Clinical Inertia in Response to Inadequate Glycemic Control

Do specialists differ from primary care physicians?

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OBJECTIVE — Diabetic patients with inadequate glycemic control ought to have their management intensified. Failure to do so can be termed "clinical inertia." Because data suggest that specialist care results in better control than primary care, we evaluated whether specialists demonstrated less clinical inertia than primary care physicians.

RESEARCH DESIGN AND METHODS — Using administrative data, we studied all non–insulin-requiring diabetic patients in eastern Ontario aged 65 or older who had A1c results >8% between September 1999 and August 2000. Drug intensification was measured by comparing glucose-lowering drug regimens in 4-month blocks before and after the elevated A1c test and was defined as *1*) the addition of a new oral drug, *2*) a dose increase of an existing oral drug, or *3*) the initiation of insulin. Propensity score-based matching was used to control for confounding between groups.

RESULTS — There were 591 patients with specialist care and 1,911 with exclusively primary care. In the matched cohorts, 45.1% of patients with specialist care versus 37.4% with primary care had drug intensification ($P = 0.009$). Most of this difference was attributed to specialists' more frequent initiation of insulin in response to elevated A1c.

CONCLUSIONS — Fewer than one-half of patients with high A1c levels had intensification of their medications, regardless of specialty of their physician. Specialists were more aggressive with insulin initiation than primary care physicians, which may contribute to the lower A1c levels seen with specialist care. Interventions assisting patients and physicians to recognize and overcome clinical inertia should improve diabetes care in the population.

Diabetes Care **28:600–606, 2005**

Clinical trials have shown that optimizing glycemic control for patients with diabetes reduces the risk of complications of the disease (1–3). As a result, clinical practice guidelines recommend that patients target A1c levels as close to normal as possible and that dietary and pharmaceutical interventions should be introduced to accomplish these goals (4). However, population-based studies show that these recommendations are frequently not met. The mean A1c for diabetic patients in the Third National Health and Nutrition Examination Study was 7.6% (5), and 41.4% of diabetic patients in two national population-based surveys had A1c levels >8% (6).

This discordance between recommendations and actual practice can be partially attributed to "clinical inertia," which has been defined as the recognition of a problem with a patient's management but a failure to act (7). Previous studies have shown that clinical inertia hinders the care of diabetic patients. In a health maintenance organization with better-than-average quality of care measures, patients had a mean of 4.5 A1c measurements >8% over 2.5 years before metformin was added to glyburide monotherapy, the first-line agent (8). A study of 1,028 patients with elevated A1c levels found that 54% had no changes to their therapy over 1 year of observation (9). A third study found that appropriate therapy was initiated for only one-half of diabetic patients not meeting glycemic control targets, one-third of patients not meeting blood pressure targets, and less than one-quarter of patients not meeting LDL cholesterol targets (10).

Although several studies have suggested that diabetic patients achieve better glycemic control with care from specialists than from primary care practitioners (11–13), the processes of care resulting in this difference have not been established. Specialists may give closer focus to diabetes issues during patient visits and offer improved access to nonphysician providers and patient education resources. In addition, specialists may have more experience and comfort with glucose-lowering medications and hence be more aggressive with their use when control is inadequate. In this study, we compared clinical inertia between specialists and primary care practitioners by evaluating whether elevated A1c levels prompted intensification of patients' glucose-lowering drug regimens.

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Received for publication 15 August 2004 and accepted in revised form 8 December 2004.

Abbreviations: ODD, Ontario Diabetes Database.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

RESEARCH DESIGN AND METHODS

Data sources

We used several administrative databases detailing health service utilization in Ontario, Canada. Data included hospitalization records, physician billing claims, and records of prescriptions filled under the provincial drug formulary, which pays much of the cost of medications for all residents aged 65 or older. Prescription data include medication strength, the number of pills dispensed, and prescription duration. All drugs paid for are recorded, including those with clinically restricted access or on special dispensation.

The Ontario Diabetes Database (ODD) identifies people diagnosed with diabetes and has been validated against chart review (14). Although it does not differentiate between types of diabetes, the overwhelming majority of diabetic patients in the population have type 2 diabetes (15).

The Database of Laboratory Tests in Eastern Ontario (DOLTEON) records test results between September 1999 and August 2000 in eastern Ontario, an area containing 1.1 million adults (16). The database captures all but three hospital and private laboratories in the region and, therefore, includes 97% of all in- and outpatient test results. Individuals were linked deterministically between databases.

Patient selection

Eligible patients from the ODD were those aged ≥65 years who had had diabetes for at least 1 year on 1 September 1999 and who lived in eastern Ontario. Records in the physician billing claims database may not be complete for practitioners affiliated with the medical school in the city of Kingston, so patients who lived in Kingston and the five surrounding counties at the time of their A1c test were excluded.

From the eligible patients, those who had A1c levels of 8% or higher were selected. Patients who died within 120 days of the test were excluded. For patients with multiple elevated A1c results, the first was selected.

Time periods

For each patient, two time periods were defined: the "pretest period," comprising the 4th through 1st months before the elevated A1c test, and the "posttest period," comprising the month of the test through the 3rd month after the test. For example, for a patient whose elevated A1c test was in April 2000, the pretest period was December 1999 to March 2000, while the posttest period was April 2000 to July 2000.

Patient assignment

Physician claims for ambulatory visits were examined for each patient during his or her posttest period, excluding claims during hospitalizations or emergency room visits. Patients with at least one claim submitted by an endocrinologist, internist, or geriatrician were defined as having received "specialist care." Of the remaining, those with at least one claim from a family physician or general practitioner were defined as having received "primary care." The remaining patients received no care in the posttest period and were therefore omitted. Care received in the pretest period was not considered because only visits in the posttest period provided an opportunity to respond to the elevated A1c. Limitations in coding of the administrative data prevented comparisons between subspecialties.

In Canada, internists and geriatricians are specialists and do not provide primary care. Any primary care physician can refer patients to any specialist, but patient self-referral is not permitted. The clinical circumstances prompting specialist referral and the extent of primary care involvement in diabetes management once specialist care has begun varies widely, depending on individual patient and physician preferences.

Outcome definitions

We anticipated that patients with A1c levels >8% ought to have had intensification of their drug regimen between the pre- and posttest periods in response. Using the prescription database, we determined for each patient and in each month the maximum daily dose of each oral glucose-lowering drug taken and whether the patient was taking insulin. Patients taking insulin in the pretest period were excluded because changes to the insulin dose could not be measured with the available data. For the remaining patients, three outcomes were measured: *1*) the addition of a new oral glucose-lowering drug in the posttest period not taken in the pretest period, *2*) an increase in the maximum daily dose of an oral glucose-lowering drug between the pre- and posttest periods, and *3*) the initiation of insulin in the posttest period. The primary outcome of drug intensification was defined as at least one of these three outcomes.

Variable definitions

A number of potential confounders that could influence both the receipt of specialist care and the likelihood of drug intensification were identified. Age, sex, and duration of diabetes (dichotomized at 5 years) were determined from the ODD. The A1c level was determined from the DOLTEON. The prescription database indicated whether patients were eligible for specific reimbursement programs for residents of long-term care facilities and for low-income earners (annual income <16,108 CAD [Canadian dollars] for individuals or 24,175 CAD for couples). Rural residence was determined by linking each patient's postal code to census data.

We measured comorbidity, diabetes complications, and other potential confounders from the hospitalization, physician claims, and prescription databases. These variables, measured for 1 year before the elevated A1c test, were hospitalization for any reason; hospitalization for each of cardiovascular disease, cardiovascular intervention, or hypo- or hyperglycemia; retinal photocoagulation treatment; the number of emergency room visits; the number of ambulatory visits to all physicians; the number of different drugs received (17); the number of capillary glucose test strips received; and prescriptions for each of oral corticosteroids, thyroid agents, or nitrates.

Statistical analysis

An individual's propensity score is defined as their predicted probability of one exposure versus another; in this case, specialist versus primary care (18). It is derived using logistic regression, modeling exposure against the potential confounding variables without any consideration of the outcomes. Individuals with the same propensity score share the same multivariate distribution of covariates on average, so differences in the observed exposure between them mimic randomization in a clinical trial. An iterative structured approach was used to construct a nonparsimonious propensity score model predicting

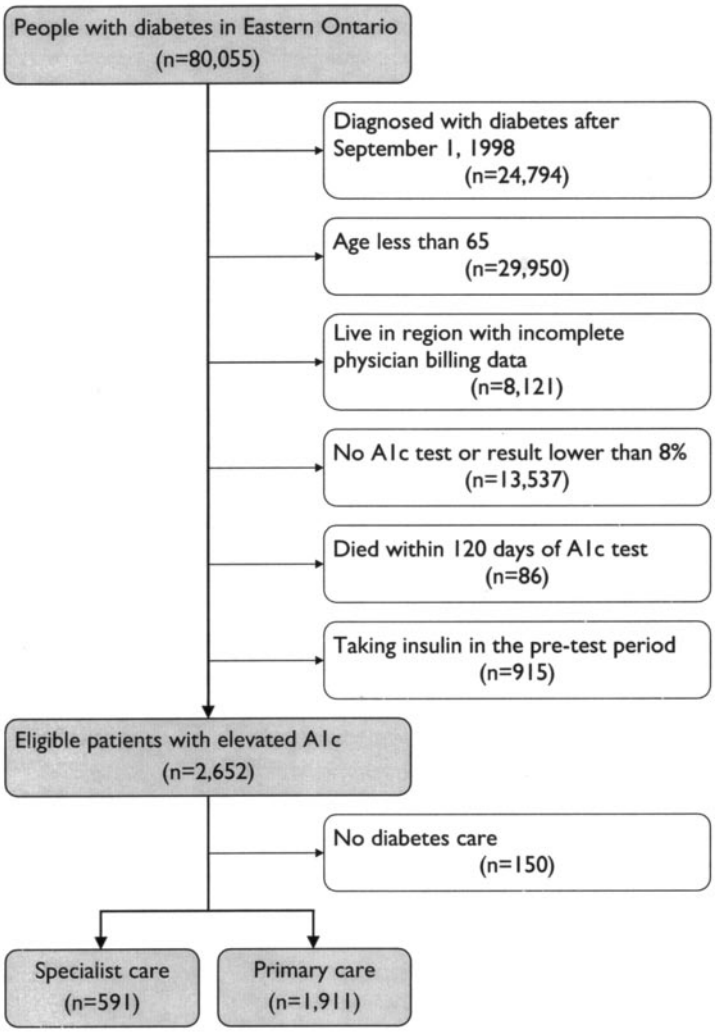

Figure 1—*Allocation of patients to the specialist and primary care exposure groups.*

specialist care (19). Adequacy of the model was determined by verifying the balance of the covariates between exposure groups within quintiles of the propensity score. Interaction and nonlinear terms were added to the model until covariate balance was achieved.

A greedy algorithm was used to match specialist patients to primary care patients on the logit of the estimated propensity score, using calipers with a width of 0.6 × the pooled standard deviation (20). Patients who could not be matched were removed. Baseline variables were compared between the two cohorts with paired *t* test for continuous variables and McNemar's test for categorical variables. The proportion of patients with drug regimen intensification was compared between cohorts with McNemar's test. Each of the three components of the primary outcome was also examined separately. SAS statistical software version 8 (SAS Institute, Cary, NC) was used.

Glyburide and metformin are the first-line oral glucose-lowering drugs in the drug formulary. Drug intensification for patients already on maximal doses of these agents requires either insulin initiation or the addition of oral medications that are not provided as general formulary benefits, such as thiazolidinediones or α-glucosidase inhibitors. Hence, these patients may be less likely to intensify their drug regimen than those on no medications, glyburide and metformin monotherapy, or submaximal doses of both. Therefore, we defined a second patient population including those with less-than-maximum first-line drug regimens in the pretest period (<20 mg glyburide and/or 2,000 mg metformin daily, with no other glucose-lowering drugs). We repeated the analysis with a new propensity score model to ascertain whether clinical inertia was less common for these patients for whom drug intensification was easier.

RESULTS — Of the 80,055 people with diabetes in eastern Ontario, 2,652 met the inclusion criteria (Fig. 1). A total of 591 patients received specialist care in the posttest period, whereas 1,911 received primary care; the remaining 150 patients received care from neither primary care physicians nor specialists and were excluded. The baseline characteristics of the two groups included are presented in Table 1. The groups differed on many important variables, including age, diabetes duration, and comorbidities.

A nonparsimonious propensity score model to predict specialist care was constructed using all of the variables from Table 1, and matched cohorts of patients receiving specialist and primary care were cre-

Table 1—*Characteristics of the whole population*

	Specialist care patients	Primary care patients	*P* value
n	591	1,911	
Male	52.6%	48.3%	0.07
Age (years)	73.1 ± 5.6	74.3 ± 6.2	<0.0001
Diabetes duration >5 years	75.3%	69.7%	0.009
A1c (%)	9.3 ± 1.3	9.1 ± 1.3	0.001
Rural residence	5.4%	18.0%	<0.0001
Long-term care resident	1.0%	3.7%	0.001
Low income (see text for definitions)	24.0%	35.2%	<0.0001
Any hospitalization in previous year	14.0%	10.7%	0.02
Hypo- or hyperglycemia hospitalization in previous year	0.2%	0.1%	0.7
Retinal photocoagulation in previous year	4.9%	2.5%	0.002
Cardiovascular disease–related hospitalization in previous year	4.9%	4.2%	0.5
Cardiovascular procedure in previous year	1.0%	1.0%	1.0
Use of nitrates in previous year	23.5%	17.9%	0.002
Use of oral corticosteroid in previous year	5.8%	4.0%	0.08
Use of thyroid drugs in previous year	13.5%	13.7%	0.9
Number of drugs prescribed in previous year	10.8 ± 6.1	9.9 ± 5.9	0.002
Number of capillary test strips received in previous year	216 ± 270	126 ± 198	<0.0001
Number of emergency department visits in previous year	0.6 ± 1.3	0.4 ± 1.0	0.0009
Number of visits to any physician in previous year	15.9 ± 10.1	13.2 ± 9.8	<0.0001

Data are means ± SD unless otherwise indicated.

ated. Six patients from the specialist care group could not be matched to someone from the primary care group, so each cohort included 585 patients. The characteristics of the matched cohorts are presented in Table 2. They were well balanced with respect to all of the measured covariates.

The proportion of patients with drug regimen intensification in response to poor glycemic control was low in both cohorts but was significantly higher in the specialist care cohort (45.1%) than in the primary care cohort (37.4%, $P = 0.009$) (Fig. 2*A*). Most of this difference occurred because five times as many specialists' patients started insulin in response to the elevated A1c (8.5 vs. 1.7%, $P < 0.0001$). Adding a new oral drug or increasing the dose of an existing oral drug was more common, but the difference between specialists and primary care providers was

Table 2—*Characteristics of matched cohorts*

	Specialist care patients	Primary care patients	*P* value
n	585	585	
Male	52.8%	52.5%	0.9
Age (years)	73.1 ± 5.6	73.1 ± 5.8	0.9
Diabetes duration >5 years	75.2%	76.4%	0.6
A1c (%)	9.3 ± 1.3	9.3 ± 1.4	0.5
Rural residence	5.5%	5.6%	0.9
Long-term care resident	1.0%	1.2%	0.7
Low income (see text for definitions)	23.6%	24.8%	0.6
Any hospitalization in previous year	13.8%	15.4%	0.5
Hypo- or hyperglycemia hospitalization in previous year	0.2%	0%	1.0
Retinal photocoagulation in previous year	4.6%	4.4%	0.9
Cardiovascular disease–related hospitalization in previous year	5.0%	6.0%	0.4
Cardiovascular procedure in previous year	1.0%	1.7%	0.3
Use of nitrates in previous year	23.4%	24.3%	0.7
Use of oral corticosteroid in previous year	5.8%	6.0%	0.9
Use of thyroid drugs in previous year	13.5%	14.0%	0.8
Number of drugs prescribed in previous year	10.8 ± 6.1	11.1 ± 6.5	0.3
Number of capillary test strips received in previous year	209 ± 253	210 ± 261	0.9
Number of emergency department visits in previous year	0.6 ± 1.3	0.7 ± 1.3	0.6
Number of visits to any physician in previous year	15.7 ± 9.7	15.8 ± 11.2	0.9

Data are means ± SD unless otherwise indicated.

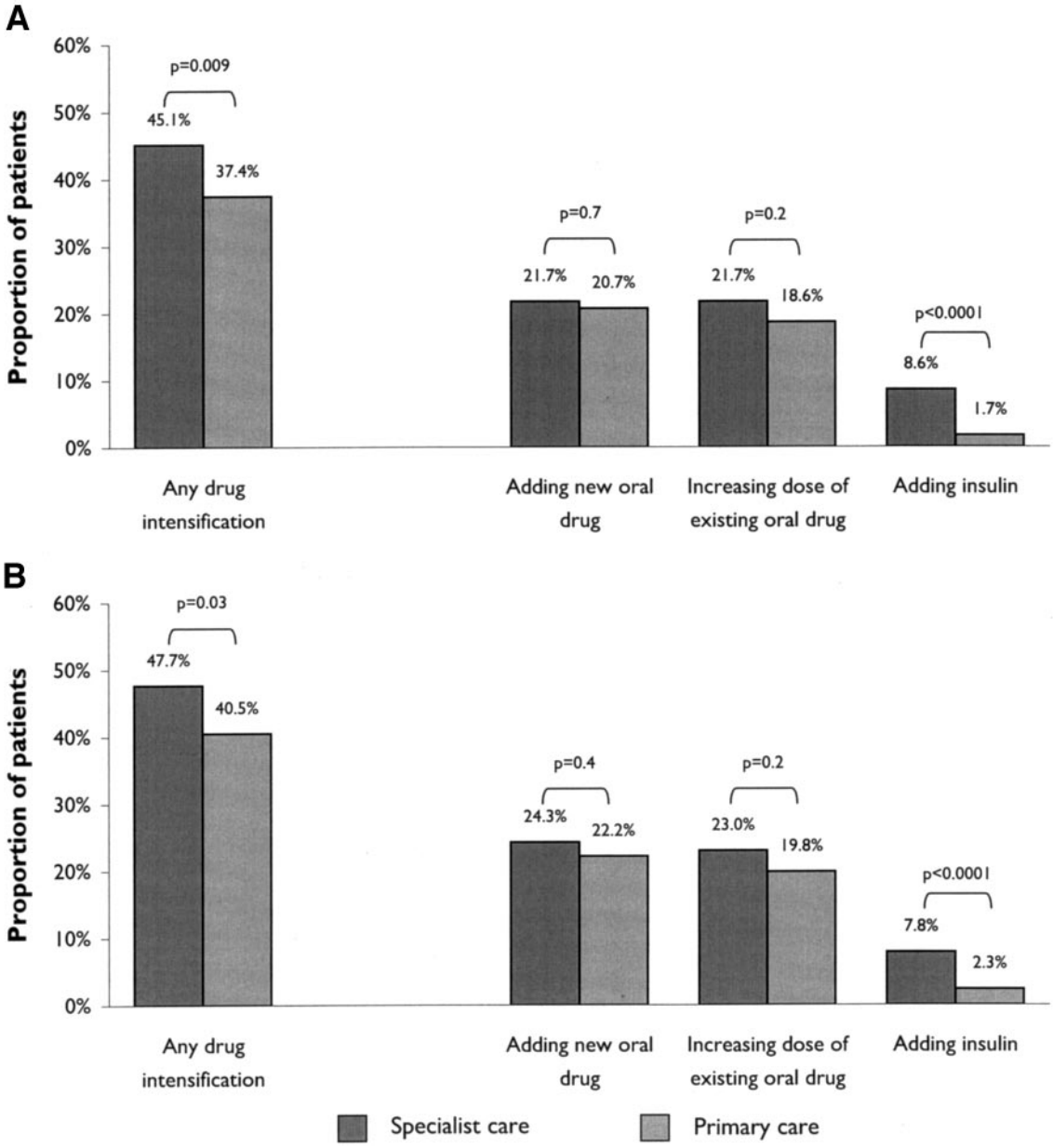

Figure 2—*Proportion of patients with drug regimen intensification in response to poor glycemic control.* A*: All eligible diabetic patients.* B*: Patients with no glucose-lowering drugs, glyburide or metformin monotherapy, or submaximal doses of both of these agents.*

small and did not reach statistical significance.

Intensifying treatment is most straightforward for patients who are taking no glucose-lowering medications, glyburide or metformin monotherapy, or less-than-maximum doses of both of these agents. Drug intensification for these patients requires neither insulin nor medications with formulary restrictions. There were 479 such patients receiving specialist care and 1,675 receiving primary care. Propensity score-matched cohorts, each containing 474 patients, were created, and all baseline characteristics were balanced between them (not shown). Only 47.7% of the specialist care cohort and 40.5% of the primary care cohort intensified their drug treatment ($P = 0.03$), again mostly due to more frequent insulin initiation (Fig. 2*B*).

Analyses using logistic regression rather than propensity score–based matching yielded similar results and are therefore not presented here. We separately examined only patients who had continuity of care, defined as at least two visits in the year before the elevated A1c test with the same physician seen in the posttest period. The results were similar to those of the main analysis, but because of a smaller sample size, they were no longer statistically significant.

CONCLUSIONS — Clinical inertia compromises the management of patients with diabetes, regardless of the specialty of their physician. Less than one-half of patients with poor glycemic control re-

ceived intensification of their glucose-lowering treatment. These population-level results corroborate the findings of previous studies of individual practices, which showed inadequate pharmacological response to poor control (8–10). For patients not taking maximum doses of glyburide and metformin, drug intensification is relatively straightforward, as it requires only the addition or increase in dose of either first-line drug. Despite this, drug intensification remained infrequent for these patients.

We do not suggest that high-quality care necessitates drug intensification for all patients with A1c elevations. There may be valid clinical or social circumstances not apparent from the data that justify not intensifying therapy, such as significant hypoglycemia despite the elevated A1c or comorbidities limiting life expectancy, where nutritional and behavioral modification is more appropriate. However, these circumstances apply to a minority of patients, and the UKPDS (U.K. Prospective Diabetes Study) showed that escalating drug therapy is required to maintain intensive control and prevent complications (21).

Specialists were less prone to clinical inertia than primary care practitioners, perhaps because specialists are able to focus more closely on diabetes and its related conditions during patient visits. Much of the difference between specialists and primary care practitioners was due to more frequent initiation of insulin therapy, which reflects specialists' greater familiarity with prescribing insulin. Furthermore, patients who are referred to specialists may be those who are more willing to accept insulin initiation, and this confounding could not be controlled for. Rather than being unwilling to initiate insulin therapy, primary care practitioners may simply have lacked the necessary resources to do so conveniently and safely. In this circumstance, the appropriate reaction to elevated A1c results would be specialist referral; however, we did not include this in our drug intensification outcome. One solution to help primary care practitioners may be to increase accessibility to diabetes educators, who can assist with teaching and monitoring patients, thereby facilitating insulin initiation in the primary care setting without the need for specialist consultation. Such changes could improve patient outcomes, particularly for those who delay or neglect starting insulin because they are unable to access specialty care.

Clinical inertia could be overestimated in this study because the data measure prescriptions actually filled in pharmacies, not what was recommended by physicians. In addition, some forms of drug intensification, such as increasing the dose of a medication that the patient already has a supply of, may not require a new prescription to be filled immediately and therefore may not be captured in the prescription database. However, the drug program only allows a 3-month supply of medications to be dispensed at a time, so the posttest period should have been sufficiently long to capture the new, higher-dosed prescription. Conversely, drug intensification may be overestimated because the data do not measure patient compliance with medications or whether newly prescribed drugs were discontinued or not tolerated. Because this study was cross-sectional in design, we were unable to determine whether drug intensification resulted in improvement in A1c, nor could we identify the length of time or number of tests with elevated A1c levels.

Of note, policies restricting formulary access to newer, more expensive medications did not appear to be important contributors to clinical inertia. Drug intensification was infrequent, even for patients not receiving the maximum dose of both first-line drugs; these policies should not hinder drug intensification for such patients.

Several causes of clinical inertia have been proposed (7). Patients may be reticent to add new medications, especially insulin, to their already complicated treatment regimens. Physicians and patients may perceive that the patient's status is already improving and therefore does not justify any action. Physicians may overestimate their own adherence with guidelines or they may lack the practice organizational structure to facilitate guideline adherence. These barriers must be overcome to counteract clinical inertia. Better awareness of glycemic control targets, electronic tracking and alerting systems for A1c results, and more tools and resources to assist with implementing intensive glucose lowering may assist physicians with adhering to the best practices.

Although there were some differences between specialists and primary care physicians, both groups were insufficiently aggressive at intensifying glucose-lowering treatment for diabetic patients with poor glycemic control. These data were collected 1 year after the publication of the UKPDS, when its findings were being widely disseminated and discussed, yet they were not broadly implemented in this population. Interventions to identify and combat clinical inertia should improve patients' care and outcomes.

Acknowledgments— The Canadian Institute of Health Research supports B.R.S. with a Clinician-Scientist Award and A.L. as a Senior Scientist. C.v.W. is a Career Scientist of the Ontario Ministry of Health. This study was presented as an abstract at the 2004 Canadian Diabetes Association Conference, Québec City, Québec, 27–30 October 2004.

We gratefully thank Dr. Peter Austin and Deanna Rothwell for assistance.

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