



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health technology assessment of chronic disease self- management support interventions

Executive summary *(extracted from main report)*

16 December 2015

Safer Better Care

Executive summary

I. Background

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.

II. 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:

- To review the clinical and cost-effectiveness of generic chronic disease self-management support interventions.
- To review the clinical and cost-effectiveness of disease-specific chronic disease self-management support interventions, including:
 - asthma
 - chronic obstructive pulmonary disease (COPD)
 - diabetes (Type 1 and Type 2)
 - stroke
 - ischaemic heart disease
 - hypertension
 - heart failure.
- Based on this assessment, to advise on the optimal chronic disease self-management support interventions to be implemented by the HSE.

This HTA was conducted using the general principles of HTA and employing the processes and practices used by the Authority in such projects.

An Expert Advisory Group was established comprising representation from the HSE (Health and Wellbeing division and Integrated Care Programme for chronic disease, Nursing and Midwifery Planning and Development unit), patient organisations, national and international experts in chronic disease management, and clinical specialists. An evaluation team was appointed comprising internal Authority staff. A Public Health Specialist Registrar in the HSE and two additional external staff assisted with the systematic review and data extraction.

III. Self-management support description

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

For the purpose of this review, the 2003 definitions of self-management and self-management support agreed by the US Institute of Medicine were used. Self-management was 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'. Self-management support was 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'. Self-efficacy 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. Many self-management support interventions target self-efficacy to improve outcomes.

Self-management support interventions to enhance core self-management skills and 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 or disease-specific. Generic self-management support interventions are not tailored for any specific disease and could, in theory, be used in populations with a range of chronic conditions, including those with more than one chronic disease.

Generic self-management supports and disease-specific self-management supports are currently provided in Ireland through a range of programmes. 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(s) that should be implemented and to whom they should be made available. It is thought that self-management support 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 self-management support interventions in the short and long term.

This uncertainty regarding the format of optimal self-management support presents an obstacle to informed decision making about the provision of this intervention in the Irish public healthcare system.

IV. Methodology

This HTA examined the clinical-effectiveness of 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, ischaemic heart disease and heart failure). 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. Where existing high quality reviews were identified, these were updated rather than undertaking a new overview of reviews.

A search for systematic reviews evaluating generic chronic disease self-management support interventions was conducted in Pubmed, Embase and the Cochrane library up to February 2015. The PRISMS review commissioned by the UK National Institute for Health Research published in 2014 was used as a starting point for the systematic reviews for asthma, COPD, Type 1 and Type 2 diabetes, stroke and hypertension. For these diseases, this assessment includes an update to the PRISMS report with additional searches run in Pubmed, Embase and the Cochrane library from 2012 to 1 April 2015. The results of the updated search as well as the original PRISMS findings are reported.

A search for systematic reviews were run in Pubmed, Embase and the Cochrane library from 2009 to 1 April 2015 for the remaining diseases included in the Terms of Reference for this project (heart failure and ischaemic heart disease), but which were not assessed in the PRISMS report.

Data extraction and quality appraisal were conducted using the general principles of HTA and in accordance with national guidelines. The cost-effectiveness of generic and disease-specific self-management support interventions was evaluated by undertaking systematic reviews of the available literature for each of the disease categories. 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 self-management support 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.

Data extraction and quality appraisal were conducted using the general principles of HTA and employing the processes and practices used by the Authority in such projects.

V. Generic (non-disease specific) self-management support interventions

As noted, generic self-management support interventions are those that can be used by any individual with one or more chronic diseases and are not tailored to support management of a specific chronic disease. These interventions aim to enhance core self-management skills and improve self-efficacy. Generic interventions include the behavioural change chronic disease self-management programmes that focus mainly on improving self-efficacy such as the UK Expert Patients Programme (peer-led), the Flinders modelTM (physician-led), and the generic version of the Stanford programme (peer-led).

Based on 25 systematic reviews (362 randomised controlled trials), a wide variety of generic self-management support interventions was identified. These were broadly grouped as chronic disease self-management programmes (mainly the Stanford model), telemedicine, web-based interventions, a range of self-management support interventions focussed on a single health outcome, and 'other' self-management support interventions.

The majority of the literature retrieved for the chronic disease self-management programmes assessed the Stanford model. The evidence was of low to very low quality and was without long-term follow-up. No evidence was found of improvements in health care utilisation. Some evidence was found of short-term improvements in the patient-reported outcome of self-efficacy and for short-term improvements in health behaviour (exercise) and health outcomes (pain, disability, fatigue and depression), primarily for the Stanford chronic disease self-management programme. Also compared were different modes of delivery for the intervention. Insufficient evidence was found to determine if computer-based chronic disease self-management programmes are superior to usual care or standard 'face to face' versions of the Stanford chronic disease self-management programme.

Based on systematic reviews and underpinning primary randomised controlled trials that were of limited quantity and quality, limited evidence was found that web-based cognitive behaviour therapy can have a positive impact on psychosocial outcomes.

Literature was found that assessed the impact of a diverse range of self-management support interventions targeting a single outcome (for example,

healthcare utilisation, quality of life, or diet adherence). Some evidence of improvements in healthcare utilisation, diet adherence, patient engagement, and self-reported health status was found, however it was not possible to determine which types of intervention or components of self-management support contributed to the positive results.

The category of 'other' self-management support interventions comprised a diverse range of other generic interventions. Some evidence of improvements in outcomes for telephone-delivered cognitive behavioural therapy (improvements in health status); nurse-led interventions using the information-motivation-behavioural skills model (improved medication adherence); with some evidence also that personalised care planning and motivational interviewing can have a positive impact on depression and physical activity, respectively. Short-term improvements in activities of daily living, instrumental activities of daily living and mobility were also observed with in-home care (defined as care predominantly in the patient's home that was curative, preventive or supportive in nature and aimed to enable clients to live at home). However, due to limited study follow-up it is not known if the effects are sustained in the longer term.

In summary, based on the available evidence for the clinical effectiveness of generic self-effectiveness interventions, the optimal format of generic self-management support, the diseases in which they are likely to provide benefit, and the duration of effectiveness, if any, is still unclear. Tailoring self-management support to a specific disease may be more beneficial as a patients' knowledge of their own disease is believed to be an essential component of self-management.

Based on 25 costing and cost-effectiveness studies, the economic literature for generic self-management support interventions was grouped into four main intervention types: chronic disease self-management programmes, telemedicine, web-based interventions and 'other' interventions. Limited evidence of cost-effectiveness for generic chronic disease self-management support interventions was found. The most consistent evidence was for chronic disease self-management programmes, but potential benefits were dependent on how efficiently the programme was run with no evidence found of longer term cost savings. Evidence of cost-effectiveness was generally of limited applicability to the Irish healthcare setting. The international literature suggests that chronic disease self-management and telephone-based telemedicine programmes are relatively cheap to implement, but the magnitude of any cost saving in terms of reduced healthcare utilisation is unclear. The short follow-up periods used in the included studies meant that it was not possible to determine if any savings were sustained. Where reported, the cost of the generic self-management support interventions was low. However, although generally inexpensive on a per patient basis, the budget impact would be sizeable if

access to generic self-management support interventions was implemented for all eligible patients with chronic disease(s).

VI. Asthma

Asthma is a chronic inflammatory condition of the airways characterised by recurrent episodes of wheezing, breathlessness, chest tightness and coughing. 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. Rates of hospitalisation and attendance at emergency departments in Ireland, as well as frequent use of unscheduled (out-of-hours) care indicate the suboptimal asthma control in the majority of patients.

Based on 12 systematic reviews (90 randomised controlled trials), a range of self-management support interventions for asthma were identified. The interventions were typically complex, that is involving multiple components and or modes of delivery of self-management support, but were typically based on patient education, skills training, and use of written action plans, with evidence also for behavioural interventions, text messaging and the Chronic Care Model to improve treatment and medication adherence.

Good evidence was found that self-management support interventions for patients with asthma can improve quality of life, reduce hospital admissions and use of urgent (emergency department visits) and unscheduled healthcare. The findings did not take consideration of the underlying risk of hospitalisations and urgent healthcare use as these were not reported in the systematic reviews, so it is not possible to quantify the absolute benefit of the interventions. Good evidence was also found that behavioural change techniques are associated with improved medication adherence and a reduction in symptoms. There was substantial heterogeneity in the format and intensity of the self-management support interventions, the study populations, study follow-up duration and assessed outcomes, which makes it difficult to formulate clear recommendations on the optimal intervention format of this self-management support. However, the evidence suggests that it 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.

The economic literature for asthma-specific self-management support interventions was broadly grouped into four main intervention types: education programmes, internet-based self-management support, telemedicine, and 'other' self-management support interventions with a total of 12 costing and cost-effectiveness studies identified. 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. Similarly, limited evidence was found that nurse-led telephone review for patients with high-risk asthma (that is, with a history of frequent hospitalisations or emergency department visits) is a relatively low cost intervention that may reduce costs by reducing healthcare utilisation, although evidence of effect in the included studies was mixed.

The 2013 Irish Asthma Control in General Practice guidelines 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. 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 health system. The findings from this review support the inclusion of evidence-based asthma self-management support interventions in Ireland.

VII. Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is a common preventable and manageable disease, characterised by persistent airflow limitation. The clinical course of COPD is one of gradual impairment with episodes of acute exacerbations that contribute to the deterioration of a person's health status. Ireland has one of the highest standardised death rates for COPD in the European Union, and also has one of the highest rates of hospital admissions for exacerbations of COPD in the OECD. Pulmonary rehabilitation is acknowledged by all international guidelines as a key component of the management of COPD.

Based on 16 systematic reviews (185 randomised controlled trials), a range of self-management support interventions for patients with COPD were identified. These included patient education and use of written action plans, pulmonary rehabilitation, telemedicine, complex self-management support interventions and outreach nursing programmes. Standard pulmonary rehabilitation comprises many aspects of chronic disease self-management support and hence is included here; however, interventions such as education, exercise and behavioural changes are also core components of pulmonary rehabilitation, so the boundary between the intervention types is ill-defined.

Very good evidence was found that education is associated with a reduction in COPD-related hospital admissions with limited evidence found that education is associated with improvements in health-related quality of life. Action plans when used alone and in the absence of other self-management supports were not found to reduce healthcare utilisation or lead to improvements in quality of life.

Very good evidence was found that pulmonary rehabilitation, which includes exercise training, is associated with clinically significant improvements in health-related quality of life. Clinically significant improvements were also reported for functional exercise capacity. Substantial variation was noted in the design, duration and intensity of the pulmonary rehabilitation programmes, making it difficult to identify their optimal format.

Good evidence was found that complex self-management support interventions (involving multiple components and, or multiple professionals with the intervention delivered by a variety of means) are associated with improvements in health-related quality of life. No evidence was found of a statistically significant benefit regarding mortality while there was limited evidence of reductions in health care utilisation. The interventions and patient populations assessed varied widely making it difficult to provide clear recommendations on the most effective components of these self-management support packages, however interventions containing education and exercise seem to be effective.

Some evidence was found that telemedicine as part of a complex health intervention decreases healthcare utilisation, with no evidence of an impact on mortality. The telemedicine interventions assessed were heterogeneous in nature, but typically were defined as healthcare at a distance that involved the communication of data (using telephones, video cameras and the internet) from the patient to the health carer, who then provides feedback regarding the management of the condition. Some evidence was also found that outreach nursing programmes improve health-related quality of life in patients with COPD.

The economic literature for COPD-specific self-management support interventions was grouped into five main intervention types: self-management support programmes, pulmonary rehabilitation, telemedicine, case management, and 'other' self-management support interventions. A total of 27 costing and cost-effectiveness studies were identified for inclusion.

Evidence from the international literature was found that self-management support education programmes could result in potential cost savings due to reduced healthcare utilisation in patients with moderate to severe disease, depending on the efficiency with which the programmes are run. Evidence was also found that case management may be cost saving for selected groups of patients with severe disease. Limited evidence was found that pulmonary rehabilitation is cost-effective in patients with moderate to severe COPD disease, with evidence from one Irish study (which was limited to 22 weeks follow-up) indicating that pulmonary rehabilitation may not be cost-effective in patients with mild to moderate disease.

Evidence for the cost-effectiveness of telemedicine interventions was mixed, with more applicable evidence suggesting that telehealth monitoring is not cost-effective. The reported per-patient cost of self-management interventions in the international literature varied according to the intensity of the intervention, but was typically low relative to the overall cost of care of these patients. Ireland has a high prevalence of COPD so the budget impact of implementing self-management support interventions for these patients is likely to be sizeable.

The applicability of the international evidence depends on the extent to which the comparator (usual care in these RCTs) is representative of usual care in Ireland. Differences may exist in how care is provided, impacting the adherence to recommended standard of care. Particular difficulties have included delays in the diagnosis of COPD due to limited access to spirometry testing in primary care. Targets have been set by the HSE's Clinical Care Programme for COPD to address this issue. Access to pulmonary rehabilitation is variable, although again improving access is a stated focus of the Clinical Care Programme.

VIII. Diabetes

Diabetes is a progressive disease with disabling long-term complications if not properly managed. Tight control of blood sugar levels and blood pressure can reduce or delay disease progression. Type 1 diabetes is characterised by deficient insulin production and requires daily administration of insulin. Type 2 diabetes results from the body's ineffective use of insulin. Type 2 diabetes comprises 90% of people with diabetes around the world, and is largely the result of excess body weight and physical inactivity.

For adults with Type 1 diabetes, two systematic reviews of self-management support interventions were identified for inclusion. Based on a single systematic review (11 randomised controlled trials), no evidence was found that psychological treatments improve glycaemic control or reduce psychological distress. Meanwhile, based on a single systematic review (15 randomised controlled trials) of structured education programmes, very limited evidence was found that these interventions lead to improved outcomes of quality of life and episodes of severe hypoglycaemia in adults with Type 1 diabetes.

For adults with Type 2 diabetes, 27 systematic reviews (347 randomised controlled trials) of self-management support interventions were identified for inclusion. The interventions were broadly grouped into education interventions, chronic disease self-management programmes, telemedicine and 'other' self-management support interventions.

Very good evidence was found that education, including culturally-appropriate education, improves blood glucose control in the short term (less than 12 months).

Good evidence was found that behavioural interventions (specifically patient activation interventions which actively engage patients by promoting increased knowledge, confidence and, or skills for disease self-management) are associated with modest improvements in blood glucose control (glycosolated haemoglobin, HbA1C). Good evidence was also found for improvements in blood glucose control in the short term with various forms of telemedicine. The interventions were heterogeneous and included computer-based software applications, telephone support, and electronically transmitted recommendations from clinicians in response to transmission of self-monitored glucometer data. Meanwhile some evidence was found that diabetes-specific chronic disease self-management programmes are associated with small improvements in blood glucose control in the short term. Evidence of improvements in blood glucose control was also found for a diverse range of SMS interventions and in particular educational interventions which differed also in their frequency, intensity and mode of delivery.

Based on the available clinical evidence, it is not possible to provide clear recommendations on the optimal content and format of self management support for adults with Type 2 diabetes. The evidence suggests that various models of delivery may be equally effective. Of note, impact on resource utilisation was not assessed in any of the reviews. Quality of life remained unaltered.

Based on 38 costing and cost-effectiveness studies, the economic literature for Type 1 and Type 2 diabetes was grouped into three main intervention types: education programmes, telemedicine, and pharmacist-led programmes. The better quality studies used data from randomised controlled trials and then extrapolated lifetime benefits using one of a number of simulation models that predict outcomes based on risk-factors.

The best economic evidence was found in support of self-management support education programmes with modelled results suggesting that the interventions are cost-effective relative to usual care. Based on limited evidence, it is not possible to say if telemedicine interventions are cost-effective relative to usual care while there was insufficient evidence of adequate quality to consider the cost-effectiveness of pharmacist-led interventions.

Structured education programmes are currently available in Ireland for adults with Type 1 and Type 2 diabetes based on a range of models. A 2009 Health Service Executive (HSE) review of diabetes structured education noted that these programmes should be integrated into standard diabetes care. The HSE's National Clinical Care Programme is currently developing a model of care through which it is proposed all patients should have access to a structured integrated care package covering all aspects of their diabetes care. The choice of a standard programme or set of programmes should be supported by the available evidence.

IX. Stroke

Stroke is the neurological condition that results from brain damage caused by either blockage or rupture of a blood vessel in the brain. Each year in Ireland, approximately 7,000 people are hospitalised following stroke. Due to an aging population, the burden of stroke-related disease is expected to increase, with predicted increases of 11% to 15% in the proportion of the population aged 65 or older by 2021. It is estimated that between 30% and 40% of stroke survivors develop some degree of functional dependence requiring assistance in performing basic activities of daily living (ADLs).

Based on 27 included systematic reviews (228 randomised controlled trials), four broad types of self-management intervention were identified for adult post-stroke patients. These focused on rehabilitation therapy (including general rehabilitation, virtual reality-based rehabilitation and telerehabilitation), self-management programmes, information provision and 'other' self-management support interventions.

Good evidence was found that general rehabilitation therapy delivered in early stroke recovery has a positive impact on activities of daily living and extended activities of daily living. Virtual reality-based rehabilitation (that is, using commercial gaming consoles or specifically developed consoles adopted in clinical settings)) was found to improve upper limb function and activities of daily living when used as an add-on to usual care, although it is still unclear which characteristics of virtual reality are most important and if the effects are sustained in the longer term. Meanwhile, based on limited evidence, telerehabilitation (using telephone or internet to facilitate communication between the patient and provider) does not appear to improve ADL or upper limb function for post-stroke patients compared with usual care.

Some evidence was found that information provision improves patient and carer knowledge of stroke, aspects of patient satisfaction, with small reductions (which may not be clinically significant) in patient depression scores. Similarly, some evidence was found that stroke liaison emphasising education and information can have a positive impact on quality of life. However, based on the available evidence, it is not possible to draw conclusions in relation to the effectiveness of self-management programmes delivered to post-stroke patients or for psychosocial interventions, motivational interviewing, lifestyle interventions, multidisciplinary care or family-orientated models of care.

The identified economic literature was limited to four costing and cost-effectiveness studies relating to exercise-based programmes and computer-based rehabilitation therapy. The four included studies provided very limited evidence regarding the costs or cost-effectiveness of self-management programmes for post-stroke patients.

As a chronic disease, stroke is very different to other long-term illnesses in that it is a sudden onset disease with varying levels of sudden, potentially permanent impairments. This is reflected in the stroke self-management support clinical-effectiveness literature retrieved, which is largely focused on rehabilitation therapy. A review of stroke services in Ireland noted gaps in care, particularly in relation to rehabilitation services. A model of care has been developed by the HSE's National Clinical Programme for Rehabilitation Medicine to address these deficits. This advocates a framework where patients are managed by specialist rehabilitation clinicians working as part of a managed clinical rehabilitation network with a view to extending access to specialist rehabilitation services for people with acquired disability.

XII. Ischaemic heart disease

Ischaemic heart disease (IHD) is a chronic condition characterised by narrowing and hardening of the arteries that supply blood to the heart muscle. IHD claims around 5,000 lives annually in Ireland, which represents approximately half of all cardiovascular deaths. As well as being associated with significant mortality, it can also weaken the heart muscle over time, which can lead to the development of heart failure and cardiac arrhythmias.

Based on 14 systematic reviews (244 randomised controlled trials), five broad types of self-management support intervention were identified for patients with ischaemic heart disease in this overview of reviews. These focused on patient education, exercise, psychosocial or behavioural changes, home-based services or telehealth. Interventions such as education, exercise and behavioural changes are noted to be core components of cardiac rehabilitation, so the boundary between standard cardiac rehabilitation services and chronic disease self-management support is ill-defined.

Good evidence of a statistically significant reduction in mortality was found for exercise programmes (including exercise-based cardiac rehabilitation) in suitable patient cohorts from studies with follow-up periods greater than 12 months. Exercise-based interventions were also found to be associated with fewer rehospitalisations, but inconsistent results have been reported for myocardial infarction rates. Limited evidence was found that comparable home- and telehealth-based cardiac rehabilitation interventions achieve similar outcomes to centre-based interventions.

Some evidence was found that patient education programmes are associated with an improvement in interim outcomes such as smoking cessation and reduced blood pressure, but there is uncertainty about how long any such effect persists. Meanwhile limited evidence was found to demonstrate the effectiveness of

behavioural modification interventions, although some studies have reported positive effects on smoking cessation and symptom management.

Based on 15 costing and cost-effectiveness studies, the economic literature was broadly grouped into four main intervention types: cardiac rehabilitation, case management, telemedicine, and 'other interventions'.

When compared with no rehabilitation, international evidence was found that cardiac rehabilitation can create cost savings as a result of reductions in health care utilisation. However, it is not possible to draw conclusions in relation to the cost-effectiveness of telemedicine-delivered self-management support interventions and nurse-led case management programmes due to the heterogeneity of the interventions assessed and equivocal findings. The reported per-patient cost of the various self-management interventions varied according to the intensity of the intervention, but was typically low relative to the overall cost of care of these patients.

The model of care developed by the national clinical programme in Ireland for acute coronary syndromes recommends that cardiac rehabilitation programmes are established within the acute setting to treat hospitalised patients prior to discharge, with follow-up secondary prevention programmes in the primary care setting. It is a stated (as of 2013) goal that 90% of eligible patients are referred to early cardiac rehabilitation services (Phase 3), within four weeks of hospital discharge. A 2013 survey identified significantly different staffing levels and resources between cardiac rehabilitation services, lengthy waiting times for some individual services and wide variation in availability of multidisciplinary teams, which meant that not all patients received the best possible cardiac rehabilitation.

X. Hypertension

The World Health Organization's Health 2020 policy identifies high blood pressure or hypertension as the world's most prevalent, but preventable disease. An estimated 64% of the population over 50 years of age in Ireland has high blood pressure. Hypertension is a serious medical condition that often has no symptoms, but significantly increases the risks of heart, brain, kidney and vascular disease. The risk associated with increasing blood pressure is continuous, with each 2 mmHg rise in systolic blood pressure associated with a 7% increased risk of mortality from ischaemic heart disease and a 10% increased risk of mortality from stroke.

Sixteen systematic reviews (240 randomised controlled trials) of the clinical-effectiveness of self-management support interventions for adults with hypertension were identified for inclusion in this overview of reviews. A diverse range of interventions was identified with the largest volume of evidence obtained for reviews

where self-monitoring of blood pressure was the main intervention. The remaining reviews assessed a range of self-management support interventions.

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

Limited evidence of effectiveness was found for patient education interventions when used alone in improving medication adherence or blood pressure control, although it is noted that these may form an important part of more complex interventions. Some evidence was found that a range of complex SMS interventions (that is involving multiple components, multiple providers and modes of delivery) lead to improvements in blood pressure control. There was substantial heterogeneity in the format and intensity of the self-management support interventions, the study populations and study follow-up duration, making it difficult to formulate clear recommendations on the optimal intervention format of self-management support for patients with hypertension. A patient-specific approach may be the most beneficial, involving components tailored to the individual patient with hypertension.

Some evidence was found that community pharmacist interventions which include patient education can lead to reductions in systolic and diastolic blood pressure. Similarly, some evidence was found that simplification of medication regimens improves adherence although the clinical significance of this effect may be small.

Based on 14 costing and cost-effectiveness studies, the economic literature assessed a diverse range of interventions with the largest volume of evidence obtained for reviews where self-monitoring of blood pressure was the main intervention. The remaining reviews assessed a range of self-management support interventions. The available international evidence was largely for patients with uncontrolled hypertension. The results were inconsistent across outcomes of ambulatory blood pressure, costs, and healthcare utilisation. In some studies, the intervention had a positive effect; in others it was negative, relative to usual care. This evidence from the international literature indicated that the cost per patient of delivering self-management support interventions was generally low.

The applicability of the findings to Ireland is affected by a number of factors including the definition of routine care. For example, usual care for hypertension in Ireland may differ to that in the UK's NHS system where adherence to quality standards is incentivised by the quality-of-outcomes framework. Data indicate high levels of undetected hypertension and poor levels of blood pressure in Ireland. This context must be considered when evaluating the applicability of the findings of this

overview. There are substantial levels of unmet need for routine care in Ireland, which may impact on whether the estimated incremental benefits of self-management support interventions for hypertension apply in the Irish setting.

XI. Heart failure

Heart failure is a chronic condition characterised by an inability of the heart to pump blood effectively, due to systolic and or diastolic dysfunction. The average age at diagnosis is 76 years and the overall prevalence of heart failure in Ireland is approximately 1.1%, with a five-year mortality rate of 36%. Prevalence is increasing due to better management of the disease and the ageing population, which has resulted in congestive heart failure becoming one of the most common reasons for emergency admission to hospitals in Ireland.

Based on 20 systematic reviews (248 randomised controlled trials), five broad types of self-management support intervention were identified. These focused on patient education, psychosocial and behavioural interventions, exercise interventions, home visits, and telehealth (including telemedicine and structured telephone support). Interventions such as education, prescribed exercise and behavioural changes are core components of cardiac rehabilitation, so the boundary between standard cardiac rehabilitation services and chronic disease self-management support is ill-defined.

Statistically significant reductions in mortality were reported for both telehealth interventions and home visit programmes in selected patients. There was however a lack of consistency across reviews that examined these types of interventions, with some studies reporting no effect. Statistically significant reductions in the rate of hospital readmissions were also noted for exercise interventions, home visit programmes and telehealth interventions for selected heart failure patients. Meanwhile, limited evidence was found to support the effectiveness of patient education programmes or behavioural modification interventions. Despite the positive results that have been reported for telemedicine and structured telephone support interventions, concerns have been raised about these being considered the standard of care for the management of heart failure patients due to inconsistent findings across studies and a lack of understanding about which specific elements of the interventions contribute to the improved outcomes.

The included economic literature was grouped into five main intervention types: education, telemedicine, multidisciplinary care, disease management and 'other' self-management support interventions. A total of 46 costing and cost-effectiveness studies were identified. The quality of the studies was generally poor, with only four identified as high-quality studies.

Based on individual randomised controlled trials that showed improvements in health-related quality of life and reductions in healthcare utilisation, the majority of telemedicine interventions reported cost savings relative to usual care, although the interventions assessed were heterogeneous. Similarly, based on individual randomised controlled trials that showed reductions in healthcare utilisation, certain disease management and education programmes were found to be cost-effective or cost saving relative to usual care.

The reported per-patient cost of self-management interventions in the international literature varied according to the intensity of the intervention, but was typically low relative to the overall cost of care of heart failure patients.

The applicability of the clinical and cost-effectiveness evidence for heart failure-specific self-management support interventions is affected by the variability in routine care including the current provision of cardiac rehabilitation services in Ireland. The HSE's clinical programme for heart failure has developed a model of care for the public health service, which describes two main models for rehabilitation programmes for heart failure patients. The extent to which this is in place was examined in a 2013 survey which found significantly different staffing levels and resources between cardiac rehabilitation services, lengthy waiting times for some individual services and wide variation in availability of multidisciplinary teams. This means that not all patients receive optimal cardiac rehabilitation. There is also considerable uncertainty about access to primary prevention services for patients with heart failure who have not been hospitalised following an acute cardiovascular event.

XIII. Discussion

In total, this HTA considered a large volume of evidence including over 2,000 randomised controlled trials as presented across 1 systematic reviews.

The overview of reviews approach used for the clinical-effectiveness review 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. However, an overview of reviews places one at a remove from the primary evidence and reliant on the quality of the available reviews. However, given their typical sample sizes, it is not possible to draw strong conclusions about effectiveness based on a single, or a number of small randomised controlled trials. Therefore it is unlikely that more recent randomised controlled trials not captured in an overview of reviews would be sufficient to substantially alter recommendations informing major policy decisions.

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 randomised controlled trials 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.

Evidence of the clinical-effectiveness of chronic disease self-management support interventions provides a complex picture. Certain forms of disease-specific interventions, as discussed above, have been shown to improve outcomes over periods of six to 12 months. Longer term outcome data are generally not collected. 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, is still unclear.

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. 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. However, 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.

With the exception of generic self-management support 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. For people with multimorbidity, a coherent evidence-based approach that acknowledges their various conditions and how they interact is essential.

XIV. Conclusion

Evidence of the clinical-effectiveness of chronic disease self-management support interventions provides a complex picture. There was a large quantity of evidence of variable quality. Although for many intervention types there was limited evidence of effect, some interventions were shown to lead to improved health and, or reduced healthcare utilisation over short-term time horizons. The best evidence of benefit is associated with disease-specific interventions.

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 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.

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.