

# The determinants of out-of-pocket health-care expenses for diabetes mellitus patients in India: An examination of a tertiary care government hospital in Delhi

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## Abstract

**Objective:** To assess the determinants of out-of-pocket (OOP) expenses on diabetes-related treatment incurred in patients attending outpatient clinics in a tertiary care hospital in Delhi, India.

**Study Design:** A cross-sectional analysis of baseline data from a quasi-experimental study was conducted over 8 months in 2016 in a major tertiary care hospital in Delhi.

**Methods:** The study included 375 diabetes patients up to 65 years of age on treatment for at least a year without significant complications. Data were collected through a patient interview schedule.

**Results:** Of the previous six scheduled appointments, at least two missed appointments were seen in 267 (71.2%) patients. The average patient's OOP expenditure on diabetes-related medicines was ₹63.5 a month, a similar amount was spent on traveling to and from health facilities. Sixty-four (17.1%) patients took antidiabetic medication for <85% of the days in the previous 3 months.

**Conclusion:** There exists a high burden of missed clinic appointments among diabetes patients in tertiary care government health settings in India. This appears to be related to the high cost in terms of both time and money involved in attending appointments for the modest benefit of a dispensation of a 15-day drug refill. Health policy measures focused on strengthening medication coverage need to explore the balance of costs and benefits when determining the frequency of clinical appointments in these settings.

**Keywords:** Delhi, diabetes, India, medication adherence, out-of-pocket expenses

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## INTRODUCTION

Diabetes mellitus (DM) and its related complications constitute a significant cause of morbidity and mortality globally. Developing countries account for 80% of the global diabetes disease burden which is expected to further increase in the coming decades as these countries increasingly adopt unhealthy dietary patterns and sedentary

lifestyles and are thus faced with an increasing obesity burden.<sup>[1-3]</sup> India has the second highest diabetes disease burden in the world.<sup>[4]</sup> However, there is considerable geographic and regional variation in this burden with urban areas and more particularly urban slums showing the highest prevalence of diabetes.<sup>[5,6]</sup>

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The cost of diabetes management involves direct, indirect, and intangible costs.<sup>[7]</sup> Direct medical costs are related to economic expenses for drug treatment of diabetes with oral hypoglycemic agents and insulin, routine investigation, and physician consultation. Indirect costs emerge from diabetic morbidity which reduces patient's creative, educational, and economic potential and productivity. The intangible costs refer to the pain and suffering of patients due to diabetes complications such as neuropathy and nephropathy that lower the patient's quality of life. In this study, we focused only on the direct costs of diabetes management.

The inability of uninsured DM patients to finance their direct medical costs by out-of-pocket (OOP) payments can result in poor medication adherence resulting in a suboptimal benefit of treatment with adverse health outcomes.<sup>[8,9]</sup> Poorly controlled diabetes due to incomplete and ineffective treatment increases the likelihood of early onset of diabetic complications which involve considerable indirect and intangible costs.<sup>[10,11]</sup> The magnitude of medical costs increases enormously in the management of vascular complications of DM such as cardiovascular disease and renal failure.<sup>[12]</sup> Medication costs in India often exceed catastrophic expenditure limits in economically disadvantaged populations, rendering them at risk of further impoverishment which in turn creates a vicious cycle of poverty and ill health.<sup>[13,14]</sup> Furthermore, in India, DM patients from the lower socioeconomic strata (SES) utilize a higher proportion of their household income on expenses related to diabetes care, contributing further to health inequity.<sup>[15]</sup>

Due to a lack of health insurance financing, health care in India is predominantly financed by OOP payments (62.4%).<sup>[16,17]</sup> An analysis of the diabetes-related OOP expenditure in India revealed that costs of medication constitute the predominant component of patient spending.<sup>[18]</sup> Consequently, India's National Health Program for Prevention and Control of Diabetes, Cardiovascular diseases, Cancer and Stroke (NPPCDS) targets the achievement of universal health coverage (UHC) by mitigating OOP health expenses.<sup>[19]</sup> Government health facilities provide free antidiabetic medications to diabetes patients availing outpatient department (OPD) or inpatient department services.

It is essential to ascertain OOP health expenditure in DM patients who receive treatment in public health facilities because large segments of the Indian population, mainly from the lower SES, mostly working in the informal sector of the economy, will continue to depend on public health facilities for diabetes care.<sup>[20]</sup> This is because most of the

Indian economy is informal; hence, much of the workforce lack social security benefits, limiting their opportunities for employer-based health coverage.<sup>[21]</sup>

The tertiary care government hospitals as per the NPPCDS have been identified as the key drivers for the provision of comprehensive noncommunicable disease care through a hub-and-spoke (district) model.<sup>[19]</sup> The objective of this study is to assess the OOP expenses on diabetes-related treatment incurred by diabetes patients attending the outpatient clinic of a tertiary care hospital in Delhi, India, and to understand the determinants of these OOP expenses.

## METHODS

### Study design

This is a cross-sectional analysis of the baseline data from a quasi-experimental trial, part of a larger study that reported on the behavioral aspects of diabetes self-care.<sup>[22]</sup>

### Study setting

The study was conducted in the outpatient clinic of a major tertiary care government hospital in Delhi, India. Diabetes Mellitus patients were dispensed antidiabetic medication refills for 15 days from the hospital pharmacy during their appointment. These medication refills include all the prescribed medications and are provided absolutely free of charge. Patients are expected to procure refills through regular follow-up appointments every 2 weeks after obtaining a written prescription order from any of the treating physicians at their designated OPDs.

### Inclusion and exclusion criteria

Adult DM patients up to 65 years of age on treatment for at least 1 year were included in the study. Patients with comorbidities and/or complications indicating advanced cardiovascular disease, renal failure requiring dialysis, previous cardiovascular accident, blindness, and needing psychotropic drugs were excluded as their health needs were expected to significantly differ from those of uncomplicated DM patients.

### Methodology

The data in the study were collected during 8 months from February to September 2016. The sampling universe comprised DM patients registered at the diabetes and endocrinology OPDs of the hospital. The proportion of patients spending OOP was expected to be equal to the national estimate of 62.4%.<sup>[17]</sup> The appropriate sample size for the study was calculated to be 371, targeting a 95% confidence level, 5% margin of error, and accounting for 10% nonresponders.

The respondents were enrolled through consecutive sampling, i.e., the DM patients were enrolled one after the other, with a maximum of 12 patients being enrolled in a day. Data were collected through face-to-face interviews using a pretested patient interview schedule. The patients were asked to self-report the OOP expenses incurred on diabetes-related medications in the previous 1-month period<sup>[23]</sup> and the usual costs of transport for traveling to and returning from the hospital. Medications for treating hypertension and/or lipid disorders in the comorbid patients were included in the total diabetes-related OOP expenses.

Refill adherence among the patients was estimated as per the proportion of days covered (PDC) method for the previous 3 months from the day of the interview. The PDC is calculated as the number of days in which a medication was available with the patient divided by the total number of days in the data analysis period. Patient medical records were evaluated to assess the ongoing drug treatment and the number of missed appointments in the previous 3 months. Furthermore, to ascertain the actual refill adherence, patients also reported their medication coverage during the period of missed appointments. A refill adherence rate of  $\geq 80\%$  for antidiabetic medication is usually considered satisfactory in DM patients.<sup>[10]</sup> However, since the PDC in our study also involved patient self-reporting which is subject to self-desirability bias, a higher refill adherence rate of  $\geq 85\%$  was accepted as the cutoff for satisfactory adherence.

The socioeconomic status of the patients was assessed using the modified Kuppaswamy classification updated using the Consumer Price Index of the Industrial Workers in India for 2016.<sup>[24]</sup>

### Ethics

Written and informed consent was taken from all the patients before enrollment in the study. Confidentiality of the collected data was maintained during all stages of the study. Institutional ethical clearance was obtained.

### Statistical analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS for Windows, Version 17.0, SPSS Inc., Chicago, IL, USA). Categorical variables were expressed in frequency and percentage, whereas quantitative variables were expressed as mean  $\pm$  standard deviation.

## RESULTS

A total of 375 adult Diabetes Mellitus patients comprising 201 males and 174 females were enrolled in the study. The

median age of the patients was 50 years. A majority of the patients were not employed (62.1%) and belonged to the lower (lower middle, upper lower, and lower) SES (75.4%). Tablet therapy was prescribed to 257 (68.5%), whereas 118 (31.5%) patients were on insulin therapy [Table 1]. In addition to the prescribed antidiabetic medication, the use of alternative medication for control of diabetes was reported by 43 (11.5%) patients.

Based on observation and patient testimony, the entire process for obtaining medication refills involving obtaining a clinic appointment, consulting the physician, and collection of medication from the hospital pharmacy ranged from 2 to 4 h of patient time.

The OOP health expenses for diabetes-related care in the patients expressed as Indian National Rupees (₹) is reported in Table 2. The average OOP expense incurred by the patients in the previous 1 month was ₹63.5 and ranged from ₹0 to ₹800. Transport costs were incurred by 305 (81.3%) patients during their clinic visits. The average

**Table 1: Distribution of sociodemographic and clinical characteristics in the DM patients (N=375)**

Variable	n (%)
Gender	
Men	201 (53.6)
Women	174 (46.4)
Education (years)	
<5	132 (35.2)
5-9	105 (28)
$\geq 10$	138 (36.8)
SES	
Upper	8 (2.1)
Upper middle	92 (24.5)
Lower middle	200 (53.4)
Upper lower	80 (21.3)
Lower	3 (0.8)
Occupational category	
Unemployed	233 (62.1)
Unskilled workers	11 (2.9)
Semi-skilled workers	47 (12.5)
Skilled workers	44 (11.7)
Clerical or business	31 (8.3)
Semi-professional	9 (2.5)
Comorbidity	
0	113 (30)
$\geq 1$	262 (70)
Treatment	
Tablet	257 (68.5)
Insulin and tablet	38 (10.1)
Insulin only	80 (21.3)
Number of oral hypoglycemic agents	
0	80 (21.3)
1	71 (19)
2	180 (48)
$\geq 3$	44 (11.7)
Alternative medication intake	
Present	43 (11.5)
Absent	332 (88.5)

SES=Socioeconomic status

transport cost per patient for each clinic visit was ₹32. This shows that, if the patients were provided long-duration medication refills, it would significantly reduce their OOP expenses. The reduction in expenses on transport if refills were provided for 90 days would be ₹160.

Of the previous six scheduled appointments for diabetes care at the hospital OPD clinics in the previous 3 months, at least two missed appointments were seen in 267 (71.2%) patients. The patients belonging to the lower SES were more regular and missed fewer appointments compared to those belonging to the higher SES [Table 3].

Patient perspectives on reasons for missed appointments identified including the long waiting queues: “ghañṭē laga jāṭē hai davā ki line mē (we need to spend several hours waiting in the queue of the hospital pharmacy), one patient remarked “pichalī bāra davā nahī milī mujhē. Itni zyādā bhīra thī” (I could not collect my medication the last time. It was so crowded!). Most patients preferred a longer duration of refill “kam SE kam mahinā bhar ki davā milani chahiye” (at least 1 month of refill should be provided, “hamē bahuta dūra SE ānā hōtā hai. Kabhī kabhī nahi aa pate. bahuta ārāma ho jāyega” (we have to come from far-off. Sometimes, we are unable to come for our appointment. It will become very comfortable [if we get longer refills]). Some patients complained, “itni bhīra mey doctor zyādā kucha nahī bāta kar

pāte” (crowding in the clinics causes inadequate doctor–patient communication).

All the patients with health insurance ( $n = 29$ ) had complete medication coverage. Noninsured patients, in the event of missed appointments, could potentially satisfy their antidiabetic medication requirements partially or completely either via another public health facility or by OOP spending [Figure 1].

A total of 278 (74.1%) patients reported 100% PDC with antidiabetic medication, 64 (17.1%) reported <85% PDC, and 33 (8.8%) reported 85%–99% of PDC. The inability to replenish the exhausted antidiabetic drug stocks in the event of missed appointments was attributed to financial constraints by 69 (18.4%) patients, all of whom belonged to the lower SES.

A total of 309 (82.4%) patients were unable to access a functional glucometer. Furthermore, among the patients on insulin therapy, only 38 (32.2%) were operating a personal glucometer, whereas the rest were dependent on their nearby local health facilities for self-monitoring of blood glucose. Nearly 181 (48.3%) patients reported difficulty in bearing the expenses related to glucometer strips required for adhering to regular self-monitoring of blood glucose.

**Table 2: Distribution of out-of-pocket diabetes healthcare expenses in the previous 30 days in the diabetic patients (n=375)**

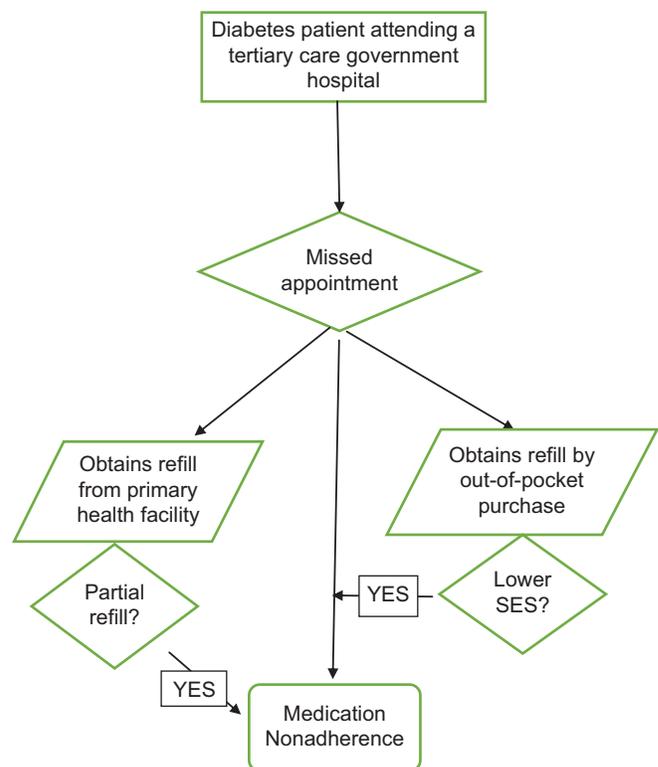
Characteristics	n (%)
Health-care insurance available,	29 (7.7)
Lost wages due to attending the OPD clinic	11 (2.9)
Spending money on transportation to reach the OPD clinic	305 (81.3)
Out-of-pocket expenses on antidiabetic medication	194 (51.7)
Out-of-pocket expenses* (₹)	
Mean±SD	
Out-of-pocket expenses incurred by the patients	63.5±110
Out-of-pocket expenses by the noncomorbid patients	47.5±89.7
Out-of-pocket expenses by the comorbid patients	70.3±117.3
Transport costs incurred on travel (two visits in 30 days)	64±3.5
Total costs on medication and transport*	127.7±148

\*All costs calculated in Indian National Rupees (₹), +Excludes costs for insulin syringes. OPD=Outpatient department, SD=Standard deviation

**Table 3: Missed appointments in the previous 90 days stratified by socioeconomic status of the diabetic patients (n=375)**

SES	Total patients (n=375), n (%)	Number of missed appointments in the previous 90 days		
		0-1	2-3	4-6
Upper	8 (2.1)	0	4 (50)	4 (50)
Upper middle	83 (22.1)	15 (18)	42 (50.6)	26 (31.3)
Lower middle	201 (53.6)	73 (36.3)	106 (52.7)	22 (10.8)
Upper lower	80 (21.4)	20 (25)	52 (65)	8 (10)
Lower	3 (0.8)	0	1 (33.3)	2 (66.6)

SES=Socioeconomic status



**Figure 1: Flow diagram of potential sequelae after missed appointments in Diabetes Mellitus patients attending a tertiary care government hospital in Delhi, India**

Plasma glucose monitoring frequency was reported as monthly by 74 (19.7%), quarterly by 260 (69.3%), and irregularly by 41 (11%) patients.

## DISCUSSION

The treatment of diabetes involves high economic costs for patients. Government health facilities providing free medication and treatment, therefore, comprise a key element for achieving UHC, especially among the low SES patients. However, our study revealed that nearly half of the DM patients who avail outpatient diabetic care in a major government tertiary hospital incur OOP expenses for antidiabetic medications. Refill nonadherence usually occurs in patients from lower SES groups when they miss their scheduled appointments.

The average monthly OOP expenses (direct costs) on diabetes-related medication incurred in our study are much lower than those reported in the study by Katam *et al.* conducted in a government-funded hospital in North India.<sup>[25]</sup> The Katam *et al.*'s study was restricted to DM patients on insulin therapy for whom medicines were subsidized compared to market rates but not provided free of cost, unlike the present study. Another study by Sharma *et al.* in South India found direct costs among urban DM patients in government outpatient settings to be ₹1856 annually equivalent to ₹156 per month.<sup>[26]</sup>

The current mechanism of drug dispensing for a short duration of 15 days for a chronic disorder like diabetes is detrimental from a systems approach view of health-care delivery. Most patients had to bear transport costs and wait in queues for many hours. Such health facility congestion can potentially compromise the quality of patient-provider communication that negatively influences patients' diabetes-related knowledge.<sup>[22]</sup> Moreover, nearly three in four patients reported missing more than one of their previous six scheduled appointments. In this regard, policy interventions for initiating long-duration dispensing of diabetes-related medications warrant consideration. Future studies should generate evidence regarding whether or not these long-duration refill-dispensing practices translate into expected gains from decongestion at clinic sites, reduction in refill nonadherence, increased treatment satisfaction, and improved health outcomes in DM patients.

The reduction in the number of planned patient appointments can also be achieved by linking patients to their nearby primary-level health facilities for routine follow-up and medication refills while reserving tertiary care hospital visits needed for specialist care at less frequent

intervals. The feasibility of such health-care linkage should be explored through operational research studies.

In our study, the mean OOP expenses in the comorbid patients were nearly 30% higher than that of noncomorbid patients although, based on retail prices, this gap should be wider. This suggests that, in the comorbid patients, nonadherence to medicines for treating hypertension or lipid disorders is unlikely to correlate with antidiabetic medications even if they are prescribed to be taken together. Future studies should evaluate adherence rates for these comorbid conditions separately. A further limitation of our study was the inability to ascertain the OOP expenses for blood investigations included in diabetes follow-up management due to the variable testing frequency observed in the study patients. Because the costs of procuring the glucometer strips were perceived by the patients as a major barrier against self-monitoring of blood glucose, the feasibility and cost-effectiveness of dispensing glucometer strips to DM patients without charge from public health facilities in India warrants exploration.

The assessment of refill adherence in our study was ascertained using a combination of approaches which included self-reporting by patients to account for gaps due to missed appointments. Self-reporting is prone to recall bias, especially when assessed over longer recall periods. Furthermore, the self-desirability bias of the patients could have resulted in a potential overestimation of the adherence levels. Some patients, especially women, who did not directly engage in the purchase of medications provided tentative estimates for their diabetes-related OOP expenses, which increases the chances of information bias. Nearly one in ten patients used alternative medication for diabetes control; however, these costs were not estimated.

The study was conducted in a single tertiary care government hospital which caters to only a small proportion of DM patients, thereby reducing the generalizability of our research findings. Nevertheless, despite the heterogeneity of health settings, these findings are still likely to be applicable across other public health facilities in India that require compliance with a similar short twice-weekly pattern of refill dispensing.

## CONCLUSION

The present study conducted in the outpatient setting of a tertiary care government hospital in Delhi, India, among uncomplicated patients with diabetes found a high burden of missed clinic appointments that was associated with

the incurrance of OOP expenses. In the event of missed appointments, suboptimal refill adherence was attributed to financial constraints by patients from lower SES.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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