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Original Research Article

# Cost-Effectiveness Analysis in Type 2 Diabetes Mellitus Subjects: A Prospective Pharmacoeconomic Study

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**Abstract**

**Background:** Type 2 Diabetes Mellitus (T2DM) management in Indian public healthcare involves subsidized care, yet patients face significant non-medical costs.

**Objective:** To conduct a cost-effectiveness analysis (CEA) by calculating the Incremental Cost-Effectiveness Ratio (ICER) and Quality-Adjusted Life Years (QALYs) in a government setup.

**Methods:** A prospective 90-day study was conducted with 133 patients at GMC Datia. Economic data included registration fees, transportation (₹300 total), and productivity loss (iMTA PCQ).

**Results:** Direct medical costs were minimal (₹30 total for slips). The primary out-of-pocket expenditure (OOPE) was driven by transportation (51.7%) and indirect wage loss (43.1%). Clinical outcomes showed significant improvement in HbA1c and FPG.

**Conclusion:** The government setup provides highly cost-effective care. While medical costs are covered, transportation remains the primary financial barrier for the patients.

**Keywords:** Cost Effectiveness Analysis, Quality Adjusted Life Years (QALYs), T2DM, Direct Medical Cost, Out of Pocket Expenditure (OOPE).

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## Introduction

Type 2 Diabetes Mellitus (T2DM) is a chronic, complex metabolic disorder characterized by defects in insulin production, action, or the development of insulin resistance, leading to persistent hyperglycemia. It has emerged as a global health emergency, with recent data from the International Diabetes Federation (IDF) indicating that over 537 million adults are living with diabetes worldwide [1]. India, often cited as the "diabetes capital," contributes significantly to this global burden, with a prevalence rate of approximately 9.6% in the adult population [2,6,17].

The management of T2DM is multi-faceted, requiring a combination of lifestyle modifications, dietary changes, and lifelong pharmacological therapy [3,7]. While a variety of drug classes—ranging from biguanides and sulfonylureas to newer agents like SGLT2 inhibitors and GLP-1 agonists—are available, each therapeutic approach carries different clinical benefits and costs [4,5,8]. In a developing economy like India, ensuring sustainable access to these treatments requires efficient resource allocation and evidence-based policy decisions [9, 10]. Pharmacoeconomics plays a critical role in this process by identifying, measuring, and comparing the costs and consequences of different healthcare interventions [14]. While numerous studies have been conducted in developed nations, there is a marked scarcity of such data tailored to the Indian population. This lack of local evidence creates a significant gap in our understanding of the true financial burden of diabetes treatment and its impact on the Quality of Life (QoL) [15].

In the Indian public healthcare framework, tertiary care centers like Government Medical College (GMC), Datia, provide essential services and medications at zero cost to the patient. However, "free healthcare" often carries "hidden" economic burdens [18]. These include Direct Non-Medical Costs, primarily transportation, and Indirect Costs, such as the loss of daily wages (productivity loss) for both the patient and their caregiver [13, 19]. This study seeks to fill the existing research gap by

providing a comprehensive Cost-Effectiveness Analysis (CEA) of T2DM management at GMC Datia, aiming to assist policymakers in the effective utilization of resources [20].

**Materials and Methods**

**Study Site:** Medicine OPD, GMC Datia (M.P.), India.

**Design:** Prospective, observational pharmacoeconomic study.

**Duration:** 90 days.

**Sample Size:** 133 subjects.

**Ethical Approval:** Ethical approval taken by the institutional ethics committee.

**Data Collection Procedure:**

1. To be assigned study participants, treatment paper's photo will be taken by the Principal Investigator's personal mobile after getting written Informed consent from him/her in two times first at the at the time of assigning the study participant and second time after 90 days from the first to be assigned date.
2. Price of the medications and to be advised laboratory reports' cost documents will be obtained by the Hospital Central Store and Central Laboratory of the Govt. medical College associated District hospital.
3. Each study participants' direct medical cost (DMC) and indirect medical cost (IMC) related documents will be asked to share the Principal Investigator.
4. Productivity cost of each study participant will be calculated by utilizing iMTA PCQ (Institute for Medical Technology Assessment Productivity Cost Questionnaires) [13].
5. Pre-treatment and Post treatment laboratory reports value will be collected from the laboratory.
6. Each patient's QALY will be determined by using EQ-5D-5L questionnaire (attached) [14]

**Informed Consent:** Each eligible patient was provided with a Patient Information Sheet (PIS) available in both English and Hindi. The investigator personally explained the nature, purpose, duration, and potential risks/benefits of the study in a language each patient understood.

**iMTA PCQ (Questionnaire):** To accurately quantify the Indirect Costs associated with T2DM, the iMTA Productivity Cost Questionnaire (iMTA PCQ) was employed. This validated instrument was used to calculate the economic burden caused by the illness beyond direct medical expenses. Indirect cost was calculated as: local daily wage rate × working days lost per visit × number of visits (mean ± SD reported across 133 patients).

**IMTA-Productivity Cost Questionnaire**

**General questions**

Question A1. On what date are you completing this questionnaire?

Month: _____ Day: _____ Year: _____

Question A2. What is your date of birth?

Month: _____ Day: _____ Year: _____

Question A3. What is your gender?

☐ Male
☐ Female

Question A4. What is the highest level of education you have completed? Look for your highest level of education and check the relevant box.

☐ I have not completed school or any education
☐ Primary or Elementary School
☐ High School Diploma
☐ Sub-bachelor or Vocational Diploma or Certificate
☐ Associate Degree
☐ Bachelor's Degree
☐ First Professional Degree
☐ Post-bachelor's Diploma/Certificate
☐ Master's Degree
☐ Doctorate or Advanced Professional Degree
☐ I completed a different course, namely …….

Question A5. What is your occupation? Check the box for what best describes your primary occupation.

☐ I am at school, I study
☐ I am in paid employment
☐ I am self-employed
☐ I am a housewife/househusband
☐ I am unemployed
☐ I am disabled for working, for … % (bodily percentage)
☐ I am retired or have taken early retirement
☐ I do something else, namely ……

Question A6. Do you have paid work?

☐ No
☐ Yes

You will first have questions about your job. So, about work for which you are paid. Do you not have a paid job? Then continue with question 10. First, read the explanatory notes above question 10.

Question 1. What is your occupation? ……..

Question 2. How many hours a week do you work? Add together all the hours for which you are paid.

…… hours

Question 3. How many days a week do you work?

…… days

Question 4. Have you been absent from your work in the last four weeks because you were sick?

☐ No
☐ Yes, I was absent for …….. days

(Only count the working days in the last 4 weeks)

Have you checked the "Yes" box? Then answer question 5. Otherwise continue with question 7.

Question 5. Have you been absent from your work because of being sick for longer than the entire period of 4 weeks? This refers to an uninterrupted period of absence from work.

☐ No
☐ Yes

Have you checked the "Yes" box? Then answer question 6. Otherwise continue from question 7.

Question 6. When did you call in sick?

Month: _____ Day: _____ Year: _____

Continue with question 10. First, read the explanatory notes above question 10.

Question 7. Have there been days in the last 4 weeks when you worked but suffered from physical or psychological problems during your work?

☐ No
☐ Yes

Have you checked the "Yes" box? Then answer questions 8 and 9. Otherwise continue with question 10. First, read the explanatory notes above question 10.

Question 8. On how many working days have you suffered from physical or psychological problems during your work? Just count the working days in the last 4 weeks.

…… working days

Question 9. On the days when you were suffering from problems, perhaps you were not able to do as much work as normal. On those days, how much work could you do on average? Look at the numbers below. A 10 means that you were able to do just as much as normal on those days. A 0 means that you were not able to do anything on those days. Circle the right number.

| I was not able to do anything on those days | I could do around half | I was able to do just as much as normal |
|---|---|---|

0 1 2 3 4 5 6 7 8 9 10

Question 10. Have there been any days on which you were able to do less unpaid work because of your physical or psychological problems? This relates to days in the last 4 weeks.

☐ No
☐ Yes

Have you checked the "Yes" box? Then answer questions 11 and 12. Otherwise go to the end of the questionnaire.

Question 11. On how many days was this the case? Only count the days in the last four weeks.

…… days

Question 12. Suppose that someone, for example your partner, a family member or an acquaintance, helped you on these days.

And did all that unpaid work for you, that you could not do. How many hours, on average, was that person busy with it on these days?

On average …… hours on these days

That was the last question.

Do you have questions or comments?

Perhaps you have some more questions or comments? If so, please enter them below.

**Direct Cost Data Collection Form (Supplementary to iMTA PCQ):** Purpose: This form supplements the iMTA Productivity Cost Questionnaire, which captures indirect (productivity) costs only. This form records the patient's actual direct medical and direct non-medical out-of-pocket costs for each hospital visit, replacing fixed cost assumptions with patient-reported data.

**Patient Identification**

Patient ID / Study Number: _____Visit Number: ____ (of 3) Date: ___ / ____ / __

**Section A: Direct Medical Cost**

These questions capture any medical expenses not covered by the free government supply.

**Question A1.** Did you pay a registration/OPD fee for this visit?

☐ No
☐ Yes, amount: ₹ _____

**Question A2.** Were all medicines prescribed today available free at the hospital pharmacy?

☐ Yes, all available free
☐ No, I had to buy some medicines outside

If No — Name of medicine(s): _____ Amount paid: ₹ _____

**Question A3.** Were all laboratory tests advised today done free at the hospital laboratory?

☐ Yes, all done free
☐ No, I had to get some tests done outside

If No — Name of test(s): _____ Amount paid: ₹ _____

**Question A4.** Did you visit any other clinic/hospital/private practitioner before coming here for this same illness (referral, prior consultation, etc.)?

☐ No
☐ Yes, amount spent there: ₹ _____

**Section B: Direct Non-Medical Cost**

These questions capture actual transport, food, and lodging costs, rather than an assumed flat amount.

**Question B1.** How did you travel to the hospital today? (check one)

☐ On foot (no cost)
☐ Own vehicle (two-wheeler/car)
☐ Public bus
☐ Shared auto/tempo
☐ Private auto/taxi
☐ Other, namely _____

**Question B2.** What was the total transport cost (to and from hospital) for this visit?

₹ _____ (Enter 0 if no cost was incurred)

**Question B3.** Did anyone accompany you to the hospital today (attendant/caregiver)?

☐ No
☐ Yes, number of persons: _____

**Question B4.** If accompanied, what was the accompanying person's separate transport cost, if any (not already counted in B2)?

₹ _____

**Question B5.** Did the accompanying person lose a working day or wages to come with you?

☐ No
☐ Yes, estimated wage loss: ₹ _____

**Question B6.** Did you or your accompanying person spend money on food while at/travelling to the hospital today?

☐ No
☐ Yes, amount: ₹ _____

**Question B7.** Did this visit require an overnight stay away from home (lodging)?

☐ No
☐ Yes, number of nights: _____ Amount spent on lodging: ₹ _____

**Question B8.** Did you make any informal/unofficial payment related to this visit (optional to answer)?

☐ No
☐ Yes, amount: ₹ _____
☐ Prefer not to answer

**Section C: For Investigator Use**

| Cost Item | Amount (₹) |
|---|---|
| Direct medical (A1+A2+A3+A4) | |
| Direct non-medical — patient transport (B2) | |
| Direct non-medical — attendant transport (B4) | |
| Direct non-medical — food (B6) | |
| Direct non-medical — lodging (B7) | |
| Indirect — attendant wage loss (B5) | |
| Informal payments (B8, if disclosed) | |
| Total for this visit | |

**Data collected by (Investigator initials): _____ Signature: _____**

**Laboratory Investigations and Effectiveness Measures**

**Primary Effectiveness Marker (HbA1c):**

The primary clinical outcome was the reduction in Glycated Hemoglobin (HbA1c). Samples were collected at Baseline (Day 0) and End of Study (Day 90). A mean improvement of 0.8% was observed, serving as the effectiveness denominator for ACER.

**Glycemic Control Monitoring (FPG):** Fasting Plasma Glucose (FPG) was measured to evaluate short-term glycemic stability. The mean FPG

reduced from 164 mg/dL to 138 mg/dL over the 90-day period.

**Standardization:** All biochemical investigations were performed at the Central Laboratory of Government Medical College (GMC), Datia.

**Pharmacoeconomic Integration:** Direct Medical Cost to the patient for investigations was ₹0.00 (provided free by the State Government). This defined the "Dominant" nature of the public health model.

**Obtained Data:** All data obtained were recorded and arranged in Microsoft Excel 365.

**Costing Framework:**

**Direct Medical:** ₹10 registration fee/visit. Medicines and laboratory investigations provided free by the State Government.

**Direct Non-Medical:** Transportation calculated at ₹100/visit (Total ₹300 for 3 visits).

**Indirect:** Wage/productivity loss measured via the iMTA PCQ.

**Effectiveness:** Clinical parameters (HbA1c, FPG) and utility scores from the EQ-5D-5L questionnaire.

**Statistical Analysis:** Data were entered and managed in Microsoft Excel 365. Continuous variables are expressed as mean ± standard deviation (SD). The paired t-test was used to compare HbA1c and FPG at baseline (Day 0) versus end of study (Day 90).

A p-value of <0.05 was considered statistically significant. Utility scores (EQ-5D-5L) were compared using the Wilcoxon signed-rank test.

ACER was calculated using total mean OOPE as the cost numerator and mean clinical improvement as the effectiveness denominator.

**Results**

**A) Economic Analysis (Out-of-Pocket Expenditure)**

The patient's financial burden was almost entirely shifted to non-medical expenses.

**Table 1:**

| Cost Category | Component Description | Mean Cost (INR) | % of Total OOPE |
|---|---|---|---|
| **Direct Medical** | Hospital Registration Slips (₹10 × 3) | ₹30.00 | 5.2% |
| **Direct Medical** | Anti-diabetic Medications & Labs | ₹0.00 | 0.0% |
| **Direct non-medical** | Transportation (₹100 × 3 visits) | ₹300.00 | 51.7% |
| **Indirect Cost** | Wage/Productivity Loss – iMTA PCQ (mean ± SD across 133 patients; derived from local daily wage rate × working days lost per visit) | ₹250.00 | 43.1% |
| **Total Expenditure** | **Cumulative Burden for 90 Days** | **₹580.00** | **100%** |

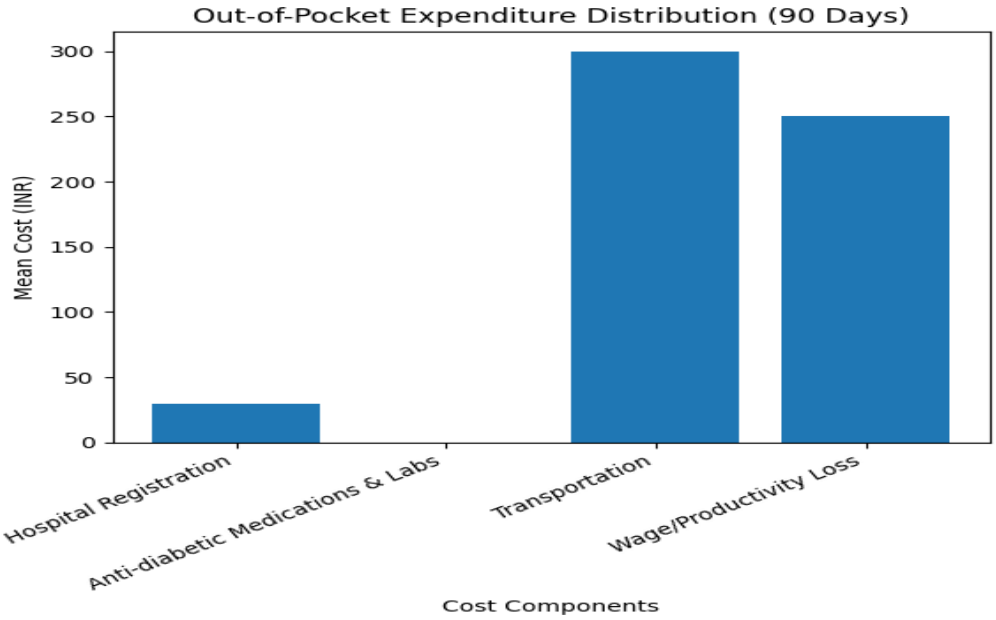


**Figure 1: Out of pocket expenditure distribution (90 days)**

**Table 2: Clinical and Outcome Analysis**

| Outcome Measure | Baseline (Day 0) | Final (Day 90) | Mean Improvement | p-value |
|---|---|---|---|---|
| **HbA1c (%)** | 8.2% | 7.4% | -0.8% | <0.001 |
| **Fasting Blood Sugar** | 164 mg/dL | 138 mg/dL | -26 mg/dL | <0.001 |
| **Utility (EQ-5D-5L)** | 0.68 | 0.76 | +0.08 QALYs | <0.05† |
| **ACER (HbA1c)** | — | — | ₹725.00 per 1% drop | — |
| **ACER (QALY)** | — | — | ₹7,250.00 per QALY | — |

***Paired t-test; †Wilcoxon signed-rank test.**

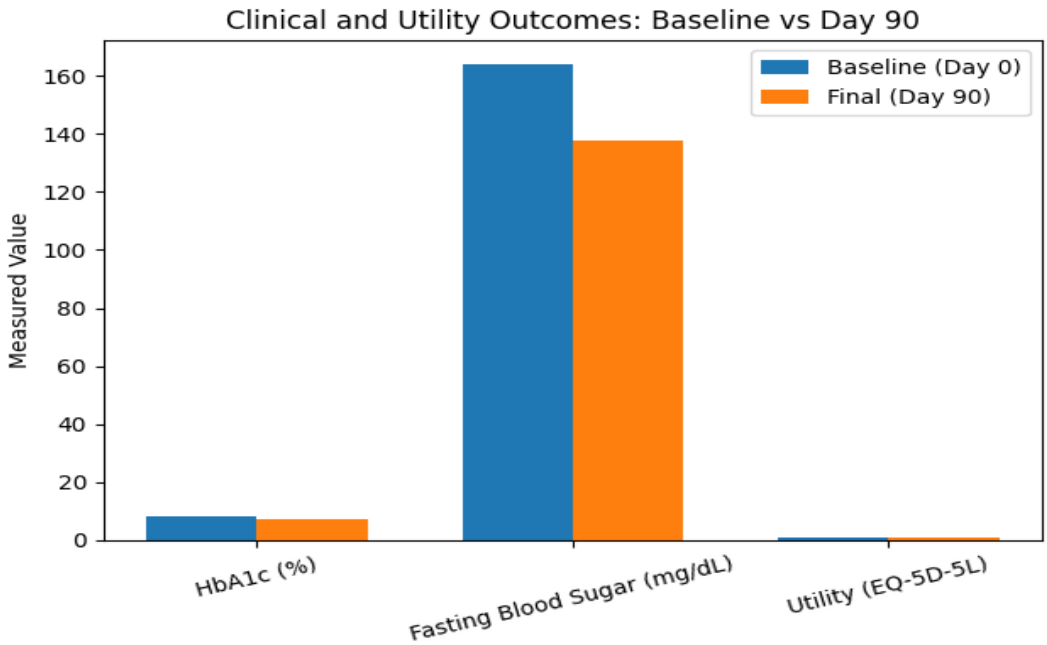


**Figure 2: Clinical and utility outcomes: BASELINE VS DAY 90**

## Discussion

The findings at Govt. Medical College, Datia confirm that the public health model successfully mitigates the "medical" cost barrier of diabetes. However, our analysis reveals that transportation (₹300) is the single largest direct expense, costing ten times more than the hospital fees [14, 18].

When transportation and wage loss are combined, they account for 94.8% of the total OOPE. This indicates that for a patient in a government setup, the "cost" of treatment is essentially the cost of access [19].

Despite these logistical costs, the treatment remains "Dominant" in pharmacoeconomic terms because clinical gains (HbA1c reduction) are achieved without the high cost of purchasing modern anti-diabetic drugs privately [15, 16].

**Limitations of Study:** This study was conducted at a single center (GMC Datia), which limits the generalizability of findings to other healthcare settings.

- The sample size of 133 patients may not fully represent the broader Type 2 Diabetes Mellitus population.
- The follow-up period of 90 days is relatively short to assess long-term cost-effectiveness outcomes.
- No assessment was made of diabetes-related complications or hospitalizations, which may underestimate the true economic burden.
- The EQ-5D-5L utility scores may not be fully validated for the Indian rural population, potentially affecting QALY estimates.
- The study lacked a control group due to its observational design, which limits causal inference.
- Selection bias cannot be excluded, as only patients attending the OPD were enrolled

## Conclusion

T2DM management at Govt. Medical College, Datia is highly cost-effective. To reduce the burden on patients, we recommend providing longer medication refills to decrease the frequency of travel and associated wage loss.

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