

# Role of Organizational Factors in Poor Blood Pressure Control in Patients With Type 2 Diabetes

*The QuED Study Group—Quality of Care and Outcomes in Type 2 Diabetes*

Fabio Pellegrini, MS; Maurizio Belfiglio, MD; Giorgia De Berardis, MScPharmChem; Monica Franciosi, MScBiolS; Barbara Di Nardo, HSDip; Sheldon Greenfield, MD; Sherrie H. Kaplan, PhD, MPH; Michele Sacco, MD; Gianni Tognoni, MD; Miriam Valentini, MD; Donatella Corrado, BioTech; Antonio D'Etterre, MScEngen; Antonio Nicolucci, MD; for the QuED Study Group

**Background:** A large body of evidence supports the need for reducing the cardiovascular burden of diabetes. Only indirect and occasional data describe the adequacy of routine management of hypertension in patients with diabetes. The aim of this study was to explore the interplay of some potential key determinants of quality of antihypertensive care, including the settings, physicians' beliefs about blood pressure (BP) control, and patient-related factors.

**Methods:** We evaluated physicians' beliefs about BP control using questionnaire responses at study entry. A sample of 3449 patients with type 2 diabetes mellitus, of whom 1782 (52%) were considered to have hypertension, was recruited by 212 physicians practicing in 125 diabetes outpatient clinics (DOCs) and 106 general practitioners (GPs). We evaluated the type and number of antihypertensive agents used and the BP values at study entry and after 1 year of follow-up. We used multilevel analysis to investigate correlates of poor BP control ( $\geq 160/90$  mm Hg).

**Results:** Only 16% of GPs and 14% of DOC physicians targeted BP values of less than 130/85 mm Hg. At study entry, 6% of the patients had values below 130/85 mm Hg, whereas 52% showed values of 160/90 mm Hg or greater. Only 12% of subjects were treated with more than 2 drugs at study entry, compared with 16% at the 1-year follow-up ( $P = .001$ ). Multilevel analysis showed that patients attending DOCs had a more than 2-fold increased risk for inadequate BP control, compared with those treated by GPs. The risk for poor BP control was 2 times higher for patients treated by male physicians compared with those treated by female physicians, and it was halved when the physician responsible for the diabetes care specialized in diabetology or endocrinology.

**Conclusion:** In a model situation of comorbidity, the overall quality of care depends on structural and organizational factors, which are likely to be more influential than existing guidelines.

*Arch Intern Med.* 2003;163:473-480

From the Department of Clinical Pharmacology and Epidemiology, Istituto di Ricerche Farmacologiche Mario Negri, Consorzio Mario Negri Sud, S Maria Imbaro, Italy (Mssrs Pellegrini and D'Etterre, Drs Belfiglio, Sacco, Tognoni, Valentini, and Nicolucci, and Mss De Berardis, Franciosi, Di Nardo, and Corrado); and the Primary Care Outcomes Research Institute, Tufts University School of Medicine, Boston, Mass (Drs Greenfield and Kaplan). A complete list of investigators of the QuED Study Group appears on page 479.

**D**URING THE PAST several years, compelling evidence from recent clinical trials<sup>1,2</sup> has increasingly underlined the fact that 2 important variables in medicine and health care, cardiovascular risk and diabetes mellitus, cannot be separated in strategies aimed at reducing the cardiovascular burden of disease. Only indirect and occasional data describe whether patients and populations with both clinical conditions undergo adequate treatment during routine health care. In particular, appropriate care for patients with type 2 diabetes requires a multidisciplinary and patient-tailored approach, which is not readily available. Despite the proliferation of several guidelines,<sup>3-5</sup> independent reports document that even the best known and most traditional risk condition, essential hypertension, is inadequately managed.<sup>6-8</sup>

The QuED Project is a nationwide initiative aimed at assessing the relationship between the quality of health care delivered to patients with type 2 diabetes and their outcomes.<sup>9-11</sup> The context of this project provided the opportunity to address the issue of the quality of health care of diabetic patients with hypertension. In particular, we explored the interplay of some of the potential key determinants of quality of care, including the contexts and providers of care (general practitioners [GPs] and physicians in diabetes outpatient clinics [DOCs]), the subjective beliefs of physicians about blood pressure (BP) control, and patient-related factors.

## METHODS

The study design has already been described in detail elsewhere.<sup>10,11</sup>

Briefly, physicians were identified in all regions of Italy and selected according to their

willingness to participate in the project. Overall, 212 diabetologists practicing in 125 DOCs and 106 GPs participated in the study.

All patients with type 2 diabetes mellitus were considered eligible for the project, irrespective of age, diabetes duration, or treatment. In the DOCs, patients were sampled by means of random lists, stratified by patient age (<65 or ≥65 years). Each center was asked to recruit at least 30 patients, whereas GPs enrolled only those patients for whom they were primarily responsible for diabetes care.

General medical history and diabetes-specific data were collected at 6-month intervals by the patients' physicians using forms specifically developed for the project by the scientific committee.

Patients were asked to fill in a questionnaire investigating different aspects of diabetes management and health care resource utilization. For this analysis, we asked the number of times each patient had seen the physician responsible for their diabetes care in the past 6 months. This information was available for 1330 patients (response rate, 75%).

Patients were defined as having hypertension according to the physicians' judgment. Patterns of care at study entry (March 1 through October 31, 1998) were compared with those at the 1-year follow-up. The analyses focused on antihypertensive treatment (ie, the type and number of drugs) and the outcome in terms of BP control.

## QUESTIONNAIRE

The physicians' survey was conducted in 1999 by means of a questionnaire that included the following questions: "For the average type 2 diabetic patient, which are the threshold values for the initiation of antihypertensive treatment?" and "For the average type 2 diabetic patient with hypertension, what do you use as target diastolic and systolic BP levels?" We did not define the average patient, because the physicians' opinions are influenced by the real patients they see in their practice and can therefore vary according to patient case-mix.

We also collected information on the sociodemographic characteristics of the physicians (age, sex, and specialty). The questionnaire was sent by mail to all the physicians participating in the project. Two additional recall mailings were sent to initial nonrespondents.

## SETTING

All Italian citizens are covered by government health insurance and are registered with a GP. An average of 1000 patients (range, 500-1500) are registered with each GP, of whom 15 to 45 are expected to have diabetes. Primary care for diabetes mellitus is provided by GPs and DOCs. The DOCs are usually staffed by diabetologists, internists, and/or endocrinologists; other specialists (eg, ophthalmologists, cardiologists) may also practice part-time in the structure. In some DOCs, patients are always treated by the same physician, whereas in other centers, patients can be seen by different physicians on different occasions. Patients can choose one of the 2 ways of access to the health care system according to their preferences or can be referred to DOCs by their GP.

## STATISTICAL ANALYSIS

The results are expressed as absolute differences (unless otherwise indicated, given as mean±SD) and percentages of difference between the 1-year follow-up and study entry. We compared the findings by the  $\chi^2$  test (for categorical variables) or the paired *t* test (for continuous measurements).

To account for the multilevel nature of the data (patients clustered within physician or practice) and to control simultaneously for the possible confounding effects of the different variables, we used multilevel logistic regression models (ie, random intercept models)<sup>12,13</sup> to investigate correlates of BP values of 160/90 mm Hg or greater. These models allow us to take into account the separated contribution to the total variance given by patient- and physician-related characteristics, thus minimizing the risk for false-positive results. We used the deviance test with a  $\chi^2$  distribution to assess whether the proportion of variance at the physicians' level significantly differed from 0, ie, whether the multilevel structure of the data needed to be taken into account. The setting of care and physician characteristics were considered level 2 variables, whereas level 1 variables consisted of all patient characteristics. In particular, we considered the following patient characteristics (for categorical variables, the first class represents the reference category): age (tested as a continuous variable), sex (male vs female), duration of diabetes (≤10, 11-20, or >20 years), duration of hypertension (<5, 5-9, or ≥10 years), number of diabetes complications (none, 1, 2, 3, or more), body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters) (men, <25, 25-27, or >27; women, <24, 24-26, or >26), diabetes treatment (diet only, oral agents, or insulin with or without oral agents), cardiac-cerebrovascular disease (yes vs no), number of antihypertensive drugs (1, 2, 3, or more), and number of visits in the previous 6 months (>3 vs ≤3).

Level 2 variables tested included physician age and sex, physician specialty (diabetologist, endocrinologist, or other or no further training), health care setting (DOC vs general practice), and diabetes care modalities (single vs multiple physicians).

To investigate the role of physicians' beliefs, we ran a separate multilevel model including only patients treated by those physicians who filled in the questionnaire. Declared target values of systolic and diastolic BP were included in this model as level 2 covariates and tested as continuous variables.

The values for all the covariates refer to the information collected at baseline.

## RESULTS

### PHYSICIAN BELIEFS

Of the 318 physicians, 182 (57%) returned the questionnaire investigating their beliefs about BP control. The response rate was 61% (65 physicians) for GPs and 55% (117 physicians) for DOC physicians. Sixty-seven percent of the respondents were male; the median age was 45 years (range, 28-70 years). In the DOCs, 29% of the physicians were diabetologists; 23%, internists; 31%, endocrinologists; and 8%, other specialists. The remaining 9% had no specialty. Among GPs, 8% had some further training in diabetology; 11%, in internal medicine; 6%, in endocrinology; 45%, in other specialties; and 30%, no further training. Sex, age, and specialty of responders did not differ from those of nonresponders.

Only a few physicians (4%) started pharmacologic therapy for BP values of 130/85 mm Hg or greater, as suggested by the most recent guidelines (the World Health Organization<sup>3</sup> and the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure<sup>4</sup>), whereas most considered 140/90 mm Hg as the threshold for the initiation of treatment. Overall, 14% of the respondents targeted BP in line with current recommendations (ie, <130/85 mm Hg); 52% tar-

geted diastolic BP values of less than 85 mm Hg and systolic values ranging from 130 to 150 mm Hg; and 33% targeted a BP of 150/85 mm Hg or greater. In particular, the proportion of physicians who pursued strict BP control (ie, BP values <130/85 mm Hg) was 16% among GPs and 14% among DOC physicians ( $\chi^2_2=4.55$ ;  $P=.10$ ). No statistically significant differences in beliefs emerged by physician characteristics (age, sex, specialty, and setting of care).

### PATTERNS OF CARE

Of 3449 patients enrolled, 1782 (52%) were considered to have hypertension, of whom 1103 (62%) had the information from the 1-year follow-up. The characteristics of hypertensive patients at study entry are reported in **Table 1**.

Mean systolic BP values were  $150.0 \pm 18.4$  mm Hg at baseline and  $149.5 \pm 18.5$  mm Hg at 12 months ( $P=.30$ ), whereas mean diastolic values were  $84.3 \pm 9.0$  mm Hg at baseline and  $83.7 \pm 8.8$  mm Hg at 12 months ( $P=.05$ ).

At study entry, only 6% of the patients had BP values of less than 130/85 mm Hg; 42%, of less than 160/90 mm Hg; and 52%, of 160/90 mm Hg or greater. The percentage of patients with BP values of 160/90 mm Hg or greater was higher among those attending DOCs compared with those treated by GPs (54% vs 45%;  $P=.02$ ). At the 1-year follow-up, the proportion of patients with values of less than 130/85 mm Hg increased to 7%; those with values of less than 160/90 reached 45%; and those with higher values decreased to 48%. Changes in BP values did not differ according to the setting of care.

Among patients with mean BP values of less than 130/85 mm Hg at baseline, mean systolic and diastolic values were significantly higher after 1 year (from  $119 \pm 5/76 \pm 5$  to  $136 \pm 20/82 \pm 9$  mm Hg;  $P<.001$  for systolic and diastolic BP). To a lesser extent, mean values also increased in those patients with mean BP values in the range of 130/85 to 160/90 mm Hg at baseline (from  $141 \pm 8/79 \pm 5$  to  $146 \pm 16/82 \pm 8$  mm Hg;  $P<.001$  for systolic and diastolic BP). On the other hand, systolic and diastolic values were significantly lower after 1 year in those patients with mean BP values of 160/90 mm Hg or greater at baseline (from  $161 \pm 17/90 \pm 8$  to  $154 \pm 19/86 \pm 9$  mm Hg;  $P<.001$  for systolic and diastolic BP).

As for the number of antihypertensive agents used, 50% of patients were treated with 1 drug at study entry, and that proportion decreased to 45% at 1 year ( $P=.001$ ). However, 12% of subjects were treated with more than 2 drugs at study entry, and at 1-year follow-up the percentage increased to 16% ( $P=.001$ ), with a relative increase of 30%.

In those patients treated with fewer than 3 drugs at baseline and with 3 or more drugs after 1 year ( $n=71$ ), mean diastolic BP significantly decreased from  $87 \pm 11$  mm Hg to  $83 \pm 11$  mm Hg ( $P=.001$ ), whereas mean systolic BP was only marginally reduced (from  $156 \pm 22$  mm Hg at baseline to  $154 \pm 24$  mm Hg after 12 months;  $P=.40$ ).

In addition, the proportion of hypertensive patients not treated was 7% at study entry and 1-year follow-up, whereas those treated with 2 drugs were 31% and 33%, respectively. Among patients left untreated, only 7% had

**Table 1. Patient Characteristics\***

Characteristics	Data
Sex	
Male	846 (47)
Female	936 (53)
Age, mean $\pm$ SD, y	62.7 $\pm$ 10.7
Diabetes duration, mean $\pm$ SD, y	11.0 $\pm$ 8.5
Male BMI	
<25	179 (22)
25-27	164 (20)
>27	487 (59)
Female BMI	
<24	125 (14)
24-26	125 (14)
>26	656 (72)
Diabetes treatment	
Diet only	264 (15)
Oral agents	1148 (64)
Insulin	191 (11)
Insulin + oral agents	172 (10)
HbA <sub>1c</sub> , mean $\pm$ SD, %	7.5 $\pm$ 1.7
Duration of hypertension, mean $\pm$ SD, y	9.1 $\pm$ 7.5
Major diabetic complications	
Retinopathy	381 (21)
End-stage renal disease	16 (1)
Foot complications	57 (3)
Neuropathy	177 (10)
Cardiac-cerebrovascular events	
Myocardial infarction	157 (9)
Coronary heart disease	199 (11)
Stroke	77 (4)
TIA	29 (2)
Comorbid conditions	
0	633 (36)
1	634 (36)
2	319 (18)
>2	196 (11)

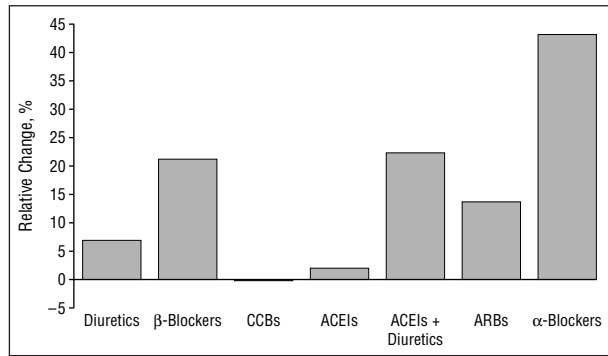
Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); HbA<sub>1c</sub>, glycosylated hemoglobin; TIA, transient ischemic attack.

\*Unless otherwise indicated, data are given as number (percentage) of patients. Percentages have been rounded and may not total 100.

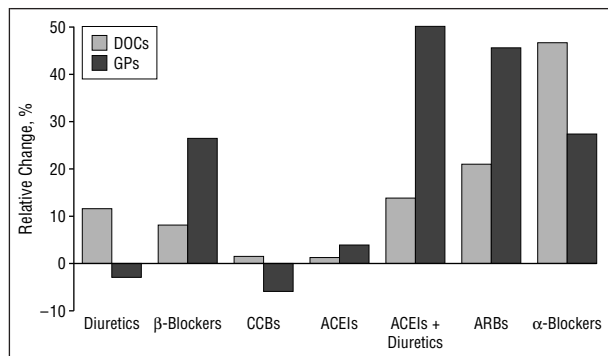
blood pressure levels of less than 130/85 mm Hg, whereas 54% had values of 160/90 mm Hg or greater.

When looking at the antihypertensive drugs used, only small absolute changes were found between baseline and 1-year follow-up. The percentages of patients treated with the different drug classes at baseline and at 1 year were 19% vs 20% for diuretics, 10% vs 13% for  $\beta$ -blockers, 39% vs 39% for calcium channel blockers, 46% vs 47% for angiotensin-converting enzyme inhibitors (ACEIs), 9% vs 10% for a combination of ACEIs and diuretics in fixed doses, 4% vs 5% for angiotensin receptor blockers, and 4% vs 5% for  $\alpha$ -blockers. Relative changes in the use of the different drugs in the whole population are shown in **Figure 1**, which demonstrates that the increase in their use is particularly evident for  $\alpha$ -blockers,  $\beta$ -blockers, and combined ACEIs and diuretics in fixed doses. The analysis according to the setting of care shows different patterns among the patients treated by GPs and those who attended DOCs (**Figure 2**).

Among patients treated with only 1 drug at baseline, the most frequently used drugs were ACEIs (51%),



**Figure 1.** Relative changes in the use of different antihypertensive drugs during the 12-month study. ACEI indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; and CCB, calcium channel blocker.



**Figure 2.** Relative changes in the use of different antihypertensive drugs according to the health care setting. DOC indicates diabetes outpatient clinic; GP, general practitioner. Other abbreviations are explained in the legend to Figure 1.

followed by calcium channel blockers (28%) and diuretics (8%). Even among elderly patients (age >65 years) with isolated systolic hypertension (systolic BP  $\geq$ 140 mm Hg and diastolic BP <90 mm Hg) who were treated with 1 drug, only 9% (13 of 146) received a diuretic (28% were treated with a calcium channel blocker and 51% with an ACEI). In those patients taking 2 antihypertensive drugs, the associations more frequently found were 32% for ACEIs and calcium channel blockers, 31% for ACEIs and diuretics, and 9% for calcium channel blockers and diuretics. In patients treated with more than 2 drugs, the most frequent combination was ACEIs, calcium channel blockers, and diuretics (48.4%).

### CORRELATES OF BP LEVELS

Of 1782 hypertensive patients, 1748 (98%) were included in a series of multilevel analyses; 34 patients were excluded due to missing values in 1 or more of the covariates investigated. In all of the models tested, a significant amount of the total variation was due to the physician specialty level (**Table 2**).

In model 1, only clinical variables were included. Of all patient-related characteristics, only BMI was associated with a significant increase in the risk for having BP values of 160/90 mm Hg or greater, whereas patients with cardiac-cerebrovascular disease showed a lower risk for inadequate BP control (Table 2).

The frequency of encounters with the physician responsible for diabetes care was then included (model 2). Those patients seen more than 3 times in the previous 6 months showed a substantial reduction in the risk for high BP values compared with those seen less frequently (odds ratio [OR], 0.46; 95% confidence interval [CI], 0.32-0.66) (Table 2). We also tested whether always seeing the same physician within the DOCs affected the risk for having inadequate BP values, but this variable was not independently associated with the outcome of interest.

In model 3, restricted to those patients always seen by the same physician, all level 2 variables were tested with clinical variables. This analysis showed that patients attending the DOCs had a more than 2-fold increased risk for inadequate BP control, compared with those treated by GPs (Table 2). Irrespective of the health care setting, the risk for poor BP control was 2 times higher for patients treated by male physicians compared with female physicians. The risk was halved when the physician responsible for the diabetes care had a specialty in diabetology or endocrinology, compared with those with other specialties or no further training.

In model 4, the number of visits in the past 6 months was added. Despite the lower statistical power related to the decrease in sample size, the role of level 2 variables was confirmed, as was the lower risk conferred by more frequent encounters with the physician responsible for diabetes care (Table 2). In models 3 and 4, physician attitudes were not independently related to BP control.

Finally, we tested the joint effect of physician and patient sex on BP control. This analysis showed that, after adjusting for all patient-, setting-, and physician-related characteristics, female patients treated by male physicians had an almost 3-fold risk for having BP values of 160/90 mm Hg or greater compared with those treated by female physicians (OR, 2.86; 95% CI, 1.61-5.10). Similarly, male patients cared for by male physicians were at higher risk for inadequate BP control compared with those treated by female physicians (OR, 1.71; 95% CI, 0.95-3.09).

### COMMENT

Previous studies have shown that hypertension is poorly controlled in the general population.<sup>6,7</sup> Our data show that BP control is unsatisfactory in a large proportion of patients with type 2 diabetes mellitus, despite the presence of a much higher cardiovascular risk. Half of these patients showed BP readings of 160/90 mm Hg or greater, and only a few (6%) were on target (BP <130/85 mm Hg). These results are particularly important in the light of recent guidelines<sup>14,15</sup> setting more stringent targets for patients with diabetes and document the gap between the desired and actual outcomes.

Furthermore, although the United Kingdom Prospective Diabetes Study has shown that one third of the patients needed more than 2 antihypertensive agents to control BP adequately,<sup>1</sup> only 12% in our sample were treated with 3 or more drugs at study entry. Our 1-year follow-up data, collected after the results of the United Kingdom Prospective Diabetes Study were largely publicized, signal only minor changes in patterns of care, as

**Table 2. Results of Multilevel Logistic Regression Analyses Modeling the Risk for Having BP Values of 160/90 mm Hg or Greater\***

Fixed Effects	OR (95% CI)			
	Model 1 (n = 1748)†	Model 2 (n = 1330)‡	Model 3 (n = 1060)§	Model 4 (n = 823)
Level 1 variables				
Cardiac-cerebrovascular disease (yes vs no)	0.66 (0.50-0.87)	0.57 (0.41-0.78)	0.75 (0.52-1.07)	0.68 (0.45-1.02)
BMI, male/female				
<25/<24	1.00	1.00	1.00	1.00
25-27/24-26	1.59 (1.09-2.31)	1.81 (1.18-2.80)	1.33 (0.81-2.17)	1.36 (0.78-2.38)
>27/>26	2.00 (1.47-2.71)	2.07 (1.46-2.94)	1.77 (1.18-2.65)	1.57 (0.99-2.50)
No. of visits in the past 6 mo (>3 vs ≤3)	...	0.46 (0.32-0.66)	...	0.58 (0.37-0.90)
Level 2 variables				
Setting (DOCs vs GPs)	...	...	2.35 (1.36-4.05)	1.92 (1.10-3.35)
Physician sex (M vs F)	...	...	2.00 (1.25-3.22)	2.24 (1.39-3.61)
Physician specialty				
Diabetology	...	...	0.54 (0.29-1.01)	0.59 (0.32-1.10)
Endocrinology	...	...	0.63 (0.32-1.22)	0.58 (0.30-1.14)
Other/none	...	...	1.00	1.00

Abbreviations: BP, blood pressure; CI, confidence interval; DOC, diabetes outpatient clinic; GP, general practitioner; OR, odds ratio.

\*Level 1 variables are patient related; level 2 variables, physician related. Models are described in the "Correlates of BP Levels" subsection of the "Results" section.

†For the deviance test for random intercept,  $\chi^2 = 105.27$  ( $P < .001$ ).

‡For the deviance test for random intercept,  $\chi^2 = 60.13$  ( $P < .001$ ).

§For the deviance test for random intercept,  $\chi^2 = 48.18$  ( $P < .001$ ).

||For the deviance test for random intercept,  $\chi^2 = 21.78$  ( $P < .001$ ).

the slight improvement in mean diastolic BP and the increase in the number of patients treated with more than 1 drug suggest. The improvement in BP control seems to be confined only to those patients with very high BP levels at baseline, suggesting that greater attention was paid only to patients at higher risk.

No major differences in the kind of antihypertensive agents used were found, with small absolute increases in the proportion of patients treated with  $\beta$ -blockers, a combination of ACEIs and diuretics in fixed doses, angiotensin receptor blockers (mainly among GPs), and  $\alpha$ -blockers (particularly in DOCs). In both settings, we observed a marked relative increase in the use of new drugs such as angiotensin receptor blockers and last-generation  $\alpha$ -blockers, probably owing to a mix of expectations of greater benefits and aggressive marketing activities. About one third of the patients treated with only 1 antihypertensive drug were taking a calcium channel blocker, despite the ongoing debate about the safety of some calcium channel blockers, particularly (but not only) short-acting dihydropyridines such as nifedipine.<sup>16</sup>

Despite the changes documented, BP control remains unsatisfactory in most patients with type 2 diabetes, as documented in other studies.<sup>17-19</sup>

The analysis of correlates of poor BP control offer important information regarding the influence of setting of care and patient-related factors. Among the former, although we documented a poor adherence to hypertension treatment guidelines and the adoption of higher thresholds, physician beliefs were not independently related to BP control. On the other hand, factors other than scientific evidence can play a crucial role in determining the outcomes of care. First, the frequency of encounters with the physician responsible for diabetes care strongly influenced the risk for poor BP control. In particular, in those patients seen at least 3 times in the past

6 months, the risk for having BP values of 160/90 mm Hg or greater was 50% lower compared with those seen less frequently. These results raise particular problems for the patients treated by DOCs, since they are generally seen every 4 to 6 months, in the absence of acute problems. Even after adjusting for the frequency of visits, patients attending DOCs still showed an increased risk for poor BP control compared with those treated by GPs. Several reasons can be responsible for these findings. Conditions of patients treated by DOCs could be more complicated and thus referred to the specialized center by their GPs. Nevertheless, we included in our models a large array of possible confounders, such as duration of diabetes and hypertension, diabetes complications, and comorbidities. The setting of care still represented an independent correlate of BP control. Another possible explanation for our findings is that physicians practicing in DOCs are more focused on metabolic control and implicitly assume that GPs should be responsible for all other aspects of care. In this respect, the lack of integration of the activities between primary care physicians and specialists and the scarcity of initiatives to promote shared care can represent a real threat for patients with type 2 diabetes.

Among physician characteristics, specialty and sex were independently associated with BP control. Irrespective of the health care setting, patients treated by physicians with further training in diabetes or endocrinology showed a 40% to 50% lower probability of having BP readings of 160/90 mm Hg or greater compared with those treated by physicians with other specialties or with no further training. The apparent contradiction between the finding of an increased risk for poor BP control for patients attending DOCs and the lower risk associated with treatment by physicians with a specialty in diabetes or endocrinology can be easily explained by the substan-

tial number of clinicians practicing in diabetes centers without further specific training.

An additional, important finding was the higher risk for poor BP control among patients treated by male physicians. Such a risk seems particularly impressive for female patients, which is almost 3 times higher for those treated by a male physician compared with those treated by a female physician.

In our study, female physicians were slightly younger than male ones (mean age,  $43 \pm 5$  vs  $47 \pm 6$  years), but did not differ as to setting of care, specialty, beliefs about BP control, or the type and number of antihypertensive agents used. Furthermore, male patients treated by female physicians were seen more often than those treated by male physicians (mean of 3.0 vs 2.3 visits in the past 6 months), whereas no major differences emerged for female patients (mean of 2.2 and 2.3 visits for those treated by female and male physicians, respectively). Our data did not allow us to ascertain whether male physicians tended to underestimate the role of cardiovascular risk factors in women or whether other factors related to practice styles could be involved. Previous studies have shown that female physicians are more likely to engage in preventive services,<sup>20</sup> communicate differently<sup>20</sup> and spend more time with their patients,<sup>21,22</sup> and have a stronger tendency to provide continuity of care.<sup>22</sup> In a recent study, female physicians were also shown to have more participatory visits with patients than did male physicians.<sup>23</sup> Nevertheless, differences in practice styles according to physician and patient sex have been mainly investigated in relation to patient satisfaction or the adoption of preventive strategies, whereas, to our knowledge, this is the first time that a sex bias relative to BP control has been documented. Further studies are thus needed to evaluate whether different practice styles can determine better compliance with medical recommendations relative to lifestyle and treatments.

Among patient-related characteristics, being overweight was strongly associated with the risk for BP values of 160/90 mm Hg or greater, as already documented in other studies.<sup>6,24</sup> On the other hand, patients with cardiac-cerebrovascular disease showed a substantial reduction in the risk for inadequate BP control, suggesting that greater attention is paid to those subjects at particularly high risk for macrovascular events.

Finally, some of the potential limitations of our study need to be discussed. First, physicians were selected according to their willingness to participate in the project. They could thus represent those clinicians, particularly among GPs, who were more interested in diabetes care and, therefore, not reflect the general attitudes of Italian physicians. Furthermore, the lack of association between physician beliefs and mean BP values may be related to physicians' tendency to declare more stringent targets than those actually pursued. From this point of view, we have no information to assess how reliably the survey reflected physicians' real behaviors.

For these reasons, the problems documented in our study could be underestimated, and the true compliance with existing guidelines could be even lower. The selection of the more motivated GPs could have also led to an overestimation of the difference in the outcome con-

sidered according to the setting of care (DOCs vs general practices). We tried to minimize this problem by recruiting a large sample of physicians practicing in different areas and settings, characterized by heterogeneous structural and organizational characteristics. Furthermore, the management of hypertension was not the primary focus of the project, thus making any selection bias according to the attitudes in treating hypertension unlikely.

The second point to be considered refers to the cross-sectional nature of our study, which correlated physician and setting characteristics with a single BP reading. However, the high number of structures involved, the large sample of patients undergoing evaluation, and the consistency of our findings even after adjusting for many potential confounders make the possibility of spurious associations very unlikely. Moreover, we found highly reproducible results when we also considered BP measurements at 6 and 12 months (data not shown).

## CONCLUSIONS

Our study shows that in a model situation of comorbidity, the contribution of different competencies and approaches to the overall quality of care depends more on structural and organizational factors than on existing guidelines.

We found several aspects of health care delivery to be associated with better BP control, some of which are more easily available in primary care, whereas others are peculiar to DOCs. General practitioners are in a better position to ensure the continuity of care and facilitate frequent encounters, essential features for adequate control of cardiovascular risk factors. However, patients treated by physicians with specific training in diabetes or endocrinology, more often available in DOCs, had a substantial reduction in the risk for poor BP control. These data strongly support the need for integrating the activities of the 2 settings of care with the definition of evidence-based, shared-care protocols. The lack of adoption of the existing guidelines and the existence of a clear sex bias also underscore the need for the promotion of educational activities at all the levels of care to increase the awareness of the importance of cardiovascular risk factors control in type 2 diabetes.

Accepted for publication June 14, 2002.

This study was supported by Pfizer Italiana SpA, Rome. Dr De Berardis is supported by a Sergio Cofferati fellowship, Milan, Italy.

Corresponding author and reprints: Antonio Nicolucci, MD, Department of Clinical Pharmacology and Epidemiology, Consorzio Mario Negri Sud, Via Nazionale, 66030 S Maria Imbaro (CH), Italy (e-mail: nicolucc@negrisud.it).

## REFERENCES

1. UK Prospective Diabetes Study Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. *BMJ*. 1998;317:703-713.
2. Adler AI, Stratton IM, Neil HA, et al. Association of systolic blood pressure with macrovascular and microvascular complications of type 2 diabetes (UKPDS 36): prospective observational study. *BMJ*. 2000;321:412-419.

## Writing Committee and Coordinating Center

Fabio Pellegrini, MS, Maurizio Bellfiglio, MD, Giorgia De Berardis, MScPharmChem, Monica Franciosi, MScBiolS, Barbara Di Nardo, HSDip, Sheldon Greenfield, MD, Sherrie H. Kaplan, PhD, MPH, Michele Sacco, MD, Gianni Tognoni, MD, Miriam Valentini, MD, Donatella Corrado, BioTech, Antonio D'Ettore, MScEngen, and Antonio Nicolucci, MD.

## Scientific Committee

Vittorio Caimi, MD, Fabio Capani, MD, Andrea Corsi, MD, Roberto Della Vedova, MD, Massimo Massi Benedetti, MD, Antonio Nicolucci, MD, Claudio Taboga, MD, Massimo Tombesi, MD, and Giacomo Vespasiani, MD.

## Investigators

*Diabetologists:* R. Rinaldi, MD, E. Papini, MD, A. Pagano, MD, and L. Petrucci, MD (*Albano Laziale [RM]*); P. Maresca, MD, and F. Malvicino, MD (*Alessandria*); A. Corsi, MD, E. Torre, MD, P. Ponzani, MD, and F. Menozzi, MD (*Arenzano [GE]*); S. Baracchi, MD, and M. Iorini, MD (*Asola [MN]*); L. Gentile, MD (*Asti*); P. Di Berardino, MD (*Atri [TE]*); P. Dell'Aversana, MD (*Aversa [CE]*); T. Savino, MD (*Bari*); G. Amore, MD (*Bassano Del Grappa [VI]*); F. Zerella, MD (*Benevento*); F. Travaglino, MD, and G. Morone, MD (*Biella*); N. Pinna, MD (*Borgosesia [VC]*); M. A. Poli, MD (*Bovolone [VR]*); A. M. Sanna, MD, L. Carboni, MD, F. Farci, MD, P. Contini, MD, and M. Brundu, MD (*Cagliari*); B. Nativo, MD, and C. Medico, MD (*Caltagirone [CT]*); F. Vancheri, MD, and A. Burgio, MD (*Caltanissetta*); M. De Fini, MD (*Carbonara [BA]*); L. Vincis, MD, and G. Renier, MD (*Carbonia [CA]*); G. Bargerò, MD, A. Caramellino, MD, G. Ghezzi, MD, and E. Venturi, MD (*Casale Monferrato [AL]*); J. Grosso, MD (*Castel di Sangro [AQ]*); G. De Simone, MD, S. Gentile, MD, and I. Gaeta, MD (*Castellammare di Stabia [NA]*); A. Cafaro, MD (*Castellana Grotte [TA]*); L. Panzolato, MD (*Castiglione delle Stiviere [MN]*); V. Trinelli, MD (*Ciriè [TO]*); C. Campanelli, MD, and R. Norgiolini, MD (*Città di Castello [PG]*); R. Pastorelli, MD, and S. Fiore, MD (*Colleferro [RM]*); S. Testero, MD (*Cologno Monzese [MI]*); A. Staiano, MD (*Corigliano Calabro [CS]*); C. Cazzalini, MD, F. Menozzi, MD, S. Inzoli, MD, and C. Valsecchi, MD (*Crema [CR]*); G. Borretta, MD, G. Magro, MD, F. Cesario, MD, A. Piovetan, MD, and M. Procopio, MD (*Cuneo*); G. De Giuli, MD (*Darfo Boario Terme [BS]*); G. Marelli, MD, and L. Bellato, MD (*Desio [MI]*); D. Richini, MD (*Esine [BS]*); A. Muscogiuri, MD, and F. Tanzarella, MD (*Francavilla Fontana [BR]*); E. Santilli, MD, and G. S. Versace, MD (*Frascati [RM]*); G. Morandi, MD, and C. Mazzi, MD (*Gallarate [VA]*); P. Melga, MD, V. Cheli, MD, A. De Pascale, MD (*Genova*); V. Majellarò, MD (*Giovinazzo [BA]*); E. D'Ugo, MD (*Gissi [CH]*); G. Pisano, MD, F. Vacca, MD, and A. Fois, MD (*Isili [NU]*); A. Morea, MD (*Isola della Scala [VR]*); L. De Giorgio, MD, and R. Lecis, MD (*La Spezia*); M. Pupillo, MD (*Lanciano [CH]*); M. Tagliaferri, MD, and C. Vitale, MD (*Larino [CB]*); M. Nuzzo, MD, G. Formoso, MD, and D. Cosi, MD (*Lecce*); A. Caldonazzo, MD (*Leno [BS]*); I. Lorenti, MD (*Lentini [SR]*); D. Barbaro, MD, and P. Orsini, MD (*Livorno*); R. Guarneri, MD, and I. Guarneri, MD (*Locri [RC]*); G. Maolo, MD, and M. Giovagnetti, MD (*Macerata*); F. Saggiani, MD, G. Pascal, MD, and E. Dina, MD (*Mantova*); L. Sciangula, MD, P. De Patre, MD, F. Azzalini, MD, C. Mauri, MD, and C. Roncoroni, MD (*Mariano Comense [CO]*); A. Venezia, MD, and R. Morea, MD (*Matera*); P. Pata, MD, T. Mancuso, MD, A. Cozzolino, MD, and C. De Francesco, MD (*Messina*); S. Negri, MD, G. Adda, MD, A. Zocca, MD, A. G. Perdomini, MD, and G. L. Pizzi, MD (*Milano*); S. Gentile, MD, G. Guarino, MD, B. Oliviero, MD, C. Scurini, MD, S. Turco, MD, A. Fischetti, MD, M. R. Marino, MD, G. Di Giovanni, MD, G. Borrelli, MD (*Napoli*); M. Trovati, MD, and M. C. Ponziani, MD (*Orbassano [TO]*); G. Torchio, MD, and P. Palumbo, MD (*Paderno Dugnano [MI]*); M. L. Belotti, MD (*Palazzolo sull'Oglio [BS]*); V. Provenzano, MD, S. Imparato, MD, and V. Aiello, MD (*Partinico [PA]*); S. Bazzano, MD, and G. Nosetti, MD (*Pavia*); E. Antonacci, MD (*Penne [PE]*); F. Capani, MD, E. Vitacolonna, MD, E. Ciccarone, MD, R. Ciancaglini, MD, G. Di Martino, MD, and G. La Penna, MD (*Pescara*); F. Galeone, MD (*Pescia [PT]*); G. D. Pierfranceschi, MD, U. De Joannon, MD, M. Matteo, MD, M. Bianco, MD, and D. Zavaroni, MD (*Piacenza*); C. Ruffino, MD (*Pietra Ligure [SV]*); E. Bassi, MD, and R. Ghirardi, MD (*Pieve di Coriano [MN]*); C. Lieto, MD (*Pomigliano d'Arco [NA]*); G. De Simone, MD, and M. Riccio, MD (*Portici [NA]*); R. Gelisio, MD, and M. Moretti, MD (*Portogruaro [VE]*); A. Bianchi, MD, and R. Dagani, MD (*Rho [MI]*); P. Tatti, MD, P. Di Mauro, MD, D. Cristofanelli, MD, D. Cappelloni, MD, A. Urbani, MD, S. Leotta, MD, G. Ceccarelli, MD, M. Mauceri, MD, M. F. La Saracina, MD, A. Baldelli, MD, A. Napoli, MD, S. Morano, MD, R. Cipriani, MD, A. Gabriele, MD, F. Pantellini, MD, M. Liguori, MD, O. Laurenti, MD, and G. De Mattia, MD (*Roma*); G. Monesi, MD, F. Mollo, MD, R. Manunta, MD, G. Lisato, MD, F. Beretta, MD, L. Bellinetti, MD, and P. Bordon, MD (*Rovigo*); E. Bagolin, MD (*San Donà di Piave [VE]*); L. Clementi, MD, and G. Vespasiani, MD (*San Benedetto del Tronto [AP]*); E. Del Vecchio, MD, F. Orio, MD, D. Caggiano, MD, M. Tenuta, MD (*Salerno*); G. M. Arca, MD, and V. Scardaccio, MD (*Sassari*); A. Diana, MD, G. Montegrosso, MD, S. Grottoli, MD, M. Tati, MD, and M. P. Della Valle, MD (*Savigliano [CN]*); P. Galenda, MD (*Sondalo [SO]*); E. Libera, MD (*Sondrio*); M. B. Diodati, MD, and A. Tritapepe, MD (*Sulmona [AQ]*); C. Coppola, MD, and M. Bosi, MD (*Suzzara [MN]*); M. Magno, MD, and E. Scarpa, MD (*Taranto*); E. Lattanzi, MD, G. Damiani, MD, D. Di Michele, MD, A. Fava, MD, E. Di Pietro, MD, and M. Brancali, MD (*Teramo*); M. Veglio, MD, M. D'Andrea, MD, A. Grassi, MD, A. Mornile, MD, A. Bruno, MD, E. Pisu, MD, G. Bruno, MD, V. Tagliaferro, MD, P. Passera, MD, and M. Trento, MD (*Torino*); A. Margiotta, MD (*Tradate [VA]*); A. Bossi, MD (*Treviglio [BG]*); C. Taboga, MD, S. Mreule, MD, C. Noacco, MD, F. Colucci, MD, and L. Tonutti, MD (*Udine*); S. Sposito, MD (*Velletri [RM]*); A. R. Bogazzi, MD (*Venaria [TO]*); E. Moro, MD, C. Zanbon, MD, M. Pais, MD, G. Bittolo Bon, MD, and A. Sfriso, MD (*Venezia*); and M. F. Francesconi, MD, and G. Erle, MD (*Vicenza*).

*General Practitioners:* D. Sabbi, MD (*Arquata Scrivia [AL]*); A. Mazzarino, MD (*Aversa [CE]*); L. Lipa, MD (*Avezzano [AQ]*); M. Casassa Vigna, MD (*Balangero [TO]*); A. D'Alessandro, MD (*Bari*); N. Caniglia, MD (*Barrea [AQ]*); F. Brancati, MD (*Brugherio [MI]*); G. Omati, MD (*Bussero [MI]*); G. Danti, MD (*Buttapietra [VR]*); L. Pascali, MD (*Camerano [AN]*); G. Raggi, MD (*Camisano Vicentino [VI]*); L. Di Paolo, MD (*Campo Di Giove [AQ]*); E. Di Febo, MD (*Carsoli [AQ]*); P. Ferrari, MD, and L. Ballarini, MD (*Castel D'azzano [VR]*); P. Tonello, MD (*Castelgomberto [VI]*); V. Capilupi, MD (*Catanzaro*); D. De Giorgi, MD (*Cavallino [LE]*); C. Spiezio, MD (*Ciriè [TO]*); F. Della Cagnoletta, MD (*Colorina [SO]*); E. Beretta, MD (*Concorezzo [MI]*); M. T. Nepote Fus, MD, and T. Rapacciuolo, MD (*Corio [TO]*); B. Cannelli, MD (*Corridonia [MC]*);

(continued)

A. Metrucci, MD (*Cutrofiano [LE]*); A. Veldorale, MD (*Druento [TO]*); E. Ioverno, MD, and G. Visentin, MD (*Dueville [VI]*); L. Bellino, MD (*Firenze*); E. Brizio, MD (*Fossano [CN]*); E. Zanellato, MD (*Front [TO]*); G. Frapporti, MD (*Fumane [VR]*); R. Della Vedova, MD (*Gradisca d'Isonzo [GO]*); F. Gesualdi, MD (*Latronico [PZ]*); E. Mola, MD, T. Bosco, MD, and D. Fiume, MD (*Lecce*); M. Falcoz, MD (*Loira [TV]*); G. Martinelli, MD (*Lovere [BG]*); M. Tombesi, MD, and L. Caraceni, MD (*Macerata*); E. Di Giovanbattista, MD (*Magnano in Riviera [UD]*); T. Ermacora, MD (*Maiano [UD]*); A. Gualtieri, MD (*Malo [VI]*); F. Morelli, MD, and G. Capozza, MD (*Matera*); M. Musso, MD (*Mathi [TO]*); S. Pagliani, MD, and P. Longoni, MD (*Milano*); V. Caimi, MD, E. Parma, MD, M. G. Riva, MD, and M. Bosisio, MD (*Monza [MI]*); L. Bertini, MD (*Monzuno [BO]*); R. Barra, MD, F. M. D'Alessandro, MD, and R. Alano, MD (*Napoli*); G. Mezzasalma, MD (*Nole Canavese [TO]*); L. Barberio, MD (*Paganica [AQ]*); F. Petrona Baviera, MD (*Palermo*); C. De Matteis, MD (*Paola [CS]*); B. Anglano, MD (*Verona*); P. Scarpolini, MD (*Pescantina [VR]*); M. Milano, MD, and S. Bernabè, MD (*Pianezza [TO]*); F. Ferrara, MD (*Pisticci [MT]*); S. Filippi, MD (*Pontremoli [MS]*); C. Tosetti, MD (*Porretta Terme [BO]*); P. Dorato, MD (*Pozzuoli [NA]*); A. Moro, MD (*Preganziol [TV]*); B. La Terra Bella, MD (*Ragusa*); M. Marziani, MD (*Reggio Emilia*); S. Burzacca, MD (*Rivalta Di Torino [TO]*); A. Zamboni, MD (*Ro [FE]*); F. Saliceti, MD, P. L. Bartoletti, MD, and L. Spalletta, MD (*Roma*); L. Bonicatto, MD (*San Francesco al Campo [TO]*); A. Catalano, MD (*San Leucio del Sannio [BN]*); L. Crapesi, MD (*San Lorenzo Isontino [GO]*); M. Greco, MD (*San Pietro in Lama [LE]*); G. Mattana, MD (*San Sperate [CA]*); M. L. Agnolio, MD (*Sandrigo [VI]*); G. Piazza, MD (*Santorso [VI]*); G. Lattuada, MD (*Saronno [VA]*); L. Gambarelli, MD (*Scandiano [RE]*); A. Bussotti, MD (*Sesto Fiorentino [FI]*); A. Pinsuti, MD (*Sinalunga [SI]*); L. Signorati, MD (*Sommacampagna [VR]*); V. Baggi, MD (*Sordio [LO]*); R. Riundi, MD (*Sumirago [VA]*); M. Uberti, MD, A. R. Mondazzi, MD, R. Massaro, MD, and M. Botto Micca, MD (*Torino*); D. Massignani, MD (*Valdagno [VI]*); F. Gazzetta, MD, F. Bianchetti, MD, and D. Molla, MD (*Varese*); R. Marino, MD, and E. Gribaldo, MD (*Venaria [TO]*); E. Aramini, MD (*Vercelli*); T. Galopin, MD, G. Pectenella, MD, and E. Bonollo, MD (*Verona*); P. F. Luvisi, MD (*Viareggio [LU]*); A. Frigo, MD, G. Cabri, MD, and C. Simionato, MD (*Vicenza*); S. Bevilacqua, MD, and L. Longhi, MD (*Viterbo*); and G. Dezio, MD (*Vittoria [RG]*).

3. Guidelines Subcommittee. 1999 World Health Organization–International Society of Hypertension. Guidelines for the management of hypertension. *J Hypertens.* 1999;17:151-183.
4. The sixth report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Arch Intern Med.* 1997;157:2413-2446.
5. American Diabetes Association: clinical practice recommendations 1999. *Diabetes Care.* 1999;22(suppl 1):S1-S114.
6. Berlowitz DR, Ash AS, Hickey EC, et al. Inadequate management of blood pressure in a hypertensive population. *N Engl J Med.* 1998;339:1957-1963.
7. Hyman DJ, Pavlik VN. Characteristics of patients with uncontrolled hypertension in the United States. *N Engl J Med.* 2001;345:479-486.
8. Grossman E, Messerli FH, Goldbourt U. High blood pressure and diabetes mellitus: are all antihypertensive drugs created equal? *Arch Intern Med.* 2000;160:2447-2452.
9. Labbrozzi D, Nicolucci A. Caring for the patients with diabetes. In: Scroccaro G, Martini N, Del Porte JP, Husson C, Walker R, eds. *Progress in Clinical Pharmacy: Clinical Trials and Pharmaco-Epidemiology: Proceedings of the 23rd European Symposium on Clinical Pharmacy, Agrigento 12-15, Oct, 1994.* Noordwijk, the Netherlands: European Society of Clinical Pharmacy; 1994: 171-175.
10. Belfiglio M, De Berardis G, Franciosi M, et al. The relationship between physicians' self-reported target fasting blood glucose levels and metabolic control in type 2 diabetes: the QuED Study Group—Quality of Care and Outcomes in Type 2 Diabetes. *Diabetes Care.* 2001;24:423-429.
11. Franciosi M, Pellegrini F, De Berardis G, et al. The impact of blood glucose self-monitoring on metabolic control and quality of life in type 2 diabetic patients: an urgent need for better educational strategies. *Diabetes Care.* 2001;24:1870-1877.
12. Snijders TAB, Bosker RJ. *Multilevel Analysis: An Introduction to Basic and Advanced Multilevel Modeling.* Thousand Oaks, Calif: SAGE Publications; 1999.
13. Sullivan LM, Dukes KA, Losina E. Tutorial in biostatistics: an introduction to hierarchical linear modelling. *Stat Med.* 1999;18:855-888.
14. Bakris GL, Williams M, Dworkin L, et al, for the National Kidney Foundation Hypertension and Diabetes Executive Committees Working Group. Preserving renal function in adults with hypertension and diabetes: a consensus approach. *Am J Kidney Dis.* 2000;36:646-661.
15. American Diabetes Association. Clinical practice recommendations 2002. *Diabetes Care.* 2002;25(suppl 1):S1-S147.
16. Cutler JA. Calcium-channel blockers for hypertension: uncertainty continues. *N Engl J Med.* 1998;338:679-681.
17. Kell SH, Drass J, Bausell RB, Thomas KA, Osborn MA, Gohdes D. Measures of disease control in Medicare beneficiaries with diabetes mellitus. *J Am Geriatr Soc.* 1999;47:417-422.
18. Hanninen JA, Takala JK, Keinanen-Kiukaanniemi SM. Blood pressure control in subjects with type 2 diabetes. *J Hum Hypertens.* 2000;14:111-115.
19. Nicolucci A, Scorpiglione N, Belfiglio M, et al, for the Italian Study Group for the Implementation of the St Vincent Declaration, Societa Italiana di Diabetologia, Associazione Medici Diabetologi. Patterns of care in an Italian diabetic population. *Diabet Med.* 1997;14:158-166.
20. Bertakis KD, Helms LJ, Callahan EJ, Azari R, Robbins JA. The influence of gender on physician practice style. *Med Care.* 1995;33:407-416.
21. Roter D, Lipkin M Jr, Korggaard A. Sex differences in patients' and physicians' communication during primary care medical visits. *Med Care.* 1991;29:1083-1093.
22. Bensing JM, van den Brink-Muinen A, de Bakker DH. Gender differences in practice style: a Dutch study of general practitioners. *Med Care.* 1993;31:219-229.
23. Cooper-Patrick L, Gallo JJ, Gonzales JJ, et al. Race, gender, and partnership in the patient-physician relationship. *JAMA.* 1999;282:583-589.
24. Lloyd-Jones DM, Evans JC, Larson MG, O'Donnell CJ, Roccella EJ, Levy D. Differential control of systolic and diastolic blood pressure: factors associated with lack of blood pressure control in the community. *Hypertension.* 2000;36:594-599.