



# Prospective, Cluster-Randomized Trial to Implement the Ottawa Model for Smoking Cessation in Diabetes Education Programs in Ontario, Canada

*Diabetes Care* 2018;41:406–412 | <https://doi.org/10.2337/dc17-1809>

Robert D. Reid,<sup>1,2</sup> Janine Malcolm,<sup>3</sup>  
Evyanne Wooding,<sup>1</sup> Amy Geertsma,<sup>1</sup>  
Debbie Aitken,<sup>2</sup> David Arbeau,<sup>4</sup>  
Chris Blanchard,<sup>5</sup> Jo-Anne Gagnier,<sup>1</sup>  
Anil Gupta,<sup>6</sup> Kerri-Anne Mullen,<sup>1</sup> Paul Oh,<sup>7</sup>  
Sophia Papadakis,<sup>1,2</sup> Heather Tulloch,<sup>1,2</sup>  
Allana G. LeBlanc,<sup>1</sup> George A. Wells,<sup>1,2</sup>  
and Andrew L. Pipe<sup>1,2</sup>

## OBJECTIVE

To test whether a practice-level intervention to promote the systematic identification, treatment, and follow-up of smokers (the Ottawa Model for Smoking Cessation [OMSC]) would improve long-term abstinence rates among smoker-patients with type 2 diabetes or prediabetes receiving care from diabetes education programs in Ontario, Canada.

## RESEARCH DESIGN AND METHODS

The Tobacco Intervention in Diabetes Education study was a matched-pair, cluster-randomized clinical trial. Within each pair, sites were randomly allocated to either an OMSC intervention ( $n = 7$ ) or a wait-list control (WLC) condition ( $n = 7$ ). Diabetes education programs in the OMSC group introduced standardized processes to identify smokers and routinely provided smoking cessation interventions and follow-up. Smokers in the OMSC group received counseling, a discount card to partially cover the cost of smoking cessation medication, and follow-up telephone calls over a 6-month period. Diabetes education programs in the WLC condition were offered the OMSC intervention after a 1-year waiting period. Smokers in the WLC group received usual care for smoking cessation from their diabetes educator. The primary end point was carbon monoxide (CO)-confirmed 7-day point prevalence abstinence from smoking at 6-month follow-up.

## RESULTS

A total of 313 smokers (OMSC group  $n = 199$ , WLC group  $n = 114$ ) with diabetes or prediabetes were enrolled. The CO-confirmed abstinence rate at 6 months was 11.1% in the OMSC group versus 2.6% in the WLC group (odds ratio 3.73 [95% CI 1.20, 11.58];  $P = 0.02$ ).

## CONCLUSIONS

Implementation of the OMSC in diabetes education programs resulted in clinically and statistically significant improvements in long-term abstinence among smokers with diabetes or prediabetes.

<sup>1</sup>Division of Prevention and Rehabilitation, University of Ottawa Heart Institute, Ottawa, Ontario, Canada

<sup>2</sup>Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada

<sup>3</sup>Division of Endocrinology and Metabolism, The Ottawa Hospital, Ottawa, Ontario, Canada

<sup>4</sup>Horizon Health Network, Fredericton, New Brunswick, Canada

<sup>5</sup>Department of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada

<sup>6</sup>Trillium Health Centre, Mississauga, Ontario, Canada

<sup>7</sup>Toronto Rehabilitation Institute, Toronto, Ontario, Canada

Corresponding author: Robert D. Reid, [breid@ottawaheart.ca](mailto:breid@ottawaheart.ca).

Received 29 August 2017 and accepted 30 November 2017.

Clinical trial reg. no. NCT01980017, [clinicaltrials.gov](http://clinicaltrials.gov).

This article contains Supplementary Data online at <http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dc17-1809/-/DC1>.

© 2017 by the American Diabetes Association. Readers may use this article as long as the work is properly cited, the use is educational and not for profit, and the work is not altered. More information is available at <http://www.diabetesjournals.org/content/license>.

Tobacco smoking is a risk factor for type 2 diabetes, increasing the likelihood for developing the disease two- to threefold (1,2). The combination of type 2 diabetes and smoking is particularly lethal. Nonsmokers with type 2 diabetes are three times more likely to die as a result of cardiovascular disease (CVD) than the general population (3), whereas smokers with type 2 diabetes are up to 8.5 times more likely to succumb to CVD than those with neither risk factor (4). Smokers with diabetes are also more likely to experience microvascular complications, such as nephropathy, microalbuminuria, neuropathy, and retinopathy (1).

Type 2 diabetes is a chronic disease that requires lifelong commitment to complex lifestyle modifications. In Canada, community-based diabetes education programs support self-care behaviors (e.g., oral medication adherence, insulin therapy, nutrition management, blood glucose monitoring, physical activity). Diabetes education programs are staffed by diabetes educators (health care professionals with specialized training and certification in diabetes education). A physician advisor also is available for consultation. Diabetes education typically covers knowledge about the disease, complications, management support, and self-management strategies; however, specific smoking cessation assistance typically is not provided despite its identification as a key vascular protection strategy (5,6). This oversight is puzzling and a missed opportunity to assist high-risk smokers.

Clinical practice guidelines for treating tobacco use and dependence are based on numerous systematic reviews and meta-analyses (7); they stress that clinicians and health care delivery systems should consistently identify and treat every tobacco user seen in a health care setting with counseling and pharmacological treatment (7). Our investigative team developed a knowledge transfer and practice change process to introduce evidence-based interventions for smoking cessation into clinical practice settings. This process is known as the Ottawa Model for Smoking Cessation (OMSC).

The OMSC program is implemented with the assistance of trained practice facilitators (8) by using a six-phase process that is based on principles of implementation science and organizational change management (9). Previous studies have demonstrated that implementation of the OMSC in hospital (9) and primary care

(10) environments is associated with increased long-term abstinence rates among smoker-patients. The objective of the current study was to test whether the OMSC intervention would improve the long-term abstinence rate of smoker-patients with type 2 diabetes or prediabetes receiving care from community diabetes education programs.

## RESEARCH DESIGN AND METHODS

### Eligibility and Study Design

The Tobacco Intervention in Diabetes Education (TIDE) study was a cluster-randomized clinical trial conducted in diabetes education programs in Ontario, Canada. Eligible diabetes education programs were located in the Champlain, South East, Central East, or Toronto Central health regions of Ontario; staffed by at least one diabetes educator to carry out a medical directive for prescribing medications; and received  $\geq 250$  referrals each year. Participating diabetes education programs were placed into matched pairs on the basis of the number of annual patient referrals and randomly assigned to either an OMSC or a wait-list control (WLC) condition. A study invitation letter was sent to all diabetes education programs in the selected health regions. Programs that expressed interest in participating met with a research coordinator to review the study protocol, ensure study eligibility, and sign a consent form. Group assignment was concealed until the program agreed to participate in the study.

The OMSC intervention was implemented with the assistance of a trained practice facilitator and consisted of four main components: 1) coaching and practice facilitation visits, 2) practice tools and real-time prompts, 3) health professional training, and 4) centralized telephone follow-up support for smoker-patients. Coaching and practice facilitation visits were conducted at the diabetes education programs. The practice facilitator worked with administrative and clinical staff to examine existing program routines and identify where evidence-based practices for tobacco dependence treatment could be placed. A clinic-specific intervention protocol was developed. Roles and responsibilities of program staff in providing specific elements were identified. Five tools were provided to programs in the OMSC group to support the integration of evidence-based smoking cessation treatments into program

flow. A tobacco use survey completed by the patient gathered information about smoking history, past quit attempts, and interest in quitting. A smoking cessation consult form provided diabetes educators with prompts and scripts related to smoking cessation counseling and contained algorithms for selecting smoking cessation pharmacotherapies. A medical directive for smoking cessation pharmacotherapies was developed and authorized by the program's medical advisor to allow diabetes educators to provide prescriptions for smoking cessation medications to patients who met predefined criteria. Medication discount cards that provided partial reimbursement (Can \$150) for smoking cessation medications were given to smoker-patients. A quit-smoking plan booklet was provided for use by diabetes educators when creating quit plans for smokers. The booklet was a written record of the agreed-upon quit date, recommended pharmacotherapy, tips to prepare for the quit day, strategies to deal with urges and cravings after the quit day, and information about telephone follow-up support. Program staff participated in a 3-h workshop on treating tobacco use and dependence. Topics included neurobiology of nicotine addiction and tobacco dependence, smoking cessation pharmacotherapies, and counseling strategies. The program-specific protocol was reviewed, and staff members were shown how to use the practice tools described above.

A summary of the OMSC patient counseling flow is provided in Supplementary Fig. 1. All patients who smoked were advised to quit smoking and informed that assistance was available. The diabetes educator assessed patient willingness to quit over the next 30 days, and counseling was tailored accordingly. If the patient was willing to quit, the diabetes educator helped to set a target quit date (TQD) and to select smoking cessation medication (nicotine replacement therapy, bupropion, or varenicline as appropriate). Instructions on how to use the selected medication were provided verbally and in the patients' quit plan booklet. The diabetes educator provided the medication discount card (Can \$150) and reviewed tips for preparing to quit and dealing with cravings provided in the booklet. The importance of follow-up was highlighted, and patients were enrolled in a centralized follow-up program unless

they chose to opt out. The follow-up program included automated telephone calls and live nurse-counselor triage calls as needed. Automated calls were made 7 days before the TQD and at 3, 14, 30, 60, 90, 120, 150, and 180 days. The call 7 days before TQD reminded patients of their quit date and asked whether their plans to quit had changed. If their plans had changed, a nurse-counselor contacted them to provide assistance. During the day 3 to day 180 calls, prerecorded questions were used to establish patient identity; smoking status; and, if quit, confidence in remaining smoke-free. Nurse-counselors monitored the system and contacted patients who had relapsed or indicated that their confidence in remaining smoke-free was low to provide additional assistance.

For patients not willing to quit over the next 30 days, a motivational counseling intervention asked patients to describe the good and not-so-good things smoking did for them and what they believed they might do about their smoking. They were offered assistance to quit when the time was right. They were provided with the quit plan booklet and offered follow-up. If patients indicated that they were interested in follow-up, they received automated telephone calls at 30, 60, 90, and 180 days after their initial visit. Prerecorded questions were used to establish patient identity, smoking status, and whether their interest in quitting had changed. Nurse-counselors contacted patients who indicated that they had become interested in quitting, assisted these patients to select a TQD and medications for smoking cessation, and mailed a medication discount card to the patient's home.

Diabetes education programs assigned to the WLC group received a copy of the 2008 update of the U.S. Department of Health and Human Services clinical practice guideline on treating tobacco use and dependence (7). They were offered the OMSC intervention after a 1-year waiting period.

A consecutive sample of eligible smoker-patients was recruited from referrals to each participating diabetes education program over a 6- to 12-month recruitment period. When patients called to make their first appointment, they were screened for smoking status by program administrative staff. Smoker-patients were asked whether they were interested in participating in a study about smoking and would agree to be contacted by a research coordinator. The research coordinators telephoned all

potential participants within 7 days of their first diabetes education program appointment, screened potential participants for eligibility, and obtained and documented verbal study consent. They completed a brief survey with consenting participants. The survey asked participants whether the diabetes educator had asked about their smoking status, assessed their interest in quitting, and provided specific assistance with quitting (i.e., setting a quit date, selecting pharmacotherapy, providing information or counseling). The survey also included questions about age, sex, education, cigarettes per day, time to first cigarette after awakening, years smoking, confidence in ability to quit, duration of diabetes or prediabetes, and comorbidities. Upon completion of the survey, participants were mailed a Can \$5 coffee shop gift card.

Smoker-patients (i.e., self-reported daily smoking of one or more cigarettes per day in the 30 days preceding recruitment) were eligible if they had been diagnosed with either type 2 diabetes or prediabetes, were age 18–80 years, were not currently involved in another smoking cessation intervention, were able to read and understand French or English, and were able and willing to provide informed consent. All participants were contacted by telephone 6 months after their index program visit by research staff blind to group assignment to ascertain smoking status and use of medications, electronic cigarettes, and extrastudy smoking cessation resources.

### Outcomes

The primary end point was carbon monoxide (CO)-confirmed 7-day point prevalence abstinence from smoking (i.e., no smoking, not even a puff, in the past 7 days) at 6-month follow-up. Patients who reported 7-day point prevalence abstinence had their smoking status verified by using CO monitoring during an in-person visit. Continuous abstinence rates (i.e., no smoking between weeks 1 and 26) also were gathered. Participants who were unavailable for follow-up or CO validation, dropped out, or were lost to follow-up were considered to be smokers for the purposes of analysis. Secondary outcomes included behaviors of diabetes education program staff. Participants were asked whether their diabetes educator had asked about smoking status; assessed their interest in quitting; and provided assistance with quitting, including help to set a

quit date, a prescription for pharmacotherapy, self-help materials, and arrangements for follow-up support. Tertiary outcomes included participant use of medications, electronic cigarettes, and extrastudy smoking cessation resources.

### Study Oversight

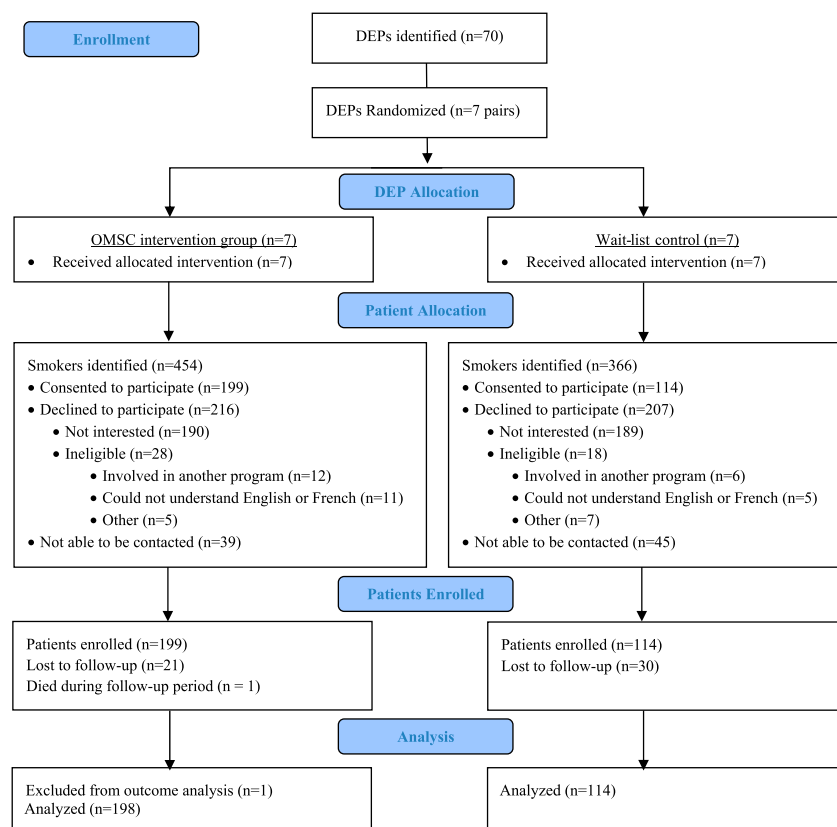
The Ottawa Health Science Network Research Ethics Board approved the study, and all participants provided informed consent before data collection.

### Statistical Analysis

Sample-size calculations took into account the complexity of the study design (i.e., matched pair and cluster randomized [unit of randomization was diabetes education program, and unit of analysis was patient]) (11). We used an intracluster correlation coefficient of 0.02 and an average cluster size of 40 smokers per program in our calculation (on the basis of unpublished data from a pilot study). We analyzed the primary smoking cessation outcomes at the cluster level by using aggregate data for each cluster on the basis of a random-effects meta-analysis (12). This method treated the results from each pair of diabetes education programs as a separate study and provided a pooled estimate of effect weighted for the size of the cluster and the size of the effects and their SEs. We used RevMan statistical software to produce weighted estimates of the overall abstinence rate differences between groups, 95% CIs, and levels of significance. For the analysis of the effects of the intervention on behaviors of diabetes education program staff, rates of asking about smoking, assessing interest in quitting, and providing various forms of assistance were compared between groups by using similar methods as for the primary outcome.

### RESULTS

Fourteen diabetes education programs were placed into seven matched pairs (Fig. 1). Within each pair, one program was randomly assigned to the OMSC group and the other to the WLC group. A total of 7,106 patients were screened for smoking status, and 820 smokers were identified. A small number of smokers were ineligible because they were already involved in a smoking cessation intervention ( $n = 18$ ), could not understand English or French ( $n = 16$ ), or could not be



**Figure 1**—Flow of participants through the study. DEP, diabetes education program.

contacted by the research coordinator ( $n = 84$ ). A total of 313 patients were enrolled, and 312 were included in the analysis (OMSC  $n = 198$ , WLC  $n = 114$ ) (Fig. 1). One participant in the OMSC group died during the follow-up period and was removed from the outcome analysis per convention in studies of smoking cessation interventions (13). Participants smoked an average of  $19.3 \pm 11.1$  cigarettes per day at baseline (Table 1), and the mean number of years they had smoked was  $35.6 \pm 11.9$ . Forty-three percent of participants ( $n = 135$ ) indicated that they were willing to quit smoking over the next 30 days, whereas 57% were not willing to quit over that period. Mean confidence in quitting on a scale of 1–10 (1 = not at all confident, 10 = completely confident) was  $5.6 \pm 3.0$  in the OMSC group versus  $5.5 \pm 3.0$  in the WLC group ( $P = 0.89$ ). The mean age of participants was  $54.4 \pm 10.6$  years; 55.9% were male, and 77.0% were Caucasian. Most participants (84.0%) had type 2 diabetes versus prediabetes (16.0%). More than one-third (35.8%) reported a history of anxiety and/or depression. There were

no differences between groups at baseline. Complete outcome data were available for 177 of 198 (89.4%) in OMSC group and 84 of 114 (73.7%) in the WLC group.

We tracked several practice- and patient-level process measures (Table 2). With regard to practice-level indicators, 47 facilitation contacts were made with the seven diabetes education programs in the OMSC intervention group (average number of contacts/program 6.7), and 70 diabetes educators received OMSC training on tobacco dependence treatment. Despite a persistent effort, none of the OMSC program sites was able to introduce a medical directive for smoking cessation medication during the study period. Patient-level process indicators were obtained from medication discount card redemption records, enrollments in the telephone follow-up system, and nurse-counselor records. Of the 88 patients in the OMSC intervention willing to quit within 30 days, medication discount cards were redeemed by 75 (85%), and 73 (83%) were enrolled in the telephone follow-up system. Nurse-counselors completed an average of 3.2 calls to each

participant enrolled in the willing-to-quit follow-up protocol. Of the 111 patients in the OMSC intervention not willing to quit, 23 (20.7%) enrolled in the telephone follow-up system, and nurse-counselors completed an average of 1.4 calls to each of these patients. Descriptive statistics for rates of use of medications, electronic cigarettes, and extrastudy smoking cessation resources among study participants are shown in Table 2.

The primary smoking cessation results are shown in Fig. 2. The CO-confirmed abstinence rate was 11.1% among OMSC participants (22 of 198 abstinent at 6-month follow-up) versus 2.6% among WLC participants (3 of 114 abstinent at 6-month follow-up) (odds ratio [OR] 3.73 [95% CI 1.20, 11.58];  $P = 0.02$ ). This means that 12 smokers would have to be treated with the OMSC intervention to achieve one 6-month quit. Sensitivity analyses were conducted by using only participants with complete outcome data to assess the impact of missing data on the results. Among those with complete data, the CO-confirmed abstinence rate was 12.4% among OMSC participants versus 3.6% among WLC participants (3.40 [1.08, 10.70];  $P = 0.04$ ).

In addition to the effect of treatment, we examined other predictors of cessation. Compared with patients who were not willing to quit in the next 30 days, those who were willing to quit were more likely to be confirmed abstinent at 6-month follow-up (OR 2.7 [95% CI 1.2, 6.6]). For smokers willing to quit within the next 30 days ( $n = 135$ ), the quit rate in the OMSC group was 18.2% versus 4.3% in the WLC group ( $P = 0.023$ ); the treatment effect was 13.9%. For smokers not willing to quit in the next 30 days ( $n = 178$ ), the quit rate in the OMSC group was 6.3% versus 3.0% in the WLC group ( $P = 0.33$ ). There was also a positive association between confidence in quitting and long-term success. For every 1-point increase in baseline level of confidence to quit there was a 22% greater likelihood that the participant would be abstinent at follow-up (95% CI 1.1, 1.6). Participants in the OMSC group were more likely than WLC participants to be asked about their smoking status (OR 2.59 [95% CI 1.00, 6.69];  $P = 0.05$ ), advised to quit smoking (7.28 [3.38, 15.70];  $P < 0.001$ ), advised that assistance to quit smoking was available (8.54 [3.37, 21.67];  $P < 0.001$ ), assisted to set a quit date (6.10 [2.20, 13.18];

**Table 1—Characteristics of smokers with diabetes or prediabetes by treatment group**

Variable	OMSC group (n = 199)	WLC group (n = 114)
<b>Demographic</b>		
Age (years)	54 ± 11	55 ± 10
Male sex	55	57
Education (years)	14 ± 3	13 ± 3
<b>Smoking related</b>		
Years smoked	36 ± 12	36 ± 11
Cigarettes/day at baseline	19 ± 11	20 ± 11
Time to first cigarette after awakening		
≤30 min	70	64
>30 min	30	36
Willingness to quit in next 30 days		
Willing to quit	44	41
Not willing to quit	56	59
Confidence in ability to quit*	6 ± 3	6 ± 3
<b>Clinical, medical history</b>		
Type 2 diabetes	84	83
Prediabetes	16	17
Hypertension	16	21
Hyperlipidemia	18	18
CVD	17	19
Cancer	8	7
COPD	12	10
Anxiety and/or depression	34	39

Data are mean ± SD or %. COPD, chronic obstructive pulmonary disease. \*Scores range between 1 and 10, where 1 is not confident at all and 10 is completely confident.

$P < 0.001$ ), assisted to select smoking cessation medications (11.24 [2.99, 42.28];  $P < 0.001$ ), provided with written materials about quitting smoking (8.66 [3.07, 24.42];  $P < 0.001$ ), and scheduled for follow-up to discuss progress with smoking cessation (6.61 [2.50, 17.50];  $P = 0.001$ ).

We calculated the costs to implement and maintain the OMSC intervention in diabetes education programs, which are summarized in Supplementary Table 1. It costs Can \$1,870 per practice to implement the OMSC program, including costs related to practice facilitation and travel to visit programs for coaching,

training, and continuous quality improvement. At the patient level, the costs of implementation varied according to the willingness of patients to quit. For those willing to quit, the cost of the OMSC intervention is Can \$262 per patient. For those initially unwilling to quit, the cost of the intervention is Can \$49 per patient.

## CONCLUSIONS

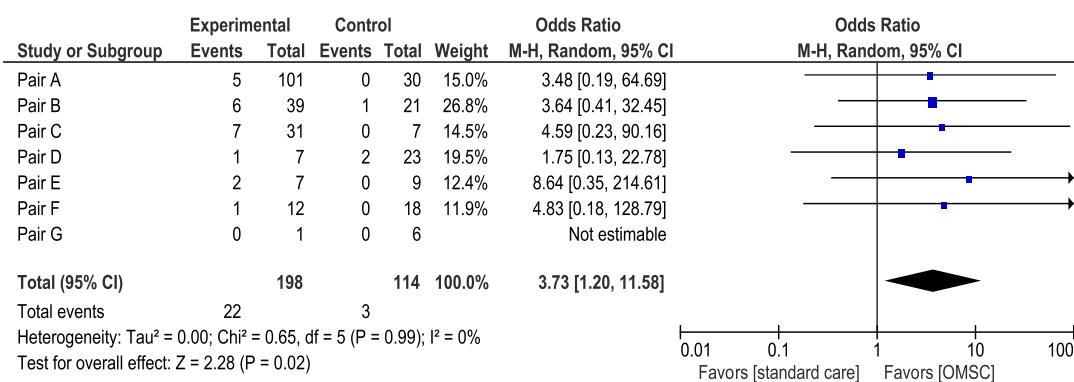
To our knowledge, this cluster-randomized study is the first of a practice-level intervention to promote the systematic identification, treatment, and follow-up of smoker-patients conducted in the diabetes education program setting and the largest randomized trial to date of a smoking cessation intervention in smokers with diabetes. Implementation of OMSC in diabetes education programs was associated with a near quadrupling of the likelihood that smokers with type 2 diabetes or prediabetes would achieve long-term abstinence. The analysis of secondary outcomes demonstrates that this practice-level intervention changes the behaviors of diabetes education program staff, ensuring that they more frequently advise, assess, assist, and arrange follow-up for their smoker-patients.

This study provides new information about scaling up smoking cessation interventions in the setting of diabetes education (i.e., it considers the effectiveness under real-life conditions). The

**Table 2—Patient-level OMSC implementation indicators and self-reported use of medications, electronic cigarettes, and extrastudy smoking cessation resources among participants at follow-up**

Variable	OMSC group (n = 199)	WLC group (n = 114)
<b>Patient-level implementation indicators (OMSC group)</b>		
Quit cards redeemed	75 (37.7)	—
Enrolled in follow-up (willing to quit)	73 (36.7)	—
Enrolled in follow-up (not willing to quit)	23 (11.6)	—
Number of nurse-counselor calls completed (willing to quit)	237	—
Number of nurse-counselor calls completed (not willing to quit)	33	—
<b>Smoking cessation medications</b>		
NRT any form	46 (23.1)	20 (17.5)
NRT patch	42 (21.1)	17 (14.9)
NRT gum	19 (9.5)	9 (7.9)
NRT inhaler	8 (4.0)	4 (3.5)
NRT lozenge	8 (4.0)	3 (2.6)
NRT oral spray	2 (1.0)	1 (0.9)
Bupropion	6 (3.0)	0 (0.0)
Varenicline	13 (6.5)	5 (4.4)
<b>Smoking cessation resource use outside study</b>		
Electronic cigarettes	25 (12.6)	18 (15.9)
Contacted external telephone quitline	8 (4.0)	1 (0.9)
Received counseling from primary care provider	48 (24.1)	29 (25.4)
Received counseling from pharmacist	3 (1.5)	0 (0.0)

Data are n (%), unless otherwise indicated. NRT, nicotine replacement therapy.



**Figure 2**—Meta-analysis for confirmed abstinence across clustered pairs. One participant (pair C, OMSC intervention group) died during the study follow-up period and was removed from the outcome analysis. M-H, Mantel-Haenszel test.

intervention was delivered at the clinic level and at the level of individual smokers in line with best practices for optimizing delivery of smoking cessation interventions in primary care (14). We included all smokers willing to participate in a trial of smoking behavior, not just those motivated to quit, and tailored interventions to smoker-patients willing and not willing to quit. The interventions were delivered by regular diabetes education staff, not research staff.

The effects of the OMSC intervention are in line with previous randomized controlled trials of smoking cessation and type 2 diabetes (15,16). In these studies, biochemically verified long-term smoking cessation rates ranged from 0% to 17% in the intervention groups and 2% to 16% in the control groups, with treatment effects ranging from 3% to 9%. In the current study, quit rates were 11.1% in the OMSC intervention group and 2.6% in the WLC group; the treatment effect was 8.5%. Among those willing to quit within the next 30 days (43% of participants), the quit rate in the OMSC group was 18.2% versus 4.3% in the WLC group; the treatment effect was 13.9%. Over time, we believe that these absolute quit rates will increase significantly. Continuous quality improvement is a critical aspect of OMSC implementation (i.e., providing feedback to clinics and frontline staff on actual performance, enabling clinics to see improvement and track progress, increasing accountability). During the study, there was insufficient time to do the several rounds of quality improvement typically required to optimize performance.

The 6-month abstinence rates observed in this trial are lower than abstinence rates typically reported in trials of

smoking cessation interventions in patients with other chronic diseases (e.g., heart disease, chronic pulmonary disease). Abstinence rates have ranged from 15% to 50% in these populations (17,18), depending on whether participants were recruited from acute or outpatient settings, which may indicate that patients with type 2 diabetes experience more difficulties in the process of quitting. The self-management of diabetes can be burdensome for patients, and quitting smoking may reflect an additional challenge they are not prepared for.

The current study highlights the need to address institutional barriers to delivery of smoking cessation interventions in the diabetes education setting. Although guidelines have identified smoking cessation as a key element of diabetes education (5,6), tobacco use is not always viewed as a priority by diabetes educators and medical advisors, whose attention is focused on glycemic control and other aspects of self-care. Over the course of the study, no OMSC group programs introduced medical directives for smoking cessation medications. There may be a need to provide specific training for medical advisors to help them to better understand smoking cessation medications and interactions between treatments for smoking cessation and glycemic control. Given staff turnover in diabetes education programs, continuous training updates are required to ensure that necessary skills are developed and to change stakeholder awareness and attitudes toward cessation.

This study had a number of important strengths. Enrolling and treating study participants according to random assignment of diabetes education programs

(clusters) reduced the risk of bias in treatment application and enhanced participant compliance with study procedures. We had relatively fewer participants lost to follow-up at 6 months (16.3%) than other studies of smoking cessation interventions (up to 40%). The study included heavy smokers with long smoking histories and comorbidities common among people with diabetes, including depression, anxiety, hypertension, and dyslipidemia. We included all smokers regardless of their motivation to quit and used a multicomponent intervention at the practice and patient levels that combined counseling with smoking cessation medications. We used CO measured in expired breath to validate self-reports of nonsmoking. Outcome assessors were blinded to treatment group assignment.

The study had some limitations. Cluster-randomized trials can be susceptible to methodological problems, including selection bias introduced through participant recruitment (19). We were unable to conceal treatment allocation from diabetes education programs or potential smoker-patients. Those recruiting participants had knowledge of their treatment allocation (OMSC or WLC) and may have recruited patients with varying prognostic characteristics on the basis of their treatment. Figure 1 shows that more smokers consented to participate in the study in the OMSC (51.4%) versus the WLC (37.6%) practices. However, the comparison of baseline demographic, smoking-related, and clinical variables did not reveal imbalances between groups, suggesting that recruitment bias did not affect the results. More people were lost to follow-up in the WLC condition; however, sensitivity analyses conducted



by using only participants with complete outcome data showed that the results were consistent after controlling for missing data. We did not gather data about the effects of the intervention on glycemic control or body weight, which are common concerns for diabetes educators. Future studies should address these outcomes alongside cessation. Our intervention was implemented by diabetes educators working with indirect physician supervision in diabetes education programs in Ontario, Canada, which may limit generalizability to other smokers with type 2 diabetes. Diabetes care may be organized differently in other jurisdictions. Finally, prescription medication use was suboptimal likely because of the lack of success in implementing medical directives.

In patients with diabetes, tobacco smoking increases the risk of death by 48%, coronary heart disease by 54%, stroke by 44%, and myocardial infarction by 52% (20). There is a direct, positive relationship between number of cigarettes smoked per day and risk for coronary heart disease, stroke, and proteinuria (21,22). Smokers with diabetes have higher glycated hemoglobin levels (23) and are more likely to experience severe hypoglycemia (24). Although smoking cessation treatments have been recommended as a routine component of the treatment of diabetes, diabetes education programs have been slow to adopt such treatments in practice. This study provides new evidence about how knowledge of smoking cessation interventions can be incorporated into routine diabetes education practice.

**Funding.** Planning, design, and preparation of the funding proposal for the TIDE study was completed as part of a Canadian Institutes of Health Research Meetings, Planning and Dissemination grant (application #256992). Pfizer funded TIDE, an investigator-initiated trial, with a Global Research Award for Nicotine Dependence. Pfizer played no role in the design, conduct, analysis, interpretation of data, or reporting of the TIDE trial.

**Duality of Interest.** The OMSC is a trademark of the University of Ottawa Heart Institute, which employs several of the authors. R.D.R., A.G., P.O., and A.L.P. have received honoraria from Pfizer for

providing continuing medical education on smoking cessation. R.D.R. and A.L.P. have received honoraria from Johnson & Johnson for providing continuing medical education on smoking cessation. No other potential conflicts of interest relevant to this article were reported.

**Author Contributions.** R.D.R. designed the study, oversaw the data collection, conducted the statistical analysis, and wrote the manuscript. J.M., D.A., C.B., A.G., K.-A.M., P.O., S.P., H.T., G.A.W., and A.L.P. designed the study. E.W., A.G., D.A., and J.-A.G. collected data. A.G.L. and G.A.W. conducted statistical analyses. All authors reviewed and edited the manuscript and approved its final form. R.D.R. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

## References

- Haire-Joshu D, Glasgow RE, Tibbs TL; American Diabetes Association. Smoking and diabetes. *Diabetes Care* 2004;27(Suppl. 1):S74–S75
- Willi C, Bodenmann P, Ghali WA, Faris PD, Cornuz J. Active smoking and the risk of type 2 diabetes: a systematic review and meta-analysis. *JAMA* 2007;298:2654–2664
- Doll R, Peto R, Boreham J, Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. *BMJ* 2004;328:1519
- Stamler J, Vaccaro O, Neaton JD, Wentworth D. Diabetes, other risk factors, and 12-yr cardiovascular mortality for men screened in the Multiple Risk Factor Intervention Trial. *Diabetes Care* 1993;16:434–444
- Cheng AY; Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2013 clinical practice guidelines for the prevention and management of diabetes in Canada. Introduction. *Can J Diabetes* 2013;37(Suppl. 1):S1–S3
- American Diabetes Association. Lifestyle management. Sec. 4. In *Standards of Medical Care in Diabetes—2017*. *Diabetes Care* 2017;40(Suppl. 1):S33–S43
- Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD, U.S. Department of Health and Human Services, Public Health Service, 2008
- Baskerville NB, Liddy C, Hogg W. Systematic review and meta-analysis of practice facilitation within primary care settings. *Ann Fam Med* 2012;10:63–74
- Reid RD, Mullen KA, Slovinc D'Angelo ME, et al. Smoking cessation for hospitalized smokers: an evaluation of the "Ottawa Model". *Nicotine Tob Res* 2010;12:11–18
- Papadakis S, Cole AG, Reid RD, et al. Increasing rates of tobacco treatment delivery in primary care practice: evaluation of the Ottawa Model for Smoking Cessation. *Ann Fam Med* 2016;14:235–243
- Campbell MK, Mollison J, Grimshaw JM. Cluster trials in implementation research: estimation of intracluster correlation coefficients and sample size. *Stat Med* 2001;20:391–399
- Thompson SG, Pyke SD, Hardy RJ. The design and analysis of paired cluster randomized trials: an application of meta-analysis techniques. *Stat Med* 1997;16:2063–2079
- West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction* 2005;100:299–303
- Papadakis S, McDonald P, Mullen KA, Reid R, Skulsky K, Pipe A. Strategies to increase the delivery of smoking cessation treatments in primary care settings: a systematic review and meta-analysis. *Prev Med* 2010;51:199–213
- Nagrebetsky A, Brettell R, Roberts N, Farmer A. Smoking cessation in adults with diabetes: a systematic review and meta-analysis of data from randomised controlled trials. *BMJ Open* 2014;4:e004107
- Li WH, Wang MP, Lam TH, et al. Brief intervention to promote smoking cessation and improve glycemic control in smokers with type 2 diabetes: a randomized controlled trial. *Sci Rep* 2017;7:45902
- Eisenberg MJ, Blum LM, Filion KB, et al. The efficacy of smoking cessation therapies in cardiac patients: a meta-analysis of randomized controlled trials. *Can J Cardiol* 2010;26:73–79
- Pires-Yfantouda R, Absalom G, Clemens F. Smoking cessation interventions for COPD: a review of the literature. *Respir Care* 2013;58:1955–1962
- Hahn S, Puffer S, Torgerson DJ, Watson J. Methodological bias in cluster randomised trials. *BMC Med Res Methodol* 2005;5:10
- Qin R, Chen T, Lou Q, Yu D. Excess risk of mortality and cardiovascular events associated with smoking among patients with diabetes: meta-analysis of observational prospective studies. *Int J Cardiol* 2013;167:342–350
- Fagard RH. Smoking amplifies cardiovascular risk in patients with hypertension and diabetes. *Diabetes Care* 2009;32(Suppl. 2):S429–S431
- Hsu CC, Hwang SJ, Tai TY, et al. Cigarette smoking and proteinuria in Taiwanese men with type 2 diabetes mellitus. *Diabet Med* 2010;27:295–302
- Nilsson PM, Gudbjörnsdóttir S, Eliasson B, Cederholm J; Steering Committee of the Swedish National Diabetes Register. Smoking is associated with increased HbA1c values and microalbuminuria in patients with diabetes—data from the National Diabetes Register in Sweden. *Diabetes Metab* 2004;30:261–268
- Hirai FE, Moss SE, Klein BE, Klein R. Severe hypoglycemia and smoking in a long-term type 1 diabetic population: Wisconsin Epidemiologic Study of Diabetic Retinopathy. *Diabetes Care* 2007;30:1437–1441