

Effect of Adding Pharmacists to Primary Care Teams on Blood Pressure Control in Patients With Type 2 Diabetes

A randomized controlled trial

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OBJECTIVE — To evaluate the effect of adding pharmacists to primary care teams on the management of hypertension and other cardiovascular risk factors in patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS — We conducted a randomized controlled trial with blinded ascertainment of outcomes within primary care clinics in Edmonton, Canada. Pharmacists performed medication assessments and limited history and physical examinations and provided guideline-concordant recommendations to optimize medication management. Follow-up contact was completed as necessary. Control patients received usual care. The primary outcome was a $\geq 10\%$ decrease in systolic blood pressure at 1 year.

RESULTS — A total of 260 patients were enrolled, 57% were women, the mean age was 59 years, diabetes duration was 6 years, and blood pressure was 129/74 mmHg. Forty-eight of 131 (37%) intervention patients and 30 of 129 (23%) control patients achieved the primary outcome (odds ratio 1.9 [95% CI 1.1–3.3]; $P = 0.02$). Among 153 patients with inadequately controlled hypertension at baseline, intervention patients ($n = 82$) were significantly more likely than control patients ($n = 71$) to achieve the primary outcome (41 [50%] vs. 20 [28%]; 2.6 [1.3–5.0]; $P = 0.007$) and recommended blood pressure targets (44 [54%] vs. 21 [30%]; 2.8 [1.4–5.4]; $P = 0.003$). The 10-year risk of cardiovascular disease, based on changes to the UK Prospective Diabetes Study Risk Engine, were predicted to decrease by 3% for intervention patients and 1% for control patients ($P = 0.005$).

CONCLUSIONS — Significantly more patients with type 2 diabetes achieved better blood pressure control when pharmacists were added to primary care teams, which suggests that pharmacists can make important contributions to the primary care of these patients.

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Type 2 diabetic patients are predisposed to a clustering of cardiovascular risk factors, including hypertension and dyslipidemia (1). Cardiovascular disease is the leading cause of death and disability in these patients and contributes to a substantial increase in an-

nual per capita management costs (2,3). Although the link between glycemic control and the reduction of myocardial infarction or stroke risk in type 2 diabetes is somewhat tenuous, it is the usual focus of diabetes management in primary care settings. Conversely, there is strong evidence

demonstrating that management of hypertension and dyslipidemia in these patients significantly lowers the risk of both microvascular and cardiovascular complications (4). Indeed, blood pressure reduction probably has a greater impact on cardiovascular disease than improved glycemic control, yet it is often considered a secondary priority (5–7).

With the heightened risk of cardiovascular disease in type 2 diabetes, aggressive cardiovascular risk-factor management is recommended (8). However, uptake of these recommendations is less than ideal. For example, in northern Alberta, Canada, only 10% of all type 2 diabetic patients simultaneously achieved guideline-recommended treatment targets for A1C, blood pressure, and cholesterol (9). These findings are consistent with observations from elsewhere in Canada, the U.S., and the European Union, where $< 5\%$ of diabetic patients met these combined treatment targets. Possible explanations for the discrepancy between evidence-based recommendations and current practice include a glucocentric focus of diabetes care and the complex medication regimens often required to achieve treatment targets. For instance, two or more antihypertensive medications may be required to achieve blood pressure targets (10).

Pharmacists are trained to optimize medication management, especially when regimens become complex. Addition of pharmacists to in-patient services and specialty clinics can improve outcomes and lower total medical costs. However, studies of pharmacist contributions to diabetes management have focused on glycemic control (11). We identified only three randomized controlled trials that examined pharmacist contributions to type 2 diabetes management and that used improvements in blood pressure control as the primary outcome (supplementary Table 1 and supplementary Fig. 1 in the online appendix, available at <http://care.diabetesjournals.org/cgi/content/full/dc10-1294/DC1>) (12–14). Although all

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three studies demonstrated benefits, it is difficult to generalize the findings to primary care settings. One study (12) was set in a university-affiliated clinic where pharmacists had prescriptive authority and direct contact with university-based specialist physicians. The other two studies (13,14) were set in community pharmacies where pharmacists indirectly communicated recommendations to primary care physicians via fax or letter. These previous studies did not examine the effects of pharmacists working directly with a primary care team.

For these reasons, we studied the effect of adding pharmacists to extant multidisciplinary primary care teams (the Canadian equivalent of the patient-centered medical home [15]) on cardiovascular risk-factor management in type 2 diabetes. We focused on hypertension because it is the most common risk factor present in type 2 diabetic patients, and any insights garnered could be easily applied to other primary care patients with hypertension. We hypothesized that compared with usual care, the addition of a pharmacist would significantly change blood pressure control.

RESEARCH DESIGN AND METHODS

This randomized controlled trial was conducted in five primary care clinics affiliated with the Edmonton South Side Primary Care Network in Edmonton, Canada. These primary care teams were akin to the patient-centered medical home (15) and consisted of physicians and nurses who had support from dietitians, physiotherapists, and social workers as needed. Patients were eligible if they had type 2 diabetes, were regularly seen by the primary care team, and did not qualify for urgent specialist referral and assessment (according to protocol, a fasting blood glucose ≥ 17 mmol/L, blood pressure $\geq 220/120$ mmHg, or triglycerides ≥ 15 mmol/L). We excluded patients who were followed in specialty clinics for diabetes, hypertension, or dyslipidemia; who were cognitively impaired; who were not responsible for their own medication administration; or who were unable to communicate in English. Blood pressure screening was not conducted during patient recruitment to minimize contamination of controls. Because type 2 diabetic patients have higher blood pressure levels than the general population (1), we felt that this approach was justifiable for a pragmatic study design.

Eligible patients were identified from

the clinic roster, and a clinic staff member made initial contact to tell patients about the study. Patients were told that the study was designed to help improve medication therapy for heart disease risk in patients with type 2 diabetes. The specific focus of the study, hypertension, was listed among other risk factors for heart disease. The University of Alberta Health Research Ethics Board approved the study protocol, and all participants gave written informed consent. Pharmacists were given access to the patient's clinical chart after consent to participate in the study was obtained.

Randomization

A central randomization service (www.epicore.ualberta.ca) provided computer-generated random sequences stratified by the primary care clinic for treatment allocation. Pharmacists, analysts, and investigators were unaware of the block size and allocation sequence to preserve allocation concealment.

Control patients

Control patients received usual care by the primary care team without contributions from study pharmacists, except for standardized blood pressure measurements at the end of the follow-up period (see below).

Intervention

Two pharmacists providing the intervention program held a Bachelor's Degree in pharmacy, were Certified Diabetes Educators, and had practiced in community pharmacies for over 5 years. Both pharmacists completed structured online training courses for hypertension and diabetes management (www.pharmalearn.com) and reviewed the Canadian Hypertension Education Program and Canadian Diabetes Association guideline recommendations prior to starting the study (16,17).

The intervention program began with an in-person visit with a study pharmacist to identify all prescription, nonprescription, complementary, and alternative medications. Pharmacists also measured the patient's height, weight, heart rate, and blood pressure. Blood pressure was measured according to the Canadian Hypertension Education Program recommendations using the BPTru BPM-100 (VSM Med Tech, Coquitlam, BC) automated machine set to report the average of five measurements at 1-min intervals (16). Pharmacists then formulated guide-

line-concordant recommendations to optimize medication management of blood pressure and other cardiovascular risk factors. These recommendations were discussed with the primary care physician who was responsible for authorizing medication changes. The pharmacist then worked independently with the patient to implement these changes.

Follow-up

Baseline characteristics were obtained from the clinic chart. Interim contact with intervention patients was made at the discretion of the pharmacist, physician, or patient and could be conducted via telephone or in person. Interim contacts were used to determine whether medication changes were implemented and to address questions or concerns since the previous encounter (e.g., side effects, adverse events, or adherence issues). Pharmacists recorded the date, duration, and nature of each contact with a study patient. After 1 year, all patients were seen in the primary care clinic to review medications, measure blood pressure with the automated machine, and obtain a fasting blood sample to measure blood glucose, A1C, and cholesterol profile. Patients also reported the number of encounters with specialists, other health care professionals, regional health care resources, emergency-room visits, and hospitalizations during the previous year.

Outcomes

The primary outcome was achievement of a clinically important reduction in blood pressure, defined as a $\geq 10\%$ decrease in systolic blood pressure at 1 year (18). Secondary outcomes included the absolute change in systolic blood pressure from baseline to 1 year, achievement of recommended blood pressure targets ($< 130/80$ mmHg) (8), and antihypertensive medication changes. We also measured the change in predicted 10-year risk of cardiovascular disease using the UK Prospective Diabetes Study (UKPDS) Risk Engine (19). Baseline and follow-up values for A1C, systolic blood pressure, total cholesterol, and HDL cholesterol were used to calculate the change in the UKPDS Risk Engine score.

Statistical analysis

Our sample size was based on observations from a previous study (20) examining the effect of a diabetes intervention program aimed at physicians. In that study, 40% of intervention patients and

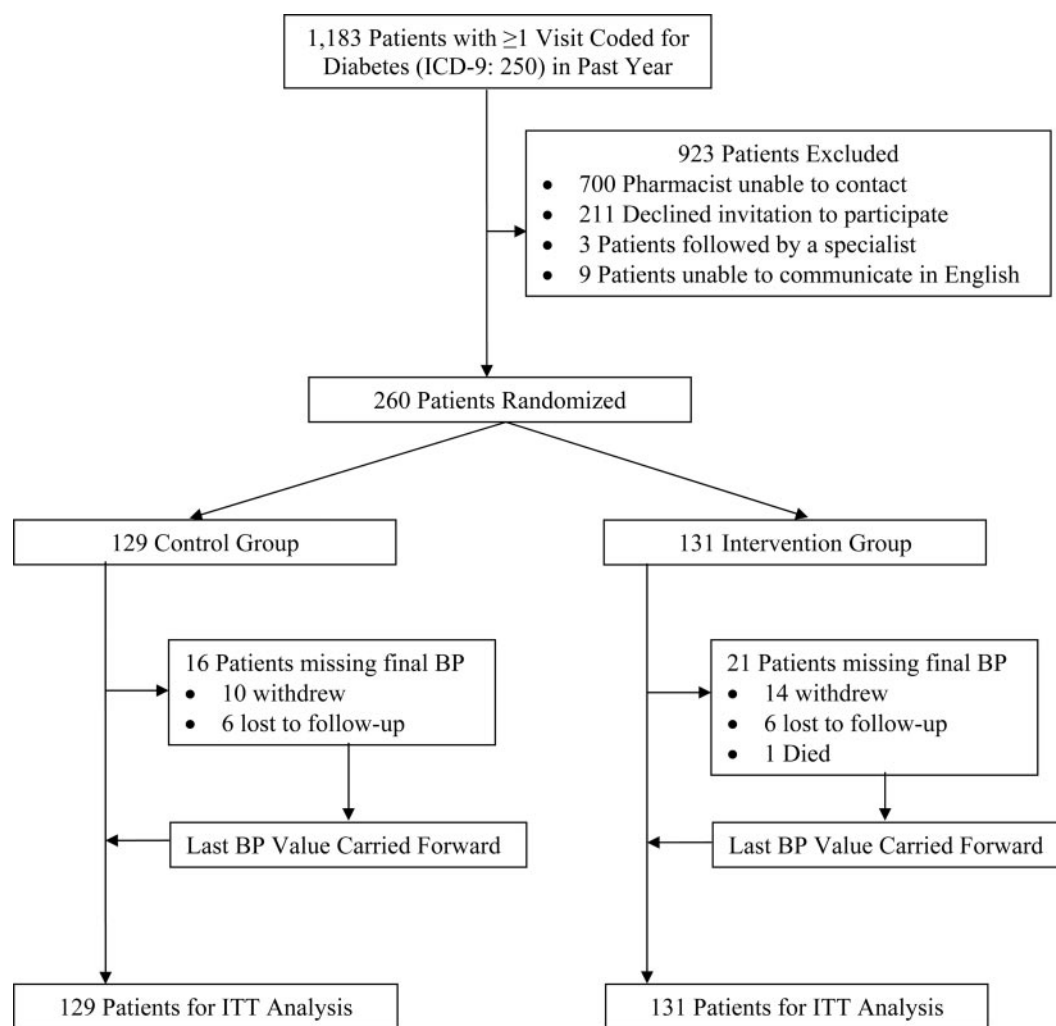


Figure 1—Study participant flowchart. ICD-9, International Classification of Diseases, 9th revision; BP, blood pressure; ITT, intention to treat.

25% of control patients achieved a $\geq 10\%$ decrease in blood pressure at 6 months. Although the current study follow-up was twice as long and the intervention was directed at patients, we estimated that the event rates would be similar. With a two-sided α of 0.05 and 80% power, we estimated the total sample size would be ~ 300 patients.

We used χ^2 statistics to test for between-group differences in the primary outcome. The association between treatment group and achievement of the primary outcome was also examined using a logistic regression model to calculate an odds ratio (OR) and 95% CI. The unit of analysis and causal inference was the patient. Based on the results of related trials in our region (13,20,21), we assumed that patient-related outcomes were statistically independent of one another, with intracluster correlation coefficients < 0.01 . All patients were evaluated in the groups to which they were randomly al-

located according to the intention-to-treat principle. Missing data were replaced by carrying the last observation forward.

To test the robustness of our observations, we restricted our analyses to patients who completed the full study protocol and patients with inadequately controlled hypertension at baseline. We also conducted two sensitivity analyses to account for potential hierarchical statistical clustering. First, we used indicator variables to directly adjust for all 18 family physicians involved in the study in a multivariate logistic regression model. Second, we used generalized estimating equation methodology to account for the potential correlations of outcomes among patients treated by the same physician. None of the sensitivity analyses changed the direction, magnitude, or statistical significance of our findings; therefore, we report only our prespecified analyses. A P value of < 0.05 was considered statisti-

cally significant, and PASW Statistics version 18.0 (SPSS, Chicago, IL) was used for all analyses.

RESULTS— We enrolled 260 patients between 28 February 2006 and 6 December 2007 and randomly allocated 131 to the intervention and 129 to the control group (Fig. 1). The main reasons for exclusion were that the pharmacist could not contact eligible patients (700 of 1,183 [59%]) and patient refusal (211 of 1,183 [18%]). The final 1-year follow-up visit was completed on 30 January 2009. There were 21 intervention patients (14 withdrew, 6 were lost to follow-up, and 1 died) and 16 control patients (10 withdrew and 6 were lost to follow-up) who did not complete the study ($P > 0.05$ for all comparisons). There were no differences in age, sex, diabetes duration, or baseline blood pressure between the patients who did or did not complete the study.

Patient characteristics

Baseline characteristics were well balanced between the groups (Table 1). There were 149 (57.3%) women, mean (\pm SD) age was 59.1 ± 11.6 years, BMI was 32.5 ± 6.5 kg/m², diabetes duration was 5.5 ± 6.5 years, and A1C was $7.4 \pm 1.4\%$. The mean blood pressure at baseline was $129.4 \pm 15.3/74.1 \pm 10.4$ mmHg, with 82 of 131 (63%) intervention patients and 71 of 129 (55%) control patients having inadequately controlled hypertension ($\geq 130/80$ mmHg; $P = 0.22$ for difference). Of 107 patients with a blood pressure $< 130/80$ mmHg, 76 were taking one or more antihypertensive medications at baseline.

Blood pressure changes

Over 1 year, there was a statistically significant reduction in systolic blood pressure for intervention patients (mean decrease 7.4 mmHg [95% CI 4.6–10.2]; $P < 0.001$) but not for control patients (2.5 mmHg [–0.1 to 5.2]; $P = 0.06$) (supplementary Fig. 1). The between-group difference in systolic blood pressure change at 1 year was 4.9 mmHg (95% CI 1.0–8.7; $P = 0.01$) (supplementary Table 2) in favor of the intervention. The primary outcome was achieved by 48 of 131 (37%) intervention patients and 30 of 129 (23%) control patients (OR 1.91 [95% CI 1.11–3.28]; $P = 0.02$) (Fig. 2). The absolute difference of 14% translates to a number needed to treat (NNT) of seven patients followed for 1 year by a pharmacist to achieve one additional patient with better blood pressure control compared with usual care.

Limiting our analyses to 223 patients who completed the study revealed similar results. The mean decrease in systolic blood pressure was 7.7 mmHg (95% CI 4.5–10.9; $P < 0.001$) for intervention patients and 2.8 mmHg (–0.2 to 5.8; $P = 0.07$) for control patients ($P = 0.03$ for between-group differences). More intervention patients achieved the primary outcome (41 of 110 [37%]) compared with control patients (30 of 113 [27%]); however, this difference was not statistically significant ($P = 0.09$).

We observed a larger treatment effect when blood pressure changes were examined in 153 patients with inadequately controlled hypertension at baseline. Mean blood pressure at baseline was $138.7 \pm 11.4/78.8 \pm 9.4$ mmHg for intervention patients and $137.9 \pm 14.1/78.1 \pm 11.4$ mmHg for control patients ($P > 0.05$). All other baseline characteristics for these

Table 1—Baseline characteristics

Characteristic	Control patients	Intervention patients
<i>n</i>	129	131
Age (years)	59.4 ± 12.1	58.8 ± 11.1
Female	75 (58.1)	74 (56.5)
Current smoker	15 (11.6)	19 (14.5)
BMI (kg/m ²)	33.4 ± 5.7	31.8 ± 7.0
Comorbidities		
Atrial fibrillation	10 (7.8)	4 (3.1)
Coronary artery disease	23 (17.8)	18 (13.7)
Stroke	3 (2.3)	7 (5.3)
Peripheral arterial disease	5 (3.9)	2 (1.5)
Depression	21 (16.3)	31 (23.7)
Duration of diabetes (years)	5.9 ± 7.8	5.0 ± 4.9
A1C (%)	7.3 ± 1.3	7.5 ± 1.6
Cholesterol (mmol/l)		
Total	4.37 ± 0.98	4.41 ± 0.96
LDL	2.41 ± 0.72	2.42 ± 0.80
HDL	1.15 ± 0.31	1.15 ± 0.25
Triglycerides	1.74 ± 0.87	1.90 ± 1.13
Blood pressure (mmHg)		
Systolic	128.3 ± 15.7	130.4 ± 14.9
Diastolic	73.9 ± 10.8	74.4 ± 10.0
Uncontrolled ($\geq 130/80$ mmHg)	71 (55.0)	82 (62.6)
UKPDS Risk Engine score (19) (%)	21.0 ± 19.5	19.5 ± 16.4

Data are means \pm SD for continuous variables and *n* (%) for categorical variables.

153 patients were well balanced between the two groups ($P > 0.05$ for all comparisons). Systolic blood pressure decreased a mean of 13.9 mmHg (95% CI 10.6–17.1; $P < 0.001$) for intervention patients and 6.7 mmHg (3.2–10.1; $P < 0.001$) for control patients ($P = 0.002$ for between-group differences) (supplementary Fig. 1). The primary outcome was achieved by 41 of 82 (50%) intervention patients and 20 of 71 (28%) control patients (OR 2.55 [95% CI 1.30–5.01]; $P = 0.007$) (Fig. 2). This absolute difference of 22% translates to an NNT of five. Moreover, among these 153 patients, 44 of 82 (54%) intervention patients and 21 of 71 (30%) control patients achieved recommended blood pressure targets at 1 year (2.76 [1.41–5.39]; $P = 0.003$; NNT = 4).

Antihypertensive medication changes

Fifty-five (42%) intervention patients had 85 changes and 32 (25%) control patients had 44 changes to their antihypertensive medication regimen (OR 2.19 [95% CI 1.30–3.71]; $P = 0.003$) (supplementary Fig. 2). Among those with uncontrolled hypertension at baseline, only 61 of 153 (40%) had changes. The most common antihypertensive medications added to a

patient's regimen were ramipril (10 patients), hydrochlorothiazide (9 patients), and irbesartan (8 patients).

Other outcomes

Although changes in glycemic control and lipid parameters all favored the intervention, other than blood pressure control, none achieved statistical significance (supplementary Table 2). Using the UKPDS Risk Engine (19), there was a statistically significant reduction in predicted 10-year risk of cardiovascular events for intervention patients (mean decrease 2.7% [95% CI 1.5–3.9]; $P < 0.001$) but not for control patients (1.2% [–0.1 to 2.4]; $P = 0.06$). The between-group difference was 1.5% (95% CI –0.2 to 3.3; $P = 0.005$) in favor of the intervention (supplementary Table 2).

The total number of health care-related contacts was 1,439 for intervention patients and 420 for control patients ($P < 0.01$; supplementary Table 3). However, 1,442 (77.6%) of these contacts were either protocol driven (baseline and 1-year follow-up) visits or interim contacts between intervention patients and study pharmacists. Two-thirds of the interim contacts were conducted over the telephone. There were no differences in

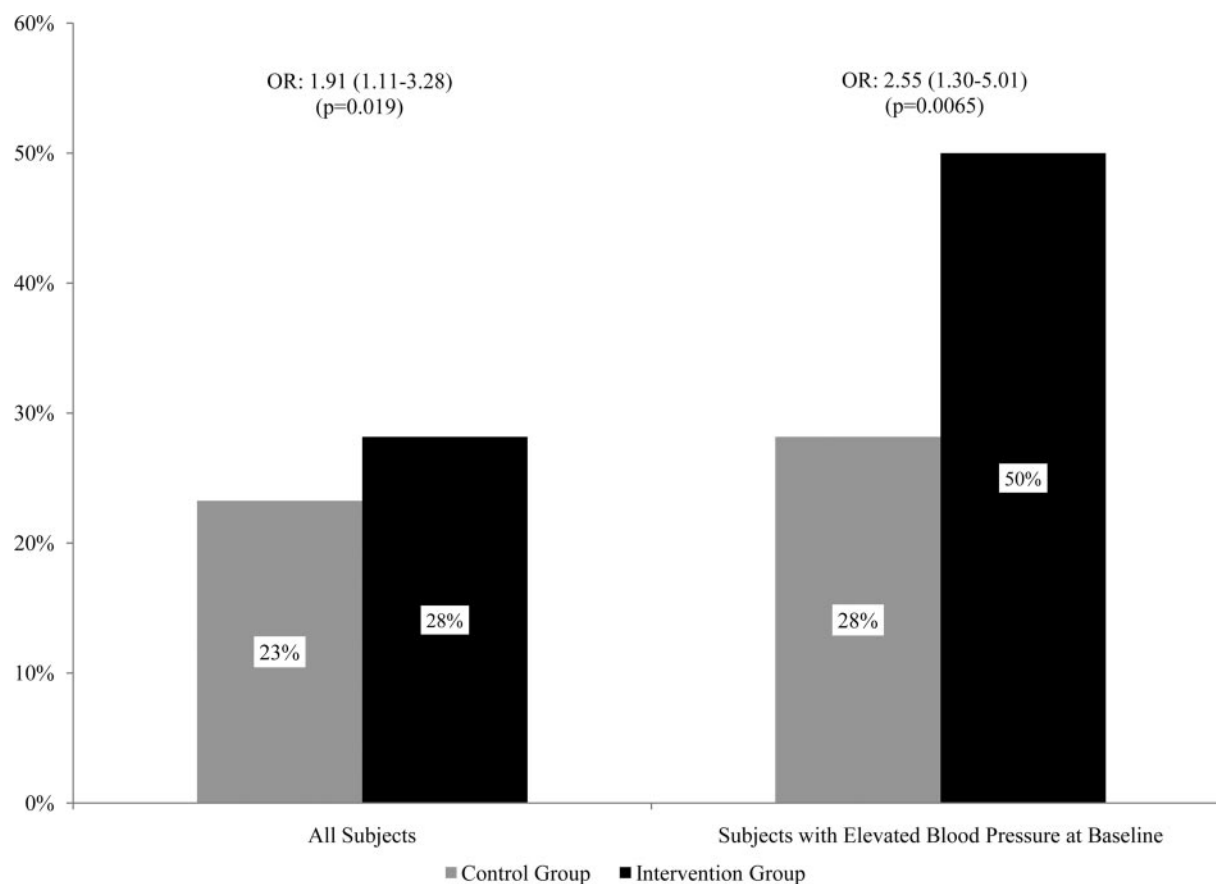


Figure 2—Proportion of patients achieving a $\geq 10\%$ decrease in systolic blood pressure at 1 year (primary outcome).

emergency-room visits (11 [8.4%] vs. 11 [8.5%]), hospitalizations (4 [3.1%] vs. five [3.9%]), or all-cause mortality (1 [0.8%] vs. 0 [0%]) between groups during the study.

CONCLUSIONS— To our knowledge, this is the largest randomized controlled trial reporting the effect of adding pharmacists to primary care teams on blood pressure control in type 2 diabetic patients. On average, most patients were relatively well controlled in terms of A1C, blood pressure, and other cardiovascular risk factors; a reflection of both the quality of usual care in this primary care network and the fact that study participants tend to be “healthier” than nonparticipants. Nevertheless, adding pharmacists to primary care teams resulted in more intervention patients achieving a clinically important reduction in systolic blood pressure at 1 year compared with control patients. The absolute difference of 14% translates to an NNT of seven, and absolute benefits were even greater among those who had inadequately controlled hypertension (i.e., 22% improvement, NNT of five). Glycemic control, cholesterol management,

and predicted 10-year risk of cardiovascular disease all showed a trend toward improvement with the pharmacist intervention.

A 10% reduction in systolic blood pressure is considered clinically worthwhile, (18) and, if sustained for another 4 years, would be associated with an $\sim 25\%$ reduction in cardiovascular events (22). Our observations are broadly consistent with three previous studies (12–14) that examined pharmacist contributions to diabetic hypertension management. All three studies reported a significant difference in systolic blood pressure change between groups and favored pharmacist intervention (supplementary Fig. 1). In our study, we might have seen a greater difference in systolic blood pressure change between groups if we had excluded people with normal blood pressure or well-controlled hypertension ($n = 107$ [41%]) or included those with elevated hypertension ($\geq 220/120$ mmHg).

We believe that the success of this study can be attributed to three critical components of the pharmacist intervention. First, pharmacists used guidelines to help formulate medication management

recommendations. These evidence-based resources provided a validated, external benchmark to identify treatment options. Second, pharmacists discussed their recommendations directly with primary care physicians and other health care professionals, which is considered an essential component of successful management programs (23). Anecdotally, these in-person “hallway” discussions facilitated a richer exchange of patient-specific ideas compared with more impersonal e-mails or faxes that are commonly used by pharmacists in the community. Third, the frequency of follow-up contact was tailored to the patient’s needs. We have found that the effects of an intervention decay over time without direct, continuous involvement and individualized support of clinicians (20,21,24).

Limitations

There are a number of limitations to consider when interpreting our results. First, we examined relatively short-term changes in surrogate measures rather than harder longer-term clinical endpoints such as myocardial infarction, stroke, or death. This limitation may be

ameliorated somewhat by the significant changes in the UKPDS risk score observed with the intervention.

Second, there was the possibility of “contamination” or “cointervention” because both intervention and control patients were drawn from the same primary care team. Although we considered a cluster-randomized trial, we estimated that there were not enough primary care teams to carry out such a study. Contamination would only tend to bias to the null, and without the pharmacist’s active intervention it is unlikely that the primary care team would pay greater attention than usual to blood pressure control in those with diabetes.

Third, our 14% drop-out rate was high but consistent with other randomized controlled trials of pharmacist involvement in diabetic hypertension management (11–14). Withdrawal rates were similar between groups, and there were no significantly different characteristics between patients who withdrew or completed the study.

Fourth, our intervention was conducted in a jurisdiction with universal health care coverage and set within established primary care teams or patient-centered medical homes, so usual care was already much better than reported in the previous literature. Nonetheless, there was still room for improvement, and adding pharmacists to this team did improve care. It is likely, therefore, that the intervention would have an even greater effect when implemented in settings with a lower baseline quality of care.

Last, the multifaceted nature of our intervention program makes it difficult to attribute the observed differences to a specific component. We believe the next stage in this line of research could be an active comparator study examining the effects of pharmacists, perhaps with prescriptive autonomy, relative to other case managers.

Conclusion

Our observations support the addition of pharmacists to primary care teams. Working in collaboration with the patient, primary care physician, and other health care professionals, pharmacists can have a significant, positive impact on blood pressure management in type 2 diabetes. We believe our results are applicable to a broad range of patients with type 2 diabetes managed in primary care settings and can be extended to nondia-

betic patients with inadequately controlled hypertension.

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S.H.S. was responsible for inception of the study, development of the methodology, protocol implementation, data analysis and wrote the manuscript. S.R.M. contributed to development of the methodology, interpretation of results and reviewed/edited the manuscript. R.T.T. contributed to development of the methodology, interpretation of results and reviewed/edited the manuscript. R.Z.L. contributed to development of the methodology, protocol implementation, interpretation of results and reviewed/edited the manuscript. R.S. contributed to protocol implementation, interpretation of results and reviewed/edited the manuscript. J.A.J. contributed to inception of the study, development of the methodology, protocol implementation, interpretation of results and reviewed/edited the manuscript.

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