Combined Task Delegation, Computerized Decision Support, and Feedback Improve Cardiovascular Risk for Type 2 Diabetic Patients

A cluster randomized trial in primary care

FRITS G.W. CLEVERINGA, MD
KEES J. GORTER, MD, PHD
MAUREEN VAN DEN DONK, PHD
GUY E.H.M. RUTTEN, MD, PHD

OBJECTIVE — The Diabetes Care Protocol combines task delegation (a practice nurse), computerized decision support, and feedback every 3 months. We studied the effect of the Diabetes Care Protocol on A1C and cardiovascular risk factors in type 2 diabetic patients in primary care.

RESEARCH DESIGN AND METHODS — In a cluster randomized trial, mean changes in cardiovascular risk factors between the intervention and control groups after 1 year were calculated by generalized linear models.

RESULTS — Throughout the Netherlands, 26 intervention practices included 1,699 patients and 29 control practices 1,692 patients. The difference in A1C change was not significant, whereas total cholesterol, LDL cholesterol, and blood pressure improved significantly more in the intervention group. The 10-year coronary heart disease risk estimate of the UK Prospective Diabetes Study improved 1.4% more in the intervention group.

CONCLUSIONS — Delegation of routine diabetes care to a practice nurse combined with computerized decision support and feedback did not improve A1C but reduced cardiovascular risk in type 2 diabetes patients.

Diabetes Care **31:2273–2275, 2008**

Improving patients' outcomes, in order to reduce cardiovascular risk, remains one of the most important goals in diabetes care. Structured and regular review of patients has been shown to improve the process of care (1), and team changes and case management have been shown to improve glycemic control (2). Computerized decision support systems (CDSSs) have been shown to improve practitioners' performance (3), and feedback on performance given to primary care physicians (PCPs) has been demonstrated by Ziemer et al. (4) to lower patients' A1C levels and improve practitioners' behavior.

Against this background, the Diabetes Care Protocol (DCP) was developed, which reduced patients' cardiovascular risk in a before-after study (5). The current randomized clinical trial aims to investigate the effects of the DCP on A1C and cardiovascular risk in type 2 diabetic patients in primary care.

RESEARCH DESIGN AND METHODS

— Primary care practices throughout the Netherlands that were not involved in other diabetes care improvement programs were block randomized to intervention (26 practices) or the control group (29 practices). The number of PCPs working in each practice and the presence of a practice nurse before intervention were taken into account before randomization. The intervention, also described elsewhere (5), consisted of *1*) diabetes consultation hour run by a practice nurse, *2*) a CDSS that contained a diagnostic and treatment algorithm based on the Dutch type 2 diabetes guidelines (6) and provided patient-specific treatment advice, *3*) a recall system, and *4*) feedback every 3 months regarding the percentage of patients meeting the treatment targets (cessation of smoking, A1C $<7\%$, systolic blood pressure <140 mmHg, total cholesterol <4.5 mmol/l, LDL cholesterol <2.5 mmol/l, and BMI <27 kg/m^2) on both the practice and the patient levels (6). The PCPs were advised that they should prescribe new medication and refer patients if necessary. The control group continued with the same diabetes care that they had received before entering the study, which means that diabetes care was provided by the PCP or by a practice nurse under PCP responsibility. The University Medical Center Utrecht ethics committee approved the study, and patients provided written consent.

From the 171,821 registered patients, all type 2 diabetic patients were identified. Patients who had a short life expectancy, were unable to visit the primary care practice, or were receiving diabetes treatment from a medical specialist were excluded. Initially, 3,979 patients were eligible (2,136 in the control group and 1,843 in the intervention group), but 548 subjects refused to participate (409 control and 139 intervention subjects), and an additional 40 (35 control and 5 intervention subjects) failed to participate for unknown reasons (for both groups, $P < 0.05$). The final, mainly Caucasian, study population consisted of 3,391 pa-

From the Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht, the Netherlands.
Corresponding author: Frits G.W. Cleveringa, f.g.w.cleveringa@umcutrecht.nl.
Received 12 February 2008 and accepted 25 August 2008.
Published ahead of print at http://care.diabetesjournals.org on 16 September 2008. DOI: 10.2337/dc08-0312. Clinical trial reg. no. ISRCTN21523044, http://www.controlled-trials.com/isrctn.

Table 1—*Baseline parameters, 1-year differences of clinical outcome parameters and process parameters within and between groups (N = 3391)*

	Intervention group (n = 1,699)		Control group (n = 1,692)		Difference in change between groups*	95% CI difference between groups*
	Baseline	After 1 year	Baseline	After 1 year		
Baseline characteristics						
Age (years)	65.2 ± 11.3		65.0 ± 11.0			
Sex (% male)	48.2		49.8			
Race/ethnicity (% Caucasian)	97.7		97.6			
Duration of diabetes (years)	5.8 ± 5.7		5.4 ± 5.8			
History of cardiovascular disease	47.1		63.3			
Current smoking	22.6	20.7	16.6	15.5	1.1†	0.7–1.7
Clinical outcome						
A1C (%)	7.1 ± 1.3	6.9 ± 1.1	7.0 ± 1.1	6.9 ± 1.0	0.07	−0.02 to 0.16
Systolic blood pressure (mmHg)	149 ± 22	143 ± 20	149 ± 21	147 ± 20.8	3.3‡	0.5–6.0
Diastolic blood pressure (mmHg)	83 ± 11	80 ± 11	82 ± 11	82 ± 10.6	2.2‡	1.0–3.5
Total cholesterol (mmol/l)	5.0 ± 1.0	4.6 ± 0.9	4.9 ± 1.1	4.8 ± 1.1	0.2‡	0.1–0.3
HDL cholesterol (mmol/l)	1.36 ± 0.36	1.37 ± 0.37	1.32 ± 0.35	1.33 ± 0.36	−0.007	−0.038 to 0.023
LDL cholesterol (mmol/l)	2.8 ± 0.92	2.5 ± 0.88	2.8 ± 0.95	2.6 ± 0.97	0.15‡	0.07–0.23
10-year UKPDS CHD risk (%)§	22.5 ± 16.5	20.6 ± 15.0	21.7 ± 15.8	21.6 ± 15.6	1.4‡	0.3–2.6
Process of care						
A1C ≤7%	60.8	68.0	61.6	64.2	1.4†‡	1.0–1.8
Systolic blood pressure ≤140 mmHg	41.0	53.9	39.5	42.2	1.7†‡	1.2–2.2
Total cholesterol ≤4.5 mmol/l	36.2	49.0	38.5	45.3	1.3†‡	1.0–1.6
LDL cholesterol ≤2.5 mmol/l	41.1	53.5	43.8	49.8	1.3†‡	1.0–2.8
All treatment targets	10.3	18.9	10.9	13.4	1.6†‡	1.3–2.1

Data are means ± SD or percent unless otherwise indicated. *Generalized linear model. †OR. ‡$P < 0.05$ for between-group comparison. §The 10-year UKPDS CHD risk (%) was calculated using date of diabetes onset (age − duration of diabetes), sex, ethnicity, smoking, A1C, systolic blood pressure, total cholesterol, and HDL cholesterol.

tients (1,692 control and 1,699 intervention). After 1 year, 2,841 patients (1,389 control and 1,452 intervention) completed a follow-up examination; 187 patients (115 control and 72 intervention) refused to participate in the final measurements, and 13 others (12 control and 1 intervention) failed to show for unknown reasons (for both groups, $P < 0.05$). The groups did not differ with regard to the number of patients who died, moved, became terminally ill, or were referred to a specialist.

Between March 2005 and August 2007, patients were each seen twice for annual diabetes checkups. Patients who did not show received one reminder. In the CDSS, age, sex, ethnicity, duration of diabetes, and smoking habits were registered. A1C, total cholesterol, and HDL cholesterol were measured in local laboratories. LDL cholesterol was calculated. Blood pressure was measured according to a standard operating procedure.

The 10-year coronary heart disease (CHD) risk estimate, as established by the UK Prospective Diabetes Study (UKPDS) (7), was calculated using the above-mentioned variables, excluding LDL cholesterol.

The primary outcome was the 1-year difference in A1C. Secondary outcomes were the 1-year difference in the 10-year UKPDS CHD risk estimate and the percentage of patients that reached A1C ≤7%, systolic blood pressure ≤140 mmHg, total cholesterol ≤4.5 mmol/l, and LDL cholesterol ≤2.5 mmol/l (6).

We performed intention-to-treat analyses with baseline values carried forward in the case of missing values. To correct for clustering at the practice level, generalized linear models were used, and after clustering had been taken into account, a 0.3% difference in A1C and a 2% difference in UKPDS CHD risk could be detected with 90% power ($\alpha = 0.05$), with at least 1,080 patients in each treatment arm.

RESULTS — There were more solo practices (58 vs. 50%) and fewer duo practices (24 vs. 30%) compared with national data (8). The mean ± SD age (46.8 ± 7.4 years) of the participating PCPs was comparable with the mean Dutch PCP age (8). Baseline characteristics of the intervention and control groups were comparable, except for smoking status, history of cardiovascular disease, and HDL cholesterol levels (Table 1).

The difference in A1C change between the two groups was not significant. Systolic and diastolic blood pressure and total and LDL cholesterol improved significantly more in the intervention group. As a result, the calculated 10-year UKPDS CHD risk decreased 1.4% more in the intervention group. After 1 year, significantly more patients in the intervention group reached the treatment targets, with 18.9% of the patients meting all treatment targets (Table 1).

CONCLUSIONS — The DCP is the first pragmatic diabetes care intervention using a CDSS that improves patient outcome. As recommended by the National Institute of Clinical Excellence, we calculated the 10-year UKPDS CHD risk estimate for all subjects and used this measurement as a determinant of clinical care. Recently, the Action in Di-

abetes and Vascular Disease (ADVANCE) study showed that A1C reduction does not prevent CHD (9). This result indicates that we should focus on the patient's total cardiovascular risk profile. Our study showed no difference in A1C change between the two treatment arms, but the DCP led to improved diabetes care, which is shown by a 1.4% higher reduction in 10-year CHD risk estimate in the intervention group.

The DCP combines several interventions. The CDSS structures diabetes care, which may lead to improvements in the process of care (1). In addition, the DCP added a practice nurse who acted as a case manager and provided periodic feedback. Both interventions can improve blood glucose control (2,4).

Practices were self-selected, which may suggest a special interest of the PCP in improving diabetes care. This could be the reason why baseline values of A1C, blood pressure, and cholesterol were lower than those of most other Dutch primary care diabetes studies (10). Because mean A1C at baseline was almost at the treatment target, there was little room for improvement. Changes in blood pressure and cholesterol, however, were significant.

The percentage of patients who reached all treatment targets remained strikingly low: 18.9%. This could be explained by overly strict targets (11), physicians inert in prescribing more medications (4), or noncompliant patients (12). Whether the effects of the DCP will sustain has to be determined by longer-term follow-up data.

Acknowledgments— For this study, we received an unrestricted grant from Pfizer B.V.

We thank the practices and patients who participated in this study and Diagnosis4Health for making the research data available.

References

1. Renders CM, Valk GD, Griffin SJ, Wagner EH, van Eijk JT, Assendelft WJ: Interventions to improve the management of diabetes in primary care, outpatient, and community settings: a systematic review. *Diabetes Care* 24:1821–1833, 2001
2. Shojania KG, Ranji SR, McDonald KM, Grimshaw JM, Sundaram V, Rushakoff RJ, Owens DK: Effects of quality improvement strategies for type 2 diabetes on glycemic control: a meta-regression analysis. *JAMA* 296:427–440, 2006
3. Garg AX, Adhikari NK, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, Sam J, Haynes RB: Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *JAMA* 293: 1223–1238, 2005
4. Ziemer DC, Doyle JP, Barnes CS, Branch WT Jr, Cook CB, El-Kebbi IM, Gallina DL, Kolm P, Rhee MK, Phillips LS: An intervention to overcome clinical inertia and improve diabetes mellitus control in a primary care setting: Improving Primary Care of African Americans with Diabetes (IPCAAD) 8. *Arch Intern Med* 166:507–513, 2006
5. Cleveringa FG, Gorter KJ, van den Donk M, Pijman PL, Rutten GE: Task delegation and computerized decision support reduce coronary heart disease risk factors in type 2 diabetes patients in primary care. *Diabetes Technol Ther* 9:473–481, 2007
6. Rutten GEHM, de Grauw WJC, Nijpels G, Goudswaard AN, Uitewaal PJM, Van der Does FEE, Heine RJ, Van Ballegooie E, Verduijn MM, Bouma M: NHG-standaard diabetes mellitus type 2 (tweede herziening). *Huisarts Wet* 49:137–152, 2006 [in Dutch]
7. Stevens RJ, Kothari V, Adler AI, Stratton IM: The UKPDS risk engine: a model for the risk of coronary heart disease in Type II diabetes (UKPDS 56). *Clin Sci (Lond)* 101:671–679, 2001
8. Registratie beroepen gezondheidszorg: percentages huisartsen naar praktijkvorm [Internet]. Available from www.nivel.nl/oc2/page.asp?pageid=1483. Accessed 1 January 2005
9. Patel A, MacMahon S, Chalmers J, Neal B, Billot L, Woodward M, Marre M, Cooper M, Glasziou P, Grobbee D, Hamet P, Harrap S, Heller S, Liu L, Mancia G, Mogensen CE, Pan C, Poulter N, Rodgers A, Williams B, Bompoint S, de Galan BE, Joshi R, Travert F: Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. *N Engl J Med* 358: 2560–2572, 2008
10. Goudswaard AN, Stolk RP, de Valk HW, Rutten GE: Improving glycaemic control in patients with Type 2 diabetes mellitus without insulin therapy. *Diabet Med* 20: 540–544, 2003
11. Winocour PH: Effective diabetes care: a need for realistic targets. *BMJ* 324:1577–1580, 2002
12. Cramer JA, Benedict A, Muszbek N, Keskinaslan A, Khan ZM: The significance of compliance and persistence in the treatment of diabetes, hypertension and dyslipidaemia: a review. *Int J Clin Pract* 62: 76–87, 2008