Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health technology assessment of chronic disease self-management support interventions

Asthma *(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 – Asthma

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

- Based on 12 systematic reviews (90 randomised controlled trials), a range of self-management support interventions for asthma were identified. These focused primarily on patient education and use of written action plans with evidence also for behavioural interventions, complex interventions comprising a range of mainly education-based supports, and use of text messaging and the Chronic Care Model to improve treatment and medication adherence.
- Good evidence was found that self-management support interventions can improve quality of life, reduce hospital admissions and use of urgent and unscheduled healthcare.
- The optimal intervention format of self-management support is not clear, but 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 are associated with improved medication adherence and a reduction in symptoms.
- Based on 12 costing and cost-effectiveness studies, the economic literature was grouped into four main intervention types: education programmes, internet-based self-management support, telemedicine, and 'other' self-management support interventions.
- Limited evidence was found to suggest that:
    - self-management support education programmes, using a combination of individual and group sessions, may be at least cost-neutral in patients with mild to moderate disease.
    - nurse-led telephone review for patients with high-risk asthma is a relatively low cost intervention that may reduce costs by reducing healthcare utilisation, although evidence of effect in the included studies was mixed.

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

Self-management support interventions for patients with asthma can improve quality of life, reduce hospital admissions and use of urgent and unscheduled healthcare. The optimal intervention format is not clear, but 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 are associated with improved medication adherence and a reduction in symptoms.

Economic studies suggest that that education programmes, using a combination of individual and group sessions, may be at least cost-neutral in patients with mild to moderate disease. Limited evidence was found to suggest that nurse-led telephone review for patients with high-risk asthma is a relatively low cost intervention that may reduce costs by reducing healthcare utilisation, although evidence of effect in the included studies was mixed. Evidence to support the cost-effectiveness of other self-management support interventions 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

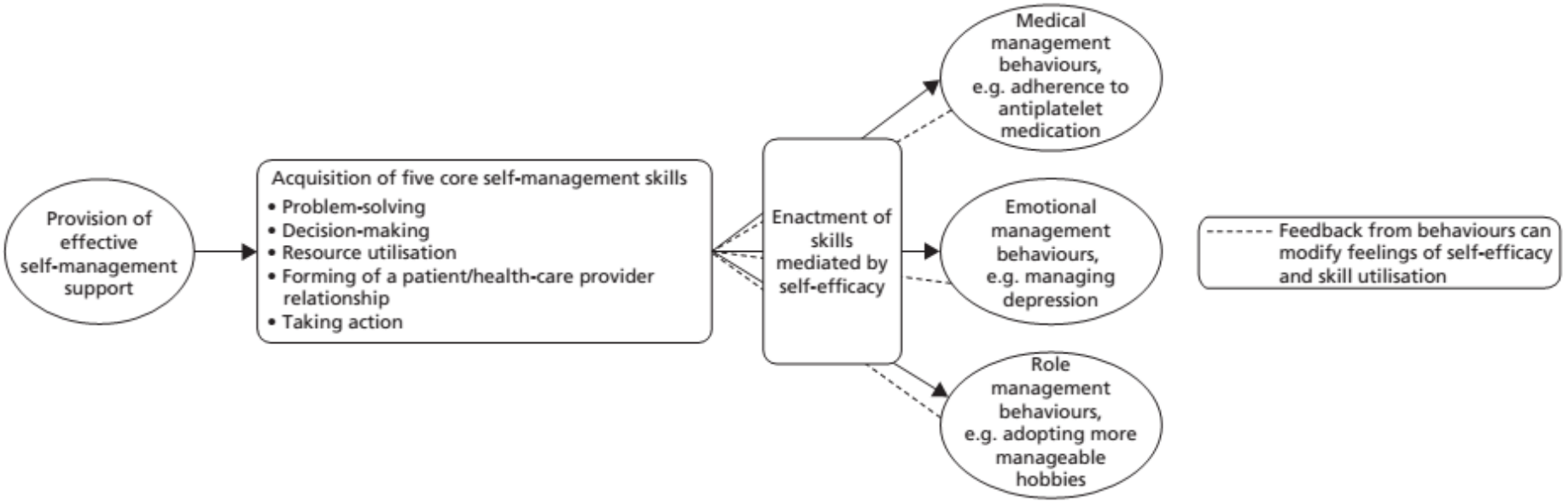
A broad range of self-management and self-management support definitions exist. For this review, the 2003 definitions agreed by the US Institute of Medicine are used:

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]

5 Asthma

This health technology assessment (HTA) of asthma self-management support (SMS) is one of a series of rapid HTAs assessing SMS interventions for chronic diseases. Section 5.1 provides a brief description of asthma followed by separate reviews of the clinical (Section 5.2) and cost-effectiveness (Section 5.3) literature for SMS interventions in asthma. Brief descriptions of the background and methods used are included with full details provided in a separate document (Chapter 3). Section 5.4 includes a discussion of both the clinical and cost-effectiveness findings. The report concludes with a list of key points in relation to asthma SMS support (Section 5.5).

5.1 Description of the disease

Asthma is a chronic inflammatory condition of the airways characterised by recurrent episodes of wheezing, breathlessness, chest tightness and coughing.[89] Ireland has the fourth highest prevalence of asthma worldwide, affecting an estimated 450,000 people. At least one person dies from asthma every week in Ireland.[89] The strongest risk factors for developing asthma are inhaled substances and particles that may provoke allergic reactions or irritate the airways.[90] Medication can control symptoms of asthma and avoidance of asthma triggers can also reduce its severity.[90] Appropriate management of asthma can enable people to enjoy a good quality of life.[90]

The Irish Asthma Control in General Practice guidelines (2013), adapted from the GINA Global Strategy for Asthma Management and Prevention, state that essential features to achieve guided self-management in asthma include: education and motivation, self-monitoring to assess control with educated interpretation of key symptoms, regular review of asthma control and a written action plan.[89] This is based on evidence rated as 'Evidence A' (rich body of randomised controlled trial [RCT] data) by GINA. The 2013 guidelines highlight rates of hospitalisation and attendance at emergency departments in Ireland, as well as frequent use of unscheduled (out-of-hours) care which indicate the suboptimal asthma control in the majority of patients. Care issues identified include low uptake of objective lung function tests for diagnosis and management, infrequent use of asthma action plans and poor patient education. Current aims of the Health Service Executive's (HSE) National Clinical Programme for asthma include that all patients diagnosed with asthma are enrolled in a structured asthma programme, to include issues such as: education about asthma, personal trigger factors and medication, assessment of control, inhaler device and technique and information about smoking cessation and exposure to second hand smoke.[91] However, the optimal format and delivery of such programmes has not been determined.

5.2 Review of clinical-effectiveness of SMS interventions

5.2.1 Background and methods

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

In December 2014 a high-quality overview of reviews was published by the National Institute for Health Research in the UK. The Practical systematic Review of Self-Management Support for long-term conditions (PRISMS) overview comprised an overview of systematic reviews of randomised controlled trials (RCTs) up to 1 June 2012. This overview was undertaken according to the principles of systematic reviewing. An update to the PRISMS report was completed by running additional searches in Pubmed, Embase and the Cochrane library from 2012 to 1 April 2015, see Appendix A3.1. As noted in Chapter 3.1.1, SMS interventions are typically complex interventions that include more than one component of SMS. For this reason, and consistent with the PRISMS report, with the exception of education interventions, this review did not assess single component SMS (for example, simple text message appointment reminders and drug reminder packaging). In accordance with the Population, Intervention, Comparator, Outcomes, Study design (PICOS) criteria agreed with the key stakeholder, this assessment is limited to SMS interventions for adults aged 18 and over. Results from the updated search are reported in addition to a summary of the findings of the PRISMS report. PRISMS did not include telehealth reviews as they were typically about mode of delivery rather than content of what was delivered, telehealth interventions that incorporated a significant component of self management support were however included in this updated review.

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 score weighting by patient or participant trial size) and meta-analyses (Higgins et al.'s quality assessment tool),[23] was undertaken. While the R-AMSTAR score was used to determine the quality of the systematic reviews, the scores were then weighted by patient or participant trial size, with the quality of evidence being downgraded if the review

was based on fewer than 1,000 participants. The quality of primary evidence was not evaluated directly; where reported, information on the risk of bias of the primary studies was extracted from the systematic reviews.

5.2.2 Description of the interventions

A general description of self-management and typical SMS interventions is included in the Background and Methods chapter. Asthma-specific interventions introduced in this Phase II report include written action (or management) plans (WAPs). These are written plans that a person with asthma develops with their doctor to help them control their condition. A written action plan typically shows their daily treatment, such as the type or types of medicine to take and when to take them. It describes how to control asthma in the long term and how to handle worsening symptoms, or attacks. The plan explains when to call the doctor or go to the emergency department.

5.2.3 Results – Clinical-effectiveness

The PRISMS review retrieved a total of 18 systematic reviews of asthma-specific self-management interventions and generic interventions used in patients with asthma. Of these, eight specifically focused on interventions in adults over 18 years of age. One additional systematic review that included both adults and children provided sufficient detail that adult-only results could be extracted.[2] The PRISMS report was updated to April 2015 using the search string in Appendix 1. A further three systematic reviews were retrieved (Figure 5.1) which assessed text messaging,[92] behaviour change techniques[93] and combinations of SMS interventions including education.[94] Summary details of the reviews are included in Table 5.1.

For the 12 reviews, the number of included RCTs per systematic review ranged from four[95] to 39[93;94] with the total number of participants ranging from 475[92] to 7,883.[96] The 12 systematic reviews contained 90 unique RCTs with study overlap between the reviews reported in Table 5.2. The publication date of the systematic reviews ranged from 2002 to 2015 while that of the included RCTs ranged from 1979[97] to 2011.[93] RCT study locations were typically in Europe or North America.

Figure 5.1. Flowchart of included studies from updated search

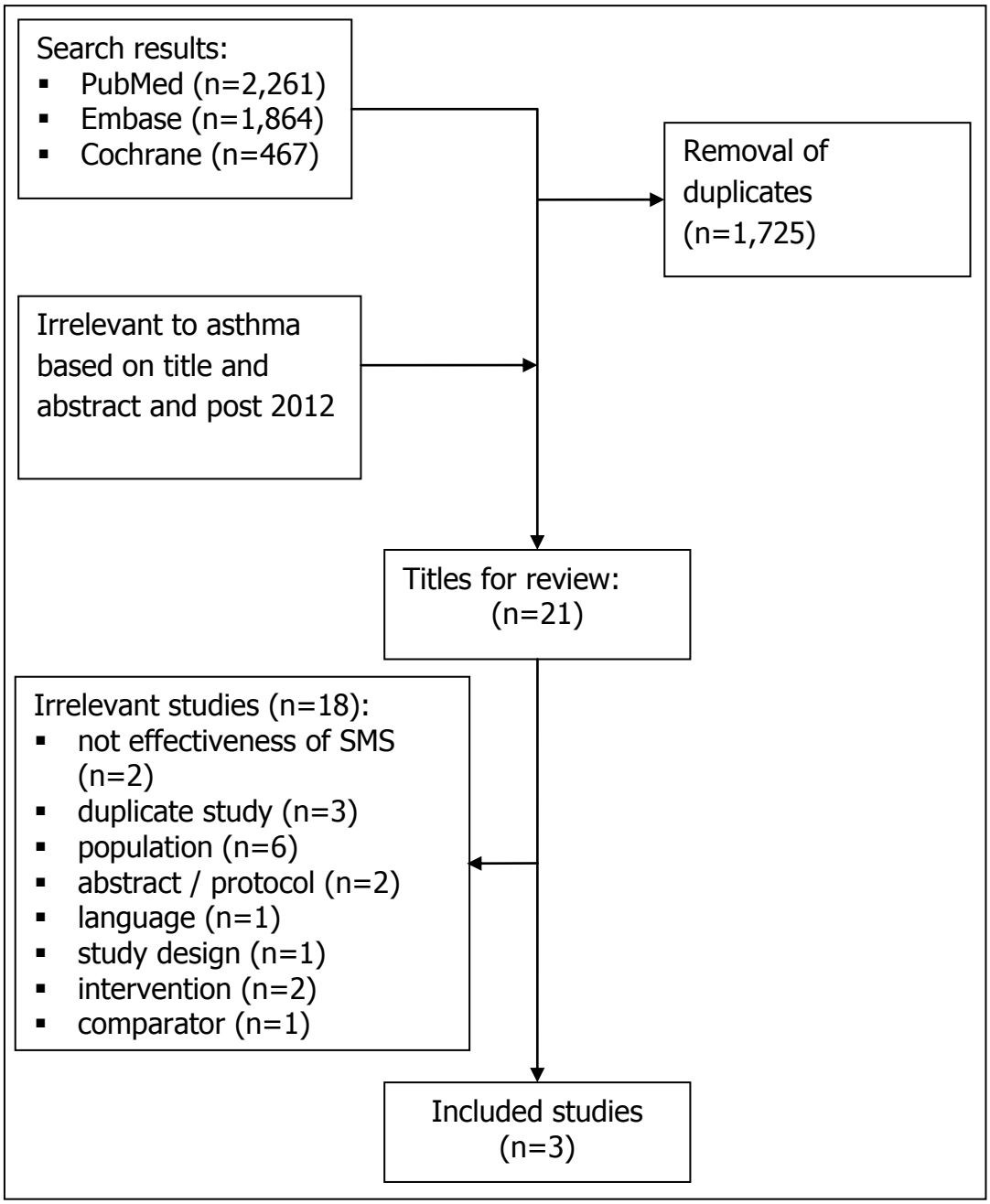


Table 5.1. Summary of systematic reviews identified for inclusion

Author (year)	Intervention
Reviews retrieved by PRISMS	
Bailey (2009)[95]	Education programmes -Culturally orientated
Tapp (2007)[97]	Education while attending emergency department
Gibson (2002)[98]	Educational programmes (including WAPs)
Powell (2002)[99]	Education (including WAPs)
Gibson (2004)[100]	Written Action Plans (WAPs)
Ring (2007)[101]	Action plans - Encourage use
Toelle (2004)[102]	WAPs
Moullec (2012)[103]	Medication adherence – components of Chronic Care Model
Newman (2004)[104]	Range of SMS interventions
Additional reviews retrieved in the updated search	
Blakemore (2015)[94]	Range of SMS interventions
Denford (2014)[93]	Range of behaviour change techniques
DiBello (2014)[92]	Text messaging – adherence to treatment and medication

Key: **SMS** = self-management support; **WAP** = written action plans.

Table 5.2 Study overlap between the included systematic reviews (PRISMS report plus the systematic reviews from the updated search).[3] Adapted from PRISMS review.[(2)]

	Review (year)	1	2	3	4	5	6	7	8		9	10	11
PRISMS retrieved reviews													
1	Bailey (2009)	**4**											
2 3	Gibson (2002) Gibson (2004)	2	**38**										
4	Moullec (2012)	0	6	**18**									
5	Newman (2004)	1	8	6	**18**								
6	Powell (2002)	0	6	2	4	**15**							
7	Ring (2007)	0	3	2	1	2	**14**						
8	Tapp (2007)	0	2	2	2	0	2	**13**					
9	Toelle (2004)	0	3	1	2	6	0	0	**7**				
Reviews retrieved in updated search													
10	Denford (2014)	1	9	7	6	2	3	5	0		**39**		
11	DiBello (2014)	0	0	0	0	0	0	0	0		0	**5**	
12	Blakemore (2015)	0	11	5	6	3	4	9	1		11	0	**39**

*The Cochrane review by Toelle et al. was withdrawn in 2011 based on the search being out of date. The author states that written action plans are now viewed as a component of asthma self-management rather than a standalone intervention.

[3]PRISMS review is based on a search from 1993 to June 2012. This search was updated to April 2015.

5.2.3.1 Summary of findings

Detailed summaries of the systematic reviews including the intervention, outcomes assessed, duration of follow-up, sample size (number of RCTs and total number of participants), and the evidence of effect are included in Appendix A.5.1. The following are reported based on the findings from PRISMS and the additional systematic reviews retrieved in the updated search. As per Chapter 3, the quality of the systematic reviews was assessed and graded. The R-AMSTAR scores ranged from 23 to 39, with scores of 31 or more indicating a high-quality systematic review. When weighted according to the number of participants in the original RCTs (<1,000 or ≥ 1,000), six of the systematic reviews were assigned the highest quality rating (three-star ***),[93;94;97-99;101] while five reviews each were rated as two-star **[95;100;102-104] and one as one-star*[92] in terms of their quality and size.

If a meta-analysis was completed, its quality was assessed as per Chapter 3 and graded as being of low, moderate or high-quality. Eight of the systematic reviews included meta-analyses, of which six were assessed as high-quality and two were assessed as low 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. Studies graded as 'high-quality' were likely to have conclusions that accurately reflected the available evidence (see also Chapter 3, Table 3.1). Table 5.3 below details the number of primary studies within the review, and the quality assessment of both the systematic reviews and meta-analyses and the evidence underpinning them and provides a summary of findings for selected outcomes from the various meta-analyses assessing the impact of SMS interventions in asthma.

Table 5.3 Study details, quality assurance and summary of findings from meta-analysis of impact of self-management support interventions on health-related quality of life and resource utilisation

Study	Quality of systematic review			Primary Studies		Meta-analysis quality	QoL (MD)	Hospitalisation (RR)[b]	ED (RR)
	R-AMSTAR score	Participants	Quality rating	n	Low risk of bias[a]				
Bailey 2009[(95)]	36	617	**	4	1	High	0.25 (0.09 to 0.41)		
Gibson 2002[(98)]	39	6,090	***	38	8	High	0.29 (0.11 to 0.47)	0.64 (0.50 to 0.82)	0.82 (0.73 to 0.94)
Gibson 2004[(100)]	39	NR	**	38	NR	Low		0.46 (0.26 to 0.81) 0.66 (0.48 to 0.91) 0.65 (0.48 to 0.88) 0.23 (0.07 to 0.71) 0.59 (0.44 to 0.78)	
Moullec 2012[(103)]	27	3,006	**	18	NR	Low			
Newman 2004[(104)]	23	2,004	**	18	NR	NA			
Powell 2002[(99)]	34	2,460	***	15	5	NA			
Ring 2007[(101)]	35	4,588	***	14	1	NA			
Tapp 2007[(97)]	39	2,157	***	13	5	High		0.50 (0.27 to 0.91)	0.66 (0.41 to 1.07)
Toelle 2004[(102)]	38	967	**	7	2	High		1.17 (0.31 to 4.43)	0.86 (0.44 to 1.67)
Denford 2014[(93)]	33	7,883	***	39	NR	High			
DiBello 2014[(92)]	30	475	*	5		NA			
Blakemore 2015[(94)]	37	4,246	***	39	8	High			

Key: **ED** = emergency department; **MD** = mean difference; **NA** = not applicable; **NR** = not reported; **QoL** = quality of life; **RR** = relative risk.

[a] Number of the total primary studies identified as being at low risk of bias. [b] Figures for Gibson 2004 relate to different action plan components

[c] It is assumed that the definitions used for unscheduled care and urgent care are similar.

Table 5.3 (continued). Study details, quality assurance and summary of findings from meta-analysis of impact of SMS interventions on health-related quality of life and resource utilisation

Study	Quality of systematic review			Primary Studies		Meta-analysis quality	Unscheduled/ urgent healthcare use (RR)[c]	Unscheduled doctor visits (RR)[c]
	R-AMSTAR score	Participants	Quality rating	n	Low risk of bias			
Bailey 2009[95]	36	617	**	4	1	High		
Gibson 2002[98]	39	6,090	***	38	8	High		0.68 (0.56 to 0.81)
Gibson 2004[100]	39	NR	**	38	NR	Low		
Moullec 2012[103]	27	3,006	**	18	NR	Low		
Newman 2004[104]	23	2,004	**	18	NR	NA		
Powell 2002[99]	34	2,460	***	15	5	NA		
Ring 2007[101]	35	4,588	***	14	1	NA		
Tapp 2007[97]	39	2,157	***	13	5	High		
Toelle 2004[102]	38	967	**	7	2	High		1.34 (1.01 to 1.77)
Denford 2014[93]	33	7,883	***	39	NR	High	0.71 (0.56 to 0.90)	
DiBello 2014[92]	30	475	*	5		NA		
Blakemore 2015[94]	37	4,246	***	39	8	High	0.79 (0.67 to 0.94)	

Key: **ED** = emergency department; **MD** = mean difference; **NA** = not applicable; **NR** = not reported; **QoI** = quality of life; **RR** = relative risk.

[a]Number of the total primary studies identified as being at low risk of bias
[b]Figures for Gibson 2004 relate to different action plan components
[c]It is assumed that the definitions used for unscheduled care and urgent care are similar.

Three star (***) reviews

Based on two 'three-star'[97;98] and two 'two-star' reviews,[100;102] PRISMS reported that there is evidence that SMS interventions for patients with asthma reduce hospital admissions. Based on one three-star, they reported that SMS interventions (including asthma education, self-monitoring of peak expiratory flow or symptoms, regular medication review, and a written action plan) increase quality of life. They noted that optimal asthma self-management should include education supported by a written asthma action plan. They also noted that symptom-based plans are as good as peak flow-based plans.

In the updated search, additional good quality evidence was retrieved to support the use of a number of SMS interventions in patients with asthma. A 2015 meta-analysis by Blakemore et al. of 39 RCTs comprising 4,246 patients assessed a number of 'complex interventions' (that is, including multiple components or modes of delivery of SMS), mainly education and skills-related for asthma self management.[94] Based on a high-quality meta-analysis, they reported that the odds of urgent healthcare use were 21% lower in the intervention group, although only eight of the 39 studies included were considered at low risk of bias. Interventions that included education, skills training and relapse prevention were found to be effective; however, the only intervention to remain significant in the multivariate meta-regression was skills training. The authors suggested therefore that improved skills training including the use of inhalers and peak flow meters would help to ensure that patients receive the optimum preventative medication and could have a central role in the reduction of urgent healthcare use for adults with asthma.

A 2014 meta-analysis of 39 RCTs comprising 7,883 patients by Denford et al. assessed a range of behaviour change techniques in asthma SMS interventions.[93] Based on a high-quality meta-analysis, they reported very strong evidence that the interventions are effective in reducing symptoms, are associated with a significant increase in adherence to preventive medication, and that there is evidence that asthma-specific SMS interventions reduce unscheduled health care use. The quality of the primary studies was evaluated, but not reported. The authors concluded that it was not possible to determine the optimal content of asthma SMS interventions from the available evidence.[93]

Two star (**) reviews

Based on one 'two-star' review (two RCTs) PRISMS reported that education should be culturally sensitive with evidence of improvements in asthma-related quality of life for culturally-orientated programmes in minority groups.[95]

Based on a further 'two-star' review, PRISMS reported that greater adherence to inhaled corticosteroids was seen when more components of the Chronic Care Model were included within interventions.[103] Components included self-management education, behavioural support, decision support, and delivery system design. However, it was noted that only a small number of component combinations were tested, limiting the ability to determine which components were most important for success.[103]

One star (*) reviews

The narrative synthesis of five RCTs and one observational study by DiBello et al. reported that text messaging intervention programmes may have a positive impact on medication adherence rates as well as perceived control of asthma.[92] The text programmes varied from medication and appointment reminders, general education and management strategies, to customised treatment instructions based on peak flow results (transmitted also by SMS), with variability also in the duration of follow-up and outcome measures used. Other clinical outcomes that may also show a positive effect from a text messaging intervention were measures of lung function. However, these results were based on small sample sizes and short-term follow-up. They also reported that there is no statistical evidence clearly indicating if the number of emergency department visits will decrease or increase with the use of a text messaging intervention.

Summary statement

Based on the quantity and quality of the systematic reviews and the underpinning primary randomised controlled trials (RCTs) there is good evidence that asthma self-management support interventions improve quality of life and reduce hospital admissions and the use of urgent and unscheduled health care. Optimal asthma self-management should include education supported by a written asthma action plan as well as improved skills training focused on the skills such as the use of inhalers and peak flow meters. Behavioural change techniques are associated with improved medication adherence and a reduction in symptoms.

5.3 Review of cost-effectiveness of self-management support interventions

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

5.3.1 Search strategy

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

The PICOS (Population, Intervention, Comparator, Outcomes, Study design) analysis used to formulate the search is presented in Table 5.4 below.

Table 5.4 PICOS analysis for identification of relevant studies

Population	Adults ≥ 18 years old that had asthma.
Intervention	Any self-management support intervention that helps patients with asthma 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.

Studies 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 2000 as it would have limited relevance.

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

5.3.2 Results – Cost-effectiveness

The initial screening retrieved 64 papers relating to asthma. Of these, 27 studies were identified for full text review, with the remaining 37 excluded as irrelevant or unsuitable based on screening of abstract or full text. A further 15 were excluded according to our various exclusion criteria, leaving 12 articles included in this review. Data extraction was carried out independently by two reviewers.

Two studies each were conducted in the United States (US), the Netherlands and the UK, with one each from Canada, Australia and Norway. Three Finnish studies were identified that examined the same cohort at one, three and five years follow-up. The included studies were all published between 1998 and 2011. The characteristics of the included studies are given in Table 5.5. Costs reported in each of the studies were inflated to 2014 pricing using the local consumer price index for health and expressed in Irish Euro using the purchasing power parity exchange rate.[105]

Table 5.5 Characteristics of the studies included

Study	Country	Intervention
Castro (2003)[106]	US	Case management
Corrigan (2004)[107]	Canada	SMS education programme
Donald (2008)[108]	Australia	Nurse-led telephone review
Gallefoss (2001)[109]	Norway	SMS education programme
Kauppinen (1998, 1999, 2001)[110-112]*	Finland	SMS education programme
Parry (2012)[113]	UK	Cognitive Behavioural Therapy (CBT) for asthma-related anxiety
Pinnock (2005)[114]	UK	Nurse-led telephone review
Shelledy (2009)[115]	US	In-house case management including environmental assessment
van der Meer (2011)[116]	Netherlands	Internet SMS programme
Willems (2007)[117]	Netherlands	Nurse-led telephone review with remote peak flow monitoring

* While studies published prior to 2000 were excluded based on limited relevance, the earlier studies by Kauppinen were included as they referred to follow-up of the same cohort over a five-year period.

Key: **SMS** = self-management support.

The studies were classified according to intervention type: SMS education programmes, internet-based SMS programmes, telemedicine and other SMS interventions. However, it is worth noting that many studies looked at a combination of interventions. In particular, written self-management plans, which are known to

be effective in asthma, featured in five studies, but were not assessed as standalone interventions.

This review captures all SMS interventions assessed for asthma and retrieved few conventional economic evaluations. Eleven of the retrieved studies gathered cost data as part of a randomised controlled trial (RCT) while data for one study was based on an observational cohort study. Five of the studies were limited to costing studies. The quality of the included studies was predominantly poor.

5.3.2.1 Self-management support education programmes

Four articles were retrieved that assessed SMS education programmes describing three unique studies (Table A5.3). Two of the studies were based on cost data gathered as part of an RCT: one study from Finland reported the one-, three- and five- year outcomes for the same RCT cohort.[110-112] One study from Norway assessed outcomes at one year.[109] The number of participants in these studies ranged from 78 to 162. Finally, a study from Canada modelled the cost of different asthma SMS education delivery models for primary care (general practitioner [GP]) practices with populations of adult asthma patients ranging from 25 to 100 patients.[107]

The interventions described in the studies varied in format and intensity. Both the studies from Norway and Finland used a combination of group and individual visits and provided participants with written self-management plans.[109-112] The Finnish study also required patients to measure their peak flows and keep a diary. The Canadian study examined the cost, from the GP perspective of different formats and durations of education sessions with initial peak flow measurement performed at the GP surgery. The Finnish and Norwegian studies examined costs and benefits from a societal perspective.

The experimental studies measured and reported undiscounted total direct and indirect asthma-related costs during the study period. Direct costs included costs to the health system, both primary and secondary care and cost to patients. Indirect costs included productivity loss due time spent ill or to attend visits.[107;109-112] Gallefoss et al. reported total mean costs of €1,768 per patient for those who participated in the education programme compared to mean total annual costs of €1,160 per patient for the control groups. In contrast, the Finnish study found slightly higher total mean annual costs in the intervention group in the first year (€438 per patient) compared with the control group (€373 per patient). Cost savings did occur at the three and five year follow-up and were mainly driven by a reduction in unscheduled attendance costs. It is important to note that the intervention was only delivered in year one and not repeated in the following years.

Only two of the studies examined clinical outcomes.[109-112] The Norwegian study found significant improvements in forced expiratory volume in one second (FEV1) and disease-specific quality of life scores (Saint George Respiratory Questionnaire scale) in the intervention group. This, coupled with lower total costs for the intervention group, resulted in an negative incremental cost-effectiveness ratio (ICER) of €497 per 5% improvement in FEV1 and of €376 per clinically significant improvement in quality of life score (10 units on the Saint George Respiratory Questionnaire scale). Reporting on a range of clinical outcomes (lung function [FEV1, FVC, PF], bronchial hyper-responsiveness [PD15] and both generic and disease-specific health related quality of life), the Finnish study noted statistically significant improvements for the intervention group in a limited number of surrogate markers at one-year (FEV1) and three-year (FEV1, PEF, and PD) follow-up, but reported no difference in clinical outcomes between the groups at five years.

Overall, evidence for the cost-effectiveness of SMS education programmes was conflicting. Both studies that examined clinical outcomes found improvements at year one, though these were not sustained. The cost of the SMS intervention was typically low, while mean total costs were typically found to be comparable or lower in the intervention group at year one.

5.3.2.2 Internet-based self-management support programme

One study, conducted in the Netherlands, evaluated the cost-effectiveness of an internet-based SMS programme (as shown in Table A5.4).[116] Two-hundred participants were enrolled in the RCT and followed up for one year. The intervention included an immediate computerised action plan based on the results of weekly monitoring of asthma control and lung function that were inputted by the participants. Other components were online and group education, and remote web communication with a specialist nurse.

The average cost of the intervention from a societal perspective was €265 per patient per year. The study found no statistically significant difference in costs or quality-adjusted life years (QALYs) between groups, but calculated an (incremental cost-effectiveness ratio) ICER of €27,829 per QALY from a societal perspective. This decreased to €1,563 per QALY if a provider perspective was adopted. Interpretation of the results of the economic analysis is complicated by the absence of a statistically significant clinical effect. As a result, the focus should be on the cost findings rather the effectiveness data.

Costs of the technological innovation (software support, electronic spirometer, Internet and mobile phone costs) were approximately 40% of the total intervention costs in year one. The fixed technological costs of software support constituted

about one third of the intervention costs, so increasing the number of users could substantially reduce the cost per user.

5.3.2.3 Telemedicine

Three studies assessed a telemedicine intervention: one UK study with a three-month follow-up directly compared the cost of a telephone-based nurse consultation with that of a face-to-face nurse consultation.[114] Another study from Australia compared the cost of six follow-up telephone consultations with usual care following an initial face-to-face educational visit for all participants (Table A5.5).[108] The third study, from the Netherlands, required participants to monitor twice-daily peak flow measurements and transfer these electronically to a nurse who would advise on therapeutic changes based on a stepwise protocol.[117]

All three studies were RCTs with the number of participants ranging from 53 to 278 adults and the follow-up from three months to one year. Both the UK and Australian studies reported cost savings in the intervention group from a healthcare provider perspective. The cost of the intervention in the Australian study was €90 per patient and of this, €40 was related to the initial educational session and the remainder to the telephone follow-up.[108] They only examined readmission cost differences between the two trial components and used a fixed tariff per admission to value these. They found that the control group had much higher readmission costs having had six episodes compared to one in the intervention group at year one follow-up. In the UK study, the total cost of the telephone review service was similar to that of the surgery review.[114] However, a higher proportion of patients completed the consultation in the telephone review service, 78% vs 48%, resulting in mean cost savings of €7 per consultation.

In the study from the Netherlands, the mean healthcare costs per patient were higher in the intervention group (€2,419) than in the control group (€1,867). This difference was mainly due to the intervention costs of €589 per person, primarily comprising fixed hardware costs. The study found no statistically significant difference in quality-adjusted life years (QALYs) between groups, but calculated an ICER of €17,069 per QALY gained from a healthcare payer perspective and €34,472 per QALY gained from a societal perspective. Removing hardware costs from the analysis reduced the ICER to €1,954 per QALY from the healthcare payer perspective. The authors postulated that with fast technological advances a reduction in the cost of monitoring could increasing the cost-effectiveness of their SMS programme.

The Australian study reported a clinically significant improvement in the Modified Marks Asthma Quality of Life Questionnaire (MAQLQ-M) in the intervention group not seen in the control group, but no difference in self-efficacy scores in either trial arm.

In contrast, the UK study found similar asthma-related quality of life scores between groups at the three month follow-up.

Evidence for the cost-effectiveness of telemedicine interventions in asthma is mixed. The cost of the intervention was low for studies involving nurse-led telephone review, but fixed hardware costs were substantial in the study involving remote peak flow monitoring. One study found improvements in clinical outcomes associated with total cost savings. The remaining studies did not find significant clinical improvements, though healthcare costs in the intervention groups were higher.

5.3.2.4 Other self-management support interventions

Three additional studies evaluating different SMS interventions were identified. Two studies describing two different multi-faceted interventions were RCTs from the US,[106;115] and one study examining a cognitive behavioural therapy (CBT) intervention for asthma-related anxiety from the UK.[113] All three were limited to costing studies undertaken alongside RCTs. Follow-up ranged from six months to one year.

In Castro et al., the intervention consisted of a nurse-led service for 'high-risk' patients which included patient education, psychosocial support, individualised asthma management plan and out-patient follow-up via telephone, home visits or GP review as required.[106] The definition of 'high-risk' included hospitalisation with an asthma exacerbation and a history of frequent healthcare use. Significant reduction in hospital readmissions (60%, $p<0.01$), total bed days (69%, $p<0.04$) and multiple readmissions (57%, $p=0.03$) were documented along with a non-significant increase in emergency department visits (34%, $p=0.52$) and healthcare provider visits (3%, $p=0.82$). There was no difference in health-related quality of life between the two arms. The cost of the intervention was estimated at €384 per patient. This resulted in a mean direct health care cost savings of €9,157 per patient. The reduction in cost was mainly due to lower hospitalisation costs. The total healthcare costs were noted to be lower even when indirect patient costs such as, lost workdays and non-professional caregiver costs, were taken into account.

Shelledy et al. randomised patients into three groups to compare an in-home asthma management intervention delivered by either a respiratory therapist or a specialist nurse with usual care.[115] The intervention was a five-week multi-faceted programme delivered at home and included education visits, peak flow diaries, written action plans and environmental assessments. The cost of the programme was $365 per patient. Both asthma management groups had significantly fewer hospitalisations than the usual care group. This resulted in net hospitalisation cost savings of $37,800 for the nurse-delivered group and $32,200 for the respiratory therapist delivered group. The hospitalisation cost difference between the two

intervention arms was not significant and there were no significant differences in emergency department visits amongst the three groups. Both asthma management groups showed statistically significant improvements in quality of life scores on SF-36 PCS scales and patient satisfaction surveys. However, only the respiratory therapist group had significantly higher scores in the Asthma Self-management questionnaire at six months compared with usual care, indicating improved knowledge of the management of an asthma episode in this group.

Parry et al. selected patients who displayed signs of asthma-related anxiety to be randomised to receive a combination of asthma and anxiety education, and CBT delivered by a trained psychologist or usual care.[113] The intervention cost an average of £378 to £798 per patient depending on the number of sessions attended. No cost offsets were observed which offered no treatment cost advantage. Improvements in asthma-specific fear, quality of life and depression between the intervention and control groups were noted; however, the effect was clinically modest and was not sustained at six months. Of note, only 18 of the 32 patients randomised to the intervention arm completed the full course of treatment visits.

Limited data from the US and UK suggest that multi-faceted programmes including education components aimed at patients with poorly controlled asthma may result in decreased healthcare utilisation and associated cost savings. However, the available evidence is limited to costing studies, with the RCT data underpinning the analyses based on small sample sizes and six to 12 months follow-up. The interventions evaluated varied in form, intensity and mode of delivery, therefore it is not possible to identify which components were more effective.

5.4 Discussion

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

5.4.1 Clinical-effectiveness

Twelve systematic reviews are included in this overview of reviews. Nine studies were identified in the PRISMS review with an additional three studies identified in the updated search. A diverse range of self-management support (SMS) interventions were assessed. The interventions differed in the frequency, intensity and mode of delivery. Despite the heterogeneity within the intervention classes, there was a tendency for their findings to be combined, so the results of the meta-analyses should be interpreted with caution.

The findings from the 2014 PRISMS systematic review and the additional findings from this updated review indicate that SMS interventions in asthma can reduce hospital admissions and urgent healthcare use (emergency department visits and

unscheduled healthcare). Of note, these findings do not take consideration of the underlying risk of hospitalisations and urgent healthcare use as these are not reported in the systematic reviews. Therefore, it is not possible to quantify the absolute benefit of the interventions. There is limited randomised controlled trial (RCT) evidence that SMS interventions improve health-related quality of life. Where recorded, it was noted that the duration of follow-up for the trials was typically short-term; it is not known if the benefits are sustained over time.

As noted, there was significant heterogeneity in the format and intensity of the SMS interventions, the study populations, study follow-up duration and assessed outcome measures which makes it difficult to formulate clear recommendations regarding the most effective form and content of SMS in asthma. However, while the optimal intervention format of SMS is not clear, it should include education supported by a written asthma action plan. Skills training which is focused on the use of inhalers and peak flow meters would help to ensure that patients receive the optimum preventative medication and could have a central role in the reduction of urgent healthcare use for adults with asthma. The HSE's National Clinical Programme for asthma plans and the 2013 Irish Asthma Control in General Practice guidelines are in line with the findings discussed above in terms of use of SMS patient education, skills training, and use of written action plans.

The included RCTs were published from 1979 to 2010 (PRISMS) and 1993 to 2011 (additional studies) and were mainly completed in Europe or North America. Given the description of the asthma patient populations and asthma epidemiology, it would appear that the evidence should be able to be applicable to the Irish healthcare setting. Potential caveats to this assumption are the extent to which the comparator (usual care) in these RCTs is representative of usual care in Ireland due to differences in the stated standards of care and how healthcare is provided. Given the increasing tendency for usual or standard of care to be determined by evidence-based clinical guidelines and the convergence of such guidelines in Western countries, the assumption that stated standard of care is similar is not unreasonable. However, differences in healthcare systems may contribute to differences in the adherence to stated standard of care. For example, usual care for asthma in the Irish primary care setting may differ to that in the UK's National Health Service (NHS) system where adherence to quality standards is incentivised by the quality of outcomes framework. Work by the HSE's National Clinical Programme for Asthma is underway to improve asthma management in Ireland. A national model of care for asthma is being finalised which includes self-management components and details a collaborative approach between primary and secondary healthcare professionals and patients to provide a safe, seamless patient experience within the heath system.[118]

Given the volume of evidence available, in the interest of efficiency this assessment of SMS interventions in adults with asthma was undertaken in the form of an overview of reviews. As discussed in Chapter 3.4.1, a disadvantage of this approach is the inability of an overview of reviews to reflect the most recent literature: following publication of an RCT, it must first be captured in a systematic review, before subsequently being captured in an overview of reviews. This approach is therefore less suitable for a fast-moving area where there are rapid advances in the technology. However, given their sample sizes, it is not appropriate to draw conclusions on the effect of an intervention based on a single, or a number of small, RCTs. Therefore it is unlikely that more recent RCTs not captured in this overview of reviews would be sufficient to substantially alter recommendations informing major policy decisions.

5.4.2 Cost-effectiveness

Our search identified 12 individual economic evaluations of SMS interventions for asthma. The interventions assessed were heterogeneous as most comprised several components including education, peak flow monitoring and personalised self-management plans. Three of the studies (five reports) described education programmes for SMS of asthma, but within this group, the format and duration of these programmes differed in delivery-mode, duration and intensity. The three telemedicine studies also described heterogeneous models of intervention with some incorporating elements of education or remote peak flow monitoring.

The majority of the studies had small sample sizes and collected cost data alongside RCTs. This raises inherent issues around whether their cost findings can be applicable to the broader population. In addition, most of the studies only followed participants for up to one year and it is therefore unclear how the clinical benefits and the healthcare utilisation would change over time. The Finnish study that followed participants for five years concluded that while there was a consistent tendency for the intervention (intensive education in year one) to be less costly, there were no significant differences in outcomes or costs at one, three or five years. Of note, costs and benefits were not discounted in this study.[110-112]

Six of the studies were limited to costing studies, a number of which did not report clear costing methodology, therefore it was difficult to determine their quality and to deduce the cost of different components of the interventions. Most of the studies adopted a societal perspective. However, it was not always clear whether costs were incurred by the provider or the patient (for example, medication costs). This limits the application of the findings to the Irish setting. The quality of the included studies was predominantly poor.

In summary, the review of cost-effectiveness found 12 studies, the majority of which collected cost data alongside RCT data. This is in contrast to the review of the clinical effectiveness literature which included 12 systematic reviews of 90 unique RCTs. In general, the cost per patient of the intervention was low and the majority of the studies reported some degree of cost savings in the short-term through reduced healthcare utilisation. There were four cost-utility analyses, all of which used data from RCTs and did not extrapolate the results beyond the duration of the trial follow-up. No significant difference in clinical effectiveness between the intervention and control arms was found in any of these studies, complicating interpretation of any ICER calculated. The short follow-up period and the relatively small sample sizes raise concerns regarding the sustainability of the interventions and how applicable the findings are.

5.5 Key points

- Twelve systematic reviews of the clinical effectiveness of self-management support (SMS) interventions in adults with asthma were identified for inclusion in this overview of reviews.
- A diverse range of interventions was identified with the largest volume of evidence obtained for a combination of asthma educational programmes plus written action plans (n=7), a range of SMS interventions (n=2) and behavioural change techniques (n=1). Other interventions assessed included text messaging (n=1) and the Chronic Care Model (n=1) for treatment and medication adherence, respectively.
- The quality of the systematic reviews was good, with six rated as being higher quality reviews.
- The primary evidence underpinning the systematic reviews was found to be generally at moderate- to high-risk of bias, meaning that studies may have over- or under-estimated the effect size. It comprised 90 unique randomised controlled trials (RCTs) published between 1979 and 2011. These were mainly completed in Europe or North America.
- Based on the quantity and quality of the systematic reviews and the underpinning primary RCTs, there is good evidence that SMS interventions can improve quality of life and reduce hospital admissions and use of urgent and unscheduled healthcare. Behaviour change techniques are associated with improved medication adherence and a reduction in symptoms. The optimal intervention format of SMS is not clear, but should include education supported by a written asthma action plan as well as well as improved skills training including the use of inhalers and peak flow monitors.
- There is very limited evidence on the cost-effectiveness of chronic disease SMS

interventions for asthma with only 12 relevant studies retrieved. These were mostly based on cost data collected alongside RCTs that used small sample sizes and short follow-up periods, limiting the applicability of the findings.

- There is limited evidence to suggest that SMS education programmes, using a combination of individual and group sessions, may be at least be cost-neutral in patients with mild to moderate disease.
- There is limited evidence to suggest that nurse-led telephone review for patients with high-risk asthma is a relatively low cost intervention that may reduce costs by reducing healthcare utilisation, although evidence of effect in the included studies was mixed.
- Based on the description of the healthcare systems, the epidemiology, and the asthma patient populations in the included studies, and assuming that what constitutes 'usual care' is similar in Western countries, it is expected that the findings of clinical effectiveness are broadly applicable to the Irish healthcare setting. The evidence of cost-effectiveness is of limited applicability to the Irish healthcare setting, with findings from the European studies being of greater relevance.

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 A5 - Asthma

Table A5.1 Results of meta-analyses from the PRISMS review plus from the update search. Table adapted from PRISMS review

Reference and weighting Outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size (# of RCTs; # of patients)	Significance [a]	Effect Size (95% CI)
Bailey (2009)[95]**	Culturally orientated programmes vs. control	Asthma specific QoL	NR	2 RCTs; 293	+*	WMD 0.25 (0.09 to 0.41)
Gibson (2002)[98]***	Asthma self-management and educational programmes (including asthma education, self-monitoring of peak expiratory flow or symptoms, regular medical review and a written action plan) vs. control	Hospital admissions	NR	12 RCTs 2,418	+++	**RR** 0.64 (0.50 to 0.82); p=0.0003
		ED visits (dichotomous)	NR	13 RCTs; 2,902	++	RR 0.82 (0.73 to 0.94); p=0.003
		ED visits (mean number)	NR	8 RCTs; 731	+*	SMD–0.36 (–0.50 to–0.21)
		Unscheduled doctor visits (dichotomous)	NR	7 RCTs; 1,556	+*	RR 0.68 (0.56 to 0.81)
		Unscheduled doctor visits (mean number)	NR	7 RCTs; 1,042	0	SMD–0.07 (–0.19 to 0.06)
		Work/school absenteeism (dichotomous)	NR	7 RCTs; 32	+*	RR 0.79 (0.67 to 0.93)
		Work/school absenteeism (mean number)	NR	13 RCTs; 1,728	+*	SMD–0.18 (–0.28 to–0.09)
		Nocturnal asthma	NR	5 RCTs; 1,136	+*	RR 0.67 (0.56 to 0.79)
		FEV1	NR	7 RCTs; 1,072	0	SMD 0.10 (–0.02 to 0.22)
		PEFR	NR	10 RCTs; 1,346	+*	SMD 0.18 (0.07 to 0.29)
		QoL	NR	6 RCTS; 515	+*	SMD 0.29 (0.11 to 0.47)

Reference and weighting Outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size (# of RCTs; # of patients)	Significance [a]	Effect Size (95% CI)
Powell (2002)[99]***	Asthma education and self-management vs. control	Mean FEV1	NR	3 RCTs	0	SMD 0.19 (–0.05 to 0.25)
Tapp (2007)[97]***	Education vs. control	Hospital admissions	NR	5 RCTs; 572	+*	**RR** 0.50 (0.27 to 0.91) Average NNT=9 Stratified by risk: lower risk NNT=20, moderate risk NNT=8, high risk NNT=4
		ED visits	NR	8 RCTs; 946	+*	RR 0.66 (0.41 to 1.07)
		Scheduled clinic attendance	NR	2 RCTs; 198	+*	RR 1.73 (1.17 to 2.56)
		Lung function, PEFR	NR	3 RCTs	0	16.89 l/minute (–11.59 to 45.73 l/minute)
		Work/school absenteeism	NR	2 RCTs; 171	0	RR 0.88 (0.44 to 1.73)
Toelle (2004)[102]**	Peak flow-based action plans vs. symptom-based action plans	Unscheduled doctor visits	NR	2 RCTs; 207	+*	RR 1.34 (1.01 to 1.77) NNT: 7 favours symptom based
		Hospital admissions	NR	3 RCTs; 283	0	RR 1.17 (0.31 to 4.43)
		ED visits	NR	3 RCTs	0	RR 0.86 (0.44 to 1.67)
Denford (2014)[93]***	Behaviour change techniques in asthma self-care interventions.	Unscheduled health care use	2 to 18 months (median 12 months)	23 RCTS;	++	OR 0.71 (95% CI 0.56 to 0.90)
		Medication adherence to preventative medication		16 RCTs;	+++	OR 2.55 (95% CI 2.11 to 3.10)
		Reduction of symptoms		27 RCTs;	+++	SMD -0.38 (95% CI -0.52 to -0.24)
Blakemore (2015)[94]***	Complex interventions to reduce use of urgent healthcare in adults with asthma. These involved multiple components	Urgent healthcare use	6 weeks to 36 months (mean = 10.8 months)	33 RCTs; 4,246	+	The odds of urgent healthcare use were 21% lower in the intervention group, OR 0.79 (95% CI 0.67 to 0.94)

Reference and weighting Outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size (# of RCTs; # of patients)	Significance [a]	Effect Size (95% CI)
	and/or multiple professionals, and could be delivered on an individual or group basis, or using technology such as telephone or computer. Interventions could include education, rehabilitation, psychological therapy, social intervention (social support, support group), organisational intervention (such as collaborative care or case management), and drug trials which targeted a psychological problem, e.g. anxiety or depression.					

Key: **NR** = Not reported; **SMS** = Short Messaging Service;

The significance rating is per Appendix 1 using the scale from the PRISMS review.

Table A5.2 Summary of results from systematic reviews in the PRISM review plus the systematic reviews from the updated search, Table extracted from PRISMS review.

Reference and weighting Outcome	Intervention	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
Bailey (2009)[95]**	Culturally orientated programmes vs. usual care or limited/non-specific education	4 RCTs; 617; 2000–8	Meta-analysis (2RCTs)	A significant benefit in asthma QoL was found in intervention compared with control.	The available evidence suggests that culturally orientated education programmes for adults and children from minority groups are effective in improving asthma QoL in both adults and children, and rates of asthma exacerbations and asthma control in children. Authors theorise that culturally specific programmes allow participants to fully engage in education, which has positive effects on QoL. *This review is limited by a small number of studies and small sample sizes in two of the studies.*
			Other	No differences between intervention and control were found in any measure of adult exacerbation. Evidence for ED visits was conflicting.	
Gibson (2002)[98]***	Self-management and educational programmes vs. usual care	36 RCTs; 6090; 1986–2001	Meta-analysis	A significant impact was found on hospitalisation rates, emergency hospital visits, unscheduled doctor visits, days off work/school, nocturnal asthma, PEFR and QoL in the intervention group compared with control. No differences in FEV1 values were found between intervention and control.	Self-management educational programmes delivered to adults with asthma result in clinically important improvements in asthma health outcomes including reduced health-care utilisation, improvement in nocturnal asthma and reduced days off work. These benefits are most pronounced with interventions which involve a WAP, self-monitoring and regular medical review. Interventions which are less intensive, especially those that do not include a WAP, are less effective.
			Other	Subgroup analysis found optimal self-management (involving provision of WAPs) led to significant reductions in asthma-related hospitalisations and ED visits. Two interventions which included regular review of medication also found significantly reduced ED visits. Six studies reported on unscheduled doctor visits, with none finding a significant effect between groups. Nocturnal asthma was explored in four studies, three finding a significant	

Reference and weighting Outcome	Intervention	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
				improvement whereas one found no significant change. Oral corticosteroids and QoL were both assessed in four studies with mixed effect	
Gibson (2004)[100]**	WAPs vs. usual care	26 RCTs; 1987–2002	Other	Hospital admissions were significantly reduced in participants using action plans based on both personal best PEFR and % predicted PEFR compared with control. Emergency room visits were significantly reduced, and airway caliber improved, in intervention arms using personal best PEFR compared with control; however, no significant benefit was seen with plans based on % predicted PEFR. Benefits were found for any number of action points (two to four). The traffic light system was not consistently better than conventional presentation. Use of inhaled and oral steroids were consistently beneficial. Efficacy of incomplete and non-specific action plans was inconclusive	The findings of this review strongly support the use of individualised complete WAPs. Effective action plans can be based on symptoms or PEFR and use two, three or four action points. PEFR-based plans should use personal best PEFR and not % predicted PEFR for the action point. Treatment instruction should include both inhaled and oral steroids *In some cases there were insufficient studies to allow a comparison and hence a type II error is possible. However, review authors report that they were cautious in their interpretation of the data.*
Moullec (2012)[103]**	Interventions for improving use of inhaled corticosteroids (ICS) vs. usual care (Chronic Care Model components categorised as: self-management education, behavioural support, decision support, and delivery system design).	18 RCTs; 3006; 1990–2010	Other	Subgroup analysis found the smallest pooled ES in adherence measures for interventions with only one component of the chronic care model (CCM). ES for adherence measures were larger for interventions with two CCM components, and larger still for interventions with four CCM components. All adherence effects were statistically significant. Out of 13 studies exploring one CCM, three found significant effects, two out of five studies exploring two CCM components found significant effects, and two out of three studies exploring four CCM components	This review concludes that the more CCM components included within interventions, the greater the effects on ICS adherence outcomes. This review also suggests that interventions which include motivational support, such as through joint decision making, may show the greatest promise in improving adherence. However, more research is needed to confirm this A small number of studies were included, particularly for subgroup analysis on interventions with four CCM components. Also, the review authors acknowledge that a small number of CCM component

Reference and weighting Outcome	Intervention	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
				found significant effects. One study compared joint decision-making negotiated between clinician and patient, with decision made by physician alone. This study found a significant effect to support joint decision-making.	combinations were tested, which limits the ability to determine which components were most important for success.
Newman (2004)[104]**	Self-management interventions vs. standard care/basic information, or direct comparison between self-management interventions	18 RCTs; 2004; 1997–2002	Other	8 out of 14 studies showed some improvement in lung function. Most of these used education with an action plan, but others that used this approach did not find any improvements. A writing intervention for emotional expression and a stress management intervention also improved lung function, suggesting methods directed at stress and emotions can improve lung function. Half of the studies measuring QoL reported significant benefits. There was no particular pattern between those that did and did not impact on QoL. Of those interventions targeting some aspect of behaviours, 57% reported a significant change in behaviour. 7 out of 11 interventions showed reduction in health-care use; all but one used education and action plans. Only one study to use this approach did not find any reduction. No differences seen with or without action plans. Little difference recorded between use of symptoms or PEFR to guide use of medication	Review authors conclude that it should be recognised that one therapy or programme might not be suitable for all patients Evidence suggests importance of action plans in combination with education for improved lung function and reduced health-care utilisation. However, no clear patterns can be established as to the optimal self-management provision *Review authors state a potential limitation of their review to be their decision to only include papers published between 1997 and 2002. They also report that not all outcomes (in particular all clinical outcomes) were included in this review*
Ring (2007)[101]***	Interventions encouraging use of action plans vs. usual care	14 RCTs; 4588; 1993–2005	Other	Self-management education interventions were explored in five RCTS: four reported a significant increase in the number of people/ parents with action plans; one reported significantly higher action plan use. Telephone consultation to reinforce action	Primary care professionals could encourage the ownership and use of action plans through the implementation of proactive practice-based organisational systems. Highlights the lack of robust evidence on the best ways for GPs and practice nurses to

Reference and weighting Outcome	Intervention	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
				plan use was investigated in two RCTS: one study reporting a significant increase in people having action plans; both RCTs reporting greater understanding of how to use their plans. Asthma clinics were used in two interventions, both reporting increased ownership at 6 months post intervention, although only one was statistically significant. Asthma management systems were used in two studies: one finding more children received action plans (NNT=5); the other reporting significantly higher action plan use. Two studies looked at interventions aimed at HCPs. One study educated HCPs, with results suggesting this may facilitate action plan use for up to 2 years post intervention. Another RCT implemented quality improvement and found no overall effect	sustain action plan use among patients in the long term. Patient self-management education, reinforcement and prompting, school asthma clinics and asthma management systems all increase patient ownership or initial use of action plans up to 1 year post intervention. However, more research is needed to determine use of action plans over the longer term Some interventions used nurses with specialist asthma training; however, not all clinical nurses providing asthma care have received such training. Research interventions may also have extra resources not otherwise available. These factors may mean reduced effectiveness in a 'real-world' setting. *The authors acknowledge the possibility of publication bias in their review; however, they state that steps were taken to minimise this possibility*
Powell (2002)[99]***	Asthma education and self-management vs. usual care or one element of self-management (regular review/basic education/self-monitoring only	15 RCTs; 2460; 1990–2001	Meta-analysis	Those in the intervention had significantly better PEFR than those in the control arm. There was no significant difference in mean FEV1between intervention and control	Optimisation of asthma control by adjustment of medications may be facilitated either by self-adjustment with the aid of a WAP or by regular medical review. Individualised WAPs based on PEFR are equivalent to action plans based on symptoms These findings are clinically important as they enable interventions to be tailored to patient preference, patient characteristics and the resources available. Reducing the intensity of self-management education or level of clinical review may reduce its effectiveness

Tapp (2007)[97]***	Asthma education after acute asthma exacerbation event vs. usual care	13 RCTs; 2157; 1979–2009	Meta-analysis	Significant benefits in terms of hospital admission rates, ED attendance and scheduled clinic attendance were reported in the intervention group compared with the control. No statistically significant difference was found for PEFR or days off work/school	Although the evidence is supportive of educational interventions to reduce readmission following an episode of acute asthma in adults, the review does not provide evidence to suggest that other important markers of long-term asthma morbidity are affected
			Other	Two RCTS detected no difference in QoL between education and control in any domain. One RCT found no difference between intervention and control in various symptom measures. One RCT found suggestive improvements in inhalation technique and awareness of PEF readings	Adults may have limited opportunities to attend educational sessions in practice due to work and child care commitments, and the format, content and uptake of educational interventions still requires quantitative and qualitative evaluation *Review authors acknowledge the possibility of publication bias, although steps were taken to avoid this*
Toelle (2004)[102]**	Individualised WAP vs. no plan; or symptom-based plan vs. peak flow-based plan	7 RCTs; 967; 1990–2001	Meta-analysis	Participants in intervention arms had significantly fewer unscheduled doctor visits compared with control. No significant effects were found on hospitalisation or ED visit rates	Authors state that it is not possible to conclude whether or not use of written management plans alone leads to an improvement in asthma management behaviours. They go on to comment that in order to deliver benefit to the patient, programmes must be comprehensive and include education, a written self-management plan and regular review Authors acknowledge that the small number of included studies that contributed data for the meta-analysis and the small number of patients recruited in the studies have limited the ability to draw conclusive findings.
			Other	Two of three RCTs found increased adherence in the peak flow-based plan compared with the symptom-based plan. Oral corticosteroid use was reported in two RCTs comparing peak flow with symptom-based plans, finding mixed results. Days lost from school/work were reported in two studies, with no significant difference found	
Denford (2014)[93]***	Behaviour change techniques in asthma self-care interventions.	38; 7,883	Meta-analysis and meta-regression	Meta-regression analyses found that some behaviour change techniques may modify the effect size.	Interventions targeting asthma self-care are effective. Active involvement of participants is associated with increased intervention effectiveness, but the use of stress management techniques may be counterproductive. Existing recommendations about the "optimal" content of asthma self-care interventions were tested but were not supported by the data. [Low to moderate risk of bias]
DiBello (2014)[92]*	Text messaging programmes, effect on adherence to	5 RCTs and 1 observational study;	Narrative synthesis	Small statistically significant differences favoring text messaging in medication adherence were reported in 2 RCTs (n=15 and	Text messaging may have a positive impact on medication adherence rates as well as measures of lung function. However, these results are based on

	treatment and medication	475		n=22). One RCT showed a statistically significant difference in peak expiratory flow variability between groups (n=16). One RCT compared lung function within each arm of the study from the beginning to the end showing a statistically significant difference within the text messaging group as opposed to the control group (n=16). One RCT showed no difference in ED usage across intervention groups and one showed a change that did not reach statistical significance. Three of the six studies reviewed made a note of participant satisfaction with the text messaging intervention.	a small number of studies, small sample sizes and short-term follow-up. There is no statistical evidence clearly indicating if the number of ED visits will decrease or increase with the use of a text messaging intervention.
Blakemore (2015)[94]***	Complex interventions to reduce use of urgent healthcare in adults with asthma.	33 RCTs; 4,246	Meta-analysis	When study effects were grouped according to the components of the interventions used, significant effects were seen for interventions that included general education, skills training and relapse prevention. In multivariate meta-regression analysis, only skills training remained significant.	The odds of urgent healthcare use were 21% lower in the intervention group. Of the interventions assessed, skills training, may be particularly effective in reducing the use of urgent healthcare in adults with asthma.

Key: **CCM** = Chronic Care Model; **ED** = Emergency department; **HCP** = Health care professionals; **ICS** = inhaled corticosteroids; **NNT** = Numbers needed to treat; **OR** = Odds ration; **PEFR** = Peak expiratory flow rate; **QoL** = Quality of life; **RCT** = Randomised controlled trial; **SMD** = Standardised mean difference; **WAPs** = Written action plans;

Table A5.3 Cost-effectiveness studies investigating SMS education programmes in asthma.

Study	Intervention	Population	Analysis Details	Clinical & QALY Outcomes	Costs	Results
Corrigan (2004)[107]	Enhanced care (standard of care plus GP-delivered asthma education (group or individual) plus spirometry	Adult asthma patients	Country: Canada Study design: Costing study for three alternative size practices (25,50 or 100 patients) Perspective: GP Discount rate: N/A Time Horizon: N/A CAD$ 2003	Not assessed	For population size of 25, 50 and 100 patients: Individual visit scenario: net mean cost/pp was $107 (€85),$100 (€80), $96(€76), respectively. Group visit scenario: net mean cost/pp (year 1) $85(€68), $78 (€62), $74 (€59), respectively and $39 (€31), $32(€25),$28 (€22) (subsequent years).	Authors concluded that cost of providing asthma education and spirometric testing are significant; in the absence of funding, this may act as a significant disincentive for physicians to provide these services.
Gallefoss (2001)[109]	Asthma education programme (group & individual education & individual management plan)	Adults aged 18 to 70 yrs with mild to moderate asthma. Mean age 42.5 years	Country: Norway Study design: CEA alongside RCT (n=78) Perspective: Societal Discount rate: N/A Time Horizon: 1 year NOK 1994	At 12 month follow-up, SGRQ total score was 16.3 units lower in the intervention group ($p<0.001$). FEV1 improved by 6.1% in the intervention group relative to the control ($p<0.05$). The NNE to make one person symptom-free (self-reported) was 2.2.	Mean total costs including the intervention were NOK16,000 (€1,768)/pp and NOK 10,500 (€1,160)/pp for the intervention and control groups, respectively. Education programme cost NOK916 (€101)/pp.	ICER of NOK-3,400 (-€376) / 10-unit improvement in SGRQ total score ICER NOK -4,500 (-€497) / 5% improvement in FEV1in the intervention group compared to the control group during a 12 month follow-up. Authors concluded that a patient education programme in asthmatics improved patient outcomes and reduced costs over a 12-month follow-up.
Kauppinen (1998, 1999, 2001)[110-112]	Intensified education (additional individual (n=1) and group (n=2) sessions in year 1)	Newly diagnosed adults (18-76) yrs with (mild) asthma. Mean age 42.7 years	Country: Finland Study design: CEA alongside RCT (n=162) Perspective: Societal Discount rate: N/R Time Horizon: 5 years (FIM 1993, 1£=8 FIM)	Relative to the CG, there were statistically significant improvements in (FEV1) only at 12 months; in FEV1 and PEF, at 3 years; but there were no significant differences at 5 years in lung function, bronchial hyper-responsiveness or in HRQOL scores.	There were no significant differences in mean total annual cost FIM 2757 (€438) in IG vs FIM 2351 (€373) in CG) at 1 year, 3 years £464 (€589) in IG vs £476 (€605) in CG or at 5 years £381 (€484) in IG vs £457 (€581) in CG).	As no significant differences in outcomes or costs, ICER was not calculated. Authors concluded that there was a consistent tendency for the intervention (intensive education in year 1) to be less costly, however there were no significant differences in outcomes or costs at 1, 3 or 5 years.

Key: **CEA** = Cost-effectiveness analysis; **CI** = Confidence Interval; **CG** = Control Group; **EQ_5D** = EuroQol 5D health related scores; **GP** = General Practitioner; **FEV1** = Forced Expiratory volume at 1 second; **HRQOL** = Health related quality of life; **ICER** = Incremental cost-effectiveness ratio; **IG** = Intervention group; **NNE** = number needed to educate; **NR** = not reported; **PEF** = peak expiratory flow; **QALY** = Quality adjusted life year; **RCT** = Randomised Control trial; **SMS** = Self-management support; **SGRQ** = Saint George respiratory questionnaire.

Table A5.4 Cost-effectiveness studies assessing internet SMS interventions for asthma

Study	Intervention	Population	Analysis Details	Clinical & QALY Outcomes	Costs	Results
Van der Meer (2011)[116]	Internet-based SMS programme plus usual vs usual care	18-50 year olds with recent prescription for inhaled steroids. Mean age 36.5 years	Country: The Netherlands Study design: Non-blinded RCT with one year follow-up (n=200) Perspective: Societal Discount rate: N/A Time Horizon: 1 year ($US 2007)	There was no significant difference in EQ-5D score at 3-month (0.037 (95% CI -0.007 to 0.081) or 12 months follow-up 0.006 (95% CI -0.042 to 0.054), or in QALYs: 0.024 (95% CI, -0.016 to 0.065).	Total intervention costs were $254(€265) (95% CI, $243-$265 (€253 to €276) per patient during the period of 1 year. Societal perspective: cost difference was $641 (€668) (95% CI, -$1957 to $3240 (€2,040 to €3,377) in favour of usual care. Health care perspective:, cost difference was $37 (€39) (95% CI,-$874 to $950 (-€911 to €990)	ICER = $26,700 (€27,829) /QALY (societal) and ICER =$1,500 (€1,563)/QALY (health care perspective with a 62% and 82% probability of being cost-effective at a willingness-to-pay threshold of $50,00 (€52,114) per QALY compared with usual care. Authors concluded that internet-based self-management of asthma can be as effective as current asthma care and that costs are similar

Key: CI = Confidence Interval; EQ_5D = EuroQol 5D health related scores; ICER = Incremental cost-effectiveness ratio; QALY = Quality adjusted life year; RCT = Randomised Control trial; SMS = Self-management support.

Table A5.5 Cost-effectiveness studies assessing telemedicine interventions for asthma

Study	Intervention	Population	Analysis Details	Clinical & QALY Outcomes	Costs	Results
Donald (2008)[108]	Nurse-led telephone review	18-55 year old adults previously admitted to hospital with asthma Mean age: N/R	Country: Australia Study design: costing study alongside RCT with 1-year F/U (n=71) Perspective: N/R Discount rate: N/A Time Horizon: 1 year (Aus $ 2002)	At 12 months, there was a clinically important difference in HRQoL (MAQLQ-M) in the IG not seen in the CG. There was no significant difference in self-efficacy score between the IG and CG	Mean cost per participant for the intervention was $90 (€90). There was a non-statistically significant reduction in readmissions in the intervention group leading to a large reduction in readmission costs. $2,063 (€2,063) vs $41,272 (€41,281)	The authors concluded that telephone-based management is a low-cost alternative to usual care that is well accepted by patients and may result in clinically important differences in HRQoL, with costs potentially offset by reductions in re-admissions in the intervention group
Pinnock (2005)[114]	Nurse-led telephone review vs face-to-face review with asthma nurse	Symptomatic asthma patients (18-65 years) that had not been reviewed in previous 12 months Mean age: N/R	Country: UK Study design: CEA alongside RCT with 3 months follow-up Perspective: Healthcare payer Discount rate: N/R Time Horizon: 3 months (GB £ 2000)	Asthma-related quality of life and morbidity at 3 months were similar for the intervention and control groups and patients were equally satisfied with the consultations.	Total cost of intervention was similar for IG and CG £725.84 (€1,302) vs. £755.70(€1,356), as were total respiratory health care costs, however participation rate was higher for IG (78% vs 48%) resulting in a saving of £3.92 (€7) per consultation.	Authors concluded that nurse-led telephone consultations enable a greater proportion of asthma patients to be reviewed thereby improving access and reducing cost per consultation achieved.
Willems (2007)[117]	Nurse-led telephone review with remote peak flow monitoring vs usual care	18-65 year old adults with persistent mild-moderate asthma) Mean age 45.8 years	Country: The Netherlands Study design: CEA alongside RCT with 1 year follow up (n= 53 adults) Perspective: healthcare and societal Discount rate: Time Horizon: 1 year (Netherlands € 2002)	There was no significant difference in generic HRQoL between the intervention and control groups	The annual cost of the intervention was €530 (€589)pp. Mean healthcare costs were higher in the intervention and control groups.	The mean ICER was €15,366 (€17,069)/QALY gained from the healthcare perspective and €31,035 (€34,476)/QALY gained from the societal perspective.

Key: **CEA** = cost-effectiveness analysis; **CG** = control group; **CI** = Confidence Interval; **EQ_5D** = EuroQol 5D health related scores; **ICER** = Incremental cost-effectiveness ratio; **IG** = intervention group; **QALY** = Quality-adjusted life year; **RCT** = Randomised Control trial; **SMS** = Self-management support.

Table A5.6 Cost-effectiveness studies assessing other SMS interventions for asthma

Study	Intervention	Population	Analysis Details	Clinical & QALY Outcomes	Costs	Results
Castro (2003)[106]	Nurse-led multifaceted intervention (including asthma education and action plan, psychological support, OPD planning, telephone and phone visits)	Hospitalised 'high-risk' asthma patients aged (18-65) Mean age: 36.4 years	Country: US Study design: Cost study alongside RCT (n=96) Perspective: N/R (assume societal) Discount rate: N/R Time Horizon: 1 year (US $ 1991)	There was a significant reduction in hospital readmissions (60%, p<0.01), total bed days (69%, p<0.04) and multiple readmissions (57%, p=0.03), and a non-significant increase in ED visits (34%, p=0.52) and healthcare provider visits (3%, p=0.82). HRQol did not differ between the intervention and control groups	Mean intervention cost was $186 (€384) per patient. Overall savings (direct and indirect) of $6,462 (€13,358) per patient were noted including a savings of $4,430 (€9,157) in direct healthcare costs per patient primarily due to a reduction in readmissions.	The authors concluded that a programme focusing on asthma patients with high healthcare use can result in improved asthma control and reduced hospital use with substantial cost savings. However, they were unable to identify which specific component of the intervention is most effective.
Parry (2012)[113]	Cognitive behavioural therapy including a minimum of 5 to 7 sessions at weekly or fortnightly intervals.	12-65 year olds with clinical diagnosis of asthma and a HADS anxiety score ≥8. Mean age 45.3 years	Country: UK Study design: Costing study alongside RCT with 1 year follow up (n= 53 adults) Perspective: Healthcare provider Discount rate: N/A Time Horizon: Six months	Slight increase in GP visits in intervention group. Reduction in asthma specific fear and improvements in asthma QoL in intervention group. There were also significant improvements in asthma specific QoL and depression following CBT compared with controls, but these were not maintained at six month follow up.	The intervention cost between £378 and £798 per participant depending on the number of sessions attended. No cost offsets were reported. Cost year N/R	The authors concluded that the study supported the short term and longer term efficacy of a CBT intervention in reducing panic fear in asthma, though the clinical significance of the effect was modest.
Shelledy (2009)[115]	Five-week in-house multi-faceted intervention by respiratory therapist (AMP-RT) vs nurse-led intervention (AMP-RN) vs usual care	18-64 year olds with recent asthma-related ED visits. Mean age 42.8 years.	Country: US Study design: Costing study alongside RCT with 6-month follow-up (n= 166) Perspective: N/R (assume provider) Discount rate: N/R Time Horizon: 6-month Cost year N/R	There were no significant differences (p > 0.05) in most measures of pulmonary function, dyspnoea or symptoms scores between the three groups at six months. Both asthma-management programme groups had significantly higher SF-36 and PS change scores when compared to the control group (p<0.005).	Intervention cost $365. The net hospitalisation direct cost savings for for the subjects in the AMP-RN groups was approximately $37,800, while the net cost savings for the AMP-RT group was $32,200.	The authors concluded that an in-home asthma management programme can be effectively delivered by respiratory therapists or nurses and may reduce hospitalisations, cost, and improve the quality of life and patient satisfaction in a population prone to asthma exacerbation.

Key: **AMP** = asthma management plan; **CBT** = cognitive behavioural therapy; **FEV1** = Forced Expiratory volume at 1 second; **HRQOL** = Health related quality of life; **N/R** = not reported; **PEF** = peak expiratory flow; **QALY** = Quality adjusted life year; **RCT** = Randomised Control trial; **RN** = registered nurse; **RT** = respiratory therapist; **SMS** = Self-management support.

Appendix A5.7 Appraisal of study quality for included cost-effectiveness studies

Study	Quality	Reasons for downgrading
Castro (2003)	Low	Costing study alongside RCT with one year follow-up of 96 patients. Poorly reported cost and outcome data.
Corrigan (2004)	Low	Poorly described costing study. Insufficient information to determine if all relevant costs were included. No outcome data considered.
Donald (2008)	Low	Costing study based on small RCT. Incomplete reporting of costs
Gallefos (2001)	Low	Effectiveness data from single RCT with one year follow-up of 78 patients. Inadequate analysis of the impact of uncertainty.
Kauppinen (1998, 1999, 2001)	High	Perspective uncertain. Discounting of costs only and limited to sensitivity analysis
Parry (2012)	Low	Costing study alongside single RCT with one year follow-up of 53 patients. Poorly reported cost and outcome data.
Pinnock (2005)	Moderate	Based on small RCT with 3-month follow-up. Limited reporting of outcome data
Shelledy (2009)	Low	Costing study alongside single RCT with 6-month follow-up of 166 patients. Poorly reported cost and outcome data.
Van der Meer (2011)	Moderate	Based on small RCT with 12-month follow-up. Inadequate analysis of the impact of uncertainty.
Willems (2007)	Low	Based on small RCT (n=53) of 4 months with results extrapolated to 12-month.

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