

Medication intensification in diabetes in rural primary care: a cluster-randomised effectiveness trial

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ABSTRACT

Objective: To determine the effectiveness of a provider-based intervention to improve medication intensification among patients with diabetes.

Design: Effectiveness cluster-randomised trial. Baseline and follow-up cross-sections of diabetes physicians' patients.

Setting: Eleven U.S. Southeastern states, 2006–2008.

Participants: 205 Rural primary care physicians, 95 completed the study.

Intervention: Multicomponent interactive intervention including web-based continuing medical education (CME), performance feedback and quality improvement tools.

Primary outcome measures: Medication intensification, a dose increase of an existing medication or the addition of a new class of medication for glucose, blood pressure and lipids control on any of the three most recent office visits.

Results: Of 364 physicians attempting to register, 102 were randomised to the intervention and 103 to the control arms; 95 physicians (intervention, n=48; control, n=47) provided data on their 1182 of their patients at baseline (intervention, n=715; control, n=467) and 945 patients at follow-up (intervention, n=479; control, n=466). For A1c control, medication intensification increased in both groups (intervention, pre 26.4% vs post 32.6%, p=0.022; control, pre 24.8% vs post 31.1%, p=0.033) (intervention, adjusted OR (AOR) 1.37; 95% CI 1.06 to 1.76; control, AOR 1.41 (95% CI 1.06 to 1.89)); however, we observed no incremental benefit solely due to the intervention (group-by-time interaction, p=0.948). Among patients with the worst glucose control (A1c >9%), intensification increased in both groups (intervention, pre 34.8% vs post 62.5%, p=0.002; control, pre 35.7% vs post 61.4%, p=0.008).

Conclusions: A wide-reach, low-intensity, web-based interactive multicomponent intervention had no significant incremental effect on medication intensification for control of glucose, blood pressure or lipids for patients with diabetes of physicians practising in the rural Southeastern USA.

Trial registration: NCT00403091.

INTRODUCTION

Diabetes mellitus is highly prevalent in the USA.¹ Diabetes research has produced clear

ARTICLE SUMMARY

Article focus

■ To determine the effectiveness of a wide-reach and low-intensity intervention aimed at providers to improve medication intensification among patients with diabetes in rural areas.

Key messages

- In an effectiveness cluster-randomised trial among 205 rural physicians in 11 US states (Southeastern states; 2006–2008; 24 months), a wide-reach, low-intensity, web-based interactive multicomponent intervention had no significant incremental effect on medication intensification for control of glucose, blood pressure or lipids for patients with diabetes.
- Medication intensification to control glucose increased in both the intervention and control groups and it was most significant at very poor levels of glucose control.

Strengths and limitations of this study

- Strengths include a designed cluster-randomised trial in a diverse rural area.
- Limitations include the self-selection of charts for data abstraction. A high attrition rate may have introduced bias.

evidence that blood glucose, lipid and blood pressure (BP) control forestall the vascular complications witnessed with uncontrolled diabetes. Thus, control of such diabetes care measures are well-accepted indicators—as intermediate process outcomes of high quality of care,^{2–3} However, diabetes care measures of their appropriate control lag behind; only 7% of diabetes patients in USA meet the American Diabetes Association recommendations for glycated haemoglobin (A1c), BP and low-density lipoprotein (LDL) control.⁴ Furthermore, diabetes is more endemic in the Southern USA and individuals with diabetes in this area have worse control.^{5–8} Hence, public health interventions, which consider distance barriers in rural setting and aimed at

improving diabetes control in patients living in rural areas, are warranted.^{9–11}

The Rural Diabetes Online Care (R-DOC) study was a rigorously tested cluster-randomised clinical trial comparing a multicomponent physician intervention including web-based continuous medical education (CME), performance feedback^{12–14} and quality improvement tools¹³ to a concurrent control website in rural Southeast USA.¹⁵ The primary outcomes were measures of acceptable and optimal control for A1c, BP and LDL; the secondary outcomes were process measures (rate of assessment and group means of A1c, BP and LDL). Despite the non-significant effect attributable to the intervention for any of the primary outcomes in the R-DOC study, we observed an absolute increase in the rates of assessment of A1c and LDL in both study arms (A1c, intervention 30%, control 29%, $p < 0.001$; LDL, intervention 35%, control 38%, $p = 0.05$).¹⁵ However, whether physicians in rural areas adjust medications to control A1c, BP or LDL has not been examined in wide-reach, low-intensity interventions^{9–11} such as the one utilised in the R-DOC study.

Thus, we now report the medication intensification outcomes of the R-DOC study—specifically, medication intensification to improve overall control of haemoglobin A1c, BP and LDL in the rural Southeastern USA. Our findings from the main R-DOC study and this report have important implications for distant CME programmes, quality improvement initiatives and implementation research.

METHODS

Study design and setting

The R-DOC study was a cluster-randomised trial (ClinicalTrials.gov identifier: NCT00403091). The main study results—effect of the intervention on diabetes control—have been published elsewhere.¹⁵ Further details of the study design, web-content, recruitment and retention processes and patient characteristics have been published elsewhere.^{15–18} Briefly, participants were family, general and internal medicine physicians located in rural areas of 11 Southeastern US states (population size <25 000 habitants). Physicians were enrolled in the study sequentially from September 2006 to September 2008, provided informed consent online, and were randomised to the intervention or control arms using block randomisation which was concealed to the investigators and statisticians. The unit of randomisation was the physician (and not a practice); however, for physicians working in a group practice, only one physician per practice could enrol in the study. The protocol was approved by the local institutional review boards at The University of Alabama at Birmingham and Tuscaloosa medical campuses.

Intervention arm description

The website focused on helping physicians to achieve A1c, BP and LDL control in their diabetic patients.^{15–18} Specifically, the intervention site contained:

(1) challenging cases; (2) individualised diabetes performance feedback reports based on the physician's own panel of patients; (3) practice timesavers; (4) practical goals and guidelines, including guidance for quality improvement and systems redesign;¹³ (5) patient resources; and (6) an area to track and view CME credit. Intervention arm physicians also received tailored email reminders about website updated and uncompleted sections of the website.¹⁵

Individualised performance feedback reports were based on physician's patients with diabetes. The feedback reports compared each intervention arm participant's personal performance compared to the performance for the top 10% of other intervention arm participants.¹² The feedback reports consisted of diabetes control (A1c <7%, systolic BP <130 mm Hg, LDL <100 mg/dl), counselling on diet or exercise and medication intensification.¹⁵

Control arm description

The control website contained: (1) links to diabetes practice guidelines and patient education materials; (2) a list of educational conferences on general medical topics (updated monthly); (3) an area to track and view their CME credit and (4) a link to an external medical blog. Physicians in the control group did not receive performance feedback reports or electronic communications.

Data sources

All participating physicians provided copies of records of 15 (intervention arm physicians) or 10 (control arm physicians) of their own consecutively seen patients with diabetes at baseline and again at follow-up (representing two cross-sectional views of each physician's panel of patients). Since the focus of the intervention was the physician, we were less interested in specific patients but rather each physician's panel on average. Therefore, two samples as serial cross-sections would better represent any change in the physician's own panel on average. This method is similar to practice feedback for quality improvement purposes.^{19–20} The number of records was selected to balance rigour and cost (see also sample size description in the statistical section below).

Patient inclusion criteria were having at least two office visits during the past year and no dialysis, dementia, organ transplantation, HIV/AIDS, terminal illness or malignancy (except for skin and prostate cancer). Data abstraction was performed by trained personnel on blinded records sent to the study centre (or abstracted on site). Details of data abstracted, quality controls and physician compensation are published elsewhere.¹⁵

Outcomes

In our main study,¹⁵ the main outcomes were measures of acceptable and optimal diabetes control.^{2–3} The main outcome for this report is medication intensification, defined as a dose increase of an existing medication or the addition of a new class of medication for glucose, blood pressure and lipids control on any of the three

most recent office visits. Medication intensification equalled the proportion of patients who had a glucose-lowering medication, antihypertensive medication or cholesterol-lowering medication added or increased over the three most recent visits divided by the total number of patients assessed at baseline or follow-up. As a secondary outcome, we also explored medication intensification by level of glucose, BP or lipid control.

Statistical approach

We calculated the sample size for the main study results.¹⁵ On the basis of clinically important differences, the study required 100 physicians per trial arm to detect a minimum of 0.4% difference in A1c, 6 mm Hg in BP and 6 mg/dl in LDL for the main outcomes (power 80%, $\alpha=0.05$, up to 20% dropout) (10 patients per physician at baseline and at follow-up).¹⁵ However, intervention arm physicians were asked to provide 15 patient records at baseline (and not at follow-up) because of the need to construct audit and feedback reports as part of the intervention^{19 20} for A1c, BP and lipids, reflecting the fact that not all diabetes patients also have hypertension and hyperlipidaemia. The initial study was not powered to perform adjusted analysis for the intensification outcomes of this report.

All analyses followed the intention-to-treat principle. The relationship between the main and secondary outcomes and the effect of the intervention were examined with generalised linear mixed models (GLMM), accounting for clustering of patients within physicians. ORs for follow-up versus baseline within the two groups were calculated, adjusting for covariates that differed between baseline and follow-up patient populations; thus, the covariates included in these adjusted analyses included race, and clinical diagnosis of hypertension or depression. GLMM was implemented by PROC GLIMMIX in SAS and was adjusted for race, and clinical diagnosis of hypertension or depression. Thus, the group coefficient represented differences between the intervention and control groups at baseline; the time of coefficient represented changes in the control group over time, thus capturing temporal trends. Finally, the group-by-time interaction coefficient represented the difference-of-differences for over-time change in the intervention versus control group, and was a direct comparison of over-time change for the intervention versus the control group. A positive OR meant that the odds of a patient being in control increased more over time for the intervention versus control group. All analyses were performed in SAS V.9.2 (Cary, North Carolina, USA).

RESULTS

Recruitment scheme, patient characteristics and web utilisation

The Consolidated Standards of Reporting Trials diagram and patients characteristics at baseline and at follow-up (modified from a prior publication¹⁵) are included in this report for completeness (figure 1 and table 1). We

obtained baseline and follow-up data on 95 physicians (intervention, n=48; control, n=47) and 1182 of their patients at baseline (intervention, n=715; control, n=467) and 945 diabetes patients at follow-up (intervention, n=479; control, n=466).

At baseline, intervention group physicians provided records for fewer African American patients and more patients with hypertension and depression compared with control group physicians. Of the 95 physicians, 90 (94.7%) had access to the Internet in the office.

Main outcomes: medication intensification

In the adjusted analysis, we saw no significant effect attributable to the intervention in the group-by-time interaction term for any of the medication intensification measures (A1c, BP and LDL; p=0.948, 0.216 and 0.995; respectively).

In the unadjusted analysis, intensification of medications to control A1c increased in both trial arms when baseline and follow-up data were compared (intervention, 26.4% vs 32.6%, p=0.022; control, 24.8% vs 31.1%, p=0.033; figure 2). This was confirmed in the adjusted analysis (intervention, adjusted OR (AOR) 1.37; 95% CI 1.06 to 1.76; control, AOR 1.41 (95% CI 1.06 to 1.89)).

In the unadjusted analysis, intensification of medications to control BP did not differ for patients cared for by physicians in either trial arm when comparing baseline and follow-up data (intervention, 12.3% vs 15.9%, p=0.080; control, 16.5% vs 16.3%, p=0.941; figure 2). This finding was consistent with the adjusted analysis (intervention, AOR 1.37 (95% CI 0.99 to 1.88); control, AOR 1.00 (95% CI 0.72 to 1.41)).

In the unadjusted analysis, intensification of medications to control LDL did not differ for patients cared for by physicians in either trial arm when comparing baseline and follow-up data (intervention, 10.6% vs 11.3%, p=0.726; control, 8.1% vs 8.4%, p=0.898; figure 2). This finding was consistent with the adjusted analysis (intervention, AOR 1.05 (95% CI 0.73 to 1.50); control, AOR 1.00, (95% CI 0.65 to 1.53)).

Secondary outcome: medication intensification by strata

In the unadjusted analysis and among patients with worse glucose control (A1c >9%), intensification of medications to control A1c increased in both trial arms between baseline and follow-up (intervention, pre 34.8% vs post 62.5%, p=0.002; control, pre 35.7% vs post 61.4%, p=0.008; figure 3 top panel). For patients whose last A1c ≥ 7 to ≤ 9 , we noted an increase in intensification between the baseline and follow-up for the intervention group (p=0.005) but no difference in the control group (p=0.164; figure 3 top panel). Among patients with best glucose control (A1c <7%), medication intensification between baseline and follow-up was similar for both trial arms (intervention, p=0.673; control, p=0.543; figure 3 top panel).

In the unadjusted analysis, intensification of BP medication between baseline and follow-up was similar at all

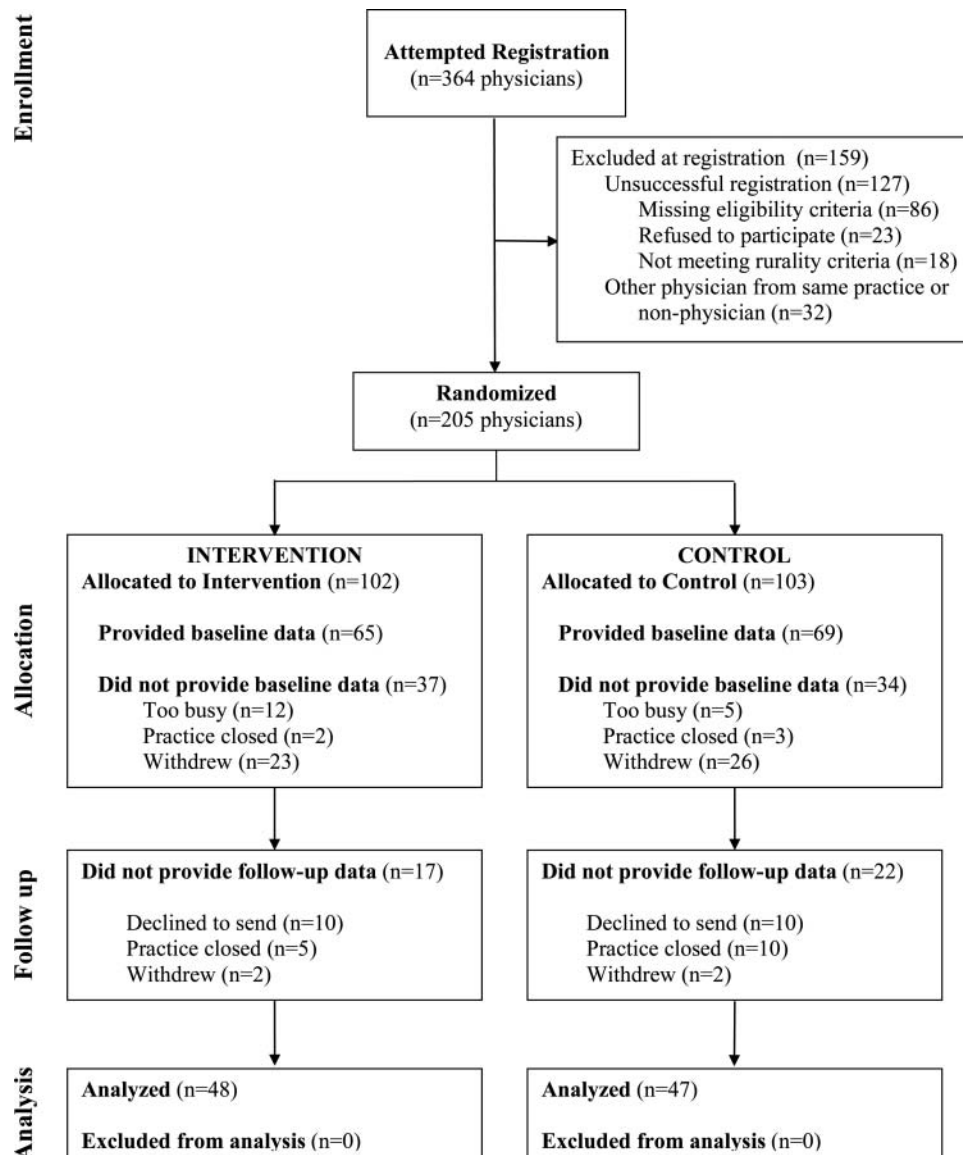


Figure 1 Consolidated Standards of Reporting Trials (CONSORT) diagram (a prior version of this figure has been reported, reproduced with permission¹⁵).

levels of BP control for both trial arms (figure 3 middle panel).

Similarly, in the unadjusted analysis, intensification of lipid-lowering medications between baseline and follow-up was similar at all levels of LDL control for both trial arms (figure 3 bottom panel).

DISCUSSION

In a rigorously designed cluster-randomised trial, a wide-reach, low-intensity web-based multicomponent intervention for primary care physicians in the rural Southern USA had no significant incremental effect on medication intensification for their diabetes patients' A1c, BP or LDL control as compared to a concurrent control website focusing on diabetes care. However, the absolute rate of intensification of medications to control A1c

increased in both study arms at the end of the study by a modest amount (~6%). Although the study was not designed to perform subgroup analysis, the rate of intensification was greatest among the worst-controlled patients (A1c >9%) in both study arms (~25–28%). Plausible explanations for our findings include the low engagement with the intervention, higher-than-anticipated attrition rate, Hawthorne's effect or no effect of the intervention^{15 18}

Medication intensification is emerging as a process measure for quality improvement efforts among patients with diabetes mellitus; pharmacotherapy intensification is strongly linked to improved A1c, BP and LDL. For example, in a study of over one million members with hypertension, hyperlipidaemia and diabetes mellitus at Kaiser Permanente Northern California, Selby *et al*²¹ found that a 5% improvement in treatment

Table 1 Characteristics of diabetes patients of 95 physicians randomised to intervention (n=48) or control (n=47) who completed follow-up

Patient characteristic	Baseline			Follow-up		
	Intervention (n=715)	Control (n=467)	Total (n=1182)	Intervention (n=479)	Control (n=466)	Total (n=945)
Age (years)	58.7 (13.59)	60.6 (13.79)	59.4 (13.70)	61.3 (13.42)	60.5 (12.71)	60.9 (13.09)
Gender, female	360 (51.1%)	230 (49.5%)	590 (50.5%)	260 (54.5%)	252 (54.4%)	512 (54.5%)
Race, African American	97 (13.9%)	99 (21.3%)	196 (16.9%)	102 (21.4%)	143 (30.9%)	245 (26.1%)
Obesity*	274 (38.3%)	193 (41.3%)	467 (39.5%)	97 (20.3%)	75 (16.1%)	172 (18.2%)
Smoker, current	85 (12.5%)	55 (12.3%)	140 (12.4%)	63 (13.8%)	53 (13.0%)	116 (13.4%)
No self-testing	168 (33.6%)	114 (36.3%)	282 (34.6%)	189 (41.4%)	183 (44.7%)	372 (43.0%)
Non-adherence to appointments	75 (11.0%)	54 (12.0%)	129 (11.4%)	10 (2.2%)	23 (5.6%)	33 (3.8%)
Insurance, Medicaid	65 (9.1%)	51 (10.9%)	116 (9.8%)	66 (13.8%)	58 (12.4%)	124 (13.1%)
Comorbidities						
Diabetes complications†	147 (20.6%)	110 (23.6%)	257 (21.7%)	156 (32.6%)	134 (28.8%)	290 (30.7%)
Insulin use	103 (14.4%)	66 (14.1%)	169 (14.3%)	84 (17.5%)	68 (14.6%)	152 (16.1%)
Hypertension	473 (66.2%)	304 (65.1%)	777 (65.7%)	327 (68.3%)	283 (60.7%)	610 (64.6%)
Hyperlipidaemia	110 (15.4%)	85 (18.2%)	195 (16.5%)	11 (2.30%)	17 (3.7%)	28 (3.0%)
Peripheral vascular disease	47 (6.6%)	31 (6.6%)	78 (6.6%)	41 (8.6%)	35 (7.5%)	76 (8.0%)
Coronary artery disease	135 (18.9%)	83 (17.8%)	218 (18.4%)	111 (23.2%)	95 (20.4%)	206 (21.8%)
Vascular intervention‡	60 (8.4%)	47 (10.1%)	107 (9.1%)	36 (7.5%)	40 (8.6%)	76 (8.0%)
Depression	105 (14.7%)	61 (13.1%)	166 (14.0%)	84 (17.5%)	60 (12.9%)	144 (15.2%)

A prior version of this table has been reported (reproduced with permission).¹⁵

Values are mean (SD) or n (%).

*Obesity: body mass index ≥ 30 kg/m² or clinical diagnosis.

†Diabetes complications: retinopathy, neuropathy or nephropathy.

‡Vascular intervention: coronary artery bypass grafting, stent, percutaneous coronary angioplasty.

intensification led to a 1.0–1.9% improvement in control for the entire population. However, the association of treatment intensification rates to improved risk factor control in rural populations has not been examined. Further evidence and reviews of the importance of medication intensification among patients with diabetes are available elsewhere^{22–27}.

Trials using medication intensification outcomes

Relatively few studies involving physicians have examined medication intensification as an outcome, none in a rural setting. Studies have tested the impact of a simulated case-based education with opinion leader feedback,²⁸ customised feedback²⁹ and real-time feedback to

patients and their physicians using cell phone software;³⁰ these studies are summarised below.

In a group randomised controlled trial²⁸ of 57 primary care physicians and 2020 patients in an urban setting, physicians were randomised to no intervention, a simulated case-based physician learning intervention, or the same case-based and leader feedback. Glucose control, mean A1c value, worsened in the control group by 0.06, improved in the simulated case-based group by 0.01, and worsened in the case-based and leader feedback by 0.18. Among the 907 patients with A1c >7%, medication intensification was similar between groups (31.5%, control; 32.6%, case-based; 36.8%, case-based and leader feedback; p=0.41). Similarly, among the 701 patients with LDL-C >99 mg/dl, medication intensification was similar between

Figure 2 Medication intensification for haemoglobin A1c (%), blood pressure (BP, mm Hg) and cholesterol (low-density lipoprotein (LDL), mg/dl) control for intervention (n=48) or control (n=47) physicians, at baseline (pre, n=1182 patients) and follow-up (post, n=945 patients). See text for definitions of medication intensification.

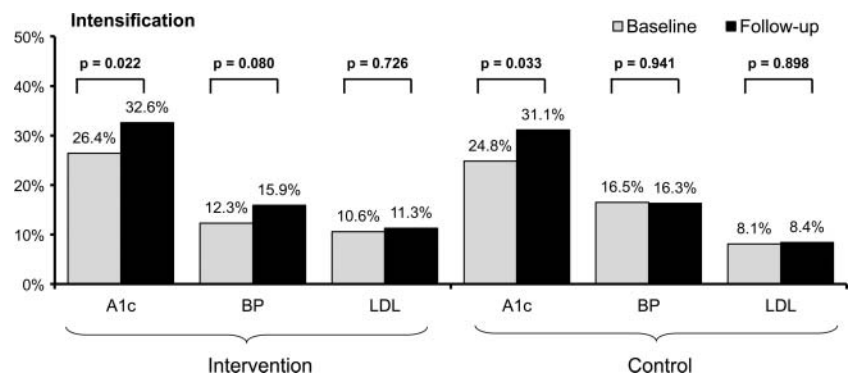
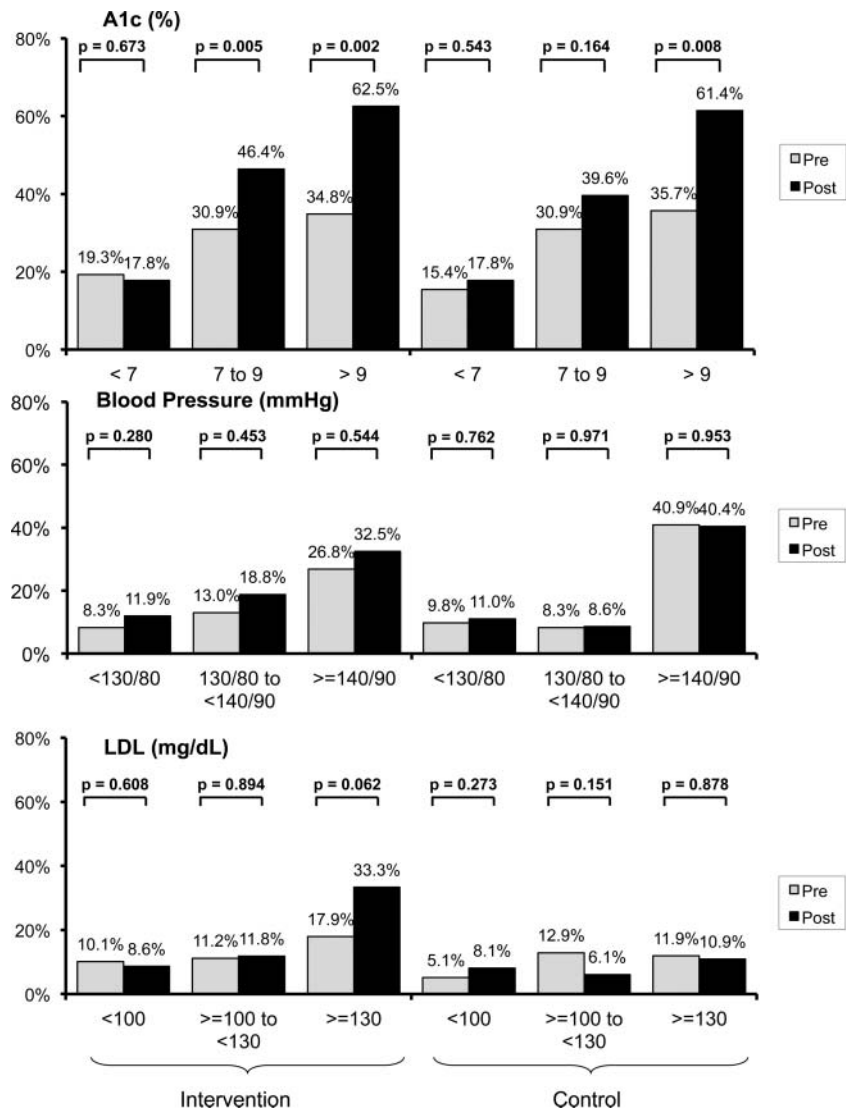


Figure 3 Medication intensification for strata of haemoglobin A1c (%), blood pressure (BP, mm Hg) and cholesterol (low-density lipoprotein (LDL), mg/dl) control. See text for definitions of medication intensification.



groups (20.8%, control; 24.2%, case-based; 21.8%, case-based and leader feedback; $p=0.66$). Finally, among the 949 patients with BP values >130 /mm Hg, medication intensification was similar between groups (27.3%, control; 24.7%, case-based; 28.2%, case-based and leader feedback; $p=0.61$). Medication intensification was defined by the initiation or titration in 12 months after the intervention for all patients with goals above target (A1c $\geq 7\%$, LDL-C ≥ 100 mg/dl, BP $>130/80$ mm Hg); insulin titration was excluded from the outcome. The attrition rate was 33% (38/59 physicians). Our case scenarios took less than 10 min to complete as compared with the ones in this study (over 60 min each).²⁸ Perhaps striking a balance between more ‘intense’ cases to increase physician engagement and providing feedback information may lead to the improvement in medication intensification. Finally, the medication intensification rates definitions were different from ones used in our study; hence, they cannot be compared.

In a randomised trial of 3703 patients with diabetes and their 123 physicians, participants were randomised to

receive customised feedback of clinical information in four groups: patient only, physician only, both the patient and physician, or neither one.²⁹ At 12 months, interventions had no effect on A1c test ordering, medication intensification or improvement in A1c or LDL control. Medication intensification was defined as in the above study.²⁸ In our study, we included customised feedback as one of the many components of the intervention.

In a pilot-controlled trial,³⁰ 30 patients with diabetes were randomised to an intervention group consisting of cell phone-based software which provided real-time feedback on glucose levels, medication regimens and suggested treatment algorithms or a control group. Intervention providers received patients’ logbooks and suggested treatment plans to reach A1c $<6.5\%$. During the 3 months of the study, the A1c levels decreased among patients in the intervention as compared with the control group (by 2.0% vs 0.7%; respectively); medications were changed or intensified in 84% in the intervention group as compared with 23% patients in the control group ($p<0.002$). The operational definition for

medication intensification in this study was not reported. Cell phone technology provides the opportunity for wide reach approach. In our study, physicians and not their patients received the customised feedback on their group of patients.

Limitations

Our study had limitations.¹⁵ First, physicians themselves provided the records of consecutively seen patients; although selection bias was a possibility, the wide range of A1c, BP and LDL values suggests that not only well-controlled patients were selected. Second, the high attrition, 95 of the 205 randomised physicians provided baseline and follow-up data, may have introduced biases. By design, to test a purely online intervention, we chose not to enhance retention activities as typically seen in randomised clinical trials and focused on several aspects of provider-based implementation tools.¹³ Although a comprehensive analysis would have been enlightening, we did not perform a systematic examination of this negative trial, or how such intervention might work it were effective. We worried that studying the study while being conducted would have introduced another variable.

Implications

A framework has been proposed to evaluate the public health impact of interventions.^{9–11} The components of the framework include reach ('How many participate?'), effectiveness ('Does it work in usual settings?'), adoption ('How many use it?'), implementation ('Is it used as intended?') and maintenance ('Is it sustained over time?') (RE-AIM). In this study, using a wide-reach approach, we examined the effectiveness of a potential public health intervention. Effective interventions may be limited by their low-reach, specificity to fewer settings, expense and limited sustainability—thus limiting their generalisability. Testing less intensive interventions with wider reach in rural settings has been advocated in public health interventions.¹¹ Finding effective strategies to accomplish continuing professional development for physicians practising in remote locations is also an important objective.³¹ In contrast, higher-intensity interventions in rural and community settings have shown promising results.^{32–36}

CONCLUSION

In conclusion, a wide-reach, low-intensity, web-based interactive multicomponent intervention had no significant incremental effect on medication intensification for control of glucose, BP or lipids for patients with diabetes of physicians practising in the rural Southeastern USA. Despite low engagement in the web-based programme, intensification measures improved in both arms of the study. Our study raises important issues for wide-reach, low-intensity CME programmes that seek to improve patient outcomes.

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Competing interests The opinions expressed in this article are those of the authors alone and do not reflect the views of the Department of Veterans Affairs.

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