

Quality of Care for Patients with Type 2 Diabetes Mellitus in the Netherlands and the United States: A Comparison of Two Quality Improvement Programs

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Objective. To assess differences in diabetes care and patient outcomes by comparing two multifaceted quality improvement programs in two different countries, and to increase knowledge of effective elements of such programs.

Study Setting. Primary care in the ExtraMural Clinic (EMC) of the Department of General Practice of the Vrije Universiteit in Amsterdam, the Netherlands, and the Group Health Cooperative (GHC), a group-model health maintenance organization (HMO) in western Washington State in the United States. Data were collected from 1992 to 1997.

Study Design. In this observational study two diabetes cohorts in which a quality improvement program was implemented were compared. Both programs included a medical record system, clinical practice guidelines, physician educational meetings, audit, and feedback. Only the Dutch program (EMC) included guidelines on the structure of diabetes care and a recall system. Only the GHC program included educational outreach visits, formation of multidisciplinary teams, and patient self-management support.

Data Collection. Included were 379 EMC patients, and 2,119 GHC patients with type 2 diabetes mellitus. Main process outcomes were: annual number of diabetes visits, and number of HbA1c and blood lipid measurements. Main patient outcomes were HbA1c and blood lipid levels. Multilevel analysis was used to adjust for dependency between repeated observations within one patient and for clustering of patients within general practices.

Principal Findings. In the EMC process outcomes and glycemetic control improved more than at GHC, however, GHC had better baseline measures. There were no differences between programs on blood lipid control. During follow-up, intensification of pharmacotherapy was noted at both sites. Differences noted between programs were in line with differences in diabetes guidelines.

Conclusions. Following implementation of guidelines and organizational improvement efforts, change occurred primarily in the process outcomes, rather than in the patient outcomes. Although much effort was put into improving process and patient outcomes, both complex programs still showed only moderate effects.

Key Words. Quality of care, type 2 diabetes mellitus, general practice, international comparison

In the last decades, care for patients with type 2 diabetes has shifted away from hospitals and toward general practice (Griffin and Kinmonth 1997; Wood 1990). Numerous general practice guidelines for diabetes care have been published. However, large proportions of patients with diabetes mellitus are not receiving care in accordance with these guidelines (Beckles et al. 1998; Grol 1990; Konings, Wijkel, and Rutten 1995; Weiner et al. 1995).

A variety of multifaceted quality improvement programs have been implemented worldwide to support guideline adherence and improved quality of care for patients with diabetes. Whether outcomes of studies in specific health care settings within countries are applicable across countries is unclear. Many studies on the effectiveness of quality improvement programs have not reported both process measures (such as number of visits or tests performed) and patient outcomes. Measures at both levels would contribute to better understanding of how to improve diabetes care (Renders, Valk, Griffin et al. 2001).

In the Netherlands, all inhabitants are registered with a general practitioner (GP). The GP is responsible for the primary care of an average of 2,350 patients. Dutch GPs are the 'gate-keepers' of the health care system

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and provide most routine medical care and diagnostic evaluations for their patients. A patient can visit a specialist only after a GP referral. Most patients with type 2 diabetes are cared for by their GP (Bouma et al. 1999).

In the United States, the health maintenance organization (HMO) is one model of integrated medical care. Many HMOs have care management systems structured around guideline- and evidence-based care.

In 1993, a quality improvement program for patients with type 2 diabetes was implemented in 22 general practices in the Netherlands: the ExtraMural Clinic (EMC) of the Department of General Practice of the Vrije Universiteit in Amsterdam. In 1995, a diabetes quality improvement program was implemented at Group Health Cooperative (GHC). The GHC is a not-for-profit HMO serving 400,000 patients in western Washington State. At GHC over 200 GPs, in 27 separate clinic locations, work in a manner that is comparable to the Dutch GPs. All patients with diabetes are under the care of the GPs. The goal of both quality improvement programs was to enhance the ability of GPs to deliver structured care to patients with diabetes mellitus.

This study had two main objectives. The first objective was to assess differences in patient outcomes and delivered care for patients with type 2 diabetes mellitus at the EMC and the GHC. The second objective was to gain insight into effective components of quality improvement programs for patients with type 2 diabetes in general practice. Therefore, we compared GP performance and patient outcomes (glycemic and lipid control) before and during implementation of the EMC and GHC quality improvement efforts.

METHODS

Study Design

We conducted a longitudinal observational cohort study with a four-year follow-up. Two quality improvement programs, directed at GP care for patients with type 2 diabetes were compared.

Study Population

In the Netherlands, the study population consisted of patients with type 2 diabetes mellitus who were registered in 1992 in the EMC and met the following inclusion criteria:

1. Type 2 diabetes mellitus: currently taking insulin and/or oral hypoglycemic agents, or two fasting plasma glucose ≥ 7.8 mmol/l, or two random plasma glucose ≥ 11.1 mmol/l.

2. Diabetes care provided by the GP.
3. Able to complete a Dutch questionnaire.

A total of 839 patients were listed as type 2 diabetics, of whom 554 were treated by the GP. Of these patients, 122 were excluded because they were not able to complete a Dutch questionnaire. Therefore, 432 patients were eligible. Comparison of GP-treated patients with patients who were under specialist care showed that GP-treated patients had a lower HbA1c (7.7 versus 8.2 percent), were older (68.1 versus 65.2 years), and were more frequently diet treated and less frequently treated with insulin. Patients who were not able to complete a Dutch questionnaire were from other than Dutch origin (e.g., Turkey, Morocco). The patients included in the study were older than those excluded (68.1 versus 64.6 years). Distribution of gender, HbA1c, and mode of treatment were similar.

At GHC, the study population consisted of patients with type 2 diabetes who in 1992 were under the care of one of 50 randomly selected GPs with at least 20 patients with type 2 diabetes mellitus in their patient panel. Patient inclusion criteria were:

1. Type 2 diabetes: currently taking, or having taken in the last three years, insulin and/or oral hypoglycemic agents, or had a total glycosylated hemoglobin ≥ 7.5 in the 12 months prior to 1992, or had two fasting plasma glucose ≥ 7.8 mmol/l in 1991, or two random plasma glucose ≥ 11.1 mmol/l in 1991, or had a hospital discharge diagnosis of diabetes at any time during their medical history with GHC.
2. No history of diabetic ketoacidosis.

At the EMC and at GHC, only patients with data from at least of 1992 and 1993 were included.

Quality Improvement Programs

The quality improvement programs of the EMC and the GHC have been described in detail previously (McCulloch et al. 1998; Renders, Valk, Franse et al. 2001). Both programs targeted GPs and were aimed at improving the quality of diabetes care in local practices (see Table 1). Both models emphasized improving the skills and knowledge of GPs and providing more structured care by introducing a diabetes registry, implementing clinical practice guidelines, providing physician educational meetings, and conducting audits and providing feedback. The EMC started in 1993 with monthly

Table 1: Quality Improvement Programs of the EMC and the GHC

<i>Year of Implementation</i>	<i>ExtraMural Clinic (Netherlands)</i>	<i>Group Health Cooperative (U.S.)</i>
1993	Organizational interventions <ul style="list-style-type: none"> • <i>Recall system</i> • <i>Diabetes registry</i> Professional interventions <ul style="list-style-type: none"> • <i>Clinical practice guidelines on structure of diabetes care and targets for glycemic control</i> • <i>Educational meetings (12 per year)</i> • <i>Audit and Feedback</i> 	—
1994	Professional interventions <ul style="list-style-type: none"> • <i>Educational meetings (12 per year)</i> • <i>Audit and feedback</i> 	—
1995	Organizational intervention <ul style="list-style-type: none"> • <i>Annual extensive control visit carried out by research assistant</i> Professional interventions <ul style="list-style-type: none"> • <i>Clinical practice guideline on targets for blood lipids</i> • <i>Educational meetings (4 per year)</i> • <i>Audit and feedback</i> 	Organizational interventions <ul style="list-style-type: none"> • <i>Diabetes registry</i> • <i>Clinical multidisciplinary teams</i> Professional interventions <ul style="list-style-type: none"> • <i>Clinical practice guidelines on retinal screening and foot care</i> • <i>Educational outreach visits</i> • <i>Educational meetings (10 per 3 years)</i> • <i>Audit and feedback</i> Patient-oriented intervention <ul style="list-style-type: none"> • <i>Self-management support</i>
1996	Organizational intervention <ul style="list-style-type: none"> • <i>Annual extensive control visit carried out by research assistant</i> Professional interventions <ul style="list-style-type: none"> • <i>Educational meetings (4 per year)</i> • <i>Audit and feedback</i> 	Professional interventions <ul style="list-style-type: none"> • <i>Clinical practice guideline on microalbuminuria screening</i> • <i>Educational outreach visits</i> • <i>Educational meetings (10 per 3 years)</i> • <i>Audit and feedback</i> Patient-oriented intervention <ul style="list-style-type: none"> • <i>Self-management support</i>
1997	—	Professional interventions <ul style="list-style-type: none"> • <i>Clinical practice guideline on glycemic management</i> • <i>Educational outreach visits</i> • <i>Educational meetings (10 per 3 years)</i> • <i>Audit and feedback</i> Patient-oriented intervention <ul style="list-style-type: none"> • <i>Self-management support</i>

physician educational meetings. It focused on supporting GPs in making organizational changes in their own practice by implementing guidelines on the structure of diabetes care, and initiating a recall system for an annual diabetes control visit. The GHC program began in 1995. It included educational outreach visits at the GP-clinic by a diabetes expert team (DET) consisting of a registered nurse certified diabetes educator (RN/CDE) and a diabetologist, who saw patients with the GP. They encouraged the formation of multidisciplinary teams and paid more attention to supporting patient self-management. Guideline implementation was supported by ten large continuing medical education courses offered over three years.

Data Collection

In the EMC, data from patients' medical records were collected from 1992 (one year prior to the first annual extensive control visit) through 1996. For data collection, data abstractors were trained to conduct medical records review in the GP-offices using computerized data entry. Tests of interrater reliability indicated good agreement ($\kappa > 0.8$) for all data elements. The data at GHC were derived from the GHC administrative systems (utilization, laboratory, and pharmacy databases). Data from 1992 through 1997 were used.

Process Outcomes

The number of diabetes visits with the GP per patient per year was determined. A visit was defined as a diabetes visit when a fasting or nonfasting blood glucose or HbA1c was performed in the month before or after the date of the visit. We also determined the number of HbA1c measurements and blood glucose measurements (fasting and non-fasting) per patient per year.

Because of guideline differences, "adequate" assessment of glycemic control was operationalized using two criteria. According to the GHC guideline, it was defined as at least one HbA1c-measurement per patient per year, and according to the EMC guideline as at least four measures of glycemic control (e.g., fasting or nonfasting blood glucose, or HbA1c) including at least one HbA1c measurement per patient per year. In addition, we determined whether at least one total cholesterol measurement and at least one serum creatinine measurement per patient per year were performed.

Finally, due to guideline differences, two measures for adequate quality of care were used. In the first measure (GHC) we determined whether the combination of: (1) at least one HbA1c, (2) at least one serum cholesterol, and (3) at least one serum creatinine per patient per year was performed. In the

second measure (EMC) we determined whether the combination of: (1) at least four measures of glycemic control of which at least one HbA1c, (2) at least one serum cholesterol, and (3) at least one serum creatinine per patient per year was performed.

Patient Outcomes

The percentage of patients with good (HbA1c < 7.0%) and acceptable (HbA1c ≤ 8.5%) glycemic control per year was determined using published guidelines (Alberti and Gries 1988). In addition, the percentage of patients with good and acceptable mean total cholesterol (< 5.2 mmol/l and < 6.5 mmol/l, respectively) and mean HDL-cholesterol (> 1.1 mmol/l and ≥ 0.9 mmol/l, respectively) per year was determined. Finally, frequency of prescription of the different types of diabetes therapy (diet, oral hypoglycemic drugs, and insulin) per patient per year were measured.

Laboratory Measurements

At the EMC, up until 1995, HbA1c, plasma glucose, and total cholesterol, HDL-cholesterol and triglycerides were assessed in different laboratories. Therefore, HbA1c values were standardized to those measured in 1995 (ion-exchange high performance liquid chromatography using a modular diabetes monitoring system: normal range 4.3–6.1 percent). At GHC, HbA1c was also measured using different techniques at different laboratories. To allow for comparison between the two countries, outcomes of HbA1c measured at GHC were standardized to those measured at the EMC in 1995.

Statistical Analysis

We used multilevel analysis to compare the EMC and GHC quality improvement programs (Goldstein 1995). Using this technique, calculated effect sizes can be adjusted for dependency of observations due to the clustering of patients within a general practice. Repeated measurements were clustered within patient, and patients were clustered within general practice. Three levels were defined in the multilevel analysis: (1) repeated measures (i.e., time), (2) patient, and (3) GP. The parameters of interest were: (1) the overall difference in outcome measures between the two programs during the whole measurement period, and (2) the interaction between the outcome measures and time, which indicates whether differences between the two quality improvement programs decreased or increased significantly over time. Because the process outcome measures (e.g., number of visits, glucose

measurements, and HbA1c measurements) are counts, a log-linear multilevel analysis was used for those outcomes. For dichotomous process outcomes (e.g., variables indicating the adequate assessment of glycemic control, adequate quality of care, and good and acceptable glycemic and lipid control) multilevel logistic analyses were performed. All analyses were controlled for age, gender, and mode of treatment. The EMC program was conducted from 1993 to 1996, while the GHC program was instituted in 1995–1997. To adjust for the influence of temporal trends, data collected from 1992 through 1996 for both health care settings were compared. In addition, to study before and after effects, Dutch data collected from 1992 through 1995 were compared to GHC data from 1994 through 1997. To adjust for case-mix differences, patients treated with insulin at baseline were excluded in additional analysis. All multilevel analyses were performed with *MlwiN* (1998, version 1.02.0002).

RESULTS

Table 2 shows characteristics of the general practices and patients at baseline. At the EMC, of 432 eligible patients, medical records of 53 patients were not available (moved, changed GP, deceased, and other). Compared to patients whose medical records were not available, included patients were significantly younger (67.7 versus 71.1 years), however, gender, HbA1c, and mode of treatment were not different (data not shown). Compared to EMC patients, GHC patients were younger, less often treated with diet only, and more frequently treated with insulin (Table 3).

Process Outcomes

At the EMC, but not at GHC, the mean number of diabetes visits, HbA1c measurements, and (fasting) blood glucose measurements per patient per year increased after implementation of the quality improvement program (Table 4). Comparison of the time periods from 1992 through 1996 showed that the mean number of diabetes visits per patient per year at the EMC was 2.5 times higher than at GHC. This difference increased during follow-up ($p < .05$). HbA1c was measured 2.3 times more often per patient per year at GHC, however, this difference between the sites decreased during follow-up ($p < .05$). Blood glucose (fasting) was measured 1.7 times more often per patient per year at the EMC. This difference increased during follow-up ($p < .05$).

Table 2: General Practice and Patient Characteristics at Baseline

	<i>ExtraMural Clinic, Netherlands</i>	<i>Group Health Cooperative, U.S.</i>
<i>General practice level</i>		
Number of GPs	22	50
Mean number in patient-panel	2,489.4 (SD 475.7)	1,535.2 (SD 353.9)
Mean number of diabetic patients	41.2 (SD 25.3)	49.4 (SD 12.9)
<i>Patient level</i>		
Number of patients included	379	2119
Mean age (years)	66.6 (SD 10.3)	59.8 (SD 12.8)
Gender (% male)	44	51

GP: general practitioner, SD: standard deviation.

Table 3: Diabetes Therapy

		1992	1993	1994	1995	1996	1997
% patients	EMC	31.2	18.8	13.6	9.7	8.3	NA
diet only	GHC	24.2	24.4	23.1	22.9	21.4	18.7
% patients	EMC	57.0	60.2	56.0	53.5	48.8	NA
SU only	GHC	50.1	46.6	43.8	33.7	26.2	24.4
% patients	EMC	1.8	2.1	1.6	1.5	1.0	NA
MF only	GHC	0	0	0	0.7	3.1	4.7
% patients	EMC	1.6	1.6	1.9	2.6	2.0	NA
INS only	GHC	20.2	22.3	25.2	25.1	23.8	24.6
% patients	EMC	8.2	16.4	25.0	27.5	31.7	NA
SU+MF	GHC	0	0	0	7.7	13.6	16.3
% patients	EMC	0	0.5	0.5	4.1	5.3	NA
SU+INS	GHC	5.6	6.7	7.9	5.9	5.3	5.1
% patients	EMC	0	0	0	0	0	NA
MF+INS	GHC	0	0	0	2.0	4.1	3.7
% patients	EMC	0	0.3	1.1	0.9	2.6	NA
SU+MF+INS	GHC	0	0	0	1.9	2.6	2.5

EMC: ExtraMural Clinic; GHC: Group Health Cooperative; NA: not available; SU: sulfonyleureas; MF: metformin; INS: insulin.

The percentage of patients that fulfilled the two criteria for adequate assessment of glycemic control per year improved dramatically at the EMC in the year after implementation of the quality improvement program in 1993. However, during follow-up these percentages decreased. At GHC, only the percentage of patients with at least one HbA1c measurement per year increased after implementation of the quality improvement program in 1995. When the time period from 1992 through 1996 was compared, the percentage of patients that fulfilled the criterion of “at least one HbA1c measurement per

Table 4: Comparison of the Process Outcomes, 1992 through 1996 for Both Health Care Settings, and 1992 through 1995 for the EMC, versus 1994 through 1997 for GHC

	1992	1993 ¹	1994	1995 ²	1996	1997	RR/OR [95% CI] NL 1992-1996 versus U.S. 1992-1996 ³	RR/OR [95% CI] NL 1992-1995 versus U.S. 1994-1997 ³
Number of patients in the study	EMC 379	379	368	342	303	NA		
	GHC 2,119	2,119	1,976	1,867	1,561	1,361		
Mean number of diabetes-visits ³	EMC 3.51	4.50	4.64	4.83	5.57	NA	RR: 2.49	RR: 3.01
	GHC 2.37	1.74	1.61	1.63	1.62	1.47	[2.20-2.82]	[2.56-3.43]
Mean number of HbA1c measurements ³	EMC 0.29	1.01	1.10	1.10	1.10	NA	RR: 0.44	RR: 0.49
	GHC 2.04	1.70	1.67	1.76	1.89	1.88	[0.37-0.52]	[0.42-0.57]
Mean number glucose measurements ³	EMC 3.52	4.50	4.64	4.82	5.54	NA	RR: 1.65	RR: 1.96
	GHC 3.38	2.79	2.56	2.57	2.55	2.28	[1.54-1.77]	[1.70-2.26]
≥ 1 HbA1c measurement ⁴	EMC 15.3	79.2	70.7	62.0	57.4	NA	OR: 0.24	OR: 0.20
	GHC 77.3	77.2	77.1	77.6	80.7	84.1	[0.17-0.35]	[0.15-0.29]
Glycemic control ^{4,5}	EMC 12.1	70.2	64.9	58.2	56.1	NA	OR: 0.62	OR: 0.79
	GHC 54.9	51.8	50.9	52.0	54.7	52.7	[0.44-0.86]	[0.55-1.13]
≥ 1 cholesterol measurement ⁴	EMC 17.9	80.5	68.8	58.5	52.8	NA	OR: 1.86	OR: 1.66
	GHC 38.1	39.1	40.9	40.8	45.8	52.6	[1.32-2.64]	[1.16-2.37]
≥ 1 serum creatinine measurement ⁴	EMC 20.3	79.2	68.2	59.6	56.1	NA	OR: 0.38	OR: 0.38
	GHC 67.6	69.3	69.2	69.6	73.4	74.4	[0.28-0.52]	[0.27-0.54]
Adequate quality of care (GHC guidelines) ^{4,6}	EMC 6.9	72.3	63.3	52.9	47.9	NA	OR: 1.80	OR: 1.50
	GHC 30.3	32.8	34.2	34.3	41.7	46.6	[1.26-2.56]	[1.05-2.13]
Adequate quality of care (EMC guidelines) ^{4,7}	EMC 5.5	64.6	57.9	50.0	46.9	NA	OR: 2.07	OR: 1.83
	GHC 23.1	24.6	25.4	26.0	32.7	34.2	[1.47-2.91]	[1.28-2.64]

EMC: ExtraMural Clinic; GHC: Group Health Cooperative; NA: not available.

¹start program in EMC (1993);

²start program in GHC (1995);

³per patient per year;

⁴percentage of patients who meet the criterion;

⁵the performance of at least four measures of glycemic control including at least one HbA1c per patient per year;

⁶the performance of the combination of: (1) at least one HbA1c; (2) at least one serum cholesterol; and (3) at least one serum creatinine, per patient per year;

⁷the performance of the combination of: (1) at least four measures of glycemic control of which includes at least one HbA1c; (2) at least one serum cholesterol; and (3) at least one serum creatinine, per patient per year;

⁸all analyses were controlled for age, gender, and mode of treatment.

RR: rate ratio; OR: odds ratio; [95% CI]: 95% confidence intervals.

year,” was 4.2 times higher at GHC. This difference decreased during follow-up ($p < .05$). The percentage of patients that fulfilled the criterion of “at least four measures of glycemic control, including at least one HbA1c per year” was 1.6 times higher at GHC, and this difference also decreased during follow-up ($p < .05$).

The percentage of patients with at least one cholesterol and at least one serum creatinine measurement per year increased after implementation of both quality improvement programs. Only at the EMC did the effect of the quality improvement program with regard to these outcomes decrease during follow-up. When the time period from 1992 through 1996 was compared, the percentage of patients whose cholesterol was measured at least one time per year was 1.9 times higher at the EMC and this difference increased during follow-up ($p < .05$). However, the proportions were virtually identical for the last year of follow up. The percentage of patients whose serum creatinine was measured at least one time per year was 2.6 times higher at GHC. This difference decreased during follow-up ($p < .05$), but in the last year of follow up the proportion was still 18 percent higher at GHC.

The percentage of patients that fulfilled the criteria for “adequate quality of care per year” increased after the implementation of both quality improvement programs. Only at the EMC did these percentages decrease during follow-up. Overall (1992–1996) the percentage of patients fulfilling the criterion for adequate quality of care according to the GHC guidelines was 1.8 times, and according to the EMC guidelines the percentage was 2.1 times higher at the EMC. These differences increased during the study period ($p < .05$). However, the proportions meeting the GHC guidelines were virtually identical (47.9 percent versus 46.6 percent) in the last year of follow-up. When patients who were treated with only insulin at GHC in 1992 were excluded from the analysis, the results did not change (data not shown).

The outcomes of the comparison of the time periods from 1992 through 1995 for the EMC versus 1994 through 1997 for GHC were in line with the outcomes of the comparison of the time periods from 1992 through 1996 for both the EMC and GHC (Table 4). Only the difference between the EMC and GHC of “the performance of at least four measures of glycemic control including at least one HbA1c per patient per year” did not reach statistical significance.

At the EMC, the percentage of patients treated only with diet decreased from 31.2 percent in 1992 to 8.3 percent in 1996. At GHC the percentage of patients treated only with diet decreased from 24.2 percent in 1992 to 21.4 percent in 1996. Insulin was prescribed more often at GHC than at the EMC.

During follow up the percentage of insulin treated patients, and the percentage of patients treated with a combination of diabetes medications increased in both health care settings (Table 3).

Patient Outcomes

Table 5 shows results of the comparison of both programs during the same period (1992–1996) to control for the influence of temporal trends. Moreover, the before and after effects are presented by comparing the periods 1992–1995 and 1994–1997: one year before implementation of the EMC and GHC programs respectively, until three years after. At the EMC, the percentage of patients with acceptable glycemic control improved after the implementation of the quality improvement program. Comparison of the time period from 1992 through 1996 showed that the percentage of patients with a mean HbA1c $<7.0\%$ was 2.7 times higher, and the percentage of patients with a mean HbA1c $\leq 8.5\%$ was two times higher at the EMC. These differences increased during follow-up ($p < .05$). At GHC, the percentage of patients with a mean total cholesterol of <5.2 mmol/l was 1.6 times higher, and with a mean total cholesterol of <6.5 mmol/l was 1.5 times higher than at the EMC. These differences did not change during follow-up ($p > .05$). The percentages of patients with a mean HDL cholesterol of >1.1 mmol/l did not differ in the time period from 1992 through 1996. However, at the EMC, the percentage of patients with a HDL cholesterol of >0.9 mmol/l was 2.1 times higher than at GHC. These differences also did not change during follow-up. When GHC patients who were treated with only insulin in 1992 were excluded from the analysis, the results did not change (data not shown).

The outcomes of the comparison of the time periods from 1992 through 1996 for the EMC versus 1994 through 1997 for GHC were similar to the outcomes of the time period from 1992 through 1996 for both programs (Table 5).

DISCUSSION

The present study was conducted to increase knowledge about the effects of unique, population-based quality improvement programs for diabetes care on process measures and patient outcomes. Before generalized interpretation of the outcomes, the limitations of the study must be recognized. First, because this is an observational study, we cannot be certain that the observed

Table 5: Comparison of the Patient Outcomes, 1992 through 1996 for Both Health Care Settings, and 1992 through 1995 for the EMC versus 1994 through 1997 for GHC

	1992	1993	1994	1995	1996	1997	OR [95% CI] NL 1992-1996 versus U.S. 1992-1996 ²	OR [95% CI] NL 1992-1995 versus U.S. 1994-1997 ²
Number of patients in the study	EMC 379	379	368	342	303	NA		
	GHC 2,119	2,119	1,976	1,867	1,561	1,361		
Mean HbA1c < 7.0% ¹	EMC 53.4	40.7	55.4	50.5	43.1	NA	OR: 2.69 [1.88-3.85]	OR: 2.61 [1.83-3.74]
	GHC 31.6	30.5	32.8	29.3	16.8	15.6		
Mean HbA1c ≤ 8.5 ¹	EMC 84.5	69.7	80.4	81.6	85.6	NA	OR: 1.99 [1.37-2.87]	OR: 1.76 [1.20-2.57]
	GHC 66.3	68.1	72.8	70.2	56.7	57.3		
Mean TC < 5.2 mmol/l ¹	EMC 14.7	20.7	19.8	27.0	23.1	NA	OR: 0.64 [0.48-0.86]	OR: 0.48 [0.35-0.65]
	GHC 22.8	28.2	29.3	29.5	40.4	48.6		
Mean TC < 6.5 mmol/l ¹	EMC 61.8	62.6	65.6	69.0	70.6	NA	OR: 0.67 [0.50-0.90]	OR: 0.47 [0.34-0.65]
	GHC 70.3	72.0	74.4	75.5	81.4	84.2		
Mean HDL cholesterol	EMC 33.3	51.0	48.3	44.7	40.7	NA	OR: 1.20 [0.90-1.61]	OR: 1.16 [0.87-1.55]
> 1.1 mmol/l ¹	GHC 40.0	43.1	44.5	42.2	43.2	45.9		
Mean HDL cholesterol	EMC 88.9	87.5	87.9	80.7	80.7	NA	OR: 2.09 [1.48-2.94]	OR: 2.03 [1.40-2.96]
≥ 0.9 mmol/l ¹	GHC 70.8	74.1	72.9	69.3	74.9	75.3		

EMC: ExtraMural Clinic; GHC: Group Health Cooperative; NA: not available; TC: total cholesterol.

¹percentage of patients who meet the criterion, per year;

²all analyses were controlled for age, gender, and mode of treatment; OR: odds ratio [95% CI]: 95% confidence intervals.

improvements were the direct result of the implementation of the quality improvement programs. However, observed trends were related to the implementation of the quality improvement programs in both health care settings. To limit the effect of temporal trends, data from 1992 through 1996 for both programs was compared. In addition, comparisons were made for the time periods from the year before implementation of both programs to follow-up at three years. A second limitation is the difference in case mix between the EMC and GHC cohorts. At GHC all patients with diabetes are under GP-care. At the EMC, patients who cannot reach adequate glycemic control are referred to specialist care and, therefore, approximately 30 percent of the patients with type 2 diabetes mellitus are under specialist care.³ Consequently, at baseline, the included patients at GHC were younger, less often treated with only diet, and more frequently treated with insulin than the EMC patients. Because of case-mix differences, improvements in glycemic control of the patients at GHC were probably more difficult to achieve than at the EMC. However, when patients who were treated with insulin only at baseline were excluded, the results did not change. Another limitation is that no blood pressure data were available in the GHC administrative systems.

The differences between the two study settings in the measurement of HbA1c or (fasting) blood glucose for the assessment of glycemic control can be at least partially explained by their respective practice guidelines. At the EMC, it was advised to use (fasting) blood glucose for the three monthly control visits, and at GHC it was advised to use HbA1c. At GHC, the performance with regard to adequate assessment of glycemic control per patient per year did not improve much during follow-up. After the implementation of the EMC program in 1993, the GPs performed better. This is at least partially due to the lower baseline performance at the EMC, leaving more room for improvement in the assessment of glycemic control. Therefore, the difference between the countries decreased significantly during follow-up.

The number of performed diabetes visits increased only at the EMC, which is in line with the EMC guideline. In addition, at the EMC the patients were called up for the annual diabetes control visit. At GHC, no guideline on the number of diabetes visits was implemented and there was no recall system. However, patient self-management support was part of the GHC program. Consequently, patients at GHC were empowered to be actively involved in self-management of their disease. The need for structured three-monthly diabetes control visits by the GP at GHC might be less than at the EMC. In addition, the number of diabetes visits at GHC could be underestimated

because of self-blood-glucose monitoring of the patients that was not recorded in the laboratory databases.

In contrast to GHC, the effect on the performance of the GPs in the EMC decreased in the course of three years. This can be explained by the lowering of the structured educational meetings from twelve to four times a year in 1995. At GHC, the quality improvement efforts were expanded during the study period. The EMC definition of quality care was more stringent than the GHC definition. By the GHC guideline, the two groups were performing equally in the last year of follow-up, while by the EMC guideline, the Dutch program performed better. Nevertheless, the difference between the percentages of patients that received adequate quality of care increased during follow-up in favor of the EMC.

At the EMC, glycemic control was better and improved more in the course of time. The program at GHC with a strong emphasis on patient self-care did not translate into substantive improvements of glycemic control. This is in line with the fact that at the EMC a guideline on targets for glycemic control was implemented in 1993. At GHC the guideline on glycemic control was actively implemented in 1997 and glycemic control could, therefore, have improved after 1997. Yet, in the United States, ADA guidelines on targets for glycemic control were available throughout the 1990s. This result may be biased by case-mix differences.

At both sites, there is evidence that the increase in number of HbA1c measures was not related to long-term improvement in HbA1c. It is possible that structured care might not affect the inexorable progress of diabetes. It can be concluded that performing more HbA1c tests does not automatically lead to improvements of HbA1c. At GHC, control of total cholesterol of the patients was better during follow-up, and at the EMC, the percentage of patients with an acceptable HDL cholesterol was higher. This indicates that both programs were effective with regard to lipid control. Comparison of the time periods that started one year before the implementation of the quality improvement programs and at three years follow-up changed the outcomes in favor of GHC program. This can be explained because at the EMC, the guideline on the management of blood lipids was not implemented until 1995, and the topic of cardiovascular risk management was emphasized in the educational meetings from that date. As a consequence, from 1995 an improvement in blood lipids in both health care settings could be expected.

In both settings, intensification of pharmacotherapy was noted during follow-up. This corresponds with the finding reported in a recent paper that in the course of 15 years, patients with type 2 diabetes mellitus needed an

increasing amount of medication to maintain stable glycemic control because of disease progression (Turner et al. 1999). Differences between the countries were observed in the prescription of metformin and insulin. At the EMC metformin was already available in 1992, whereas at GHC metformin was not available until 1995. Insulin was prescribed more often at GHC, which reflects case-mix differences.

In conclusion, outcomes of the implemented quality programs were partly attributable to nonmodifiable differences between the patient populations and health care settings. Such differences between settings have to be taken into account in interpreting the results of quality improvement efforts. The EMC guidelines on structure of care and annual recall of patients led to more structured care than the GHC program that focused more on patient self-management and multidisciplinary teams. Following implementation of guidelines and organizational improvement efforts, change occurred primarily in the process outcomes, rather than the patient outcomes. Although much effort was put into improving process and patient outcomes, both complex programs had only moderate effects on patient outcomes. This is in agreement with moderate effects that are found in other studies that evaluated complex intervention programs aimed at improving structured diabetes care (Renders, Valk, Griffin et al. 2001). Future research should attempt to disentangle the effects of different components or combinations of components of complex interventions aimed at improving structured diabetes care, particularly with regard to efforts that encourage patient self-management.

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REFERENCES

- Alberti, K. G., and F. A. Gries. 1988. "Management of Non-Insulin-Dependent Diabetes Mellitus in Europe: A Consensus View." *Diabetic Medicine* 5 (3): 275-81.

- Beckles, G. L., M. M. Engelgau, K. M. Narayan, W. H. Herman, R. E. Aubert, and D. F. Williamson. 1998. "Population-Based Assessment of the Level of Care among Adults with Diabetes in the US." *Diabetes Care* 21 (9): 1432-8.
- Bouma, M., J. H. Dekker, J. T. M. van Eijk, F. G. Schellevis, D. M. W. Kriegsman, and R. J. Heine. 1999. "Metabolic Control, Symptoms and Morbidity of Type 2 Diabetic Patients in a General Practice Network." *Family Practice* 16 (4): 402-6.
- Goldstein, H. 1995. *Multilevel Statistical Models*, 2d ed. London: Edward Arnold.
- Griffin, S., and A. Kinmonth. 1997. "The Management of Diabetes by General Practitioners and Shared Care." In *Textbook of Diabetes*, edited by J. Pickup and G. Williams. Oxford: Blackwell Scientific.
- Grol, R. 1990. "National Standard Setting for Quality of Care in General Practice: Attitudes of General Practitioners and Response to a Set of Standards." *British Journal of General Practice* 40 (338): 361-4.
- Konings, G. P. J. M., D. Wijkkel, and G. E. H. M. Rutten. 1995. "The Dutch Standard for Diabetes Mellitus Type II, Does It Work?" [In Dutch: Lukt het werken volgens de NHG-standaard Diabetes Mellitus Type II?]. *Huisarts Wet* 38 (1): 10-14.
- McCulloch, D. K., M. J. Price, M. Hindmarsh, and E. H. Wagner. 1998. "A Population-Based Approach to Diabetes Management in a Primary Care Setting: Early Results and Lessons Learned." *Effective Clinical Practice* 1 (1): 12-22.
- MlwiN. 1998. *MlwiN* software (version 1.02.0002). London: Multilevel Models Project Institute of Education.
- Renders, C.M., G. D. Valk, L. V. Franse, F. G. Schellevis, J. Th. M. van Eijk, and G. van der Wal. 2001. "The Long-term Effectiveness of a Quality Improvement Program for Patients with Type 2 Diabetes in General Practice." *Diabetes Care* 24 (8): 1365-70.
- Renders, C. M., G. D. Valk, S. J. Griffin, E. H. Wagner, J. Th. M. van Eijk, and W. J. J. Assendelft. 2001. "The Effectiveness of Interventions Directed at Improvement of the Management of Diabetes Mellitus in Primary Care, Outpatient and Community Settings." In *Cochrane Database System Review* (1): CD001481.
- Turner, R. C., C. A. Cull, V. Frighi, and R. R. Holman. 1999. "Glycemic Control with Diet, Sulfonylurea, Metformin, or Insulin in Patients with Type 2 Diabetes Mellitus. Progressive Requirement for Multiple Therapies (UKPDS 49)." *Journal of the American Medical Association* 281 (21): 2005-12.
- Weiner, J. P., S. T. Parente, D. W. Garnick, J. Fowles, A. G. Lawthers, and R. H. Palmer. 1995. "Variation in Office-Based Quality. A Claims-Based Profile of Care Provided to Medicare Patients with Diabetes." *Journal of the American Medical Association* 273 (19): 1503-8.
- Wood, J. 1990. "A Review of Diabetes Care Initiatives in Primary Care Settings." *Health Trends* 22 (1): 39-43.

