Quality of Care of People With Type 2 Diabetes in Eight European Countries

Findings from the Guideline Adherence to Enhance Care (GUIDANCE) study

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OBJECTIVE—We sought to determine levels of adherence in eight European countries to recommendations for the management of type 2 diabetes and to investigate factors associated with key intermediate outcomes.

RESEARCH DESIGN AND METHODS—GUIDANCE was a cross-sectional study including retrospective data extraction from the medical records of people with type 2 diabetes recruited, using a shared protocol, from primary and specialist care sites in the following eight European countries: Belgium, France, Germany, Italy, Ireland, Sweden, the Netherlands, and the United Kingdom. The dataset for analysis comprised 7,597 cases. Proportions meeting process and outcome criteria were determined, including between-country variations. Logistic regression was used to investigate potential predictors of meeting targets for HbA_{1c}, blood pressure, and LDL cholesterol.

RESULTS—In the total sample, adherence to process recommendations was high for some measures, for example, HbA_{1c} recorded in past 12 months in 97.6% of cases. Target achievement for intermediate outcome measures was lower, with only 53.6% having HbA_{1c} <7%. Considerable between-country variation was identified for both processes and outcomes. The following characteristics were associated with an increased likelihood of meeting targets for all three measures considered (HbA_{1c}, blood pressure, LDL cholesterol): shorter diagnosis of diabetes; having one or more macrovascular complications; lower BMI; being prescribed lipid-lowering medication; and no current antihypertensive prescribing.

CONCLUSIONS—Compared with earlier reports, we have suggested some encouraging positive trends in Europe in relation to meeting targets for the management of people with type 2 diabetes, but there is still scope for further improvement and greater between-country consistency.

Diabetes Care 36:2628–2638, 2013

Type 2 diabetes can have serious consequences in terms of a negative impact on quality of life and the development of debilitating and life-threatening microvascular and macrovascular complications. These consequences have implications not only for patients but also in relation to health care costs (1,2). The number of people with type 2 diabetes is likely to increase, with a predicted worldwide burden of 552 million cases of diabetes by 2030 (3). The importance of secondary prevention strategies based on optimal management therefore remains at a premium. Analysis of data for >5,000 patients in Italy confirmed a strong association between quality of care and long-term cardiovascular disease outcomes (4).

Good quality of care can be measured in terms of process measures, for example, regular checking and recording of HbA_{1c} levels, and also intermediate outcome measures such as achievement of good blood glucose control. Local, national, and international guidelines have been developed to support health care professionals in good management of their patients with type 2 diabetes. The quality and consistency of guidelines may, however, limit their credibility and effectiveness; a study evaluating and comparing guidelines used in a range of European countries identified broad consensus between recommendations but some shortcomings in the methodology used to develop the guidelines and detailed variations between proposed targets (5). It also has been noted that process improvements may have a limited influence on outcomes (6–11). In addition, the appropriateness of guidelines has been questioned in relation to treatment goals (12) and the management of specific subgroups such as older people with multiple comorbidities (13). Despite these limitations, guidelines provide evidence-based practical guidance and also can be used as tools for measuring quality of care against agreed standards.

Understanding the factors that influence quality of care can assist with identifying strategies for improvement. A range of such factors has been previously identified, for example, management by specialists or nonspecialists (14), socioeconomic differences (15–17), ethnic minority status (15,18), and duration of diabetes (19). Geographical differences

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Received 30 August 2012 and accepted 8 February 2013.
DOI: 10.2337/dc12-1759
This article contains Supplementary Data online at http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dc12-1759/-/DC1.
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also have been described, including large variations in the quality of care between districts within the state of Thuringia in Germany (20) and between states in the United States (21). Similarities and differences within and between countries may be partly explained by factors such as deprivation, as listed, but additional considerations, including the organization and financing of care, also may contribute. Observations regarding the quality of care of people with type 2 diabetes in specific geographic areas may be relevant not only to those locations but also more generally in terms of broad lessons and opportunities for comparison. We identified only a small number of previously published studies of this type conducted in more than one European country (22–26).

Data were collected for the GUIDANCE study from a large sample of patients with type 2 diabetes and their health care providers in the following eight European countries: Belgium, France, Germany, Italy, Ireland, Sweden, the Netherlands, and the United Kingdom. The broad aims of the study were to provide an overview of the quality of care of people with type 2 diabetes in a sample of European countries and to consider between-country similarities and differences. The specific objectives addressed in this article were to determine levels of adherence to management guidelines and to investigate factors associated with key intermediate outcomes, including HbA_{1c}. Levels of adherence are considered in the overall sample and in terms of between-country variations.

RESEARCH DESIGN AND METHODS

Study design, protocol, and approvals

GUIDANCE was designed as a cross-sectional study based on retrospective data extraction from the medical records of people with type 2 diabetes and combined with questionnaire data collected from patients and physicians. Data collection occurred concurrently in the eight participating countries between March 2009 and December 2010. A protocol was used to promote standardization of procedures, but the overall study design included a degree of pragmatism, recognizing the need for some flexibility because of differences in the organization of care in participating countries. Each country was responsible for obtaining appropriate permissions, including Ethical Committee approval.

Recruitment and sample size

The study protocol allowed recruitment of physicians from both primary and specialist care. Participating countries had flexibility in terms of strategies for recruitment of sites (hospitals or primary care centers), physicians working within these units, and patients managed by those physicians. Potential patient participants were recruited either by direct consecutive approach when attending hospital outpatient or general practice appointments or by mailed invitation. It was recommended that a maximum of 100 patients should be recruited from each site, with a further recommendation of a maximum of 30 patients under the care of each participating physician. Each country was given a recruitment target of 1,000 patients, a figure selected to be able to make useful overall comparisons between findings from the eight participating countries. Using this sample size, it was determined that it would be possible to detect a difference of 3.5% between two countries for a binary outcome (based on 90% compared with 93.5% for potential high adherence to recommendations, as anticipated for some process measures) with 80% power by a standard χ^2 test ($\alpha = 5\%$).

Physicians with any level of involvement in the care of people with type 2 diabetes were eligible for the study. Adult patients (aged 18 years or older) with type 2 diabetes were eligible, but patients with other types of diabetes were excluded. Patients also were excluded if they were not usually managed at the recruited site. Depression was not an exclusion criterion, but physicians could, at their discretion, exclude patients for whom an approach was considered inappropriate because of severe physical or mental health conditions. Additional exclusion criteria were current pregnancy, inability or unwillingness to provide written consent, and current participation in a research study involving an intervention. All patient participants provided written informed consent; this included giving permission to extract relevant data from their medical records.

Data collection

The findings presented in this article are based mainly on data collected from participating patients' medical records; collection of survey data are, therefore, described only briefly. A standardized self-completion questionnaire was used to collect data from participating physicians and the survey instrument for patients comprised a study-specific questionnaire combined with two previously validated instruments, the Diabetes Treatment Satisfaction Questionnaire (27) and EQ5-D visual scale (28). Data derived from these questionnaires used for the current article included primary versus specialist care management (from the physician questionnaire) and receipt of diabetes education and home glucose monitoring (from the study-specific patient questionnaire). Presentation of findings derived from the remainder of the questionnaire data are not within the scope of the current article.

A data collection form was developed for systematically collecting relevant data from the medical records of participating patients. Data extracted were related to the 12 months immediately preceding the date of recruitment of individual patients. Information collected included demographic details, anthropometric measurements, relevant laboratory test results, diabetes complications, and prescribed medication.

Preparation and statistical analysis of data

Completed questionnaires and data collection forms were sent to the study coordinating center in Germany for data input, collation, and statistical analysis. The study teams in each participating country were asked to provide details about the HbA_{1c} values reported for their samples; based on responses, values for Swedish HbA_{1c} (29) were converted to be consistent with those obtained using Diabetes Control and Complications Trial–aligned analyzers in the remaining seven countries.

For consistency in assessing levels of adherence to current guidance for process and outcome measures, we used recommendations and targets derived from the internationally recognized American Diabetes Association guidelines for 2009 (30) rather than national guidelines for each country. If no recommendation was available from this document (for example, for waist size), then guidance identified in our review of European guidelines (5) was used. For descriptive purposes we report proportions with their 95% Wald CIs and exact 95% CIs in cases in which Wald intervals were undefined. Data for continuous variables are

reported using means and SDs. For identification of statistically significant differences between countries, 95% CIs were calculated. For these analyses, cases with missing data were excluded.

Logistic regression modeling was used to investigate factors independently associated with the following key intermediate outcome measures that are likely to influence the development of diabetes complications: HbA_{1c} <7%; blood pressure <130 mmHg (systolic) and <80 mmHg (diastolic); and LDL cholesterol <2.6 mmol/L. Potential predictors that were included in the models were as follows: age (continuous variable); gender; BMI (continuous); recruitment from primary versus specialist care; self-reported status as current smoker versus nonsmoker; duration of diabetes (continuous); self-reported receipt of group or individual diabetes education versus neither; prescribing versus nonprescribing of medication relevant to the respective outcome; self-reported (blood or urine) home glucose monitoring versus none (as an indicator of self-management activity); one or more recorded microvascular complications versus none; and one or more recorded macrovascular complications versus none. Microvascular complications identifiable from the data collected were foot sensation abnormality, blindness or retinopathy present, and end-stage renal disease. Macrovascular complications were history of ischemic heart disease, stroke, peripheral arterial disease (including nonpalpable tibial or dorsal pulses), and amputation. Inclusion of all these potential predictors was favored over stepwise exclusion of variables from the model because of the well-documented problems for data-dependent covariate selection (31). To minimize exclusion of cases from the regression model attributable to missing data, values for continuous variables were imputed using multiple imputation (32). Missing values for binary covariates were imputed by logical reasoning, for example, it was assumed that no education had been received if neither "yes" nor "no" had been recorded for receipt of diabetes education (27 cases only). However, we did not impute values for gender (93/7,597, 1.2% cases with missing data) or for the main outcome measure undergoing investigation. To account for the hierarchical dependencies in the study data (patients nested within physicians, physicians nested within countries), random effects for physicians and countries were included into the logistic regression models and parameters were estimated by penalized quasi-likelihood methods (SAS, GLIMMIX procedure). Results from these models are given as odds ratios (ORs). Sensitivity analysis was conducted with country included as a fixed, rather than random, effect.

All statistical analysis was conducted using SAS version 9.2 (SAS Institute, Cary, NC). Multiple imputation was performed by the MI and the MIANALYZE procedures with 20 imputed datasets and the default Markov Chain Monte Carlo (MCMC) imputation algorithm. Problems with *P* values and CIs are an ongoing topic for debate (33–35), but for this study CIs rather than *P* values were favored (33) for presentation and interpretation of findings. *P* values, however, are also provided for information regarding results from the regression analysis. Both *P* values and CIs should be interpreted bearing in mind that there was no adjustment for multiple comparisons. HbA_{1c} data were collected and analyzed for the study using percentage values but converted to International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) values in mmol/mol are also cited for key values reported in the text and tables.

RESULTS—Of the 7,760 participants for whom any forms were returned to the coordinating center, 63 were excluded because the eligibility criteria had not been met ($n = 25$), the information needed to assess eligibility was incomplete ($n = 35$), or the data collection form was missing ($n = 3$). Usable combined data therefore were available for 7,597 participants; 5,599 (73.7%) of these were recruited from primary care and 1,998 (26.3%) were recruited from specialist care. Recruitment from Sweden was well below target (550 cases) because of logistical problems linked to changes in the organization of care at the time of the study; the range of cases from the other participating countries was 950–1,056. Participants in the overall sample (Table 1) had a mean age of 66.5 years (SD, 10.8), 56% were male, and mean HbA_{1c} was 7.1% (SD, 1.1; 54 mmol/mol), with a between-country range of 6.7% (50 mmol/mol) for the Netherlands to 7.5% (58 mmol/mol) for Italy and the United Kingdom. Treatment patterns varied between countries, including rates of prescribing of insulin and more recently introduced therapies such as glucagon-like peptide 1 analogs; statistically significant variations included proportions prescribed any insulin when comparing countries where recruitment was predominantly or exclusively from primary care, for example, 16.3% (95% CI, 14.0–18.5%) in the sample from the Netherlands compared with much higher proportions in samples from Germany (38.0%; 34.9–41.0%) and Sweden (37.5%; 33.4–41.5%). Management in primary rather than specialist care was predominant in the samples from all countries except Ireland and Italy.

Adherence to recommendations: process measures

Adherence in terms of conducting and recording recommended processes in the previous 12 months (Table 2) was high for some measures, notably HbA_{1c} (criterion met in 97.6% of cases) and blood pressure (98.3%), with minimal between-country differences of 4.6 and 5.4%, respectively. For some measures, much lower overall levels of adherence and wider variations were noted, for example, 33.4% overall with a between-country difference of 54% for waist circumference measurement and 59.4% overall (variation 63.6%) for assessment of microalbuminuria.

Adherence to recommendations: intermediate outcome measures

Proportions meeting targets for intermediate outcome measures (Table 3) also varied, both between variables and between countries. High levels of variation included 46.2, 36.8, and 34.8% variation for LDL, diastolic blood pressure, and HbA_{1c}, respectively. Only 14.7% of all cases had BMI <25 kg/m^2 (not overweight) and low proportions (men 15.4%, women 5.0%) had a waist measurement below recommended levels.

Factors associated with good quality of care

Statistically significant associations that emerged between individual key intermediate outcome measures and potential predictors (Table 4) were not straightforward, as illustrated by the following examples. People with a higher BMI were significantly less likely to have well-controlled HbA_{1c} and blood pressure (OR, 0.98; 95% CI, 0.96–0.99 in both instances), but there was no association with LDL cholesterol (OR, 1.01; 1.00–1.02). Those using diabetes medication and antihypertensive drugs were less likely to meet targets for HbA_{1c} (OR, 0.20; 0.16–0.25) and blood pressure (OR,

Table 1—*Characteristics of participants in the GUIDANCE study, by country*

	Belgium	France	Germany	Ireland	Italy	The Netherlands	Sweden	United Kingdom	Total sample
Total participants	1,044	1,056	959	950	984	1,021	550	1,033	7,597
Descriptive values									
Male, % (95% confidence limits)	50.7 (47.6–53.7)	58.2 (55.2–61.2)	48.5 (45.3–51.7)	59.8 (56.7–63.0)	55.0 (51.9–58.1)	55.7 (52.7–58.8)	60.2 (56.0–64.4)	60.5 (57.5–63.5)	55.8 (54.7–57.0)
Mean age at recruitment (SD)	68.7 (10.6)	65.4 (11.1)	67.7 (10.0)	64.6 (11.6)	68.0 (9.4)	66.2 (10.2)	67.7(10.7)	64.2 (11.9)	66.5 (10.8)
Recruited from primary care, % (95% confidence limits)	96.1 (94.9–97.3)	97.2 (96.2–98.2)	87.5 (85.4–89.6)	28.4 (25.6–31.3)	12.0 (10.0–14.0)	100 (99.7–100)	100 (99.5–100)	74.7 (72.1–77.4)	73.7 (72.7–74.7)
Mean years diagnosed (SD)	8.4 (7.1)	8.8 (7.6)	9.7 (7.2)	7.1(5.9)	12.9 (8.6)	6.2 (4.0)	10.1 (7.6)	8.1 (6.1)	8.8 (7.1)
Current |smokers, % (95% confidence limits)	12.5 (10.4–14.5)	9.8 (8.1–11.6)	9.2 (7.3–11.0)	14.0 (11.8–16.2)	11.8 (9.8–13.8)	13.5 (11.4–15.6)	14.2 (11.3–17.1)	11.2 (9.3–13.2)	11.9 (11.2–12.6)
Any microvascular complications (95% confidence limits)	30.9 (28.1–33.7)	23.4 (20.8–25.9)	37.4 (34.4–40.5)	26.3 (23.5–29.1)	30.0 (27.1–32.8)	25.4 (22.7–28.0)	26.5 (22.9–30.2)	21.8 (19.3–24.3)	27.7 (26.7–28.7)
Any macrovascular complications (95% confidence limits)	14.9 (12.8–17.1)	15.1 (12.9–17.2)	30.1 (27.2–33.0)	16.4 (14.1–18.8)	30.2 (27.3–33.1)	16.7 (14.4–18.9)	36.4 (32.3–40.4)	38.1 (35.2–41.1)	24.0 (23.0–24.9)
Medication, % with current prescription (95% confidence limits)									
No diabetes medication (95% confidence limits)	3.6 (2.5–4.8)	0.7 (0.2–1.2)	10.1 (8.2–12.0)	12.4 (10.3–14.5)	7.3 (5.7–8.9)	16.7 (14.4–18.9)	15.6 (12.6–18.7)	16.6 (14.3–18.8)	10.0 (9.3–10.7)

Continued on p. 2632

Table 1—*Continued*

	Belgium	France	Germany	Ireland	Italy	The Netherlands	Sweden	United Kingdom	Total sample
Any oral glucose-lowering medication (95% confidence limits)	88.5 (86.6–90.4)	96.1 (95.0–97.3)	70.0 (67.1–72.9)	83.4 (81.0–85.7)	72.6 (69.8–75.3)	80.1 (77.7–82.6)	69.5 (65.6–73.3)	74.2 (71.6–76.9)	80.1 (79.2–81.0)
Sulphonylureas	38.4 (35.5–41.4)	46.5 (43.5–49.5)	20.4 (17.9–23.0)	41.3 (38.1–44.4)	28.6 (25.7–31.4)	33.7 (30.8–36.6)	19.1 (15.8–22.4)	31.6 (28.7–34.4)	33.4 (32.3–34.4)
Biguanides	71.0 (68.2–73.7)	78.8 (76.3–81.3)	53.4 (50.2–56.5)	72.2 (69.4–75.1)	60.7 (57.6–63.7)	72.2 (69.4–74.9)	58.0 (53.9–62.1)	62.9 (60.0–65.9)	66.8 (65.7–67.8)
Meglitinides	6.5 (5.0–8.0)	7.5 (5.9–9.1)	6.8 (5.2–8.4)	0.4 (0.0–0.8)	16.9 (14.5–19.2)	0.3 (0.0–0.6)	6.2 (4.2–8.2)	2.0 (1.2–2.9)	5.8 (5.3–6.3)
Thiazolidinediones	4.2 (3.0–5.4)	10.4 (8.6–12.3)	1.6 (0.8–2.3)	3.3 (2.1–4.4)	9.2 (7.4–11.1)	2.9 (1.9–4.0)	1.5 (0.5–2.5)	9.9 (8.1–11.7)	5.7 (5.2–6.2)
α-Glucosidase inhibitors	0.1 (0.0–0.5)	3.9 (2.8–5.2)	2.1 (1.3–3.2)	0.2 (0.0–0.8)	2.3 (1.5–3.5)	0.0 (0.0–0.3)	0.0 (0.0–0.5)	0.2 (0.0–0.7)	1.2 (0.9–1.4)
GLP-1 analogs	1.5 (0.8–2.3)	3.2 (2.2–4.3)	2.0 (1.1–2.9)	1.3 (0.6–2.0)	1.6 (0.8–2.4)	0.2 (0.0–0.5)	0.4 (0.0–0.9)	7.5 (5.9–9.1)	2.3 (2.0–2.7)
DPP-4 inhibitors	2.0 (1.2–2.9)	10.5 (8.7–12.4)	8.3 (6.6–10.1)	3.7 (2.5–4.9)	1.2 (0.5–1.9)	2.4 (1.5–3.4)	1.5 (0.5–2.5)	3.3 (2.2–4.4)	4.3 (3.8–4.7)
Any insulin	19.1 (16.7–21.4)	16.7 (14.4–18.9)	38.0 (34.9–41.0)	19.9 (17.4–22.4)	39.0 (36.0–42.1)	16.3 (14.0–18.5)	37.5 (33.4–41.5)	29.0 (26.3–31.8)	26.1 (25.1–27.1)
Antihypertensive, any	81.2 (78.8–83.6)	78.4 (75.9–80.9)	89.5 (87.6–91.5)	84.3 (81.9–86.6)	80.5 (78.0–82.9)	71.7 (68.9–74.4)	82.2 (79.0–85.4)	81.2 (78.8–83.6)	80.9 (80.0–81.8)
Lipid-lowering, any	64.8 (61.9–67.7)	70.4 (67.6–73.2)	46.5 (43.4–49.7)	84.0 (81.7–86.4)	55.1 (51.9–58.2)	70.3 (67.5–73.2)	62.5 (58.5–66.6)	83.9 (81.6–86.1)	67.6 (66.5–68.6)
Mean values (SD) for intermediate outcome measures									
HbA_{1c} (%; mmol/mol)	7.0 (1.1; 53)	6.9 (1.1; 52)	7.2 (1.1; 55)	7.2 (1.4; 55)	7.5 (1.3; 58)	6.7 (0.8; 50)	7.1 (1.1; 54)	7.5 (1.4; 58)	7.1 (1.2; 54)
Systolic blood pressure, mmHg	134 (14)	134 (12)	140 (15)	137 (180)	137 (19)	137 (15)	135 (15)	135 (15)	136 (16)
Diastolic blood pressure, mmHg	78 (7.8)	77 (7.4)	82 (8.8)	76 (10.0)	78 (9.5)	78 (9.6)	76 (9.2)	76 (9.7)	78 (9.2)
BMI	30 (5.3)	30 (5.9)	31 (5.5)	31(6.6)	29 (5.0)	30 (5.2)	29 (4.9)	32 (6.3)	30 (5.7)
Total cholesterol mmol/L	4.8 (1.1)	4.7 (1.2)	5.3 (1.2)	4.0 (0.9)	4.9 (1.0)	4.4 (1.0)	4.7 (1.0)	4.2 (1.0)	4.6 (1.1)
Serum creatinine μmol/L	85.5 (30.8)	87.5 (49.5)	83.7 (22.0)	89.2 (35.8)	89.6 (36.8)	84.6 (24.1)	81.8 (31.2)	89.6 (29.6)	86.7 (32.6)

Percentages and values are based on complete data for each item.

Table 2—*Adherence to recommendations: process measures recorded in medical records or reported by patients as applicable in past 12 months*

Process measure	Percentage (95% confidence limits) meeting criterion									Variation (%)*
	Belgium	France	Germany	Ireland	Italy	The Netherlands	Sweden	United Kingdom	Total sample	
From medical records										
HbA_{1c} checked	97.3 (96.3–98.3)	98.2 (97.4–99.0)	95.8 (94.6–97.1)	94.7 (93.3–96.2)	98.9 (98.2–99.5)	99.3 (98.8–99.8)	98.5 (97.5–99.5)	98.3 (97.5–99.1)	97.6 (97.3–98.0)	4.6
BP checked	97.8 (96.9–98.7)	99.2 (98.7–99.8)	98.9 (98.2–99.5)	94.1 (92.6–95.6)	99.1 (98.5–99.7)	99.3 (98.8–99.8)	99.5 (98.8–100)	99.1 (98.6–99.7)	98.3 (98.1–98.6)	5.4
Total cholesterol checked	98.0 (97.1–98.8)	90.2 (88.4–91.9)	84.9 (82.6–87.1)	92.6 (91.0–94.3)	97.6 (96.6–98.5)	98.8 (98.2–99.5)	88.5 (85.9–91.2)	93.9 (92.4–95.4)	93.4 (92.8–94.0)	13.9
HDL checked	97.3 (96.3–98.3)	88.7 (86.8–90.6)	60.3 (57.2–63.4)	90.5 (88.7–92.4)	97.0 (95.9–98.0)	98.9 (98.3–99.6)	70.9 (67.1–74.7)	77.1 (74.5–79.6)	86.1 (85.3–86.9)	38.6
LDL checked	95.2 (93.9–96.5)	87.9 (85.9–89.8)	66.9 (64.0–69.9)	86.9 (84.8–89.1)	74.8 (72.1–77.5)	96.8 (95.7–97.9)	63.5 (59.4–67.5)	74.4 (71.8–77.1)	82.0 (81.2–82.9)	33.3
Triglycerides (fasting) checked	96.4 (95.2–97.5)	89.5 (87.6–91.3)	74.7 (71.9–77.4)	85.3 (83.0–87.5)	96.6 (95.5–97.8)	98.4 (97.7–99.2)	74.0 (70.3–77.7)	89.1 (87.2–91.0)	89.0 (88.3–89.7)	24.4
Weight/BMI checked	91.9 (90.2–93.5)	97.1 (96.0–98.1)	94.9 (93.5–96.3)	86.9 (84.8–89.1)	99.0 (98.4–99.6)	99.0 (98.4–99.6)	94.7 (92.9–96.6)	98.9 (98.3–99.6)	95.4 (94.9–95.9)	12.1
Waist circumference checked	41.2 (38.2–44.2)	39.4 (36.4–42.3)	28.3 (25.4–31.1)	11.1 (9.1–13.0)	45.4 (42.3–48.5)	38.3 (35.3–41.3)	65.1 (61.1–69.1)	11.2 (9.3–13.2)	33.4 (32.3–34.4)	54.0
Serum creatinine checked	88.4 (86.5–90.4)	57.1 (54.1–60.1)	72.8 (70.0–75.6)	92.0 (90.3–93.7)	89.0 (87.1–91.0)	97.7 (96.8–98.7)	94.4 (92.4–96.3)	94.7 (93.3–96.0)	85.2 (84.4–86.0)	40.6
Microalbuminuria checked	26.7 (24.0–29.4)	66.4 (63.5–69.2)	26.8 (24.0–29.6)	58.1 (55.0–61.2)	60.9 (57.8–63.9)	90.3 (88.5–92.1)	75.6 (72.0–79.2)	76.1 (73.5–78.7)	59.4 (58.3–60.5)	63.6
Eyes checked	58.0 (55.0–60.9)	68.6 (65.8–71.4)	78.1 (75.5–80.7)	63.2 (60.1–66.2)	80.4 (77.9–82.9)	86.3 (84.2–88.4)	76.2 (72.6–79.7)	88.6 (86.6–90.5)	74.8 (73.8–75.8)	30.6
Foot pulses checked	67.4 (64.6–70.3)	79.6 (77.2–82.1)	81.8 (79.3–84.2)	67.8 (64.8–70.8)	51.7 (48.6–54.8)	89.4 (87.5–91.3)	65.8 (61.9–69.8)	77.1 (74.5–79.6)	73.1 (72.1–41.74.1)	37.7
Foot sensation checked	49.2 (46.2–52.3)	67.0 (64.1–69.8)	75.4 (72.7–78.1)	59.7 (56.6–62.8)	47.8 (44.6–50.9)	89.5 (87.6–91.4)	70.5 (66.7–74.4)	78.9 (76.4–81.4)	67.1 (66.0–68.2)	41.7
Patient reported										
Education received (group or individual)	95.7 (92.0–99.4)	96.4 (93.0–99.9)	92.6 (89.9– 95.3)	98.4 (96.6–100)	67.3 (61.5–73.1)	98.7 (97.4–100)	94.6 (90.0–99.2)	97.3 (94.4–100)	91.4 (89.9–92.8)	31.4
Smoking cessation advice (smokers only)	54.1 (46.0–62.1)	40.0 (31.2–48.8)	11.9 (5.6–18.2)	61.5 (53.6–69.3)	56.3 (47.7–64.8)	43.8 (35.8–51.9)	31.1 (19.5–42.8)	55.4 (46.5–64.2)	46.6 (43.4–49.7)	49.6

BP, blood pressure. *Difference between proportions for highest and lowest scoring countries.

Table 3—*Intermediate outcome measures: proportions meeting recommended targets in past 12 months*

Outcome measure	Target	Percentage (95% confidence limits) meeting target								Total sample	Variation (%)*
		Belgium	France	Germany	Ireland	Italy	The Netherlands	Sweden	United Kingdom		
HbA_{1c} (%)	<7% (53 mmol/mol)	59.7 (56.7–62.8)	65.3 (62.4–68.2)	48.6 (45.4–51.9)	53.4 (50.2–56.7)	35.7 (32.7–38.7)	70.5 (67.7–73.3)	56.5 (52.3–60.6)	39.1 (36.1–42.1)	53.6 (52.5–54.8)	34.8
BMI (not overweight)	<25 kg/m^2	17.7 (14.7–20.7)	14.2 (11.8–16.6)	10.5 (8.3–12.8)	12.0 (9.4–14.6)	20.4 (17.8–23.1)	15.1 (12.8–17.4)	18.4 (14.7–22.0)	10.5 (8.6–12.5)	14.7 (13.8–15.6)	9.9
Waist circumference, men	<94 cm	17.1 (12.3–21.9)	17.0 (12.4–21.6)	6.6 (2.2–10.9)	19.0 (8.9–29.1)	19.0 (13.9–24.0)	15.3 (10.5–20.2)	11.8 (7.5–16.2)	16.2 (7.4–24.9)	15.4 (13.5–17.3)	12.4
Waist circumference, women	<80 cm	4.1 (1.3–7.0)	4.3 (1.2–7.5)	4.8 (1.3–8.2)	4.3 (0.0–10.0)	6.2 (2.9–9.5)	4.6 (1.5–7.7)	5.3 (1.5–9.1)	8.5 (0.5–16.5)	5.0 (3.8–6.3)	4.4
Systolic BP	<130 mmHg	29.3 (26.5–32.1)	26.3 (23.7–29.0)	19.0 (16.5–21.5)	32.9 (29.8–36.0)	31.8 (28.9–34.7)	27.8 (25.1–30.6)	35.3 (31.3–39.3)	32.5 (29.7–35.4)	29.0 (28.0–30.0)	16.3
Diastolic BP	<80 mmHg	36.5 (33.5–39.4)	38.8 (35.8–41.7)	22.4 (19.7–25.0)	57.3 (54.0–60.5)	42.1 (39.0–45.2)	49.2 (46.1–52.2)	53.7 (49.6–57.9)	59.2 (56.2–62.2)	44.3 (43.2–45.5)	36.8
BP (combined)	<130/80 mmHg	17.6 (15.3–20.0	14.9 (12.7–17.1)	7.4 (5.7–9.1)	24.9 (22.1–27.8)	20.8 (18.2–23.3)	20.3 (17.9–22.8)	27.1 (23.3–30.8)	25.0 (22.3–27.7)	19.3 (18.4–20.2)	19.7
Total cholesterol	<4 mmol/L	23.1 (20.5–25.7)	25.7 (23.0–28.5)	11.7 (9.5–13.9)	52.6 (49.3–55.9)	19.7 (17.2–22.2)	34.5 (31.6–37.4)	22.8 (19.1–26.5)	45.5 (42.3–48.6)	30.0 (28.9–31.1)	40.9
HDL, men	>1 mmol/L (>40 mg/dL)	76.2 (72.5–79.9)	74.2 (70.6–77.9)	67.0 (61.5–72.5)	56.4 (52.0–60.7)	75.7 (72.0–79.4)	62.2 (58.2–66.2)	66.8 (60.5–73.1)	50.1 (45.6–54.6)	66.2 (64.7–67.8)	26.1
HDL, women	>1.3 mmol/L (>50 mg/dL)	59.8 (55.5–64.1)	53.8 (48.8–58.7)	56.5 (50.8–62.1)	37.0 (31.8–42.1)	58.1 (53.3–62.8)	49.4 (44.8–54.1)	48.0 (40.1–56.0)	33.8 (28.5–39.0)	50.5 (48.7–52.3)	26.0
LDL	<2.6 mmol/L (<100 mg/dL)	49.7 (46.6–52.8)	52.4 (49.2–55.6)	30.7 (27.1–34.3)	76.9 (74.0–79.8)	40.4 (36.8–43.9)	58.9 (55.8–62.0)	47.3 (42.0–52.5)	74.5 (71.4–77.6)	55.0 (53.8–56.3)	46.2
Fasting triglycerides	<1.7 mmol/L	60.8 (57.8–63.9)	64.4 (61.4–67.5)	43.2 (39.5–46.8)	60.0 (56.6–63.4)	67.2 (64.2–70.2)	63.3 (60.3–66.3)	61.9 (57.2–66.6)	52.1 (48.8–55.3)	59.5 (58.3–60.7)	24.0

BP, blood pressure. *Difference between proportions for highest and lowest scoring countries.

0.62; 0.53–0.73), respectively, whereas people prescribed lipid-lowering medication were more likely to have LDL cholesterol within target (OR, 2.95; 2.60–3.35).

Analysis involving the composite intermediate outcome measure (HbA_{1c}, blood pressure, and LDL cholesterol all within target) (Table 4) identified longer duration of diabetes (OR, 0.98; 95% CI, 0.95–1.00), higher BMI (OR, 0.96; 0.94–0.99), and treatment with BP-lowering medication (OR, 0.74; 0.56–0.97) as negative predictors of this combined target. Treatment with lipid-lowering medication (OR, 1.70; 1.29–2.25) and having one or more macrovascular complications (OR, 1.31; 1.02–1.69) emerged as positive predictors. The association between the combined measure and the following variables was nonsignificant: age; diabetes medication; smoking status; home glucose monitoring; gender; having one or more microvascular complications; and recruitment from primary or specialist care. In addition to the findings regarding predictors presented in Table 4, it was noted that the proportion of patients in our sample meeting all three targets was very low (393 of the 6,012 cases included in this analysis, 6.5%). Sensitivity analysis with country as a fixed effect (Supplementary Table 1) had minimal impact on the findings presented in Table 4. In common with results for the combined sample, country-specific findings showed some inconsistencies and meaningful results could not be computed for some countries for the combined target because of low numbers meeting this composite measure (Supplementary Table 2). Some broad similarities in terms of predictors in individual countries and the total sample emerged, most notably, longer diagnosis as a negative predictor of HbA_{1c} <7%.

CONCLUSIONS—Results from the GUIDANCE study presented in this article suggest encouraging levels of adherence to key recommended process measures, but achievement of targets for intermediate outcome measures was much lower, with approximately half of the total sample having HbA_{1c} within target and only 6.5% meeting all three targets for HbA_{1c}, blood pressure, and LDL cholesterol. Considerable between-country variation was identified. In the overall sample, patients were more likely to have within-target levels for all three of the measures considered (HbA_{1c}, blood pressure, LDL cholesterol) if they had a

Table 4—*Association between key variables and markers of good quality of care (intermediate outcome measures)*

Potential predictor (no. of observations)	HbA_{1c} <7% (n = 7,326)	BP <130/80 mmHg (n = 7,383)	LDL cholesterol <2.6 mmol/L (n = 6,159)	All 3 targets met (n = 6,012)
Age	1.01 (1.00–1.02), <0.01	1.00 (0.99–1.00), 0.16	1.01 (1.00–1.01), 0.01	1.00 (0.99–1.01), 0.69
Any diabetes medication (oral or injected)	0.20 (0.16–0.25), <0.01	NA	NA	0.90 (0.65–1.26), 0.55
Any BP-lowering medication	NA	0.62 (0.53–0.73), <0.01	NA	0.74 (0.56–0.97), 0.03
Any lipid-lowering medication	NA	NA	2.95 (2.60–3.35), <0.01	1.70 (1.29–2.25), <0.01
Current smoker	0.79 (0.67–0.93), 0.01	1.18 (0.98–1.41), 0.08	0.99 (0.83–1.18), 0.89	1.01 (0.73–1.39), 0.96
Glucose monitoring (blood or urine)	0.62 (0.55–0.70), <0.01	1.09 (0.94–1.25), 0.25	1.15 (1.01–1.31), 0.03	0.84 (0.66–1.07), 0.16
Male	1.07 (0.96–1.19), 0.23	0.86 (0.76–0.97), 0.02	1.33 (1.19–1.50), <0.01	1.00 (0.81–1.25), 0.98
One or more microvascular complications	0.72 (0.63–0.82), <0.01	0.87 (0.74–1.01), 0.07	1.02 (0.88–1.18), 0.78	0.93 (0.70–1.22), 0.58
One or more macrovascular complications	0.98 (0.86–1.12), 0.80	1.50 (1.30–1.74), <0.01	1.15 (1.00–1.32), 0.05	1.31 (1.02–1.69), 0.03
Recruitment from primary care	1.26 (0.97–1.64), 0.08	0.80 (0.60–1.08), 0.14	0.78 (0.59–1.03), 0.08	0.95 (0.61–1.46), 0.81
BMI	0.98 (0.96–0.99), <0.01	0.98 (0.96–0.99), <0.01	1.01 (1.00–1.02), 0.08	0.96 (0.94–0.99), <0.01
Years diagnosed with diabetes	0.95 (0.94–0.96), <0.01	1.00 (0.99–1.01), 0.46	1.01 (1.00–1.02), 0.02	0.98 (0.95–1.00), 0.02

Data presented as OR (95% confidence limits), P value for total sample for associations between adherence to quality of care markers and potential predictors. Microvascular complications include abnormal foot sensation, blindness or retinopathy present, and end-stage renal disease. Macrovascular complications include ischemic heart disease, stroke, peripheral arterial disease (including nonpalpable dorsal or tibial pulses), and amputation. All participants from the Netherlands and Sweden were recruited from primary care. BP, blood pressure.

shorter diagnosis, had lower BMI, had one or more cardiovascular complications, were using lipid-lowering medication, and were not currently prescribed antihypertensive medication.

In common with earlier evidence (6–11), our findings suggest that process adherence may have a limited influence in terms of improved intermediate outcomes related to risk factor control or to enhanced management, for example, appropriate adjustments to medication. Outcomes also may be influenced by structural factors associated with the organization of care, although our findings suggested that in our sample there was a lack of influence related to management in primary or specialist care. Additional factors that may have an impact but that we were unable to investigate from the data available include clinical inertia (inadequate intensification of therapy) and levels of patient–health care provider concordance, including medication adherence. The extent and impact of poor adherence are particularly difficult to measure accurately.

Findings from the GUIDANCE study also support previous reports of between-country variations in terms of the quality of care of people with type 2 diabetes in Europe (23–26), some of which may be linked to organizational differences. However, results suggest that in the past decade there have been some improvements regarding intermediate outcomes. The Cost of Diabetes in Europe–Type II (CODE-2) study (24) used 6-month data from 1998 to 1999 from eight European countries (matching those in our study with the exception of Spain in place of Ireland). In the total CODE-2 sample, the mean values for HbA_{1c} and blood pressure were 7.5% and 146/82 mmHg, respectively, compared with mean values of 7.1% and 136/78 mmHg in the GUIDANCE study.

Some of the findings from our exploration of factors that may influence intermediate outcomes may, at first glance, appear inconsistent or unexpected. Although these apparent anomalies could be the result of additional confounders not included in the regression modeling, there are also some potential explanations. People using diabetes medication and antihypertensive drugs, for example, were less likely to meet targets for HbA_{1c} and blood pressure respectively; this observation may suggest that the correct people are being treated with medication, but that these treatments are not always effective. However, our finding of a positive association between treatment with lipid-lowering medication and within-target LDL cholesterol (and also with meeting all three targets) suggests that lipids are more easily managed by pharmaceutical intervention. The association between higher BMI and a lower likelihood of meeting targets for HbA_{1c} and blood pressure, but no association with the target for LDL cholesterol, may be the result of more active lipid management in people who are overweight or obese. Similarly, it may be considered surprising that having one or more macrovascular complications emerged as a positive predictor of meeting the combined target, but this finding could be linked to more frequent appointments and more aggressive risk factor management in people in this category. Overall, when considering positive and negative predictors of achieving intermediate outcomes that emerged in our study, it should be noted that inferences based on cross-sectional data should be treated with caution. Furthermore, in a large sample even small differences (as reflected in the ORs) may be statistically significant. Therefore, the difference between statistically and clinically significant differences needs to be borne in mind.

The GUIDANCE study has contributed to filling a gap in the literature

relating to the current quality of care of people with type 2 diabetes across Europe. Previous studies have limitations linked to quality and relevance. Some European studies with the advantage of large sample sizes have used aggregated or survey data rather than information collected at individual patient level (22,23), and in one of these studies only two of the seven contributing countries (England and Scotland) were from Europe (22). Findings from a sample of >7,000 cases based on data from the late 1990s (24) are useful but cannot be assumed to reflect recent quality of care and a more recent study using data from 2006 to 2007 was focused mainly on hypoglycemia (25). A study involving 12 European countries provided limited data from a small pilot-level sample (26).

The study has the advantages of a large sample size and data collection from a range of countries. Data for a high number of variables were collected using both self-report and medical records review, resulting in a rich overall dataset. However, it is acknowledged that the data available for analysis were not exhaustive, for example, in terms of complications of diabetes and also in relation to structural factors, which are likely to vary between countries (Supplementary Table 3). Although the comparability of the samples from participating countries may be limited by some flexibility relating to recruitment procedures, the study design included the use of a standardized protocol with shared inclusion and exclusion criteria. To facilitate direct comparisons and overall findings for the combined sample, we used the same recommendations (mainly derived from the American Diabetes Association) for assessing quality of care in participating countries, although it is acknowledged that there are some variations within the national guidelines for these countries (5). Assessment of adherence to national guidelines is outside the scope of this article but will be considered separately.

A potentially important limitation of our study data is that people who agreed to participate in the study are unlikely to be fully representative of all those with type 2 diabetes in participating countries. It is acknowledged that levels of adherence to targets are likely to be overestimated in our findings because of the absence of data for persistently nonattending patients and possibly those with high levels of complications, who may be less able or willing to consent to take part in research. Participating in this nonintervention study, however, involved a low level of commitment and, although formal data regarding uptake were not collected, information provided by the study teams in each country indicated good overall levels of agreement to participate. It is also likely that physicians with a particular interest in diabetes would have been more likely to agree to participate in this study and that the patients included in our dataset therefore were benefiting from enhanced management. These limitations are frequently applicable to datasets collected from prospectively recruited patients, but the use of routine data sources also may present problems relating to availability, accuracy, and completeness (36).

The need for realistic targets that are appropriate for individual patients with diabetes is not a new concept (37), but the limitations of using rigid targets for outcomes such as HbA_{1c} have been strongly re-emphasized in a recent joint position statement from the American Diabetes Association and the European Association for the Study of Diabetes (12,38). This statement regarding the management of hyperglycemia highlights the importance of patient-centered management, including tailored treatment and individualized targets. National guidelines, such as those produced by the National Institute for Health and Clinical Excellence in the United Kingdom (39), also have recommended involving patients in setting individual HbA_{1c} targets. The American Diabetes Association/European Association for the Study of Diabetes position statement questions the use of proportions meeting targets to indicate quality of care. Although we agree that, clinically, accurate assessment should take account of the medical and personal characteristics of individual patients, we argue that the use of target adherence measurement nevertheless may be useful for providing a broad overview of care, including between-country comparisons, in research involving large samples.

In conclusion, despite some acknowledged limitations, findings from the GUIDANCE study provide some broad messages for those involved in the management of people with type 2 diabetes in Europe and more widely, including reiteration of the importance of identifying ways of ensuring that improvements in processes of care lead to better outcomes for patients. Our detailed findings have highlighted shared and specific areas where improvements are particularly needed within participating countries. Our exploration of associations between potential predictors and key intermediate outcomes has confirmed that pharmaceutical management of glucose levels and blood pressure may be challenging. Ways of overcoming these challenges require further investigation. Overall, whereas we have suggested some encouraging changes for the better when comparing our findings with those from the earlier CODE-2 study (24), our study also suggests that there is considerable scope for further improvement and greater consistency in the quality of care of people with type 2 diabetes in Europe.

Acknowledgments—The GUIDANCE study was funded by the European Association for the Study of Diabetes from a grant from Merck & Co. (Whitehouse Station, NJ). Merck scientists participated in the initial conceptualization and protocol development but were not involved in the conduct of the study or in the analysis and interpretation of the data collected. No other potential conflicts of interest relevant to this article were reported.

M.A.S. was involved in the conduct of the study in the United Kingdom, contributed to interpretation of findings, and wrote the paper. G.C. contributed to the conception and design of the study, was involved in the conduct of the study in France, and critically reviewed the manuscript, including interpretation of findings. K.D. was involved in the conduct of the study in Belgium and critically reviewed the manuscript, including interpretation of findings. O.K. designed and was responsible for the statistical analysis and critically reviewed the manuscript, including interpretation of findings. U.L. contributed to the conception and design of the study, was involved in the conduct of the study in Sweden, and critically reviewed the manuscript, including interpretation of findings. C.K. was involved in the conduct of the study in Germany and critically reviewed the manuscript, including interpretation of findings. J.N. contributed to the conception and design of the study, was involved in the conduct of the study in Ireland, and critically reviewed the manuscript, including interpretation of findings. A.P. was involved in the conduct of the study in Ireland and critically reviewed the manuscript, including interpretation of findings. G.R. contributed to the conception and design of the study, was involved in the conduct of the study in the Netherlands, and critically reviewed the manuscript, including interpretation of findings. M.T. contributed to the conception and design of the study, was involved in the conduct of the study in Italy, and critically reviewed the manuscript, including interpretation of findings. K.K. contributed to

the conception and design of the study, was involved in the conduct of the study in the United Kingdom, and was involved in the writing of the manuscript, including interpretation of findings. O.K. and K.K. are joint guarantors on behalf of the GUIDANCE Study Group. O.K. had full access to the data and takes responsibility for the integrity and the accuracy of the analysis. K.K. takes responsibility for the integrity of the presentation of the findings.

Some preliminary data were presented at the European Association for the Study of Diabetes conference, Lisbon, Portugal, 12–18 September 2011.

The authors thank all the participating primary and specialist care sites and the individuals and organizations (including the funders of those organizations) who contributed to facilitating or conducting recruitment and data collection in each country. The authors specifically mention the following people who contributed to the conduct of the study: Navneet Aujla, University of Leicester, Leicester, United Kingdom; Odile Juy, Centre of Study and Research for Intensification of Diabetes Treatment, Corbeil, France; Lisa Killarney, St. James's Hospital, Dublin, Ireland; Héloïse Laroye, Centre of Study and Research for Intensification of Diabetes Treatment, Corbeil, France; and Jeremy Towns, Health Research Board Centre for Clinical Research, Dublin, Ireland. The authors thank the following people for contributing to the study design: Nathalie Clochard, Scientific Institute of Public Health, Brussels, Belgium; Noëmi Debacker, Scientific Institute of Public Health, Brussels, Belgium; Giorgio Grassi, University of Turin, Turin, Italy; and Lena Minning, University of Halle-Wittenberg, Halle, Germany. These people helped with the collation, cleaning, and analysis of the data. Preparation of the paper was conducted by the authors without editorial assistance. In addition to those cited in the main list of authors at the start of this article, the following members of the GUIDANCE Study Group contributed to the design of the study and have critically reviewed the manuscript, including interpretation of findings, and therefore should be regarded as additional authors: Kees Gorter, MD, PhD, University Medical Centre, Utrecht, the Netherlands; Arne Melander, MD, PhD, Lund University, Lund, Sweden; Ulrich A. Müller, MD, MSc, University Hospital, Jena, Germany; and Massimo Porta, MD, PhD, University of Turin, Turin, Italy.

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