Introduction

The prevalence of diabetes in all age groups worldwide had been estimated to reach 2.8% in 2000 and 4.4% by 2030. By then, the total number of people with diabetes is projected to rise from 171 million to 366 million [1]. Nearly two-thirds of individuals with diabetes live in developing countries such as Brazil, India, and China, where this number is expected to increase during the next two decades [2]. A single nationwide study was carried out in Brazil in the late 1980s and results showed 7.6% prevalence of diabetes in people aged 30 to 69 years [3]. It is remarkable that nearly 50% of those diagnosed with diabetes were not aware of their disease and only 25% reported receiving care. More recent regional studies showed an increase in prevalence rates: 12.1% in the city of Ribeirão Preto [4], 12.4% in Porto Alegre [5], and 13.5% in São Carlos [6].

The Brazilian Public Health System (SUS) consists of a network of district or basic health care units, hospitals, laboratories, and blood banks essentially institutionalized to provide all Brazilian citizens with comprehensive care.

Because direct and indirect costs of diabetes in Brazil are unknown, public health policymakers and managers cannot properly assess the real needs of patients with diabetes. Therefore, different management approaches are inadequately evaluated and resources are not correctly and sufficiently allocated. Moreover, the difficulty in accessing health services makes it even harder to measure the actual burden of diabetes in Brazil.

In 2007, the Brazilian Society of Diabetes created a working group with the purpose of estimating diabetes care costs in Brazil. Initially, the group conducted the Brazilian Study on Diabetes Costs (ESCUlDI study) to estimate direct and indirect costs of outpatient care of a selected sample of type 2 diabetes patients in the SUS.

Subjects and methods

A retrospective study based on data collected from different levels of care (primary, secondary, and tertiary care units) in eight Brazilian cities was carried out during the year 2007. Those cities were selected based on geographical criteria (northwest, south, and southeast), where health services were fairly organized, medical
records were available at different levels of care, and research on diabetes was being conducted by local experienced investigators.

The study design included 50 patients per level of care, a total of 100 patients from medium-sized cities (Bauru, Itabuna, and Campina Grande) and 150 patients from large cities (Fortaleza, Rio de Janeiro, Porto Alegre, Ribeirão Preto, and São Paulo). In the city of São Paulo, the only patients included were the ones from the secondary and tertiary levels; altogether the final sample comprised 1000 patients. The inclusion criteria were being older than age 30 years and having been followed-up at the health center for at least 1 year. Exclusion criteria were being pregnant, older than age 75 years, or having other diseases (human immunodeficiency virus, cancer, or hepatic failure) that could significantly affect the analysis of resource use. Patients scheduled to attend the centers were randomly selected for a face-to-face interview, which consisted of a questionnaire developed by the main research group. The basis of such research instrument came from a Pan American Health Organization questionnaire, which had been previously used in the Caribbean. The questionnaire was tested with 15 individuals and amendments were made. It was administered in two phases: patient data were collected through personal interviews, and then data were collected by systematically reviewing medical records.

The subjects were classified into groups: those who had microvascular (retinopathy, neuropathy, or nephropathy) and/or macrovascular (cerebrovascular, coronary, or peripheral artery disease) complications. Such subdivision could only be possible once they had reported signs or symptoms of any of those diseases or had information in their medical records.

To participate in the study, all subjects read and signed an informed consent form. The study was previously approved by the Research Ethics Committee of the University of São Paulo/Ribeirão Preto campus. Investigators conducted the research in accordance with the principles of the Declaration of Helsinki.

**Estimated costs**

The economic effects of outpatient diabetes care were assessed from the SUS and society perspectives over the course of 1 year. Direct and indirect costs were taken into account.

There were costs in Brazilian currency (R$) attributed to all resources utilized for the year 2007, which were then converted into US dollars during the analysis using a purchasing power parity basis for 2005: US$1 = R$ 1.4 [7].

Direct costs were estimated using a bottom-up approach for primary data collection [8] and divided into medical and nonmedical costs. The direct medical costs assessed included medications, diagnostic tests, procedures, medical supplies (such as blood glucose test strips), visits with health professionals (physicians, nurses, nutritionists, physical therapists, dentists, and psychologists), and hospital costs for emergency room visits (including provider fees only). Medications used were categorized into four groups: diabetes and obesity, cardiovascular and dyslipidemia, psychiatric, and others (all other classes of medications).

The direct nonmedical costs assessed included expenses with artificial sweeteners and diet products, patient transportation to attend clinic visits and laboratory testing, and expenses for hiring a temporary caregiver during a patient recovery period. Due to the wide variety of urban means of transport available (bus, train, subway, car), a minimum amount corresponding to two regular bus fares (US$3.10) was set to assess transportation expenses.

Total direct outpatient costs of diabetes care were defined as the sum of all direct medical and nonmedical costs. Primary data collection on hospitalization costs was not performed.

Medical procedures, health professionals’ visits, and supplies were assessed through reimbursements given to health centers based on SUS management of Procedures, Medications, and Special Supplies and Equipment System [9]. As for the assessment of medications covered by SUS, the weighted mean of the last three medication purchases made by public health units in 2007 was based on the Brazilian Ministry of Health price database [10]. Medications purchased at discount pharmacies cost nearly as much as those covered by SUS. Medications purchased at private pharmacies included the price of generic medications, if available; if not, the corresponding brand-name drug was obtained online through a publication on medication prices with an added tax of 18% [11].

The indirect costs assessed were absenteeism and resulting loss of productivity for the patients and their caregivers, sick leave, and early retirement. The human capital approach was adopted to estimate indirect costs. The mean monthly income and the value of working hours were used to calculate workdays lost [8].

**Statistical analysis**

Data collected through questionnaires were electronically compiled by Epi-info 2000 (Centers for Disease Control and Prevention, Atlanta, GA). The statistical analysis was performed using SAS/STAT version 9 (SAS Institute, Inc, Cary, NC). Variance analysis models were constructed to compare quantitative variables from the different levels of care, diabetes complications, and different disease durations. Fisher’s exact test was carried out for comparison. A 5% significance level was set.

**Results**

**Sample characteristics**

There were a greater proportion of women receiving medical care (66.5% women vs. 33.5% men). Mean age was 59.0 ± 9.1 years and mean duration of diabetes diagnosis was 11.2 ± 7.8 years.

The self-reported prevalence of coronary artery disease was 70.4%, with a higher prevalence at the tertiary level compared to the secondary and primary levels (P < 0.001). The prevalence of self-reported arterial hypertension (79.6%), cerebrovascular disease (7.6%), and hypercholesterolemia (70.4%) were similar at all different levels of care.

Home blood glucose monitoring was reported by 34.3% of the sample (n = 343).

Information on chronic diabetes complications was not available in 38% of the sample (n = 380) due to missing information in the medical records. Out of the remaining patients (n = 620), 28.9% had at least one microvascular complication (micro group; n = 289), 17% had at least one macrovascular complication (macro group; n = 171) and 16% had at least one microvascular and one macrovascular complication associated (micro/macro group; n = 160).

The mean monthly income in the sample was US$543.35 and the income of each day of work was US$18.11.

**Direct costs**

Total direct outpatient cost of diabetes care was US$1335 per patient/year, out of which US$1014 per patient/year expended on direct medical costs and US$321 per patient/year on non-medical costs. (Table 1 in Supplemental Materials at: doi:10.1016/j.jval.2011.05.009).

Total annual cost of medications for 1000 patients was US$747,356; US$563,506 paid by the public health system (SUS) (75.4%) and US$183,849 paid by patients in private pharmacies (24.6%). The expenses per patient/year with different medication groups were: US$249 with diabetes/obesity (n = 959); US$397 with cardiovascular/dyslipidemia (n = 905); US$321 with psychiatric conditions (n = 170), and US$285 with other medications (n = 335). (See Table 2 in Supplemental Materials at: doi:10.1016/j.jval.2011.05.009).

The total cost of exams and procedures summed US$1216 per patient/year and the cost for health professionals’ consultations was US$794 per patient/year.
The cost of home blood glucose monitoring was US$102,748 (US$299 per patient/year; n = 343).

Annual expenses with artificial sweeteners and diet products amounted to US$258,617 (US$286 per patient). Expenses related to blood pressure monitoring were reported by 62 patients (US$59 per patient) and only 15 patients reported expenses with hiring a temporary caregiver (US$599 per patient). Patient transportation costs for attending consultations and/or undergoing diagnostic tests totaled US$50,964 (US$52 per patient).

There was an increment in direct costs with diabetes progression and presence of diabetes complications (data not shown).

**Indirect costs**

Total indirect costs were US$773,212 (US$773 per patient/year), which corresponds to 36.7% of total diabetes costs. (See Table 1 in Supplemental Materials found at: doi:10.1016/j.jval.2011.05.009).

The lost of workdays corresponded to a loss of productivity of US$437 per patient/year from those who reported having an income (n = 829). A total of 32 (3.2%) and 74 (7.4%) subjects reported diabetes-related sick leave and early retirement, respectively, associated with US$103,680 and US$410,702 expenses paid by the government. Job loss due to diabetes was reported by 127 subjects (12.7%).

There was an increment in indirect costs with diabetes progression and presence of diabetes complications (data not shown).

**Total costs**

In the sample studied, the sum of direct and indirect costs amounted to US$2,108,287 for 1,000 patients per year (US$2,108 per patient).

Total costs of diabetes care was US$1,144 per patient at the primary care level, US$2445 at the secondary level and US$2810 at the tertiary level, with significant differences among total costs at the primary level and those at the secondary and tertiary levels (P < 0.01). (See Fig. 1A in Supplemental Materials found at: doi:10.1016/j.jval.2011.05.009).

In regard to diabetes duration, there was an increment in total costs as diabetes progressed: US$1971 per patient with diabetes duration 10 years or fewer; US$2173 per patient in those with diabetes duration between 10 and 19 years and US$2544 per patient in those with 20 years or more of diabetes duration (P < 0.01 among all the groups). (See Fig. 1B in Supplemental Materials found at: doi:10.1016/j.jval.2011.05.009).

Total costs per patient from diabetes complications were as follows: US$2062 per patient in the micro group (n = 289); US$2517 per patient in the macro group (n = 171) and US$3199 per patient in the micro/macro group (n = 160) (P < 0.01 among all the groups). (See Fig. 1C in supplemental Materials found at: doi:10.1016/j.jval.2011.05.009).

**Discussion**

ESCUDEI is the first study conducted in Brazil showing a breakdown of costs of type 2 diabetes outpatient care in the SUS. Data were collected in eight cities with the purpose of describing health care in different Brazilian regions (southern, southeastern, and northeastern). Total cost of diabetes outpatient care during a 1-year period was US$2108 per patient/year, out of which 63.3% was direct costs and 36.7% was indirect costs. As expected, costs increased as diabetes progressed (23% cost increment in those with 10 or fewer years of diabetes duration compared to those with diabetes duration of 20 years or more) and with the presence of chronic complications (25% cost increment in those with both complications compared to those with only one microvascular or macrovascular complication). Similar results were described in a previous cost analysis of chronic diabetes complications [12].

There was no difference in direct costs between secondary and tertiary levels of care, but in general, costs were higher than the primary care level, where majority of patients are being treated.

A great and significant portion of costs (36.7%) were due to indirect costs of diabetes, which also include hidden expenditures paid by society that are usually little known and not included in government budget analyses. When comparing the annual costs made by the individuals (nonmedical direct costs, purchased medications, and loss of productivity) with their mean annual income (US$6520), we could demonstrate that 14.4% of their income was used for treatment.

The greatest portion of direct costs was attributed to medication (48.2%). Although the Brazilian health system has the responsibility to provide drug treatment for any chronic disease, 24.6% of the patients bought medicines from private pharmacies.

Previous studies on costs of diabetes clearly show that the greatest proportion of costs is attributed to hospital admissions. The CODE-2 study [13] demonstrated the medical costs of diabetes care in eight European countries based on primary data collection and database analysis. The estimated cost per patient per year was €2834 and the largest portion of these costs was attributed to hospital admissions (55%), mostly due to chronic diabetes complications, whereas only a small portion accounted for medication (4%). Those European results are hardly comparable to our Brazilian ones because these two studies had different approaches and the former included costs of hospital admissions, which are very high. The most recent American study on diabetes costs [14] shows an estimated cost of US$174 billion in 2007, out of which US$116 billion was spent on health resources and US$58 billion was attributed to loss of productivity. Similar to the CODE-2 study [13], the largest portion of costs were attributed to hospital admissions (50%), followed by medication and medical supplies (12%) [14]. Again, these results cannot be appropriately compared to the Brazilian ones because different methods were used (top-down approach vs. bottom-up approach). The ratio of direct cost to indirect cost was similar in the Brazilian and American studies, reinforcing the heavy burden of diabetes to individuals and society.

Rosa et al. [15] investigated the costs of public hospital admissions in Brazil during 2 years (1999–2001) using diabetes as the main diagnosis and the method of attributable risk associated to all admissions. The estimated number of hospital admissions was 836,300 per year (49.3/104 inhabitants), with a cost of US$243,900 per year (€2834 and the largest portion of these costs was attributed to hospital admissions (50%), mostly due to chronic diabetes complications, whereas only a small portion accounted for medication (4%). Those European results are hardly comparable to our Brazilian ones because these two studies had different approaches and the former included costs of hospital admissions, which are very high. The most recent American study on diabetes costs [14] shows an estimated cost of US$174 billion in 2007, out of which US$116 billion was spent on health resources and US$58 billion was attributed to loss of productivity. Similar to the CODE-2 study [13], the largest portion of costs were attributed to hospital admissions (50%), followed by medication and medical supplies (12%) [14]. Again, these results cannot be appropriately compared to the Brazilian ones because different methods were used (top-down approach vs. bottom-up approach). The ratio of direct cost to indirect cost was similar in the Brazilian and American studies, reinforcing the heavy burden of diabetes to individuals and society.

Our study has some limitations, such as lack of knowledge on the actual situation of patients with diabetes regarding their regional distribution, access to care, and disease severity, as well as the fact that cities were randomly selected for data collection and are not representative of the whole country. Because the patient selection process was not ideal, some selection bias could be observed, such as that the majority of included patients were women or workers. Moreover, considering the lack of information on chronic complications in medical records, we analyzed the results separately. By doing so, we conclude that, regarding level of care, age, social level, or other identifiable factor that can be considered a systematic selection bias, there were no differences between those individuals with available data which allowed the classification of the presence of chronic complications (n = 620) and those without (n = 380).

For the above reasons, results obtained in this sample may not accurately reflect average costs of diabetes care in the whole country. As a cost-of-Illness study, the results were only descriptive, without comparisons to other populations. The possibility to compare the costs in a similar group without diabetes would in fact be much more informative to managers of the SUS. However, there are no published cost studies with primary data collection of the general Brazilian population that could be used to compare to our results. Because our
study did not collect data from patients without diabetes, we cannot ensure that the costs were attributed exclusively to diabetes.

The findings of our study indicate a serious economic threat posed by diabetes that public authorities and all social sectors have to face. The noninclusion of hospital costs in the analysis resulted in an underestimate of the actual total cost of diabetes care in Brazil. The high percentage of indirect costs reveals hidden losses posed by diabetes that need to be taken into account. However, even with the inclusion of nonmedical and indirect costs in the study, not all the harm caused by diabetes were considered. There are intangible costs such as pain, suffering, and loss of quality of life that were not shown.

The increasing incidence and prevalence of diabetes evidenced by epidemiologic studies worldwide represents a growing burden that most health systems are unable to deal with. There is an imperative need to develop and improve interventions toward prevention of diabetes and its complications and to reorganize resources to improve the effectiveness of health care. If this is not done, the public financing of diabetes treatment will be unviable in a near future, with deleterious consequences for the health of the Brazilian population.

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Supplemental Materials

Supplemental material accompanying this article can be found in the online version as a hyperlink at doi:10.1016/j.jval.2011.05.009, or if hard copy of article, at www.valueinhealthjournal.com/issues (select volume, issue, and article).

REFERENCES