Turning data into information

The use of new technologies to improve the delivery of healthcare for people with diabetes

Dr Nicholas Thomas Conway MBChB MRCPCH MPH

Thesis in submission towards a Doctorate of Medicine,

University of Dundee, September 2017.

Contents

1.1 Acknowledgements

I am indebted to Dr Debbie Wake who supervised this thesis, for providing guidance, opportunity and inspiration, and for being a valued colleague.

I am grateful too, to Prof Blair Smith who co-supervised this work and ensured that this work has been completed with the necessary academic rigour.

This work was only possible thanks to the staff and patients of Ninewells Hospital diabetes clinic; the Mill Practice diabetes clinic; and St John's Hospital diabetes clinic.

In addition, I am indebted to the following people:

- Mr Massimo Brilliante, NHS Tayside
- Ms Iona Campbell, University of Dundee
- Mr Chaloner Chute, Digital Health & Care Institute
- Dr Scott Cunningham, University of Dundee
- Dr Lynda Cochrane, Clinical Statistical Consultants
- Dr Alistair Emslie- Smith, NHS Tayside
- Mr Charles Flach, NHS Tayside
- Dr Paula Forbes, Abertay university
- Dr Timo Haikonen, Duodecim Medical Publications Ltd.
- Dr Annemie Heselmans, School of Public Health, Katholieke Universiteit, Leuven
- Dr Illa Kunnamo, Duodecim Medical Publications Ltd.
- Dr Peter Nyberg, Duodecim Medical Publications Ltd.
- Mr Faiyaz Shaik, NHS Education for Scotland
- Mr Andrew Taylor, NHS Tayside
- Dr Ann Wales, NHS Education for Scotland
- Dr Clare Webster, NHS Tayside

This work was funded by a grant from the Digital Health & Care Institute[1]. Aridhia Informatics ltd [2] provided additional funding, via a fellowship post that ran concurrently with the initial stages of the project.

1.2 Statement of Authorship

With reference to this thesis being submitted to the University of Dundee for fulfilment of the degree Doctor of Medicine (MD), Dr Nicholas Conway declares that:

- He is the sole author of this thesis
- The candidate has consulted all cited references.
- This thesis contains no material extracted in whole or in part from a thesis, dissertation or research paper, except where specific reference is made in the main text of the thesis.
- This thesis has not been submitted for the award of any other degree or diploma in any other tertiary institution.

Signed _____

Date _____

1.3 List of Tables

1.4 List of Figures

1.5 List of Abbreviations

Abbreviation	Definition
ACE	Angiotensin Converting Enzyme
ACR	Albumin Creatinine Ratio
ADHD	Attention Deficit Hyperactivity Disorder
AE	Adverse Events
AHP	Allied Health Professional
AHPs	Allied Health Professionals
BMI	Body Mass Index
BNF	British National Formulary
BP	Blood Pressure
CAD	Coronary Artery Disease
CCI	Charlson Co-Morbidity Index
CCT	Controlled Clinical Trials
CDSS	Clinical Decision Support Systems
CHI	Community Health Index
CHO	Carbohydrate
CI	Confidence Interval
CKD	Chronic Kidney Disease
COPD	Chronic Obstructive Pulmonary Disease
CPD	Continuing Professional Development
CVD	Cardiovascular Disease
DBP	Diastolic Blood Pressure
DKA	Diabetic Ketoacidosis
DSN	Diabetes Specialist Nurse
DSS	Decision Support System
EBM	Evidence Based Medicine
EBMeDS	Evidence Based Medicine Electronic Decision Support
EHR	Electronic Healthcare Record
ePHR	Electronic Patient Health Record
EPOC	Effective Practice And Organisation Of Care Group
EWS	Early Warning Score
FDA	U.S. Department of Health and Human Services - Food and Drug Administration
FG	Focus Group
GP	General Practitioner
HbA1c	Haemoglobin A1c
HBGM	Home Blood Glucose Monitoring
HBM	Health Belief Model
HCP	Health Care Professional
HIV	Human Immunodeficiency Virus
ID	Identifier
iOS	Operating System
IQ	Interquartile

IQR	Interquartile Range
IT	Information Technology
ITS	Interrupted Time Series Analysis
LDL	Low Density Lipoprotein
LoS	Length Of Stay
MDMW	Mydiabetesmyway
MHRA	Medicines & Healthcare products Regulatory Agency
MDT	Multidisciplinary Team
NES	NHS Education For Scotland
NHS	National Health Service
NHST	NHS Tayside
NICE	National Institute For Health And Care Excellence
NWH	Ninewells Hospital
PHR	Personal Health Record
PREMs	Patient Reported Experience Measures
PRISMA	Preferred Reporting Items For Systematic Reviews And Meta-Analyses
PU	Pressure Ulcer
QoL	Quality Of Life
QPI	Quality Performance Indicator
RCT	Randomised Controlled Trial
SAS	Scottish Ambulance Service
SCT	Social Cognitive Theory
SBP	Systolic Blood Pressure
SCCR	Shared Clinical Care Record
SCI	Scottish Care Information
SD	Standard Deviation
SDRN	Scottish Diabetes Research Network
SIGN	Scottish Intercollegiate Guidelines Network
SIMD	Scottish Index Of Multiple Deprivation
SJH	St John's Hospital
SMBG	Self-Monitored Blood Glucose Levels
SMS	Short Message System
StR	Specialist Registrar
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
TSH	Thyroid stimulating hormone
UACR	Urinary Albumin/Creatinine Ratio
UI	User Interface
UK	United Kingdom
US	United States
USA	United States Of America
UTAUT	Unified Theory Of Acceptance And Use Of Technology

1.6 Abstract

1.6.1. Introduction

The rapid growth and maturation of Information technologies over recent decades has had a transformative effect on healthcare delivery. As our use of such systems increases, so too does the volume of routinely collected patient data. Accessing these data with a view to providing meaningful information to individuals remains a challenge. This thesis aims to assess the effectiveness of eHealth interventions that tailor information to users' specific requirements; and describe the implementation and evaluation of a clinical decision support system (CDSS) for diabetes with a view to improving the care of those with diabetes.

1.6.2. Methods

This study consisted of two phases:

- A systematic review was conducted for trials of tailored eHealth messaging in the management of chronic disease, assessing objectively measured clinical processes and outcomes.
- Following this, a CDSS for diabetes was developed and implemented within a diabetes electronic health record. The CDSS was evaluated via a mixed methods approach to assess user satisfaction and interaction with the system and to detect any changes in clinical processes and outcomes.

1.6.3. Results

The systematic review identified 22 studies that met the eligibility criteria. There was limited evidence that tailored eHealth messaging was associated with improved clinical processes and outcomes, but study quality was poor.

The CDSS was successfully implemented within the diabetes EHR with favourable feedback from users and evidence of improved efficiencies in working practices. Adherence to guidelines was markedly improved when compared to a closely matched control population. There was an observed small but significant improvement in glycaemic control and a decrease in progression of kidney disease.

1.6.4. Conclusion

The ubiquitous nature of information technologies is testimony to the benefits that they bring to our everyday lives, including within the healthcare setting.

This study has demonstrated that healthcare professionals (HCPs) caring for people with diabetes recognise the value of informatics in routine care via the use of a CDSS. This study has shown that a CDSS has the potential to improve clinical outcomes primarily by its effect on clinical processes i.e. adherence to guidelines.

The diverse and complex nature of such technologies makes it difficult to assess the active component(s) effecting behaviour change. Ultimately, this limits generalisability into other settings. In this study, the active components of the CDSS can be identified as being improved efficiencies in working practices, whilst avoiding adverse effects on patient or user experience.

It is tempting to infer that tailoring the CDSS messages to end-users (either patient or HCP) will improve outcomes further, however the existing evidence does not allow for this specific conclusion to be drawn. It is therefore imperative that future studies attempt to address this by recognising the complex nature of eHealth interventions and attempting to delineate the active component(s).

2. Project-related research output

2.1 Published articles

See appendix (section 20) for full text of published articles.

- Conway NT, Adamson KA, Cunningham SG, Emslie Smith A, Nyberg P, Smith BH, Wales A, Wake DJ. Decision support for Diabetes in Scotland – implementation and evaluation of a clinical decision support system. Journal of Diabetes Science and Technology 2017 (in press)
- Conway NT, Webster C, Smith B, Wake, D. eHealth and the use of individually tailored information: a systematic review. Health Informatics Journal 2016 (epub):
- Conway NT, Campbell I, Forbes P, Cunningham SG, Wake DJ. mHealth applications for diabetes – user preference and implications for app development. Health Informatics Journal 2015 (epub)

2.2 Peer reviewed conference abstracts (*oral presentations)

See appendix (section 19) for full text of abstracts published.

- *NT Conway, SG Cunningham, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of user acceptance, clinical processes and outcomes. International Diabetes Federation, World Diabetes Congress, Dubai 2017.
- *NT Conway, SG Cunningham, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of clinical processes and outcomes. Informatics for Health conference, Manchester 2017.
- NT Conway, K Adamson, SG Cunningham, A Emslie-Smith, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of user attitudes and system usage. Diabetes UK conference, Manchester 2017
- NT Conway, K Adamson, SG Cunningham, A Emslie-Smith, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of clinical processes and outcomes. Diabetes UK conference, Manchester 2017
- *Conway NT, Campbell I, Forbes P, Cunningham SG, Wake DJ. mHealth applications for diabetes – user preference and implications for app development.. Farr Institute International Conference, St Andrews 2015.

- Conway NT, Campbell I, Forbes P, Cunningham SG, Wake DJ. mHealth applications for diabetes – user preference and implications for app development.. International Diabetes Federation, World Diabetes Congress, Vancouver 2015.
- Conway NT, Cunningham SG, Forbes P, Shaik F, Emslie-Smith A, Wales A, Wake DJ. Decision Support for Diabetes: Implementation and evaluation of the EBMeDS project within NHS Scotland. International Diabetes Federation, World Diabetes Congress, Vancouver 2015.
- *Conway NT, Wales A, Cunningham S, Walker J, Locke R, Emslie-Smith A, Shaik F, Wake DJ. Decision support for diabetes: embedding knowledge in care processes. Health Informatics Scotland Conference, Glasgow 2014.
- Campbell IJM, Cunningham SG, Conway NT, Wake DJ. Mobile technology as a tool for patient education and self-management in the diabetic population. Diabetes UK Professional Conference, Liverpool 2014
- Campbell IJM, Cunningham SG, Conway NT, Wake DJ. Mobile technology as a tool for patient education and self-management in the diabetic population. International Conference on Advanced Technologies & Treatments for Diabetes, Vienna 2014.

2.3 Other reports and awards

- Final report for funders (DHI): *Project "Bain". Clinical decision support for diabetes in Scotland – implementation and evaluation of EBMeDS within SCI-Diabetes*
- Final report for NES: *Clinical decision support for NHS Scotland. Evaluation of the Evidence Based Medicine electronic Decision Support (EBMeDS) system within SCI-Diabetes*
- Scottish Government eHealth website – good practice case studies: http://www.ehealth.nhs.scot/case-studies/clinical-decision-support-for-diabetes-in-scotland/
- Quality in Care (Diabetes) award finalists: Clinical Decision Support for Diabetes in Scotland - http://www.qualityincare.org/diabetes/awards/results/qic_diabetes_2016_results/digital_and_technology_solutions_in_the_treatment_and_management_of_diabetes

3. Introduction

3.1 Diabetes

An estimated 385 million of the world's 7 billion population have diabetes, with this number estimated to increase to nearly 600 million by the year 2035 [3]. In the UK, nearly 3 million people have been diagnosed with diabetes, which accounts for over 6% of adults in the UK. The Scottish prevalence of diabetes is rising and is expected to double over the next 2 decades [4–6].

The majority of care for those with diabetes is conducted in the community via primary care and outpatient departments. This care aims to improve glycaemic control, thereby reducing the incidence of diabetes-related complications as well as providing early detection and effective treatment of these complications. Diabetes-related complications place a substantial burden on secondary care services. A national English inpatient audit of over 200 hospital sites found that those with diabetes accounted for 15% of inpatient admissions, over half of whom were admitted specifically for care related to diabetes [7].

Taking into account both direct and indirect costs, it has been estimated that the direct cost of diabetes care within the UK in 2010/11 was £9.8bn, equivalent to approximately 10% of NHS annual spending [8]. Taking into account indirect costs e.g. lost earnings, the current overall cost to the UK economy rises to £23.7 billion per year [8]. As the burden of disease increases, it is estimated that by 2035/36 this proportion will rise to 17% of health spending in the UK.

3.2 Delivery of diabetes care – national context

Best practice in the management of diabetes has been established by the use of national guidelines based on an appraisal of the available evidence [9–11]. Diabetes care in Scotland relies on a series of managed clinical networks supported by a national informatics platform, SCI-Diabetes [12]. The prevalence of diabetes in Scotland has increased over the past decade [4]. Despite this, there has been a sequential improvement in quality performance indicators and the incidences of diabetes-related complications have decreased [4,13,14].

Improving the delivery of care for those with diabetes can lead to improved clinical outcomes [15]. Specifically, interventions that involve audit tools and feedback to health professionals can improve diabetes outcomes (when implemented in conjunction with interventions aimed at patient behaviour). In Scotland, regional and national audits are published on an annual basis using data extracted from SCI-Diabetes [4,16]. These audits report on a series of quality performance indicators (QPIs), which are agreed at a national level and allow regional and international comparisons to be drawn. These QPIs (which include the monitoring of biochemistry, anthropometrics, and attendance at screening activities) are broadly aligned with the "15 care essentials" advocated by Diabetes UK, the UK's largest charity for those with diabetes [17].

In 2004, the then Scottish Executive commissioned a report into the future direction of the NHS in Scotland and how healthcare should be delivered [18,19]. Recommendations included a shift towards preventative services that are targeted towards at-risk individuals and an increased emphasis on self-care and intensive support for those with long-term conditions. In addition, an eHealth strategy was described which recognised the importance of developing an electronic health record that enables integrated care across services [20]. The Scottish Diabetes Action plan emphasised the need for a "person-centredness" approach to allow people living with diabetes to be supported in managing their own condition [21].

In their 2008 report, the King's Fund recognised that the NHS is slow to adopt new technologies and that improvements can be made at national and local levels [22]. In addition, it was recommended that in an effort to increase demand, clinicians should be encouraging patients to use available technologies. In order to achieve this "person-centredness" approach these technologies should be "predictive, preventive, personal and participatory" [23].

3.3 Turning data into information

This lack of "patient-centredness" and the inability to access meaningful information from available data were recurring themes identified in the recent Francis report arising from the Mid Staffordshire NHS Foundation Trust Public Inquiry [24]. The report makes 290 recommendations of which many are concerned with the transformation of data into meaningful information that is accessible and tailored to health professionals and patients as well as the local context:

> *There is a need for all to accept common information practices, and to feed performance information into shared databases for monitoring purposes...Systems should be designed to include prompts and defaults where these will contribute to safe and effective care...[they]...should include a facility to alert supervisors where actions which might be expected have not occurred, or where likely inaccuracies have been entered...[and]...be capable of collecting performance management and audit information automatically, appropriately anonymised direct from entries. Systems must be capable of reflecting changing needs and local requirements over and above nationally required minimum standards* [25].

Following the Francis report, the government commissioned the NHS confederation to investigate and report on how data can be used more effectively within the NHS [26]. The vast amount of data collected by the NHS is highlighted in the subsequent report - the authors estimate that that NHS clinical staff spend between 2-10 hours per week collecting, recording or validating data and that data collection and processing costs the NHS £300-£500 million per year. These "precious" data are often inaccessible to clinicians and frontline staff and are therefore of little value to users. The report found that the value of these datasets could be increased by: linking to patient outcomes and clinical decision making; improving feedback mechanisms; and increasing accessibility for staff.

3.4 Information systems

3.4.1. eHealth, shared clinical care records and personal health records

The World Health organisation has defined eHealth as *"the cost-effective and secure use of information and communication technologies in support of health and health-related fields"* and has encouraged member states to incorporate eHealth into health systems and services [27].

eHealth has increased the opportunity for sharing information between primary and secondary care via a shared clinical care record (SCCR), in the hope that this will improve clinical outcomes. However, the effectiveness of such an approach has been found to be limited. A Cochrane review assessing whether or not SCCRs improve clinical outcomes for those with long term health conditions concluded that there was insufficient evidence to recommend the widespread adoption of SCCR beyond the research setting [28]. The review identified 20 studies (19 of which were randomised controlled trials) and outcomes included clinical (mental or physical health); psychosocial (disability, functioning, hospital admissions); adherence to guidelines; service utilisation; and prescribing practice. Of all measured outcomes, SCCR showed significant improvement only in prescribing practice. However, there were a number of shortcomings identified in the studies included in the review including:

many of the studies failed to meet Cochrane's Effective Practice and Organisation of Care Group (EPOC) guidelines in terms of adequate randomisation and prevention of contamination between intervention groups; the duration of follow up was limited (range 3-24 months); and participation rates were not reported making it difficult to comment on external validity.

Three of the 20 studies eligible for inclusion in the above review were directly related to diabetes care [29–31]. Meta-analysis of biomedical outcomes failed to demonstrate any improvement in HbA1c, systolic BP or BMI between intervention and control groups. Two of these studies [30,31] were also included in an earlier systematic review which concentrated exclusively on SCCRs in diabetes care [32]. This review included descriptive studies in addition to RCTs and did not include a meta-analysis. Many of the studies included in this earlier review predated widespread adherence to national guidelines and so analysis was confounded by a lack of structured primary care in the non-intervention arm. Common to all of the above evaluation of SCCRs was a lack of utilisation of electronic means in sharing the clinical record.

A personal health record (PHR) is an electronic application through which individuals can manage and share their health information (and that of others for whom they are authorised) in a private, secure, and confidential environment [33]. A PHR which is managed by the individual but which is interconnected with an electronic SCCR provides the optimum combination of patient empowerment whilst ensuring that the PHR contains validated, objective data that is relevant to the individual and remains up to date.

The concept of a PHR has been reported in the literature since the 1960's. With the adoption of electronic medical records the number of publications concerning the use of PHR has increased exponentially over the last decade [34]. A systematic review in 2010 [35], identified 14 studies in total, of which 3 were concerned with diabetic care (total n>3800, reported in 4 papers [36–39]). The objective of this review was not explicitly stated, however it is inferred that the authors were assessing whether PHRs confer any clinical benefit. There were some marginal gains in HbA1c reported, in addition to some improvement in patient knowledge and health-care delivery (e.g. attendance at foot clinic) however the review authors questioned the validity of the included studies owing to concerns regarding bias. More recently, a further RCT assessing effectiveness of a PHR in diabetes found no significant difference in biomedical markers between study groups [40]. However, small numbers (n~100) and short duration of study (9 months) make a type 2 error more likely. Of note, this study used a paper-based PHR whilst the authors of the systematic review also restricted the inclusion criteria to paper-based systems.

3.4.2. mHealth

Whereas eHealth technologies are based on the use of personal computing and the internet, the use of mobile devices to improve health outcomes, healthcare services or health related research has become known as mHealth [41].

The worldwide mobile phone market continues to grow year on year with over 1.3 billion units being shipped in 2014, 72% of which were smartphones [42]. The World Bank estimates that in 2013, there were 92 subscriptions to mobile phone providers per 100 people in the world [43]. Developing countries have demonstrated the largest increase in ownership in the past few years and it was anticipated that ownership in these countries would exceed those in developed countries for the first time by the end of 2014 [44].

The ubiquitous nature of mobile technologies across the full socio-economic spectrum has led to a number of public-private partnerships aiming to exploit this new area of healthcare delivery within both the developed and the developing world (e.g. the mHealth alliance [45]). A Cochrane review of the published mHealth literature with regards to health outcomes is currently underway [46].

A number of smartphone and tablet apps are available for managing diabetes. These include: recording and trend analysis of glucose measurements, apps aimed at improving medication adherence; and lifestyle modification including exercise monitors and nutritional support. A 2011 systematic review of apps available from online vendors as well as the published literature, identified over a hundred such apps [47]. By 2013, this figure had increased to over 650. Functionality that was most prevalent included: insulin and medication recording; data export and communication; recording of dietary intake; and weight monitoring. Very few apps were designed to improved diabetes knowledge (in contrast to published guidelines which emphasise the need for patient education) and there was no identified formal evaluation of the role of social media in diabetes care. Most of the commercially available apps rely on manual data entry, whereas the majority of published studies utilised bluetooth or wifi connectivity to upload personal data to a SCCR.

Outcome data for mHealth-based interventions are mainly restricted to interventions that predate the advent of smartphone technology. A systematic review of published literature from the 10 years preceding 2007 concluded that there were gains to be made in both glycaemic control and patient self efficacy and knowledge [48]. However, it should be noted that the interventions were primarily based on short message system (SMS) text messaging in response to self-reported glucose readings, as opposed to the apps described above.

In general, web-based interventions aimed at improving the management of type 2 diabetes have been shown to improve clinical outcomes when subjected to systematic review [49]. It is more difficult to establish which components are important to achieve these improvements however, due to the complex nature of each intervention. Ramadas et al conclude that interventions that feature self monitoring; a local point of contact; and mobile phone technology would appear to be the most likely to succeed in improving clinical outcomes. Brown et al reach a similar conclusion in their narrative review of the same subject [50]. In addition, they conclude that the use of tailoring content to individuals is most likely to result in improvements to clinical outcomes.

3.4.3. Clinical Decision Support Systems

Long term conditions like diabetes, affect one in five people yet account for 80% of general practice consultations [51]. It is estimated that more than half of all clinical decisions fail to take account of the best available evidence [52]. In addition, evidence-based guidelines often do not accommodate co-morbidities and multiple medications [53–55]. There is a recognised need to find innovative ways of integrating knowledge into clinical workflow; to contextualise and personalise care; and to manage the complex care needs and human factors which contribute to unwanted variation in practice [56,57].

Clinical Decision Support Systems (CDSS) utilise algorithms of varying complexity that are applied to existing eHealth systems. CDSS can be: tools for attention focussing (flagging of abnormal results or investigations/management pending); patient-specific assessment and advice (diagnostic or prognostic inferences); or tools for critiquing and planning (sensitivity analysis and hypothesis testing whereby a clinician can test his/her proposed management plan using historical data) [58].

The use of automated reminders via CDSS has been shown to be one of the most consistently successful approaches to encourage clinicians to adopt evidence-based practice [59]. In terms of efficacy, a 2005 systematic review concluded that whilst a number of studies showed an improvement in clinical processes (e.g. adherence to guidelines), there was a lack of evidence demonstrating improved clinical outcomes [60]. In the same year, a separate systematic review found that CDSS which incorporated contemporaneous recommendations (as opposed to simple summaries of data) and were available within the normal work stream were more likely to result in improved clinical outcomes - 90% (30/32) of interventions which included these features demonstrated improved outcomes [61].

3.4.4. Tailoring

Targeted health information or education is that which is designed to reach a specific demographic within the population and is based on the concept of "market segmentation", a decades-old device employed by business and the advertising sectors [62] . As with all targeted communication, there is an underlying assumption that the target population is relatively homogenous in its composition i.e. similar demographics, socioeconomic status etc. In addition, targeted information takes no account of the recipients' individual circumstances e.g. health beliefs or health literacy. Tailored health information takes into account of both of these shortcomings, whereby there is an assessment of the individual who is to receive the information, which is then conveyed to an individual in a manner that is specific to that individual [63].

By way of illustration, consider the BERTIE online Type 1 diabetes education programme [64]. This could be regarded as a form of targeted education in that is designed specifically for the Type 1 diabetes population. However, this is a heterogeneous population on a number of levels e.g. differing levels of glycaemic control, diabetes health literacy, diabetes self-efficacy etc. If the intervention were to include an assessment of these variables (e.g. an individual is identified as having poor glycaemic control) and then deliver the information in a manner suited to the individual (e.g. the same individual has low levels of health literacy), then it would be considered to be *tailored* to that individual.

The tailoring of messages to specific individuals is viewed as the most sophisticated form of automated communication and has been used to deliver health education and material, primarily for the purposes of health promotion [65]. Tailoring has been defined as:

"any combination of strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment" [66].

The theory underpinning the use of such methods draws heavily on a number of behaviour change theories including the Health Belief Model [67], Bandura's Social Cognitive Theory [68] and Prochaska and DiClemente's *Stages of Change* [69] Common to all of these models is the recognition that the main determinant of health-related behaviours is not a matter of simple demographics, but a far more complex interplay of perceived vulnerability and the anticipated benefits of what behaviour change can bring.

The Health Belief Model (HBM) identified five basic cognitive dimensions as a basis for behaviour: perceived severity of the condition, perceived susceptibility or vulnerability to the disease process, perceived benefits (i.e. belief in efficacy of the intervention), costs/barriers, and cues to action - which may be internal (e.g. symptoms) or external (e.g. health education, illness of family or friend).

Social cognitive theory (SCT) builds on this by addressing one of the main criticisms of the HBM - a lack of consideration of an individual's past experiences and social environment [68]. A key construct of SCT is an individual's self-efficacy. Self-efficacy is the confidence that an individual has in his/her ability to successfully complete a task and is influenced by past experience, as well as current facilitators and barriers, and can be measured using validated tools [70].

In contrast to HBM and SCT that concentrate on the cognitive processes associated with behaviour change, Prochaska and DiClemente's *Stages of Change* concentrates on the behavioural aspects of behaviour change as well as considering time as a key determinant [69]. It does so by describing a series of key stages that are common to all individuals when attempting to change their behaviour . Theses stages range from the pre-contemplative (i.e. not ready to make any changes) through to acting and maintaining the change in behaviour. During this process, individuals may recycle through stages or demonstrate regression to earlier stages. Again, validated tools can determine which stage an individual is at any given time, with a view to tailoring interventions appropriately [71]

As previously stated, an integral component of a tailored intervention is that it incorporates an individual-level assessment of the recipient. This assessment is dependent on the type of intervention and the target audience, but could be based on routinely collected data (e.g. professional role; socioeconomic status; health records; or clinical parameters) or data collected from the individual with the specific intention of formulating a tailored message (e.g. health literacy; self-efficacy; or pre-existing attitudes and knowledge). Interventions that utilise tailored messages tend to involve the distribution of printed material aimed at primary health promotion e.g. dietary advice [72–74], smoking cessation [75,76], or uptake of screening [77].

Reviewers of these and other studies conducted in the late 20th century concluded that tailored print communication was more effective than non-tailored interventions, however the lack of a systematic approach by the reviewers limits the generalizability of the findings [78,79].

More recently, systematic reviews (some utilising meta-analysis) have reached similar conclusions with regards to tailored interventions aimed at improving physical activity, ambulatory care, health care practitioner behaviour (HCP), smoking cessation, and communication of risk to improve uptake of screening tests [80–84]. A meta-analysis of studies utilising paper-based tailored communications identified 57 studies in total, of which 40 compared tailored with non-tailored/generic communication [85]. The combined mean sample size-weighted effect size was $r = 0.058$, equivalent to an odds ratio of 1.21 (no confidence interval provided). The authors conclude that these results suggest paper-based tailored communications confer a small but significant benefit over the generic equivalent, however the do also concede that the stated effect size falls below the threshold for what is considered a "small" effect size ($r = 0.1$) [86]. Furthermore, the meta-analysis identified significant effect modifiers using regression techniques. Factors that were predictive of greater effect included patients with higher socioeconomic status (SES), printed material of shorter length and repeated messages through time. In addition, effect size increased with the number of theoretical constructs that were used in the assessment of the individual e.g. self-efficacy, stage of change etc.

There is a lack of literature concerning the use of tailored messages aimed at changing health care practitioner (HCP) behaviour. There is also a lack of evidence to inform the design and modality of tailored messaging, and whether the effectiveness of existing eHealth technologies (e.g. CDSS) can be improved were they to incorporate tailored messaging.

3.4.5. Barriers to adopting systems

Assessing how and why individuals and groups choose to adopt new information systems has been the subject of much research [87]. Various factors that can influence this process have been identified including individuals' attitudes to new technology; their intention to use such systems; and organisational or environmental conditions required to increase uptake. As a result, several models have been proposed which include some or all of these factors. The Unified Theory of Acceptance and Use of Technology (UTAUT) model was formulated by identifying the similarities between 8 different models, combining them and then validating the resultant model [88]. This model has been used to predict the likelihood that a new technology will be adopted by users, as well as allowing organisations to identify user groups that may require additional support during the implementation phase. The model consists of four key determinants: Performance expectancy (how much an individual believes the technology will assist them); effort expectancy (how much an individual perceives the technology will be easy to use); social influence; and other facilitating conditions (e.g. organisational factors) [88], in addition to a number of demographic modifiers. The model is widely cited, however the applicability to academic or health environments is still not known [87]. More recently, Venkatesh tested the UTAUT within the healthcare setting and found that the primary determinant of adoption of a new electronic health record by HCPs was age (as opposed to the constructs cited above), highlighting the importance of context when evaluating adoption of new systems [89].

3.4.6. Safety and risk

Developing a new drug from "bench to bedside" is a notoriously expensive and time consuming process. The pharmaceutical industry estimates that the average new drug takes 12 years to develop, at a cost of over £1 billion [90]. This cost is partly due to the necessary pharmacovigilance associated with developing a new product, but also due to the high attrition rate of new drugs during this process – only 1/5000 new compounds developed in the

lab will make the successful journey to the healthcare market, with the remainder discarded owing to concerns related to efficacy, safety, or both [90].

In contrast, the development of mHealth apps available to consumers takes place in a largely unregulated environment, resulting in concerns regarding conflicts with current guidance [47] and the efficacy of such products [91]. In a systematic review of mHealth apps designed to calculate doses of insulin boluses, Huckvale et al demonstrated inherent risks in the majority of available apps [92]. Nearly all (91%) of the 46 apps that met the inclusion criteria failed to validate inputted data, resulting in potentially lethal insulin dosage advice being given, whilst half (48%) of the apps assessed gave advice that violated basic clinical assumptions (e.g. in the event of missing blood glucose data, blood glucose was assumed to be 0 mmol/l) [92].

These identified risks have led to calls for greater regulation of the market in general, and the need for regulation to take into account the safety and efficacy of such products [93]. The U.S. Department of Health and Human Services Food and Drug Administration (FDA) have recently issued advice on what types of mHealth apps constitute a “medical device”, thereby requiring them to adhere to necessary regulatory standards [94]. In the UK, the Medicines & Healthcare products Regulatory Agency (MHRA) provide similar advice on how to ensure mHealth apps meet regulatory requirements, thereby allowing them to be marketed to users throughout the EU [95]. It should be noted that neither US nor UK regulatory authorities consider a product’s efficacy as part of this process.

3.5 Summary

Diabetes represents a growing public health problem that currently places a large burden on healthcare spending and is projected to grow in the coming years. Effective diabetes care can reduce the risk of developing diabetes-related complications and that care can be improved with the use of emerging technologies. However, owing to the complex nature of interventions that use new technologies, it is difficult to identify which components can effectively be implemented and which are effective in improving care.

Both government and opinion leaders have articulated the need to explore the use of new technologies in improving the "patient-centredness" of care and the transformation of clinical data into meaningful information. Furthermore, there is the potential to tailor this information to specific user groups including patient sub-populations and health care professionals. This study will test whether either approach results in improved healthcare processes and/or clinical outcomes for those with diabetes.

4. Aims and objectives

4.1 Aims

The study aims to:

1. Determine the effectiveness of eHealth interventions designed to improve the management of chronic diseases by providing tailored information to health care practitioners, patients and/or carers
2. Describe the implementation and evaluation of a clinical decision support system (CDSS) within a shared clinical care record (SCCR) for those with diabetes

4.2 Objectives

In order to achieve these aims, the study will be conducted in three main parts and will address the following objectives:

1. Evaluation of the literature:
    - Conduct a systematic review of the published literature on of eHealth interventions designed to improve the management of chronic diseases by providing tailored information to health care practitioners, patients and/or carers
2. Implementing and evaluating a CDSS:
    - Describe the development and testing of a CDSS to be integrated within an existing SCCR
    - Develop a framework to evaluate the CDSS
    - Within that framework:
        - Conduct focus groups of system users to assess the acceptability of the CDSS

- Develop and distribute a questionnaire survey to users of the CDSS to assess the usefulness and usability of the CDSS and to identify barriers and facilitators to widespread adoption
- Develop and distribute a questionnaire survey of patients subject to the intervention to ensure that the CDSS has no adverse impact on the consultation process
- Conduct a case-control comparison of system usage to assess whether the CDSS changes user behaviour
- Conduct a case-control comparison of clinical outcomes to assess whether the CDSS improves clinical outcomes
- Make recommendations for the future development of the CDSS

Finally, this thesis will apply the findings from all of the above to propose how current systems could be adapted to take full advantage of tailoring and CDSS to improve patient care.

5. Systematic review

5.1 Abstract

5.1.1. Background

Tailored messages are those that specifically target individuals following an assessment of their characteristics and can influence health-related decisions when delivered using traditional media.

5.1.2. Purpose

This systematic review aims to assess the evidence regarding the effectiveness of tailoring within eHealth interventions aimed at improving the management of chronic diseases.

5.1.3. Data Sources

OVID Medline and Embase databases were searched from inception to May 2014, without language restriction, for trials of tailored eHealth messaging.

5.1.4. Study Selection

Randomised controlled trials; controlled clinical trials; controlled before-after studies; and interrupted time series analyses were considered. Objectively measured clinical processes or outcomes were considered where comparison was made with no intervention and/or existing practice.

5.1.5. Data Extraction and synthesis

Two reviewers independently extracted data and assessed quality. The review included 22 papers: 6 studies with fully tailored messaging; 16 studies that included partially tailored messages. Two studies isolated tailored messages as the active component. The remainder compared intervention with standard care. Twelve of 16 studies measuring clinical processes reported positive outcomes; and 2 of 6 studies reporting clinical outcomes showed improvements. Positive findings were reported for interventions aimed at both patients and healthcare practitioners.

5.1.6. Limitations

Overall, study quality was low. Study design did not allow for identification of the interventions' active component. Study heterogeneity precluded quantitative or meta-analysis.

5.1.7. Conclusion

There is evidence that tailored eHealth messaging improves clinical processes/outcomes, however this review was unable to demonstrate that tailoring itself has specific additional benefit owing to limited quality and quantity of evidence. Future studies are needed to improve quality in this area. Studies that allow for isolation of the intervention's active component and are designed to reduce potential bias will support the evidence base.

5.2 Objective

This systematic review aimed to assess the published evidence regarding the effectiveness of eHealth interventions designed to improve the management of chronic diseases by providing information or advice that has been tailored to the recipients i.e. health care practitioners or patients.

The research question was: Does the cumulative published research evidence support the hypothesis that a system that incorporates messages specifically tailored to an individual (health care practitioner or patient) results in improve clinical processes or outcomes in the management of long term conditions?

5.3 Method

5.3.1. Types of studies

Randomised controlled trials, controlled clinical trials, controlled before and after studies and interrupted time series analyses were considered for inclusion in the review. Studies published in any language were considered.

5.3.2. Types of recipients

Studies that involved patients with a specified long term condition receiving health care (any setting), and/or health care practitioners responsible for the care of those with long term conditions (any setting), were considered.

5.3.3. Types of interventions

We considered interventions that used eHealth technologies to deliver tailored information to patients or HCPs within the care setting. The search strategy therefore included a combination of terms relating to eHealth, health records and communication strategies (including tailoring of information).

5.3.4. Types of outcomes

Any outcome was considered where a comparison was drawn between the intervention and no intervention and/or existing practice with regards to objectively measured professional performance, clinical outcome, or patient behaviour. The study's stated primary outcome was our main outcome of interest, with consideration also given to any stated secondary outcomes or *post hoc* analyses. Patient and professional satisfaction was also recorded, but studies were not included if this was the sole outcome.

5.3.5. Search strategy

A search strategy was devised to include keywords and text words relating to the following terms: chronic disease; methodology; eHealth; health records; communication; and user groups (see appendix - section 10). Text words were appropriately truncated to maximise returns. Terms were combined using Boolean logic. There was no keyword identified for tailored messaging and so we adopted a broad search strategy. As well as including variations of tailored messaging as text words, we included an exploded search of other communication-related keywords in an effort to capture studies that utilised tailored messages but did not refer to it as such (see appendix - section 10). The search was run against both Ovid Medline (1946-present) and Embase (1974-present), with no restrictions placed on language.

5.3.6. Eligibility criteria for inclusion

Studies that were RCTs or CCTs were deemed eligible if the other criteria mentioned above were met. Additional methodologies (controlled before-after studies and interrupted time series analyses) were considered if they met quality criteria specified by the Cochrane Effective Practice and Organisation of Care Group (EPOC) data collection checklist [96]. In accordance with the EPOC criteria the quality criteria for inclusion of both types of studies were as follows:

- Controlled before-after studies were only eligible if the control site was deemed suitable; there was evidence of contemporaneous data collection; and there were ≥2 intervention and ≥2 control sites.
- Interrupted time series analyses were included if there was a clearly recorded point in time when the intervention began and where there were ≥3 data points recorded both before and after the intervention commenced. Given the potential heterogeneity of the studies relevant to the review, study inclusion was not based on a minimum cut-off for methodological quality.

5.3.7. Data collection and analysis

Titles and abstracts were initially reviewed by a single reviewer (NTC) and discarded if deemed not to be relevant to the research question. A shortlist was then compiled (for which full text articles were sought) and independently reviewed by 2 reviewers - NTC and CW*. Any discrepancies were resolved by consensus. An online data abstraction form (modified from the EPOC data collection checklist [96]) was used for data collection [97]. An overall quality rating was assigned to RCTs based on the following criteria: allocation concealment; blinded or objective assessment of primary outcome(s); completeness of follow up; reliable primary outcome; and protection against bias. In accordance with previously published EPOC systematic reviews [98,99], studies were rated as being of high quality if the first 3 criteria were met with no additional concerns. Studies were of moderate quality if ≤2 criteria were "not done" or "not clear" and of low quality if this applied to >2 criteria. Results were presented in accordance with the standards set out by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [100]. The PRISMA checklist is shown in the appendix (see section 9).

5.3.8. Assessing tailoring

Kreuter et al [66] judged that an intervention incorporated tailored messaging if the intervention included both:

1. An assessment of individual patient characteristics; and
2. Communication that was specifically targeted at that individual.

Owing to the limited number of published studies that the search strategy returned, we accepted interventions that included either of these criteria, as agreed by the two reviewers.

---

* NTC = Dr Nicholas Conway, consultant paediatrician (author). CW = Dr Clare Webster, consultant paediatrician.

5.4 Results

5.4.1. Search results

The search strategy was run twice - September 2013 and again in May 2014. The final yield from both searches was 1074 returns, of which 89 were duplicates. Of the remaining 985 studies, 818 were initially rejected based on title alone, with a further 112 discarded after review of the abstract (see Figure 1). Full text papers were sought for the provisional shortlist of 55 studies and were available for 45 of these. The abstracts of the remaining 10 studies were assessed, and included if there was sufficient information to meet the inclusion criteria. Fifteen papers were rejected owing to the absence of any tailoring component in the intervention. The remaining 40 papers were then reviewed by the 2 reviewers. A further 18 papers were then rejected as they failed to meet (or had insufficient detail to satisfy) the eligibility criteria, leaving 22 papers to be considered in the review.

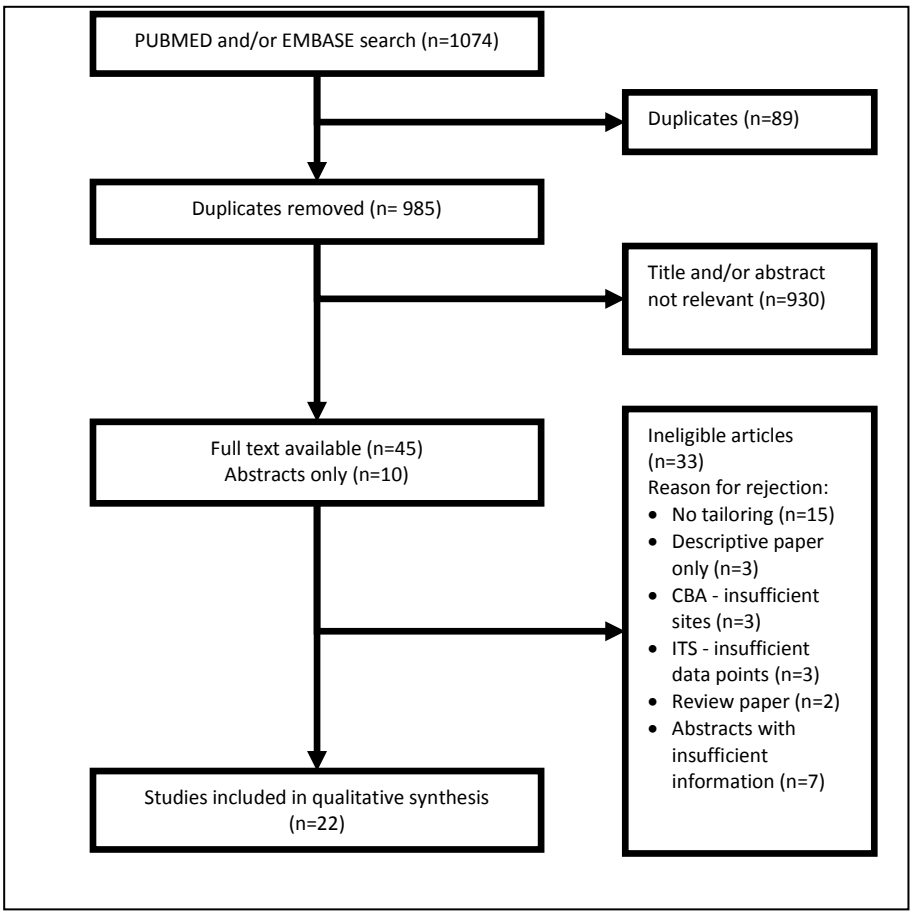

Figure 1. PRISMA diagram of literature search

These 22 studies are shown in Table 1 (sorted by first author). All of the studies were published since 2002 and most were conducted in North America [101–116]. The majority were RCTs [101,103,105–109,111,112,114–120]. The clinical problem addressed by the various interventions varied, but the most common applications were diabetes [101,102,110,111,114,119], cardiovascular disease [107,110,114,118], and the prescribing of medication [105,106,112,121].

Table 1. Studies eligible for inclusion in the review.
**Denotes abstract only. RCT = Randomised controlled trial, ITS = interrupted time series analysis, CCT = controlled clinical trial*

First Author [ref]	Year	Design	Country	Clinical speciality	Clinical problem
Avery [121]	2012	RCT	UK	General/family practice	Medication prescribing
Boukhors [101]	2003	RCT	Canada	General/family practice	Diabetes
Cafazzo [102]	2012	ITS	Canada	Paediatrics	Diabetes
Carroll [103]	2012	RCT	USA	Psychiatry	Maternal depression
Cruz-Correia [117]	2007	RCT	Portugal	Other	Asthma
Epstein [104]	2011	RCT	USA	Paediatrics	ADHD
Field [105]	2009	RCT	Canada	General/family practice	Medication prescribing
Fossum [122]	2011	CCT	Norway	Other	Pressure ulcers
Gurwitz [106]	2008	RCT	USA/Canada	Other	Medication prescribing
Jones [123]	2011	ITS	UK	General medicine	Acute medicine
Kinn [107]	2002	RCT	USA	Other	Hypertension
Mcdonald [108]	2005	RCT	USA	Paediatrics	preventative service
Nagykaldi [109]	2012	RCT	USA	General/family practice	preventative care
Persell [110]	2010	ITS	USA	General medicine	CVD, diabetes and cancer
Persell [118]	2013	RCT	USA	General/family practice	CVD
Pinnock [120]	2013	RCT	UK	General medicine	COPD
Quinn [111]	2008	RCT	USA	Other	Diabetes
Raebel [112]	2007	RCT	USA	Obstetrics and Gynaecology	Medication prescribing
Ross [119]	2006	RCT	USA	General medicine	Diabetes
Sequist [114]	2005	RCT	USA	General medicine	CVD and diabetes
Tierney [115]	2005	RCT	USA	General medicine	Asthma
Vollmer [116]	2011	RCT	USA	NOT CLEAR	Asthma

5.4.2. Setting and characteristics of participating health care providers

Most studies were undertaken in either an outpatient or community-based setting and involved physicians – see Table 2. Other professional groups included nurses and pharmacists. The studies were undertaken in both academic and non-academic settings. There was a general lack of information describing the experience or qualifications of the various professional user groups.

5.4.1. Characteristics of the intervention

Thirteen of the studies directed the intervention at HCPs [103–107,110,112,114,115,120–123]. The remainder directed the intervention at patients [102,108,109,116–119], or at both HCPs and patients [111]. Each of the interventions is described in detail in the appendix (see section 11).

5.4.2. Influence of tailoring component on intervention design

All of the studies included in the review incorporated some degree of individual patient assessment. This assessment was made via automated data queries of routinely-collected clinical datasets or via additional data entry completed by patient and/or HCP – see Table 3.

Table 2. Clinical setting and characteristics of providers

First Author	Location of care	Academic status	Profession involved	Level of training	Mean age (yr)	Years in practice
Avery [121]	Community based care	-	Physicians, Pharmacists	-	-	-
Boukhors [101]	Outpatient care	-	Physicians	-	-	-
Cafazzo [102]	Outpatient care	-	Physicians	-	-	-
Carroll [103]	Outpatient care	University /teaching setting	Physicians	-	-	-
Cruz-Correia [117]	Outpatient care	-	Physicians	-	-	-
Epstein [104]	Community based care	-	Physicians	Accredited and/or licensed	47	-
Field [105]	Community based care	Non-teaching setting	Physicians	-	-	-
Fossum [122]	nursing home	Non-teaching setting	Nurses	Accredited and/or licensed	-	-
Gurwitz [106]	Inpatient care	University /teaching setting	Physicians, Nurses	-	-	-
Jones [123]	Inpatient care	University /teaching setting	Physicians, Nurses	-	-	-
Kinn [107]	Outpatient care	-	Physicians	Accredited and/or licensed	-	-
Mcdonald [108]	Outpatient care	University /teaching setting	Physicians	Accredited and/or licensed	-	post grad level 1-3
Nagykaldi [109]	Community based care	Non-teaching setting	Physicians, Nurses	-	-	-
Persell [110]	Community based care	University /teaching setting	Physicians	-	-	-
Persell [118]	Inpatient care	University /teaching setting	Physicians	In training	-	-
Pinnock [120]	Outpatient care	-	Physicians	-	-	-
Quinn [111]	Outpatient care	-	Physicians	-	-	-
Raebel [112]	Pharmacy	Non-teaching setting	Pharmacists	-	-	-
Ross [119]	Outpatient care	-	-	-	-	-
Sequist [114]	Outpatient care	University /teaching setting	Physicians	Mixed	40	-
Tierney [115]	Outpatient care	Non-teaching setting	Physicians, Pharmacists	Mixed	-	-
Vollmer [116]	Community based care	-	-	-	-	-

Table 3. Role of tailoring in the interventions.
"Tailored assessment" relates to the assessment of individual patient characteristics and how that data was collated. "Tailored communication" describes whether or not communication was specifically targeted to an individual. HCP= Healthcare professional

First Author [ref]	Tailored assessment	Tailored communication	Recipient of communication	Tailored communication detail
Avery [121]	Automated data query	None	HCP	Message contents dependent on data
Boukhors [101]	Data from patient	None	Patient	Message contents dependent on data
Cafazzo [102]	Data from patient	Tailored to user	Patient	Message contents dependent on data and tailored to user requirements (trend wizard)
Carroll [103]	Data from parent and HCP	None	HCP	Message contents dependent on data
Cruz-Correia [117]	Data from patient and HCP	None	Patient	Message contents dependent on data
Epstein [104]	Data from patient and HCP	None	HCP	Message contents dependent on data
Field [105]	Automated data query	None	HCP	Message contents dependent on data
Fossum [122]	Automated data query	None	HCP	Message contents dependent on data
Gurwitz [106]	Automated data query	None	HCP	Message contents dependent on data
Jones [123]	Automated data query	None	HCP	Message contents dependent on data
Kinn [107]	Automated data query	None	HCP	Message contents dependent on data
Mcdonald [108]	Data from patient	Tailored to user	Patient	Message contents dependent on individual data taking into account individual circumstances
Nagykaldi [109]	Data from patient and HCP	Tailored to user	Patient	Message contents dependent on individual data taking into account individual circumstances
Persell [110]	Automated data query	None	HCP	Message contents dependent on data
Persell [118]	Automated data query	Tailored to user	Patient	Message contents dependent on individual data taking into account individual circumstances
Pinnock [120]	Data from patient	None	HCP	Message contents dependent on data
Quinn [111]	Data from patient and HCP	None	Patient and HCP	Message contents dependent on data
Raebel [112]	Automated data query	None	HCP	Message contents dependent on data
Ross [119]	Automated data query	Tailored to user	Patient	Message contents dependent on individual data taking into account individual circumstances
Sequist [114]	Automated data query	None	HCP	Message contents dependent on data
Tierney [115]	Automated data query	None	HCP	Message contents dependent on data
Vollmer [116]	Automated data query	Tailored to user	Patient	Message contents dependent on individual data taking into account individual circumstances

The use of individually tailored communication was only evident in a minority of studies [102,108,109,116,118,119]. All of these studies delivered messages to individual patients based on data specific to that patient e.g. risk of illness/injury and how this might be modified for the individual [108,109,118]; individualised educational content [116,119]; or individualised clinical results [102]. For the remainder of studies, the content of communication was dictated by automated algorithms based on the individual assessment rather than the specific circumstances of the end-user. For example, it was common that automated CDSS aimed at HCPs would provide prompts based on an assessment of a patient's data, but the prompt provided by the system was generic to the system and not tailored to the HCPs job-description or clinical context.

Of the 6 studies that fulfilled both criteria for having used tailored communication (as dictated by Kreuter et al [66]), the primary outcomes (where stated) were patient self-care (improved) [102], serum lipids (no difference) [118] and medication adherence (better than control but reduced overall) [116]. The remainder of studies did not state the primary outcome, but reported on service uptake (improved in intervention group) [119], patient knowledge (improved in intervention group, but multiple comparisons made) [108], patient centredness (improved in intervention group) [109].

5.4.3. Comparison – tailored intervention versus non-tailored intervention

Two studies compared an intervention which utilised tailoring with an intervention that included untargeted activity [108,119] (see appendix – section 11). Neither study specified the primary outcome of interest in the methods. Both studies provided tailored educational material to patients and compared outcomes with patients who had received non-tailored material. For example in one study [108], parents completed a questionnaire designed to assess previous injuries sustained by their child as well as parental perceptions of their child's current risk of injury. The educational material then incorporated the events previously described as well as addressing any misconceptions in injury risk identified from parental responses. Tailoring resulted in an increase in patient service uptake in one study [119], with multiple comparisons being made in the other, introducing the possibility of a type 1 error [108].

5.4.4. Comparison – intervention versus no intervention

The primary outcome was not overtly stated in 8 of the studies. Of the 22 studies included in the review, the main outcome of interest related to clinical processes and performance in 14, with the remainder concerned with clinical outcomes– see Table 4.

Table 4. Reported outcomes and main results from studies included in the review.
*A more detailed version of this table detailing all comparisons made is available in the appendix (see section 12). Study quality score compiled for RCTs only – see appendix (section 11) for study characteristics used for grading. AE = adverse event; HbA1c = glycated haemoglobin; LoS = Length of stay; EWS = Early Warning Score; LDL = low density lipoprotein; QPI = Quality performance indicators; COPD = Chronic obstructive pulmonary disease; QoL = Quality of life, BP = blood pressure; IQR = interquartile range; SD = standard deviation; ITS = interrupted times series analysis; *Denotes primary outcome(s) where stated.*

Study	Study quality	Outcome(s)	Main results of the outcome(s)
Avery [121]	Moderate	Number of potential drug AE*	Intervention group significantly less likely to have been prescribed contraindicated medication (all 3 measures)
Boukhors [101]	Low	Number of hypoglycaemic events*	No significant difference in incidence of hypoglycaemia
Cafazzo [102]	ITS	Number of blood glucose tests Glycaemic control (HbA1c)*	Number of blood glucose tests increased with intervention. No difference in secondary outcomes - incidence of hyperglycaemia & glycaemic control
Carroll [103]	Low	Number of mothers identified as having depressive symptoms, Number of mothers referred for psychiatric assessment	Intervention groups more likely to have depression detected and more likely to be referred to specialist
Cruz-Correia [117]	Low	Patient satisfaction, Patient adherence to recommended monitoring	Patients were satisfied with system Patients adherence was not altered with electronic system - if anything adherence improved with paper system
Epstein [104]	Low	Proportion using recommended diagnostic tools at follow up*	Significant increase in use of diagnostic questionnaires
Field [105]	Moderate	Alert rate*, Type of alert* - incorrect dose, incorrect frequency, drug should be avoided, incomplete clinical information (creatinine)	Overall, no difference in rate of alerts between groups.
Fossum [122]	Low	Proportion with malnourishment, Proportion at risk of malnourishment and pressure ulcer	no change in risk of PU no change in prevalence of PU No change in prevalence of malnourishment
Gurwitz [106]	Low	Number of drug-related AE*	No significant difference in AE's between intervention and control
Jones [123]	ITS	Length of stay (LoS)*, Accuracy of early warning score (EWS), Adherence to protocol, Clinical response to EWS alert, Rate of cardiac arrests, Number of critical care bed days, Mortality rate	Significant decrease in LoS during intervention period
Kinn [107]	Low	Likelihood of being diagnosed with hypertension, Likelihood of receiving ≥1 antihypertensive, Number of antihypertensives per patient, Use of combination therapy, BP	Significantly more patients receiving appropriate diagnosis in intervention group; Intervention group significantly more likely to be on anti-hypertensive. Intervention group had significantly less antihypertensive agents prescribed.

Table 4 (cont.). Reported outcomes and main results from studies included in the review.
QoL = quality of life; ITS = interrupted time series analysis; QPI = quality performance indicator; COPD = chronic obstructive pulmonary disease; LDL = low density lipoprotein; HCP = healthcare professional

Study	Study quality	Outcome(s)	Main results of the outcome(s)
Mcdonald [108]	Low	Parent safety knowledge, prevention beliefs, and safety behaviours	Improved safety knowledge at follow up.
Nagykaldi [109]	Low	Provision of preventative services, Number of log ins to portal, Patient centredness	Minimal use of portal Patient centredness score improved in intervention group
Persell [110]	Low	LDL cholesterol*, Change in BP, Smoking cessation, Prescription of a statin, Number of office visits	No significant difference in rate of lowered LDL No significant difference in attendance at clinic Significantly more statins prescribed in intervention group
Persell [118]	ITS	16 quality performance indicators (QPIs) - prescribing for chronic disease and screening procedures*	Performance measures improved
Pinnock [120]	High	Time to admission to hospital with exacerbation of COPD*, Time to admission, number and duration of admissions, deaths, QoL, number of patient contacts	No significant difference in admission rate or quality of life in those receiving intervention.
Quinn [111]	Low	Physician satisfaction, Diabetes self-care, Glycaemic control	Physicians satisfied Glycaemic control improved Patients self-care improved
Raebel [112]	Low	Proportion of pregnant women dispensed a contraindicated medication*	Intervention group were significantly less likely to be prescribed a contraindicated medication
Ross [119]	Low	System usage	Intervention group had greater usage of system
Sequist [114]	Low	Receipt of recommended care*, HCP perceptions surrounding guideline adherence	Patients in intervention group significantly more likely than control patients to receive recommended diabetes care and CAD care
Tierney [115]	Low	Percentage adherence to management recommendations*	No significant differences in adherence to guideline between groups
Vollmer [116]	Low	Patient adherence to medication*, Patient QoL, Reliever medication use, Asthma control, Healthcare utilisation	Small but significant increase in adherence

Studies where the stated primary outcome related to clinical processes included: HCP adherence to existing guidelines [104,110,114,115]; avoidance of adverse drug events [105,106,112,121]; patient adherence to medication [116]; and patients' frequency of clinical testing [102]. Of the 6 studies which failed to stipulate the primary outcome, one measured HCP adherence to an existing guideline aimed at improving diagnosis rates [111].

Twelve of the 16 studies concerned with clinical processes reported a favourable outcome. For those studies aiming to assess HCP adherence to guidelines, most reported an improvement [103,104,107,110,114]; however one of these studies also noted a pre-intervention improvement in the ITS analysis, introducing the possibility that secular change was responsible for the observed improvement [110]. The rate of potential adverse drug events was significantly reduced in half of the relevant studies [112,121]. When compared with controls, patient medication adherence was said to be higher, however the actual difference was small and both groups' overall adherence fell during the study period [116]. The other measures of patient-driven clinical processes also improved (blood sugar testing [102] and service uptake [119]).

Two of the 6 studies concerned with clinical outcomes reported positive findings. Four studies measured clinical parameters as the primary outcome which included glycaemic control (unchanged) [101]; length of hospital stay (improved) [123]; change in serum lipids (unchanged) [118]; and time to admission to hospital (unchanged) [120]. Clinical parameters were also measured in two further studies and included glycaemic control (improved) [111]; and presence of malnourishment and/or pressure ulcers (unchanged) [122].

5.4.5. Comparing patient-orientated interventions with HCP-orientated interventions

Eight of the studies targeted patients with the intervention [101,102,108,109,116–119], one study involved an intervention aimed at both HCPs and patients [111] and the remainder focussed solely on HCPs – see Table 2.

For the 8 studies where the intervention targeted patients, five (63%) reported that the intervention produced a positive effect. This included increased patient satisfaction [117]; monitoring of blood glucose [102]; adherence to medication [116]; system usage [119]; and knowledge [108] – see Table 4.

For the 14 studies where the intervention was targeted at HCPs, a similar proportion reported positive findings (8/14, 57%). These included improved adherence to guidelines [104,110,114]; detection of morbidity [103,107] decreased adverse drug events [112,121]; and length of hospital stay [123] – see Table 4.

5.4.6. Risk of bias in included studies

There was a high risk of bias for all studies included in the review, with the exception of one high quality study [120] – see Table 4. Three studies were assessed as having concealed allocation adequately [112,115,120]. The remaining studies either failed to do so or did not provide sufficient information. Four studies reported that the assessors were sufficiently blinded to allocation group [105,106,115,120]. Of the remainder, 10 studies derived outcome data from automated data queries, making assessment bias unlikely [103,104,107,112,114–116,118,119,122]. Seven studies were assessed as having adequate follow up of professionals and/or patients [105,107,108,116,120–122].

Three of the studies were interrupted time series analyses [102,110,123]. All three used a reliable outcome measure. It was unclear how either of these studies protected against detection bias (in terms of either data collection or blinded assessment) or secular changes in the population being studied. One study reported on the completeness of the dataset which was assessed as being satisfactory [110].

5.5 Discussion

In order to assess the effectiveness of tailored messages within eHealth interventions, a comparison needs to be made between outcomes of tailored interventions and non-tailored interventions. However, based on the results of this review, the research question remains incompletely answered for a number of reasons.

First, any direct comparison between tailored and non-tailored interventions was limited to a minority of the included studies. Nearly all studies compared the intervention to a no change/standard practice control group as opposed to a non-tailored intervention. This makes it impossible to ascertain whether any improvements were secondary to the tailoring component of the intervention *per se*.

Secondly, the outcome of either of these comparisons presented a mixed picture. A number of studies concluded there was improvement in clinical processes e.g. adherence to guidelines; avoidance of prescription errors; and increased service uptake when compared to no intervention. However, most of these studies presented methodological weaknesses meaning that these conclusions should be met with caution.

Thirdly, only a minority of studies included in the review included an intervention that fulfilled both criteria for what is considered to be tailoring of information. All of the other studies included in the review incorporated only one of the two components that define true tailoring. The adoption of studies meeting this less strict definition increased the number of studies eligible for inclusion but made it difficult to address the research question specifically.

Finally, the quality of most of the included studies was assessed as low. However, the introduction of methodological quality as an eligibility criterion for inclusion would have excluded almost all of the studies identified. Meta-analysis was not possible owing to the heterogeneous nature of the interventions and outcomes of the studies reviewed.

5.6 Significance

Despite these limitations, some limited conclusions can be drawn. Irrespective of the degree to which the intervention incorporated tailoring, or the degree to which tailoring was responsible for the observed outcomes, it is notable that 14 of the 22 studies included reported positive findings. These improvements were largely limited to clinical processes as opposed to clinical outcomes and were observed in interventions aimed at both patients and HCPs. This study restricted analysis to quantifiable outcomes and so it not know *why* there was an observed improvement in outcome. Whilst it could be inferred that this is a direct result of HCP behaviour change, this remains conjecture. It is also notable that none of the included studies reported any harm. Again, this could lead to the suggestion that personalised eHealth interventions (aimed at either patients or HCPs) can *safely* effect behaviour change, however it is acknowledged that the studies did not specifically aim to measure harm, therefore absence of evidence cannot be regarded as equivalent to evidence of absence in this case.

The lack of studies that combine eHealth technologies with interventions that utilise tailoring of information is surprising, given the evidence that tailoring is effective when used in conjunction with traditional media and the ease with which tailoring algorithms can be incorporated into new technologies [66]. This may reflect the fact that both are relatively recent innovations. Given the existing evidence that tailored messages via traditional media can effect behaviour change it would seem a logical extension to incorporate them into eHealth interventions. Clearly, there is a need for additional work in this area. Future research should

delineate the role of tailoring in eHealth by comparing it with non-tailored interventions as opposed to no intervention or standard care.

5.7 Conclusion

Tailoring of information to recipients has previously been shown to be an effective way of changing behaviour when used with traditional media. This review suggests that eHealth tailored information delivery may improve clinical care, but there is currently a lack of evidence to conclude that the use of tailoring within an eHealth context confers any benefits over non-tailored eHealth interventions. This lack of evidence reflects the low number of good quality studies in this area. It is only by designing studies where the role of tailoring is isolated as the active component in the intervention, that the effectiveness of tailoring can be adequately assessed.

6. Clinical Decision Support systems

6.1 Abstract

6.1.1. Introduction

Clinician Decision Support Systems (CDSS) provide health care professionals (HCPs) with automated advice about best practice patient care. Prompts are provided via IT software and are tailored to the individual patient based on the real time data available. CDSS have been shown to effectively influence HCP behaviour, in terms of adherence to guidelines and avoidance of drug errors. The Evidence Based Medicine electronic Decision Support (EBMeDS) system is a CDSS that was developed in conjunction with health care providers, in line with the best evidence base (including SIGN guidelines) and was successfully implemented within SCI-Diabetes, the Scottish national electronic health record for diabetes.

6.1.2. Methods

EBMeDS has been live to users within NHS Tayside and NHS Lothian since December 2013 onward (serving a combined diabetes population of approximately 30,000). An evaluation was undertaken over two quality improvement cycles adopting a mixed methods approach to: assess users' and patients' reaction to the EBMeDS system; to demonstrate that there are no unintended adverse effects attributable to the system; and to quantify any change in clinical processes and/or outcomes. The evaluation was based on NHS Education for Scotland's *Knowledge into Action* framework.

6.1.3. Results

The use of the EBMeDS system had no adverse effects on patient experience, clinic consultation or working practices. The system was associated with improved efficiency in working practices, but at the same time has resulted in a dramatic improvement in adherence to national guidelines e.g. patients were 3-4 times more likely to receive appropriate screening for diabetes-related complications. There were modest, but significant, improvements in blood glucose control.

6.1.4. Discussion

The CDSS in its current form prompts HCPs to consider screening for complications as well as optimisation of current management. If our findings were replicated across Scotland, thousands more individuals would receive screening for complications in accordance with national guidelines. These evidence-based, early interventions can significantly impact on costly and devastating complications such as foot ulcers, amputations, cardiovascular disease, renal failure and death.

Future work will aim to: a) develop and implement additional rule-based algorithms based on user feedback and emerging literature/guidelines; b) tailor messages to user group (HCPs and patients), c) improve the integration of the system within primary care systems and d) roll out CDSS to all users of SCI-Diabetes (patients and HCPs) across the whole of NHS Scotland.

Not only does the study add to the evidence-base for CDSS, it serves as an exemplar for decision support across healthcare systems in Scotland, including primary care. Therefore, the potential benefits of this project extend beyond the Scottish diabetes population, as NHS Scotland considers how best to realise the full potential of CDSS described in the national eHealth strategy.

6.2 Introduction

As previously discussed, Clinical Decision Support Systems (CDSS) have been shown to be one of the most consistently successful approaches to encourage clinicians to adopt evidence-based practice [59]. The Evidence Based Medicine electronic Decision Support (EBMeDS) system is an example of a CDSS and is currently integrated within the Finnish national electronic healthcare record (EHR). It provides decision support to healthcare professionals and members of the public on a wide variety of health-related issues. EBMeDS has been developed by the Finnish Medical Society, Duodecim [124]. This project arose via a collaboration between Duodecim and NHS Education for Scotland (NES), whereby NES are actively exploring CDSS options for NHS Scotland, in accordance with the refreshed national eHealth strategy [57]. This strategy envisages that by 2020, healthcare professionals will have access to *"…increasing amounts of clinical guidance and decision support that is relevant to the specific patient context, including highlighting any substantial variation from expectations, and generating appropriate prompts and alerts."* NES and Duodecim entered into a service level agreement in March 2013, whereby EBMeDS would be implemented and evaluated within SCI-Diabetes (Scotland's national informatics platform and EHR for people with diabetes), by way of a service improvement project assessing the feasiblity and utility of such a system within the Scottish context. A project team was formed, comprising the author; a project manager; local clinicians; SCI-Diabetes developers; and representatives from Duodecim. The project team met regularly via teleconference on a 1-2 monthly basis to discuss progress, review timelines and agree content of the CDSS. The author was responsible for much of the development work and testing of the system as well as conducting all activities related to evaluation.

6.2.1. EBMeDS architecture

EBMeDS relies on the ability of an EHR to summarise clinical data in a structured way. When a patient record is opened, the EHR sends an individual's clinical data to the EBMeDS server (hosted by Duodecim). These data are initially converted into a standardised coded structure before being run through the EBMeDS "engine". This "engine" consists of a series of algorithms based on boolean logic, each written to address a specific clinical problem. There are approximately 1000 such scripts, covering a wide variety of clinical specialities. If the algorithm (or "script") returns a positive result, then this clinical problem is identified as being an active issue. A decision support message is then generated and transmitted back to the EHR, for displaying to the end user via the EHR user interface (UI). If the script returns a negative result, then no such message is generated. The system is summarised in Figure 2.

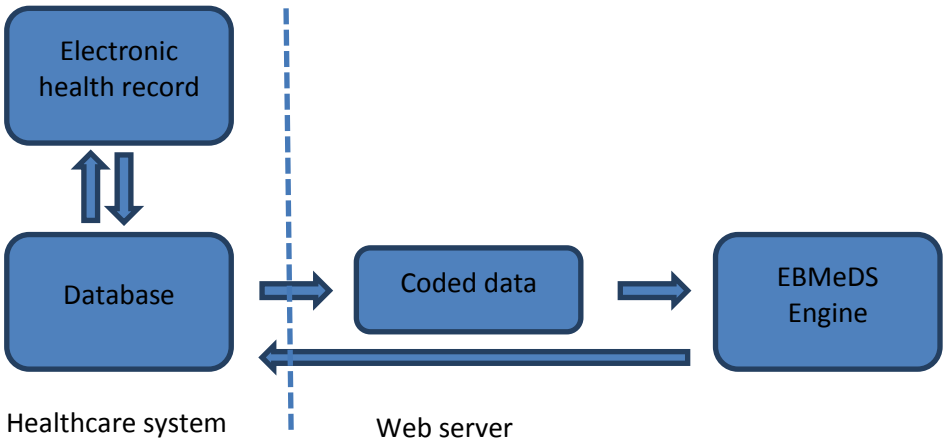

Figure 2. EBMeDS system architecture
EBMeDS = Evidence Based Medicine electronic Decision Support

EBMeDS is a "system-agnostic" service whereby it can be integrated into any EHR containing coded data. There is no "front-end" to the system, so the appearance and behaviour of the end message is dictated by the EHR system administrators and developers.

6.2.2. SCI-Diabetes architecture

The SCI-Diabetes informatics platform has evolved from what was initially a local diabetes registry linking data from a number of sources [125] into a more comprehensive electronic health record, serving the whole of Scotland [12]. The Scottish Care Information – Diabetes Collaboration (SCI-DC) system was initially composed of a collection of informatics products designed to retrieve individual patient data from a number of sources and link these data using the community health index unique identifier [126]. These products were consolidated in 2011 and renamed SCI-Diabetes [127]. SCI-Diabetes is built upon a healthcare domain model, with each domain being based on geography, service provider, or demographics. For example, NHS Tayside (one of 14 geographical health boards in Scotland) comprises one tertiary centre; three district general hospitals; 67 primary care practices; and a number of health and community care centres. The number of SCI-Diabetes healthcare domains within NHS Tayside reflects this diversity e.g. individual hospital clinic; primary care; paediatric population etc.

HCP users are granted access to the domains that are deemed relevant to their role, thereby allowing access to all patient records attributed to that specific domain. This compartmentalisation of the national register can then be exploited for the purposes of audit, data backup and the phased implementation of updates to the system.

6.2.3. NHS Education for Scotland

This project was sponsored by NHS Education for Scotland, who have proposed a new model to promote the integration of knowledge from research, practice and experience into everyday clinical practice - the NHSScotland Knowledge into Action framework [128]. The overall ambition of this strategy is to embed knowledge in care processes in real-time, making the EBMeDS system an ideal exemplar of this approach. The framework has been adopted as a way to structure the evaluation of this project and involves a mixed methods approach – see Figure 3.

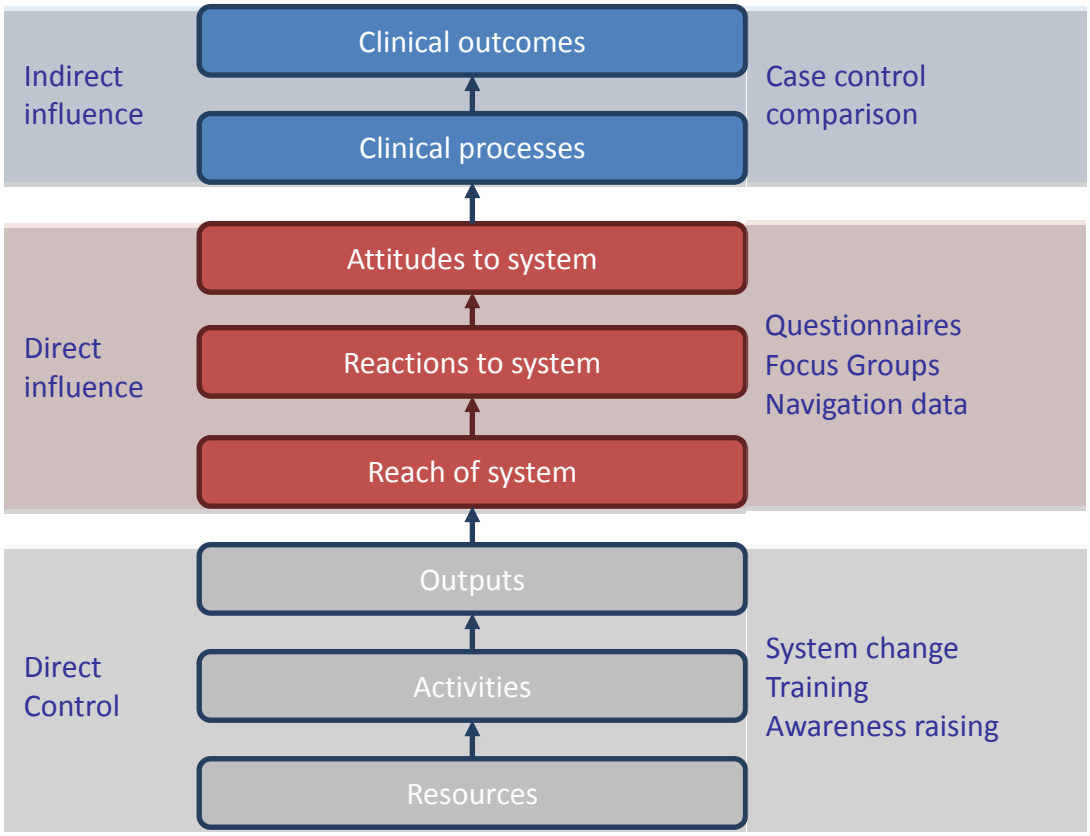

Figure 3. NES Knowledge into action framework.

6.3 Aims and objectives

The project aims to implement decision support scripts derived from the SIGN guideline and local handbook information for diabetes, within the SCI-Diabetes system in NHS Tayside and West Lothian. This will serve as a demonstrator to inform recommendations for the implementation of decision support systems at a national level.

The evaluation of this project aims to assess users' and patients' reaction to the EBMeDS system; to demonstrate that there are no unintended adverse effects attributable to the system; and to quantify any change in clinical processes and/or outcomes.

The objectives of the evaluation are:

1. To describe users' navigation of the SCI-Diabetes system and to quantify changes in usage patterns following an EBMeDS prompt.
2. To record Patient Reported Experience Measures (PREM's) for those attending the diabetes clinics during the demonstrator project and to compare PREM's for patients that were subject to an EBMeDS alert with those that weren't.
3. To quantify whether or not the use of EBMeDS is associated with changes in clinical process measures and clinical outcomes (blood glucose control, renal disease, and risk of cardiovascular disease).

6.4 Methods - implementation

6.4.1. Script selection

The EBMeDS system in Finland contains approximately 1000 scripts, each targeting a specific clinical problem within a variety of clinical specialities. Approximately 100 of these scripts relate directly to diabetes and were identified using associated metadata. Following review by the project group, a decision was made to select those scripts that aligned most closely to diabetes care in Scotland. This pragmatic choice was made in an effort to maximise the efficiency in which the scripts could be adapted to local use. The scripts were selected using a Delphi type approach, whereby a document describing each script was circulated to all clinicians within the project group and local diabetes team for comment. A consensus was reached and the chosen scripts were then amended to conform to national guidelines. This process was completed by the author over a number of weeks and involved a variety of steps including: changing of scientific notation; altering of value thresholds; amending text of decision support messages; and identifying the relevant evidence behind each decision support message. See appendix (section 13) for a summary and full details of each script.

6.4.2. User interface

Decisions on how EBMeDS message was to appear within the SCI-Diabetes UI were made in conjunction with project team members; SCI-Diabetes developers; and SCI-Diabetes users. Again, email correspondence sought opinion from all stakeholders, with various proposed "mock ups" circulated for comment. At the outset, it was acknowledged that any automated reminders need to be suitably placed so that users are aware of them, whilst avoiding user-fatigue and annoyance. The use of a "pop-up" dialogue box that appears on opening an individual patient record before automatically disappearing after a predetermined period, was felt to offer this correct balance. Following user feedback, there have been a couple of iterations of the behaviour and appearance of the UI over the course of the project. Further details on this feedback are available in sections 6.6 and 6.7. Figure 4 shows the UI displaying the "pop-up" dialogue box.

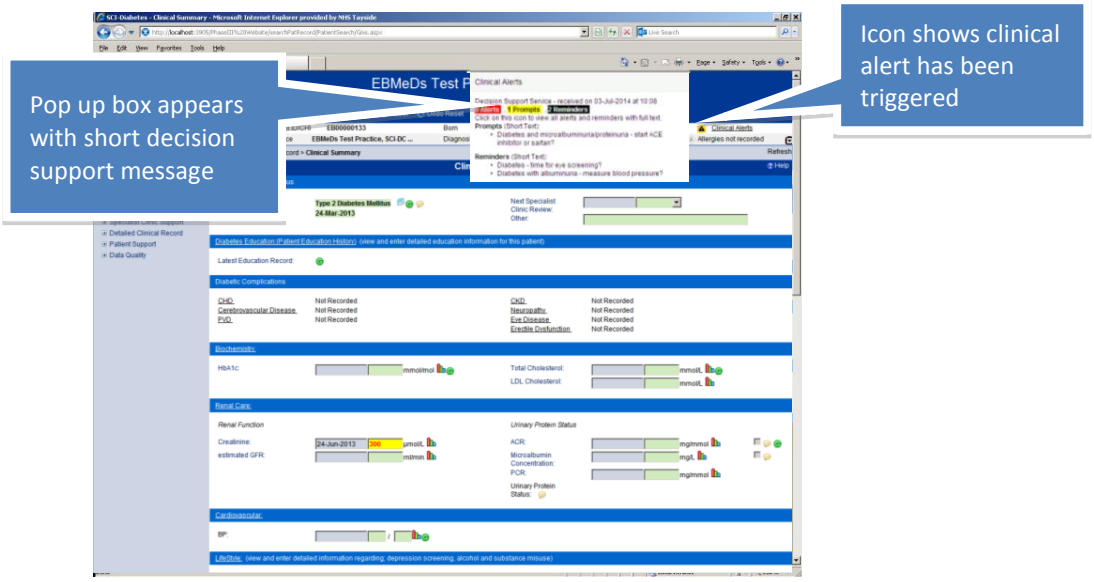

Figure 4. Screenshot of SCI-Diabetes user interface showing EBMeDS short message pop up dialogue box.

In addition to this initial short message, users have the option to seek further information behind the decision support message. This is achieved by navigating to a "long message" within SCI-Diabetes, that contains further details behind the clinical guidance, as well as a hyperlink to the relevant evidence (e.g. national guidelines) – see Figure 5.

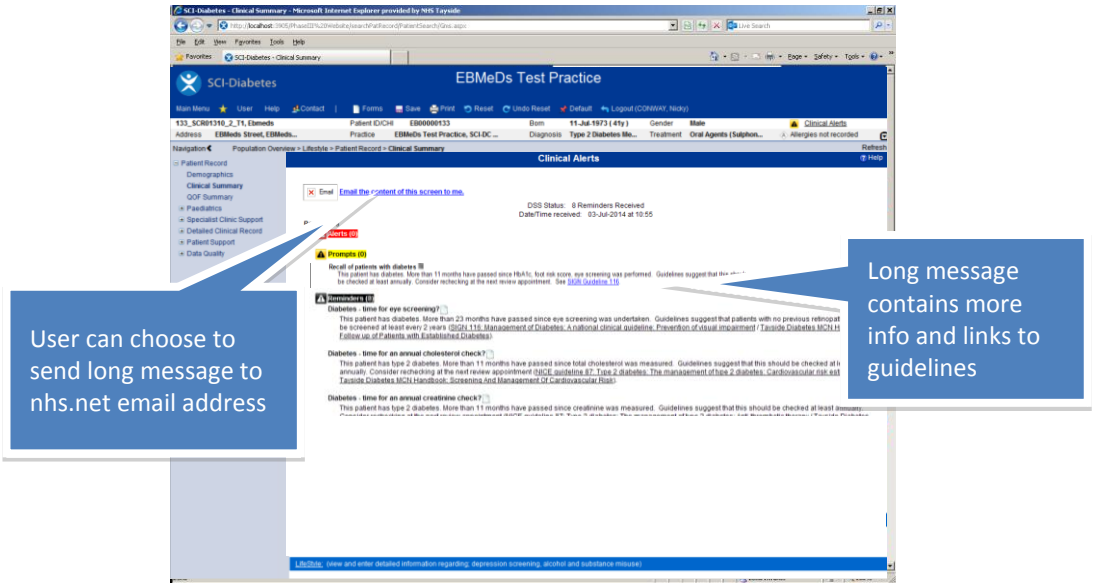

Figure 5. Screenshot of SCI-Diabetes user interface showing EBMeDS long message and links to relevant evidence

6.4.3. System testing

Once the scripts were amended to reflect national clinical practice, they were implemented within the EBMeDS server. A system of testing was devised to ensure that the scripts behaved as expected within SCI-Diabetes. This process involved the creation of multiple fictitious patients within a testing environment. The clinical data associated with each of these fictitious patients were designed to either trigger or suppress each of the scripts. Due to the large number of variables and threshold values contained within each script, this dataset contained a large number of dummy patients (approximately 1500). Each of these dummy patient records was manually opened, in turn, with the tester noting how the system behaved. Scripts that were not suppressed or triggered as expected were then reviewed and amended as appropriate.

The work described above represented a significant proportion of the overall project with the author dedicating approximately 9 months to the process prior to the implementation of the live system (see Figure 6).

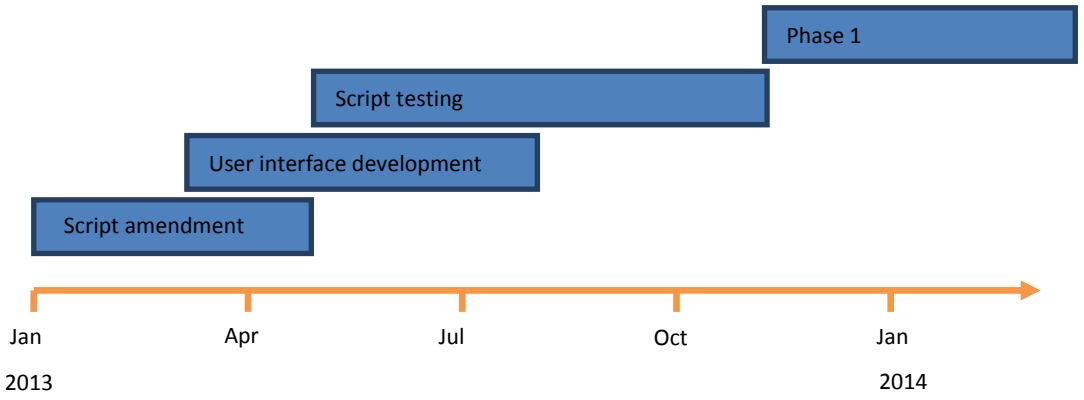

Figure 6. Timeline illustrating the process by which the EBMeDS scripts were developed to the local context and tested prior to implementation. Further script development and testing was required in response to user feedback – see figure 7.

6.4.4. Implementation

The SCI-Diabetes healthcare domain architecture allows EBMeDS to be switched on or off to specific user groups (see section 6.2.1). Prior to being switched on in any given domain, a series of awareness-raising activities took place, including: questionnaire distribution; focus groups; email updates; and departmental presentations (see sections 6.6 to 6.7).

6.4.5. Participants

Implementation adopted a quality improvement approach whereby the system was introduced to a limited number of users; evaluated for acceptability; adapted in light of user feedback; and then introduced more widely. Two such "improvement cycles" ran over the course of an 18 month period: cycle 1 - implementation and evaluation in Ninewells Hospital (NWH) and one primary care general practice in Dundee (16 weeks); and cycle 2 - implementation and evaluation throughout the Tayside area (including Perth and Kinross and Angus) and St John's Hospital (SJH), Livingston (16 weeks) – see *Figure 7*

.

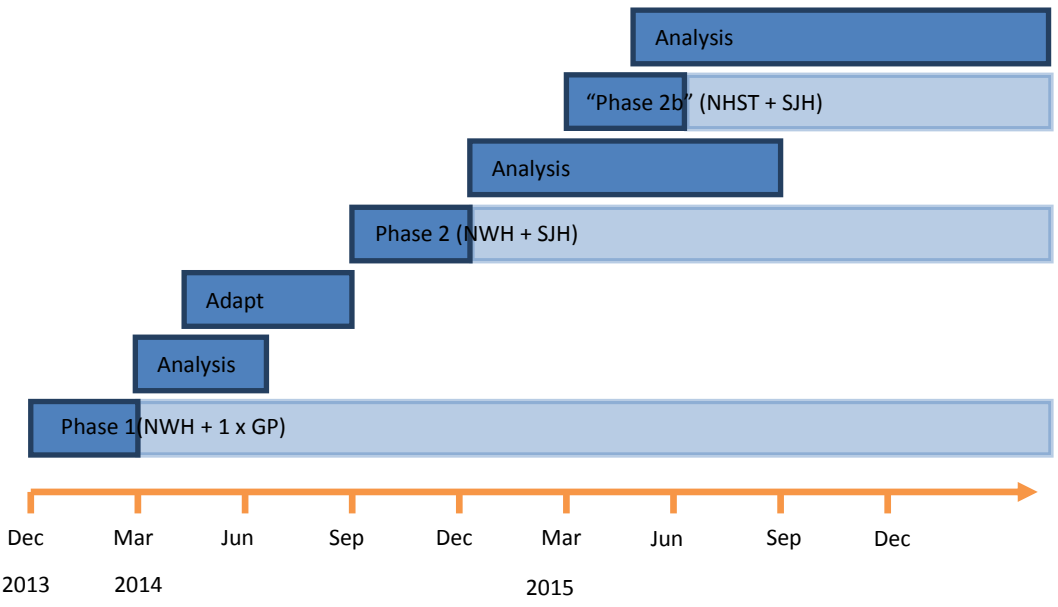

Figure 7. Project timeline.
NWH= Ninewells Hospital; GP= General Practice; SJH=St John's Hospital; NHST=NHS Tayside (primary and secondary care)

Cycle 1

Participants included HCP users of the SCI-Diabetes system in NHS Tayside secondary care. The total number of users registered within NHS Tayside secondary care is 157. This includes all health care professionals, of which approximately 25 use the system regularly within the NWH diabetes outpatient clinic. In NWH, there are approximately 170 patients appointed to attend a diabetes clinic per week (4 doctor-led clnics with 18 patients/doctor and 1 nurse-led clinic with 10/nurse).

Cycle 2

Participants included all HCP users of the SCI-Diabetes system throughout NHS Tayside primary and secondary care as well as SJH, Livingston. The number of registered users in each area is known, but it is less clear which of these are regular users. It was estimated that cycle 2 would involve approximately 120 users, based on the following:

- Number of NHS Tayside primary care practices = 67 (assuming 1 regular user per practice of the 98 registered doctors in primary care)
- Number of NHS Tayside secondary care registered users = 157 (of which it was estimated there would be 40 regular users across all sites)
- Number of NHS Lothian secondary care registered users = 12 (assuming all are regular users)

Approximately 500 patients were appointed to the diabetes clinic in SJH, Livingston for both of the 3-month improvement cycles that they participated in. Quantifying patient numbers for the whole of NHS Tayside primary and secondary care requires extrapolation from aggregate figures. Based on 2013 data, there were approximately 20,800 patients with diabetes living in NHS Tayside [16]. Assuming all of these patients visit an HCP at least once during a 12 month period, we can expect approximately half will be seen during the 3 months of cycle two and 3 months of cycle 3 combined i.e. approximately 10,000 patients.

6.4.6. Evaluation

The evaluation adopted a mixed methods approach, and included 6 different components. Each component is described in the following sections (sections 6.5 to 6.10 where methods and results are reported concurrently.

6.5 Patient reported experience measures (PREMs)

6.5.1. Abstract

6.5.1.1. Introduction

The clinical consultation and the "doctor-patient" relationship can be influenced by the way in which computers are used by the health care professional (HCP). The Evidence Based Medicine electronic Decision Support (EBMeDS) clinical decision support system (CDSS) is designed to provide health care professionals with advice within the normal workflow and does so by providing messages to the HCP during the consultation. This study was designed to evaluate patient reported experience measures (PREMs) for patients attending a diabetes clinic, and to assess whether or not the EBMeDS system affects patient experience.

6.5.1.2. Methods

A PREMs questionnaire was devised and distributed to patients attending diabetes clinics at three sites: Ninewells hospital, Dundee; St John's hospital, Livingston; and a primary care diabetes clinic within Dundee city. Questionnaires were distributed at 2 time points, December 2013-February 2014 (improvement cycle 1) and August 2014-February 2015 (improvement cycle 2), with dedicated research staff employed during cycle 2. The questionnaire consisted of a series of closed, 5-point Likert scale items grouped within different domains: interaction with doctors; interaction with nurses; use of medication; and general satisfaction. A score was calculated for each domain and used as a dependent variable in a multivariable linear regression analysis. Predictors included demographic variables and the presence or absence of a CDSS message.

6.5.1.3. Results

A total of 359 questionnaire responses were received from cycle 1 and 2 combined, from a total population of 2,072 clinic attendances (17%). Response rates were higher for cycle 2 (281/471, 60%). Responses to all domains were overwhelmingly favourable with >90% or respondents reporting positively to each item. Owing to data availability, regression analysis was limited to a subset of 71 patients from cycle 1. Within this subset, there was no significant association between presence or absence of a CDSS message and domain score in either domain. Various demographic variables were predictive of domain scores e.g. greater deprivation was associated with less satisfaction with doctor interaction (β=0.04, p=0.01).

6.5.1.4. Conclusion

In general, patients reported high rates of satisfaction with the service that they received. There was no association between presence or absence of a CDSS message and patient satisfaction. This would imply that the EBMeDS system is having no adverse impact on the consultation.

6.5.2. Introduction

The role of the computer within the consultation and the potential for both positive and negative effects on the doctor-patient relationship has been widely discussed [129]. In Scotland, computer use is an integral part of the consultation with patients with diabetes owing to the widespread use of the SCI-Diabetes electronic health record. The EBMeDS clinical decision support system has been implemented within SCI-Diabetes to provide users with prompts and reminders via the user interface. EBMeDS is primarily aimed at health care practitioners as an additional tool that seamlessly integrates into the normal consultation. There is no patient-orientated interface or communication from EBMeDS. From the patients' perspective, the implementation of EBMeDS should therefore have no adverse effects on the consultation.

Patient reported experience measures (PREMs) are an integral part of quality assurance for the NHS in the UK [56,130,131]. Both NHSScotland and the NHS in England regularly survey large samples of the population to gain insight into patients' experiences at both primary and secondary care and publish these results annually [132,133]. Questions have been written to assess PREMs following consultation with stakeholders, and have been cognitively tested with the public to ensure their validity [134]. These questions are freely available for local use thereby allowing for comparison with results obtained nationally [134,135]. The NHSScotland patient survey is primarily aimed at assessing patients' experience of visiting the GP but is easily adapted to the outpatient setting.

6.5.3. Aims

- To record patient reported experience measures (PREMs) following a visit to the diabetes clinic where EBMeDS was introduced
- To compare PREMs between those patients whose health care practitioner (HCP) received an EBMeDS prompt and those whose HCP didn't.

6.5.4. Methods

6.5.4.1. PREMs questionnaire

The NHSScotland PREMs questionnaire was adapted for use in both outpatient and primary care settings and consists of 32 items within 4 domains: interaction with the doctor; interaction with the nurse; understanding of medication; and overall satisfaction. The final questionnaire is available in the appendix (see section 14), as well as online at http://tinyurl.com/zd8sxwz. Respondents were given the opportunity to complete and anonymously return the survey immediately. Alternatively, respondents could return the completed questionnaire to the postal address provided (postal costs were not covered). The online version was also made available to respondents.

The questionnaire was distributed during both improvement cycle 1 and 2 during the EBMeDS project. Cycle 1 took place in the NWH diabetes outpatient clinic between December 2013 and February 2014 whilst cycle 2 involved the whole of NHS Tayside plus SJH, Livingston during August 2014 to February 2015. The questionnaire was initially distributed via outpatient clerical staff with the aim to offer it to all patients attending the outpatient clinic for the 3 months of cycle 1. Patients were issued with a questionnaire on arrival by reception staff and asked to return the completed form at the end of their appointment. These methods were adapted in light of a poor response rate and for cycle 2, a research assistant was employed to distribute the questionnaire for a more concentrated period. All patients waiting in the outpatient clinic were approached by the research assistant and were invited them to take part.

6.5.4.2. Sample size

From national results, we initially expected that approximately 90% of patients will be positive about their clinic experience [132]. In cycle 1, approximately 95% of respondents to the question "Overall, how would you rate the care provided by the diabetes clinic?" gave an "excellent" or "good" response. The null hypothesis is that there is no difference in overall rating between those whose HCP received an EBMeDS notification and those that didn't. The alternative hypothesis is that there is a difference between the two groups.

In the event of 320 responses being received, it was estimated that approximately 100 will be in the intervention group (assuming 20-30% of consultations will be subject to an EBMeDS prompt). If the proportion of patients who rate overall care as "good" or "excellent" fell to 85% in the intervention group, then the null hypothesis would be rejected with 82% power (alpha error 5%).

Approximately 320 patients visit the diabetes clinics involved in the project every week. Assuming a 10% non-attendance rate [136] and a return rate of 60%, questionnaires were distributed within NHS Tayside for 2 weeks and SJH for 1 week (total anticipated n=540). Distribution was not on consecutive days, but all clinics were equally covered to ensure adequate representation of all patient groups.

6.5.4.3. Statistical analysis

Responses to questions containing a 5 point Likert scale were recoded into “positive”, “neutral” or “negative” responses for the purposes of graphical representation. Control and intervention group demographics were compared using Chi Square. A domain score for each individual was calculated by summing the total for each domain, before dividing by the highest possible score available in that domain to give a total out of 1. Comparison between control and intervention groups was made using these domain scores. The domain scores were considered as the dependent variable. Demographic variables were considered potential confounders and so each were entered into a univariable linear regression model. These independent variables were retained if $p<0.1$ for the final model, containing presence or absence of DSS prompt.

6.5.4.4. Approval

Permission was granted by the national Caldicott Guardian to collect identifiable information. Probabilistic matching was completed to match respondents with CHI data, which in turn allowed individuals’ SCI-Diabetes data to be accessed. All resultant data queries were provided in a pseudo-anonymised format.

6.5.5. Results

Analysis of both cycle 1 and cycle 2 data was restricted to aggregate data only. The planned regression to compare responses between intervention and control groups was limited to cycle 1 data owing to a lack of data at the individual level – cycle 2 demographic variables were not available at the time of analysis.

6.5.5.1. Aggregates

During cycle 1, 78 responses were obtained from a total of 1601 attendances (5%). During cycle 2, 221 responses were obtained from a total of 391 attendances in NHS Tayside secondary care (57%) and an additional 20 responses were obtained from 2 primary care diabetes clinics (100% response rate). 40 responses were obtained from a total of 60 attendances in SJH (60%). Data were combined from cycles 1 and 2 to provide a total of 359 responses. 201 (56%) of total responses were from males, 341 (95%) described themselves as "white" ethnicity and 144 (40%) described their general health as "good".

PREMs for each of the 4 domains was overwhelmingly positive, reflecting high patient satisfaction with the service that they received (see Figure 8 to Figure 11). 233 (65%) of patients had a consultation with a doctor; 217 (60%) had a consultation with a nurse; and 95 (26%) had their medication changed (resulting in questions being answered on the use of medications).

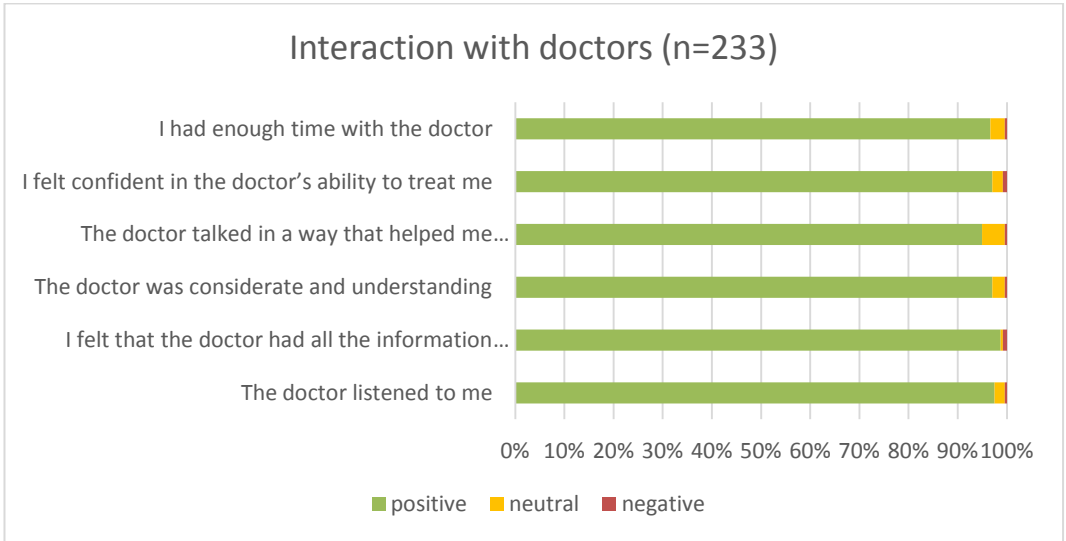

Figure 8. Stacked bar charts for responses to items relating to interaction with doctors. 5 point Likert scale was collapsed into positive, neutral or negative responses.

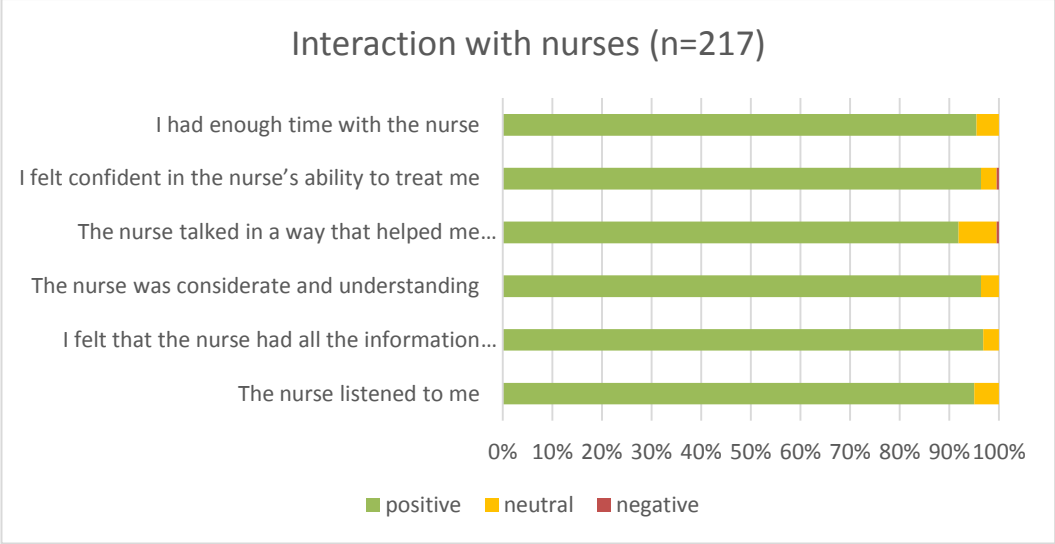

Figure 9. Stacked bar charts for responses to items relating to interaction with nurses. 5 point Likert scale was collapsed into positive, neutral or negative responses.

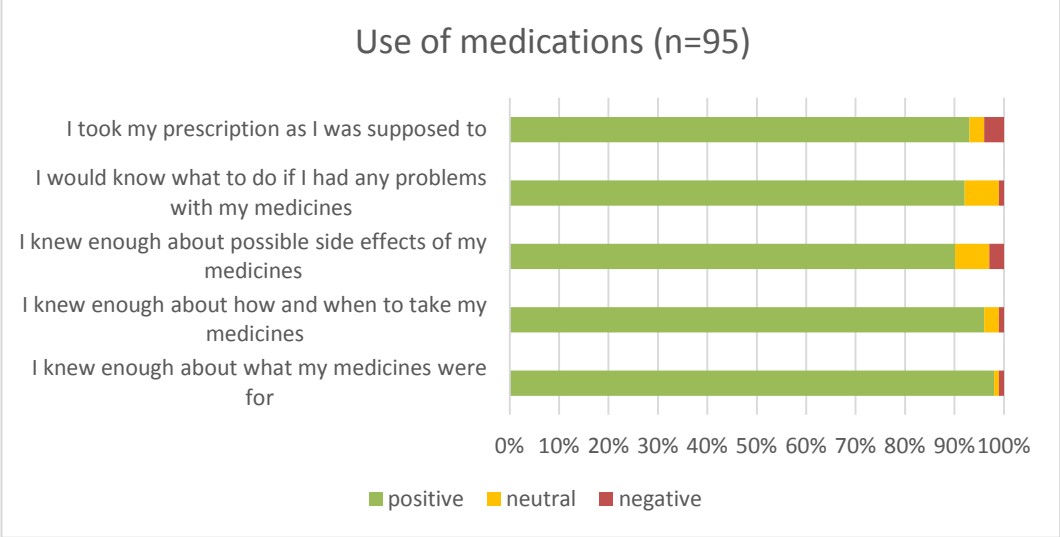

Figure 10. Stacked bar charts for responses to items relating to use of medication. 5 point Likert scale was collapsed into positive, neutral or negative responses.

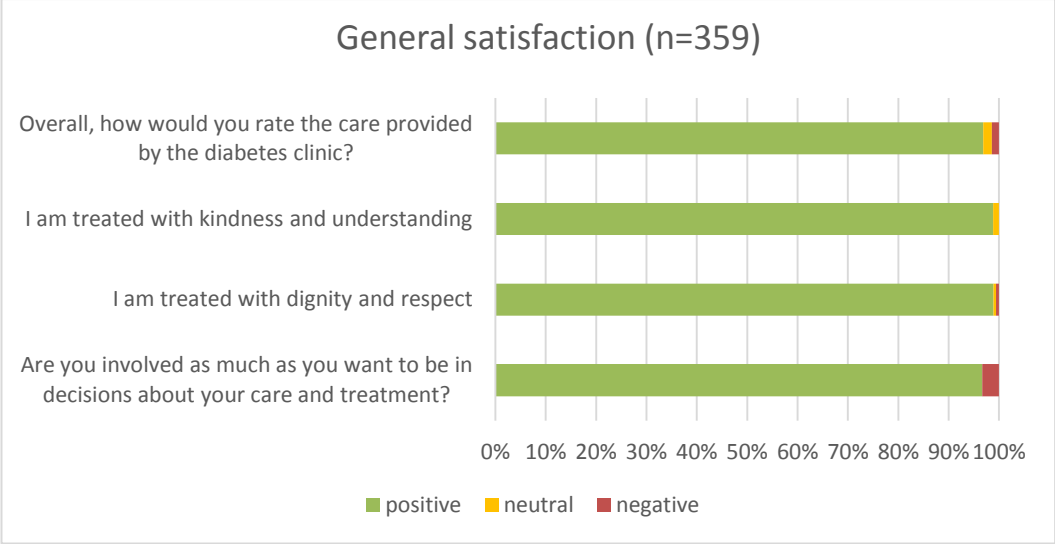

Figure 11. Stacked bar charts for responses to items relating to overall satisfaction.
5 point Likert scale was collapsed into positive, neutral or negative responses.

In keeping with the above, the domain scores were similarly positive (see Figure 12).

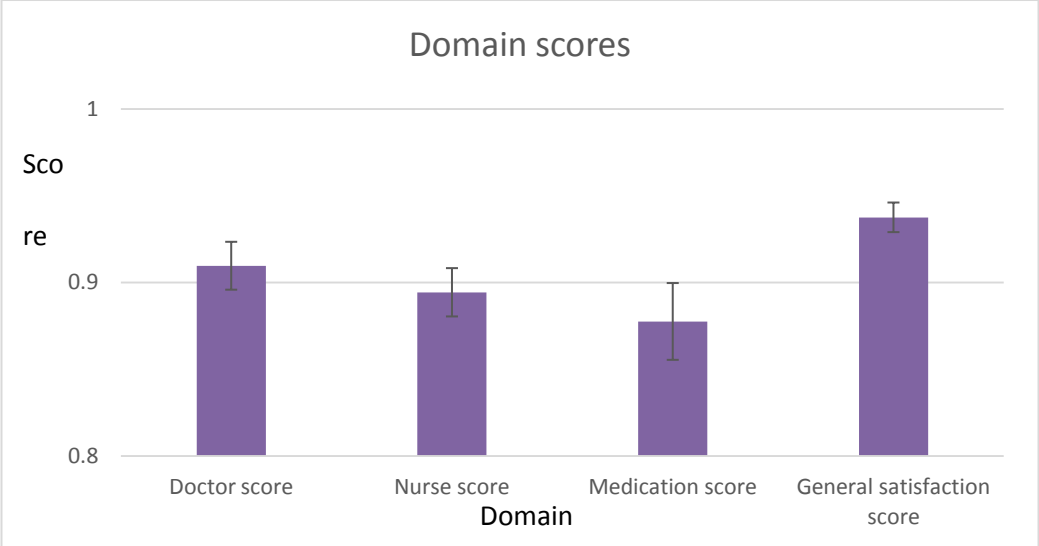

Figure 12. Mean score for each of the 4 questionnaire domains.
Score calculated as a proportion of highest total possible. Error bars show 95% CI.

6.5.5.2. Comparison

Of the 78 respondents in cycle 1, 71 were successfully identified within SCI-Diabetes. The HCP opening the patient record received a DSS message in 25/71 (35%) cases i.e. similar to the overall proportion of patient records subject to a DSS prompt (see section 6.8). Demographic variables were very similar between respondents whose HCP received a prompt and those whose HCP didn't (see Table 5). Unsurprisingly, those that did receive a prompt had greater comorbidity (see section 6.8.4 for comorbidity score description).

Table 5. Demographic variables for cycle 1 PREMs respondents. Comparison made using Chi Square

	DSS message received		
	Yes (n (% of N))	No (n (% of N))	p
Total N	46	25	0.439
Male	18 (39%)	7 (29%)	1
Age >=60 years	20 (47%)	11 (50%)	0.282
Ethnic group "white"	45 (98%)	23 (96%)	0.594
Most deprived SIMD quintile	12 (26%)	8 (32%)	1
Self reported health "good"	17 (37%)	9 (36%)	0.307
High comorbidity score	5 (11%)	5 (20%)	0.256
Type 2 diabetes	32 (70%)	21 (84%)	0.576
Insulin therapy	35 (76%)	17 (68%)	0.131

When subject to univariable analysis, a few demographic variables reached significance and so were entered into the multivariable model in conjunction with presence or absence of a DSS prompt (see Table 6 and Table 7).

*Table 6. PREMS respondents - univariable significance of each predictor variable for domain scores. *Denotes predictors reaching significance <0.1. B = correlation coefficient*

Predictor variables (univariable)	Domain							
	Doctor		Nurse		Medication		General satisfaction	
	B	p value	B	p value	B	p value	B	p value
gender	-0.21	0.698	0.07	0.138	0.09	0.159	0.04	0.125
Age category (decades)	-0.01	0.729	-0.03	0.188	0.06	0.084	-0.01	0.151
Ethnic group	0.03	0.599	-0.08	0.076	0.01	0.93	-0.06	0.176
SIMD quintile	0.04	0.01	0	0.938	-0.01	0.745	0	0.858
Self reported health status	-0.03	0.375	-0.02	0.614	0.07	0.151	0.04	0.023
Comorbidity group	-0.02	0.635	-0.07	0.079	0.02	0.732	-0.01	0.597
Diabetes type	0.05	0.435	-0.04	0.508	0.29	0.001	0	0.881
DSS message displayed	0.02	0.709	0	0.967	0.04	0.575	0.01	0.829

Table 7. PREMS respondents - significant univariable predictors entered into a multivariable model. NB. presence or absence of DSS message retained as a predictor. B= correlation coefficient

Predictor variables (multivariable)	Domain							
	Doctor		Nurse		Medication		General satisfaction	
	B	p value	B	p value	B	p value	B	p value
gender	-	-	-	-	-	-	-	-
Age category (decades)	-	-	-	-	0.03	0.301	-	-
Ethnic group	-	-	-0.08	0.076	-	-	-	-
SIMD quintile	0.04	0.01	-	-	-	-	-	-
Self reported health status	-	-	-	-	-	-	0.07	0.14
Comorbidity group	-	-	-	-	-	-	-	-
Diabetes type	-	-	-	-	0.26	0.015	-	-
DSS message displayed	0.03	0.476	0.03	0.606	0	0.942	0.05	0.465

Of note from the above tables:

- Domain scores were not significantly predicted by presence or absence of a DSS message.
- Greater deprivation was predictive of a lower doctor domain score.
- Ethnicity as a predictor of nursing score approached significance, however, actual numbers of non-white ethnic groups were extremely low (2 in total).
- Presence of Type 1 diabetes was predictive of a lower medication score.

- Lower self reported health status showed some association with overall lower satisfaction with the service.

6.5.6. Discussion

Patient satisfaction was generally high for those attending the diabetes clinics during the period of assessment and were in keeping with results obtained from a similar PREMs questionnaire distributed to primary care users [132]. This analysis has demonstrated no difference in patient satisfaction between patients whose HCP received a CDSS message, and those that did not. There are several limitations in study design, making it difficult to draw firm conclusions.

Despite the improved response rate demonstrated within cycle 2, the regression analysis is limited to cycle 1 data (71/299 total responses). This decision was based on data availability, whereby at the time of writing, the data custodians lacked sufficient capacity to make the requisite query. It is acknowledged that this invalidates the initial power calculation that assumed 320 questionnaires would be returned. It is anticipated that future multivariable analysis will include all respondents' data once these data are available. The smaller patient numbers (and less representative sample) limits the conclusions that can be drawn in terms of statistical inference. However, the aggregate statistics from cycle 2 were very similar to those obtained in cycle 1, and it is not anticipated that future analyses will arrive at a different conclusion.

The questionnaire itself was adapted from a similar instrument used for a national survey [134]. This national survey was developed following a consultation process with patients and HCPs and was "cognitively validated" with regards to language and structure. However, the national questionnaire was not used to calculate "domain scores" as per the methods employed in this study. The use of this domain score in this study is, therefore, not a validated measure with which to compare patient sub-groups and may not be discriminatory. The results obtained in

this study were similar to the national survey, in that both demonstrated high rates of patient satisfaction. Whilst this is obviously encouraging from a service delivery perspective, these high satisfaction rates may be further compounding this lack of discrimination, by masking any difference between patients whose HCP received a CDSS message and those that didn't.

The potential for respondent bias is acknowledged, whereby respondents may be self-selecting, following a particularly good (or bad) experience. This was of concern during cycle 1, where response rates were particularly low. However, the targeted approach adopted during cycle 2, (whereby a dedicated research assistant approached patients within the clinic) improved response rates markedly.

Despite these limitations, it is notable that presence or absence of a CDSS prompt had no bearing on patients' self-reported experience with doctors or nurses, nor did the CDSS impact upon overall satisfaction. Given the high levels of satisfaction demonstrated, this is perhaps unsurprising and would suggest that the CDSS is having no adverse effects on the consultation. It is also notable that, despite the small numbers included within the regression analysis, patients with more complex needs had lower satisfaction with the service. In addition, patients with greater deprivation were less positive about their experience with the doctor. National patient surveys have previously demonstrated a negative correlation between deprivation and satisfaction [137,138]. The cause of such an association remains speculative, however it may be both measures would improve with appropriate targeting of the relevant patient and HCP groups.

6.5.7. Conclusion

This study has demonstrated that there are high rates of patient satisfaction with the care received within primary and secondary care diabetes clinics. Despite the fact that a similar analysis has not yet been completed with cycle 2 data, the high levels of satisfaction would suggest that the EBMeDS system is not having an adverse effect on the consultation process, and it would seem unlikely that future analysis will detect any significant difference between intervention and control groups.

6.6 Health Care Professional (HCP) user opinion survey

6.6.1. Abstract

6.6.1.1. Introduction

There are a variety of factors that can potentially influence the uptake and use of a new information system, including performance expectancy (i.e. the degree to which an individual believes the system will help them with their work); effort expectancy (i.e. perceived ease of use); social influence; and facilitating conditions. The Evidence Based Medicine electronic Decision Support (EBMeDS) system was introduced to SCI-Diabetes as a clinical decision support system (CDSS). This study aimed to describe users' attitudes to the use of CDSS prior to, and following, implementation of EBMeDS with a view to identifying facilitators and barriers to system uptake and usage.

6.6.1.2. Methods

Two questionnaires were developed for distribution to health care professional (HCP) users of SCI-Diabetes. They were distributed to HCPs prior to, and at the end of each 3-month quality improvement cycle in both primary and secondary care. The questionnaires were available in electronic and paper versions and consisted of a series of closed 5-point Likert scale questions grouped by theoretical construct. Theoretical constructs were derived from the Unified Theory of Acceptance and Use of Technology (UTAUT) model, that aims to predict whether or not new technology will be adopted by users. A score was calculated for each construct and was used as a dependent variable in a multivariable linear regression analysis with users' demographics entered as the independent predictors.

6.6.1.3. Results

The response rate for pre and post intervention questionnaires was 57/105 (54%) and 39/105 (37%), respectively. Respondents tended to be more senior members of staff. Prior to the intervention, HCPs reported that most reading of literature and guidelines occurred after or unrelated to the consultation and attitudes to a CDSS were mixed. Post-intervention attitudes to the EBMeDs system were similarly mixed. The majority of respondents had a positive or neutral response to the content of the reminders in terms of relevance, clarity and quality. Similarly, most respondents were positive or neutral to questions relating to ease of use. Despite this, self reported use of the system was low. Work role predicted users' performance expectancy (i.e. the degree to which an individual believes the system will help them with their work), which was significantly higher for nurses.

6.6.1.4. Conclusion

In general, HCPs expressed positive attitudes to the use of CDSS, however self reported use was low. This may reflect users' pre-existing work patterns and may also be attributed to the relative seniority of respondents. Actual use of the system was the subject of further quantitative research. In addition, further qualitative work with users was required to identify any particular barriers/facilitators that may improve uptake.

6.6.2. Introduction

When implementing any new information system, it is essential that there is clear understanding of the factors that may influence potential users to successfully adopt it. The decision whether or not to do so is highly subjective. Various factors that can influence this process have been identified including: individuals' attitudes to new technology; their intention to use such systems; and organisational or environmental conditions required to increase uptake. As a result, several models have been proposed which include some or all of these factors. These include the Theory of Reasoned Action [139]; the Technology Acceptance Model [140]; and Social Cognition Theory [141] amongst others. The Unified Theory of Acceptance and Use of Technology (UTAUT) model was formulated by identifying the similarities between eight different models, combining them and then validating the resultant model [88]. This model can be used to evaluate the likelihood of whether a new technology will be adopted by users as well as allowing organisations to identify user groups that may require additional support during the implementation phase. The UTAUT has been used in a variety of contexts to explore user acceptance of new technologies, including the adoption of electronic health records [89,142] and the use of telemedicine in diabetes care [143]

The UTAUT identifies four main constructs (common to all the previous models), which were found to be significant predictors of user acceptance and usage behaviour. These are: performance expectancy (i.e. the degree to which an individual believes the system will help them with their work); effort expectancy (i.e. perceived ease of use); social influence; and facilitating conditions (see Figure 13). These in turn are influenced by a number of independent variables including gender, age and experience.

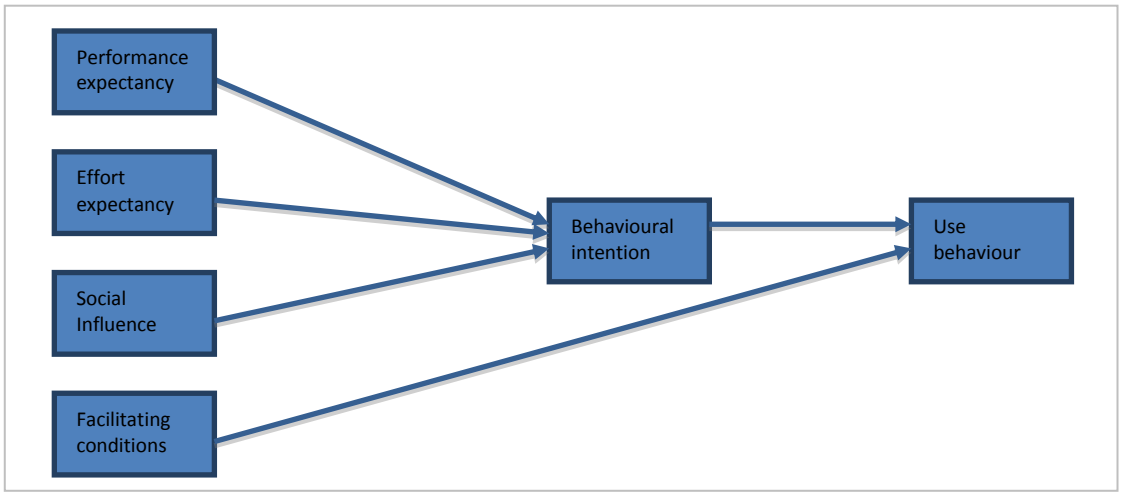

Figure 13. The Unified Theory of Acceptance and Use of Technology. Adapted from Venkatesh et al [88] (putative modifiers omitted).

6.6.3. Objectives

The objectives of this study were to:

- Describe HCPs' use of evidence based medicine (EBM) resources prior to and following implementation of the CDSS
- Explore HCPs' attitudes to the use of a CDSS prior to and following implementation
- Identify potential facilitators/barriers to HCPs' use of CDSS elsewhere

6.6.4. Methods

The UTAUT model was used to develop a user experience questionnaire aimed at users of the clinical decision support system (CDSS) implemented within SCI-Diabetes. Additional constructs were also added including: attitude to CDSS reminders; general satisfaction; and perceived use of the system. This work drew on the experience of Heselmans et al who have previously assessed the use of the Evidence Based Medicine electronic Decision Support system (EBMeDS) within their local context [144]. An additional, pre-implementation questionnaire was also developed for this study that aimed to assess users' attitudes to CDSS prior to the implementation of EBMeDS. This would allow comparisons of user attitudes before and after the introduction of the CDSS.

The resultant two questionnaires consisted of: a 37-item baseline questionnaire (see section 15 appendix or http://tinyurl.com/zmsp7tk for the online version); and a 42-item follow up questionnaire (see section 16 appendix or http://tinyurl.com/hqsdztz for the online version).

SCI-Diabetes users were emailed links to the online version of the questionnaire and paper copies were made available at departmental meetings. Secondary care users were contacted via grouped email lists held by the managed clinical network manager.

In secondary care, there were 22 registered users during cycle 1 (Ninewells Hospital (NWH)) and 16 users during cycle 2 (SJH). Primary care users were included in cycle 2. The total number of registered users in the NHS Tayside primary care domain was 97, distributed amongst 67 primary care health centres. Practice managers for each health centre were contacted via an email asking them to forward the invitation to the most appropriate user in the practice. For the purposes of analysis, it was therefore assumed that one user per practice was invited to respond (n=67).

The email to the secondary care team was also used to invite recipients to take part in focus groups (see section 6.7, HCP user opinion focus groups). When tested prior to administering, both pre and post-intervention questionnaires took less than 5 minutes to complete. In an effort to improve response rates, the cycle 1 post-implementation questionnaire included the option to be entered into a prize draw (for a £50 shopping voucher), as a contingent incentive. No personal identifiable information was collected.

Both questionnaires consisted of mainly closed questions with the option for additional free text comments. Responses to questions containing a 5 point Likert scale were recoded into "positive", "neutral" or "negative" responses for the purposes of graphical representation[2]. Items corresponding to UTAUT constructs were grouped to allow a construct score for each individual to be calculated. This construct score was calculated by summing the total for each construct, before dividing by the highest possible score available in that construct to give a total out of 1[3]. Unless otherwise stated, the cycle 1 and 2 responses to both pre and post-implementation questionnaire were combined for analysis. Multivariable linear regression was used to look for significant demographic predictors of each construct score. The independent predictors entered were age category; workplace (primary or secondary care); number of years' experience; and work role (doctor or nurse).

[2] Scores 1-2 = "positive", score 3 = "neutral", score 4-5 = "negative"

[3] Scoring for negatively worded questions was reversed by using the following equation: 5+1-score (where 5 is the maximum value of response scale and "score" is the individual's response. This results in a reversal of scores i.e. 1=5, 2=4 and vice versa).

6.6.5. Results

Pre-intervention questionnaires were returned by 57 users (cycle 1=9/22 (response rate 41%), cycle 2=48/83 (58%) whilst 39 users responded to the post-intervention questionnaire (cycle 1=5/22(23%), cycle 2=34/83(41%)). Demographic variables were similar between pre and post intervention respondents. The majority of respondents were 50 years or older (pre-intervention=35/57 (61%), post-intervention 23/39 (59%)) and worked in primary care (pre-intervention=35/57 (61%), post-intervention=30/39 (77%)). Most respondents were nurses (pre-intervention=30/57 (53%), post-intervention=24/39 (62%)) and most had >10 years' experience of working with patients with diabetes (pre-intervention=44/57 (77%), post-intervention=29/39 (74%) – see Table 8.

Table 8. Demographic variables of respondents to pre and post intervention questionnaires.
NB. Data are combined from cycles one and two

		Pre-intervention (n=57)		Post-intervention (n=39)	
		n	%	n	%
Age	20-29 years	1	1.8%	0	0.0%
	30-39 years	4	7.0%	4	10.3%
	40-49 years	17	29.8%	12	30.8%
	50-59 years	34	59.6%	23	59.0%
	60+ years	1	1.8%	0	0.0%
Role	AHP	2	3.5%	0	0.0%
	Doctor	24	42.1%	12	30.8%
	Nurse	30	52.6%	24	61.5%
	Specialist practitioner	1	1.8%	0	0.0%
	Administrator	0	0.0%	3	7.7%
Setting	Primary care	35	61.4%	30	76.9%
	Secondary care	16	28.1%	5	12.8%
	Both primary and secondary care	6	10.5%	4	10.3%
Average hours worked per week	<17 hours	1	1.8%	1	2.6%
	17-32 hours	19	33.3%	15	38.5%
	33+ hours	36	63.2%	21	53.8%
Experience	<5 years	8	14.0%	4	10.3%
	5-10 years	5	8.8%	6	15.4%
	10+ years	44	77.2%	29	74.4%

Respondents to both pre- and post-intervention questionnaires were asked about their use of guidelines and literature during a typical working week. Over half of respondents to either questionnaire (52/96, 54%) spent <1 hour per week doing so, whilst the remainder spent 1-5 hours/week. The most commonly used guideline was the local diabetes handbook (85/96, 86%), followed by guidance from the Scottish Intercollegiate Guidelines Network (SIGN) (80/96, 83%) and the National Institute for Health and Care Excellence (NICE) (43/96, 45%). A minority (7/96, 7.3%) sought guidance from elsewhere.

6.6.5.1. Pre-intervention questionnaire

Respondents to the pre-intervention questionnaire were asked about when they accessed these resources (relative to the clinical consultation). Most reading took place either after or unrelated to the consultation. Prior to and during the consultation, guidelines were more commonly accessed than other literature (e.g. journal articles) – see Figure 14.

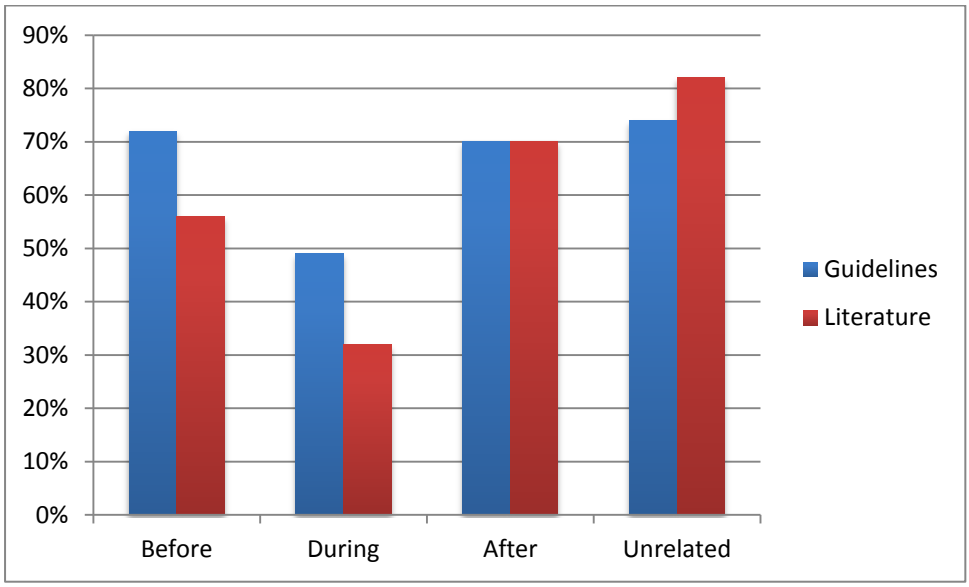

Figure 14. Respondents' access to guidelines and literature, relative to the clinical consultation (n=57)

Clinical queries that emerge were usually answered by either searching the literature/guidelines or by asking a colleague for advice. The majority of respondents to the pre-intervention questionnaire reported that they had adequate time to search the literature and that their reading usually resulted in the query being answered. This reading was often not recorded for continuing professional development (CPD) purposes, and the majority of respondents agreed that a system that could do this automatically would be worth considering – see Figure 15.

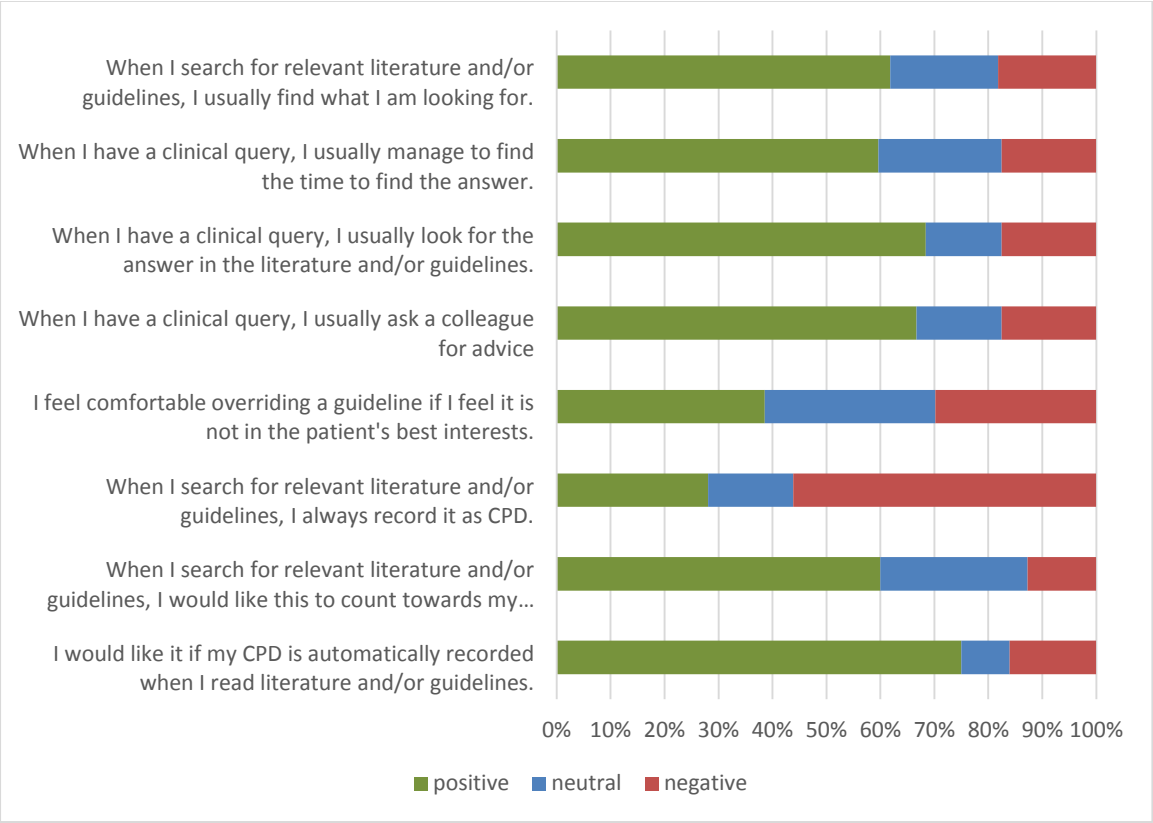

Figure 15. Pre-intervention access to literature and guidelines (n=57).
5 point Likert scale was collapsed into positive, neutral or negative responses.

Prior to the intervention, attitudes to CDSS were mixed. Over half of respondents either disagreed or were not sure that a CDSS would lead to better quality care – see Figure 16. Similarly, most respondents did not feel that they could trust a CDSS and would want to know the underlying evidence behind the CDSS message. Over half of respondents were also fearful that users would become reliant on the system. A similar proportion hoped that they would be given the opportunity to turn the CDSS off.

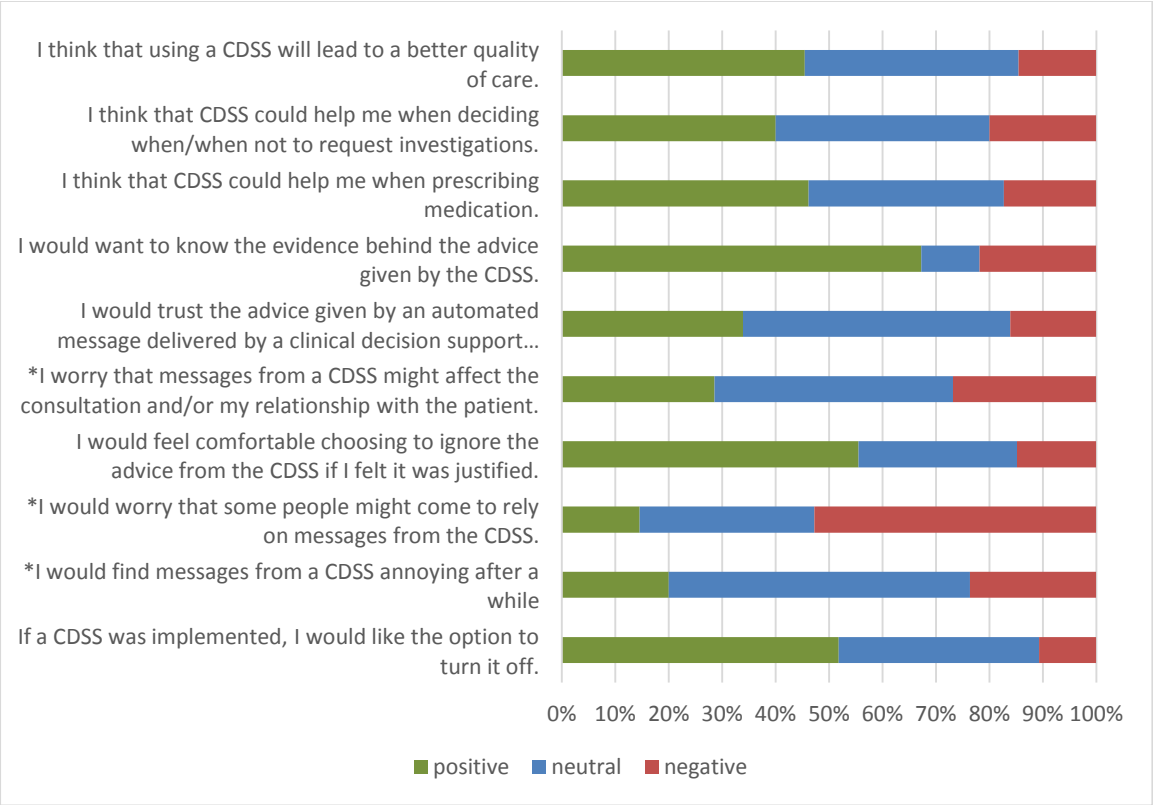

Figure 16. Pre-intervention attitudes to CDSS (n=57).
*5 point Likert scale was collapsed into positive, neutral or negative responses. *Denotes negatively worded stems where scoring was reversed – see methods.*

6.6.5.2. Post-intervention questionnaire

Responses to the post-intervention questionnaire are displayed in Figure 17 to Figure 21, grouped by questionnaire construct. Responses to items within each construct followed a similar pattern, whereby most respondents gave a neutral response to statements and those with either positive or negative attitudes were in the minority. For example, 4/18 (22%) agreed that the CDSS has "changed my way of working", whereas 5/18 (28%) disagreed with this statement – the remainder (9/18, 50%) had a neutral attitude to the statement.

6.6.5.2.1. Attitudes to reminders (Figure 17)

Attitudes to the CDSS in the post-implementation questionnaire were similar to those expressed prior to implementation. The majority of respondents had a positive or neutral response to the actual content of the reminders in terms of relevance, clarity and quality. In accordance with the pre-implementation questionnaire, users felt comfortable in overriding the advice if it was felt to be not relevant. The option to turn off reminders polarised opinion, but 5 individuals only answered this - 3/5 (60%) would like the option to do so whilst 2/5 (40%) did not.

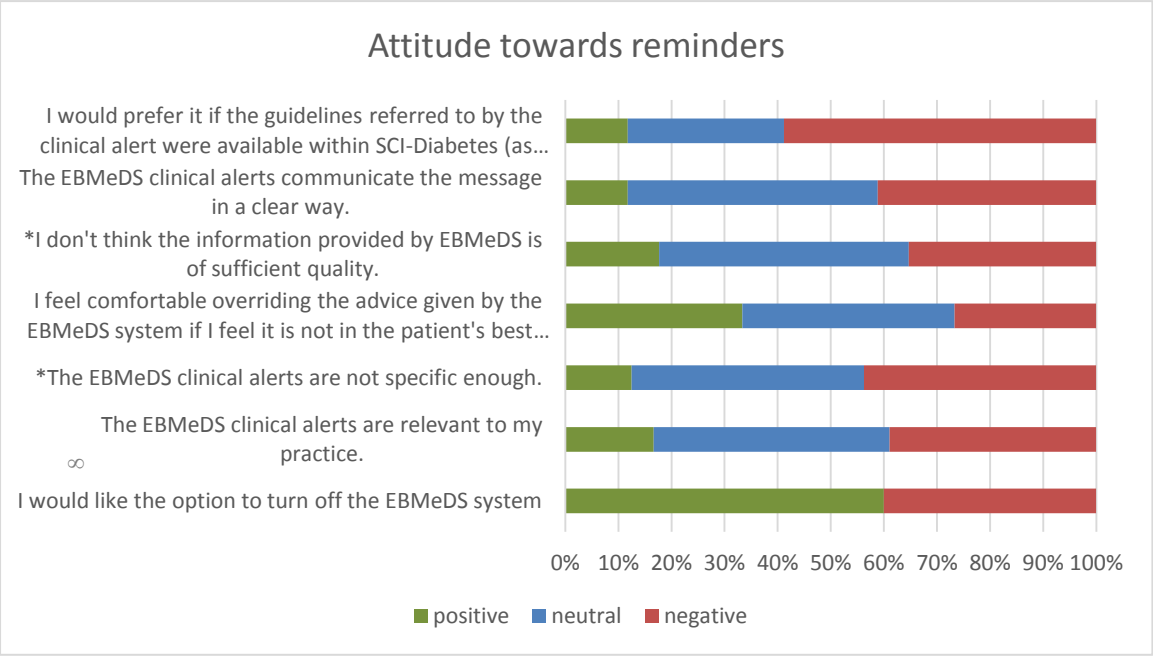

Figure 17. Post-intervention attitudes to CDSS – attitude towards reminders
*5 point Likert scale was collapsed into positive, neutral or negative responses. *Denotes negatively worded stems where scoring was reversed – see methods. n=18, ∞ denotes n=5.*

6.6.5.2.1. UTAUT constructs (Figure 18 to Figure 21)

Social influence – a minority of respondents felt that their decision to use the CDSS was affected by whether or not colleagues were using the system.

Performance expectancy – a minority of respondents felt that the CDSS conferred benefit in terms of time to complete task or improving clinical knowledge.

Facilitating conditions – The majority of respondents did not experience technical problems. A minority of respondents felt that they were given insufficient information and a minority also did not feel that technical support was available when needed.

Effort expectancy – the system was easy to use, with only a minority finding it difficult to adapt to.

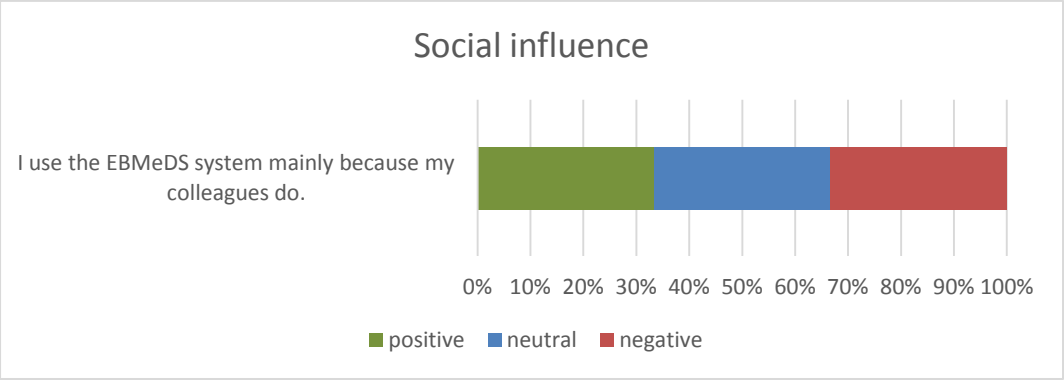

Figure 18. Post-intervention attitudes to CDSS – social influence on decision to use CDSS (n=18)
5 point Likert scale was collapsed into positive, neutral or negative responses.

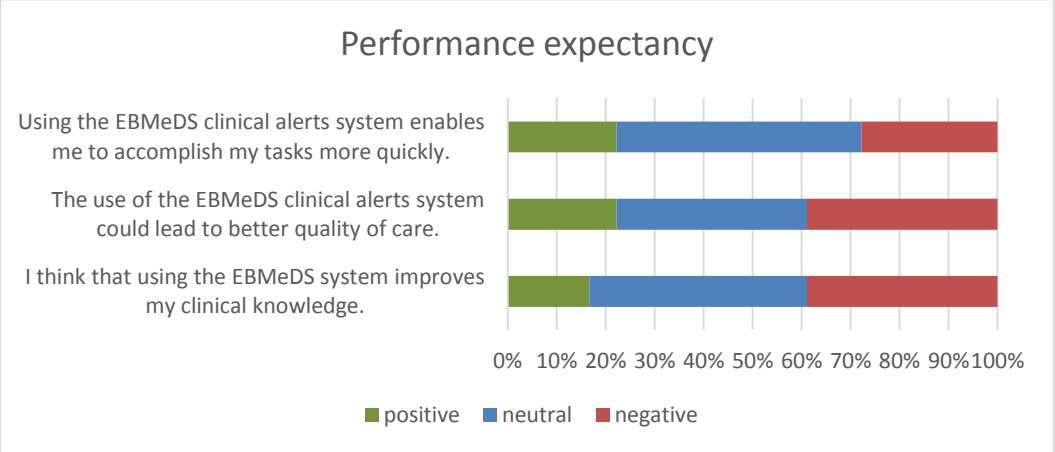

Figure 19. Post-intervention attitudes to CDSS – users' perception of performance expectancy (n=18)
5 point Likert scale was collapsed into positive, neutral or negative responses.

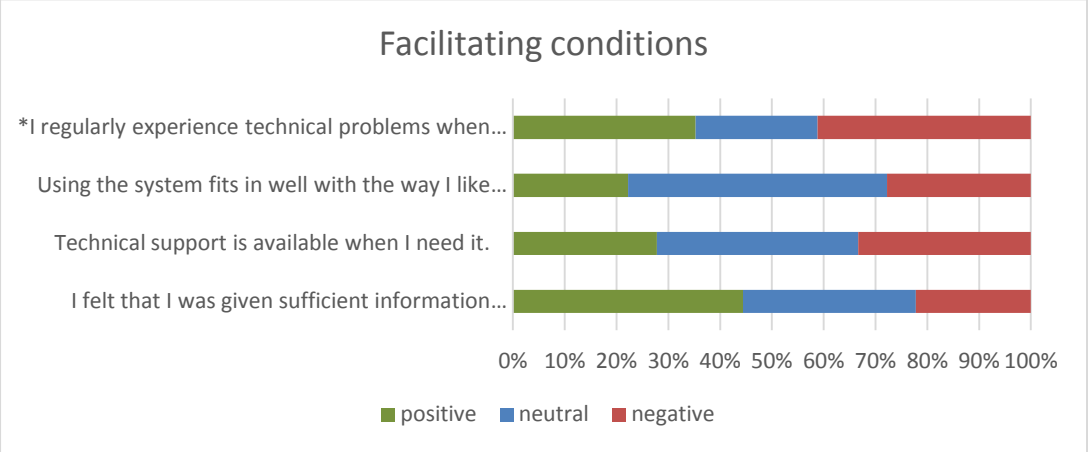

Figure 20. Post-intervention attitudes to CDSS – conditions that may facilitate adoption (n=18).
*5 point Likert scale was collapsed into positive, neutral or negative responses. *Denotes negatively worded stems where scoring was reversed – see methods.*

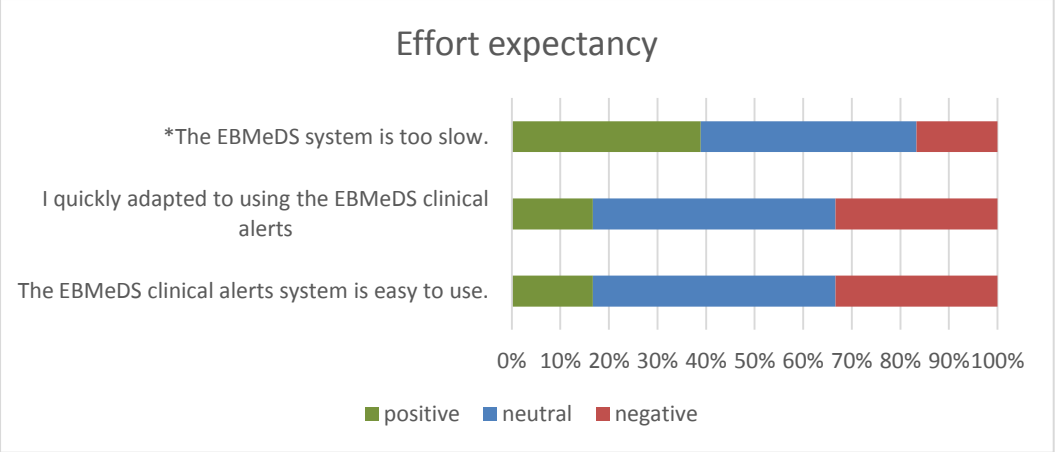

Figure 21. Post-intervention attitudes to CDSS – effort expectancy (n=18).
*5 point Likert scale was collapsed into positive, neutral or negative responses.*Denotes negatively worded stems where scoring was reversed – see methods.*

The construct scores were moderate for all areas (see Figure 22). Comparison between cycle 1 and cycle 2 was not possible owing to low numbers of respondents in cycle 1 (n=5), and so data were combined for analysis.

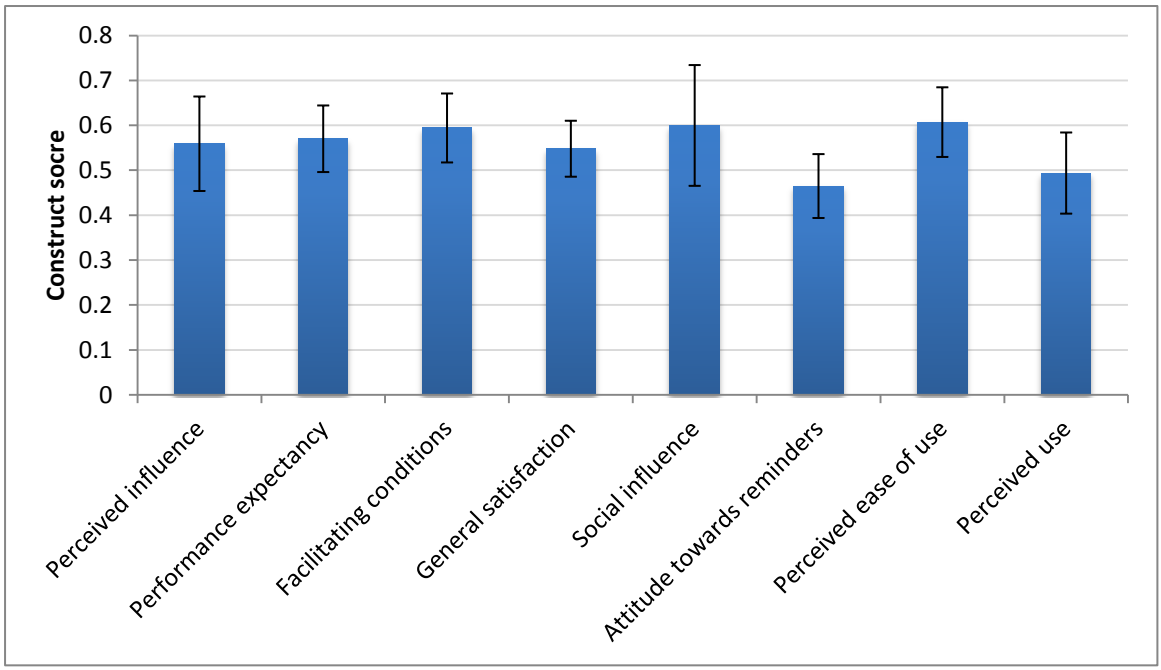

Figure 22. UTAUT and other construct scores from post-implementation questionnaire. cycles 1 and 2, n=18. Error bars show 95% CI.

There were no obvious demographic predictors for either of these construct scores, with the exception of work role. Nurses' scoring of performance expectancy was significantly higher than that given by doctors – see Table 9.

Table 9. UTAUT construct scores - Mean (95%CI) by demographic subgroups.
*p values obtained via forced entry linear regression of all demographic variables. *denotes statistical significance. "–" denotes insufficient data. "Number of years' experience" omitted owing to insufficient data in those with <10 years experience.*

		Performance expectancy score		Facilitating conditions score		Social influence score		Effort expectancy score		Perceived use score		Attitude towards reminders score		General satisfaction score	
	category	**mean(95% CI)**	**p**	**mean (95% CI)**	**p**	**mean (95% CI)**	**p**	**mean (95% CI)**	**p**	**mean (95% CI)**	**p**	**mean (95% CI)**	**p**	**mean (95% CI)**	**p**
work role	Doctor	0.47(0.33-0.6)	0.01*	0.68(0.5-0.85)	0.45	0.43(0.15-0.71)	0.14	0.69(0.54-0.83)	0.61	0.43(0.29-0.58)	0.29	0.59(0.43-0.75)	0.11	0.58(0.47-0.7)	0.55
	Nurse	0.62(0.52-0.72)		0.55(0.46-0.65)		0.68(0.51-0.86)		0.57(0.46-0.68)		0.53(0.39-0.66)		0.40(0.33-0.48)		0.53(0.44-0.62)	
work setting	Primary care	0.58(0.49-0.68)	0.17	0.54(0.44-0.65)	0.78	0.69(0.52-0.87)	0.80	0.55(0.44-0.67)	0.47	0.49(0.38-0.61)	0.17	0.38(0.31-0.44)	0.28	0.50(0.42-0.58)	0.12
	Secondary care	0.50(0.19-0.81)		0.73(0.51-0.94)		0.35(0.05-0.66)		0.70(0.42-0.98)		0.40(0.18-0.63)		0.68(0.62-0.74)		0.61(0.39-0.82)	
	Both primary and secondary care	0.62(0.09-1.15)		0.62(0.15-1.09)		0.60(-0.39-1.59)		0.69(0.59-0.78)		0.63(-0.17-1.43)		0.50(0.18-0.83)		0.64(0.31-0.98)	
Age category	30-39 years	0.47(-1.23-2.16)	0.57	0.35(-0.92-1.62)	0.80	0.40(-2.14-2.94)	0.56	-	0.95	0.35(-0.29-0.99)	0.29	0.39(-0.16-0.93)	0.54	0.35(-0.29-0.99)	0.65
	40-49 years	0.65(0.38-0.92)		0.66(0.43-0.89)		0.75(0.45-1.06)		0.67(0.31-1.02)		0.63(0.21-1.04)		0.47(0.21-0.73)		0.63(0.32-0.95)	
	50-59 years	0.56(0.46-0.66)		0.61(0.52-0.71)		0.58(0.39-0.78)		0.62(0.53-0.71)		0.48(0.37-0.58)		0.48(0.37-0.58)		0.55(0.5-0.61)	

6.6.5.2.2. Perceived use and influence (Figure 23 and Figure 24)

Perceived use - two items recorded perceived use of the CDSS. It is notable that the majority of respondents gave a negative response to both, however this was in response to absolute statements ("I always read the EBMeDS clinical alerts..." and "I always read the guidelines cited by EBMeDS...").

Perceived influence – The CDSS only influenced a minority of people in terms of self-reported prescribing practices; requesting investigations; and their way of working.

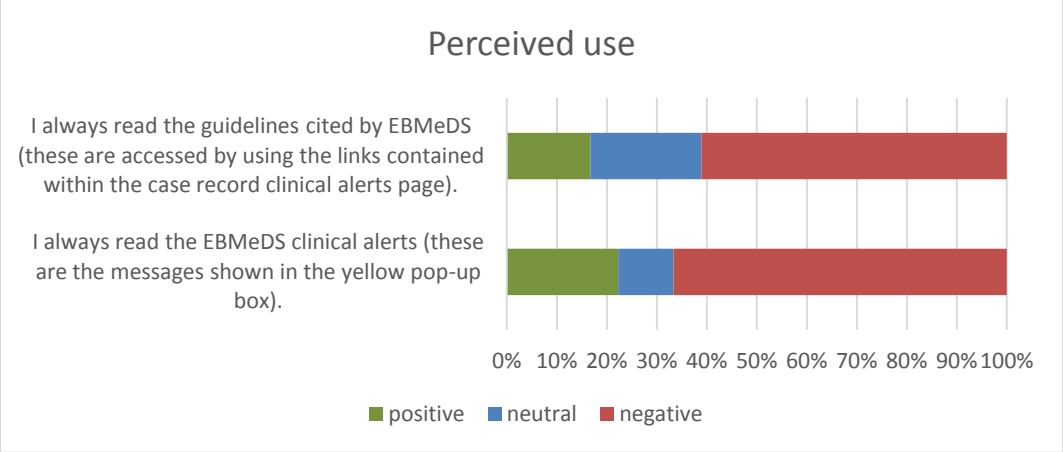

Figure 23. Post-intervention attitudes to CDSS – users' reported use of the system (n=18).
5 point Likert scale was collapsed into positive, neutral or negative responses.

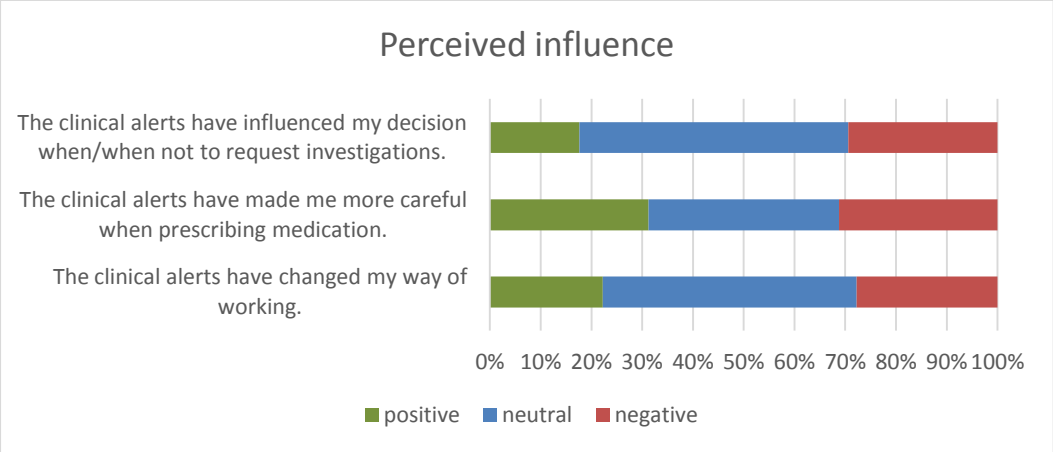

Figure 24. Post-intervention attitudes to CDSS - perceived influence of the alerts (n=18)
5 point Likert scale was collapsed into positive, neutral or negative responses.

6.6.5.2.3. General satisfaction (Figure 25)

Respondents were more negative than positive with regards to the content of the alerts and the reliability of the system. Only a minority of respondents intended to keep using the system and most would not recommend it to colleagues.

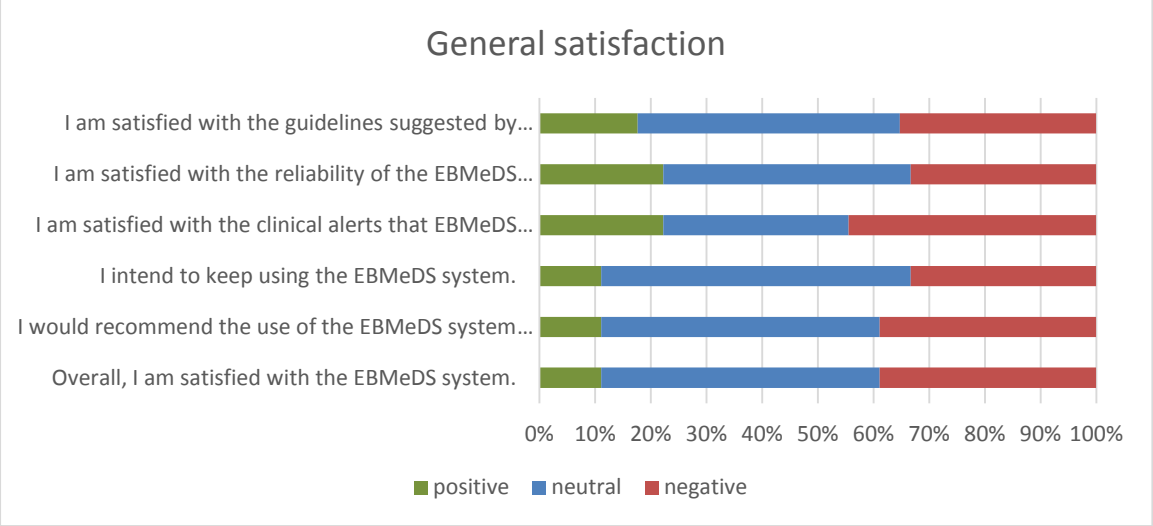

Figure 25. Post-intervention attitudes to CDSS – general satisfaction with CDSS (n=18)
5 point Likert scale was collapsed into positive, neutral or negative responses.

6.6.6. Discussion

Respondents to both pre- and post-intervention questionnaires reported regular use of literature and guidelines to support clinical decision-making – most of this knowledge acquisition took place out with the clinical consultation. Prior to the intervention, the idea of using a CDSS was met with a favourable response with very few misgivings being expressed. However, despite expressing satisfaction with the content of the CDSS alerts, the majority did not find the system useful and reported that they were unlikely to continue using it in the future.

The UTAUT constructs provide a useful model to conceptualise possible facilitators and barriers to system usage. Previous studies have reported on user experience with EBMeDS which serve as a useful comparison to these local results, aided by the fact that the present study adopted the questionnaire used by Heselmans et al [144]. Despite a small number of respondents, the questionnaire developed by this Belgian research team proved to be reliable with Cronbach's alpha for the various constructs ranging between 0.65 and 0.95 [144].

Construct scoring was comparable across these two studies, suggesting a similar user experience with EBMeDS. That being said, all of the construct scores in this study were similar, making it difficult to identify any particular aspects that require further investigation. Of note, nurses' scoring of items related to performance expectancy was significantly higher than doctors. This would suggest that the former group are more likely to view the CDSS as a way of improving job performance. There were no other significant demographic predictors of UTAUT score.

It is notable that age was not a significant predictor of any of the constructs, including perceived use. The UTAUT was developed within the context of the computer sciences and it is only recently that it has been tested within a healthcare setting [89]. Venkatesh et al found that the primary predictor of adoption of a new electronic health record was user age, resulting in modifications being made to the model for future use within a health context [89].

6.6.6.1. Limitations

The lack of a robust denominator with regards to SCI-Diabetes users made response rates difficult to calculate. Whilst a user may be registered on the system, they may have very little day-to-day interaction with SCI-Diabetes. This was of particular issue when distributing the questionnaire to primary care users. In primary care, most system access and data entry is carried out by practice nurses, however some general practitioners may use the system more extensively (if, for example, they have a special interest in diabetes).

Neither pre nor post-intervention questionnaires were validated. The post-intervention questionnaire had been adapted from a previous study by translating from Flemish into English by the authors. The questionnaire constructs in the original questionnaire demonstrated good internal consistency, but neither Flemish or English versions of questionnaire were validated. This makes it difficult to draw any firm conclusions when analysing construct scores – it may be that the lack of significant findings simply reflects lack of face validity. The decision to adapt the Flemish questionnaire was made with a view to allowing future collaboration between study groups, making validation a future possibility.

The low number of respondents made it difficult to draw any statistical inference. This was in part a reflection of the low number of users to whom the questionnaire was distributed. Whilst not particularly high, the response rate was comparable to other electronic questionnaires [145]. The chosen medium of distribution affects response rate, with online questionnaires resulting in one of the lowest rates [146]. Financial inducements have been shown to improve response rates [145],however these vary depending on how the inducement is made – prepaid, small, monetary incentives have been shown to significantly increase response rates in comparison to rewards made contingent on return of the questionnaire [147], and this is worth considering in the future.

The lack of identifiers meant that analysis was unable to draw any paired comparisons between before and after EBMeDS implementation. The decision to only collect anonymous data was made from an information governance perspective. This allowed the use of a cloud-based server (Google Drive) to distribute the questionnaire and collect responses electronically, with a view to improving response rates.

6.6.6.2. Conclusion

There would appear to be a degree of mismatch between HCPs' positive attitudes to the use of a CDSS and low reported usage once the system was implemented. This is perhaps unsurprising given that reported access to EBM prior to the intervention was mostly outwith the clinical consultation. The relative seniority of the HCPs that took part in this study may also influence system usage, in that the CDSS may have less utility for this group.

The moderate scoring within each of the questionnaire's constructs meant that the theoretical model failed to identify any particular facilitators or barriers to uptake. These scores are consistent with EBMeDS evaluations reported elsewhere.

Most users expressed ambivalence to the system (as opposed to complete rejection). Further qualitative work was therefore required to identify which aspects of the system were most useful to users and which, less so (see section 6.7).

6.7 User opinion focus groups - Health Care Professionals

6.7.1. Abstract

6.7.1.1. Introduction

Clinical Decision Support Systems (CDSS) offer automated prompts to Health Care Professionals (HCPs) via the electronic health record (EHR), within the normal clinical workflow. There is a lack of published literature concerning factors that influence CDSS uptake. This study adopts a qualitative approach to explore attitudes to CDSS within a diabetes EHR and to identify facilitators and barriers to effective uptake of the CDSS. This study forms one aspect of a wider quality improvement project assessing the effectiveness of the CDSS.

6.7.1.2. Methods

Three focus groups were conducted, each comprising 8-9 HCPs of varying roles within the diabetes departments taking part in the study. The first focus group explored attitudes to CDSS and the use of guidelines in general prior to implementation of the CDSS. The second group gave initial reaction and feedback following the first improvement cycle. The system was amended in light of this feedback and the third focus group gave their reaction to these changes. A constant comparative approach identified emergent themes, which were then related to a recently published theoretical model describing the differing attitudes to CDSS adoption.

6.7.1.3. Results

Prior to implementation, HCPs were generally receptive to the idea of a CDSS and could appreciate its utility. There were concerns regarding: user fatigue; insufficient tailoring to role; covert surveillance of system use; and the applicability of guidelines in general to a complex patient population. Following implementation, there was evidence of early adopters using the system within their normal clinical workflow in order to improve the efficiency of their EHR use. However, most users reported minimal usage, despite seeing the potential advantages of the system. Amongst the secondary care specialist team, It was felt that the CDSS had greatest utility in an educational capacity for other, less experienced HCPs. Barriers to adoption included: lack of time; fatigue at the number of messages displayed; problems with the underlying EHR (e.g. data feed); and the user interface (UI). The UI was amended prior to the second improvement cycle and subsequent feedback was positive.

6.7.1.4. Conclusion

Whilst the CDSS has become part of the normal workflow for some users, for most, engagement is limited. Users acknowledged that the CDSS has its merits, thereby making it likely that usage will increase as content and functionality improve in light of feedback.

6.7.2. Introduction

There are a number of technical features within clinical decision support systems (CDSS) that have been found to be associated with successful adoption [61]. These facilitators include the automatic provision of treatment/management recommendations (as opposed to simple assessments), via computer systems that act within the normal workflow. There is a paucity of published studies assessing cultural/sociological factors that lead to successful adoption of CDSS. This study sought to build upon this limited evidence by engaging with health care professionals (HCPs) in an effort to identify facilitators and barriers to using a CDSS.

6.7.3. Objectives

Prior to implementation of the CDSS, a focus group was convened in order to:

- Describe the role that clinical guidelines and other resources currently play in clinical decision-making and practice, and how these are accessed.
- Explore attitudes to the possibility of embedding automated, tailored clinical decision support tools within the SCI-Diabetes electronic health record

Following each improvement cycle a further focus group was held with users of the system. There was a degree of overlap with the pre-implementation focus groups in that they were designed to:

- Explore attitudes to using the Evidence Based Medicine electronic Decision Support (EBMeDS) system
- Identify potential barriers/facilitators to effective adoption elsewhere
- Identify potential improvements to the system

6.7.4. Methods

Participants were identified as a convenience sample of workers within the NHS Tayside and NHS Lothian diabetes teams. Participants were invited to attend by an email that contained a participant information sheet. Attendance was voluntary, with the meetings held in place of regular, lunchtime departmental meetings and took place in a variety of venues within the relevant hospital. Consent was obtained from all participants to retain and use their anonymised data for research and publication.

There were 3 focus groups held in total – one prior to implementation (NWH) and one each at the end of improvement cycles 1 (NWH) and 2 (SJH). For the pre-implementation focus group, seating was arranged in a semi-circle with the moderator seated in the centre, and lunch was not provided. Both of the subsequent focus groups took place round a table, over lunch that was provided for participants. Participants for the pre-implementation focus group were 4 Diabetes Specialist Nurses (DSNs); 3 consultant physicians; 1 GP; and 1 specialist trainee. The post-cycle 1 focus group comprised: 3 DSNs; 1 consultant physician; and 2 specialist trainees. Additional feedback was provided, via a trainee, from a consultant who gave his apologies. Finally, the post-cycle 2 focus group comprised: 4 DSNs; 2 consultant physicians; 1 staff grade physician; and 1 podiatrist. There were two additional observers from the project group present at focus groups 1&2 and one additional observer at focus group 3 who help with administrative tasks and took contemporaneous field notes.

Meetings lasted for approximately 45 min. A topic guide was prepared prior to the meetings that were facilitated by the moderator (researcher) - see appendix (section 17) for the pre-implementation topic guide. Discussions were digitally recorded via a laptop computer. Field notes were taken and summarised by the moderator immediately after each meeting. The audio files were later analysed in greater depth by the researcher using a constant comparative approach whereby data were grouped into themes and categorised [148]. This was achieved using audio file annotation software (Sonocent, audionotaker) that parsed the recording into manageable sections that could then be classified and extracted according to category [149]. Data from both post-implementation focus groups were considered together to identify emergent themes. Quotes of interest were initially highlighted using the audio annotation software before being transcribed by the researcher to be included in the final report. Anonymised identifiers were generated for each participant and consisted of two parts: the focus group that the participant took part in (e.g. FG*x*) and the role of the participant (e.g. DSN*y*).

6.7.5. Results: focus group 1 (pre implementation)

6.7.5.1. General support

There was general support for the idea of a CDSS, so long as it did not detract from the consultation or become intrusive. In particular, there were a number of possible advantages identified, including its use to encourage holistic care:

> *"One of the good things about this will not be so much the decision support, but the reminder to act…Quite often people [HCPs] are not doing the things that are seen as important, because other things are taking priority, but if a patient leaves having had a more holistic care package offered to them, then that's beneficial".* FG1 GP.

Another potential advantage was that the system could be used when training junior members of staff. For example, the resources referred to by the CDSS could be used to justify/explain why a particular management decision has been made. However, the use of the system in this way would again be dependent on how much time the clinician had within the outpatient clinic:

> *"If you had a student in with you in clinic, and you had lots of time [laughter], and you weren't seeing lots of patients, then you could say "this is how we managed Mr X and the blood pressure target was based upon that guideline or this guideline and you could refer them to it. So there it would be great, useful tool. But you could have that as a separate lane that may be used for teaching purposes"* FG1 Consultant 2.

In response to the problem of time, it was suggested that a "dummy", training SCI-Diabetes environment could be used. Not only would this allow new SCI-Diabetes users to practice using SCI-Diabetes, but it would enable them to use the CDSS and access the additional resources that it links to.

There was a lack of enthusiasm for the CDSS to play a role in recording Continuing Professional Development (CPD). This was partly as there were concerns that the recording of reading for CPD purposes does not reflect whether or not the individual has learnt to apply their knowledge:

> *"It just tells you that you've read it, it doesn't tell you if you've learnt it"* FG1 DSN2

There were also concerns regarding the surveillance of users and if this information could be used in a negative way:

> *"It's a good thing if it records it, but it's a bad thing if when you go for your appraisal they say "well, actually, it looks like you haven't looked at these guidelines at all, whereas you may well have looked at them in a different context. So it's a good idea, so long as it doesn't work against you".* FG1 Consultant 1.

6.7.5.2. Tailoring

All participants agreed that the typical patient that is seen in a secondary care clinic differs from that seen in primary care. In the latter setting, it was considered that the majority of patients seen with diabetes are those with T2D who are on minimal medication and have little co-morbidity, whereas those seen in secondary care tend to have more complex medical issues and poorer control. It was argued that many guideline suggestions are not applicable for a lot of these patients, and that management should be guided primarily by clinical expertise:

> *"In hospitals, it's almost a license not to practise guidelines and to use your expertise to say that the guidelines are going to be inappropriate for this individual, for whatever reason. Or, not aggressive enough for this individual, because they are actually 16 and you want them to spend their entire life at much, much lower levels"* FG1 Consultant2

This contrast was one of the reasons why a "one size fits all" approach would not be welcomed, as targets for clinical outcomes may be unachievable in certain patient groups.

6.7.5.3. Facilitators

The concept of tailoring message to professional role was raised as a possible way to avoid user fatigue:

> *"Could the system depend on which clinician is using the system? Say for example [name] was doing her clinic and she felt that she was overseeing this patient that she knew, but me as a member of staff would actually like all these clinical alert messages coming, so that I gained that experience. So I have the alerts switched on, but [name] has the alerts switched off"* FG1 DSN1

However, it was pointed out by others that this may impact on the users' awareness of clinical targets in that users may become *"a bit blasé"* about targets in general.

Another possible solution to user fatigue was colour-coding alerts to differentiate between important safety issues ("red alerts") and more general reminders.

6.7.5.4. Interface between primary and secondary care

There was a tension between primary and secondary care that emerged when discussing the role of reminders for screening tests e.g. blood pressure or urinary samples. There are prescribed intervals for each of these investigations (described in national guidelines) that form the basis of quality performance indicators (QPI). These QPIs form the basis of the primary care Quality & Outcomes Framework [150] which provides a financial incentive for primary care practitioners to adhere to best practice. As a result, it was felt that those working in secondary care are perhaps not as aware of the importance of QPIs, to the detriment of patient care and efficient working practices:

> *"What primary care would say, is that they get distressed for contractual reasons when people are seen at the hospital and don't get their feet checked for example, or don't get a urinary ACR* [Albumin Creatinine Ratio] *checked and we have to pull them back in just for that, so from my perspective, something that works effectively to remind [name] to check the ACR, or [name] to check the feet. But then that's because primary care has a performance related pay issue. But it's also good for the patient. So if there are aspects of what's considered to be "good quality review" that are being forgotten and can be reminded, that, to me, is good".* FG1 GP

In mitigation, those in secondary care argued that often a test is not completed owing to other uncontrollable (i.e. patient) factors and this does not necessarily reflect a lack of awareness by the diabetes specialist; that"*It's not usually because we are being negligent about not doing it…"* (FG1 consultant 1)

6.7.5.5. Limitations of guidelines

One of the main limitations of a CDSS from the perspective of the participants was its reliance on clinical guidelines that are not always applicable to certain patient groups:

> *"I think it [CDSS] is a reasonable approach, I think the limitation of a clinical decision making system is that it is based upon guidelines, which are in themselves limited - they're based upon populations and not individuals… Within the specialist setting…there is a need to individualise therapy. We're all aware of guidelines, we have to adapt those guidelines to suit the individual"* FG1 Consultant 2.

As well as being population-based, it was suggested that guidelines are quickly rendered out of date; are unable to be updated timeously; that supporting evidence is often from trials involving a cohort that is unrepresentative of the average clinic patient (e.g. the frail elderly with co-morbidity); and that the evidence base is lacking due to the tendency for industry-sponsored clinical trials being designed to show lack of harm as opposed to clinical benefit.

Unsurprisingly, the decision to override a guideline was something that more senior members of the team were more comfortable with. Less experienced staff (e.g. trainees) and those from non-medical backgrounds (e.g. DSNs) would consult with their senior colleagues before making such decisions, in recognition that the resultant advice may not only differ from the guideline (*"you have to weigh up experience, that carries a lot of weight"* FG1 StR) but may differ between individuals:

> *"If you ask several seniors, then you might get different answers…because if it's not within the guideline, then it will be "expert opinion" which will therefore vary, but doesn't mean to say that one's right or wrong"* FG1 DSN3

Again, the contrast between this arrangement and the circumstances of those working in isolation was made:

> *"I think we're very fortunate in that we are surrounded by experts who are very experienced, but I think it would be a very different story in primary care."* FG1 DSN1

> *"We are much more reliant on local or national guidelines and would follow them moderately slavishly."* FG1 GP

Whilst it was noted that strictly following guidelines has the potential to prompt GPs to adopt a more aggressive treatment option that may not be in the patients' best interests, there was agreement that this is a limitation of guidelines and not the CDSS *per se* and that CDSS may confer additional advantages to the lone worker in primary care:

> *"So that's no worse than the situation at the moment. Whereas at the moment we would try and find out what the guideline said, and that might not be very easy to do and we might also miss situations that we should have picked up on if they weren't pointed out to us".* FG1 GP

6.7.5.6. Fatigue

Owing to the complex nature of the patients seen in secondary care, there was an anxiety that alerts would be triggered for almost all patients attending clinic. As a result, it was feared that the alerts would initially be "intrusive" before being "devalued" as users start to ignore them. This could potentially impact upon patient safety if users fail to differentiate between types of alerts e.g. if "*the ones [alerts] that are focused on targets may put at risk the ones that perhaps are more to do with clinical safety"* (FG1 GP). Again, this led to the suggestion that the CDSS may be more applicable to primary care patients with less complicated disease. An alternative to CDSS was also mooted, whereby the existing SCI-Diabetes audit system was used more effectively e.g. monthly QPI reports.

6.7.5.7. Other risks

There was agreement that users should not infer that absence of a prompt is indicative of no active clinical problems. The risk of others doing so was felt to be low.

Of greater concern was the question of clinical responsibility for those that receive prompts from the CDSS. The DSNs are the most frequent users of SCI-Diabetes and access the system in a variety of settings, including telephone contacts. It was suggested that the presence of a CDSS alert, that is unrelated to the task in hand, may introduce an unsustainable increase in DSN's workload, as they may feel that failure to act on the advice may be construed as being negligent:

> *"Potentially the nurses could have all these alerts coming up, but it's not appropriate for them to deal with them at that time, but they might feel that actually they need to do something about this."* FG1 DSN1

This, in turn, introduces an additional problem for the DSN, as it may not be immediately clear which clinician they should liaise with (e.g. GP, consultant or trainee). There is also the potential for patient anxiety, if the DSN chooses to share the information with the patient when it may not be appropriate to do so.

Similarly, non-clinical staff (e.g. administrators) accessing the system may also be confronted with alerts, which may place them in the vulnerable position of being unable to assess which alerts require immediate action (e.g. those related to patient safety).

6.7.6. Results: focus groups 2&3 – post implementation

6.7.6.1. Use of CDSS and SCI-Diabetes in general

When assessing reaction towards the CDSS, consideration must be given to the context in which SCI-Diabetes is being used. For example, the greatest users of SCI-Diabetes are the DSNs and much of their time using the system is in order to answer quick queries about a specific problem (e.g. telephone advice regarding blood glucose readings), as opposed to more involved use when patients are inpatient or in clinic.

SCI-Diabetes is also used for retrospective data entry following a clinical encounter. In these cases the CDSS message is no longer relevant to the task in hand.

All users observed that a CDSS message was triggered in the vast majority of patients (*"I haven't opened a record and it hasn't had an alert"* FG2 DSN3). As a result, the absence of an alert was considered unusual[4]*:*

> *"I've occasionally had a patient that hasn't had an alert, and I've thought, "why's he not got an alert?"* FG2 C3.

The most useful component of the CDSS system was the short message displayed in the initial pop up window. It was felt to contain sufficient information was easy to refer to. Users (nurses and doctors) reported using this to guide the subsequent consultation by briefly noting the contents:

> *"I give it a quick scan"* (FG3 DSN1)

[4] In light of these observations, script thresholds and content were reviewed, resulting in a reduction in the number of messages being triggered.

There was no evidence of the CDSS adversely affecting the consultation or normal workflow. Some SCI-Diabetes users open the patient record prior to seeing a patient, in which case they have time to consider the recommendations and, if appropriate, guide the subsequent consultation to address them. Further navigation within an individual's clinical record does not result in the short message being displayed again (unless the user floats over the alert icon). This was considered a good thing (FG3 DSN1).

It was rare for users to report navigating to the long message and no users used the hyperlink to navigate to the underlying guidelines.

> *"We generally know why it's prompting us…you know, I think we know what we should be doing…and sometimes it doesnae get done when it should get done…but I think we generally know the evidence behind it"* (FG3 DSN2)

The participants were keen to feedback on their experience of SCI-Diabetes in general as there were obvious frustrations with the existing system (unrelated to the CDSS). It was noted that if the system were to be broadened to other health boards and clinical settings, uptake would vary markedly owing to differing usage of SCI-Diabetes and varying levels of IT literacy.

6.7.6.2. Facilitators to using the CDSS

6.7.6.2.1. Clinically useful

There was some evidence that the CDSS messages are influencing clinician behaviour by highlighting issues that may not have been addressed.

> *"I generally have gone into the alerts and had a look at them, and most of the stuff is stuff that I would have picked up on anyway, but there has been the occasional thing that has prompted me to ask an additional question or two."* (FG2 C3)

For example, reminding the clinician of a possible use for metformin in specific patients. In practice, all patients that were asked had a good reason for why they are not on it, but *"it was probably still useful to go through the process"* (FG2 C3)

Clinicians reported that the CDSS is enabling users to make targeted data queries for items that they currently find it difficult to locate within SCI-Diabetes:

> *"one of the things that I find more useful is the things that I'm not very good at* …[finding]*…so, I'll see someone's blood pressure, and I'll know it's high, but if the computer is prompting me that they've also got microalbuminuria then it, kind of, saves me looking it up…and if it's prompting me that they've got a high cholesterol and they're not on a statin, it's, again, it's something that's just an extra prompt for things that I kind of forget."* (FG3 C1)

> *"It then saves you going into all the individual screens and looking at things, and, you know, SCI-Diabetes is getting bigger and bigger all the time and so there's more to look at, so it lets you be more…choosy about what you look at"* (FG3 DSN2)

Despite the fact that some messages were not directly applicable to the user's role within the multidisciplinary team, it was felt that this was still useful information as it may serve to guide subsequent clinical decisions. For example, nurses who do not prescribe are still involved in the decision to commence/discontinue medication - *"we* advise [laughs] *doctors what to prescribe"* (DSN2).

6.7.6.2.2. Educational role

The CDSS messages were felt to be of greatest utility to someone who is new to the team and who has not previously worked with SCI-Diabetes.

"Because we've not had alerts before, I've got into the habit that when you open up the record, you scan down: when did they last get they're feet screened; when did they last get their last diabetes eye check done, and you almost go through an automatic process….whereas somebody new who is not tuned into that way…[of working]*…they may go straight into an alert and the alert tells them all of that information"* (FG2 C3)

If I was new into the team, I'd probably be wanting to read all of these things to make sure I wasn't missing anything…[I wonder]*…if our response is because we're maybe a bit more familiar with what we are looking for."* (FG2 DSN3)

There was little use of the CDSS for medical education purposes, mainly due to time constraints within the clinical context.

"Generally yeah, it'll lead you onto something else...it was highlighting something to you…but then the link that you are going into is also time consuming" (FG2 DSN4)

6.7.6.3. Barriers to using the CDSS

6.7.6.3.1. Time and fatigue

A recurring them between both focus groups was one of user fatigue:

"I think I've started to ignore them" (FG2 DSN3)

"Because there's too many?" (moderator)

"Yeah" (FG2 DSN3)

"Is it annoying?" (moderator)

"I just don't bother with it now" (FG2 DSN3)

…and lack of time:

"It's time consuming, doing SCI-Diabetes, at the best of times…with those popping up, it's just something else that you've got to look at, and sometimes I look at them, but generally…" (FG2 DSN4)

6.7.6.3.2. Context

As mentioned above, usage of SCI-Diabetes varies and so the CDSS message may not be appropriate to the context in which it is being used. For example the CDSS message may remind the HCP to check the patient's feet during a phone call related to glucose control. In this example, there is very little the HCP can do other than to recommend a visit to the GP. In other instances, the CDSS message is directly relevant to the clinical encounter, however the consultation has been planned in advance to address the very issues identified by the CDSS message e.g. an annual review appointment:

> *"the annual review stuff I find less helpful because usually we're doing it anyway...there are too many things…and you won't look at it…and if it alerts every single time that you open it up, you kind of think, "oh, it's just alerting me again because it's a year since I last saw them"* (FG3 C1)

In addition to problem of lack of relevance to the clinical context, the messages are not always relevant to the clinical role. Whilst it is acknowledged that messages can influence the working of the multidisciplinary team (MDT) beyond traditional roles (see above), not all users find all messages to be of utility e.g. a podiatrist using SCI-Diabetes.

6.7.6.3.3. Data

It was noted that there is a lag period between data being entered into the SCI-Diabetes system and the CDSS considering these new data, however this is related to the SCI-Diabetes data feed and not a problem inherent with the CDSS *per se*.

6.7.6.3.4. User interface (UI)

The appearance of the CDSS message evolved during the course of the study in response to user feedback. Initially, the short CDSS message appeared as a yellow box in the bottom right of the screen. Whilst this was easily visible (*"Well you certainly can't miss it!"* FG2 DSN3), there was a lack of awareness as to how to access further content once the initial message had disappeared:

"[Once the short message has faded away] *I don't know where to go…"* (FG2 StR2)

The behaviour of the short message was altered in response to this initial feedback - the short message was reconfigured to appear as a tool tip, associated with an alert icon in the top right corner of the screen. This change resulted in most focus group 3 users expressing satisfaction with the UI. However the change was problematic for some as the tool tip temporarily covers a commonly used tab (tab to navigate to clinical comments page). As a result, some users had developed workarounds in order to navigate past the CDSS message quickly.

The time that the short message is displayed (default is 5 seconds) was not always ideal. For some it is too short:

> *"It pops up and it disappears quite quickly, usually in the time that I haven't read all of the things it suggests, but I guess it's usually stuff that you would be, hopefully, thinking about anyway"* (FG3 C2).

> *"I rarely have time to read it, probably because I open someone's record whilst talking to them…and when I turn back to the screen, that's usually gone…it's good that it comes up because it will remind me to click on the clinical alert [icon]…It jogs my memory, but I rarely have time to read it before it goes"* (FG2 C3)

Whereas for others, the 5 seconds default is too long. This latter group are mainly the nursing staff that would like to access parts of the UI that are obscured by the message:

> *"*[the short message] *gets in the way…[of]…clinical comments and new comments"* (FG3 DSN1)

> *"The alert is always where you want to click on to make a new contact!"* (FG3 DSN2)

Users were seemingly unaware of the option to configure the behaviour of the short message (available under user settings) that would solve this issue.

6.7.6.4. Possible amendments

Participants were asked for possible changes that could make the system better. One such change has already been mentioned (appearance of the short message). Other suggestions included:

- Flagging of recent adverse events e.g. recent hospital admissions; hypoglycaemic events
- Data entry validation for data items that require manual entry e.g. a reminder to record when a patient has taken part in an educational course.
- Development of algorithms that process blood glucose data with the aim to improve glycaemic control
- Avoidance of repetition (*"the trouble is that during the next consultation they'll probably get asked the same question again."* FG2 C3)
- Greater user control over system behaviour
- Tailoring of system to user role and context

6.7.7. Discussion

The emergent themes from both pre and post-implementation focus groups are presented in Table 10.

Table 10. Emergent themes from focus groups

Pre-implementation	Post-implementation
General support for concept of CDSS	Facilitators:
Possible facilitators:	Clinically useful and relevant
Educational role – staff induction	Educational role
Tailor messages to role	Barriers:
Colour coding of message importance	Lack of time
Possible barriers:	User fatigue
Surveillance of use	Lack of clinical context
Limitation of guidelines	Data feed issues
User fatigue	User interface
Inappropriate responsibility to take action	

Prior to implementation, there was a general consensus that the concept of CDSS was a valid and potentially useful addition to the clinician's toolkit. There were some minor concerns expressed e.g. user fatigue; covert monitoring of system usage; and concerns regarding the messages not taking into account user role. There were no concerns that the CDSS would have an adverse effect on the consultation or doctor-patient relationship. The biggest shortcomings identified were actually unrelated to the CDSS *per se*. Firstly, there was an obvious tension between the perceived contrasting working practices in primary and secondary care. Secondly, there was an acceptance that the guidelines on which the CDSS is based are themselves limited in terms of applicability to the more complex patients seen in secondary care.

The post-implementation focus groups demonstrated general support for the CDSS with some suggested amendments to improve functionality. There was also a desire for the system to be more tailored to clinical context and role, thereby echoing the pre-implementation focus group findings. Again, there were issues identified that were unrelated to the CDSS *per se* and were principally related to the SCI-Diabetes data feeds, whereby certain data items were not updated in real time. It should be acknowledged that the CDSS relies on contemporaneous data to deliver relevant advice. For example, when metformin is indicated, the relevant script makes an assessment of renal status and advises a dose reduction if function is impaired. If an individual's renal function has recently deteriorated, the absence of the relevant biochemistry results could result in an inappropriately high dose of metformin being prescribed. Whilst this could be viewed as a clinical risk, it could also be argued that this risk is not increased by the use CDSS – the prescriber needs to take account of renal function before prescribing the drug and should, therefore, review the most recent results before doing so.

Some of the suggested amendments from focus group 2 were implemented prior to focus group 3. These changes mostly related to the UI and included:

- The short message was amended to include colour coding of message importance

- Users could now choose the duration that the short message is displayed prior to fading automatically
- The short message was moved to become associated with a CDSS icon that persists after the message fades
- "Floating" over the CDSS icon will result in the short message being viewed again.
- Removal of scripts that, although different in their logic, resulted in similar advice to the user e.g. the prescription of antihypertensive medication for patients with renal disease and/or hypertension. In the event of both clinical entities, messages were displayed in duplicate.

Following these changes, the feedback was generally positive. Users within focus group 3 reported that the system supported more efficient working practices by enabling them to quickly identify problem areas. There was clear evidence of fatigue, however, with most users reporting that their use of the system was limited to the short initial message as opposed to looking at the longer message or the evidence behind the prompt. It was felt that this latter feature was perhaps more suited to an educational context where there was greater time available to the individual.

Studies concerning CDSS tend to concentrate on describing the practical and technical nature of the intervention and the subsequent effect on clinical processes and outcomes. There are very few studies examining why and how CDSS become adopted by users. The generalisability of such studies is limited owing to the differing nature of the CDSS; the clinical context; and the setting [151–155]. In accordance with previous qualitative work assessing HCPs' views on CDSS (and the practice of evidence based medicine (EBM) in general) [151,152,156], all users reported a lack of time to fully engage with the CDSS when seeing patients. In their recently published qualitative study of Italian HCPs working with a CDSS, Liberati et al identified six distinct groupings of attitude [153]. These groupings were dependent on two main factors – acceptance of technology and readiness to accept evidence based medicine – and were arranged along a spectrum ranging from complete rejection to successful integration of CDSS into the clinical workflow (see Figure 26). These 6 groups are described as being:

1. Total rejection – EBM is not useful and technology is viewed as a threat to status
2. Threatened control – CDSS could be adopted, but this would usurp all expertise, resulting in a dichotomy of total rejection or total acceptance towards all CDSS advice.
3. Distrust of the evidence – The technology is seen as less of a threat, however users feels that the evidence is potentially flawed e.g. distrust of guidelines.
4. Instrument of the other – The usefulness and applicability of the CDSS is acknowledged, but is seen as a something of use to someone else.
5. Potential recognised – The CDSS content is accepted but technological competence acts as a barrier.
6. Fully integrated and competent – The user has fully adopted the CDSS within the normal workflow and the CDSS becomes an instrument of a "shared community of practice" whereby users collaborate to improve the system.

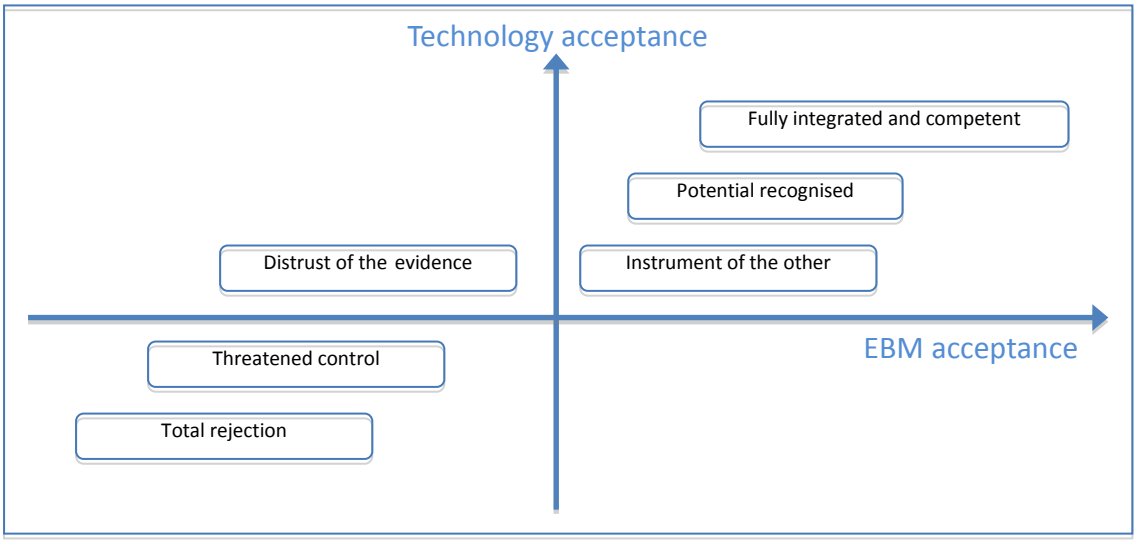

Figure 26. Theoretical model for identifying users' readiness to adopt CDSS. Adapted and translated from Liberati et al [153].

When relating this model to the focus group discussions, it was clear that, aside from a few early adopters, most participants were in the “instrument of the other” group whereby the usefulness of the system is acknowledged, but it was felt to not apply directly to their own work. Instead, the participants of the focus group felt that the CDSS had greater applicability to the stand-alone general practitioner who may not be as familiar with current guidelines. This may well be the case, however it would be wrong to suggest that there is no room for improvement in clinical care provided by the participating secondary care teams. It is, therefore, incumbent upon system developers to ensure that all users can realise the potential of the system – by adapting content and/or functionality improving functionality, it is hoped that the CDSS will become part of normal working patterns.

6.7.7.1. Limitations

The decision to adopt a convenience sample for the focus groups was made out of necessity, owing to participant numbers. Nevertheless, it was felt that data saturation had been reached and there were no new, emergent themes by the end of the third focus group. It is acknowledged that within this sample of workers from within the same organisation, there are likely to be power differentials that may affect how ideas are expressed and may also skew findings. Nevertheless, it was felt that all participants were given equal opportunity to contribute, and the multidisciplinary nature of the clinical team meant that participants were used to contributing to group discussions amongst colleagues.

There was a tendency for senior clinicians to contribute more to the discussion than their nursing colleagues. This was especially evident during the pre-implementation focus group. The decision to provide lunch and arrange seating around a table had a positive effect in encouraging all to participate as the tone of the meeting became more relaxed and less staid.

Finally, it is acknowledged that there is a high probability for observer bias. The researcher who moderated and analysed the focus groups has also worked on developing and implementing the CDSS. The inclusion of additional observers from the project team allowed field notes to be compared. In addition, user questionnaires were also distributed (see section 6.6) in an effort to triangulate the measurement processes.

6.7.8. Conclusion

The focus group findings suggest that there is evidence of the CDSS becoming part of the normal workflow for some users. For most, however, their engagement with the system is currently limited. Users acknowledge that the CDSS has its merits and so there is the potential for increasing system use. It is incumbent on system developers to improved content and functionality in line with user feedback. In particular, there would seem to be less demand for greater access to the evidence underpinning the CDSS recommendations and it may be that consideration should be given to reconfiguring this particular aspect of the system in an effort to improve accessibility and increase uptake.

6.8 Use of the system

6.8.1. Abstract

6.8.1.1. Introduction

System usage is an important consideration in the evaluation of whether or not an information system (i.e. EBMeDS) has been successfully adopted. The SCI-Diabetes audit trail allows for interrogation of user behaviour within the system. This study aimed to characterise usage patterns for different health care professional (HCP) roles; to quantify time spent accessing clinical records with respect to these different user groups; and to compare usage patterns between instances where users received a clinical decision support system (CDSS) with instances where no such message was displayed.

6.8.1.2. Methods

Data were extracted from the SCI-Diabetes audit trail for all users of the system within the Ninewells diabetes clinic domain, over a 3-month period, commencing December 2013. The primary outcomes were number of user "clicks" within patient record and duration of time that the patient record opened. Comparison was made between presence or absence of EBMeDS message using multivariable generalised estimating equations. Possible confounders included within the model were: number of EBMeDS messages; patient comorbidity score; diabetes type; insulin therapy and socioeconomic status.

6.8.1.3. Results

The SCI-Diabetes audit trail contained 760,666 rows of data for the time period being considered. Within these data, 17,280 patient records were opened, belonging to 5355 unique patients. The median number of times a record was opened was 3 (range 2-56, IQ range 4). A CDSS message was displayed on opening 6665/17280 patient records (39%). When displayed, the median number of messages was 3 (range 1-12). Presence of a CDSS message had no association on the duration that the record was viewed by nurses, however the number of mouse clicks made by nurses within the patient record was significantly increased when a CDSS message was displayed (median number of clicks (IQ range) 19 (8-37) versus 16 (7-32), adjusted p=0.014). For doctors, the duration that the record was viewed was significantly reduced when a DSS message was displayed (median duration (IQ range) 33 sec (5-86) vs 38 sec (12-97), adjusted p=0.032), with no other significant confounders. The presence or absence of a CDSS message had no relationship with number of clicks made by doctors.

6.8.1.4. Conclusion

This analysis has quantified system usage by members of the multidisciplinary team in terms of duration that the record is viewed and the number of user clicks within that record. The presence of a message was associated with some differences in user behaviour, but this was dependent on user role. The clinical significance of these observed difference remain unknown and inference is limited by study design. Further analysis is required to assess whether these differences translate into changes in clinic processes and outcomes.

6.8.2. Introduction

When determining how succesful an information system is, attention must be given to what defines success. DeLone and McLean attempted to do so by developing their *model of information systems success*, based on a review of the literature from the preceding two decades [157]. The resultant debate amongst sociologists regarding the validity of their proposed model is well documented by the original authors in further updates [158], but it would appear that consensus has emerged that it is a valid approach [159]. The model identifies 6 main dimensions that are postulated as being causal determinants of success: system quality; information quality; system usage; user satisfaction; individual impact and organisational impact (see Figure 27).

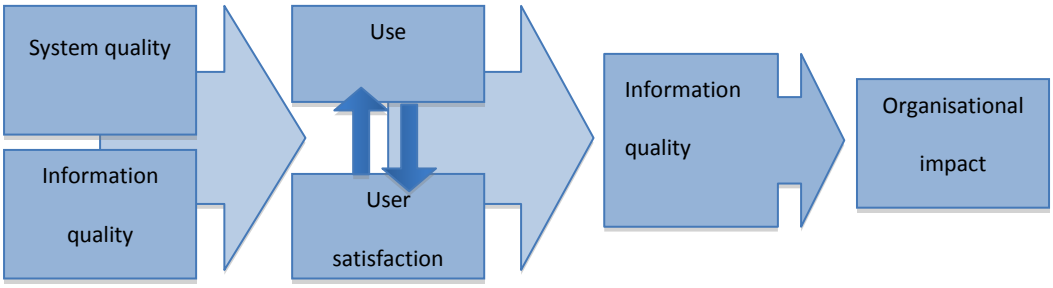

Figure 27. DeLone and McLean's Model of information systems success. Adapted from original paper [157]

The previously described qualitative work assessed attitudes to (and satisfaction with) the clinical decision support system (CDSS) - questionnaires described self-reported indvidual use (section 6.6), whilst focus groups explored use of the system at the group level (section 6.7). This study is designed to further describe individual usage of the CDSS by quantifying users' behaviour within the SCI-Diabetes electronic health record (EHR), with a view to assessing whether or not the CDSS had any effect on this (in terms of navigation through the system).

The SCI-Diabetes audit trail allows remote observation of users' interaction with the system. Users consent to remote monitoring when agreeing to the terms and conditions of use. Log files prospectively collect usage data and record when users retrieve or submit clinical information and how they navigate through the system. These files contain a large dataset, comprising a logged event(s) for every interaction that users have with SCI-Diabetes. These data were used to address the question – is the CDSS associated with a change in system usage?

6.8.3. Objectives

- To characterise typical usage patterns within SCI-Diabetes within different user groups (e.g. doctor, nurse etc.)
- To quantify time spent accessing clinical records with respect to these different user groups
- To compare usage patterns between instances where a CDSS message was displayed and when there was no CDSS message.

6.8.4. Methods

Data were extracted for the relevant SCI-Diabetes domains that took part in improvement cycle one. This included the NWH diabetes outpatient clinic and one primary care practice within NHS Tayside between 2/12/13 and 1/3/14 inclusive.

Owing to the large amount of extraneous data the files requiring extensive data cleaning prior analysis. Data cleaning was conducted using SPSS syntax written by the author (see appendix - section 18).

The data cleaning process reduced the file down to the following variables:

- User ID – anonymised HCP identifier
- User role – HCP discipline
- Patient ID – anonymised patient identifier
- Time when patient record opened
- Number of user “clicks” within patient record
- Duration of time that patient record opened
- Presence or absence of EBMeDS message
- Number of EBMeDS messages displayed

In addition to navigation data, a separate data query was made with respect to potential patient confounders. These included:

- Diabetes type
- Diabetes treatment
- Co-morbidities
- Deprivation category (SIMD)

Co-morbidity was considered a confounder as this has the potential to influence consultation time and management – it was assumed that a patient with much co-morbidity is more likely to have active medical problems, necessitating a longer consultation time. SCI-Diabetes data were used to construct a "comorbidity score", which was calculated using a modified version of the Charlson Co-morbidity Index (CCI) [160]. SCI-Diabetes routinely records 7 of the 19 conditions that contribute to the CCI – see Table 11.

Table 11. Charlson co-morbidity index and the availability of these data within SCI-Diabetes

Score	Condition	SCI-Diabetes data item
1	Myocardial Infarction	Yes
	Congestive heart failure	Yes
	Peripheral vascular disease	Yes
	Cerebrovascular disease	Yes
	Dementia	No
	Chronic pulmonary disease	Yes
	Connective tissue disease	No
	Peptic ulcer disease	No
	Mild liver disease	No
	Diabetes with no complications	Yes
2	Hemiplegia	No
	Moderate or severe renal disease	Yes
	Diabetes with end organ damage	Yes
	Tumour (without metastases)	No
	Leukaemia	No
	Lymphoma	No
3	Moderate or severe liver disease	No
6	Metastatic solid tumour	No
	Aids (not simply HIV+)	No

Not all of the SCI-Diabetes data items were exact matches for the CCI and so some inference was required to attribute scores. In particular, diabetes with "end organ damage" was inferred present if any of the following were recorded in the patient record: retinopathy; maculopathy; foot risk score of medium, high or active foot disease (or amputation).

A modified comorbidity score was then calculated out of a possible total of 9 based on presence or absence of the conditions listed in Table 11. An analysis of frequencies was used to determine appropriate bins for score (e.g. tertiles versus quartiles).

Generalised estimating equations were used to allow for analysis of repeated measures. There were 2 potential dependent variables of interest that could be used to address the research question – number of user "clicks" in patient record and duration that patient record opened. The independent variables of interest include user role; presence or absence of EBMeDS message; number of EBMeDS messages; patient comorbidity; diabetes type; insulin therapy and socioeconomic status. Univariable analysis was initially undertaken for each dependent variable, with a view to including all independent variables with significance to $p<0.1$ within the multivariable analysis. In an effort to achieve a model with best fit, both poisson and gamma distributions were considered for the dependent variables as was the use of log transformation. Assessment of residuals for evidence of random distribution determined the model of best fit.

6.8.5. Results

The cycle 1 raw data file contained 760,666 rows of data. After cleaning, the dataset contains 17,280 rows – each one representing a patient record being opened. The 17,280 records being opened were for 5355 unique patients. The median number of views of each patient record was 3 (range 2-56, IQ range 4).

Patient records were viewed for a median duration of 38 seconds (IQ range: 11-94 seconds). Whilst open, the median number of user clicks within each patient record was 13 (IQ range: 6-27). Most records were opened between the hours of 11:00 and 15:00 (Median 12:46, IQ range 08:32-17:00)

Diabetes Specialist Nurses (DSNs) were the most frequent users of SCI-Diabetes, opening 9107/17280 patient records (53%). Doctors opened 2709/17280 (16%) of records and Allied Health Professionals (AHPs) opened 472/17280 (2.7%) of records. The remainder of records were opened by admin staff or those with unknown role (3151/17280, 18% and 1217/17280, 7% respectively).

A CDSS message was displayed when opening 6665/17280 patient records (39%). When displayed, the median number of messages was 3 (range 1-12) - see Figure 28.

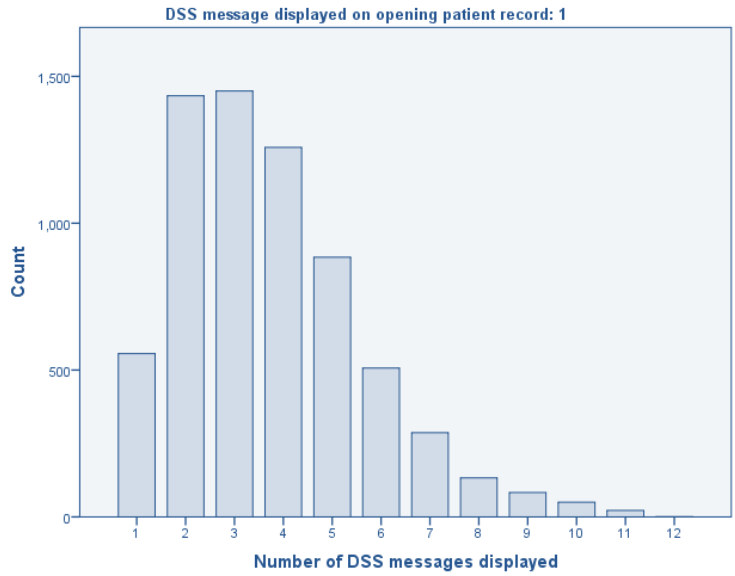

Figure 28. Number of CDSS messages displayed to user on opening each clinical record. n=17,280.

1352/5355 (25.2%) of patients had T1D and 3777(70.5%) had T2D. 3421/5355 (63.9%) were treated with insulin, with a small minority using pump therapy (138/3421, 4%).

4293/5355 (83%) of patients had a co-morbidity score of 2/9 or less and so patients were grouped pragmatically into low (score <2/9, n=2012/5355 38%), moderate (score=2/9, n=2475/5355, 46%) and high (score>2/9, n=859/5355, 16%) co-morbidity groups.

There were higher numbers of those from more deprived areas, however all socio economic groups were represented – see Figure 29.

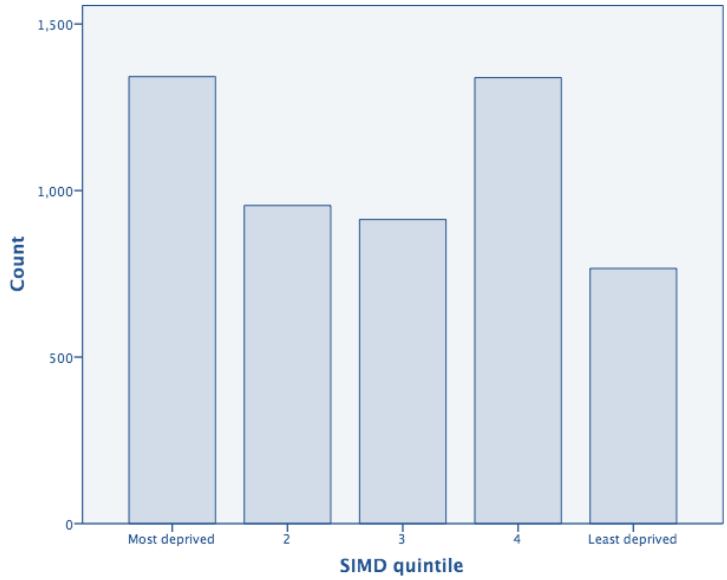

Figure 29. Deprivation categories for patients seen in the NWH diabetes outpatient clinic during improvement cycle 1 Deprivation categories expressed as SIMD quintiles. Dec 13 - Feb 14: N=5355

Both dependent variables (duration that patient record viewed and number of user clicks within each patient record) showed clear left skew with significant outliers – see figure 30 and figure 31.

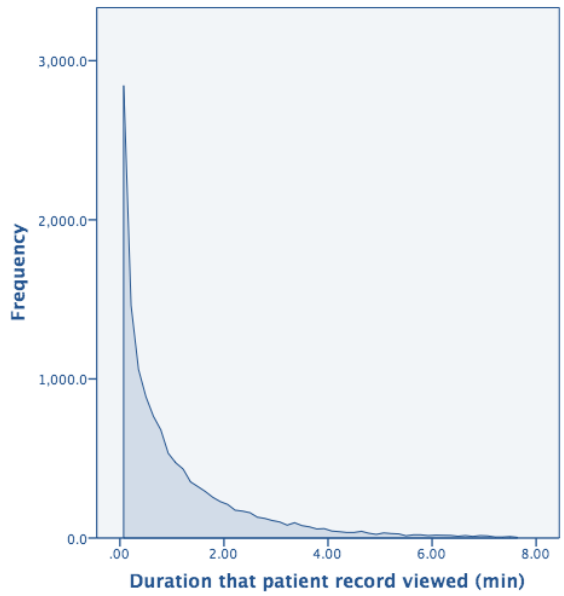

Figure 30. Histogram showing duration that each patient record was viewed. Filtered for outliers (SDS>3 and non – clinical users. N= 12,756.

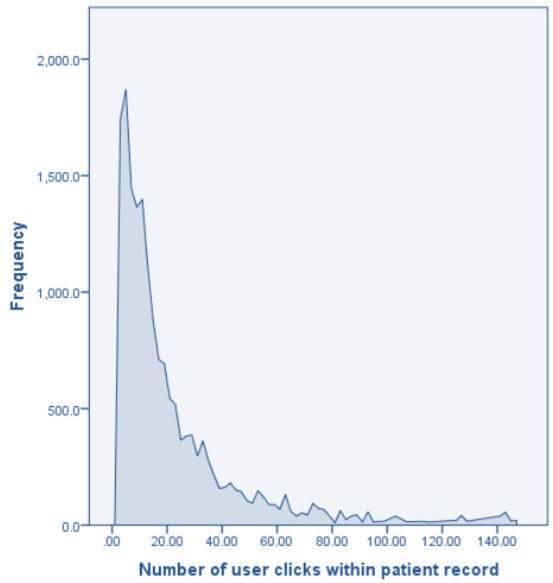

Figure 31. Histogram of number of user clicks within each patient record viewed. N=17,280.

Outliers were subsequently removed from analysis by filtering for records that were viewed for a duration >3SD greater than the mean (n=231). Records opened by administrative staff and unknown users were also filtered from further analysis, reducing the total number of opened records included in the analysis to 12,756.

The univariable analysis for each dependent variable is provided in Table 12.

Table 12. Duration that patient record viewed within SCI-Diabetes and number of user clicks within patient record.
*Stratified by independent variables and analysed by Generalised Estimating Equations. Independent variables entered into multivariable analysis if univariable p<0.1. *Denotes independent variable withheld from multivariable analysis due to colinearity. DSS = decision support system; SIMD = Scottish index of multiple deprivation; SD = standard deviation; IQ = interquartile*

		n	Duration record opened				Number of clicks			
			mean (SD)	median (IQ range)	p (univariable)	p (multivariable)	mean (SD)	median (IQ range)	p (univariable)	p (multivariable)
DSS message displayed	yes	6155	62 (77)	32 (8-86)	0.061	0.280	25 (26)	15 (7-34)	0.001	0.202
	no	6601	67 (77)	39 (14-90)			22 (24)	14 (6-29)		
Number of DSS messages	mean (SD)	1.8 (2.3)	-	-	0.038	0.176			0.009	0.664
User role	Associate specialist	244	65 (78)	34 (5-98)	<0.001	<0.001	8 (5)	6 (4-10)	<0.001	<0.001
	Consultant	1463	64 (78)	36 (8-89)			6 (4)	5 (3-8)		
	Dietician	464	65 (78)	36 (8-94)			20 (14)	17 (10-29)		
	DSN	9012	65 (80)	37 (11-88)			28 (27)	19 (9-37)		
	GP	745	67 (80)	37 (11-93)			10 (8)	8 (5-13)		
	Practice nurse	80	44 (79)	22 (7-38)			6 (2)	5 (4-8)		
	Research nurse	541	52 (69)	25 (8-60)			14 (16)	5 (3-23)		
	StR	207	60 (78)	27 (5-89)			10 (8)	8 (4-15)		
***User role collapsed**	Doctor	2659	65 (79)	36 (8-90)	0.927	-	8 (6)	6 (4-9)	<0.001	-
	AHP	464	65 (78)	36 8-94)			20 (14)	17 (10-29)		
	Nurse	9633	64 (76)	36 (9-37)			28 (27)	19 (9-37)		
morbidity group	Low	4655	64 (77)	36 (10-90)	0.366	-	27 (30)	16 (7-35)	0.079	0.025
	Moderate	5888	65 (78)	36 (11-89)			22 (24)	13 (6-29)		
	High	2213	62 (74)	35 (11-84)			21 (18)	14 (7-31)		
SIMD	1	3124	63 (75)	35 (11-86)	0.539	-	26 (27)	15 (7-34)	0.23	-
	2	2228	66 (79)	36 (11-90)			21 (20)	15 (7-30)		
	3	2138	63 (77)	34 (10-83)			22 (24)	13 (6-31)		
	4	3307	64 (77)	36 (10-89)			24 (25)	14 (6-32)		
	5	1862	67 (79)	37 (9-97)			24 (26)	13(6-31)		
Diabetes type	T1D	3809	64 (77)	37 (11-88)	0.154	-	23 (26)	13 (6-29)	0.004	0.204
	T2D	8428	64 (77)	35 (10-88)			24 (24)	15 (7-32)		
	Other diabetes	408	70 (84)	38 (13-98)			31 (28)	19 (7-44)		
	Unknown	103	47 (54)	30 (11-69)			17 (9)	17 (10-25)		
Insulin	yes	9871	64 (77)	36 (11-88)	0.296	-	24 (25)	14 (7-32)	<0.001	<0.001
	no	2885	63 (77)	34 (9-85)			16 (20)	8 (4-20)		

For duration of record viewed, the following independent variables were entered simultaneously: presence or absence of a CDSS message; number of CDSS messages; and user role. Of these, user role exerted a highly significant effect on the final model ($p<0.001$) (see Table 12).

The dependent factors that were significantly associated with number of user clicks on univariable analysis were: presence or absence of a CDSS message; number of CDSS messages; user role; morbidity group; diabetes type and insulin therapy. Of these, user role ($p<0.001$); morbidity group ($p=0.025$); and presence of insulin therapy ($p<0.001$) were retained within the final model (see Table 12).

Given the strong effect that user role exerted on both of these models, the multivariable analysis for both dependent variables was repeated for each collapsed user role category i.e. doctor, nurse and AHP. For doctors, the duration that the record was viewed was significantly reduced when a DSS message was displayed ($p=0.032$), with no other significant confounders (see Table 13). There was no significant association between the independent variables and the number of clicks that a doctor made within the patient record (see Table 14).

Table 13. Duration (seconds) that patient record viewed by doctors.
Mulitvariate analysis of main effects on doctors' interaction with SCI-Diabetes. DSS = decision support system; SIMD = Scottish index of multiple deprivation; SD = standard deviation; IQ = interquartile

Doctor		n	mean (SD)	median (IQ range)	p (univariable)	p (mulitvariate)
DSS message displayed	Yes	**1280**	61 (76)	33 (5-86)	<0.001	0.032
	No	**1379**	69 (83)	38 (12-97)		
Number of DSS reminders	mean (SD)	**2 (2)**	-	-	0.016	0.85
Co-morbidity group	Low	**945**	63 (76)	36 (9-88)	0.43	-
	Moderate	**1297**	67 (83)	36 (8-93)		
	High	**417**	62 (76)	36 (7-92)		
Insulin	Yes	**1902**	65 (79)	36 (8-90)	0.768	-
	No	**757**	66 (82)	35 (7-93)		
Diabetes type	T1D	**827**	67 (80)	37 (11-92)	0.13	-
	T2D	**1773**	64 (80)	34 (7-92)		
	Other diabetes	**44**	65 (69)	46 (12-95)		
	Unknown	**15**	42 (37)	34 (10-66)		
SIMD	1	**658**	62 (76)	36 (9-88)	0.641	-
	2	**439**	63 (78)	32 (9-86)		
	3	**444**	70 (87)	37 (9-95)		
	4	**663**	65 (80)	36 (6-93)		
	5	**437**	65 (78)	36 (7-94)		

Table 14. Number of user clicks within each patient record - doctors.
Mulitvariate analysis of main effects on doctors' interaction with SCI-Diabetes. DSS = decision support system; SIMD = Scottish index of multiple deprivation; SD = standard deviation; IQ = interquartile

Doctor		n	mean (SD)	median (IQ range)	p (univariable)	p (mulitvariate)
DSS message displayed	yes	1280	7 (5)	6 (4-9)	0.929	-
	no	1379	7 (6)	6 (3-9)		
Number of CDSS reminders	mean (SD)	2 (2)	-	-	0.765	-
Comorbidity group	low	945	7 (5)	6 (4-9)	0.212	-
	moderate	1297	7 (5)	6 (4-9)		
	high	417	8 (7)	6 (4-9)		
Insulin	yes	1902	8 (6)	6 (4-9)	0.026	0.164
	no	757	7 (5)	6 (4-9)		
Diabetes type	T1D	827	8 (6)	6 (4-10)	0.124	-
	T2D	1773	7 (5)	6 (4-9)		
	Other diabetes	44	5 (3)	5 (3-7)		
	Unknown	15	15 (13)	10 (4-32)		
SIMD	1	658	8 (7)	7 (4-10)	0.014	0.070
	2	439	7 (5)	6 (4-9)		
	3	444	7 (5)	6 (3-8)		
	4	663	7 (6)	6 (3-9)		
	5	437	7 (6)	6 (3-9)		

When nurses used SCI-Diabetes, the duration that the record was viewed was significantly different between the different SIMD categories (p=0.031), but this effect did not follow a socioeconomic gradient (see Table 15). The number of mouse clicks made by nurses within the patient record was significantly increased when a CDSS message was displayed (p=0.014). Nurses had more interaction with the system if patients had a low comorbidity score (p<0.001); the patient had type 1 diabetes (p<0.001); and they were receiving insulin (p<0.001) (see Table 16).

Table 15. Duration that patient record viewed by nurses.
Mulitvariate analysis of main effects on nurses' interaction with SCI-Diabetes. DSS = decision support system; SIMD = Scottish index of multiple deprivation; SD = standard deviation; IQ = interquartile

Nurse		n	mean (SD)	median (IQ range)	p (univariable)	p (mulitvariate)
DSS message displayed	Yes	4585	62 (77)	31 (8-84)	0.128	-
	No	5048	66 (76)	39 (14-88)		
Number of DSS reminders	mean (SD)	2 (2)	-	-	0.119	-
Co-morbidity group	Low	3515	65 (77)	36 (10-90)	0.543	-
	Moderate	4369	64 (76)	36 (11-85)		
	High	1749	61 (73)	34 (11-82)		
Insulin	Yes	7574	64 (76)	36 (11-87)	0.243	-
	No	2059	62 (76)	34 (10-83)		
Diabetes type	T1D	2701	64 (76)	37 (11-87)	0.083	0.075
	T2D	6484	63 (76)	34 (10-86)		
	Other diabetes	353	75 (86)	45 (15-99)		
	Unknown	87	57 (70)	34 (14-73)		
SIMD	1	2384	63 (75)	35 (11-87)	0.024	0.031
	2	1705	65 (79)	36 (11-88)		
	3	1598	60 (72)	34 (10-79)		
	4	2518	65 (77)	37 (11-89)		
	5	1356	64 (78)	35 (9-88)		

Table 16. Number of user clicks within each patient record - nurses.
Mulitvariate analysis of main effects on nurses' interaction with SCI-Diabetes. DSS = decision support system; SIMD = Scottish index of multiple deprivation; SD = standard deviation; IQ = interquartile

Nurse		n	mean (SD)	median (IQ range)	p (univariable)	p (mulitvariate)
DSS message displayed	yes	4585	28 (18)	19 (8-37)	0.001	0.014
	no	5048	24 (24)	16 (7-32)		
Number of CDSS reminders	mean (SD)	2 (2)	-	-	0.004	0.545
Comorbidity group	low	3515	29 (30)	19 (8-37)	0.017	<0.001
	moderate	4369	25 (25)	16 (8-33)		
	high	1749	22 (18)	16 (8-33)		
Insulin	yes	7574	28 (27)	19 (9-37)	<0.001	<0.001
	no	2059	20 (22)	12 (5-26)		
Diabetes type	T1D	2701	27 (29)	17 (7-36)	<0.001	<0.001
	T2D	6484	26 (25)	17 (8-34)		
	Other diabetes	353	25 (23)	16 (7-37)		
	Unknown	87	16 (9)	16 (7-24)		
SIMD	1	2384	27 (27)	17 (8-36)	0.094	0.080
	2	1705	23 (20)	17 (8-33)		
	3	1598	24 (25)	16 (8-32)		
	4	2518	27 (28)	17 (8-35)		
	5	1356	28 (27)	18 (8-40)		

In contrast to doctors and nurses, AHPs had much less interaction with SCI-Diabetes in general, with only 464 patient records being viewed during the period of study. The duration that these records were viewed was significantly longer when a CDSS message was displayed; the patient had less comorbidities; the patient had type 2 diabetes; the patient was on insulin; and they were from a more deprived background (all $p<0.001$ – see Table 17). The presence of a CDSS message had no effect on the number of clicks that AHPs made within the patient record (see Table 18).

Table 17. Duration that patient record viewed by AHPs.
Mulitvariate analysis of main effects on AHPs' interaction with SCI-Diabetes. DSS = decision support system; SIMD = Scottish index of multiple deprivation; SD = standard deviation; IQ = interquartile

AHP		n	mean (SD)	median (IQ range)	p (univariable)	p (mulitvariate)
DSS message displayed	Yes	290	72 (85)	39 (8-105)	<0.001	<0.001
	No	174	50 (57)	31 (8-72)		
Number of DSS reminders	mean (SD)	2 (2)	-	-	0.095	<0.001
Co-morbidity group	Low	195	65 (79)	35 (8-90)	0.031	<0.001
	Moderate	222	62 (77)	32 (7-94)		
	High	47	61 (57)	49 (16-93)		
Insulin	Yes	395	65 (78)	36 (8-93)	<0.001	<0.001
	No	69	55 (66)	29 (7-92)		
Diabetes type	T1D	281	64 (80)	33 (8-93)	<0.001	<0.001
	T2D	171	64 (71)	42 (9-96)		
	Other diabetes	11	35 (48)	10 (5-46)		
	Unknown	1	-	-		
SIMD	1	82	66 (92)	31 (7-73)	0.867	<0.001
	2	84	64 (73)	36 (7-97)		
	3	96	62 (71)	37 (9-89)		
	4	126	62 (72)	38 (10-90)		
	5	69	62 (77)	30 (7-104)		

Table 18. Number of user clicks within each patient record - AHPs.
Mulitvariate analysis of main effects on AHPs' interaction with SCI-Diabetes. DSS = decision support system; SIMD = Scottish index of multiple deprivation; SD = standard deviation; IQ = interquartile

AHP		n	mean (SD)	median (IQ range)	p (univariable)	p (mulitvariate)
DSS message displayed	yes	290	21 (14)	16 (10-33)	0.007	0.362
	no	174	17 (13)	13 (6-24)		
Number of CDSS reminders	mean (SD)	2 (2)	-	-	0.349	-
Comorbidity group	low	195	17 (11)	14 (8-23)	<0.001	<0.001
	moderate	222	19 (14)	15 (8-29)		
	high	47	31 (19)	34 (13-36)		
Insulin	yes	395	20 (14)	17 (10-29)	<0.001	<0.001
	no	69	16 (14)	9 (5-23)		
Diabetes type	T1D	281	19 (13)	15 (9-33)	<0.001	<0.001
	T2D	171	21 (16)	16 (9-26)		
	Other diabetes	11	7 (5)	4 (3-9)		
	Unknown	1	-	-		
SIMD	1	82	16 (13)	12 (5-23)	<0.001	0.087
	2	84	16 (10)	15 (9-26)		
	3	96	25 (18)	19 (12-36)		
	4	126	23 (14)	20 (11-35)		
	5	69	12 (7)	11 (6-17)		

6.8.6. Discussion

In terms of typical SCI-Diabetes usage, this analysis has demonstrated the following:

- Nurses are the most frequent users of the system in terms of number of patient records viewed.
- Nurses and AHP's use of the system involves greater interaction (as measured by number of user clicks). This could be due to either more pages being viewed within the patient record and/or greater volume of data entry.
- Regardless of user role, the median time that a patient record is viewed is 30-40 seconds, whilst outliers increase the average time to just over a minute.
- Comorbidity and socioeconomic status are associated with differences in system usage by nurses and AHP's (but not doctors). These differences are inconsistent and do not follow any particular gradient.

The CDSS displayed a message in approximately 40% of patient records that were opened. It should be noted that this was in contrast to earlier observations made within the focus groups, whereby it was felt that messages were displayed for nearly all patients (section 6.7.6.1). The presence of a message was associated with some differences in user behaviour, but this was dependent on user role. When doctors received a CDSS message, the duration that the record was viewed reduced by an average of 8 seconds. Whilst statistically significant, it could be argued that this has little clinical significance. That being said, this may reflect observations made by senior medical staff that the system enables a more targeted approach to consultations (see section 6.7). These results are in keeping with previous studies that found CDSS was related to increased efficiencies in working practices, although the level of evidence to support this hypothesis remains low [161,162]. It is important to note, that the improved efficiencies in working patterns was not at the expense of patient satisfaction as measured by PREMs (see section 6.5). Again, this reflects previous (low quality) studies that demonstrated no negative impact on patient satisfaction [162].

In contrast to doctors, when nurses received a CDSS message there was no difference in the duration that the record was viewed, but the number of user clicks was significantly greater for both nurses (and AHPs) when a CDSS message was displayed (by approximately 25%). Again, it is difficult to see how clinically significant this difference is without greater insight into the underlying clinical processes (e.g. adherence to guidelines) and clinical outcomes. One possible explanation is that the CDSS may be the catalyst for users to increase their data entry, but this remains speculative at this stage.

Patient socioeconomic class and morbidity exerted an inconsistent effect on system usage by nurses and AHPs. Greater co-morbidity is closely associated with deprivation [163], however lower socioeconomic class is not necessarily associated with greater health care utilisation [164]. In particular, deprivation is associated with less use of preventative services. Given that much of diabetes care is concerned with the prevention of secondary complications, it is less surprising that there is a lack of a clear gradient between socioeconomic class (or morbidity) and system usage by HCPs.

SCI-Diabetes is an electronic health record that is accessed by a wide variety of health professionals for various reasons. Whilst an audit trail exists for every user interaction within the system, these data are not specifically collected to assess user behaviour. Certain assumptions must therefore be made in order to use these data in such a way. The duration that the patient record was viewed and number of user clicks within the patient record were used as proxies for user behaviour. These somewhat crude measures assume that each time a patient record is opened, the user is doing so for reasons related to clinical management (as opposed to e.g. answering simple queries, data entry etc). There is also an assumption that the duration that the record is opened represents *active* use by the HCP, however it is clear from the large number of outliers that in many cases a patient record is left open indefinitely (until the user is automatically logged out of the system).

Despite these limitations, these proxy measures of user behaviour do serve as an objective measure by which to characterise an individuals' system use and to compare the effects of the CDSS in general. Filtering by user role and the removal of outliers goes some way to addressing the above limitations. In addition, the "noise" created by everyday use (e.g. patient record left open for prolonged periods of time) is independent of the presence or absence of a CDSS message and so does not introduce bias into the analysis. System usage has previously been quantified via duration of use and number of interactions with the system in question [159]. The EBMeDS intervention is an adjunct to an existing information system and so it impossible to compare our findings with these previous studies that are largely concerned with the evaluation of newly implemented systems where success is determined by the fact that the system is being used at all.

This study has characterised individual system usage of an existing EHR. It has demonstrated that a CDSS may have some impact on user behaviour, but the clinical significance of these changes remains unknown. The following chapters attempt to resolve this unanswered question by investigating whether the CDSS has resulted in any change in clinical processes and outcomes.

6.9 Clinical processes

6.9.1. Abstract

6.9.1.1. Introduction

The main determinant of the success of an information system is the impact that the system has on the organisation itself. Routine diabetes care is informed by national evidence-based guidelines. These include recommendations for the screening and treatment of diabetes-related complications. This study will assess whether the CDSS intervention resulted in change at an organisational level, by measuring the impact (if any) on a range of quality performance indicators (QPIs) derived from national guidelines.

6.9.1.2. Methods

Data were extracted from the SCI-Diabetes electronic health record for both improvement cycle one (Ninewells hospital diabetes clinic and one NHS Tayside primary care diabetes clinic, Dec 13 – Feb 14) and cycle two (St John's hospital diabetes clinic, Aug 14 – Nov 14). Cases were all patients attending the diabetes clinic whose health care professional (HCP) received a CDSS message during this time. Control were matched in a ratio of 1:2 for age; sex; type and duration of diabetes; BMI; and attendance at a clinic not taking part in the study.

Improvement in adherence to the QPIs served as the primary outcomes. These included screening for: foot disease (standardised foot screening); hyperlipidaemia (serum cholesterol); thyroid disease (serum thyroid stimulating hormone (TSH)); and kidney disease (serum creatinine and urinary albumin/creatinine ratio (UACR)). Adherence was considered to be improved if patients with no recorded results within the previous 15 months (24 months for TSH) proceeded to have the screening test done within 30 days post-appointment. Cases and controls were compared by multivariable linear regression taking into account potential demographic confounders.

6.9.1.3. Results

An EBMeDS prompt was displayed to an HCP in 1883 cases attending the clinic (cycle 1 = 1116, cycle 2 = 767 cases). Prior to the intervention, adherence to each of the QPIs was greater than 60%. Patient group (i.e. case or control) was a significant predictor of whether or not a patient received appropriate screening following a clinic appointment for each of the QPIs.

Improvement cycle one: the intervention was significantly associated with increased uptake of screening for foot disease (adjusted OR 1.4, 95%CI: 1.0-2.1, p=0.045) and urinary protein (2.0 (1.5-2.7), p<0.001) and decreased uptake of screening for thyroid disease (0.2 (0.1-0.2) p<0.001) when compared to controls.

Improvement cycle two: patients were significantly more likely than matched controls to undergo screening for all of the outcomes, the odds of which were far greater than those observed in cycle 1. Cases were over 4 times more likely than cases to have their feet, cholesterol and creatinine checked (adjOR (95%CI): 4.5 (3.2-6.3); 4.5 (2.3-8.6); 4.2 (2.7-6.5) respectively, all p<0.001); 9 times more likely to have TSH checked (9.1 (6.2-13.2) p<0.001); and twice as likely to have UACR checked (2.7 (2.0-3.6) p<0.001) compared with the control group.

6.9.1.4. Conclusion

The study has demonstrated a large improvement in adherence to current guidelines, when compared to a closely matched control population. This improvement was more marked within improvement cycle two, which may reflect improved functionality of the system following iterations made in light of user feedback, however it is acknowledged that clinical practices will differ between sites. It is hoped that improved adherence to guidelines will translate to improved clinical outcomes in due course. The limitations of the study preclude any causal inference, but would support the on going use of the CDSS system

6.9.2. Introduction

As previously discussed, DeLone and McLean's *model of information systems success* [157] attempts to define by which criteria a new information system can be considered to be effective (see section 6.8.2). The model was initially developed within a business management context, but has since been applied to medical information systems [159]. Ultimately, the model describes a new information system as being a success if it is associated with a positive effect on the organisation itself. From the perspective of a diabetes clinic, the metrics by which organisational performance can be quantified fall into two key areas: clinical processes and clinical outcomes. Clinical processes include tasks undertaken by HCPs in an effort to provide effective healthcare, ideally in accordance with evidence-based clinical guidelines. Adherence to these guidelines can therefore be regarded as a metric of success and are used as quality performancy indicators (QPIs) of regional and national performance [4]. It is hoped that by improving clinical processes, clinical outcomes will improve. Clinical outcomes for diabetes principally include glycaemic control as well as a range of other measures that serve to characterise levels of morbidity amongst the population. Both processes and outcomes have the potential to be *indirectly* influenced by improvements to the information system (see section 6.2.3), and it is the former that proves most amenable to improvement by the introduction of a CDSS [162].

This study will assess whether the intervention has resulted in change at an organisational level, by measuring the impact (if any) on clinical processes, as measured by a range of QPIs. These include screening for thyroid, kidney and foot disease; as well as hyperlipidaemia.

6.9.3. Methods

Data were extracted from those attending the NWH diabetes outpatient clinic and one primary care practice within NHS Tayside between 2/12/13 and 1/3/14 inclusive (improvement cycle 1). In addition, data from those attending the SJH diabetes clinic between 18/08/14 and 15/11/14 (improvement cycle 2) were also included in the analysis.

Cases were defined as those patients who attended the diabetes clinic within the specified date and whose HCP received an EBMeDS alert on that date. Controls were selected from the SCI-Diabetes Scottish national dataset from geographical areas not exposed to the intervention. Controls were matched to cases based on the following criteria: age ($\pm$2 years); gender; diabetes type; duration of diabetes ($\pm$2 years); BMI ($\pm$2 kg/m^2); and attendance at clinic between January to December 2014. If an individual had multiple appointments during these 12 months, data were extracted relative to the earliest appointment during the year.

Where possible, 2 controls were matched to each case (however, a ratio of 1:1 was accepted in order to improve case retention). The dependent variables were not considered when matching controls to cases. Demographic features were compared between cases and controls using Student's t test and Chi-square as appropriate.

Improvement in adherence to the QPIs served as the primary outcomes. The QPIs were :

- Proportion of patients where foot risk screening was completed within 15 months of the clinic appointment.
- Proportion of patients where serum thyroid stimulating hormone (TSH) was measured within 24 months of the clinic appointment.
- Proportion of patients where serum creatinine was measured within 15 months of the clinic appointment.
- Proportion of patients where serum cholesterol was measured within 15 months of the clinic appointment.
- Proportion of patient where urinary albumin creatinine ratio (ACR) was measured within 15 months of the clinic appointment.

Patients in whom the above screening tests were not completed within the preceding specified period were considered to be non-adherent to current guidelines [9], and were included in the subsequent analysis – see Figure 32. In each instance, cases' HCP received a CDSS message alerting them to this fact, whereas no such message was displayed to controls' HCP. Adherence was considered improved if these patients proceeded to have the screening test done within 30 days post-appointment.

Figure 32. Schema demonstrating selection of cases and controls included in the analysis of clinical processes. The foot screening QPI is used as an example, with the same attrition methods used for the other QPIs.

The secondary outcomes related to prescribed medication in the 30 days following a clinic consultation. Individuals were considered naïve to oral hypoglycaemics if they had had not been prescribed Metformin, Glibenclamide, Gliclazide, Glipizide, Glimepiride, or Tolbutamide prior to the consultation. The proportion of oral hypoglycaemic drug naïve patients that went on to receive one of these drugs in the 30 days following the consultation was then compared between cases and controls.

6.9.3.1. Statistical analysis

All outcomes were initially cross-tabulated and compared using Chi-square. Patients' data were entered into a logistical regression analysis if they were non-adherent to the QPI prior to the clinic appointment. The dichotomous dependent variable was whether or not they went on to receive screening within 0-30 days following the appointment date. Intervention group and demographics were considered as independent variables and entered on a univariable basis. All variables significant to $p<0.3$ were retained and entered simultaneously in the multivariable analysis. Previous analyses used a more stringent cut off of $p<0.1$ (see section 6.5.4.3), however a more liberal approach was adopted in this instance to ensure potentially important demographic predictors were included in the multivariable analysis.

Power calculations were made based on the foot-screening primary outcome within the context of the NWH diabetes clinic. The proportion of those in whom this was done within the preceding 15 months was 62% of those with T1D and 85% of those with T2D - equivalent to 82% overall [165]. It was anticipated that 1200 patients would attend NWH during the three-month period of improvement cycle 1. Of these, it was anticipated that HCPs would receive a foot-screening prompt indicating that the patient had not had his/her feet screened in approximately 216 consultations (18% of 1200 = 216 patients). In order to maintain a steady state of 82% patients screened within the past 15 months, an average of 12 of these 216 patients who are over the 15-month threshold are screened every month, regardless of the intervention (i.e. 82% of 216 divided by 15 months = 11.8) - failure to do so would result in the proportion of individuals not screened for the past 15 months growing ever larger through time. If the clinical alert provoked the HCP to complete foot screening for an additional 8 patients per month (equivalent to a 67% increase) then over the course of the 3-month period, 60 patients who had not received foot screening for 15-months (i.e. 3*(8+12)) would receive foot screening in the intervention clinic (60/1200 = 5%). It was assumed that the control patient group (anticipated n=2400) was subject to the same background rate of foot screening. This would result in 24 patients per month who had not received screening in the past 15-months, receiving foot screening through routine care - equivalent to 72/2400 (3%) over the three-month period. The resulting difference between the 2 samples (5% of 1200 vs. 3% of 2400) would allow the null hypothesis that there is no difference between the 2 groups to be rejected with 90% power.

6.9.4. Results

6.9.4.1. Matching

During the two improvement cycles, 5692 patients were the subject of an EBMeDS prompt when their patient record was opened. These were successfully matched to 10,677 controls (see section 6.10.5.1 for further details). Of these, the date of the EBMeDS prompt corresponded with a clinic appointment date in 1883 cases, matched to 3557 controls (1674 cases were matched to two controls, 209 cases were matched to one control patient). As expected, for each of the matching variables there were no significant differences between cases and controls (see Table 19).

Table 19. Demographic characteristics of cases and controls
No significant differences demonstrated between either group (continuous variables compared with Student's t test, categorical variables compared with Chi Square). BMI = body mass index; SD = standard deviation

	Cases	Controls	p
n	1883	3557	-
Male	1072 (57%)	2045 (58%)	0.708
Type 1 Diabetes	588 (31%)	1103 (31%)	0.878
Type 2 Diabetes	1269 (67%)	2450 (69%)	0.27
Duration of diabetes [years] (SD)	17.9 (12.5)	17.5 (11.6)	0.32
BMI [kg/m^2] (SD)	30.6 (6.8)	30.5 (6.3)	0.5
Mean age [years] (SD)	59.8 (16.5)	59.5 (16.4)	0.63

Improvement cycle 1 (NWH) contributed 1116/1883 cases (59%), whilst improvement cycle 2 (SJH) involved 767 cases (41%).

6.9.4.2. Quality performance indicators

Prior to the intervention, adherence to each of the QPIs was greater than 60% (see Figure 33). The proportion of all cases that had had foot screening in the previous 15 months was significantly greater amongst cases (76.5% versus 73.4%, $p<0.001$), whereas controls had significantly greater adherence to screening for TSH, creatinine and cholesterol.

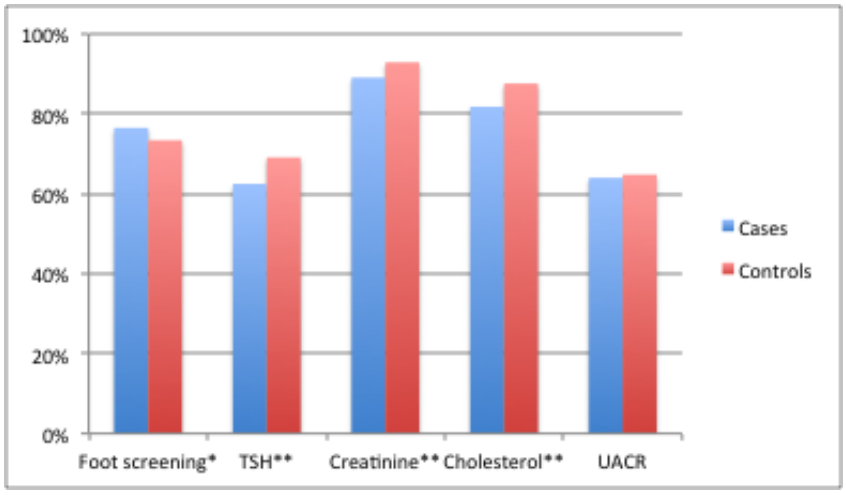

Figure 33. Pre-intervention adherence to Quality Performance Indicators (QPIs).
*See methods for definition of QPIs. * denotes p<0.05, ** denotes p<0.001. Cases n=1883, controls n=3557.*

Of those patients attending clinic that had not received screening within the recommended period, significantly more received screening for foot disease, renal disease and hypercholesterolaemia in the intervention sites in the 30 days following the clinic appointment where an EBMeDS message was received. TSH monitoring was significantly more prevalent in the control population (see Table 20).

Table 20. Adherence to Quality Performance Indicators in the 30 days following a clinic appointment

	Cases requiring screening		Controls requiring screening		
	n	**Received screening, n(%)**	**n**	**Received screening, n(%)**	**p**
Foot screening	443	243 (54.9%)	945	281 (29.7%)	<0.001
TSH	707	229 (32.4%)	1100	408 (37.1%)	0.02
Creatinine	206	168 (81.6)	252	162 (64.3%)	<0.001
Cholesterol	342	236 (69.0%)	442	213 (48.2%)	<0.001
UACR	678	277 (40.9%)	1252	287 (22.9%)	<0.001

6.9.4.3. Univariable and multivariable analysis

Patient group (i.e. case or control) was a significant predictor of whether or not a patient received appropriate screening following a clinic appointment for each of the QPIs – see Figure 34. During cycle 1 (NWH), the intervention was significantly associated with increased uptake of screening for foot disease and urinary protein and decreased uptake of thyroid disease when compared to matched controls. Patients attending clinic in cycle 2 (SJH) were significantly more likely than matched controls to undergo screening for all of the outcomes, the odds of which were far greater than those observed in cycle 1 - see Figure 34.

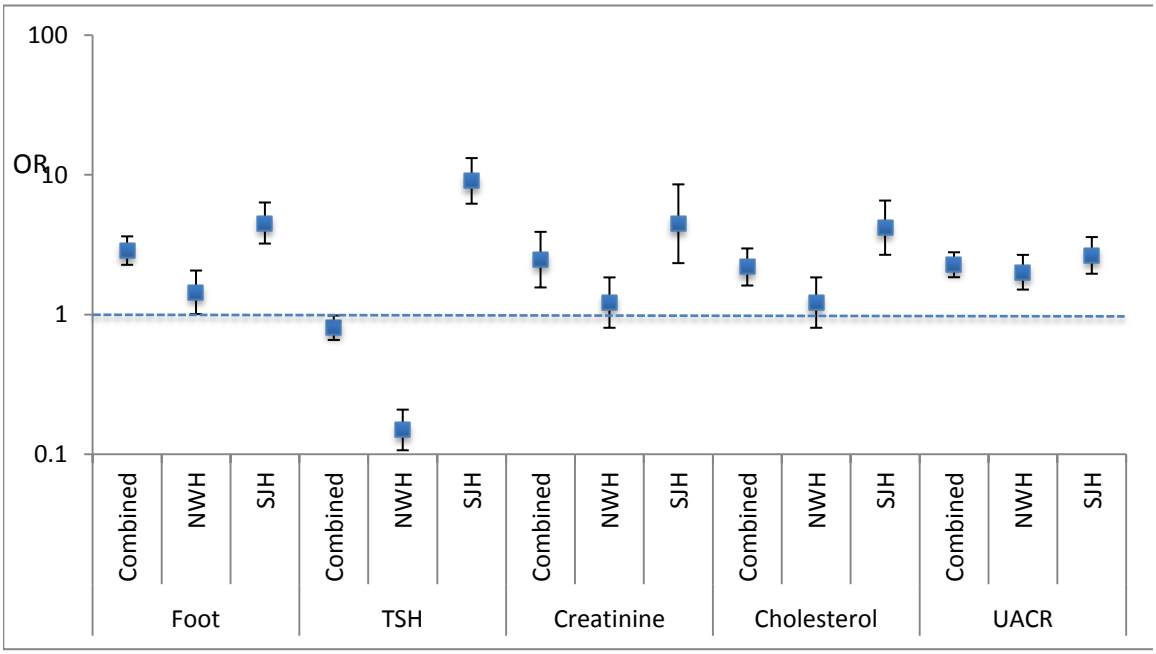

Figure 34. Adjusted odds ratios for each of the primary outcomes, by site
Odds represent the probability of a case receiving screening for the complications of diabetes following a clinic appointment, compared with controls. Adjusted for Age, diabetes type and duration, gender and BMI. Intervention group compared with controls. Note log scale on y axis.

6.9.4.3.1. Cycle 1 – Ninewells hospital, Dundee

For those patients whose HCP received an EBMeDS alert prompting the need for foot screening, the adjusted odds of subsequently receiving that screening were 1.4 when compared with the control population (95%CI: 1.01-2.07, p=0.045) – see Table 21.

Table 21. Logistic regression showing significant predictors of foot screening in NWH. Cases n=170, controls n=561. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	p	OR	CI	p
Group	1.448	1.012-2.072	0.043	1.444	1.009-2.068	0.045
Age	1.007	0.999-1.015	0.102	1.007	0.999-1.015	0.107
T2D	0.982	0.717-1.344	0.993	-		
Gender	0.858	0.627-1.176	0.342	-		
Duration of diabetes	1.002	0.992-1.013	0.67	-		
BMI	0.992	0.969-1.016	0.532	-		

The adjusted odds for receiving screening for thyroid disease following an EBMeDS prompt were significantly reduced in the intervention group, when compared to controls (OR 0.15, 95%CI: 0.11-0.21, p<0.001).

Table 22. Logistic regression showing significant predictors of TSH screening in NWH. Cases n=473, controls n=658. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	p	OR	CI	p
Group	0.15	0.108-0.210	<0.001	0.15	0.107-0.209	<0.001
Age	0.995	0.988-1.002	0.182	0.993	0.986-1.001	0.092
T2D	0.844	0.649-1.097	0.309	-		
Gender	1.112	0.857-1.443	0.425	-		
Duration of diabetes	0.994	0.984-1.005	0.267	0.996	0.985-1.008	0.53
BMI	0.999	0.980-1.020	0.958	-		

The intervention was not associated with increased odds of having serum creatinine or cholesterol checked in clinic – see Table 23 and Table 24. Increasing age was associated with increased odds of having creatinine checked (OR 1.02, 95%CI: 1.00-1.04, p=0.036). Similarly, those with a higher BMI were more likely to have cholesterol checked (OR 1.05, 95%CI: 1.02-1.09, p=0.007).

Table 23. Logistic regression showing significant predictors of creatinine screening in NWH.
Cases n=81, controls n=131. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	p	OR	CI	P
Group	1.246	0.663-2.341	0.494	-		
Age	1.024	1.007-1.042	0.007	1.019	1.001-1.038	0.036
T2D	1.069	0.581-1.967	0.831	-		
Gender	0.843	0.457-1.554	0.583	-		
Duration of diabetes	1.013	0.988-1.038	0.325	-		
BMI	1.078	1.016-1.144	0.013	1.059	0.996-1.125	0.065

Table 24. Logistic regression showing significant predictors of cholesterol screening in NWH.
Cases n=142, controls n=252. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	P	OR	CI	P
Group	1.219	0.805-1.847	0.35	-		
Age	1.01	1.000-1.020	0.062	1.004	0.993-1.015	0.446
T2D	1.104	0.741-1.644	0.823	-		
Gender	0.75	0.501-1.121	0.16	1.467	0.968-2.224	0.071
Duration of diabetes	1.016	0.998-1.034	0.08	1.016	0.999-1.034	0.071
BMI	1.05	1.014-1.088	0.006	1.053	1.015-1.094	0.007

An HCP receiving an EBMeDS prompt to check urinary ACR were twice as likely to receive this test in comparison to the control group (OR 2.01, 95%CI: 1.51-2.67, p<0.001) – see Table 25. Increasing age and female sex were also significantly associated with increased odds of having UACR checked.

Table 25. Logistic regression showing significant predictors of UACR screening in NWH.
Cases n=322, controls n=739. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	P	OR	CI	P
Group	1.951	1.472-2.586	<0.001	2.011	1.511-2.676	<0.001
Age	1.013	1.005-1.021	0.001	1.014	1.006-1.022	0.001
T2D	1.158	0.881-1.523	0.323	-		
Gender	0.738	0.562-0.968	0.028	1.435	1.085-1.898	0.011
Duration of diabetes	1.001	0.991-1.011	0.856	-		
BMI	1.011	0.991-1.032	0.296	1.007	0.985-1.029	0.561

Of the 491 cases not previously prescribed oral hypoglycaemic agents prior to the consultation, 5 (1.0%) were started on this medication following an appointment. Of the 1036 controls, 24 (2.3%) were started on hypoglycaemics following an appointment. Patient group (i.e. cases or controls) was not associated with receiving a new prescription for oral hypoglycaemics, whereas shorter duration of diabetes and increased BMI were significantly associated with receiving a prescription – see Table 26.

Table 26. Logistic regression showing significant predictors of starting an oral hypoglycaemic following appointment in NWH.
Cases n=491, controls n=1036. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	P	OR	CI	P
Group	0.434	0.165-1.144	0.091	0.513	0.193-1.366	0.182
Age	1.009	0.989-1.029	0.389	-	-	-
Gender	1.353	0.649-2.823	0.42	-	-	-
Duration of diabetes	0.925	0.883-0.97	0.001	0.922	0.877-0.969	0.001
BMI	1.091	1.038-1.146	0.001	1.089	1.035-1.146	0.001

6.9.4.3.2. Cycle 2 – St John's hospital, Livingston

Patients attending the SJH diabetes clinic whose HCP received an EBMeDS prompt for foot screening were over 4 times more likely to receive this when compared to their closely matched controls (OR 4.52, 95%CI: 3.22-6.34, p<0.001). Increased duration of diabetes and higher BMI were also significantly associated with receiving the test – see Table 27.

Table 27. Logistic regression showing significant predictors of foot screening in SJH.
Cases n=273, controls n=384. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	P	OR	CI	P
Group	4.494	3.224-6.263	<0.001	4.522	3.224-6.344	<0.001
Age	1.014	1.005-1.022	0.002	1.008	0.998-1.018	0.112
T2D	0.945	0.693-1.289	0.721	-		
Gender	0.963	0.708-1.311	0.811	-		
Duration of diabetes	1.017	1.004-1.031	0.011	1.021	1.006-1.035	0.005
BMI	1.037	1.013-1.061	0.002	1.028	1.001-1.055	0.04

Similarly, patients were 9 times more likely to receive screening for thyroid disease if their HCP received a prompt for this (OR 9.05, 95%CI: 6.22-13.18, p<0.001) – see Table 28.

Table 28. Logistic regression showing significant predictors of TSH screening in SJH.
Cases n=234, controls n=442. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	P	OR	CI	P
Group	8.743	6.047-12.642	<0.001	9.053	6.217-13.183	<0.001
Age	0.994	0.984-1.003	0.186	1	0.987-1.014	0.945
T2D	0.669	0.489-0.914	0.012	0.587	0.377-0.914	0.061
Gender	1.073	0.787-1.462	0.655	-		
Duration of diabetes	0.998	0.985-1.011	0.781	-		
BMI	1.001	0.978-1.025	0.917	-		

The odds of a patient receiving screening for kidney disease (via serum creatinine and urinary ACR) were also greatly increased in the intervention group (OR 4.47, 95%CI: 2.34-8.55, p<0.001 and OR 2.65, 95%CI 1.96-3.59, p<0.001 respectively) – see Table 29 and Table 30. Increasing age was predictive of both tests being completed and females were more likely to have UACR checked than males.

Table 29. Logistic regression showing significant predictors of creatinine screening in SJH.
Cases n=125, controls n=121. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	P	OR	CI	P
Group	4.48	2.421-8.291	<0.001	4.468	2.335-8.550	<0.001
Age	1.033	1.016-1.051	<0.001	1.025	1.001-1.049	0.037
T2D	1.81	1.001-3.272	0.146	0.768	0.299-1.970	0.582
Gender	0.99	0.568-1.726	0.971	-		
Duration of diabetes	1.042	1.101-1.075	0.01	1.035	1.000-1.071	0.05
BMI	1.071	1.017-1.127	0.01	1.038	0.974-1.107	0.252

Table 30. Logistic regression showing significant predictors of UACR screening in SJH.
Cases n=356, controls n=513. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	P	OR	CI	P
Group	2.793	2.076-3.757	<0.001	2.653	1.961-3.588	<0.001
Age	1.011	1.002-1.020	0.021	1.013	1.001-1.024	0.029
T2D	1.146	0.851-1.543	0.144	0.726	0.484-1.090	0.115
Gender	0.715	0.535-0.957	0.024	1.496	1.102-2.031	0.01
Duration of diabetes	0.999	0.988-1.011	0.908	-		
BMI	1.023	1.002-1.045	0.029	1.024	0.999-1.049	0.056

The odds of having serum cholesterol measured following an EBMeDS prompt were 4 times greater than the control population (OR 4.19, 95%CI: 2.68-6.55, p<0.001). Increasing age was again predictive of receiving the test – see Table 31.

Table 31. Logistic regression showing significant predictors of cholesterol screeningin SJH.
Cases n=200, controls n=190. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	P	OR	CI	P
Group	4.674	3.021-7.231	<0.001	4.188	2.679-6.549	<0.001
Age	1.024	1.012-1.035	<0.001	1.017	1.003-1.03	0.014
T2D	1.349	0.897-2.029	0.355	-		
Gender	0.921	0.615-1.379	0.688	-		
Duration of diabetes	0.999	0.984-1.015	0.924	-		
BMI	1.052	1.018-1.087	0.003	1.013	0.976-1.052	0.492

Of the 397 cases not receiving an oral hypoglycaemics prior to the consultation, 8 (2%) were started on this medication following an appointment. Of the 641 controls, 16 (2.5%) were started on hypoglycaemics following the consultation. Patient group was not significantly associated with the odds of receiving this prescription. Again, shorter duration of diabetes and increasing BMI were significant predictors of receiving an oral hypoglycaemic – see Table 32.

Table 32. Logistic regression showing significant predictors of receiving a new oral hypoglycaemic following appointment at SJH.
Cases n=397, controls n=641. All univariable predictors significant to p<0.3 entered simultaneously. OR = Odds ratio; BMI = body mass index; CI = 95% confidence interval.

	Univariable			Multivariable		
	OR	CI	P	OR	CI	P
Group	0.803	0.341-1.895	0.617	-	-	-
Age	1.015	0.992-1.039	0.197	1.016	0.99-1.043	0.226
Gender	0.545	0.231-1.286	0.166	0.476	0.195-1.16	0.102
Duration of diabetes	0.947	0.906-0.99	0.016	0.936	0.899-0.985	0.011
BMI	1.098	1.043-1.156	<0.001	1.091	1.031-1.155	0.002

6.9.5. Discussion

This study has demonstrated a large improvement in nearly all of the QPIs in the month following a clinic appointment, when compared to closely matched controls. The early detection of diabetes-related complications via these secondary prevention interventions is associated with reduced morbidity and are associated with substantial economic savings [8]. This is discussed in greater detail later – see section 6.11.1. The improved adherence to clinical guidelines is consistent with previously studied CDSS [162], however the observed improvements in this study are of a far greater magnitude.

The study failed to show any difference between cases and controls in the odds of receiving a newly commenced oral hypoglycaemic in the month following a consultation. Perhaps unsurprisingly, shorter duration of diabetes (i.e. more recently diagnosed) and higher BMI (i.e. greater insulin resistance) were highly significant predictors of starting this medication. The CDSS included HCP prompts to consider ways of improving glycaemic control, but these would have appeared to have no effect on prescribing practices. It could be argued that decision support has less value in this context as the primary drivers of HCP behaviour within clinic is the need to improve glycaemic control, therefore reminders to consider this are perhaps less warranted.

An additional secondary outcome to be considered was the prescription of antihypertensive agents (Angiotensin-converting enzyme inhibitors and Angiotensin-II receptor antagonists) in the month following a clinic appointment. There is perhaps greater scope for improvements in this area – guidelines suggest that patients with positive screening results (i.e. albuminuria) are commenced on these drugs, yet this is often overlooked [166]. Unfortunately, these data were not yet available at the time of writing.

A note of caution must be struck when interpreting the above findings, owing to limitations in study design. For example, the QPI improvements observed in cases during cycle two were far greater than those in cycle one. It is tempting to infer that these observed differences were as a result of system iterations (in response to user feedback). However, it is far more likely that local variation in clinical practices was responsible for the observed differences. It transpired that in the Livingston clinic (cycle 2), health care assistants responsible for identifying patients requiring screening tests during their clinic visit were using the CDSS for this specific task as a way of quickly interrogating the EHR [K Adamson, email communication]. This serves as a reminder that the effects of a CDSS are limited/enhanced by human factors and the processes in place around the system. In this context, the CDSS could be viewed as an enhancement to an existing system, resulting in behaviour change within the MDT.

Matching between cases and controls did not include the dependent variables at baseline e.g. the presence or absence of pre-existing foot screening was not considered. This pragmatic decision was based upon the need to improve the probability of a successful match and to allow the same control population to be used throughout the investigation. Ultimately, this resulted in a large control population, closely matched for a variety of demographics. The observed differences between cases and controls in the primary outcomes prior to the intervention were therefore unavoidable but unsurprising, given the likelihood of local variation in practice. The proportion of cases that went on to receive screening in the month following a clinic appointment was several magnitudes greater that those controls that were due screening (with the exception of thyroid disease), and remained highly significant after correcting for potential confounders. This would suggest that the intervention played a greater role than any baseline differences between the two groups.

These findings are consistent with the substantial body of evidence suggesting that a CDSS can result in improvements in clinical processes [167]. What remains more challenging is converting this improved health care delivery into meaningful improvements in clinical outcomes.

6.10 Clinical outcomes

6.10.1. Abstract

6.10.1.1. Introduction

The Evidence Based Medicine electronic Decision Support system (EBMeDS) delivers a clinical decision support system (CDSS) that is available to clinicians within the normal work stream. This type of CDSS has been shown to result in positive behaviour change by health care professionals (HCPs), but there is a lack of evidence that this translates into improved patient outcomes. This case-control study utilises data from improvement cycles one and two of the EBMeDS project to quantify changes in glycaemic control (and a range of other secondary outcomes) through time and to compare these outcomes between cases and controls.

6.10.1.2. Methods

Data were extracted from the SCI-Diabetes electronic health record for patients attending the Ninewells hospital diabetes clinic between 2/12/13 and 1/3/14 inclusive (improvement cycle 1) and the St John's hospital diabetes clinic between 18/08/14 and 15/11/14 (improvement cycle 2). Cases were all patients whose health care professional (HCP) received a CDSS message during this time. Control data were anonymously extracted from SCI-Diabetes and matched in a ratio of 1:2 for age; sex; type and duration of diabetes; BMI; and attendance at a clinic not taking part in the study. Paired data were obtained for each dependent variable from baseline and follow up at 9-15 months. The primary outcome was change in HbA1c at one year. Secondary outcomes included change in serum cholesterol, blood pressure and urinary albumin/creatinine ratio (UACR). Cases and controls were compared by multivariable linear regression taking into account potential demographic confounders.

6.10.1.3. Results

During the 3-month period of study, CDSS messages were generated for 5,692 cases, of which 5,432 were matched to 10,667 controls. There were no significant differences between the groups in terms of demographic variables. Paired baseline-follow up HbA1c values were available for 2662/5432 (47%) cases and 6203/10,677 (58%) controls. Both cases and controls showed small, but significant improvements in HbA1c (mean change in HbA1c: -2.3 mmol/l vs. -1.1, B 1.2 95% CI 0.4 to 2.0, p=0.003). There were no significant differences in cholesterol and diastolic blood pressure between the groups. Systolic blood pressure improved more in the control group (mean change in SBP: -1.3 mmHg vs. -3.3, B -2.0, 95%CI: -3.0 to -1.0, p<0.001). UACR increased in both groups but significantly more in the control group (mean change in UACR: 1.6 vs. 4.4, B 2.9, 95%CI 0.7 to 5.1, p=0.01).

6.10.1.4. Conclusion

The study has demonstrated a small improvement in glycaemic control and a decrease in progression of kidney disease when compared to a closely matched control population. The limitations of the study preclude any causal inference, but would support the ongoing use of the CDSS system. This study has shown how a national informatics platform can be readily utilised to evaluate research questions arising from quality improvement interventions.

6.10.2. Introduction

The use of automated reminders via a Clinical Decision Support System (CDSS) has been shown to be one of the most consistently successful approaches to encourage clinicians to adopt evidence-based practice [59]. Whilst a number of studies have demonstrated improvements in clinical processes (e.g. adherence to guidelines), there is a lack of evidence for improved clinical outcomes [60]. The Evidence Based Medicine electronic Decision Support system (EBMeDS) delivers CDSS that incorporates contemporaneous recommendations (as opposed to simple summaries of data) within the normal work stream. Interventions of this kind are more likely than other forms of CDSS to result in behaviour change [61].

The long term medical management of diabetes is aimed at maintaining normoglycaemia and reducing cardiovascular risk factors, in an effort to reduce the risk of long term complications [9,168,169]. The risk of microvascular complications (e.g. kidney disease) is greatly reduced by reducing instances of hyperglycaemia[170] and controlling other cardiovascular risk factors[9]. Screening tests are undertaken regularly to detect such complications (e.g. urinary protein to detect kidney disease). In the event of a positive screening result, early intervention can halt progress (e.g. ACE inhibitors in patients with urinary microalbuminuria).

For the purposes of this study, the metrics by which clinical outcomes were assessed reflect diabetes control (glycated haemoglobin [HbA1c] as a measure of average blood glucose); risk of diabetes-related complications (hyperlipidaemia and hypertension as risk factors for cardiovascular disease); and presence of diabetes-related morbidity (microalbuminuria as a measure of kidney disease and an indicator of micro-vascular complications). A variety of CDSS messages are displayed for each of these clinical outcomes within the EBMeDS system. In the absence of a recent result, the message prompts health care professionals (HCPs) to offer/suggest the test to the patient. In the presence of an abnormal result, the message suggests possible medical interventions. The chosen thresholds for when a message is displayed and the advice contained therein varies according to potential clinical outcome and are based on the national guideline [9]. For example, it is recommended that urinary albumin/creatinine ratio (UACR) should measured on an annual basis in all patients over the age of 12 years – a message is triggered if there is no record of this being done within the last 13 months. If the UACR is raised, then it is recommended that an adult with diabetes is commenced on a specific type of antihypertensive drug (ACE inhibitor) – a message to this effect is triggered in the presence of a raised UACR and the absence of ACE inhibitors being already prescribed.

6.10.3. Aims

- To identify a cohort of patients who were the subject of a CDSS prompt (by virtue of their HCP opening the patient's electronic health record during the period of study).
- To identify appropriate controls from elsewhere in Scotland, matched to cases on the basis of age, sex, type and duration of diabetes, BMI and recent clinic attendance.
- To quantify change in glycaemic control through time for this case group and compare this change with the control population.
- To quantify change in a range of secondary clinical outcomes through time and similarly compare cases with controls.

6.10.4. Methods

Data were extracted from those attending the NWH diabetes outpatient clinic and one primary care practice within NHS Tayside between 2/12/13 and 1/3/14 inclusive (improvement cycle 1). In addition, data from those attending the SJH diabetes clinic between 18/08/14 and 15/11/14 (improvement cycle 2) were also included in the analysis. Cases were defined as those patients whose HCP received a CDSS message when their clinical record was opened during the above period. Controls were selected from the SCI-Diabetes Scottish national dataset from geographical areas not exposed to the intervention. Further details on matching procedures are contained in the previous chapter (see section 6.9.3).

The primary outcome was change in HbA1c (mmol/mol). Secondary outcomes included changes in total cholesterol (mmol/l)); systolic blood pressure (SBP, mmHg); diastolic blood pressure (DBP, mmHg); and urinary albumin/creatinine ratio (UACR, mg/mmol). Baseline data were taken from the last available value for each patient seen during the three months of data capture. Baseline data were considered eligible for inclusion if they were recorded $\pm$ 1 month from the date of the clinical record being opened. This was to ensure that investigations completed prior to, or as a result of attending the clinic (e.g. blood tests done in primary care) were included in the analysis. Follow up data were taken as the last available value for each patient within 9-15 months following the data of the initial clinical consultation.

Data validation within SCI-Diabetes ensured that all clinical data entered onto the system by an HCP are biologically plausible values. Similarly, biochemical data extracted from clinical systems (via an existing data feed) are subject to strict clinical and information governance practices thereby minimising the risk of incorrect values being recorded.

6.10.4.1. Statistical analysis

The change in absolute value was calculated for each dependent variable. Cases and controls were excluded from analysis in the absence of paired data. Groups were initially compared using Student's t test and Chi Square, as appropriate. Multivariable analysis was then undertaken, taking into account potential confounders, using linear regression. Variables with significance of $p<0.3$ on initial univariable regression were retained in the final model.

Statistical power was calculated prior to the study, based on a number of assumptions. It was anticipated that up to 1,200 patients would be seen in the outpatient clinic during the 60 day demonstrator period, of which it was assumed that a prompt would be displayed to the HCP in 20% of cases (n=240). Prior to the study, the mean HbA1c for patients in Tayside was 59 mmol/mol [165]. A 2 mmol/mol reduction in mean HbA1c in cases, with no observed difference in controls at follow up would result in the rejection of the null hypothesis that there was no difference between the groups with 81% power (assuming SD=10).

Post hoc comparison between groups was undertaken using Chi Square, assessing the proportion of patients with glycaemic control within a target range of $\leq$53 mmol/mol (as defined by national guidance [9]) at baseline and follow up. Further comparison was made between groups using Cox Regression, assessing the proportion of patients in each group moving from above target HbA1c to within target HbA1c range.

6.10.5. Results

6.10.5.1. Matching

A CDSS message was generated for 5,692 cases in total (including the 1,883 cases visiting clinic). Of these, 5,245 were successfully matched to two controls. An additional 187 cases were matched to one control, resulting in a total control population of 10,677. The remaining 260 cases were unable to be matched on the defined criteria and so were excluded from analysis.

There were no significant differences between cases and controls in terms of demographic variables. Similarly, there was no significant difference in HbA1c between cases and controls at baseline (71.4mmol/mol (6.5%) vs. 70.6 (6.5%), p=0.086). Baseline cholesterol, SBP and UACR were significantly greater in controls ($p<0.001$, $p<0.001$, $p=0.028$ respectively) and baseline DBP was significantly higher in cases ($p<0.001$) – see Table 33.

6.10.5.2. Data completeness

Paired baseline-follow up HbA1c values were available for 2,662/5,432 (47%) cases and 6203/10,677 (58%) controls. Data were more complete for the sub-group of patients who attended clinic during the period of study (n=1,883). In this group, the majority of cases and controls had paired data available for baseline and follow up (937/1116 NWH cases; 558/767 SJH cases; 2649/3557 controls). The least well-captured dependent variable was UACR (539/1116 NWH cases; 319/767 SJH cases; 1199/3557 controls) – see Figure 35.

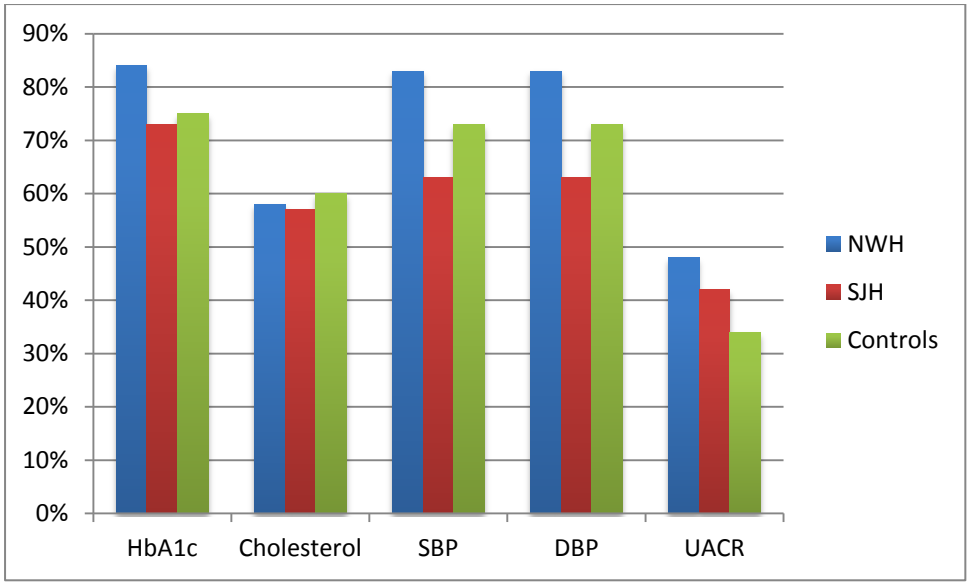

Figure 35. Data completeness for each dependent variable in those attending clinic (n=1,883).
Cases and control included in analysis if paired data available and baseline data recorded ±1 month of initial clinical consultation. SBP = systolic blood pressure; DBP = diastolic blood pressure; UACR = urinary albumin creatinine ratio.

6.10.5.3. Clinical outcomes

Cases were compared with controls at 9-15 months following the initial consultation. There were small improvements observed within the intervention group (NWH and SJH combined) for HbA1c, cholesterol, and systolic & diastolic blood pressure – see Table 33. In contrast, UACR increased in both groups. When compared with controls, the reduction in mean HbA1c was significantly greater at follow up (mean change in HbA1c: -2.3 mmol/l vs. -1.1, p=0.002). The increase in mean UACR was less pronounced in cases compared with controls (mean change in UACR: 0.6 vs. 4.6, p=0.025). Systolic blood pressure showed significantly greater improvements in the control group (mean change in SBP: -1.3 mmHg vs. -3.3, p<0.001). The difference in change in diastolic blood pressure and cholesterol did not reach significance.

Table 33. Univariable comparison of dependent outcomes.
*SBP = systolic blood pressure; DBP = diastolic blood pressure; UACR = urinary albumin creatinine ratio; SD = standard deviation. *UACR presented as median (IQR) with comparison made between mean change in UACR (change in UACR is normally distributed).*

	Cases, mean(SD)			Controls, mean (SD)			Mean difference (95% CI), p
	Baseline	Follow up	Change	Baseline	Follow up	Change	
HbA1c (mmol/mol)	71.4 (19.7)	69.1 (17.9)	-2.3 (16.8)	70.6 (19.8)	69.5 (18.2)	-1.1 (17.3)	-1.2 (-2.0 to -0.4), p=0.002
Cholesterol (mmol/l)	4.2 (1.1)	4.1 (1.1)	-0.1 (0.8)	4.3 (1.1)	4.3 (1.1)	-0.05 (0.0)	0.0 (-0.1 to 0.0), p=0.549
SBP (mmHg)	136.5 (18.5)	135.2 (17.6)	-1.3 (19.5)	137.8 (19.9)	134.5 (8.1)	-3.3 (20.4)	2.0 (1.0 to 2.9), p<0.001
DBP (mmHg)	75.7 (10.8)	75.0 (10.6)	-0.8 (11.2)	74.5 (12.0)	73.4 (10.9)	-1.1 (12.4)	0.4 (-0.2 to 0.9), p=0.244
UACR*	1.5 (4.5)	1.6 (6.3)	0.0 (2.3)	2.2 (6.7)	2.6 (9.0)	0.2 (3.5)	-4.0 (-7.5 to -0.5), p=0.025

Patient group (i.e. case or control) remained a significant predictor of change in HbA1c (p=0.003), when adjusted for potential confounders – see Table 34. Of the potential confounders, increased duration of diabetes and lower BMI was associated with significant reductions in HbA1c (p<0.001 and p=0.022, respectively).

Table 34. Linear regression showing predictors of change in HbA1c.
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

HbA1c	Univariable			Multivariable		
	B	CI	p	B	CI	p
Group	1.208	0.429 - 1.987	0.002	1.198	0.418 - 1.978	0.003
Age	0.012	-0.01 - 0.34	0.277	-0.006	-0.035 - 0.024	0.703
Diabetes type	-0.568	-1.344 - 0.208	0.151	0.499	-0.637 - 1.635	0.389
Gender	-0.286	-1.004 - 0.432	0.435	-		
Duration of diabetes	0.112	0.076 - 0.148	<0.001	0.114	0.073 - 0.155	<0.001
BMI	-0.078	-0.133 - -0.024	0.005	-0.069	-0.128 - -0.010	0.022

Change in cholesterol values between the intervention and follow up periods was independent of patient group. Similarly, none of the potential confounders were found to be significant – see Table 35.

.

Table 35. Linear regression showing predictors of change in cholesterol.
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

Cholesterol	Univariable			Multivariable		
	B	CI	p	B	CI	p
Group	0.016	-0.037 - 0.069	0.549	-		
Age	0	-0.002 - 0.001	0.831	-		
Diabetes type	-0.055	-0.106 - -0.003	0.037	-0.037	-0.095 - 0.020	0.203
Gender	0.043	-0.003 - 0.090	0.069	0.045	-0.002 - 0.092	0.059
Duration of diabetes	0.003	0.000 - 0.005	0.027	0.002	0.000 - 0.004	0.102
BMI	-0.002	-0.006 - 0.001	0.232	-0.001	-0.005 - 0.003	0.716

There was an observed decrease in systolic blood pressure that was significantly greater in the control group. This remained highly significant, once adjusted for potential confounders (p<0.001) – see Table 36. Age was the only significant confounder, whereby reductions in SBP were greater with increased age (p<0.001). In contrast, changes in diastolic blood pressure were unrelated to patient group or any of the independent variables entered – see Table 37.

Table 36. Linear regression showing predictors of change in systolic blood pressure.
All univariable predictors significant to p<0.3 entered simultaneously. . B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

SBP	Univariable			Multivariable		
	B	CI	p	B	CI	p
Group	-1.953	-2.184 - -0.503	0.002	-1.987	-2.975 - -1.000	<0.001
Age	-0.066	-0.094 - -0.037	<0.001	-0.07	-0.107 - -0.033	<0.001
Diabetes type	-0.969	-1.933 - -0.005	0.049	0.486	-0.917 - 1.889	0.497
Gender	0.012	-0.867 - 0.890	0.979	-		
Duration of diabetes	-0.035	-0.079 - 0.009	0.114	-0.018	-0.069 - 0.032	0.475
BMI	-0.049	-0.118 - 0.020	0.161	-0.058	-0.133 - 0.017	0.127

Table 37. Linear regression showing predictors of change in diastolic blood pressure.
All univariable predictors significant to p<0.3 entered simultaneously. . B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

DBP	Univariable			Multivariable		
	B	CI	p	B	CI	p
Group	-0.757	-1.262 - -0.52	0.244	-0.367	-0.960 - 0.226	0.226
Age	-0.021	-0.807 - 1.354	0.619	-		
Diabetes type	-0.601	-1.008 - 1.064	0.958	-		
Gender	-0.228	-1.278 - -0.503	0.396	-		
Duration of diabetes	0.026	-0.001 - 0.052	0.055	0.024	-0.003 - 0.051	0.076
BMI	-0.022	-0.063 - 0.019	0.294	-0.02	-0.061 - 0.022	0.359

As previously noted, observed increases in urinary ACR were greater in controls compared with cases. This difference remained significant once adjustment was made for potential confounders – see Table 38. None of these potential confounders significantly predicted change in urinary ACR.

Table 38. Linear regression showing predictors of change in urinary albumin/creatinine ratio. All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

UACR	Univariable			Multivariable		
	B	CI	p	B	CI	p
Group	4.003	0.494 – 3.787	0.025	3.931	0.419 – 7.443	0.028
Age	0.094	0.000-0.187	0.049	0.035	-0.086 – 0.155	0.573
Diabetes type	2.799	-0.364 – 5.962	0.083	2.516	-1.950 – 6.983	0.269
Gender	0.854	-1.932 – 3.640	0.548	-	-	
Duration of diabetes	0.121	-0.021 – 2.64	0.096	0.160	-0.002 – 0.322	0.053
BMI	0.150	-0.072 – 0.371	0.186	0.101	-0.139 – 0.340	0.409

6.10.5.4. Cycle one – Ninewells Hospital, Dundee

In the 9-15 month period following the initial consultation, both mean HbA1c and mean blood pressure (systolic and diastolic) reduced slightly in cases and controls – see Table 39. UACR increased in both groups, whilst cholesterol was largely unchanged.

*Table 39. Improvement cycle one - baseline and follow up values for dependent variables, by intervention group. SBP = systolic blood pressure; DBP = diastolic blood pressure; UACR = urinary albumin creatinine ratio; SD = standard deviation. *UACR presented as median (IQR) with difference between cases and controls as mean (SD) (change in UACR is normally distributed)*

	Cases			Controls		
	Baseline mean(SD)	Follow up mean (SD)	Mean difference (SD)	Baseline mean(SD)	Follow up mean (SD)	Mean difference (SD)
HbA1c (mmol/mol)	72.3 (19)	70.4 (17.2)	-1.3 (14.8)	71.7 (19.9)	70.8 (18.9)	-0.8 (16.9)
Cholesterol (mmol/l)	4.1 (1)	4.1 (1)	0 (0.7)	4.4 (1.2)	4.3 (1.1)	0 (0.9)
SBP (mmHg)	138.4 (19.2)	137.2 (17.6)	-1.4 (19.7)	134.4 (19.2)	133.7 (17.9)	-2.1 (19.9)
DBP (mmHg)	75.7 (11.2)	75.7 (10.6)	-0.2 (11.2)	74 (11.9)	73.3 (10.9)	-0.8 (12.3)
UACR* (mg/mmol)	1.3 (4.5)	1.3 (6.5)	0.0 (2,1)	2.2 (6.7)	2.5 (8.9)	3.3 (35.0)

There was no statistically significant observed difference between cases and controls for any of the dependent variables – see Table 40 to Table 44. Increased duration of diabetes was associated with a significant improvement in HbA1c (Table 40), whilst increasing BMI was associated with a

deterioration in UACR (Table 44).

Table 40. Linear regression showing cycle one predictors of change in HbA1c.
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

HbA1c	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	0.55	-0.76-1.87	0.408	-		
Age (years)	0.03	-0.01-0.07	0.101	0.03	-0.15-0.065	0.218
Diabetes type	0.16	-1.2-1.53	0.813	-		
Gender	0	-1.29-1.28	0.996	-		
Duration of diabetes (years)	0.08	0.02-0.15	0.013	0.07	0.01-0.14	0.025
BMI	-0.04	-0.14-0.06	0.433	-		

Table 41. Linear regression showing cycle one predictors of change in cholesterol.
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

Cholesterol	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	-0.04	-0.12-0.04	0.329	-		
Age (years)	0	0-0	0.322	-		
Diabetes type	-0.01	-0.09-0.08	0.908	-		
Gender	0.07	-0.01-0.15	0.085	0.07	-0.01-0.15	0.085
Duration of diabetes (years)	0	0-0.01	0.686	-		
BMI	0	-0.01-0.01	0.882	-		

Table 42. Linear regression showing cycle one predictors of change in systolic blood pressure (SBP)
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

SBP	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	-0.75	-2.37-0.87	0.363	-		
Age (years)	-0.05	-0.09-0	0.067	-		
Diabetes type	-1.23	-2.91-0.45	0.151	-0.8	-2.64-1.05	0.398
Gender	0.01	-1.58-1.59	0.995	-		
Duration of diabetes (years)	-0.03	-0.11-0.05	0.458	-		
BMI	-0.1	-0.22-0.02	0.114	-0.08	-0.21-0.06	0.277

Table 43. Linear regression showing cycle one predictors of change in diastolic blood pressure (DBP). All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

DBP	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	-0.58	-1.56-0.39	0.239	-0.61	-1.59-0.36	0.216
Age (years)	0.02	-0.01-0.05	0.2	0.02	-0.01-0.05	0.257
Diabetes type	-0.2	-1.21-0.8	0.691	-		
Gender	0.02	-0.93-0.97	0.968	-		
Duration of diabetes (years)	0.03	-0.02-0.07	0.274	0.02	-0.03-0.07	0.379
BMI	-0.03	-0.1-0.05	0.458	-		

Table 44. Linear regression showing cycle one predictors of change in urinary albumin creatinine ratio (UACR). All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

UACR	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	2.17	-1.64 – 5.97	0.264	2.28	-1.52 – 6.08	0.239
Age (years)	0.08	-0.05 – 0.21	0.202	0.06	-0.07 – 0.19	0.330
Diabetes type	1.36	-2.93 – 5.65	0.534	-		
Gender	2.27	-1.58 – 6.12	0.248	2.52	-1.34 – 6.38	0.201
Duration of diabetes (years)	0.09	-0.10 – 0.29	0.352	-		
BMI	0.37	0.08 - -0.67	0.014	0.38	0.08 – 0.68	0.013

6.10.5.5. Cycle two – St John's Hospital, Livingston

During the 9-15 months following the initial outpatient appointment, there were small reductions in HbA1c in both cases and controls – see Table 45. Cholesterol remained relatively stable in both groups. Systolic and diastolic BP increased in cases, whilst a decrease was observed in controls. UACR increased in both groups, but more so in cases.

*Table 45. Improvement cycle two - baseline and follow up values for dependent variables, by intervention group. SBP = systolic blood pressure; DBP = diastolic blood pressure; UACR = urinary albumin creatinine ratio; SD = standard deviation. *UACR presented as median (IQR) with difference between cases and controls as mean (SD) (change in UACR is normally distributed)*

	Cases			Controls		
	Baseline mean(SD)	Follow up mean (SD)	Mean difference (SD)	Baseline mean(SD)	Follow up mean (SD)	Mean difference (SD)
HbA1c (mmol/mol)	68.5 (18.3)	68.2 (17.6)	-0.4 (16.4)	71.4 (19.3)	70.4 (18.1)	-0.8 (18)
Cholesterol (mmol/l)	4.4 (1.1)	4.4 (1.1)	0 (0.9)	4.4 (1.1)	4.3 (1.1)	-0.1 (0.8)
SBP (mmHg)	131.1 (17.1)	134.1 (17.3)	2.7 (19.3)	136.5 (19.6)	133.9 (18)	-2.2 (20.6)
DBP (mmHg)	75.3 (10.8)	75.3 (10.3)	0.4 (11)	75.2 (11.4)	73.9 (10.8)	-0.8 (12.3)
UACR* (mg/mmol)	1.7 (4.5)	2.3 (6.2)	0.1 (2.4)	2.4 (8.7)	2.7 (8.5)	6.8 (41.1)

The presence of an EBMeDS prompt was not associated with improvements in any of the dependent variables (see Table 46 to Table 50). The observed decrease in blood pressure within the control group was highly significant (see Table 48 and Table 49). Mirroring cycle one results, increased duration of diabetes was associated with improved HbA1c (Table 46) as well as worsening UACR (Table 50). Type 2 diabetes was also significantly associated with worsening UACR.

Table 46. Linear regression showing cycle two predictors of change in HbA1c.
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

HbA1c	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	-1.15	-2.93-0.63	0.205	-1.15	-2.94-0.63	0.206
Age (years)	-0.04	-0.1-0.01	0.132	-0.06	-0.13-0.01	0.116
Diabetes type	-1.61	-3.37-0.15	0.072	1.19	-1.4-3.78	0.368
Gender	0.24	-1.46-1.94	0.78	-		
Duration of diabetes (years)	0.1	0.01-0.18	0.025	0.11	0.01-0.21	0.025
BMI	-0.19	-0.32--0.05	0.006	-1.18	-0.32--0.03	0.019

Table 47. Linear regression showing cycle two predictors of change in cholesterol.
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

Cholesterol	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	-0.05	-0.15-0.05	0.325	-		
Age (years)	0	-0.01-0	0.272	0	-0.01-0	0.343
Diabetes type	-0.04	-0.14-0.06	0.413	-		
Gender	0.04	-0.06-0.13	0.463	-		
Duration of diabetes (years)	0	0-0.01	0.533	-		
BMI	0	-0.01-0	0.294	0	-0.01-0	0.373

Table 48. Linear regression showing cycle two predictors of change in SBP.
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

SBP	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	-4.93	-7.11--2.76	0	-4.92	-7.1--2.73	<0.001
Age (years)	-0.06	-0.13-0.01	0.087	-0.06	-0.13-0.01	0.076
Diabetes type	0.32	-1.79-2.44	0.764	-		
Gender	0.42	-1.63-2.48	0.686	-		
Duration of diabetes (years)	-0.06	-0.16-0.04	0.238	-0.05	-0.15-0.05	0.312
BMI	-0.02	-0.18-0.14	0.807	-		

Table 49. Linear regression showing cycle two predictors of change in DBP.
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

DBP	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	-1.28	-2.56-0	0.05	-1.3	-2.58--0.02	0.047
Age (years)	-0.03	-0.07-0.01	0.091	-0.03	-0.07-0.01	0.084
Diabetes type	-0.63	-1.87-0.61	0.317	-		
Gender	-0.56	-1.76-0.64	0.36	-		
Duration of diabetes (years)	0.03	-0.03-0.09	0.358	-		
BMI	-0.02	-0.12-0.07	0.645	-		

Table 50. Linear regression showing cycle two predictors of change in UACR.
All univariable predictors significant to p<0.3 entered simultaneously. B = correlation coefficient; 95% CI = 95% confidence interval; BMI = body mass index.

UACR	Univariable			Multivariable		
	B	95% CI	p	B	95% CI	p
Group	5.82	-0.64 – 12.29	0.077	4.76	-1.55 – 11.07	0.139
Age (years)	0.11	-1.11 – 0.32	0.326	-		
Diabetes type	6.31	-0.412 – 13.03	0.066	9.16	2.24 – 16.08	0.010
Gender	-2.11	-8.60 – 4.38	0.523	-		
Duration of diabetes (years)	0.41	0.08 – 0.73	0.014	0.55	0.20 – 0.89	0.002
BMI	-0.02	-0.51 – 0.48	0.942	-		

6.10.5.6. Post hoc analysis

Cases from both cycle one and cycle two were considered within the *post hoc* analysis, which compared the proportion of cases and controls moving from above to within target HbA1c (≤53mmol/mol). There was a slightly greater proportion in the intervention group, but this failed to reach significance – see Table 51.

Table 51. Proportion of cases and controls with HbA1c above and within target range (≤53mmol/mol) at baseline and follow up.

HbA1c	Baseline		Follow up	
	Cases	Controls	Cases	Controls
above target	2081 (82.4%)	5014 (81.0%)	20159 (81.5%)	5082 (82.1%)
within target	446 (17.6%)	1174 (19.0%)	468 (18.5%)	1106 (17.9%)
Total	2527	6188	2527	6188

Of those cases that had an HbA1c above target at baseline, 208/2,527 (8.2%) moved to within target at follow up. In contrast, 468/6188 (7.6%) controls moved from above to within target HbA1c during the period of study. Multivariable cox regression did not demonstrate any significant difference between study groups (B 0.932, 95%CI 0.791-1.099, p=0.404, see Figure 36.

Those with T2D were 1.3 times more likely than those with T1D to move within the target range (95%CI: 1.076-1.606, p=0.007)). Duration of diabetes was also predictive of moving into the target range – the probability decreased by 1.7% for every year of having diabetes (Exp(B) 0.983, 95%CI: 0.975-0.992, p<0.001). There was no association between the probability of moving into target range and gender or BMI.

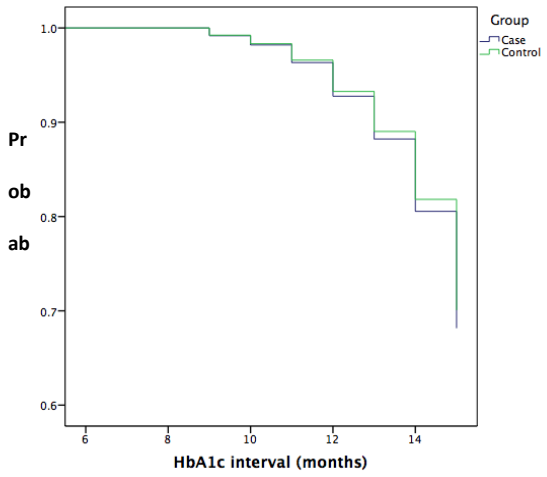

Figure 36. Probability of HbA1c moving from above target to within target through time. Time=0 is the date the clinical record was opened. Target HbA1c defined as ≤53mmol/mol.

6.10.6. Discussion

The analysis has demonstrated a significant improvement in glycaemic control in the patients for whom the HCP received a CDSS message, when compared with matched controls living elsewhere in Scotland. In addition, patients who were subject to a CDSS message showed significantly less deterioration in kidney disease when compared to control subjects. Both patient groups showed small decreases in SBP, however the improvement in SBP shown in the control group was significantly greater than in the cases. It is difficult to compare these findings with previous studies owing to heterogeneity of interventions. With regards to diabetes care specifically, most studies (included in a systematic review that evaluated computerised prompting of diabetes care) limit their analyses to clinical processes (e.g. adherence to guidelines) as opposed to clinical outcomes [171]. Studies included in this systematic review that did include glycaemic control as an outcome measure failed to demonstrate any improvement.

It should be acknowledged that the mean improvement in glycaemic control amongst cases is probably of little clinical significance. This is demonstrated by the *post hoc* analysis that failed to demonstrate any significant improvement in the proportion of patients in whom glycaemic control could be considered within target. The chosen target of HbA1c ≤53mmol/mol was based on available national guidance for those with T2D [9] which, in turn, is based on evidence that an HbA1c ≤53mmol/mol is associated with improved clinical outcomes [170].

It is plausible that the lack of deterioration in kidney disease observed in cases could be a direct result of the CDSS – many of the messages prompt users to screen for and treat microalbuminuria. It is more difficult to provide an explanation for the observed improvements in control group SBP, which may be accounted for by one or more of the limitations in this study that will now be considered.

6.10.6.1. Power calculation

Patient numbers used within the pre-study power calculation were based on data derived from outpatient clinic information systems. In addition, the anticipated CDSS message frequency was a rough approximation based on no empirical data. As demonstrated previously (see section 6.8), the most frequent users of SCI-Diabetes are nursing staff. These users often open patient records in a non-clinical context e.g. retrospective data entry, audit, telephone queries etc. In addition, the CDSS message frequency was approximately double that expected (39% of all records opened – see section 6.8). All of these factors contributed to far higher patient numbers than were initially anticipated, producing results that in some instances are statistically, but not clinically significant. Future analyses could limit cases to those whose electronic health record was opened within a clinical context e.g. outpatient clinic.

6.10.6.2. Selection bias

Despite the high numbers of cases, this patient group may not be representative of the wider diabetes community. The mean HbA1c for both cases and controls was higher than the regional average[4] which is unsurprising, given that both groups are attending secondary care clinics (where there tends to be more complex disease). There was also a greater proportion of those with T1D compared with the national average[4], however age and sex distributions were similar to national averages, as was duration of diabetes. Inclusion relied on clinic attendance, therefore non-attenders/less engaged patients were less likely to be included due to their records not being opened. The analysis also relied on paired data samples, measured at baseline and follow up. This resulted in significant attrition and further increased the risk of selection bias. Imputation was not considered appropriate, owing to the lack of repeat measures from which to impute.

6.10.6.3. Study design

Whilst controls were closely matched to cases by demographic variables, there was no ability to match local clinical practice. Most diabetes centres work to national guidelines, however it is highly likely that there will be variation in practice across the country, thereby limiting the ability to infer that the intervention is responsible for observed differences. Another consideration is the matching of cases to controls on demographics alone. A more sophisticated approach would be to also match controls on the dependent outcome at baseline i.e. the controls' data would have triggered the same CDSS message if the system was operating in their locality. Unfortunately, this was not technically feasible.

Patients were assigned to being a "case" if the HCP received a CDSS message on opening their record. The subject of that message was not considered in this analysis and may not have been related to the primary outcome (e.g. the message may have been a reminder to assess foot risk score i.e. unrelated to glycaemic control). This was a pragmatic decision based on data availability, and it is acknowledged that future analyses should address this shortcoming. This could be achieved by including CDSS message relevance to the outcome being considered, as a dichotomous independent variable within the multivariable analysis which would delineate the impact of the intervention more clearly.

6.10.6.4. Study implications

Despite these limitations, it is notable that this study has provided evidence that the CDSS is associated with improvements in clinical outcomes – an important finding given the lack of evidence in this area [60]. Whilst the modest improvement in glycaemic control is thought to be of little clinical significance in this study population, there are potential gains to be made at a population level. Small improvements in glycaemic control are associated with considerable long-term savings due to reduced complications. For example, if the current UK Type 1 diabetes population reduced their HbA1c by 4mmol/mol (0.4%) the estimated saving would be £39m over 5 years (£995m after 25 years)[172].

Our findings demonstrated a non-significant increase in the proportion of cases with an HbA1c $\leq$53 mmol/mol - increasing from 17.6% to 19.0%. If this improvement were replicated at a national level (276,430 people diagnosed with diabetes in Scotland [4]), this could potentially account for nearly 4,000 individuals reducing their HbA1c to $\leq$53 mmol/mol. An HbA1c within this range is associated with a 35-76% decrease in microvascular complications compared to those with poorer glycaemic control (median HbA1c 74 mmol/mol) at long term follow up [170].

The lack of progression in kidney disease (as measured by UACR) amongst cases compared to controls is also worth noting. Approximately three quarters of patients with diabetes in England & Wales have some form of chronic kidney disease (CKD), the vast majority of whom have early onset disease (CKD stages 1-2) [173]. Treatment with ACE inhibitors can not only prevent microalbuminuria from progressing to macroalbuminuria, but can also induce regression to no albuminuria [174]. CKD is a risk factor for cardiovascular disease (CVD) and people with CKD are more likely to die of CVD than end stage renal failure [175]. Therefore, any reduction in incidence or progression of CKD has the potential to not only improve morbidity but also to reduce all cause mortality for a substantial proportion of people with diabetes.

With regards to other cardiovascular risk factors, it is notable that whilst both cases and controls demonstrated a reduction in systolic blood pressure, this decrease was significantly greater in controls. Again, is arguable that the magnitude of the observed reduction is such that this is probably of little clinical significance at an individual level. However, at a population level, small reductions in mean blood pressure can result in large improvements in the risk of an adverse cardiovascular event [176]. It is unclear as to why such a difference was observed and the study methodology does not allow for this question to be answered. Blood pressure was chosen as a secondary outcome as many of the CDSS messages are concerned with the initiation of blood pressure lowering therapy. At the very least, it could be argued that these messages have had little effect in changing user behaviour and that the observed differences are a result of variation in local practice. Perhaps more importantly, consideration should be given to the possibility that the CDSS is having an adverse effect on user behaviour e.g. the multiple messages displayed by the CDSS may distract a user from their normal clinical practice, resulting in a lack of attention being paid to management of hypertension. Whilst it is acknowledged that the existing system is associated with a degree of user fatigue (see sections 6.6 and 6.7), questionnaire respondents and focus group contributors did not report any adverse effects.

Further work is required in this area. The analysis above was unable to take account of message contents. It is therefore not known if the observed difference in Systolic BP can be attributed to the contents of the message *per se*. There is scope to consider message contents and the other potential distractors (i.e. additional messages) in the analysis of clinical outcomes, and it could be argued that this is essential from a quality assurance and safety perspective.

6.10.7. Conclusion

The study has demonstrated a small improvement in glycaemic control and a decrease in progression of kidney disease when compared to a closely matched control population. The limitations of the study preclude any causal inference and the observed differences are of limited clinical significance (but may have implications at the population level). This study has shown how a national informatics platform can be readily utilised to evaluate research questions arising from quality improvement interventions.

6.11 Summary of EBMeDS project findings

The use of the EBMeDS system had no adverse effects on patient experience, clinic consultation or working practices. Quantification of system usage supports users' assertion that the system encourages more efficient working practices. For clinical processes, the odds of a patient receiving an appropriate screening investigation following a clinic appointment were significantly raised. With regards to clinical outcomes, the presence of an EBMeDS message was associated with small improvements in glycaemic control.

6.11.1. Implications

Aside from the health benefits afforded by early intervention, there are considerable potential economic savings. This is explored in greater depth using foot screening as an example.

Diabetes-related foot complications currently account for nearly £1 billion per year of UK healthcare spending[8]. In Scotland, approximately one quarter of patients with diabetes (n~70,000) have not received foot screening in the past 15 months[4]. If the observed improvement in screening were extrapolated to the whole country, an additional 15,000 patients would receive foot screening every year. Screening for foot disease reduces the risk of ulceration by approximately a third[177]. Taking into account the current prevalence of foot disease, 750 of this 15,000 cohort are at risk of developing ulceration in the absence of screening. Screening could therefore prevent ~250 episodes of ulceration per year. Assuming that patients with ulceration require at least one admission to hospital per year[178], this represents an annual saving of ~£500k per year. Those with a history of ulceration are also at high-risk of future amputation. For each high-risk patient identified and effectively managed, it is estimated that ~£1000-1500 is saved per year[179]. Taking into account the above assumptions, if the system was available on a national basis it is estimated that an additional ~500 high-risk patients would be identified per annum. Effective management of this cohort would therefore save an additional £500k-£750k per year i.e. a potential total saving of £1m per year for NHS Scotland.

Similar magnitudes of improvement were observed in screening for kidney disease and serum cholesterol. Extrapolated to the Scottish population, this would result in an additional ~15,000 patients having UACR checked and ~4,000 individuals having serum creatinine and cholesterol measured annually, increasing the potential for early intervention to prevent costly cardiovascular events and renal disease.

Despite the observed modest improvements in glycaemic control it is worth noting that even small improvements in glycaemic control are associated with considerable long-term savings due to reduced complications. For example, if the current UK Type 1 diabetes population reduced their HbA1c by 4mmol/mol (0.4%) the estimated saving is £39m over 5 years (£995m after 25 years)[180].

6.11.2. Risks

Just as small improvements in glycaemic control can improve long term outcomes, so too can small reductions in blood pressure result in improved cardiovascular outcomes. In one randomised controlled trial conducted over a period of 4 years, there was a twofold increase in risk of a major cardiovascular event in those assigned to a diastolic BP of less than 90mmHg versus the group assigned to less than 80mmHg, despite relatively small differences in the observed BP (mean achieved BP 85mmHG versus 81mmHg)[176]. In this study, the control population systolic BP improved significantly more than cases (see section 6.10). Given the long-term effects of such an improvement, this observed difference should not simply be attributed to methodological weakness – further investigation is required.

This study did not demonstrate any adverse effects on patient satisfaction, as measured by PREMs (see section 6.5). It is acknowledged that this analysis was conducted on a sub-population of respondents and that in order to satisfy the initial power calculation, further analysis is required. In general, the impact of computer use and electronic medical records on the doctor-patient relationship remains a much debated phenomenon [129]. Whilst some studies have demonstrated an adverse effect on the clinical encounter (e.g. decreased patient-centredness), the evidence also

points to improvements in the consultation (e.g. communication of information and patient reported satisfaction) [129,181]

More broadly, consideration should also be given to both the regulatory framework within which CDSS is developed, as well as the legal liabilities of developers and users of such systems. According to MHRA definitions, CDSS is considered a medical device and is therefore subject to the same oversight as any other physical device [95]. What is less clear is who is liable for such devices if (and no doubt when) they go wrong. There are three main stakeholders in the successful implementation and use of a CDSS – software developers; purchasing organisations who implement the system; and health care practitioners who use the system [182]. Fox et al note there is an absence of case law precedent in the UK, but that it is reasonable to assume that developers of CDSS have a legal *duty of care* to the users of such systems [183]. Accordingly, it is incumbent on developers to develop CDSS in accordance with appropriate quality and safety protocols and to risk assess each constituent part of the system [183]. Risk management of such systems rely on a trade off between maximising safety and minimising additional use of finite resources, with the aim to achieve a risk that is "as low as is reasonably practical" [183]. Quality assurance is recommended at all stages of a product's life cycle, but until recently, there had been little practical guidance as to how best to achieve this [184]. The GUIDES project has convened a panel of internationally sourced experts, and aims to address this shortfall this by providing explicit advice on the development and implementation of CDSS via a checklist of essential considerations (contributing author - article in press) [185].

6.11.3. Benefits

6.11.3.1. Academic

This study demonstrated improved HCP adherence to guideline-driven care and directly contributes to the evidence base for CDSS in general. To date, the work has been presented at national and international conferences, and has been accepted for publication by peer-reviewed journals. The project has been selected as a finalist for the 2016 Quality in Care, Diabetes awards [186].

It is envisaged that the system will be adapted to provide tailored decision support for patients, delivered through the patient portal, mydiabetesmyway[187,188]. This will include decision support based on self-monitored blood glucose uploaded from home. Future research will aim to identify the role of tailoring of messages to individuals, by taking account of medical co-morbidities, health literacy and levels of engagement with the service

6.11.3.2. Civic

This project was a collaboration between Duodecim, NES and the Digital Health & Care Institute (DHI)[1], which funded the project. Further funding from DHI has been established to define the system architecture necessary to integrate with existing primary care systems and to provide patient-directed decision support. There is widespread awareness and clinical support through the Scottish Diabetes Group and Diabetes Managed Clinical Networks throughout Scotland.

The CDSS in its current form prompts HCPs to consider screening for complications as well as optimisation of current management. These evidence-based, early interventions can significantly impact on costly and devastating complications such as foot ulcers, amputations, cardiovascular disease, renal failure and death.

There may also be potential efficiencies and wider cost savings by decision prompts which negate the need for wider interrogation of the medical record. Not only does the study add to the evidence-base for CDSS, it serves as an exemplar for decision support across healthcare systems in Scotland, including primary care [189]. Therefore, the potential benefits of this project extend beyond the Scottish diabetes population, as NHS Scotland considers how best to realise the full potential of CDSS described in the national eHealth strategy [57].

6.11.3.3. Business

The CDSS is an example of a "system-agnostic" tool, which can be integrated into any EHR. System behaviour is dictated by administrators and advice is customisable to local context. The various algorithms that have been developed locally can be implemented into any CDSS, making commercialisation of the system a realistic prospect.

The SCI-diabetes project has been instrumental in guiding the Scottish government in assessing the benefits of decision support and is driving the wider use of CDSS across national healthcare systems [189]. Long term funding and wider procurement of decision support systems across NHS Scotland are currently being secured with Scottish Government support [190].

The diabetes digital landscape continues to evolve at a rapid pace. Scotland's national informatics platform for diabetes ensures that widespread implementation is technically straightforward. This work could easily be adapted in other areas of the UK and beyond. This project can be viewed as an exemplar of good practice for other healthcare organisations considering such innovations, potentially improving the safety, quality and standardisation of diabetes care.

7. Overall discussion

7.1 Summary of Findings

The overarching aims of this investigation were to:

1. Determine the effectiveness of eHealth interventions designed to improve the management of chronic diseases by providing tailored information to health care practitioners, patients and/or carers
2. Describe the implementation and evaluation of a clinical decision support system (CDSS) within an electronic health record for those with diabetes

The investigation found that:

1. Information provided to individuals in a tailored way through traditional media is more effective at effecting behaviour change than generic information. However, there is a lack of evidence to suggest that similar tailoring of information within eHealth systems provides added benefit.
2. The CDSS that was successfully implemented within the SCI-Diabetes electronic health record was well received by staff, with no adverse effects on the clinical consultation. The system was associated with greatly improved adherence to guidelines. There were modest improvements in some clinical outcomes, of limited clinical significance.

7.2 Strengths of the investigation

The investigation has provided a wealth of evidence to support the assertion that decision support can improve clinical care, by demonstrating large improvements in adherence to clinical guidelines and significant improvements in clinical outcomes. As previously discussed (see section 6.11), extrapolating these findings to a national level highlights the potential for the prevention of diabetes-related complications in a sizable proportion of the diabetes population. The investigation has also identified research questions that remain unanswered, and has highlighted the need for a

rigorous approach to governance and quality assurance when developing and implementing any system that has implications for patient safety.

The investigation has benefitted from a multi-faceted approach, utilising both quantitative and qualitative methodologies. This is borne out in the findings of the main body of the work - the implementation and evaluation of the CDSS. The use of a theoretical framework for evaluation ensured that these methods (and the wealth of data that they generated) created a rich picture of how people interact with the system and the effects that this has on patient management. The system was implemented at a population level (in more than one health board), thereby further adding to the sheer volume of data that were successfully exploited for the purposes of assessing efficacy.

The collaboration with private industry and national governmental agencies has ensured that the project remained achievable and relevant to the national context. As the study draws to a close, the reported results have contributed to on going government support of CDSS within diabetes care. Furthermore, the investigation is serving as an exemplar for decision support more widely within NHS Scotland.

7.3 Weaknesses of the investigations

The systematic review was conducted prior to the CDSS being fully developed and implemented. At its inception, the research question posed by the systematic review was designed to inform CDSS development. It was envisaged that the CDSS that was developed would have provided tailored information to the recipient. However, owing to the lack of evidence demonstrated by the systematic review, a pragmatic decision was made to limit the scope of the CDSS to providing non-tailored messages. This could be viewed as a missed opportunity to add to the evidence base in this area, but can be justified in terms of ensuring that the project was achievable within the given constraints.

The CDSS system can be adapted to provide tailored advice based on user role (e.g. doctor, nurse

etc.) and can also be adapted to provide patient advice via the MyDiabetesMyWay patient portal. It is therefore conceivable that future work can address the question as to whether or not tailoring provides added benefit.

Whilst the collaboration with multiple agencies added value to the investigation, the logistics of project management were sometimes made more difficult. Different partners had differing priorities with regards to their involvement in developing and evaluating the CDSS, and these priorities often shifted throughout the course of the investigation. The various agencies were often limited in terms of resources and time, with a knock-on effect on the project timeline. For example, recruitment to focus groups was limited by staff availability; data acquisition was delayed owing to lack of resource etc. Nevertheless, the completion of the investigation represents an example of successful cross-sector working that positively impacted upon patient care.

There are various methodological weaknesses noted throughout the investigation, discussed within the appropriate chapters. Whilst these methodological weaknesses limit both inference and generalisability of the findings, it is difficult to envisage how they could be avoided. This service improvement project was conducted within a real-life working clinical environment with limited resources, as opposed to a fully funded, carefully controlled, multicentre trial. From a personal perspective, this work will directly inform future study design in this area, in order to address these weaknesses.

7.4 Issues for further research

7.4.1. Turning data into information

The scope for developing and improving the CDSS is huge. It is technically possible to make the system available to the whole of NHS Scotland, with immediate effect. Before doing so, consideration must be given to the governance and quality assurance of the system. This investigation did not identify any safety concerns nor any negative impact on patient experience. However, it did demonstrate a significant improvement in systolic blood pressure when controls

were compared with cases. The chosen methods did not allow further investigation of this observation and future work should delineate whether the system had a causative role (see section 6.10.6.4 for further discussion). Furthermore, it could be argued that oversight of the system should embed quality improvement methods, whereby automated reports could be used to identify unforeseen adverse impacts on clinical processes and outcomes.

National roll out of the system will no doubt result in additional user feedback, with the possibility of the need to develop additional rule-based algorithms in response to this. In addition, the algorithms will need to be continually updated as new evidence and guidelines emerge. This could potentially reduce the observed delay in translating new evidence into everyday practice [191].

Ultimately, the aim would be to develop algorithms that cross reference different guidelines simultaneously. Given the prevalence of multi-morbidity in the diabetes population, this would seem to be an area where the CDSS has greatest relevance [55]. The CDSS could also potentially be adapted to other chronic illness for integration within the relevant electronic health record.

Each of the iterations described above represents an opportunity to test whether clinical care and outcomes improve as a result. Prospective trials, using cluster randomisation of geographical areas would overcome many of the methodological weaknesses identified within the current study.

Clinical decision-making by HCPs is a complex process that has been the subject of much research [192]. For example, diagnostic reasoning requires the clinician to formulate a list of differential diagnoses. When doing so, the clinician must first use the available clinical data to form a hypothesis (via a process of abstraction and abduction) then test that hypothesis (via deduction and inductive reasoning). Hypothesis testing relies on the clinician using a combination of working memory and long-term memory. The clinicians' long-term memory can be viewed as a biomedical repository that is stored in an ontological manner. As experience grows, pattern recognition ensures the system becomes more efficient, resulting in differing cognitive processes being employed by experts and non-experts in any given specialty [192]. Just as the cognitive processes employed by experts and non-experts differ when making clinical decisions, so too does the way in which they utilise clinical guidelines. Whilst the former tend to use the guidance as an aide memoir, the latter use guidelines to fill gaps in their own knowledge base [193].

Given the complexity of human clinical reasoning, it is perhaps unsurprising that CDSS in general (including that which was developed in this study) do not attempt to replicate this approach. Instead, the CDSS will typically consist of a decision tree (based on a pre-existing clinical guideline) which employs Boolean logic to convert clinical data into a suggested outcome [61]. However, this simplistic approach fails to take into account the vast number of data points relevant to the individual patient that are stored within the electronic health record (as well as other data silos) – data that is stored in both structured (i.e. coded) and unstructured (e.g. free text) formats. In addition, the increasing use of biomedical sensors within wearable technology (e.g. fitness devices) represents additional opportunity to mine data for useful information [194,195].

The increased prevalence of multi-morbidity presents a challenge to clinicians, whereby they must navigate several clinical guidelines in order to make informed decisions [55]. Added to which, the clinician is increasingly being asked to consider genomic and other lab-based data as diagnostic procedures become increasingly sophisticated and personalised. A CDSS that relies primarily on Boolean logic within a decision tree will soon become unfeasibly complex as the programmer tries to take account of the multiple disease combinations and permutations that any given patient may be experiencing. Instead, consideration must be given to the use of artificial intelligence (AI) as a means to process such volumes of data.

Machine learning is a form of AI that enables computer systems to learn to perform tasks from data as opposed to relying on specific programmes. In recent years, machine learning has been increasingly used within medical research and care. For example, the Cochrane library are developing machine learning techniques to construct search strategies [196]. There are also a number of disease-specific instances where machine learning has been employed to provide decision support [197]. To date, there are very few instances where AI has been used in order to improve care to those with multimorbidity [198]. Ultimately, an AI system should be capable of processing both structured and unstructured data to arrive at clinically relevant and informative decisions. Significant advances have already been made in this area, however these remain largely experimental [199]. Just as “Moore’s law” predicted the exponential rise in computing processing power [200], so too is it likely that the scope and complexity of CDSS will increase in the coming years. Machine learning may well provide a means to realise this, and should be explored within future clinical research.

7.4.2. Turning information into action

In addition to considering how the CDSS can be optimised in terms of data usage and processing, it is clear that additional work is required in deciding how the resultant information is best communicated to service users. This investigation has demonstrated that within eHealth interventions, there is a lack of evidence for tailoring of eHealth information to user group. In addition, this study has demonstrated a mismatch between the scope of existing diabetes-related mHealth apps and the priorities of the user.

The CDSS that was developed has the capability to provide a degree of tailoring to user group, be it professional role or patient. In effect, the clinical advice that is provided can be configured to be more relevant to the user e.g. medication advice to prescribers; screening advice for primary care etc. For patients, tailored advice can be delivered via the MyDiabetesMyWay patient portal, thereby empowering the "expert patient" to share in decision making with their clinician.

However, any such intervention is complicated by the need to consider how best to convey these messages so that they have maximum impact. Diabetes outcomes are poorer in those with lower health literacy [201,202], yet there is a lack of understanding as to how best to address this inequality[203]. Given that decision support messages have the potential to convey relatively abstract concepts (e.g. perception of risk), it is imperative that any future developments consider the role of health literacy when tailoring messages to patients (and HCPs).

Similarly, when developing mHealth apps (regardless of whether or not they incorporate an element of decision support), consideration must be given to users' literacy levels, in addition to stakeholder opinion. Failure to do so would only serve to widen the health inequality gap further [204]. Each of these potential developments offers a multitude of research opportunities from the qualitative work required in developing content and evaluating acceptability, to the quantitative assessment of how such changes can impact upon clinical outcomes.

8. References

1. Digital Health & Care Institute. Digital Health & Care Institute, https://dhi-scotland.com/ (accessed 27 January 2016).
2. Aridhia Informatics Ltd, http://www.aridhia.com/ (2013).
3. International Diabetes Federation. *IDF Diabetes Atlas*. 6th editio. Brussels, Belgium: International Diabetes Federation, http://www.idf.org/diabetesatlas/ (2013).
4. Scottish Diabetes Survey Monitoring Group. *Scottish Diabetes Survey 2014*. 2014.
5. Keenan K, Grant I, Ramsy J. *Scottish Health Survey: Topic Report; Obesity*, http://www.scotland.gov.uk/Publications/2011/10/1138/0 (2011).
6. Scottish Government. *The Scottish Health Survey; Topic Report; Older people's health*, http://www.scotland.gov.uk/Publications/2011/11/24083430/0 (2011).
7. Health and social care information centre. *National Diabetes Inpatient Audit*, http://www.rcn.org.uk/__data/assets/pdf_file/0018/531531/National-Diabetes-Inpatient-Audit-2012INTERACTIVE-PDF27-June-2013.pdf (2012).
8. Hex N, Bartlett C, Wright D, et al. Estimating the current and future costs of type 1 and type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabet Med* 2012; 29: 855–862.
9. Scottish Intercollegiate Guidelines Network. 116. Management of Diabetes. A national clinical guideline, http://www.sign.ac.uk/pdf/sign116.pdf (2010).
10. National Institute for Health and Care Excellence. *Diagnosis and management of type 1 diabetes in children, young people and adults (CG15)*, http://guidance.nice.org.uk/CG15 (2004).
11. National Institute for Health and Care Excellence. *Type 2 diabetes: The management of type 2 diabetes (CG87)*, http://publications.nice.org.uk/type-2-diabetes-cg87 (2009).
12. Cunningham S, McAlpine R, Leese G, et al. Databases for Diabetes Epidemiology: Using Web Technology to Support Population-Based Diabetes Care. *J Diabetes Sci Technol* 2011; 5: 523.
13. Schofield CJ, Yu N, Jain AS, et al. Decreasing amputation rates in patients with diabetes—a population-based study. *Diabet Med* 2009; 26: 773–777.
14. Vallance JH, Wilson PJ, Leese GP, et al. Diabetic Retinopathy: More Patients, Less Laser A longitudinal population-based study in Tayside, Scotland. *Diabetes Care* 2008; 31: 1126–1131.
15. Renders CM, Valk GD, Griffin SJ, et al. Interventions to Improve the Management of Diabetes in Primary Care, Outpatient, and Community Settings A systematic review. *Diabetes Care* 2001; 24: 1821–1833.
16. NHS Tayside Diabetes Managed Clinical Network. *Quality Care for Diabetes in Tayside. Annual Report of NHS Tayside Diabetes Managed Clinical Network 2012/13*, http://www.diabetes-healthnet.ac.uk/Documents/Uploaded/Annual_Report_2012-13.pdf (2013).
17. Diabetes UK. 15 Healthcare essentials, http://www.diabetes.org.uk/Documents/Guide to diabetes/15-healthcare-essentials-checklist-0913.pdf.
18. Scottish executive health department. National Framework for NHS Scotland, www.sehd.scot.nhs.uk/nationalframework/ (2004).
19. Scottish Government. *Delivering for health*, http://www.scotland.gov.uk/Publications/2005/11/02102635/26356 (2005).

20. Scottish Government. *NHS Scotland eHealth strategy 2008-2011*. 2008.

21. Scottish Government. *Diabetes Action Plan 2010. Quality care for diabetes in Scotland*, www.diabetesinscotland.org.uk/Publications/DAP2010.pdf (2010).

22. Liddell A, Adshead S, Burgess E. *Technology in the NHS : transforming the patient's experience of care*, www.kingsfund.org.uk/sites/files/kf/Technology-in-the-NHS-Transforming-patients-experience-of-care-Liddell-Adshead-and-Burgess-Kings-Fund-October-2008.pdf (2008).

23. Dixon A. *Engaging patients in their health : how the NHS needs to change*, http://www.kingsfund.org.uk/publications/engaging-patients-their-health-how-nhs-needs-change (2007).

24. Francis R. *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*, http://www.midstaffspublicinquiry.com/report (2013).

25. Francis R. *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Executive Summary*, http://www.midstaffspublicinquiry.com/sites/default/files/report/Executive summary.pdf (2013).

26. NHS Confederation. *Challenging Bureaucracy*, http://www.nhsconfed.org/Publications/Documents/challenging-bureaucracy.pdf (2013).

27. Al-Shorbaji N, Geissbuhler A. Establishing an evidence base for e-health: the proof is in the pudding. *Bull World Health Organ* 2012; 90: 322–322A.

28. Smith SM, Allwright S, O'dowd T. Effectiveness of shared care across the interface between primary and specialty care in chronic disease management. *Cochrane Database Syst Rev* 2007; 3.

29. Smith S, Bury G, O'leary M, et al. The North Dublin randomized controlled trial of structured diabetes shared care. *Fam …*, http://fampra.oxfordjournals.org/content/21/1/39.short (2004, accessed 24 October 2013).

30. Hoskins PL, Fowler PM, Constantino M, et al. Sharing the care of diabetic patients between hospital and general practitioners: does it work?. *Diabet Med*; 10: 81–86, http://ovidsp.ovid.com/athens/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med3&AN=8435994 (1993).

31. Naji S, Cameron I, Russell I, et al. Integrated care for diabetes: clinical, psychosocial, and economic evaluation. *Br Med J* 1994; 308: 1208–1212.

32. Greenhalgh PM. Shared care for diabetes. A systematic review. *Occas Pap R Coll Gen Pract* 1994; i.

33. Tang PC, Ash JS, Bates DW, et al. Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. *J Am Med Informatics Assoc* 2006; 13: 121–126.

34. Kim J, Jung H, Bates DW. History and Trends of 'Personal Health Record' Research in PubMed. *Healthc Inform Res* 2011; 17: 3–17.

35. Ko H, Turner T, Jones C, et al. Patient-held medical records for patients with chronic disease: a systematic review. *Qual Saf Heal Care* 2010; 19: 1–7.

36. Dijkstra R, Braspenning J, Grol R. Implementing diabetes passports to focus practice reorganization on improving diabetes care. *Int J Qual Heal Care* 2008; 20: 72–77.

37. Dijkstra RF, Braspenning JCC, Huijsmans Z, et al. Introduction of diabetes passports involving both patients and professionals to improve hospital outpatient diabetes care. *Diabetes Res Clin Pract* 2005; 68: 126–134.

38. Dijkstra RF, Niessen LW, Braspenning JCC, et al. Patient-centred and professional-directed implementation strategies for diabetes guidelines: a cluster-randomized trial-based

cost-effectiveness analysis. *Diabet Med* 2005; 23: 164–170.

39. Simmons D, Gamble GD, Foote S, et al. The New Zealand Diabetes Passport Study: a randomized controlled trial of the impact of a diabetes passport on risk factors for diabetes-related complications. *Diabet Med* 2004; 21: 214–217.

40. Irwig MS, Sood P, Ni D, et al. A diabetes scorecard does not improve HbA1c, blood pressure, lipids, aspirin usage, exercise and diabetes knowledge over 9 months: a randomized controlled trial. *Diabet Med* 2012; 29: 1206–1212.

41. Health Resources and Services Administration. mHealth, http://www.hrsa.gov/healthit/mhealth.html (2012, accessed 12 December 2014).

42. mobiForge. Mobile hardware statistics 2014, http://mobiforge.com/research-analysis/mobile-hardware-statistics-2014 (2015, accessed 1 March 2015).

43. The World Bank. Mobile cellular subscriptions (per 100 people). *World bank open data*, http://data.worldbank.org/indicator/IT.CEL.SETS.P2/countries/1W?display=graph (2013, accessed 1 March 2015).

44. The Guardian. Smartphone explosion in 2014 will see ownership in India pass US, http://www.theguardian.com/technology/2014/jan/13/smartphone-explosion-2014-india-us-china-firefoxos-android (2014, accessed 1 March 2015).

45. mHealth Alliance. mHealth Alliance. 2012; 2012.

46. Phillips G, Felix L, Galli L, et al. The effectiveness of M-health technologies for improving health and health services: a systematic review protocol. *BMC Res Notes* 2010; 3: 250.

47. Chomutare T, Fernandez-Luque L, Årsand E, et al. Features of mobile diabetes applications: review of the literature and analysis of current applications compared against evidence-based guidelines. *J Med Internet Res* 2011; 13.

48. Krishna S, Boren SA. Diabetes self-management care via cell phone: a systematic review. *J diabetes Sci Technol* 2008; 2: 509.

49. Ramadas A, Quek KF, Chan CKY, et al. Web-based interventions for the management of type 2 diabetes mellitus: a systematic review of recent evidence. *Int J Med Inform* 2011; 80: 389–405.

50. Brown LL, Lustria MLA, Rankins J. A review of web-assisted interventions for diabetes management: maximizing the potential for improving health outcomes. *J diabetes Sci Technol* 2007; 1: 892.

51. Auditor General for Scotland. *Managing long-term conditions*, http://www.audit-scotland.gov.uk/docs/health/2007/nr_070816_managing_long_term.pdf (2007).

52. McGlynn E, Asch S. The quality of health care delivered to adults in the United States. *N Engl J Med*; 348: 2635–45, http://www.nejm.org/doi/full/10.1056/nejmsa022615 (2003, accessed 20 November 2013).

53. Lugtenberg M, Burgers J, Clancy C, et al. Current guidelines have limited applicability to patients with comorbid conditions: a systematic analysis of evidence-based guidelines. *PLoS One*; 6: e25987, http://dx.plos.org/10.1371/journal.pone.0025987 (2011, accessed 20 November 2013).

54. Nobili A, Garattini S, Mannucci P. Multiple diseases and polypharmacy in the elderly: challenges for the internist of the third millennium. *J Comorbidity*; 1: 28–44, http://jcomorbidity.com/index.php/test/article/view/4 (2011, accessed 20 November 2013).

55. Guthrie B, Payne K, Alderson P, et al. Adapting clinical guidelines to take account of multimorbidity. *Br Med J*; 345: e6341, http://www.ncbi.nlm.nih.gov/pubmed/23036829

(2012, accessed 20 November 2014).

56. Scottish Government. *The Healthcare Quality Strategy for NHSScotland*, http://www.scotland.gov.uk/Resource/Doc/311667/0098354.pdf (2010).

57. Scottish Government. *NHS Scotland eHealth strategy 2014-2017*, http://www.gov.scot/Resource/0047/00472754.pdf (2015).

58. Lisboa PJG. A review of evidence of health benefit from artificial neural networks in medical intervention. *Neural Networks* 2002; 15: 11–39.

59. Bero L, Grilli R, Grimshaw J, et al. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. *Br Med J*; 317: 465, http://www.bmj.com/content/317/7156/465.short (1998, accessed 25 June 2014).

60. Garg AX, Adhikari NKJ, McDonald H, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes. *J Am Med Assoc* 2005; 293: 1223–1238.

61. Kawamoto K, Houlihan CA, Balas EA, et al. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ*; 330: 765, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=555881&tool=pmcentrez&rendertype=abstract (2005, accessed 21 July 2014).

62. Smith W. Product differentiation and market segmentation as alternative marketing strategies. *J Mark*, http://www.jstor.org/stable/1247695 (1956, accessed 7 July 2017).

63. Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. *Psychol Bull* 2007; 133: 673.

64. Royal Bournemouth and Christchurch hospitals NHS Foundation Trust. BERTIE Online, https://www.bertieonline.org.uk/ (accessed 7 July 2017).

65. Kreuter MW, Strecher VJ, Glassman B. One size does not fit all: the case for tailoring print materials. *Ann Behav Med*; 21: 276–83, http://www.ncbi.nlm.nih.gov/pubmed/10721433 (1999, accessed 24 June 2014).

66. Kreuter M, Farrell D, Olevitch L, et al. *Tailoring Health Messages: Customizing Communication with Computer Technology*. New Jersey: Lawrence Erlbaum associates, http://books.google.co.uk/books/about/Tailoring_Health_Messages.html?id=fUEFV4wkJKgC&pgis=1 (2000, accessed 24 June 2014).

67. Rosenstock I. Social learning theory and the health belief model. *Heal Educ Behav*; 15: 175–183, http://heb.sagepub.com/content/15/2/175.short (1988, accessed 25 June 2014).

68. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev*; 84: 191–215, http://psycnet.apa.org/journals/rev/84/2/191/ (1977, accessed 25 June 2014).

69. Prochaska J, DiClemente C. *Treating addictive behaviors: processes of change. Chapter 1: Towards a comprehensive model of change*. 1st ed. Plenum press, NY, http://link.springer.com/chapter/10.1007/978-1-4613-2191-0_1 (1986, accessed 25 June 2014).

70. Al Sayah F, Williams B, Johnson JA. Measuring Health Literacy in Individuals With Diabetes. *Heal Educ Behav*; 40: 42–55, http://journals.sagepub.com/doi/10.1177/1090198111436341 (2013, accessed 19 May 2017).

71. Jones H, Cleave B, Tomlinson G, et al. Stages of Intensive Therapy: Validation of a New Measurement Tool. *Can J Diabetes*; 30: 21–29, http://linkinghub.elsevier.com/retrieve/pii/S1499267106010057 (2006, accessed 19 July

2017).

72. Brug J, Steenhuis I, Assema P van, et al. The impact of a computer-tailored nutrition intervention. *Prev Med (Baltim)*; 25: 236–242, http://www.sciencedirect.com/science/article/pii/S0091743596900523 (1996, accessed 25 June 2014).

73. Brug J, Glanz K, Assema P Van, et al. The impact of computer-tailored feedback and iterative feedback on fat, fruit, and vegetable intake. *Heal Educ Behav*; 25: 517–531, http://heb.sagepub.com/content/25/4/517.short (1998, accessed 25 June 2014).

74. Campbell M. Improving dietary behavior: the effectiveness of tailored messages in primary care settings. *Am J Public Health*; 84: 783–787, http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.84.5.783 (1994, accessed 25 June 2014).

75. Prochaska J, DiClemente C, Velicer W, et al. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. *Heal Psychol*; 12: 399–405, http://psycnet.apa.org/journals/hea/12/5/399/ (1993, accessed 25 June 2014).

76. Strecher V, Kreuter M, Boer D Den, et al. The effects of computer-tailored smoking cessation messages in family practice settings. *J Fam Pract*; 39: 262–270, http://doi.apa.org/psycinfo/1995-14964-001 (1994, accessed 25 June 2014).

77. Skinner C, Strecher V, Hospers H. Physicians' recommendations for mammography: do tailored messages make a difference? *Am J Public Health*; 84: 43–49, http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.84.1.43 (1994, accessed 25 June 2014).

78. Skinner CS, Campbell MK, Rimer BK, et al. How effective is tailored print communication? *Ann Behav Med*; 21: 290–8, http://www.ncbi.nlm.nih.gov/pubmed/10721435 (1999, accessed 19 July 2017).

79. Rimer BK, Glassman B. Is there a use for tailored print communications in cancer risk communication? *J Natl Cancer Inst Monogr*; 140–8, http://www.ncbi.nlm.nih.gov/pubmed/10854470 (1999, accessed 19 July 2017).

80. Kroeze W, Werkman A, Brug J. A systematic review of randomized trials on the effectiveness of computer-tailored education on physical activity and dietary behaviors. *Ann Behav Med*; 31: 205–223, http://www.ncbi.nlm.nih.gov/pubmed/16700634 (2006, accessed 19 July 2017).

81. Revere D, Dunbar PJ. Review of computer-generated outpatient health behavior interventions: clinical encounters "in absentia". *J Am Med Inform Assoc*; 8: 62–79, http://www.ncbi.nlm.nih.gov/pubmed/11141513 (2001, accessed 19 July 2017).

82. Baker R, Camosso-Stefinovic J, Gillies C, et al. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. *Cochrane database Syst Rev*; CD005470, http://www.ncbi.nlm.nih.gov/pubmed/20238340 (2010, accessed 19 July 2017).

83. Lancaster T, Stead L. Self-help interventions for smoking cessation. In: *Cochrane Database of Systematic Reviews*. Chichester, UK: John Wiley & Sons, Ltd, p. CD001118, http://www.ncbi.nlm.nih.gov/pubmed/12137618 (2002, accessed 19 July 2017).

84. Edwards AG, Naik G, Ahmed H, et al. Personalised risk communication for informed decision making about taking screening tests. In: Edwards AG (ed) *Cochrane Database of Systematic Reviews*. Chichester, UK: John Wiley & Sons, Ltd, p. CD001865, http://www.ncbi.nlm.nih.gov/pubmed/23450534 (2013, accessed 19 July 2017).

85. Noar S, Benac C, Harris M. Does tailoring matter? Meta-analytic review of tailored print

health behavior change interventions. *Psychol Bull*, http://psycnet.apa.org/psycinfo/2007-09203-006 (2007, accessed 25 June 2014).

86. Cohen J. *Statistical power analysis for the behavioral sciences*. Academic Press, http://www.sciencedirect.com/science/book/9780121790608 (1977, accessed 19 July 2017).

87. Straub ET. Understanding Technology Adoption: Theory and Future Directions for Informal Learning. *Rev Educ Res*; 79: 625–649, http://journals.sagepub.com/doi/pdf/10.3102/0034654308325896 (2009, accessed 16 August 2017).

88. Venkatesh V, Morris MG, Davis GB, et al. User acceptance of information technology: Toward a unified view. *MIS Q* 2003; 425–478.

89. Venkatesh V, Sykes T, Zhang X. 'Just what the doctor ordered': a revised UTAUT for EMR system adoption and use by doctors. In: *44th Hawaii International Conference on System Sciences*, http://ieeexplore.ieee.org/abstract/document/5718549/ (2011, accessed 20 July 2017).

90. Torjesen I. Drug development: the journey of a medicine from lab to shelf | Career Feature | Pharmaceutical Journal. *The Pharmaceutical Journal*, http://www.pharmaceutical-journal.com/publications/tomorrows-pharmacist/drug-development-the-journey-of-a-medicine-from-lab-to-shelf/20068196.article (2015, accessed 7 July 2017).

91. McCartney M. How do we know whether medical apps work? *BMJ*; 346, http://www.bmj.com/content/346/bmj.f1811.long (2013, accessed 7 July 2017).

92. Huckvale K, Adomaviciute S, Prieto JT, et al. Smartphone apps for calculating insulin dose: a systematic assessment. *BMC Med*; 13: 106, http://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-015-0314-7 (2015, accessed 6 July 2017).

93. Hirsch IB, Parkin CG. Unknown Safety and Efficacy of Smartphone Bolus Calculator Apps Puts Patients at Risk for Severe Adverse Outcomes. *J Diabetes Sci Technol*; 10: 977–80, http://www.ncbi.nlm.nih.gov/pubmed/26798082 (2016, accessed 7 July 2017).

94. U.S. Department of Health and Human Services Food and Drug Administration. *Mobile Medical Applications. Guidance for Industry and Food and Drug Administration Staff*, https://www.fda.gov/downloads/MedicalDevices/…/UCM263366.pdf (2015, accessed 7 July 2017).

95. Medicines and Healthcare products Regulatory Agency. Medical devices: software applications (apps), https://www.gov.uk/government/publications/medical-devices-software-applications-apps (2014, accessed 7 July 2017).

96. Cochrane Effective Practice and Organisation of Care Group. Data Collection Checklist, http://epoc.cochrane.org/sites/epoc.cochrane.org/files/uploads/datacollectionchecklist.pdf (2002).

97. Conway NT. Data collection checklist, https://docs.google.com/forms/d/1bvbbI3z-LW06y0h-XdqVKY9w8s4Je3jPF0CRbQqI8z8/viewform (2014, accessed 6 June 2014).

98. Cheater F, Baker R, Gillies C, et al. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*, http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005470.pub2/pdf/standard (2005, accessed 4 December 2013).

99. Jamtvedt G, Young J, Kristoffersen D, et al. Audit and feedback: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*, http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000259.pub2/pdf/standard (2006,

accessed 25 June 2014).

100. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med*; 6: e1000097, http://dx.plos.org/10.1371/journal.pmed.1000097 (2009, accessed 18 October 2013).

101. Boukhors Y, Rabasa-Lhoret R, Langelier H, et al. The use of information technology for the management of intensive insulin therapy in type 1 diabetes mellitus. *Diabetes Metab*; 29: 619–27, http://www.sciencedirect.com/science/article/pii/S1262363607700782 (2003, accessed 17 October 2013).

102. Cafazzo J, Casselman M, Hamming N, et al. Design of an mHealth app for the self-management of adolescent type 1 diabetes: a pilot study. *J Med Internet Res*; 14: e70, http://www.jmir.org/2012/3/e70/?utm_source=twitterfeed&utm_medium=twitter&utm_campaign=Feed:+Top10V1+(Top+10+JMIR+Articles:+Most+Viewed+(Past+1+month)++) (2012, accessed 17 October 2013).

103. Carroll AE, Biondich P, Anand V, et al. A randomized controlled trial of screening for maternal depression with a clinical decision support system. *J Am Med Inform Assoc*; 20: 311–6, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3638168&tool=pmcentrez&rendertype=abstract (2013, accessed 2 June 2014).

104. Epstein JN, Langberg JM, Lichtenstein PK, et al. Use of an Internet portal to improve community-based pediatric ADHD care: a cluster randomized trial. *Pediatrics*; 128: e1201-8, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3208964&tool=pmcentrez&rendertype=abstract (2011, accessed 18 June 2014).

105. Field TS, Rochon P, Lee M, et al. Computerized clinical decision support during medication ordering for long-term care residents with renal insufficiency. *J Am Med Informatics Assoc*; 16: 480–5, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2705250&tool=pmcentrez&rendertype=abstract (2009, accessed 2 June 2014).

106. Gurwitz J, Field T, Rochon P, et al. Effect of Computerized Provider Order Entry with Clinical Decision Support on Adverse Drug Events in the Long-Term Care Setting. *J Am Geriatr Soc*; 56: 2225–2233, http://onlinelibrary.wiley.com/doi/10.1111/j.1532-5415.2008.02004.x/full (2008, accessed 17 October 2013).

107. Kinn J, Marek J, O'Toole M, et al. Effectiveness of the electronic medical record in improving the management of hypertension. *J Clin Hypertens*; 4: 415–419, http://onlinelibrary.wiley.com/doi/10.1111/j.1524-6175.2002.01248.x/full (2002, accessed 17 October 2013).

108. McDonald E, Solomon B, Shields W, et al. Evaluation of kiosk-based tailoring to promote household safety behaviors in an urban pediatric primary care practice. *Patient Educ Couns*; 58: 168–181, http://www.sciencedirect.com/science/article/pii/S0738399104002654 (2005, accessed 17 October 2013).

109. Nagykaldi Z, Aspy CB, Chou A, et al. Impact of a Wellness Portal on the delivery of patient-centered preventive care. *J Am Board Fam Med*; 25: 158–67, http://www.ncbi.nlm.nih.gov/pubmed/22403196 (2012, accessed 10 June 2014).

110. Persell S, Kaiser D, Dolan N, et al. Changes in performance after implementation of a multifaceted electronic-health-record-based quality improvement system. *Med Care* 2011; 49: 117–25.

111. Quinn C, Clough S, Minor J, et al. WellDoc™ mobile diabetes management randomized controlled trial: change in clinical and behavioral outcomes and patient and physician satisfaction. *Diabetes Technol Ther*; 10: 160–8,

http://online.liebertpub.com/doi/abs/10.1089/dia.2008.0283 (2008, accessed 17 October 2013).

112. Raebel M, Carroll N, Kelleher J, et al. Randomized trial to improve prescribing safety during pregnancy. *J Am Med Informatics Assoc*; 14: 440–450, http://www.sciencedirect.com/science/article/pii/S1067502707001156 (2007, accessed 17 October 2013).

113. Siek KA, Khan DU, Ross SE, et al. Designing a personal health application for older adults to manage medications: a comprehensive case study. *J Med Syst* 2011; 35: 1099–1121.

114. Sequist T, Gandhi T, Karson A, et al. A randomized trial of electronic clinical reminders to improve quality of care for diabetes and coronary artery disease. *J Am Med Informatics Assoc*; 12: 431–437, http://www.sciencedirect.com/science/article/pii/S1067502705000605 (2005, accessed 17 October 2013).

115. Tierney WM, Overhage JM, Murray MD, et al. Can computer-generated evidence-based care suggestions enhance evidence-based management of asthma and chronic obstructive pulmonary disease? A randomized, controlled trial. *Health Serv Res*; 40: 477–97, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1361152&tool=pmcentrez&rendertype=abstract (2005).

116. Vollmer WM, Feldstein A, Smith DH, et al. Use of health information technology to improve medication adherence. *Am J Manag Care* 2011; 17: SP79-SP87.

117. Cruz-correia R, Fonseca J, Lima L, et al. Web-based or paper-based self-management tools for asthma-Patients' opinions and quality of data in a randomized crossover study. *Stud Health Technol Inform*; 127: 178–89, http://www.researchgate.net/publication/5942393_Web-based_or_paper-based_self-management_tools_for_asthma--patients'_opinions_and_quality_of_data_in_a_randomized_crossover_study/file/d912f50aab686e21a9.pdf (2007, accessed 17 October 2013).

118. Persell S, Lloyd-Jones D, Friesema E, et al. Electronic health record-based patient identification and individualized mailed outreach for primary cardiovascular disease prevention: a cluster randomized trial. *J Gen Intern Med*; 28: 554–60, http://link.springer.com/article/10.1007/s11606-012-2268-1 (2012, accessed 18 October 2013).

119. Ross S, Haverhals L, Main D, et al. Adoption and use of an online patient portal for diabetes (Diabetes-STAR). In: *AMIA Annual symposium proceedings*, p. 1080, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1839692/ (2006, accessed 17 October 2013).

120. Pinnock H, Hanley J, McCloughan L. telemonitoring integrated into existing clinical services on hospital admission for exacerbation of chronic obstructive pulmonary disease: researcher blind, multicentre,. *Br Med J*; 347: f6070, http://www.bmj.com/content/347/bmj.f6070 (2013, accessed 1 August 2014).

121. Avery A, Rodgers S, Cantrill J, et al. A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. *Lancet*; 379: 130–1319, http://www.sciencedirect.com/science/article/pii/S0140673611618175 (2012, accessed 18 June 2014).

122. Fossum M, Alexander G, Ehnfors M, et al. Effects of a computerized decision support system on pressure ulcers and malnutrition in nursing homes for the elderly. *Int J Med Inform*; 80: 607–617, http://www.sciencedirect.com/science/article/pii/S1386505611001316 (2011, accessed 17 October 2013).

123. Jones S, Mullally M, Ingleby S, et al. Bedside electronic capture of clinical observations and

automated clinical alerts to improve compliance with an Early Warning Score protocol. *Crit Care Resusc*; 13: 83–88, http://ecite.utas.edu.au/78044/1/Bedside Electronic Capture of Clinical Observations and Automated Clinical Alerts to Improve Compliance with an Early Warning Score Protocol.pdf (2011, accessed 17 October 2013).

124. Duodecim Medical Publications Ltd. EBMeDS clinical decision support, http://www.ebmeds.org/web/guest/home?p_id=129190&b_id=129273&s_id=129273&lang=en (2014).

125. Morris AD, Boyle DIR, MacAlpine R, et al. The diabetes audit and research in Tayside Scotland (DARTS) study: electronic record linkage to create a diabetes register. *Bmj* 1997; 315: 524–528.

126. NHS Services Information services division. ISD Data Dictionary, http://www.ndc.scot.nhs.uk/Dictionary-A-Z/Definitions/index.asp?ID=128&Title=CHI Number (2016, accessed 14 November 2016).

127. Scottish Care Information – Diabetes Collaboration (SCI-DC). SCI-Diabetes, http://www.sci-diabetes.scot.nhs.uk/ (2015, accessed 2 September 2016).

128. NHSScotland. *Getting Knowledge into Action to Improve Healthcare Quality : Report of Strategic Review and Recommendations*. 2012.

129. Shachak A, Reis S. The impact of electronic medical records on patient–doctor communication during consultation: a narrative literature review. *J Eval Clin Pract*, http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2753.2008.01065.x/full (2009, accessed 7 August 2013).

130. Department of Health. *High Quality Care For All*. 2008.

131. Department of Health. *Understanding what matters: A guide to using patient feedback to transform services*. 2009.

132. Scottish Government. *Patient Experience Survey of GP and Local NHS Services 2011 / 12 Volume 1 : National Results*. 2011.

133. NHS surveys. About NHS patient surveys, http://www.nhssurveys.org/ (2013).

134. Scottish Government. *Patient Experience Survey of GP and Local NHS Services 2011 / 12 Volume 2 : Technical Report*. 2011.

135. Department of Health. Outpatients Questionnaire. 1–19, http://www.nhssurveys.org/Filestore//documents/Outpatient_allquestions.pdf (2011).

136. Auditor General for Scotland. *Mind the gap. Management information for outpatient services.*, http://www.audit-scotland.gov.uk/docs/health/2001/nr_010921_outpatient_services.pdf (2001).

137. Gray J, Richmond N. Influences on patient satisfaction survey results: is there a need for a rethink? *Qual Prim Care*, http://primarycare.imedpub.com/influences-on-patient-satisfaction-survey-results-is-there-a-need-for-a-rethink.pdf (2010, accessed 20 July 2017).

138. Ashworth M, Seed P, Armstrong D, et al. The relationship between social deprivation and the quality of primary care: a national survey using indicators from the UK Quality and Outcomes Framework. *Br J Gen Pract*; 57, http://bjgp.org/content/57/539/441.long (2007, accessed 20 July 2017).

139. Fishbein M, Ajzen I. Belief, attitude, intention and behavior: An introduction to theory and research, http://trid.trb.org/view.aspx?id=1150648 (1975, accessed 13 September 2013).

140. Davis F. Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS Q*, http://www.jstor.org/stable/10.2307/249008 (1989, accessed 19 August

2013).

141. Bandura A. Social foundations of thought and action. *Englewood Cliffs, NJ*, http://books.google.co.uk/books?hl=en&lr=&id=PdY9o3l5vpYC&oi=fnd&pg=PA94&dq=Social+Foundations+of+Thought+and+Action:+A+Social+Cognitive+Theory&ots=uDh-pU-h7L&sig=Vqk5_nhdROnB1hZh0XyuAD1rB9s (1986, accessed 13 September 2013).

142. Wills M, El-Gayar O, Bennett D. Examining healthcare professionals' acceptance of electronic medical records using UTAUT. *Issues Inf Syst*, http://iacis.org/iis/2008/S2008_1053.pdf (2008, accessed 20 July 2017).

143. Rho M, Kim H, Chung K, et al. Factors influencing the acceptance of telemedicine for diabetes management. *Cluster Comput*, http://link.springer.com/article/10.1007/s10586-014-0356-1 (2015, accessed 20 July 2017).

144. Heselmans A, Aertgeerts B, Donceel P, et al. Family physicians' perceptions and use of electronic clinical decision support during the first year of implementation. *J Med Syst*; 36: 3677–84, http://www.ncbi.nlm.nih.gov/pubmed/22402980 (2012, accessed 13 September 2013).

145. Edwards PJ, Roberts I, Clarke MJ, et al. Methods to increase response to postal and electronic questionnaires. *Cochrane database Syst Rev*; MR000008, http://www.ncbi.nlm.nih.gov/pubmed/19588449 (2009, accessed 20 August 2015).

146. Cook C, Heath F, Thompson R. A meta-analysis of response rates in web-or internet-based surveys. *Educ …*, http://epm.sagepub.com/content/60/6/821.short (2000, accessed 16 May 2014).

147. Church A. Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opin Q*, http://poq.oxfordjournals.org/content/57/1/62.short (1993, accessed 16 May 2014).

148. Kreuger RA, Casey MA. *Focus Groups. A practical guide or applied research*. 4th ed. Sage Publications Ltd, 2009.

149. Sonocent. Audio notetaker, http://www.sonocent.com/en/the_software/audio_notetaker/ (2015, accessed 1 May 2015).

150. Information and statistics division. ISD Scotland, http://www.isdscotland.org/ (2013).

151. Kastner M, Li J, Lottridge D, et al. Development of a prototype clinical decision support tool for osteoporosis disease management: a qualitative study of focus groups. *BMC Med Inform Decis Mak*; 10: 40, http://www.biomedcentral.com/1472-6947/10/40 (2010, accessed 6 August 2015).

152. Short D, Frischer M, Bashford J. Barriers to the adoption of computerised decision support systems in general practice consultations: a qualitative study of GPs' perspectives. *Int J Med Inform*; 73: 357–62, http://www.sciencedirect.com/science/article/pii/S1386505604000152 (2004, accessed 6 August 2015).

153. Liberati EG, Galuppo L, Gorli M, et al. Barriere e facilitatori all'implementazione dei sistemi di supporto decisionale computerizzati in ospedale: Uno studio 'grounded theory'. *Recenti Prog Med*; 106: 180–191, http://www.scopus.com/inward/record.url?eid=2-s2.0-84927151855&partnerID=tZOtx3y1 (2015).

154. Kazemi A, Ellenius J, Tofighi S, et al. CPOE in Iran--a viable prospect? Physicians' opinions on using CPOE in an Iranian teaching hospital. *Ovid Medlin 1946 to Present with Dly Updat J Med Informatics* 1946; 78: 199–207.

155. Vedanthan R. BE. TN. KJ. ML. TD. HC. ADD. KS. FV. WMC. Usability and feasibility of a tablet-based decision-support and integrated Record-keeping (DESIRE) tool in the nurse

management of hypertension in rural western Kenya. *EmbaseInternational J Med Informatics* 2015.

156. Hannes K, Leys M, Vermeire E, et al. Implementing evidence-based medicine in general practice: a focus group based study. *BMC Fam Pract*; 6: 37, http://www.biomedcentral.com/1471-2296/6/37 (2005, accessed 6 August 2015).

157. DeLone W, McLean E. Information systems success: The quest for the dependent variable. *Inf Syst Res*, http://pubsonline.informs.org/doi/abs/10.1287/isre.3.1.60 (1992, accessed 6 November 2015).

158. Delone WH, McLean ER. The DeLone and McLean Model of Information Systems Success: A Ten-Year Update. *Journal of Management Information Systems*, http://www.tandfonline.com.libproxy.dundee.ac.uk/doi/abs/10.1080/07421222.2003.11045748 (2014, accessed 6 November 2015).

159. van der Meijden MJ. Determinants of Success of Inpatient Clinical Information Systems: A Literature Review. *J Am Med Informatics Assoc*; 10: 235–243, http://jamia.oxfordjournals.org/content/10/3/235.abstract (2003, accessed 12 October 2015).

160. Charlson M, Szatrowski TP, Peterson J, et al. Validation of a combined comorbidity index. *J Clin Epidemiol*; 47: 1245–1251, http://www.sciencedirect.com/science/article/pii/0895435694901295 (1994, accessed 14 May 2015).

161. Wagholikar KB, Hankey RA, Decker LK, et al. Evaluation of the effect of decision support on the efficiency of primary care providers in the outpatient practice. *J Prim Care Community Health*; 6: 54–60, http://www.ncbi.nlm.nih.gov/pubmed/25155103 (2015, accessed 25 August 2017).

162. Bright T, Wong A, Dhurjati R. Effect of clinical decision-support systems a systematic review. *Ann Intern …*, http://annals.org/article.aspx?articleid=1206700&bcsi_scan_D06E2443DD272A5C=dieX76qzzGgEOGHWT3TzZvVX4zAAAAvT5CEg==&bcsi_scan_filename=article.aspx (2012, accessed 7 August 2013).

163. McLean G, Gunn J, Wyke S, et al. The influence of socioeconomic deprivation on multimorbidity at different ages: a cross-sectional study. *Br J Gen Pract* 2014; 64.

164. Goddard M, Smith P. Equity of access to health care services:: Theory and evidence from the UK. *Soc Sci Med*, http://www.sciencedirect.com/science/article/pii/S0277953600004159 (2001, accessed 14 September 2016).

165. Scottish Diabetes Survey Monitoring Group. *Scottish Diabetes Survey 2012*, http://www.diabetesinscotland.org.uk/Publications/SDS 2012.pdf (2012).

166. Johnson SL, Tierney EF, Onyemere KU, et al. Who Is Tested for Diabetic Kidney Disease and Who Initiates Treatment?, http://care.diabetesjournals.org/content/29/8/1733.full-text.pdf (accessed 3 March 2017).

167. Jaspers MWM, Smeulers M, Vermeulen H, et al. Effects of clinical decision-support systems on practitioner performance and patient outcomes: a synthesis of high-quality systematic review findings. *J Am Med Inform Assoc*; 18: 327–34, http://jamia.bmj.com/content/18/3/327.short (2011, accessed 7 August 2013).

168. National Institute for Health and Care Excellence. *Type 2 diabetes in adults: management (NG28)*, https://www.nice.org.uk/guidance/ng28 (2015).

169. National Institute for Health and Care Excellence. *Diabetes (type 1 and type 2) in children and*

young people: diagnosis and management (NG18), http://www.nice.org.uk/guidance/ng18 (2015).

170. Nathan DM. The diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: overview. *Diabetes Care*; 37: 9–16, http://care.diabetesjournals.org/content/37/1/9.full (2014, accessed 3 November 2015).

171. Balas E, Krishna S, Kretschmer R. Computerized knowledge management in diabetes care. *Med Care*, http://www.jstor.org/stable/4640793 (2004, accessed 14 January 2016).

172. Baxter M, Hudson R, Mahon J, et al. Estimating the impact of better management of glycaemic control in adults with Type 1 and Type 2 diabetes on the number of clinical complications, and the associated financial benefit. *Diabet Med* 2016.

173. NHS Information Centre for Health and Social Care. *National Diabetes Audit 2012-13. Report 2: complications and mortality*, http://www.hscic.gov.uk/catalogue/PUB16496/nati-diab-audi-12-13-rep2.pdf (2015).

174. Strippoli G, Bonifati C. Angiotensin converting enzyme inhibitors and angiotensin II receptor antagonists for preventing the progression of diabetic kidney disease. *Cochrane …*, http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006257/full (2006, accessed 14 January 2016).

175. Sarnak MJ, Levey AS, Schoolwerth AC, et al. Kidney disease as a risk factor for development of cardiovascular disease: a statement from the American Heart Association Councils on Kidney in Cardiovascular Disease, High Blood Pressure Research, Clinical Cardiology, and Epidemiology and Prevention. *Circulation*; 108: 2154–69, http://circ.ahajournals.org/content/108/17/2154.full (2003, accessed 14 January 2016).

176. Hansson L, Zanchetti A, Carruthers SG, et al. Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomised trial. HOT Study Group. *Lancet (London, England)*; 351: 1755–62, http://www.ncbi.nlm.nih.gov/pubmed/9635947 (1998, accessed 28 August 2017).

177. McCabe C, Stevenson R, Dolan A. Evaluation of a diabetic foot screening and protection programme. *Diabet Med*, http://onlinelibrary.wiley.com/doi/10.1002/(SICI)1096-9136(199801)15:1%3C80::AID-DIA517%3E3.0.CO;2-K/abstract (1998, accessed 4 December 2013).

178. Margolis D, Malay D, Hoffstad O. Economic burden of diabetic foot ulcers and amputations, http://www.ncbi.nlm.nih.gov/books/NBK65152/ (2011, accessed 4 December 2013).

179. Ollendorf D, Kotsanos J. Potential economic benefits of lower-extremity amputation prevention strategies in diabetes. *Diabetes …*, http://care.diabetesjournals.org/content/21/8/1240.short (1998, accessed 4 December 2013).

180. Baxter M, Hudson R, Mahon J, et al. Estimating the impact of better management of glycaemic control in adults with Type 1 and Type 2 diabetes on the number of clinical complications, and the associated financial benefit. *Diabet Med*, http://www.ncbi.nlm.nih.gov/pubmed/26773733 (2016, accessed 27 May 2016).

181. Alkureishi MA, Lee WW, Lyons M, et al. Impact of Electronic Medical Record Use on the Patient–Doctor Relationship and Communication: A Systematic Review. *J Gen Intern Med*; 31: 548–560, http://link.springer.com/10.1007/s11606-015-3582-1 (2016, accessed 28 August 2017).

182. Kesselheim AS, Cresswell K, Phansalkar S, et al. Clinical decision support systems could be modified to reduce 'alert fatigue' while still minimizing the risk of litigation. *Health Aff (Millwood)*; 30: 2310–7, http://www.ncbi.nlm.nih.gov/pubmed/22147858 (2011, accessed 28

August 2017).

183. Fox J, Thomson R. Clinical decision support systems: a discussion of quality, safety and legal liability issues. *Proceedings AMIA Symp*; 265–9, http://www.ncbi.nlm.nih.gov/pubmed/12463828 (2002, accessed 28 August 2017).

184. Huckvale C, Car J, Akiyama M, et al. Information technology for patient safety, http://qualitysafety.bmj.com/content/qhc/19/Suppl_2/i25.full.pdf (accessed 28 August 2017).

185. GUIDES Project, https://www.guidesproject.org/ (accessed 28 August 2017).

186. QiC. Quality in Care Diabetes 2016: Digital and technology solutions in the treatment and management of diabetes, http://www.qualityincare.org/diabetes/awards/results/qic_diabetes_2016_results/digital_and_technology_solutions_in_the_treatment_and_management_of_diabetes (2016, accessed 21 October 2016).

187. Cunningham SG, Wake DJ, Waller A, et al. My Diabetes My Way: an electronic personal health record for diabetes. *Br J Diabetes Vasc Dis*; 13: 143–149, http://www.scopus.com/inward/record.url?eid=2-s2.0-84880753542&partnerID=tZOtx3y1 (2013, accessed 31 October 2014).

188. Wake DJ, He J, Czesak AM, et al. MyDiabetesMyWay. *J Diabetes Sci Technol*; 10: 1050–1058, http://dst.sagepub.com/lookup/doi/10.1177/1932296816648168 (2016, accessed 3 March 2017).

189. Scottish Government eHealth Division. eHealth Good Practice Case Studies, http://www.ehealth.nhs.scot/case-studies/clinical-decision-support-for-diabetes-in-scotland/ (2016, accessed 21 October 2016).

190. The Scottish Government. Supply clinical decision support software system to NHS Scotland. *Government online: government tenders, news and information*, http://www.government-online.net/supply-clinical-decision-support-software-system-to-nhs-scotland/ (2016, accessed 21 October 2016).

191. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. *J R Soc Med*; 104: 510–20, http://www.ncbi.nlm.nih.gov/pubmed/22179294 (2011, accessed 15 November 2016).

192. Arocha JF, Wang D, Patel VL. Identifying reasoning strategies in medical decision making: A methodological guide. *J Biomed Inform* 2005; 38: 154–171.

193. Patel VL, Arocha JF, Diermeier M, et al. Cognitive psychological studies of representation and use of clinical practice guidelines. *Int J Med Inform* 2001; 63: 147–167.

194. Banaee H, Ahmed M, Loutfi A. Data mining for wearable sensors in health monitoring systems: a review of recent trends and challenges. *Sensors*, http://www.mdpi.com/1424-8220/13/12/17472/htm (2013, accessed 3 March 2017).

195. Heintzman ND. A Digital Ecosystem of Diabetes Data and Technology. *J Diabetes Sci Technol*; 10: 35–41, http://journals.sagepub.com/doi/10.1177/1932296815622453 (2016, accessed 3 March 2017).

196. Mavergames C, Becker L, Everett J, et al. Cochrane PICO Annotator and PICOfinder: Using semantically-enabled evidence to find what works in health care. *ceur-ws.org*, http://ceur-ws.org/Vol-1546/paper_6.pdf (accessed 15 November 2016).

197. Tsoukalas A, Albertson T, Tagkopoulos I. From Data to Optimal Decision Making: A Data-Driven, Probabilistic Machine Learning Approach to Decision Support for Patients With Sepsis. *JMIR Med Informatics*; 3: e11, http://medinform.jmir.org/2015/1/e11/ (2015,

accessed 15 November 2016).

198. Fraccaro P, Arguello Castelerio M, Ainsworth J, et al. Adoption of Clinical Decision Support in Multimorbidity: A Systematic Review. *JMIR Med Informatics*; 3: e4, http://medinform.jmir.org/2015/1/e4/ (2015, accessed 15 November 2016).

199. Castaneda C, Nalley K, Mannion C, et al. Clinical decision support systems for improving diagnostic accuracy and achieving precision medicine. *J Clin Bioinforma*; 5: 4, http://www.ncbi.nlm.nih.gov/pubmed/25834725 (2015, accessed 21 November 2016).

200. Schaller R. Moore's law: past, present and future. *IEEE Spectr*, http://ieeexplore.ieee.org/xpls/abs_all.jsp?arnumber=591665 (1997, accessed 11 December 2016).

201. Schillinger D, Grumbach K, Piette J, et al. Association of health literacy with diabetes outcomes. *JAMA J Am Med Assoc* 2002; 288: 475–482.

202. Sarkar U, Karter AJ, Liu JY, et al. Hypoglycemia is more common among type 2 diabetes patients with limited health literacy: the Diabetes Study of Northern California (DISTANCE). *J Gen Intern Med* 2010; 25: 962–968.

203. Boren SA. A review of health literacy and diabetes: opportunities for technology. *J diabetes Sci Technol* 2009; 3: 202.

204. Volandes AE, Paasche-Orlow MK. Health Literacy, Health Inequality and a Just Healthcare System. *Am J Bioeth*; 7: 5–10, http://www.tandfonline.com/doi/abs/10.1080/15265160701638520 (2007, accessed 3 March 2017).

9. Appendix: Systematic review - PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	n/a
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	32
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	n/a
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	33
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n/a
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	35
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	35
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	appx 11
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	37
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	37

Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	37
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	37
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	n/a
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n/a

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	ecify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective	n/a
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	38
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	40
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	47 + appx 12
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	47 +appx 12
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a

DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	51
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	51
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	53
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	n/a

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

10. Appendix: Systematic review - exact search strings and results

Search ran on 9th May 2014

	<chronic disease terms>	Results
1	exp long-term care/	970678
2	exp chronic disease/	367248
3	(continuity adj3 care).tw.	10514
4	(long adj term).tw. or chronic.tw.	2804248
5	exp diabetes mellitus/	899426
6	exp hypertension/	694011
7	exp asthma/	292761
8	exp pulmonary disease chronic obstructive/ or (chronic adj2 obstructive adj2 pulmonary).tw.	122429
9	exp thyroid diseases/	290518
10	exp hyperlipidemia/	164759
11	exp arthritis rheumatoid/	239948
12	exp mental disorders/	2473309
13	exp substance-related disorders or exp substance abuse/	472702
14	exp hiv infections/	527209
15	or/1-14	8184509
	<methodology terms>	
16	randomized controlled trial.pt.	372741
17	controlled clinical trial.pt.	88283
18	randomized controlled trials/	143696
19	random allocation/	142234
20	random assignment/	0
21	comparative study/	2306285
22	exp evaluation studies/	197553
23	intervention studies/	25984
24	follow-up studies/	1284534
25	prospective studies/	613217

26	(randomised or randomized).tw.	832198
27	(random$ adj1 (allocat$ or assign$)).tw.	191822
28	(control$ or prospectiv$ or volunteer$).tw.	6517515
29	experiment$.tw.	2849094
30	(time adj series).tw.	31318
31	((pre adj test) or pretest or (post adj test) or posttest).tw.	34916
32	or/16-31	11821519
	<eHealth terms>	
33	exp Telemedicine/	34575
34	(telemedicine OR telehealth).tw.	15255
35	exp computer communication networks/	75077
36	(ict or information communication technolog$).tw.	5865
37	exp Medical Informatics/	334389
38	(digital OR technol$ OR online OR tele$ OR ehealth OR e-health OR mhealth OR m-health OR computer$ OR cloud OR (web ADJ site$) OR (web site$) OR internet).tw	1450716
39	Patient Identification Systems/	7738
40	(blog$ or weblog$ or web-log$).tw.	1745
41	(bulletin board$ or bulletinboard$ or messageboard$ or message board$ or forum$).tw.	23032
42	OR/33-41	1765310
	<health record terms>	
43	exp Medical Records/	223046
44	exp Nursing Records/	143949
45	exp Hospital Records/	140812
46	((medical OR health) AND Record$).tw.	322918
47	(case ADJ (note$ OR Record$)).tw	30879
48	(log-book$ OR logbook$).tw	2095
49	(personal ADJ3 health ADJ3 record).tw	675
50	(passport$ OR kiosk$ OR portal$).tw	136970
51	OR/43-50	637032
	<communication terms>	
52	exp computer literacy/	6065
53	exp information literacy/	1809
54	exp access to information/	17586

55	exp information dissemination/	23788
56	exp Information storage and retrieval/	328
57	exp Information services/	877443
58	exp health communication/	51670
59	(tailor$ adj4 (messag$)).tw.	606
60	(Information adj4 (need$ or seek$ or us$ or util$ or literac$)).tw.	223643
61	communicat$.tw.	375054
62	exp user-computer interface/	48968
63	exp attitude to computers/	6387
64	OR/52-63	1569294
	<**user groups terms>**	
65	Caregivers/	60200
66	exp disabled persons/	71277
67	exp patients/	1291601
68	(Patient$ or consumer$ or carer$ or caregiver$ or lay$).mp	11746992
69	exp health personnel/	1271329
70	or/65-69	12545531
	<combinations>	
71	AND/15,32,42,51,64,70	1073

11. Appendix: Systematic review - characteristics of the interventions.

Means and proportions are approximations only, based on published data.

Avery [121]

Design	RCT
Follow up of professionals	Done
Follow up of patients or episodes of care	Done
Blinded assessment of primary outcome(s)	Done
Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Done
Concealment of allocation	Not done
Protection against contamination	Not done
Profession group	Physicians, Pharmacists
Patients - number	Not clear
Patients - age (mean(yrs))	Not clear
Patients - gender (% female)	Not clear
Patients - predominant ethnic group (%)	Not clear
Total number of intervention groups	1
Type of targeted behaviour	Prescribing
Control groups used	standard practice plus verbal feedback
type of intervention	Professional
intervention sub category	educational outreach visits
intervention further details	Pharmacist led information technology complex intervention
Primary outcome	Adverse drug event
Health professional outcomes/process measures	Not done
Patient outcomes	number of drug-related adverse events

Boukhors [101]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done

Reliable primary outcome measure(s)	Done
Power calculation	Done
Concealment of allocation	Not clear
Protection against contamination	Not clear
Profession group	Physicians
Patients - number	10
Patients - age (mean(yrs))	39
Patients - gender (% female)	not clear
Patients - predominant ethnic group (%)	not clear
Total number of intervention groups	1
Type of targeted behaviour	General management of a problem, Patient education/advice, Professional-patient communication, Record keeping
Control groups used	cross over trial - normal care as control
type of intervention	Professional
intervention sub category	patient mediated Audit and feedback
intervention further details	Patient mediated - SMBG levels Audit and feedback – automated advice based on glucose readings
Primary outcome	clinical outcome
Health professional outcomes/process measures	Not done
Patient outcomes	primary outcome - number of hypoglycaemic events secondary outcomes - number of hypers, glycaemic control, behaviour and knowledge change, change in insulin doses

Cafazzo [102]

Design	ITS
Follow up of professionals	NA
Follow up of patients or episodes of care	NA
Blinded assessment of primary outcome(s)	NA
Baseline measurement	NA
Reliable primary outcome measure(s)	NA
Power calculation	Not done
Concealment of allocation	NA
Protection against contamination	NA

Profession group	Physicians
Patients - number	12
Patients - age (mean(yrs))	15
Patients - gender (% female)	50%
Patients - predominant ethnic group (%)	NOT CLEAR
Total number of intervention groups	1
Type of targeted behaviour	Patient education/advice, Professional-patient communication, Record keeping
Control groups used	NA
type of intervention	Organisational
intervention sub category	Patient orientated intervention
intervention further details	mHealth app providing tailored communication
Primary outcome	Self care
Health professional outcomes/process measures	Not done
Patient outcomes	primary - number of blood glucose tests secondary - HbA1c

Carroll [103]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Not done
Baseline measurement	Not done
Reliable primary outcome measure(s)	Done
Power calculation	Done
Concealment of allocation	Not clear
Protection against contamination	Not clear
Profession group	Physicians
Patients - number	3520
Patients - age (mean(yrs))	Not clear
Patients - gender (% female)	100%
Patients - predominant ethnic group (%)	Hispanic (40%)
Total number of intervention groups	2
Type of targeted behaviour	Diagnosis, Referrals, Patient education/advice
Control groups used	Generic information
type of intervention	Professional

intervention sub category	Distribution of educational materials Patient mediated interventions
intervention further details	Group 1: Recommendation to refer to psychiatry based on depression score plus patient education. Group 2: Recommendation to refer to psychiatry based on depression score only.
Primary outcome	Not stated
Health professional outcomes/process measures	Number of mothers referred for psychiatric assessment
Patient outcomes	Number of mothers identified as having depressive symptoms

Cruz-correia [117]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Not done
Concealment of allocation	Not done
Protection against contamination	Not done
Profession group	Physicians
Patients - number	21
Patients - age (mean(yrs))	29
Patients - gender (% female)	71%
Patients - predominant ethnic group (%)	Not clear
Total number of intervention groups	1
Type of targeted behaviour	Patient education/advice Professional-patient communication
Control groups used	cross over trial with paper system
type of intervention	Professional
intervention sub category	patient mediated interventions
intervention further details	asthma self monitoring - data upload and analysis
Primary outcome	Not stated
Health professional outcomes/process measures	Not done
Patient outcomes	patient satisfaction patient adherence to recommended monitoring

Epstein [104]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Not done
Concealment of allocation	Not done
Protection against contamination	Not clear
Profession group	Physicians
Patients - number	238
Patients - age (mean(yrs))	not clear
Patients - gender (% female)	not clear
Patients - predominant ethnic group (%)	not clear
Total number of intervention groups	1
Type of targeted behaviour	Diagnosis
Control groups used	No intervention control group
type of intervention	Professional
intervention sub category	Educational outreach Educational materials
intervention further details	Internet based educational programme plus face-face didactic teaching/workshop
Primary outcome	Adherence - guidelines
Health professional outcomes/process measures	Proportion using recommended diagnostic tools at follow up
Patient outcomes	Not done

Field [105]

Design	RCT
Follow up of professionals	Not done
Follow up of patients or episodes of care	Done
Blinded assessment of primary outcome(s)	Done
Baseline measurement	Not done
Reliable primary outcome measure(s)	Done

Power calculation	Not done
Concealment of allocation	Not done
Protection against contamination	Not done
Profession group	Physicians
Patients - number	833
Patients - age (mean(yrs))	86
Patients - gender (% female)	68%
Patients - predominant ethnic group (%)	NOT CLEAR
Total number of intervention groups	1
Type of targeted behaviour	Prescribing
Control groups used	No intervention control group
type of intervention	Professional
intervention sub category	Reminders
intervention further details	Clinical alert displayed when prescribing medication, based on patient's calculated creatinine clearance.
Primary outcome	Adverse drug event
Health professional outcomes/process measures	Alert rate Type of alert - incorrect dose, incorrect frequency, drug should be avoided, incomplete information (creatinine)
Patient outcomes	Not done

Fossum [122]

Design	CCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Done
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Done
Concealment of allocation	Not clear
Protection against contamination	Not clear
Profession group	Nurses
Patients - number	491
Patients - age (mean(yrs))	85
Patients - gender (% female)	75%

Patients - predominant ethnic group (%)	NOT CLEAR
Total number of intervention groups	2
Type of targeted behaviour	Clinical prevention services, Diagnosis
Control groups used	Standard practice control group
type of intervention	Professional
intervention sub category	Educational Reminders
intervention further details	Intervention 1 - CDSS within EHR plus educational meeting/info Intervention 2 - educational meeting/info only
Primary outcome	Not stated
Health professional outcomes/process measures	Not done
Patient outcomes	Proportion of patients: with malnourishment, at risk of malnourishment, with PU and at risk of PU

Gurwitz [106]

Design	RCT
Follow up of professionals	Not done
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Done
Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Done
Concealment of allocation	Not done
Protection against contamination	Not done
Profession group	Physicians, Nurses
Patients - number	1118
Patients - age (mean(yrs))	87
Patients - gender (% female)	1
Patients - predominant ethnic group (%)	Not clear
Total number of intervention groups	1
Type of targeted behaviour	Prescribing
Control groups used	Standard practice control group
type of intervention	Professional
intervention sub category	Reminders
intervention further details	prescribing, electronic

Primary outcome	Adverse drug event
Health professional outcomes/process measures	Not done
Patient outcomes	number of drug-related adverse events

Jones [123]

Design	ITS
Follow up of professionals	NA
Follow up of patients or episodes of care	NA
Blinded assessment of primary outcome(s)	NA
Baseline measurement	NA
Reliable primary outcome measure(s)	NA
Power calculation	Done
Concealment of allocation	NA
Protection against contamination	NA
Profession group	Physicians, Nurses
Patients - number	1481
Patients - age (mean(yrs))	65
Patients - gender (% female)	47%
Patients - predominant ethnic group (%)	Not clear
Total number of intervention groups	1
Type of targeted behaviour	Clinical prevention services, Diagnosis
Control groups used	historical
type of intervention	Professional
intervention sub category	Reminders
intervention further details	Use of automated early warning score alert to hospital doctors
Primary outcome	Clinical outcome
Health professional outcomes/process measures	Secondary - EWS accuracy, timeliness of obs recheck, clinical response to EWS alert
Patient outcomes	Primary - Length of stay Secondary - cardiac arrest, critical care bed days, deaths

Kinn [107]

Design	RCT
Follow up of professionals	Done
Follow up of patients or episodes of care	Done

Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done
Reliable primary outcome measure(s)	Not done
Power calculation	Not clear
Concealment of allocation	Not done
Protection against contamination	Done
Profession group	Physicians
Patients - number	1799
Patients - age (mean(yrs))	69
Patients - gender (% female)	32%
Patients - predominant ethnic group (%)	Not clear
Total number of intervention groups	1
Type of targeted behaviour	Diagnosis, General management of a problem, Patient outcome
Control groups used	No intervention control group
type of intervention	Professional
intervention sub category	Audit and feedback
intervention further details	Computer assisted hypertension management programme
Primary outcome	Not stated
Health professional outcomes/process measures	Performance - likelihood of a patient receiving a diagnosis of hypertension from this professional
Patient outcomes	Likelihood to receive at least 1 antihypertensive drug Number of blood pressure medications per patient Use of combination therapy Systolic blood pressure Diastolic blood pressure Achieves blood pressure target

McDonald [108]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Done
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Not done
Concealment of allocation	Not done

Protection against contamination	Not clear
Profession group	Physicians
Patients - number	144
Patients - age (mean(yrs))	26
Patients - gender (% female)	100%
Patients - predominant ethnic group (%)	African American (92%)
Total number of intervention groups	1
Type of targeted behaviour	Clinical prevention services, Patient education/advice
Control groups used	Untargeted activity
type of intervention	Organisational
intervention sub category	Patient orientated intervention
intervention further details	Tailored information for parents based on beliefs and knowledge
Primary outcome	Not stated
Health professional outcomes/process measures	Not done
Patient outcomes	Parent safety knowledge, prevention beliefs, and safety behaviours

Nagykaldy [109]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done
Reliable primary outcome measure(s)	Not clear
Power calculation	Done
Concealment of allocation	Not clear
Protection against contamination	Not clear
Profession group	Physicians, Nurses
Patients - number	538
Patients - age (mean(yrs))	52
Patients - gender (% female)	61%
Patients - predominant ethnic group (%)	White (82%)
Total number of intervention groups	1
Type of targeted behaviour	Patient education/advice, Patient outcome

Control groups used	Standard practice control group
type of intervention	Professional
intervention sub category	patient mediated interventions
intervention further details	Online clinical portal to upload clinical data, providing tailored information
Primary outcome	Not stated
Health professional outcomes/process measures	provision of preventative services
Patient outcomes	number of log ins to portal patient centredness

Persell [118]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Done
Concealment of allocation	Not done
Protection against contamination	Not clear
Profession group	Physicians
Patients - number	435
Patients - age (mean(yrs))	60
Patients - gender (% female)	23%
Patients - predominant ethnic group (%)	White (50%)
Total number of intervention groups	1
Type of targeted behaviour	Patient education/advice
Control groups used	Standard practice control group
type of intervention	Organisational
intervention sub category	Patient orientated intervention
intervention further details	provision of tailored CVS risk info mailed out to patients using automated data query to identify patients at risk
Primary outcome	Clinical outcome
Health professional outcomes/process measures	Prescription of a statin Number of office visits

Patient outcomes	Primary outcome - LDL cholesterol change in BP smoking cessation

Persell [110]

Design	ITS
Follow up of professionals	NA
Follow up of patients or episodes of care	NA
Blinded assessment of primary outcome(s)	NA
Baseline measurement	NA
Reliable primary outcome measure(s)	NA
Power calculation	Not done
Concealment of allocation	NA
Protection against contamination	NA
Profession group	Physicians
Patients - number	106 - 7462 (varies with outcome)
Patients - age (mean(yrs))	60
Patients - gender (% female)	43 - 75%
Patients - predominant ethnic group (%)	White (50%)
Total number of intervention groups	1
Type of targeted behaviour	Clinical prevention services, Prescribing
Control groups used	No intervention control group
type of intervention	Professional
intervention sub category	Reminders Audit and feedback
intervention further details	Reminders provided to physicians via EHR. Quarterly QI reports to physicians (not new practice)
Primary outcome	Adherence - guidelines
Health professional outcomes/process measures	16 performance measures - prescribing for chronic disease and screening procedures
Patient outcomes	Not done

Pinnock [120]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Done
Blinded assessment of primary outcome(s)	Done

Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Done
Concealment of allocation	Done
Protection against contamination	Not clear
Profession group	Physicians
Patients - number	256
Patients - age (mean(yrs))	69.4
Patients - gender (% female)	55%
Patients - predominant ethnic group (%)	Not clear
Total number of intervention groups	1
Type of targeted behaviour	Clinical prevention services, Diagnosis
Control groups used	Standard practice control group
type of intervention	Professional
intervention sub category	Patient medicated intervention - new clinical information
intervention further details	New clinical information supplied by patient and HCP alerted to intervene based on automated algorithms
Primary outcome	Time to first hospital admission with a primary diagnosis of an exacerbation of COPD
Health professional outcomes/process measures	Patient contacts Duration of hospital admission
Patient outcomes	Duration of hospital admission Death Quality of life Number of COPD exacerbations

Quinn [111]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not done
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Not done
Concealment of allocation	Not done

Protection against contamination	Not clear
Profession group	Physicians
Patients - number	30
Patients - age (mean(yrs))	51
Patients - gender (% female)	65%
Patients - predominant ethnic group (%)	African American (62%)
Total number of intervention groups	1
Type of targeted behaviour	Patient education/advice, Professional-patient communication
Control groups used	Standard practice control group
type of intervention	Professional
intervention sub category	patient mediated interventions
intervention further details	new clinical data submitted by patient and recommendation made using automated algorithm
Primary outcome	Not stated
Health professional outcomes/process measures	Satisfaction
Patient outcomes	Diabetes self care Glycaemic control

Raebel [112]

Design	RCT
Follow up of professionals	Not done
Follow up of patients or episodes of care	Not done
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Done
Reliable primary outcome measure(s)	Done
Power calculation	Not done
Concealment of allocation	Done
Protection against contamination	Not clear
Profession group	Pharmacists
Patients - number	11100
Patients - age (mean(yrs))	29
Patients - gender (% female)	100%
Patients - predominant ethnic group (%)	Not clear
Total number of intervention groups	1

Type of targeted behaviour	Prescribing
Control groups used	Standard practice control group
type of intervention	Professional
intervention sub category	Reminders
intervention further details	Drug pregnancy alert to pharmacists dispensing medication that is contraindicated for pregnant women.
Primary outcome	Adverse drug event
Health professional outcomes/process measures	Not done
Patient outcomes	Proportion of pregnant women dispensed a category D or X medication

Ross [119] (abstract only)

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Not clear
Reliable primary outcome measure(s)	Not clear
Power calculation	Not clear
Concealment of allocation	Not clear
Protection against contamination	Not clear
Profession group	Not clear
Patients - number	328
Patients - age (mean(yrs))	59
Patients - gender (% female)	45%
Patients - predominant ethnic group (%)	Not clear
Total number of intervention groups	1
Type of targeted behaviour	Patient education/advice
Control groups used	Untargeted activity
type of intervention	Professional
intervention sub category	patient mediated interventions
intervention further details	tailored education and reminders
Primary outcome	Not stated
Health professional outcomes/process measures	Not clear

Patient outcomes	system usage

Sequist [114]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Not clear
Reliable primary outcome measure(s)	Done
Power calculation	Done
Concealment of allocation	Not clear
Protection against contamination	Not clear
Profession group	Physicians
Patients - number	6243
Patients - age (mean(yrs))	63
Patients - gender (% female)	56%
Patients - predominant ethnic group (%)	White (50%)
Total number of intervention groups	1
Type of targeted behaviour	Clinical prevention services, Test ordering, Prescribing
Control groups used	No intervention control group
type of intervention	Professional
intervention sub category	Reminders
intervention further details	Automated electronic reminders to adhere to guidelines
Primary outcome	Adherence - guidelines
Health professional outcomes/process measures	Perceptions surrounding guideline adherence
Patient outcomes	receipt of recommended care

Tierney [115]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Not clear
Blinded assessment of primary outcome(s)	Not done
Baseline measurement	Not done
Reliable primary outcome measure(s)	Done

Power calculation	Done
Concealment of allocation	Done
Protection against contamination	Not clear
Profession group	Physicians, Pharmacists
Patients - number	706
Patients - age (mean(yrs))	51
Patients - gender (% female)	66%
Patients - predominant ethnic group (%)	White (60%)
Total number of intervention groups	3
Type of targeted behaviour	General management of a problem, evidence based practice
Control groups used	No intervention control group
type of intervention	Professional
intervention sub category	Reminders
intervention further details	Group 1: electronic suggestions for care displayed to primary care physicians Group 2: reminder for community pharmacists only Group 3: reminder for physician and community pharmacists
Primary outcome	Adherence - guidelines
Health professional outcomes/process measures	Percentage of suggestions adhered to
Patient outcomes	Not done

Vollmer [116]

Design	RCT
Follow up of professionals	Not clear
Follow up of patients or episodes of care	Done
Blinded assessment of primary outcome(s)	Not clear
Baseline measurement	Not done
Reliable primary outcome measure(s)	Done
Power calculation	Not done
Concealment of allocation	Not clear
Protection against contamination	Not done
Profession group	Not clear
Patients - number	14064
Patients - age (mean(yrs))	54

Patients - gender (% female)	66%
Patients - predominant ethnic group (%)	NOT CLEAR
Total number of intervention groups	1
Type of targeted behaviour	Prescribing, Patient education/advice
Control groups used	No intervention control group
type of intervention	Organisational
intervention sub category	patient orientated
intervention further details	automated phone calls reminding of need for inhaled corticosteroid prescription, based on data query from HER – tailored communication
Primary outcome	Adherence - patient
Health professional outcomes/process measures	Not done
Patient outcomes	medication adherence patient satisfaction - questionnaire

12. Appendix: Systematic review reported outcomes and comparisons

This table complements . Study quality score compiled for RCTs only – see section 11 for study characteristics used for grading. AE = adverse event; HbA1c = glycated haemoglobin; LoS = Length of stay; EWS = Early Warning Score; LDL = low density lipoprotein; QPI = Quality performance indicators; COPD = Chronic obstructive pulmonary disease; QoL = Quality of life, BP = blood pressure; IQR = interquartile range; SD = standard deviation *Denotes primary outcome(s) where stated.

Study	Study quality	Outcome(s)	Comparison (intervention vs control)	Main results of the outcome(s)
Avery[121]	Moderate	Number of potential adverse drug events*	Patients with DU - NSAID prescribed without PPI OR 0.58 (95%CI: 0.38-0.89); Patients with asthma - β blocker prescribed OR 0.73 (95%CI: 0.58-0.91); Patients ≥75 years receiving long-term ACE inhibitors or loop diuretics without u&e monitoring in the previous 15 months OR 0·51 (0·34–0·78)	Intervention group significantly less likely to have been prescribed contraindicated medication (all 3 measures)
Boukhors[101]	Low	Number of hypoglycaemic events*	hypoglycaemic events - 7.9/patient month vs 7.1/patient month, ns	No significant difference in incidence of hypoglycaemia
Cafazzo[102]	ITS	Number of blood glucose tests Glycaemic control (HbA1c)*	Mean number of tests/day = 3.6 vs 2.4 p=0.006 No change in HbA1c	Number of blood glucose tests increased with intervention. No difference in secondary outcomes - incidence of hyperglycaemia & glycaemic control
Carroll[103]	Low	Number of mothers identified as having depressive symptoms, Number of mothers referred for psychiatric assessment	No baseline comparison Intervention 1 depression detected - OR 8.1 (95% CI: 4.61-14.25); referred - OR 2.06 (95% CI: 1.08-3.93); Intervention 2 depression detected - OR 7.93 (95% CI: 4.51-13.96); referred - OR 2.06 (95% CI: 1.08-3.93)	Intervention groups more likely to have depression detected and more likely to be referred to specialist
Cruz-Correia[117]	Low	Patient satisfaction, Patient adherence to recommended monitoring	Adherence to recommended monitoring – 41% vs 92%, p<0.001	Patients were satisfied with system Patients adherence was not altered with electronic system - if anything adherence improved with paper system

Study	Study quality	Outcome(s)	Comparison (intervention vs control)	Main results of the outcome(s)
Epstein[104]	Low	Proportion using recommended diagnostic tools at follow up*	Change in proportion using questionnaires: Use of parent rating scale: 23.8% v 5.7%, p=0.03; Use of teacher rating scale: 22.6% v 6.0%, p=0.04; Use of DSM criteria for diagnosis: 47.3% vs 17.9%, p=0.03; Referral to outside provider for diagnosis: 60.7% vs -10.7%, p=0.0001; Parent ratings to monitor response 48.2% vs 25.0%, p=0.07; Teacher ratings to monitor response 38.7% v 6.3%, p=0.003	Significant increase in use of diagnostic questionnaires
Field[105]	Moderate	Alert rate*, Type of alert* - incorrect dose, incorrect frequency, drug should be avoided, incomplete clinical information (creatinine)	Alert rate 2.5/1000 resident days vs 2.4/1000 resident days RR 1.2, (95% CI:1.0-1.4); Type of alert: Dose appropriate RR 0.95 (95% CI: 0.83-1.1); Incorrect frequency 61.2% vs 25.7%, p<0.05; Drug should be avoided 40.6% vs 15.4%, p<0.05; Incomplete clinical info 63.8% vs 34.8%, p<0.05	Overall, no difference in rate of alerts between groups.
Fossum[122]	Low	Proportion with malnourishment, Proportion at risk of malnourishment and pressure ulcer	Intervention 1 (CDSS plus education) vs intervention 2 (education only) vs control: At risk of PU at follow up: 27% vs 36% vs 28%; No PU at follow up: 89% vs 83% vs 91%; Malnourished at follow up: 20% vs 25% vs 25% No comparisons made between above numbers owing to different baseline prevalences. Instead, difference between baseline and follow up calculated and then compared between groups. Difference in no PU prevalence: -1.9% vs -2.0% vs 2.3%; Difference in malnutrition prevalence: 9%, 7.1%,-3.9% (p=0.05)	no change in risk of PU no change in prevalence of PU No change in prevalence of malnourishment
Gurwitz[106]	Low	Number of drug-related adverse events (AE)*	AE's 10.8/100 v 10.4/100 resident months; preventable AE's 4.0/100 v 3.9/100 resident months, ns	No significant difference in AE's between intervention and control
Jones[123]	ITS	Length of stay (LoS)*, Accuracy of early warning score (EWS), Adherence to protocol, Clinical response to EWS alert, Rate of cardiac arrests, Number of critical care bed days, Mortality rate	LoS 6.9 days vs 9.7 days, p<0.001; adherence to clinical protocol 78% vs 29%, p<0.001; Cardiac arrest 0% vs 3%, p=0.21; Critical care bed days 26/9222 v 51/10802, p=0.04; Mortality rate 7.6% v 9.5%, p=0.19	Significant decrease in Length of Stay during intervention period
Kinn[107]	Low	Likelihood of being diagnosed with hypertension, Likelihood of receiving ≥1 antihypertensive, Number of antihypertensives per patient, Use of combination therapy, Blood pressure	Hypertensive patients diagnosed with hypertension: 90% vs 77%, p<0.001; Patients on at least 1 anti-hypertensive drug: 94% vs 90%, p<0.01; Number of BP medications per patient: 1.67 vs 2.63 1.67, p<0.001; Combination therapy: 81% vs 51%; Systolic BP 138.9mmHg vs 147.1mmHg, p<0.001; Diastolic BP: 76.8 mmHg vs 80.6 mmHg, p<0.001	Significantly more patients receiving appropriate diagnosis in intervention group; Intervention group significantly more likely to be on anti-hypertensive. Intervention group had significantly less antihypertensive agents prescribed.
Mcdonald[108]	Low	Parent safety knowledge, prevention beliefs, and safety behaviours	Analysis restricted to individual questionnaire item comparisons. Multiple comparisons used (approx.. 30).	Improved safety knowledge at follow up.

Study	Study quality	Outcome(s)	Comparison (intervention vs control)	Main results of the outcome(s)
Nagykaldi[109]	Low	Provision of preventative services, Number of log ins to portal, Patient centredness	patient centredness score: +0.32 points vs -0.43 points, p=0.037; Portal use average 2 log ins /year	Minimal use of portal Patient centredness score improved in intervention group
Persell[110]	Low	LDL cholesterol*, Change in BP, Smoking cessation, Prescription of a statin, Number of office visits	lowered LDL OR 0.99, (95% CI: 0.56-1.74); Prescription of statins OR 2.13 (95% CI: 1.22-3.72)	No significant difference in rate of lowered LDL No significant difference in attendance at clinic Significantly more statins prescribed in intervention group
Persell[118]	ITS	16 quality performance indicators (QPIs) - prescribing for chronic disease and screening procedures*	Adherence to QPI measured annually. Modelled rate of change in adherence calculated for each year - 1 year pre and 1 year post intervention. Results (Pre-intervention rate of change % per year; Post-intervention rate of change % per year; Diff in rate of change, p) Coronary Heart disease: Antiplatelet drugs - 0.5, 4.9, 4.1, 0.02; lipid lowering drugs - -1.5, 5., 7.3, <0.001; Beta blocker in MI - 3.3, 5.8, 1.9, NS; ACEI or ARB, 1.9, 5.1, 3.2 <0.001. Heart failure: ACEI or ARB in LVSD - -0.1, 5.2, 5.3, <0.001; Beta blocker in LVSD - 1.6, 7.3, 5.7, <0.001; Anticoagulants in atrial fibrillation - -3.2, 16.6, 18.1, <0.001. Diabetes mellitus: HbA1c control - -0.7, 2.1, 3.1 NS, LDL control - 0.8, 4.8, 4.1, <0.001; Aspirin for primary prevention - 2.1, 11,2, 8.8, <0.001; Nephropathy screening or Mx - -0.2, 5.7, 6.3, <0.001. Primary prevention: Mammography - 2.0, -4.3, -6.3, <0.001; Cervical screening - numbers not given; Colorectal screening - 2.8, 4.9, 2.2. NS; Pneumococcal vaccine - 8.5, 9.1, 0.2, NS; Osteoporosis screening - 5.7, 4.1, -1.7, 0.02	Performance measures improved
Pinnock[120]	High	Time to admission to hospital with exacerbation of COPD*, Time to admission, Number and duration of admissions, Deaths, QoL, Number of patient contacts	Median time to first hospital admission (median number of days, IQR) 362 (131->365) v 361 (113->365), Hazard ratio 0.98 95%CI 0.66-1.44, ns. Number of COPD-related admissions (mean, SD) 1.2(1.9) v 1.1 (1.6) point estimate 1.1 (0.78-1.56), ns Duration of COPD-related hospital admissions (mean days, SD): 9.5 (19.1) vs 8.8 (15.9), point estimate 1.03 (0.71-1.5), ns. Deaths: 16 (13%) vs 21(16%), OR 0.66 (0.29-1.48, ns); QoL score (SD): 68.2 (16.3) vs 67.3 (17.3), ns; Patient contacts higher in intervention group but no statistical comparison made.	No significant difference in admission rate or quality of life in those receiving intervention.
Quinn[111]	Low	Physician satisfaction, Diabetes self-care, Glycaemic control	Physicians: Perceived patient self-management 100% vs 15% p<0.001; Received more diabetes data 100% vs 23% p<0.001. Patients: Change in HbA1c - -2.03% vs -0.68%, p=0.04; Self-reported diabetes knowledge - 100% vs 50% p=0.062; Self-reported diabetes confidence - 100% vs 75%. ns.	Physicians satisfied Glycaemic control improved Patients self care improved
Raebel[112]	Low	Proportion of pregnant women dispensed a contraindicated medication*	Overall difference in proportion prescribed a medication contraindicated during pregnancy 2.9% v 5.5% p<0.001; Study terminated early due to high rate of false positive alerts	Intervention group were significantly less likely to be prescribed a contraindicated medication

Study	Study quality	Outcome(s)	Comparison (intervention vs control)	Main results of the outcome(s)
Ross[119]	Low	System usage	Number of days system used by patients: 772 days vs 319 days p=0.001	Intervention group had greater usage of system
Sequist[114]	Low	Receipt of recommended care*, HCP perceptions surrounding guideline adherence	Recommended diabetes care OR 1.3 (1.01-1.67); CHD care OR 1.25 (1.01-1.55)	Patients in intervention group significantly more likely than control patients to receive recommended diabetes care and CAD care
Tierney[115]	Low	Percentage adherence to management recommendations*	Adherence to suggested tests and treatments (both interventions v pharmacist intervention v physician internvention v control): 37% v 32% v 32% v 32% (ns)	No significant differences in adherence to guideline between groups
Vollmer[116]	Low	Patient adherence to medication*, Patient QoL, Reliever medication use, Asthma control, Healthcare utilisation	Mean difference in change in adherence 0.02, 95%CI 0.01 - 0.03). Both groups adherence fell during study period. No difference in effects of reliever medication use, QoL, asthma control or rate of healthcare utilisation	Small but significant increase in adherence

13. Appendix: EBMeDS script selection

13.1 Summary of scripts

Script	Title	Aim	Method	Modifications made in light of feedback
01299	TSH monitoring	To ensure screening for hypothyroidism in risk group	Checks most recent thyroid function and prompts user to consider checking where appropriate	None
01292	Laboratory follow-up in patients with type 1 diabetes	To ensure adequate reactions to results of laboratory follow-up of type I diabetes	Checks glycaemic control, renal function and BP and highlights need for appropriate intervention	None
01305	UKPDS Risk engine to calculate cardiovascular and stroke risk in patients with type 2 diabetes	To highlight when patient has high risk of cardiovascular event or stroke	Calculates risk based on known risk factors and alerts user if risk is high	Deleted
01306	Weight gain in type 2 diabetes	To remind users to highlight the importance of exercise	Checks BMI through time and highlights upward trends	None
01307	Weight gain in type 1 diabetes	To ensure that the correct insulin dose is being prescribed	Checks BMI through time and highlights upward trends	None
01297	Nephropathy screening in type 1 diabetes	To promote regular screening for nephropathy	Checks most recent UACR recording and prompts user to consider checking where appropriate	Deleted
01300	Screening for diabetic nephropathy in type 2 diabetes	To promote regular screening for nephropathy	Checks most recent UACR recording and prompts user to consider checking where appropriate	Deleted
01301	Managing hypertension in diabetic nephropathy	To encourage intervention for those with nephropathy and hypertension	Checks BP and nephropathy status and prompts user to intervene as appropriate	None
01302	Intensifying diabetes treatment in recently diagnosed type 2 diabetes	To ensure that pharmacological management has been considered	Checks glycaemic control and current medications and gives appropriate advice in the event of poor control	Amended – threshold raised (48mmol/mol increased to 58mmol/mol)
01303	ACE inhibitor or sartan for diabetic patients with albuminuria	Secondary prevention of further renal insufficiency	Checks for evidence of nephropathy and current medications and gives advice accordingly	None
01304	ACE inhibitors or angiotensin-receptor blockers for patients with diabetes and hypertension but no microalbuminuria	Primary prevention of renal insufficiency	Checks for evidence of hypertension, nephropathy and current medications and gives advice accordingly	None
01296	Routine procedures when starting a glitazone	To ensure that consideration is given to potential side effects or contraindications	Checks current medications and for presence of anaemia. Advice given for monitoring of potential side effects	None
01309	Glimepiride warning in renal insufficiency	To avoid risks with glimepiride in patients with renal insufficiency	Checks current medications and renal function and gives advice accordingly	None
01310	Glipizide warning in renal insufficiency	To avoid risks with glipizide in patients with renal insufficiency	Checks current medications and renal function and gives advice accordingly	None
01318	Recall of patients with type 1 diabetes	To ensure patients have had routine screening for complications of diabetes	Checks when the following parameters were last checked and highlights those that fall out with guidelines: HbA1c; BMI; foot risk; BP; UACR; creatinine; and cholesterol.	None

Script	Title	Aim	Method	Modifications made in light of feedback
01319	Recall of patients with type 2 diabetes	To ensure patients have had routine screening for complications of diabetes	Checks when the following parameters were last checked and highlights those that fall out with guidelines: HbA1c; BMI; foot risk; BP; UACR; creatinine; and cholesterol.	None
01320	Recall of patients for retinal screening	To ensure patients have had routine screening for complications of diabetes	Checks retinopathy status and date of last screening and gives advice accordingly	Amended – temporary suspension enabled (based on clinical grounds)
01312	Phosphodiesterase inhibitors for erectile dysfuntion in patients with diabetes mellitus	To promote effective treatment of erectile dysfunction	Checks for presence of erectile dysfuntion and current (and previous) medications and gives advice if indicated	None
01313	Metformin is the first choice oral hypoglycaemic agent in type 2 diabetes	To promote improved glycaemic control	Checks age; current medications; glycaemic control; and renal function and gives advice accordingly	None

13.2 01299 TSH monitoring

13.2.1. Aim

To ensure screening for hypothyroidism in risk group

13.2.2. Method

The script ensures that patients with diabetes are annually (children and young people (<18 years old) or bi-annually (adults aged ≥ 17 years old) screened for hypothyroidism. This script runs for all patients, regardless of whether they have a current diagnosis of hypothyroidism.

13.2.3. Decision Support Messages for Professionals

1. Annual screening for hypothyroidism is recommended for children aged under 17 with diabetes. Consider checking TSH even if asymptomatic (or currently being treated with thyroxine).[5]
2. Adults with diabetes are at increased risk of thyroid disease. Please consider checking TSH if symptomatic (or currently being treated with thyroxine)[6]

13.2.4. Short message

1. Type 1 diabetes - check TSH?
2. Type 1 diabetes - check TSH?

[5] http://www.sign.ac.uk/pdf/qrg116.pdf#page=44
[6] http://www.sign.ac.uk/pdf/qrg116.pdf#page=44

13.3 01292 Laboratory follow-up in patients with type 1 diabetes

13.3.1. Aim

To ensure adequate reactions to results of laboratory follow-up of type I diabetes

13.3.2. Method

The script is launched if the patient has a previous diagnosis of type 1 diabetes and =>17yo. Subsequently, his/hers gender and the following last laboratory results are checked:

B-HbA1c >= 58mmol/mol

U ACR >= 2.5 (males) or 3.5 (females);

eGFR-calculated <60.

If one or more are true, and the corresponding lab-tests are at most 13 months old, adequate reminders are shown.

13.3.3. Decision Support Messages for Professionals

1. This patient has type 1 diabetes and his/her glycaemic control is suboptimal (HbA1c = @1). Consider whether the diabetes treatment can be improved.
2. This patient has type 1 diabetes and renal impairment (calculated GFR = @1 ml/min). Please refer to local referral protocol[7]
3. This patient has type 1 diabetes and proteinuria. Please refer to local referral protocol[8]
4. This patient has type 1 diabetes and microalbuminuria. Please confirm with a repeat sample and optimise glycaemic and BP control.[9]

13.3.4. Short message

1. Type 1 diabetes with suboptimal glycaemic control
2. Type 1 diabetes and renal impairment
3. Type 1 diabetes and proteinuria

[7] http://www.diabetes-healthnet.ac.uk/Default.aspx?pageid=50#UrineProteinCreatinineRatio
[8] http://www.diabetes-healthnet.ac.uk/Default.aspx?pageid=50#UrineProteinCreatinineRatio
[9] http://www.sign.ac.uk/pdf/sign116.pdf#page=94

13.4 01305 UKPDS Risk Engine to calculate cardiovascular and stroke risk in patients with type 2 diabetes

13.4.1. Aim

The UKPDS calculators for cardiovascular and stroke risk are applied to the patient data. If the cardiovascular risk in 10 years exceeds 10% or the stroke risk exceeds 5%, a reminder is shown. Given that the presence of atrial fibrillation is not known, the default setting “no atrial fibrillation” is applied and the reminder is shown if the risk exceeds 10% or 5%. If the smoking status is not known, the reminder is shown if the risks exceed 10% or 5% by using the default settings "non-smoker".. If the 10-year risk of cardiovascular disease is above 10% reminder 1 (or 3) is shown. If the 10-year stroke risk is above 5% reminder 2 (or 4) is shown.

13.4.2. Decision Support Messages for Professionals

1. The risk of cardiovascular event is @1% in ten years according to the UKPDS risk engine. This risk may be increased if this patient has atrial fibrillation.[10]
2. This patient's ten-year risk of stroke is @1%, as calculated with the UKPDS Risk Engine. This risk may be increased if this patient has atrial fibrillation.[11]
3. This patient's ten-year risk of a cardiovascular event is @1%, as calculated with the UKPDS Risk Engine. Since information about this patient's smoking status was not found, the risk was calculated for a non-smoker. If the patient is a smoker, the ten-year risk is @2%. This risk may be increased if this patient has atrial fibrillation.[12]
4. This patient's ten-year risk of stroke is @1%, as calculated with the UKPDS Risk Engine. Since information about this patient's smoking status was not found, the risk was calculated for a non-smoker. If the patient is a smoker, the ten-year risk is @2%. This risk may be increased if this patient has atrial fibrillation.[13]

13.4.3. Short message

1. Type 2 diabetes - increased cardiovascular risk (UKPDS)
2. Type 2 diabetes - increased stroke risk (UKPDS).
3. Type 2 diabetes, unknown smoking status - increased cardiovascular risk (UKPDS)
4. Type 2 diabetes, unknown smoking status - increased stroke risk (UKPDS)

13.4.4. Amendment

Feedback from cycle 1 suggested that this alert was being triggered on almost all patients, resulting in user fatigue.

---

[10] http://www.dtu.ox.ac.uk/riskengine/
[11] http://www.dtu.ox.ac.uk/riskengine/
[12] http://www.dtu.ox.ac.uk/riskengine/
[13] http://www.dtu.ox.ac.uk/riskengine/

Decision made to remove script from system.

13.5 01306 Weight gain in type 2 diabetes

13.5.1. Aim

To remind of importance and effectiveness of exercise in the treatment of type 2 diabetes

13.5.2. Method

The purpose of the script is to ensure that weight gain in patients with type 2 diabetes is adequately noticed. The script applies to adults with type 2 diabetes. If BMI is above 25 and BMI change after previous measurement is above 2 kg/m², the user is reminded of paying attention to weight control.

13.5.3. Decision Support Messages for Professionals

1. This patient with diabetes has gained weight @1 since the last visit. Pay special attention to weight control. Do you want to write a prescription for exercise?[14]

13.5.4. Short message

1. Weight gain noted?

[14] http://www.sign.ac.uk/pdf/sign116.pdf#page=27

13.6 01307 Weight gain in type 1 diabetes

13.6.1. Aim

To remind of checking insulin dose during weight gain

13.6.2. Method

The purpose of the script is to ensure, that in those patients with type 1 diabetes AGED => 17, who have put on weight, the insulin dosage is checked not to be too high. The script is applied in persons with type 1 diabetes AGED => 17. The DS ensures that the patient is not underweight (BMI > 20 kg/m2 in patients 17 years of age or older; Subsequently, the DS calculates the BMI difference between now and at the time of last measurement (BMI now – BMI before). If the difference is > 2 kg/m2, the user is asked to check the insulin dosage (reminder 1).

13.6.3. Decision Support Messages for Professionals

1. This patient has gained weight significantly since the last visit. Is the insulin dose correct? Is hypoglycaemia an issue?[15] Discuss calorie intake, exercise and lifestyle[16].

13.6.4. Short message

1. Weight gain in a patient with diabetes

[15] http://www.sign.ac.uk/pdf/sign116.pdf#page=38
[16] http://www.sign.ac.uk/pdf/sign116.pdf#page=24

13.7 01297 Nephropathy screening in type 1 diabetes

13.7.1. Aim

Promote regular screening for nephropathy in patients with type 1 diabetes.

13.7.2. Method

The script targets patients who are at least 12 years old and do not yet have laboratory evidence of microalbuminuria. If such a patient has not been screened for microalbuminuria during the last 13 months, reminder 1 will be shown to remind of the need for regular screening.

13.7.3. Decision Support Messages for Professionals

1. This patient has type 1 diabetes and has not had urinary ACR measured during the last year. Annual screening for microalbuminuria by urine ACR measurement is recommended in type 1 diabetes[17]

13.7.4. Short message

1. Type 1 diabetes - time for nephropathy screening?

13.7.5. Amendment

Feedback from cycle 1 highlighted duplication between content of this script and that of script 01318, message 5.

Decision made to delete this script from system.

[17] http://www.sign.ac.uk/pdf/sign116.pdf#page=93

13.8 01300 Screening for diabetic nephropathy in type 2 diabetes

13.8.1. Aim

Early detection of diabetic nephropathy by reminding of regular screening for microalbuminuria.

13.8.2. Method

The script targets patients with type 2 diabetes who do not yet have microalbuminuria. If albuminuria has not been screened for during the last 1 year for such a patient, a reminder to perform screening is shown.

13.8.3. Decision Support Messages for Professionals

1. This patient has type 2 diabetes, and has not had urinary ACR measured during the last year. Annual screening for microalbuminuria by urine ACR is recommended in type 2 diabetes.[18]

13.8.4. Short message

1. Type 2 diabetes - time for nephropathy screening?

13.8.5. Amendment

Feedback from cycle 1 highlighted duplication between content of this script and that of script 01319, message 5.

Decision made to delete this script from system.

[18] http://www.sign.ac.uk/pdf/sign116.pdf#page=93

13.9 01301 Managing hypertension in diabetic nephropathy

13.9.1. Aim

In the case where the patient already has type 1 or 2 DM and has microalbuminuria, Blood pressure should be reduced to the lowest achievable level. For the purposes of clinical alerts, BP thresholds are as follows: reminder 1 is shown about the ideal blood pressure of <130/80 mmHg. If the patient has macroalbuminuria (>300 mg/day) OR ACR>30 OR PCR>50, ideal blood pressure level is <125/75 mmHg (reminder 2). If the patient with diabetes has albuminuria, but no recent (< 9 months) blood pressure reported, reminder 3 is given about measuring blood pressure.

13.9.2. Decision Support Messages for Professionals

1. The patient has diabetes mellitus and microalbuminuria and the latest blood pressure for a patient with diabetes and microalbuminuria was @1 mmHg, Blood pressure should be reduced to the lowest achievable level[19]
2. The patient has diabetes and proteinuria > 300 mg/day and the latest blood pressure was @1 mmHg. Blood pressure should be reduced to the lowest achievable level.[20]
3. The patient has diabetes and albuminuria, and no recent blood pressure measurement results are found. A blood pressure measurement is recommended[21]

13.9.3. Short message

1. Diabetes mellitus and microalbuminuria - is the BP level optimal?
2. Diabetes and proteinuria > 300 mg/day - is the blood pressure optimal?
3. Diabetes with albuminuria - measure blood pressure?

[19] http://www.sign.ac.uk/pdf/sign116.pdf#page=96
[20] http://www.sign.ac.uk/pdf/sign116.pdf#page=96
[21] http://www.sign.ac.uk/pdf/sign116.pdf#page=96

13.10 01302 Intensifying diabetes treatment in recently diagnosed type 2 diabetes

13.10.1. Aim

If a patient with fresh (at most 2 years old) type 2 diabetes has an elevated HbA1c level >48 mmol/mol but no insulin or sulphonylurea treatment, the user is recommended to intensify hyperglycaemia treatment according to the SIGN Guidelines and local protocols

13.10.2. Decision Support Messages for Professionals

1. This patient has type 2 diabetes and the HbA1c value is high (@1). Consider intensifying diabetes treatment.[22]

13.10.3. Short message

1. Type 2 diabetes and high HbA1c - intensify diabetes treatment?

13.10.4. Amendment

Feedback from cycle 1 highlighted low threshold for HbA1c. Current local practice aims to keep HbA1c <58 mmol/mol. Whilst it is desirable to aim for as low an HbA1c as possible, the original threshold resulted in alerts being triggered for the majority of patients, resulting in user fatigue.

[22] http://www.sign.ac.uk/pdf/sign116.pdf#page=46

13.11 01303 ACE inhibitor or sartan for diabetic patients with albuminuria

13.11.1. Aim

To prevent renal insufficiency in patients with diabetes

13.11.2. Method

This script is launched when albuminuria is detected (U ACR>= 2.5 (males) or 3.5 (females)), or microalbumin >30. First, the script checks diagnosis for diabetes. If the patient has diabetes, the script checks, whether medication list contains either ACE-inhibitor or ATRB. If the medication list does not contain drugs from either group, message (1) is shown.

13.11.3. Decision Support Messages for Professionals

1. This patient has microalbuminuria/proteinuria. Treatment with an ACE inhibitor or a sartan is recommended unless otherwise contraindicated[23]

13.11.4. Short message

1. Diabetes and microalbuminuria/proteinuria - start ACE inhibitor or sartan?

[23] http://www.sign.ac.uk/pdf/sign116.pdf#page=96

13.12 01304 ACE inhibitors or angiotensin-receptor blockers for patients with diabetes and hypertension but no microalbuminuria

13.12.1. Aim

Primary prevention of nephropathy in patients with diabetes and hypertension by promoting use of ACEI/ARB medication.

13.12.2. Method

If a patient with diabetes and hypertension, but no microalbuminuria or diabetic nephropathy, is not using an ACE inhibitor or an angiontensin-receptor blocker, a reminder on the benefit of these drugs is shown.

13.12.3. Decision Support Messages for Professionals

1. This patient has diabetes and hypertension, but is not using an ACE inhibitor or an angiotensin-receptor blocker. A Cochrane review found ACE inhibitors to significantly reduce the development of microalbuminuria when compared to treatment with placebo or calcium-channel blockers[24]

13.12.4. Short message

1. Diabetes and hypertension - start an ACE inhibitor or angiotensin-receptor blocker to prevent microalbuminuria?

[24] http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004136.pub3/abstract

13.13 01296 Routine procedures when starting a glitazone

13.13.1. Aim

The script guides the clinician to pay attention to relevant factors when initiating glitazone medication.

13.13.2. Method

This script is launched on initiation of glitazone treatment. First the script reviews current drug list for insulin use and if present, reminder (1) is shown. Next the script reviews the last B-Hb measurement and if it is less than 120 g/L (OR 12g/dl), reminder (2) is shown. Next the script reviews drug list for any other drug which may cause hypoglycemia (coded as BNF 6.1.2 Antidiabetic drugs), in which case message (3) is shown. Message (4) is shown last and patient information for this drug is printed out.

13.13.3. Decision Support Messages for Professionals

1. This patient is receiving insulin treatment. The combined use of Glitazones and insulin therapy increases the risk of heart failure, especially in those with predisposing risk factors.[25]
2. This patient is anaemic. Glitazones may decrease haemoglobin concentrations. The patient should be informed of this possibility and of the signs and symptoms of anaemia.[26]
3. This patient has previously been prescribed a medicine which lowers the blood glucose. Glitazones may potentiate its effect. Should symptoms of hypoglycaemia occur, the dose of both medicines should be reduced.[27]
4. Glitazones may cause fluid retention, which manifests itself through weight gain. The patient may be given printed information at the time of issuing the prescription. Liver enzyme values should be checked at regular intervals. The onset of action of glitazones is slow and often becomes evident only after several weeks.[28]

13.13.4. Short message

1. Glitazone treatment about to start - contraindicated due to insulin treatment?
2. Glitazone treatment about to start - information given about the risk of anaemia?
3. Glitazone treatment about to start - possible interactions noted?
4. Glitazone treatment about to start - weight monitoring arranged?

[25] http://www.medicinescomplete.com/mc/bnf/current/PHP4194-pioglitazone.htm
[26] http://www.medicinescomplete.com/mc/bnf/current/PHP4194-pioglitazone.htm
[27] http://www.medicinescomplete.com/mc/bnf/current/PHP4194-pioglitazone.htm
[28] http://www.medicinescomplete.com/mc/bnf/current/PHP4194-pioglitazone.htm

13.14 01309 Glimepiride warning in renal insufficiency

13.14.1. Aim

To avoid risks with glimepiride in patients with renal insufficiency

13.14.2. Method

The script is launched if the patient is on glimepiride. If the calculated glomerular filtration rate (GFR) is between 30 and 50 ml/min, reminder (1) is shown. If the calculated GFR is less than 30 ml/min, reminder (2) is shown.

13.14.3. Decision Support Messages for Professionals

1. This patient's calculated glomerular filtration rate (GFR) is between 30-49 ml/min (@1). Consider a lower than usual dose of glimepiride[29]
2. This patient's calculated glomerular filtration rate (GFR) is less than 30 ml/min (@1). Glimepiride is contraindicated[30]

13.14.4. Short message

1. Glimepiride treatment - impaired renal function noted?
2. Discontinue glimepiride due to impaired renal function?

[29] http://www.medicinescomplete.com/mc/bnf/current/PHP4129-sulfonylureas.htm#PHP4134
[30] http://www.medicinescomplete.com/mc/bnf/current/PHP4129-sulfonylureas.htm#PHP4134

13.15 01310 Glipizide warning in renal insufficiency

13.15.1. Aim

To avoid risks with glipizide in patients with renal insufficiency

13.15.2. Method

The script is launched if the patient is on glipizide. If the calculated glomerular filtration rate (GFR) is 30-50 ml/min, reminder (1) is shown. If the calculated GFR is less than 30 ml/min, reminder (2) is shown.

13.15.3. Decision Support Messages for Professionals

1. This patient's calculated glomerular filtration rate (GFR) is between 30-49 ml/min (@1). Consider a lower than usual dose of glipizide[31]
2. This patient's calculated glomerular filtration rate (GFR) is less than 30 ml/min (@1). Glipizide is contraindicated[32]

13.15.4. Short message

1. Glipizide treatment - impaired renal function noted?
2. Discontinue glipizide due to impaired renal function?

[31] http://www.medicinescomplete.com/mc/bnf/current/PHP4129-sulfonylureas.htm#PHP4134
[32] http://www.medicinescomplete.com/mc/bnf/current/PHP4129-sulfonylureas.htm#PHP4134

13.16 01318 Recall of patients with type 1 diabetes

13.16.1. Aim

If none of the following laboratory tests has been taken during the last 11 months, a reminder on recalling the patient is shown.
All patients: no HbA1c (message 1), no BMI (message 2), no foot risk score (message 3),
Patients >11 years old: no blood pressure (message 4), U ACR (message 5), creatinine (message 6).
Adults (≥17years old): no total cholesterol (message 7)

13.16.2. Decision Support Messages for Professionals

1. This patient has type 1 diabetes. More than 11 months have passed since HbA1c was measured. Guidelines suggest that this should be checked at least 6 monthly. Consider rechecking at the next review appointment.[33]
2. This patient has type 1 diabetes. More than 11 months have passed since BMI was measured. Guidelines suggest that this should be checked at least 6 monthly. Consider rechecking at the next review appointment.[34]
3. This patient has type 1 diabetes. More than 11 months have passed since a foot risk score was calculated. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[35]
4. This patient has type 1 diabetes. More than 11 months have passed since blood pressure was measured. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[36]
5. This patient has type 1 diabetes. More than 11 months have passed since U ACR was measured. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[37]
6. This patient has type 1 diabetes. More than 11 months have passed since creatinine was measured. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[38]
7. This patient has type 1 diabetes. More than 11 months have passed since total cholesterol was measured. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[39]

13.16.3. Short message

1. Diabetes - time for an HbA1c?
2. Diabetes - time for a BMI check?
3. Diabetes - time for an annual foot assessment?
4. Diabetes - time for an annual BP check?
5. Diabetes - time for an annual U ACR check?
6. Diabetes - time for an annual creatinine check?
7. Diabetes - time for an annual cholesterol check?

---

[33] http://publications.nice.org.uk/type-1-diabetes-cg15/guidance#blood-glucose-control-and-insulin-therapy
[34] http://www.diabetes-healthnet.ac.uk/Default.aspx?pageid=42
[35] http://www.sign.ac.uk/pdf/sign116.pdf#page=111
[36] http://publications.nice.org.uk/type-1-diabetes-cg15/guidance#control-of-arterial-risk
[37] http://www.sign.ac.uk/pdf/sign116.pdf#page=93
[38] http://publications.nice.org.uk/type-1-diabetes-cg15/guidance#identification-and-management-of-complications
[39] http://publications.nice.org.uk/type-1-diabetes-cg15/guidance#control-of-arterial-risk

13.17 01319 Recall of patients with type 2 diabetes

13.17.1. Aim

If none of the following laboratory tests has been taken during the last 11 months, a reminder on recalling the patient is shown.

no HbA1c (message 1), no total cholesterol (message 2), no BMI (message 3), no blood pressure (message 4), no foot risk score (message 5), U ACR (message 6) and creatinine (message 7).

13.17.2. Decision Support Messages for Professionals

1. This patient has type 2 diabetes. More than 11 months have passed since HbA1c was measured. Guidelines suggest that this should be checked at least 6 monthly. Consider rechecking at the next review appointment.[40]
2. This patient has type 2 diabetes. More than 11 months have passed since BMI was measured. Guidelines suggest that this should be checked at least 6 monthly. Consider rechecking at the next review appointment.[41]
3. This patient has type 2 diabetes. More than 11 months have passed since a foot risk score was calculated. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[42]
4. This patient has type 2 diabetes. More than 11 months have passed since blood pressure was measured. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[43]
5. This patient has type 2 diabetes. More than 11 months have passed since U ACR was measured. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[44]
6. This patient has type 2 diabetes. More than 11 months have passed since creatinine was measured. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[45]
7. This patient has type 2 diabetes. More than 11 months have passed since total cholesterol was measured. Guidelines suggest that this should be checked at least annually. Consider rechecking at the next review appointment.[46]

13.17.3. Short message

1. Diabetes - time for an HbA1c?
2. Diabetes - time for a BMI check?
3. Diabetes - time for an annual foot assessment?
4. Diabetes - time for an annual BP check?
5. Diabetes - time for an annual U ACR check?
6. Diabetes - time for an annual creatinine check?
7. Diabetes - time for an annual cholesterol check?

---

[40] http://publications.nice.org.uk/type-2-diabetes-cg87/guidance#glucose-control-levels
[41] http://www.diabetes-healthnet.ac.uk/Default.aspx?pageid=42
[42] http://www.sign.ac.uk/pdf/sign116.pdf#page=111
[43] http://publications.nice.org.uk/type-2-diabetes-cg87/guidance#blood-pressure-therapy
[44] http://www.sign.ac.uk/pdf/sign116.pdf#page=93
[45] http://publications.nice.org.uk/type-2-diabetes-cg87/guidance#anti-thrombotic-therapy
[46] http://publications.nice.org.uk/type-2-diabetes-cg87/guidance#cardiovascular-risk-estimation

13.18 01320 Recall of patients for retinal screening

13.18.1. Aim

This script checks for presence of previously diagnosed diabetic retinopathy and length of time since the patient was last screened. This script applies only to patients >11 years old. If there is previous retinopathy and there has been no diabetic retinal screening over the last 11 months, reminder (1) is shown. If there is no previous retinopathy and there has been no retinal screening over the last 23 months, reminder (2) is shown

13.18.2. Decision Support Messages for Professionals

1. This patient has diabetes. More than 11 months have passed since eye screening was undertaken. Guidelines suggest that this should be checked at least annually if there is retinopathy.[47]
2. This patient has diabetes. More than 23 months have passed since eye screening was undertaken. Guidelines suggest that patients with no previous retinopathy should be screened at least every 2 years.[48]

13.18.3. Short message

1. Diabetes - time for eye screening?
2. Diabetes - time for eye screening?

13.18.4. Amendment

Feedback from cycle 1 highlighted that patients can be temporarily or permanently suspended from retinal screening programme due to a number of clinical reasons. Additional rules have been added to the script to suppress reminders that are not applicable to individual patients.

[47] http://www.sign.ac.uk/pdf/sign116.pdf#page=104
[48] http://www.sign.ac.uk/pdf/sign116.pdf#page=104

13.19 01312 Phosphodiesterase inhibitors for erectile dysfunction

13.19.1. Aim

Promote effective treatment of erectile dysfunction in men with diabetes.

13.19.2. Method

If a male patient with diabetes and a diagnosis of erectile dysfunction has never used phosphodiesterase inhibitors, a reminder on the effectiveness of these drugs is shown. However, if the patient is using nitrates, or has a registered adverse event for phosphodiesterase inhibitors, the reminder will not be shown.

13.19.3. Decision Support Messages for Professionals

1. This patient has been diagnosed with erectile dysfunction and diabetes. However, there is no record of previous treatment with a phosphodiesterase inhibitor or contraindications to the treatment, e.g. nitrate use. There is sufficient evidence on the effectiveness of phosphodiesterase inhibitors in improving erectile dysfunction in men with diabetes[49]

13.19.4. Short message

1. Erectile dysfunction and diabetes - try a phosphodiesterase inhibitor?

[49] http://www.medicinescomplete.com/mc/bnf/current/PHP5154-phosphodiesterase-type-5-inhibitors.htm

13.20 01313 Metformin in type 2 diabetes

13.20.1. Aim

Patients with Type 2 diabetes should be on metformin if no contraindications exist

13.20.2. Method

The script is launched if the diagnosis is type 2 diabetes and the patient is under 80 years old. First, the script checks whether the drug list contains metformin and whether HbA1c is below 48 mmol/mol If not, the script checks for the plasma/serum creatinine value. If the GFR is in the normal range, reminder 1 is shown. If GFR is 30-45 ml/min, reminder 2 is shown. If GFR is missing or not checked within the last 12 months reminder 3 is shown.

13.20.3. Decision Support Messages for Professionals

1. This patient has type 2 diabetes. Metformin is the drug of choice for better glycaemic control[50]
2. This patient's glomerular filtration rate, calculated with the MDRD formula (@1), is at a level where a lower than usual dose of metformin should be considered[51]
3. This patient has type 2 diabetes. Metformin is the drug of choice for better glycaemic control. Consider checking renal function and starting metformin[52]

13.20.4. Short message

1. Type 2 diabetes - start metformin?
2. Type 2 diabetes - start metformin? Note GFR.
3. Type 2 diabetes - check renal function and start metformin?

[50] http://www.sign.ac.uk/pdf/sign116.pdf#page=48
[51] http://www.medicinescomplete.com/mc/bnf/current/PHP4161-metformin-hydrochloride.htm
[52] http://www.sign.ac.uk/pdf/sign116.pdf#page=48

14. Appendix: PREMS questionnaire

NHS Tayside diabetes clinic patient experience survey

Dear sir/madam,

I would like to invite you to take part in a survey about your experience of visiting the diabetes clinic. It is important that we get the opinions of as many people as possible, so please take a few minutes to complete the survey if you can.

The questions in the survey are about your visit to the diabetes clinic today. Please take a couple of minutes to complete the survey **after you have been seen** - we would like you to think about your experience with the doctor and/or nurse that you saw today when answering the questions.

Nobody in the clinic or NHS board will know that you have taken part in the survey, and they will only see anonymous results. The information will help to improve the service we provide at the diabetes clinic.

If you have any questions or need help filling in the survey, please ask at the clinic reception desk. Please take a few minutes to complete the survey at the end of your appointment and return it in the box on your way out. If you don't have the time to complete it today, you can return it to the address below in the envelope provided or you can complete it on online at **http://tinyurl.com/obvvl93**.

Thank you very much for your time.

Yours sincerely,

Dr Nicholas Conway

Senior clinical research fellow/honorary consultant
University of Dundee and NHS Tayside
MACHS building, Ninewells Hospital,
Dundee, DD1 9SY.

Some Questions & Answers

What is this survey for?

The survey asks about your experiences with the diabetes clinic during this most recent appointment. We have recently changed some features of the computer system used by the doctors and nurses and we are interested in finding out if this has had any effect on your appointment. The information that you give is important because it will help us to understand more about the quality of service, and what needs to be improved. The University of Dundee Research Ethics Committee has reviewed and approved this study.

Can someone help me with this survey?

A relative, friend or carer may help you to fill in the survey, but please remember that you should give all of the answers from your own point of view.

Do I have to answer every question?

No, taking part is voluntary, and you don't have to answer every question if you don't want to. Please fill in as much as you can though, because the more that people answer, the more we can understand about the different experiences of people across Tayside. Sometimes we will ask you to skip a question if it doesn't apply to you.

Will my doctor or nurse see my answers?

No. The staff at the clinic do not know who has filled in the survey, and they will only see anonymous results.

What happens to the results?

The survey results will be presented at local meetings and will be included in a report to be published in a medical journal that is available to the public. This report will only contain anonymous results.

You can fill in the survey online at http://tinyurl.com/obvvl93

1. **What is your name?**

_____

2. **Did you see a doctor when you visited the diabetes clinic today?**

No ☐ ⟶ Go straight to question 9

Yes ☐

↓

Seeing the doctor

Thinking about the last time you saw a doctor at the diabetes clinic, how much do you agree or disagree with each of the following?

Please select one choice for each of the following statements

3. **The doctor listened to me**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

4. **I felt that the doctor had all the information needed to treat me**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

5. **The doctor was considerate and understanding**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

6. **The doctor talked in a way that helped me understand my condition and treatment**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

7. **I felt confident in the doctor's ability to treat me**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

8. **I had enough time with the doctor**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

9. **Did you see a nurse when you visited the diabetes clinic today?**

No ☐ ⟶ Go straight to question 16

Yes ☐

↓

Seeing the nurse

Thinking about the last time you saw a nurse at the diabetes clinic, how much do you agree or disagree with each of the following?

Please select one choice for each of the following statements

10. **The nurse listened to me**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

11. **I felt that the nurse had all the information needed to treat me**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

12. **The nurse was considerate and understanding**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

13. **The nurse talked in a way that helped me understand my condition and treatment**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

14. **I felt confident in the nurse's ability to treat me**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

15. **I had enough time with the nurse**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

16. **When you visited the diabetes clinic today, were you started on any new medicines or were your existing medicines changed?**

No ☐ → Go straight to question 22

Yes ☐ ↓

Having your medicines changed

Thinking about the change in your medicines made at the diabetes clinic, how much do you agree or disagree with each of the following?

Please select one choice for each of the following statements

17. **I knew enough about what my medicines were for**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

18. **I knew enough about how and when to take my medicines**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

19. **I knew enough about possible side effects of my medicines**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

20. **I would know what to do if I had any problems with my medicines**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

21. **I took my prescription as I was supposed to**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Your overall experience

How much do you agree or disagree with each of the following about how you are treated by the staff at the diabetes clinic?

Please select one choice for each of the following statements

22. **I am treated with dignity and respect**

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

23. I am treated with kindness and understanding

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

24. Are you involved as much as you want to be in decisions about your care and treatment?

Please tick ONE choice only

- I am involved more than I want to be ☐
- I am involved as much as I want to be ☐
- I am not involved enough ☐
- I do not wish to be involved ☐
- Not relevant ☐

25. Overall, how would you rate the care provided by the diabetes clinic?

Excellent	Good	Fair	Poor	Very poor
☐	☐	☐	☐	☐

26. If there is anything else you would like to tell us about your experience at your most recent visit to the diabetes clinic, please feel free to add this below

_____
_____
_____
_____
_____

About you

This information will help us to find out if different groups of people in Tayside have different experience of treatment at their outpatient clinic. Nobody at your clinic will be able to see your answers. If you would prefer not to answer a particular question then you can miss it out.

27. Are you male or female?

Please tick ONE choice only

- **Male** ☐
- **Female** ☐

28. What year were you born?

_____

29. What is your postcode?

_____

30. How would you rate your health in general?

Please tick ONE choice only

- **Good** ☐
- **Fair** ☐
- **Bad** ☐

31. What is your ethnic group?

Tick ONE box which best describes your ethnic group

- **White** ☐
- **Mixed or multiple ethnic groups** ☐
- **Asian, Asian Scottish or Asian British** ☐
- **African, Caribbean or Black** ☐
- **Other ethnic group** ☐

32. Do you need an interpreter or other help to communicate?

Please tick ONE choice only

- **No** ☐
- **Yes** ☐

This is the end of the questionnaire. Thank you for taking the time to complete it.
Please return it in box in the clinic or post it to the address at the front using the envelope provided.

15. Appendix: HCP questionnaire - baseline

Survey of attitudes towards clinical decision support systems

Dear sir/madam,

I would like to invite you to take part in a survey about your use of clinical guidelines and other evidence when making clinical decisions, and how this fits into your everyday working.

It is important that we get the opinions of as many people as possible, so please take a few minutes to complete the survey if you can.

I would be grateful if you could complete the following questions, regardless of whether or not you are a frequent user of SCI-Diabetes. The questionnaire consists of 36 questions in total and should take you less than 5 minutes to complete. Further information about the survey is available on the attached participant information sheet.

You can fill in the survey in one of 3 ways:

1. Print it out and post the completed form back to the address below
2. Or, fill it in electronically and send it as an attachment to n.z.conway@dundee.ac.uk
3. Or, complete the survey online by clicking on this link: http://tinyurl.com/qgak7a9

If you have any questions about the survey or the project in general, please contact me via email at n.z.conway@dundee.ac.uk. Thank you very much for your time.
Yours sincerely,

Dr Nicholas Conway
Senior clinical research fellow/honorary consultant
University of Dundee and NHS Tayside
MACHS building, Ninewells Hospital,
Dundee, DD1 9SY

About you

1. What is your age?

Please tick ONE choice only

- 20-29 years ☐
- 30-39 years ☐
- 40-49 years ☐
- 50-59 years ☐
- 60+ years ☐

2. How many hours do you work on average per week?

Please tick ONE choice only

- Up to 16 hours ☐
- 17-32 hours ☐
- 33 hours or more ☐

3. Where do you work?

Please tick ONE choice only

- Primary care ☐
- Secondary care ☐
- Both primary and secondary care ☐
- Other ☐

4. What is the name of the practice in which you are based?

_____

5. Which of the following best describes your job?

Please tick ONE choice only

- Doctor ☐
- Nurse ☐
- Allied heath professional ☐
- Other ☐

You can fill in the survey online at http://tinyurl.com/qgak7a9

Your work with patients with diabetes

6. Are you a registered user of SCI-Diabetes?

Yes ☐ No ☐ Don't know ☐

7. How long have you worked with people with diabetes?

Please tick ONE choice only

- Less than 5 years ☐
- 5 to 10 years ☐
- More than 10 years ☐

8. Which, if any, protocols or guidelines do you use when managing patients with diabetes?

Select any number of the following choices

- NHS Tayside Diabetes Managed Clinical Network Handbook ☐
- SIGN guideline ☐
- NICE guideline ☐
- None of the above ☐
- Other ☐

9. In an average week, how long do you spend searching and/or reading diabetes-related literature (including guidelines)?

Please tick ONE choice only

- Less than 1 hour ☐
- 1 to 5 hours ☐
- More than 5 hours ☐

Your use of guidelines and literature

10. When do you access diabetes-related guidelines and/or literature

For each column, please select any number of the following choices

	Guidelines	Literature
Before the consultation	☐	☐
During the consultation	☐	☐
After the consultation	☐	☐
Unrelated to the consultation	☐	☐
Never	☐	☐

11. How do you access this diabetes-related guidelines and/or literature?

For each column, please select any number of the following choices

	Guidelines	Literature
Textbooks (hard copy)	☐	☐
Journals (hard copy)	☐	☐
Computer at work	☐	☐
Computer at home	☐	☐
Not applicable	☐	☐
Other	☐	☐

12. How often does your reading affect your clinical practice?

For each column, please tick ONE choice only

	Guidelines	Literature
Never	☐	☐
Seldom	☐	☐
Sometimes	☐	☐
Often	☐	☐
Not applicable	☐	☐

13. What are the most common reasons for choosing NOT to follow a guideline?

Select any number of the following choices

- Not applicable, I always follow guidelines ☐
- Experience tells me the guideline is incorrect ☐
- The guideline fails to take into account patient co-morbidities ☐
- The guideline is difficult to access ☐
- The guideline contradicts or is in conflict with guidelines for other conditions ☐
- The guideline contradicts or is in conflict with local policy ☐
- Other ☐

For each of the following statements, please select ONE response to show how much you agree or disagree with it.

14. When I have a clinical query, I usually ask a colleague for advice

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

15. When I have a clinical query, I usually look for the answer in the literature and/or guidelines.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

16. When I have a clinical query, I usually manage to find the time to find the answer.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

17. When I search for relevant literature and/or guidelines, I usually find what I am looking for.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

18. I feel comfortable overriding a guideline if I feel it is not in the patient's best interests.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

19. When I search for relevant literature and/or guidelines, I would like this to count towards my continuing professional development (CPD).

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

20. When I search for relevant literature and/or guidelines, I always record it as CPD.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

21. I would like it if my CPD is automatically recorded when I read literature and/or guidelines.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Your attitude to decision support systems

Decision support is when you are automatically alerted to the presence of an abnormal result or a potential problem. This is usually when using an electronic health record (like SCI-Diabetes). The alert might also suggest what might be appropriate management of the problem.

22. Have you ever been aware of using a decision support system in the past?

Please tick ONE choice only

- **Yes** ☐
- **No** ☐
- **Don't know** ☐

23. If yes, when did you find it most useful

Select any number of the following choices

- **Before the consultation** ☐
- **During the consultation** ☐
- **After the consultation** ☐
- **Unrelated to the consultation** ☐
- **Not applicable** ☐

For each of the following statements, please select ONE response to show how much you agree or disagree with it.

24. I would trust the advice given by an automated message delivered by a clinical decision support system (CDSS).

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

25. I would want to know the evidence behind the advice given by the CDSS.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

26. I think that CDSS could help me when prescribing medication.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

27. I think that CDSS could help me when deciding when/when not to request investigations.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

28. I think that using a CDSS could lead to a better quality of care.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

29. I would find messages from a CDSS annoying after a while

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

30. I would worry that some people might come to rely on messages from the CDSS.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

31. I would feel comfortable choosing to ignore the advice from the CDSS if I felt it was justified.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

32. I worry that messages from a CDSS might affect the consultation and/or my relationship with the patient.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

33. 4.12 If a CDSS was implemented, I would like the option to turn it off.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Any other comments

34. If you have previously used a CDSS, what are the things you like best about them?

_____

_____

_____

35. If you have previously used a CDSS, what are the things you dislike most about them?

_____

_____

_____

36. Please feel free to tell us any other concerns or suggestions that would help in the development process.

_____

_____

_____

This is the end of the questionnaire. Thank you for taking the time to complete it. Please return it to the box at the door.

16. Appendix: HCP questionnaire – follow up

EBMeDS evaluation – user experience survey

Dear sir/madam,

Thanks for agreeing to take part in this survey. It is designed to assess how well the EBMeDS clinical alert system within SCI-Diabetes is performing, and hopefully help us improve it.

I would be grateful if you could complete the following questions, regardless of whether or not you have received any clinical alerts whilst working with SCI-Diabetes in the past couple of months. The questionnaire is designed in 6 parts and should take you less than 5 minutes to complete.

All of the information that you provide will be treated in a confidential manner and we will always ensure that your anonymity is protected.

You can fill in the survey in one of 2 ways:

1. Print it out and post the completed form back to the address below
2. Or, complete the survey online by clicking on this link:

If you have any questions about the survey or the project in general, please contact me via email at n.z.conway@dundee.ac.uk. Thank you very much for your time.
Yours sincerely,

Dr Nicholas Conway
Senior clinical research fellow/honorary consultant
University of Dundee and NHS Tayside
MACHS building, Ninewells Hospital,
Dundee, DD1 9SY

About you

1. Are you a registered user of SCI-Diabetes?

Yes ☐ **No** ☐ **Don't know** ☐

If yes, proceed to question 2

If no, then please forward this to a SCI-Diabetes user within your workplace. Thanks.

2. What is your age?

Please tick ONE choice only

20-29 years ☐
30-39 years ☐
40-49 years ☐
50-59 years ☐
60+ years ☐

3. How many hours do you work on average per week?

Please tick ONE choice only

Up to 16 hours ☐
17-32 hours ☐
33 hours or more ☐

4. Where do you work?

Please tick ONE choice only

Primary care ☐
Secondary care ☐
Both primary and secondary care ☐
Other ☐

5. What is the name of the practice/hospital in which you are based?

_____

6. Which of the following best describes your job?

Please tick ONE choice only

Doctor ☐
Nurse ☐

Allied heath professional ☐

Other ☐

Your work with patients with diabetes

7. How long have you worked with people with diabetes?

Please tick ONE choice only

Less than 5 years ☐

5 to 10 years ☐

More than 10 years ☐

8. Which, if any, protocols or guidelines do you use when managing patients with diabetes?

Select any number of the following choices

NHS Tayside Diabetes Managed Clinical Network Handbook ☐

SIGN guideline ☐

NICE guideline ☐

None of the above ☐

Other ☐

9. In an average week, how long do you spend searching and/or reading diabetes-related literature (including guidelines)?

Please tick ONE choice only

Less than 1 hour ☐

1 to 5 hours ☐

More than 5 hours ☐

10. Does your reading affect your clinical practice?

Please tick ONE choice only

Never ☐

Seldom ☐

Sometimes ☐

Often ☐

Not applicable ☐

11. Over the past couple of months, how often have you received an EBMeDS clinical alert whilst using SCI-Diabetes?

Please tick ONE choice only

Seldom ☐

Sometimes ☐

Often ☐

Never ☐

Not applicable ☐

If never or not applicable, please stop here and return questionnaire to the address provided

Your work and EBMeDS

For each of the following statements, please select ONE response to show how much you agree or disagree with it.

12. The clinical alerts have changed my way of working

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

13. The clinical alerts have made me more careful when prescribing medication.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

14. The clinical alerts have influenced my decision when/when not to request investigations.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

15. I think that using the EBMeDS system improves my clinical knowledge.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree

☐ ☐ ☐ ☐ ☐

16. The use of the EBMeDS clinical alerts system could lead to better quality of care.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Your overall opinion on the EBMeDS clinical alert system

For each of the following statements, please select ONE response to show how much you agree or disagree with it.

17. I felt that I was given sufficient information before the EBMeDS system was introduced.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

18. Technical support is available when I need it.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

19. Using the system fits in well with the way I like to work.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

20. Overall, I am satisfied with the EBMeDS system.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

21. I would recommend the use of the EBMeDS system to others.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

22. I use the EBMeDS system mainly because my colleagues do.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

23. Using the EBMeDS clinical alerts system enables me to accomplish my tasks more quickly.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

24. I intend to keep using the EBMeDS system.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Your interaction with EBMeDS

For each of the following statements, please select ONE response to show how much you agree or disagree with it.

25. The EBMeDS clinical alerts system is easy to use.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

26. I quickly adapted to using the EBMeDS clinical alerts

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

27. I always read the EBMeDS clinical alerts (these are the messages shown in the pop-up box).

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

28. I always read the guidelines cited by EBMeDS (these are accessed by using the links contained within the case record clinical alerts page).

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

29. The EBMeDS system is too slow.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

30. I regularly experience technical problems when using the EBMeDS system.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

Your opinion on the content of the messages

For each of the following statements, please select ONE response to show how much you agree or disagree with it.

31. The EBMeDS clinical alerts are relevant to my practice.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

32. I am satisfied with the clinical alerts that EBMeDS gives.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

33. I am satisfied with the reliability of the EBMeDS system.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

34. I am satisfied with the guidelines suggested by EBMeDS.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

35. The EBMeDS clinical alerts are not specific enough.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

36. I feel comfortable overriding the advice given by the EBMeDS system if I feel it's not in the patient's best interests.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

37. I don't think the information provided by EBMeDS is of sufficient quality.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

38. The EBMeDS clinical alerts communicate the message in a clear way.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

39. I would prefer it if the guidelines referred to by the clinical alert were available within SCI-Diabetes (as opposed to an external site)

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
☐	☐	☐	☐	☐

40. What are the most common reasons for choosing NOT to follow the advice given by EBMeDS?

	Yes	No
Not applicable, I always follow the advice given	☐	☐
Experience tells me that the advice given is incorrect	☐	☐
The advice fails to take into account patient co-morbidities	☐	☐
The advice fails to take into account patient circumstances	☐	☐
The advice is difficult to access	☐	☐
The advice contradicts or is in conflict with guidelines for other conditions	☐	☐
The advice contradicts or is in conflict with local policy	☐	☐

Other(please specify):_____

Ways to make EBMeDS better

41. What are the things you like best about EBMeDS?

_____
_____
_____

42. What are the things you dislike most about EBMeDS?

_____
_____
_____

43. What are the most common reasons for ignoring the EBMeDS clinical alerts?

_____
_____
_____

44. What would help you in deciding to use the EBMeDS clinical alerts more?

_____
_____
_____

45. What improvements could be made to the EBMeDS system?

_____
_____
_____

This is the end of the questionnaire. Thank you for taking the time to complete it. Please return it to the address shown on page 1.

17. Appendix: Focus group topic guide

17.1 Part 1: Introductions

Introduce self and current role within research team

Reason for research

- EBMeDS pilot – describe system
- Baseline data to evaluate attitudes to system

Objectives

- Role of SCI-diabetes in participants' everyday work
- Role of guidelines etc in management decisions
- Attitude to clinical decision support
- Potential barriers/facilitators to effective adoption

Housekeeping

- Confidentiality of data and anonymisation process
- Recording of data and transcription
- Archiving

17.2 Part 2: Main discussion

Participant's background

- Role within MDT
  - Examples of management decision that participant might have to make
  - In the past week, how many drug changes/referrals to other specialities/screening tests requested.

Use of Sci-Diabetes

- Attitude to computers in general
  - General attitude to computers at work
  - Use of computers out with work space
- When is data entered – before/during/after consultation
- Other times when SCI-Diabetes is accessed
  - When
  - Purpose
- Barriers to current usage – time, context, doctor-patient relationship, UI, hardware
- Potential improvements to SCI-Diabetes?

How to apply best practice guidelines to the management of patients with diabetes

- Overall attitude to current practice in general

        - What works well
        - What could be improved
    - Resources currently used
        - Tayside handbook, SIGN, NICE, google, websites (name), textbook, journals, BNF, colleagues?
        - *How* references are accessed – electronic, book
        - When are these used – before/during/after
        - Perceived need for references: "in the past week, how many times have you *felt the need* to refer to...."
        - *Actual* use of references: "in the past week....."
            - What proportion of these was enquiry successful i.e. info found
            - If discrepancy between perceived and actual – why?
    - Role of guidelines when managing those with complex co-morbidities
        - Do guidelines help or hinder?
        - Need to over-ride guidelines – frequency, instances, problems with doing this?
    - Accreditation of CPD
        - Attitude to automated system of collecting.

Attitude to decision support tools

"Imagine you had a clinical query regarding a problem patient..."

    - Attitude to other colleagues' recommendations
        - Confidence and trust/acceptance in implementing advice directly
            - Factors which influence decision – seniority of adviser, time, access to appropriate resource, individual experience (trust judgment of colleague)
    - Attitude to automated recommendations
        - Non-specific versus tailored – preference
        - Value of non-specific advice – how often is it followed - some/all/never
        - General opinion on the EBMeDS system as described
            - Attitude to tailored advice – confidence and trust/acceptance
            - More or less trusted than senior colleague
        - Potential role in consultation
            - Value placed in prompt
                - Pay attention? Nuisance? Noise? Alert fatigue?
            - Reassurance from *lack* of prompt
                - Would you gain reassurance?
            - Can you see it changing your practice?
    - Perceived barriers to implementation
        - Expand on each
        - Strategies to overcome each

Conclude.

18. Appendix: SPSS syntax for data cleaning

The following is an account of the process used to clean SCI-Diabetes navigation data obtained for cycle 1 of the project.

The following syntax was developed to initially clean the data:

Number of rows of data (n)=760,666

```
*Filter out all non-patient related activity.
FILTER OFF.
USE ALL.
SELECT IF (LinkId > 0).
EXECUTE.
```

n=684,601. Saved as "…cleaning1.sav"

```
*assign value to missing values in message by recoding into message_coded.
AUTORECODE VARIABLES=Message
  /INTO message_coded
  /PRINT.
```

```
*Filter out all non-clicks - coding: 1=EBMeDS request, 10=page access successful i.e. clicked on a page.
FILTER OFF.
USE ALL.
SELECT IF (RANGE(message_coded,1,1,10,10)).
EXECUTE.
```

N=114,234 Saved as "…cleaning2.sav"

```
*extract date numbers from string.
compute date=number(substr("Timestamp",1,23),f4).
string n1 to n4 (a24).
compute n1=char.substr(Timestamp,1,24).
COMPUTE year=NUMBER(SUBSTR(n1,1,4),f4).
COMPUTE month=NUMBER(SUBSTR(n1,6,2),f2).
COMPUTE day=NUMBER(SUBSTR(n1,9,2),f2).
COMPUTE hour=NUMBER(SUBSTR(n1,12,2),f4).
COMPUTE minute=NUMBER(SUBSTR(n1,15,2),f2).
COMPUTE second=NUMBER(SUBSTR(n1,18,5),f5).
execute.
```

```
* Date and Time Wizard: date_var.
COMPUTE  date_var=DATE.DMY(day, month, year) + TIME.HMS(hour, minute, second).
VARIABLE LABELS  date_var "".
VARIABLE LEVEL  date_var (SCALE).
FORMATS  date_var (EDATE10).
VARIABLE WIDTH  date_var(10).
EXECUTE.
```

```
* Date and Time Wizard: Time.
COMPUTE  Time=TIME.HMS(hour, minute, date_var).
VARIABLE LABELS  Time "".
VARIABLE LEVEL  Time (SCALE).
FORMATS  Time (TIME8).
VARIABLE WIDTH  Time(8).
EXECUTE.

*assign case number.
COMPUTE id=$CASENUM.
FORMAT id (F8.0).
EXECUTE.

*assign userid (NB anonymised for reporting purposes).
RECODE User ('xxxx'=1)
('xxxx'=2)….[repeat for each user]…
…('xxxx'=63) INTO userid.
execute.

*recode events for merging with event types categorised.
RECODE Event ('Active Clinical Domains'=1)
('Acute Complications'=2)
('Ad-Hoc Queries'=3)
('Administration Facilities'=4)
('Advice History'=5)
('Audit Patient Contacts'=6)
('Blood Pressure Summary'=7)
('Body Mass Index & Smoking Summary'=8)
('Carbohydrate Assessment'=9)
('Cardiovascular System'=10)
('Change Password'=11)
('Change User Options'=12)
('CHI Override'=13)
('Clinic Information & Contacts'=14)
('Clinic Letter History'=15)
('Clinic Letter Management'=16)
('Clinic Letters'=17)
('Clinic Utilisation'=18)
('Clinic/Practice Information & Contacts'=19)
('Clinical Alerts'=20)
('Clinical Comment Record'=21)
('Clinical Domains History'=22)
('Clinical Summary'=23)
('Clinical Summary'=24)
('Create New  PHS'=25)
('Create User Account'=26)
('Current Gestational Diabetes'=27)
```

('Current Retinal Screening Patients'=28)
('Deceased Patients'=29)
('Demographics'=30)
('Diabetes in Remission'=31)
('Diabetes Resolved'=32)
('Diabetes Type Unknown'=33)
('Diabetic Retinal Screening'=34)
('Diagnostic Admin Form'=35)
('Diagnostic Admin Form History'=36)
('Diagnostic Information'=37)
('Dietetic Patient Review'=38)
('Discharge Patient'=39)
('Discharge Patient (from a Clinic)'=40)
('DRS Register'=41)
('Drug Reactions/Allergies'=42)
('DSN Form'=43)
('DSN Form History'=44)
('EBMeDS Request'=45)
('Edit User Account'=46)
('Education Establishment'=47)
('Enrol Patient'=48)
('Enrol Patient (into Clinic)'=49)
('Erroneous Data'=50)
('Exception'=51)
('Eye Image'=52)
('Eye Images - DRS'=53)
('Eye Screening'=54)
('Eye Screening Summary'=55)
('Eye Summary'=56)
('Find and Register a Patient'=57)
('Find and Select a Patient'=58)
('Foot Screening'=59)
('Foot Screening History'=60)
('Foot Screening Summary'=61)
('Foot Screening Tool (Risk Stratification)'=62)
('Foot Summary'=63)
('General Audit'=64)
('Glycaemic Control'=65)
('Glycaemic Control Summary'=66)
('Inpatient Episodes'=67)
('Inpatient Overview'=68)
('Insert New Comment'=69)
('Insulin Pump Monitoring'=70)
('Laboratory Results'=71)
('Letters'=72)
('Lifestyle'=73)
('Login'=74)
('Main Menu'=75)

('Manage Contacts'=76)
('Manage Patient Consent'=77)
('Manage User Population'=78)
('Medical History'=79)
('Neuropathy'=80)
('No Diagnosis Made'=81)
('Other Types of Diabetes'=82)
('Paediatrics'=83)
('Paediatrics'=84)
('Patient Audit'=85)
('Patient Diary'=86)
('Patient Diet Assessment'=87)
('Patient Education History'=88)
('Patient List Management'=89)
('Patient Record'=90)
('Patient Record'=91)
('Patient Search'=92)
('Patient Status'=93)
('Patients Pending Confirmation of Unsuspension'=94)
('Patients With Deteriorating Recordings'=95)
('PHS History'=96)
('Population Overview'=97)
('Population Summary'=98)
('Pre-Diabetic Conditions'=99)
('Primary Care Prescribing Record'=100)
('Recently Diagnosed Patients'=101)
('Regional Comparison'=102)
('Renal Care'=103)
('Routine Clinic Recording'=104)
('Routine Clinic Recording History'=105)
('Scottish Diabetes Survey 2012'=106)
('SDRN Admin '=107)
('Search For A Patient Record'=108)
('Search Results'=109)
('Sexual Health'=110)
('Specialist Prescribing Advice'=111)
('Suspended Patients'=112)
('System Maintenance Notification'=113)
('Treatment Type'=114)
('Type 1 Diabetes - Population Overview'=115)
('Type 2 Diabetes - Population Overview'=116)
('Ulcer Management'=117)
('User Account Management'=118)
('View My Contacts'=119)
('View Patient Removal History'=120) into event_type_coded.
Execute.

N=114,234 Saved as “…cleaning3.sav”

```
*Count number of events for each patient record.  N.B. rename id in original file into EventID.
RECODE EventID (ELSE=1) INTO count.
EXECUTE.

SORT CASES BY LinkId userid.
AGGREGATE
  /OUTFILE=* MODE=ADDVARIABLES
  /PRESORTED
  /BREAK=LinkId userid
  /linkID_events=SUM(count).
EXECUTE.

*Calculate number for each record in file.
SORT CASES BY EventID(A).
COMPUTE RecordNumber=$CASENUM.
EXECUTE.

*Identify when patient record opened.
RECODE Event_type_coded (90=1) (48=1) (ELSE=0) INTO RecordOpen.
EXECUTE.

*Identfy record number for new login session, and then subtract 1 using LAG function.
IF  (RecordOpen=1) NumberRecordPreviousPatient=lag(RecordNumber).
EXECUTE.

*Identify data and time of record open.
IF  (RecordOpen=1) DateTimeRecordOpen=date_var.
execute.

*Identify start time when record opened.
IF  (RecordOpen=1) TimeRecordOpen=Time.
EXECUTE.

*Identify end time of session.
*Identify time of last record closed during previous session using LAG function.
*NB need to align times after DSS info aligned to login.
IF  (RecordOpen=1) TimePreviousRecordClosed=Lag(time).
EXECUTE.

*Associate RecordOpen with EBMeDS request.
CREATE DSSCodeRecordOpen = LEAD (DSSMessageLogId,2).
EXECUTE.

CREATE DSSCodeRecordOpenReminders = LEAD (Reminders,2).
EXECUTE.

RECODE DSSCodeRecordOpenReminders (SYSMIS=0) (0=0) (ELSE=1) INTO DSSpresentRecordOpen.
EXECUTE.
```

```
*Select patientRecordOpen records.
FILTER OFF.
USE ALL.
SELECT IF (RecordOpen=1).
EXECUTE.
```

N=19,994, Saved as "…cleaning4.sav"

```
*Align patient record open and close times using LEAD.
CREATE TimeRecordClose = LEAD(TimePreviousRecordClosed,1).
EXECUTE.

*Calculate duration of time for record being used.
COMPUTE RecordDuration=(TimeRecordClose - TimeRecordOpen)/60.
EXECUTE.

*Delete instances <1sec duration as assumed to be system error rather than true user behaviour.
FILTER OFF.
USE ALL.
SELECT IF (RecordDuration >= 1).
EXECUTE.
```

N=17,280, Saved as "…cleaning5.sav"

19. Published conference abstracts relevant to the thesis

This work has directly contributed to the following abstracts being accepted for presentation at conferences (*denotes oral presentations):

- *NT Conway, SG Cunningham, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of user acceptance, clinical processes and outcomes. International Diabetes Federation, World Diabetes Congress, Dubai 2017.
- *NT Conway, SG Cunningham, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of clinical processes and outcomes. Informatics for Health conference, Manchester 2017.
- NT Conway, K Adamson, SG Cunningham, A Emslie-Smith, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of user attitudes and system usage. Diabetes UK conference, Manchester 2017
- NT Conway, K Adamson, SG Cunningham, A Emslie-Smith, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of clinical processes and outcomes. Diabetes UK conference, Manchester 2017
- *Conway NT, Campbell I, Forbes P, Cunningham SG, Wake DJ. mHealth applications for diabetes – user preference and implications for app development.. Farr Institute International Conference, St Andrews 2015.
- Conway NT, Campbell I, Forbes P, Cunningham SG, Wake DJ. mHealth applications for diabetes – user preference and implications for app development.. International Diabetes Federation, World Diabetes Congress, Vancouver 2015.
- Conway NT, Cunningham SG, Forbes P, Shaik F, Emslie-Smith A, Wales A, Wake DJ. Decision Support for Diabetes: Implementation and evaluation of the EBMeDS project within NHS Scotland. International Diabetes Federation, World Diabetes Congress, Vancouver 2015.
- *Conway NT, Wales A, Cunningham S, Walker J, Locke R, Emslie-Smith A, Shaik F, Wake DJ. Decision support for diabetes: embedding knowledge in care processes. Health Informatics Scotland Conference, Glasgow 2014.

- Campbell IJM, Cunningham SG, Conway NT, Wake DJ. Mobile technology as a tool for patient education and self-management in the diabetic population. Diabetes UK Professional Conference, Liverpool 2014
- Campbell IJM, Cunningham SG, Conway NT, Wake DJ. Mobile technology as a tool for patient education and self-management in the diabetic population. International Conference on Advanced Technologies & Treatments for Diabetes, Vienna 2014.

The full text of each abstract is provided in the following pages

<u>*NT Conway</u>, SG Cunningham, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of user acceptance, clinical processes and outcomes. International Diabetes Federation, World Diabetes Congress, Dubai 2017.

Introduction

Clinician Decision Support Systems (CDSS) are associated with improved adherence to clinical guidelines in the care of those with diabetes. CDSS was implemented within the Scottish national electronic health record, SCI-Diabetes and has been live to users within NHS Tayside and Lothian since Dec'13, serving a combined diabetes population of ~30,000. This study aims to describe users' attitudes and reactions to the system and to quantify impact on clinical processes and outcomes.

Method

Health care professional (HCP) opinion was sought via focus groups and questionnaires. SCI-Diabetes data were extracted for two time periods: Dec'13-Feb'14 (Ninewells hospital, Dundee) and Aug'14-Nov'14 (St John's hospital, Livingston).

SCI-Diabetes usage was quantified using HCP interaction ("mouse-clicks") and time spent within the patient record. HCP behaviour was compared between instances where CDSS messages were displayed, with instances where not (corrected for user-role, patient age, diabetes type/duration, co-morbidity and deprivation).

Case-control comparison was made to assess clinical processes and outcomes. Cases were patients whose HCP received a CDSS message during the intervention period. Controls were matched for age; sex; diabetes type and duration; BMI and clinic attendance in areas outwith the pilot. Clinical process measures were taken within 30 days of the clinic consultation and included screening for hypercholesterolaemia, kidney, foot and thyroid disease. Additional process measures were the proportion of patients newly prescribed oral hypoglycaemic agents and angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) in the month following clinic. Clinical outcomes included HbA1c; cholesterol; blood pressure, and urinary albumin/creatinine (UACR) at 1 year. Comparison was made using multivariable regression.

Results

Pre and post-intervention HCP questionnaire response rate was 57/105 (54%) and 39/105 (37%). Three focus groups were held (n=8-9/group). The majority of respondents/participants had a positive or neutral response to the system. Early-adopters reported usage within clinical workflow. CDSS messages were displayed on opening 6,665/17,280 (39%) records. For nurses, presence of CDSS message was associated with increased SCI-Diabetes usage, compared with instances where no message was displayed (median "clicks" 19(IQrange:8-37) vs. 16(7-32), adj.p=0.014). For doctors, CDSS messages were associated with reduced time within the patient record (median duration 33 (IQrange:5-86) vs. 38(12-97) secs,adj.p=0.032).

1,883 cases attended clinic, matched to 3,557 controls. Probability of receiving screening more than doubled for hypercholesterolaemia (adjOR 2.4, (95%CI: 1.6-3.0)); creatinine (2.5(1.6-3.9)); UACR (2.3(1.9-2.8)); and foot screening (2.9(2.3-3.6)) – all $p<0.001$. Screening for hypothyroidism decreased slightly (0.8(0.7-1.0), p=0.035). Prior to the intervention, 995/1883 (52.8%) cases and

1880/3557 (52.8%) controls were prescribed an oral hypoglycaemic agent. Of those that were not previously on an oral hypoglycaemic agent, 15/888 (1.5%) cases and 40/1677 (2.4%) controls were commenced on one in the 30 days following their clinic appointment, with no significant difference noted after correcting for age, BMI, diabetes type and duration. Prior to the intervention, 1160/1,883 (61.6%) cases and 2196/3557 (61.7%) controls were prescribed an ACEI or ARB. Of those not previously on an ACEI or ARB, 11/723 (1.5%) cases and 32/1361 (2.4%) controls were commenced on one in the 30 days following their clinic appointment. There were no significant difference noted between groups after correcting for age; BMI; pre-intervention microalbuminuria or hypertension.

Of all patients whose HCP received a CDSS prompt during the intervention period (i.e. not solely within the clinic environment, n=5,692), there were small improvements in mean HbA1c compared to controls (n=10,667) (baseline mean HbA1c 71.4 mmol/mol vs. 70.6, falling by -2.3 vs.-1.1, p=0.003). Mean UACR increased in both groups but moreso in controls (baseline 8.7mg/mmol vs. 9.3, increasing by +1.6 vs.+4.4, p=0.01). Both serum cholesterol and blood pressure fell in both groups with no significant differences noted (with the exception of systolic BP – controls experienced significantly greater decrease (baseline mean SBP 137mmHg versus 138, falling by -1.3 vs. -3.3, $p<0.001$)).

Discussion/conclusion

The CDSS was associated with improved efficiencies in working practices (dependent on role) and large improvements in guideline adherence. If replicated nationally, thousands more individuals would receive appropriate screening tests. These evidence-based, early interventions can significantly impact on costly and devastating complications such as foot ulcers, amputations, cardiovascular disease, renal failure and death. The potential benefits of this project extend beyond the Scottish diabetes population, as NHS Scotland considers how best to realise the full potential of CDSS.

<u>*NT Conway</u>, SG Cunningham, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of clinical processes and outcomes. Informatics for Health conference, Manchester 2017.

Introduction

Nearly 3 million people in the UK have diabetes (>6% of adults), with prevalence expected to double over the next 2 decades. Clinician Decision Support Systems (CDSS) are associated with improved adherence to clinical guidelines. CDSS was implemented within the Scottish national electronic health record, SCI-Diabetes and has been live to users within NHS Tayside and Lothian since Dec'13, serving a combined diabetes population of ~30,000. This study aims to describe users' attitudes and reactions to the system and to quantify impact on clinical processes and outcomes.

Method

Health care professional (HCP) opinion was sought via focus groups and questionnaires. SCI-Diabetes data were extracted for two time periods: Dec'13-Feb'14 (Ninewells hospital, Dundee) and Aug'14-Nov'14 (St John's hospital, Livingston).

SCI-Diabetes usage was quantified using HCP interaction ("mouse-clicks") and time spent within the patient record. HCP behaviour was compared between instances where CDSS messages were displayed, with instances where not (corrected for user-role, patient age, diabetes type/duration, co-morbidity and deprivation).

Case-control comparison was made to assess clinical processes and outcomes. Cases were patients whose HCP received a CDSS message during the consultation. Controls were matched for age; sex; diabetes type and duration; BMI and clinic attendance in areas outwith the pilot. Clinical process measures were screening for hypercholesterolaemia, kidney, foot and thyroid disease. Clinical outcomes included HbA1c; cholesterol; blood pressure, and urinary albumin/creatinine (UACR) at 1 year. Comparison was made using multivariable regression.

Results

Pre and post-intervention HCP questionnaire response rate was 57/105 (54%) and 39/105 (37%). Three focus groups were held (n=8-9/group). The majority of respondents/participants had a positive or neutral response to the system. Early-adopters reported usage within clinical workflow. CDSS messages were displayed on opening 6,665/17,280 (39%) records. For nurses, presence of CDSS message was associated with increased SCI-Diabetes usage, compared with instances where no message was displayed (median "clicks" 19(IQrange:8-37) vs. 16(7-32), adj.p=0.014). For doctors, CDSS messages were associated with reduced time within the patient record (median duration 33 (IQrange:5-86) vs. 38(12-97) secs,adj.p=0.032).

1,883 cases attended clinic, matched to 3,557 controls. Probability of receiving screening more than doubled for hypercholesterolaemia (adjOR 2.4, (95%CI: 1.6-3.0)); creatinine (2.5(1.6-3.9)); UACR (2.3(1.9-2.8)); and foot screening (2.9(2.3-3.6)) – all $p<0.001$. Screening for hypothyroidism increased slightly (0.8(0.7-1.0), p=0.035). For those attending clinic, study group did not predict clinical outcomes at 1 year. Post hoc analysis of all patients with a CDSS prompt (n=5,692) showed small improvements in mean HbA1c (-2.3mmol/mol vs.-1.1, B1.2(0.4-2.0),p=0.003) compared to controls

(n=10,667). Mean UACR increased in both groups but moreso in controls (baseline 8.7mg/mmol vs. 9.3, increasing by +1.6 vs.+4.4, B2.9(0.7-5.1),p=0.01).

Discussion/conclusion

The CDSS was associated with improved efficiencies in working practices (dependent on role) and large improvements in guideline adherence. If replicated nationally, thousands more individuals would receive appropriate screening tests. These evidence-based, early interventions can significantly impact on costly and devastating complications such as foot ulcers, amputations, cardiovascular disease, renal failure and death. The potential benefits of this project extend beyond the Scottish diabetes population, as NHS Scotland considers how best to realise the full potential of CDSS.

NT Conway, K Adamson, SG Cunningham, A Emslie-Smith, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of user attitudes and system usage. Diabetes UK conference, Manchester 2017

Aims

Clinician Decision Support Systems (CDSS) provide health care professionals (HCPs) with automated advice, resulting in improved adherence to guidelines. CDSS was implemented within the Scottish national electronic health record, SCI-Diabetes, in NHS Tayside and Lothian. This study aims to describe users' attitudes and reactions to the system.

Methods

HCP opinion was sought via focus groups and questionnaires. SCI-Diabetes usage was quantified using data from Dec 13-Feb 14 (Ninewells hospital, Dundee) and Aug 14-Nov 14 (St John's hospital, Livingston). User behaviour was compared between instances where CDSS messages were displayed with instances where not (corrected for user-role, patient age, diabetes type/duration, co-morbidity and deprivation). Quantitative outcomes were interaction ("mouse-clicks") and time spent within the patient record.

Results

Pre and post-intervention questionnaire response rate was 57/105 (54%) and 39/105 (37%). Three focus groups were held (n=8-9/group). The majority of respondents/participants had a positive or neutral response to the system. Early-adopters reported usage within clinical workflow, however most reported low use. Worker role predicted users' attitudes and system usage. CDSS messages were displayed on opening 6,665/17,280 (39%) records. Presence of CDSS message was associated with increased SCI-Diabetes usage by nurses (median "clicks" 19(IQrange:8-37) vs. 16(7-32), adj.p=0.014). For doctors, CDSS messages were associated with reduced time within the patient record (median duration 33sec(IQrange:5-86) vs. 38(12-97),adj.p=0.032).

Conclusion

The system was associated with improved efficiencies in working practices, dependent on role. Active users of the CDSS are in the minority, however user attitudes make it likely that usage will increase as content and functionality improve.

NT Conway, K Adamson, SG Cunningham, A Emslie-Smith, A Wales, DJ Wake. Clinical Decision Support for Diabetes in Scotland: evaluation of clinical processes and outcomes. Diabetes UK conference, Manchester 2017

Aims

Clinician Decision Support Systems (CDSS) provide health care professionals (HCPs) with automated advice, based on clinical guidelines. CDSS was implemented within the Scottish national electronic health record, SCI-Diabetes. This study aims to quantify impact on clinical processes and outcomes.

Methods

Cases were those where an HCP received a CDSS message during Dec 13-Feb 14 (Ninewells hospital, Dundee) and Aug 14-Nov 14 (St John's hospital, Livingston). Controls were matched for age; sex; diabetes type and duration; BMI and clinic attendance in areas outwith the pilot. Clinical process measures were screening for hypercholesterolaemia, kidney, foot and thyroid disease. Clinical outcomes included HbA1c; cholesterol; blood pressure, and urinary albumin/creatinine (UACR) at 1 year. Comparison was made with multivariable regression.

Results

1,883 cases attended clinic, matched to 3,557 controls. Probability of receiving screening more than doubled for hypercholesterolaemia (adjOR 2.4, (95%CI: 1.6-3.0)); creatinine (2.5(1.6-3.9)); UACR (2.3(1.9-2.8)); and foot screening (2.9(2.3-3.6)) – all $p<0.001$. Screening for hypothyroidism increased slightly (0.8(0.7-1.0), $p=0.035$). Study group did not predict clinical outcomes at 1 year. Secondary analysis of all patients with a CDSS prompt (n=5,692) showed small improvements in mean HbA1c (-2.3mmol mol-1 vs.-1.1, B1.2(0.4-2.0),$p=0.003$) compared to controls (n=10,667). Mean UACR increased in both groups but moreso in controls (baseline 8.7mg mmol-1 vs. 9.3, increasing by +1.6 vs.+4.4, B2.9(0.7-5.1),$p=0.01$).

Conclusion

This low-cost intervention has demonstrated large improvements in adherence to guidelines with the potential for future improvement in clinical outcomes. If replicated nationally, thousands more individuals would receive these evidence-based interventions resulting in avoidance of costly and devastating complications.

***Conway NT, Campbell I, Forbes P, Cunningham SG, Wake DJ. mHealth applications for diabetes – user preference and implications for app development.. Farr Institute International Conference, St Andrews 2015.**

Background

Increasing diabetes prevalence is driving a demand for more sustainable yet person-centred service. As the worldwide smartphone market continues to grow, the number of diabetes self care mHealth applications also grows exponentially. mHealth can improve clinical outcomes, but current usage patterns, effectiveness and valued features are unclear. This study sought to assess levels of engagement with mHealth technologies within a subset of the Scottish diabetes population; to identify specific demographic sub-groups of interest; and draw comparisons between desirable and currently available features of diabetes mHealth applications.

Methods

A snapshot analysis of the diabetes mHealth app marketplace was undertaken in July 2014. Available features were used to construct a questionnaire. A random sample of 400 patients (stratified by diabetes type and age) was obtained from the Scottish Diabetes Research Network (n=200) and users of patient health record (MyDiabetesMyWay, n=200). Demographic variables (age group, gender and diabetes type) were cross-tabulated with preference for mHealth technologies and loglinear analysis was used to identify significant interactions. Desirable features of a diabetes mHealth app were compared with currently available diabetes apps.

Results

Available app features include: data storage/graphical presentation; integration with other apps; exercise tracking; health/diet tracking; reminders/alarms; and education. 59% (234/400) people responded to the questionnaire; 62% (144/233) owned a smartphone. Most smartphone users expressed a preference towards mHealth apps (101/142 (71%)) (especially younger age groups), although mobile phone app use for diabetes self management was low (12/163 (7%)). Older women with T2D were significantly less likely to favour diabetes mHealth apps. Respondents favoured a wide variety of potential features, contrasting with current availability: patient education – favoured by 45% (98/220) users but available in 14% (10/74) apps; personal health record - favoured by 40% (89/220) users but unavailable on apps reviewed.

Discussion/conclusion

mHealth has the potential to empower patients; improve outcomes; and provide service in a sustainable way. This study demonstrates that mHealth acceptance is high, but current engagement is low and functionality does not match potential user preferences. Engagement and functionality could perhaps be improved by including relevant stakeholders in future development, driven by clinical and user need.

Conway NT, Campbell I, Forbes P, Cunningham SG, Wake DJ. mHealth applications for diabetes – user preference and implications for app development.. International Diabetes Federation, World Diabetes Congress, Vancouver 2015.

Background

Increasing diabetes prevalence is driving a demand for more sustainable yet person-centred service. As the worldwide smartphone market continues to grow, the number of diabetes self care mHealth applications also grows exponentially. mHealth can improve clinical outcomes, but current usage patterns, effectiveness and valued features are unclear. This study sought to assess levels of engagement with mHealth technologies within a subset of the Scottish diabetes population; to identify specific demographic sub-groups of interest; and draw comparisons between desirable and currently available features of diabetes mHealth applications.

Methods

A snapshot analysis of the diabetes mHealth app marketplace was undertaken in July 2014. Available features were used to construct a questionnaire. A random sample of 400 patients (stratified by diabetes type and age) was obtained from the Scottish Diabetes Research Network (n=200) and users of patient health record (MyDiabetesMyWay, n=200). Demographic variables (age group, gender and diabetes type) were cross-tabulated with preference for mHealth technologies and loglinear analysis was used to identify significant interactions. Desirable features of a diabetes mHealth app were compared with currently available diabetes apps.

Results

Available app features include: data storage/graphical presentation; integration with other apps; exercise tracking; health/diet tracking; reminders/alarms; and education. 59% (234/400) people responded to the questionnaire; 62% owned a smartphone. Most smartphone users expressed a preference towards mHealth apps (especially younger age groups) although mobile phone app use for diabetes self management was low (12/163 (7%)). Older women with T2D were significantly less likely to favour diabetes mHealth apps. Respondents favoured a wide variety of potential features, contrasting with current availability: patient education – favoured by 45% (98/220) users but available in 14% (10/74) apps; personal health record - favoured by 40% (89/220) users but unavailable on apps reviewed.

Discussion/conclusion

mHealth has the potential to empower patients; improve outcomes; and provide service in a sustainable way. This study demonstrates that mHealth acceptance is high, but current engagement is low and functionality does not match potential user preferences. Engagement and functionality could perhaps be improved by including relevant stakeholders in future development, driven by clinical and user need.

Conway NT, Cunningham SG, Forbes P, Shaik F, Emslie-Smith A, Wales A, Wake DJ. Decision Support for Diabetes: Implementation and evaluation of the EBMeDS project within NHS Scotland. International Diabetes Federation, World Diabetes Congress, Vancouver 2015.

Introduction

Over 80% of people with diabetes have co-morbidities, which increase in number with age. Evidence-based guidelines for these conditions are developed on a disease-specific basis, resulting in multiple guidelines. Approximately half of Healthcare Professional (HCP) clinical decisions fail to take account of the best available evidence. Clinical decision support systems (CDSS) within an electronic health record (EHR) can improve HCP performance by providing automated, tailored, evidence-based advice. This project aims to implement and evaluate the Evidence Based Medicine electronic Decision Support (EBMeDS) system within a national EHR for diabetes.

Methods

EBMeDS algorithms were developed with reference to national clinical guidelines and implemented within Scotland's EHR for diabetes, SCI-Diabetes. A cyclical, quality improvement approach was used to adapt the system in light of user feedback. Evaluation used a mixed methods approach involving: HCP & patient questionnaires; focus groups; system navigational data; and case control comparisons of clinical processes & outcomes.

Results

19 EBMeDS scripts aimed at screening for complications and treatment optimisation were developed. Improvement cycle 1 ran from Dec 13-Feb 14 involving a tertiary centre diabetes clinic (~500 patients/month). The system was adapted prior to cycle 2 that involved primary and secondary care within a defined geographical area (pop. 412,160, number of people with diabetes 22,033).

17,280 patient EHRs were opened during cycle 1, 6665 (39%) of which triggered an EBMeDS message. The median number of messages was 3 (IQ range 2-5). The presence of a message was associated with a significant reduction in duration that the EHR was viewed: median duration 40 sec (IQ range 13-93) vs 32 sec (IQ range 7-84), $p<0.001$.

User feedback was favourable with individuals reporting more efficient clinical practices. Patient and HCP feedback did not identify any adverse effects on the consultation. Users requested that messages are tailored to context and role.

Discussion

This service improvement project highlights the benefits of an iterative approach that adapts to users' needs. The system has been well received and has the potential to improve efficiency in decision making with no reported adverse effects. Evaluation of clinical processes and outcomes is ongoing. Ultimately, the system has the potential to incorporate any number of relevant guidelines whilst tailoring messages to user role and clinical context.

***Conway NT, Wales A, Cunningham S, Walker J, Locke R, Emslie-Smith A, Shaik F, Wake DJ. Decision support for diabetes: embedding knowledge in care processes. Health Informatics Scotland Conference, Glasgow 2014.**

Introduction

Long term conditions affect one in five people, and account for 80% of general practice consultations in Scotland [Auditor General for Scotland 2007]. Approximately half of all clinical decisions made by Health Care Practitioners (HCPs) fail to take account of the best available evidence [McGlynn and Asch 2003] and guidelines often do not accommodate co-morbidities and multiple medications [Lugtenberg et al. 2011; Nobili et al. 2011]. There is a recognised need to find innovative ways of integrating knowledge into clinical workflow; to contextualise and personalise care; and to manage the complex care needs and human factors which contribute to unwanted variation in practice.

Clinical decision support systems (CDSS) within an electronic health record (EHR) provide HCP's with automated, tailored, evidence-based advice. This project aims to implement and evaluate the Evidence Based Medicine electronic Decision Support (EBMeDS) system [Duodecim Medical Publications Ltd. 2014] within SCI-Diabetes, the national EHR for diabetes in Scotland [Cunningham et al. 2011].

Methods

EBMeDS utilises structured patient data from EHRs and provides automated reminders, therapeutic suggestions and diagnosis-specific links to guidelines and literature [Duodecim Medical Publications Ltd. 2014]. EBMeDS scripts were adapted to the Scottish context and integrated within SCI-Diabetes. Implementation is following a phased approach - phase 1 involves NHS Tayside secondary care, phase 2 will include NHS Lothian and primary care.

Ongoing evaluation is based upon the NES knowledge into action framework [NHSScotland 2012] and involves: user and patient questionnaires; HCP focus groups; quantitative analysis of usage data; and case control comparisons of guideline adherence and clinical outcomes. User questionnaires were adapted from a previous evaluation of the EBMeDS system [Heselmans et al. 2012] which utilised the Unified Theory of User Acceptance of Technology (UTAUT) model [Venkatesh et al. 2003].

Results

19 EBMeDS scripts were developed for a variety of clinical situations e.g. optimising glycaemic control; uptake of screening services. Alerts and reminders are displayed to users on opening the clinical record of an individual patient record.

Phase 1 commenced December 2013 and involved 24 HCP's within the diabetes clinic (approximately 500 patients/month). Questionnaire and focus group feedback suggests that users are receptive to using CDSS. However, self-reported system use is minimal. Barriers to adoption include: clinical time; low relevance to the secondary care context; and limited applicability to individual patient circumstances and co-morbidities. There were no reported adverse effects, with high patient satisfaction recorded during the period of evaluation. Scripts have been amended in light of user feedback – thresholds have been altered; additional rules created; and additional user-control has

been introduced. Quantitative data analysis of user navigation data and quality performance indicators is ongoing.

Discussion

This service improvement project involves the implementation and evaluation of a CDSS. The potential of the system is acknowledged but needs to adapt in response to user feedback. Script development is ongoing with a view to phase 2 implementation in August 2014. The ultimate aim is to develop a national system taking into account patient co-morbidities and clinical context.

Campbell IJM, Cunningham SG, Conway NT, Wake DJ. Mobile technology as a tool for patient education and self-management in the diabetic population. Diabetes UK Professional Conference, Liverpool 2014

Objectives

This study aims to ascertain the desire for mobile technology, namely Smartphone apps (SA), which can support patient education, self-management and data sharing with the health-care team.

Methods

This prospective questionnaire study sampled 200 Patients from My Diabetes My Way (MDMW), an interactive database for patients in Scotland allowing access to personal online clinical information and educational resources. Questions for the survey were formed using a prior literature review and SA feature summary of 53 apps on the Apple platform (January 2013). The anonymous questionnaire explored areas of current management techniques, technology literacy, patient education, self-management and desirable features for a future SA. Prior consent for patient contact had been agreed.

Results

200 patients from MDMW were contacted via email. 122/200 participants responded. Results below highlight response 1 or 2 versus response 4 or 5 on a likert scale (1=strongly agree and 5 =strongly disagree). There is a strong desire for SA development (48/68, 71%, 95%CI 59-80). Half of the participants would use SA for education (60/119, 50%, 95%CI 42-59) and a similar number (54%) would prefer SA to current methods of self-management (37/68, 54%, 95%CI 42-66). Desirable features included social media integration (70/116, 6%, 95% CI 51-69). Carbohydrate tracking was undesirable (58/119, 52%, 95% CI, 42-61).

Conclusions and Discussions

Preliminary results from the study suggest that there is a desire for SA. In particular offering integration with health-care systems. Providing patients with contemporary methods to support their care will enable better health outcomes to be achieved and maintained.

Campbell IJM, Cunningham SG, Conway NT, Wake DJ. Mobile technology as a tool for patient education and self-management in the diabetic population. International Conference on Advanced Technologies & Treatments for Diabetes, Vienna 2014.

Objectives

This study aims to ascertain the desire for mobile technology, namely Smartphone apps (SA), which can support patient education, self-management and data sharing with the health-care team.

Methods

This prospective questionnaire study sampled 200 Patients from My Diabetes My Way (MDMW), an interactive database for patients in Scotland allowing access to personal online clinical information and educational resources. Questions for the survey were formed using a prior literature review and SA feature summary of 53 apps on the Apple platform (January 2013). The anonymous questionnaire explored areas of current management techniques, technology literacy, patient education, self-management and desirable features for a future SA. Prior consent for patient contact had been agreed.

Results

200 patients from MDMW were contacted via email. 122/200 participants responded. Results below highlight response 1 or 2 versus response 4 or 5 on a likert scale (1=strongly agree and 5 =strongly disagree). There is a strong desire for SA development (48/68, 71%, 95%CI 59-80). Half of the participants would use SA for education (60/119, 50%, 95%CI 42-59) and a similar number (54%) would prefer SA to current methods of self-management (37/68, 54%, 95%CI 42-66). Desirable features included social media integration (70/116, 6%, 95% CI 51-69). Carbohydrate tracking was undesirable (58/119, 52%, 95% CI, 42-61).

Conclusions and Discussions

Preliminary results from the study suggest that there is a desire for SA. In particular offering integration with health-care systems. Providing patients with contemporary methods to support their care will enable better health outcomes to be achieved and maintained.

20. Published papers relevant to the thesis

This work has directly contributed to the following publications:

- Conway NT, Webster C, Smith B, Wake, D. eHealth and the use of individually tailored information: a systematic review. Health Informatics Journal 2016.
- Conway NT, Campbell I, Forbes P, Cunningham SG, Wake DJ. mHealth applications for diabetes – user preference and implications for app development. Health Informatics Journal 2015.
- Conway NT, Adamson KA, Cunningham SG, Emslie Smith A, Nyberg P, Smith BH, Wales A, Wake DJ. Decision support for Diabetes in Scotland – implementation and evaluation of a clinical decision support system. Journal of Diabetes Science and Technology 2017 (in press)

The full text of each article is provided in the following pages.

Article

Health Informatics Journal

Health Informatics Journal
2017, Vol. 23(3) 218–233

DOI: 10.1177/1460458216641479
journals.sagepub.com/home/jhi

eHealth and the use of individually tailored information: A systematic review

Nicholas Conway
University of Dundee, UK

Clare Webster
NHS Tayside, UK

Blair Smith and Deborah Wake
University of Dundee, UK

Abstract

Tailored messages are those that specifically target individuals following an assessment of their unique characteristics. This systematic review assesses the evidence regarding the effectiveness of tailoring within eHealth interventions aimed at chronic disease management. OVID Medline/Embase databases were searched for randomised control trials, controlled clinical, trials, before -after studies, and time series analyses from inception - May 2014. Objectively measured clinical processes/outcomes were considered. Twenty-two papers were eligible for inclusion: 6/22 used fully tailored messaging and 16/22 used partially tailored messages. Two studies isolated tailoring as the active component. The remainder compared intervention with standard care. In all, 12/16 studies measuring clinical processes and 2/6 studies reporting clinical outcomes showed improvements, regardless of target group. Study quality was low and design did not allow for identification of interventions' active component. Heterogeneity precluded meta-analysis. This review has demonstrated that there is a lack of evidence to suggest that tailoring within an eHealth context confers benefit over non-tailored eHealth interventions.

Keywords

clinical decision-making, decision-support systems, eHealth, evidence-based practice, information and knowledge management

Corresponding author:
Nicholas Conway, MACHS building, Tayside Children's hospital, Ninewells hospital, DD1 9SY, Dundee, UK.
Email: n.z.conway@dundee.ac.uk

Background

Long-term conditions affect one in five people, yet account for 80 per cent of general practice consultations.[1] More than half of all clinical decisions fail to take account of the best-available evidence.[2] In addition, evidence-based guidelines often do not accommodate co-morbidities and multiple medications.[3–5] There is a recognised need to find innovative ways of integrating knowledge into clinical workflow, to contextualise and personalise care, and to manage the complex care needs and human factors which contribute to unwanted variation in practice.[6]

Clinical decision support systems (CDSSs) utilise algorithms of varying complexity that are applied to existing eHealth systems. Typically, a CDSS within an electronic health record (EHR) will present the user of the EHR with a series of messages designed to improve clinical care, for example, identification of possible drug interactions or prompts to consider clinical investigations. The use of such automated reminders via CDSS has been shown to be one of the most consistently successful approaches to encourage clinicians to adopt evidence-based practice.[7] In terms of efficacy, a 2005 systematic review concluded that while a number of studies showed an improvement in clinical processes (e.g. adherence to guidelines), there was a lack of evidence demonstrating improved clinical outcomes.[8] In the same year, a separate systematic review found that CDSSs, which incorporated contemporaneous recommendations (as opposed to simple summaries of data) and were available within the normal work stream, were more likely to result in improved clinical outcomes − 90 per cent (30/32) of interventions which included these features demonstrated improved outcomes.[9]

Communicating with messages that are specifically tailored to an individual has been found to be more effective than generic messages at changing behaviour.[10] The theory underpinning the use of such methods draws heavily on a number of behaviour change theories, including the Health Belief Model,[11] Prochaska and DiClemente's[12] Stages of Change, and Bandura's[13] Social Cognitive Theory. The tailoring of messages to specific individuals is viewed as the most sophisticated form of automated communication that can be used to deliver health education and material aimed at health promotion.[14] Tailoring has been defined as 'any combination of strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment'.[15] This assessment is dependent on the type of intervention and the target audience, but could be based on routinely collected data (e.g. professional role, socioeconomic status, health records or clinical parameters) or data collected from the individual with the specific intention of formulating a tailored message (e.g. health literacy, self-efficacy or pre-existing attitudes and knowledge). Interventions that utilise tailored messages tend to involve the distribution of printed material aimed at primary health promotion, for example, dietary advice,[16–18] smoking cessation,[19,20] or uptake of screening.[21]

There is a lack of literature concerning the use of tailored messages aimed at changing healthcare practitioner (HCP) behaviour. There is also a lack of evidence to inform the design and modality of tailored messaging, and whether the effectiveness of existing eHealth technologies (e.g. CDSS) can be improved were they to incorporate tailored messaging.

Objective

This systematic review aimed to assess the published evidence regarding the effectiveness of eHealth interventions designed to improve the management of chronic diseases by providing information or advice that has been tailored to the recipients, that is, HCPs or patients.

The research question was as follows: Does the cumulative published research evidence support the hypothesis that a system that incorporates messages specifically tailored to an individual

(HCP or patient) results in improved clinical processes or outcomes in the management of long-term conditions?

Method

Types of studies

Randomised controlled trials (RCTs), controlled clinical trials (CCTs), controlled before and after studies, and interrupted time series (ITS) analyses were considered for inclusion in the review. Studies published in any language were considered.

Types of recipients

Studies that involved patients with a specified long-term condition receiving healthcare (any setting), and/or HCPs responsible for the care of those with long-term conditions (any setting), were considered.

Types of interventions

We considered interventions that used eHealth technologies to deliver tailored information to patients or HCPs within the care setting. The search strategy, therefore, included a combination of terms relating to eHealth, health records, and communication strategies (including tailoring of information).

Types of outcomes

Any outcome was considered where a comparison was drawn between the intervention and no intervention and/or existing practice with regards to objectively measured professional performance, clinical outcome, or patient behaviour. The study's stated primary outcome was our main outcome of interest, with consideration also given to any stated secondary outcomes or post hoc analyses. Patient and professional satisfaction was also recorded, but studies were not included if this was the sole outcome.

Search strategy

A search strategy was devised to include keywords and text words relating to the following terms: chronic disease, methodology, eHealth, health records, communication, and user groups (available on request). Text words were appropriately truncated to maximise returns. Terms were combined using Boolean logic. There was no keyword identified for tailored messaging, and so we adopted a broad search strategy. As well as including variations of tailored messaging as text words, we included an exploded search of other communication-related keywords in an effort to capture studies that utilised tailored messages but did not refer to it as such. The search was run against both Ovid Medline (1946–present) and Embase (1974–present), with no restrictions placed on language.

Eligibility criteria for inclusion

Studies that were RCTs or CCTs were deemed eligible if the other criteria mentioned above were met. Additional methodologies (controlled before–after studies and interrupted time series

analyses) were considered if they met quality criteria specified by the Cochrane Effective Practice and Organisation of Care Group (EPOC) data collection checklist.[22] In accordance with the EPOC criteria, the quality criteria for inclusion of both types of studies were as follows:

- Controlled before–after studies were only eligible if the control site was deemed suitable; there was evidence of contemporaneous data collection, and there were ⩾2 intervention and ⩾2 control sites.
- Interrupted time series analyses were included if there was a clearly recorded point in time when the intervention began and where there were ⩾3 data points recorded both before and after the intervention commenced. Given the potential heterogeneity of the studies relevant to the review, study inclusion was not based on a minimum cut-off for methodological quality.

Data collection and analysis

Titles and abstracts were initially reviewed by a single reviewer (N.T.C.) and discarded if deemed not to be relevant to the research question. A shortlist was then compiled for which full-text articles were sought. These were independently reviewed by two reviewers (N.T.C. and C.W.). Any discrepancies were resolved by consensus. An online data abstraction form (modified from the EPOC data collection checklist[22]) was used for data collection.[23] An overall quality rating was assigned to RCTs based on the following criteria: allocation concealment, blinded or objective assessment of primary outcome(s), completeness of follow-up, reliable primary outcome, and protection against bias. In accordance with previously published EPOC systematic reviews,[24,25] studies were rated as being of high quality if the first three criteria were met with no additional concerns. Studies were of moderate quality if ⩽2 criteria were 'not done' or 'not clear' and of low quality if this applied to >2 criteria.

Assessing tailoring

Kreuter et al.[15] judged that an intervention incorporated tailored messaging if the intervention included both the following:

1. An assessment of individual patient characteristics;
2. Communication that was specifically targeted at that individual.

Owing to the limited number of published studies that the search strategy returned, we accepted interventions that included either of these criteria, as agreed by the two reviewers.

Protocol

A review protocol has not been published but is available from the corresponding author on enquiry.

Results

Search results

The search strategy was run twice – September 2013 and again in May 2014. The final yield from both searches was 1074 returns, of which 89 were duplicates. Of the remaining 985 studies, 818 were initially rejected based on title alone, with a further 112 discarded after review of the abstract

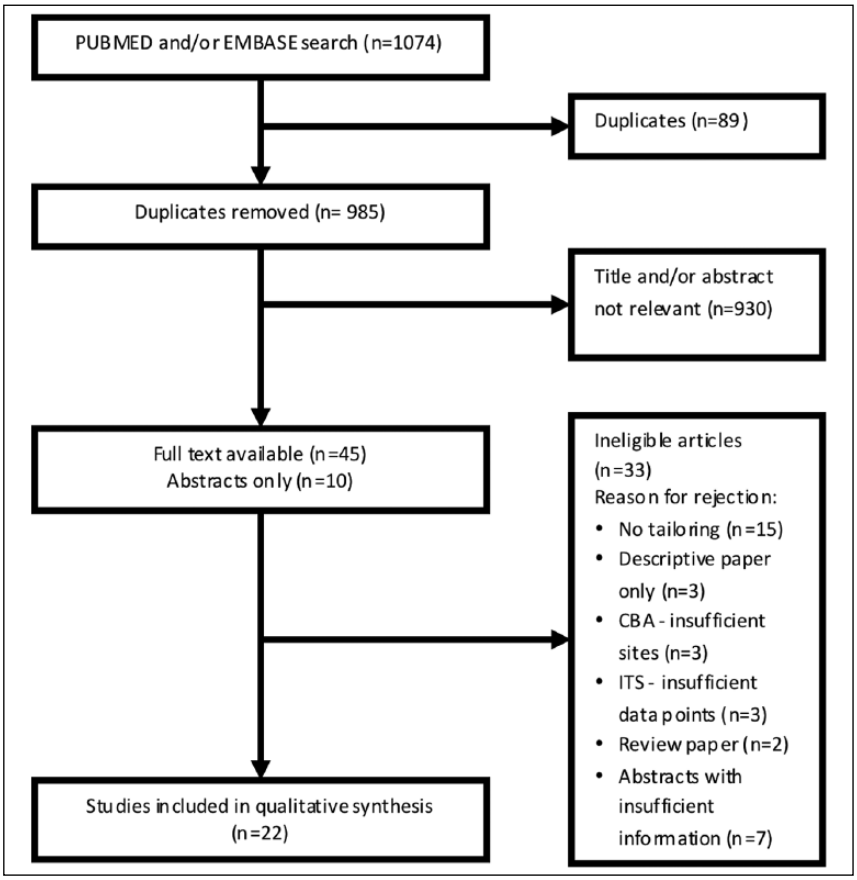

Figure 1. PRISMA diagram of literature search.

(see Figure 1). Full-text papers were sought for the provisional shortlist of 55 studies and were available for 45 of these. The abstracts of the remaining 10 studies were assessed and included if there was sufficient information to meet the inclusion criteria. Owing to the absence of any tailoring component in the intervention, 15 papers were rejected. The remaining 40 papers were then reviewed by the two reviewers. Furthermore, 18 papers were then rejected as they failed to meet (or had insufficient detail to satisfy) the eligibility criteria, leaving 22 papers to be considered in the review.

These 22 studies are shown in Table 1 (sorted by first author). All of the studies were published since 2002 and most were conducted in North America.[26–41] The majority were RCTs.[26,28,30–34,36,37,39–45] The clinical problem addressed by the various interventions varied, but the most common applications were diabetes,[26,27,35,36,39,44] cardiovascular disease,[32,35,39,43] and the prescribing of medication.[30,31,37,46]

Setting and characteristics of the studies

Most studies were undertaken in either an outpatient or community-based setting and involved physicians (see Table 2). Other professional groups included nurses and pharmacists. The studies

Table 1. Studies eligible for inclusion in the review.

First author (ref)	Year	Design	Country	Clinical speciality	Clinical problem
Avery[46]	2012	RCT	UK	General/family practice	Medication prescribing
Boukhors[26]	2003	RCT	Canada	General/family practice	Diabetes
Cafazzo[27]	2012	ITS	Canada	Paediatrics	Diabetes
Carroll[28]	2012	RCT	USA	Psychiatry	Maternal depression
Cruz-Correia[42]	2007	RCT	Portugal	Other	Asthma
Epstein[29]	2011	RCT	USA	Paediatrics	ADHD
Field[30]	2009	RCT	Canada	General/family practice	Medication prescribing
Fossum[47]	2011	CCT	Norway	Other	Pressure ulcers
Gurwitz[31]	2008	RCT	USA/Canada	Other	Medication prescribing
Jones[48]	2011	ITS	UK	General medicine	Acute medicine
Kinn[32]	2002	RCT	USA	Other	Hypertension
Mcdonald[33]	2005	RCT	USA	Paediatrics	Preventative service
Nagykaldi[34]	2012	RCT	USA	General/family practice	Preventative care
Persell[35]	2010	ITS	USA	General medicine	CVD, diabetes, and cancer
Persell[43]	2013	RCT	USA	General/family practice	CVD
Pinnock[45]	2013	RCT	UK	General medicine	COPD
Quinn[36]	2008	RCT	USA	Other	Diabetes
Raebel[37]	2007	RCT	USA	Obstetrics and gynaecology	Medication prescribing
Ross[44]	2006	RCT	USA	General medicine	Diabetes
Sequist[39]	2005	RCT	USA	General medicine	CVD and diabetes
Tierney[40]	2005	RCT	USA	General medicine	Asthma
Vollmer[41]	2011	RCT	USA	Not clear	Asthma

RCT: randomised controlled trial; ITS: interrupted time series; ADHD: attention-deficit hyperactivity disorder; CCT: controlled clinical trial; CVD: cardiovascular disease; COPD: chronic obstructive pulmonary disease.

were undertaken in both academic and non-academic settings. There was a general lack of information describing the experience or qualifications of the various professional user groups. Thirteen of the studies directed the intervention at HCPs.[28–32,35,37,39,40,45–48] The remainder directed the intervention at patients,[27,33,34,41–44] or at both HCPs and patients.[36] Study quality is noted in Table 4. Further details on individual study characteristics are available on request.

Influence of tailoring component on intervention design

All of the studies included in the review incorporated some degree of individual patient assessment. This assessment was made via automated data queries of routinely collected clinical datasets or via additional data entry completed by patient and/or HCP (see Table 3).

The use of individually tailored communication was only evident in a minority of studies.[27,33,34,41,43,44] All of these studies delivered messages to individual patients based on data specific to that patient, for example, risk of illness/injury and how this might be modified for the individual;[33,34,43] individualised educational content;[41,44] or individualised clinical results.[27] For the remainder of studies, the content of communication was dictated by automated algorithms based on the individual assessment rather than the specific circumstances of the end-user. For example, it was common that automated CDSS aimed at HCPs would provide prompts based on

Table 2. Clinical setting and characteristics of providers.

First Author (ref)	Location of care	Academic status	Profession involved	Level of training	Mean age (year)	Years in practice
Avery[46]	Community-based care	–	Physicians, pharmacists	–	–	–
Boukhors[26]	Outpatient care	–	Physicians	–	–	–
Cafazzo[27]	Outpatient care	–	Physicians	–	–	–
Carroll[28]	Outpatient care	University/teaching setting	Physicians	–	–	–
Cruz-Correia[42]	Outpatient care	–	Physicians	–	–	–
Epstein[29]	Community-based care	–	Physicians	Accredited and/or licensed	47	–
Field[30]	Community-based care	Non-teaching setting	Physicians	–	–	–
Fossum[47]	Nursing home	Non-teaching setting	Nurses	Accredited and/or licensed	–	–
Gurwitz[31]	Inpatient care	University/teaching setting	Physicians, nurses	–	–	–
Jones[48]	Inpatient care	University/teaching setting	Physicians, nurses	–	–	–
Kinn[32]	Outpatient care	–	Physicians	Accredited and/or licensed	–	–
Mcdonald[33]	Outpatient care	University/teaching setting	Physicians	Accredited and/or licensed	–	Post-graduate level 1–3
Nagykaldi[34]	Community-based care	Non-teaching setting	Physicians, Nurses	–	–	–
Persell[35]	Community-based care	University/teaching setting	Physicians	–	–	–
Persell[43]	Inpatient care	University/teaching setting	Physicians	In training	–	–
Pinnock[45]	Outpatient care	–	Physicians	–	–	–
Quinn[36]	Outpatient care	–	Physicians	–	–	–
Raebel[37]	Pharmacy	Non-teaching setting	Pharmacists	–	–	–
Ross[44]	Outpatient care	–	–	–	–	–
Sequist[39]	Outpatient care	University/teaching setting	Physicians	Mixed	40	–
Tierney[40]	Outpatient care	Non-teaching setting	Physicians, pharmacists	Mixed	–	–
Vollmer[41]	Community-based care	–	–	–	–	–

Table 3. Role of tailoring in the interventions. 'Tailored assessment' relates to the assessment of individual patient characteristics and how that data was collated. 'Tailored communication' describes whether or not communication was specifically targeted to an individual.

First Author (ref)	Tailored assessment	Tailored communication	Recipient of communication	Tailored communication detail
Avery[46]	Automated data query	None	Healthcare practitioner (HCP)	Message contents dependent on data
Boukhors[26]	Data from patient	None	Patient	Message contents dependent on data
Cafazzo[27]	Data from patient	Tailored to user	Patient	Message contents dependent on data and tailored to user requirements (trend wizard)
Carroll[28]	Data from parent and HCP	None	HCP	Message contents dependent on data
Cruz-Correia[42]	Data from patient and HCP	None	Patient	Message contents dependent on data
Epstein[29]	Data from patient and HCP	None	HCP	Message contents dependent on data
Field[30]	Automated data query	None	HCP	Message contents dependent on data
Fossum[47]	Automated data query	None	HCP	Message contents dependent on data
Gurwitz[31]	Automated data query	None	HCP	Message contents dependent on data
Jones[48]	Automated data query	None	HCP	Message contents dependent on data
Kinn[32]	Automated data query	None	HCP	Message contents dependent on data
Mcdonald[33]	Data from patient	Tailored to user	Patient	Message contents dependent on individual data taking into account the individual circumstances
Nagykaldi[34]	Data from patient and HCP	Tailored to user	Patient	Message contents dependent on individual data taking into account the individual circumstances
Persell[35]	Automated data query	None	HCP	Message contents dependent on data
Persell[43]	Automated data query	Tailored to user	Patient	Message contents dependent on individual data taking into account the individual circumstances
Pinnock[45]	Data from patient	None	HCP	Message contents dependent on data
Quinn[36]	Data from patient and HCP	None	Patient and HCP	Message contents dependent on data
Raebel[37]	Automated data query	None	HCP	Message contents dependent on data
Ross[44]	Automated data query	Tailored to user	Patient	Message contents dependent on individual data taking into account the individual circumstances
Sequist[39]	Automated data query	None	HCP	Message contents dependent on data
Tierney[40]	Automated data query	None	HCP	Message contents dependent on data
Vollmer[41]	Automated data query	Tailored to user	Patient	Message contents dependent on individual data taking into account the individual circumstances

Table 4. Reported outcomes and main results from studies included in the review. Study quality score compiled for RCTs only (see 'Methods').

Study	Study quality	Outcome(s)	Main results of the outcome(s)
Avery[46]	Moderate	Number of potential drug AE*	Intervention group significantly less likely to have been prescribed contraindicated medication (all three measures)
Boukhors[26]	Low	Number of hypoglycaemic events*	No significant difference in incidence of hypoglycaemia
Cafazzo[27]	ITS	Number of blood glucose tests and glycaemic control (HbA1c)*	Number of blood glucose tests increased with intervention. No difference in secondary outcomes – incidence of hyperglycaemia and glycaemic control
Carroll[28]	Low	Number of mothers identified as having depressive symptoms and number of mothers referred for psychiatric assessment	Intervention groups more likely to have depression detected and more likely to be referred to specialist
Cruz-Correia[42]	Low	Patient satisfaction and patient adherence to recommended monitoring	Patients were satisfied with system Patients adherence was not altered with electronic system – if anything adherence improved with paper system
Epstein[29]	Low	Proportion using recommended diagnostic tools at follow-up*	Significant increase in use of diagnostic questionnaires
Field[30]	Moderate	Alert rate*, Type of alert* – incorrect dose, incorrect frequency, drug should be avoided, incomplete clinical information (creatinine)	Overall, no difference in rate of alerts between groups.
Fossum[47]	Low	Proportion with malnourishment, proportion at risk of malnourishment and pressure ulcer	No change in risk of PU No change in prevalence of PU No change in prevalence of malnourishment
Gurwitz[31]	Low	Number of drug-related AE*	No significant difference in AE's between intervention and control
Jones[48]	ITS	Length of stay (LoS)*, accuracy of early warning score (EWS), adherence to protocol, clinical response to EWS alert, rate of cardiac arrests, number of critical care bed days, and mortality rate	Significant decrease in LoS during intervention period
Kinn[32]	Low	Likelihood of being diagnosed with hypertension, likelihood of receiving ≥1 antihypertensives, number of antihypertensives per patient, and use of combination therapy, BP	Significantly more patients receiving appropriate diagnosis in intervention group Intervention group significantly more likely to be on antihypertensive. Intervention group had significantly less antihypertensive agents prescribed.

(Continued)

Table 4. (Continued)

Study	Study quality	Outcome(s)	Main results of the outcome(s)
Mcdonald[33]	Low	Parent safety knowledge, prevention beliefs, and safety behaviours	Improved safety knowledge at follow-up.
Nagykaldi[34]	Low	Provision of preventative services, number of log ins to portal, and patient centredness	Minimal use of portal Patient centredness score improved in intervention group
Persell[35]	Low	LDL cholesterol*, change in BP, smoking cessation, prescription of a statin, and number of office visits	No significant difference in rate of lowered LDL No significant difference in attendance at clinic Significantly more statins prescribed in intervention group
Persell[43]	ITS	16 quality performance indicators (QPIs) – prescribing for chronic disease and screening procedures*	Performance measures improved
Pinnock[45]	High	Time to admission to hospital with exacerbation of COPD*, time to admission, number and duration of admissions, deaths, QoL, and number of patient contacts	No significant difference in admission rate or QoL in those receiving intervention.
Quinn[36]	Low	Physician satisfaction, diabetes self-care, and glycaemic control	Physicians satisfied Glycaemic control improved Patients self-care improved
Raebel[37]	Low	Proportion of pregnant women dispensed a contraindicated medication*	Intervention group were significantly less likely to be prescribed a contraindicated medication
Ross[44]	Low	System usage	Intervention group had greater usage of system
Sequist[39]	Low	Receipt of recommended care* and HCP perceptions surrounding guideline adherence	Patients in intervention group significantly more likely than control patients to receive recommended diabetes care and CAD care
Tierney[40]	Low	Percentage adherence to management recommendations*	No significant differences in adherence to guideline between groups
Vollmer[41]	Low	Patient adherence to medication*, patient QoL, reliever medication use, asthma control, and healthcare utilisation	Small but significant increase in adherence

AE: adverse event; HbA1c: glycated haemoglobin; LoS: length of stay; EWS: early warning score; LDL: low-density lipoprotein; QPI: quality performance indicators; COPD: chronic obstructive pulmonary disease; QoL: quality of life; BP: blood pressure; IQR: interquartile range; SD: standard deviation; ITS: interrupted time series; CAD: coronary artery disease; PU: peptic ulcer; HCP: healthcare practitioner.
*Denotes primary outcome(s) where stated

an assessment of a patient's data, but the prompt provided by the system was generic to the system and not tailored to the HCP's job-description or clinical context.

Of the six studies that fulfilled both criteria for having used tailored communication (as dictated by Kreuter et al.[15]), the primary outcomes (where stated) were patient self-care (improved),[27] serum lipids (no difference),[43] and medication adherence (better than control but reduced overall).[41] The remainder of studies did not state the primary outcome, but reported on service uptake (improved in intervention group),[44] patient knowledge (improved in intervention group, but multiple comparisons made),[33] and patient centredness (improved in intervention group).[34]

Comparison – tailored intervention versus non-tailored intervention

Two studies compared an intervention which utilised tailoring with an intervention that included untargeted activity.[33,44] Neither study specified the primary outcome of interest in the methods. Both studies provided tailored educational material to patients and compared outcomes with patients who had received non-tailored material. For example in one study,[33] parents completed a questionnaire designed to assess previous injuries sustained by their child as well as parental perceptions of their child's current risk of injury. The educational material then incorporated the events previously described as well as addressing any misconceptions in injury risk identified from parental responses. Tailoring resulted in an increase in patient service uptake in one study,[44] with multiple comparisons being made in the other, introducing the possibility of a type 1 error.[33]

Comparison – intervention versus no intervention

The primary outcome was not overtly stated in eight of the studies. Of the 22 studies included in the review, the main outcome of interest was related to clinical processes and performance in 14, with the remainder concerned with clinical outcomes (see Table 4).

Studies where the stated primary outcome related to clinical processes included HCP adherence to existing guidelines,[29,35,39,40] avoidance of adverse drug events,[30,31,37,46] patient adherence to medication,[41] and patients' frequency of clinical testing.[27] Of the six studies which failed to stipulate the primary outcome, one measured HCP adherence to an existing guideline aimed at improving diagnosis rates.[36]

A total of 12 among the 16 studies concerned with clinical processes reported a favourable outcome. For those studies aiming to assess HCP adherence to guidelines, most reported an improvement;[28,29,32,35,39] however, one of these studies also noted a pre-intervention improvement in the ITS analysis, introducing the possibility that secular change was responsible for the observed improvement.[35] The rate of potential adverse drug events was significantly reduced in half of the relevant studies.[37,46] When compared with controls, patient medication adherence was said to be higher; however, the actual difference was small and both groups' overall adherence fell during the study period.[41] The other measures of patient-driven clinical processes also improved (blood sugar testing[27] and service uptake[44]).

Two of the six studies concerned with clinical outcomes reported positive findings. Four studies measured clinical parameters as the primary outcome which included glycaemic control (unchanged),[26] length of hospital stay (improved),[48] change in serum lipids (unchanged),[43] and time to admission to hospital (unchanged).[45] Clinical parameters were also measured in two further studies and included glycaemic control (improved)[36] and presence of malnourishment and/or pressure ulcers (unchanged).[47]

Comparing patient-orientated interventions with HCP-orientated interventions

Eight of the studies targeted patients with the intervention,[26,27,33,34,41–44] one study involved an intervention aimed at both HCPs and patients,[36] and the remainder focussed solely on HCPs (see Table 3).

For the eight studies where the intervention targeted patients, five (63%) reported that the intervention produced a positive effect. This included increased patient satisfaction,[42] monitoring of blood glucose,[27] adherence to medication,[41] system usage,[44] and knowledge[33] (see Table 4).

For the 14 studies where the intervention was targeted at HCPs, a similar proportion reported positive findings (8/14, 57%). These included improved adherence to guidelines,[29,35,39] detection of morbidity,[28,32] decreased adverse drug events,[37,46] and length of hospital stay[48] (see Table 4).

Risk of bias in included studies

There was a high risk of bias for all studies included in the review, with the exception of one high-quality study[45] (see Table 4). Three studies were assessed as having concealed allocation adequately.[37,40,45] The remaining studies either failed to do so or did not provide sufficient information. Four studies reported that the assessors were sufficiently blinded to allocation group.[30,31,40,45] Of the remainder, 10 studies derived outcome data from automated data queries, making assessment bias unlikely.[28,29,32,37,39–41,43,44,47] Seven studies were assessed as having adequate follow-up of professionals and/or patients.[30,32,33,41,45–47]

Three of the studies were ITS analyses.[27,35,48] All three used a reliable outcome measure. It was unclear how either of these studies protected against detection bias (in terms of either data collection or blinded assessment) or secular changes in the population being studied. One study reported on the completeness of the dataset, which was assessed as being satisfactory.[35]

Discussion

In order to assess the effectiveness of tailored messages within eHealth interventions, a comparison needs to be made between outcomes of tailored interventions and non-tailored interventions. However, based on the results of this review, the research question remains incompletely answered for a number of reasons.

First, any direct comparison between tailored and non-tailored interventions was limited to a minority of the included studies. Nearly all studies compared the intervention to a no change/standard practice control group as opposed to a non-tailored intervention. This makes it impossible to ascertain whether any improvements were secondary to the tailoring component of the intervention per se.

Second, the outcome of either of these comparisons presented a mixed picture. A number of studies concluded that there was improvement in clinical processes, for example, adherence to guidelines, avoidance of prescription errors, and increased service uptake when compared to no intervention. However, most of these studies presented methodological weaknesses meaning that these conclusions should be met with caution.

Third, only a minority of studies included in the review included an intervention that fulfilled both criteria for what is considered to be tailoring of information. All of the other studies included in the review incorporated only one of the two components that define true tailoring. The adoption of studies meeting this less strict definition increased the number of studies eligible for inclusion but made it difficult to address the research question specifically.

Last, the quality of most of the included studies was assessed as low. However, the introduction of methodological quality as an eligibility criterion for inclusion would have excluded almost all

of the studies identified. Meta-analysis was not possible owing to the heterogeneous nature of the interventions and outcomes of the studies reviewed.

It should be noted that this review is limited to describing the *effectiveness* of tailored messages within eHealth systems and has done so by adopting a quantitative approach. For those studies that demonstrate improved outcomes, no attempt has been made to assess which components of the intervention were responsible. This will no doubt vary by setting (e.g. patient-orientated versus HCP-orientated interventions) and would require alternative methodologies.

Significance

Despite these limitations, some limited conclusions can be drawn. Irrespective of the degree to which the intervention incorporated tailoring, or the degree to which tailoring was responsible for the observed outcomes, it is notable that 14 of the 22 studies included reported positive findings. These improvements were largely limited to clinical processes as opposed to clinical outcomes and were observed in interventions aimed at both patients and HCPs. It is also notable that none of the included studies reported any harm. This would suggest that personalised eHealth interventions (aimed at either patients or HCPs) can safely effect behaviour change which may in turn reduce unwanted variation in practice. To what extent tailoring of messages is responsible for this effect is unknown.

The lack of studies that combine eHealth technologies with interventions that utilise tailoring of information is surprising, given the evidence that tailoring is effective when used in conjunction with traditional media, and the ease with which tailoring algorithms can be incorporated into new technologies. This may reflect the fact that both are relatively recent innovations. Given the existing evidence that tailored messages via traditional media can effect behaviour change, it would seem a logical extension to incorporate them into eHealth interventions. Clearly, there is a need for additional work in this area. Future research should delineate the role of tailoring in eHealth (e.g. by comparing it with non-tailored interventions as opposed to no intervention or standard care) as well as identifying which are the active components of such interventions (e.g. via future qualitative studies).

Conclusion

Tailoring of information to recipients has previously been shown to be an effective way of changing behaviour when used with traditional media. This review suggests that eHealth-tailored information delivery may improve clinical care, but there is currently a lack of evidence to conclude that the use of tailoring within an eHealth context confers any benefits over non-tailored eHealth interventions. This lack of evidence reflects the low number of good quality studies in this area. It is only by designing studies where the role of tailoring is isolated as the active component in the intervention, that the effectiveness of tailoring can be adequately assessed.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

Financial support for this study was provided in part by a grant by the Digital Health Institute, University of Edinburgh (http://dhi-scotland.com/). The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report.

References

1. Auditor General for Scotland. Managing long-term conditions, 2007, http://www.audit-scotland.gov.uk/docs/health/2007/nr_070816_managing_long_term.pdf
2. McGlynn E, Asch S, Adams J, et al. The quality of health care delivered to adults in the United States. *N Engl J Med* 2003; 348: 2635–2645, http://www.nejm.org/doi/full/10.1056/nejmsa022615 (accessed 20 November 2013).
3. Lugtenberg M, Burgers J, Clancy C, et al. Current guidelines have limited applicability to patients with comorbid conditions: a systematic analysis of evidence-based guidelines. *PLoS ONE* 2011; 6: e25987, http://dx.plos.org/10.1371/journal.pone.0025987 (accessed 20 November 2013).
4. Nobili A, Garattini S and Mannucci P. Multiple diseases and polypharmacy in the elderly: challenges for the internist of the third millennium. *J Comorbidity* 2011; 1: 28–44, http://jcomorbidity.com/index.php/test/article/view/4 (accessed 20 November 2013).
5. Guthrie B, Payne K, Alderson P, et al. Adapting clinical guidelines to take account of multimorbidity. *BMJ* 2012; 345: e6341, http://www.ncbi.nlm.nih.gov/pubmed/23036829 (accessed 20 November 2014).
6. Scottish Government. The healthcare quality strategy for NHSScotland, 2010, http://www.scotland.gov.uk/Resource/Doc/311667/0098354.pdf
7. Bero L, Grilli R, Grimshaw J, et al. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. *BMJ* 1998; 317: 465, http://www.bmj.com/content/317/7156/465.short (accessed 25 June 2014).
8. Garg AX, Adhikari NK, McDonald H, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes. *JAMA* 2005; 293: 1223–1238.
9. Kawamoto K, Houlihan CA, Balas EA, et al. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ* 2005; 330: 765.
10. Noar SM, Benac CN and Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. *Psychol Bull* 2007; 133: 673–693.
11. Rosenstock I, Strecher VJ and Becker MH. Social learning theory and the health belief model. *Health Educ Behav* 1988; 15: 175–183, http://heb.sagepub.com/content/15/2/175.short (accessed 25 June 2014).
12. Prochaska J and DiClemente C. Chapter 1. Towards a comprehensive model of change. In: Miller MR and Heather N (eds) *Treating addictive behaviors: processes of change*. 1st ed. New York: Plenum Press, 1986, http://link.springer.com/chapter/10.1007/978-1-4613-2191-0_1 (accessed 25 June 2014).
13. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev* 1977; 84: 191–215, http://psycnet.apa.org/journals/rev/84/2/191/ (accessed 25 June 2014).
14. Kreuter MW, Strecher VJ and Glassman B. One size does not fit all: the case for tailoring print materials. *Ann Behav Med* 1999; 21: 276–283, http://www.ncbi.nlm.nih.gov/pubmed/10721433 (accessed 24 June 2014).
15. Kreuter M, Farrell D, Olevitch L, et al. *Tailoring health messages: customizing communication with computer technology*. Mahwah, NJ: Lawrence Erlbaum Associates, 2000, http://books.google.co.uk/books/about/Tailoring_Health_Messages.html?id=fUEFV4wkJKgC&pgis=1 (accessed 24 June 2014).
16. Brug J, Steenhuis I, van Assema P, et al. The impact of a computer-tailored nutrition intervention. *Prev Med* 1996; 25: 236–242, http://www.sciencedirect.com/science/article/pii/S0091743596900523 (accessed 25 June 2014).
17. Brug J, Glanz K, van Assema P, et al. The impact of computer-tailored feedback and iterative feedback on fat, fruit, and vegetable intake. *Health Educ Behav* 1998; 25: 517–531, http://heb.sagepub.com/content/25/4/517.short (accessed 25 June 2014).
18. Campbell M. Improving dietary behavior: the effectiveness of tailored messages in primary care settings. *Am J Public Health* 1994; 84: 783–787, http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.84.5.783 (accessed 25 June 2014).
19. Prochaska J, DiClemente C, Velicer W, et al. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. *Health Psychol* 1993; 12: 399–405, http://psycnet.apa.org/journals/hea/12/5/399/ (accessed 25 June 2014).
20. Strecher V, Kreuter M, Den Boer D, et al. The effects of computer-tailored smoking cessation messages in family practice settings. *J Fam Pract* 1994; 39: 262–270, http://doi.apa.org/psycinfo/1995-14964-001 (accessed 25 June 2014).

21. Skinner C, Strecher V and Hospers H. Physicians' recommendations for mammography: do tailored messages make a difference? *Am J Public Health* 1994; 84: 43–49, http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.84.1.43 (accessed 25 June 2014).
22. Cochrane Effective Practice and Organisation of Care Group. Data collection checklist, 2002, http://epoc.cochrane.org/sites/epoc.cochrane.org/files/uploads/datacollectionchecklist.pdf
23. Conway NT. Data collection checklist, 2014, https://docs.google.com/forms/d/1bvbbI3z-LW06y0h-XdqVKY9w8s4Je3jPF0CRbQqI8z8/viewform (accessed 6 June 2014).
24. Cheater F, Baker R, Gillies C, et al. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*, 2005, http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005470.pub2/pdf/standard (accessed 4 December 2013).
25. Jamtvedt G, Young J, Kristoffersen D, et al. Audit and feedback: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*, 2006, http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000259.pub2/pdf/standard (accessed 25 June 2014).
26. Boukhors Y, Rabasa-Lhoret R, Langelier H, et al. The use of information technology for the management of intensive insulin therapy in type 1 diabetes mellitus. *Diabetes Metab* 2003; 29: 619–627, http://www.sciencedirect.com/science/article/pii/S1262363607700782 (accessed 17 October 2013).
27. Cafazzo J, Casselman M, Hamming N, et al. Design of an mHealth app for the self-management of adolescent type 1 diabetes: a pilot study. *J Med Internet Res* 2012; 14: e70, http://www.jmir.org/2012/3/e70/?utm_source=twitterfeed&utm_medium=twitter&utm_campaign=Feed:+Top10V1+(Top+10+JMIR+Articles:+Most+Viewed+(Past+1+month)++) (accessed 17 October 2013).
28. Carroll AE, Biondich P, Anand V, et al. A randomized controlled trial of screening for maternal depression with a clinical decision support system. *J Am Med Inform Assoc* 2013; 20: 311–316, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3638168&tool=pmcentrez&rendertype=abstract (accessed 2 June 2014).
29. Epstein JN, Langberg JM, Lichtenstein PK, et al. Use of an Internet portal to improve community-based pediatric ADHD care: a cluster randomized trial. *Pediatrics* 2011; 128: e1201–e1208, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3208964&tool=pmcentrez&rendertype=abstract (accessed 18 June 2014).
30. Field TS, Rochon P, Lee M, et al. Computerized clinical decision support during medication ordering for long-term care residents with renal insufficiency. *J Am Med Inform Assoc* 2009; 16: 480–485, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2705250&tool=pmcentrez&rendertype=abstract (accessed 2 June 2014).
31. Gurwitz J, Field T, Rochon P, et al. Effect of computerized provider order entry with clinical decision support on adverse drug events in the long-term care setting. *J Am Geriatr Soc* 2008; 56: 2225–2233, http://onlinelibrary.wiley.com/doi/10.1111/j.1532-5415.2008.02004.x/full (accessed 17 October 2013).
32. Kinn J, Marek J, O'Toole M, et al. Effectiveness of the electronic medical record in improving the management of hypertension. *J Clin Hypertens* 2002; 4: 415–419, http://onlinelibrary.wiley.com/doi/10.1111/j.1524-6175.2002.01248.x/full (accessed 17 October 2013).
33. McDonald E, Solomon B, Shields W, et al. Evaluation of kiosk-based tailoring to promote household safety behaviors in an urban pediatric primary care practice. *Patient Educ Couns* 2005; 58: 168–181, http://www.sciencedirect.com/science/article/pii/S0738399104002654 (accessed 17 October 2013).
34. Nagykaldi Z, Aspy CB, Chou A, et al. Impact of a Wellness Portal on the delivery of patient-centered preventive care. *J Am Board Fam Med* 2012; 25: 158–167, http://www.ncbi.nlm.nih.gov/pubmed/22403196 (accessed 10 June 2014).
35. Persell S, Kaiser D, Dolan N, et al. Changes in performance after implementation of a multifaceted electronic-health-record-based quality improvement system. *Med Care* 2011; 49: 117–125.
36. Quinn C, Clough S, Minor J, et al. WellDoc™ mobile diabetes management randomized controlled trial: change in clinical and behavioral outcomes and patient and physician satisfaction. *Diabetes Technol Ther* 2008; 10: 160–168, http://online.liebertpub.com/doi/abs/10.1089/dia.2008.0283 (accessed 17 October 2013).

37. Raebel M, Carroll N, Kelleher J, et al. Randomized trial to improve prescribing safety during pregnancy. *J Am Med Inform Assoc* 2007; 14: 440–450, http://www.sciencedirect.com/science/article/pii/S1067502707001156 (accessed 17 October 2013).
38. Siek KA, Khan DU, Ross SE, et al. Designing a personal health application for older adults to manage medications: a comprehensive case study. *J Med Syst* 2011; 35: 1099–1121.
39. Sequist T, Gandhi T, Karson A, et al. A randomized trial of electronic clinical reminders to improve quality of care for diabetes and coronary artery disease. *J Am Med Inform Assoc* 2005; 12: 431–437, http://www.sciencedirect.com/science/article/pii/S1067502705000605 (accessed 17 October 2013).
40. Tierney WM, Overhage JM, Murray MD, et al. Can computer-generated evidence-based care suggestions enhance evidence-based management of asthma and chronic obstructive pulmonary disease? A randomized, controlled trial. *Health Serv Res* 2005; 40: 477–497, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1361152&tool=pmcentrez&rendertype=abstract
41. Vollmer WM, Feldstein A, Smith DH, et al. Use of health information technology to improve medication adherence. *Am J Manag Care* 2011; 17: SP79–SP87.
42. Cruz-correia R, Fonseca J, Lima L, et al. Web-based or paper-based self-management tools for asthma–patients' opinions and quality of data in a randomized crossover study. *Stud Health Technol Inform* 2007; 127: 178–189, http://www.researchgate.net/publication/5942393_Web-based_or_paper-based_self-management_tools_for_asthma–patients'_opinions_and_quality_of_data_in_a_randomized_crossover_study/file/d912f50aab686e21a9.pdf (accessed 17 October 2013).
43. Persell S, Lloyd-Jones D, Friesema E, et al. Electronic health record-based patient identification and individualized mailed outreach for primary cardiovascular disease prevention: a cluster randomized trial. *J Gen Intern Med* 2012; 28: 554–560, http://link.springer.com/article/10.1007/s11606-012-2268-1 (accessed 18 October 2013).
44. Ross S, Haverhals L, Main D, et al. Adoption and use of an online patient portal for diabetes (diabetes-STAR). In: *AMIA annual symposium proceedings*, 2006, p. 1080, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1839692/ (accessed 17 October 2013).
45. Pinnock H, Hanley J, McCloughan L, et al. Effectiveness of telemonitoring integrated into existing clinical services on hospital admission for exacerbation of chronic obstructive pulmonary disease: researcher blind, multicentre, randomised controlled trial. *BMJ* 2013; 347: f6070, http://www.bmj.com/content/347/bmj.f6070 (accessed 1 August 2014).
46. Avery A, Rodgers S, Cantrill J, et al. A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. *Lancet* 2012; 379: 130–1319, http://www.sciencedirect.com/science/article/pii/S0140673611618175 (accessed 18 June 2014).
47. Fossum M, Alexander G, Ehnfors M, et al. Effects of a computerized decision support system on pressure ulcers and malnutrition in nursing homes for the elderly. *Int J Med Inform* 2011; 80: 607–617, http://www.sciencedirect.com/science/article/pii/S1386505611001316 (accessed 17 October 2013).
48. Jones S, Mullally M, Ingleby S, et al. Bedside electronic capture of clinical observations and automated clinical alerts to improve compliance with an Early Warning Score protocol. *Crit Care Resusc* 2011; 13: 83–88, http://ecite.utas.edu.au/78044/1/BedsideElectronicCaptureofClinicalObservationsandAutomatedClinicalAlertstoImproveCompliancewithanEarlyWarningScoreProtocol.pdf (accessed 17 October 2013).

Health Informatics Journal

Article

mHealth applications for diabetes: User preference and implications for app development

Health Informatics Journal
1–10

DOI: 10.1177/1460458215616265
jhi.sagepub.com
SAGE

Nicholas Conway, Iona Campbell, Paula Forbes, Scott Cunningham and Deborah Wake
University of Dundee, UK

Abstract

Increasing diabetes prevalence has led to the need for more sustainable and person-centred services. The diabetes self-care mHealth marketplace is growing, but most effective/valued features are unknown. This study gauges diabetes app user opinion to inform development work. An analysis of diabetes mHealth apps informed design of a questionnaire sent to a random sample of 400 patients stratified by diabetes type and age. Responses were analysed by sub-group, and preferences were compared with current diabetes apps. App features included data storage/graphics, exercise tracking, health/diet, reminders/alarms, education. Questionnaire response rate was 59 per cent (234/400); 144/233 (62%) owned smartphones. Smartphone users expressed preference towards mHealth (101/142 (71%)), although diabetes use was low (12/163 (7%)). Respondents favoured many potential features, with similar preferences between diabetes types. This study demonstrates that while mHealth acceptance is high, current engagement is low. Engagement and functionality could be improved by including stakeholders in future development, driven by clinical/user need.

Keywords

diabetes mellitus, mHealth, mobile applications, patient engagement, self-care

Introduction

An estimated 385 million of the world's 7 billion population have diabetes, over three quarters of whom live in low or middle income countries.[1] Diabetes currently accounts for 11 per cent of worldwide healthcare spending with projected costs set to increase, as the numbers affected are estimated to reach nearly 600 million by the year 2035.[1]

The worldwide mobile phone market continues to grow year on year with over 1.3 billion units being shipped in 2014, 72 per cent of which were smartphones.[2] The World Bank[3] estimates that worldwide in 2013, there were 92 subscriptions to mobile phone providers per 100 people.

Corresponding author:
Nicholas Conway, University of Dundee, MACHS Building, Ninewells Hospital, Dundee DD1 9SY, UK.
Email: n.z.conway@dundee.ac.uk

Developing countries have demonstrated the largest increase in ownership in the past few years, and it was anticipated that ownership in these countries would exceed those in developed countries for the first time by the end of 2014.[4]

The use of mobile devices to improve health outcomes, healthcare services or health related research has become known as mHealth.[5] Many different smartphone and tablet apps are available for managing diabetes, the number of which is rising exponentially.[6,7] Functionality that is most prevalent included insulin and medication recording, data export and communication, recording of dietary intake and weight monitoring.[6] Very few apps are designed to improved diabetes knowledge (in contrast to published guidelines which emphasise the need for patient education[8–10]), and there has been no identified formal evaluation of the role of social media in diabetes care.

In general, web-based interventions aimed at improving the management of diabetes have been shown to improve clinical outcomes.[11,12] It is more difficult to establish which components are important to achieve these improvements, however, due to the complex nature of each intervention. Published findings from studies that specifically report on mHealth-based interventions are mainly restricted to those interventions which predate the advent of smartphone technology, but have concluded that the use of mHealth can result in improved glycaemic control and patient self-efficacy and knowledge.[13]

Local context

Diabetes care in Scotland relies on a series of managed clinical networks supported by a national informatics platform.[14] Despite an increase in diabetes prevalence, there has been a sequential improvement in quality performance indicators and the incidences of diabetes-related complications have decreased.[15–17] The informatics platform has also enabled the creation of the Scottish Diabetes Research Network (SDRN)[18] – a national clinical trials infrastructure that comprises 10,000 registered patients to date. My Diabetes My Way (MDMW) is a national electronic patient health record (ePHR) that is integrated with the national diabetes informatics platform.[19] There are approximately 10,400 registered users to date.[20] Registration for SDRN and MDMW is not mutually exclusive; however, the similarity between the numbers registered with both is purely coincidental.

Project aims

This project aims to utilise the SDRN and MDMW patient cohorts to

- Assess levels of engagement with web-based and mHealth technologies within the Internet-using Scottish diabetes population,
- Identify demographic sub-groups that are more or less likely to use such technologies,
- Draw comparisons between features that are currently available within the app market and features that are most desirable to those with diabetes.

Methods

Review of available diabetes mobile apps

Prior to questionnaire design, a search was conducted of the Apple app store in July 2014. This snapshot search was limited to the search term ‘glucose tracking’ and was principally aimed at developing a broad understanding of the diabetes app market; therefore, informing questionnaire

content. Apps were included (regardless of price) if they specifically targeted diabetes. Search results were then downloaded and reviewed by a single reviewer (I.C.), who identified and categorised available features. The identified features were then incorporated into the questionnaire to assess user preference (see below). User preference was also sought for features not identified from the snapshot analysis, but thought to be relevant for future app development.

Diabetes patient mHealth Questionnaire

A 39-item questionnaire was designed in four parts: demographics, current use of technology in diabetes self-care, preference for mHealth and preferred features/functionality of mHealth applications developed in the future (questionnaire available on request). The questionnaire was written in an electronic format and posted online. No identifiable data were collected. All items utilised a categorical response in order to improve response rate and quality of data. Permissions to gather data were obtained from the local Caldicott Guardian. All patients contacted had previously given consent to be contacted via unsolicited email during the enrolment process for both SDRN and/or MDMW. Ethics permission was sought and deemed unnecessary as this work was related to ongoing service improvement.

The MDMW and SDRN datasets were randomly sampled in a stratified way (via a random number generator) to return 200 patients, consisting of 50 patients from the following four groups: T1D < 50 years old; T1D ⩾ 50 years old; T2D < 50 years old; T2D ⩾ 50 years old. Both samples were also mutually exclusive, that is, individuals in the MDMW sample were excluded prior to sampling the SDRN dataset. All individuals were resident in Scotland and had an active email address that was used to invite them to take part in the survey. This invitation email contained a link to the online questionnaire. The MDMW survey took place between August–October 2013 and formed the basis of an undergraduate student project. The SDRN survey took place between April and June 2014, in an effort to draw comparisons between the findings of the MDMW survey and the wider diabetes community.

Statistical analysis

Initial analysis demonstrated that mHealth preference was the same across both groups (see results) and so responses from both surveys were combined into one dataset. Preference for mHealth apps was measured via two questionnaire items that were conditional on the respondent owning a smartphone (respondents were asked to reflect on current diabetes management and were asked to agree with the following statements: 'A smartphone app to manage my diabetes would be a positive development' and 'I would prefer to use a smartphone app to manage my diabetes'. Both items were agree/disagree questions that utilised a 5-point scale). The internal consistency of these items as a measure of preference for an mHealth app was tested using the Kappa statistic. The two items were then summed to produce a score (out of 10) that was used as a summary of an individual's preference for the use of mHealth technologies – the *mHealth preference* scale. A higher score on the scale (0–10) was interpreted as an individual being enthusiastic about using mHealth technologies. Demographic variables (age group, gender and diabetes type) were crosstabulated with mHealth preference to identify sub-groups of interest. Categories within the demographic variables and mHealth preference were collapsed as appropriate, in order to achieve representation in each of the cells (see results). Denominators were adjusted to take into account missing data. Loglinear analysis was used to identify interactions between demographic sub-groups and mHealth preference. Cases with missing data were excluded from analysis of that data field. Significant interactions identified in the loglinear analysis were then explored in greater depth using Chi Square and odds ratios.

Table 1. Frequency of mHealth app features identified during snapshot analysis. Total apps analysed was 74.

Feature	Available	
	n	%
Password protection	9	12
Graphic display/analysis	56	76
Education	10	14
CHO counter	26	35
Data backup	14	19
Email backup	47	64
Glucose monitor	74	100
Physiology tracker	32	43
Download meter	1	1
Weight tracker	33	45
Medication log	24	32
Activity tracker	25	34
Reminders/alarms	21	28
Insulin logger	31	42
Ratio wizard	0	0
Social media	11	15

In addition to mHealth preference, respondents were asked about current use of technology. Responses were analysed with respect to demographic sub-groups that were found to be significantly associated with mHealth preference. Finally, all respondents were asked which of the features commonly found in mHealth diabetes apps would be most desirable with responses stratified according to diabetes type.

Results

mHealth apps

A total of 74 diabetes-related apps were identified through the Apple Store and analysed. Approximately half (39/74, 53%) were free, while the others ranged in price from £0.69 to £6.99 (€0.87–€8.83, US$1.09–US$11.06). In all, 16 separate features were identified. The median number of features was 5 (range 2–11). All apps had the facility to record blood glucose results, while only one incorporated a blood glucose monitor. The available features and the frequency with which they were available are listed in Table 1.

Demographics

Responses to the questionnaire were received by 121/200 (60.5%) of the MDMW sample and 113/200 (56.5%) of the SDRN sample. Data quality was good with very little missing data – for example, completion rate was 98–100 per cent for gender, diabetes type, duration of diabetes, treatment and phone ownership. Age group was completed by 218/234 (93%). When compared with MDMW respondents, the SDRN group were more likely to be older (SDRN median age group 56–65 years compared to MDMW median age group 46–55 years, $U = 4232$, $z = -3.771$, $p < 0.001$), male (SDRN: 79/112 (70.5%) male c.f. MDMW: 66/117 (56.4%) male, $p = 0.029$) and have T2D

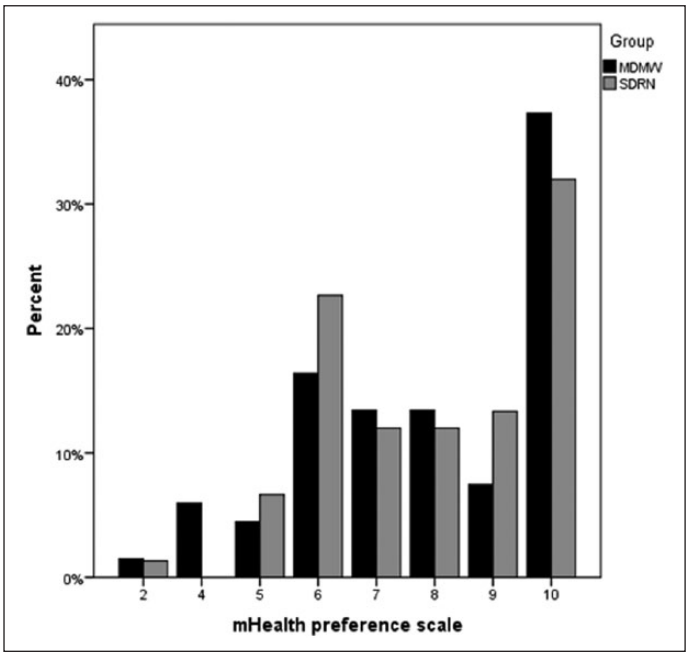

Figure 1. mHealth preference scale by respondents' group. Percentages calculated using group totals (MDMW: n = 67, SDRN n = 75) as denominator.

(SDRN: 80/109 (73.4%) T2D c.f. MDMW: 59/121 (48.8%), $p < 0.001$) (age categories were decades from the age of 16, i.e., 16–25, 26–35, etc.). There was no significant difference in smartphone ownership between both groups (SDRN: 75/112 (67%) c.f. MDMW: 69/121 (57%), $p = 0.077$). Similarly, there was no significant difference in prevalence of smartphone ownership when those with T1D (55/91, 60.4%) were compared with T2D (85/138, 61.6%). These similarities allowed for data to be pooled for subsequent analysis. The majority of respondents (176/229, 77%) use self-monitored blood glucose (SMBG) levels in their diabetes management.

mHealth preference

In all, 144/233 (62%) people owned a smartphone, of which 142 gave their preference for mHealth technologies. The majority expressed an interest in the use of mHealth apps to manage their diabetes – 101/142 (70.1%) agreed or strongly agreed with the statement *a smartphone app to manage my diabetes would be a positive development*, and 79/142 (54.9%) agreed or strongly agreed with the statement *I would prefer to use a smartphone app to manage my diabetes*. As expected, there was a statistically significant correlation between responses for each of these statements, which demonstrated moderate agreement (Kappa = 0.45, $p < 0.001$, 95% confidence interval (CI): 0.35–0.56). The responses to both of these items were then summed to calculate an individual's mHealth preference score, available for 127/144 (88%) of respondents.

mHealth preference was skewed towards high preference (see Figure 1). The score was therefore collapsed into high (7–10) and low (2–6) preference categories in order to combine the low numbers of respondents at the lower end of the scale. When comparing mHealth preference categories for each of the demographic groups (age category, gender and diabetes type), there were no

Table 2. mHealth preferences stratified by demographic sub-groups.

Gender	Diabetes type	Age (years)	mHealth preference scale (collapsed)				Total	p value
			Low		High			
			n	%	n	%		
Female	Type 1	<56	6	28.6	15	71.4	21	0.138
		⩾56	1	100.0	0	0.0	1	
	Type 2	<56	3	15.8	16	84.2	19	0.002
		⩾56	6	85.7	1	14.3	7	
Male	Type 1	<56	2	11.8	15	88.2	17	0.561
		⩾56	2	20.0	8	80.0	10	
	Type 2	<56	4	19.0	17	81.0	21	0.351
		⩾56	11	34.4	21	65.6	32	

significant differences noted, although there was a trend for people ⩾56 years to express less preference (data not shown).

The four-way loglinear analysis produced a final model that retained the interaction between gender, mHealth preference and age (χ^2 (1) = 4.16, p = 0.04) as well as diabetes type and age (χ^2 (1) = 9.58, p = 0.02). The former was explored in greater detail. There was a highly significant association between age and mHealth preference for women with T2D (p = 0.002) but not T1D, whereas there was no such association in men – see Table 2. Odds ratios indicated that women ⩾56 years of age (with T1D or T2D) were 28 times *less* likely than younger women to express a preference for mHealth applications to help with their diabetes. In comparison, older men (with T1D or T2D) were only two times less likely to express a preference when compared to younger men.

Smartphones and use of technology for diabetes

With regard to current use of technology, of the 144 people who owned a smartphone, 121 (84%) used their phone more than once a day. The use of the two main operating systems was roughly equivalent (Android: 69/144, 48%; iOS: 57/144, 40%). Both men and women ⩾56 years of age were significantly less likely to find the use of smartphone apps 'enjoyable' when compared with younger adults (females who found apps enjoyable: ⩾56 years 1/8 (12.5%) vs 26/41 (63.4%) < 56 years, p = 0.001; males who found apps enjoyable: ⩾56 years 20/44 (45.5%) vs 28/39 (71.7%) < 56 years, p = 0.042).

In all, 176/229 (76.9%) respondents reported that they needed to check blood glucose regularly as part of their diabetes self-care, including the majority of those with T2D (T1D: 89/90, 98%; T2D: 87/139, 63%). Of those who did use blood glucose monitoring as part of their diabetes self-management, the majority did not use any device to remind them to do so (116/163, 71.8% (NB. 13 individuals did not respond)) (response to the question: How do you remind yourself to take medication and/or check blood sugars? Tick all that apply from the following: Just remember without aids/I use an alarm/I have a set routine/I use my phone to set reminders/Someone Reminds Me/Somebody (carer, relative or friend) does it for me), with no significant differences between demographic sub-groups (data not shown). The most common way of recording the result was via the monitor device (87/163, 53.4%) or a written diary (56/163, 34.4%). Use of other technologies was minimal – 12/163 (7.4%) used their phone and 17/163 (10.4%) used their home computer (via a

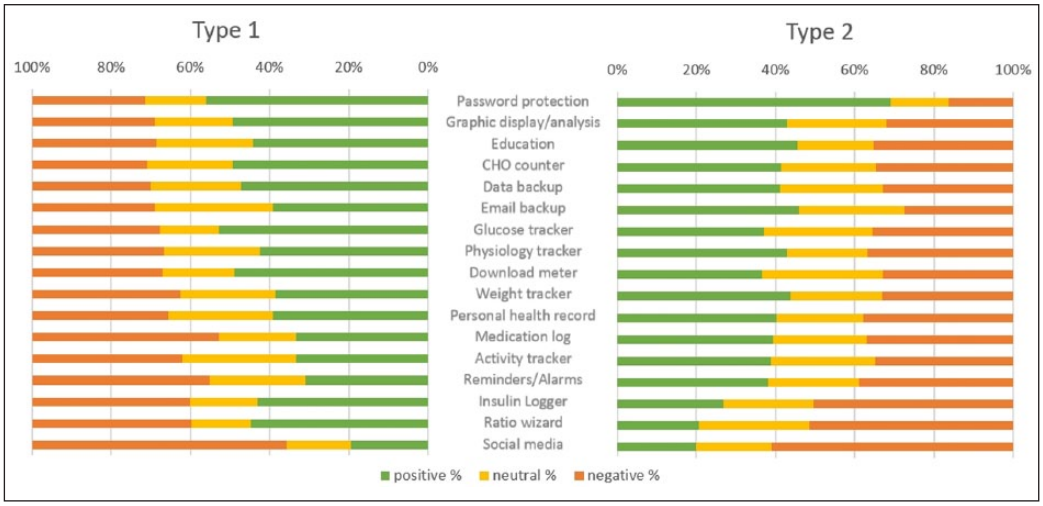

Figure 2. Preferred features of an mHealth app, stratified by diabetes type. Features are arranged in descending order of preference (T1D and T2D combined). Denominators for preference vary depending on number of respondents to each item (total n = 213–226). 'Strongly agree' and 'agree' were categorised as being positive responses. 'Strongly disagree' or 'disagree' responses were categorised as being negative.

spreadsheet). The only significant difference between age categories for either gender was that women ⩾56 years were significantly less likely to use their home blood glucose monitor (HBGM) to record results (9/24, 37.5% women ⩾56 years vs 28/43, 65.1% women < 56 years, p = 0.027).

Preferences for mobile technology use and app features

Preferences were analysed with respect to diabetes type. Response rates for each of the suggested features varied between 84–87/91 (92–96%) for those with type 1 diabetes and 123–135/139 (88%–97%) for those with type 2 diabetes. If available, the feature that both types of users would most commonly use was password protection (47/84, 56% for T1D and 89/129, 69% for T2D) – see Figure 2. Thereafter, approximately 40–50 per cent of respondents indicated that they would use the various suggested features, irrespective of diabetes type, for example, preference for features relating to activity and exercise did not differ markedly between those with T1D and T2D.

Diabetes type did have some influence on the types of features that would be desirable, for example, those with T1D showed higher preference for a ratio wizard (39/87, 45% vs 25/122, 21%; p < 0.001) and logging of insulin (38/88, 43% vs 33/123, 27%; p = 0.02). If this comparison was restricted to only those who used insulin, this significance was lost or reduced (ratio wizard: 39/87 vs 10/40 p < 0.05; insulin logger 38/88 vs 13/39, p = 0.07). Preference for a glucose-monitoring feature was also higher for those with T1D (T1D: 46/87, 53%; T2D 50/135, 37%; p = 0.03). Again, there was no such difference between diabetes types if analysis was restricted to those who self-monitor blood glucose (46/87 vs 32/85, p = 0.1).

The lowest rated feature was social media integration (positive response: T1D 17/87, 20%; T2D 26/131, 20%). Preference for social media integration was compared with respect to age group, with those < 56 years demonstrating higher preference (30/97, 30.9% positive) to those ⩾56 years (14/108, 13.0%, p = 0.008). This significance was lost when stratified by gender, owing to smaller numbers.

Discussion

This study has demonstrated interesting insights regarding the use and preferences for mobile technology in a diverse diabetes population. In general, smartphone ownership and use was high and in keeping with UK usage.[21] However, users did not tend to use these or other technologies when managing their diabetes. For example, for those who use SMBG, approximately a quarter used some form of reminder (e.g. alarm on phone) to do so. Half of this group used their blood glucose monitor to record their results and a small minority used some form of other technology (e.g. spreadsheet on desktop computer). It is perhaps unsurprising, therefore, that when asked about preferences for app development, a minority felt that reminders and alarms in an app would be useful, and less than half felt similarly for the inclusion of the facility to record blood glucose data using an app. This contrasts with Dobson and Hall[22] who concluded that the majority of respondents would welcome the ability to track blood glucose data.

A comprehensive review of app features currently available concluded that usability is inversely correlated with number of features contained within the app.[7] In our study, there was a marked contrast between the availability of features on the apps included in the snapshot analysis and the features that users showed greater preference for. For example, the majority of respondents indicated that patient education would be a useful addition to an app, whereas this feature is currently only available in a minority of apps. There was a notable lack of enthusiasm for social media integration with any future app development – while younger people were significantly more likely to show preference for this feature, only one-fifth of respondents were positive overall.

The digital diabetes landscape has grown rapidly over the past decade and there is evidence that web-based interventions can lead to improved clinical outcomes.[11,12] The use of mHealth applications has the potential to improve access to such services, thereby addressing a key component of the 'digital divide'.[23] However, there is increasing evidence that Internet usage patterns reflect underlying demographic and socioeconomic differences, with the potential to increase health inequalities.[24] In this study, most respondents expressed a preference for mHealth apps to manage their diabetes; however, gender, diabetes type and age were significant confounders – women $\geqslant$56 years were significantly less likely to express a preference for mHealth apps. This is in keeping with findings from elsewhere[22] Again, this has implications for future app development in terms of ensuring that population sub-groups do not feel alienated or become disenfranchised.

Limitations

There are a number of limitations acknowledged in this study. The sample size was one of convenience as opposed to the result of a power calculation. The use of stratified sampling from more than one dataset ensured that the respondents included sub-groups of the wider diabetes community in terms of diabetes type and age, although the number of those with T1D was over-represented when compared with national data.[20] In addition, low numbers in certain demographic sub-groups (e.g. older women) make it difficult to make robust statistical inference. Young people $<$16 years old were not included, and it could be argued that this user group would provide a very different perspective on the use of mHealth technologies. It should also be noted that the MDMW and SDRN cohorts may have some inherent biases in that both datasets may represent a more engaged section of the diabetes community – they have all given prior consent to be contacted for research and all those contacted were Internet users (contact was via email address). In addition, subscribers to the online MDMW portal are probably more likely to be engaged with modern technology, tend to be younger and, by implication, have less comorbidities. While not being representative of the wider diabetes community, it could be argued that the sample demographic is a potential strength of the study as this population is more likely to use mHealth technologies. We did not gather data on

questionnaire respondents' ethnicity. The sample was drawn from a population who are 96 per cent White.[25] This limits the generalisability to other populations, given that ethnicity is associated with the likelihood of engaging with mHealth technologies.[26] Another potential shortcoming is that the use of categorical responses introduced limitations to the analysis. However, the relatively high response rate can in part be attributable to the ease in which the questionnaire can be completed, and so we believe this design was justified. The search strategy of available apps was limited in terms of search terms and marketplace (iOS apps only). The decision to limit the search in this way was a pragmatic choice that was primarily intended to inform questionnaire design. We believe the results to be representative of the wider app market.

Conclusion

The growing prevalence of diabetes accounts for an ever-increasing proportion of healthcare spending. There is a recognised need to improve the way that care is delivered to provide a more sustainable and person-centred service. The integration of mHealth technologies within existing informatics systems has the potential to empower patients, increase patient choice, improve outcomes and provide service in a different and sustainable way.

This study has demonstrated that in this sample of people with diabetes, most would welcome the development of mHealth technologies to help manage their condition. However, we have also shown that the functionality of existing apps does not currently meet the preferences of this potential user group. Both functionality and user engagement could be improved by including relevant stakeholders in future app development, which should be driven by clinical and user need as opposed to what is easiest to develop.

Acknowledgements

The authors thank the patients and staff of the Scottish Diabetes Research Network and also thank the patients and staff of My Diabetes My Way.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: I.C. was supported to complete this work via a Dundee Clinical Academic Track scholarship awarded by the University of Dundee.

Supplementary material

Access to research materials, including questionnaire and data, is available from the corresponding author.

References

1. International Diabetes Federation. *IDF diabetes atlas*. 6th ed. Brussels: International Diabetes Federation, 2013.
2. mobiForge. Mobile hardware statistics 2014, http://mobiforge.com/research-analysis/mobile-hardware-statistics-2014 (accessed 1 March 2015).
3. The World Bank. Mobile cellular subscriptions (per 100 people), http://data.worldbank.org/indicator/IT.CEL.SETS.P2/countries/1W?display=graph (2013, accessed 1 March 2015).

4. The Guardian. Smartphone explosion in 2014 will see ownership in India pass US, http://www.theguardian.com/technology/2014/jan/13/smartphone-explosion-2014-india-us-china-firefoxos-android (2014, accessed 1 March 2015).
5. Health Resources and Services Administration. mHealth, http://www.hrsa.gov/healthit/mhealth.html (2012, accessed 12 December 2014).
6. Chomutare T, Fernandez-Luque L, Årsand E, et al. Features of mobile diabetes applications: review of the literature and analysis of current applications compared against evidence-based guidelines. *J Med Internet Res* 2011; 13: e65.
7. Arnhold M, Quade M and Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. *J Med Internet Res* 2014; 16: e104.
8. National Institute for Health and Care Excellence. Type 2 diabetes: the management of type 2 diabetes (CG87), 2009, https://www.nice.org.uk/guidance/cg87
9. National Institute for Health and Care Excellence. Diagnosis and management of type 1 diabetes in children, young people and adults (CG15), 2004, https://www.nice.org.uk/guidance/cg15
10. Scottish Intercollegiate Guidelines Network. 116: Management of diabetes – a national clinical guideline, 2010, http://www.sign.ac.uk/pdf/sign116.pdf
11. Ramadas A, Quek KF, Chan CKY, et al. Web-based interventions for the management of type 2 diabetes mellitus: a systematic review of recent evidence. *Int J Med Inform* 2011; 80: 389–405.
12. Pereira K, Phillips B, Johnson C, et al. Internet delivered diabetes self-management education: a review. *Diabetes Technol Ther* 2014; 17: 55–63.
13. Krishna S and Boren SA. Diabetes self-management care via cell phone: a systematic review. *J Diabetes Sci Technol* 2008; 2: 509–517.
14. Cunningham S, McAlpine R, Leese G, et al. Databases for diabetes epidemiology: using web technology to support population-based diabetes care. *J Diabetes Sci Technol* 2011; 5: 523–534.
15. Scottish Diabetes Survey Monitoring Group. Scottish diabetes survey 2013, http://www.diabetesinscotland.org.uk/Publications/SDS2013.pdf
16. Schofield CJ, Yu N, Jain AS, et al. Decreasing amputation rates in patients with diabetes – a population-based study. *Diabet Med* 2009; 26: 773–777.
17. Vallance JH, Wilson PJ, Leese GP, et al. Diabetic retinopathy: more patients, less laser: a longitudinal population-based study in Tayside, Scotland. *Diabetes Care* 2008; 31: 1126–1131.
18. Scottish Diabetes Research Network. *Annual report* 2012, https://www.sdrn.org.uk/node/402
19. Cunningham SG, Wake DJ, Waller A, et al. My Diabetes My Way: an electronic personal health record for diabetes. *Br J Diabetes Vasc Dis* 2013; 13: 143–149.
20. Scottish Diabetes Survey Monitoring Group. Scottish diabetes survey 2014, http://www.diabetesinscotland.org.uk/Publications/SDS2014.pdf
21. eMarketer. Nearly half of UK consumers will use smartphones this year, http://www.emarketer.com/Article/Nearly-Half-of-UK-Consumers-Will-Use-Smartphones-This-Year/1009956 (accessed 2013).
22. Dobson KG and Hall P. A pilot study examining patient attitudes and intentions to adopt assistive technologies into type 2 diabetes self-management. *J Diabetes Sci Technol* 2015; 9: 309–315.
23. Norris P. *Digital divide: civic engagement, information poverty, and the Internet worldwide*. Cambridge: Cambridge University Press, 2001.
24. Van Deursen AJ and Van Dijk JA. The digital divide shifts to differences in usage. *New Media Soc* 2013; 16: 507–526.
25. The Scottish Government. Summary: ethnic group demographics, http://www.gov.scot/Topics/People/Equality/Equalities/DataGrid/Ethnicity/EthPopMig (2014, accessed 18 February 2015).
26. Bender MS, Choi J, Arai S, et al. Digital technology ownership, usage, and factors predicting downloading health apps among Caucasian, Filipino, Korean, and Latino Americans: the digital link to health survey. *JMIR Mhealth Uhealth* 2014; 2: e43.

Journal of Diabetes Science and Technology
1–8

DOI: 10.1177/1932296817729489
journals.sagepub.com/home/dst
SAGE

Decision Support for Diabetes in Scotland: Implementation and Evaluation of a Clinical Decision Support System

Nicholas Conway[1,2], Karen A. Adamson[3], Scott G. Cunningham[2], Alistair Emslie Smith[2], Peter Nyberg[4], Blair H. Smith[2], Ann Wales[5], and Deborah J. Wake[1,2]

Abstract

Background: Automated clinical decision support systems (CDSS) are associated with improvements in health care delivery to those with long-term conditions, including diabetes. A CDSS was introduced to two Scottish regions (combined diabetes population ~30 000) via a national diabetes electronic health record. This study aims to describe users' reactions to the CDSS and to quantify impact on clinical processes and outcomes over two improvement cycles: December 2013 to February 2014 and August 2014 to November 2014.

Methods: Feedback was sought via patient questionnaires, health care professional (HCP) focus groups, and questionnaires. Multivariable regression was used to analyze HCP SCI-Diabetes usage (with respect to CDSS message presence/absence) and case-control comparison of clinical processes/outcomes. Cases were patients whose HCP received a CDSS messages during the study period. Closely matched controls were selected from regions outside the study, following similar clinical practice (without CDSS). Clinical process measures were screening rates for diabetes-related complications. Clinical outcomes included HbA1c at 1 year.

Results: The CDSS had no adverse impact on consultations. HCPs were generally positive toward CDSS and used it within normal clinical workflow. CDSS messages were generated for 5692 cases, matched to 10 667 controls. Following clinic, the probability of patients being appropriately screened for complications more than doubled for most measures. Mean HbA1c improved in cases and controls but more so in cases (–2.3 mmol/mol [–0.2%] versus –1.1 [–0.1%], $P = .003$).

Discussion and Conclusions: The CDSS was well received; associated with improved efficiencies in working practices; and large improvements in guideline adherence. These evidence-based, early interventions can significantly reduce costly and devastating complications.

Keywords

decision support systems, clinical, diabetes mellitus, guideline adherence, process assessment (health care)

Best practice in the management of diabetes has been established by the use of national guidelines based on an appraisal of the available evidence.[1-3] Diabetes care in Scotland relies on a series of managed clinical networks supported by a national informatics platform—the Scottish Care Information Diabetes Collaboration (SCI-Diabetes).[4] Regional and national audits of clinical practice are published on an annual basis using data extracted from SCI-Diabetes.[5] Despite the rising prevalence of diabetes in Scotland there has been a sequential improvement in QPIs and the incidences of diabetes-related complications have decreased.[6-8] However, there is room for improvement in adherence to guidelines, as evident when comparing with the international community.[9]

It is estimated that more than half of all clinical decisions fail to take account of the best available evidence.[10] In addition, evidence-based guidelines often do not accommodate comorbidities and multiple medications.[11-13] There is a recognized need to find innovative ways of integrating knowledge into clinical workflow, to contextualize and personalize care, and to manage the complex care needs and human factors that contribute to unwanted variation in practice.[14,15]

Clinical decision support systems (CDSS) utilize

[1]NHS Tayside, Ninewells Hospital Dundee, Dundee, UK
[2]University of Dundee, Ninewells Hospital Dundee, Dundee, UK
[3]NHS Lothian, St John's Hospital, Howden Road West, Howden, Livingston, UK
[4]Duodecim Medical Publications, Helsinki, Finland
[5]NHS Education for Scotland, Glasgow, UK

Corresponding Author:
Nicholas Conway, MACHS building, Tayside Children's Hospital, Ninewells Hospital, Dundee, DD1 9SY, UK.
Email: n.z.conway@dundee.ac.uk

algorithms of varying complexity that are applied to existing eHealth systems. The use of automated reminders via CDSS has been shown to be one of the most consistently successful approaches to encourage clinicians to adopt evidence-based practice,[16] although there is a lack of evidence to demonstrate that this translates into improved clinical outcomes.[17]

This study reports on a project that aimed to pilot a CDSS within the SCI-Diabetes system within two regions in Scotland. The evaluation aimed to assess users' and patients' reaction to the CDSS, to demonstrate whether there were no unintended adverse effects attributable to the system, and to quantify any change in clinical processes or outcomes.

Methods

The CDSS was based on the Evidence Based Medicine electronic Decision Support (EBMeDS) system developed by the Finnish Medical Society—Duodecim Medical Publications Ltd, who collaborated on the project.[18] The various algorithms used to generate CDSS messages were amended to conform to Scottish national guidelines,[1] with full details of the final scripts available via the EBMeDS website.[19] EBMeDS is accredited by the UK National Institute for Health and Care Excellence (NICE),[20] and is currently being evaluated in a number of settings.[21-25] Messages could be grouped into 3 main categories:

1. Reminders of pending investigations, eg, screening tests for diabetes-related complications
2. Prompts to consider intervention, eg, initiating a treatment associated with improved long-term outcomes
3. Alerts to a potentially deleterious situation, eg, prescribing of a contra-indicated medication or inappropriate dose

The SCI-Diabetes user interface (UI) was adapted to display these messages within a "pop-up" dialogue box that appears on opening an individual patient record, the appearance and behavior of which was adapted in light of user feedback (see Figure 1).

All people with diabetes in Scotland are registered to SCI-Diabetes (approximately 280 000 individuals).[5] The system encrypts and transmits compressed, coded data via the NHS N3 network. HCP access is dependent on which health care domain the user is employed. All study data were extracted in a pseudo-anonymized format. Data controllers retained the cipher and all data was transferred to the researchers using a secure NHS file sharing network. Permission to access these data was granted via the national Caldicott Guardian, in accordance with the UK Data Protection Act 1998.[26] The service improvement nature of the project precluded the need for formal research ethics review.

Implementation of the CDSS within SCI-Diabetes adopted a quality improvement approach whereby the system was introduced to a limited number of health care domains; evaluated for acceptability; adapted in light of user feedback; and then introduced more widely. Two such "improvement cycles" ran over the course of an 18-month period. Cycle 1 was conducted in Tayside, Scotland, and included Ninewells hospital diabetes clinic plus one general practice. Cycle 2 widened coverage to include St John's hospital, Livingston diabetes clinic. The system was then implemented for the whole of NHS Tayside (including primary care) to cover a combined diabetes population of ~30 000. This study reports on data obtained from improvement cycles 1 and 2 (see Figure 2).

Patient Reaction

A patient-reported experience measures (PREMs) questionnaire was devised and distributed to patients attending diabetes clinics at two time points: December 2013-February 2014 (cycle 1) and August 2014-February 2015 (cycle 2). The questionnaire was adapted from the NHS Scotland Patient Survey[27,28] and consisted of a series of closed, 5-point Likert-type scale items grouped within different domains: interaction with doctors and nurses, use of medication, and general satisfaction. A copy of the questionnaire is available within the supplementary files. Scores were calculated for each domain. The domain scores served as dependent variables in a multivariable linear regression analysis. Patient demographics and presence/absence of a CDSS message displayed to the HCP were entered as independent predictors.

Health Care Professional Reaction

Two questionnaires were developed for distribution to health care professional (HCP) users of SCI-Diabetes and distributed prior to, and at the end of each 3-month quality improvement cycle in both primary and secondary care. The questionnaires were available in electronic and paper versions and consisted of a series of closed 5-point Likert-type scale questions grouped by theoretical construct, derived from the Unified Theory of Acceptance and Use of Technology (UTAUT) model,[29] and adapted from the work of Heselmans et al.[30] Construct scores served as dependent variables in a multivariable linear regression analysis. HCP demographics were entered as the independent predictors.

Three HCP focus groups were conducted, each comprising 8-9 HCPs of varying roles within the diabetes departments taking part in the study. The first focus group explored attitudes to CDSS prior to implementation. The second group gave reaction and feedback following the first improvement cycle. The system was amended in light of this feedback and the third focus group gave their reaction to these changes. A constant comparative approach identified emergent themes describing the differing attitudes to CDSS adoption.

For the quantitative analysis of HCP system usage, data were extracted from the SCI-Diabetes audit trail for improvement cycle 1. The outcomes of interest were the

number of user "clicks" within patient record and the duration of time that the patient record was viewed.

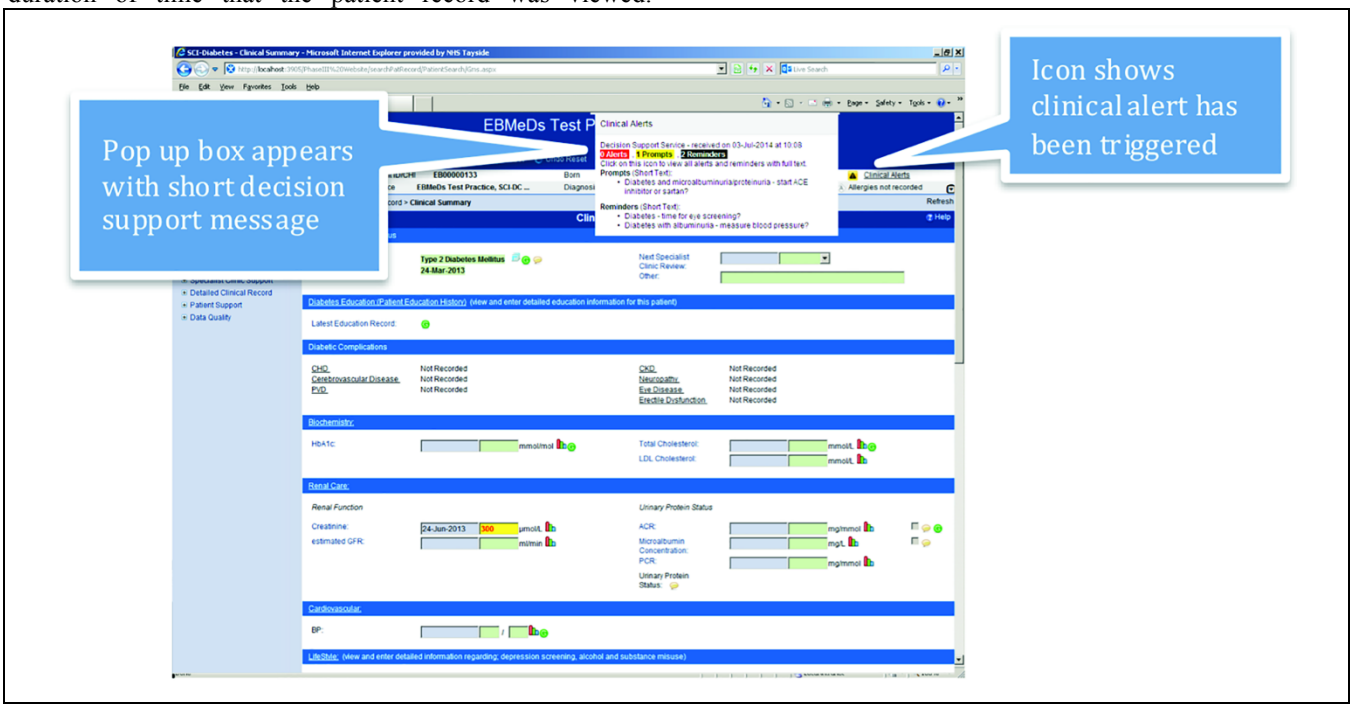

Figure 1. Screenshot of SCI-Diabetes user interface showing CDSS short message pop up dialogue box within a test page.

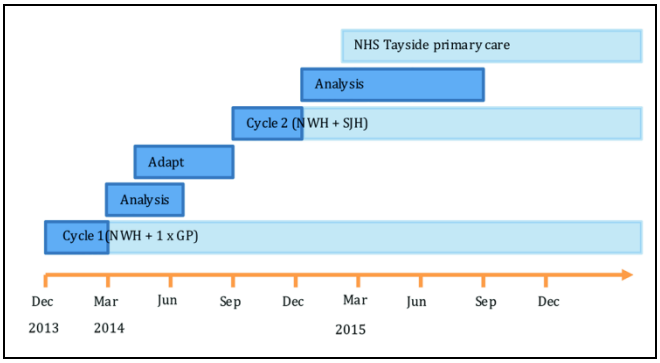

Figure 2. Project timeline showing the 2 improvement cycles. NWH, Ninewells Hospital; GP, General Practice; SJH, St John's Hospital.

Comparison was made between presence or absence of a CDSS message using multivariable generalized estimating equations, correcting for number of CDSS messages; patient comorbidity score; diabetes type; insulin therapy and socioeconomic status.

Clinical Processes

The outcomes of interest included adherence to guideline recommendations (as measured by QPIs). The QPIs included screening for foot disease (standardized foot screening in accordance with Scottish diabetes group guidance);[31] hyperlipidemia (serum cholesterol); thyroid disease (serum thyroid stimulating hormone [TSH]); and kidney disease (serum creatinine and urinary albumin/creatinine ratio [UACR]).

Cases were defined as those patients where the HCP received a CDSS message during the period of study. Cases were matched to controls residing in regions within Scotland that were not taking part in the study (ie, their HCP did not receive any CDSS messages), and who had attended their local diabetes clinic during the period of study. Controls were matched in a ratio of 2:1 based on the following criteria: age (±2 years); gender; diabetes type; duration of diabetes (±2 years); BMI (±2 kg/m^2); and attendance at clinic during the study period.

Cases and controls were included in the analysis of each QPI if there were no recorded screening tests within the previous 15 months (24 months for TSH). In each instance, cases' HCP received a CDSS message alerting them to this fact, whereas no such message was displayed to controls' HCP. Adherence was considered improved if those patients with no recorded screening activity proceeded to have the screening test done within 30 days postappointment. Cases and controls were compared by multivariable linear regression taking into account potential demographic confounders (user role, patient age, diabetes type/duration, comorbidity, and deprivation).

Power was calculated using the foot disease screening primary outcome. Based on national data, 82% of patients would have received foot screening in the preceding 15 months.[32] Approximately 1200 patients would attend clinic during the period of study, 216 (18% of 1200) of whom would have had no foot screening in the past 15 months. With no intervention, it was assumed that 12 of these

patients would receive foot screening every month (ie, background screening rate: 82% of 216 divided by 15 months = 11.8). If the CDSS resulted in the HCP screening an additional 8 patients per month then over the course of the 3-month study period, 60 patients who had not received foot screening for 15-months (ie, 3*(8+12)) would receive foot screening in the intervention clinic (60/1200 = 5%). It was assumed that the control patient group (anticipated n = 2400) was subject to the same background rate of foot screening, resulting in 24 patients per month who had not received screening in the past 15-months receiving foot screening through routine care—equivalent to 72/2400 (3%) over the three-month period. The resulting difference between the 2 samples (5% of 1200 vs 3% of 2400) would allow the null hypothesis that there is no difference between the 2 groups to be rejected with 90% power.

Clinical Outcomes

This analysis considered all cases in whom a CDSS message was displayed to HCPs (ie, including those instances outside the diabetes clinic environment) during improvement cycles 1 and 2, matched in the same way to controls living outside the study area, that is, the controls had attended the diabetes clinic but the decision support system was not available. The main clinical outcome of interest was change in glycemic control (HbA1c) at one year following the initial CDSS message (cases) or one year following the initial consultation (controls).

Secondary outcomes included change in serum cholesterol, blood pressure (systolic [SBP] and diastolic [DBP]) and urinary albumin/creatinine ratio (UACR). All samples were processed and analyzed by local NHS biochemistry laboratories (fully accredited to ISO 15189 by the United Kingdom Accreditation Service). Paired data were obtained for each dependent variable from baseline and follow-up at 9-15 months. Comparison of baseline data was made using Student's T test. The difference between baseline and follow-up values were calculated and then cases and controls were compared by multivariable linear regression, taking into account potential demographic confounders. Independent variables with significance of $P < .3$ on initial univariate regression were retained in the final model.

Power calculations were based on 1200 patients attending clinic during the study period, of which it was assumed that a prompt would be displayed to the HCP in 20% of cases (n = 240). Prior to the study, the mean HbA1c for patients in Tayside was 59 mmol/mol.[32] A 2 mmol/mol reduction in mean HbA1c in cases, with no observed difference in controls at follow-up would result in the rejection of the null hypothesis that there was no difference between the groups with 81% power (assuming SD = 10).

Results

Patient Reaction

A total of 359 questionnaire responses were received from cycles 1 and 2 combined, from a total population of 2072 clinic attendances (17%). Response rates were higher for cycle 2 (281/471, 60%), following the introduction of dedicated research staff to improve distribution. Responses to all domains were overwhelmingly favorable with >90% or respondents reporting positively to each item. There was no significant association between presence or absence of a CDSS message and score in any of the domains, suggesting that the CDSS had no impact on patient satisfaction with the consultation.

Health Care Professional Reaction

The response rate for pre and post intervention questionnaires was 57/105 (54%) and 39/105 (37%), respectively. Attitudes to the CDSS were mixed. The majority of respondents had a positive or neutral response to the content of the reminders (in terms of relevance, clarity, and quality) and ease of use. Despite this, self-reported use of the system was low. Work role predicted users' performance expectancy (ie, the degree to which an individual believes the system will help them with their work), which was significantly higher for nurses.

The focus groups demonstrated that HCPs were generally receptive to the idea of a CDSS and could appreciate its utility. There were concerns regarding user fatigue; insufficient tailoring to role; covert surveillance of system use; and the applicability of guidelines in general to a complex patient population. Following implementation, there was evidence of some users using the system within their normal clinical workflow to improve the efficiency of their use of SCI-Diabetes. System behavior was amended in light of feedback prior to the second improvement cycle and subsequent feedback was positive.

With regards to system usage, there were 5355 unique patient records opened during improvement cycle 1, each record being opened a median of 3 times (range 2 to 56, interquartile range (IQR) 4). The total number of records opened was 17 280. CDSS messages were displayed on opening 6665/17 280 patient records (39%). When displayed, the median number of CDSS messages was 3 (range 1 to 12, IQR 3). Presence of a CDSS message had no association with the duration that the record was viewed by nurses, however the number of mouse clicks made by nurses within the patient record was significantly increased when a CDSS message was displayed (median number of clicks (IQR) 19 (29) versus 16 (25), adjusted $P = .014$). Among doctors, the duration that the record was viewed was significantly reduced when a CDSS message was displayed (median duration (IQR) 33 sec (81) vs 38 sec (85), adjusted $P = .032$), with no other significant confounders. The presence or absence of a CDSS message had no relationship with number of mouse clicks made by doctors.

Clinical Processes

A CDSS message was displayed to an HCP in 1883 cases attending the diabetes clinic (cycle 1 = 1116, cycle 2 = 767 cases), of which 1749 were matched to two controls. An additional 59 cases were matched to one control, resulting in a comparator group of 1808 controls. The remaining 75 cases were unable to be matched on the defined criteria and so were excluded from analysis. There were no significant differences between cases and controls for any of the matching criteria, that is, age, gender, diabetes type and duration, and BMI.

Prior to the intervention, adherence to each of the QPIs was greater than 60% (Table 1). The proportion of all cases that had had foot screening in the previous 15 months was significantly greater amongst cases than amongst controls (76.5% versus 73.4%, $P < .001$), whereas controls had significantly greater adherence to screening for TSH, creatinine and cholesterol. There was no difference between groups in previous adherence to UACR screening (see Table 1).

In the month following a clinic appointment, a significantly greater proportion of cases than controls received appropriate screening for foot disease, kidney disease and hypercholesterolemia (Table 1). After adjusting for potential confounders, patient group (ie, case or control) was a significant predictor of whether or not a patient received appropriate screening following a clinic appointment for each QPI. The size of this effect varied by hospital site. During improvement cycle 1, the intervention was significantly associated with increased uptake of screening for foot disease (adjusted OR 1.4, 95% CI: 1.0 to 2.1, $P = .045$) and urinary protein (2.0 (1.5 to 2.7), $P < .001$) but decreased uptake of thyroid disease screening (0.2 (0.1 to 0.2) $P < .001$). During improvement cycle 2, cases were significantly more likely than matched controls to undergo screening for all of the outcomes, the odds of which were far greater than those observed in cycle 1. Cases were over 4 times more likely than cases to have their feet, cholesterol and creatinine checked (adjusted OR (95% CI): 4.5 (3.2 to 6.3); 4.5 (2.3 to 8.6); 4.2 (2.7 to 6.5) respectively, all $P < .001$); 9 times more likely to have TSH checked (9.1 (6.2 to 13.2) $P < .001$); and twice as likely to have UACR checked (2.7 (2.0 to 3.6) $P < .001$). The overall probability of receiving screening more than doubled for hypercholesterolemia (adjusted OR 2.4 (95% CI: 1.6 to 3.0)); creatinine (2.5 (1.6 to 3.9)); UACR (2.3 (1.9 to 2.8)); and foot screening (2.9 (2.3 to 3.6)), all $P < .001$. Screening for hypothyroidism decreased slightly (0.8 (0.7 to 1.0), $P = .035$) (see Figure 3).

Clinical Outcomes

A CDSS message was generated for 5692 cases in total (including the 1883 cases visiting clinic). Of these, 5245 were successfully matched to two controls. An additional 187 cases were matched to one control, resulting in a total control population of 10 677. The remaining 260 cases were unable to be matched on the defined criteria and so were excluded from analysis.

There were no significant differences between cases and controls in terms of demographic variables nor HbA1c baseline (71.4 mmol/mol (6.5%) vs 70.6 (6.5%), $P = .086$). Baseline cholesterol, SBP and UACR were significantly greater in controls ($P < .001$, $P < .001$, $P = .028$ respectively) and baseline DBP was significantly higher in cases ($P < .001$) (see Table 2).

Paired baseline-follow-up HbA1c values were available for 2662/5432 (47%) cases and 6203/10 677 (58%) controls. Both cases and controls showed small, but significant improvements in HbA1c (mean change in HbA1c: ,2.3 mmol/l (–0.2%) vs –1.1 (–0.1%), B 1.2 95% CI 0.4 to 2.0, $P = .003$). There were no significant differences in change in cholesterol and DBP between the groups. SBP improved more among controls (mean change in SBP: –1.3 mmHg vs –3.3, B –2.0, 95% CI: –3.0 to –1.0, $P < .001$). UACR increased in both groups but significantly more in the control group (mean change in UACR: 1.6 vs 4.4, B 2.9, 95% CI 0.7 to 5.1, $P = .01$) (see Table 2).

Discussion

This study showed that the use of the CDSS has not had any demonstrable adverse effects on patient experience, clinic consultation or working practices. In addition, this study has demonstrated improved HCP adherence to guideline-driven care. There may also be potential efficiencies and wider cost savings by decision prompts which negate the need for wider interrogation of the medical record. The modest improvements demonstrated in glycemic control have the potential to reduce diabetes-related complications in the long term. These findings are in keeping with other smaller studies assessing the effects of CDSS on the management of long-term conditions, including diabetes.[17] This study further adds to the evidence base by demonstrating how an iterative, quality improvement approach can lead to effective implementation at a population level with large improvements in adherence to guidelines.

This study has also identified differences in working patterns between members of the multidisciplinary team. When subject to a CDSS prompt, on average, doctors would spend less time within the patient record. This may reflect focus group findings that the system enables a more targeted approach to consultations. In contrast to doctors, nurses' time within the clinical record was unchanged by the CDSS, however their interaction with the system increased (as measured by user clicks). In this case, the CDSS may be acting as a catalyst for users to increase their data entry and is consistent with the questionnaire findings that nurses had greater performance expectancy. Regardless of such supposition, it is worth noting that any change in consultation style or efficiencies had no demonstrable negative impact on patients' experience of the consultation, as measured by PREMs.

Diabetes-related complications place a substantial burden on health care services. It has been estimated that the overall cost of diabetes within the United Kingdom in 2010/11 was £23.7 billion, with direct costs equivalent to approximately 10% of NHS annual spending.[33] As disease

prevalence increases, it is estimated that by 2035 this proportion will rise to 17% of health spending in the United Kingdom. Small improvements in glycemic control are associated with considerable long-term savings due to reduced complications.[34]

Table 1. Adherence to Guidelines in Cases and Controls, Before and After Clinic Appointment.

	Preclinic			Postclinic		
	Cases (n = 1883)	Controls (n = 3557)	*P*	Cases, n(%)	Controls, n(%)	*P*
Foot screening	1440 (76.5%)	2612 (73.4%)	.008	243/443 (54.9%)	281/945 (29.7%)	<.001
TSH	1176 (62.5%)	2457 (69.1%)	<.001	229/707 (32.4%)	408/1100 (37.1%)	.02
Creatinine	1677 (89.1%)	3305 (92.9%)	<.001	168/206 (81.6)	162/252 (64.3%)	<.001
Cholesterol	1541 (81.8%)	3115 (87.6%)	<.001	236/342 (69.0%)	213/442 (48.2%)	<.001
UACR	1205 (64.0%)	2305 (64.8%)	.287	277/678 (40.9%)	287/1252 (22.9%)	<.001

Preclinic data are those patients who have had a screening test in the preceding 15 months (or TSH within 24 months). Postclinic data relate to patients who did not have screening test prior to clinic but went on to receive test in 30 days following clinic appointment.

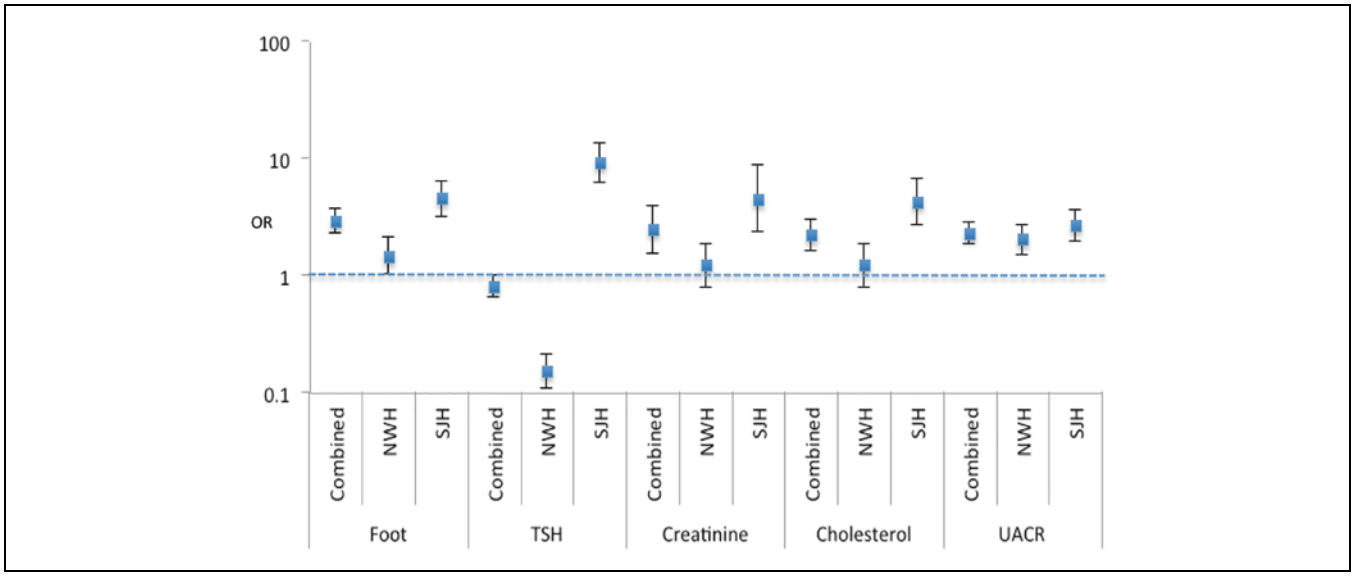

Figure 3. Adjusted odds ratios for each of the primary outcomes, stratified by site. Odds represent the probability of a case receiving screening for the complications of diabetes following a clinic appointment, compared with controls. Adjusted for age, diabetes type and duration, gender and BMI. NWH, Ninewells hospital; SJH, St John's hospital; OR, Odds ratio (log scale); TSH, Thyroid stimulating hormone; UACR, urinary albumin/creatinine ratio.

Table 2. Linear Regression Used to Determine Significance of Patient Group as a Predictor of Clinical Outcomes.

	Cases, mean (SD)			Controls, mean (SD)			Mean difference (95% CI), univariable *P*	Multivariable *P*
	Baseline	Follow-up	Change	Baseline	Follow-up	Change		
HbA1c (mmol/mol)	71.4 (19.7)	69.1 (17.9)	–2.3 (16.8)	70.6 (19.8)	69.5 (18.2)	–1.1 (17.3)	–1.2 (–2.0 to –0.4), *P* = .002	*P* = .003
Cholesterol (mmol/l)	4.2 (1.1)	4.1 (1.1)	–0.1 (0.8)	4.3 (1.1)	4.3 (1.1)	–0.05 (0.0)	0.0 (–0.1 to 0.0), *P* = .549	—
SBP (mmHg)	136.5 (18.5)	135.2 (17.6)	–1.3 (19.5)	137.8 (19.9)	134.5 (8.1)	–3.3 (20.4)	2.0 (1.0 to 2.9), *P* < .001	*P* < .001
DBP (mmHg)	75.7 (10.8)	75.0 (10.6)	–0.8 (11.2)	74.5 (12.0)	73.4 (10.9)	–1.1 (12.4)	0.4 (–0.2 to 0.9), *P* = .244	*P* = .226
UACR	8.7 (20.2)	10.3 (24.4)	1.6 (19.8)	9.3 (18.6)	13.7 (37.3)	4.4 (30.0)	–2.7 (–5.0 to –0.5), *P* = .015	*P* = .01

All predictors with *P* < .3 entered into multivariable model. Potential confounders entered into multivariable model included patient age, diabetes type, gender, duration of diabetes, and BMI.

As the prevalence of diabetes grows, so too does the role of primary care in delivering care.[35] Primary care HCPs are tasked with navigating between multiple guidelines in an effort to deliver effective care to a population with increasing comorbidities.[13] In this context, the potential utility of decision support systems becomes increasingly apparent.

There are a number of limitations in study design that limit the generalizability of our findings. Questionnaire response rate was generally low and focus groups were based on convenience samples of HCPs. The proxy measures of user-interaction with the system (mouse "clicks" and time spent within the case record) were blunt instruments. When analyzing QPIs, controls were closely matched to cases by demographic variables, but there was no ability to match local clinical practice. All centers follow the same national guidance,[1] however it is acknowledge that practice will likely vary by center, as borne out by the comparison of guideline

adherence at baseline. It is notable that these observed differences in adherence at baseline were often in the opposite direction to the differences observed at follow-up, suggesting that the intervention had a real impact.

Future work should include further analysis of emergent data; widening the scope of the investigation to cover additional clinical outcomes (eg, prescribing practices); the development and implementation of additional rule-based algorithms based on further user feedback and emerging literature/guidelines; and the effect of tailoring of messages to user group (HCPs and patients).

Conclusions

The diabetes digital landscape is evolving at a rapid pace. Scotland's national informatics platform for diabetes ensures that widespread implementation of a CDSS is technically straightforward. This work could easily be adapted to systems within other countries as well as other chronic diseases. This project can be viewed as an exemplar for other health care organizations considering such innovations with the potential to improve the safety, quality, and standardization of diabetes care.

Abbreviations

ACE, angiotensin converting enzyme; BMI, body mass index; CDSS, clinical decision support systems; CI, confidence interval; DBP, diastolic blood pressure; EBMeDS, evidence-based medicine electronic decision support; GP, general practitioner; HbA1c, hemoglobin A1c; HCP, health care professional; IDF, International Diabetes Federation; IQR, interquartile range; NHS, National Health Service; NWH, Ninewells Hospital; OR, odds ratio; PREMs, patient-reported experience measures; QPI, quality performance indicator; SBP, systolic blood pressure; SD, standard deviation; SJH, St John's Hospital; TSH, thyroid stimulating hormone; UACR, urinary albumin/creatinine ratio; UI, user interface; UK, United Kingdom; UTAUT, unified theory of acceptance and use of technology.

Acknowledgments

We acknowledge the help and support of staff and patients of NHS Tayside and NHS Lothian.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: PN is employed by Duodecim Medical Publications, developers and owners of the EBMeDS proprietary system that was used in this study.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by a grant from the Digital Health & Care Institute.

References

1. Scottish Intercollegiate Guidelines Network. 116. *Management of Diabetes. A National Clinical Guideline*. 2010. Available at: http://www.sign.ac.uk/pdf/sign116.pdf. [AQ2]
2. National Institute for Health and Care Excellence. *Diagnosis and Management of Type 1 Diabetes in Children, Young People and Adults (CG15)*. 2004. Available at: http://guidance.nice.org.uk/CG15.
3. National Institute for Health and Care Excellence. *Type 2 Diabetes: The Management of Type 2 Diabetes (CG87)*. 2009. Available at: http://publications.nice.org.uk/type-2-diabetes-cg87. [AQ3]
4. Cunningham S, McAlpine R, Leese G, et al. Databases for diabetes epidemiology: using web technology to support population-based diabetes care. *J Diabetes Sci Technol*. 2011;5(3):523.
5. Scottish Diabetes Survey Monitoring Group. *Scottish Diabetes Survey 2015*. 2015. Available at: http://diabetesinscotland.org.uk/Publications/SDS2015.pdf. Accessed July 26, 2017.
6. Scottish Diabetes Survey Monitoring Group. *Scottish Diabetes Survey 2014*. 2014. Available at: http://www.diabetesinscotland.org.uk/Publications/SDS2014.pdf.
7. Schofield CJ, Yu N, Jain AS, Leese GP. Decreasing amputation rates in patients with diabetes—a population-based study. *Diabet Med*. 2009;26(8):773-777.
8. Vallance JH, Wilson PJ, Leese GP, McAlpine R, MacEwen CJ, Ellis JD. Diabetic retinopathy: more patients, less laser: a longitudinal population-based study in Tayside, Scotland. *Diabetes Care*. 2008;31(6):1126-1131.
9. McKnight JA, Wild SH, Lamb MJE, et al. Glycaemic control of Type 1 diabetes in clinical practice early in the 21st century: an international comparison. *Diabet Med*. 2015;32(8):1036-1050.
10. McGlynn E, Asch S. The quality of health care delivered to adults in the United States. *N Engl J Med*. 2003;348:2635-2645.
11. Lugtenberg M, Burgers J, Clancy C, Westert G, Schneider E. Current guidelines have limited applicability to patients with comorbid conditions: a systematic analysis of evidence-based guidelines. *PLOS ONE*. 2011;6(10):e25987.
12. Nobili A, Garattini S, Mannucci P. Multiple diseases and polypharmacy in the elderly: challenges for the internist of the third millennium. *J Comorbidity*. 2011;1:28-44.
13. Guthrie B, Payne K, Alderson P, McMurdo MET, Mercer SW. Adapting clinical guidelines to take account of multimorbidity. *BMJ*. 2012;345:e6341.
14. Scottish Government. *The Healthcare Quality Strategy for NHS Scotland*. 2010. Available at: http://www.scotland.gov.uk/Resource/Doc/311667/0098354.pdf.
15. Scottish Government. *NHS Scotland eHealth Strategy 2014-2017*. 2015. Available at: http://www.gov.scot/Resource/0047/00472754.pdf.
16. Bero L, Grilli R, Grimshaw J, Harvey E, Oxman A, MA T. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. *BMJ*. 1998;317:465.
17. Garg AX, Adhikari NKJ, McDonald H, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes. *JAMA*. 2005;293(10):1223-1238.
18. Duodecim Medical Publications Ltd. EBMeDS clinical decision support. 2014. Available at: http://www.ebmeds.org/

web/guest/home?p_id=129190&b_id=129273&s_id=129273&lang=en.
19. Duodecim Medical Publications Ltd. Scripts—EBMeDS. 2015. Available at: http://www.ebmeds.org/web/guest/scripts?p_id=130805&b_id=130801&s_id=130801&lang=en. Accessed July 26, 2017.
20. UK National Institute for Health and Care Excellence. *NICE Accreditation*. 2017. Available at: https://www.nice.org.uk/about/what-we-do/accreditation. Accessed July 30, 2017.
21. Sönnichsen A, Trampisch US, Rieckert A, et al. Polypharmacy in chronic diseases—reduction of inappropriate medication and adverse drug events in older populations by electronic decision support (PRIMA-eDS): study protocol for a randomized controlled trial. *Trials*. 2016;17(1):57.
22. Moja L, Polo Friz H, Capobussi M, et al. Implementing an evidence-based computerized decision support system to improve patient care in a general hospital: the CODES study protocol for a randomized controlled trial. *Implement Sci*. 2015;11(1):89.
23. Kortteisto T, Raitanen J, Komulainen J, et al. Patient-specific computer-based decision support in primary healthcare—a randomized trial. *Implement Sci*. 2014;9(1):15.
24. Heselmans A, Van de Velde S, Ramaekers D, Vander Stichele R, Aertgeerts B. Feasibility and impact of an evidence-based electronic decision support system for diabetes care in family medicine: protocol for a cluster randomized controlled trial. *Implement Sci*. 2013;8(1):83.
25. Moja L, Passardi A, Capobussi M, et al. Implementing an evidence-based computerized decision support system linked to electronic health records to improve care for cancer patients: the ONCO-CODES study protocol for a randomized controlled trial. *Implement Sci*. 2016;11(1):153.
26. GOV.UK. UK Caldicott Guardian Council. Available at: https://www.gov.uk/government/groups/uk-caldicott-guardian-council. Accessed July 26, 2017.
27. Department of Health. Outpatients Questionnaire. 2011:1-19. Available at: http://www.nhssurveys.org/Filestore//documents/Outpatient_allquestions.pdf.
28. Scottish Government. Patient Experience Survey of GP and Local NHS Services 2011/12 volume 2: technical report. 2011. Available at: http://www.gov.scot/Publications/2012/05/1477/12.
29. Venkatesh V, Morris MG, Davis GB, Davis FD. User acceptance of information technology: toward a unified view. *MIS Q*. 2003:425-478.
30. Heselmans A, Aertgeerts B, Donceel P, Geens S, Van de Velde S, Ramaekers D. Family physicians' perceptions and use of electronic clinical decision support during the first year of implementation. *J Med Syst*. 2012;36(6):3677-3684.
31. Diabetes in Scotland. Foot Action Group. Available at: http://www.diabetesinscotland.org.uk/Groups.aspx?catId=C4. Accessed December 15, 2016.
32. Scottish Diabetes Survey Monitoring Group. *Scottish Diabetes Survey 2012*. 2012. Available at: http://www.diabetesinscotland.org.uk/Publications/SDS 2012.pdf.
33. Hex N, Bartlett C, Wright D, Taylor M, Varley D. Estimating the current and future costs of type 1 and type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabet Med*. 2012;29(7):855-862.
34. Baxter M, Hudson R, Mahon J, et al. Estimating the impact of better management of glycaemic control in adults with type 1 and type 2 diabetes on the number of clinical complications and the associated financial benefit. *Diabet Med*. 2016;33(11):1575-1581.
35. Care Quality Commission. *My Diabetes, My Care*. 2016. Available at: http://www.cqc.org.uk/sites/default/files/20160907_CQC_Diabetes_final_copyrightnotice.pdf.