Implementation research on diabetes in India: A systematic review

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\textbf{Background:} There is a wide range of effective interventions for the prevention of diabetes, but few of these approaches have been extensively utilized in real-world settings. The objective of this systematic review was to assess and collate existing evidence in implementation research (IR) on prevention, control and treatment of Diabetes Mellitus (DM) in India.

\textbf{Methods:} The Preferred Reporting Items for Systematic Reviews and Meta-analyses - Protocol (PRISMA-P) guidelines were used to create the protocol for the systematic review. Articles published in the previous 20 years (2001–2020) and published in English language were included in the study. Electronic databases such as MEDLINE (through PubMed gateway), EMBASE, and Science Direct; search engines like Google Scholar and ProQuest were systematically searched using separate search protocols for each database. Retrieved articles were screened for titles and abstracts and assessed by two independent reviewers. Using standard checklists, the articles also underwent a risk of bias assessment, and a narrative summary was written using SWiM guidelines.

\textbf{Results:} Sixteen studies were included in the review, which included three implementation studies related to screening of diabetes, three studies on the management of diabetes, three studies related to lifestyle interventions, one on behavioral intervention, two on electronic support system-based interventions, and the remaining four studies explored IR in other areas of diabetes. The key attributes of implementation research such as acceptability, feasibility, adoption, economic evaluation measures like cost-effectiveness, operational issues like barriers, and facilitating factors were addressed by most of the studies, in varying extents.

\textbf{Conclusion:} Implementation research on diabetes mellitus in India is very limited which underscores the importance of creating awareness about the need of IR and building capacity and skills for conducting IR among various stakeholders.

\section{1. Introduction}

Noncommunicable diseases (NCDs) such as diabetes, cancer, cardiovascular disease, and chronic respiratory disease are the leading causes of mortality worldwide, and they pose an emerging global health hazard. NCDs are responsible for 41 million deaths every year worldwide; of these 15 million deaths occur prematurely, and 85% of these occur in low and middle-income countries. NCDs contribute to 62% of total deaths in India and 48% of these deaths are preventable and premature.

Diabetes is one of the world’s most serious public health issues, posing a significant threat to public health and socioeconomic development. According to the International Diabetes Federation (IDF), 451 million adults globally had diabetes in 2017, which is expected to rise to 693 million by 2045 if no effective preventive measures are adopted. Diabetes is linked to an increased risk of death from infections, cardiovascular disease, stroke, chronic kidney disease, chronic liver disease, cancer, and other causes. In India, there were 65 million diabetes in 2016 compared to 26 million in 1990. This figure further increased to 74.2 million in 2021. According to projections, India could have up to 124.9 million diabetics by 2045. Additionally, among persons 20 years of age and older, the prevalence of diabetes increased from 5.5% in 1990 to 8.3% in 2021. According to the National Family Health Survey (NFHS-5), 16.1% of adults aged 15 and older have diabetes.\textsuperscript{7–9}

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There is adequate evidence that risk factor modification, early diagnosis and treatment, and proper rehabilitation are viable options, but there are more obstacles to overcome in getting these interventions to the right people. Effectively implementing these interventions, especially for the difficult-to-reach rural and tribal population, is another challenge in itself. Thus, there is a need for systematically understanding the challenges faced in making these interventions available, acceptable, feasible, and cost-effective in these specific settings. It’s critical to recognize the gaps and devise methods to bridge them so that services may be provided. This is where the role of implementation research becomes pivotal.

Implementation research (IR) deals with the exploration of strategies used to integrate evidence-based practices into real-world settings. This avenue of research is fast expanding and frequently necessitates large multidisciplinary cooperation and has a lot of potential to revolutionize the way health care is delivered in the community. In addition to identifying strategies that are replicable, effective, and feasible, IR studies also focus on the effects of contextual factors and relevant characteristics of the intervention that may have an impact on its implementation.

The objective of this systematic review was to assess and collate existing evidence in implementation research on prevention, control and treatment of Diabetes Mellitus (DM) in India.

2. Methods

The Preferred Reporting Items for Systematic Reviews and Meta-analyses - Protocol (PRISMA-P) guidelines were used to create the protocol for the systematic review. The completed protocol was forwarded to the PROSPERO website for registration (Registration No: CRD42021290574). Preferred Reporting Items for Systematic Reviews and Meta-Analyses Literature Search Extension (PRISMA-S) criteria were used to report the search results. The study selection, screening, analysis, and results for the review have been drafted in accordance with the latest Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA-2020) guidelines. The systematic review was guided by the PICO (Population, Intervention, Comparator, Outcome) framework as detailed below.

Population: All age groups, who were either part or target population of an implementation project/research focused on diabetes, conducted in India.

Intervention: Any diabetes-related intervention with embedded implementation research undertaken in India.

2.1. Comparator: wherever applicable e.g.: comparison studies including RCTs, case control studies

Outcome: Assessment of reporting of implementation descriptors was done as per the “Key Principles and Concepts of IR Activities”.

2.2. Inclusion criteria

Implementation research studies conducted in India, using the following study designs, were included: randomized and non-randomized controlled trials; observational analytical study designs such as cross-sectional, case-control and cohort studies; full or partial economic evaluation studies; qualitative study designs including qualitative case studies, and narrative studies.

Articles published in the English language were only included. Though other language articles were decided to be included on a case-to-case basis depending on the availability of reliable translation, no such articles were found in our initial search.

2.3. Exclusion criteria

Implementation research not conducted in India; study designs such as case reports, case series, policy briefs, editorials, letters; policy/program documents without details of study design used for implementation research; studies/reports published in a language that was not understood by the investigation team member(s) or would require considerable time and effort to translate were excluded.

Time period:
Articles published in the previous 20 years (January 2001–December 2020) that met the aforementioned inclusion criteria were included.

2.4. Search strategy and information sources

The investigators, in cooperation with the subject and methodology experts, developed the search strategy, relevant synonyms, and search string formulation (with appropriate modifications as required depending on the database examined). Electronic databases such as MEDLINE (through PubMed gateway), EMBASE, and Science Direct; search engines like Google scholar and ProQuest were systematically searched using separate search protocols for each database. It is mentioned in Table 1. First, a preliminary limited search of the database was conducted to identify articles on the topic. To construct a thorough search strategy, selected words from the titles and abstracts of relevant articles, as well as the index keywords used to characterise the articles, were utilized. Controlled vocabularies (e.g. Medical Subject Heading terms, EMTREE terms, etc.) were used to identify synonyms. PROSPERO and Cochrane Database of Systematic Reviews were used to search for any ongoing or recently completed systematic reviews. In addition to the aforementioned sources, studies were also identified using screening of bibliography and forward citations of included studies. PRISMA flow chart for screening and selecting articles for the review is outlined in Fig. 1.

2.5. Study selection and screening process

The studies were compiled using citation managing software. As a first stage, all identified studies were pooled and uploaded into Rayyan QCRI portal with duplicates removed. Subsequently, two independent reviewers used Rayyan QCRI to screen and evaluate the titles and abstracts against the inclusion and exclusion criteria. This was followed by retrieval of the articles and a full-text review. Reasons for exclusion of full-text studies were recorded and any disagreements between the reviewers were resolved through discussion or in consultation with the designated adjudicator wherever needed.

2.6. Data extraction

Relevant data from the selected studies such as publication date, location, setting, study design, study population, sample size, and key findings were extracted. Depending on the nature of the study, relevant outcome measures related to implementation research in terms of effectiveness, feasibility, fidelity, cost, scalability, barriers, facilitating factors etc. were also extracted.

2.7. Risk of bias assessment

To assess the risk of bias within included studies, the methodological quality of potential studies was assessed by the reviewers at the outcome and study level, using the contemporary versions of the relevant checklists, in accordance with the respective study designs.

2.8. Data synthesis

The data synthesis was aimed at describing the strategies, contexts, concepts, methods, and outcomes reported in the reviewed studies using the Synthesis without Meta-analysis (SWiM) guidelines.
Table 1
Search strategy summary – IR on diabetes in India.

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3. Results

For this systematic review, IR was defined as any research that focussed on implementation determinants or implementation strategies or mechanisms/processes through which an implementation strategy operates or outcomes including implementation outcomes such as acceptability, feasibility, adoption, appropriateness, cost, effectiveness, fidelity, penetration, sustainability; service outcomes measured as efficiency, safety, effectiveness, equity, patient-centeredness, timeliness; and client outcomes measured as satisfaction, function, and symptomatology.

The stated search strategy for retrieving IR on diabetes in India returned 791 studies, of which 35 were deemed to be appropriate for full-text evaluation. Subsequently, 14 studies were found suitable for inclusion. Another 16 studies were proposed by subject experts to be checked for eligibility, and two of these were found to be eligible. Thus, a total of 16 studies were included in this review.

Table 2 depicts the characteristics of the included studies. The
majority of studies (11 out of 16) were published during the year 2018–2020. The majority of the research was carried out in four Indian states: Tamil Nadu (5), Kerala (3), Karnataka (3), and Delhi (3). Study settings were diverse; spread across public health care facilities, private sector hospitals, retail pharmacies, and communities. Target populations included individuals with/without the disease (11), health care providers (4), and organizations (4). Our review included eight studies using a mixed methods design, three were randomized control trials, one was action research in nature, and the remaining four did not specifically mention their study design.

This systematic review included three implementation studies related to screening of diabetes, three studies on the management of diabetes, three related to lifestyle interventions, one on behavioral interventions, two on electronic support system-based interventions, and the remaining four studies explored IR in other areas of diabetes. The key attributes of implementation research such as acceptability, feasibility, adoption, economic evaluation measures like cost-effectiveness, operational issues like barriers, and facilitating factors were addressed by most of the studies, in varying extents.

### 3.1. Summary of the risk of bias assessment

Following observations were made on the risk of bias assessment in the studies that were finalized for full-text reviews consequent to the screening of the search results. These were rated YES on the implementation and intervention scale with 27 checklist items. The STARI checklist, which consists of 27 items, was used to score all 16 studies. Implementation received a score of 15–22, while intervention assessment received a score of 15–21.

One economic evaluation study was rated 20 out of 24 using the CHEC and CHEERS checklist. Eight mixed-methods studies were scored using MMAT checklist. Three had a rating of 7, three had a rating of 6, whereas one study each had a rating of 5 and 3, on a scale of 7. Three studies were RCTs and were evaluated using CONSORT Checklist. One study had score of 13, one scored 7, and another had a score of 4 out of 13.

### 4. Discussion

This is the first systematic review to assess and collate the existing evidence in implementation research on diabetes mellitus conducted in India. In this review, we tried to identify studies focussing on the implementation of evidence-based interventions related to diabetes mellitus in India.

Implementation research aims to bridge the gap between research and real-world practice. It explains this gap between efficacy and effectiveness of intervention through evidence-based practice by identifying enablers and barriers in an intervention.

### 4.1. Screening programs for DM

We observed that three studies tested the implementation (feasibility and acceptability) of screening programs and evaluated the barriers and enablers in their implementation. 

Anand et al. in their study assessed the feasibility, yield, and acceptability of a two-stage integrated screening of NCDs and their risk factors among tuberculosis patients who were being treated in DOTS centres of two medical colleges in Delhi. Both patients and healthcare workers were involved in this intervention.
providers agreed that the screening was useful and acceptable. Waiting time and expenses associated with blood tests were cited as major obstacles in the implementation of the screening program by patients, while increased workload, limited medical supplies, and inadequate skills and expertise were cited by health practitioners. Integration of NCD screening in TB treatment facilities was hypothesized to improve healthcare delivery in both disease areas.

In another study conducted in Haryana, tuberculosis patients were subjected to screening for diabetes mellitus and vice versa. The barriers to screening were low patient awareness, poor understanding of guidelines by health care providers (HCPs), shortage of staff, and inadequate training, whereas HCPs and program staff’s positive attitudes were the facilitators. The authors concluded that the implementation of bidirectional screening was poor and suggested that improving awareness among HCPs and patients regarding the need for screening, training of HCPs in screening methods, and making tests for DM available at the facilities would improve the screening for DM.

Raghvveer et al. observed in their study that patients’ willingness to undergo screening and understanding of the importance of screening were screening enablers whereas overworked staff, shortage of glucose meter strips and medicines, non-availability of transportation facilities, inadequate diagnostic services at PHCs, administrative delay in the release of funds, lengthy reporting formats, delay in submission of reports, etc. were the barriers. This highlights that there has been very little IR conducted in India about the screening of diabetes mellitus.

4.2. Management of DM

There were three studies related to management of diabetes mellitus.

Flor et al. studied community-based NCD interventions (HealthRise programme) in two Indian cities (Udaipur and Shimla) and three other countries (Brazil, the United States, and South Africa) from 2016 to 2018. Screening for diabetes and follow-up, care coordination technology, workforce development, and clinical and non-clinical patient support were among the key HealthRise interventions in India. Patients and health care providers reported improved patient empowerment through gain in knowledge about NCDs and greater confidence in managing these conditions. HCPs also learned more about NCDs and disease management practices. Insufficient medication supplies, inadequate staffing, and poor referral processes were the gaps identified in the health system. Socio-demographic factors including poverty, low levels of health education, and limited access to nutritious food were the main challenges.

In an earlier study, Tripathy et al. described existing diabetes care services at public health facilities, highlighted challenges, and proposed solutions for the same. The challenges identified were the non-maintenance of patients’ records at the facilities, non-availability of HbA1C and other diagnostic services at primary and secondary health care facilities. Other impediments found were a lack of a formal referral process, insufficient follow-up, patient overload and the lack of specialized training. On the positive side, most facilities offered lifestyle modification support and anti-diabetic medications.

With regard to the management of diabetic foot complications in India, Harrison-Blount et al., identified five themes namely fragmented service, lack of understanding of need by local service providers, absence of standardized care pathways, poorly structured assessments, and no system of periodic screening of foot. After identifying the themes, the authors recommended that a formal system of foot assessment should be developed and implemented.

4.3. Lifestyle intervention

Three implementation studies addressed the issue of lifestyle intervention for diabetes prevention in India. 

Aziz et al. carried out a study to see the efficacy of a group-based lifestyle intervention approach and identified provider and user level factors that influenced diabetes risk reduction. Twelve-month intervention program included a group-based peer support program, peer-leader training, diabetes education materials, and community engagement strategies. Positive provider-level drivers appeared to be a high degree of attendance and appreciation for the quality of the training materials. From the participants’ perspective, even though the handbooks and related materials were appreciated, inconvenient time and location of the sessions were observed to be important barriers. Both providers and participants in a community context considered the Kerala Diabetes Prevention Program (KDPP) to be feasible and acceptable for reducing the risk of diabetes mellitus. A positive commitment from the local partners and political functionaries was observed to be a good driver for better uptake of the program.

In another study, Mathews et al. described the process of changing the components of an original program for its adaptation in India. The challenges of implementation were establishing a strong link between prevention and disease management, and low participation of males. The authors attributed the success of this pilot program to the engagement of participants, peer leaders, and local resource persons. They also took care to modify the content of the program in a manner relevant to the participants. The authors also noted that the utilization of lay peer leaders over health workers strengthened the program and also reduced the need for resource-intensive health professionals. The authors concluded that the locally modified KDPP program was a success and demonstrated the feasibility of adapting an evidence-based prevention program originally designed for high-income countries to an LMIC setting such as India.

In the Diabetes Community Lifestyle Improvement Program, Islek et al. conducted economic assessment research to determine the cost-effectiveness of a stepwise strategy involving 578 persons with impaired glucose tolerance, impaired fasting glucose, or both. The intervention group was given a 6-month lifestyle change program, as well as metformin, which was given to them in stages, while standard lifestyle advice was given to the control group. The authors suggested that even after adding screening expenses for identifying high-risk patients, a step-wise strategy for diabetes prevention was expected to be cost-effective.

4.3.1. Behavioral interventions

Johnson et al. in their study investigated how patients responded to changes made to a care coordinator-led behavioral intervention. The study involved 62 patients and three care coordinators from two diabetes clinics in Chennai and Delhi, who were chosen for their engagement in the Integrating DEPReSsioN and Diabetes Treatment (INDEPENDENT) care model. The authors showed that modifying elements of an integrated care model might improve patient satisfaction and participation in behavioral interventions.

4.3.2. Electronic decision support systems

Two studies were conducted on the implementation of electronic decision support systems at health facilities.

Ajay et al. did a study in Himachal Pradesh to develop a feasible and scalable intervention for hypertension and diabetes mellitus care enrolling 6797 individuals in five Community Health Centres (CHCs). The authors demonstrated that the nurse-facilitated, mobile phone-based Decision Support System (mDSS) enabled intervention was feasible in India’s primary care context. It was also inferred that this intervention had the potential to be scaled up in low-resource countries’ public health systems.

In their study, Jindal et al. outlined key strategies for implementing the intervention, mPower Heart electronic Clinical Decision Support System (e-CDSS) across government health facilities in Tripura. Various strategies used were: establishing a technical coordination-cum-support unit, change management, creating an enabling environment, tailoring the intervention with a user-centered
approach, and improving the Health Information System. The authors indicated that for effective scaling up of research-based interventions, multiple strategies are needed.

A large-scale community-based project namely Prevention Awareness Counselling Evaluation (PACE) diabetes project was carried out in selected communities in Chennai to raise awareness regarding diabetes and its complications through public education, media campaigns, general practitioner training, blood sugar screening, and a community-based “real life” prevention programme. The authors suggested that widespread public awareness and screening programmes were viable and that they may aid in the prevention and control of NCDs such as diabetes and its consequences.

Myers et al. carried out a randomized clustered trial to compare the outcomes of patients with type 2 diabetes mellitus who received diabetologists’ usual care (UC) against patients who got evidence-based nutrition practice guideline (EBNPG) care. Significant improvements in HbA1c were seen in the EBNPG and UC groups. At six and twelve months, EBNPG-treated individuals were more likely to achieve their serum low-density lipoprotein, high-density lipoprotein, and triglyceride-level targets.

An earlier study was conducted to examine insulin availability, costs, and variables impacting insulin supply and demand in the health sectors of Bengaluru. The study highlighted that there was a scarcity of insulin at public hospitals and it was still expensive in both the private and governmental sectors. The qualitative findings suggested that barriers to patient insulin access mainly included lack of market competition and doctors’ preference for non-Indian insulin. Another impediment to insulin access was the continuing shift from human to analogue insulin.

Ravindranath et al. wanted to enhance and improve the Kerala Diabetes Prevention Program (K-DPP) so that it may be used more widely in Kerala, India. The objectives were to develop a scalable program delivery model in Kerala as well as to improve the target population’s cardio-metabolic risk factors by a considerable amount. The study discovered that by partnering with a large community-based organization, it was possible to educate a significant number of women peer leaders to implement community-based diabetes prevention programmes in three distinct districts of Kerala. The authors concluded that the technique for scaling up K-DPP and executing it was successful in reaching out to a large number of people in Kerala and there were also some substantial improvements in major cardio-metabolic risk variables after one-year intervention.

4.4. Limitations

This review has a few limitations. First, the results of the study are based solely on peer-reviewed and published English-language articles. Second, the inconsistency of terminology used in studies made it difficult to place the articles in the appropriate category. Meta-analysis and other quantitative summaries of the findings of the included studies could not be performed due to paucity of studies.

5. Conclusion and recommendation

Implementation research on diabetes mellitus in India was largely restricted to a handful of states, namely Tamil Nadu, Karnataka, Kerala, and Delhi. Further, most of the studies were published in the last 3 years alone. There is a definite lacuna in the application of implementation science principles to explore better management of DM at the community or state level. In short, we may conclude that there have been insufficient IR studies conducted in India so far. The studies were spatially covering a very narrow territory of the vast country; it addressed only the minuscule components of the big public health issues of diabetes mellitus. The scope of the studies also was wanting in terms of their ground covered, as there was hardly any study that comprehensively looked at all tenets of IR i.e. adoption, adherence, fidelity, effectiveness, and cost-effectiveness.

Such paucity of literature points towards a lack of awareness, interest, and felt need for carrying out IR studies to address such pressing issues of control of such an important non-communicable disease of public health significance. As the formal requests sent to all important government agencies in the country to share any implementation research carried out or being conducted at present met with no meaningful reply is the most significant pointer to general indifference towards the need for IR. In view of the findings of our study, following recommendations are made.

- Create awareness about the need for conducting IR to address the issue of acceptability, feasibility, adaptability, effectiveness, and cost-effectiveness of diabetes control programs among the stakeholders, namely the state health functionaries, state health missions, health care professionals, and health researchers in medical colleges and public health institutions.
- Build capacity and skills in conducting IR among public health institutions and departments that are responsible for launching and running the diabetes control programs at the national or state level. This can be introduced systematically by making IR a part of the curriculum in graduate and post-graduate medical education, especially in community medicine and public health.
- Evaluate the implementation of effective interventions targeting diverse populations and community settings and consider standardized reporting measures in IR as this will help in comparison of different implementation studies.

Ethical considerations

Not applicable.

Author credit statement


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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.
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TB: Tuberculosis
UC: Usual Care
WHO: World Health Organization