Abstract

India has approximately 73 million people living with diabetes and another 37 million with prediabetes while nearly 47% of the diabetes cases are undiagnosed. The high burden of poor glycemic control and early onset of complications with associated economic costs indicates a high prevalence of poor self-management practices. It is well-established that achieving patient-centered primary care consistent with a chronic care model ensures optimum diabetes self-management support and improves long-term clinical and health outcomes in diabetes patients. The public sector primary care system in India provides services free of cost to beneficiaries but lacks patient-centered care that undermines diabetes self-management education and support. Furthermore, factors like poor patient knowledge of diabetes, suboptimal medication adherence, persistent clinical inertia, lack of data for monitoring and evaluation through clinical audit worsens the standards of diabetes care in primary care settings of India. There is a need for government initiatives to be directed towards the provision of comprehensive outpatient care that is inclusive of uninterrupted supply of drugs, provision of essential laboratory investigations, training and availability of qualified diabetes educators and availability of specialist support when required. Furthermore, the integration of depression screening and smoking cessation services at the primary care level is warranted.

Key words: Primary care; Diabetes; Self-care; Adherence; India
screening and inadequate assistance for tobacco cessation. Developing prospective registries with predefined data standards in Indian primary care facilities is essential for enabling clinical audits and monitor the quality of patient care.

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INTRODUCTION

India has approximately 73 million people living with diabetes and another 37 million with prediabetes while nearly 47% of the diabetes cases are undiagnosed\(^{[1,2]}\). The steady increase in diabetes burden in India since 1990 is attributed to the ongoing epidemiological, nutritional, social and economic transitions along with an increase in the prevalence of overweight and obesity\(^{[3,4]}\). Diabetes and related complications impose a high-burden of catastrophic economic costs on the poorest populations in India by increasing out of pocket spending\(^{[5]}\). However, India is committed to achieving universal health coverage for effective diabetes management by expanding services for diabetes prevention and control with targets to provide essential medicines and diagnostics to at-least 80% of the cases by 2025\(^{[6]}\).

Diabetes is a chronic disease requiring daily self-management by establishing and maintaining a continuum of care for the attainment of optimal health outcomes. Failure to do so increases the risk of early onset and development of microvascular and macrovascular complications of diabetes\(^{[7]}\). Persons with diabetes themselves need to become caregivers and sustain a multitude of daily self-management decisions that include: (1) Adherence to medications in terms of the correct dose, frequency, route and protection against adverse effects; (2) Lifestyle modifications: Adequate physical activity and daily exercise with a healthy diet; (3) Cessation from smoking and harmful use of alcohol; (4) Self-monitoring of blood glucose; and (5) Foot-care\(^{[8]}\). Diabetes self-management education and support (DSME/S) for educating the patient on diabetes self-care is an integral component of the chronic care model for primary-care clinics which is effective in improving diabetes-related health outcomes\(^{[9,10]}\). The American Diabetes Association (ADA) has recommended measurement and monitoring of the key outcomes of DMSE/S including self-management, clinical outcomes, health status, and quality of life\(^{[10]}\).

There is also growing recognition of the need for high quality and patient-centered primary medical care focusing on both the primary and secondary levels of diabetes prevention\(^{[10]}\). Primary care refers to the first level of contact with the health system that is equitable and accessible to individuals and provides integrated medical care services with scope for timely specialist referral thereby meeting the health needs of a majority of the population\(^{[12,13]}\). According to the World Health Organization, people-centered primary-care should be comprehensive and continuous focusing on individual health-needs and preferences and enabling care from a trusted provider\(^{[14]}\).

The role of primary health care is particularly relevant in catering to the diabetes-related health needs of the Indian population due to its majority rural and large urban slum cluster population having a high diabetes burden\(^{[15]}\). Moreover, there exists a large proportion of the functionally illiterate population with consequently poor health literacy underlining their ability for correct self-management of chronic illnesses like diabetes\(^{[16]}\). However, the provision of high-quality diabetes care through primary care clinics and its physicians is a major public health challenge even in the developed world. A study among primary-care physician treated diabetes patients in the United States observed most had suboptimal health outcomes due to lack of medication intensification\(^{[17]}\). Similarly, in the United Kingdom, more than one-third of type 2 diabetes patients on treatment have suboptimal glycemic control highlighting inadequate empowerment of patients towards self-care\(^{[18,19]}\). The functioning of primary care systems in India, a developing, lower-middle income country, therefore, needs evaluation for identification of gaps, deficiencies and recommendations in promoting patient efficacy for diabetes self-care.
SEARCH STRATEGY

We summarized evidence regarding the standards of diabetes self-care in primary health facilities of India and challenges in achieving optimum patient-centered care (PCC) consistent with a chronic care model. We browsed PubMed and Scopus databases using the keywords with country (India) restricted searches applied: (Primary Health Care OR Primary Care) AND (Diabetes); (Diabetes) AND (Adherence OR Compliance); (Diabetes) AND (Self-care OR Self-management); (Diabetes) AND (Knowledge OR Awareness); (Diabetes) AND (Depression) We also screened the reference list of the selected articles to find other relevant articles.

STRUCTURE OF PRIMARY CARE HEALTH-DELIVERY MECHANISMS IN INDIA AND DIABETES-CARE

Public sector delivery of primary care services in India includes a distinctive primary health care approach in the rural areas and underserved regions of urban areas that provide free of cost services to all beneficiaries. The importance of primary care for meeting the healthcare needs of the rural population was recognized as early in 1946 in the Health Survey and Development committee report. The goal of PHC is emphasized as the provision of comprehensive health-care inclusive of adequate preventive, curative and promotive health services that are readily available, affordable and accessible for the target predominantly rural population. The expansion of PHC in India has continued over the years, but limited funding and persistent underutilization by target beneficiaries is a cause for concern.

The public sector PHC delivery system includes a network of female voluntary community health workers termed Accredited Social Health Activists (ASHAs) with 1 ASHA catering to approximately every one thousand population. The community workers link the vulnerable population with the public health sector, government health initiatives and the national health programs. The PHC facilities in rural areas include sub-centers that are peripheral outposts (1 for every 3000-5000 population) and primary-health centers (1 for every 20000-30000 population). Community health centers and district hospitals have the capacity for providing secondary-care including referral services. Nevertheless, India also has a complex and diverse private healthcare sector that accounts for a majority of both outpatient and in-patient visits and also contributes substantially higher to the total health expenditure. However, the standards and quality of care in the private sector are highly variable depending upon location, cost of service and local factors. Moreover, the private sector contributes to escalating out of pocket expenses and is fundamentally inequitable leading to its inadequacy in attaining universal health coverage, especially amongst the economically disadvantaged populations.

A salient feature of the Indian public health-care system is its alignment with various vertical health programs. India also has a national program for prevention and control of cancer, diabetes, cardiovascular diseases and stroke (NPCDCS), operationalized across all the districts of the country in 2016. The NPCDCS prescribes a package of services for NCD control at each level of the public health-care delivery system in India inclusive of behavior change counseling, screening, diagnosis, clinical treatment and referral services. The program also recommends regular patient education for effective diabetes management during the initial and follow-up patient visits.

CURRENT STATUS OF DIABETES SELF-CARE PRACTICES IN PRIMARY CARE FACILITIES IN INDIA

The heterogeneous health system in India means that primary medical care can be extended by various health facilities ranging from the primary health centers to secondary/district hospitals or even tertiary care hospitals depending upon accessibility, affordability, and patient preference.

A study from Northern India (n = 385) in three government health facilities had found 25.5% patients non-adherent to anti-diabetic medications, 29% were non-adherent to dietary recommendations and 52% non-adherent to exercise recommendations. Another study conducted at a community health center in Northern India (n = 256) reported non-compliance to medications in 46.5% patients and non-compliance to dietary recommendations in 23.5% diabetes patients. A study from a rural health facility in Western India (n = 307) reported poor pharmacological
compliance in 23.7% and poor non-pharmacological compliance in 49.1% diabetes patients\(^{[27]}\). A study from Southern India (n = 162) reported 95.6% of diabetes patients were adherent to medications and 82.1% were adherent to exercise\(^{[28]}\). There exist very few studies that have assessed self-care and adherence characteristics in diabetes patients from rural India.

**CHALLENGES IN THE PROVISION OF DIABETES SELF-MANAGEMENT SUPPORT THROUGH PUBLIC SECTOR PRIMARY CARE IN INDIA**

**Lack of readiness for PCC for diabetes self-management**

PCC promotes a non-authoritarian patient guided shared decision-making approach in patient-provider relationships\(^{[29]}\). PCC includes respect for individual patient preferences, integration of care, information and education, access to care, the involvement of family and outlining care continuity and transition\(^{[30]}\). Achieving high-quality diabetes PCC requires effective DMSE/S that is respectful and responsive to individual patient preferences for the realization of desired health goals. DMSE delivery is indicated at four key time-points: (1) At the time of diagnosis; (2) During an annual assessment; (3) At the time when complications arise; and (4) When there is a transition in care\(^{[31]}\). Studies have shown that PCC empowers patients and increases their efficacy of self-care for medication adherence and healthy lifestyle choices\(^{[32]}\). In contrast, ineffective communication between health-care providers and diabetes patients results in suboptimal diabetes care and lowers patient adherence to their prescribed self-care practices\(^{[33]}\).

Adopting a patient-centered approach also enables health-system planning for reducing the risk of diabetes complications by appropriate monitoring and adequately treating comorbidities like hypertension, hyperlipidemia and risk factors like tobacco smoking and obesity\(^{[34]}\).

The prerequisites for implementing PCC includes a team-based approach inclusive of trained diabetes educators, community involvement and maintenance of updated treatment registers (documenting demographic details, blood pressure and glycemic status readings, patient follow-up, referral, and complication data) consistent with a chronic care model\(^{[31]}\).

The Indian NPCDCS also recommends training of nurses as diabetes educators\(^{[24]}\). Nevertheless, the implementation mechanisms for attaining optimal glycemic control in diabetes patients through effective DMSE remains a low priority across the healthcare delivery spectrum in India including specialist tertiary care hospitals\(^{[25-34]}\). An important reason for ineffectual DMSE in primary care settings in India is the inadequate availability of trained diabetes educators rendering patient education as an additional function for physicians who can be ill-equipped for the task in the absence of any curricular or formal training and certification\(^{[35]}\). Moreover, in the Indian context, the counseling of young diabetes patients is particularly challenging due to disease-related stigma\(^{[16]}\). There also can exist diminished motivation for physicians to engage in patient education due to preexisting heavy patient load and congestion at clinic sites that limit avenues for patient-provider communication\(^{[36]}\). Specialist referral for diabetes management is also a fundamental challenge in remote and rural primary care facilities, often lacking trained diabetes specialists\(^{[27,28]}\).

**Poor patient knowledge of diabetes**

It is well-established that patient knowledge of diabetes improves health outcomes in diabetes patients which include improved glycemic control and reduced complications\(^{[39]}\). Studies from India have mostly reported poor patient knowledge of diabetes. A study in government health facilities of Northern India (n = 385) found only 38.5% diabetes patients were aware of symptoms of hypoglycemia while 74% were aware of plasma glucose levels indicating good glycemic control\(^{[40]}\). A study from Western India (n = 400) reported only 29 (9.4%) diabetes patients had good diabetes-related knowledge, whereas 219 (71.3%) had moderate and 59 (18.2%) patients had poor knowledge\(^{[27]}\). A study in a rural community in Southern India found nearly half (48.8%) diabetes patients were unaware that diabetes is an incurable disease and almost none of the patients were aware of the importance of foot-care for diabetes patients\(^{[41]}\). However, another study from a rural hospital in Southern India found nearly 75% of diabetes patients having good foot-care knowledge scores\(^{[42]}\). Low educational status is consistently reported as a predictor of poor knowledge of diabetes\(^{[27,43]}\).

**Suboptimal medication adherence and clinical inertia**
Medication Adherence is the “extent to which a patient acts by the prescribed interval, and a dose of a prescribed regimen”[43]. Suboptimal medication adherence in diabetes patients worsens glycemic control and other therapeutic outcomes by precluding the full benefit of treatment and increases the need for hospital admissions[44,45]. Both patient-related and healthcare system related factors influence medication adherence[46]. There is a need to improve medication adherence assessment measures in India by developing psychometrically valid scales particularly when measuring insulin adherence. The newer scales need to be culturally valid and focus upon constructs like belief in medications and traditional concepts relating to “hot” and “cold” medicines[47].

In comparison to community-based studies in rural and underserved areas, public health facility-based studies conducted in India usually show higher rates of medication adherence in diabetes patients probably due to a regular supply of free of cost medications which are particularly beneficial for patients belonging to the lower socioeconomic classes[25,41,42,47]. However, the high proportion of adherent patients is often found not correlating with their glycemic status[48]. A multicenter study reported a mean HbA1c of 9.2% in a large cohort of 20554 Indian diabetes patients[45]. Clinical inertia, the failure to intensify the treatment of a diabetic patient despite not meeting recommended glycemic targets also contributes to poor glycemic control. This phenomenon has been linked to limited drug armamentarium and failure of a timely switch to insulin therapy by Indian physicians[48,49,50]. Reasons for delayed insulin initiation by Indian physicians include concerns over side-effects like hypoglycemia and ethical concerns due to doubtful patient self-efficacy[48,51]. Moreover, lower SES patients may be unable to afford glucometers and strips that are not provided by the public health system[47].

**Lack of diabetes clinical audits and prospective registries**

Diabetes is a “whole-life” disease requiring a sustained continuum of care. The ADA recommends the standards of diabetes care should include a 3-6 monthly clinical review of the diabetes patient that includes plasma glucose and blood pressure examination, HbA1c investigation at least twice a year, annual foot examination and chronic kidney disease diagnosis. Furthermore, patients are expected to assess their therapeutic response to anti-diabetic therapy by regular self-monitoring of blood glucose[48]. Facilities for these laboratory investigations are not regularly available in Indian primary health facilities thereby needing a further referral and associated with risk of patient non-compliance. Clinical audits of diabetes registries is a valuable tool for increasing health-system accountability, monitoring health outcomes, efficiency and improving the quality of care[52]. A record based audit of a primary health facility in Southern India reported an increase in patients with ideal monitoring from 3.2% in the first year to 48.2% patients in the second audit year[53].

The Indian NPCDCS recommends the maintenance of NCD treatment registers from primary-care level onwards although no data standards are specified[24]. Moreover, in the absence of electronic or digital health records, lack of clinical audits and a scarcity of published literature, there is limited scope for ascertaining treatment outcomes of diabetes patients treated in primary care settings.

**Lack of integration of mental health services with diabetes care**

Patients with type 2 diabetes mellitus (T2DM) are two times more likely to have depression compared to the general population[54]. Depression tends to lower adherence to self-care practices and is associated with poor glycemic control and more complications[55]. The prevalence of depression in T2DM patients in India shows considerable variation with estimates ranging from 8% to 84%[56]. There is growing recognition that depressive symptomology needs to be identified and treated in primary care settings and diabetes educators can be trained to address diabetes-related distress[56]. In countries with limited mental health infrastructure like India[57], the implementation of such an approach can be particularly valuable.

**Enabling smoking and tobacco cessation**

Smoking cessation counseling for diabetes patients who are also tobacco smokers is an integral component of diabetes care[58]. Approximately 19% of Indian men are current tobacco smokers of whom less than half (48.8%) were advised to quit smoking by a health-care provider[59]. Promotion of smoking cessation as part of diabetes care should involve sensitization and training of all health-care providers involved in diabetes care. Mobile-health text-message or smartphone applications like mCessation should be evaluated for their effectiveness in improving quit-rates among diabetes patients[59].
WAY FORWARD

Primary care facilities in the public sector cater to millions of diabetes patients but are deficient in characteristics compatible with a functioning, chronic care model. Team-based DSME/S for patients in primary care need high-quality training of nurses, multipurpose workers and other paramedical stuff like pharmacists as diabetes educators. Decision support like when to initiate insulin to avoid clinical inertia can be provided to medical doctors working in rural and suburban areas through telemedicine-based consultation with specialists. Peer-support based community linkages may help patients cope with stress and reduce physical inactivity through health promotion activities like yoga and meditation.

Strengthening public primary health facilities for the provision of comprehensive outpatient care requires sustained political commitment and adequate funding. The government of India has already initiated a national program to push for upgrading 150000 sub-centers, the bottom-most primary care facility to health and wellness centers with additional staffing through mid-level service providers and capable of the provision of comprehensive non-communicable disease management. The feasibility of medication adherence support through patient counseling, peer education, and mHealth interventions also need exploration in Indian primary care settings. The provision of an uninterrupted supply of drugs and diagnostics is imperative in this regard as medicinal costs constitute the highest proportion of out of pocket spending in diabetes-related outpatient care in India. To promote refill adherence, a national program is currently operational that promotes ubiquitous availability of high-quality generic drugs at significantly lower costs compared to branded medicines to all patients.

Future Indian diabetes care research should also focus quality of diabetes care accorded in primary care facilities especially those in resource-constrained settings. A national audit on diabetes care standards and patient health outcomes in primary care is also urgently needed to understand the measures needed to limit the continuously escalating costs for managing complicated diabetes patients (Table 1).
### Table 1 Major challenges and potential solutions for promoting effective diabetes self-management through enhanced primary care

| Major challenges                                      | Potential solutions                                                                                                                                 |
|-------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Strengthening primary-care facilities for providing comprehensive outpatient care | Sustained political will and financial commitment towards NPCDCS  
Expand basket of laboratory investigations for maintaining the continuum of care  
Upgrading and maintaining registers by the introduction of data indicators and data standards with timely centralized data collection for the performance of clinical audits |
| Patient-centered care                                  | Training paramedical staff as certified diabetes educators for enhanced DMSE/R  
m-Health applications for health education and behavior change communication  
Community outreach |
| Patient isolation and stress                           | Peer support  
Community linkages: yoga, meditation |
| Suboptimal adherence                                   | Ensuring uninterrupted supply of drugs, promotion of generic drugs to reduce out of pocket expenses, expansion of drug types and availability of insulin with the development of proper storage facilities |
| Drug availability and refill adherence                 | Development of culturally valid adherence scales |
| Correct adherence assessment                           | Health education, mHealth |
| Adherence Support                                      | Intervention studies to improve patient-centered care, adherence support, and DMSE/R  
Cohort studies to evaluate the quality of care and assess long-term health outcomes |
| Avoiding clinical inertia                               | Training health workers for the correct dispensation of insulin therapy  
Regular availability of insulin and syringes to eliminate any out of pocket expenses |
| Implementation research                                | Promotion of community linkage in primary care for diabetes patients |
| Operational research                                   | Cost-effectiveness of diabetes management with primary care compared to specialist treatment |
| Economic evaluations                                   | Does provision of free glucometers and strips increase patient adherence to SMBG and improve treatment outcomes (improved glycemic control, fewer hypoglycemic episodes) |
| Health technology assessment                           |                                                                                                                                                   |

DMSE: Diabetes self-management education; NPCDCS: National program for prevention and control of cancer, diabetes, cardiovascular diseases and stroke.

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