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Bridging Evidence Gaps in Diabetes Devices in India: The Role of HTA in Policy and Value Assessment

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Abstract:

The prevalence of diabetes in India is rising rapidly, which results in substantial economic burden and productivity loss. Diabetes devices including continuous glucose monitors (CGMs), insulin pumps, and smart insulin pens, are critical for effective diabetes management. However, they remain underutilized due to high out-of-pocket expenditures, limited insurance coverage, and regional disparities in healthcare access. This paper highlights the need for economic evaluation of diabetes management devices in the Indian healthcare setting to improve accessibility and health outcomes. This paper also provides actionable insights for strengthening health technology assessment guidance for diabetes devices such as the need to establish real-world evidence (RWE) registries, incentivize local manufacturing, and integrate cost-effectiveness assessment into national/state health policy programs to improve access. We also provide guidance for future research to strengthen public-private partnership and incorporation of equity considerations in policy development. Strengthening economic evaluation is essential to achieve sustainable diabetes care in India.

Keywords: diabetes management devices; smart insulin pens; health technology assessment; health equity; healthcare policy; real-world evidence registries

1. Introduction

In India, diabetes is the leading public health concern and results in considerable morbidity and mortality [1]. The high prevalence may be attributed to urbanization, which has led to the rise of sedentary lifestyles and changing dietary patterns [2]. According to the Indian Council of Medical Research–India Diabetes (ICMR-INDIAB) study, in 2021, about 101 million adults were living with diabetes in India [1]. Additionally, the prevalence of diabetes in India has been

reported to have nearly doubled, from being about 3,141 per 100,000 in 1990 to 5,804 per 100,000 in 2021 [2]. The ICMR-INDIAB study reported a significantly higher prevalence of diabetes in urban areas (16.4%) than in rural areas (8.9%) of India, whereas prediabetes prevalence was comparable between urban (15.4%) and rural (15.2%) areas. Overall, the prevalence of prediabetes (15.3%) exceeded that of diabetes (11.4%), highlighting a substantial population at risk of developing diabetes [1]. These findings highlight an urgent need for better management of T2DM in the Indian population to tackle this public health crisis.

Diabetes can result in severe complications, which place a significant financial burden on patients, caregivers, communities, and the healthcare system. Uncontrolled diabetes can result in cardiovascular disease, nephropathy, retinopathy, neuropathy, and amputations [3], [4]. A recent community-based study among patients with T2DM in urban Northern India estimated the total annual costs associated with type 2 diabetes in India to be ₹17,113, with out-of-pocket costs approximately being ₹10,424 [5]. Separately, another study conducted in Punjab reported that direct costs associated with diabetes have more than doubled over the last two decades, from approximately ₹15,460 in 1999 to ₹34,100 in 2021 [6]. Although these estimates are not directly comparable due to differences in study populations, settings, and cost measures, they highlight the substantial financial burden of diabetes care in India. Thus, there is an unmet need for policies addressing affordability and equity in diabetes care, specifically, diabetes monitoring.

Medical devices can play a critical role in all aspects of diabetes care [7]. Blood glucose meters and continuous glucose monitors (CGM) help patients track blood glucose levels through individual measurements and continuous monitoring, respectively, while insulin delivery technologies, including insulin pumps and connected insulin pens facilitate insulin administration and support more precise insulin dosing [8]. These devices support patients and healthcare providers in monitoring glucose levels, identifying episodes of hyperglycemia and hypoglycemia, and optimizing diabetes management, if utilized consistently and appropriately [9]. Therefore, in order to shift the diabetes management approach from reactive to proactive, such medical device technologies are essential.

2. Types of Diabetes Management Devices

A wide range of devices now available to help glucose monitoring, insulin delivery, and integrated digital solutions. These devices not only improve glycemic control but also enhance convenience, patient engagement, and quality of life [10]. The major categories of diabetes management devices are described below. (Figure 1)

2.1 Self-Monitoring of Blood Glucose (SMBG)

Self-monitoring using glucometers and test strips is the one of the most traditional approaches to glucose monitoring. SMBG requires patients to obtain a blood sample by pricking their finger and then use the device to assess the blood glucose level. SMBG is widely used due to its affordability and accessibility, as they are portable and provide quick point-in-time readings [11]. However, they are associated with challenges. Adherence poses a significant challenge when using SMBG due to the need for frequent testing which is also an issue if the patient is at work or travelling [12]. Other issues include inconsistency of readings, anxiety, and hesitance associated

with finger prick, which can discourage patients from consistently using the device and therefore limit its effectiveness [13], [14].

2.2 Continuous Glucose Monitoring (CGM)

Other advances in glucose sensing have been introduced to overcome the challenges with SMBG. CGM is a tool which consists of small wearable sensors inserted under the skin [15]. CGMs provide real-time glucose readings and contain provisions for alarms and alerts for hyperglycemia and hypoglycemia. They are connected with apps that collate blood glucose trend data, which can be shared real-time with the clinical team, if the patient chooses, and thus aid efficient and timely clinical decision-making. The CGMs are more useful for those requiring very careful glucose monitoring such as those with type 1 diabetes [15]. In a retrospective analysis of U.S administrative claims, Hannah et al studied 790 commercially insured, CGM-naïve adults with T2DM receiving insulin therapy. They reported that the initiation of Dexcom G6 real-time CGM was associated with a 30% reduction in proportion of patients with at least one diabetes-related emergency department visit ($p=0.01$) and a 41.5% reduction in those with at least one inpatient visit ($p<0.0001$) [16]. Flash glucose monitors (FGMs) represent a variation of CGM, which does not provide automatic alerts, but users can access their blood glucose information by scanning a sensor with a reader or smartphone. Compared to CGMs, FGMs are less expensive and are a promising option for patients who do not need round-the-clock monitoring. A budget impact analysis conducted in Germany indicated that although FGM systems might result in additional upfront costs, FGMs could be cost-saving compared with conventional SMBG among patients with T2DM receiving intensive insulin therapy, owing to reductions in hypoglycemia-related costs and healthcare resource utilization [17].

2.3 Insulin Delivery Devices.

Multiple insulin delivery options are available for patients requiring insulin therapy. Traditional insulin syringes require patients to be comfortable with administering injections which can be challenging for some patients. Most patients favor insulin pens- either pre-filled or refillable because of their ease of use and convenience. An alternative delivery method is the insulin pump which provides continuous subcutaneous insulin infusion (CSII) via a programmable device to overcome adherence challenges. Patch insulin pumps which deliver insulin directly through the skin without the need for tubing. This improves discretion and privacy in insulin administration. More recently, smart insulin pens have emerged which can be integrated with mobile applications to track insulin dosing, provide dose reminders, suggestions for appropriate bolus dose based on food intake, and can generate actionable insights for patients and providers. Among patients using CGMs, insulin smart pen use was associated with lower hypoglycemic events and lower healthcare costs [18].

2.4 Digital and Connected Solutions.

With the rise of smartphone use, digital health tools have become an increasingly important aspect of diabetes management. Mobile apps and smart platforms can now integrate with CGMs, pumps, and pens to help patients track glucose patterns, health-related behaviors, and optimize insulin dosing, etc. Wearable devices, including smartwatches and fitness trackers, are being readily adopted and these can now sync with diabetes management tools, offering real-time feedback on diabetes-related outcomes. An additional avenue for improvement in diabetes management would be linking these devices with health technologies in the clinicians' offices,

through remote monitoring platforms, to further support timely and efficient diabetes care. Table 1 describes the types of devices used in diabetes management and their application. Patient and health outcomes presented in Table 1 encompass clinical, behavioral, and patient-reported outcomes. Clinical outcomes may include HbA1c, time in range, glucose variability, and hypoglycemic events; behavioral outcomes may include adherence and self-management behaviors; and patient-reported outcomes may include treatment satisfaction, treatment burden, and health-related quality of life [19], [20], [21]. The specific outcomes and measures relevant to an economic evaluation depend on the device, population, comparator, and perspective of the assessment.

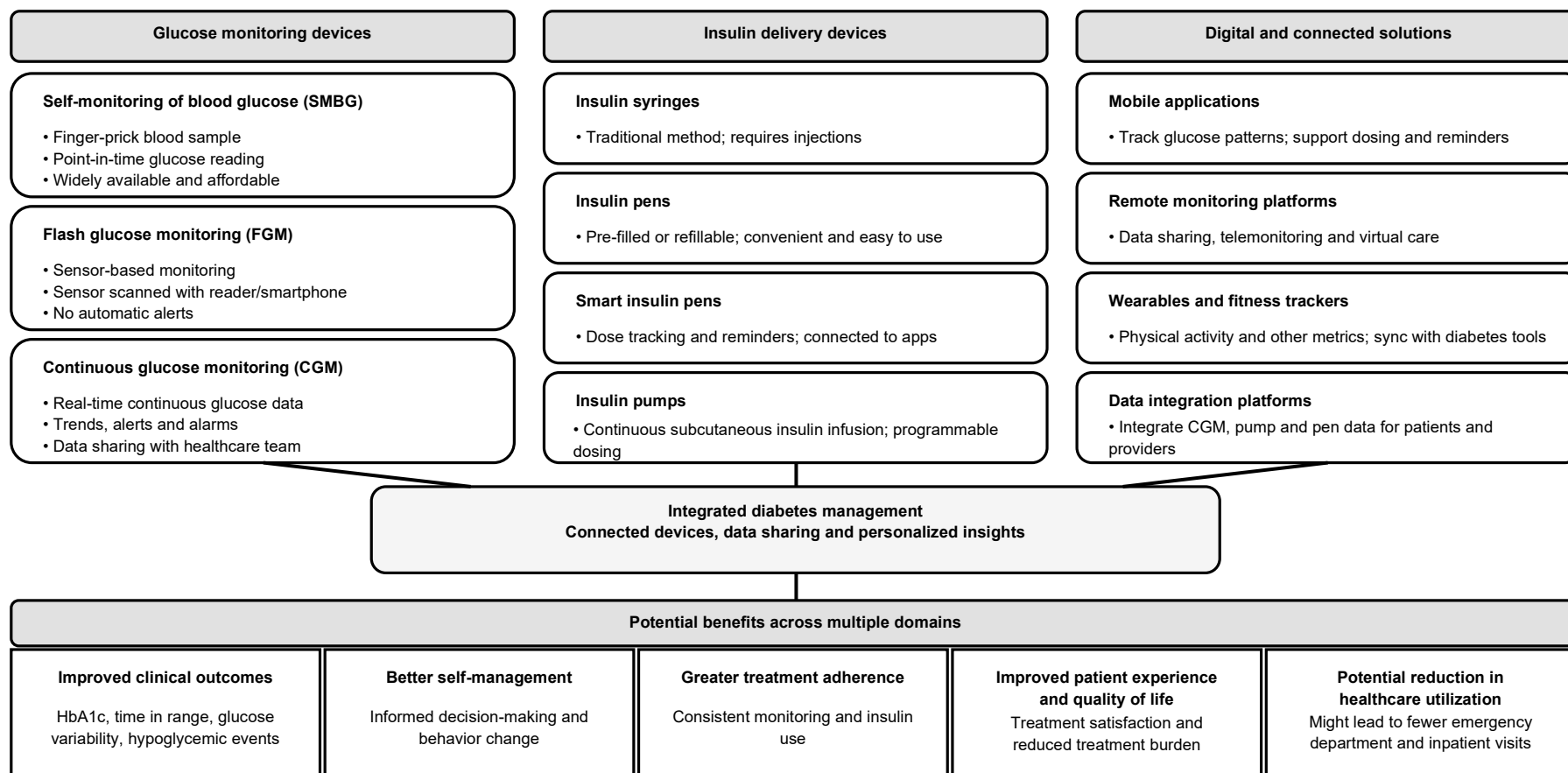
Table 1. Role of Medical Devices in Diabetes Care

Device Type	Purpose	Impact on Care Process	Example of Patient/Health Outcomes*
Self-Monitoring of Blood Glucose (SMBG)	Glucose monitoring	Home-based tracking of blood glucose Informs insulin/medication adjustments	Glycemic control: hemoglobin A1c (HbA1c) and blood glucose levels; Hypoglycemia: frequency of hypoglycemic events; Self-management: frequency of glucose monitoring and adherence to recommended monitoring
Continuous Glucose Monitors (CGMs)	Real-time monitoring & control	Provides continuous data, trend analysis, alerts for hypo/hyperglycemia	Glycemic control: HbA1c, time in range, time above/below range, and glucose variability; Hypoglycemia: frequency and duration of hypoglycemic events; Patient-reported outcomes: treatment satisfaction and health-related quality of life
Flash Glucose Monitors (FGM)	Convenient glucose checks	Quick, minimally invasive readings; encourages frequent monitoring	Glycemic control: HbA1c and time in range; Self-management: frequency of glucose monitoring and adherence; Patient-reported outcomes: treatment satisfaction and treatment burden

Insulin Pens & Smart Pens	Insulin delivery accuracy	Precise dosing, memory for dose timing/amount	Glycemic control: HbA1c; Safety: dosing errors and hypoglycemic events; Adherence: adherence to prescribed insulin regimen; Patient-reported outcomes: treatment satisfaction and treatment burden
Insulin Pumps (including patch pumps)	Advanced insulin delivery	Basal–bolus infusion mimicking physiology	Glycemic control: HbA1c and time in range; Hypoglycemia: frequency/time below range; Patient-reported outcomes: treatment satisfaction, treatment burden, and health-related quality of life; Self-management: treatment adherence
Mobile Apps & Wearables	Patient engagement	Diet, activity, and medication reminders	Self-management: adherence to medication, monitoring, diet, and physical activity recommendations; Glycemic control: HbA1c and/or time in range; Patient-reported outcomes: treatment satisfaction and health-related quality of life

**Illustrative only; not an exhaustive list*

Figure 1. Diabetes management devices and their integration in diabetes care



3. Importance of Economic Evaluation

Economic evaluation of diabetes management devices has the potential to provide insights into the affordability and impact of adopting different strategies. Common types of economic evaluations include Cost-Effectiveness Analysis (CEA), Cost-Utility Analysis (CUA), and Cost-Benefit Analysis (CBA), each providing a distinct perspective into the economic implications of interventions in question and can be tailored to diverse settings. These analyses help support informed decisions about resource allocation. Examples of economic evaluations are presented in Table 2.

Table 2. Examples of some economic evaluation methods.

Economic Evaluation	Purpose	Outcome Measure	Example
Cost-Effectiveness Analysis (CEA)	Compare the costs and health outcomes of two or more interventions to identify the option that provides better value.	Cost per unit of health outcome (e.g., cost per 1% reduction in HbA1c).	Jendle et al. reported that flash glucose monitoring using the FreeStyle Libre system was a cost-effective alternative to self-monitoring of blood glucose (SMBG) in individuals with T2DM [22].
Cost-Utility Analysis (CUA)	Incorporates both survival and quality of life into the evaluation.	Cost per quality-adjusted life year (QALY) gained.	Donlo et al. reported an incremental cost-utility ratio of €29,947 per QALY gained for continuous subcutaneous insulin infusion (CSII) compared with multiple daily injections in patients with T1DM [23].
Cost-Benefit Analysis (CBA)	Compares the monetary value of an intervention's benefits with its costs.	Net monetary benefit or benefit-to-cost ratio.	Deng et al. found that an Internet blood glucose monitoring service (IBGMS) improved health outcomes while reducing overall costs compared with routine diabetes care [24].

Economic evaluations use a range of outcome measures to determine the effectiveness of interventions and in diabetes management, the following indicators are commonly used:

- **HbA1c Reduction:** A key measure of glycemic control. Studies show that even a 1% decrease has been associated with better clinical outcomes and may contribute to lower healthcare costs in the long term [25].
- **Hypoglycemia Events Prevented:** This outcome is crucial as reducing the frequency of hypoglycemia can have an impact on healthcare utilization and thereby associated costs as it averts the needs for medical care for such events and can improve daily functioning and overall well-being for patients
- **Disability-Adjusted Life Years (DALYs) Averted:** The long-term complications associated with diabetes results in disability and reduced functioning in some patients. The concept of DALYs is often utilized to understand the potential impact of adopting a

diabetes treatment as it can reflect a comprehensive perspective of the disease burden [26].

Thus, economic evaluations can support a more informed healthcare decision-making with respect to wider adoption of diabetes management devices in India.

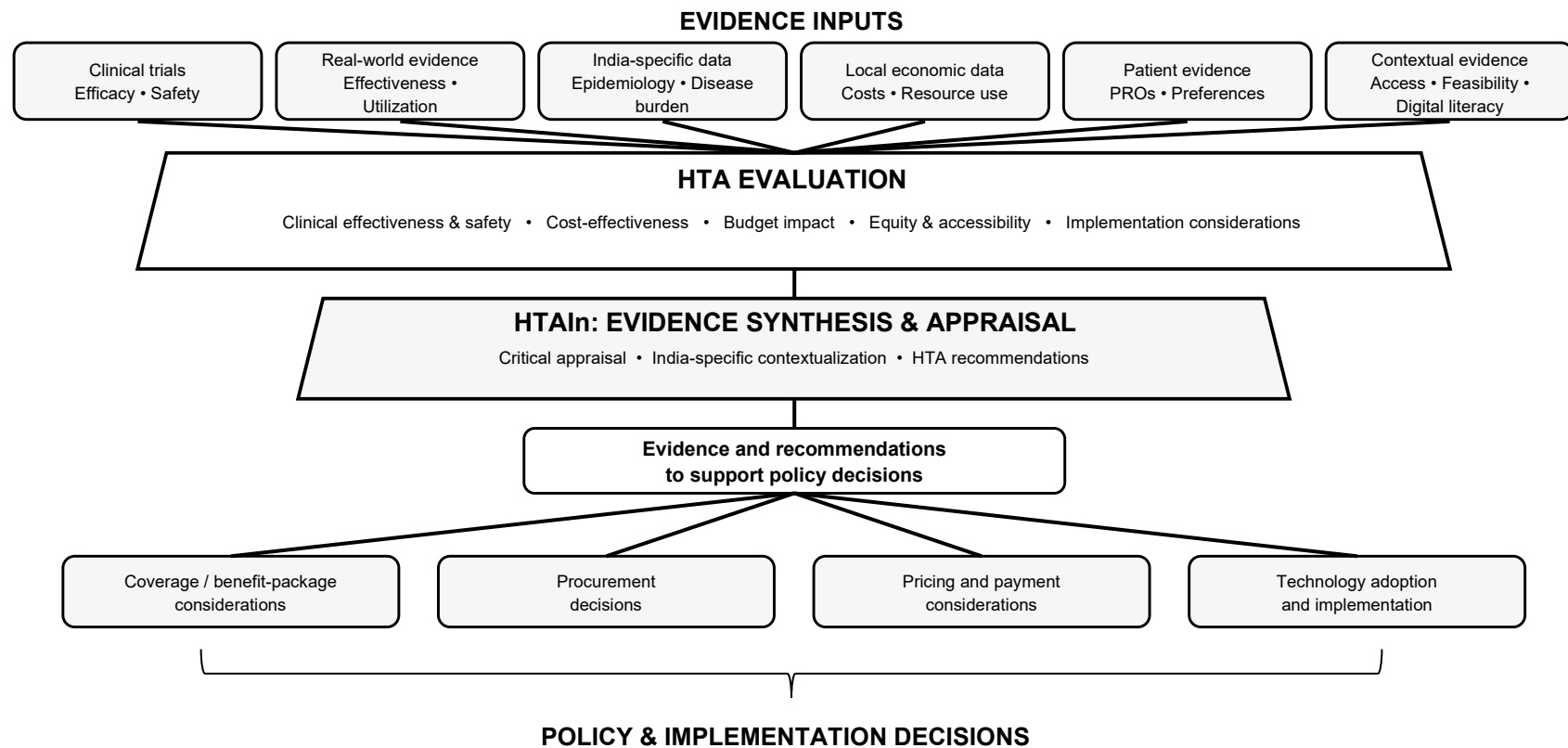
4. Health Technology Assessment (HTA) in India

The rising prevalence of diabetes in India emphasizes the need for careful evaluation of the economic and societal impact of adopting diabetes management devices, especially in the light of fragmented healthcare financing and unequal access. Although diabetes technologies improve disease management, they differ considerably in their costs, implementation requirements, and real-world performance. The advantage of adopting an HTA framework is that it enables the assessment of comparative effectiveness, full lifecycle costs (including strips, sensors, and infusion sets), and broader outcomes beyond HbA1c (e.g. time-in-range, hypoglycemic events, hospitalizations, quality of life, and productivity). However, in a setting as diverse as India, HTA frameworks also need to reflect the gaps between urban and rural healthcare access, differences in digital literacy, and the affordability, among other factors. Real-world health outcomes data can be crucial in informing the HTA about diabetes devices utilizing methods such as scenario analyses for specific contexts (e.g. evaluating the effects of price caps or local manufacturing), can provide a clearer understanding of what is practical in the local context. HTA helps us consider clinical benefits along with economic impact, enabling evidence-backed decisions around coverage, procurement, and payment approaches [27]. This helps the adoption of technologies that improve patient outcomes without placing excessive strain on individuals or the healthcare system, especially in resource-constrained settings such as India. (Figure 2)

India has established the institution, HTA in India (HTAIn) under the Department of Health Research, Ministry of Health and Family Welfare, which reflects their recognition of the importance of incorporating systematic evaluations of medical technologies into India's healthcare policy [28]. HTAIn is responsible for examining the clinical effectiveness, safety, and economic value of health technologies, with the goal of supporting evidence-based policy decisions and more efficient use of limited resources. Despite these advances, the focus of HTA assessments in India remain pharmacological medications and assessments of diabetes management devices remain relatively scarce, particularly for technologies such as insulin pumps, CGM systems, and telemonitoring platforms. This lack of device-focused HTA studies restricts informed decision-making regarding their adoption and reimbursement. Several factors might contribute to this gap, including the high cost of devices, lack of robust infrastructure to generate India-specific evidence on their real-world effectiveness and economic value, and the complexity of the healthcare system.

Addressing these gaps needs to be prioritized so that HTAs are adopted more widely in India. Policies informed by robust HTA evidence are better positioned to consider both clinical outcomes and economic value when determining coverage. HTA can also assist in identifying devices that provide the greatest benefit to patients and have a positive impact for resource allocation. Thus, further strengthening HTA efforts in India, particularly in relation to diabetes devices, will be critical in light of the growing diabetes burden.

Figure 2. Evidence synthesis through HTA for diabetes technology decision-making in India



5. Implications for Decision-Making

5.1 Strengthen reimbursement policies for devices

Payers and policymakers in India should consider HTA evidence when making reimbursement decisions for diabetes management devices, taking into account their clinical benefits, costs, and long-term impact on healthcare spending. Raviteja et al. demonstrated the clinical utility of professional CGM in glycemic management among children with type 1 diabetes mellitus (T1DM), while Shivaprasad et al. demonstrated its utility in detecting hypoglycemic episodes among patients with diabetes of the exocrine pancreas [29], [30]. Such evidence helps demonstrate how the inclusion of these findings highlights the importance of considering clinical evidence alongside economic evaluations when developing reimbursement policies for CGMs under public and private insurance programs in India.

5.2 Support value-based procurement (cost vs outcomes)

Value-based procurement decisions weigh the initial cost of devices against their long-term clinical and economic advantages. For example, a cost-effectiveness study in India found that insulin pumps, provided substantial health benefits, including better glycemic control and fewer complications, despite higher costs (around Indian rupees (INR) 1,286,215 over an 8 year modelling period), and resulted in an incremental cost-effectiveness ratio of INR 978,114 per QALY gained [31]. Such evidence can inform value-based contracting arrangements where manufacturers and payers negotiate device prices or reimbursement terms based on the health benefits achieved, potentially improving access to effective diabetes devices while managing healthcare costs.

5.3 Guide budget planning for public health programs

Economic modeling using real-world evidence (RWE) can inform national and state-level budgeting for diabetes programs. For instance, A budget impact analysis in Andhra Pradesh, India, suggested that the adoption of a mobile application-based reimbursement strategy could improve access to essential diabetes medications with an estimated additional cost of only ₹166 per eligible patient. The authors suggested that this strategy could improve access to essential diabetes medications among economically disadvantaged patients [32]. Although this study focused on medications rather than devices, it demonstrates how budget impact analyses can help policymakers estimate the financial implications of expanding reimbursement programs. Similar approaches could be applied to diabetes management devices to inform coverage decisions and budget planning.

6. Key Challenges, Recommendations & Future Directions

6.1 Limited adoption of standardized methodological guidance

There is a greater need of standardized methodological guidance for conducting CEA in India. A review of international repositories such as The Professional Society for Health Economics and Outcomes Research (ISPOR) and Guide to Economic Analysis and Research (GEAR) identified 47 economic evaluation guidelines globally up to August 2020, but none were specific to India [33]. India specific CEA guidance should specify methodological choices for the Indian context such as perspective, time horizon, discounting, and reporting standards to improve quality and comparability of economic evidence. These should be benchmarked against international

guidelines to ensure the quality of the analysis. Sharma et al. developed a standardized set of guidelines for conducting economic evaluation in India, referred to as the Indian Reference Case [33]. Further research into the applicability of the guidelines should be conducted and improved to ensure methodological rigor. Developing India-specific HTA guidelines for diabetes devices would enhance the credibility of economic evaluations.

6.2 Direct and indirect costs not well captured

A major challenge is the lack scarcity of high-quality, India-specific data to inform cost-effectiveness models. RWE on healthcare costs across Indian settings is limited. Most existing evidence is derived from small local studies or extrapolated from international sources, which may not be generalizable to the broader Indian context. Public health authorities should invest in the creation of nationally representative datasets that integrate epidemiological, clinical, and economic data such as the Medical Expenditure Panel Survey (MEPS) in the United States to enable the generation of robust, generalizable estimates [34]. Additionally, most existing studies focus narrowly on direct medical costs. Indirect costs such as productivity losses, caregiver burden, transportation expenses, and long-term disability are not well understood in India. These indirect costs are substantial in the Indian setting, where informal employment and family caregiving are common. Their exclusion can lead to an underestimation of the true economic impact of diseases and interventions. Thus, real world evidence generation needs to be robust.

To achieve this investment in local economic evaluation research is needed. Strengthening national capacity for conducting high-quality cost-effectiveness and budget impact studies play an important role in improving policy and reimbursement decisions. Partnerships across government, academia, and industry can support this effort by expanding training opportunities, encouraging responsible data sharing, and developing the research infrastructure needed for rigorous evaluation. Aligning industry incentives with public health priorities will also be important, and structured approaches such as expert consensus and Delphi panel discussions can help move this process forward. At the same time, investing in real-world data systems and device registries would allow for more comprehensive tracking of utilization patterns, clinical outcomes, and associated costs for diabetes technologies. Over time, this type of evidence can provide a stronger foundation for real-world evaluations and enable policymakers and payers to make more informed judgments about cost-effectiveness.

6.3 Regional Variability: Differences in access between urban and rural areas

India's healthcare landscape is highly diverse, and Access to diagnostic tools, medications, and advanced medical devices vary considerably between urban and rural areas. Urban centers are often well-equipped and benefit from greater availability of newer technologies, whereas rural areas frequently contend with shortages of trained providers, limited diagnostic capacity, and inconsistent access to essential medicines. Diabetes patterns also reflect this regional heterogeneity. For example, southern and western states such as Tamil Nadu and Goa have reported some of the highest incidence rates, while mortality trends are more varied [2]. In addition, disparities in smartphone ownership, internet connectivity, digital literacy, and health literacy across geographic regions, socioeconomic groups, and age populations may limit the reach and effectiveness of digital health interventions, highlighting the need for context-specific and inclusive implementation strategies to ensure equitable access to care. Failing to account for

these differences can lead cost-effectiveness analyses to overlook the barriers faced by rural populations and potentially overstate the broader benefits of certain interventions.

6.4 Affordability & Equity: High out-of-pocket costs and gaps in insurance coverage

India operates within a multi-payer healthcare system. Services are funded and delivered through a combination of public, private, and social insurance mechanisms. The public sector is funded by central and state governments, delivers care through a tiered structure including primary health centers (PHCs), community health centers (CHCs), and district hospitals. At the same time, the private sector has expanded rapidly and plays a major role in both outpatient and inpatient care, with many services financed through out-of-pocket spending. The adoption of insulin pumps, CGM systems, and other advanced diabetes technologies in India may be constrained by high upfront and maintenance costs, limited availability of trained healthcare professionals, variable access to supporting infrastructure, and challenges related to patient education and long-term device utilization, particularly in resource-limited settings

While social health insurance programs like Ayushman Bharat–(PM-JAY) and various state-level schemes have improved financial protection for some underserved populations, coverage continues to be uneven [35]. Economic evaluations should be interpreted alongside affordability and access, as favorable cost-effectiveness findings alone may not translate into equitable access. The following policy-related future directions may help address these challenges:

- HTAIn Alignment – The HTAIn mandate should be expanded to include systematic evaluation of diabetes devices, with special attention to consumable costs (test strips, sensors, infusion sets).
- Ayushman Bharat Integration – The benefits under the Ayushman Bharat PM-JAY should be expanded to include cost-effective diabetes devices such as glucometers, CGMs, and insulin pens or pumps in order to improve timely access to care for underserved populations.
- Price Regulation by the National Pharmaceutical Pricing Authority (NPPA) – Greater attention to the pricing of glucose test strips and CGM sensors, may help improve affordability of diabetes management devices for patients. Admittedly, while pricing interventions may improve affordability, excessively restrictive price controls could inadvertently affect product availability, supply continuity, and manufacturer participation; therefore, policies should balance cost containment with incentives that support local manufacturing, innovation, and sustainable market access.
- Public–Private Partnerships (PPP) – Pilot PPP models assessing the feasibility of private device manufacturers supplying CGMs and pumps to government hospitals at subsidized rates while supporting longer-term procurement arrangements need to be evaluated.
- Make-in-India Incentives – Research and development grants and tax-incentives can be planned for domestic manufacturing of strips, sensors, and pumps to reduce import dependence.

- **Digital Health Integration** – Under the Ayushman Bharat Digital Mission, the healthcare focus should be on initiative like, linking data from wearable devices with information collected in clinics and hospitals [36]. Such integration would strengthen telemedicine services, improve continuity of care, and support the development of national diabetes registries.
- **Equity-Focused Subsidies** – Targeted subsidies can be allotted to rural populations, women, and lower-income groups to address disparities in device adoption. Future HTA frameworks and reimbursement policies should incorporate explicit equity criteria, including stratification by socioeconomic status, geographic location, healthcare access, and disease burden, to prioritize high-need populations and minimize disparities in access to diabetes technologies across urban and rural settings.
- **Capacity Building for Health Economics and Outcomes Research**– There is an urgent need to invest in training public health researchers, health economists and real-world data experts in India who can carry out robust cost-effectiveness analyses. Development of such a curriculum such be prioritized by universities in India.
- **Healthcare Provider Training for Diabetes Device Adoption**: The endocrinologists primary care physicians, and appropriate paramedical staff need to be trained to recommend device use to patients with diabetes and be able to interpret the evidence from the same, to offer appropriate care.
- **School & Workplace Screening Programs** – Integrating discussions on glucose monitoring and device access into school health services and workplace wellness initiatives may help improve awareness, support earlier detection, and encourage better self-management among patients.
- **Additional Research to Address Barriers**: Future research should examine the political, economic and institutional barriers that may contribute to the differential prioritization of pharmacological therapies and medical devices within HTA in India, as such analyses could provide deeper insights into structural factors influencing evidence generation, assessment, and policy adoption of diabetes technologies.

Improving research capacity, cross-sector collaboration, and equitable access will support the effective implementation of diabetes management technologies in India. The challenges and potential strategies are summarized in Table 3.

Table 3: Key Challenges and Potential Strategies for Cost-Effectiveness Studies in India

Key Challenge	Description	Potential Strategies / Recommendations
Limited adoption of standardized methodological guidance	Limited India-specific methodological guidance for Cost-effectiveness analysis (CEA); the Indian	• Refine the Indian Reference Case to specify perspective, time horizon, discounting, and reporting standards.

	Reference Case provides an important foundation but requires broader validation and uptake	• Benchmark CEA methods in the Indian context against international best practices. • Standardize methodologies and framework for diabetes Health Technology Assessment (HTA) in India (e.g., modeling approaches, cost-effectiveness thresholds, equity adjustments). • Expand the mandate of HTA in India (HTAIn) to include evaluation of diabetes management devices. • Strengthen capacity building in HTA and health economics training within state and national health care-related educational degree programs.
Direct and indirect costs not well captured	Limited availability of high-quality, nationally representative cost data	• Provide research grants for local economic evaluation research to capture epidemiology, costs, and patient preferences in the Indian context. • Establish annual comprehensive national health expenditure surveys and registries to capture diabetes related direct healthcare costs and indirect costs (e.g. productivity loss, caregiver burden, transportation, long-term disability). • Promote Make-in-India incentives for domestic manufacturing of devices to reduce manufacturing costs.
Regional variability (urban vs. rural)	Large disparities in healthcare infrastructure, access to services, and disease burden across states and between rural and urban areas	• Enable real-world data generation through device registries with a particular focus on region-specific coverage. • Stratify CEAs by urban–rural and socioeconomic groups. • Encourage state-level device schemes to provide access to diabetes management devices through public health facilities. • Provide subsidies for high-risk groups, rural populations, and low-income individuals with diabetes. • Prioritize diabetes device access in school workplace wellness initiatives to enable early detection and management.

Affordability & equity	India's multi-payer healthcare system and insurance coverage is variable	• Incorporate cost-effective diabetes devices into Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (PM-JAY) benefit schemes, giving priority to high-risk groups. • Have a balanced price regulation by the National Pharmaceutical Pricing Authority (NPPA), alongside incentives for local manufacturing, innovation, and long-term market sustainability.. • Pilot Public–Private Partnership (PPP) models should be conducted where private firms can be contracted with to provide subsidized devices. • Expand and strengthen national and state insurance coverage or subsidies to reduce out-of-pocket expenses. • Align with the Ayushman Bharat Digital Mission (ABDM) and create robust and secure channels through which blood glucose data from devices can synchronize with the doctor's office notes and national diabetes registries - thus improving continuity of care.
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7. Conclusion

In light of the growing prevalence of diabetes in India, high diabetes related healthcare costs and limited access to medical technologies, highlights the importance of HTA for diabetes management devices, in India. The devices have the potential to improve blood glucose control, lower the risk of complications, and enhance patients' quality of life. However, high cost and practical barriers to use continue to limit widespread adoption of the same. Although available evidence suggests that insulin pump therapy may be cost-effective, the substantial upfront acquisition costs and recurring consumable expenses may limit affordability for a large proportion of Indian patients, highlighting the need for reimbursement mechanisms, targeted subsidies, and public procurement strategies to improve access. Where India-specific evidence was unavailable, international economic evaluations were included for illustrative purposes only. However, these findings should be interpreted cautiously because differences in healthcare delivery systems, reimbursement mechanisms, treatment costs, out-of-pocket expenditures, and resource utilization patterns may limit their applicability to the Indian setting. Conducting India-specific HTAs of diabetes management devices that incorporate RWE, local cost data, and equity considerations, can help create a transparent framework for assessing the value of these devices

in the Indian healthcare context and inform healthcare decision-making. Future HTAs in India should adopt a broader societal perspective that systematically incorporates productivity losses, caregiver time and burden, transportation expenses, and other indirect costs using real-world data sources and validated economic modeling approaches to better capture the full impact of diabetes and its management. Policy initiatives such as price regulation, integration into Ayushman Bharat scheme, and investment in RWE generation could be critical steps for consistent adoption. Future research should also examine how public payers, private insurers, and patients paying out-of-pocket may differentially interpret and respond to HTA evidence, as well as the institutional and political feasibility of implementing value-based coverage and reimbursement approaches for diabetes devices in India. Building stronger HTA capacity and integrating it into both national and state-level decision-making is the key to enabling adoption of innovation while keeping in mind affordability and equity.

List of Abbreviations

ABDM: Ayushman Bharat Digital Mission

CBA: cost-benefit analysis

CEA: cost-effectiveness analysis

CHC: community health centers

CGM: continuous glucose monitors

CSII: continuous subcutaneous insulin infusion

CUA: cost-utility analysis

DALY: disability-adjusted life years

FGM: flash glucose monitors

GEAR: Guide to Economic Analysis and Research

HbA1c: hemoglobin A1c

HTA: health technology assessment

HTAIn: Health Technology Assessment in India

IBGMS: internet blood glucose monitoring service

INR: Indian rupees

ISPOR: The Professional Society for Health Economics and Outcomes Research

MEPS: Medical Expenditure Panel Survey

NPPA: National Pharmaceutical Pricing Authority

PHC: primary health centers

PM-JAY: Pradhan Mantri Jan Arogya Yojana

PPP: public-private partnerships

QALYs: quality-adjusted life years

RWE: real-world evidence

SMBG: self-monitoring of blood glucose

T2DM: type 2 diabetes mellitus

T1DM: type 1 diabetes mellitus

Author contributions:

PM: Conceptualization; Methodology; Writing – Original Draft; Writing – Review & Editing.

SG: Conceptualization; Methodology; Supervision; Project Administration; Writing – Original Draft; Writing – Review & Editing.

SB: Methodology; Writing – Original Draft; Writing – Review & Editing.

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Conflicts of Interest

PM is an employee of UCB, Inc. and owns stock or stock options in the company. UCB Inc. has no role in this paper SG is an employee of Neurocrine Biosciences, Inc. and owns stock or stock options in the company. Neurocrine Biosciences, Inc. has no role in this paper. SB has no financial interests to declare.

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