ORIGINAL ARTICLE

Controlled trial of an intervention to improve cholesterol management in diabetes patients in remote Aboriginal communities

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Received 25 October 2008; Accepted 1 April 2010

ABSTRACT

Objectives. Aboriginal communities have a high prevalence of diabetes and heart disease, and limited resources to address them. The objective of this study was to test the effectiveness of prioritizing care with audit and feedback on cholesterol management of diabetic patients.

Study design. A controlled before-after intervention trial was conducted among health care providers in Oji-Cree reserves in Sioux Lookout Zone, Ontario. Two communities were randomized to receive an interactive educational workshop and chart audit with feedback on cholesterol management; 2 control communities received usual care.

Methods. The primary outcome measure used was the proportion of patients on statins, and the secondary outcome measure was the proportion of patients with LDL>2.5 mmol/L or TC/HDL>4.0 on statins. Outcomes were assessed by chart review at baseline and 10 months post-intervention.

Results. Patients in the 2 intervention communities (n=170) and the 2 controls (n=170) were comparable at baseline. The intervention did not increase the proportion of diabetic patients on statins overall or in the subset of patients with elevated cholesterol. The proportion of patients with elevated cholesterol on statins went from 46% to 53% (p=0.48) in the intervention group and from 47% to 50% (p=0.25) in the control group.

Conclusions. Audit and feedback listing patients requiring treatment did not increase statin prescription rates in diabetic patients in remote Aboriginal settings. This may be due to elevated baseline rates, the low intensity of feedback and the constraints of the practice environment, such as low staffing and high staff turnover.

( Int J Circumpolar Health 2010; 69(4):333-343)

Keywords: diabetes, quality improvement, Aboriginal health, cholesterol management
INTRODUCTION

Diabetes has traditionally been rare in Canada’s Aboriginal population (1). In the last 50 years, however, diabetes has emerged as a health issue of epidemic proportions among First Nations people in Canada (2). More recent increases observed among the Inuit population (3), which have remained lower than the rates of both First Nations and Métis people in Canada (4–6), have helped refocus attention on the impact that this disease has on all Aboriginal groups — First Nations, Métis, and Inuit — in Canada. Since cardiovascular disease is the largest cause of mortality among diabetic persons (7), cardiovascular health of the Aboriginal population in Canada is particularly important to consider. Unfortunately, statistics showing hospital admissions for myocardial infarction are rising among Aboriginal groups in northern Canada, while they are declining in the general population (8). Cholesterol management with statins is an effective way of reducing cardiovascular and all-cause mortality in diabetic populations (9,10). Despite the simplicity and value of this intervention, the current quality of cholesterol management in diabetes patients is suboptimal (11). This is true in the general populations of Canada and the United States (11,12), as well as in their Aboriginal communities (13–15). For example, only 45% of diabetic patients in the general population of the Canadian province of Saskatchewan achieved treatment targets for low-density lipoprotein (LDL) levels (below 2.5 mmol/L) (16); this was the case for only 39% of patients in the Oji-Cree community of Sandy Lake, Ontario (14).

Suboptimal diabetes care is due to problems ranging from patient compliance, provider attitude and knowledge and a health system that does not support proactive chronic disease management (17,18). Remote Aboriginal communities have additional barriers related to their geographic isolation, poverty, short-staffing and high staff turnover (19,20). There have been numerous quality improvement studies on diabetes, but no consensus on which approaches are most effective (21). There are few studies of diabetes quality improvement in Aboriginal communities, and most are of poor quality; only 2 of these studies were controlled trials (22–26). Audit and feedback is a quality improvement method where providers’ charts are reviewed (audit) and presented with a summary of their clinical quality of care (feedback). Feedback, which provides the names of patients in whom suboptimal care has been identified, may increase the effectiveness of this tool, as it identifies how care can be improved with limited effort (27). A Cochrane Review of audit and feedback that did not include any studies on Aboriginal groups found that this method is generally effective, though it has a small to moderate impact on quality of care (28). Audit and feedback is widely used in the Indian Health Services in the United States (29) and among the James Bay Cree in Quebec (30), but it has not been tested in a controlled study within Aboriginal communities in Canada.

In addition to the potential effectiveness of audit and feedback in improving patient care, health providers’ adherence to treatment recommendations has been associated with reduced complexity in observational studies (31–33). Complexity can be reduced by negotiating key priorities with providers by taking the evidence base, health impact and ease of implementation into account, which is an inexpensive and replicable strategy for low-resource settings. The purpose of this study
was to test the impact of a brief interactive workshop on priorities in diabetes care along with audit and feedback on statin prescription among diabetic patients in remote Aboriginal communities.

MATERIAL AND METHODS

This study was a controlled before-after intervention trial where the unit of assignment was the community, the participants were the community health care providers and the unit of analysis was the patient. The 4 communities in the Sioux Lookout Zone that participated in this study were randomly assigned to receive the intervention or usual care. The communities were told whether they were in the intervention or the control group, but were not told what outcomes were being measured. Outcome data were collected from individual patients nested within these communities and analysed accordingly. A companion study, not reported here, incorporated a concomitant qualitative evaluation using key informant interviews and focus groups to assess the degree of implementation and acceptability of the intervention (34,32).

Setting

Sioux Lookout Zone is home to 16,000 people in 28 Oji-Cree communities scattered across a vast sub-Arctic boreal forest in the northwestern part of Ontario. Between 50 and 2,000 people live in these communities, most of which are only accessible by plane. Physicians are based in the Zone Hospital, which is located in the town of Sioux Lookout, and have designated communities for which they are responsible. The larger communities, such as the ones included in this study, have nursing stations with 2 to 4 permanent nursing staff and a physician who visits 3 to 10 days a month. Community health representatives (CHR) — lay health workers with limited formal training who aid doctors and nurses with drug dispensing, translation, and public health activities (35) — are also a part of the community health team.

Sample size, community assignment and study participants

All patients who screen positive for diabetes are put on a registry that is maintained by the nursing station and the Sioux Lookout Diabetes Program. Patients in this study were sampled from the Diabetes Program registry after adding any new patients from the community’s own registry. We excluded patients who were under the age of 18 and who were pregnant. We chose an intracluster correlation coefficient (ICC) of 0.01 for the sample size calculation, which is close to the median value from a review of ICCs for various interventions in primary care (36). Using an ICC of 0.01, we required 80 patients per community (a total of 320) in order to detect a 20% change in primary outcome with a power of 80% and an α error level of 0.05.

In Sioux Lookout Zone, only 7 communities have more than 80 known diabetic patients. Two communities were excluded because they were much larger, had continuous physician presence and were thus less representative of the Zone as a whole, and 1 was excluded because it did not have accommodations for visitors. In the end, 4 communities were included in this study: 2 communities received the intervention and 2 communities were in the control group. They were randomly assigned to inter-
vention or control by selecting identical papers with the name of each community written on the side which was face down.

The providers involved in the study were the doctors, nurses and community health representatives (CHR) responsible for these communities. Physicians are each responsible for 1 medium-sized community, but they spend most of their time in the same base hospital in Sioux Lookout, so there was some opportunity for interaction between the different doctors that could have contaminated the separation between the control and intervention communities. Nurses and community health representatives have only rare contact with providers from other communities, so they were not considered a potential contamination factor.

The intervention
The intervention had 2 parts: (1) an interactive educational workshop on prioritized key points in diabetes care and (2) an audit and feedback. The educational workshop was 90 minutes long and was conducted in the nursing station; nurses, community health representatives and clerical staff attended. A similar workshop was held in the Zone Hospital so that physicians from the participating communities could attend; physicians from the control communities did not attend. The results of the site-specific baseline audit were presented to nursing station staff, including a variety of quality indicators, and compared to the average scores across all 4 communities in the study. This was supplemented by a list of diabetic patients from their community over 35 years old with poor lipid control (LDL>2.5 or TC/HDL>4) divided into those currently on statins and those not receiving statins. It also introduced a series of prioritized key points in diabetes care.

A prior study in the same community showed that health care providers felt it was not possible to follow all of the guideline recommendations, and they did not have clear criteria by which they could prioritize the various elements of diabetes care (34). Prioritized key points were developed to help resolve indecision regarding how to use limited time and energy, since diabetes care processes have varying degrees of health impact and feasibility. These priorities were developed by reviewing the evidence and impact of each recommendation on health outcomes, as well as providers’ comments on the degree to which a recommended activity could be consistently performed. This process will be described in a forthcoming article. The priorities were to prescribe statins if LDL>2.5 mmol/L or total cholesterol/HDL>4.0, control blood pressure to 130/80 mmHg, prescribe angiotensin conversion enzyme inhibitors if urine albumin:creatinine >2.0, control glycemia to HbA1c < 7.0% and promote exercise for 30 minutes 5 times a week.

Control communities were informed that they were in the study, and were visited once for baseline chart review and again to repeat the chart review at the end of the study. The results of the audit were not available to the providers in the control group until after the post-intervention chart review was completed.

Outcome measurements and analysis
The primary outcome was the percentage of diabetic patients over 35 years on statins, and the secondary outcome was the percentage of diabetic patients over 35 years with LDL>2.5 or TC/HDL>4.0 on statins. Data were collected by chart review. The charts of patients from
the diabetes register of the Sioux Lookout Diabetes Program for all 4 communities were randomly selected for baseline assessment, and the same charts were reviewed 1 year later (10 months after the intervention). A baseline chart review was done by 2 chart abstractors (1 physician and 1 research assistant) and a post-intervention chart review was done by 1 physician abstractor. A random subset of 10% of the charts was re-examined each time to check for reliability. The abstractors were aware of the assignment of the clinics, but the statistician doing the analysis was not.

McNemar’s test was used to compare the proportion of patients on a statin at baseline (pre-intervention) and at post-intervention to check for a significant change in either group. All patients who were assigned to the intervention or control group were analysed within that group, in accordance with intention to treat analysis.

Ethics
The study was approved by the Ethics Review Board of the University of Toronto, Health Canada and the Meno-Ya-Win Health Centre in Sioux Lookout. Institutional approval was given by the First Nations Health Authority of Sioux Lookout Zone.

RESULTS

Study population
Four communities participated in this study. The study profile in Figure 1 shows the pattern of patient recruitment and follow-up. As stated earlier, 80 patients per community were required to detect a 20% change in primary outcome. One community had 144 diabetic patients, so a random sample of 89 patient charts was chosen. In the other 3 communities, each with about 100 diabetic patients on the register, all patients were included. During the chart review process, 22 patients were excluded from the intervention group (9 had moved, 5 were deceased and 8 charts could not be found), and 6 from the control (5 had moved and 1 patient appeared under 2 different family names).

When reviewing the clinical profiles of the patients, it was found that several patients had a hemoglobin A1c (HbA1c) below 6.0% and were not on any medical treatment. After discussion with the providers, it was determined that some may have been put on the list because they were considered high-risk. This was discovered after data collection was completed, so patients with an HbA1c of 6.0% and not on any hypoglycemiant drugs were excluded from the analysis. This removed 11 patients from the intervention group and 11 from the control. In the year between the 2 chart reviews, 6 patients had moved and 1 had died in the intervention group, with no change in the control group. This resulted in a 5% loss to follow-up after the baseline assessment in the intervention group and 0% in the control group.

Clinic, provider and patient characteristics
The communities and providers in the intervention and control groups were similar, though 1 of the control communities was larger than the others, having 40% more diabetic patients and 1 extra nurse. Each community had 1 physician, 2 to 4 nurses and 1 or 2 diabetes-related CHRs. Patient characteristics, including demographic, diabetes complication risk factor management and rates of prescription of recommended
medications were balanced between the intervention and control communities (see Table I). The proportions did not always correspond to the total number of patients. This is because some patients had not been tested for certain parameters. The analysis was repeated for the subset of patients with LDL > 2.5 mmol/L or total cholesterol/HDL > 4 and this subgroup was also comparable between the intervention and control group at baseline (data not shown).

The measures of diabetic outcomes in Table I show that many patients have suboptimal control of glycemia and cholesterol, with relatively high rates of prescription of aspirin and ACE inhibitor or angiotensin receptor blockers and lower rates of statin prescription. There were 362 charts abstracted initially, of which 40 (11%) were randomly selected for reabstrac-

**Figure 1.** Trial profile.
tion and comparison. There were 40 charts containing 25 items per chart, resulting in 1,000 pieces of information. Inconsistencies were found in 18 items, giving an error rate of approximately 1.8%.

**Study outcomes**

The outcomes of the study are shown in Table II. For the primary outcome of percentage of patients on statins, there was no significant change in either group. The intraclass correlation coefficient was 0.001 and not significant, so this did not affect the power of the study. The secondary outcome of percentage of patients with elevated cholesterol on statins increased from 44% to 50% in the intervention group, and from 40% to 43% in the control group, neither of which was significant.

### Table I. Patient characteristics at baseline.

| Characteristic       | Control communities | Intervention communities | p value |
|----------------------|---------------------|---------------------------|---------|
| Patients             | n=170               | n=170                     |         |
| Mean age             | 50.0                | 50.9                      | 0.59    |
| Women                | 66 (112)            | 66 (112)                  | 0.94    |
| Mean years w/DM*     | 10.4                | 11.2                      | 0.35    |
| Mean A1C*            | 7.9                 | 8.3                       | 0.17    |
| Mean LDL*            | 2.48                | 2.60                      | 0.16    |
| Mean TC/HDL*         | 3.65                | 3.62                      | 0.78    |
| A1C<7%*              | 53/132 (40%)        | 53/165 (32%)              | 0.15    |
| A1C>9%*              | 32/132 (24%)        | 53/165 (32%)              | 0.14    |
| LDL>2.5*             | 67/138 (49%)        | 87/164 (53%)              | 0.44    |
| % w/TC/HDL>4*        | 39/138 (28%)        | 41/164 (25%)              | 0.50    |
| % on statin          | 70/170 (41%)        | 81/170 (48%)              | 0.23    |
| % on ACE or ARB      | 114/170 (67%)       | 116/170 (68%)             | 0.82    |
| % on ASA             | 104/170 (61%)       | 102/170 (60%)             | 0.82    |
| % on insulin         | 14/170 (8%)         | 22/170 (13%)              | 0.16    |

Results show % (n) or means ± SD.  
*Some values were missing from these variables. DM=diabetes mellitus, A1C=glycosylated haemoglobin, LDL=low density lipoprotein cholesterol, TC/HDL=total cholesterol/ high density lipoprotein cholesterol, ACE=angiotensin conversion enzyme inhibitor, ARB=angiotensin receptor blocker, ASA=acetylsalicylic acid.

### Table II. Study outcomes.

| Outcome                              | Control group | n=170 | Post | p value | Intervention group | n=170 | Post | p value |
|--------------------------------------|---------------|-------|------|---------|--------------------|-------|------|--------|
| On statins                           |               |       |      |         |                    |       |      |        |
| On statins                           | 70/170 (41%)  | 71/170 (42%) | 0.79 | | 81/170 (48%)      | 83/170 (49%) | 0.74 |
| Patients with LDL>2.5 or TC/HDL>4*   | 31/77 (40%)   | 33/77 (43%) | 0.48 | | 44/95 (46%)       | 50/95 (53%) | 0.22 |

* For this measure, the control group n=77 and intervention group n=95.
DISCUSSION

The results suggest that an educational workshop around key points in diabetes care with audit and feedback does not increase statin prescription rates in a remote Aboriginal setting. The audit and feedback intervention focused on the identification and treatment of patients with elevated cholesterol as recommended in the Canadian Diabetes Association’s 2003 and 2008 clinical practice guidelines (37,38). However, this caused only a minor increase in prescription rates in this subgroup that was not statistically significant. The intervention required little personnel time, approximately 1 day for 1 auditor and a 90-minute workshop for 1 instructor, but was perhaps not sufficiently intensive to change behaviour. It was acceptable to providers who did not consider it onerous, though it did increase their workload slightly.

The results of this study do not coincide with the conclusion of a 2006 systematic Cochrane Review of audit and feedback, which noted that audit and feedback has generally small to moderate effects (28). They determined that the relative effectiveness is likely to be greater when baseline adherence to recommended practice is low and when feedback is delivered more intensively. An earlier article looked at the subset of 4 randomized controlled trials of audit and feedback of diabetes in a primary care setting and found that it was more effective than doing nothing. The lack of impact in this setting may be due to particular constraints, such as high staff turnover and chronic understaffing, which may have influenced the implementation of the intervention (19). One interrupted time series in remote Aboriginal communities in Australia showed a benefit in multiple processes of care using audit and feedback along with several other interventions, such as transfer of governance and electronic patient records (39). Observational studies of quality of diabetes care in 2 Aboriginal diabetes programs that regularly conduct chart audits with feedback, such as the Indian Health Services (IHS) in the United States and the Cree Diabetes Information System (CDIS) among the James Bay Cree in Quebec, Canada, showed a quality of care that was comparatively high (22,29,30). This suggests that longer-term and more intense interventions may prove to be more effective in the future.

This trial had a controlled design with random allocation of units and measured a process which has a significant impact on cardiovascular mortality in diabetic patients (9). The main limitations of the study are the small number of randomized clusters, which may not control for unmeasured confounders and could have led to significant baseline imbalance. As a result, we have called this a controlled before-after rather than a randomized controlled trial (40). The abstractors were not blinded to allocation of the communities, which could have biased their measurements in favour of a treatment effect; since a treatment effect was not observed, however, this impact is unlikely to affect the results. Further, the error rate of 1.8% was modest and, therefore, unlikely to affect the direction of the results. The loss to follow up was 5% in the intervention group and 0% in the control group, so if
we conservatively assume that none of these patients were on statins at the end, the results would be unchanged. Lastly, the short duration (10 months) of the study may have been insufficient to observe a change in prescription, though other interventions targeting prescribing behaviour have demonstrated effects in 6 months (23).

Conclusions
This study follows the recommendation from a recent Cochrane Review that diabetes quality improvement studies should focus on cardiovascular risk management, not exclusively on glycaemic control (21). It tests the impact of audit and feedback in a controlled trial, a quality improvement method that has been used in the IHS in the United States (29) and with the CDIS in Quebec, Canada (30). The negative result here suggests that the comparatively good measures and outcomes of the diabetes care process in these sites may be due to factors other than their audit and feedback system or that they use a more effective approach to feedback than the one tested here. In terms of the intervention, the workshop may not have been appropriate to all groups: nurses and CHRs could not remember the key points, which doctors could. The lack of impact on statin prescription may be due to the low intensity of the intervention, high staff turnover and possibly a ceiling effect. As many of these issues are chronic problems in the North and in Aboriginal communities, their impact on research will be important to consider in the future. There were other influences on the study: the nurse in charge in one of the intervention groups changed, baseline prescription rates were comparatively high and there were numerous women of childbearing age among diabetic patients, who may not be appropriate candidates for statins given their teratogenicity (41).

Future work should also identify whether other ways of presenting the feedback data and key points would be more effective, given that this intervention has worked in other settings. The barriers to diabetes care should be carefully incorporated into the design of future interventions, particularly staff turnover, as this can undermine the effectiveness and sustainability of any effort. Diabetes quality improvement work in Aboriginal communities is particularly important given their high risk of complications and the distinct barriers to care in this context. Future studies should work more closely with local health authorities, community health practitioners and community leaders, so that they can promote the sustainability of high-quality diabetes care for their people.

Acknowledgements
This study was supported by the Canadian Institutes of Health Research team’s grant Knowledge Translation Improved Clinical Effectiveness Behavioural Research Group (KT-ICEBeRG); a Canadian Institutes of Health Research Doctoral Fellowship: Transdisciplinary Understanding and Training on Research-Primary Health Care (TUTOR-PHC); a Canadian College of Family Physicians Janus Research Grant; and a Society for Academic Continuing Medical Education Endowment.

Conflict of interest statement
Onil Bhattacharyya has no conflict of interest. Jan Barnsley has no conflict of interest. Merrick Zwarenstein has no conflict of interest. Stewart Harris has no conflict of interest.

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