

evidence | *note*

In response to an enquiry from the Quality and Efficiency Support Team (QuEST), Scottish Government and the Scottish Centre for Telehealth and Telecare, NHS 24

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What is the clinical effectiveness, cost effectiveness and safety of home and mobile health monitoring in addition to usual care compared with usual care for adults with diabetes (Type 1 and Type 2)?

What is an evidence note?

Evidence notes are rapid reviews of published secondary clinical and cost-effectiveness evidence on health technologies under consideration by decision makers within NHSScotland. They are intended to provide information quickly to support time-sensitive decisions. Information is available to the topic referrer within a 6-month period and the process of peer review and final publication of the associated advice is usually complete within 6–12 months. Evidence notes are not comprehensive systematic reviews. They are based on the best evidence that Healthcare Improvement Scotland could identify and retrieve within the time available. The evidence notes are subject to peer review. Evidence notes do not make recommendations for NHSScotland, however the Scottish Health Technologies Group (SHTG) produces an Advice Statement to accompany all evidence reviews.

Key points

- Studies relating to home and mobile health monitoring (HMHM) interventions for patients with diabetes showed multiple differences in population characteristics, technological and clinical aspects of interventions, and usual care comparators, preventing firm conclusions being drawn.
- Evidence was consistent with an improvement in blood glucose control with HMHM use. However, it is unclear whether the reductions in HbA1c are clinically significant, sustainable and independent of other aspects of diabetes care.
- No evidence was identified to determine whether there was a difference in the safety and cost effectiveness of HMHM compared with usual care.
- A recent qualitative study conducted in Scotland and England explored patient and professional experiences of supported telemonitoring in a trial setting and found it to be feasible and convenient for patients. However, some professionals had concerns relating to increased workload and cost.

Definitions

Home and mobile health monitoring (HMHM):

The use of digital remote monitoring technology to enable patients outside of hospital to receive, record and relay clinically relevant information about their current health and wellbeing. It is used to inform or guide self-management decisions by the patient and to support diagnosis, treatment and care decisions by professionals¹. HMHM is understood in this evidence note as distinct from manual self-monitoring, which patients may be advised to carry out at home as part of usual care²

Type 1 diabetes (T1D): An autoimmune mediated condition where insulin production is deficient and daily administration of insulin is required³. Around 10% of diagnoses are T1D: it cannot be prevented⁴.

Type 2 diabetes (T2D): A condition where, typically, the body uses insulin ineffectively (insulin resistance)³. Around 90% of diagnoses are T2D: lifestyle changes may prevent development, control symptoms and minimise complications⁴.

HbA1c: Glycated haemoglobin reflects average plasma glucose over the previous two to three months in a single measure. It is a key measure for assessing glycaemic control in people with diabetes and does not require any special preparation such as fasting⁵. In 2015, the NICE Type 2 diabetes in adults guideline development group agreed a difference in HbA1c of 0.5%/5 mmol/mol as a minimal difference which would be considered to be clinically important⁶.

Literature search

Methods

A systematic search of the secondary literature was carried out between 24-27 February 2017 to identify systematic reviews, health technology assessments and other evidence based reports. Medline, Medline in process, Embase, Cinahl, and Web of Science databases were also

searched for systematic reviews and meta-analyses.

The primary literature was systematically searched between 24–27 February 2017 using the following databases: Medline, Medline in process, Embase, Cinahl and Web of Science. Results were limited to English language papers published from 2011 onwards.

Concepts used in all searches included: Diabetes – Type 1, Type 2, self-care/management telehealth/telemedicine/telemonitoring/teleconferencing/telecare, telephone support, home telemonitoring, e-health, mhealth, mobile smartphone, digital. A full list of resources searched and terms used are available on request.

A detailed search for qualitative research relating to staff and patient experience(s) or perceptions was beyond the remit of this evidence note. However, qualitative literature identified during the clinical and cost effectiveness search was considered.

Introduction

The growing number of people with long term conditions, such as diabetes, is a major challenge for health and social care in Scotland⁷. In 2010, the Scottish Government published a Scottish Diabetes Action Plan⁸, describing quality principles in diabetes care. This included a key focus on people with diabetes managing their own condition for at least 95% of the time through a partnership between people with diabetes and their healthcare teams. A national diabetes improvement plan has also been published⁹.

Technology-enabled care has been identified as a national priority focus to support people to manage aspects of their own health and care for long term conditions as part of an effort to deliver care closer to home¹⁰. From 2013-2016, NHS 24 led a three year European large scale telemonitoring deployment programme aiming to support and improve the care and self-

management of diabetes and other long-term conditions. Scotland was one of the largest deployment sites, which involved NHS Ayrshire and Arran, NHS Lanarkshire, and NHS Greater Glasgow and Clyde¹¹. In addition, NHSScotland has an interactive diabetes website for patients and carers called 'My Diabetes My Way', which is funded and supported by the Scottish Diabetes Group, who offer expert advice to the Scottish Government¹².

This evidence note summarises published secondary evidence (two systematic reviews) and subsequently published primary evidence (a qualitative interview study with patients and professionals in Scotland, and a large observational study conducted across nine European countries, including Scotland, funded by the European Commission and following the Model for Assessment of Telemedicine Framework (MAST) reporting structure).

Health technology description

Home and mobile health monitoring (HMHM) does not have a universally agreed definition. The terms telecare, telehealth, telemonitoring and telemedicine are often used interchangeably. This review adopts the SCTT definition of HMHM as: '*... the use of digital remote monitoring technology to enable patients outside of hospital to receive, record and relay clinically relevant information about their current health and wellbeing. It is used to inform or guide self-management decisions by the patient and to support diagnosis, treatment and care decisions by professionals*¹.

For the purposes of this evidence note, HMHM was further defined as health monitoring of diabetes at home or via mobile technology, which was digital, and where associated data was used as part of patient care by a healthcare professional (whether contemporaneously monitored or not) and incorporated at least one of the following aspects based on elements selected from the Practical Review of Self-Management Support (PRISMS) self-management taxonomy¹³:

- monitoring of condition plus feedback
- information about condition and/or management
- agreement on specific clinical action plans or medication
- practical support with adherence
- easy access to advice or support
- lifestyle advice/support, for example diet, or
- social support.

Epidemiology

Diabetes is a long term condition which is associated with elevated blood glucose, cardiovascular risk and development of microvascular complications⁴. Approximately one in 20 people in Scotland have diabetes (284,122 in 2015)¹⁴. In the UK, around 90% of adults with diabetes have Type 2 diabetes (T2D)⁴.

Management of diabetes involves control of blood glucose, blood pressure, cholesterol and weight, podiatry checks and regular screening for retinopathy and early signs of diabetes-related kidney disease¹⁵. People with Type 1 diabetes (T1D) require regular insulin injections for life⁴. T2D typically gets worse over time and management of T2D may involve lifestyle behaviour change (such as stopping smoking, maintaining healthy body weight and physical activity) oral medication, or injections of insulin². Self-monitoring of blood glucose levels at home may also be recommended to inform control of the condition⁷. Target HbA1c level will usually be less than 59mmol/mol (7.5%), although it can be as low as 48mmol/mol (6.5%)².

An estimated 808,160 consultations in Scotland with a GP or practice nurse were related to people diagnosed with diabetes in the year 2012/13 (the last year for which such data was formally collated)¹⁶.

Clinical effectiveness

Two systematic reviews (SRs) of randomised controlled trials (RCTs)^{17, 18} were considered. Both investigated telemedicine interventions. One, with search to February 2014, focused on T2D only¹⁷ and the other, with search to April 2012, included studies relating to T1D and T2D¹⁸. A large European observational study¹⁹ published subsequently to the reviews was also identified along with a qualitative study related to an RCT conducted in Scotland and England²⁰.

There are challenges associated with reviewing evidence on the effectiveness of HMHM. There is an absence of a standard definition of HMHM and there was widespread heterogeneity in participants and interventions described in studies included in the SRs. For example, there were differences or uncertainties related to how well participants' diabetes was usually controlled, which technological devices were used in interventions, care settings, extent and delivery of clinical feedback, duration of interventions and study follow-up periods.

In addition to the complex nature of the intervention, usual care also varies depending on the configuration and quality of care provided. This complexity affects the design, delivery and assessment of trials investigating the effectiveness of the intervention. For this evidence note, conventional care, control, usual care and disease management were all considered as 'usual care': usual care comparators may differ from the usual care provided in Scotland. The outcomes considered within this review were: HbA1c level, weight, body mass index (BMI), diet (specifically changes in intake of saturated fat, fibre and sugar) and level of physical activity; service outcomes such as consultations and hospitalisation rates, and staff and patient satisfaction and experience were also considered.

Table 1 summarises key information about the included studies.

Table 1: Summary table of key information and results from included secondary evidence

First author and study design	Diabetes type	Number of RCTs (number of participants)	Definition of HMHM type intervention used to select studies	Description of HMHM intervention(s) found in studies	Mean difference in (%) HbA1c [mmol/mol] HMHM-Usual care	Outcomes related to weight HMHM-Usual care
Zhai (2014) SR of RCTs	Type 2	35 (8,149)	'Tele-medicine' based on WHO definition ²¹ (examples given of web-based systems, teleconferencing, mobile and landline-based telephones)	Telephone-based interventions aimed at supporting and educating self-management, including periodic conversations with a healthcare advocate or automated text messaging, web-based interventions with uploaded blood	Mean difference -0.37 (95% CI -0.49 to -0.25) [NR] (SS*)	NR

				glucose and similar internet-transmitted interventions		
Marcolino (2013) SR of RCTs	Type 1 Type 2	13 (4,207)	'Tele-medicine' (personalised feedback from a healthcare practitioner to the patient about forwarded clinical data)	Computerised systems for information exchange, video conferencing, and exchange of information via telephone or other mobile devices, SMS or internet	Mean difference -0.44 (95% CI -0.61 to -0.26) [-4.8] (95% CI -6.7 to -2.8) (SS*)	BMI: 2 studies (n=397) reported reductions (NNS)

BMI: body mass index

CI: confidence interval

SS: statistically significant

NNS: not statistically significant

NR: not reported

* statistically significant heterogeneity reported

Outcomes

HbA1c was the most frequently reported outcome. Table 1 summarises the reported HbA1c data, plus BMI findings from one review. In 2015, the NICE Type 2 diabetes in adults guideline development group agreed by consensus a minimal clinically important difference of 0.5%/5 mmol/mol⁶.

The most recent secondary evidence was an SR¹⁷ of the clinical and cost effectiveness of telemedicine in people with T2D. The definition for interventions included in this review was based on the World Health Organization (WHO) definition of telemedicine: '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'²¹.

In this analysis of 35 RCTs comparing various telemedicine approaches with usual care

(n=8,149; four RCTs in common with the 2013 SR), the pooled mean difference in %HbA1c between study groups was 0.37, in favour of the intervention (-0.37%; 95% confidence interval (CI) -0.49% to -0.25%; p<0.001). Substantial heterogeneity was reported (I²= 75.5%). Significant publication bias was identified by the authors. The duration of interventions ranged from 3-60 months.

A second SR¹⁸ investigated telemedicine applications combined with usual care compared to usual care alone in people with T1D or T2D. Inclusion criteria were defined as 'computerised systems for information exchange, video conferencing, and exchange of information via telephone or other mobile devices, SMS or internet'. Included trials were restricted to those which studied outpatients. In the analysis of 13 RCTs (n=4,207)[two in Type 1 (n=145), six in Type 2 (n=1,180) three in Type 1 and 2 (n=2,362) two unspecified (n=520)] the pooled mean difference in %HbA1c was 0.44 (-0.44; 95% C.I. -0.61 to -0.26; p<0.001) and -4.8mmol/mol (95% CI -6.7 to -2.8; p<0.001). Substantial heterogeneity was reported (I²= 73%). Duration of follow-up ranged from 6-21

months. Two studies within the review (n=397) examined BMI. Each reported a reduction in BMI which was not statistically significant.

A pragmatic observational study of varied telehealth interventions for diabetes using the model of assessment for telemedicine (MAST) (United4Health) was undertaken across nine regions in Europe during 2014 and 2015 and included 3,521 patients¹⁹. The SCTT participated using an intervention aimed to enable positive changes to behaviour and lifestyle through digitalised self-monitoring of blood glucose. In an analysis of eight sites, including Scotland, after 12 months the primary outcome of number of face to face contacts with GP or diabetologist per year increased significantly in the intervention group (3.2 contacts; C.I. not reported; p=0.000) compared to controls and the authors found that %HbA1c reduced significantly more in the intervention group than the comparator group: -0.22 (C.I. not reported; p=0.000). The intervention and comparator groups were not similar at baseline which may have introduced selection bias: the authors advised methodological limitations should be taken into account when considering the results.

Health service use outcomes were not reported in the secondary literature. The United4Health study¹⁹ authors reported an overall increase in number of patient visits to GPs per year (2.35; no CI reported; p=0.000), and reductions in emergency department visits (-0.06%; no CI reported; p=0.012) and outpatient visits (-0.83%; no CI reported; p=0.000) per year in the intervention group. Non-statistically significant reductions were also reported in number of days hospitalised (-0.21%; no CI reported; p=0.365), number of patients admitted to hospital (-2.1%, no CI reported; p=0.196), number of hospital admissions (-0.03; no CI reported; p=0.237) and diabetologist contacts (-0.18; no CI reported; p=0.783). It is unclear exactly which countries were included for the GP outcome of this analysis, which should be considered when interpreting these results.

A nested qualitative study²⁰ within a UK RCT carried out semi-structured interviews with

patients (n=23) and professionals (n=10) from 12 primary care practices in Scotland and England to explore their experiences of participation. An interpretive descriptive approach was used to analyse the data collected. The authors concluded that for patients, telemonitoring led to an increase in motivation to improve self-management and was well accepted. Some professionals were concerned about increased workload and cost and the shift away from face to face care, but these concerns were not universal. The United4Health study¹⁹ used the Service User Technology Acceptability Questionnaire (SUTAQ) which originated from another UK RCT²² to assess patient satisfaction in 949 patients, including 24 patients from Scotland. They found that, in general, patients were very satisfied with the 'kit' and felt that it enhanced care, but were indifferent as to whether the kit could substitute usual face to face care. The authors highlighted that as the questionnaire was developed in the UK, it may not perform similarly in the other healthcare settings.

Safety

Adverse events were not reported in any of the literature identified for this evidence note.

Cost effectiveness

Both SRs^{17, 18} reported a lack of available cost-effectiveness evidence for analysis. No appropriately conducted cost-effectiveness evidence was identified by the literature search undertaken for this evidence note.

Economic modeling of cost effectiveness based upon an RCT carried out in Scotland is reported to be in progress²³.

Conclusion

HMHM lacks a universal definition, and literature identified in relation to this evidence note was heterogenous, making synthesis of the evidence challenging and preventing definitive conclusions. Statistically significant heterogeneity was reported in meta-analyses.

Overall, the available evidence relating to HMHM was consistent with a small reduction in HbA1c in patients receiving an HMHM intervention compared with those who did not, but the clinical importance of the reductions found would depend on the level set for their clinical relevance. Reduction in outcomes related to weight were reported in a small number of studies and did not show a statistically significant difference between groups. It is unclear whether the reductions in HbA1c are sustainable and independent of other aspects of diabetes management or therapy.

No evidence was identified to determine whether there was a difference in the cost effectiveness or safety of HMHM compared with usual care. A qualitative study found the intervention was convenient for patients, but some professionals raised concerns about cost and workload.

Determination of the components of a home and mobile health type intervention which may be effective was beyond the scope of this evidence note. Longer term follow-up of the interventions was advocated in the secondary literature identified research gaps. The consistent use of an established intervention reporting framework to describe HMHM interventions within studies would be advantageous. All quantitative literature within this evidence note reported that further research was required relating to identifying the optimal design of interventions, determining whether intervention effects are sustained over time, and examining cost effectiveness. There appears to be a lack of routinely collected evidence relating to patient satisfaction with interventions.

Identified research gaps

The consistent use of an established intervention reporting framework to describe HMHM interventions within studies would be

advantageous. All quantitative literature within this evidence note reported that further research was required relating to identifying the optimal design of interventions, determining whether intervention effects are sustained over time, and examining cost effectiveness. There appears to be a lack of routinely collected evidence relating to patient satisfaction with interventions.

Equality and diversity

Healthcare Improvement Scotland is committed to equality and diversity in respect of the nine equality groups defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion, sex, and sexual orientation.

The process for producing evidence notes has been assessed and no adverse impact across any of these groups is expected. The completed equality and diversity checklist is available on www.healthcareimprovementscotland.org

About evidence notes

This evidence note will be considered for review 2 years post-publication, and at 2-yearly intervals thereafter. For more information about the evidence note process see:

www.healthcareimprovementscotland.org/our_work/clinical_cost_effectiveness/shtg/standard_operating_procedures.aspx

To propose a topic for an evidence note, email shtg.hcis@nhs.net

References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network www.knowledge.scot.nhs.uk, or by contacting your local library and information service.

A glossary of commonly used terms in Health Technology Assessment is available from htaglossary.net.

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