Introduction

Diabetes mellitus (DM) is one of the leading causes of death\(^1\) and the most common noncommunicable diseases (NCDs) affecting the global population with increasing incidence in many developing countries of the world.\(^3\) Type 2 DM accounts for approximately 90% of all diabetes cases worldwide.\(^4\) Approximately 71.4 million people are suffering from diabetes in the South-East Asia region and this number is expected to increase to 120.9 million by 2030.\(^5\) India with 61.3 million diabetic population ranks second position after China.\(^6\) In the coming years, India is expected to experience an increased burden of diabetes\(^5,5^4\) and become the largest contributor to regional mortality with 983,000 deaths attributable to this disease.\(^2\) Presently, 43% of the disability-adjusted life years is attributable to diabetes.\(^7,5^9\)

As the disease is chronic and progressive in nature, it implicates substantial financial burden on the patient.\(^8\) As per a study, in India, the average annual expenditure by patients on diabetes care was INR 10,000 in urban areas and INR 6260 in rural areas, and as per another study the average annual direct cost was INR 8822.\(^9\) Furthermore, an increase of 113% was observed with regard to the total expenditure toward diabetes care among the urban

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Abstract

Introduction: The burden of diabetes mellitus (DM) is increasing in India and across states. Given the chronic and progressive nature of the disease, it implicates huge financial burden on patients. Given this, the objectives of this study are to estimate the out-of-pocket (OOP) expenditure on diabetes care and assess the magnitude of medication adherence among patients in a public hospital. Materials and Methods: A cross-sectional survey was conducted among 206 patients with age ≥25 years visiting the outpatient department of a tertiary care hospital in Odisha. Cost data were collected from April to June 2016 using a structured questionnaire, and drug adherence was assessed using the Morisky Medication Adherence Scale. Results: The average total expenditure per patient per month was INR 1265 (95% confidence interval 1178–1351), of which medical expenditure was INR 993 (95 confidence interval 912–1075) and that of nonmedical expenditure was INR 271 (95 confidence interval 251–292). Expenditure on medicine constituted around 65% of total medical expenditure. The other drivers of medical expenditure were diagnostics services constituting 13.2% and transportation (11.8%). Overall, only 15% of the patients reported high adherence to medication. Discussion: This study generated evidence on OOP expenditure on diabetics in Odisha which are comparable to many Indian studies. One of the critical findings of this study was that a majority of patients visiting public hospitals had to spend OOP on medicine and diagnostic services. These findings could be used to design appropriate financing strategies to protect the interest of the poor who largely use public health facility in Odisha.

Keywords: Diabetes mellitus type 2, healthcare financing, private expenditure
population between 1998 and 2005. The costs, however, vary with respect to states/regions and health facilities, that is, whether public or private facility.

Given the severity of the disease, adherence to prescribed treatment procedures is regarded essential on the part of the patient. Poor adherence to prescribed therapy is a growing concern which undermines the benefits of the current medical care. According to studies, low adherence to prescribed medications accounts for 30%–50% of treatment failures, leading to worse treatment outcomes.

Treatment failure is associated with reduced treatment benefits and can have a negative financial burden on both individual patients and the society at large. Moreover, it has been estimated that as many as 50% of the patients with chronic disease do not adhere to proper treatment procedures, resulting in additional expenses up to $100 billion in each year on hospitalizations; which is avoidable. Despite such serious implications on cost in India, where the out-of-pocket (OOP) expenditure of people is very high, that is, 67% of the total expenditure, the OOP expenditure incurred toward diabetes care must be explored.

There are only a few studies from India on the cost of diabetes care and adherence to treatment. A study estimated that each 10% increase in medication adherence results in a mean decrease of 6.6% in all-cause hospitalizations. As per another study, healthcare expenditures on diabetes accounted for 11.6% of the total healthcare expenditure in the world in 2010. By 2030, this amount is expected to exceed USD 490 billion. The direct cost on diabetes healthcare is usually very high for people in developing countries. In a study in North India, the total annual cost of care for diabetes was INR 14,508. As per this study, the patients and their families paid more than 95% of the total treatment cost. Similarly, in a study in South India, the estimated average expenditure during hospitalization of patients with diabetes was found to be about INR 5300. As type 2 diabetes is one of the major disease conditions affecting majority of the population in the country, it is important to examine the preparedness of the system regarding the provisioning of drugs and diagnostic services. In addition, it needs to be studied how far the system has been successful in creating awareness regarding the ill effects of the disease. In addition to that, information should be gathered regarding the behavior of the people, especially adherence to medicine and OOP expenditure to treat it, and other relevant information should also be collected on a regular basis to provide inputs for designing appropriate policy and programs related to it.

Odisha, being one of the backward states of India in terms of performance in health indicators, crippled with multiple challenges due to growing burden of NCD with an already high burden of morbidity and mortality caused due to communicable diseases which are preventable requires intervention in the related areas and especially given its high incidence and prevalence which is growing day-by-day. In compliment to that, the high OOP burden and less allocation by the government both at the center and state compounds this problem by multiple folds. Therefore, it is necessary that cost burden of diabetes toward OOP also be estimated so that necessary, state-specific, measures may be suggested to address the issue.

And to initiate the process and gather a glimpse of the problem, the authors conducted a study to estimate the OOP expenditure incurred toward treatment for diabetes in a government-run healthcare facility. And for doing so, the largest government healthcare facility of the state was chosen. The focus area was (a) studying the OOP expenditure incurred toward treatment of diabetes and its management and (b) to add to existing knowledge on the effects of medicine nonadherence on cost.

The objectives of the study were (a) to assess the OOP expenditure among subjects with type 2 diabetes attending outpatient department of a tertiary care hospital in Odisha and (b) to assess the magnitude of medication adherence and factors associated with it among patients with type 2 diabetes in a tertiary care hospital in Odisha.

### Materials and Methods

A cross-sectional survey was carried out during the period of April–June 2016 at Sri Ramachandra Bhanja Medical College Hospital, the largest public healthcare institution of Odisha. Patients who were more than 25 years and diagnosed with DM type 2 for at least a year were included in the study. The sample size was calculated using the following formula:

\[ n = \frac{z^2pq}{d^2} \]  

where \( z = 1.96, p = \text{prevalence of diabetes (7%)}, q = 1 - p, d = \text{precision (0.05)} \)

The sample size was estimated to be 206. The outpatient register has been used as a sampling frame to randomly select eligible study subjects. Study participants were selected using a systematic sampling procedure; every second person age 25 years and older who visited outpatient department during study period was included in the sample.

Data collection was done by administering structured questionnaire. The study questionnaire contained details such as sociodemographic, diabetes history, presence of diabetes complications, education status, occupation details, family history of diabetes, diabetic complications, habits, treatment details, and medical and nonmedical costs which were recorded. The direct medical cost per patient was assessed based on the expenditure for medical consultations, laboratory charges, medicines, and money spent on other investigations such as radiological examination, and the nonmedical costs included the cost of accompanying attendant and transportation charges. Adherence was assessed using the eight-item Morisky Medication Adherence Scale (MMAS-8), already used by researchers in India.
Data analysis

The information from MMAS-8 was interpreted using its keys. Accordingly, individuals were classified as low adherence if the mean score was less than 6, medium adherence if the mean score was 6 and 7, and high adherence if the mean score was 8.\(^{26,27}\) OOP expenditures of patients for medical treatment of type 2 diabetes were estimated based on price data collected by patients. The information obtained from general questionnaire was coded and entered using IBM, SPSS version 20.\(^{28}\) The demographic variables that were normal distributed were summarized as mean and standard deviation. The categorical variables were presented in the form of frequency distribution. The matrices against which the \(P\) value was less than 0.05 were considered as statistically significant.

Results

Among the total sample (\(n = 206\)), 67% were male and 33% were female. The average age of the population was 54 ± 12.13 years. The sample mainly comprised people belonging to 40–60 years old age group. As for educational status, 24% had finished primary education, 23% had attended secondary education, and 28% had completed high school. The proportion of population who had attended university was only 17%. Regarding occupation status, it was found that the majority of the sampled diabetic population was employed (39%), followed by housewife (31%). Of the total sample, 52% of the patients were those who were detected of diabetes in the past 5 years. There were 29% of people who were suffering from the disease since past 6–9 years, and among 19% of the patients diabetes has been prevalent for more than 10 years [Table 1].

Nearly one-third of the total patients, reportedly, had complications. The comparatively common complication was renal complication (27.3%), followed by cardiovascular (12.7%) and retinol complication (10.9%); around 45% of the patients reported of other complications such as hypertension. About 30% had positive family history. The majority of the population (44.6%) had reported family history with father.

Around 50% of the patients were prescribed for oral hypoglycemic agents and 40.3% were prescribed for insulin. There were reportedly 10.2% of the patients who were prescribed for both.

It was found that only 1% of the population received drugs completely free of cost; 42.7% people had to pay partially and 55.8% had to spend entirely from their pocket to avail drugs. With regard to diagnostic services, the entire sample population, except one, reported to have availed the services at their own expense [Table 2].

The average total expenditure of type 2 diabetes per patient was INR 1264.80. The mean total medical expenditure was INR 993 and nonmedical expenditure was INR 271; among the total cost, the highest share was accrued toward medicines (65%) followed by diagnostics (13.2%) and transportation (11.8%) [Table 3].

### Table 1: Sample characteristics

| Variable                        | Percentage |
|---------------------------------|------------|
| **Sample background**           |            |
| Age distribution (years)        |            |
| 20-40                           | 12.1       |
| 40-60                           | 62.1       |
| 61+                             | 25.7       |
| Sex                             |            |
| Male                            | 62.6       |
| Female                          | 37.4       |
| Education                       |            |
| Illiterate                      | 6.8        |
| Literate without formal schooling| 2.9        |
| Primary                         | 19.9       |
| Middle                          | 23.8       |
| Higher secondary                | 30.6       |
| Graduate                        | 16         |
| Occupation                      |            |
| Labor                           | 28.2       |
| Employed                        | 39.3       |
| Others                          | 32.5       |
| **Diabetes background**         |            |
| Duration (years)                |            |
| 1-5                             | 52.9       |
| 6-10                            | 28.2       |
| >10                             | 18.9       |
| Complication                    |            |
| Renal                           | 26.7       |
| Cardiovascular                  | 23.3       |
| Foot                            | 12.7       |
| Retinol                         | 10.9       |
| Presence of above two complication| 1.8       |
| Other                           | 45.4       |
| Family history                  |            |
| Father                          | 31.6       |
| Mother                          | 44.6       |
| Both parents                    | 35.4       |
| Siblings                        | 7.7        |
| Treatment pattern               |            |
| OHA                             | 49.5       |
| Insulin                         | 40.3       |
| OHA + insulin                   | 10.2       |

### Table 2: Availability of medical service and resource utilisation in last visit (%)

| Service                        | Free | Partly free | On payment |
|--------------------------------|------|-------------|------------|
| Medicine                       | 1    | 42.7        | 55.8       |
| X-ray/ECG/EEG/scan              | 0.5  | 0.5         | 98.5       |
| Other diagnostic test           | 0    | 0           | 100        |

\(\text{ECG}: \text{Electrocardiogram}; \text{EEG}: \text{Electroencephalography}\)
diabetes for 10 years or more, the cost was INR (1509.9 ± 804.5) per month [Table 4].

The OOP expenditure among patients with reported complication was INR (1649.7 ± 760.3) and among those without complication was INR (1124.6 ± 509.6). The difference in OOP expenditure between two groups was statistically significant.

It was found that among 62% of the patients, adherence to medication was low; among 23% patients, it was medium and among 15% it was high [Table 5]. Males reported comparatively higher adherence than females.

It was observed that in relation to education, the people who had completed higher secondary reported better adherence than those who were illiterate. And those who were graduate reported better adherence compared with those completed higher secondary. Thus, revealing a biological gradient or dose–response relation between level of education and medication adherence.

According to occupation, medication adherence can be summarized as 71% patients with low adherence, 16% patients with medium adherence, and 13% with high adherence. In case of employed, 58% showed low adherence, 25% medium adherence, and 16% high adherence. And with others (housewife and employed), low adherence was with 60% cases, 28% medium adherence, and 12% high adherence.

It was found that among those recently detected of diabetes, adherence was high among 14%, medium among 21%, and low among 67% of the population. Among those suffering diabetes for the past 5–10 years, adherence was high only among 12%. Adherence to medication was comparatively high among patients with diabetes for more than 10 years, the proportion being 21%.

Adherence to medications was higher among patients with reported complications compared with those without complications, the proportion being 15% and 14%, respectively. The group with medical complications had also showed positive results in terms of better adherence to prescribed medications.

**Discussion**

This study, based on primary data from a tertiary care hospital in Odisha, has generated evidence about OOP expenditure of the patients availing outpatient care and also studied adherence to medicine among those patients. In a state like Odisha where the majority of the population belong to low-income group, the expenditure occurring for diabetes is becoming a major burden for individual and to the society.

From this study, it was found that the average OOP expenditure of an individual toward diabetes care was INR 1264 per annum, which is similar to the study findings by Kumar and Mukherjee in the year 2014, according to which the mean expenditure was INR 920. The findings from this study also revealed that with progress in the stage of the disease, the OOP expenditure also increased. The OOP expenditure was found to be higher by an amount of INR 525 among population with complications compared with those without complications. This is also in consonance with the result published by Akari et al. Moreover, there are also studies

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**Table 3: Out-of-pocket expenditure with type 2 diabetes mellitus patients in last visit**

|               | Mean±SD   | Median | Range     | 95% CI     |
|---------------|-----------|--------|-----------|-------------|
| Medicine      | 824.91±561.17 | 705    | 0-3127    | 747.83-902.00 |
| Diagnosis     | 168.49±167.26  | 80     | 40-1200   | 145.51-191.46 |
| Total medical | 993.3981±592.857 | 848    | 80-3507   | 911.9853-1074.83 |
| Transport     | 150.29±101.452 | 100    | 30-1000   | 136.35-164.23 |
| Other         | 121.12±70.650  | 100    | 0-500     | 111.41-130.82 |
| Total nonmedical | 271.4078±151.191 | 250    | 50-1200   | 250.63-292.17 |
| Total         | 1264.8058±629.768 | 1126   | 350-4707  | 1178.29-1351.31 |

SD: Standard deviation; CI: 95% confidence interval

**Table 4: Variation in out-of-pocket expenditure across different patient groups**

| Duration of diabetes (years) | Mean±SD | 95% CI | Median | Range | P  |
|------------------------------|---------|--------|--------|-------|----|
| 1-5                          | 1181.18±537.16 | 1079.19-1283.16 | 1110 | 369-2636 | 0.265 |
| 6-10                         | 1257.15±627.43  | 1092.18-1422.13  | 1110 | 505-4707 | 0.161 |
| >10                          | 1509.89±804.49  | 1249.10-1770.68  | 1466 | 350-3210 | 0.841 |

Complication

| Present | 1649.72±760.38  | 1444.16-1855.28  | 1560 | 369-4707 | 0.002 |
| Absent  | 1124.60±509.67  | 1042.64-1206.55  | 1080 | 350-2570 |

SD: Standard deviation; CI: 95% confidence interval

**Table 5: Variation in medication adherence level among study subjects**

| Sex        | High adherence (%) | Medium adherence (%) | Low adherence (%) | P   |
|------------|--------------------|----------------------|------------------|-----|
| Male       | 15                 | 19                   | 66               | 0.161 |
| Female     | 14                 | 33                   | 32               |     |

Duration of diabetes (years)

| 1-5 | 14 | 21 | 67 | 0.447 |
| 6-10| 12 | 21 | 67 |
| >10 | 21 | 32 | 46 |

Complication

| With complications | 15 | 26 | 59 | 0.841 |
| Without complications | 14 | 22 | 63 |

Education

| Illiterate | 13 | 13 | 75 | 0.917 |
| Up to higher secondary | 14 | 25 | 61 |
| Graduate and above | 16 | 20 | 64 |
that have proven that presence of complications further increases the cost of treatment.\cite{7,30,31,32} An independent association was demonstrated between total cost and complications ($P = 0.012$) by Andayani \textit{et al.} and Redekop \textit{et al.} (2002).\cite{7,30,31}

A decomposition of the OOP among different headings revealed that the majority (65\%) of the cost was due to purchase of drugs followed by diagnostics, which is similar to findings by other researchers.\cite{8} In the state, overall, OOP expenditure constitutes 76\% of the total health expenditure, of which 58\% was toward drugs. The findings from this study further reinforce the fact that people in Odisha incur huge OOP expenditure due to drugs. Such findings from the premier medical college hospital of the state underline the fact that the government has not yet taken up the matter as seriously as is the requirement.\cite{21}

There is no denying the fact that the government has established a free drug distribution center – “Niramaya” for the poor, but it has also been realized that most of the time there is shortfall of drugs. And whatever few generic medicines are available, those are rarely prescribed by the physicians. Insulin being the most requisite drug was also, reportedly, out of stock at times as a result patients had to pay for it.

However, some blame for high OOP may also be attributed to the fact that the majority of the patients were unaware of the availability of free insulin and generic drugs at the drug distribution center. Which is perhaps due to the biological gradient between education/ knowledge and adherence to medication, as established in this study and also other studies in different parts of the country.\cite{29}

As evident from the results, diagnostic tests also play a major role in expenditure.\cite{22,34} People generally prefer private laboratories despite high cost to avoid the usual delay in government pathology laboratories for various activities such as collection and report despatch. The laboratory investigation at the government hospitals is free of cost for BPL categories. But most of the patients were unaware about it, and some patients although aware did not prefer the service as they perceived the system to be very complicated and time taking.

With regard to adherence to prescribed medication, it was found that only 30\% people reported high adherence to medications. Some of the reasons or predictors of poor adherence may be high pill burden, complexity of drug regimens, forgetfulness, high cost of medications, presence or perceived fear of adverse effects, and poor knowledge about the disease condition. In lower-income groups, the cost of medications may be a reason behind lack of adherence. Interaction between patients with diabetes and their healthcare providers has also been shown to have an impact on adherence to medication.\cite{35}

### Conclusion

The current scenario of diabetes in India is likely to worsen in the coming decade. The maximum number of people with diabetes belong to the 40–59 years age group.\cite{36} Worryingly diabetes is now being found to be associated with a spectrum of complication\cite{8,36} (https://www.sciencedirect.com/topics/medicine-and-dentistry/complications-of-diabetes-mellitus) occurring mostly at a relatively younger, productive, age group and is also expected to increase tremendously by 2025.\cite{8} Therefore, immediate health policy restructuring and investment is needed to control the economic burden of the patient.\cite{7}

Strategies aiming to reduce the escalating cost burden must focus on achieving targeted glycemic control\cite{8,37} as defined by the ICMR criteria, prompt and effective management of complications operationalize regular and early screening for complications.\cite{8} Strategies should include a reduction in complexity of the prescription regimen, educational initiatives, improved doctor–patient communication, reminder systems, and reduced costs. Patients presenting with DM must be initially encouraged to maintain a healthy diet and exercise regimen,\cite{8} followed by early medication that generally includes one or more oral antidiabetic drugs and later may include an injectable treatment. The government should take measures to increase expenditure in health sector to equip the presently ill-equipped health facilities for better management of the disease\cite{8} and educate people, given the derived evidence of relation between education and adherence from the study, for diabetes prevention.\cite{8}

Finally, this study based upon primary data collected from the outpatient center of a tertiary care hospital has generated evidence on OOP on diabetes care and drug adherence by patients, which could be useful to design intervention strategies to reduce OOP for a disease which is disproportionately affecting poor. The limitation of the study was relatively small sample size, since the study setting was only one public hospital; the concerns and barriers might not be generalized beyond the studied population. The results might be biased by socially acceptable statements rather than actual practices. However, to minimize such biases, the researcher had checked the physician prescription and asked for the last month expenditure.

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### Conflicts of interest

There are no conflicts of interest.
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