compared standard care (33 sessions over three months) with distributed care (33 sessions over 12 months) delivery. At two years, the total direct costs of the distributed rehabilitation were €6,073 (€875 for programme delivery + €5,198 for cardiac healthcare costs) versus €5,918 for standard cardiac rehabilitation (€785 for programme delivery + €5,132 for cardiac healthcare costs). There were no clinically meaningful or statistically significant differences between the groups for outcomes at 12 or 24 months; however, generic and heart disease health-related quality of life (HRQoL) were noted to improve for both groups.

9.3.2.2 Telemedicine programmes

Two studies were retrieved that evaluated telemedicine programmes. Both were cost-utility studies that collected cost and utility data alongside randomised controlled trials (RCTs). The studies were from the Netherlands and Australia, and had trial follow-up periods of six months. See Table A9.4 in the appendices for a summary of the study details and results.

The 2013 Australian RCT (n=430) by Turkstra et al.[316] evaluated a telephone-delivered health-coach intervention versus usual care as secondary prevention for adult myocardial infarction patients. Primary outcome variables were health-related quality of life (HRQoL) and physical activity levels. The intervention consisted of ten 30-minute scripted telephone health coaching sessions over a six-month period from a qualified health professional or 'health coach'. Usual care involved providing existing written educational resources. The cost of the health coach was €26 per session, which accounted for little of the overall costs. The major difference in costs between groups was the cost for hospitalisation, with higher average hospitalisation costs (€4,893 versus €3,565) and total treatment costs (€7,563 versus €6,104) for patients randomised to the intervention group. Compared with usual care, the intervention was more costly (increase of €1,459) and more effective (0.012 additional quality adjusted life years [QALYs]), generating an incremental cost-effectiveness ratio (ICER) of €61,102 per QALY. It was concluded that the telemedicine intervention was not a cost-effective intervention in the short-term compared with usual care.

In a 2015 Dutch study, Berndt et al.[306] compared usual care with a combination of telephone or face-to-face smoking cessation counselling in addition to nicotine replacement therapy in ischaemic heart disease patients. This RCT (n=625) with six-month follow up included patients over 18, who were recently hospitalised and who smoked five or more cigarettes on average per day prior to admission or quit smoking less than four weeks prior to admission. Usual care comprised a risk assessment, advice to quit smoking, and occasionally written educational material; no follow up was included. Telephone counselling lasted for three months and consisted of seven telephone calls of 10 to 15 minutes each. Face-to-face counselling delivered by nurses comprised six sessions of 30 to 45 minutes each over three months and concluded with a follow-up call five weeks after the last session. Compared with usual care, a significantly higher proportion of patients in the telephone group and face-to-face-based counselling groups achieved continued abstinence (37.9%, 54.1%, 51.6%, respectively) and seven-day abstinence (41.5, 57.1, 54.9, respectively) at six-months follow-up. The cost-utility analysis was undertaken from the societal perspective with results reported as costs per QALY. Telephone counselling had lower costs and slightly higher effects than either usual care or face-to-face counselling, and thus dominated the other treatments. In contrast, face-to-face counselling was dominated by usual care as it was more costly and less effective. The reported QALYS for usual care, telephone- and face-to-face-based counselling were 0.489, 0.491 and 0.487 respectively, while societal costs were €9,372, €8,293and €9,175 respectively.

The authors concluded that assuming a willingness-to-pay of €20,000 per abstinent patient, telephone counselling combined with nicotine replacement therapy would be a highly cost-effective smoking cessation intervention assisting cardiac patients to quit. However, they highlighted the lack of consensus concerning the willingness-to-pay per quitter and noted that studies with extended follow-up periods are needed to capture late relapses and possible differences in QALYs.

9.3.2.3 Case management

Two studies were identified that evaluated the cost-effectiveness of nurse-delivered case management programmes for patients with ischaemic heart disease . The studies from Germany and the UK gathered cost and utility data alongside RCTs with 12-month follow-up. See Table A9.5 in the appendices for a summary of the study details and results.

A nurse-based case management programme for elderly patients (65 years and older) with a recent myocardial infarction (n=329) was evaluated in a 2014 paper by Seidl et al.[314]. The intervention comprised at least one home visit and quarterly telephone calls, with additional visits and calls according to the patient's needs and risk levels. Usual care comprised regular physician visits, in-hospital cardiac

rehabilitation and or long-term disease management programmes offered by health insurance companies. On average, patients received 1.41 home visits and 3.85 telephone interviews in the intervention group. The cost of the intervention was estimated at €145 per patient. Utility scores measured using the EQ-5D-3L were significantly increased from baseline in the intervention group at month three (0.077) and month six (0.0509), but returned towards baseline levels by month 12.

The mean QALY difference at 12 months, adjusted for gender, age in groups and number of co-morbidities, between the intervention and control groups was -0.0163 (p=0.536). Total costs for the intervention and control groups were €9,223 and €9,881, respectively; the average overall cost difference per patient at 12 months was -€20 (p=0.9856). Direct healthcare costs were driven by hospitalisation costs (60%), which were not significantly lower in the intervention group (-€466). The study concluded that the case management intervention was not an effective or cost-effective alternative to usual care within a time horizon of one year.

A 2014 UK pilot study by Barley et al.[305] evaluated the UPBEAT programme for adults with symptomatic coronary heart disease, reporting symptoms of depression. This was a multi-centre outcome assessor-blinded, parallel group study (n=81) with eligible patients randomised to personalised care or treatment as usual for six months and followed for one year. The intervention consisted of standardised, face-to-face, biopsychosocial assessments by nurse case managers, the results of which were used to help patients to increase their self-efficacy to achieve their desired goals. Follow-up telephone interviews to determine progress and or set new goals were conducted initially weekly then at increasing intervals according to patient need. A unit cost of GBP £36 per hour was attached to the average intervention duration for each patient. The total cost of the personalised care and control groups at baseline was €2,322 and €4,721, respectively; this decreased after six months to €1,090 and €1,560, respectively, increasing after 12 months to €1,425 and €2,638, respectively. Both groups improved on all outcomes. The largest between-group difference was in the proportion no longer reporting chest pain (personalised care 37% versus control 18%; OR 2.21 95% CI 0.69-7.03) with some evidence that self-efficacy (mean scale increase of 2.5 versus 0.9) and illness perceptions (mean scale increase of 7.8 versus 2.5) had improved compared with the control group at one year.

While the intervention demonstrated good acceptability and feasibility, there were no significant differences between groups on any measure of depression, in the proportion reporting chest pain, or in resource use or utility scores at six or 12 months. This pilot study was underpowered to detect between group differences over time. The authors calculated an incremental cost-effectiveness ratio (ICER) of €39,193 per additional QALY. The point estimate of the incremental cost-

effectiveness ratio fell in the south-western (SW) quadrant, representing the situation where the personalised care group has reduced costs and worse outcomes. The authors concluded that personalised care appeared to be more cost-effective up to a QALY threshold of approximately £3,000.

9.3.2.4 Other self-management support interventions

Four additional studies evaluating different SMS interventions were identified. Two economic modelling studies from the US assessed interventions to improve medication adherence and smoking cessation, respectively. The third study, also an economic modelling study, from the UK assessed a lay-facilitated angina management programme. The fourth was a UK cost-effectiveness analysis of nurse-led secondary prevention clinics for coronary heart disease based on four years' follow up of a randomised controlled trial. See Table A9.6 in the appendices for a summary of the study details and results.

A 12-week lay-facilitated angina management programme was compared with usual care (routine advice and education from a specialist nurse) in a 2012[309] pragmatic RCT (n=142) in the UK of patients with new stable angina. The intervention consisted of stress management and a relaxation programme combined with a 45-minute individual educational session delivered by trained lay facilitators that focused on goal setting to increase physical activity and reduce behavioural risks. Progress was tracked with brief follow-up telephone calls (10-15 minutes) or home visits as agreed between the facilitator and participant. There was no important difference in angina frequency at six months. The intervention group had significantly higher mean quality of life as measured by EQ-5D index scores, at both three (0.82 [0.21] versus 0.70 [0.28], p=0.01) and six months 0.82 [0.24] versus 0.68 [0.32], p=0.008). The remaining outcomes (anxiety, depression, angina misconceptions) were not significantly different between the two groups.

In the regression model, the average cost per patient in the control group was €1,743 compared with €2,071in the intervention group, however, the difference between the two groups was not significantly different. There was a statistically significant difference in average QALY per patient of 0.045 (CI: 0.005–0.085). The authors concluded that at a willingness-to-pay threshold of €27,680 per QALY, the intervention had an 80% probability of being cost-effective.

A 2012 US modelling study by Ito et al.[310] evaluated the comparative cost-effectiveness of interventions to improve adherence to prescribed secondary prevention medications among post-myocardial infarction (MI) patients. The interventions were categorised by different targets for adherence improvement: informational (mailed education), behavioural (disease management), or complex (polypill combined with either mailed education or disease management).

All the interventions were compared with usual care, defined as the absence of adherence interventions. The analysis found that all the interventions resulted in a higher total QALY gain than usual care. Compared with usual care, only mailed education had both improved health outcomes and reduced spending. In an incremental analysis, only mailed education had an ICER of less than €92,053 per QALY and was therefore identified as the optimal strategy. It was noted that polypill use, particularly when combined with mailed education, could be cost-effective, and potentially cost saving if its price decreased to less than €92 per month.

Using a Monte Carlo model, the 2011 US study by Ladapo et al.[312] evaluated a smoking cessation intervention for a hypothetical US cohort of 327,600 smokers that had been hospitalised with acute myocardial infarction. The study, which was undertaken from a societal perspective, compared routine care (consisting of advice to quit smoking) with nurse-led counselling plus supportive telephone follow-up post discharge. The programme was estimated to cost €530 per quitter and €19,447 per acute myocardial infarction avoided (considering only intervention costs), generating an ICER of €4,272 per life-year and €4,960 per QALY gained. It was concluded that nurse-led smoking cessation counselling with post-discharge support had the potential to be cost-effective relative to the usual care.

Finally, a cost-effectiveness analysis of a nurse-led secondary prevention programme for ischaemic heart disease patients that was based on four years of follow-up data from a UK RCT found that the intervention was likely to be highly cost effective, with an ICER of €2,015/QALY.[317]

9.4 Discussion

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

9.4.1 Clinical effectiveness

Exercise programmes were the only intervention for which a statistically significant beneficial effect on mortality was found. In the only high-quality review that reported this significant result, the control groups receiving usual care were given advice about diet and exercise, but no formal exercise programme. There was a high degree of heterogeneity in the intervention groups, which differed considerably in programme duration (range 1–30 months), exercise frequency (1–7 sessions per week), and exercise session duration (20–90 minutes per session). The effect was only evident in studies that had greater than 12-months' follow-up, which gives an indication of the minimum time frame needed in order to realise the beneficial effect of these types of programmes. This study also found reductions in hospitalisation rates over a shorter time horizon. Interestingly, despite reduced mortality and hospitalisation rates, the intervention had no significant effect on the rate of myocardial infarction or revascularisation rates (percutaneous transluminal coronary angioplasty [PTCA] or coronary artery bypass graft [CABG]). Another, moderate quality, review of exercise programmes also found a reduction in all-cause mortality, as well as a reduction in the rate of reinfarction. A review of interventions that combined multiple types of interventions, including exercise, in the same self-management programme also reported reductions in all-cause and disease-specific mortality.

The degree to which exercise-based self-management support interventions can be considered separate to standard cardiac rehabilitation is questionable, as exercise is a core component of cardiac rehabilitation programmes.[288] The evidence presented here is specific to the exercise component as it compares exercise-based interventions (including exercise-only cardiac rehabilitation and exercise as part of comprehensive cardiac rehabilitation) with a non-exercise intervention arm. It is likely that exercise interventions of some sort are already provided through cardiac rehabilitation services.

There is some evidence to show that patient education programmes may be beneficial in terms of achieving their immediate goal of raising the level of awareness and understanding that patients have about their disease, as well as their ability to make positive changes to their diet and lifestyle. However, there is a lack of evidence that these are translated into changes in meaningful clinical outcomes. This may be partly related to uncertainty about the persistence of such effect in the long

term, with a beneficial effect reported at four months not being maintained at 12 months.

A Cochrane review of service organisation for the secondary prevention of ischaemic heart disease in primary care was not included in this review as it focussed primarily on service organisation rather than self-management strategies.[318] This review did, however, include studies that looked at improving patient education along with regular planned recall of patients for appointments, structured monitoring of risk factors and prescribing, and found weak evidence that these are associated with improvements in cholesterol and blood pressure control.

Limited evidence was found to demonstrate the effectiveness of behavioural modification interventions, although some researchers have reported positive effects on smoking cessation and symptom management.

The choice of comparator is particularly important when considering the effectiveness of telehealth or home-based interventions. Studies comparing the intervention with a standard of care that does not involve a structured cardiac rehabilitation are reporting the incremental effect of both the programme and the methods used to deliver it, rather than the incremental benefit of the mode of delivery itself. A review that compared home-based interventions with usual care found improvements in quality of life, blood pressure, cholesterol and smoking cessation. It is impossible in these types of comparisons to separate the effect of the cardiac rehabilitation programme from the effect of its mode of delivery.

In contrast, another review compared home-based versus centre-based cardiac rehabilitation programmes and found that there was no discernible difference in clinical outcomes. This would imply that it is the cardiac rehabilitation, rather than the fact that it is carried out at home, that is the most important factor. Similarly, when telehealth interventions are compared with usual care there appears to be a beneficial effect on some intermediate outcomes such as blood pressure and smoking cessation. However, when the mode of delivery is examined in isolation, by providing the same basic programme to both intervention and control groups, but varying how it is delivered (telehealth or centre-based), no difference in clinical outcomes were reported.

The findings of a 2014 Cochrane overview summarising six Cochrane reviews of cardiac rehabilitation for people with heart disease (ischaemic heart disease and heart failure) are consistent with the evidence presented here. This found that exercise-based cardiac rehabilitation interventions with over 12-months' follow up were associated with a beneficial effect on both overall and cardiovascular mortality; psychological and education-based interventions appear to have little impact on mortality or morbidity, but may improve HRQL. Home- and centre-based

programmes are equally effective in improving HRQL at similar costs. The authors concluded that exercise-based cardiac rehabilitation is effective and safe in the management of clinically stable CAD patients.[319]

Assuming that the comparator (usual care) in the primary literature on which these systematic reviews are based is representative of usual care in Ireland, it would appear that the evidence should be broadly applicable to the Irish healthcare setting given the description of the patient populations and the healthcare systems in which the interventions were provided. With the increasing tendency for usual or standard of care to be determined by evidence-based clinical guidelines and the convergence of such guidelines in Western countries, this assumption is not unreasonable. However, this assumption depends on adherence to the stated standard of care and access to cardiac rehabilitation services for people with ischaemic heart disease in Ireland. The model of care developed by the national clinical programme in Ireland for acute coronary syndromes recommends that cardiac rehabilitation programmes are established within the acute setting to treat hospitalised patients prior to discharge, with follow-up secondary prevention programmes in the primary care setting. In-hospital cardiac rehabilitation should begin as soon as the patient is clinically well enough to receive it, while patients should receive an invitation to early cardiac rehabilitation services (Phase 3), within four weeks of hospital discharge. It is a stated (as of 2013) goal that 90% of eligible patients are referred.[320]

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 the best possible cardiac rehabilitation.[321] There is also considerable uncertainty about access to primary prevention services for patients who have not been hospitalised for an acute event or revascularisation procedure associated with ischaemic heart disease. Furthermore, international evidence suggests that even where available, uptake of cardiac rehabilitation is variable, with participation rates as low as 20% to 50% reported. Barriers to participation include poor referral rates for certain groups (women, elderly, ethnic minorities, low socio-economic classes), logistical issues, and patient factors such as multi-morbidities, obesity and psychological wellbeing.[288] As evidenced in this assessment, novel mechanisms of providing cardiac rehabilitation are emerging including alternative modes of delivery (centre-based, home or online programmes) aimed at improving uptake across all groups of cardiac patients.

9.4.2 Cost-effectiveness

Fifteen economic evaluation studies of chronic disease self-management support (SMS) interventions for patients with ischaemic heart disease were identified as relevant. The majority of studies evaluated cardiac rehabilitation (n=7), with the remainder investigating telemedicine (n=2), case management (n=2) and other SMS interventions (n=4). The quality of the studies was generally poor. Most economic analyses were conducted alongside RCTs with small sample sizes and a short duration of follow-up, typically six to 12 months' duration, limiting the applicability of the findings presented in this section. The interventions described by the included studies were heterogeneous and frequently comprised multiple components. What constituted usual care also differed, so that the control groups (no SMS intervention) are not necessarily comparable. Given the diverse range of study populations, health systems and methodological approaches used to estimate the cost-effectiveness of different self-management programmes for ischaemic heart disease, the applicability of the available evidence to a prospective Irish programme is considered relatively low.

The largest body of evidence was found for cardiac rehabilitation, however, the delivery and components of the programmes differed significantly across studies, as well as the choice of comparator. When compared with no rehabilitation, the intervention was found to be clinically and cost-effective. However, when comparing different modes of delivery of cardiac rehabilitation (home versus hospital-based, or intensive versus dispersed delivery), no difference in outcomes was observed, while costs were similar.

While two studies were identified that evaluated the impact of telemedicine-based self-management support interventions, the SMS interventions evaluated differed. Both comprised economic evaluations conducted alongside RCTs with short-term follow up. A health-coach delivered educational programme was found not to be clinically or cost-effective in the short-term compared with usual care, while a smoking cessation intervention (telephone-based or face-to-face counselling) found that telephone-based SMS intervention dominated (was more effective and less costly) than either usual care or face-to-face counselling. However, in the latter study, nicotine replacement therapy was also included in the intervention arms, so it is not possible to conclude if the outcomes observed were due to this treatment or the telemedicine support.

Equivocal results were found for two economic evaluations that evaluated nurse-led case management interventions. Both were conducted alongside a RCT with short-term follow-up. One study concluded that the case management intervention was not an effective or cost-effective alternative to usual care within a time horizon of

one year, while the other, which was underpowered to detect a clinical effect, concluded that case management had the potential to be cost-effective.

There was insufficient evidence of adequate quality or relevance to consider the cost-effectiveness of interventions discussed in the 'other SMS' section.

Overall, the findings for SMS interventions in ischaemic heart disease were equivocal, and the quality of the included economic evaluations was as noted, predominantly poor. The majority of studies reported either similar or reduced costs (predominantly as a result of reduced healthcare usage) for the intervention group. Clinical outcomes were typically similar between the intervention and control arms, with no significant differences in HRQOL reported in most of the studies. Several of the RCTs were noted by the authors to be underpowered to detect differences in outcomes while short follow-up periods were also noted to be limiting factors. Where reported, the cost of the SMS intervention was typically low relative to the overall cost of care.

9.5 Key points

- Fourteen systematic reviews of self-management support interventions in adults with ischaemic heart disease 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 higher quality reviews, with an R-AMSTAR score of at least 31 out of 45.
- These reviews included five broad types of self-management support intervention, which were focused on patient education, exercise, psychosocial or behavioural changes, home-based services or telehealth. 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.
- The only single intervention with evidence for a statistically significant reduction in mortality is exercise programmes for suitable patient cohorts with follow-up of greater than 12 months. Exercise-based interventions are also associated with fewer hospitalisations, but there is conflicting evidence about myocardial infarction rates or revascularisation procedures.
- There is some evidence that patient education programmes are associated with an improvement in interim outcomes such as smoking cessation and reduced blood pressure, but there is uncertainty about how long any such effect persists.
- There is limited evidence to demonstrate the effectiveness of behavioural modification interventions, although some studies have reported positive effects on smoking cessation and symptom management.

- There is limited evidence that comparable home- and telehealth-based cardiac rehabilitation interventions achieve similar outcomes to centre-based interventions.
- Fifteen economic evaluation studies of chronic disease self-management interventions for patients with ischaemic heart disease were identified as relevant.
- The self-management interventions assessed in the included studies tended to be multi-faceted and therefore heterogeneous. Most economic analyses were conducted alongside RCTs with 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 and savings could be sustained. However, where reported, the cost of the self-management support interventions was typically noted to be low, relative to the overall cost of care.
- The largest body of evidence was found for cardiac rehabilitation. When compared with no rehabilitation, the interventions were found to be clinically effective and to create cost savings as a result of reductions in healthcare usage.
- Equivocal results have been reported for telemedicine-delivered self-management support interventions and nurse-led case management programmes. Due to the heterogeneity of the interventions assessed, it is not possible to draw conclusions in relation to the cost-effectiveness of these interventions.
- Based on the description of the healthcare systems, the epidemiology, and the ischaemic heart disease 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.[6] 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 of 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:

Chronic disease terms	(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])

AND

Self-management terms	(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)

AND

Systematic review terms or filter	(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)

Clinical Effectiveness Review Basic search strategy:

Phase I	Search from 2009 to February 2015.
Phase IIa	Use PRISMS results prior to 2012. New search from 2012 to April 2015.
Phase IIb	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 A9 – Ischaemic heart disease

Table A9.1 Ischaemic heart disease: results of meta-analyses

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance	ES (95% CI)
Barth (2015)[293]***	Psychosocial interventions for smoking cessation	Abstinence from smoking	6 to 12 months	37 RCTs; n=7,682	+++	RR 1.22 (95% CI: 1.13 to 1.32) [result with outliers removed]
				31 RCTs, n=4,968	+++	More intense interventions: RR 1.28 (95% CI: 1.17 to 1.40)
				5 RCTs, n=2,693	0	Brief interventions: RR 1.01 (95% CI: 0.91 to 1.12)
Brown (2011)[292]***	Patient information was the primary intention of the intervention, with a minimum follow-up of 6 months.	Mortality	6 to 60 months; median 18 months	6 RCTs; n=2,330	0	RR 0.79 (95% CI: 0.55 to 1.13)
		Myocardial infarction		2 RCTs, n=209	0	RR 0.63 (95% CI: 0.26 to 1.48)
		Revascularisation		2 RCTs, n=209	0	RR 0.58 (95% CI: 0.26 to 1.48)
		Hospitalisation		4 RCTs; n=12,905	0	RR 0.83 (95% CI: 0.65 to 1.07)
		Drop-out		8 RCTs; n=2,862	0	RR 1.03 (95% CI: 0.83 to 1.27)
Clark (2010)[298]**	Home-based (HB) interventions, relating to prevention, rehabilitation and support services. Comparators: usual care (UC), cardiac rehabilitation (CR).	All-cause mortality	1 to 14 months	4 RCTs, n=2,510	0	HB vs UC, RR 1.22 (95% CI: 0.83 to 1.80)
				6 RCTs, n=1,548	0	HB vs CR, RR 1.08 (95% CI: 0.73 to 1.60)
		Cardiovascular events		5 RCTs, n=2,078	0	HB vs UC, RR 0.91 (95% CI: 0.78 to 1.05)
				3 RCTs, n=778	0	HB vs CR, RR 0.90 (95% CI: 0.33 to 2.43)
		Quality of life		5 RCTs, n=644	+	HB vs UC, WMD 0.23 (95% CI: 0.02 to 0.45)
				5 RCTs, n=1,070	0	HB vs CR, WMD 0.13 (95% CI: -0.03 to 0.30)
Heran (2011)[296]***	Exercise-based cardiac rehabilitation: either exercise alone or in combination with	Overall mortality	≥ 12 months	16 RCTs, n=5,790	+	RR 0.87 (95% CI: 0.75 to 0.99)
		Cardiovascular mortality	≥ 12 months	12 RCTs, n=4,757	+++	RR 0.74 (95% CI: 0.63 to 0.87)

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance	ES (95% CI)
	psychosocial or educational interventions. Usual care could include standard medical care, such as drug therapy, but did not receive any form of structured exercise training or advice.	Hospital admissions	<12 months	4 RCTs, n=463	+	RR 0.69 (95% CI: 0.51 to 0.93)
Huang (2014)[300]**	Telehealth delivered cardiac rehabilitation	All-cause mortality	2 to 24 months; one study with six year follow-up	10 RCTs, n=1,303	0	RR 1.15 (95% CI: 0.61 to 2.19)
		Blood pressure (systolic)		6 RCTs, n=903	0	MD -1.27 (95% CI: -3.67 to +1.13)
		Blood pressure (diastolic)		5 RCTs, n=777	0	MD 1.00 (95% CI: -0.42 to 2.43)
		Weight		5 RCTs, n=532	0	SMD -0.13 (95% CI: -0.30 to 0.05)
		Smoking prevalence		5 RCTs, n=856	0	RR 1.03 (95% CI: 0.78 to 1.38)
		Exercise capacity		11 RCTs, n=1,269	0	SMD -0.01 (95% CI: -0.12 to 0.10)
Kotb (2014)[301]**	Telephone support	All-cause mortality	1.25 to 48 months	11 RCTs, n=2,937	0	OR 1.12 (95% CI: 0.71 to 1.77)
		Hospitalisation		4 RCTs, n=706	+	OR 0.62 (95% CI: 0.40 to 0.97)
		Smoking cessation		6 RCTs, n=1,727	++	OR 1.32 (95% CI: 1.07 to 1.62)
		Depression		5 RCTs, n=1,491	+	SMD -0.10 (95% CI: -0.21 to -0.00)
McGillion (2014)[294]**	Self-management	Frequency of angina symptoms	Up to 6 months	7 RCTs, n=732	+++	SMD 0.30 (95% CI: 0.14 to 0.47)
		Reduction in SL Nitrate use		2 RCTs, n=195	+++	SMD -0.49 (95%CI -0.77 to -0.20)
		Physical limitation (SAQ)		4 RCTs, n=606	+++	SMD 0.38 (95%CI 0.20 to 0.55)

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance	ES (95% CI)
		Depression score		3 RCTs, n=478	+	SMD -1.38 (95%CI -2.46 to -0.30)
Neubeck (2009)[302]**	Telehealth intervention	All-cause mortality	3 to 48 months	8 RCTs, n=2,918	0	RR 0.70 (95% CI: 0.45 to 1.10)
		Total cholesterol		8 RCTs, n=2,501	+++	WMD -0.37 mmmol/L (95% CI: -0.56 to -0.19)
		Blood pressure (systolic)		5 RCTs, n=1,728	+++	WMD -4.69 mmHg (95% CI: -6.47 to -2.91)
		Smoking prevalence		7 RCTs, n=296	+	RR 0.83 (95% CI: 0.70 to 0.99)
Taylor (2010)[299]***	Home-based cardiac rehabilitation programme	Exercise capacity	≥ 12 months	3 RCTs, n=1,074	0	SMD 0.11 (95% CI: -0.01 to 0.23)
		Blood pressure (systolic)	< 12 months	8 RCTs, n=1,053	0	MD 0.58 (95% CI: -3.29 to 4.44)
		Total cholesterol	< 12 months	7 RCTs, n=1,019	0	MD -0.13 (95% CI: -0.31 to 0.05)
		Smoking prevalence	< 12 months	5 RCTs, n=922	0	RR 1.00 (95% CI: 0.71 to 1.41)
		Mortality		4 RCTs, n=909	0	RR 1.31 (95% CI: 0.65 to 2.66)
Whalley (2014)[295]**	Psychological interventions in which treatment was delivered directly to patient	All-cause mortality	6 to 69 months	17 RCTs, n=6,852	0	RR 0.89 (95% CI: 0.75 to 1.05)
		Cardiac mortality		5 RCTs, n=3,893	+	RR 0.80 (95% CI: 0.64 to 1.00)
		Revascularisation		12 RCTs, n=6,670	0	RR 0.95 (95% CI: 0.80 to 1.13)
		Non-fatal MI		11 RCTs, n=7,535	0	RR 0.87 (95% CI: 0.67 to 1.13)
		Depression		12 RCTs, n=5,041	++	SMD -0.21 (95% CI: -0.35 to -0.08)
		Anxiety		8 RCTs, n=2,771	+	SMD -0.25 (95% CI: -0.48 to -0.03)
Cole (2011)[303]**	A combination of dietary changes, exercise, education, psychological or	All-cause mortality	3-5 years	6 RCTs n=7,053	++	RR 0.75 (95% CI: 0.65 to 0.87)
		Cardiovascular mortality	2-5 years	8 RCTs n= 7,188	++	RR 0.63 (95% CI: 0.47 to 0.84)

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance	ES (95% CI)
	organisational changes.	Non-fatal cardiac events (MI/PCI/CABG/coronary angioplasty)	1-5 years	9 RCTs n=13,349	++	RR 0.68 (95% CI: 0.55 to 0.84)
Lawler (2011)[297]**	Exercise-based cardiac rehabilitation	All-cause mortality	3 to 120 months	15 RCTs n=2,547	+	OR 0.74 (95% CI: 0.58 to 0.95)
		Cardiac mortality		18 RCTs n=2,200	++	OR 0.64 (95% CI: 0.46 to 0.88)
		Reinfarction		27 RCTs n=4,812	+++	OR 0.54 (95% CI: 0.38 to 0.76)
Schadewaldt (2011)[401]*	Nurse led clinics	Blood pressure (systolic)	6 to 8 months	2 RCTs n=260	0	MD -6.59 (95% CI: -18.11 to 4.94)
		Blood pressure (diastolic)		2 RCTs n=260	0	MD -6.99 (95% CI: -18.79 to 4.80)
		Total cholesterol		2 RCTs n=162	0	MD -0.30 (95% CI: -0.63 to 0.03)
		Smoking cessation	1 to 3 months	2 RCTs n=125	0	OR 0.92 (95% CI: 0.72 to 1.17)

Key: **RCT** = randomised controlled trial; **RR** = relative risk; **SMD** = standardised means difference; **WMD** = weighted mean difference.

Table A9.2 Ischemic heart disease: summary of results from quantitative systematic reviews

Reference and weighting outcome	Focus	Synthesis	RCTs, n; participants, n; date range	Main results	Main conclusions (review author); important quality concerns (review author)
Barth (2015)[293]***	Psychosocial interventions for smoking cessation	Meta-analysis	40 RCTs; n=7,682; 1974-2012	Positive effect on abstinence after 6 to 12 months (RR 1.22, 95% CI (1.13 to 1.32), I2 54%, Abstinence rate treatment group 46%, Control group 37.4%, Heterogeneity reported as substantial; RR across different intervention strategies were similar (Behavioural, telephone support or self-help); More intense interventions showed increased quit rates (RR 1.28, 95% CI 1.17 to 1.40, I2 58%) compared to brief interventions, which were not effective (RR 1.01, 95% CI 0.91 to 1.12, I2 0%). Long-term follow-up did not show any benefits.	Psychosocial smoking cessation interventions are effective in promoting abstinence up to one year, provided they are of sufficient duration. Favourable effects were reported after one year.
Brown (2011)[292]***	Patient information was the primary intention of the intervention, with a minimum follow-up of 6 months.	Meta-analysis	13 RCTs; n=68,556; 1991-2009	Mortality (6 Studies): RR 0.79, (95% CI 0.55, 1.13), I2 16%; Myocardial infarction (2 Studies): RR 0.63 (95% CI 0.26, 1.48) I2 0%; Revascularisation (2 Studies): RR 0.58 (95% CI 0.26, 1.48) I2 0%; Hospitalisation (4 Studies) RR 0.83 (95% CI 0.65, 1.07) I2 32%; Drop out (8 Studies) RR 1.03 (95% CI 0.83, 1.27) I2 34%. Heterogeneity reported in outcome measures and reporting methods: Over 60 months, 14 scores were significantly in favour of exercise and 67 scores showed no difference between exercise and control. No studies showed HQRoL scores that favoured the control group.	There was no strong evidence to support the hypothesis that education improves all-cause mortality or cardiac morbidity, at a median of 18 months follow-up, in patients with CHD compared to usual care. The study found that HQRoL scores improved with educational interventions, which may reduce downstream healthcare utilisation and costs.
Clark (2010)[298]**	Home-based (HB) interventions, relating to prevention, rehabilitation and support services. Comparators: usual care (UC), cardiac	Meta-analysis	36 RCTs; n=8,297; 1983-2007	All-cause mortality: HB vs UC (n=2510): RR 1.22 (95%CI 0.83-1.80) I2 = 0%; HB vs CR (n=1548): RR 1.08 (95% CI 0.73-1.60) I2 = 0%; Cardiovascular events: HB vs UC (n=2078): RR 0.91 (95%CI 0.78-1.05) I2 = 0%; HB vs CR (n=778): RR 0.90 (95%CI 0.33-2.43) I2 = 90%; QoL: HB vs UC (n=644)	Home-based interventions for the secondary prevention of CHD showed a number of benefits on the QoL and CHD risk factors when compared to usual care.

Reference and weighting outcome	Focus	Synthesis	RCTs, n; participants, n; date range	Main results	Main conclusions (review author); important quality concerns (review author)
	rehabilitation (CR).			0.23 (95%CI 0.02-0.45), with more significant improvements in short-term effects; HB vs CR (n=1070): RR 0.13 (95%CI -0.03-0.30) not significant. Significant benefits were also noted in resting systolic blood pressure, cholesterol levels, smoking cessation rates and depression scores for home-based interventions over usual care, but not cardiac rehabilitation.	
Cole (2011)[303]**	Lifestyle and /or behavioural interventions in the primary or community care setting for the secondary prevention of CHD including dietary, exercise, psychological. Educational, multifactorial, organisational interventions vs usual care.	Systematic review	21 RCTs N=10,799 1993-2010	All cause mortality RR: 0.75 (95%CI 0.65-0.87) (significant effect observed in 4 of 6 RCTs); Cardiovascular mortality RR: 0.63 (95%CI 0.47-0.84) (significant effect observed in 3 of 8 RCTs); Non-fatal cardiac events RR: 0.68 (95%CI 0.55-0.84) (significant effect observed in 5 of 9 RCTs);	*The effectiveness of lifestyle interventions within secondary prevention of CHD remains unclear. The overall results for modifiable risk factors suggested improvement in dietary and exercise outcomes, but no overall effect on smoking outcomes. The heterogeneity between trials and generally poor quality trials make any concrete conclusions difficult, however the beneficial effects observed are encouraging.*
Heran (2011)[296]***	Exercise-based cardiac rehabilitation: either exercise alone or in combination with psychosocial or educational interventions.	Meta-analysis	47 RCTs; n=10,794; 1975-2008	Exercise-based cardiac rehabilitation reduced overall and cardiovascular mortality in medium to longer term studies (≥ 12 months follow-up) [RR 0.87 (95% CI 0.75 to 0.99) and 0.74 (95% CI 0.63 to 0.87), respectively]. In the shorter term (< 12 months follow-up), hospital admissions were reduced [RR 0.69 ((5% CI 0.51 to 0.93)]. Cardiac rehabilitation did not reduce the risk of MI, CABG or PTCA. In most trials, HRQoL scores were significantly higher in exercise-based cardiac rehabilitation compared with usual care.	Exercise-based cardiac rehabilitation is effective in reducing hospital admissions in the short term and in reducing total and cardiovascular mortality in the longer term. Population characteristics were predominantly low risk, middle aged males; more representative RCTs in CHD patients required.

Reference and weighting outcome	Focus	Synthesis	RCTs, n; participants, n; date range	Main results	Main conclusions (review author); important quality concerns (review author)
Huang (2014)[300]**	Telehealth delivered cardiac rehabilitation	Meta-analysis	9 RCTs; n=1,546; 1984-2011	No significant differences were reported between telehealth or centre delivered cardiac rehabilitation: All-cause mortality: RR 1.15 (95% CI 0.61 to 2.19); Blood pressure (Systolic: MD 1.27 (95% CI -3.67 to +1.13; Diastolic: MD 1.00 (95% CI -0.42 to 2.43); Weight SMD -0.13 (95% CI -0.30 to 0.05); Smoking: RR 1.03 (95% CI 0.78 to 1.38); Exercise Capacity SMD -0.01 (95% CI -0.12 to 0.10); lipid profile, quality of life and psychological state.	Telehealth intervention delivered cardiac rehabilitation has similar outcomes to centre-based supervised programmes in low to moderate risk CAD patients.
Kotb (2014)[301]**	Telephone support	Meta-analysis	26 RCTs; n=4,081; 1985-2011	No difference observed for mortality OR 1.12 (95% CI 0.71 to 1.77); Fewer hospitalisations were recorded for intervention group OR 0.62 (95% CI 0.40 to 0.97); Smoking cessation favoured the intervention group: OR 1.32 (95% CI 1.07 to 1.62); Intervention favoured lowering of systolic BP WMD -0.22 (95%CI -0.24 to -0.04); No difference was reported for LDL cholesterol WMD -0.10 (95% CI -0.23 to +0.03).	Regular telephone support and monitoring can reduce certain risk factors in CAD patients; reducing depression, improved control over cardiac risk factors and fewer hospitalisations; thereby potentially reducing some of the burden on the healthcare system.
Lawler (2011)[297]**	Exercise-based cardiac rehabilitation among post MI patients	Meta-analysis	34 RCTs N=6,111 1979-2009	Patients randomised to exercise-based cardiac rehabilitation had a lower risk of all-cause mortality (OR 0.74, 95%CI 0.58-0.95); cardiac mortality (OR 0.64, 95%CI 0.46-0.88); and re-infarction (OR 0.53, 95%CI 0.38-0.76);	*Exercise-based cardiac rehabilitation is associated with reductions in mortality and re-infarction post-MI. Secondary analyses suggest that even shorter CR programmes (1-3 months) may translate into improved long-term outcomes, although these results need to be confirmed in an RCT.* Of note, 89% of included patients were men with mean age 54.7 years - *additional studies are required among women and older patients.*
McGillion (2014)[294]**	Self-management interventions	Meta-analysis	9 RCTs; n=1,282; 1994-2012	Significant improvements were reported for: Frequency of angina symptoms: SMD 0.30 (95% CI 0.14 to 0.47); Reduction in sub-	SM interventions significantly improve angina frequency and physical limitation, reduce sub-lingual nitrate use and improve

Reference and weighting outcome	Focus	Synthesis	RCTs, n; participants, n; date range	Main results	Main conclusions (review author); important quality concerns (review author)
				lingual nitrate use: SMD -0.49 (95%CI -0.77 to -0.20); Physical limitation (SAQ): SMD 0.38 (95%CI 0.20 to 0.55) and Depression scores: SMD -1.38 (95%CI -2.46 to -0.30). No differences were reported between groups on HRQoL dimensions of angina stability, disease perception and treatment satisfaction.	depression scores.
Neubeck (2009)[302]**	Telehealth Intervention	Meta-analysis	11 RCTs; n=3,145; 1994-2007	Intervention was associated with non-significant reduction in all-cause mortality: RR 0.70 (95% CI 0.45 to 1.10); Significant reduction in total cholesterol: WMD 0.37 mmol/L (95% CI 0.19 to 0.56), Systolic BP WMD 4.69 mmHg (95% CI 2.91 to 6.47), fewer smokers RR 0.84 (95% CI 0.65 to 0.98). Favourable changes were also found in HDL and LDL levels.	Effective risk factor reduction was observed with the use of telehealth interventions. Optimal frequency or duration of interventions to improve cardiovascular risk profiles was not established. The improvement in survival observed, although non-significant, would benefit from larger trial to improve statistical power to establish effect.
Schadewaldt (2011)[401]*	Nurse-led clinics for patients with coronary heart disease (adults admitted to a hospital or general practice with newly diagnosed or existing CHD) comprising health education, counselling behaviour change and promotion of a healthy lifestyle vs. usual care	Systematic review and meta-analysis	7 RCTs N=3,246 1998-2007	No pooling of data was possible for short-term BP results up to 6-mo f/u ; No difference in BP at 6-8mo f/u (systolic p=0.26, diastolic p=0.25); No improvements in long term BP outcomes, in total cholesterol, or HDL levels; No difference in smoking cessation in short term; or in body weight in short or long term; equivocal results for improvements in medication compliance reported in individual studies (n=2) variable results for improvements in quality of life (SF36) with improvements noted in four of eight domains up to one year.	*The results indicated that care was equivalent to non-nurse managed clinics, and there was no greater risk of poorer outcomes in the nurse-led clinics. The effectiveness of the clinics may depend on the intensity of nursing support. The combination of counselling and regular assessment of risk factors and health status delivered at nurse-led clinics is supported by the available research, and given equivalent outcomes with non-nurse led clinic. Further research should investigate the cost-effectiveness of the different models of care.* Although conclusions compared nurse-led clinics with other clinics, standard of care described in the included RCTs was 'no clinic'.

Reference and weighting outcome	Focus	Synthesis	RCTs, n; participants, n; date range	Main results	Main conclusions (review author); important quality concerns (review author)
Taylor (2010)[299]***	Home-based cardiac rehabilitation programme	Meta-analysis	12 RCTs; n=1,938; 1984-2007	No differences in outcomes of home versus centre-based cardiac rehabilitation programmes were reported with respect to mortality risk, cardiac events, exercise capacity or in modifiable risk factors (systolic BP, diastolic BP, total cholesterol, HDL and LDL cholesterol, in the proportion of smokers at follow up or in HRQoL scores. No consistent difference in healthcare costs was observed.	Home and centre-based cardiac rehabilitation appear to be equally effective in improving clinical and HRQoL outcomes in acute MI and revascularisation patients. Home based cardiac-rehabilitation would support greater choice for patients' preferences, which may improve cardiac rehabilitation uptake.
Whalley (2014)[295]**	Psychological interventions in which treatment was delivered directly to patient	Meta-analysis	26 RCTs; n=9,296; 1984-2008	There was no evidence of significant effect on all-cause mortality: RR 0.89 (95% CI 0.75 to 1.05). There was some evidence of reduced cardiac mortality: RR 0.80 (95% CI 0.64 to 1.00). There was no evidence of significant effect on revascularisation or non-fatal MI. A significant reduction in depression was observed: SMD -0.21 (95% CI -0.35 to -0.08); and anxiety: SMD -0.25 (95%CI -0.48 to -0.03).	Psychological interventions appear effective in treating psychological symptoms of CAD patients. There is uncertainty about differential benefit with respect to patient subgroups and the most successful intervention characteristics.

Key: **BP** = blood pressure; **CABG** = coronary artery bypass graft; **CAD** = coronary artery disease; **CHD** = coronary heart disease; **CR** = Cochrane review; **HDL** = high-density lipoprotein; **HRQoL** = health-related quality of life; **LDL** = low-density lipoprotein; **MI** = myocardial infarction; **PTCA** = percutaneous transluminal coronary angioplasty; **QoL** = quality of life; **RCT** = randomised controlled trial; **RR** = relative risk; **SM** = self-management; **SMD** = standardised means difference; **WMD** = weighted mean difference.

Table A9.3 Summary of cost-effectiveness studies for cardiac rehabilitation

Study	Intervention	Population	Analysis details	Clinical and QALY Outcomes	Costs	Authors' conclusions
Ballegaard (2004)[304]	Integrated rehabilitation (IR) (Acupuncture, self care programme, stress management and lifestyle adjustments)	168 patients with severe angina pectoris (no high risk patients were included)	Country: Data from US but adopted to Danish population Study Design: Retrospective cohort study Perspective: health care Discount rate: NA Time horizon: 13.5 year Costs: 1999 Danish Krone	The three year accumulated risk of death was 2.0% for patients requiring invasive treatment compared to 6.4% in the general Danish population. After the 3 year follow up the IR group had a reduction of 96% in hospitalisations, 88% reduction in family doctor visits, 84% reduction in heart failure specialist visits and medication expenditure fell by 78%.	Cost savings for the IR group were US$12,000 (€10,518) and US$7,500 (€6,574) yearly per patient, respectively for patients who did and did not proceed to surgery. Cost savings over 3 years were US$36,000 (€31,555) for surgical and US$22,000 (€19,284) for non-surgical patients.	IR reduced the risk of dying and the need for invasive treatment among patients with severe angina pectoris.
Briffa (2005)[307]	18 sessions of Cardiac rehabilitation (CR) versus conventional care	113 CAD patients aged 41–75 years who experienced an acute coronary syndrome, were self-caring and literate in English.	Country: Australia Study Design: RCT Perspective: health system Discount rate: NA Time horizon: 1 year Costs: 1998 AUSD	At 6 months, the mean incremental improvement in health utility was 0.012 for conventional care and 0.016 for rehabilitation care, respectively. At 12 months, there was a non-significant improvement from baseline of 0.010 in conventional care and a significant improvement of 0.026 in rehabilitation care.	Estimated base-case incremental cost per QALY saved for CR was AUS$42,535 (€43,589), when modelling included treatment effect on survival. This increased to AUS$70,580 (€72,330) per QALY saved if survival effect not included.	The findings of the study strengthen the case for rehabilitation services to be made available and routinely offered to all survivors of acute coronary syndromes. The advantages in QOL were mostly non-significant, but the cost of delivering rehabilitation was low.
Dendale (2008)[308]	Cardiac rehabilitation	Patients post percutaneous coronary intervention (PCI)	Country: Belgium Study Design: CBA Perspective: Health care provider Discount rate: NR Time horizon: 4.5 year Costs: 2005 euro	CR resulted in a significant reduction in hospitalisations for angina (75% vs 45%) and coronary revascularisations (17% vs 7%); however a significant increase in MI was reported (2.5% vs 7.5%). Overall, reported incidence of cardiac events were IG 0.93 events/patient and CG 1.52 events/patient.	Cost of one CR session was €23.25 (€27) per patient. The total health care cost (including cost of CR) at 4.5 years was €4,862 (€5655)/patient in IG compared with €5,498 (€6395)/patient in CG.	CR following PCI significantly reduces the number of cardiac events and results in costs savings for the health payer.

Study	Intervention	Population	Analysis details	Clinical and QALY Outcomes	Costs	Authors' conclusions
Jolly (2007)[311]	Home-based programme of cardiac rehabilitation using the Heart Manual, compared with centre-based programmes.	Patients who experienced an MI or coronary revascularisation within the previous 12 weeks from four hospitals in predominantly inner-city, multi-ethnic, socio-economically deprived areas	Country: UK Study Design: RCT Perspective: Societal Discount rate: NR Time horizon: 24 month Costs: 2001 GBP	At all three follow-up points no clinically or statistically significant differences were found in any of the primary outcome measures between the home- and centre-based groups or in any of the secondary outcomes. QALYS reported after 24 months for home based and centre based were .731 and .753 a difference of 0.022	The mean cost per patient referred to CR in the home-based arm was £198 (€337), approximately 25% above that of the hospital arm of £157 (€267). From an NHS perspective, the home-based arm was more costly than the hospital-based arm. From a societal perspective, however, the inclusion of patient travel costs and travel time increased the mean cost of the hospital-based arm to £181 (€308).	For low- to moderate-risk patients following CAD event, a home-based cardiac rehabilitation programme does not produce inferior outcomes compared with the traditional centre-based programmes. With the level of home visiting in this trial, the home-based programme was more costly to the health service, but with the difference in costs borne by patients attending centre-based programmes.
Marchionni (2003)[402]	Cardiac rehab (exercise program) 1)hospital-based CR (Hosp-CR) 2)home-based CR (Home-CR) 3) no CR	270 post myocardial infraction patients without cardiac failure, dementia, disability, or contraindications to exercise	Country: Italy Study design: RCT Perspective: Healthcare Discount rate: N/A Time horizon: 14 month Costs: USD 2000	TWC improved in the Hosp-CR and Home-CR groups but not in controls, with no significant difference between Hosp-CR and Home- CR. In middle-aged and old patients, HRQL improved significantly over the entire study duration regardless of treatment assignment, whereas in very old patients, HRQL improved significantly with either active treatment but not with no CR	Direct costs, calculated as the sum of CR programme and healthcare utilisation costs over the study duration, amounted to $21,298 (€26.234) ($8,841±$12,457) for Hosp- CR, $13,246 (€16,316) ($1,650±$11,596) for Home-CR, and $12,433 (€15,315) (healthcare utilisation costs only) for no CR. Fewer medical visits (6.5±0.5 versus 7.1±0.6 versus 9.2±0.9, *P*=0.018) and rehospitalisations (0.33±0.07 versus 0.46±0.10 versus 0.49±0.10, *P*=0.492) in Home-CR compared with Hosp-CR and no-CR patients	Post-MI Hosp-CR and Home-CR are similarly effective in the short term and improve TWC and HRQL in each age group. However, with lower costs and more prolonged positive effects, Home-CR may be the treatment of choice in low-risk older patients.

Study	Intervention	Population	Analysis details	Clinical and QALY Outcomes	Costs	Authors' conclusions
					contributed, at least in part, to produce the differences.	
Reid (2005)[313]	Cardiac rehabilitation (CR) (standard (33 sessions for 3 months) versus distributed (33 sessions for 12 months)	392 patients with severe CAD	Country: Canada Study Design: RCT Perspective: Health system Discount rate: 5% Time horizon: 24 month Costs: 2004 USD	There were no clinically meaningful or statistically significant between group differences for outcomes at 12 or 24 months. Both groups showed improvements over time in cardio respiratory fitness, daily physical activity, low-density lipoprotein cholesterol, generic and heart disease HRQL, and depressive symptoms.	At 2 years, the total direct costs of DCR were $5,267 (€6,073) ($759 [€875] for programme delivery + $4508 [€5198] for cardiac health care costs) versus $5132 (€5,918) for SCR ($681 [€785] for programme delivery + $4451 [€5,132] for cardiac health care costs)	Our data indicate that there are no clinically meaningful or statistically significant differences between a standard 3-month, 33-session programme of CR and one that has the same number of contacts distributed over a 12-month period.
Taylor (2007)[315]	Home-based versus hospital-based rehabilitation	104 patients with an uncomplicated acute myocardial infarction and without major co morbidity	Country: UK Study Design: CEA Perspective: Health service Discount rate: NA Time horizon: 9 month Costs: 2002 GBP	Mean utility values for the home and hospital groups were comparable at baseline (0.76 vs. 0.74), and 9 months (0.74 vs 0.78). Although there was a small mean QALY gain from baseline to nine months for the hospital-based group and a small QALY loss for the home based group, no significant difference was seen between the groups (−0.06)	The mean cost of cardiac rehabilitation was lower by £30 (€51) per patient for the home-based group than the hospital-based group. This difference was primarily the result of reduced personnel costs. the overall healthcare costs of the home-based and hospital-based groups did not differ significantly	Although the mean QALY and healthcare cost favoured the hospital group, the difference in QALYs and costs between groups was small and was highly variable. Individual simulations included all four-quadrants of the cost effectiveness plane and ranged from a small QALY gain and lower cost in favour of hospital to a small QALY gain and lower cost in favour of home. Results were similar for each group.

Table A9.4 Summary of cost-effectiveness studies for telemedicine

Study	Intervention	Population	Analysis details	Clinical and QALY Outcomes	Costs	Authors' conclusions
Berndt (2015)[306]	Smoking cessation counselling delivered via usual care (UC) (n=245), vs. telephone counselling (TC) (n=223) or face-to-face counselling (FC)(n=157). TC and FC arms included access to nicotine replacement therapy	Patients over 18 recently hospitalised and who smoked on average >5 cigarettes per day prior to admission or quit smoking < 4 weeks prior to admission	Country: Netherlands Study Design: RCT with 6months follow-up Perspective: Societal Discount rate: NA Time horizon: 6 month Costs: 2011 Euro	Compared with UC, a significantly higher proportion of patients in the TC and FC groups achieved continued abstinence (37.9%, 54.1%, 51.6%, respectively) and 7-day abstinence (41.5, 57.1, 54.9, respectively). Reported QALYS for UC TC AND FC were 0.489, 0.491 and 0.487, respectively.	Societal costs over the 6-month follow-up period were lowest in the TC group at €8,124 (€8,293), compared to €8,988 (€9,175) in the FC group and €9,181 (€9,372) in the UC group.	TC dominated (more effective and less costly) UC and FC. FC was dominated by UC, since FC was more costly and reached somewhat lower effects in QALYs gained compared to UC. Assuming a willingness-to-pay of €20,000/ abstinent patient, telephone counselling would be a highly cost-effective smoking cessation intervention assisting cardiac patients to quit.
Turkstra (2013)[316]	Telephone delivered CHD secondary prevention programme (ProActive Heart [HC])	430 adult myocardial infarction patients	Country: Australia Study Design: RCT Perspective: Health care Discount rate: NA Time horizon: 12 month Costs: 2008 AUSD	Incremental health status after 12 months was 0.132 for HC and 0.120 for usual care. The incremental effectiveness was 0.012 QALYs	Higher hospitalisation ($6,841 vs. $4,984 [€4,893 vs. €3,565]) and total treatment cost ($10,574 versus $8,534 [€7,563 versus €6,104]) were observed for patients randomised to receive HC versus usual care. The incremental cost was $2,040 (€1,459). The cost of the health coaching sessions was $37 (€26) per session.	The incremental cost-effectiveness ratio (ICER) of HC vs. usual care for patients with a recent MI was $85,423 (€61,102)/QALY. ProActive Heart, was not a cost-effective intervention in the short-term compared to UC. There was no significant improvement in utility and it resulted in significantly increased costs.

Table A9.5 Summary of cost-effectiveness studies for case management

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
Seidl (2014)[314]	Nurse-based case management	Elderly (≥65 years) patients with myocardial infarction	Country: Germany Study Design: RCT Perspective: Societal Discount rate: NA Time horizon: 12 month Costs: 2010 Euro	The mean QALY difference, adjusted for gender, age in groups and number of co morbidities, between the intervention and control groups was -0.0163. Utility scores from EQ-5D-3L were significantly increased in the intervention group at month 3 (0.077) and month 6 (0.0509), but returned towards baseline levels in month 12.	Cost of the intervention was €130(€145)/patient. Total costs for the intervention and control groups were €8,289 and €8,880 (€9223 and €9881). The adjusted overall cost difference was estimated at €17.61 (€20). The ICER was calculated to be €1,080 (€1202)/QALY, representing the savings per additional QALY lost.	In conclusion, the KORINNA study failed to show that the case management intervention was an effective and cost effective alternative to usual care within a time horizon of one year.
Barley (2014)[305]	UPBEAT Nurse-Delivered Personalised Care (PC) Intervention (standardised, face to face, bio-psychosocial assessment) with telephone follow-up	Adults with symptomatic CHD, reporting depression symptoms were eligible	Country: UK Study Design: RCT Perspective: Healthcare Discount rate: NA Time horizon: 12 month Costs: 2010 GBP	The average EQ-5D utility scores at baseline were slightly higher for the PC group, although the difference between groups was not statistically significant In terms of QALYs, the control group showed an incremental QALY gain of 0.038 compared to personalised care over the 12-month treatment period.	(Total cost PC vs control, mean: baseline £1,773 vs £3,604[€2,322 vs €4,721]; 6 months £832 vs £1,191[€1,090 vs €1,560]; 12 months £1,088 vs £2,014[€1,425 vs €2,638]) Hospital services were used more intensively by the control group than the PC group at all time points, and as a result recorded higher inpatient costs. For the PC group, the intervention itself accounted only for 6.7% of total costs.	Cost-utility results yielded an incremental cost-effectiveness ratio (ICER) of £29,921 (€39,193) per additional QALY. The point estimate of the incremental cost-effectiveness ratio falls in the south-western (SW) quadrant, representing the situation where the PC group has reduced costs and worse outcomes.

Table A9.6 Summary of cost-effectiveness studies for other self-management support interventions

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
Furze (2012)[309]	Lay-facilitated angina management programme (LAMP) vs routine care	Participants with new stable angina (n=142)	Country: UK Study Design: RCT Perspective: NHS Discount rate: NA Time horizon: 6 Month Costs: 2008 GBP	There was no important difference in angina frequency at 6 months. The LAMP group had significantly higher quality of life as measured by EQ-5D index scores, at both 3 months = 0.82 vs. 0.70 and at 6 months = 0.82 vs. 0.68. There was a statistically significant difference in average QALY per patient of 0.045.	A total of six lay facilitators were recruited in the LAMP trial and each cost £179 (€248) for training. The average cost per patient in the control group was £1,259 (€1743) whilst in the intervention group it was £1,496 (€2071). the average incremental net benefit of LAMP over control was positive (£354.60 [€490.60]).	The intervention was found to be cost-effective and at a willingness-to-pay (WTP) threshold of £20,000 (€27,680) the probability of LAMP being cost-effective is 80%, increasing to 90% at a threshold of £30,000 (€41,521) /QALY
Ito (2012)[310]	The study evaluated mailed education, disease management, polypill use, and combinations of these interventions	Hypothetical cohort of patients' post-myocardial infarction.	Country: USA Study Design: Markov Perspective: Societal Discount rate: 3% Time horizon: Lifetime Costs: 2010 USD	All interventions had a higher total QALY gain than usual care which had a QALY of 4.4756 while the interventions ranged from 4.4848 to 4.5235.	The calculated cost per QALY gained were mailed education plus disease management $74,600 (€68,672), disease management $69,200 (€63,701), polypill use $133,000 (€122,431), polypill use plus mailed education $113,000 (€104,020), polypill plus disease management $142,900 (€131,544). Mailed education was the only intervention with an ICER <$100,000 (€92,053) per QALY.	Mailed education and a polypill, once available, may be cost-saving strategies for improving post-MI medication adherence.
Ladapo (2011)[312]	Nurse-led smoking cessation counselling plus post-discharge follow-up	Hypothetical US cohort of 327,600 smokers hospitalised with AMI.	Country: US Study Design: Monte Carlo model Perspective: Societal Discount rate: 3%	Both patients in both groups experienced a decrease in QALYs however there was 32,950 additional patients who resulted in a QALY loss	The intervention was estimated to cost US$27.3 (€27) per patient per year; however, the intervention resulted in a decrease in	Nurse-led smoking cessation counselling with post-discharge follow-up has the potential to be cost-effective relative to

Study	Intervention	Population	Analysis details	Clinical and QALY outcomes	Costs	Authors' conclusions
			Time horizon: 10 year Costs: 2008 USD	in the control group (154,700 vs 121,700). The control group also had higher numbers of death, AMI episodes, more continued to smoke and there was greater number of patients with life years lost.	total health costs of $894 (€878). The programme would cost $540 (€530) per quitter and $19,800 (€19,447) per AMI avoided (considering only intervention costs), and the cost-effectiveness would be $4,350 (€4,272) per life-year and $5,050 (€4,960) per QALY (considering all health care costs).	the standard of care and may lead to significant reductions in the incidence of smoking and its associated adverse health events and social costs.
Raftery (2005)[317]	Nurse led secondary prevention clinics for coronary heart disease	1343 patients (673 in intervention group and 670 in control group) aged under 80 years with a diagnosis of coronary heart disease but without terminal illness or dementia and not housebound.	Country: UK Study Design: CEA alongside RCT Perspective: Societal Discount rate: 3.5% Time horizon: 4.7 years RCT follow up Costs: 1999 GBP	Overall, 28 fewer deaths occurred in the intervention group leading to a gain in mean life years per patient of 0.110 and of 0.124 QALYs.	The cost of the intervention (clinics and drugs) was £136 (€251) per patient higher in the intervention group, but the difference in other NHS costs, although lower for the intervention group, was not statistically significant. The incremental cost per life year saved was £1236 (€2,282) and that per QALY was £1097 (€2,025).	Nurse led clinics for the secondary prevention of coronary heart disease in primary care seem to be cost effective compared with most interventions in health care, with the main gains in life years saved.

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