The National Diabetes Register in Sweden

An implementation of the St. Vincent Declaration for Quality Improvement in Diabetes Care

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OBJECTIVE — To monitor glycemic control, treatable risk factors, and treatment profile for quality assessment of diabetes care on a national scale.

RESEARCH DESIGN AND METHODS — Four samples of 23,546, 32,903, 30,311, and 29,769 patients with diabetes (1996–1999) were studied based on a repeated national screening and quality assessment of diabetes care by the National Diabetes Register, Sweden, with participation of both hospitals and primary health care. Clinical characteristics included were age, sex, diabetes duration and treatment, glycemic control (HbA_{1c}), office blood pressure (BP), BMI, smoking habits, and use of lipid-lowering drugs in patients with type 1 or type 2 diabetes.

RESULTS — Favorable decreases of mean HbA_{1c} and BP values were registered during the 4-year study period for both type 1 (HbA_{1c} 7.5–7.3% and BP 130/75–130/74 mmHg) and type 2 diabetic patients (HbA_{1c} 7.0–6.7% and BP 151/82–147/80 mmHg). Treatment aims of HbA_{1c} and BP levels were also achieved in increasing proportions for type 1 (HbA_{1c} <7.5%: 50–58% and BP ≤140/85 mmHg: 77–79%), and type 2 diabetic patients (HbA_{1c} <7.5%: 66–73% and BP ≤140/85 mmHg: 32–42%). The use of lipid-lowering drugs increased for type 1 (4–11%) and type 2 diabetic patients (10–22%). In type 2 diabetic patients, treatment with oral agents alone decreased, but combination therapy (insulin and oral agents) increased during the study period. Mean BMI increased during 1996–1999 in type 2 diabetic patients. High HbA_{1c} and BP values in 1999 were predicted by high BMI values 1996 and by high increase of BMI during the period, independent of diabetes duration, age, and sex.

CONCLUSIONS — Decreasing mean HbA_{1c} and BP levels and the wider use of lipid-lowering drugs during the late 1990s in patients with diabetes in a national sample from Sweden should translate into clinical benefits regarding micro- and macrovascular complications as well as diabetes-related mortality.

Diabetes Care 26:1270–1276, 2003

The Swedish National Diabetes Register (NDR) was initiated in 1996 by the Swedish Society for Diabetology as a response to the demands of the St. Vincent Declaration for Quality Assurance in Diabetes Care (1). National guidelines for diabetes care were established at the same time (2), and indicators of quality were introduced. These guidelines have recently been revised (3). Thus, the NDR was started as a tool for local quality control and benchmarking against the national treatment aims, based on several large randomized intervention trials in both type 1 and type 2 diabetic patients. These important trials included the Diabetes Control and Complications Trial (DCCT) (4) and the U.K. Prospective Diabetes Study (UKPDS) (5).

One aim of the NDR is that all diabetic patients in Sweden should ideally be reported yearly, based on registered annual data from actual patient visits in primary health care (PHC) or at hospital outpatient clinics for departments of medicine (HCMs). Demographic data, diabetes duration, treatment modalities, as well as various risk factors and diabetes complications are reported. After statistical analysis, all participating centers have received a yearly report with local results as well as comparisons with national data. NDR is probably among the largest national diabetes registers in the world, and the unique size of NDR, with repeated annual surveys and with the geographical distribution all over Sweden, should reasonably well mirror the treatment traditions and results at large in Sweden. It is therefore of interest to compare these repeated population-based data of NDR in order to investigate whether clinical practice in the management and care of diabetes has changed during recent years, as measured by changes in mean/median levels of the variables, e.g., HbA_{1c} and blood pressure (BP) levels.

In this first general report from NDR, the aim has been to present data from type 1 and type 2 diabetic patients irrespective of health care level, regarding age, sex, diabetes duration and treatment, HbA_{1c}, BP, BMI, smoking, and use of lipid-lowering drugs from 1996 to 1999. During this period, several major clinical trials in the area of diabetes care were published (4,5). A second report from

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Received for publication 21 May 2002 and accepted in revised form 10 January 2003.

Abbreviations: ADA, American Diabetes Association; BP, blood pressure; DCCT, Diabetes Control and Complications Trial; HCM, hospital outpatient clinic for departments of medicine; LDC, Lund's Data Central; NDR, National Diabetes Registry; NHANES, National Health and Nutrition Examination Study; PHC, primary health care; UKPDS, U.K. Prospective Diabetes Study.

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

Table 1—*Number of patients from NDR 1996–1999 included in this study, with either type 1 or type 2 diabetes, followed at HCMs or at PHCs*

	Type 1 diabetes		Type 2 diabetes		Total *n* in	Total *n* in
Year	HCM	PHC	HCM	PHC	this study	NDR
1996	6,274	560	5,708	11,004	23,546	27,213
1997	9,879	249	9,546	13,229	32,903	41,154
1998	9,616	190	7,988	12,517	30,311	36,518
1999	9,918	174	7,665	12,012	29,769	41,151

NDR will shortly be published regarding BP control in diabetic patients on antihypertensive treatment or with nephropathy (6).

RESEARCH DESIGN AND METHODS

— Our data represent diabetic patients from ~75% of 80 HCMs and ~15% of nearly 900 PHCs, collected from all parts of Sweden. A total of 46 HCMs in 1996, 60 in 1997, 55 in 1998, and 57 in 1999 participated. A total of 162, 174, 139, and 141 PHCs participated in the respective years. Only adult patients (>18 years of age) were registered. All patients gave written informed consent to participate. However, the participation in NDR was nonmandatory for patients and treatment units. The mean number of subjects with diabetes was 314–439 patients per HCM unit and 78–127 patients per PHC unit, implying that the main part of all diabetic patients per unit of HCM and PHC were included in NDR by most of the participating centers.

Registrations at local centers were generally performed by experienced physicians and nurses. All participating diabetic patients were registered on a paper form or via a specially designed database software supplied on diskette or CD-ROM, developed by Lund's Data Central (LDC), Lund, Sweden. All registrations were sent to a central database and analyzed by use of SAS (SAS, Cary, NJ). The registrations have so far been performed during the year after the clinical data were collected, i.e., data from 1999 were registered in the year of 2000. Yearly reports of all registered diabetic patients separated into HCMs and PHCs have been presented by NDR to Swedish authorities (also available online at www.ldc.lu.SE/ndr).

The Swedish Health Care system for diabetic patients

This health care system is generally organized by 25 regional county councils, and HCMs and PHCs are managed separately. Diabetes care at HCMs is managed by specialists in internal medicine or endocrinology/diabetology and by specialized nurses. Diabetic patients generally visit their physicians and nurses several times per year. The health care at PHCs is normally delivered by two or more specialists in general medicine with individual responsibility for each patient and by specialized nurses. The patients in PHCs visit their general practitioners at least once per year, but more often when complications occur, and they also visit their nurses several times per year.

Definitions of study participants

In this report, we aimed to describe the treatment situation for patients with type 1 and type 2 diabetes in Sweden, irrespective of health care level. Almost all of the type 1 diabetic patients in Sweden are treated in an HCM. Most type 2 diabetic patients, however, are treated in a PHC, whereas those with diabetes complications and multiple drug treatment are often treated in an HCM after being referred from a PHC.

The definition of type 1 diabetes was based on onset of diabetes before the age of 30 years in combination with treatment with insulin only. The corresponding definition of type 2 diabetes was onset of diabetes at the age of 40 years or above, irrespective of type of treatment. This means that all patients with diabetes onset between 30 and 39 years, as well as all patients with diabetes onset before the age of 30 years on oral treatment or on combined oral and insulin treatment were excluded from further analyses. Furthermore, some patients also had to be excluded due to missing data regarding various measured variables, e.g., diabetes duration.

Clinical investigations

The registered variables presented here were the following: type of diabetes treatment, age at diabetes onset, weight, height, HbA_{1c}, and BP. Questions (yes/no) regarding smoking and lipid-lowering treatment (from 1997) were also included. The patients were screened by use of local methods and devices. An HbA_{1c} level <6.5% was regarded as excellent glycemic control. BMI was calculated as weight divided by height squared. A standard recommendation for BP recordings has been published in Sweden (7,8), stating that a mean of two readings (Korotkoff 1–5) in the supine position shall be recorded, using a cuff of appropriate size. These recommendations were further endorsed by instructions from NDR

Statistical methods

Mean levels with SDs and proportions were calculated for the variables separately for patients with type 1 and type 2 diabetes. Comparisons were performed between the first year (1996) and the last year (1999) of registrations, regarding mean levels by use of the Student's *t* test for unpaired samples and regarding proportions by use of the χ^2 test. In a subset of data from repeated measurements in the same patients (cohort subanalysis), mean levels were compared between years by use of a paired Student's *t* test. Multivariate analyses (standard least squares) were performed with HbA_{1c} and BP for 1999 as dependent variables and with age, sex, diabetes duration, BMI, the BMI change from 1996 to 1999, and smoking as independent variables. A *P* value <0.05 was considered to be significant.

RESULTS

Number of patients included in NDR

All diabetic patients included in the NDR from HCMs and PHCs during the years 1996–1999 are shown in Table 1. The larger proportion of patients that were excluded from this study in 1999 was due to missing data regarding onset of diabetes, mainly in PHCs.

Table 2—*Age, sex, diabetes duration, BMI, smoking, and use of lipid-lowering drugs in type 1 and type 2 diabetic patients from 1996 to 1999*

	1996	1997	1998	1999	1996–1999 (*P*)*
Type 1 diabetes					
Age (years)	38.6 ± 13.1	38.5 ± 12.9	39.2 ± 13.0	39.5 ± 13.0	<0.001
Sex M/F (%)	54/46	54/46	54/46	55/45	NS
Diabetes duration (years)	23.2 ± 13.4	23.1 ± 13.4	23.6 ± 13.5	24.0 ± 13.5	<0.001
BMI (kg/m^2)					
Men	24.8 ± 3.2	24.9 ± 3.2	25.0 ± 3.3	25.1 ± 3.3	<0.001
Women	24.8 ± 3.9	24.9 ± 3.9	25.0 ± 4.0	25.1 ± 3.9	<0.01
Smokers (%)	14.5	15.0	11.7	13.5	NS
Lipid-lowering drug use (%)	NA	4.0	6.6	11.4	<0.001
Type 2 diabetes					
Age (years)	67.5 ± 10.6	66.9 ± 10.7	67.1 ± 10.8	66.9 ± 10.7	<0.001
Sex M/F (%)	54/46	55/45	55/45	56/44	<0.001
Diabetes duration (years)	8.5 ± 7.1	8.5 ± 7.3	8.6 ± 7.4	8.8 ± 7.4	<0.001
BMI (kg/m^2)					
Men	28.0 ± 4.2	28.0 ± 4.3	28.1 ± 4.3	28.2 ± 4.4	<0.001
Women	28.6 ± 5.5	28.6 ± 5.4	28.7 ± 5.4	28.9 ± 5.9	<0.001
Smokers (%)					
Aged <60 years	21.5	21.3	20.0	20.4	NS
Aged ≥60 years	7.8	9.1	7.5	7.6	NS
Lipid-lowering drug use (%)	NA	9.5	14.4	21.8	<0.001

Data are means ± SD and %. **P* for differences between 1996 and 1999. NA, not available; NS, not significant.

Clinical characteristics of type 1 and type 2 diabetic patients

Patient characteristics concerning age, sex, duration of diabetes, BMI, and smoking habits are shown in Table 2. Mean age was lower in type 1 (39 years) than in type 2 (67 years) diabetic patients, but mean duration of diabetes was longer in type 1 (23 years) than in type 2 (9 years) diabetic patients. The proportions of men/women were similar in the type 1 and type 2 diabetic patients, ~55/45%. Mean BMI levels increased significantly from 1996 to 1999 in both type 1 diabetic men (24.8 to 25.1 kg/m^2) and women (24.8 to 25.1 kg/m^2). This was also seen in type 2 diabetic men (28.0 to 28.2 kg/m^2) and women (28.6 to 28.9 kg/m^2). Smoking frequency was unchanged in type 1 diabetic patients from 1996 to 1999 (14.5 to 13.5%) but was higher in younger type 2 diabetic patients <60 years of age (21.5 to 20.4%) than in older type 2 diabetic patients ≥60 years of age (7.8 to 7.6%). The proportion of patients prescribed lipid-lowering drugs increased significantly from 1997 to 1999, both in type 1 (4 to 11%) and type 2 diabetic patients (10 to 22%).

Trends in glycemic and BP control

Mean HbA_{1c} levels decreased significantly from 1996 to 1999, both in type 1 (7.5 to 7.3%) and type 2 (7.0 to 6.7%) diabetic patients (Table 3). The proportion of patients with diabetes that reached the national treatment target level of HbA_{1c} <7.5% increased significantly from 1996 to 1999 in type 1 (50 to 58%) as well as in type 2 (66 to 73%) diabetic patients. Similar tendencies were seen regarding limits of excellent treatment levels (HbA_{1c} <6.5%) and poor treatment levels (HbA_{1c} ≥9.0%).

Mean BP levels also decreased significantly from 1996 to 1999, concerning diastolic BP (130/75–130/74 mmHg) in type 1 diabetic patients and combined systolic and diastolic BP (151/82–147/80 mmHg) in type 2 diabetic patients (Table 3). The proportion of diabetic patients who reached BP target levels ≤140/85 mmHg increased significantly from 1996 to 1999 in type 1 (77 to 79%) as well as type 2 (32 to 42%) diabetic patients.

Trends in glycemic control based on individual data

In a substudy of patients (cohort substudy) with repeated individual data for HbA_{1c}, a significant trend for better glycemic control was observed from 1996 to 1999 for both type 1 (7.4 to 7.3%) and type 2 diabetic (7.0 to 6.8%) patients (Table 4).

Type 2 diabetes in HCMs and PHCs

For type 2 diabetic patients in 1999, we found that those treated in PHCs constituted 61% (not shown). Compared with those in HCMs, patients treated in PHCs were older (mean age 69 vs. 64 years; $P < 0.001$), had a shorter mean diabetes duration (7 vs. 11 years; $P < 0.001$), had a higher mean BMI (men 28.5 vs. 27.8 kg/m^2; women 29.2 vs. 28.2 kg/m^2; both $P < 0.001$), and were less often smokers (11 vs. 13%; $P < 0.001$). They also had a lower mean HbA_{1c} (6.5 vs. 7.1%), a higher rate of HbA_{1c} <7.5% (80 vs. 63%; $P < 0.001$), a higher mean BP (149/80 vs. 144/79 mmHg; $P < 0.001$), a lower proportion of BP ≤140/85 mmHg (37 vs. 50%), and less use of lipid-lowering drugs (18 vs. 28%).

Trends in the treatment profile for diabetes

Concerning changes of treatment from 1996 to 1999 in type 2 diabetic patients (Table 5) it was found that the main types of treatments at HCMs were insulin treatment, with or without combination with oral drugs (76 to 81%), while the main treatment categories in PHCs were diet alone or oral drugs (76 to 72%). However, monotreatment with oral drugs decreased significantly from 1996 to 1999 in both

Table 3—*Glycemic and BP control*

	1996	1997	1998	1999	*P**
Type 1 diabetes					
HbA_{1c}	7.5 ± 1.4	7.4 ± 1.4	7.3 ± 1.4	7.3 ± 1.4	<0.001
HbA_{1c} <6.5%	20.9	24.6	25.6	26.8	<0.001
HbA_{1c} <7.5%	49.9	54.9	56.4	58.3	<0.001
HbA_{1c} ≥9.0%	13.9	12.2	11.2	10.6	<0.001
Systolic BP	129.6 ± 17.4	130.1 ± 17.7	129.8 ± 17.3	129.7 ± 17.2	NS
Diastolic BP	74.9 ± 9.0	75.1 ± 9.0	74.8 ± 8.9	74.2 ± 8.9	<0.001
BP ≤140/85 mmHg	76.9	76.8	77.6	78.6	<0.01
BP <130/85 mmHg	46.7	46.6	46.1	46.6	NS
Type 2 diabetes					
HbA_{1c}	7.0 ± 1.5	6.9 ± 1.5	6.8 ± 1.5	6.7 ± 1.5	<0.001
HbA_{1c} <6.5%	40.1	42.9	45.9	48.4	<0.001
HbA_{1c} <7.5%	65.8	68.5	71.2	73.3	<0.001
HbA_{1c} ≥9.0%	10.3	9.2	8.1	7.4	<0.001
Systolic BP	150.6 ± 20.0	149.4 ± 20.1	148.2 ± 19.8	147.1 ± 19.8	<0.001
Diastolic BP	81.9 ± 9.2	81.0 ± 9.4	80.4 ± 9.4	79.5 ± 9.6	<0.001
BP ≤140/85 mmHg	32.4	36.5	38.3	41.7	<0.001
BP <130/85 mmHg	10.4	11.7	13.0	13.7	<0.001

Data are means ± SD and %. **P* for differences between 1996 and 1999 for type 1 and type 2 diabetic patients, respectively. NS, not significant.

HCM (18 to 11%) and PHC patients (49 to 44%). On the contrary, combination treatment with oral drugs and insulin increased significantly from 1996 to 1999 in HCM (15 to 24%) and PHC (7 to 14%) patients.

Predictors of HbA_{1c} and BP in type 2 diabetes

A prospective multivariate analysis was performed in type 2 diabetic patients (n = 5,426), with HbA_{1c} (1999) and BP (1999) as dependent variables, and with baseline (1996) age, sex, diabetes duration, smoking, and BMI, plus increase of BMI from 1996 to 1999, as independent predictors (Table 6). It was found that both a high HbA_{1c} value and high systolic and diastolic BP values at follow-up (1999) were independently and significantly related to a high BMI value in 1996 and also to a high increase of BMI from 1996 to 1999. Diabetes duration but not age was positively related to HbA_{1c} at follow-up (1999). Age, but not diabetes duration, was positively related to systolic BP (1999), while age and diabetes duration were both negatively related to diastolic BP at follow-up.

CONCLUSIONS — The main findings of this study, based on a repeated cross-sectional, large-scale screening of various risk factors in patients with diabetes at four independent surveys during 1996–1999 in Swedish healthcare, are the tendencies of decreasing mean HbA_{1c} and BP values in both type 1 and type 2 diabetic patients. Furthermore, for both type 1 and type 2 diabetic patients a tendency was also demonstrated for improving achievement of treatment target levels of HbA_{1c} (<6.5% or <7.5%) and BP (≤140/85 mmHg or <130/85 mmHg). The mean decrease of HbA_{1c} (0.3%) from 1996 to 1999 in type 2 diabetic patients of this study (Table 3) can be approximately calculated to correspond to a reduction of 4% in any diabetes complications and of 8% in microvascular complications, as a conservative estimation based on UKPDS predictions in all diabetic patients (5). Similarly, the mean decrease of systolic BP 3.5 mmHg in type 2 diabetic patients of this study should approximately correspond to a reduction of 3.5% in any diabetes complications, 5% in diabetes-related deaths, 3.5% in myocardial infarctions, and 4% in microvascular complications (9). The trend was further strengthened by the prospective analysis of those patients (cohort substudy) with available repeated measurements from 1996 to 1999 (Table 4), showing a significant decrease in mean HbA_{1c} levels. The benefit of lowering HbA_{1c} levels in order to prevent diabetes complications has been clearly demonstrated in recent intervention studies, e.g., DCCT (4), the Stockholm study (10), the Kumamoto study (11), and UKPDS (5).

A troubling finding was the relatively high frequency of smokers in middle-

Table 4—*Changes in mean HbA_{1c} levels for type 1 (n = 1,006) and type 2 (n = 3,269) diabetic patients (cohort substudy) with repeated HbA_{1c} recordings at all four annual screenings*

	1996	1997	1998	1999	*P**
Type 1 diabetes					
Mean HbA_{1c}	7.4 ± 1.2	7.3 ± 1.2	7.3 ± 1.2	7.3 ± 1.2	<0.0001
Median HbA_{1c}	7.4	7.2	7.2	7.1	
HbA_{1c} <7.5% (%)	51.3	57.0	56.8	60.9	<0.0001
Type 2 diabetes					
Mean HbA_{1c}	7.0 ± 1.4	6.9 ± 1.4	6.9 ± 1.4	6.8 ± 1.4	<0.0001
Median HbA_{1c}	6.8	6.8	6.8	6.7	
HbA_{1c} <7.5% (%)	65.6	68.2	68.9	70.9	<0.0001

Data are means ± SD, median, and %. **P* for differences between 1996 and 1999.

Table 5—*Proportions (%) from 1996 to 1999 of all type 2 diabetic patients and of type 2 diabetic patients with an HbA_{1c} <7.5% and a BP ≤140/85 mmHg by treatment category*

	Diet only	Oral agents	Insulin plus oral agents	Insulin only
HCM				
All patients	6.1–7.5*	18.2–11.3†	14.8–24.1†	60.9–57.1†
HbA_{1c} <7.5%	85.5–78.9*	64.4–75.0†	44.4–57.9†	50.7–61.4†
BP ≤140/85 mmHg	41.4–42.5	37.4–43.5‡	36.0–48.8†	44.0–51.9†
PHC				
All patients	26.7–27.9*	49.2–43.9†	7.3–13.5†	16.8–14.7†
HbA_{1c} <7.5%	94.2–95.4*	69.5–79.2†	43.1–60.8†	57.6–67.7†
BP ≤140/85 mmHg	27.9–38.1†	26.9–34.8†	26.5–36.6†	30.5–40.1†

*$P < 0.05$, †$P < 0.001$, ‡$P < 0.01$.

aged patients with type 2 diabetes (<60 years of age), similar to figures for the nondiabetic Swedish population in the same age-group. These findings underline the need for further tobacco preventive measures in middle-aged subjects (12,13), being a highly cost-effective intervention regarding prevention of cardiovascular complications (14,15).

We also documented an increasing use of lipid-lowering drugs from 1996 to 1999 in type 1 as well as in type 2 diabetic patients. Several recent large-scale studies, e.g., 4S (16) and the Heart Protection Study (17), have shown the importance of treating diabetic patients with lipid-lowering drugs in order to decrease the risk for macrovascular complications and cardiovascular mortality. These important findings seem to have influenced clinical practice.

Limitations of the study

Our definitions of type 1 and type 2 diabetes chosen for this report were based on accessible data in NDR, according to age of diabetes onset and treatment. The epidemiological definition of type 1 diabetes can alternatively be based on treatment with insulin within 1 year after diabetes diagnosis, but such data were not available in NDR. Those subjects with age of diabetes onset <30 years and treatment with insulin only should reasonably well exclude type 2 diabetic patients. Using age of onset ≥40 years for type 2 diabetes assured that all patients with onset age 30–39 years, and therefore difficult to classify with certainty for diabetes category, were eliminated in this study. Our definitions could still be open for some degree of misclassification, e.g., for type 1 diabetes with late adult-onset and for type 2 diabetes in the young, a phenomenon probably more prevalent in the U.S. than in Sweden.

The increasing participation by HCMs all over Sweden from 1996 to 1999, currently 71%, should make the sample of 6,000–10,000 type 1 diabetic patients in this study sufficiently representative for the whole population of ~30,000–40,000 such patients (in all age-groups) in Sweden. Similarly, the sample of type 2 diabetic patients from HCMs should be a representative sample of this population. One problem thus far has been the lower participation rate (15%) in NDR of the PHC centers in Sweden, making the samples of 17,000–22,000 type 2 diabetic patients in this study less representative for the total Swedish type 2 diabetic population of ~260,000–270,000 patients. However, the participating centers were distributed in all parts of the country, with a mean number of as high as 78–127 registered patients per PHC unit, implying that the sample should be fairly representative of the typical Swedish PHC center with two or more general practitioners and other staff. It should be noted that a higher participation rate by PHC centers would have yielded a larger proportion of type 2 diabetic patients from PHCs than the rate of ~60% in this study.

Our findings were somewhat limited, as they were based on a comparison of data from four cross-sectional surveys. We have, however, shown that the favorable trend in glycemic control was still present in a substudy of subjects (cohort study) with repeated measurements (Table 4). In absolute terms, the reduction of HbA_{1c} was small, but this is in our view a marker for more general trends in the diabetes population and therefore of interest.

Obesity trends and treatment changes in NDR

We found that type 2 diabetic patients had increasing mean BMI values from 1996 to 1999. Overweight/obese (BMI ≥27 kg/m^2) type 2 diabetic patients in 1999 had higher mean HbA_{1c} and BP values than nonobese (data not shown). This finding was underlined by the prospective analysis demonstrating that both high BMI values in 1996 and a high increase of BMI from 1996 to 1999 were associated with high HbA_{1c} and BP values in 1999 (Table 6). This implies that further lifestyle measures should be of value for the treatment of obese type 2 diabetes. It should, however, also be kept in mind that treatment with sulfonylureas or insulin could further increase weight while improving glycemic control and prevent-

Table 6—*Prospective multivariate analyses in type 2 diabetic patients with HbA_{1c} (1999) and BP (1999) as dependent variables and with baseline (1996) age, sex, diabetes duration, BMI, and smoking, as well as increase of BMI from 1996 to 1999 (ΔBMI), as independent predicting variables*

	HbA_{1c} (1999)	Systolic BP (1999)	Diastolic BP (1999)
n	5,426	5,426	5,426
R^2	0.07	0.09	0.06
Predictors (t ratio)			
Age	−13.0*	18.9*	−3.4*
Female sex	3.0†	4.5*	−3.7*
Diabetes duration	15.2*	0.1	−10.3*
BMI	8.2*	8.1*	11.8*
ΔBMI	5.4*	4.6*	5.1*
Smoking	1.3	−1.5	−1.7

*$P < 0.001$, †$P < 0.01$.

ing microvascular complications (5). Therefore, the two goals of weight control and improved glycemic control while using sulfonylureas or insulin therapy is not easy to accomplish for many patients.

Type 2 diabetic patients treated with oral agents constituted 44% in PHCs but only 11% in HCMs (1999), with a tendency toward a decreasing use of oral agents in monotherapy from 1996 to 1999 in both PHCs and HCMs. Concomitantly, we found an increasing use of the combination therapy of oral agents and insulin from 1996 to 1999, with a higher rate in HCMs (24%) than in PHCs (14%) in 1999.

The tendency seen in NDRs from 1996 to 1999 of a decreasing use of oral agents and of a concomitant increasing use of insulin combined with oral agents in both PHCs and HCMs should reflect ongoing discussions in Swedish health care regarding the best treatment choice for diabetes with progressive secondary failure.

The role of NDR and standardization procedures

Health care for diabetic patients in PHCs and HCMs should be improved according to empirical data and previous studies. It has been previously shown that a large proportion of elderly patients with diabetes is not receiving a standard of care in accordance with the published guidelines of the American Diabetes Association (ADA) (18,19). Additionally, a Dutch study observed that management of type 2 diabetic patients in primary care only partly adhered to the published Dutch guidelines (20). Management of type 1 diabetes has also been found to be suboptimal (21).

NDR has therefore been initiated as a national tool for a continuous quality assessment of diabetes care in Sweden. One aim is to provide population data regarding clinical practice, complementary to data from previous and ongoing clinical trials. Another aim is to provide local centers with data regarding the quality indicators of diabetes care, also making a comparison possible with the national or regional NDR data. Further quality validation of sampled data should be of value.

Local reports are used by the physicians and nurses for a continuous evaluation and quality assessment of diabetes care, with the aim to increase the degree of fulfillment of treatment goals regarding glucose, BP, and other variables and with the assistance by regional NDR coordinators. NDR also intends to introduce the use of an Internet-based data registration, which will further simplify the process and allow individual patients to follow their own diabetes data by use of the Internet. Validation has been carried out continuously by communication between participating centers and the central database at LDC. Regarding HbA_{1c}, Swedish HCM and PHC centers nowadays take part in a quality validation assessed by a collaboration between all laboratories measuring HbA_{1c} (a project called Equalis that started in 1995). This means that HbA_{1c} measurement has been quality-assured since the beginning of NDR by calibration to the standard Swedish high-performance liquid chromatography Mono-S method (22,23).

NDR in comparison with U.S. data

NDR is probably among the largest diabetes registers currently known. Comparatively, the National Health and Nutrition Examination Study (NHANES) III is a nationally representative sample of the U.S. noninstitutionalized civilian population, although with somewhat differing HbA_{1c} reference levels compared with the Swedish levels. In a sample of 1,482 self-reported type 2 diabetic patients from 1988 to 1994 (24,25), a mean HbA_{1c} of 7.7% was reported in individuals aged 65–74 years compared with a mean HbA_{1c} of 6.7% in this study with mean age of 67 years. Among NHANES III participants aged 65 years or older, former ADA guidelines goal for glycemic control (HbA_{1c} <7%) in individuals using diet alone, oral agents, or insulin were achieved by 71, 44, and 27%, respectively, compared with 79–95, 75–79, and 58–68%, respectively, in this study. Another sample of 733 adult type 2 diabetic patients from NHANES III from 1991 to 1994 (26) showed that 76% were treated with oral agents or insulin compared with 72% in PHCs and 93% in HCMs of this study.

In conclusion, the NDR is a tool for continuous quality assessment of Swedish diabetes care. Improving trends based on results from 1996 to 1999 were seen in both type 1 and type 2 diabetes according to decreasing mean HbA_{1c} and BP values and increasing use of lipid-lowering drugs. These trends could translate into clinical benefits regarding micro- and macrovascular complications and diabetes mortality. Obesity and smoking are still major health problems that need to be addressed in the diabetic population.

Acknowledgments— NDR is financially supported by the Swedish Board of Health and Welfare, Stockholm.

The NDR Working Group consists of Soffia Gudbjörnsdottir (National Coordinator), Björn Eliasson, Jan Cederholm, Peter Nilsson, Thomas Fritz (representative of primary health care centers), and Christian Berne (President of the Swedish Society for Diabetology). Anders Nilsson and Göran Blohmé were in charge of the registry from 1996 to 2000. Carl-David Agardh implemented the idea of a national diabetes registry in 1995.

We thank all of the participating physicians, nurses, and other staff members who contributed data to NDR. Most of all we thank the diabetic patients who both individually and collectively, via the organization of the Swedish Diabetes Federation, have supported NDR.

Data management and its compilation into the computerized register has been handled on a daily basis by staff at LDC, Lund, Sweden.

References

1. Diabetes care and research in Europe: the Saint Vincent declaration. *Diabet Med* 7:360, 1989
2. Agardh C-D, Berne C ,Carlgren G, Olsson B, Blohmé G, Adamsson U, et al: *National Guidelines for Treatment of Diabetes Mellitus*. Sweden, Swedish National Board of Health and Welfare, 1999
3. Östman J, Agardh C-D, Almér O, Reichard P, Asp N-G, Vessby B, et al: *Workshop on Treatment of Insulin Dependent Diabetes Mellitus*. Uppsala, Sweden, Drug Information Committee of the Swedish National Board of Health and Welfare, 1990
4. The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 329:977–986, 1993
5. UK Prospective Diabetes Study Group: Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 352:837–853, 1998
6. Nilsson PM, Gudbjörnsdottir S, Eliasson B, Cederholm J, for the Steering Committee of the National Diabetes Register in Sweden: hypertension in diabetes: trends in clinical control in repeated national surveys from Sweden 1996–99. *J Hum*

Hypertens 17:37–44, 2003
7. Östman J, Efendic S, Smith U, Lithell H, Lindgarde F, Vessby B, et al: *Workshop on Treatment of Non-Insulin Dependent Diabetes Mellitus*. Uppsala, Sweden, Drug Information Committee of the Swedish National Board of Health and Welfare, 1990
8. Smith U, Arnquist HJ, Berne C, Ostensson GG, Henriksson F, Hanssen KF, et al: *Workshop on Treatment of Diabetes Mellitus*. Uppsala, Sweden, Swedish Medical Products Agency, 2000
9. Adler AI, Stratton IM, Neil HAW, Yudkin JS, Matthews DR, Cull CA, Wright AD, Turner RC, Holman RR, on behalf of the UK Prospective Diabetes Study Group: Association of systolic blood pressure with macrovascular and microvascular complications of type 2 diabetes (UKPDS 36): prospective observational study. *BMJ* 321:412–419, 2000
10. Reichard P, Pihl M, Rosenqvist U, Sule J: Complications in IDDM are caused by elevated blood glucose level: the Stockholm Diabetes Intervention Study (SDIS) at 10-year follow up. *Diabetologia* 39:1483–1488, 1996
11. Shichiri M, Kishikawa H, Ohkubo Y, Wake N: Long-term results of the Kumamoto Study on optimal diabetes control in type 2 diabetic patients. *Diabetes Care* 25 (Suppl. 2):B21–B29, 2000
12. Canga N, de Irala J, Vara E, Duaso MJ, Ferrer A, Martinez-Gonzales MA: Intervention study for smoking cessation in diabetic patients: a randomized controlled trial in both clinical and primary health care settings. *Diabetes Care* 23:1455–1460, 2000
13. Persson L-G, Lindström K, Lingfors H: Quality improvement in primary health care using computerised journal, exemplified by a smoking cessation programme for diabetic patients. *Scand J Prim Health Care* 18:252–253, 2000
14. Yudkin JS: How can we best prolong life? Benefits of coronary risk factor reduction in non-diabetic and diabetic subjects. *BMJ* 306:1313–1318, 1993
15. Haire-Joshu D, Glasgow RE, Tibbs TL: Smoking and diabetes. *Diabetes Care* 22: 1887–1898, 1999
16. Scandinavian Simvastatin Survival Study Group: Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S). *Lancet* 344:1383–1389, 1994
17. Heart Protection Study Collaborative Group: MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. *Lancet* 360:7–22, 2002
18. Weiner JP, Parente ST, Garnick DW, Fowles J, Lawthers AG, Palmer RH: Variation in office-based quality: a claims-based profile of care provided to Medicare patients with diabetes. *JAMA* 273:1503–1538, 1995
19. Beckles GL, Engelgau MM, Narayan KM, Herman WH, Aubert RE, Williamson DF: Population-based assessment of the level of care among adults with diabetes in the U.S. *Diabetes Care* 21:1432–1438, 1998
20. Grol R: National standard setting for quality of care in general practice: attitudes of general practitioners and response to a set of standards. *Br J Gen Pract* 40:361–364, 1990
21. Tuttleman M, Lipsett L, Harris MI: Attitudes and behaviors of primary care physicians regarding tight control of blood glucose in IDDM patients. *Diabetes Care* 16:765–772, 1993
22. Swedish Society for Diabetology: *National Guidelines for Standardisation and Quality Control of the Analysis of HbA_{1c} in Sweden: A Report (in Swedish)*. Linköping, Sweden, Diabetes Forum, 1997
23. Nordin G: *Quality Assurance of Laboratory Investigations With Special Reference to Diabetes (in Swedish)*. Uppsala, Sweden, Equalis Inc., 2001
24. Shorr RI, Franse LV, Resnick HE, Di Bari M, Johnson KC, Pahor M: Glycemic control of older adults with type 2 diabetes: findings from the Third National Health and Nutrition Examination Survey, 1988–1994. *J Am Geriatr Soc* 48:264–267, 2000
25. Saadine JB, Engelgau MM, Beckles GL, Gregg EW, Thompson TJ, Narayan KM: A diabetes report card for the United States: quality of care in the 1990s. *Ann Internal Med* 136:565–574, 2002
26. Harris MI: Health care and health status and outcomes for patients with type 2 diabetes. *Diabetes Care* 23:754–758, 2000