DR KAVITA SINGH (Orcid ID : 0000-0003-4330-666X)

Article type : Research Article

Title: Diabetic Medicine

Created by: Maria Davie

Email proofs to: nikhil_tandon@hotmail.com

Article no.: DME-2018-00015

Article type: Research Article

Short title/Authors running head: Decision-support EHR acceptability and impact on diabetes care goals • *K. Singh et al.*

Acceptability of a decision-support electronic health record system and its impact on diabetes care goals in South Asia: a mixed-methods evaluation of the CARRS trial

K. Singh[1,2,3], L. Johnson[4], R. Devarajan[5], R. Shivashankar[1,2], P. Sharma[6,7], D. Kondal[1], V. S. Ajay[1,2], K. M. Venkat Narayan[4], D. Prabhakaran[1,2], M. K. Ali[4] and N. Tandon[3]

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/dme.13804

[1]Centre for Chronic Conditions and Injuries, Public Health Foundation of India, Gurgaon, Haryana, India, [2]Centre for Chronic Disease Control, Gurgaon, Haryana, India, [3]Department of Endocrinology and Metabolism, All India Institute of Medical Sciences, New Delhi, India, [4]Rollins School of Public Health, Emory University, Atlanta,GA, USA, [5]Centre of Excellence - Centre for Cardio-metabolic Risk Reduction in South Asia, [6]St. Georges Medical University of London, London, UK and [7]Plovdiv Medical University, Plovdiv, Bulgaria

Correspondence to: Nikhil Tandon. Email: nikhil_tandon@hotmail.com

What's new?

- This is the first study to quantify the impact of physicians' acceptance of decision-support electronic health records (DS-EHR) on diabetes care goals in South Asia using a mixed-methods evaluation.
- The study shows that physicians' adherence to DS-EHR prompts with regard to diabetes management was associated with significantly large improvements in blood pressure and LDL cholesterol levels and small reductions in HbA_{1c} levels.
- The study results provide perspectives from busy healthcare providers in South Asia on the relative benefits, challenges and value of DS-EHR, which has implications for wider adoption and scale-up of this intervention.

Abstract

Aims To describe physicians' acceptance of decision-support electronic health record system and its impact on diabetes care goals among people with Type 2 diabetes.

Methods We analysed data from participants in the Centre for Cardiometabolic Risk Reduction in South Asia (CARRS) trial, who received the study intervention (care coordinators and use of a decision-support electronic health record system; *n*=575) using generalized estimating equations to estimate the association between acceptance/rejection of decision-support system prompts and outcomes (mean changes in HbA_{1c}, blood pressure and LDL cholesterol) considering repeated measures across all time points available. We conducted in-depth interviews with physicians to understand the benefits, challenges and value of the decision-support electronic health record system and analysed physicians' interviews using Rogers' diffusion of innovation theory.

Results At end-of-trial, participants with diabetes for whom glycaemic, systolic blood pressure, diastolic blood pressure and LDL cholesterol decision-support electronic health record prompts were accepted vs rejected, experienced no reduction in HbA_{1c} [mean difference: –0.05 mmol/mol (95% CI –0.22, 0.13); *P*=0.599], but statistically significant improvements were observed for systolic blood pressure [mean difference: –11.6 mmHg (95% CI –13.9, –9.3); $P \leq 0.001$], diastolic blood pressure [mean difference: –5.2 mmHg (95% CI –6.5, –3.8); $P \leq 0.001$] and LDL cholesterol [mean difference: –0.7 mmol/l (95% CI –0.6, –0.8); $P \leq 0.001$], respectively. The relative advantages and compatibility of the decision-support electronic health record system with existing clinic set-ups influenced physicians' acceptance of it. Software complexities and data entry challenges could be overcome by task-sharing.

Conclusion Wider adherence to decision-support electronic health record prompts could potentially improve diabetes goal achievement, particularly when accompanied by assistance from a non-physician health worker.

Introduction

Diabetes is a major public health concern worldwide [1–3], and a condition which requires regular medical care and patient self-management education to prevent future complications [4–6]. Approximately half of people with diabetes, however, do not achieve glycaemic, blood pressure (BP) and lipid level targets [7]. Healthcare systems in low- and middle-income countries, for example, in South Asia, are ill-equipped to cope with escalating diabetes burdens. Several provider-, patient- and health system-level barriers hinder achievement of diabetes care goals. Examples of physician barriers include insufficient time, lack of knowledge regarding updated treatment guidelines, and poor record keeping. People with diabetes often lack awareness of risk factors, have difficulties adhering to medications, find treatments expensive, and have inaccurate perceptions of the disease [4,8]. Health system barriers include fragmented healthcare delivery, lack of follow-up visit planning, non-availability of drugs, and limited insurance coverage [9]. For these reasons, context-specific and cost-effective models of integrated healthcare delivery are required in resource-constrained settings to improve the quality of diabetes care delivery and reduce the number of costly diabetes complications [10–13].

To overcome these barriers, we designed and demonstrated the effectiveness of a multicomponent intervention consisting of decision-support electronic health records (DS-EHR) and non-physician care coordinators in the randomized controlled Centre for Cardiometabolic Risk Reduction in South Asia (CARRS) trial [14]. To inform wider

adoption and implementation of DS-EHR in routine practice in South Asia, however, more data are needed to help clinicians assess the relative benefits, challenges and value of DS-EHR. The diffusion of innovation theory has been commonly used to study the adoption of technology, and has more recently been applied within healthcare settings to understand the adoption of different types of computerized healthcare services and information technologies [15–17]. The aim of the present study was to describe physicians' acceptance of DS-EHR prompts and the impact of this system on achievement of diabetes care goals among people with Type 2 diabetes using a mixed-methods evaluation of the CARRS trial.

Methods

Research setting

A diverse mix of 10 publicly funded, semi-private and private outpatient diabetes clinics in India and Pakistan were involved in this mixed-methods evaluation. Each participating centre was led by a site principal investigator (senior endocrinologist) and supported by one or two co-investigators. Institutional ethics committees at each participating centre and the research coordinating centres, the Public Health Foundation of India, Gurgaon and Emory University, Atlanta, GA, USA, approved the study. All participants gave written informed consent prior to participating. Figure 1 shows the study flow and mixed-methods analysis nested in the CARRS trial. The CARRS trial enrolled a total of 1146 participants (intervention group, n = 575; usual care group, n = 571). In the present study, we restricted our analysis to participants in the intervention group for whom data on acceptance or rejection of DS-EHR prompts were available at 12-month, 24-month and end-of-study visits to understand the acceptability and impact of DS-EHR on risk factors.

Design and implementation of the DS-EHR

The DS-EHR software was designed by a Delhi-based e-health software company, with significant inputs from the research team for specifications and iterative testing. The DS-EHR was integrated into the existing set-up at all participating centres, with technical support from the RCC on request.

Details of the intervention components have been published previously [14]. Briefly, the DS-EHR stored all consultations, laboratory, self-care and adverse event data for participants in one easily accessible portal that could be used to monitor participant progress and that provided decision-support system (DSS) prompts regarding guideline-recommended glycaemic (HbA_{1c}), BP and lipid goals (Appendix S1).

The care coordinator fully managed the DS-EHR data entry for intervention group participants and all communication of DSS prompts to the physician during consultations via print-out or electronic display. Physicians could, at their discretion, accept or reject DSS prompts and modify treatment plans based on clinical judgement, so long as justification was provided. The DS-EHR logged physician acceptances/rejections of treatment prompts. Additionally, HbA_{1c}, BP and LDL cholesterol values were recorded for all participants with diabetes at baseline, during, and at end-of-study (mean follow-up 30 months).

DS-EHR prompt analysis

We conducted an observational analysis of the participants in the intervention arm of the CARRS trial. The primary exposure was physician adherence to DSS prompts (whether the DSS prompt was accepted) and the primary outcomes were longitudinal changes in the participants' mean HbA_{1c}, BP and LDL cholesterol levels at the 12-month, 24-month and end-of-study assessments. We estimated the mean changes in outcomes associated with DSS

adherence using linear regression with generalized estimating equations to account for the correlation of observations within participants over the three time points [18,19]. The linear model included an indicator of adherence to the DSS prompt, time of assessment, and an interaction term between adherence to the DSS prompt and time of assessment. The model was also adjusted for age, sex, duration of diabetes, BMI, and the corresponding baseline values of HbA_{1c}, BP and LDL cholesterol, respectively.

We also examined achievement of multiple risk factor control [defined as HbA_{1c} <53 mmol/mol (<7%) and BP <130/80 mmHg or LDL cholesterol <2.6 mmol/l (<100 mg/dl)] as an outcome. The longitudinal odds of meeting multiple risk factor control targets were analysed using logistic regression with generalized estimating equations, also incorporating all time points available. The model was adjusted for the same variables as for the linear regression generalized estimating equation model. All generalized estimating equation analyses were performed using STATA 14.1 version (College Station, TX, USA; Appendix S2).

Physician interviews

We conducted in-depth interviews in English with site physicians who were involved in implementation of the intervention. The interviews aimed to collect information on physicians' diabetes care practices and their views on the multicomponent intervention. Physicians' perceptions of the DS-EHR were captured longitudinally throughout the implementation process, with the same physicians being re-interviewed. A total of 39 interviews were conducted at baseline (prior to trial implementation; *n*=19), 1-year (interim; *n*= 9), and end-of-study (*n*=11). As a result of resource constraints, we included only a sub-sample at interim, and because of poor participant recruitment, one site was excluded at end-

of-study; however, saturation was achieved with this sample because physicians with expert knowledge of the implementation of the CARRS trial from each clinic were included.

We conducted interviews in-person (baseline and interim) and over the telephone (end-of-study). All interviews were audio recorded. A sample of the interview topic guide used at baseline, interim and end-of-study is provided in the Supporting Information (Appendix S3).

Interview data analysis

We transcribed and verified interview recordings verbatim. Guided by Rogers' diffusion of innovation theory, we developed a codebook with deductive codes representing the five characteristics of an innovation: 1) relative advantage (how the DS-EHR compared with the previously used care process in the clinic; 2) compatibility (how well the DS-EHR fitted in with the clinic/hospital's existing norms, values and beliefs of either the physicians); 3) acceptability (the physician's belief that the software was or was not appropriate within their care setting); 4) complexity (the degree to which physicians found the DS-EHR challenging to use), and 5) **observability** (degree to which the DS-EHR could be demonstrated prior to being implemented in the clinic/hospital). For quality assurance, authors L.J. and K.S. randomly selected three transcripts, representing baseline, interim and end-of-study interviews, for review and coding. We compared the coded transcripts for consistency in applying codes before the remaining transcripts were coded. All coding was completed using qualitative data analysis software (MAXQDA). Once coding was complete, we thematically analysed the data segments within each code [20].

Results

Physician demographics

The mean (±SD) age of physicians was 43 (±8) years, 80% of them were men, all were trained in endocrinology, they had a mean (±SD) length of diabetes practice of 13 (±6) years, and one-third worked at government hospitals. From 2011 to 2014, the DSS generated 3365 glycaemic, 3446 BP, and 3288 lipid target prompts. Overall, physicians' acceptance rates of glycaemic, BP and LDL cholesterol target prompts were 54.5%, 79.2% and 71.1%, respectively.

DS-EHR prompt adherence and impact on diabetes care goals

At end-of-trial, compared with participants for whom glycaemic, systolic BP, diastolic BP and LDL cholesterol DS-EHR prompts were rejected, participants for whom the prompts were accepted experienced no reduction in HbA_{1c} [mean difference: –0.05 mmol/mol (95% CI –0.22, 0.13); P =0.599], but statistically significant improvements in systolic BP [mean difference: –11.6 mmHg (95% CI –13.9, –9.3); $P \leq 0.001$], diastolic BP [mean difference: –5.2 mmHg (95% CI –6.5, –3.8); $P \leq 0.001$] and LDL cholesterol were observed [mean difference: –0.7 mmol/l (95% CI –0.6, –0.8) or –28.3 mg/dl (95% CI –31.6, –25.0); $P \leq 0.001$ (Table 1a)]. Using a different approach (as a sensitivity analysis) to demonstrate the change in risk factors by 'level of adherence' to DSS prompts, we obtained similar results (Table 1b and Fig. 1a–d). Also, in the group for whom glycaemic, BP and lipid prompts were accepted a greater proportion of participants achieved multiple risk factor control than in the group for whom these prompts were rejected: 24.7% vs 10.1% (P <0.001),19.5% vs. 12.2% (P <0.02), and 21.1% vs 10.2% (P <0.001), respectively (Table 2).

Physicians more frequently accepted DS-EHR prompts 'reinforce lifestyle counselling' and 'continue with existing regimen' (87–95%) than prompts relating to uptitration of medication (24–45%) or addition of insulin (54%; Table 3).

Innovation factors over time

Relative advantage

Baseline. In comparison with using paper records, physicians anticipated that DS-EHR would allow them to more efficiently track participants' health indicators across clinic visits. One physician noted that such a system would make it easier for people with diabetes to switch to another facility because the clinic would be able to provide them with a printed report.

Because no clinic was using a treatment algorithm prior to the CARRS trial, the physicians anticipated benefitting from the up-to-date treatment guideline reminders. Most physicians assumed the software functionality would allow them to query clinic-level data on participants' outcomes, giving them the advantage of being able to audit their clinic, improve diabetes care practices, and document burden of disease.

Interim. All but one of the physicians stated that the DS-EHR was advantageous to their practice, with the majority stating that they benefitted from having historical and current reports with participants' laboratory results. The prompts forced physicians to take more time to consider their treatment decisions because they rejected the DSS prompt and needed to justify it. One physician stated, '[the DS-EHR] has made me think 10 times as to whether I am achieving standard of care or not.' Treatment prompts were commonly perceived to reduce the occurrence of treatment errors in clinic. The consensus among physicians reached

was that prompts are well suited to high-volume clinics where physicians have less time to consult with people with diabetes.

End-of-study. Perceived benefits of the DS-EHR after 36 months of implementation included increasing consistency in diabetes care, having readily accessible patient information, and increasing physicians' confidence in diabetes care practices. In reflecting on the DS-EHR prompts, physicians from all clinics highlighted that the intervention improved their monitoring of LDL cholesterol. Additionally, as one physician commented, 'It saves a lot of time because we have all the previous values on the sheet that made it very easy to have a decision', emphasizing the ease of use and time-saving characteristics of the DS-EHR, compared with usual consultation practices.

Complexity

Baseline. Although they did not get to test the system before installation, physicians were trained on the study protocol and use of the DS-EHR. The consensus after training was that the software would better facilitate patient follow-up care.

Interim. Physicians found that the software's limitations inhibited ease of use by making them spend more time considering and rejecting flawed prompts. The most frequently cited flawed prompt occurred where people with diabetes were adherent to medication, diet and exercise, but, because their biochemical variables did not change in the short term, the prompts recommended medication increases without permitting participants additional time for their lifestyle changes to deliver physiological benefits. One physician also expressed frustration over the software's data entry requirements, stating it was 'tedious' for care coordinators and could result in incorrect prompts if newer laboratory reports were not available for all required components. Another physician explained, 'It is useful, but the thing

is we have to call the patient first to take a sample then the report will come afterward, then once again he [the participant with diabetes] has to come for review'. The number of steps required to fully use the DSS increased the perceived complexity of the software.

End-of-study. At end-of-study, physicians noted that the DS-EHR was straightforward in the type of data it required, but physicians had to take into account situations where the software would provide unsuitable prompts before taking next steps. These situations occurred when: (1) physicians wanted to allow more time for the participants with diabetes to change their behaviour; (2) a lack of new biochemical data led to repeat prompts to increase medication dosages; and (3) the participants with diabetes showed trends towards improvement, but were still out of range for controlled target values. Despite these gaps in software functionality, physicians found the rejection option to be an easy way of overriding the DS-EHR prompt.

Compatibility

Baseline. Physicians reported two different processes of clinic flow: (1) having participants register, complete tests and consult with the physician on the same day at their clinic or (2) having participants complete tests at the same clinic or at a clinic near their home and then bring reports to their clinic on another day. All the physicians noted the value of diet and lifestyle education for participants, complementary to medication adherence, and hoped that the addition of the care coordinator and DS-EHR would better facilitate responsive, holistic care after the transition to e-records. Physicians in private hospitals had mixed feelings about how receptive people with diabetes would be to receiving reminders for follow-up care, some fearing that they would think their clinic was trying to make money from more frequent visits.

Interim. Physicians identified two major areas of need in their clinics that the DS-EHR would help address: (1) targeting high-risk participants, and (2) timely access to participant records. As diabetes specialists, there was little perceived need for the DSS because physicians felt that they were aware of treatment targets and guidelines for care. At least one clinic reported not using the DSS prompts at all in their practice. The remaining clinics viewed the treatment prompts as a safety-net system that would replace the junior colleagues who usually take histories and assist in consultations with people with diabetes.

End-of-study. Perceptions of compatibility were different when physicians considered how it affected their role vs that of the care coordinator, and clinic operations, separately. Physicians recognized that the processes required by the DS-EHR system can be time-consuming, but because the care coordinator's managed those tasks, they found their role did not change much with this intervention.

The issue of physician time constraint repeatedly surfaced, as captured in the following physician statement: 'The biggest problem is that this hospital has such a big OPD [outpatient department] …[that], you would look at the patient ..and within 2 or 3 minutes you would come to a conclusion as to what needs to be done, in this there are times when you miss doing things which were supposed to be done in that particular time.' It was a common perception that the DS-EHR would support decision-making in these short consultations, particularly in primary care settings where physicians did not have specialized knowledge of diabetes treatment guidelines.

Observability

Baseline. The DS-EHR was not being tested or used by the clinics prior to implementation.

Interim. Physicians reported a visible improvement in the efficiency of clinic processes and procedures. One physician added, 'DS-EHR is useful, it keeps all the data, saves space', emphasizing the physical benefits of moving to an electronic record-keeping system.

Physicians agreed that having clinic records of the three previous visits was useful, as noted by one physician, 'If the patient comes to me today with the investigation, then I examine him today and based on today's report...the fact that I have historical data has helped me make better decisions.'

End-of-study. At end-of-study, physicians reported that they had improved follow-up time with participants and faster consultations, they felt there were fewer instances of overlooking an issue with LDL cholesterol or BP, and that their burden as a physician had been reduced.

Discussion

Physicians accepted a high proportion of DS-EHR BP and lipid level target prompts, and moderate to low proportions of physicians accepted glycaemic prompts in the present study. The improvements in achievement of diabetes goals mirrored prompt adherence: glycaemic control improved for all participants with diabetes, regardless of prompt adherence or rejection by their physicians, while BP and LDL cholesterol reductions were greater among those whose physicians accepted all DSS prompts. Physician interviews suggest that healthcare providers in diverse settings were supportive of a DS-EHR tool in their regular clinics that helped support the care of the people with diabetes in their, generally limited, consultation times. This study provides evidence that integrated DS-EHR can be effective in

changing routine behaviours amongst clinicians, as well as in achieving diabetes goals. The DS-EHR has a number of features that were noted to be critical to its success in the study (Fig. 2). These were provision of web-based clinical decision-support at the time and location of decision-making, and data entry challenges being handled by the care coordinator.

To some extent, the software reinforced adherence to current diabetes guidelines by reminding physicians to attend to all risk factors. In general, the software was least effective when the participant did not have recent laboratory values because, in those cases, the DSS prompts did not produce a valid diabetes management plan. Even though the use of the DS-EHR had the potential to lengthen consultation time, the physicians thought it helped improve participant engagement and quality of care. As they got used to it, the continued use of the DS-EHR tool led to physician-reported decreases in consultation time.

There are several probable reasons that explain the heterogeneity observed in the adherence to DSS prompts and improvements in HbA_{1c}, BP and LDL cholesterol levels. First, the traditional glucocentric care by diabetes-focused physicians meant that these sites already felt confident in managing glycaemia, whereas they had probably not been paying as much attention to lipid levels and BP, which the DSS prompts forced them to do. Second, the control of HbA_{1c} is far more complex than that of BP and LDL cholesterol, and given that the DSS prompts were unable to factor in participants' diet, physical activity and stressors, the DSS glycaemia prompts were not as accurate as were those for lipids or BP.

The analysis by the authors of a 2009 systematic review of randomized trials evaluating features predicting the success of computerized decision support for prescribing did not confirm that any particular feature was associated with improved patient outcomes because of the small number of studies and a lack of diversity of outcomes [21]; however, by using mixed-methods evaluation in the present study, we were able to suggest mechanisms

that may have been involved in DS-EHR-associated improvements in diabetes care goals. Despite differences in site-specific clinic norms at the pre-adoption phase, physicians supported the use of this intervention. After adopting the system, users found it was compatible with their practice norms, treatment knowledge and care values, which encouraged continued use. If issues related to complexity could be easily remedied, in this case by identifying where system gaps occur (if participants are advised to come with recent HbA_{1c}, LDL, BP results on scheduled visits, occurence of unsuitable prompts could be avoided and thereby their rejections) and using the DSS prompts rejection function when applicable, then physicians would continue to use the software because they felt the benefits outweighed the corrective efforts. Feedback from physicians showed that it is important to get 'buy-in' at pre-adoption for initial use, but unanticipated benefits (perceptions of reduced error, increased confidence, and having a safety net) identified at interim and end-of-study interviews played an important role in the continued use of the DS-EHR.

The improvements seen in glycaemia, BP and LDL cholesterol in the present study were consistent with a previously reported systematic review and meta-analysis of randomized trials evaluating the effectiveness of quality improvement strategies with regard to the management of diabetes [22]. That systematic review showed that quality improvement strategies reduced HbA_{1c} values by a mean difference of 0.37%, systolic BP by 3.13 mmHg and LDL cholesterol by 3.8 mg/dl. Larger reductions were noted in the present study as a result of higher baseline concentrations of HbA_{1c} [85 mmol/mol (9.9%)], systolic BP (144 mmHg) and LDL cholesterol [3.2 mmol/l (123.2 mg/dl)]. Furthermore, qualitative findings from the present study are similar to those of a recent study from Australia, which reported that an electronic decision-support tool was helpful to summarize patient information and provide reminders to physicians, and that it improved patient--physician communication [23].

The major strength of the present study is the use of mixed-methods evaluation of a rigorously conducted large randomized controlled trial with qualitative assessments at three different time points (baseline, interim, end-of-study) using standard interview tools.

The study also had some limitations. First, it was a *post hoc* secondary data analysis of the intervention arm of the CARRS trial and findings should be viewed as hypothesis-generating and should be tested in future studies. Second, the software algorithm was not updated during the study period; however, the final treatment plan was prescribed at physicians' discretion. Third, qualitative interviews may have been subject to social desirability bias, with site physicians being inclined to speak positively about the DS-EHR because they were willing participants who showed interest in the study. Although generalizability of the present study is limited by the restricted sample size, the variability in clinic type and geographic location make the study's findings representative of a multitude of factors influencing diabetes care in tertiary clinics in South Asia.

In the present study, a number of barriers were found to the use of the DS-EHR, which are consistent with previous reports: uncertainty about the optimal level of decision support, and resistance to DS-EHR use by time-conscious senior physicians [21,23]. DS-HER is believed to improve diabetes care goals through enhanced education and through reduced therapeutic inertia. The present real-world implementation trial shows that, with use of DS-EHR, small improvements in HbA_{1c} and significantly large reductions in BP and LDL cholesterol levels are possible. Further, there is scope for improvement in the DS-EHR such as factoring in medication and lifestyle change adherence and stressors, and using graphic reports to motivate self-management. Notably, to fully utilize the features of the DS-EHR, there is a need to deploy a trained care coordinator, for example, a nurse, dietitian, social worker or physician assistant to perform clinical assessments, enter participant data, and remind doctors and people with diabetes to adhere to recommended treatments.

Improvements in users' computer skills, compliance with technology, and the integration of 'open' EHR that are edited by both people with diabetes and healthcare providers, as well as the input of mobile smartphone tools, for example, to provide real-time support to users, may bring a new paradigm shift in the organization and delivery of diabetes care [24–26].

In conclusion, gGiven the high physician acceptance of DS-EHR prompts for people with Type 2 diabetes, there may be value in scaling up this intervention to primary care centres. The DS-EHR based treatment strategy can further be expanded to other chronic conditions to reduce disparities in healthcare safety and quality in resource-constrained settings.

Funding sources

The CARRS trial was funded in part by the National Heart, Lung, and Blood Institute, National Institutes of Health, US Department of Health and Human Services, under contract number HHSN268200900026C, and by United Health Group, Minneapolis, Minnesota. Several members of the research team at the Public Health Foundation of India and Emory University were supported by the Fogarty International Clinical Research Scholars and Fellows programme through grant number 5R24TW007988 from the National Institutes of Health, Fogarty International Center through Vanderbilt University, Emory Global Health Institute, and D43 NCDs in India Training Programme through award number 1D43HD05249 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and Fogarty International Center. K.S. was supported by the Fogarty International Center, National Institutes of Health, under award number D43TW008332 (ASCEND Research Network). M.K. A. is supported by the National Institute of Mental

Health supplemental grant under award number: R01MH100390-04S1. R.S. is supported by a Wellcome Trust Capacity Strengthening Strategic Award Extension phase to the Public Health Foundation of India and a consortium of UK universities (WT084754/Z/08/A). The funding sources were not involved in the data collection, analysis, writing or interpretation of the manuscript or the decision to submit it for publication.

Competing interests

None declared.

Acknowledgements

We acknowledge the contributions to this study of the software development team, Mr Prashant Tandon and Mr Ajeet Kushwaha.

References

1. IDF Diabetes Atlas 7th Edition. Available at http://www.diabetesatlas.org/atlas/atlas.html. Last accessed 15 March 2017.

2. Khan NA, Wang H, Anand S, Jin Y, Campbell NR, Pilote L *et al*. Ethnicity and sex affect diabetes incidence and outcomes. *Diabetes Care* 2011; **34**: 96–101.

3. Deepa M, Anjana RM, Manjula D, Narayan KM, Mohan V. Convergence of prevalence rates of diabetes and cardiometabolic risk factors in middle and low income groups in urban India: 10-year follow-up of the Chennai Urban Population Study. *J Diabetes Sci Technol* 2011; **5**:918–927.

4. Wangnoo SK, Maji D, Das AK, Rao PV, Moses A, Sethi B *et al*. Barriers and solutions to diabetes management: An Indian perspective. *Indian J Endocrinol Metab* 2013; **17**:594–601.

5. Deepa M, Grace M, Binukumar B, Pradeepa R, Roopa S, Khan HM *et al.* High burden of prediabetes and diabetes in three large cities in South Asia: The Center for cArdio-metabolic Risk Reduction in South Asia (CARRS) Study. *Diabetes Res Clin Pract* 2015;**110**:172–182.

6. Anjana RM, Deepa M, Pradeepa R, Mahanta J, Narain K, Das HK *et al.* Prevalence of diabetes and prediabetes in 15 states of India: results from the ICMR-INDIAB population-based cross-sectional study. *Lancet Diabetes Endocrinol* 2017; **5**:585–596.

7. Shivashankar R, Kirk K, Kim WC, Rouse C, Tandon N, Narayan KM *et al*. Quality of diabetes care in low- and middle-income Asian and Middle Eastern countries (1993-2012): 20-year systematic review. *Diabetes Res Clin Pract* 2015; **107**:203–223.

8. Sohal T, Sohal P, King-Shier KM, Khan NA. Barriers and Facilitators for Type-2 Diabetes Management in South Asians: A Systematic Review. *PLoS One* 2015; **10**:e0136202.

9. Ross SA. Breaking down patient and physician barriers to optimize glycemic control in type 2 diabetes. *Am J Med* 2013; **126**:S38–48.

10. Shojania KG, Ranji SR, McDonald KM, Grimshaw JM, Sundaram V, Rushakoff RJ *et al*. Effects of quality improvement strategies for type 2 diabetes on glycemic control: a meta-regression analysis. *JAMA* 2006; **296**: 427–440.

11. Worswick J, Wayne SC, Bennett R, Fiander M, Mayhew A, Weir MC *et al*. Improving quality of care for persons with diabetes: an overview of systematic reviews - what does the evidence tell us? *Syst Rev* 2013;**2**:26.

12. Davy C, Bleasel J, Liu H, Tchan M, Ponniah S, Brown A. Effectiveness of chronic care models: opportunities for improving healthcare practice and health outcomes: a systematic review. *BMC Health Serv Res* 2015;**15:**194.

13. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness: the chronic care model, Part 2. *JAMA* 2002; **288**:1909–1914.

14. Ali MK, Singh K, Kondal D, Devarajan R, Patel SA, Shivashankar R *et al*. Effectiveness of a Multicomponent Quality Improvement Strategy to Improve Achievement of Diabetes Care Goals: A Randomized, Controlled Trial. *Ann Intern Med* 2016; **165**:399–408.

15. Rogers EM, Singhal A. Diffusion of Innovations. New York, NY: The Free Press, 1962.

16. Rogers EM, Singhal A. Diffusion of Innovations. In: Salwen M, Mahwah SD (eds), *An Integrated Approach to Communication Theory and Research, 10th edn*. NJ: LEA, 2003.

17. Tomatzky LG, Klein KJ. Innovation characteristics and innovation adoption-implementation: A meta-analysis of findings. *IEEE Trans Eng Manag* 1982;**29**:28–45.

18. Pan W. Akaike's information criterion in generalized estimating equations. *Biometrics* 2001; **57**:120–125.

19. Hardin JW, Hilbe JM. Generalized Estimating Equations. Boca Raton, FL: Chapman & Hall/CRC, 2003.

20. Guest G. Applied thematic analysis. Thousand Oaks, CA: Sage, 2012.

21. Mollon B, Chong J, Jr, Holbrook AM, Sung M, Thabane L, Foster G. Features predicting the success of computerized decision support for prescribing: a systematic review of randomized controlled trials. *BMC Med Inform Decis Mak* 2009; **9**:11.

22. Tricco AC, Ivers NM, Grimshaw JM, Moher D, Turner L, Galipeau J *et al*. Effectiveness of quality improvement strategies on the management of diabetes: a systematic review and meta-analysis. *Lancet* 2012; **379**:2252–2261.

23. Wan Q, Makeham M, Zwar NA, Petche S. Qualitative evaluation of a diabetes electronic decision support tool: views of users. *BMC Med Inform Decis Mak* 2012;**12**:61.

24. Baker AM, Lafata JE, Ward RE, Whitehouse F, Divine G. A Web-based diabetes care management support system. *Jt Comm J Qual Improv* 2001; **27**:179–190.

25. Bu D, Pan E, Walker J, Adler-Milstein J, Kendrick D, Hook JM *et al.* Benefits of information technology-enabled diabetes management. *Diabetes Care* 2007; **30**:1137–1142.

26. Green CJ, Fortin P, Maclure M, Macgregor A, Robinson S. Information system support as a critical success factor for chronic disease management: Necessary but not sufficient. *Int J Med Inform* 2006;**75**:818–828.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Adherence to glycaemic, blood pressure (BP) and lipids decision-support system. prompts and mean change in HbA_{1c}, systolic BP, diastolic BP and LDL cholesterol, respectively.

Appendix S1. Example of Decision-Support Software Recommended Print-out prompts for Provider, Intervention group.

Appendix S2. GEE analysis description**.**

Appendix S3. CARRS trial - sample of interview topic guides**.**

FIGURE 1 Centre for Cardiometabolic Risk Reduction in South Asia (CARRS) trial schematic – mixed methods study design, participant flow and study measures. EHR, electronic health records; SBP, systolic blood pressure.

FIGURE 2 Innovation factors influencing the acceptability of decision-support electronic health records (DS-EHR) during the Centre for Cardiometabolic Risk Reduction in South Asia (CARRS) trial.

Table 1 (a) Adherence to decision-support electronic health record prompts and risk factor changes over the trial period

	Month 12	**Month 24**	**End-of-study**	**Overall**
Glycaemic outcomes				
Number of participants	493	244	471	
Glycaemic prompts accepted:				
Mean (SE) Hb**A$_{1c}$, mmol/mol**	68 (0.09)	65 (0.12)	67 (0.09)	67 (0.07)
Mean Hb**A$_{1c}$, %**	8.37	8.13	8.28	8.29
Glycaemic prompts rejected:				
Mean (SE) HbA$_{1c}$, **mmol/mol**	69 (0.1)	66 (0.12)	67 (0.1)	68 (0.07)
Mean HbA$_{1c}$, **%**	8.48	8.19	8.25	8.33
Difference (95% CI)	–0.10 (–0.35, 0.14)	–0.06 (–0.39, 0.26)	0.02 (–0.22, 0.27)	–0.05 (–0.22, 0.13)
P*	0.397	0.709	0.844	0.599
BP **outcomes**				
Number of participants	492	244	486	
BP **prompts accepted:**				
Mean (SE) systolic **BP, mmHg**	125.4 (0.73)	125.8 (0.98)	123 (0.72)	124.6 (0.52)
BP **prompts rejected:**				
Mean (SE) systolic **BP, mmHg**	137.2 (1.33)	136.6 (2.1)	135.3 (1.55)	136.3 (1.01)
Difference (95% CI)	–11.8 (–14.8, –8.8)	–10.8 (–15.3, –6.2)	–12.3 (–15.7, –8.9)	–11.6 (–13.9, –9.3)
P*	<0.001	<0.001	<0.001	<0.001
BP **prompts accepted:**				
Mean (SE) diastolic **BP**, **mmHg**	75.7 (0.43)	74.5 (0.58)	73.1 (0.43)	74.5 (0.32)
BP **prompts rejected:**				
Mean (SE) diastolic **BP**, **mmHg**	81.5 (0.78)	78.1 (1.23)	79.2 (0.91)	79.9 (0.6)
Difference (95% CI)	–5.8 (–7.6, –4.1)	–3.6 (–6.3, –1)	–6.1 (–8.1, –4.2)	–5.2 (–6.5, –3.8)
P*	<0.001	0.008	<0.001	<0.001
Lipids outcomes				
Number of participants	491	241	482	
Lipids prompts accepted:				
Mean (SE) **LDL cholesterol mmol/l**	2.3 (1.3)	2.3 (1.67)	2.2 (1.27)	2.3 (0.93)
Mean LDL cholesterol, mg/dl	90.0	88.6	85.2	87.8
Lipids prompts rejected:				
Mean (SE) **LDL cholesterol mmol/l**	3.0 (1.81)	3.1 (2.99)	2.9 (2.02)	2.9 (1.38)
Mean LDL cholesterol, mg/dl	117.6	120.1	111.0	115.5
Difference (95% CI)	–0.7 (–0.6, –0.8)	–0.8 (–0.6, –0.8)	–0.7 (–0.5, –0.8)	–0.7 (–0.6, –0.8)
P*	<0.001	<0.001	<0.001	<0.001

BP, blood pressure.

Overall mean differences were obtained via linear regression models using generalized estimating equations.

Model terms included: prompt accepted (yes/no), time, prompt accepted and time interaction, respective baseline value, age, gender, baseline BMI, duration of diabetes and site.

Difference = (prompt accepted – prompt rejected).

*Prompt accepted vs rejected at each time point.

See Appendix S2 for more details on statistical analysis methods.

Table 1 (b) Adherence to decision-support electronic health record prompts and risk factor changes over the trial period (*n* =558)

	All prompts rejected	Prompts accepted at any one annual visit	Prompts accepted at any two annual visits	All prompts accepted
Glycaemic prompts, *n* (%)	160 (28.7)	179 (32.1)	165 (29.6)	54 (9.7)
Mean (SD) HbA_{1c}, mmol/mol at 12 months, 24 months, end-of-study	70 (14.4)	68 (16.5)	64 (14.4)	65 (16.5)
Adjusted* mean HbA_{1c} (95% CI), mmol/mol	69 (66, 72)	67 (65, 69)	65 (62, 67)	68 (64, 73)
Mean (SD) baseline HbA_{1c}, mmol/mol	84 (14.4)	87 (15.4)	85 (15.4)	83 (14.4)
Mean (SD) end-of-study HbA_{1c}, mmol/mol	69 (15.4)	68 (18.5)	62 (16.5)	67 (15.4)
Mean (95% CI) change in HbA_{1c} from baseline to end-of-study*, mmol/mol	–13.4 (–16.5, –9.3)	–18.5 (–20.6, –15.4)	–17.5 (–19.6, –15.4)	–15.4 (–19.6, –12.4)
BP prompts, *n* (%)	73 (13.1)	122 (21.9)	238 (42.7)	125 (22.4)
Mean (SD) SBP, mmHg at 12 months, 24 months, end-of-study	144.5 (15.4)	134.2 (15.8)	123.1 (13.4)	121.4 (11.3)
Adjusted* mean (95% CI) systolic BP, mmHg	137.6 (133.8, 141.5)	131.9 (129.6, 134.1)	125.4 (123.9, 126.9)	121.6 (119.6, 123.6)
Mean (SD) diastolic BP, mmHg at 12 months, 24 months, end-of-study	81.9 (8.4)	78.9 (9.4)	74.4 (8.0)	72.7 (6.2)
Adjusted* mean (95% CI) diastolic BP, mmHg	80.2 (77.8, 82.5)	78.9 (77.5, 80.2)	74.7 (73.8, 75.6)	73.3 (72.1, 74.5)
Mean (SD) baseline systolic BP, mmHg	143.5 (19.0)	144.8 (18.4)	143.3 (18.3)	147.3 (20.8)
End-of-study systolic BP, mmHg	129.1 (19.5)	125.8 (19.6)	122.5 (16.7)	123.1 (16.1)
Mean change in SBP from baseline to end-of-study*(95%CI)	-7.3 (-12.8, -1.8)	-10.1 (-13.5, -6.7)	-19.9 (-21.8, -17.9)	-23.5 (-26.1, -20.9)
Mean (SD) baseline diastolic BP, mmHg	81.9 (10.9)	82.5 (11.9)	81.3 (9.6)	84.8 (11.3)
Mean (SD) end-of-study diastolic BP, mmHg	75.6 (9.7)	74.5 (10.2)	73.6 (9.5)	72.5 (10.5)
Mean (95% CI) change in diastolic BP from baseline to end-of-study*	–3.4 (–6.6, –0.2)	–2.2 (–4.2, -0.2)	–9.1 (–10.2, –7.9)	–10.4 (–11.9, –8.9)
Lipids prompts, *n* (%)	104 (18.6)	160 (28.7)	192 (34.4)	102 (18.3)
Mean (SD) LDL cholesterol at 12 months, 24 months, end-of-study, mmol/l	3.3 (0.6)	2.6 (0.6)	2.3 (0.5)	2.1 (0.4)
Adjusted* LDL cholesterol (95% CI), mmol/l	3.2 (3.1, 3.3)	2.5 (2.5, 2.6)	2.3 (2.3, 2.4)	2.2 (2.1, 2.3)
Mean (SD) baseline LDL cholesterol, mmol/l	3.3 (0.9)	3.0 (0.9)	3.1 (0.8)	3.2 (0.8)
Mean (SD) end-of-study LDL cholesterol, mmol/l	2.5 (0.8)	2.4 (0.7)	2.3 (0.6)	2.3 (0.6)
Mean (95% CI) change in LDL cholesterol from baseline to end-of-study*	–0.2 (–0.3, –0.1)	–0.7 (–0.8, –0.6)	–0.8 (–0.9, –0.7)	–1.1 (–1.2, –0.9)

BP, blood pressure.

*Multiple linear regression model adjusted for site, age, gender, baseline HbA_{1c}, systolic BP, diastolic BP and LDL cholesterol.

Statistical analysis method: We generated a predictor variable for acceptance or rejection of decision-support system prompts combining data of all time points together: 12 months, 24 months and end-of-study: all accepted, any two accepted, any one accepted or all rejected. We reported the average HbA1c considering all time points across the four categories of decision-support system prompts acceptance/rejection scenarios and a regression analysis was carried out to adjust for variables: site, age, gender. Also, we calculated mean changes in HbA_{1c}, BP, LDL cholesterol from baseline-to-end-of-study across the four categories of DS-EHR prompts adherence/rejection scenarios. We used multiple linear regression models to assess the mean changes in HbA_{1c}, BP and LDL cholesterol, by DS-EHR prompts adherence, adjusted for site, age, gender, and baseline values of HbA1c, BP and LDL cholesterol.

Table 2 Adherence to glycaemic, blood pressure and lipid level prompts and achievement of multiple risk factor control

	Multiple risk factor control achieved*			
	At 12 months	At 24 months	At end-of-study	Overall, %
Glycaemic prompts accepted, % (**SE**)				
Yes	21.5 (0.02)	23.6 (0.04)	28.7(0.03)	24.7 (0.02)
No	6.9 (0.02)	13.9 (0.03)	11.7 (0.02)	10.1 (0.01)
***P*†**	<0.001	0.045	<0.001	<0.001
BP **prompts accepted**, % (SE)				
Yes	16.8 (0.02)	20.2 (0.03)	21.9 (0.02)	19.5 (0.01)
No	10.1 (0.03)	12.2 (0.05)	14.4 (0.04)	12.2 (0.02)
P†	0.091	0.211	0.146	0.02

Lipid level **prompts accepted**, % (SE)				
Yes	18.7 (0.02)	22.7 (0.03)	22.9 (0.02)	21.1 (0.02)
No	8.5 (0.02)	5.3 (0.03)	14.4 (0.03)	10.2 (0.02)
P[†]	0.003	0.006	0.034	<0.001
Glycaemic + (BP **or** l**ipid** level**) prompts accepted**, % (SE)				
Yes	23.4 (0.03)	24.3 (0.04)	30.7 (0.03)	26.4 (0.02)
No	6.1 (0.02)	13.2 (0.03)	10.7 (0.02)	9.3 (0.01)
P[†]	<0.001	0.023	<0.001	<0.001
Glycaemic + BP + l**ipid** level **prompts accepted**, % (SE)				
Yes	24.4 (0.03)	25.1 (0.04)	31.2 (0.03)	27.2 (0.02)
No	9.9 (0.02)	14.5 (0.03)	13.9 (0.02)	12.4 (0.01)
P[†]	<0.001	<0.031	<0.001	<0.001

BP, blood pressure.

Marginal probabilities reported from generalized estimating equations logistic regression model. Model terms included- Prompt accepted (Yes/No), time, prompt accepted and time interaction, respective baseline values of HbA_{1c}, SBP, DBP and LDL cholesterol, age, gender, baseline BMI, duration of diabetes and site.

[*]Mutliple risk factor control definition: HbA_{1c}< 53mmol/mol or <7%, and BP: <130/80mmHg, or LDL cholesterol< 2.6 mmol/l or <100 mg/dl at end-of-study.

[†]Prompt accepted vs rejected at each time point.

See Appendix S2 for details of statistical analysis methods.

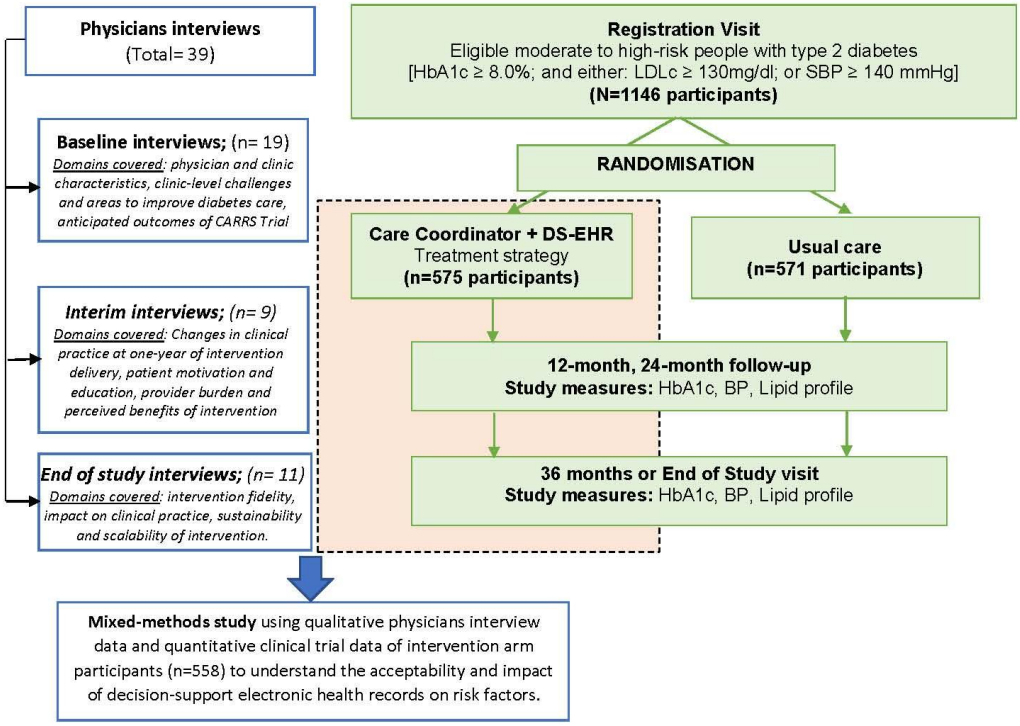
Table 3 Physician's adherence to different types of decision-support electronic health record prompts

Type of DSS prompts	Glycaemic prompts		BP prompts		Lipid level prompts	
	Total, *N*	Adherence, *n* (%)	Total, *N*	Adherence, *n* (%)	Total, *N*	Adherence, *n* (%)
Reinforce lifestyle counselling	87	80 (92)	221	205 (93)	-	-
Continue with existing regimen	151	131 (87)	654	615 (94)	753	715 (95)
Uptitration of oral hypoglycaemic agents or increase BP/cholesterol-lowering treatment by one increment	742	334 (45)	292	128 (44)	309	102 (33)
Add insulin/ uptitrate insulin or increase BP/lipid-lowering drugs by two increments	220	119 (54)	55	25 (45)	152	36 (24)

BP, blood pressure; NA, not applicable.

Definition for increase in BP/lipid-lowering treatment by one or two increment(s): see Appendix S4.

Figure 1: CARRS Trial schematic – mixed methods study design, participant flow and study measures



Abbreviations: CARRS=Centre for Cardiometabolic Risk Reduction in South Asia, DS-EHR=decision-support electronic health records; HbA1c=glycated haemoglobin, SBP=systolic blood pressure, LDLc=low-density lipoprotein cholesterol

Figure 2: Innovation factors influencing the acceptability of decision-support electronic health records (DS-EHR) during the CARRS Trial