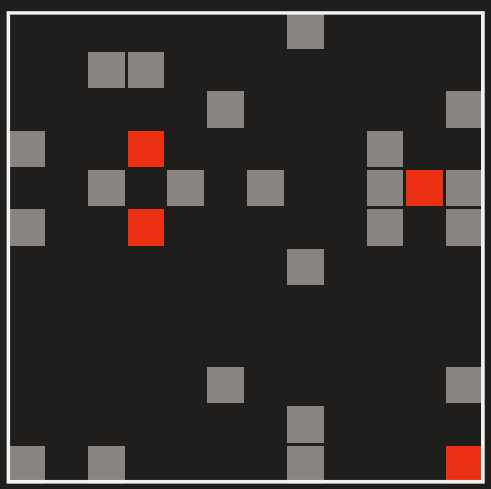
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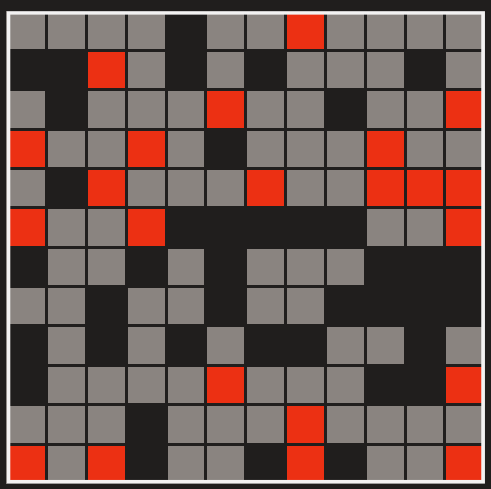
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Impact of Community Health Worker Training on Competence of Type 2 Diabetes Screening, Management, and Complications in Rural India

BEFORE TRAINING



AFTER TRAINING



Anirudh Gaurang Gudlavalleti

MAASTRICHT 2026

IMPACT OF COMMUNITY HEALTH WORKER TRAINING ON COMPETENCE OF TYPE 2 DIABETES SCREENING, MANAGEMENT, AND COMPLICATIONS IN RURAL INDIA

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CHAPTER 1

Chapter 1: General Introduction

1.1 The Global Burden of Diabetes Mellitus

Diabetes Mellitus is a rapidly expanding global public health challenge, affecting individuals living with the condition as well as the health systems and economies of nations with a high prevalence of diabetes. The 2025 International Diabetes Atlas, published by the International Diabetes Federation (IDF), reports that an estimated 589 million adults (approximately 11.1% of the global population) aged 20 to 79 years worldwide have diabetes (1, 2).

When we compare this with the 151 million number of individuals living with diabetes in 2000, the marked 290% increase over the last two decades is concerning (1, 2). The atlas also reports that the highest prevalence of diabetes is found in the low-and middle-income countries (LMICs), with almost 475 million people, around 81% of all adults with diabetes globally (1, 2). Further, this is projected to increase in number to nearly 853 million adults living with diabetes in LMICs, especially the LMICs of Asia and Africa, by 2050.

An additional challenge facing the LMICs is the large number of undiagnosed individuals living with diabetes. Data from the atlas also estimates that nearly 42.8% of individuals living with diabetes have undiagnosed diabetes (1, 2). The rates of undetected diabetes were highest in Africa (72.6%), Western Pacific (50%), and South East Asia (42.7%) (1, 2). Of these projections for global diabetes growth, nearly 95% is expected to occur in LMICs, thus disproportionately affecting resource-constrained countries (1, 2).

Providing care for individuals living with diabetes in LMICs is complicated due to multiple barriers hindering the health systems in these countries. Some common barriers shared by most LMICs are systemic barriers such as inadequate diagnostic facilities, poor road infrastructure, improper availability of required medicines, poor quality of care in rural areas, and inadequate insurance coverage. Additionally, the increasing urbanisation of rural areas, affecting lifestyle, like increasing sedentary behaviour and processed food consumption, also acts as a barrier (3-11).

Diabetes is also one of the largest causes of disability and mortality across the globe; nearly 3.4 million died from diabetes in 2024 (1). Uncontrolled diabetes affects almost all major organ systems of the body, like the cardiovascular system, and often results in complications like a stroke or peripheral arterial disease (1, 12, 13). Concurrently, uncontrolled diabetes also affects

the microvasculature, leading to nerve damage (diabetic neuropathy), with complications such as diabetic foot ulcers and subsequent amputations, eye damage (diabetic retinopathy), which may result in vision loss, sometimes irreversible; and kidney damage (diabetic nephropathy), which can lead to severe complications requiring dialysis (1, 2, 12-14).

Lastly, the economic impact of diabetes has also grown significantly. The global expenditure on diabetes and related complications has increased from USD 232 billion in 2007 to USD 1,015 billion in 2024 (1, 15).

1.2 Diabetes Burden in India

Among the most affected LMICs, India represents one of the highest burdens of diabetes, with the second largest number of people living with diabetes (1). The Indian Council of Medical Research (ICMR) conducted a comprehensive, multi-phased, population-based survey at the national level, comprising Phase I from 2008 to 2015 across fifteen states, and Phase II from 2017 to 2020 encompassing all remaining Indian states and union territories. This initiative is recognised as the ICMR-INDIAB study, a significant and landmark investigation within the Indian context (16, 17). The study reported that the weighted national prevalence of diabetes among adults was 11.4%, equivalent to nearly 101 million people (16-18). However, the IDF Atlas estimates that nearly 89.8 million people have diabetes, with an age-adjusted prevalence of 10.5% (1). Both estimates still project a large proportion of the Indian population will be living with diabetes in the future, with the IDF Atlas estimating nearly 156.7 million people in India will be living with diabetes by 2050 (1).

The rapid increase in the prevalence of diabetes over the last two decades is concerning. With India now having become the most populous country in the world (19), it will soon have the largest number of individuals living with diabetes across the globe. The ICMR-INDIAB study also reported a wide heterogeneity in diabetes prevalence across Indian states, ranging from 4.3% in Bihar to 13.6% in Goa and 26.4% in the Union Territory of Puducherry (17). Further, the study reported that, though the current prevalence was higher in urban areas (16.4%) than in rural areas (8.9%), this gap has been steadily narrowing over the last two decades (17). The study, along with other evidence, has reported that the South Indian states of Andhra Pradesh, Karnataka, Tamil Nadu, and Telangana consistently reported higher diabetes prevalence compared to the national average, with a narrower difference between the urban (15%) and rural (10%) areas, again higher than the national average (17, 20). A closer look at the findings

reveals an increased burden of diabetes, with rates rising steadily in rural areas, where prevalence has risen from 2.4% in 1970 to 10% in 2020, while urban prevalence has remained relatively stable (21, 22). This presents an alarming situation since more than 50% of the Indian population resides in rural areas (23, 24). At the moment, already more than 50% of all individuals living with diabetes are coming from rural areas (17, 22). Thus, this increase will put a significant burden on the rural public health systems.

This escalating rural burden can be ascribed to genetic susceptibility of the South Indian population and the adoption of urbanised practices impacting rural lifestyles, such as an increased intake of calorie-dense processed foods, a rise in sedentary behaviours, a higher prevalence of obesity, and an escalation in psychosocial stress, which fosters insulin resistance and results in suboptimal glycaemic regulation (25-30). These factors, together with existing barriers to equitable healthcare, such as a shortage of trained doctors in villages, limited access to nearby public health facilities, inadequate transport infrastructure, like public transport and roads, and high out-of-pocket costs due to low health insurance coverage, often result in poor health outcomes. This situation places a heavy burden on individuals with diabetes and adds substantial strain to the already overwhelmed public tertiary healthcare system (6, 8-11).

Only 23.4% of people living with diabetes in India manage to keep their glycosylated haemoglobin (HbA1c) levels at or below the recommended target of ≤7.0% (≤53 mmol/mol) (31, 32).

1.3 Diabetes Burden in Rural Telangana

Telangana, India's youngest state, formed in 2014 after bifurcating from Andhra Pradesh, has over 35 million residents, with 60% (21.4 million) in rural areas (33, 34). The state has high economic growth and also faces a high diabetes burden, with a prevalence of more than the national prevalence (17) and with 2.45 million diagnosed and rising cases (35). The Indian government's National Family Health Survey-5 (NFHS-5), conducted between 2019 and 2021, reports self-reported diabetes prevalence of 13.8% among men and 10.2% among women in Telangana (33, 35). Still, these may underestimate the actual burden, as these are self-reported surveys. A major concern from the data was the younger age at which diabetes onset occurred, decreasing from 50 years in 2006 to 20-30 years in 2016. Indians are diagnosed nearly 10 years earlier than their global (European, Chinese, and Japanese) counterparts (29, 36), leading to a longer diabetes duration with an increased risk of complications.

Recently, the urban-rural gap in Telangana has narrowed, with rural prevalence rates reaching 15-16%, doubling previous benchmarks (17, 37). This demonstrates that rural risk factors are likely accelerating and that rural area determinants are mirroring those of urban areas. The current actual burden of diabetes is hidden because of the many undiagnosed people living with it. The IDF and similar publications estimate that over 40% of rural and 22% of urban people are undiagnosed (38-40). Like the rest of the country, this rapid increase in diabetes prevalence in Telangana is mainly due to increased urbanisation of rural areas, economic growth, mechanised agricultural practices, and lifestyle changes among rural residents, leading to lower energy expenditure (25, 26) and higher consumption of calorie-dense processed foods, while a traditional whole-grains diet is declining (26, 41). Sedentary lifestyles and decreased physical activity are also contributing, with prediabetes rates rising faster in rural areas and the gap narrowing with urban areas (22, 26, 27). Combined with genetic predisposition among South Indian people, Telangana faces a high risk of a long-term diabetes epidemic (29, 30). This predisposition is characterised by the thin-fat phenotype, in which Indians have more body fat than Caucasians, with higher central obesity and insulin resistance. This phenotype is present from birth and is influenced by genetic, intrauterine, and lifestyle factors throughout life (42). Studies from Telangana report inadequate diabetes awareness, poor health-seeking behaviour, and barriers like financial, geographical, cultural, and infrastructural issues (3, 5, 43, 44). These lead to late diagnosis and complications. Community-based interventions are urgent to effectively improve healthcare access for rural populations.

1.4 Barriers to Healthcare in Rural India

After assessing the clinical and economic outcomes of diabetes, we must address barriers to healthcare access in rural India, including Telangana. The main obstacles are geographical distance, healthcare availability, cost, and cultural acceptability.

i. Geographical Accessibility

Geographical accessibility is a significant barrier to healthcare delivery in rural areas. It pertains to the ease with which an individual can reach a healthcare facility. Extensive distances between public healthcare institutions and rural residences, coupled with a lack of organised public transportation and inadequate road infrastructure, primarily underpin this challenge. Effective management of diabetes requires periodic visits to healthcare centres for consultations, medication refills,

monitoring, and screening for complications. Consequently, this obstacle predominantly leads to delayed diagnoses, hindered monitoring, and poor adherence to established diabetes management protocols (6, 11).

ii. Availability of Healthcare

Another important barrier is access to healthcare, which depends on infrastructure such as diagnostic facilities and trained healthcare personnel. In India, both professionals (especially specialists such as endocrinologists, ophthalmologists, nephrologists, cardiologists, and neurologists) and facilities are more concentrated in urban areas. The Indian government is addressing this by building more facilities and hiring dedicated personnel in the Ayushman Bharat program health and wellness centres, hitherto known as sub-centres, which are integral to primary health care. These health and wellness centres, called Ayushman Arogya Mandir, aim to shift from selective to comprehensive healthcare by offering preventive, promotive, curative, rehabilitative, and palliative services. The 150,000 Mandirs provide universal, free Primary Health Care focused on wellness, and will offer care for non-communicable diseases, with free drugs and diagnostics (45). But the integration and penetration of these services will take time and will not meet the immediate rural requirements (5, 6).

iii. Affordability of Healthcare

The third barrier is healthcare affordability. This is important for lifelong diabetes management, encompassing clinic visits, periodic monitoring, medication refills, and screening and management of complications. In India, limited health insurance coverage leads to nearly 47.1% of health expenditure being borne out of pocket. This often causes families to delay seeking healthcare or face catastrophic health expenses. (46-48). A recent Indian study reports that individuals with diabetes face the highest catastrophic expenses, nearly 30% of their annual income (46, 49). This financial strain on rural populations forces these difficult choices between healthcare and other needs, especially when seeking private care. The government of India has rolled out a national health insurance scheme, providing $5000 to over 100 million families to overcome this barrier, but its integration and penetration will take time (45).

iv. Acceptability of Healthcare

The final challenge in healthcare is acceptability, influenced by socio-cultural factors. India's diverse customs, cultures, beliefs, and myths are especially pronounced in rural areas, where they often hinder people with diabetes from seeking medical care, taking medications, or trusting allopathic treatments. Additional barriers include gender-based obstacles for women, caste-related issues, and stigma linked to diabetes diagnosis and management within rural communities. These factors collectively contribute to poor health-seeking behaviours and low adherence to treatment protocols, frequently leading to worse clinical outcomes for diabetes and its complications (3, 5).

1.5 Task Shifting for Improved Healthcare Delivery in Rural India

Most LMICs across the globe are utilising task shifting as an effective strategy to overcome the limited human resources in the healthcare barrier, manifesting in the form of professionals in low-resource settings. The World Health Organization (WHO) defines task shifting as "*the rational redistribution of tasks among health workforce teams. The specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications to make more efficient use of available human resources for health.*" (50). This was inspired by the success of utilising lay health workers in the HIV/AIDS epidemic of South Africa for improving the antiretroviral therapy coverage due to an acute shortage of doctors. The WHO further established guidelines for task shifting in 2008. These were endorsed by the World Medical Association's resolution in 2009 and have thus been adopted by LMICs (50, 51). Additional examples of successful task shifting include managing COVID-19 globally during the pandemic and detecting and treating hepatitis, malaria, tuberculosis, and chronic conditions, such as hypertension and diabetes (52-55). Literature reviews have also reported that well-designed and meticulously implemented task-shifting interventions have resulted in programmes achieving health outcomes comparable to those delivered by physicians, while improving overall care coverage, reducing costs for both patients and health systems, and enhancing patient satisfaction (52, 53, 56).

Systematic reviews evaluating task shifting for diabetes outcomes in LMICs reported improved HbA1c outcomes (53). Many Indian studies reported successful task shifting, using nurses and

other mid-level healthcare workers for diabetes management in primary healthcare facilities, comparable to physician care (53, 57-59). One study reported that patients managed by skilled Accredited Social Health Activists (ASHAs) in India reduced HbA1c by >0.5% after nine months, using a clinical decision support system for the ASHAs to identify people with diabetes (59).

The Indian government has recognised these initiatives and incorporated task shifting into its national non-communicable disease (NCD) control policies. It initially established the National Programme for Prevention and Control of Non-Communicable Diseases (NPCDCS), which focuses on task-shifting as a core strategy to improve healthcare outcomes at the primary level. Recently, this program was expanded to the National Program for Prevention and Control of Non-communicable Diseases (NP-NCD) to cover a broader range of conditions, including chronic respiratory diseases, chronic kidney conditions, and non-alcoholic fatty liver disease. These programmes define the roles of each health worker cadre along the care continuum pathways. The government has set up health and wellness clinics at the village level to provide basic health services. Telangana has around 150 of these clinics, using task shifting through community health workers for screening, case detection, patient referrals, and follow-up of infectious diseases and NCDs. LMICs should develop task-shifting strategies to manage NCD care effectively over the lifespan.

1.6 Role of Community Health Workers in Task Shifting

Community health workers (CHWs) are a specific cadre of health workers who are extremely important for successful task shifting in low-resource settings, such as India. The WHO defines them as "*health workers who receive standardised training outside formal nursing or medical curricula to deliver a range of basic health, promotional, educational, and prevention services, and who are members of the communities where they work.*" (60). Thus, there is a significant focus on community-based CHWs, trained as conduits between health systems and their communities. Successful CHW-led interventions have addressed many health domains, including maternal and child health, infectious diseases, NCDs, psychological health, and health promotion. Evidence reported CHWs' success in achieving population-level outcomes, such as disease or condition screening, supporting patient compliance and adherence, and managing emergencies, including COVID-19 and hypoglycaemia (52, 54, 56, 58, 61-89). CHW-led interventions have reported promising results for NCD management and patient

outcomes, especially in LMICs, including India. Some systematic reviews have reported (indications of) improvements in glycaemic control, diabetes knowledge, and self-care behaviours. Even minor improvements can have a greater impact on glycaemic control and reduce the risk of subsequent complications (58, 62, 82, 86, 89-94).

Building upon this evidence, the Indian government established a cadre of Community Health Workers known as Accredited Social Health Activists (ASHAs) in 2005. Currently, this represents one of the largest community health worker initiatives worldwide, with over 1 million ASHAs deployed across India. These ASHAs are women who serve in villages with populations ranging from 3,000 to 5,000 residents. Initially trained in maternal and childcare, their roles have expanded and are now integrated into more than 30 national health programmes, acting as the primary interface between the public healthcare system and rural communities. According to the operational guidelines of the NP-NCD (formerly NPCDCS), ASHAs bear specific responsibilities in the management of diabetes. These responsibilities include opportunistic and targeted door-to-door screening for diabetes, patient education, community awareness campaigns, collection of field data, monitoring and surveillance activities, reporting data to higher authorities, assisting patients during consultations with doctors or nurses, and supporting patients in adhering to prescribed management protocols.

Despite their existing roles and responsibilities, evidence reports of gaps in ASHAs' competencies essential for diabetes management. This highlights the need to establish a structured training program to address these gaps.

1.7 Need for Competency Training for Community Health Workers

The existing evidence highlighting the need for competency training for CHWs is important for policymakers to recognise and incorporate into existing systems, while also highlighting the importance of training quality (44, 63, 86, 95). This quality includes the training content, its frequency, monitoring and surveillance of training activities, and the administration's support for these efforts.

Currently, the guidelines developed by the government of India are used for introductory orientation training for CHWs, but there is no structured training module focused on diabetes. The existing trainings vary widely in their content, delivery methods, duration, intensity, and quality, making it difficult to establish a clear structure (44, 86). Studies from India support this, reporting a deficiency in CHW knowledge and related competencies in diabetes management

(44, 86). Telangana has more than 10,000 villages with at least one ASHA per village employed in its service. Insufficient training, affecting the success of the task shifting, will severely impact the large number of individuals living with diabetes in the state unless addressed and rectified.

1.8 Eye Complications of Diabetes

As previously articulated, the microvascular complications associated with unmanaged diabetes mellitus impact the ocular system, renal function, and neural structures. The term 'diabetic eye disease' is employed to collectively refer to all ocular conditions that are directly or indirectly influenced by diabetes mellitus, including diabetic retinopathy, diabetic macular oedema, cataract, glaucoma, and infections of the external eye.

Evidence reports that cataracts develop earlier in people with diabetes compared to those without diabetes (96). However, cataracts that impair vision are easier to identify compared to other conditions, such as diabetic retinopathy or diabetic macular oedema, which require an eye examination with indirect ophthalmoscopy or fundus imaging to diagnose and confirm.

The IDF reports on global diabetes epidemiology using seven geographic regions. A recent systematic review of estimates from retinal imaging studies conducted across these regions from 2017 to 2024 found that 23% of all people with diabetes have some form of diabetic retinopathy (DR) (95% CI: 20-26%), and 11% have sight-threatening diabetic retinopathy (95% CI: 9-14%). Comparing this data to the 2015-2019 period, the overall rate of any DR has decreased from 27% to 23%, likely due to improved glycaemic and blood pressure management in higher-income areas. Meanwhile, the rate of proliferative DR has rose from 1.4% to 6%, probably reflecting increased detection in previously under-screened populations. (97).

The South-East Asia region of the IDF, including the Indian population-based estimates report lower regional rates of DR than the global average; any form of DR affects nearly 12.5% populations, ranging from 9.9% to 15.4% (98), and vision threatening forms affecting 3-6% of these population, the lowest of all the seven IDF regions (99). This is consistent with the existing wider body of evidence, which reports lower prevalence of DR among Asian populations with diabetes, when compared to similar populations of European or Middle Eastern ancestry (100). Yet, as this region is home to nearly 18% of all individuals with diabetes globally, even these lower regional rates will lead to a huge burden of avoidable vision loss

(101). Indian data estimates that nearly 3 million aged 40 years or above have sight threatening diabetic retinopathy (14). Sight threatening DR is estimated to affect nearly 5-7% of Indians living with diabetes, which is 3-4.5 million people (102), many of whom are still undiagnosed, not screened, and thus not treated. Evidence from the national Blindness and Visual Impairment Survey reported that nearly 90% of people with diabetes had never had a fundus examination, while another survey from rural north India reported that about 85% of people with diabetes did not undergo DR screening (103, 104). Further operational evidence from India reported prevalence of DR as high as 16.2% and of sight-threatening DR as high as 7.2% across 10 states and more than 66,000 patients (105). Comparable evidence by Murthy et al. also reported a successful pilot model, wherein an integrated DR screening and management embedded in the public health system was found to be feasible and scalable, and to result in a seven-fold increase in the number of people living with diabetes screened per 100,000 population (screening uptake) (105). The same study also highlights a critical challenge: only 10.1% of the initially screened and referred patients return for an annual follow-up screening. This highlights that detection alone is not enough without community-level mechanisms to ensure initial and periodic follow-up screening adherence in patients to prevent vision loss (105). The evidence above identifies gaps in the initial DR screening and the low annual follow-up screening rate (10.1%). Our trial's outcome addresses the initial DR screening gap, as CHWs are well-positioned within the community to identify and facilitate this process.

1.9 Existing Research Gap and Study Rationale

No randomised controlled trial has evaluated a structured CHW competency training program on diabetes care pathways and its impact on patient and health system outcomes, especially in rural areas. Most existing studies are either cross-sectional or focus on clinical outcomes such as glycaemic control (54, 57, 58, 90). Moreover, there are very few studies, especially from India.

Thus, the questions regarding the design, development, implementation, and sustainability of such task-shifting interventions for CHWs, and their translation into scalable models for similar geographies, remain unanswered at this stage. A study designed for this purpose will also help evaluate other factors, such as the quality of training, surveillance mechanisms, community engagement, and the health system's readiness and limitations. This is an important requirement for policymakers in implementing this initiative.

Consequently, we addressed this gap by designing a cluster-randomised controlled trial to assess the impact of a structured training program aimed at enhancing CHW knowledge and practice behaviour competencies on patient outcomes related to diabetes screening, referral, case detection, and diabetic retinopathy screening within rural Telangana. Eight clusters were selected in the Ranga Reddy district of Telangana as the study sites.

1.10 Research Question and Objectives

Research Question: Does a structured, competency-based (knowledge and practice behaviours) training from community health workers in rural Telangana improve their knowledge and practice behaviours, and do these changes result in improvement of diabetes screening, diagnostic testing uptake, confirmed diabetes detection, and diabetic retinopathy screening, compared to standard care provided by CHWs in the control arm?

Objectives: To evaluate the effectiveness of the CHW training, compared to the control arm, we assessed the following outcomes:

i. CHW level outcomes:
    a. Change in CHW knowledge scores related to type 2 diabetes mellitus and its complications, its screening, testing, and management.
    b. Change in CHW practice behaviour scores related to type 2 diabetes management, its screening, testing, and referral, along with its complications.

ii. Patient-level outcomes:
    a. The proportion of screened and referred high-risk individuals who underwent diabetes diagnostic testing (diagnostic testing rate).
    b. The proportion of tested individuals confirmed with diabetes (confirmed diabetes detection rate).
    c. The proportion of patients confirmed with diabetes who underwent diabetic retinopathy screening after being referred for it (DR screening rate).

All these outcomes were compared between the intervention arm, in which the CHWs received training, and the control arm, in which the CHWs continued with standard care without structured training.

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CHAPTER 2

Chapter 2: Does training of Community Health Workers in diabetes lead to improved outcomes for diabetes, screening and management in low-and middle-income countries: A systematic review protocol

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Abstract:

Introduction: Diabetes is a growing concern worldwide, particularly in low- and middle-income countries (LMICs). Type 2 Diabetes Mellitus (T2DM) constitutes a significant proportion of cases and is associated with debilitating microvascular complications. T2DM is steadily increasing among the LMICs where many barriers to healthcare exist. Thus, task shifting to community health workers (CHWs) has been proposed as a solution to improve diabetes management in these settings. However, CHWs often lack the necessary training to manage diabetes effectively. Thus, a systematic review is required to present evidence of the highest degree for this intervention, and this protocol aims to establish the outline for such a review. These protocols have been registered with PROSPERO at PROSPERO 2022 CRD42022341717.

Methodology: Using the PICOTS framework, this protocol outlines a systematic review aiming to evaluate the impact of training programs for CHWs in diabetes management in LMICs. Quantitative studies focusing on CHWs, diabetes training, focusing on diabetes management outcomes like HbA1c levels and fasting blood glucose levels, between January 2000 and December 2023 and found on databases like PubMed, Ovid Medline, EMBR, BASE, Google Scholar, Web of Science, etc. will be included. We will include RCTs but will include observational studies if we find less than 5 RCTs. Three reviewers will form the author committee, where two will conduct the review independently while the third will resolve all disputes. The ROB-2 tool will be used for assessing the risk of bias and the GRADE approach for the meta-analysis and narrative synthesis analysis will be utilized. The results will be presented in a PRISMA diagram.

Results: The review will begin in May 2024 and conclude in three months.

Conclusion: The review will synthesize existing evidence and provide insights into the effectiveness of such programs, informing future research and practice in diabetes care in LMICs.

Introduction

Diabetes is a global epidemic that is threatening to grow exponentially and impact the lives of those affected. The International Diabetes Federation (IDF) estimates 463 million people who have Diabetes globally and projects this number increasing to 700 million by 2045)[1]. Almost eighty per cent of the world's diabetes patients reside in low-and-middle-income countries [2]. Type 2 Diabetes Mellitus (T2DM) constitutes a majority of diabetes patients (almost 90%) and it severely affects the patients by causing microvascular complications that are often

debilitating and morbid[3]. The condition itself is a risk factor for many other conditions like stroke, cancer, tuberculosis, etc. and causes damage to critical organs like the heart, kidneys, eyes and the limbs [4][5]. The immunocompromised nature of the patients makes them susceptible to infections and contributes to poorer health outcomes.

The Low- and Middle-Income Countries (LMICs) are also gradually witnessing a rise in the prevalence of the disease in rural areas[6]. The LMICs are also plagued with barriers like trained healthcare professionals who are required to cater to this growing number of diabetic patients, large distances to the health centres, lack of transport facilities, etc. often causing poorer uptake of health services[7–9].

The T2DM disease burden has increased exponentially in LMICs due to continuous upward growth in the trajectory of common risk factors responsible for T2DM. These have caused an increase in the comorbidities associated with the condition across the LMICs[10]. Similarly, the age-standardized death rates over the past decade have seen a two to three-fold increase in the LMICs, when compared to the Upper or Middle-Income countries[11]. Recent studies have shown an increase in the prevalence of T2DM in lower socio-economic areas of LMICs[6,12]. They also show that the increase in the prevalence of prediabetes is greater in these areas than the rate of increase in urban areas.[13,14]. Hence, the burden is set to increase amongst populations that have remote access to healthcare services or cannot afford the life-long management costs associated with T2DM[14–18].

Thus, a potential method of overcoming these barriers has been the use of community health workers (CHWs) for task shifting in LMICs for both infectious diseases and non-communicable diseases (NCDs) [19–27]. All such task shifting initiatives need to ensure that the participating CHWs are provided requisite training. Most CHW studies have found them to be deficient in knowledge and associated skills and hence training them for any task-shifting initiative is critical for its success[28–31].

Where training has been provided, the results have generally been encouraging. However, such training programs have been few, and their evaluations have been rare. Evidence is found wanting for the efficiency of trained CHWs in LMICs in screening and managing patients with diabetes. Hence a systematic review is required to present evidence of the highest degree for this intervention, and we propose to conduct the systematic review to understand if training of community health workers in diabetes would lead to improved outcomes for diabetes, screening and management in low- and middle-income countries.

Thus, the objective of this paper is to establish the protocols for the systematic review.

The systematic review has been registered with PROSPERO, at PROSPERO 2022 CRD42022341717[32].

Methodology: The criteria for considering studies for the systematic review would be done according to PICOTS framework. Therefore, we would be considering the studies under the following the condition, the participants, the intervention, the comparators, the outcomes, the types of studies, the timing of the study. Along with these, the databases to be used for the search will also be considered.

Description of condition: Type 2 diabetes mellitus will be the condition of interest. It accounts for almost 90% of diabetes globally and thereby affects a larger proportion of the population suffering from it. We will consider the WHO cut-off value of 126mg/dl for fasting plasma glucose or 200 mg/dl for 2-hour post food plasma glucose to classify a person as suffering from diabetes[33].

Description of participants: Community Health Workers (CHWs) of Low- and middle-income countries (LMICs) will be considered participants for studies/trials to be included in this review. The World Health Organization (WHO) defines a community health worker to be *members of the communities where they work, should be selected by the communities, should be answerable to the communities for their activities, should be supported by the health system but not necessarily be a part of its organization, and have shorter training than professional workers*[34]. Hence, we will include all studies which include the CHWs in LMICs. The LMICs will be defined according to the World Bank definition of economies as those with a Gross National Income (GNI) per capita between $1,136 and $4,465, calculated using the World Bank Atlas method[35]. A detailed list of the countries is given in Annexure 1.

Description of the intervention: The CHWs employed for task shifting have been found to have deficient knowledge. This can be corrected by providing them with the requisite training as training has been evidenced as an effective instrument for improving their knowledge, skills, and practices in LMICs[36,37]. Training in Type 2 Diabetes Mellitus (T2DM) management includes the systematic application of formal processes to impart knowledge and help people acquire the skills necessary for them to perform their jobs satisfactorily. Hence, studies reporting any training related to the knowledge, skills and

performance of the CHWs will be included. Some of the common aspects of training might include,

- Screening of glycemia,
- Lifestyle advice and education for patients,
- Measurement of glycemia, and
- Referral indications related to the above items.

Description of the Comparator: Standard training given to CHWs will be considered as the comparator. Therefore, any such training (whether focused on diabetes or even no training) provided to the CHWs would be included as the comparator.

Description of Studies: For the review, we will include randomised control trials as the first choice of studies, conducted between January 2000 to December 2023, in LMICs and published in English. This is due to the fact they present the highest degree of scientific evidence and the World Health Organization and the World Medical Association published their guidelines and resolutions on task shifting respectively[38,39] around this time period. If there are less than 5 such studies, we will then include observational studies as well. For the purpose of high scientific evidence, we will exclude qualitative studies. The included studies will focus on the training of CHWs in diabetes and look at diabetes management as their outcome. The details about the outcomes are detailed in the section below.

Description of Outcomes: As we wish to study the effect of the training on diabetes management, we will include studies reporting any of the following outcomes with the respective measures of effect:

- Referral for diabetes- Change in the number of referrals
- Screening for diabetes- Change in the number of screenings
- HbA1c values- Change in the mean HbA1c values
- Fasting blood glucose values- Change in the mean fasting blood glucose values

Databases for search: For our review, we would search for appropriate studies on the following databases:

- Ovid MEDLINE,
- PubMed
- Scopus,
- Cochrane Central
- Evidence Based Medicine Reviews

Additionally, we will also search the bibliographies of all the trials included based on our search strategies to identify further relevant studies. We will also be searching for all pertinent grey literature as this will help us identify the case studies and reports in greater detail. This will include a search of databases about grey literature like BASE, Google Scholar, WHO International Clinical Trials Registry Platform and World Cat. These will help us identify reports of studies conducted by private and civil society organizations or by other PhD students. The provisional search strategy for PubMed has been described in Annexure 2.

Study selection for the review: Study titles and abstracts, which will be obtained through electronic source search, will be independently read by the authors (AG & R). The articles would then be selected for eligibility, based on the criteria above. Articles that the authors find to be eligible will be retrieved in the full-text form. In case any of these articles are later found to be unsuitable for inclusion in our review, they would be mentioned separately in detail in a tabular manner, titled Table of excluded studies. The PRISMA-P[40] guidelines have been adhered to for this protocol and PRISMA guidelines will be adhered to for the conduct of the review (PRISMA-P checklist attached as Annexure-3). The full-text review will be carried out independently by both the authors (AG & R). The third author (GRB) will resolve any disagreements which might arise.

Data Extraction & Synthesis: The data extraction will be done by two reviewers independently. They will first develop a custom-made data extraction form using the Cochrane collaboration template for Randomised Controlled Trials (RCTs) & non-RCTs. This form will first be piloted with a small sample of study designs included in the review. The data will be extracted to prespecified and pre-approved sheets using Microsoft Excel. These forms will be prespecified by the authors to include a recording of the study characteristics, the outcomes of interest and all relevant information. Furthermore, these forms will be shared with the author committee members for their feedback and for them to further pilot it put on a small number of studies. Based on this the forms would either be revised or finalized. In this manner, these forms would be pre-approved and finalized. The final version of the form will be used to extract & subsequently collect data from all the included studies by the review authors. Any disagreements will be resolved by the third reviewer.

If the data extracted is found to be limited, then we will contact the study authors for further information. Finally, we will also contact the authors of the included trials or studies to ascertain if they would like to answer any questions regarding the trials or studies. All the results will be presented in an appendix. Any missing or otherwise relevant information will be obtained from the primary authors of the original trials or studies (if needed).

Lastly, in cases of multiple publications, we will consider the final or the updated version of each study as the primary reference. This will ensure that the latest evidence is included in the review.

The following information will be extracted from the studies included:

- Training Characteristics: We will extract characteristics like the duration of training, Frequency of training, the content of training, location of training
- The outcomes as reported by the study authors and will include the following outcomes:
    - Referral for Diabetes
    - Screening for diabetes
    - HbA1c scores
    - Fasting Blood glucose values

We will use the desktop version of software like COVIDENCE or SysRev for the extraction process.

Risk of bias (quality) assessment

We will follow the revised risk of bias version 2 (ROB) tool[41], which is a modified version of the Cochrane risk of bias tool to assess the internal validity of the included randomized controlled trials. The tool includes an assessment of sequence generation and allocation concealment, blinding of participants and outcome assessment, incomplete outcome data and selective outcome reporting.

We will use ROBINS risk of bias tool in non-randomised studies (if included) of intervention for assessing the risk of bias in non-randomised studies included in the review. This will be done at the outcome level. All three reviewers (AGG, R and GRB) will be a part of the review. The first two will be conducting the review and in case of any disagreement which can't be resolved between them, the third reviewer will resolve the disagreement, and his decision will be final. If the information available from the sources is inadequate, then we will contact the primary authors of the studies to include details to request any missing data on items that could have contributed to the risk of bias. The individual bias items will be evaluated based on the items described in the *Cochrane Handbook for Systematic Review of Interventions-version 6.1, 2020*[42].

Strategy for data synthesis

A preliminary search for studies showed a lot of heterogeneity, in terms of the training, like the study settings, participant education, professional experience, training frequency, training duration and training content. Expecting this trend in the studies to be extracted & included, the authors will synthesize the training component narratively as per the Cochrane Handbook's suggestion.

The preliminary search also showed homogeneity in terms of the outcome results, like the mean change in fasting blood glucose values and the mean change in HbA1c values. We will perform a meta-analysis and report the results in a PRISMA- diagram[43].

The data points which the reviewers would look for synthesis are:

i. The effect of the intervention: Authors will determine if studies are estimating the same underlying treatment/intervention effect. As our review focuses on CHW training as the intervention, we will be looking to see if the studies are estimating the intervention effect in terms of knowledge, skills and performance of the CHWs related to diabetes, i.e. the interventions focusing on:
    - Screening
    - Referral
    - HbA1c levels &
    - Fasting blood glucose levels

Additionally, the methodology & participant(s) being studied will also be studied.

ii. The factors affecting the implementation of the study interventions.

For the continuous data points, we would use the mean difference method for meta-analysis while we would use the odds ratio and the risk ratio methods for the discrete data points. In both cases the confidence intervals would be 95%.

The narrative synthesis will be carried out by developing a general framework using a set of tools like MS Excel and Mendeley or Endnote. This will be executed using the following steps:

- Develop a theory of change to understand how the intervention works, why it works and for whom it best works
- Development of preliminary synthesis of findings of all the studies to be included
- Exploration of relationships across the entire data from the included studies.
- Assessment of the robustness of synthesis.

The main narrative findings will be reported in a table titled 'Summary of Findings' by using the GRADE approach as mentioned in the Cochrane Handbook. The within-study risk of bias to assess the methodological quality, the directness of the evidence, the heterogeneity, the precision effect estimates, and the risk of publication bias will also be considered.

Eventually, a rating system to rate the quality of the evidence for each of the outcomes in terms of high, moderate, low & very low will be created. The same GRADE method will also be used for the meta-analysis findings.

Analysis of subgroups or subsets

We plan to perform subgroup analysis according to the following factors:

• Types of community health workers (nurses, lay health workers, etc.)

• Demographic factors of health workers (education, work experience, etc.)

These factors will be analysed for homogeneity or heterogeneity using the chosen software. All data would be entered into the software and tabulations would be carried out concerning each of the factors mentioned above to assess the heterogeneity/homogeneity. We would be utilizing the Q statistics and I-square methods for assessing the heterogeneity. Further relationships will be explored within the data using the aforementioned factors and the predefined outcomes. A statistical test of significance will be carried out for each of the mentioned factors and an eventual summary will be presented to showcase statistical significance (if present) based on the p-value of the association using the one-tailed test for each factor and its relationship with each outcome.

Results:

The review will be started in May 2024 and will be completed in a timeframe of 3 months. This will include the screening, abstract review, full-text review, data extraction and data synthesis.

Discussion:

Diabetes is a pressing global health challenge, particularly affecting low- and middle-income countries (LMICs), where the prevalence is rapidly increasing among sections that are unable to afford or access quality healthcare. These patients are at high risk of developing complications which affect the critical organs of the body. This combined with the delayed wound healing and their immunocompromised status, contributes to poorer outcomes for them. This underscores the importance of developing effective strategies for managing T2DM, particularly in LMICs where access to healthcare services can be limited.

One such strategy is use of community health workers (CHWs) for task shifting. CHWs, who are often members of the communities they serve, play a vital role in delivering healthcare services, including diabetes management, in LMICs. However, CHWs lack the necessary

knowledge and skills to manage diabetes and thus require training to improve their capacities. While there is some evidence to suggest that such training programs are successful in improving the CHWs knowledge, skills, and performance in diabetes management, such studies are few and their evaluations are rare. Therefore, there is a need for a systematic review to assess the impact of training programs for CHWs on diabetes outcomes in LMICs.

This protocol aims to establish the outline for such a systematic review and has been registered with PROSPERO.

Possible findings from the review may include evidence supporting the effectiveness of training programs in improving CHWs' ability to screen for diabetes, refer patients for further care, and manage diabetes-related outcomes such as HbA1c levels and fasting blood glucose values. The review may also identify gaps in the existing literature, such as the lack of rigorous evaluations of training programs or the need for more studies in certain geographical regions or among specific populations.

The limitations of the study would be possible deviations from the protocols due to unexpected results in terms of number of studies, language restrictions, type and number of studies and the quality of studies.

In conclusion, our protocol aims to establish a systematic review that will have the potential to influence future efforts of CHW training for effective diabetes management in LMICs.

Author Contributions: Conceptualisation: A.G.G., S.K, G.R.B., N.C.S. and O.C.P.v.S. Validation: N.C.S., G.R.B. and O.C.P.v.S. Data curation: A.G.G., S.K and G.R.B. Funding acquisition: NA. Methodology: A.G.G., S.K, G.R.B., G.V.S.M., N.C.S. and O.C.P.v.S. Project administration: A.G.G. S.K. Resources: A.G.G., S.K, G.R.B. Software: NA. Supervision: S.K, G.R.B., G.V. S.M., N.C.S. and O.C.P.v.S. Writing-original draft: A.G.G. Writing-review and editing: A.G.G., S.K, G.R.B., G.V.S.M., N.C.S. and O.C.P.v.S. All authors have read and agreed to the published version of the manuscript

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Conflicts of interest: The authors do not report any conflict of interest.

Abbreviations: CHW- Community Health Worker; LMIC- Low and Middle Income Country; T2DM- Type 2 Diabetes Mellitus; RCT- Randomised Controlled Trial

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Data Availability: As the article is a protocol for a systematic review, hence there is no data. All supplementary materials are provided as annexures. In case of any queries, the corresponding author can be contacted, and they will ensure the requisite query/ data is provided.

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CHAPTER 3

Chapter 3: Training Community Health Workers for diabetes management in low- and middle-income countries: A systematic review

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https://diabetes.jmir.org/2026//e84508/

Abstract:

Background:

Type 2 diabetes mellitus (T2DM) is a significant public health challenge that disproportionately impacts low- and middle-income countries (LMICs), which account for 73% of the global cases. Owing to resource constraints, these nations have adopted task-shifting strategies utilizing community health workers (CHWs); however, there is limited and at most indirect evidence regarding the effectiveness of training CHWs in diabetes management. This reflects the limited number of eligible studies, the variability in training methodologies and the multicomponent nature of the interventions, which restricts the ability to attribute outcomes solely to CHW training.

Objective:

A systematic review was conducted to answer the question: Does training community health workers in diabetes (Type 2) improve the efficacy of diabetes screening and management at the community level in LMICs?

Methods:

The review was conducted by two reviewers, supervised by two supervisors, and adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA) guidelines. We conducted a comprehensive search across databases, including PubMed, MEDLINE Ovid, Scopus, EBMR, and CINAHL, for studies published between January 2000 and April 2024. All randomized and non-randomized controlled trials and observational studies assessing CHW training in diabetes management in LMICs were included. The primary outcome of interest was the mean change in HbA1c percentage levels. Data were synthesized narratively for training characteristics and study outcomes. The Risk of Bias 2 tool and the ROBINS-I tool were used for quality assessment.

Results: A total of 3,387 studies were screened, 69 were found eligible for full-text review, and four (three RCTs and one observational stepped wedge study, totalling ~1,000 patients) were included for further narrative analysis. One of the three RCTs reported statistically significant effects, with a mean HbA1c difference of –0.24% (p=0.001), but HbA1c was not its primary outcome of interest, and the majority of its sample consisted of normoglycemic, prediabetic and patients with diabetes. In contrast, all other studies reported reduced HbA1c levels that were not statistically significant. Risk of bias among RCTs was generally moderate (some concerns, with one trial at high risk), and the observational study had a serious risk of bias. A meta-analysis was not performed due to the limited number of RCTs.

Conclusions:

Training CHWs in diabetes (Type 2) management has shown limited and at most indirect effects for improving glycemic control in LMIC settings, limited by the small number of eligible studies, heterogeneity in training methodologies and the multicomponent nature of the included interventions with one trial demonstrating a statistically significant yet small reduction in HbA1c (-0.24%). Our review included only four eligible studies with a small representation of CHWs and multicomponent interventions. Considering the limited number of eligible studies, the heterogeneity in training methodologies and study designs, and the multicomponent nature of the included interventions, the existing evidence remains inadequate to definitively conclude if CHW training significantly improves diabetes management across LMICs. Therefore, strengthening and standardizing CHW training might be an effective strategy to enhance diabetes care in underserved settings. Future larger trials and implementation research can help maximize the impact of CHWs against the growing diabetes burden.

Trial registration: PROSPERO CRD42022341717

Keywords: Community Health Workers, Community Health Workers Training, Diabetes Management, Task Shifting, HbA1c, LMICs, Systematic Review

Introduction:

Rationale

Diabetes mellitus is a growing pandemic in the global community, with 589 million people suffering from it [1], whilst also representing one of the leading factors of mortality and morbidity globally [2]. Nearly 430 million people with diabetes, which is 73% of such patients, reside in low and middle-income countries (LMICs) [1]. The steadily rising prevalence [3] imposes a substantial burden on health systems due to the complexity of accessing healthcare in these countries [4-6]. Furthermore, individuals residing in rural areas encounter numerous barriers to accessing healthcare, which can be broadly categorized into four key areas: geographical accessibility, healthcare availability, financial accessibility, and the acceptability of care. Geographical accessibility refers to the ease or difficulty of reaching healthcare facilities, which is more pronounced in rural areas. This is due to the large distances rural patients must traverse and the limited transportation infrastructure. Healthcare access is limited by shortages of facilities and trained staff, especially in rural areas. Financial barriers, particularly out-of-pocket costs prevent many people, especially those from lower socio-

economic groups, from accessing healthcare. Additionally, sociocultural factors like mistrust or stigma can deter patients from seeking care. These barriers disproportionately affect rural populations and those from lower socioeconomic strata [2, 7-12].

Many LMICs employ local community health workers (CHWs) to improve access to healthcare. CHWs are usually individuals from the communities they serve, selected by those communities, and accountable to them for their work. While CHWs should receive support from the health system, they are not required to be formally integrated into its organizational structure. Additionally, their training is typically shorter than that of professional healthcare workers [13]. Referred to, as task shifting, using the CHWs for disease management is effective for infectious diseases (e.g., Human Immunodeficiency Virus infections and hepatitis), especially in pregnant women, newborns, and mothers [14, 15], and for non-communicable diseases, like diabetes and cardiovascular diseases [16-25]. While most LMICs consider skilling and implementing task shifting using CHWs to improve care quality [20], they are limited by a lack of clarity on the exact nature, content, and skills of the CHWs. Evidence suggests that the quality of healthcare at the primary care level is associated with the limited knowledge and requisite skills among the CHWs. Hence, most task-shifting initiatives also focus on imparting requisite training to the CHWs [9, 26-32]. Despite many CHW training programs, there is limited systematic evidence of their impact on diabetes outcomes in LMICs. While some reviews have examined CHW roles in diabetes globally, none have specifically focused on the effect of CHW training in LMIC contexts. Despite this, the evidence regarding the impact of CHW training in LMICs is still limited and mostly indirect, and no systematic review has specifically addressed this issue. Hence, this paper aims to systematically review the available evidence to answer the question: Does training community health workers in diabetes improve the efficacy of diabetes screening and management at the community level in LMICs?

Objective

We hypothesize that CHW training will improve glycaemic control among patients managed by the trained CHWs. By identifying and synthesizing existing studies, this review also aims to assess if training can be a necessary but insufficient component of a multi-component intervention of an effective CHW-led diabetes management highlighting knowledge gaps and inform future improvements in community-based diabetes care. This review also aims to identify gaps in the reporting of CHW training.

Methods:

Study Design and Registration

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA) guidelines [33, 34]. The review was registered with PROSPERO under the ID number CRD42022341717 and has been published previously [35].

Eligibility Criteria

We included randomized controlled trials (RCTs), non-randomised controlled trials, and observational studies that assessed the training of community health workers (CHWs) in the management of type 2 diabetes mellitus. The CHWs were included using the definition of the World Health Organization (WHO) [36]. We used the population, intervention, comparator, outcome and study setting (PICOS) framework for finalising the specific inclusion criteria, which were:

- **Population**: The population included was CHWs, managing persons with type 2 diabetes, from LMICs. We used the WHO's definition of CHW, which defined them as "members of the communities where they work, should be selected by the communities, should be answerable to the communities for their activities, should be supported by the health system but not necessarily be a part of its organization, and have shorter training than professional workers" [13]. We only included studies where the target population was 18 years or older. The baseline CHW qualifications of the CHWs were not reported in the included studies.
- **Intervention**: The review included any study in which CHWs received training in diabetes management, focusing on their knowledge, skills, and practices in diabetes management in LMICs, including blood glucose monitoring, lifestyle modification, and prevention of complications. All the included studies were implemented in a multi-component nature, wherein they combined training with other components of the intervention, and only one of them (Catley et al.) isolated the intervention effect. Thus, the intervention's (training's) effects could not be isolated from the delivery intensities of the interventions reported in the included studies.
- **Comparator**: Standard diabetes care, no intervention, or other training programs unrelated to diabetes served as comparators.
- **Outcomes**: The primary outcome of interest was the mean change in the glycosylated haemoglobin (HbA1c) levels of the individuals with diabetes managed by the CHWs.

We included HbA1c values even if they were reported as secondary outcomes in a study. The secondary outcomes of interest were other clinical measures such as random and fasting blood glucose, lipid profile, total cholesterol, and blood pressure (systolic and diastolic). A study was included only when HbA1c levels were reported. HbA1c was chosen as the primary clinical outcome of interest as it is the gold standard recommended by the World Health Organization and the International Diabetes Federation as it reports the glycaemic control of the patient over a 3-months. However, limiting to only this outcome would have excluded studies using alternative clinical outcome, thereby limiting our conclusion of the effect of CHW training on diabetes outcomes. Also, our research question encompassed diabetes screening along with management, but we did not find any eligible studies reporting screening outcomes.

Study Setting: Studies conducted in LMICs, as defined by the World Bank, were included (countries with a gross national income per capita between US$ 1136 and US$ 4465) [37]. **Exclusion Criteria**:

We excluded studies which did not have CHWs as defined by the WHO; studies which did not train CHWs; studies which did not report HbA1c as an outcome; studies which were not conducted in LMICs; studies which were protocols, reviews, qualitative studies, editorials and conference abstracts and studies which were not published in English.

It is important to note that CHW capacity building and service delivery exposure are distinct components of the intervention. The capacity building refers to the structured training interventions provided to the CHWs with their diversity in the curriculum, pedagogy, mode of training and frequency of training. The service delivery component refers to the activities concentrating on the contact between the CHWs and the patients, like type of contact, clinical monitoring and paraclinical support. Thus, the capacity building component focused on the CHW competency, the service delivery component focused on the post intervention implementation. Both these components together represent the effectiveness of the intervention.

Search Strategy

A comprehensive search was conducted across the following databases: PubMed, MEDLINE Ovid, Scopus, Evidence-Based Medicine Reviews (EBMR), and the Cumulative Index to Nursing and Allied Health Literature (CINAHL), spanning the period from January 2000 to April 2024. This period was chosen since the World Medical Association and the WHO published their respective task-shifting guidelines using CHWs around this time [38, 39]. The

search was limited to studies published in the English language. It used MeSH terms and free text related to community health workers, type 2 diabetes, training, and outcome measures like HbA1c, random blood glucose, oral Glucose Tolerance Test, and microvascular complications. Additional searches were conducted in grey literature databases such as the WHO International Clinical Trials Registry Platform and clinicaltrials.gov. The detailed search strategy is provided in Annexure 2.

Study Selection and Data Extraction

Two reviewers (AGG & SK) independently screened titles and abstracts of studies that might meet the inclusion criteria. Data were retrieved for full-text review, and those that fulfilled the inclusion criteria were extracted. A third reviewer (GRB) resolved any disagreements.

Data extraction was conducted using a customized version of the standardized form developed in Covidence software. An initial preliminary round of data extraction was performed with four studies each by AGG and SK. Once their inter-reviewer consistency was confirmed, further extraction was carried out. The data collected included study characteristics (author, year, country, and sample size), details of the intervention (CHW training content, duration, and frequency), and outcome measures (mean change in HbA1c, expressed as a percentage, and secondary outcomes). Additionally, all training-related data points were extracted, including the contents of the training module, mode of delivery, duration, and frequency of training and refresher sessions (if applicable). This was done to assess whether any of these factors were related to our outcome of interest and, if so, to what extent. All data were organized into tables for narrative comparison among the studies.

Quality Assessment

The quality of the included studies was assessed using the second version of the Cochrane's Risk of Bias 2 (RoB 2) tool [40] for RCTs and the ROBINS-I tool [41] for non-RCTs. The RoB 2 tool evaluated RCTs across five domains: bias from randomization, deviations, missing data, outcome measurement, and reporting. The ROBINS-1 tool assessed non-RCTs across seven domains: bias from confounding, participant selection, intervention classification, deviations, missing data, outcome measurement, and reporting. Each domain was scored as follows: low risk, some concerns, moderate, serious, and critical. Additionally, the masking of the assessors was not reported in the included studies, so it is not clear whether these studies were (partly) blinded or not.

Data Synthesis and Analysis:

The data from all of the included studies were extracted using forms we developed with the Covidence software. All data were exported into MS Excel (Office 2021). The studies were subsequently analysed narratively, considering the aim and objectives, the inclusion and exclusion criteria, the training characteristics, the outcome values for HbA1c, and the strengths and limitations of each study. We summarized the findings descriptively in text and a comparative table, recording which training features seemed most aligned with improved glycaemic control. This approach enabled us to explore thematic links between specific training modalities and HbA1c outcomes without formally combining effect sizes into a single quantitative estimate. A meta-analysis was not performed in accordance with the Cochrane handbook's recommendation for a meta-analysis with a fewer number of studies, as the pooled evidence may report an unreliable precision and heterogeneity among the studies [42]. The heterogeneity among the studies was conceptual and intervention-based, rather than statistical.

Results:

We identified 3387 studies for abstract screening, of which 69 were found eligible for full-text review (Figure 1). Upon further screening, four studies conducted in LMICs were included, all of which involved the assessment of the impact of the training of CHWs on the mean reduction of HbA1c levels. However, none of these studies reported any diabetes screening outcomes. Table 1 presents the study characteristics, training characteristics, sample sizes, and primary and secondary outcomes.

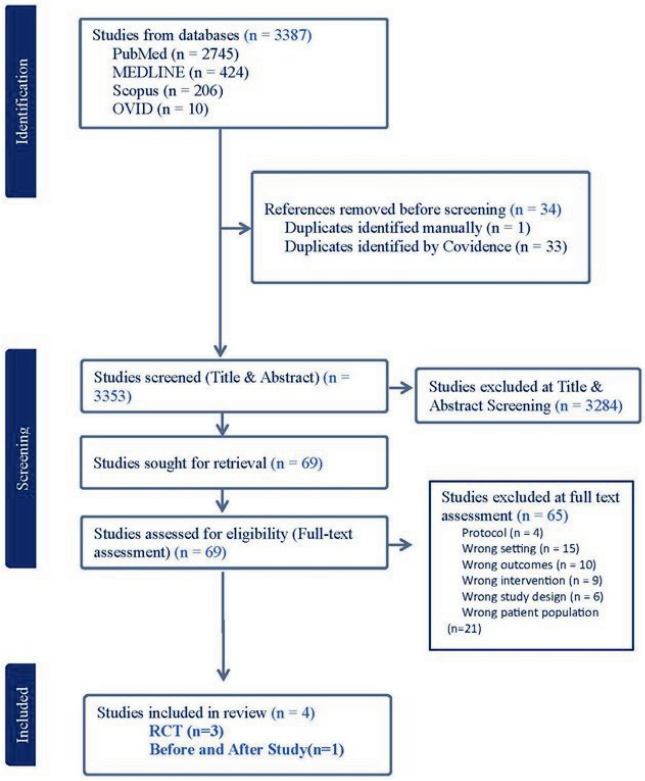


Figure 1: PRISMA 2020 Flowchart Diagram: Interventions Involving CHW Training for Diabetes in LMICs

Figure 1: PRISMA 2020 Flowchart Diagram: Interventions Involving CHW Training for Diabetes in LMICs

Overall, four studies involving a total of at least 10 CHWs and around 1000 patients were eligible for inclusion, of which three were randomized controlled trials (RCTs) [43-45] and one was an observational stepped wedge study [46]. We observed that the training varied in content, delivery, duration, frequency, and settings (Table 1). However, some of the content overlapped with common topics, such as diabetes management, lifestyle modification, and patient education strategies.

Jain et al. conducted an open-label RCT in rural Maharashtra, India, with 299 type 2 diabetes patients: 153 in the intervention arm (trained community health workers) and 146 in the control. At 6-month follow-up, 290 participants responded: 151 from the intervention group and 139 from the control group. Two CHWs trained in a 7-day workshop carried out four home visits and 12 phone reminders over six months. Results reported no significant between-arm differences in HbA1c at 6 months ($p = 0.51$). Both arms reduced HbA1c from baseline (Intervention: 7.63 + 2.16% vs Control: 7.64 + 1.79%, p=0.95; see Table 1). Similarly, no differences were found for glucose, blood pressure, LDL, HDL, or triglycerides. The RoB 2 assessment indicated some concerns and the number of CHWs included was very small in the intervention arm (n=2) the number in the control arm was not reported.

The study by Catley et al. was a cluster-randomised controlled trial in Cape Town suburbs, assessing weight loss as the primary outcome and HbA1c changes as a secondary outcome. Twenty-eight clusters were randomized between the intervention (Lifestyle Africa) and the control. The intervention, Lifestyle Africa, was adapted from the Diabetes Prevention Program, a lifestyle modification program, targeting weight loss through motivational interviewing and behaviour change methods. Out of 494 enrolled overweight or obese adults, 438 completed the 7–9-month follow-up : 215 in the intervention group and 223 in the control group; Out of the enrolled, 28.8% in the intervention arm and 22.4% in the control arm had diabetes. The intervention group (n=240) included 27.1% adults with normal glucose metabolism status, 44.2% with prediabetes, and 28.8% with diabetes, these categories were based on HBA1c. The control group (n=254) had 24.4% adults with normal glucose, 53.1% with prediabetes, and 22.4% with diabetes. The CHWs attended a 3-day workshop and eight sessions with 17 videos on motivational interviewing and behaviour change. CHWs role-played as mock participants, practicing activities like weighing participants, using video equipment, and facilitating discussions. The intervention arm (Lifestyle Africa) participants had a significant reduction in HbA1c compared to the control group (adjusted mean difference –0.24%, $p = 0.001$). No significant changes were observed in the primary outcomes, including blood pressure, LDL, HDL, triglycerides, and cholesterol levels. Participants in the intervention arm had a higher

probability of improving and a lower probability of raising their glucose metabolism status by at least 1 category (odds ratio [OR] = 1.52, 95% CI 1.04, 2.22, p = 0.03). The overall RoB 2 assessment indicated some concerns. Therefore, the HbA1c reduction reported reflects the shift in the overall glycaemic risk of the overweight adult population of the study and not a trial designed to test the efficiency of diabetes among patients with diabetes.

The study by de Souza et al. was a randomised controlled trial conducted in Porto Alegre, Brazil. The study aimed to measure the percentage change in mean HbA1c between intervention and control groups; 118 patients were randomly allocated to eight CHWs, with four trained in diabetes via four weekly 60-minute sessions (covering diabetes definition, lifestyle, medications, complications) in the intervention arm, including 62 patients, and four in the control arm with 56 patients were trained in unrelated health topics like tuberculosis, asthma, and contraception. All CHWs made monthly home visits. At the 3-month follow-up , there was no statistically significant difference in the percentage of mean HbA1c between the arms (Intervention: 7.9 ± 1.9% and Control: 8.4 + 2.5%, p=0.13). The total cholesterol and triglyceride levels declined more in the intervention group, whereas blood pressure and HDL levels changed similarly in both groups. The overall RoB 2 score was high risk and the number of CHWs in each arm was relatively small (n=4 in each arm)

The study by Worster et al. was an observational study conducted in the communities of Chiapas, Mexico. It aimed to study changes in diabetes and hypertension prevalences among patients through CHWs in primary care settings. In total 149 patients were included, with 73 treated for diabetes. The study followed an observational stepped wedge design over 12 months, with data collection at baseline and at every three months for 12 months after the implementation of the intervention with newly trained CHWs. In the subgroup of subjects with diabetes and a baseline HbA1c ≥9%, this value significantly decreased by ~0.96% (p = 0.01), but for all diabetes patients the mean decrease (~0.35%) was not statistically significant (p = 0.21). The risk of bias was assessed as serious using the ROBINS-I tool. (The detailed scores with explanations of the various domains for both RoB-2 and ROBINS-I tool are shown in Annexure 3.)

Table 1: Study Characteristics of Interventions Involving CHW Training for Diabetes in LMICs

Study	Study design	Number of CHWs Trained	CHW Training	Participants characteristics	HbA1c%			HbA1c Outcome	Follow-up
					Arm comparison at Follow-up	Change within arms	Arm comparison at follow-up		
Jain et al. (2018) [40]	Open-label RCT; 6 months follow-up; Maharashtra, India	INT: 2 new CHWs CON: N.M	7-day workshop on communication, adherence, complication recognition, and monitoring of diabetes	Patients with type 2 diabetes	INT (n=151): 7.63 ± 2.16 CON (n=139): 7.64 ±1.79 (at 6 months)	INT: p<0.01 CON: p<0.01 Statistical test: paired t-test;	p=0.95 Statistical test: ANCOVA adjusting for baseline	Primary	6
Catley et al. *	Cluster RCT; 7-9 months follow-up; Cape Town, South Africa	N.M	3-day workshop and eight weekly half-day experiential sessions on motivational interviewing and behaviour-change techniques.	Patients with BMI ≥ 25 kg/m^2; support group members receiving health services from local non-governmental organizations INT (n=240): Normoglycemia (N=65, 27.1%), prediabetes (N=106, 44.2%), diabetes (N=69, 28.8%)	INT: (n=215): 6.32 ± 1.34. normoglycemia (N=72, 34%), prediabetes (N=80, 37.7%), diabetes (N=60, 28.3%).	INT: N.M. CON: N.M.	Adjusted mean difference: –0.24 ± 0.08; p=0.001 Statistical Test: Multilevel ANCOVA fixed effects: arm &	Secondary	7-9

				CON (n=254):Normoglycemia (N=62, 24.4%), prediabetes (N=135, 53.1%), diabetes (N=57, 22.4%).	CON: (n=223) 6.38 ± 1.54. Normoglycemia (N=64, 28.7%), prediabetes (N=106, 47.5%), and diabetes (N=53, 23.8%).		baseline value		
deSouza et al	RCT;3 months follow-up; Conducted in São Pedro, Brazil	INT: 4 new CHWs CON: 4 New CHWs	INT: Four weekly 60-min diabetes sessions on diabetes definition, lifestyle therapy, pharmacological options, and chronic complications. CON: Four classes on TB, asthma & contraception. All CHWs made monthly home-visits	Patients with type 2 diabetes are included in CHW care.	INT: (n=62): 7.9 ± 1.9 CON: (n=56): 8.4 ± 2.5	INT: p<0.001 CON: p<0.001	p=0.13 Statistical Test: Student's t-test (HbA1c); Repeated-measures ANOVA; log-transform for skewed TG	Primary	3

Worster et al.	Observational Stepped Wedge Study with quarterly follow-up for 12 months. Conducted at Chiapas, Mexico	N.M	One month, 16-session course with monthly refreshers on pathophysiology, motivational interviewing, and home visit logistics. The CHWs received refresher training throughout the 12-month period.	Patients (>18 years) diagnosed with and being treated for diabetes &/or hypertension	N.A	-0.35% (95 % CI –0.90, 0.20), p = 0.21 s	Linear mixed-effects (random intercepts for person & community)	Primary (for patients with diabetes)	12

CT: Randomised Controlled Trial; INT: intervention arm; CON: control arm; CHW: Community Health Worker; HbA1c: Glycosylated Hemoglobin; G: Triglycerides; HDL/LDL: Lipoproteins; ANCOVA: Analysis of covariance; N.M: Not mentioned; N.A: Not Applicable;
Catley et al is the only study to report a statistically significant HbA1c difference between the arms

Discussion

The decision to choose a systematic review over a scoping review was intentional because our focus was on the effect, specifically, whether CHW training improves glycaemic control in LMICs. This approach required clear eligibility criteria, a formal risk-of-bias assessment, and a synthesis of the results, unlike a descriptive analysis typical of a scoping review. The identification of only four eligible studies highlights the evidence gap our review aims to address. We registered the review with a database such as PROSPERO to follow PRISMA-P guidelines, ensuring that the peer-reviewed protocol detailed the analysis plan in advance and reducing the risk of selective reporting.

The results of our systematic review show that improvement in HbA1c (at the population level) was moderate and statistically significant in only one study (Catley et al, 2022) [43]. Since HbA1c was not the primary outcome of interest, among its sample of normoglycemic, prediabetic and patients with diabetes, our review concludes that the evidence for training of CHWs in diabetes management in LMICs is limited and at most indirect. The limited number of eligible studies, the heterogeneity in training methodologies ranging from four-hour sessions to workshops across days and study designs, and the multicomponent nature of the included interventions, the existing evidence remains inadequate to definitively conclude if CHW training significantly improves diabetes management across LMICs.

The Catley study evaluated 'Lifestyle Africa', an adapted version of the Diabetes Prevention Program, a structured lifestyle modification program that primarily targeted weight loss through motivational interviewing and behaviour change techniques. The study involved CHW-patient contact after CHW training, with nearly 29 sessions (17 core and 12 post-core sessions) and a maximum follow-up period of 12 months (varying from 3 months to 12 months), thereby providing the study with sufficient time to detect a significant difference in HbA1c levels. However, the study included subjects who were normoglycemic, prediabetic, and patients with diabetes, and the change in HbA1c values (a secondary outcome) was recorded for this total population. Thus, the results may not be attributed directly to people with diabetes or generalized to the subgroup of people with only diabetes. The other two RCTs (Jain et al. and De Souza et al.) showed a reduction in HbA1c levels within both arms, but no difference was observed between the study arms. Both studies had shorter CHW-patient interactions (16 contacts and three contacts, respectively) and shorter follow-up periods (six months and three months, respectively). Meanwhile, the observational study (Worster et al.) documented a statistically significant change in the percentage of mean HbA1c levels only in

patients with HbA1c >9%. However, this could have been due to the regression to the mean effect [47], which could have arisen due to the selection of patients with extreme HbA1c values. In addition, the use of unadjusted statistical test, like the student's t-test, could have potentially overestimated the actual effect of the intervention. All included studies showed varying bias levels, affecting interpretation. Jain et al. and Catley's RCTs had some concerns; de Souza et al.'s RCT had high bias; Worster et al.'s observational study was rated serious. These ratings highlight the possibility of systematic errors affecting the reliability of and confidence in conclusions derived from the intervention outcomes.

Regarding treatment in the control arms, the participants of Jain et al. and deSouza et al. had received enhanced usual care, and this could have led to change in behaviour and reduced HbA1c levels in the control arms of these studies. Specifically, in the study conducted by Jain et al., control participants attended regular physician clinics and interacted frequently with their doctors. In the study by de Souza et al., although the CHWs in the control arm were not explicitly trained in diabetes management, they still conducted monthly home visits addressing other health topics (e.g., maternal health, immunization, TB, asthma), thereby ensuring consistent personal contact. These activities introduce two well-documented mechanisms for glycemic improvement. First, repeated contact, measurement, and observation can enhance patients' self-monitoring and adherence to lifestyle advice (the Hawthorne effect), even when the advice is unrelated to diabetes. Second, regular supportive contact (non-diabetes-focused contact) from a trusted CHW or physician can provide non-specific therapeutic exposure, improving self-efficacy, medication adherence, and problem-solving behaviours, which are known to lower HbA1c [47,48]. Therefore, reductions seen in the control arms are expected to be probable and reasonable, potentially attenuating the intervention effect size.

The outcome variation across studies may result from several factors, primarily due to varying intensity, duration, and content of the training program of the CHWs. The trial with significant HbA1c benefit (Catley et al.) involved a 3-day workshop and eight follow-up sessions with ongoing support via videos and SMS for CHWs spanning 7-9 months. The study's training emphasized practical skills, such as motivational interviewing and behavior-change techniques, to enhance patient engagement and coaching. In contrast, the trial of deSouza et al. featured a short, single 4-hour training session that emphasized basic diabetes knowledge but lacked ongoing mentorship, leading to no meaningful improvements in glycaemic control. These trends may suggest a dose-response relationship, where more intensive, skill-focused training of CHWs improves patient outcomes. These findings imply that CHW training interventions can potentially improve diabetes outcomes, particularly in subpopulations with

uncontrolled glycaemia; however, consistent and significant effects were not observed across all settings. Published evidence from higher-income countries and from peer led interventions using CHWs (study details are mentioned below) has demonstrated the success of these interventions, advocating for their trial and implementation in LMICs, where a shortage of rural doctors is prevalent. The systematic review by Werfalli et al. [50] of peer/CHW-led self-management support in LMICs (where patients managed their diabetes with CHW guidance) reported a statistically significant reduction in HbA1c across studies. Meanwhile, the review by Palmas et al. [51] reported modest HbA1c reduction against standard care. The review by Shah et al. [52] reported comparable results. Similarly, the DIALBEST trial by Perez-Escamilla et al. [53] and the study by Aponte et al. [54] conducted in the United States of America also reported a statistically significant change in the HbA1c percentage for CHW-led groups compared to the study's control arm. These studies were excluded from our review due to their intervention or location not satisfying our inclusion criteria. Recently, the systematic review by Evans et al. reported positive effects across a broader set of studies [55]. Our review differed in scope since we focused on CHW training as the intervention for LMICs and HbA1c as the inclusion criterion. The findings from Evans et al.'s and our reviews highlighted that, while CHW involvement in diabetes care may be beneficial, the specific and independent contribution of CHW training in LMICs to diabetes care require further investigation.

The United Kingdom Prospective Diabetes Study [56] showed that a modest reduction in HbA1c levels can be associated with meaningful clinical benefits, such as lowering the risk of future diabetic complications in the eyes, kidneys, and nerves. Even a 1% decrease in the HbA1c levels can result in a 37% reduction in combined microvascular complications ($p<0.001$), a 21% reduction in risk for any endpoint related to diabetes ($p<0.001$), and a 21% reduction in the deaths related to diabetes ($p<0.001$) [56, 57]. Thus, even the ~0.3–0.5% HbA1c reductions seen in one of our included studies could translate into clinically important benefits. Secondary outcomes such as random and fasting blood glucose, lipid profile, total cholesterol, and systolic and diastolic blood pressure were extracted but not analysed or tabulated because their measurements varied across the included RCTs, making direct comparison difficult. Since the main goal of the review was to assess the impact of CHW training on glycaemic control (HbA1c), these secondary measures, which were reported inconsistently, were not emphasised. However, if a secondary outcome was deemed useful, it was described in the study.

Strengths and Limitations

The study has several strengths. This review is one of the first to outline the advantages of training CHWs for improved glycaemic control over generic methods used in Low- and

Middle-Income Countries (LMICs). The review also establishes robust methodological rigour, supported by a registered protocol, a PRISMA-guided screening process, and a formal Risk of Bias (RoB) 2 and ROBINS-I appraisal. By integrating a 24-year multi-database search with pooled and narrative analyses on training intensity and content, this review provides insights relevant to policy and scalable within task-shifting programmes. Although the protocol had planned for a meta-analysis of homogeneous clinical outcomes, the authors decided not to undertake it because only four studies met the eligibility criteria and reported highly heterogeneous clinical outcomes. Thus, the authors undertook only the narrative analysis mentioned in the protocol and not the meta-analysis. This study faced limitations, including variability among included studies in design, intervention, and outcomes. The follow-up periods of all studies varied considerably from 3 months to 12 months. Our adherence to LMICs could have narrowed the evidence base while not reflecting the success of CHW training from high income countries. Thus, the results need to be interpreted cautiously and might not be generalizable. With only four trials, testing for publication bias was not performed [58]. Three studies did not isolate the intervention effects of CHW training from other intervention components, so HbA1c changes reflect combined effects, not just training. Only Catley et al. isolated the effect of lifestyle coaching statistically. Other studies risked performance and Hawthorne effects due to additional contact and training, possibly blurring causality. Small sample sizes in Jain et al. and de Souza et al. may limit external validity as well. The scale-up of programs with diverse CHWs may overestimate effects. The implementation of skills gained by CHWs was not reported, which is crucial. Overall, evidence quality has concerns due to biases and deviations. The certainty of the evidence was low to moderate, with concerns surrounding performance bias that might have introduced Hawthorne effects. The high risk of bias in deSouza et al. along with the concerns about the randomization process, raises a question about the equal distributions between the arms at baseline. The serious risk of bias in Worster et al. due to confounding and deviations from the interventions also raise question about the causal inference. All interventions were multi-component, so individual effects cannot be separated. Despite extensive searches, unpublished studies might be missed, risking publication bias.

Implications

While results across RCTs might suggest potentially beneficial effects despite limitations (with only one study showing a significant effect) of introducing CHWs in diabetes care in LMICs, the small number of trials and their limitations preclude the drawing of firm conclusions.

Therefore, we suggest that training characteristics, subsequent community interventions, and data collection and analyses must be studied further to develop an optimal training program for CHWs to manage diabetes and monitor the performance of the CHWs at the community level. In addition, such trials should be sufficiently powered, with adequate numbers of both CHWs and patients included. Additional trials, designed to isolate the impact of CHW training from other intervention components, such as service delivery intensity and CHW-patient contact frequency, are necessary to thoroughly establish a link between CHW training and diabetes care in LMICs. Lastly, we realize that many studies may not have met our stringent eligibility criteria, and thus the results cannot be generalised. We thus propose future scoping reviews be carried out to improve on this shortcoming.

This review highlights significant implications for healthcare practice and policy in LMICs. CHWs are essential for improving healthcare delivery to underserved groups. Offering them contextually relevant, standardized, and comprehensive training, along with ongoing support and periodic refresher sessions, can help sustain and boost the effectiveness of these interventions over time. Policymakers and health leaders should consider incorporating structured diabetes management training into CHW curricula and conducting regular reviews and refresher courses to maintain their skills. Future research should focus on identifying which CHW training elements have the greatest impact. Larger RCTs with more CHWs and standardized outcomes beyond just HbA1c are necessary to better assess specific component efficacy. Moreover, qualitative studies exploring CHWs' experiences and challenges in implementing diabetes care can offer valuable insights into improving training programs and support systems, complementing the findings from RCTs.

Conclusion

In conclusion, our review suggests that structured CHW training may be an avenue to improve diabetes outcomes in low-resource settings, but current evidence is insufficient and more robust scientific evidence is needed before firm conclusions can be drawn. Moreover, its implementation should be accompanied by rigorous evaluation to assess and optimize its impact.

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Data Availability: The data supporting the results of our review were obtained from the study-level data of the included publications, which are presented in the manuscript and the table. The

data extraction forms used for the review will be available from the corresponding author upon reasonable request.

Conflict of Interest: All the authors of our review confirm that no conflicts exist in relation to the research, authorship, or publication of the manuscript.

Author Contributions: AGG: Conceptualisation, Data Curation, Formal Analysis, Investigation, Methodology, Writing-Original Draft, Writing-Review and Editing; SK: Conceptualisation, Data Curation, Investigation, Methodology, Writing-Review and Editing; SV: Methodology, Writing-Review and Editing; GVSM: Validation, Supervision, Writing-Review and Editing; NCS: Validation, Supervision, Writing- Review and Editing; GRB: Conceptualisation, Methodology, Supervision, Validation, Writing-Review and Editing; OvS: Supervision, Validation, Writing- Review and Editing

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Annexure-1: PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Page 1
ABSTRACT			

Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Pages 2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Page 4
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Pages 5-6
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Pages 6-7
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Annexure-2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and, if applicable, details of automation tools used in the process.	Page 7
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and, if applicable, details of automation tools used in the process.	Page 7
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results compatible with each outcome domain in each study were sought (e.g., for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Page 8
	10b	List and define all other variables for which data were sought (e.g., participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Page 8
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study, and whether they worked independently, and if applicable, details of automation tools used in the process.	Page 7 and Annexure-3
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Pages 8-11
Synthesis methods	13a	Describe the processes to decide which studies were eligible for each synthesis (e.g., tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Pages 9-13
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling missing summary statistics or data conversions.	NA
	13c	Describe any methods used to tabulate or visually display the results of individual studies and syntheses.	NA
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Narrative Analysis was performed. Details given on Page 7
	13e	Describe any methods to explore possible causes of heterogeneity among study results (e.g., subgroup analysis, meta-regression).	NA due to a small number of

			studies included
	13f	Describe any sensitivity analyses conducted to assess the robustness of the synthesized results.	NA
Reporting bias assessment	14	Describe any methods used to assess the risk of bias due to missing results in a synthesis (arising from reporting biases).	RoB-2 and ROBINS-I were used. Details in Annexure-3
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	NA, explained in Discussion

Annexure-2: Search Strategies

PubMed

(((community health worker[MeSH Terms]) OR (community health workers[MeSH Terms])) OR (lay worker))) OR (CHW)) OR (health worker)) OR (health worker, community[MeSH Terms])) OR (health worker, village[MeSH Terms])) OR (health workers, community[MeSH Terms])) OR (ASHA)) OR (ANM)) OR (MPHW)) OR (JHA)) OR (MPW)) OR (MPHA)) AND (academic training[MeSH Terms])) OR (traini[MeSH Terms])) OR (activities, training[MeSH Terms])) OR (training)) OR (capacity building[MeSH Terms])) OR (activities, educational[MeSH Terms])) OR (activity, educational[MeSH Terms])) OR (education)) OR (hospital, teaching[MeSH Terms])) OR (hospitals, teaching[MeSH Terms])) OR (method, teaching[MeSH Terms])) OR (teaching)) OR (interactive tutorial[MeSH Terms])) OR (tutoring)) OR (coaching)) OR (supervision[MeSH Terms])) AND (effect, placebo[MeSH Terms])) OR (effects, placebo[MeSH Terms])) OR (placebo effect[MeSH Terms])) OR (placebos[MeSH Terms])) OR (placebo effects[MeSH Terms])) OR (care standard[MeSH Terms])) OR (care standards[MeSH Terms])) OR (standard training)) AND (type 2 diabetes mellitus[MeSH Terms])) OR (Typ[MeSH Terms])) OR (blood glucose[MeSH Terms])) OR (home blood glucose monitoring[MeSH Terms])) OR (monitoring, home blood glucose[MeSH Terms])) OR (Fasting Blood Glucose)) OR (FBS)) OR (Random Blood Glucose)) OR (Random Blood Sugar)) OR (Fasting Blood Sugar)) OR (RBS)) OR (consultation and referral[MeSH Terms])) OR (hospital referral[MeSH Terms])) OR (hospital referrals[MeSH Terms])) OR (referrals, hospital[MeSH Terms])) OR (referrals[MeSH

Terms])) OR (referrals, hospital[MeSH Terms])) OR (self referrals, physician[MeSH Terms])) OR (screening))) OR (a1b hemoglobin, glycosylated[MeSH Terms])) OR (glycosylated a1b hemoglobin[MeSH Terms])) OR (glycosylated hemoglobin[MeSH Terms])) OR (HbA1c)) OR (ogtt[MeSH Terms])) OR (glucose tolerance test[MeSH Terms])) OR (glucose tolerance tests[MeSH Terms])) OR (glucose tolerance, oral[MeSH Terms])) OR (microvascular complications)) OR (DR Screening)) OR (Diabetic Retinopathy Screening)) OR (Peripheral Neuropathy Screening) AND (clinicaltrial[Filter] OR meta-analysis[Filter] OR randomizedcontrolledtrial[Filter])) AND (countries, developing[MeSH Terms])) OR (countries, developing[MeSH Terms])) OR (countries, less developed[MeSH Terms])) OR (LMIC)) OR (Low and Middle Income Country)) OR (Low and Middle Income Countries) **Filters:** Clinical Trial, Clinical Trial, Phase III, Controlled Clinical Trial, Meta-Analysis, Pragmatic Clinical Trial, Randomized Controlled Trial, Systematic Review, Adult: 18+ years, from 2000/1/1 - 2024/4/1

Scopus

(TITLE-ABS-KEY ("community health worker" OR "community health workers" OR CHW OR "lay health worker" OR "health worker" OR "village health worker" OR ASHA OR ANM OR MPHW OR JHA OR MPW OR MPHA)
AND TITLE-ABS-KEY (training OR "academic training" OR "capacity building" OR education OR teaching OR supervision OR coaching OR tutorial OR tutoring)
AND TITLE-ABS-KEY ("type 2 diabetes mellitus" OR "blood glucose" OR HbA1c OR "glycosylated hemoglobin" OR "fasting blood glucose" OR "random blood glucose" OR "glucose tolerance test" OR OGTT OR "diabetic complications" OR "microvascular complications")
AND TITLE-ABS-KEY ("clinical trial" OR "randomized controlled trial" OR "meta-analysis" OR "systematic review")
AND TITLE-ABS-KEY ("low and middle income country" OR "low and middle income countries" OR LMIC OR "developing country" OR "developing countries")
AND PUBYEAR > 1999 AND PUBYEAR < 2025

Medline (OVID)

1 community {No Related Terms} (39719)
2 health worker {No Related Terms} (6629)
3 1 and 2 (377)
4 lay health worker {No Related Terms} (3986)
5 community health worker {No Related Terms} (1233)
6 CHW {No Related Terms} (1452)

7 4 or 5 or 6 (5764)
8 4 and 5 and 6 (194)
9 diabetes mellitus {No Related Terms} (10248)
10 type 2 diabetes {No Related Terms} (15087)
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13 DM {No Related Terms} (3275)
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18 capacity building {No Related Terms} (3142)
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20 guidance {No Related Terms} (8044)
21 teaching {No Related Terms} (15209)
22 tutoring {No Related Terms} (917)
23 supervision {No Related Terms} (4734)
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28 screening {No Related Terms} (13838)
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4 lay health worker {No Related Terms} (3986)
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EBMR

1. (community health worker* OR community health workers OR CHW OR lay health worker* OR health worker* OR village health worker* OR ASHA OR ANM OR MPHW OR JHA OR MPW OR MPHA)
2. (training OR academic training OR capacity building OR education OR teaching OR supervision OR coaching OR tutorial OR tutoring)
3. (type 2 diabetes mellitus OR blood glucose OR HbA1c OR glycosylated hemoglobin OR fasting blood glucose OR random blood glucose OR glucose tolerance test OR OGTT OR diabetic complications OR microvascular complications)
4. (clinical trial OR randomized controlled trial OR meta-analysis OR systematic review)
5. (low and middle income country OR low and middle income countries OR LMIC OR developing country OR developing countries)
6. 1 AND 2 AND 3 AND 4 AND 5
7. Limits: Publication date from 2000/01/01 to 2024/04/01

WHO ITCRP

Conditions or Disease: Type 2 Diabetes Mellitus, Blood Glucose, HbA1c
Other Terms: Community Health Worker, CHW, Health Worker, Lay Worker
Study Type: Interventional Studies (Clinical Trials)
Study Results: All Studies
Age Group: Adult (18+)
Location: Low and Middle-Income Countries (LMICs)
Study Start From: 01/01/2000
Study End Before: 12/31/2024

Clinicaltrials.gov

Advanced Search Fields:

- **Condition/Disease**: Type 2 Diabetes Mellitus, Blood Glucose, HbA1c
- **Intervention**: Community Health Worker, Lay Worker, CHW, Health Worker
- **Study Type**: Randomized Controlled Trial, Meta-analysis, Clinical Trial
- **Recruitment Status**: All
- **Age Group**: Adults
- **Countries of Recruitment**: Developing Countries, LMIC

Annexure 3: Risk of Bias Assessment

Risk of Bias 2 Tool for RCTs

Domain	Jain et al. (2018)	Catley et al. (2022)	de Souza et al. (2017)
Randomization Process	Low risk	Low risk	Some concerns
Deviations from Intended Interventions	Some concerns	Some concerns	Some concerns
Missing Outcome Data	Low risk	Low risk	Some concerns
Measurement of the Outcome	Some concerns	Some concerns	Some concerns
Selection of the Reported Result	Low risk	Some concerns	Low risk
Overall Risk of Bias	Some	Some concerns	High risk

	concerns		

Risk of Bias for Non-RCTs (using ROBINS-I)

Study	Confounding	Selection of Participants	Classification of Interventions	Deviations from Interventions	Missing Data	Measurement of Outcomes	Selection of Reported Results	Overall Bias
Worster et al., 2020	Serious	Moderate	Moderate	Serious	Low	Moderate	Low	Serious

CHAPTER 4

Chapter 4: Evaluation of Competence Training for the minimally trained health worker in type 2 diabetes: A cluster randomised controlled trial- Study Protocol

Published As: *Gudlavalleti AG, Babu GR, van Schayck OCP, Schaper NC, Lewis MG, Murthy GVS. Evaluation of competence training for the minimally trained health worker in type 2 diabetes: A cluster randomized controlled trial. Medicine (Baltimore). 2020 Oct 30;99(44):e22959. doi: 10.1097/MD.0000000000022959. PMID: 33126364; PMCID: PMC7598789.*

https://journals.lww.com/md-journal/fulltext/2020/10300/evaluation_of_competence_training_for_the.68.aspx

Abstract:

Introduction: Type 2 diabetes mellitus is responsible for high mortality and morbidity globally and in India. India has high prevalence of the condition, and the burden is set to increase exponentially in the next decade. Indians traditionally reside in rural or semi-urban areas with limited access to healthcare facilities. To overcome this the government has introduced a cadre of health workers called Accredited Social Health Activists (ASHA) for such areas. These workers were initially trained to provide maternal & infant care but now need improved competence training to improve type 2 diabetes screening & management in these locations. The objective of the study is to assess the competence training provided to ASHA workers at the chosen study sites.

Methodology: A cluster randomized control trial has been designed. It will be conducted across 8 centres in Hyderabad & Ranga Reddy districts of Telangana, India. The training will be provided to ASHA workers. The tool used for training will be developed from existing sources with an emphasis on topics which require training. The training will be delivered across 6 months at each centre as a classroom training. Each participant's baseline competence will be recorded using a questionnaire tool and a practical evaluation by trained public health experts. The same experts will use the same tools to assess the training post the intervention.

Discussion: This trial will evaluate the use of health worker training as a tool for improving the clinical competence in relation to type 2 diabetes mellitus. We anticipate that the module will provide a greater understanding of type 2 diabetes mellitus, the importance of screening of both disease and complications and improved skills for the same. The study has received the ethical approval form the Institutional Ethics Committee of the Indian Institute of Public Health Hyderabad. The registration number is: IIPHH/TRCIEC/218/2020. The trial has also been registered under the Clinical trial registry of India (CTRI) on 27th July 2020. The registration number of the trial is: CTRI/2020/07/026828. The URL of the registry trial is: http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=45342&EncHid=&userName=CTRI/2020/07/026828

Introduction:

Type 2 diabetes mellitus results in high mortality and morbidity globally[1]. The International Diabetes Federation estimates 75 million persons living with diabetes mellitus in India.

Amongst them, 1.1 million adults (aged 20-79 years) die annually due to type 2 diabetes mellitus[2]. Estimates also indicate around 42.2 million Indians currently living with undiagnosed type 2 diabetes mellitus[2]. The total type 2 diabetes mellitus disorder burden in India is enormous, and the burden is set to increase if not managed. Hence, timely diagnosis/screening and management need to be scaled up in the country. The Indian Council of Medical Research has set forth guidelines for screening and management of type 2 diabetes[3].

Most Indians (66.4% in 2017) live in the rural and semi-urban areas[4]. They have limited access to healthcare facilities due to socio-economic status, distance, availability of facilities, inadequate number of skilled doctors, etc.[5–10]. Concurrently, the prevalence of type 2 diabetes mellitus is increasing in rural and semi-urban India. More individuals from the lower socio-economic status are now being identified with type 2 diabetes mellitus[11]. Such persons with diabetes mellitus face catastrophic consequences. This is due to increasing type 2 diabetes mellitus burden and poor accessibility to public healthcare facilities. Hence, an innovative and feasible strategy is needed to improve access for efficient type 2 diabetes mellitus screening and management.

The use of minimally trained health workers in improving access to healthcare facilities has proven successful in low and middle-income countries[12–14]. The successes have been observed for communicable and non-communicable diseases[15-26]. Hence, type 2 diabetes mellitus screening and management by health workers in India offers a potentially feasible strategy. It can improve screening and subsequent management of type 2 diabetes mellitus and associated complications at the community level.

The Indian government in 2005, created a new cadre of non-physician minimally trained health volunteers. They are called accredited social health activists. These activists are female health volunteers. They are the primary interface between the public health care facilities and rural communities. They handle social mobilization and awareness in the 1000 residents of their community. Their primary activities include mobilizing women and children for reproductive and child health services, immunization of newborn, accompanying the referred cases for complications, etc. They are paid case-based incentives for her services[5, 17]. Currently, the government is also looking at utilizing the accredited social health activists' services for non-communicable disease management[27]. In lieu of the same, the government's National

Program for prevention and control of Cancer, Diabetes, Cardiovascular diseases and Stroke has also formulated operational guidelines for the health workers[28]

Competence has been explained as the "*possession of requisite skills, knowledge, education and capacity*"[29]. The competence about type 2 diabetes mellitus and its complications is a limiting factor in utilizing this workforce. It is important to provide standardized training to the health workers and then utilize their services in type 2 diabetes mellitus[18]. Ultimately the training should improve the competency of the health workers to improve type 2 diabetes mellitus screening at the public healthcare facilities.

Aim & Objectives of the Study:

Aim: We aim to assess the effect of health worker training in improving their competence with respect to type 2 diabetes mellitus.

Objectives of the study: The following are the objectives:

a. To train the health workers in competency-based training for type 2 diabetes mellitus.
b. To evaluate the training in realizing the change in the competence of the health workers.

Primary Hypothesis: We hypothesize that the competence levels of the health workers in the intervention package will increase the competence levels to 60% compared to an estimated level of 30% at the baseline.
Since there are no published estimates of this health workers' competence in diabetes care, a 30% baseline was used as a likely current estimate. This figure was based on consultations with government representatives and their field experience.

Methods

Preliminary Phase: This phase involves, identification of the study areas, the needs assessment with important stakeholders in these study areas and the designing and validation of the training module.

The training module will be collated using the modules developed by the Ministry of Health and Family Welfare, Government of India, The Indian Council of Medical Research, The National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke, The Indian Institute of Public Health-Hyderabad and the Public Health Foundation of India will be utilized [30][31][3][32]

Subsequently, a customized tool (questionnaire) will be developed for the evaluation of the competence, which will have both theoretical and practical components.

- *Identification of Study area:* Eight health centres across Hyderabad & Ranga Reddy districts of the state of Telangana will be identified as the study sites. Caution will be exercised to ensure that the eight centres are spread widely across the district. It will ensure no contamination of health workers and their patients from the intervention to the control group or vice-versa. These centres will also be identified based on their consent and the availability of health workers

- *Needs Assessment:* A needs assessment exercise will be conducted involving the important stakeholders involved. The stakeholders will consist of government officials, the medical officer at the health centre and the health workers from the cadre of workers to be trained.

- *Designing and Validation of Intervention package (training and evaluation tools):* The training module and evaluation questionnaires developed will be used for validating the entire intervention package at a neutral site with 10% of the calculated sample size, i.e. 30 health workers. The questionnaire will be developed to assess the change in competence pertaining to type 2 diabetes mellitus and its associated complications after the training. Pre and post-test assessment using the questionnaire and practical tools will be conducted in the test population for validating the training and evaluation tool.

Intervention Phase: This phase will mainly consist of clustering of the health centres randomly into the intervention and control clusters, the identification and recruitment of health workers into the study based on the inclusion and exclusion criteria and the data collection procedure for training evaluation.

- *Clustering of health centres:* This stage will entail the random division of the identified eight health centres into two clusters namely the intervention cluster and the control cluster.

- *Identification & Recruitment of Health Workers:* In this stage after the health centres have been randomized into the intervention and control clusters, the health workers will be screened for eligibility. Those eligible will be inducted into the study based on their consent. The selection will be dependent on the inclusion and exclusion criteria mentioned under study design. The participants will be explained about the process using a participant information sheet. (See document- Appendix 1Supplemental Digital Content 1(Appendix 1), which illustrates the Participant Information sheet). This sheet will be shared with each participant after translating it into their vernacular language.

- *Data Collection:* Using a baseline questionnaire, we will understand their competence in type 2 diabetes mellitus. This tool will be developed using Michigan University's Diabetes Knowledge Test-2[33, 34], evaluation tools developed by the government of India and PHFI along with inputs from endocrinologists/physicians/public health experts. This will help us assess the baseline competence levels of the health workers. This tool will also capture the baseline data for the clinical competence of the participating health workers. All socio-demographic details and baseline details will be collected, entered and analyzed later.

Study design:

We will conduct a 12 month, prospective, unblinded, parallel cluster randomized controlled trial. The study will measure changes in healthcare worker competence levels related to type 2 diabetes mellitus and complications. The health centres chosen as the clusters will be then randomized into intervention and control arms. The health workers at the respective health centre will be thus assigned to the respective cluster arm. The clusters will be chosen such that they are geographically distinct. This will avoid any possible contamination within the groups. Health workers in the control group will continue to deliver services according to the current government standards and guidelines[28, 30, 31, 35]. They will continue their mandated duties as elucidated in the guidelines, namely the population enumeration, home screening, motivating patients to maintain a healthy lifestyle and attend regular complication screenings,

supervising of tasks undertaken by junior cadres, conducting meetings with local essential stakeholders, overseeing the data from their health centre, and sharing the data with the authorities.The intervention group participants will undergo additional training. This will be spread over six months and delivered for 20 hours[36]. It will entail pre and post-assessment questionnaires and practical assessments as the modality of evaluation.

Population, sample, and setting

Our target population will be health workers working in chosen health centres of Hyderabad & Ranga Reddy districts of Telangana. The requisite number of health workers (See document-Appendix 2, Supplemental Digital Content (Appendix 2), which illustrates the probable sites of study) will be chosen upon satisfying the inclusion criteria mentioned later.

Sample size calculations:

The sample size is calculated based on the following formulae:

$$n=\frac{2\left[Z_{1-\frac{\propto}{2}}+Z_{1-\beta}\right]^2\left[1+(m-1)\rho\right]}{d^2}$$

Where

$Z_{1-\frac{\alpha}{2}}=¿$ Corresponds to two tailed at 5% significance level =1.96

$Z_{1-\beta}=¿$ Corresponds to 80% power =0.84

d=effect size (estimated) =0.5 (medium effect based on Cohen's d)

m= cluster size = 30 (minimum number of health workers at one health centre)

ρ = intracluster correlation coefficient (estimated)= 0.03

we get n as 117 HWs per group. Adjusting the same for a dropout rate of 20%,

$n_{new}=\frac{n}{1-NR}$; we get n as 147 per cluster group, i.e. 294 HWs across both arms. Therefore, 294 HWs across 8 clusters will be needed with 37 HWs across each cluster arm. Each cluster has 40-45 health workers and hence the sample size calculated is feasible for the study.

Study Participants: All health workers will be screened for eligibility based on the following inclusion criteria[5, 18, 19]:

i. Health workers employed as accredited social health activists

ii. Health workers living within a radius of 40kms from the identified health centres

i. Pregnant health workers

ii. Health workers unwilling/unable to provide written informed consent.

iii. Health workers with terminal illnesses

Pregnant health workers will not be enrolled in the study due to their expected maternity leave overlapping with the study period and because the intervention's physical demands might be challenging for them. However, pregnant workers will still have access to training and all standard care services provided to other health workers.

Sampling Method: Cluster sampling method will be utilized for the study. Firstly, eight health centres will be chosen from the Hyderabad & Ranga Reddy districts and will further be then randomized as clusters into either the intervention or the control arms. All health workers at the respective clusters will be included in the respective arms based on their eligibility and consent. A total of approximately. 294 health workers will participate in the study, encouraged both by getting continuing education and by being urged by a district health officer to participate. We expect that approximately 147 health workers will enter the intervention arm, wherein they will participate in 20 hours of the intervention to be considered as trained. Evidence shows that even brief interventions have an impact on effective knowledge[36]. The principal investigator and the field staff will take the requisite permission form authorities and enroll the participants into the study based on their consent, which will be recorded using a consent form.

To prevent possible confounding and effect modification of patients' characteristics, we will divide the health centres into pairs. The pairs will have the following characteristics: male/female ratio, percentage of patients ≥60years old, percentage of patients on treatment and the prevalence of patients suffering from chronic diseases. The centres will be then randomly allocated into an experimental group and a control group and will be compared to ascertain the balance of the allocation. This will be done using computer generated random number using the MS Excel software. Pre- and post-assessment scores will be recorded at baseline and at after the intervention. These scores will serve as the data regarding competence assessment. Health workers' characteristics will be not included in the randomization process. This data is not available prior to the information from the baseline questionnaire being received (Figure 1 emphasizes the relationship, being examined in the evaluation). The intervention is randomized and is hence an important variable between exposure and outcome in the experimental group as well as the evaluation method (e.g., before and after study). Concurrently potential confounders will also be identified and would majorly consist of health workers'

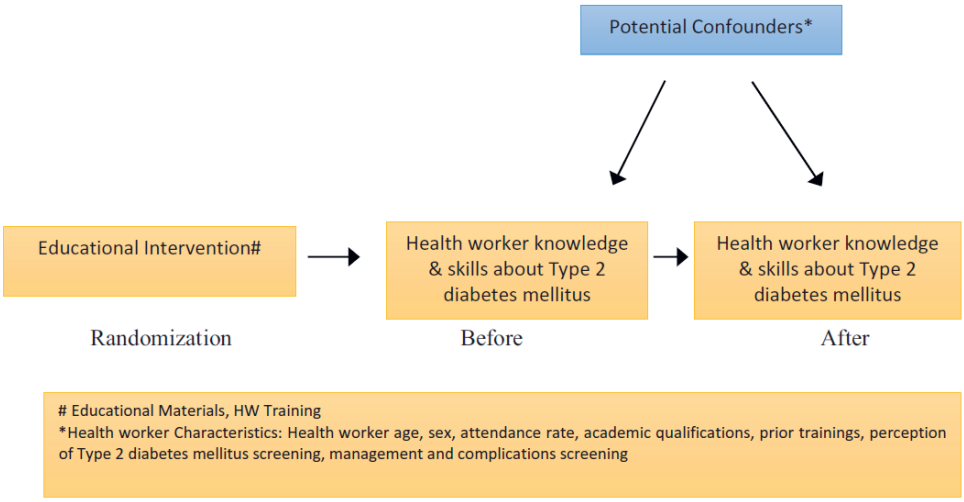


Figure 1: Primary Hypothesis displaying intervention, intermediate and outcome of interest

Intervention:

Implementation of Intervention

The implementation of the intervention package consists of training of health workers and evaluation of the training on the clinical competence of the health workers undergoing the training. The intervention will be implemented in the following manner:

1. Identification & Selection of health centres
2. Needs assessment of important stakeholders to improve the efficacy of the subsequent training
3. Development of Intervention package and its validation
4. Identification & recruitment of health workers for study
5. Delivery of Intervention package:

a. Health worker Training: The first part of the package will focus on the training of the health workers in the intervention arm.

b. Evaluation of training: The second part of the package will focus on the evaluation of the training. This will be done using the questionnaire tool developed for pre and post-session and pre- and post-intervention evaluation of the theoretical competence. An additional practical evaluation will be conducted by a neutral doctor to assess that change in clinical competence using a standardised rubric. The neutral doctor would be masked to the health worker arm allocations and would not participate in delivering the training. Instead, trained research associates, who are independent of the neutral doctor, would handle the training. Consequently, because the evaluation would be carried out by a single masked, independent assessor (the neutral doctor), inter-rater reliability would not be relevant. The evaluation mechanism will be identical in both the control and the intervention arms (Figure 2 showcases the overview of the intervention).

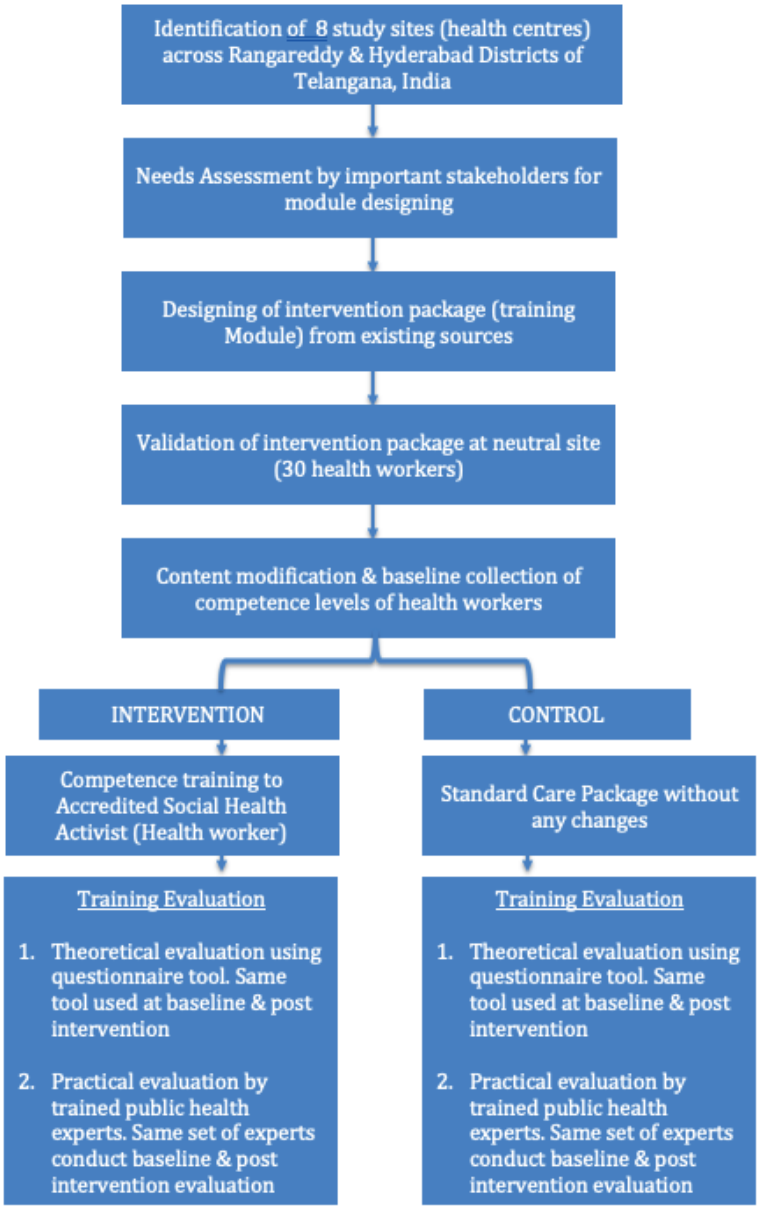


Figure2: Overview of the Intervention

Training of health workers: The HWs in the intervention arm will then undergo the customized training. The training module will include the following topics[3, 28]:

- NCD's and their prevalence in rural areas
- Importance of prevention, early detection and management
- Diabetes and its prevalence in India and rural India
- Diabetes Pathogenesis,
- Signs and symptoms and basic pathology of diabetes
- Common drugs used, Insulin,
- Importance of self-management,
- Key Skills- Using risk assessment tools, generating awareness history taking, behaviour counselling
- Screening, Measurement of blood glucose (using glucometer)
- Complications-
    - Hypoglycemia
    - Wound and ulcers in diabetes
    - Oral complication of diabetes
    - Diabetic Foot
    - Diabetic Nephropathy
    - Diabetic Retinopathy, etc.
- Follow-up & its importance: Motivation for follow-up, Motivation & Support for lifestyle changes, community meetings, patient support groups, continuity of care
- Indian Health System and approach to primary care

The module will be collated using the available modules which were developed and published by the Ministry of Health and Family Welfare, Government of India, Indian Council of Medical Research operational guidelines, The National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke operational guidelines and literature from Indian Institute of Public Health-Hyderabad & Public Health Foundation of India.

After the six-month training phase, an evaluation will occur. The evaluation will consist of theoretical and practical components which will be conducted using the developed questionnaire and the same set of trained public health experts respectively. The same tools would also be used for baseline collection. Both techniques will help assess the change in effective knowledge as well the practical skills about type 2 diabetes mellitus & associated complications. The detailed training plan is described below:

a. The trainers will teach the health workers about type 2 diabetes mellitus, its screening, complications and their screening. The trainers will be chosen based on prior knowledge of type 2 diabetes mellitus and prior teaching experience of evidence-based medicine in community health programs. Their willingness to be facilitators will also be an important factor for their selection.
b. The trainers will participate in a 2-hour course [36]focusing on type 2 diabetes mellitus and its complications. Two experienced faculty with extensive teaching experience will bear responsibility for the same. This training aims to provide the facilitators with sufficient skills and tools to conduct the training meetings successfully.
c. The trainers will be provided with a detailed curriculum to be used in all meetings.
d. An additional 2.5-hour session for trainers will be held three months into the academic detailing phase (i.e., after three meetings). This will support trainers during this phase of the intervention. They will also receive an ongoing email and phone support.
e. The trainers will then impart training across a 6-month, 20-hour training to the health workers in the intervention group.
f. The intervention will attempt to facilitate a change in the clinical competence of the health worker undergoing training.

Table 1: A description of the training schedule of health workers in the intervention group

Module Type	Topics Covered	Month-wise and session-wise distribution
NCD's	Baseline competence- practical & paper-based assessment	Month 1
	Indian health system overview, what are NCD's & prevalence in India	Month 1
	importance of prevention, early detection and management	Month 1
Diabetes Specific General Module	Diabetes-Introduction & rural prevalence; Signs & Symptoms	Month 2
	Pathology of Diabetes	Month 2
	Common drugs used, Insulin and its effects	Month 3
	Self-management in diabetes	Month 3
Diabetes screening, related skills & its Complications	Diabetes Screening (Blood glucose testing using glucometer; HbA1c and its indications)	Month 4
	Key Skills training: Using risk assessment tools, generating awareness, history taking, behavior counselling	Month 4
	Complications of diabetes- Emergency & Microvascular	Month 5
	Follow-up & importance	Month 5
Revision Class	Indian Health System Overview	Month 6
End Exam	Post-intervention competence evaluation- paper- based & practical assessment	Month 6

Evaluation:

The evaluation of the intervention package will help us understand the change in the competence of health workers in relation to type 2 diabetes mellitus and its complications. It will be conducted in the following manner for both the intervention & the control groups:

Paper Based

Overall pre and post-test questionnaire, which will be derived from the diabetes knowledge test 2 of the Michigan University[33, 34], the inputs from the physician/endocrinologist stakeholders, the assessment tools used by government training modules and evaluation tools developed by PHFI for diabetes training. This will help us understand the change in effective knowledge in the health workers in terms of type 2 diabetes mellitus, screening and complications.

Practical Based

This will be a practical test based on the training. It will help understand how effectively the training will be implemented by the health workers, when they are in contact with the diagnosed and undiagnosed patients. The scores of this assessment will be compared with the practical assessment carried out at the baseline.

Both the baseline and post training practical evaluation will be conducted by the same set of trained public health experts.

A combination of both paper-based and practical score will elucidate the change in the competence of the health workers.

Both the evaluation methods will be assessed according to objective parameters. It will ensure a comprehensive evaluation of all the components on which training will be provided.

Data Collection, Management & Analysis:

All the data will be collected from both the arms at pre-specified intervals. Pre and post-intervention data will be collected from the control arm. In the intervention arm, pre and post-training data will be collected, at the baseline and after the intervention is concluded. Hence evaluation will be conducted across both the groups at identical time points to obtain an accurate comparison of the training imparted. Qualitative and quantitative data will be

collected during and after the intervention. The collected data will be coded and recorded in Microsoft Excel version 2020 (MS Excel). We will use MS Excel for summarizing the descriptive statistics.

These will be obtained from the socio-demographic characteristics, socioeconomic characteristics, lifestyle characteristics, type 2 diabetes screening, health centre visits for physician follow-up and health centre visits for medicine refill. We will use STATA for data analysis. The principal analysis strategy will be the use of linear mixed models using the R statistical package for computing. This approach provides a simple method to incorporate baseline values and the correlation of each participant over time (using a random effect). This model is more potent than the repeated measures analysis of variance. It can easily examine differences between the trial groups at all time points and can accommodate potential confounders. Subsequent adjustments will be made for potential confounding variables as necessary, such as baseline parameters that may vary between groups.

Data on the confounding factors including sex, literacy, distance from the health centre, marital status will be collected at baseline. Other socio-demographic details, socioeconomic status, and occupation will also be recorded at baseline.

Secondary contrasts will be used to examine differences from baseline for all other time points. However, these will be of exploratory interest only.

Data Safety & Monitoring: The data will be kept safe with the principal investigator (PI) and later with the data manager on a separate hard disk and local server (password protector) with the access to the same being provided to stakeholders only on a need to share basis.

Data Confidentiality: All the information collected will be stored only with the investigators and the data manager. The publications will not reveal any private information of any of the participants. If any qualitative aspect is added at a later stage (like a case study), it will only be done with the participant's consent.

As of now we are not planning on collecting any confidential data which might be harmful for the participants.

Discussion:

This trial will evaluate the use of health worker training as a tool for improving the clinical competence in relation to type 2 diabetes mellitus. We anticipate that the module will provide a

greater understanding of type 2 diabetes mellitus, the importance of screening of both disease and complications and improved skills for the same.

Though many studies have focused on health worker training in the high-income nations, there is a dearth of evidence about a competence focused training package for health workers in type 2 diabetes mellitus in low- and middle-income countries like India. The findings of the study can serve as a cornerstone for training policies for health workers. It may help in reducing the cost burden of type 2 diabetes mellitus management on the public sector and the persons living with diabetes mellitus but more research on the impact of such a study will be needed to be undertaken for realizing the same. The results of the study will be disseminated by publishing them in peer reviewed journals.

Strengths: The principal merit of the study is that it is one of a kind. It will help develop a standardized training and evaluation, competence package for health workers, specific to type 2 diabetes mellitus. Very few studies have focused on the same.

Limitations: The study is limited to one district of the country. Hence, local factors contributing to the study's success or failures might not be replicable in all states. Objective measurements are time and resource-consuming and hence subjective practical evaluations are incorporated.

Abbreviations:

- **PHFI:** Public Health Foundation of India
- **IIPHH:** Indian Institute of Public Health, Hyderabad
- **CTRI:** Clinical Trial Registry of India
- **PI:** Principal Investigator

Declarations Page

Ethics Approval & Consent to participate:

The ethics approval and the consent to participate has been received from the Institutional Ethics Committee of the Indian Institute of Public Health Hyderabad under the application number: IIPHH/TRCIEC/218/2020. The approval was obtained on 30th June 2020. The ethics committee can be contacted at: trciec@iiphh.org. The trial has been registered under the Clinical trial registry of India (CTRI). The registration number of the trial is: CTRI/2020/07/026828. The trial was registered on 27th July 2020. The URL of the registry trial is:http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=45342&EncHid=&userName=CTRI/2020/07/026828

The principal investigator and the field staff will take the requisite permission form authorities and enrol the participants into the study based on their consent, which will be recorded using a consent form

Consent for publication: All authors have given their consent for publication of the protocols.

Availability of data & material: NA

Funding: The study has not received any external funding but has only received internal funding from the host institution, the Indian Institute of Public Health Hyderabad. Authors belonging to the host institution are responsible for the study conceptualization, designing, intellectual content definition, manuscripts preparation, manuscript editing, manuscript reviewing and literature search.

Competing Interests: The author(s) of this work have nothing to disclose.

Author contributions:

AGG is the principal investigator of the study. He is a research fellow at IIPHH/PVRI. He has conceptualized, designed, defined intellectual content, conducted literature search, prepared, edited the manuscript and is the guarantor for the manuscript.

GRB is a professor & HOD-life epidemiology course at IIPHH/PHFI. He has been involved in conceptualizing, designing, editing and reviewing of the manuscript. He has been pivotal in guiding the research design and methodology.

OCPVS is the head of CaRe at Maastricht University. He has been involved in conceptualizing, designing, editing and reviewing of the manuscript. He has also provided crucial technical, scientific & methodological advice.

NCS is a professor at Maastricht University. He has been involved in conceptualizing, designing, editing and reviewing of the manuscript. He has also provided crucial technical, scientific & methodological advice.

MGL is a senior lecturer at the IIPHH. She has provided crucial support in the design of the study.

GVSM is the director of IIPHH and an adjunct professor at the London School of Hygiene & Tropical Medicine. He has played a crucial part in designing, editing and reviewing the manuscript.

All authors have read and approved the manuscript.

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CHAPTER 5

Chapter 5: Undesirable Levels of Practice Behaviours and Associated Knowledge amongst Community Health Workers in Rural South India Responsible for Type 2 Diabetes Screening and Management

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Abstract:

Background: Type 2 diabetes (T2DM) poses an enormous global health care challenge, especially among rural communities. Healthcare in these areas can be inadequate and inaccessible due to socio-demographic barriers. To overcome this situation, many low- and middle-income countries are resorting to task shifting, using community health workers (CHWs) for diabetes management. However, its successful implementation depends on the practice behaviours and knowledge of these workers. Objective: This cross-sectional study aimed to evaluate the proficiency of CHWs involved in diabetes screening and management in rural South India by identifying the existing practice behaviours and knowledge gaps. Methods: Employing a customised questionnaire, developed through inputs from experts and government officials, we assessed practice behaviours and the corresponding knowledge base of 275 CHWs. Analytical methodologies consisted of descriptive statistics, logistic regression, and mosaic plots for comprehensive data interpretation. Results: The study showcased significant deficiencies in both practice behaviours (97%) and knowledge (95%) with current mean levels ranging from 48 to 50%, respectively, among the participants. The identified areas of insufficiency were broadly representative of the core competencies required for effective diabetes management, encompassing diabetes diagnosis and referral, HbA1c testing, diabetes diet, diabetes type and self-management, microvascular complications and their screening, peripheral neuropathy management, and diabetes risk assessment. In several areas, correct practice behaviour was reported by a relatively large number of CHWs despite incorrect answers to the related knowledge questions such as referral to the health centres, self-management, and calculation of diabetes risk assessment. Conclusion: This study highlights widespread deficiencies (97% CHWs) in diabetes management practices and knowledge (95% CHWs). To overcome these deficiencies, a thorough needs assessment is vital for effective CHW training. Training of CHWs should not only identify prior knowledge and/or behaviour but also their interrelationship to help create a robust and flexible set of practice behaviours.

Keywords: community health workers; health worker diabetes knowledge; health worker diabetes practice; health worker diabetes behaviour; South-East Asia

1. Introduction

Type 2 diabetes mellitus (T2DM) is a pressing global health concern, with an estimated 537 million adults living with the condition worldwide, and 74.2 million cases in India alone [1].

The World Bank data estimates that in 2021, the prevalence of T2DM in Indian adults was 5% [2]. The International Diabetes Federation (IDF) reported that nearly 50% of persons are living with undiagnosed diabetes in India [1]. The report also estimates that this Indian burden is set to grow to 125 million by 2045 significantly affecting a major proportion of its population [1]. Recent trends have indicated the growing prevalence of diabetes amongst lower socioeconomic stratum and rural populations especially in LMICs [3]. With nearly 65% of Indians residing in such areas [4], diabetes poses a huge threat to the population. Prolonged exposure to high blood glucose levels can lead to severe health consequences, particularly micro- and macrovascular complications often leading to morbidity and mortality [1]. An Indian study showed that patients already had some form of diabetic retinopathy at the time of their eye clinic visits, with a potential for blindness if left untreated [5]. Thus, detection and management of T2DM in these areas is extremely critical but is a challenge due to factors like limited access to healthcare services especially in rural areas, lack of trained personnel, unsatisfactory health-seeking behaviour, and long travel distances [3,6–8]. Therefore, healthcare systems must develop innovative service models to overcome these barriers.

Task shifting of certain duties of medically trained healthcare workers in rural areas to frontline community health workers (CHWs) is one of the methods used to improve the accessibility of care and reduce the burden on the more qualified health workforce [9]. This approach is being carried out by several developing countries [10–15]. In India, multipurpose health workers/assistants and accredited social health activists, typically members of the local communities, are nowadays involved in task shifting in various national health programs for the prevention and management of diabetes, cardiovascular disease, cancer, and stroke [10,16–20]. However, before entrusting the CHWs with the management of the entire spectrum of diabetes screening and management, along with the medical officers, we need to ascertain their capabilities in carrying out the prescribed duties. Evidence reveals a lack of knowledge among these health workers [21–23] and we need to better understand what these gaps in knowledge and associated practice behaviours are.

The current study was undertaken to define the current practice behaviours of CHWs responsible for screening and managing diabetes in rural South India and to determine if these behaviours were associated with specific gaps in knowledge. These data would be used as the starting point for the development of a specific training program tailored to the needs of these healthcare workers.

Hence, the research question of this study is as follows: what are the existing gaps in the practice behaviours and knowledge of the CHWs involved in the screening and management of diabetes in rural South India?

2. Methodology

This study had a cross-sectional design and included the CHWs involved in diabetes screening and management at the community level and working in eight healthcare administrative regions of Telangana, South India between August 2021 and March 2022. Telangana has approximately 21,400,000 (21.4 million) rural inhabitants, which is almost 62% of its total population. These workers are primarily tasked with population enumeration, home screening, motivating patients to maintain a healthy lifestyle and attend regular complication screenings, supervising of tasks undertaken by junior cadres, conducting meetings with local essential stakeholders, overseeing the data from their health centre, and sharing the data with the authorities.

We used a questionnaire to assess the practice behaviour of the participants and associated knowledge. To develop this questionnaire, we first interviewed senior government officials and medical officers about the common situations faced by CHWs in the community. In these interviews, the most important practice behaviours of the CHWs were identified, as was the knowledge deemed conditional for these practice behaviours. The questionnaire was developed in both English and Telugu (vernacular language) and consisted of 19 questions. This was then piloted with 10 CHWs not included in the study. Based on the feedback received, it was edited and eventually, the validated questionnaire consisted of 17 questions, 10 on practice behaviours and 7 on associated knowledge, as shown in Appendix A.1 and summarised in Table 1.

Table 1. The associations of practice behaviour with knowledge in the questionnaire (complete questionnaire in Appendix A.1). Bold text indicates a correct answer.

Practice Behaviour & Related Knowledge Questions with Correct Answers in Bold	
Practice Behaviour Questions	**Knowledge Questions**
PbQ1: You encounter a 40-year-old individual who is 5 feet 4 inches tall and weighs 87 kg. This person reports the following concerns: 1. Frequent urination 2. Excessive thirst 3. Increased appetite 4. Unexplained rapid weight loss What guidance or recommendations would you offer in response to these symptoms?:	KnQ1: A 40-year-old woman has a condition where her body doesn't make enough insulin. She experiences more urination at night, and increased hunger, and thirst. What's this condition called, and what can she do to feel better? Answer Options (1). Type 1 Diabetes; only exercise (2). **Type 2 Diabetes; exercise, medication & diet**

Answer options: (1). **Refer to the nearest health centre for random blood glucose/HbA1c testing** (2). Refer to the nearest health centre for blood pressure testing (3). Refer to the nearest health centre for thyroid hormone tests (4). None of the above	**control with medicines** (3). Gestational Diabetes; do nothing (4). Monogenic Diabetes; only medication This knowledge question, KnQ1 is associated with practice behaviour questions: PbQ1 and PbQ3
PbQ2: How would you approach the assessment of blood glucose control for a 38-year-old patient with diabetes who refrains from regular blood glucose checks due to a fear of multiple pricks? Answer Options: (1). Advise Fasting blood glucose test at the nearest facility **(2). Advise Glycosylated Hemoglobin- HbA1c test at the nearest facility** (3). Advise Random blood glucose test at the nearest facility (4). Both 1. and 2	KnQ2: Which of these signs indicate diabetes, how is it diagnosed, and where should someone go for treatment? Answer Options (1). Increased Blood Glucose levels, diagnosed using HbA1c and managed at Primary Health Centre (PHC) (2). Increased Blood pressure, diagnosed using HbA1c and managed at PHC (3). Random blood glucose values above or equal to 200mg/dl, diagnosed using Random or fasting glucose and managed at PHC **(4). Both 1. and 3** This knowledge question, KnQ2 is associated with practice behaviour questions: PbQ2 and PbQ7
PbQ3: You have a 48-year-old patient who has had diabetes for three years. They have given you their blood sugar readings from the past two months, and most of them are consistently over 200 mg/dL. What would you suggest helping this patient improve their blood glucose control? Answer Options (1). Regular exercise for at least 30 min for five days a week (2). Consuming a diet rich in proteins (3). Reducing or eliminating habits like smoking, alcohol, tobacco chewing, etc **(4). All of the above**	KnQ3: Which of the following organs or body parts is affected by uncontrolled Diabetes and what is an unexpected fall in blood glucose called Answer Options (1). Stomach; Hyperglycemia **(2). Retina; Hypoglycemia** (3). Both the above are correct (4). None of the above are correct This knowledge question, KnQ3 is associated with practice behaviour questions: PbQ4
PbQ4: A 57-year-old diabetic patient, on insulin for 5 years, experiences symptoms like sweating, tremors, hunger, a fast heartbeat, dizziness, and confusion at night. If his wife calls you for help, what would you advise her to do immediately to improve his condition? Answer Options: (1). Advise the patient to take more Insulin **(2). Advise the patient to take glucose or sugar dissolved in water immediately** (3). Advise the patient to sleep and it will be fine in the morning (4). Will not give any advice to the patient	KnQ4: A 47-year-old man, diabetic for 15 years, reports tingling and burning sensations in his feet. What could this be, and how often should he get checked for it? Answer Options (1). Hypoglycemia; Checked once every year **(2). Peripheral Neuropathy; Checked once every year** (3). Diabetic Ketoacidosis; Checked twice every year (4). Diabetic Retinopathy; Checked twice every year This knowledge question, KnQ4 is associated with practice behaviour questions: PbQ5 and PbQ6
PbQ5: You're overseeing the care of a 65-year-old diabetic patient. How frequently should you remind her to undergo	KnQ5: What will you advise for a Diabetic patient during the COVID-19 Pandemic?

screening for diabetes-related chronic complications of the eye & kidneys? What should you advise to prevent/manage COVID-19?

Answer Options
(1). Once every 2 years/Exercise
(2). Once every 3 months/COVID Medicine
(3). Once every year (Annually)/COVID-vaccination
(4). Once every 3 years/Nothing can be done

Answer Options
(1). To maintain blood glucose levels within the prescribed range (< 140 mg/dl)
(2). To keep a stock of all important medicines
(3). To consult a doctor if they have any flu-like symptoms
(4). All of the above
This knowledge question, KnQ5 is associated with practice behaviour questions: PbQ5

PbQ6: A 69-year-old farmer, who has had diabetes for 10 years, had a burning sensation in his feet for a few weeks. He received treatment at a nearby clinic. What advice would you provide to ensure this problem doesn't come back?

Answer Options
(1). To be barefoot all the time
(2). To wash and inspect feet daily
(3). To use boiling water to clean feet
(4). To leave the feet dry

KnQ6: What foods would you recommend for individuals with diabetes or those at risk of developing diabetes?

Answer Options
(1). Samosas (Indian fried snack)
(2). Bajji/Pakodas (Indian Fritters)
(3). Black Chana (Black Grams)
(4). Laddoos (Indian Dessert)

This knowledge question, KnQ6 is associated with practice behaviour questions: PbQ8

PbQ7: Your friend is upset and tells you that her 71-year-old diabetic mother, who has been on medication for 12 years, is experiencing dizziness, burning sensations in her feet, overall tiredness, and easy fatigue. She thinks the medicines aren't working and asks for your help. What can you do to assist her mother?

Answer Options
(1). Change her medicine based on her blood glucose values
(2). Send her to the ANM to get her medicines changed/modified
(3). Refer her to the Medical Officer at the nearest health centre to change her medicines if needed
(4). Ask her to change her medicines as per the pharmacist's advise

KnQ7: What does a score below four in the Community Based Assessment Checklist (CBAC)* Assessment mean, and what should be done if the score is less than four?

Answer Options
(1). The person is free from Non-Communicable (Diseases (NCDs)
(2). The person is at higher risk of getting NCDs
(3). The person still needs to be screened for NCDs annually
(4). The person may not attend the weekly NCD Meeting

This knowledge question, KnQ7 is associated with practice behaviour questions: PbQ9 & PbQ10

PbQ8: Your patient, aged 46 with diabetes, indulges in sweets and sugarcane juice. Which food can you recommend for satisfying their sweet cravings naturally without impacting their diabetes?

Answer Options
(1). Mangoes
(2). Chikus/Sapotas
(3). Grapes
(4). Apples

PbQ9: 53-year-old man, who does not move around much, has a family history of diabetes, a waist size over 100 cm, and smokes while drinking alcohol daily. When using the Community Based Assessment Checklist (CBAC), what will be his total score?

Answer Options
(1). Seven
(2). Fifteen
(3). Four
(4). Ten

PbQ10: As a Community Health Worker (CHW) doing health checks in your village. A 41-year-old woman comes up to you, saying she does not have a history of diabetes or high blood pressure, and she doesn't seem to have any symptoms of these conditions. What should you do in this situation?

Answer Options
(**1). Screen the person every year (annually)**
(2). No need to screen the person again
(3). Screen the person after 2 years
(4). Screen the person every 5 years

We administered the questionnaire to 275 CHWs on paper in a face-to-face manner. Because of the diversity in reading and linguistic skills (due to differences in dialects) the content of the questionnaire was explained by two research assistants during group sessions of approximately 25–30 CHWs per session. After all the queries of the CHWs were answered by the research assistants, participants were asked to fill in the answers individually and arrangements were made to ensure no discussion among the participants during this phase of the meeting was possible. The duration of each session was approximately 3.5–4 h. Each session was presided over by two research associates, and eight meetings were held in the region where the CHWs were working. The two research associates were trained beforehand and were provided with a handbook to assist them in their roles.

A digital version of the questionnaire was created for each participant in Microsoft (MS). Access and data were imputed by coding for correct and incorrect answers along with missing values. The imputed data were cross verified by the lead researcher and wherever an error was discovered, those physical forms were accessed again to rectify the error. To ensure the veracity of the data, 10% of participants were contacted telephonically for verification. Once confirmed, the data were saved as an Excel workbook which was exported to STATA version 17 for analysis. For scoring the answers to each question, each correct answer was graded as 1 and a wrong answer, a double answer, or no answer was graded as zero. In the initial phase, we asked the government officials and the doctors involved in the development of the questionnaire for the minimal number of correct answers and they formulated a benchmark of 75% correct answers, which we used as an external benchmark for sufficient practice behaviours and knowledge.

Statistical Analysis

The data were analysed using mean ± standard deviation, median with interquartile ranges (IQR), and frequencies wherever appropriate. The association between correct practice behaviours and their associated knowledge was explored using logistic regression to better understand the relationship between specific gaps in the practice behaviours and knowledge.

To assess whether these item-level associations were independent of socio-demographic factors, each model was adjusted for age, education category and work experience. However, a covariate-adjusted model of the overall practice behaviour and the overall knowledge could not be reliably estimated because few CHWs met the necessary threshold (as reported in the results). Finally, to study the relation of correct practice behaviours with incorrect knowledge we used mosaic plots as graphical representations. These plots are divided into four parts; each part depicts the relationship between participants' practice behaviours (correct or incorrect) with the participant's knowledge (correct or incorrect). All the significant results were tabulated and are presented in the results section. More details on the plots and the relationships can be found in b.3. Results

All participants (n = 275) filled in the questionnaire; all were females with a mean age of 38.0 + 7.1 years. A majority (approx. 94%) completed high school. The median (IQR) work experience was 10 years (6–15 years). The median overall number of correct answers was 8 (7–10) out of 17 questions. Only 11 participants (4%) crossed the 75% external benchmark of correct answers (2 participants had 14 and 9 participants had 13 correct answers).

In the practice behaviour questionnaire, the median overall number of correct answers was 5 (IQR 4–6) out of 10; only 9 participants (3.3%) crossed the 75% benchmark. The correctly answered percentages for each of the questions are depicted in Table A2 of the electronic supplement. The participants reported sufficient practice behaviours for hypoglycemia management (78% had correct answers) and frequency of risk screening (75%) while the score for health centre referral, self-management, and diabetes signs and symptoms were insufficient (9.8% to 51.3%). The detailed question-wise practice behaviour scores for correct answers have been demonstrated in Table A2 of Appendix A.2.

In the knowledge questionnaire, the median overall number of correct answers was 4 (IQR 3–4) out of 7, only 15 participants (5.5%) crossed the 75% benchmark. The correctly answered percentages for each of the questions are depicted in Table A3 in the electronic supplement. The knowledge about diabetes diet (89.5% correct answers) and diabetic retinopathy/hypoglycemia (85.1%) was sufficient. The knowledge about diabetes diagnosis and referral, types and self-management, and microvascular complications and their screening was insufficient, (30.6% to

57.0% correct answers). The detailed question-wise knowledge scores for correct answers have been demonstrated in Table A3 of Appendix A.3.

In order to study the association between practice behaviour with knowledge, their overall mean scores were standardised to a scale of 10 with overall mean scores of 5.5 and 4.8, respectively. Practice behaviour was associated with knowledge with an odds ratio of 1.64 and a standardised regression coefficient (beta) of 0.50 with a *p*-value < 0.01. Subsequently, for each pair of questions, we examined the association between practice behaviour and knowledge to determine to which extent specific practice behaviour was associated with knowledge on this topic. In Table 2, the associations with a *p* value below 0.2 are shown. The highest odds ratio (1.99) was observed for the association of microvascular complication screening with the knowledge question on this topic (beta-coefficient of 0.68) with a *p*-value of 0.09. This means that having knowledge about the signs and screening of microvascular complications would lead the CHW to practice the correct microvascular screening process 99% more effectively. Similarly, the CHWs were 97% more likely to follow correct practices for peripheral neuropathy management if they had correct knowledge about microvascular complications: signs and screening (odds ratio of 1.97 and beta of 0.68 ($p = 0.01$)). This correct knowledge would also result in the CHWs following the correct practices for identifying the diabetes signs and symptoms in 91% more cases (odds ratio of 1.91 and beta of 0.64 ($p = 0.01$)). The only other pair for which a significant association was observed was for HbA1c testing and diabetes, diagnosis and referral with an odds ratio of only 0.53 and a beta of -0.61 ($p = 0.04$). The detailed correlations between the practice behaviours and the respective knowledge questions are presented in the Appendix A.4.

Table 2. Logistic regression between practice behaviour and knowledge questions.

Practice Behaviour Question	Knowledge Question	Odds Ratio	Coefficient	*p*-Value
HbA1c Testing	Diabetes, Diagnosis and referral	0.53	−0.61	0.04
Self-Management	Diabetes: Types and Self-Management	0.67	−0.39	0.13
Microvascular Complication Screening	Microvascular Complications: Signs and Screening	1.99	0.68	0.09
Peripheral Neuropathy Management	Microvascular Complications: Signs and Screening	1.97	0.68	0.01
Risk Assessment Screening	Diabetes Risk Assessment	0.64	−0.43	0.12
Identifying Diabetes Signs and Symptoms	Microvascular Complications: Signs and Screening	1.91	0.64	0.01

These associations remained mostly unchanged after adjusting for age, education, and work experience. The odds ratio for Hba1c testing changed slightly from 0.53 to 0.52 (p=0.03); signs

and symptoms of diabetes from 1.91 to 1.92 (p=0.01); peripheral neuropathy management from 1.97 to 2.06 (p=0.01); and microvascular screening from 1.99 to 2.10 (p=0.08). These factors did not significantly affect the associations.

We used the mosaic plots to analyse the relationship between correct answers to practice behaviours questions with incorrect knowledge to determine common misconceptions and myths in diabetes care amongst community health workers. There were indeed four such instances where the CHWs correctly answered more than 50% of the practice behaviour questions and incorrectly answered knowledge questions. Table 3 depicts these relationships and their frequencies in detail. The mosaic plots can be found in the Appendix A.5.

Table 3. Relationship of incorrect knowledge and correct practice behaviours among CHWs.

Knowledge	Practice Behaviour	Correct Practice Behaviours Despite Incomplete/Incorrect Knowledge Responses
Knowledge about referral criterion and pathway	Practice Behaviour about Referral to the Health Centre	123 out of 183 participants (67.2%) displayed correct practice behaviour despite incomplete knowledge responses
Knowledge about types of Diabetes	Practice Behaviour about Self-Management	105 out of 143 participants (73.4%) displayed correct practice behaviour despite incomplete knowledge responses
Knowledge about types of diabetes	Practice Behaviour about identifying type 2 diabetes signs and symptoms	99 out of 141 participants (70.2%) displayed correct practice behaviour despite incomplete knowledge responses
Knowledge about diabetes risk assessment	Risk Assessment Screening	122 out of 208 participants (58.7%) displayed correct practice behaviour despite incomplete knowledge responses

4. Discussion

The study revealed insufficient practice behaviours and knowledge in ≥95% of CHWs working in rural areas in India and who are responsible for diabetes screening and management. The identified areas of insufficiency were broadly representative of the core competencies required for effective diabetes management, encompassing diabetes diagnosis and referral, HbA1c testing, diabetes diet, diabetes type and self-management, microvascular complications and their screening, peripheral neuropathy management, and diabetes risk assessment.

Our observations align with the existing literature [24–27] documenting incorrect practices among CHWs due to limited or insufficient knowledge. Hughes et al. [24] emphasise the lack

of knowledge among the healthcare workers as a barrier to utilise them in the screening and management of diabetes. Ferguson and Lemay's study [25] showcases the necessity of case-based training of health workers and elucidates the wide range of topics which need to be taught. Tripathy et al.'s study [26] elucidates the rise of diabetes in rural parts of the country and thus, the increasing need for health workers in controlling this epidemic. Rendrayani et al.' systematic review [27] reveals the small percentage of studies (less than 30%) showcasing considerable knowledge and positive attitudes towards diabetes management. This underscores the need for thorough needs assessments to identify existing knowledge gaps and incorrect practices among CHWs. By addressing these gaps, we can enhance the effectiveness of CHW training programs and ultimately improve diabetes management outcomes.

Our results showed that the practice behaviours for hypoglycemia management and frequency of risk screening were above desired levels (>75%). The CHWs are often managed with hypoglycemic patients in their course of work within their communities and thus are aware of its management. Similarly, the CHWs receive periodic intimation about screening at-risk individuals from the local governments and thus we see these practices as satisfactory. On the other hand, they have limited training or intimation about referring individuals to health centres, how to promote self-management in patients with diabetes and identifying patients presenting with symptoms of diabetes as this happens most commonly at the health centres and with a doctor. We also find similar results in the knowledge domain, where CHWs are well versed in diet and hypoglycemia/diabetic retinopathy management. This is due to them being trained in these topics, due to various government initiatives. But their deficient knowledge about diagnosis referral, types of diabetes and microvascular complications underscores that their training does not emphasise on these topics and needs to be revised to include these.

The summary score of knowledge revealed a stronger association (OR 9.03, $p = 0.09$) with the summary score of practice behaviours compared to associations of knowledge with practice behaviour when each pair of questions was analysed separately (highest OR 1.99, $p = 0.09$). This observation suggests that while overall knowledge levels tended to positively influence practice behaviours, the relationship was not as evident at the level of specific questions. To further investigate this discrepancy, we employed mosaic plots, which provided insights into potential associations between correct practice behaviours as reported by the respondents and incorrect knowledge. Interestingly, we identified several instances where CHWs reported correct practice behaviours despite possessing incorrect knowledge. This could be attributed to several factors, including prior training, educational differences, or the non-essential nature of specific knowledge for certain practices after adequate training. However, it is crucial to note

that even in these cases, incorrect knowledge may hinder the long-term sustainability of the observed correct practice behaviours as it is more likely to push forth incorrect or out-of-date practice behaviours. Thus, all future educational material developed for the health workers related to diabetes screening and management should refrain from focusing on only knowledge or practice. Both of them should be presented as case-based scenarios while integrating the findings of our study. Focusing on only one will yield in incomplete understanding by the CHWs, often leading to either incorrect practices in the field or dissemination of incorrect knowledge amongst the community, causing more harm than benefit. For example, Hughes et al. [24] reported that CHWs in South Africa believed that the main cause for diabetes was higher sugar consumption, due to either poor knowledge or poor knowledge dissemination. In our case, we see that the scores for practices in identifying signs and symptoms for diabetes are low, this would mean that the CHWs might know what these are but may miss out on identifying them when presented by the patient. It is also possible that knowledge regarding diet alone might cause problems, with the CHWs advocating the removal of a macronutrient from the patient's diet, like carbohydrates, despite this not being a plausible solution in practice. We also see that the CHWs know how to proceed with screening for diabetic retinopathy, but due to their deficient knowledge about peripheral neuropathy, they will not be able to direct any patient to the doctor for any foot-related issue which might result in a gangrene for the patient. Overall, focusing on knowledge or practice in a case-based manner will help the training achieve the end objective of an CHW workforce effective in task shifting for diabetes screening and management.

The major strengths of this study were that the questionnaire was developed in close cooperation with the medical staff ultimately responsible for diabetes care, as well as using input and feedback from the target group studied. We were therefore able to develop the questionnaire into an accessible tool that could be readable and understandable for all CHWs. In addition, we recruited a relatively large number of participants from multiple rural areas, increasing the external validity of our observations. The study also has high generalisability in similar geographies of rural Southeast Asia which bear similarities to our study site like similar diversities of linguistics, education, cultures, practices, and socio-demographic factors. Given the time necessary to explain and subsequently fill in the questionnaire, we had to restrict the number of questions for each domain. Moreover, in a few cases, we had to combine two questions into one question, which might have caused difficulty in comprehension for the CHWs and which may have weakened the associations between knowledge and practice behaviour for a specific topic.

The limitations of the study mainly include the data collection tool's complexity, wherein the questions were composite in nature, and the answers were unable to correctly point out the correlation between the practice behaviour and the knowledge. A covariate-adjusted model of the overall association could not be estimated stably, due to the small number of CHWs meeting the threshold requirements. For further studies, the tool should be further simplified in order to interpret the correlations better.

Finally, some areas require further exploration, like the correct practice behaviours linked with the incorrect practice behaviours, and vice versa; the barriers and enablers for such relationships also need exploration. The analysis surprisingly discovered that the use of HbA1c testing in daily practice was negatively associated with knowledge of diabetes, diagnosis, and referral, with an odds ratio of 0.53, beta-coefficient of 0.61, and *p*-value 0.04. This finding, which is currently difficult to explain, needs further exploration in order to improve future training.

5. Conclusions

To conclude, the vast majority of the CHWs involved in diabetes screening and management in rural areas reported inadequate practice behaviour and had insufficient knowledge underlying these behaviours. Defining these gaps in knowledge and practice behaviour is very informative in setting up tailored education programs. However, in several areas, correct practice behaviour was reported by a relatively large number of CHWs despite incorrect answers to the related knowledge questions. Hence, training of CHWs, should not only identify prior knowledge and/or behaviour, but also their interrelationship, to help create a robust and flexible set of practice behaviours that are in line with the guidelines on diabetes care, which are continuously changing over time.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional ethics committee of the Indian Institute of Public Health Hyderabad, with the registration number: IIPHH/TRCIEC/218/2020. The trial has also been registered under the Clinical trial registry of India (CTRI) on 27 July 2020. The registration number of the trial is: CTRI/2020/07/026828. The URL of the registry trial is: http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=45342&EncHid=&userName=CTRI/2020/07/026828 (accessed on 27 July 2020).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. Consent was also obtained to publish the data anonymously.

Data Availability Statement: The anonymised data will be available on request for those interested due to ethical considerations.

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Appendix A

Appendix A.1. Questionnaire Used for Data Collection

Table A1.

General Information of CHWs	
Name of CHW	**Name of PHC**
Age of CHW	Designation of CHW
Gender of CHW	Educational Qualification of CHW
Marital Status of CHW	Work Experience of CHW (in Yrs)
Address of VHW (village Name)	Diatance of residence from

		PHC
Practice Behaviour & Knowledge Assessment		
Question	Answer Options	
Q1. Which of these signs indicate diabetes, how is it diagnosed, and where should someone go for treatment??	1. Increased Blood Glucose levels, diagnosed using HbA1c and managed at Primary Health Centre (PHC) 2. Increased Blood pressure, diagnosed using HbA1c and managed at PHC 3. Random blood glucose values above or equal to 200mg/dl, diagnosed using Random or fasting glucose and managed at PHC 4. Both 1. and 3	
Q2. A 40-year-old woman has a condition where her body doesn't make enough insulin. She experiences more urination at night, and increased hunger, and thirst. What's this condition called, and what can she do to feel better?	(1). Type 1 Diabetes; only exercise (2). Type 2 Diabetes; exercise, medication & diet control with medicines (3). Gestational Diabetes; do nothing (4). Monogenic Diabetes; only medication	
Q3-A 38-year-old patient with diabetes is under your care. However, he does not get his blood glucose levels checked regularly due to a fear of multiple pricks. What will you do in this case to get to know his blood glucose control?	1. Advise Fasting blood glucose test at the nearest facility 2. Advise Glycosylated Hemoglobin-HbA1c test at the nearest facility 3. Advise Random blood glucose test at the nearest facility 4. Both 1. and 3.	
Q4-A 65-year-old known diabetic is under your care. How often will you recommend herself be screened for diabetes-associated chronic complications? What should you advise to prevent/manage COVID-19?	(1). Once every 2 years/Exercise (2). Once every 3 months/COVID Medicine (3). Once every year (Annually)/COVID-vaccination (4). Once every 3 years/Nothing can be done	
Q5-A 57-year-old diabetic patient under your care has been on insulin for 5 years. Suddenly at night, his wife calls to tell you that he is suffering from Sweating, Tremors, Hunger, Fast heartbeat, Dizziness, Confusion What will you advise the wife to improve the patient's condition immediately	1. Advise the patient to take more Insulin 2. Advise the patient to take glucose or sugar dissolved in water immediately 3. Advise the patient to sleep and it will be fine in the morning 4. Will not give any advice to the patient	
Q6-A 47-year-old male with diabetes for 15 years comes to you with a complaint of tingling sensations in the feet and sometimes a burning sensation in the feet. What could this be, and how often should he get checked for it?	(1). Hypoglycemia; Checked once every year (2). Peripheral Neuropathy; Checked once every year (3). Diabetic Ketoacidosis; Checked twice every year (4). Diabetic Retinopathy; Checked twice every year	
Q7-Your friend has been troubled over the past few days and approaches you in tears. She tells you that her 71-year-old mother who has been a diabetic for 12 years and is on medicines has been experiencing dizziness, burning sensation in her feet,	1. Change/Modify her medicine based on her blood glucose values 2. Send her to the ANM to get her medicines changed/modified 3. Refer her to the Medical Officer at the nearest health centre 4. Ask her to change/modify her medicines as	

overall lethargy and getting tired easily. She thinks her mother's medicines are notper the pharmacist's advise having any effect and wants your help. What can you do to help her mother?	
Q8-Which of the following foods will you advise for any person with diabetes or at risk of developing diabetes?	1. Samosas 2. Bajjis/Pakodas 3. Black Chana 4. Laddoos
Q9-A 46-year-old patient with diabetes who is under your care is constantly taking sweets and sugarcane juice. What can you suggest as a natural alternative to satisfy their sweet tooth?	1. Mangoes 2. Chikus/Sapotas 3. Grapes 4. Apples
Q10-A 48-year-old patient with diabetes for the last 3 years has come to you with his blood glucose readings for the past two months. You observe that most of his readings are over 200 mg/dl. In such case what can you advise the patient to help them improve their glucose control?	1. Regular exercise for at least 30 min for five days a week 2. Consuming a diet rich in proteins 3. Reducing or eliminating habits like smoking, alcohol, tobacco chewing, etc 4. All of the above
Q11-What will you advise for a Diabetic patient during the COVID-19 Pandemic?	1. To maintain blood glucose levels within the prescribed range (< 140 mg/dl) 2. To keep a stock of all important medicines 3. To consult a doctor if they have any flu-like symptoms 4. All of the above
Q12-Which of the following organs or body parts is affected by uncontrolled Diabetes and what is an unexpected fall in blood glucose called	(1). Stomach; Hyperglycemia (2). Retina; Hypoglycemia (3). Both the above are correct (4). None of the above are correct
Q13-A 69-year-old farmer who has been diabetic for the last 10 years has been complaining to you about a burning sensation in his feet for the last couple of weeks. You sent him to the nearest health facility where the doctor treated it. Now what should be your advice to ensure that this condition does not arise for the patient again?	1. To be barefoot all the time 2. To wash and inspect feet daily 3. To use boiling water to clean feet 4. To leave the feet dry
Q14-A 40-year-old person, with a height of 5'4 and weight of 87 kgs presents to you with the following problems: Frequent urination, Excessive thirst & Increased hunger Sudden weight loss. What would you advise?	1. Refer to the nearest health centre for random blood glucose testing/HbA1C testing 2. Refer to the nearest health centre for blood pressure testing/ 3. Refer to the nearest health centre for thyroid hormone tests 4. None of the above
Q15-A 53-year-old male who leads a sedentary lifestyle with a family history of Diabetes, a waist circumference of more than 100cm and habits of smoking, and consuming alcohol daily has undergone CBAC Assessment. What will be the total	1. Seven 2. Fifteen 3. Four 4. Ten

score?	
Q16-What does a score less than four in the CBAC Assessment imply?	1. The person is free from NCDs 2. The person is at higher risk of getting NCDs 3. The person still needs to be screened for NCDs annually 4. The person may not attend the weekly NCD Meeting
Q17-You are a part of the NCD screening in your village this year. A 41-year-old female comes to enquire about what is happening. On further interaction, you learn that she has no history of diabetes or hypertension and also does not share any signs/symptoms of either. In such a case what will be your plan of action?	1. Screen the person every year (annually) 2. No need to screen the person again 3. Screen the person after 2 years 4. Screen the person every 5 years

Appendix A.2. Question-Wise Practice Behaviour Scores of the Community Health Workers

Table A2.

Practice Behaviour Scores			
Themes	**Questions**	**Percentage of Participants with Correct Answers % (n)**	**Confidence Intervals**
Practice behaviour	Diabetes signs and symptoms	51.3% (141)	45–57%
	Referral to health centre	66.5% (183)	60–72%
	HbA1c testing	31.6% (87)	26–37%
	Diabetes diet	41.8% (115)	35–47%
	Self-management	52% (143)	45–58%
	Hypoglycemia management	78% (215)	72–82%
	Microvascular complication screening	9.8% (27)	6–13%
	Peripheral neuropathy management	29.5% (81)	24–35%
	Calculation of diabetes risk score	26.6% (73)	21–32%
	Frequency risk screening	75.6% (208)	70–80%

Appendix A.3. Question-Wise Knowledge Scores of the Community Health Workers

Table A3.

Knowledge Score			
Themes	**Questions**	**Percentage of Participants with Correct Answers % (n)**	**Confidence Intervals**
Knowledge questions	Diabetes, diagnosis and referral	31.6% (87)	26–37%
	Diabetes: types and self-management	30.6% (84)	25–36%
	Diabetes diet	89.5% (246)	85–92%
	Diabetic retinopathy and Hypoglycemia (combined question)	85.1% (234)	80–89%
	Microvascular complications: signs and screening	36.7% (101)	31–42%
	Diabetes and COVID-19	57.1% (157)	51–63%
	Diabetes risk assessment	44% (121)	38–50%

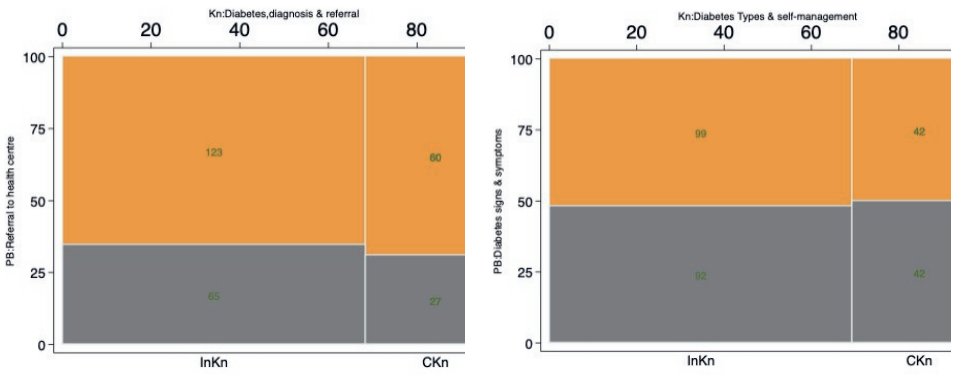
Appendix A.4. Logistic Correlations between Practice behaviours and Knowledge Themes

Table A4.

Practice Behaviour Theme	Knowledge Theme	Odds Ratio	Coefficient	*p*-Value
HbA1c Testing	Diabetes, Diagnosis and referral	0.53	−0.61	0.04
Diabetes patient referral to health centre	Diabetes, Diagnosis and referral	1.17	0.16	0.56
Self-Management	Diabetes: Types and Self-Management	0.67	−0.39	0.13
Diabetes signs and symptoms	Diabetes: Types and Self-Management	0.92	−0.07	0.77
Identifying signs and symptoms of diabetes	Microvascular Complications: Signs and Screening	1.91	0.64	0.01
Microvascular complications screening	Microvascular Complications: Signs and Screening	1.99	0.68	0.09
Peripheral Neuropathy Management	Microvascular Complications: Signs and Screening	1.97	0.68	0.01
Microvascular complication management: Hypoglycemia	Microvascular complication knowledge: Hypoglycemia & DR	1.6	0.47	0.21
Practice: Diabetes Diet	Diabetes Diet	1.68	0.52	0.21
Risk Assessment Calculation	Diabetes Risk Assessment	0.78	−0.23	0.39
Risk Assessment Screening	Diabetes Risk Assessment	0.64	−0.43	0.12
Overall Practice Behaviour	Overall Knowledge	9.03	0.499	0.09

Appendix A.5. Mosaic Plots Depicting the Strong Relationship between Correct Practice Behaviour and Incorrect Knowledge

Each mosaic plot consists of four sections. Each plot has the number of participants answering knowledge questions on the *X*-axis and practice behaviour questions on the *Y*-axis. In the plot, there are two columns, each divided into two parts. The left column shows the number of participants who answered knowledge questions incorrectly. The right column shows the same for correctly answered knowledge questions. The upper part of each column shows the number of participants who answered practice behaviour questions correctly and the lower part who answered incorrectly. Further, the upper right section shows the number of participants who answered both knowledge and practice behaviour questions correctly, and the upper left section shows the number of participants who answered the practice behaviour questions correctly but the knowledge questions incorrectly. The lower left section shows the number of participants who answered both the knowledge and practice behaviour questions incorrectly. The lower right section shows the number of participants who answered knowledge questions correctly but practice behaviour questions incorrectly.



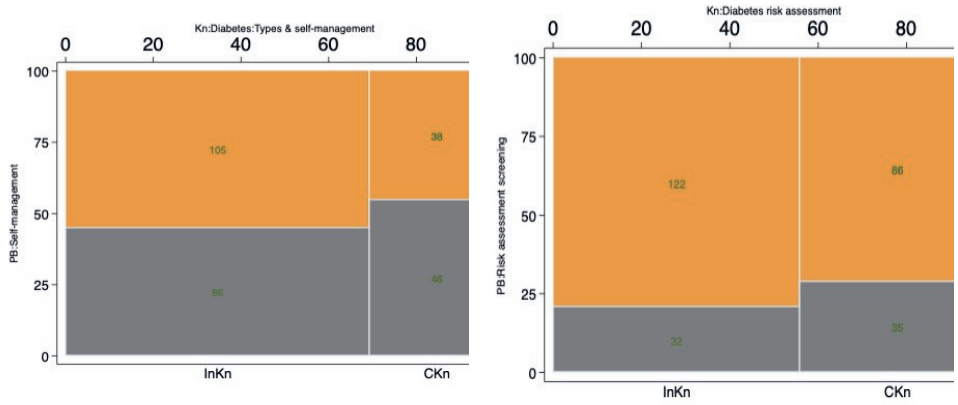


Figure A1.

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CHAPTER 6

Chapter 6: Strengthening diabetes care through task-shifting: Effects of structured community health worker training on diabetes and diabetic retinopathy screening and referral outcomes in rural South India- a cluster randomised controlled trial

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Abstract

Community health workers (CHWs) are essential for managing non-communicable diseases in resource-constrained low- and middle-income countries, but their skills are generally inadequate. Our study aimed to assess whether a structured, competency-based training program for CHWs could improve diabetes screening volume, diagnostic testing rates, confirmed diabetes detection rates and diabetic retinopathy (DR) screening rate, in rural India.

We conducted a parallel, cluster-randomised controlled trial in eight primary health centres in Ranga Reddy District, Telangana, India. Clusters were randomised equally to the intervention and control arms and matched on sociodemographic characteristics. The intervention consisted of structured, competency-based training on diabetes and DR screening. The main outcomes were the proportion of high-risk individuals screened and referred for diagnostic testing, the confirmed diabetes detection rate, and the proportion of referred patients who underwent DR screening. Analysis used difference-in-differences (DiD) multilevel logistic regression models.

We recruited 240 CHWs (113 intervention; 127 control arms) who screened more than 25,000 individuals and referred them for testing across both the arms. The diagnostic testing rate increased from 50.1% to 66.4% in the intervention arm while remaining nearly the same at 49.5% against 48.9% in the control arm (DiD odds ratio [OR] 2.02, 95% CI 1.76–2.32; $p<0.001$) during the same period. Confirmed diabetes detection rates increased from 51.6% to 78.4% in the intervention arm versus 48.8% to 49.7% in the control arm (DiD OR 3.27, 95% CI 2.73–3.92; $p< 0.001$) among the tested individuals. The DR screening rate increased from 7.3% to 13.8% in the intervention arm, while it decreased from 5.9% to 3.9% in the control arm (DiD OR 3.10, 95% CI 1.06–9.07; $p=0.039$) among patients referred for DR screening.

A structured, competency-based CHW training significantly improved diabetes screening and referral, diagnostic testing rate, confirmed diabetes detection, and DR screening rate among patients compared with standard care in rural India. Task-shifting for diabetes care can yield effective outcomes when trained CHWs are incorporated into standard care. These findings support the incorporation of such CHW training initiatives into national policies for diabetes and potentially for other non-communicable diseases in rural settings as well.

This trial was registered with CTRI (CTRI/2020/07/026828) and approved by the IEC at IIPH-Hyderabad (IIPHH/TRCIEC/218/2020).

Introduction

Diabetes mellitus (DM) is one of the foremost causes of morbidity and mortality across the globe[1]. The International Diabetes Federation estimates an exponential increase in the DM burden, from the current estimate of 589 million people in 2025 to nearly 853 million by 2050[2]. India bears the second-largest share of the global DM burden, with an estimated prevalence of 11.4%, affecting approximately 103 million individuals[3]. Once perceived as a predominantly urban disease, DM has now emerged as a major public health challenge in rural India, where prevalence has risen sharply from 2.4% in 1970 to 9.4% in 2020, and nearly 57% of all individuals with diabetes currently reside in rural areas[3-5]. This sharp increase has been attributed to rural populations mirroring urbanised lifestyles, including unhealthy diets and reduced physical activity. This burden is compounded by persistent barriers to healthcare access, inadequate screening, delayed referrals, higher costs, and poor-quality healthcare services.[5, 6]

Poorly controlled diabetes leads to earlier onset of macrovascular and microvascular complications, including diabetic retinopathy, diabetic nephropathy, and diabetic neuropathy[2, 3, 6, 7]. These complications worsen health and increase healthcare costs, especially for rural patients due to poor screening and referral possibilities, leading to late diagnoses and delayed treatment and management. There is substantial epidemiological evidence that diabetic retinopathy (DR) is an early predictor of other complications such as kidney disease, stroke, and cardiovascular events. DR is therefore a useful proxy indicator of microvascular complications in India, given its relatively high prevalence, the feasibility of non-invasive community screening, and its endorsement as a quality indicator in international diabetic care guidelines[3, 6, 8]. Early detection of DR and other complications can reduce progression and prevent avoidable blindness and health expenditures associated with related complications.

The World Health Organization and the World Medical Association endorse community health workers (CHWs) as an evidence-based, scalable workforce to address healthcare inequities through task-shifting[9, 10]. Empirical evidence from large-scale programmes for both communicable and non-communicable diseases has demonstrated that CHWs can effectively contribute to prevention and management, including diabetes care, when supported by appropriate training, supervision, and health-system integration [11-13]. The Indian government, aligned with global health policy frameworks, and institutionalised a cadre of female CHWs (e.g., Accredited Social Health Activists) within national health programs, initially for maternal and child health, and later expanding their mandate to include non-

communicable diseases such as diabetes, hypertension, stroke, and cancers [14]. Such task-sharing is critical because access to formal healthcare in many rural areas is limited. At the community level, however, the effectiveness of CHWs' impact on diabetes care depends on adequate training, knowledge, skills, and referral capacity, and our earlier work in Telangana has documented the gaps in these areas limiting the program's impact [15, 16]. These system-level gaps are prominent in rural settings undergoing rapid epidemiological transition, where diabetes prevalence is rising alongside persistent deficits in awareness, health literacy, and care-seeking practices.

Diabetes and DR management in rural areas are further hindered by a shortage of skilled workers in rural India, leading to delayed diagnosis, restricted screening, and avoidable vision loss. One multicentre study in India reported that 45% of persons with DM had visual loss at first presentation to an eye facility[17]. Community-based screening for diabetes complications by trained CHWs could be a practical, cost-effective approach to improve early detection of microvascular complications and enable timely preventive therapy.

Strategies involving CHW-led task-sharing can strengthen primary health systems in low- and middle-income countries. Despite CHWs being fundamental to India's primary healthcare system, there is limited high-quality evidence on whether structured, competency-based training can enhance CHWs' knowledge, clinical practices, and, crucially, patient outcomes related to diabetes and diabetic retinopathy (DR). Recent programmatic initiatives in India and Telangana, including the deployment of trained optometrists and the integration of non-mydriatic fundus cameras into primary health centres, represent an important step toward decentralised DR screening[18, 19]. Nevertheless, the effectiveness, equity, and sustainability of such initiatives depend on well-trained CHWs. These trained CHWs can identify high-risk individuals, facilitate screening uptake, and strengthen linkages between communities and the health system while their inconsistencies will limit these crucial health system outcomes.

An evaluation of structured CHW training intervention to understand its success for patients outcomes is therefore essential to inform evidence-based policy and guide scale-up of integrated diabetes (and if needed, combined with eye-care) services [20, 21]. Evaluating a structured CHW training program can assess whether increased knowledge and skills improve health care provision and primary diabetes care, as well as DR screening in rural areas. We aimed to determine whether a structured, competency-based training programme for CHWs improves their knowledge and practice behaviours and results in improved patient outcomes related to diabetes management and diabetic retinopathy screening in rural South India. The baseline values of knowledge and practice behaviours have been published in an earlier

manuscript by Gudlavalleti et al.[22] Specifically, the objective was to determine the effect of structured CHW training on the proportion of individuals screened for diabetes, referred for further diagnostic testing, confirmed diabetes detection rate, referred patients undergoing DR screening by trained CHWs through a structured training program, compared to untrained CHWs (control group).

Methods

Study design and setting: We conducted a parallel, cluster-randomised controlled trial from 1st March 2021 to 31st March 2023 at eight primary health centres in Ranga Reddy District, Telangana, India (see our protocol paper, Gudlavalleti et al.[22]). Each primary health centre and its network of affiliated CHWs was defined as a cluster. The clusters were randomly assigned (1:1) to the intervention or control arm. Randomisation was stratified by key characteristics (catchment population size and sociodemographic profile) using administrative health department data to ensure comparability between arms. An independent researcher generated the allocation sequence using a computer-generated random scheme. Given the nature of the intervention, participants and investigators were not masked to allocation.

Participants: CHWs affiliated with the selected health centres were the primary participants for the training intervention. High-risk individuals in the community (identified via CHW screening) constituted the population used to measure patient outcomes. All CHWs within the selected health centres were included unless they were unavailable due to unforeseen circumstances (e.g., extended leave or death). A sample size of 147 CHWs per arm (294 in total) was determined for CHW knowledge and practice behaviours (continuous outcomes) using standard formulas for cluster randomised controlled trials[23], with moderate effect size (Cohen's d=0.5), 80% power, 5% level of significance, and intracluster correlation coefficient (ICC) of 0.03 (derived from published evidence from the Kerala diabetes prevention study 2018[24] and described in detail in our published protocol)[22, 25]. Attendance was recorded for all CHWs during the training sessions. A few did not return for follow-up sessions due to COVID-19 disruptions. Only those who completed the training and participated in both the baseline and post-training assessments were included in the study. CHWs who attended the first session or returned after the study period received training but were not part of the study. For the included CHWs, attendance and training completion were fully documented.

Intervention: The intervention consisted of a structured, bilingual (English and Telugu) CHW training module on DR screening[22]. This module was developed by consolidating existing

training materials from public health authorities and CHW training experts, then pilot-tested and refined the CHW training module (see Appendix1 for the training module). The training was delivered in person over four sessions (totalling 20 contact hours across six months) by certified trainers. CHW knowledge and practice behaviours were assessed before the training (baseline) and three months after the training (follow-up) using a validated questionnaire that measures diabetes-related knowledge and screening as well as referral practices. These instruments had been contextually validated and used in our prior publication[16]. These validated instruments were used to collect both baseline and post-intervention data.

Procedures: In their routine activities post-training, CHWs in both arms identified individuals at high risk of diabetes using a government-validated screening checklist included in the training module[14, 22]. In addition, CHWs in the intervention arm had been specifically trained to administer this checklist correctly as a screening tool and to refer high-risk individuals for blood glucose testing at the health centres. At health centres, doctors or trained nurses performed diagnostic confirmation of diabetes (via blood tests), according to the national guidelines of the Indian Council of Medical Research. Persons identified as having DM were subsequently referred for DR screening.[14, 20] All processes – from initial community screening and referral for blood glucose testing, to test results, diabetes diagnosis, referral for DR screening, and DR screening – were documented by CHWs using standardised logbooks. Each entry in the logbook included the individual's details, a unique study ID, and a referral slip that was given to the patient. Study supervisors periodically reviewed the logbooks for completeness and accuracy, cross-checking entries against health centre registers and collecting referral slips. In case of any discrepancy, the official health centre records were considered the source of truth, since they reflect the public health system's documentation.

Outcomes: The main outcomes compared groups pre- and post-intervention, in line with the research questions and study design[22]. We used a difference-in-differences (DiD) analysis, in which the interaction term between the study arms (intervention and control) and the time period (before and after the intervention) measured the intervention's effect. This was our primary variable of interest, and it reported whether the intervention arm changed significantly when compared to the control arm. The patient outcomes of diabetes screening, diagnostic testing rate, confirmed diabetes detection rate, and DR screening rate among referred patients were analysed. We classified the outcomes as process outcomes (diabetes screening, diagnostic testing rate among referred individuals, and DR screening rate among referred patients) and clinical outcomes (confirmed diabetes detection rate).

Statistical analysis:

We followed an intention-to-treat approach for all analyses. Descriptive statistics were reported as means and standard deviations (SD) for continuous variables and as frequencies and percentages for categorical variables. Baseline characteristics were reported in accordance with the CONSORT guidelines for cluster RCTs.

We conducted the analysis at two levels. First, patient-level outcomes were analysed using multilevel logistic regression models to account for the hierarchical data structure. Patient-level data did not include CHW identifiers. Thus, the CHW-level random effects could not be evaluated. Models for patient outcomes accordingly only included a random intercept for the health centres. Results are presented as odds ratios (ORs) with 95% CIs. The magnitude of the clustering effect at the health centre level was assessed using the ICC (latent-variable approach) [26]. Then, we integrated the random effects to estimate the population-averaged differences in probabilities. This gives the number of percentage points of absolute increase in the probability of patient-level outcomes compared to the control clusters. We also conducted a sensitivity analysis excluding one intervention cluster (Centre CI) with substantially higher patient volume at baseline to ensure that this cluster did not unduly influence the results.

For CHW-specific outcomes (knowledge and practice scores), we used linear mixed-effects models with random intercepts for health centers to estimate the DiD intervention effect. DiD intervention effects for these continuous outcomes are presented as mean differences adjusted for baseline trends (β coefficients) with 95% CIs.

Within-arm changes over time (pre vs post in the same arm) were examined in secondary analyses. ICC values below 0.05 were considered to indicate minimal clustering effect, 0.05–0.15 moderate, and >0.15 high clustering effect[27]. Missing data were minimal: there were no missing values for CHW knowledge/practice outcomes, and <2% missing for patient outcome data. Missingness was similar in both arms and was unrelated to outcomes (presumed missing at random); thus, we used complete-case analysis without imputation. [28] All analyses were conducted using Stata version 18SE, with significance set at $p < 0.05$.

Ethics: The ethical approval was obtained from the institutional ethics committee of the Indian Institute of Public Health Hyderabad (IIPHH/TRCIEC/218/2020). Written informed consent was obtained from all participants.

Results

A total of 240 CHWs (113 in the intervention arm; 127 in the control arm) participated in the trial out of the 294 planned, with the difference due to COVID-19-related CHW attrition. These CHWs screened and referred 25,493 high-risk individuals for diabetes across the eight clusters during the study period (Table 1). Table 1 presents the cluster level data.

Table 1: Overview of patient-level Data Across Both Arms and Time Periods

Centre	Arm	Pre-Intervention					Post-Intervention				
		Screened & Referred for Testing	Tested for Diabetes	Detected with Diabetes	Referred for DR Screening	Screened for DR	Screened & Referred for Testing	Tested for diabetes	Detected with Diabetes	Referred for DR Screening	Screened for DR
Intervention											
AI	Intervention	612	320	163	111	9	858	545	406	166	24
BI	Intervention	204	101	48	16	2	286	177	132	49	10
CI	Intervention	7019	3505	1829	658	52	9875	6638	5228	1234	165
DI	Intervention	1160	578	286	106	2	1623	1036	815	191	28

Intervention Total		8995	4504	2326	891	65	12642	8396	6581	1640	227
Control											
AC	Control	105	48	22	7	1	112	55	27	8	0
BC	Control	164	80	40	7	1	103	50	24	5	0
CC	Control	918	456	221	99	7	776	371	182	61	3
DC	Control	809	404	199	57	1	869	433	219	78	3
Control Total		1996	988	482	170	10	1860	909	452	152	6
Overall Total		10991	5492	2808	1061	75	14502	9305	7033	1792	233

Grand Total across both arms and both time periods	
Total Screened & Referred for Testing	25493
Total Tested for Diabetes	14797
Total Detected with Diabetes	9841
Total Referred for DR Screening	2853
Total Screened for DR	308

DR=Diabetic Retinopathy

Note: Centre CI (Intervention) had substantially higher baseline screening volume and was excluded in sensitivity analysis. All primary results remained significant after this exclusion.

The eight primary health centre clusters were randomly assigned to the intervention (4 clusters) and control (4 clusters) arms (Figure 1). Figure 1 presents the CONSORT flow diagram of clusters, CHWs, and patients through the trial phases. The sociodemographic characteristics of

the CHWs were comparable between the two arms (Table 2). The ICCs at the cluster level were (<0.001), and a likelihood ratio test comparing the cluster-level intercept model against a logistic regression model did not report an improvement in the model fit (diagnostic testing rate: χ^2=0.28, p=0.30; diabetes detection: χ^2~0, p>0.99). Thus, the multilevel models for patient outcomes included random intercepts at the cluster (health centre) level only.

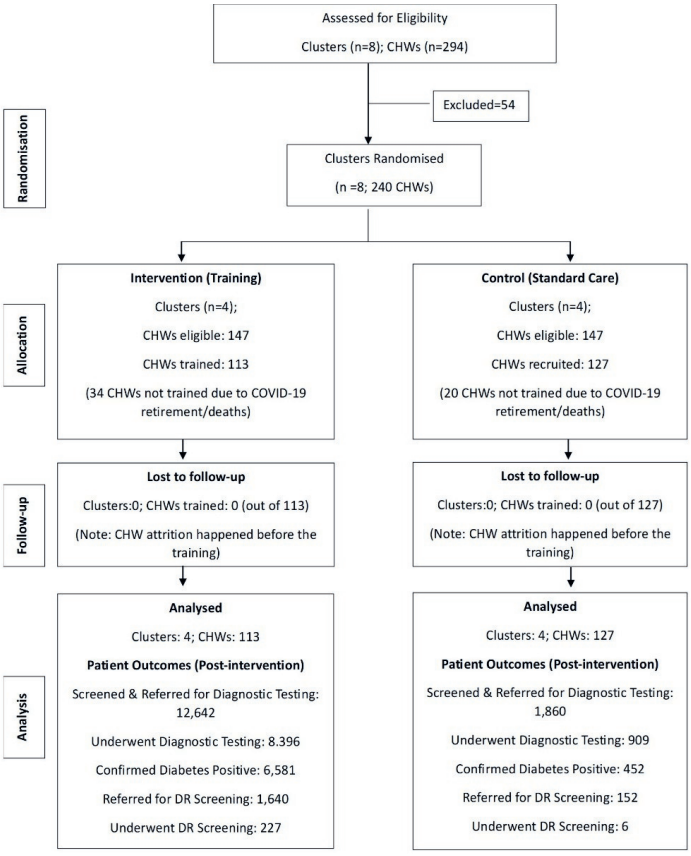


Figure 1: Title: CONSORT Flow diagram of Clusters, CHWs and patients across trial phases

Note: The intervention CHWs screened nearly 6.8 times more patients than the control arm across the post-intervention period, despite being almost similar in number

Table 2: Sociodemographic characteristics of community health workers

Characteristic	Intervention (n=113)	Control (n=127)
Age, Mean ± SD (years)	38.2 ± 7.0	38.0 ± 7.2
Education, n (%)		
Up to secondary	71 (62.8)	81 (63.8)
Higher secondary or above	42 (37.2)	46 (36.2)
Work experience, n (%)		
≤10 years	53 (46.9)	79 (62.2)
>10 years	60 (53.1)	48 (37.8)
Distance home to health centre, Mean ± SD (km)	7.5 ± 7.6	9.4 ± 12.9

SD=Standard Deviation; km=Kilometres

The intervention demonstrated significant effects on CHW knowledge and practice behaviours (Table 3).

Table 3: Comparison of Community Health Workers' Knowledge and Practice Behaviours across both arms

Outcome	**Group**	**Pre Mean (SD)**	**Post Mean (SD)**
Knowledge	Intervention (n=113)	3.21 (1.29)	6.01 (0.86)
	Control (n=127)	3.75 (1.18)	3.84 (1.28)
	DiD β	2.68 (95% CI: 2.27–3.09)	$p < 0.001$; ICC = 0.041
Practice	Intervention (n=113)	4.49 (1.48)	8.54 (0.94)
	Control	5.23 (1.45)	5.79 (1.40)

	(n=127)		
	DiD β	3.54 (95% CI: 3.03–4.05)	p < 0.001; ICC = 0.049

CI = Confidence Interval; ICC = Intraclass Correlation Coefficient; SD = Standard Deviation, β (Beta): The Difference-in-Differences (DiD) coefficient representing the intervention effect over time relative to the control; Note: The baseline data in the table are from our previous publication, Gudlavalleti et al.[22]

Community health workers in the intervention group had a mean knowledge score of 3.21 (SD 1.29) before the intervention and 6.01 (0.86) after. In the control group, means were 3.75 (1.18) and 3.84 (1.28), respectively. The difference-in-differences analysis confirmed a strong intervention effect on knowledge (β=2.68, 95% CI 2.27–3.09; p<0.001), with very small clustering effects (ICC=0.041).

A similar pattern was observed for practice behaviours. Following the intervention, mean practice scores increased from 4.49 (1.48) to 8.54 (0.94) in the intervention group, compared with 5.23 (1.45) to 5.79 (1.40) in the control group. The intervention was associated with a significant improvement in practice behaviours over time in the intervention group as compared to the control group (β=3.54, 95% CI 3.03–4.05; p<0.001), again with low intraclass correlation (ICC=0.049). (Table 3)

The intervention further demonstrated significant effects on diabetes screening volume, diagnostic testing rate, and confirmed diabetes case detection (Table 4).

Table 4: Overview of patient outcomes in intervention and control arms before and after the intervention

Outcome	Group	Baseline n/N (%)	Endline n/N (%)
Diagnostic Testing Rate	Intervention	4,504/8,995 (50.1%)	8,396/12,642 (66.4%)
(Screened → Tested)	Control	988/1,996 (49.5%)	909/1,860 (48.9%)
	DiD OR (95%CI)	2.02 (1.76–2.32)	p < 0.001
Confirmed Diabetes Detection Rate	Intervention	2,326/4,504 (51.6%)	6,581/8,396 (78.4%)
(Tested → Positive)	Control	482/988 (48.8%)	452/909 (49.7%)
	DiD OR (95%CI)	3.27 (2.73–3.92)	p < 0.001
DR Screening Rate	Intervention	65/891 (7.3%)	227/1,640 (13.8%)
(Positive → Screened)	Control	10/170 (5.9%)	6/152 (3.9%)
	DiD OR (95%CI)	3.10 (1.06–9.07)	p = 0.039

CI = Confidence Interval; DiD OR = Difference-in-Differences Odds Ratio; DR = Diabetic Retinopathy; n = number of participants with the outcome; N = total number of participants in the group. Note: The number of individuals screened increased in the intervention arm (from 8,995 to 12,642) and decreased in the control arm (from 1,996 to 1,860).

Descriptively, the diagnostic testing rate increased significantly from 50.1% to 66.4% in the intervention group, while it decreased slightly from 49.5% to 48.9% in the control group. The multilevel mixed-effects logistic regression with an arm x time interaction (on N=25,493 individuals across 8 clusters) showed a strong intervention effect on the diagnostic testing rate process outcome in the intervention arm as compared to the control arm, with an odds ratio for DiD of 2.02 (95% CI: 1.76-2.32). This indicates that, after accounting for baseline values and clustering at the centre level, the centres in the intervention arm reported a more than doubling in the odds of undergoing diagnostic testing after being screened when compared with the control arm. The ICC was very low (<0.001), suggesting minimal clustering at the centre level. In absolute terms, the intervention improved the probability of undergoing diagnostic testing after being screened by 17 percentage points (95% CI: 14.3-19.7) when compared with the control arm. Figure 2 shows the diagnostic testing rate.

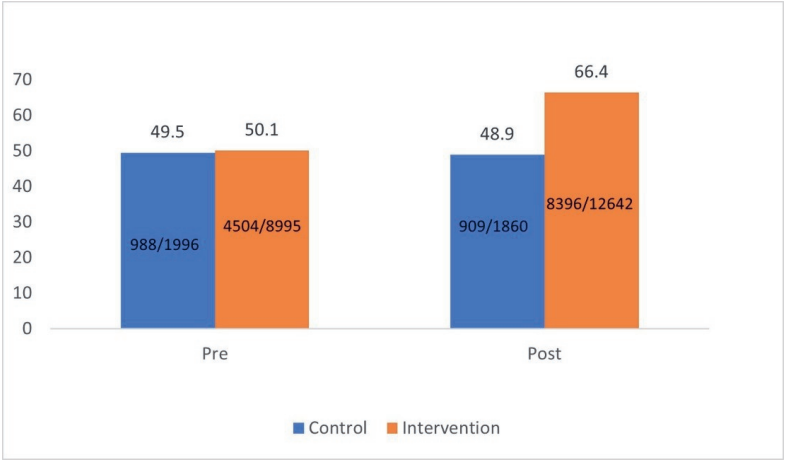


Figure 2: Title: Overview of patients screened and referred, and their diagnostic testing rate

Note: The numerator represents the number of people undergoing diabetes diagnostic testing after referral and the denominator represents the number of people screened and referred for diagnostic testing

Figure 3 presents the details of diabetes screening volumes and the confirmed diabetes detection rate. The percentage of positive cases in the intervention group rose from 51.6% to 78.4%, whereas it stayed nearly unchanged in the control group, from 48.8% to 49.7%. A strong effect of the intervention was also observed. The multilevel mixed-effects logistic regression with an arm x time interaction (on N=14,797 patients across 8 clusters) showed a strong intervention effect as compared to the control group, with an odds ratio for DiD of 3.27 (95% CI: 2.73–3.92, p<0.001). This indicates that the odds of detecting diabetes in the intervention group post-intervention were more than three times higher compared to the control group, after accounting for baseline trends and clustering. In absolute terms, the intervention improved the probability of confirmed detection of diabetes by 26 percentage points (95% CI: 23.5-28.5) when compared to the control.

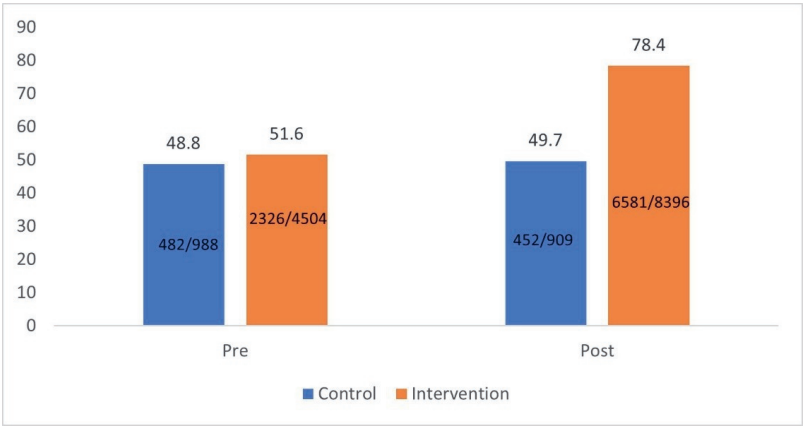


Figure 3: Title: Overview of patients referred and their confirmed diabetes detection rate

Note: The numerator represents the number of people confirmed with diabetes after testing and the denominator represents the number of people who went for diagnostic testing of diabetes after referral

Finally, the intervention produced substantial improvements in the diabetic retinopathy screening rate. Descriptively, the DR screening rate among referred patients increased from 7.3% to 13.8% in the intervention arm and decreased from 5.9% to 3.9% in the control arm (Figure 4). The multilevel mixed-effects logistic regression showed that the arm x time interaction (for n=2853 referred patients across eight centres) corresponded to a DiD odds ratio of 3.10 (95% CI: 1.06–9.07). This indicates that the odds of the DR screening rate in the intervention group post-intervention were three times higher than those in the control arm after accounting for baseline trends and clustering. In absolute terms, the intervention improved the probability of the DR screening rate by 8 percentage points (95% CI: 0.5-15.5) in the intervention arm when compared with the control arm.

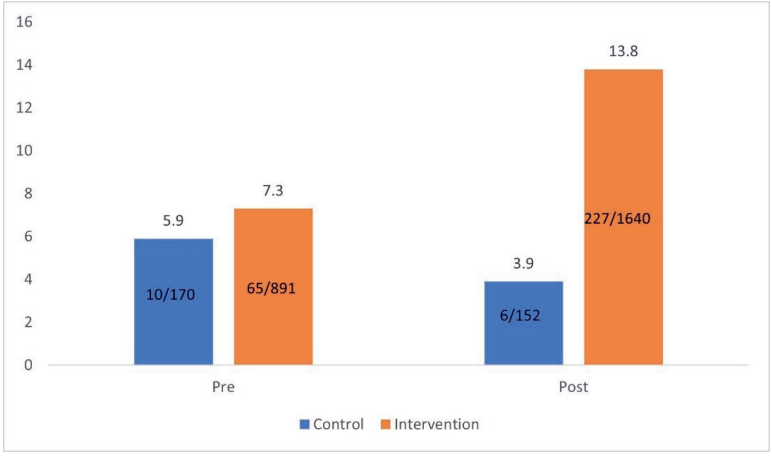


Figure 4: Title: Overview of DR Screening rate in referred patients

Note: The numerator represents the number of people with diabetes who went for DR Screening and the denominator represents the number of people with diabetes referred for DR Screening

The sensitivity analysis after excluding the data from one intervention centre with a high patient volume (78.1% of patients in intervention arm) at both baseline and post-intervention reported that the effects on confirmed diabetes detection were of similar magnitude and significance levels, DiD OR 3.25 (95% CI: 2.541-4.15; p<0.001). The effect on diagnostic testing rate was

reduced but significant (DiD OR 1.75, 95% CI 1.47-2.08; p< 0.001) and the effect on DR screening rate was larger but significant (DiD OR: 4.64, 95% CI: 1.39-15.53; p=0.013). .

Table 4 reports all patients' outcomes, diagnostic testing rate, confirmed diabetes detection rate, and DR screening rate, analysed using a multi-level model.

Discussion

The analysis of all the outcomes measured reported that structured CHW training improves their diabetes-related knowledge and practices, resulting in significant increases in diabetes screening, diagnostic testing rate, confirmed diabetes detection rate, and DR referrals and screening rate, compared with current standard care in rural India. The DiD analysis reported that these effects were due to the intervention and most likely, not attributable to secular trends. Though there is no prior evidence on the link between CHW training and patient-level outcomes, our findings align with earlier observations supporting the use of CHWs in task shifting for achieving such outcomes in India and other low- and middle-income countries (LMICs) after being trained[12, 13, 29]. In our present study, the CHWs in the intervention group reported significantly higher knowledge and practice behaviour scores than those in the control arm. This contributed directly to improved patient outcomes with increased diagnostic testing rates, confirmed diabetes detection rates, and increased DR Screening rates in the intervention arm compared to the control arm post intervention.

The persistent associations across all primary outcomes after adjusting for clustering confirm the intervention effect. The intervention clusters experienced an 86% (from 4504 to 8396 in the intervention arm) expansion in diabetes screening coverage and a 183% (from 2326 to 6581 in the intervention arm) increase in new diagnoses. This relatively large increase in confirmed diagnoses, compared with the overall increase in volume, is not due to changes in diagnostic criteria. Since CHWs did not perform diagnoses, these were carried out at health centres by qualified nurses or doctors following guidelines from the Indian Council for Medical Research (ICMR), the increase likely reflects improved screening accuracy by trained CHWs. This enhanced screening process raised the likelihood of confirming diabetes cases, rather than reducing the diagnostic threshold. The multilevel logistic regression confirmed these

population-level impact of the intervention, if scaled up in rural areas. Evidence from similar settings has reported more modest improvements in task shifting outcomes [11, 12] than our study's findings. This could be explained by the new healthcare resource allocation in rural India, the strict implementation and surveillance of the study, and the heightened concern for healthcare among both the government and the public due to the COVID-19 pandemic. Additionally, the scope of such studies in India is higher due to poor baseline records and a dearth of structured, periodic CHW training. The randomised controlled design helps to attribute the results to the training intervention rather than temporal trends or increased surveillance.

These patterns indicate that improved CHW knowledge and practice behaviour are translated into both quantitative gains (more screening, more referrals) and qualitative improvements (better case detection). Indian studies have established that improving the CHW knowledge and practice behaviours leads to improved screening and referral outputs[13, 30]. The improvement in the rate of DR screening in the intervention arm, compared with a decrease in the control arm, demonstrates the effect of the CHW training in reducing the delayed diagnosis of microvascular complications. However, the comparatively lower improvement in DR screening rate as compared to the other outcomes suggest that improved DR screening among referred patients would require efforts beyond training of the CHWs and that this is a reflection of the systemic barriers like accessibility to eye care services, low patient health literacy (e.g. for diabetic complications), lack of transport facilities, financial and non-financial costs associated with healthcare for rural areas and poor referral follow-ups [8, 18]. The Indian DR screening guidelines and needs assessments have highlighted such implementation barriers, and these cannot be addressed through CHW training alone and need more implementation research [17, 18].

There has been strong evidence for CHW-facilitated care for diabetes and non-communicable diseases, across international systematic reviews, World Health Organization recommendations, and recent Indian policy and economic analyses [1, 10, 25]. Our study's findings are consistent and add to the evidence base by demonstrating effectiveness through our rigorously designed study, confirmed by convincing results. This evidence lays the groundwork for policy-level integration of CHW competency building into their knowledge and practice behaviours, with adequate monitoring and surveillance, which is crucial for achieving sustainable, cost-effective, and community-level impact.[13, 25]. The results also advocate for retraining CHWs to sustain such programs. The study was conducted using existing public CHWs and public health systems, thereby offering high scalability potential.

Some noteworthy strengths of the study are a cluster-randomised design, balanced baseline characteristics for the CHWs and matched clusters, measurement of both CHW competencies and subsequent patient outcomes, and the DiD analyses accounting for baseline differences and temporal trends between the arms over time. The results of the study strengthen confidence in the intervention's effectiveness. The analysis also accounted for the cluster effects, and two sensitivity analysis were conducted. Excluding the high-volume centre, the sensitivity analysis confirmed The direction and statistical significance of all three patient-level effects remained consistent when excluding the high-volume intervention centre (78.1% of patients), although the size of the effects on diagnostic testing and DR screening varied. A methodological transparency note requires attention first: the trial's registered and published protocol[22] looked at the CHW competencies as the primary outcomes of interest. As the trial progressed the current infrastructure of the data collection health centres was found to be capable of reliably capturing patient level outcomes, thereby expanding the study's original scope. As we were unaware of this capability at the time of the protocol registration, this expansion is not a post-hoc revision of the outcomes and thus both these outcome types were reported. Additionally, there are limitations of the trial as well. A major limitation was our reliance on health centre data, which could have been subject to errors and biases, though we had implemented adequate monitoring mechanisms to mitigate this. Second, the follow-up period might not have been long enough to assess the intervention's sustainability. Thirdly, the smaller number of clusters (n=8) might have limited statistical power for cluster-level analyses, although the large number of individual-level observations provided adequate power for these analyses. Another limitation was the baseline imbalance in CHWs' work experience, with 53.1% of CHWs in the intervention arm having over 10 years of experience, compared to 37.8% in the control arm. Randomization occurred at the cluster (health centre) level to match clusters rather than individual CHWs, since the health centre registered only patient outcomes and not individual CHW data. The imbalance was concentrated at a single intervention centre, where 89.4% of CHWs had more than ten years of work experience and was subsequently excluded in a sensitivity analysis. The results indicated that the effect on diagnostic testing and confirmed diabetes detection remained consistent (DiD OR 2.05, 95% CI 1.79-2.36 and DiD OR 3.22, 95% CI 2.64-3.93; both $p<0.001$), whereas the DR screening effect was of similar magnitude but was not statistically significant (DiD OR 2.77, 95% CI 0.94-8.16; $p=0.064$)), a reflection of the smaller volume of screened patients. Excluding this centre, the proportion of CHWs with over ten years of experience was 27.3% in the intervention group compared to

37.7% in the control group, reversing the baseline imbalance while the effects for two outcomes remained consistent.

Finally, the geographic setting of the study can limit its generalizability to different geographies with distinct cultural characteristics.

Together, the study's results provide a strong evidence base that a structured, competency-based CHW training can result in significant improvements in diabetes screening, diagnostic testing, and confirmed diabetes detection outcomes in rural India. This can be extremely useful for policymakers while developing and implementing CHW training-related policies, while also justifying the allocation of monetary resources towards the same. A comprehensive economic evaluation was outside the scope of the study; however, the increase in diagnostic testing rate and confirmed diabetes detection, relative to the minimal health system's expenditure in CHW training, indicates a most-likely positive cost-benefit output if compared to developing parallel structures or treating patients (with complications) at tertiary centres. However, more attention needs to be given to possible systemic barriers (eye care infrastructure, patient-level barriers, linkage systems) for improved DR screening rate among the patients.

In conclusion, a structured, knowledge and practice behaviour-focused CHW training can result in improved diabetes screening, detection and diabetic retinopathy referral compared to the current standard practices. Newer initiatives focused on strengthening existing health systems need to prioritise strategies for diabetes and non-communicable disease management in India and similar geographies.[1, 10, 11, 13, 25]. Future research is needed to assess the sustainability, cost-effectiveness, and integration with public innovations and systems to overcome the current barriers to healthcare access for rural populations.

Author Contributions: Conceptualization: AGG, GVSM, OCPvS, GRB; Data Curation: KP; Formal Analysis: AGG, KP; Funding Acquisition: AGG, GVSM, GRB; Investigation: AGG, GVSM; Methodology: AGG, GVSM, OCPvS, GRB; Project Administration: AGG, GVSM; Resources: AGG, GVSM, SV, OCPvS, GRB; Software: KP, SV; Supervision: GVSM, GRB; Validation: GVSM, SV, OCPvS, GRB; Visualization: AGG, KP, SV; Writing- Original Draft Preparation: AGG; Writing-Review and Editing: AGG, GVSM, SV, OCPvS, GRB.

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Data Access: Authors AGG and KP accessed the data and verified the data reported in the manuscript.

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Data Availability: The data for our study are obtained from government health department records and are thereby subject to restrictions on public sharing. Anonymised dataset supporting the findings of our study will be made available to researchers with legitimate scientific interest upon receival of a reasonable written request to the corresponding author; Anirudh G. Gudlavalleti. All requests will be reviewed on a case-by-case basis and will be subject to compliance of the applicable data governance and participant confidentiality regulations.

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CHAPTER 7

Chapter 7: General Discussion

7.1 Introduction and Overview

Our trial aimed to evaluate whether the structured, competency-based training program we developed for community health workers (CHWs) in rural Telangana would impact their knowledge and practice behaviours related to diabetes, and whether these changes would translate into improved patient outcomes for diabetes screening, referral, and detection, as well as enhanced screening and referral for diabetic retinopathy. To this end, we conducted three studies: a cross-sectional baseline assessment of CHW knowledge and practice behaviours in South India, a systematic review of global evidence on CHW training for diabetes management in low- and middle-income countries (LMICs), and a cluster randomised controlled trial (RCT) evaluating the structured CHW training module across eight health centres in Ranga Reddy district, Telangana. In this discussion chapter, we will present the findings of each study and provide a thematic interpretation of the results across the three studies. This will be followed by a discussion of methodological considerations and will conclude with policy implications, priorities, and recommendations for future research.

7.2 Main Findings

The systematic review, baseline cross-sectional study, and cluster RCT form a unified argument, connected through four themes. First, the disconnect between knowledge and practice behaviour is recurrent; the baseline found that correct practices did not always align with correct knowledge. This informed the case-based training design, which later showed improvements in both knowledge and practice. Second, training alone is necessary but insufficient within a multi-component system. The review indicated that training's effect on glycaemic control was limited and indirect, while the trial demonstrated strong impacts on diabetes screening and detection, with a weaker influence on DR screening due to systemic barriers. Third, the screening-to-treatment cascade revealed that task shifting has the greatest impact on detection and diagnosis, but the least on complication follow-up. Fourth, the discrepancy between significant results in the cascade and the review’s indirect effect on glycaemic control arises from differences in the outcomes studied, not from the underlying effects.

The cross-sectional baseline assessment Chapter 5 identified deficiencies in the knowledge and practical conduct of the current Community Health Workers (CHWs) responsible for diabetes screening and management in rural South India. According to the study, 95% of the CHWs reported insufficient knowledge, while 97% indicated inadequate practice behaviours concerning diabetes and its complications (1). These findings demonstrate that the existing orientation and training programs for CHWs have led to practice behaviours that lack the requisite foundational understanding for reliable and consistent application. Furthermore, the results underscore the necessity for a structured training intervention prior to expecting improvements at the patient level.

The systematic review was conducted in accordance with our published protocol (2). The systematic review Chapter 3 identified four eligible studies from a search of 3,387 studies, comprising three randomised controlled trials and one observational stepped-wedge study. These investigations involved nearly 10 Community Health Workers (CHWs) and approximately 1,000 patients, assessing the impact of CHW training on diabetes outcomes across Low and Middle-Income Countries (LMICs). The review reported limited and indirect evidence supporting the notion that CHW training enhances glycaemic control in patients. Only one trial demonstrated a statistically significant reduction in HbA1c (-0.24 percentage points; p=0.001). However, this trial's population included normoglycemic, prediabetic, and diabetic participants, thereby reflecting a shift in overall glycaemic risk rather than a definitive effect on diabetes management. No studies meeting eligibility criteria reported outcomes related to diabetes screening. Furthermore, the review underscored considerable heterogeneity in training content, intensity, frequency, and delivery methods across the studies. It emphasises the need for larger, more comprehensive trials that evaluate CHW competency in patient screening and referral processes.

Our cluster-randomised controlled trial (Chapter 6) was conducted from 1st March 2021 to 31st March 2023 across eight health centres in the Ranga Reddy district of Telangana, rural South India. The study recruited 240 CHWs (113 intervention and 127 control), and data were generated from more than 25,000 individuals screened across both arms throughout the study. At the CHW level, we conducted a structured four-session, 20-contact-hour training program, as described in our study protocol (3), that resulted in statistically significant improvements in knowledge and practice behaviour scores in the intervention arm, while the control arm scores remained largely unchanged. At the patient level, the diagnostic testing rate increased from 50.1% to 66.4% in the intervention arm, while it reduced slightly from 49.5% to 48.9% in the control arm; (DiD odds ratio (OR): 2.02, 95% Confidence Intervals (CI) 1.76-2.32; p<0.001).

The confirmed diabetes detection rate increased from 51.6% to 78.4% in the intervention arm while it changed slightly from 48.8% to 49.7% in the control arm; (DiD OR: 3.27; 95% CI 2.73-3.92; p<0.001) and the diabetic retinopathy (DR) screening rate increased from 7.3% to 13.8% in the intervention arm while it decreased from 5.9% to 3.9% in the control arm; (DiD OR: 3.10, 95% CI 1.06-9.07; p=0.039).

One intervention centre reported markedly higher patient volumes, approximately 78%, both prior to and following the intervention, in comparison to the other centres. Given that only four intervention sites participated in our trial, this discrepancy could have biased the results by exaggerating the observed effect sizes. Consequently, we performed a sensitivity analysis excluding this centre to assess the robustness of our findings. All results continued to be statistically significant even after the exclusion of this high-volume centre from the analysis.

7.2.1 Reducing the competency gap

An important finding across the studies in the systematic review was that the CHW competency gaps reported at baseline could be addressed through a structured training intervention. The baseline study established the magnitude of the problem, and our interactions with the CHWs and administrators helped us to develop the module, resulting in significant improvements in both knowledge and practice behaviours. We realised that the existing practices were not grounded in the correct knowledge base, so our training module incorporated case studies on practice scenarios that require the correct knowledge base, while basing the content on the best current practices and available guidelines for it, and implementing it in a case-based bilingual module Chapter 6. The improvement in competencies translated into patient outcomes throughout the diabetes care pathways, including diagnostic testing, confirmed diabetes detection, and DR screening. This suggested that the intervention was not only an improvement in numbers but also in the quality of care delivered by the trained CHWs. The trained CHWs were able to utilise the government screening tools more effectively, counsel patients better, and motivate them to achieve the necessary patient outcomes, compared to pre-intervention. This ensured improved competencies as required by the government under the NP-NCD guidelines (4, 5).

7.2.2 Participatory Approach for Intervention Development

One of the key factors contributing to the success of the intervention was the employment of a participatory approach during its development. The training module was meticulously designed through engagement with the relevant Community Health Workers (CHWs) and administrative stakeholders it intended to serve. This process was conducted in four distinct phases. The initial phase involved a comprehensive review of existing literature from government entities and civil society organisations concerning CHW competencies in diabetes and diabetic retinopathy (DR) screening and management. The second phase entailed consultations with CHWs, CHW trainers, and public health authorities, facilitating an evaluation of existing gaps in the current literature. The third phase was a baseline assessment, which revealed significant knowledge gaps (95%) and practice behaviours (97%) among participating CHWs, indicating the necessity for the training to better integrate theoretical knowledge and practical application. The final phase involved reviewing the modified training module with relevant authorities and the CHWs to be trained, leading to the development of a bilingual format, case-based learning strategies, and data collection instruments. This collaborative development process of the training module is likely to account for the substantial improvements observed in CHWs' knowledge and practice behaviours.

The results of our trial reported that the effects were larger than those reported earlier, both in India (6) and across the globe (7, 8). Our understanding might explain this, that the knowledge and practice behaviours were inadequate in Telangana, thereby leaving more room for improvement. So, the success might also be attributed to the trial's design and structure, in which the module aligned with the CHW's required roles and responsibilities for diabetes management and was designed with their input, along with other inputs.

7.2.3 Contribution to the limited existing evidence

The systematic review we conducted found only four studies eligible out of 3,387 we screened. This exemplifies the scarcity of evidence on CHW training for diabetes management in LMICs before our trial. The four included studies also had many limitations, such as a small sample of trained CHWs, heterogeneity, inadequately reported training, short follow-up periods, and reliance on glycaemic values (HbA1c) as the main outcome of choice for diabetes management: only one study, Catley et al. (9) reported a statistically significant outcome, but the diabetes outcome was secondary, and the study included fewer than 29% of participants with diabetes: the other three studies, deSouza et al., Worster et al., and Jain et al. (10-12), which used HbA1c as the primary outcome, reported no statistically significant reduction in HbA1c. The short

follow-up periods could have contributed to this result, as HbA1c changes require a longer time frame due to multiple factors involved, including medication adherence, dietary compliance, physical activity, and quality of facility-level care. (13, 14). The CHWs cannot influence many of these factors, but they can influence other patient-level outcomes in the diabetes care pathways, such as screening, testing, and referral. Thus, we prioritised these outcomes in our study to help detect the real-world effects of CHW training.

Our trial also addressed another gap identified by our systematic review: none of the studies reported any diabetes-related screening outcomes. Our current randomised controlled trials' (RCTs) recruitment of community health workers (CHWs) and the outcomes for CHWs and patients, using the difference-in-differences (DiD) analysis, are documented, whereas the methodological rigour is lacking in the studies included in the systematic review. The studies presented in this thesis collectively contribute evidence regarding CHW training and its effectiveness in diabetes and diabetic retinopathy (DR) screening and referral outcomes in low- and middle-income countries (LMICs), a topic that has been previously underrepresented.

7.2.4 Integrating Diabetes and Diabetic Eye Disease care through the CHW workforce

An important finding from our randomised controlled trial (RCT) was a statistically significant increase in the diabetic retinopathy (DR) screening rate in the intervention group compared with the control group. Currently, DR constitutes one of the leading causes of preventable blindness in India (15). When addressed early, DR can be effectively managed. It may also serve as a surrogate marker for other microvascular complications associated with diabetes, such as diabetic neuropathy and an elevated cardiovascular risk (16). Population-level research has demonstrated that between 5-7% of Indians with diabetes suffer from sight-threatening DR, and at their initial presentation to any ophthalmic facility, nearly 45% of these individuals already exhibit some degree of vision loss (17).

At present, the disparity between individuals with diabetes who are appropriately screened and those who require screening is substantial and increasing. Following the training intervention, community health workers (CHWs) successfully motivated more patients to undergo DR screening at centres within the intervention group. Conversely, this improvement was not observed in the control group. This underscores the critical role of CHWs in the diabetes care continuum, where installing new equipment and specialist services alone cannot sufficiently address the existing gap. Nevertheless, the screening rate for DR remains lower than that for

other patient outcomes, indicating additional barriers warranting further consideration, as detailed in Chapter 6.

7.2.5 Methodological Considerations

7.2.5.1 Trial Design

Considering the implications of our study, we intentionally designed the trial to be pragmatic. All community health workers (CHWs) affiliated with the selected health centres were included unless they were unwilling or unavailable due to health conditions or death. No exclusions were made intentionally. The eight sites were selected because they represent the public healthcare system, where the intervention, if successful, could be scaled up rather than confined to a laboratory setting. All analyses were conducted using the intention-to-treat approach. In accordance with these methodological choices, the findings can be reported with real-world applicability, suggesting that such an approach is likely feasible for implementation, potentially with some customisation of necessary components.

7.2.5.2 Strengths and Internal Validity

Our randomised controlled trial (RCT) possessed numerous strengths, supporting the robustness of our reported findings. The randomisation conducted at the health centre level, stratified by catchment population and sociodemographic profile, incorporated provider behaviour within our geographic sites and simultaneously mitigated the risk of inter-arm contamination. The difference-in-differences (DiD) multilevel logistic regression analysis accounted for pre-existing differences among clusters and controlled for temporal trends. This methodology is more suitable than a mere pre- and post-intervention comparison. The low intraclass correlation coefficient (ICC) values (<0.001) suggested that variation primarily occurred at the individual level rather than the cluster level. The robustness of these findings was further assessed through two sensitivity analyses excluding the highest-patient volume centre and the centre with highest CHW work experiencein the intervention arm. Two patient-level outcomes (diagnostic testing and confirmed diabetes detection) remained statistically significant, while the third patient outcome (DR screening) reported a similar magnitude but was not statistically significant due to the exclusion of a large volume (78.1%) of patients. An additional merit of our study was the employment of validated instruments to assess knowledge and practice behaviours, which we documented in Chapter 5. We measured competency

directly through these instruments, rather than inferring it from patient outcomes or utilising public healthcare facility data, both of which were verified against CHW logbooks and referral slips validated by our team, thus enhancing confidence in the patient-level outcomes.

7.2.5.3 External Validity and Generalisability

A key strength of our study was its external validity, the extent to which the results can be generalised to settings where the intervention could be implemented. The study sites in rural Telangana reflected the typical low-resource public health infrastructure found in most rural parts of India. Conversely, the participants were CHW cadres responsible for diabetes and DR screening nationwide under the National Programme for Prevention and Control of Non-Communicable Diseases. Three considerations are important: first, the study took place during the second COVID-19 wave, when community members and CHWs were more aware of and receptive to healthcare activities. Second, Telangana's government prioritises diabetic retinopathy screening at primary healthcare centres, having invested in non-mydriatic fundus cameras and trained optometrists in line with the Ayushman Bharat guidelines. This may have limited the potential for improvement during the RCT. Lastly, unlike Telangana, other Indian states and similar regions may lack supportive administrative structures.

7.2.5.4 Limitations and Threats to Internal Validity

The results should be interpreted cautiously due to certain limitations. The study was conducted in a rural healthcare setting with clearly defined roles and responsibilities for CHWs; therefore, applying these findings to other contexts may be misleading. With only eight clusters included, the precision of cluster-level estimates was limited, and assessing heterogeneity between sites was challenging. Nevertheless, the large number of individual observations ensured sufficient power for the main analysis. Patient outcome data were gathered from health centre records, which, despite strict monitoring, are still prone to human error. Finally, the study did not evaluate long-term patient outcomes such as HbA1c levels, complications, protocol adherence, or quality of life factors that could have offered further insights into the effectiveness of CHW training throughout the entire diabetes care pathway.

Our study demonstrated minimal instances of missing data. No absent values were noted for the outcomes concerning CHW knowledge and practice behaviours, as the implementation team rigorously adhered to established protocols, thereby ensuring thorough data collection.

Concerning patient outcomes, our monitoring instrument, the CHW logbooks, was validated against health centre registries to evaluate data integrity, revealing that less than 2% of data was missing due to registry inaccuracies. To address potential errors in our analysis, we used all available data without imputing the missing data.

The pre- and post-training competency assessment, which was a context-validated tool, served as the primary measure of training implementation and adherence to protocol (The notable enhancements in knowledge and practice behaviour scores among Community Health Workers (CHWs) within the intervention group, contrasted with minimal changes observed in the control group, substantiate that the training was executed as intended).

7.2.6 Implications for Practice and Policy

The findings of our study have direct implications for existing diabetes and DR programmes in rural India, especially those with a high burden of diabetes. Telangana's diabetes burden has shown a worrying trend, with higher prevalence and a narrowing prevalence gap between urban and rural areas, as discussed in the Introduction Chapter. Along with the documented CHW competency gaps in Chapter 5, this evidence supports the assumption that the current CHW workforce is ill-equipped to manage this upcoming diabetes epidemic. Our trial has provided strong evidence for implementing a structured, well-designed training intervention, combined with evidence-based surveillance mechanisms, to significantly improve CHWs' outcomes in addressing this diabetes epidemic. The intervention model we implemented can be integrated into existing health systems and cover all roles and responsibilities assigned to CHWs under the existing National Programme for Prevention and Control of Non-Communicable Diseases guidelines (4, 18). The curriculum can be adapted, and the validated instrument can be used to monitor training outcomes in comparable contexts. The trial also provides strong evidence for a model that integrates all the requisite tasks for CHWs in the management of diabetes and possibly other NCDs, as mandated by the Indian government. The DR screening findings also suggested an important policy implication. It suggests that DR knowledge, screening awareness, and referral pathway knowledge should be integrated into the diabetes training modules to improve these outcomes. These implications hold great value for Indian states that have adopted the Ayushman Bharat scheme to integrate eye care into primary healthcare facilities.

The long-term sustainability of the initiative by CHWs, who are already burdened with government schemes, raises concerns. The intervention aimed to address this by enhancing the

competencies of CHWs involved, aligning with the government's NP-NCD programme, rather than deploying a standalone intervention. However, future similar interventions should incorporate a self-care model that encourages patients to seek healthcare and understand their conditions and management, ensuring sustainable support for better management and adherence to treatment for complications.

7.2.7 Pathways for Future Research

One of the most important future research priorities would be the long-term follow-up of patients identified in our trial. Although our trial reported statistically significant improvements in the outcomes of interest, it was not designed to assess long-term outcomes, such as glycaemic control, patient adherence to protocols, and the reduced incidence and progression of complications. Concurrently, implementation research on CHW training will help us provide evidence on key elements, including the duration and frequency of refresher training, the preferred mode of refresher training, and the most effective mechanism to monitor the effects of the training on CHW competencies. These prospective follow-up studies would provide necessary evidence and directly address the evidence gap identified in our systematic review chapter (Chapter 3).

The next priority would be an economic evaluation of such a training program at scale. Our trial reported significant improvements in all patient-related outcomes, including diabetes screening, testing, and confirmation rates, as well as DR screening, at a modest investment in training and simple surveillance mechanisms integrated within the existing health systems. A comprehensive formal cost-effectiveness analysis comparing our model with existing models of community health camps and physician- or nurse-led screenings would generate important economic evidence for policymakers in India and similar global geographies. The last research priority would be to investigate the interplay between our suggested model and the broader health systems involved in the diabetes care pathways. These would include the availability of diagnostic facilities, the availability of necessary medicines, the quality of health information systems, and the penetration and acceptance of newer public health insurance schemes for patients' financial security. This will help identify systemic barriers or driving mechanisms that can hinder or amplify the training effects, ultimately enabling the implementation of this model across diverse Indian and global contexts.

7.3 Conclusion

This dissertation aimed to evaluate whether a structured, competency-based CHW training would improve CHW competencies and whether these improved competencies would lead to better diabetes screening, referral detection, and DR screening in rural South India. The results of the studies we conducted consistently reported positive findings in this regard. They confirmed our hypothesis that structured, competency-based training for CHWs would improve their diabetes knowledge and practice behaviour competencies. These improvements would lead to improved diabetes screening, diagnostic testing, confirmed diabetes detection, and DR screening among patients in the intervention arm, compared to the control arm. Eventually, our model led to a doubling of the odds of diabetes diagnosis, a tripling of the odds of confirmed diabetes, and a tripling of the odds of DR screening compared to the control arm (standard care). These results provide strong evidence for integrating a structured, competency-based CHW training programme into the existing National Programme for Prevention and Control of Non-Communicable Diseases initiative. This will establish a validated training and evaluation model for CHWs within existing resources and scalable throughout the country across the responsible cadres of CHWs, which can be tested for other NCD conditions. Future research is needed to build on our reported findings and strengthen the evidence base for our model.

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CHAPTER 8

Chapter 8: Research Impact

This chapter elaborates on the societal significance and wider influence of our research. One of our principal deliverables, the community health worker (CHW) training module, has been adopted and modified by the government of Telangana and is currently employed by trainers within the public healthcare infrastructure.

8.1 Societal and Economic Relevance

Today, India has an estimated 90 to 101 million people living with diabetes according to IDF or the ICMR INDIAB estimates respectively, and 40% of them are undiagnosed. This means these individuals might suffer from macro- and microvascular damage and are diagnosed late, with nearly 45% of cases being diagnosed late, often presenting with vision loss at their first visit to an eye facility. The economic burden of diabetes is also substantial, with worldwide diabetes-related expenditures increasing to more than USD 1,000 billion in 2024 from merely USD 232 billion in 2007. This burden disproportionately impacts rural patients due to out-of-pocket costs and various barriers, thereby complicating their ability to absorb these expenses. For rural populations in India, the resolution of these healthcare challenges can be effectively shifted to Community Health Workers (CHWs), who serve as vital connectors between public healthcare systems and rural communities but often lack sufficient training to bridge this divide.

This dissertation addresses two interrelated gaps. The first is a competency gap: CHWs responsible for diabetes and DR screening in rural India lack the structured, evidence-based training required to effectively carry out their mandated roles. The second is a research gap: no rigorously designed cluster-randomised controlled trial has evaluated whether a structured CHW competency training programme could improve patient-level outcomes in diabetes screening, diagnostic testing, and referrals in a low-resource setting. Our baseline assessment chapter (Chapter 5) established that among CHWs tasked with managing diabetes and DR screening and management, 95% had inadequate knowledge and 97% exhibited inadequate practice behaviours. This evidence, for the first time in this context, demonstrated that the problem was not a shortage of CHWs but a lack of proper training. Our systematic review chapter (Chapter 3) indicated limited evidence that CHW training improved glycaemic outcomes in LMIC settings, but evidence on screening outcomes was inconclusive or non-existent. This highlights the need for a comprehensive evaluation. Our cluster randomised controlled trial (RCT) chapter (Chapter 6) found that a well-designed, structured training

programme doubled the likelihood of appropriate diagnostic testing, tripled the likelihood of confirmed diabetes detection, and tripled the likelihood of DR screening uptake compared to the control arm (standard care). These improvements were achieved within existing health systems and are therefore scalable within comparable systems in India. Even if a modest number of the currently available CHWs (totalling more than one million in India) can be further trained, the outcomes will be highly significant for India, where the number of people diagnosed with diabetes and integrated into the system will increase, thereby improving their future management of diabetes and its complications. This expanded scale will also benefit economic outcomes by lowering associated costs for both patients and health systems.

8.2 From Study to State Policy: Adoption of Training Module by State Government

The training module we developed utilised existing government systems and feedback from all necessary stakeholders. A review of health centre records enabled government authorities to assess the intervention's effectiveness, leading to the module's formal incorporation into the state's training programme. Currently, more than 2,500 CHWs have been trained to provide diabetes care across five districts in the state. This transition of the training module from our study into the state's implementation policy represents the most direct societal impact of this dissertation.



CHW teaches the patients in her village using the new integrated module



CHW performs Glucose testing on



Our Module and Logbook with existing government literature at the health centre



CHWs filling in their new integrated logbooks while interacting with patients

8.3 Target Populations

Our training and evaluation model presents advantageous opportunities for both state authorities and the managers of the National Programme for Prevention and Control of Non-Communicable Diseases. These managers will have access to a validated, field-tested model for Community Health Worker (CHW) training and patient outcomes, which can be analysed accordingly. Moreover, healthcare facilities in Telangana equipped with non-mydriatic fundus cameras and trained optometrists will also benefit from our model, as these resources are currently underutilised. The training module is documented as a supplementary material: Appendix : CHW Training Module.

8.4 Innovativeness

Based on our literature review, we can assert that our study was the first cluster randomised controlled trial in India to assess the relationship between community health worker (CHW) competency training and patient-level outcomes across diabetes and diabetic retinopathy (DR) screening and referral pathways. These outcomes may serve as significant process indicators for subsequent research. Our training module was delivered in both Telugu and English, constituting the first context-validated competency training and assessment instrument for CHWs in India, and is also freely accessible for adaptation by relevant authorities.

8.5 Future Pathways

The adoption of our training module at the state level presents an immediate opportunity for implementation research, facilitating the assessment of training fidelity and long-term clinical outcomes. Additionally, we intend to perform a cost-effectiveness analysis of our intervention, as its findings could significantly influence policymakers involved in rural diabetes care.

CHAPTER 9

Chapter 9: Summary

The first chapter of this Thesis provided an overview of the background of the research questions. It highlighted that Type 2 diabetes mellitus is becoming a major global public health concern. According to the International Diabetes Federation's 2025 atlas, an estimated 589 million adults worldwide will have diabetes, with low- and middle-income countries carrying the highest burden of the disease. India has the second-largest number of people living with diabetes globally, with the Indian Council of Medical Research's (ICMR) ICMR-INDIAB study reporting a weighted national prevalence of 11.4%, which equates to nearly 101 million people. In India, the South Indian state Telangana has a higher-than-average diabetes prevalence, with an increasing burden in rural areas, where over 60% of the state's population resides. Rural populations face multiple barriers to diabetes care, such as geographical inaccessibility, affordability of treatment, limited availability of trained health personnel, and socio-cultural barriers (acceptability) that discourage health-seeking behaviour. To address these barriers, the Indian government institutionalised a cadre of community health workers known as Accredited Social Health Activists (ASHA) in 2005, now numbering over one million nationwide. Although their roles in diabetes screening, enumeration, referral, and follow-up under the National Programme for Prevention and Control of Non-Communicable Diseases (NP-NCD) were well-defined, existing evidence identified significant gaps in their knowledge and practice. After reviewing available literature, we identified a significant gap: very few randomised controlled trials have evaluated the impact of a structured Community Health Worker (CHW) competency training program on diabetes care pathways and patient-level outcomes in rural low- and middle-income countries (LMICs), particularly in India. Our dissertation addressed that gap by following a structured research process, progressing from needs assessment to protocol development, systematic review, trial implementation, and synthesis to evaluate the effectiveness.

The second chapter outlined the protocol for the systematic review. Utilising the PICOTS framework, the protocol specified an assessment of how CHW training interventions impacted diabetes management outcomes in low- and middle-income countries (LMICs), with glycosylated haemoglobin (HbA1c) designated as the primary outcome. The review included randomised and non-randomised controlled trials, as well as observational studies, with comprehensive searches conducted across PubMed, Ovid MEDLINE, Scopus, EBMR, and CINAHL for studies published from January 2000 to December 2023. Two independent reviewers undertook the screening of studies and data extraction, with a third reviewer designated to resolve disagreements. Quality assessment was conducted utilising the Cochrane Risk of Bias 2 tool and the ROBINS-I framework. The results were presented in a PRISMA flow diagram, and the protocol was registered with PROSPERO (CRD42022341717) and subsequently published. This established a transparent, prespecified framework for the subsequent systematic review.

The third chapter summarised the results of the systematic review. An extensive search identified 3,387 studies, of which 69 were selected for full-text evaluation. Ultimately, four studies were considered eligible for inclusion. Of these, three were randomised controlled trials (RCTs), and one was an observational stepped-wedge study, involving totally 1,000 patients. The certainty of the studies was low to moderate, with their risk of bias ranging from some concerns to serious concerns. Only one of the three RCTs reported a statistically significant effect, with a mean reduction of -0.24% (p=0.001), although HbA1c was not its primary outcome, and the sample included normoglycaemic and prediabetic individuals as well as patients with diabetes. The remaining studies reported reductions in HbA1c values; however, these reductions were not statistically significant between the groups. In line with the Cochrane handbook's guidelines, a meta-analysis was not conducted due to the small number of studies and the variability in design and interventions. The review concluded that training CHWs in

diabetes management reported limited, mostly indirect, effects on improving HbA1c control in LMIC settings and recommended more rigorous trials with clearer reporting of training content, intensity, and well-defined outcomes.

The fourth chapter described the study protocol for the cluster randomised controlled trial (RCT). Type 2 diabetes mellitus poses a significant burden of mortality and disability globally and within India. In this latter country, the extensive rural population has limited access to healthcare services. Accredited Social Health Activists (ASHAs), initially trained for maternal and infant care, were identified as a cadre requiring improved competency training to improve diabetes screening and management. The protocol described the RCT to be conducted across eight health centres in the Ranga Reddy district of Telangana. A training tool was developed from existing resources, with a focus on areas needing improvement, and delivered over six months through classroom-style training. The baseline and post-intervention competencies were evaluated using a validated questionnaire administered by trained public health experts. The trial was registered with the Clinical Trials Registry of India (CTRI/2020/07/026828) and received ethical approval from the Institutional Ethics Committee of the Indian Institute of Public Health Hyderabad (IIPHH/TRCIEC/218/2020).

The fifth chapter described the baseline cross-sectional survey conducted before the trial to assess the existing knowledge and practice behaviour competencies of the CHWs responsible for diabetes management in Telangana. Using a customised questionnaire developed with input from diabetes and public health experts, government officials, and CHWs, the study assessed the competencies of 275 CHWs. The study reported significant gaps in knowledge (95% inadequate) and practice behaviours (97% inadequate). The areas of insufficiency broadly represent core competencies needed for diabetes management: diabetes diagnosis and referral, HbA1c testing, diabetes diet, self-management, screening for microvascular complications, and diabetes risk assessment. Notably, a relatively large number of CHWs reported correct

practice behaviours despite providing incorrect answers to related knowledge questions across many domains, such as referral to health centres and adequate self-management. These results guided us in developing and refining the content and design of our structured training intervention (detailed in the next chapter).

The sixth chapter presented the findings of the cluster randomised controlled trial involving 240 CHWs across eight health centres. Of these, 113 were in the intervention arm and 127 in the control arm. The intervention included a structured, competency-based training module on diabetes and diabetic retinopathy (DR), including their screening and referral pathways. Throughout the study, CHWs screened over 25,000 individuals, the diagnostic testing rate decreased from 49.5% to 48.9% in the control arm. Confirmed diabetes detection rate increased from 51.6% to 78.4% in the intervention arm compared with 48.8% to 49.7% in the control arm, with a DiD odds ratio of 3.27 (95% CI 2.73 to 3.92; $p<0.001$). The DR screening rate increased from 7.3% to 13.8% in the intervention arm while decreasing from 5.9% to 3.9% in the control arm, with a DiD odds ratio of 3.10 (95% CI 1.06 to 9.07; $p=0.039$). The intervention health centres reported an 86% increase in patient-level diabetes screening coverage and a 183% increase in new diagnoses. These results highlight that a structured, competency-based CHW training program significantly enhances diabetes and DR screening and referral outcomes compared to standard care in India.

The seventh chapter discussed all our research findings in relation to the existing literature. Our baseline study had reported gaps in CHW knowledge and practice behaviours, while our intervention study reported that the training effectively addressed these gaps rather than just making minor improvements. Compared with existing CHW training focused on HbA1c, our trial provided additional evidence on process and clinical outcomes across the screening and referral pathway. It used a cluster randomised controlled trial design with difference-in-differences analysis and was integrated into the government's NP-NCD structure.

Methodological strengths were the study design, a low intraclass correlation coefficient, and robust sensitivity analyses. The limitations included the confined district setting, a small number of clusters, potential secular confounding from COVID-19-related changes in health-seeking behaviour, and the lack of longer-term outcomes, such as glycaemic control or complication incidence.

The policy implications involved a recommendation for the government to assess the feasibility of scaling this structured CHW training across the state-level NP-NCD guidelines for rural healthcare centres, utilising existing cadres and supervisory structures. The priorities for future research include long-term outcome evaluations, implementation research on optimal training frequency and delivery modes, and cost-effectiveness assessments of the training, as well as process and clinical outcomes.

The eighth chapter reflected on the impact of our research. Combining the baseline competency assessment, the system review, and the cluster randomised controlled trial, this Thesis presented a continuum of care from needs assessment to training design, implementation, and evaluation across multiple levels of the health system. Our trial was one of the few cluster-randomised controlled trials to link CHW competency gains to patient-level outcomes for both diabetes and DR in a real-world setting. The results provided scientific evidence for integrating a structured, competency-based CHW training into both national and state-level NCD programmes across Indian states and similar LMICs. The outputs comprised a registered systematic review protocol with PROSPERO, a published study protocol, a baseline CHW competency assessment, and both a systematic review and an intervention trial submitted to JMIR Diabetes and PLOS Global Health, respectively. All of these collectively demonstrated that structured, carefully implemented training can improve CHW competencies and the capacity of existing healthcare systems to detect and manage diabetes and DR in low-resource settings.

Chapter 9: Samenvatting

Het eerste hoofdstuk van dit proefschrift gaf een overzicht van de achtergrond van de onderzoeksvragen. Het benadrukte dat diabetes mellitus type 2 een belangrijk wereldwijd volksgezondheidsprobleem aan het worden is. Volgens de atlas van de International Diabetes Federation uit 2025 zullen naar schatting 589 miljoen volwassenen wereldwijd diabetes hebben, waarbij lage- en middeninkomenslanden de grootste ziektelast dragen. India heeft wereldwijd het op één na grootste aantal mensen met diabetes; de ICMR-INDIAB-studie van de Indian Council of Medical Research rapporteert een gewogen nationale prevalentie van 11,4%, wat neerkomt op bijna 101 miljoen mensen. In India heeft de Zuid-Indiase staat Telangana een bovengemiddelde prevalentie van diabetes, met een toenemende ziektelast in landelijke gebieden, waar meer dan 60% van de bevolking woont. Plattelandsbevolkingen worden geconfronteerd met meerdere barrières in de diabeteszorg, zoals geografische ontoegankelijkheid, beperkte betaalbaarheid van behandelingen, een tekort aan opgeleid zorgpersoneel en sociaal-culturele barrières (acceptatie) die het zoeken naar zorg ontmoedigen. Om deze barrières aan te pakken, heeft de Indiase overheid in 2005 een kader van gemeenschapsgezondheidswerkers ingesteld, bekend als Accredited Social Health Activists (ASHA), inmiddels meer dan één miljoen landelijk in India. Hoewel hun rol in diabetes-screening, registratie, verwijzing en follow-up binnen het National Programme for Prevention and Control of Non-Communicable Diseases (NP-NCD) goed was gedefinieerd, bleken er aanzienlijke lacunes aanwezig te zijn in kennis en praktijk. In een literatuuronderzoek identificeerden we dat er zeer weinig gerandomiseerde gecontroleerde studies zijn die het effect evalueren van een gestructureerd trainingsprogramma voor competenties van Community Health Workers (CHW's) op diabeteszorgtrajecten en patiëntuitkomsten in landelijke lage- en middeninkomenslanden (LMIC's), met name in India. Dit proefschrift heeft die leemte aangepakt door een gestructureerd onderzoeksproces te volgen, van behoefteanalyse tot

protocolontwikkeling, systematische review, uitvoering van een trial en evaluatie van de effectiviteit.

Het tweede hoofdstuk beschreef het protocol voor de systematische review. Met behulp van het PICOTS-raamwerk werd gespecificeerd hoe trainingsinterventies voor CHW's de uitkomsten van diabetesmanagement in LMIC's beïnvloeden, waarbij HbA1c de primaire uitkomstmaat was. De review omvatte gerandomiseerde en niet-gerandomiseerde gecontroleerde studies, evenals observationele studies, met uitgebreide zoekacties in PubMed, Ovid MEDLINE, Scopus, EBMR en CINAHL voor studies gepubliceerd van januari 2000 tot december 2023. Twee onafhankelijke beoordelaars voerden de selectie van studies en data-extractie uit, met een derde beoordelaar om eventuele meningsverschillen op te lossen. De kwaliteitsbeoordeling werd uitgevoerd met behulp van de Cochrane Risk of Bias 2-tool en het ROBINS-I raamwerk. De resultaten werden gepresenteerd in een PRISMA-stroomdiagram, en het protocol werd geregistreerd bij PROSPERO (CRD42022341717) en vervolgens gepubliceerd. Dit vormde een transparant, vooraf gespecificeerd kader voor de systematische review.

Het derde hoofdstuk vat de resultaten van de systematische review samen. Een uitgebreide zoekactie identificeerde 3.387 studies, waarvan er 69 werden geselecteerd voor volledige tekstbeoordeling. Uiteindelijk werden vier studies geschikt bevonden voor inclusie. Hiervan waren er drie gerandomiseerde gecontroleerde studies (RCT's) en één een observationele stepped-wedge studie, met in totaal 1.000 patiënten. De bewijskracht van de studies was laag tot matig, met matig tot ernstig risico op bias. Slechts één van de drie RCT's rapporteerde een statistisch significant effect, met een gemiddelde reductie van -0,24% (p=0,001), hoewel HbA1c niet de primaire uitkomst was en de steekproef normoglycemische en prediabetische personen omvatte naast diabetespatiënten. De overige studies rapporteerden dalingen in

HbA1c-waarden, maar deze waren niet statistisch significant tussen de groepen. In lijn met de richtlijnen van het Cochrane-handboek werd geen meta-analyse uitgevoerd vanwege het kleine aantal studies en de variabiliteit in studieopzet en interventies. De review concludeerde dat training van CHW's in diabetesmanagement beperkte, grotendeels indirecte effecten heeft op het verbeteren van HbA1c-controle in LMIC-settings en adviseerde meer robuuste studies met duidelijkere rapportage van trainingsinhoud, intensiteit en goed gedefinieerde uitkomsten.

Het vierde hoofdstuk beschreef het studieprotocol voor de cluster-gerandomiseerde gecontroleerde trial (RCT). In India heeft de omvangrijke plattelandsbevolking beperkte toegang tot gezondheidszorg. Accredited Social Health Activists (ASHAs), oorspronkelijk opgeleid voor moeder- en kindzorg, werden geïdentificeerd als een groep die verbeterde competentietraining nodig heeft om diabetes-screening en -management te verbeteren. Het protocol beschreef een RCT die werd uitgevoerd in acht gezondheidscentra in het district Ranga Reddy in Telangana. Een trainingsinstrument werd ontwikkeld op basis van bestaande literatuurbronnen, met focus op geconstateerde verbeterpunten, en gedurende zes maanden aangeboden via klassikale training. De basis- en post-interventiecompetenties werden geëvalueerd met een gevalideerde vragenlijst, afgenomen door getrainde volksgezondheidsexperts. De trial werd geregistreerd bij het Clinical Trials Registry of India (CTRI/2020/07/026828) en verkreeg ethische goedkeuring van de Institutional Ethics Committee van het Indian Institute of Public Health Hyderabad (IIPHH/TRCIEC/218/2020).

Het vijfde hoofdstuk beschreef de cross-sectionele nulmeting die vóór de trial werd uitgevoerd om de bestaande kennis en praktijkcompetenties van CHW's, verantwoordelijk voor diabetesmanagement in Telangana, te beoordelen. Met behulp van een op maat gemaakte vragenlijst, ontwikkeld met input van diabetes- en volksgezondheidsexperts,

overheidsfunctionarissen en CHW's, werden de competenties van 275 CHW's geëvalueerd. De studie rapporteerde aanzienlijke hiaten in kennis (95% onvoldoende) en praktijkgedrag (97% onvoldoende). De tekortkomingen betroffen kerncompetenties voor diabetesmanagement, zoals diagnose en verwijzing, HbA1c-testen, dieet, zelfmanagement, screening op microvasculaire complicaties en risicobeoordeling. Opvallend was dat CHW's regelmatig correct praktijkgedrag rapporteerden ondanks onjuiste antwoorden op gerelateerde kennisvragen, bijvoorbeeld bij verwijzingen en adequaat zelfmanagement. Deze resultaten vormden de basis voor het ontwikkelen en verfijnen van de inhoud en het ontwerp van de gestructureerde trainingsinterventie (beschreven in het volgende hoofdstuk).

Het zesde hoofdstuk presenteerde de bevindingen van de cluster-gerandomiseerde gecontroleerde trial met 240 CHW's in acht gezondheidscentra. Hiervan bevonden zich 113 in de interventiegroep en 127 in de controlegroep. De interventie bestond uit een gestructureerde, competentiegerichte trainingsmodule over diabetes en diabetische retinopathie (DR), inclusief screening en verwijzingsroutes. Tijdens de studie screenden CHW's meer dan 25.000 personen. Het percentage diagnostische testen daalde licht in de controlegroep (van 49,5% naar 48,9%). De detectie van bevestigde diabetes steeg in de interventiegroep van 51,6% naar 78,4%, tegenover 48,8% naar 49,7% in de controlegroep, met een DiD oddsratio van 3,27 (95% BI 2,73–3,92; $p<0,001$). Het screeningspercentage voor DR steeg van 7,3% naar 13,8% in de interventiegroep, terwijl het daalde van 5,9% naar 3,9% in de controlegroep, met een DiD oddsratio van 3,10 (95% BI 1,06–9,07; $p=0,039$). De interventiecentra rapporteerden een stijging van 86% in diabetes-screening en 183% meer nieuwe diagnoses. Deze resultaten tonen aan dat een gestructureerd, competentiegericht trainingsprogramma voor CHW's de screening en verwijzing voor diabetes en DR aanzienlijk verbetert ten opzichte van standaardzorg in India.

Het zevende hoofdstuk besprak de onderzoeksresultaten in relatie tot de bestaande literatuur. De nulmeting toonde lacunes in kennis en praktijkgedrag van CHW's, terwijl de interventiestudie aantoonde dat training deze lacunes effectief kan verbeteren. In vergelijking met bestaande CHW-trainingen gericht op HbA1c leverde deze studie extra bewijs over proces- en klinische uitkomsten binnen het screening- en verwijzingstraject. De studie gebruikte een cluster-gerandomiseerd ontwerp met difference-in-differences-analyse en was geïntegreerd in de NP-NCD-structuur van de overheid. Methodologische sterktes waren het ontwerp, een lage intraclass correlatiecoëfficiënt en robuuste sensitiviteitsanalyses. Beperkingen waren onder andere de beperkte geografische setting, een klein aantal clusters, mogelijke verstorende factoren door COVID-19-gerelateerde veranderingen in zorgzoekgedrag en het ontbreken van langetermijnuitkomsten zoals glykemische controle of complicaties.

De beleidsimplicaties omvatten de aanbeveling aan de overheid om de haalbaarheid te onderzoeken van opschaling van deze gestructureerde CHW-training binnen de NP-NCD-richtlijnen op staatsniveau voor plattelandsgezondheidscentra, met gebruik van bestaande kaders en supervisiestructuren. Prioriteiten voor toekomstig onderzoek zijn onder meer evaluaties van lange termijn uitkomsten, implementatieonderzoek naar optimale trainingsfrequentie en -vormen, en kosteneffectiviteitsanalyses, evenals proces- en klinische uitkomsten.

Het achtste hoofdstuk reflecteerde op de impact van het onderzoek. Door de nulmeting, de systematische review en de cluster-gerandomiseerde trial te combineren, presenteerde dit proefschrift een continuüm van zorg: van behoefteanalyse tot trainingsontwerp, implementatie en evaluatie op meerdere niveaus van het gezondheidssysteem. De trial behoort tot een van de weinige cluster-gerandomiseerde studies die verbeteringen in CHW-competenties koppelen

aan patiëntuitkomsten voor zowel diabetes als DR in de dagelijkse praktijk. De resultaten leveren wetenschappelijk bewijs voor de integratie van gestructureerde, competentiegerichte CHW-training in nationale en deelstaatprogramma's. De output omvatte een geregistreerd systematisch reviewprotocol bij PROSPERO, een gepubliceerd studieprotocol, een nulmeting van CHW-competenties en zowel een systematische review als een interventiestudie ingediend bij respectievelijk JMIR Diabetes en PLOS Global Health. Gezamenlijk tonen deze aan dat gestructureerde, zorgvuldig geïmplementeerde training van competenties van CHW's bestaande gezondheidssystemen kan verbeteren om diabetes en DR in kwetsbare geboeden te detecteren en te behandelen.

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APPENDIX: CHW Training Module

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HEALTH WORKER TRAINING MODULE ON DIABETES

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WHAT IS DIABETES?

All food that we eat is broken down into a sugar called glucose. Blood carries glucose to all the parts of the body to give energy. The hormone that helps glucose move from the blood into the cells is called INSULIN.

Insulin helps to keep the blood sugar levels normal. In certain individuals, the body either does not produce insulin or cannot use it properly. The glucose builds up in the blood, resulting in high blood glucose levels called Diabetes.

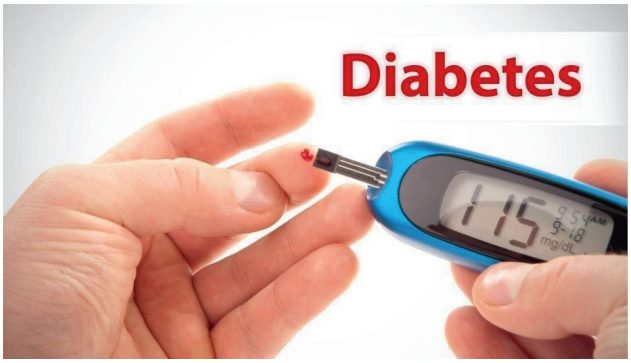


Figure 1: Diabetes values

Types of Diabetes	What is it?	Features
Type 1 Diabetes	The body does not produce insulin at all. People with this form of Diabetes require daily insulin injections to control blood glucose levels.	The disease can affect people of any age but usually starts in childhood or young adulthood.
Type 2 Diabetes	This is the most common type of Diabetes. The body produces some insulin, but not enough.	This type of Diabetes used to be seen only in adults, but it is now also occurring increasingly in children and adolescents. It is seen in those with a family history of Diabetes, excess body weight, lack of physical activity, and as people grow older.
Gestational Diabetes	Diabetes , which occurs among women during pregnancy.	Has a risk of complications during pregnancy and delivery. The children of women with Gestational Diabetes are at an increased risk of type 2 diabetes in the future.

DIFFERENCES BETWEEN TYPE 1 AND TYPE 2 DIABETES:

	Type 1 Diabetes	Type 2 Diabetes
Age at diagnosis	Usually in childhood and adolescence, but it can also occur in adults	Usually postpubertal; most common in middle to later age groups
Prevalence	10%	90%
Diabetes in 1st degree relative	Unusual	Common
Severe osmotic symptoms/ ketosis at diagnosis	Can occur	Rare
Markers of insulin resistance	Absent	Present

OTHER TYPES OF DIABETES

- **Secondary/ Monogenic Diabetes:** It is much less common and represents 1.5–2% of al cases, though this may well be underestimated. It is often misdiagnosed as either type 1 or type 2 diabetes. These monogenic forms present a broad spectrum, from neonatal diabetes mellitus (sometimes called 'monogenic diabetes of infancy'), maturity-onset Diabetes of the young (MODY) and rare diabetes-associated syndromic diseases.
- Diabetes is caused by **diseases of the exocrine pancreas**, such as pancreatitis, trauma, infection, pancreatic cancer and pancreatectomy.
- Diabetes is due to **endocrine disorders** that cause excess secretion of hormones that antagonise insulin.
- **Drug and chemical-induced diabetes** from drugs that disrupt insulin secretion or insulin action.
- **Infection-related Diabetes** is caused by a viral infection associated with beta-cell destruction.
- Uncommon specific forms of immune-mediated Diabetes (e.g. immunological disorders other than those that cause type 1 diabetes).
- Other genetic syndromes sometimes associated with Diabetes (i.e., Prader-Willi syndrome, Down's syndrome, Friedreich's ataxia).

Prevalence of Diabetes in India

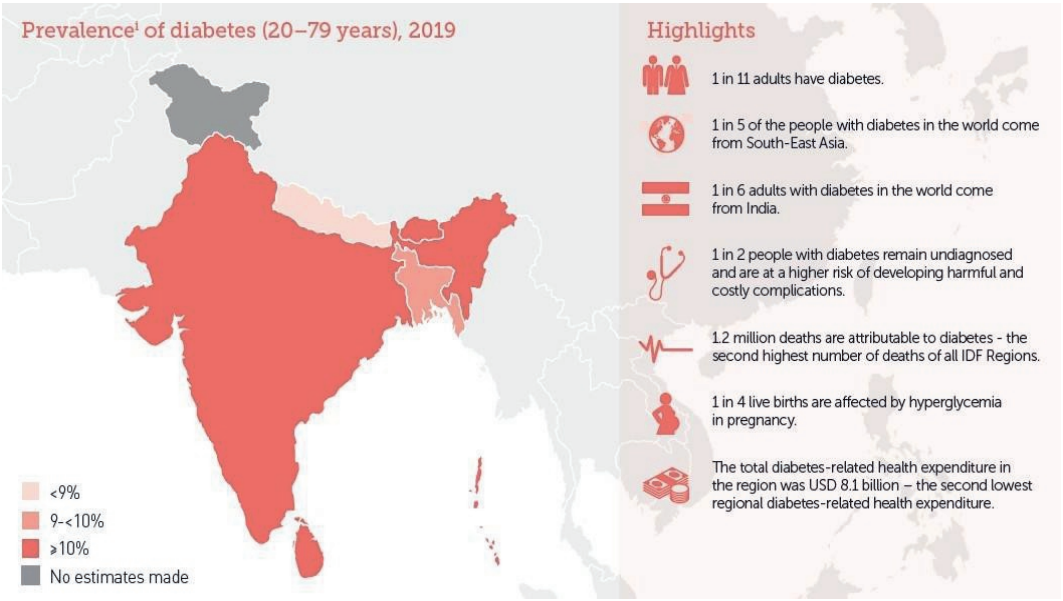


Figure 2: Prevalence of Diabetes in India, 2019

- The prevalence of Diabetes (20-79 years) in India in 2019 was 8.9%; the age-adjusted comparative prevalence was 10.4%.
- The number of Diabetes-related deaths in 2019 was 1,010,262. One in eleven individuals has Diabetes, and the proportion of undiagnosed Diabetes was 57%.

RISK FACTORS FOR TYPE 2 DIABETES

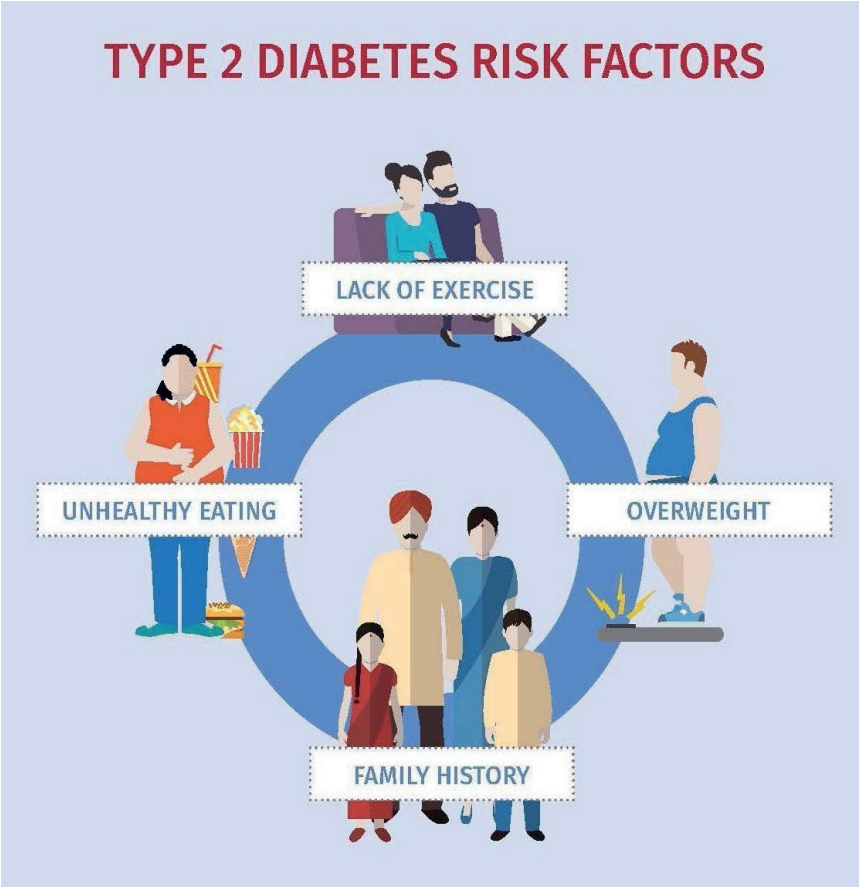


Figure 3: Risk factors for Type 2 Diabetes

- Family history of Diabetes
- Age ≥ 40 years old
- Being overweight/having a BMI ≥ 23.0 kg/m^2
- Unhealthy eating habits
- Lead an inactive lifestyle
- High blood pressure
- Have abnormal blood cholesterol/ lipid levels
- Addictions like tobacco use, drugs, and harmful use of alcohol

- If the mother during pregnancy had Diabetes or even a mild elevation of blood sugar level.
- Have impaired glucose tolerance or impaired fasting glucose

SIGNS AND SYMPTOMS OF TYPE 2 DIABETES

- Frequent urination.
- Increased hunger.
- Excessive thirst.
- Unexplained Weight loss.
- Lack of energy, extreme tiredness.
- Blurred vision.
- Repeated or severe infections such as vaginal infections.
- Slow healing of wounds.

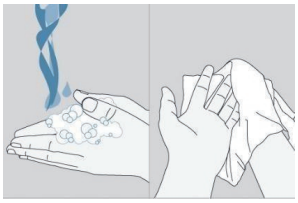


Figure 4: Signs and Symptoms of Type 2 Diabetes

PREVENTION AND CONTROL OF TYPE 2 DIABETES

1. Exercise regularly and control weight/BMI of 20 – 23 kg/m^2.
2. Avoid excess sugar, sweets, ice cream, chocolate, candies, fried foods, e.g. poori, paratha, potatoes, pakodas, sweet potatoes, fruits with high sugar, e.g. grapes, mangoes, bananas etc.
3. Avoid tobacco use, alcohol, junk food, e.g. aerated drinks, pizzas, burgers, and other kinds of fast foods.
4. Cook food in minimal oil.
5. Increase intake of seasonal green leafy vegetables.
6. Get Blood Sugar checked regularly. If high (>126 mg/dL or > 7mmol-Fasting; >200mg/dL- random or 2-hour post-glucose load), consult a doctor at the nearest health centre.
7. Do not stop or change medication on your own or with the advice of friends.
8. Take advice from the doctor for regular tests, e.g. kidney function, eye check-up, etc.

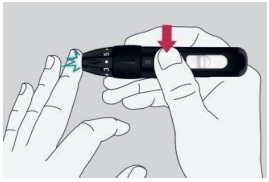
BLOOD GLUCOSE ESTIMATION



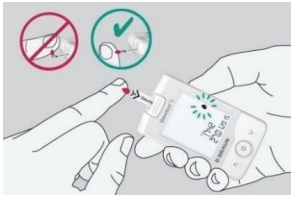
Wash your hands and ask the participant to wash their hands to prevent infection.



Turn on the glucometer and place a test strip when the machine is ready.



Clean the subject's fingertip. Use a lancet to prick the side or top of the finger to get a small amount of blood.



Place the drop of blood on the test strip. The blood drop is to be placed against the edge or top of the strip.



Watch the glucometer screen. It will produce a beep when the sample has been tested. The results will be displayed as a number on the screen.



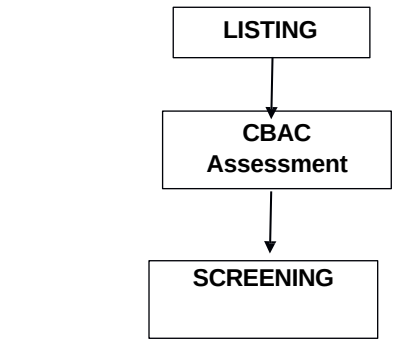
Note the reading in the notebook or family folder of the subject. Discard the needle and test strip appropriately.

Figure 5: Steps of Blood Glucose Estimation

Ref: https://www.bbraun.com/en/patients/diabetes-care-for-patients/blood-glucose-measurement/typical-steps.html

Use an alcohol-based wipe to clean the meter, ensuring all external surfaces are clean. If the reading is high, the individual should be referred to a medical professional for a check-up.

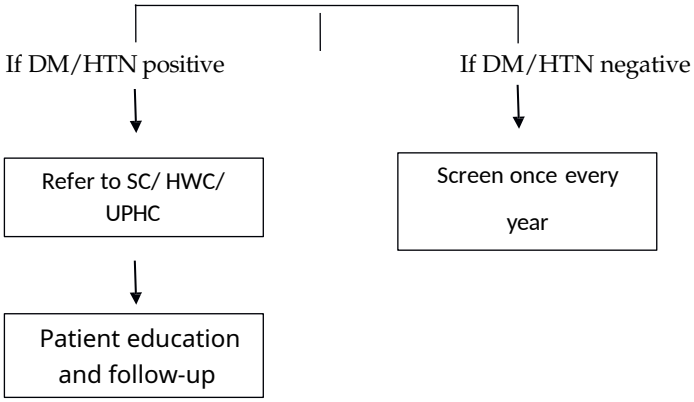
ROLE OF ASHA IN POPULATION-BASED SCREENING



ASHA will list all women and men who are 30 years of age and above

A score below 4 indicates low risk. Those with a score greater than 4 should be given priority on the day of screening.

On a fixed day each week, the health worker will conduct screening for hypertension and diabetes.



1) **LISTING:** ASHA will list all women and men who are 30 years of age and above. This list is to be updated every 6 months. The information is then to be given to the AF/ANM who

manages the sub-centre of your area.

2) **COMPLETION OF COMMUNITY-BASED ASSESSMENT CHECKLIST (CBAC):** This form is intended to capture data related to age, family history for any of the NCDs, waist circumference, and risky behaviours such as physical inactivity, use of/or exposure to tobacco and alcohol use. This section of the form has questions that are allocated a score. **A score of below four implies Low risk**.

A low-risk score **does not mean** the individual is exempt from screening, as NCDs can exist even in the absence of risk factors. **The scoring is not a point of elimination, but a means to highlight risk factors.** CBAC Checklist in Annexure - Ⅰ. Step-by-step measurement of waist circumference in Annexure- Ⅱ.

3) **SCREENING:** On a fixed day, every week, the health worker will undertake screening for hypertension and diabetes. The screening should be conducted every year. Depending on the distance, the screening can take place at the village or the sub-centre. In urban areas, this can take place in the Urban PHC or outreach sessions. Screening involves the ANM measuring BP and glucose. ASHA will also be trained to use the BP apparatus and glucometer and support the ANM during the screening process.

Type of NCD	Frequency of screening	If positive on screening at the Village/SC/PHC, then the role of the medical officer
Diabetes	Once a year	Confirmation of DM, CVD risk assessment, treatment, and management, in case of complications, referral to CHC/DH, follow-up & support.
Hypertension	Once a year	Confirmation of HT, CVD risk assessment, treatment, and management, in case of complications, referral to CHC/DH, follow-up & support.

4) **MOBILIZE** the community to attend the screening on the date and time of the ANMs visit to the village or the date they need to go to the sub-centre. On a particular day, about 30

These will be spread over the entire year.

The ANM will schedule screenings in her area, and ASHA will obtain the dates. ASHA will also help the ANM in recording the measurements. On every screening day, ASHA will also have to ensure that VHSNC (Village Health Sanitation & Nutrition Committee) and MAS (Mahila Arogya Samithi) members are present and support her in undertaking health promotion activities.

People who have already been diagnosed with one of these conditions should measure their BP and glucose monthly, and not necessarily on the screening day.

5) UNDERTAKING HEALTH PROMOTION: Health promotion to reduce the specific risk behaviours, e.g., unhealthy diets, physical inactivity, tobacco, and harmful drinking, etc., for the prevention of NCDs.

ASHA should ensure that health promotion activities are continuous and not limited to the screening day alone. She will use Home Visits, the Village Health Nutrition Day (VHND), and meetings of the Village Health Sanitation & Nutrition Committee (VHSNC)/MAS for health promotion activities.



Figure 6: Undertaking Health Promotion

6) UNDERTAKING FOLLOW-UP FOR TREATMENT ADHERENCE AND ENABLING LIFESTYLE CHANGES:

If an individual is referred by the ANM to the PHC-MO, the ASHA needs to follow up with them or escort them to the health facility for examination by the MO. Some of them may be put on treatment for blood pressure or Diabetes.

Once an individual is put on treatment for hypertension or Diabetes, the treatment is most likely lifelong. **ASHA will ensure that they obtain their drug supply from the subcenter or PHC and take the medicines regularly.** She will also need to undertake home visits **for treatment adherence, enabling lifestyle changes** and referring in case of any complications to the MO (PHC).

7) CREATING PATIENT SUPPORT GROUPS: ASHA will try to form groups of patients diagnosed with hypertension and diabetes. Patients/friends/families/and frontline workers can form these groups to help each other by coming together.

Patient support groups help patients and their family members by providing mutual support, information about diseases, raising awareness of complications, countering discrimination and stigma associated with a particular disease, and enabling support for treatment continuation and lifestyle changes.

The ASHA should ensure that individuals who are part of marginalised groups and have a disease condition are also encouraged and supported to become part of these groups



Figure 7A: Peer support group



Figure 7B: Peer support group



Figure 7C: Peer support group

Criteria for diagnosis of T2DM using venous blood samples [WHO Guidelines]

	Fasting glucose	2-hour Post-GLucose-Load
Diabetes Mellitus	≥126 mg/dl or	≥ 200 mg/dl
Impaired Glucose Tolerance	< 126 mg/dl and	>140 to < 200 mg/dl
Impaired Fasting Glucose	≥ 110 to < 126 mg/dl	

**WHO Definition 1999*

The capillary blood glucose value is also sufficient. Where capillary blood glucose measured by a glucometer is used in the fed state (i.e., post food/post glucose/post-meal), the >200 mg/dl cut off may be revised to >220 mg/dl.

Criteria for diagnosis of T2DM [ICMR Guidelines]

	Normal	Prediabetes	Diabetes
Fasting plasma glucose	< 100mg/dl	100 - 125 mg/dl	≥ 126 mg/dl
2-hour Post-Glucose-Load	< 140 mg/dl	140 - 199 mg/dl	≥ 200 mg/dl
HbA1c	< 5.7%	5.7 - 6.4%	≥ 6.5%
Random			≥ 200 mg/dl

Targets for metabolic control in Diabetes [ICMR Guidelines]

	Ideal	Satisfactory	Unsatisfactory
Fasting plasma glucose	80-110 mg/dl	111-125 mg/dl	> 125 mg/dl
2-hour postprandial glucose	120-140 mg/dl	141-180 mg/dl	> 180 mg/dl
Blood pressure	< 130/80 mm Hg	< 140/90 mm Hg	> 140/90 mm Hg
Body Mass Index	20-23 kg/m^2	23.1-25 kg/m^2	> 25 kg/m^2

HbA1C	**< 7 %**	**≥ 7 - < 8 %**	**≥ 8 %**

Table: Targets for lipid control in Diabetes [ICMR Guidelines]

Total Cholesterol	< 200 mg/dl
HDL Cholesterol	> 40 for men > 50 for women
LDL Cholesterol	< 100 mg/dl
Non-HDL Cholesterol	< 130 mg/dl
Triglycerides	< 150 mg/dl

Diabetes patient education and diet counselling

Patient education on diabetes management and lifestyle modifications is the cornerstone of effective diabetes control, management, and prevention of complications. At the PHC level, nurses/multipurpose health workers can be trained to undertake this activity. At sub-district and district-level hospitals, dieticians/counsellors and nurses can undertake diabetes patient education. Patient education topics to cover during the initial visit and follow-up visits are listed in the table on the next page.

TABLE: Topics to be covered

Initial visits	**Follow-up visits**
What is Diabetes?	Importance of Glycaemic Control
Why does it occur?	Prevention of Complications
Lifestyle measures: Diet, Exercise	Foot Care
Detailed lifestyle advice	Newer modalities of treatment
Use of Oral Drugs	Marriage Counselling
Advice on identifying signs and symptoms of hypoglycaemia and hyperglycaemia and their Management.	Pre-conceptional counselling regarding the importance of glucose control prior to Pregnancy.
Patient should be informed about the importance of factors other than glucose control, such as cholesterol, blood pressure, and stopping smoking/tobacco use, etc.	

Lifestyle Counselling



Figure 8: Lifestyle Counselling

DIET:

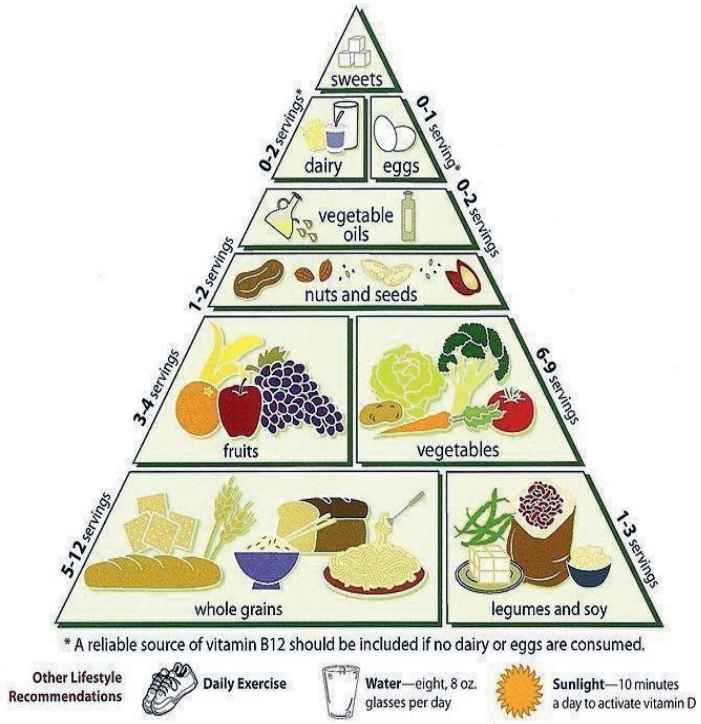


Figure 9: Diet for people with Diabetes

Follow-up

Annual assessment of patients has to be carried out at the CHC/secondary care level for follow-up of blood glucose, urinary microalbuminuria, fundus examination (eyes), kidney tests, blood lipids, creatinine, feet examination and patient education.

i. Those with a **systolic BP of over 140 and a diastolic BP of over 90 mm of Hg, or a random blood sugar of 140 mg/dl and above would be referred to a medical officer at the nearest facility** for confirmation, conducting relevant laboratory investigations, and initiation of treatment.



Figure 10: Measurement of Blood Pressure by a health worker

ii. Once the diagnosis of HTN/Diabetes is established, the patient must receive at least a month's supply of drugs from the PHC. Once the condition is stable, the state could also decide to provide the patient with a three-month supply, with the ANM/ASHA visiting the patient each month to ensure compliance, check on diet and lifestyle modification, and measure blood pressure/ blood glucose. Alternatively, a three-month drug supply could be stocked with the ANM at the Sub Centre, to be given each month. Either way, sufficient drug supplies need to be made available at the PHC.

iii. The patient will need to go to the PHC for the first follow-up at the end of the first three months after diagnosis and sooner if required. An annual specialist consultation at the nearest nodal CHC with an NCD clinic is also recommended, based on the MO's decision at the PHC.

iv. Those individuals who are already on treatment under the care of a private practitioner could be offered the choice of taking drugs from the public health system after appropriate confirmation. However, these individuals would be visited regularly by frontline workers, monitored for adherence to treatment/lifestyle changes, and recorded on the health card.

v. Community Follow-up of these individuals would be by the ASHA, making visits to enable positive behaviour modifications, treatment compliance, and encouraging patients to go to the sub-centre for regular BP/blood glucose check-ups. Some states have also provided the ASHA with BP apparatus and glucometers to undertake regular examinations at the village level. The ASHA will prioritise those households where there are treatment defaulters or those who experience complications. The aim is to minimise treatment defaulters and achieve hypertension and glycaemic control at both the individual and population levels. The ANM would also conduct regular home visits.

Drug availability:

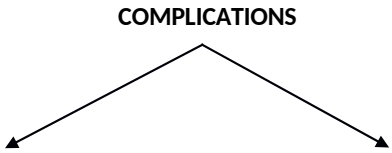
i. Patient refills of drugs for HT and Diabetes would be made available by the PHC and recorded and reported by the ANM while distributing at the SC/HWC. A tablet count of remaining drugs would be made at the time of each refill.

CHECKLIST FOR DIABETES COMPLICATIONS

Every 3-6 months, the patient should have a physical review by the physician.

Checklist for the follow-up	**Yes/ No**
Test blood sugar levels	
Test glycosylated haemoglobin levels (HbA1C)	
Examine feet for sensations and circulation; Also, for calluses, dryness, sores, infections, injuries.	
Check blood pressure	
Help the patient to give up tobacco if he/she continues to use tobacco.	
Reinforce lifestyle measures- increase physical activity levels and improve diet	
Referral to a specialist for appropriate complications screening	

DIABETES COMPLICATIONS AND MANAGEMENT



ACUTE COMPLICATIONS

- DKA (Diabetic keto acidosis)
- Hypoglycaemia
- HHS (Hyperglycaemic hyperosmolar state)

CHRONIC COMPLICATIONS

- Cardiovascular diseases
- Diabetic eye disease
- Diabetic kidney disease
- Nerve/ Vascular complications

ACUTE COMPLICATIONS

Acute diabetes complications resulting from extremes of blood glucose levels are common in type 1 Diabetes. They can occur, with certain medications, in type 2 Diabetes and other forms of the condition as well. They can lead to permanent neurological consequences or death.

1. **DKA (Diabetic ketoacidosis):** If the initial diagnosis of type 1 diabetes is delayed, it typically presents with a build-up of ketones in the body or diabetic ketoacidosis (DKA). DKA is a complex metabolic disorder that requires expert guidelines-based management.

   DKA is characterised by abdominal pain and is manifested by breathlessness, vomiting, altered sensorium and dehydration. The patient should be immediately taken to the hospital emergency department.

2. **Hypoglycaemia:** It is common in both type 1 and type 2 diabetes, especially when insulin or sulfonylureas are used. Symptoms often include hunger, sweating, tremors, palpitations, and potential loss of consciousness.

   A rapid-acting carbohydrate, such as a sweetened drink, glucose tablets, or sweets, can treat mild hypoglycemia. Severe hypoglycemia occurs when the person with Diabetes requires external assistance and can develop quickly into seizure and coma. Prompt treatment with glucagon or intravenous dextrose or glucose is required. The most useful treatment is oral glucose, 3-4 spoons in one glass of water, repeated after 5 minutes. If glucose is unavailable, the patients should mix sugar and water (3-4 spoons in 1 glass) and follow the same procedure.

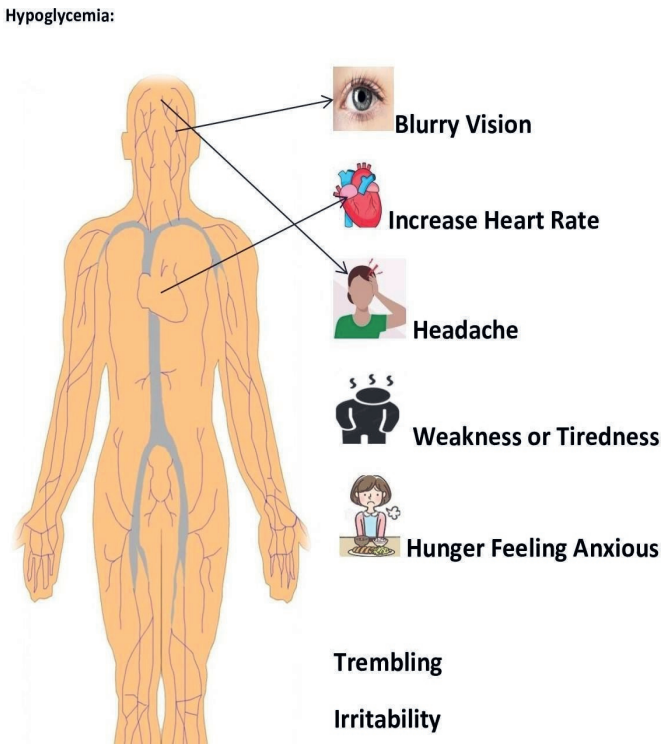


Figure 11: Symptoms of Hypoglycemia

3. **HHS (Hyperglycaemic hyperosmolar state):** The symptoms of HHS are predominantly neurological; dehydration is usually more profound, but abdominal pain is uncommon. The elderly, the chronically ill and institutionalised populations are at increased risk for HHS. Accurate diagnosis and careful treatment are required to achieve good clinical outcomes.

CHRONIC COMPLICATIONS

Diabetes mellitus is a systemic disorder that can potentially cause serious organ damage involving the eyes, heart, kidneys, nerves, and limbs, which can ultimately lead to blindness, heart attack, kidney failure, and limb amputation, respectively. If diagnosed early and treated in time appropriately, the damage to some of these organs can be largely prevented or reversed.

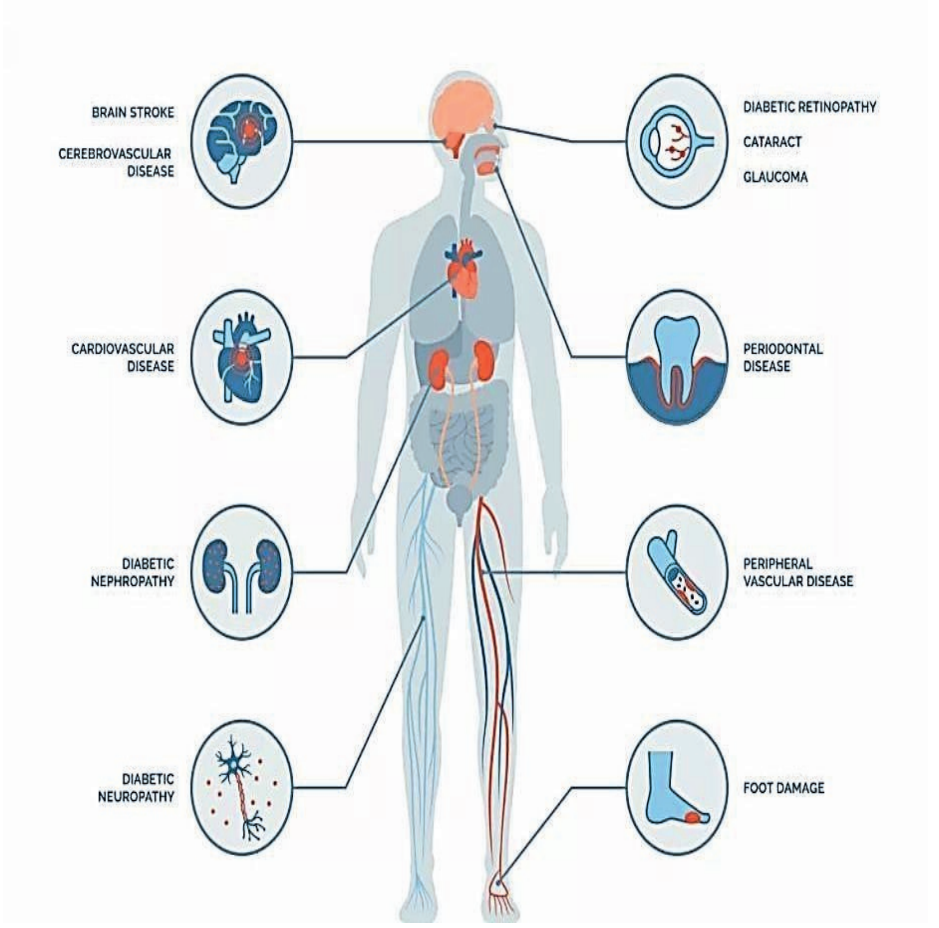


Figure 12: Chronic Complications of Diabetes

1. **Cardiovascular diseases:** Diabetes/high blood sugars and elevated blood pressure are associated with an approximate doubling of cardiovascular disease risk. The most common and classic types of CVD associated with Diabetes are coronary heart disease, cerebrovascular disease, peripheral artery disease, and congestive heart failure.

   Lowering high blood pressure and high glucose levels and using drugs that lower cholesterol can significantly reduce the risk of CVD outcomes. All known patients should have their cardiac profile examined annually if normal, or every 6 months if affected.



Figure 13: BMI as part of a heart examination

2. **Diabetic eye disease:** Diabetic eye disease (DED) is a much-feared complication of Diabetes, consisting predominantly of diabetic retinopathy (DR), diabetic macular oedema (DMO), cataract and glaucoma, but also double vision and inability to focus.

   Those patients with a long history of Diabetes, poor glycaemic control, concurrent hypertension, and nephropathy are more likely to have diabetic retinopathy. All known patients should get their eyes examined annually if normal or every six months if affected.

Figure 14A: NORMAL EYE

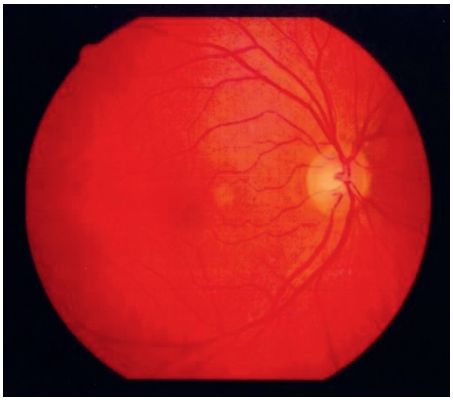


Figure 14B: DIABETIC RETINOPATHY



Screening recommendation for retinal examination

Patient group	When to screen first	Routine follow-up
Type 1 diabetes	Within 5 years of diagnosis	Annually thereafter
Type 2 diabetes	At the time of diagnosis	Annually thereafter

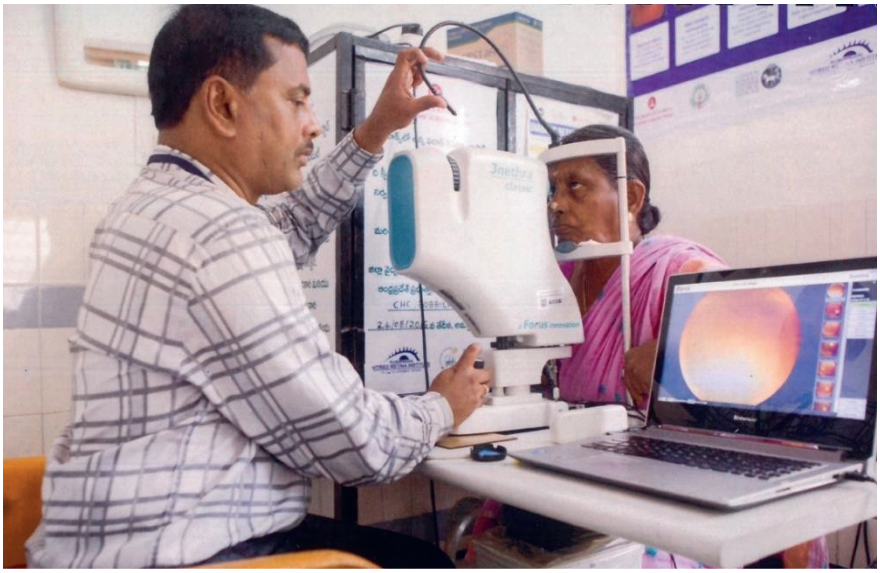


Figure 15: Eye examination

Maintaining Overall Eye Health (Do's & Don'ts)

Do's	Don'ts
Eat balanced and healthy food for the eyes	Self-medication
Include eggs, carrots, papayas, green leafy vegetables, and almonds	Rubbing eyes
Exercise regularly	Smoking
Sleep adequately	
Maintain good hygiene	
Use medications as instructed	
Regular eye check-ups	
Keep blood sugar under control	

3. **Diabetic kidney disease:** Diabetes, hypertension and CKD are highly interlinked. Chronic kidney disease (CKD) in people with Diabetes can result from diabetic nephropathy or can be the result of other associated conditions, such as hypertension, polyneuropathic bladder dysfunction, increased incidence of relapsing urinary tract infections, or macrovascular angiopathy.

   Investigations required are Urine microscopy (Casts and pus cells, RBC), Blood Urea, Serum creatinine, Calculate eGFR, Microalbuminuria, USG abdomen (if feasible) and Serum sodium and potassium. The most effective strategies to reduce the impact of kidney disease in Diabetes are to prevent type 2 diabetes and to diagnose and treat kidney disease early and effectively in people already living with Diabetes.

   All known patients should get their kidneys examined annually if normal or every 6 months if affected.



Figure 16: Kidney Examination

4. **Nerve/ Vascular complications:** Peripheral neuropathy is the most common form of Diabetes-related neuropathy. It affects the distal nerves of the limbs, particularly those of the feet. Symptoms include tingling sensations, numbness, pain, or increased sensitivity. These conditions facilitate ulcers resulting from external trauma and abnormal distribution of the internal bone pressure (the so-called 'diabetic foot).

   Neuropathy can cause foot deformities and dryness of the plantar skin, leading to neuropathic foot ulcers. If not treated appropriately at the early stages, limb amputation will be required.

Foot care advice

i. Inspect your feet daily for cracks, blisters, infections, and injuries. If you can't easily see the bottom of your feet, use a mirror.

ii. Cleanse your feet daily as you bathe or shower, using warm water and mild soap. Dry your feet with a soft towel, making sure to dry between the toes. Don't use hot water. Moisturise dry skin by using oil.

iii. Clip toenails straight across. Use a nail cutter; don't use scissors and also smooth down the edges. Never be barefoot. Always wear something on your feet (socks, slippers, shoes) to protect from injury - even in your house.

iv. Choose soft, good shoes. Let them be a size bigger than what you feel is appropriate. Wear socks made of cotton or wool (in winter).

v. Treat minor breaks in the skin promptly. Cleanse the area with soap and water, dry it, and cover it with clean gauze. Observe for signs of infection such as redness, swelling, warmth, pain, or drainage. Don't put weight on the foot that has an injury.

vi. See your doctor to check your feet during your regular visits for diabetes care. Take off your shoes and socks at every visit.



Figure 17: Foot care for people with Diabetes

Ref: https://www.crh.org/healthy-tomorrow/healthy-tomorrow/2018/10/24/diabetic-foot-care

COVID-19 AND DIABETES: COVID-19 is a new and potentially serious coronavirus. The World Health Organization (WHO) has declared the COVID-19 outbreak to be a public health emergency of international concern.

Older people and people with pre-existing medical conditions (such as Diabetes, heart disease, and asthma) appear to be more vulnerable to becoming severely ill with the COVID-19 virus. People with Diabetes are more likely to have serious complications from COVID-19.

For people living with Diabetes, it is important to take precautions to avoid the virus if possible. The recommendations widely issued to the public are doubly important for people living with Diabetes and for anyone in close contact with them.

General precautions: wash your hands, wear a mask (double-mask if possible), maintain social distance, disinfect frequently touched surfaces, and avoid touching your face.

If you have Diabetes:

- Prepare in case you get ill.
- Make sure you have all relevant contact details to hand in case you need them.
- Pay extra attention to your glucose control. Regular monitoring can help prevent complications caused by high or low blood glucose levels.
- If you do show flu-like symptoms (raised temperature, cough, difficulty breathing), it is important to consult a healthcare professional.
- Any infection will raise your glucose levels and increase your need for fluids, so make sure you can access a sufficient supply of water.
- Make sure you have a good supply of the diabetes medications you need. Think about what you would need if you had to quarantine.
- Make sure you have access to enough food.
- Make sure you will be able to correct the situation if your blood glucose drops suddenly.
- If you live alone, make sure someone you can rely on knows you have diabetes, as you may require assistance if you get ill.
- Keep a regular schedule, avoiding overwork and having a good night's sleep.

ECONOMIC IMPACT

- The health costs of detection and treatment of diabetes-related complications are high. All the complications of Diabetes, both acute and long-term, contribute significantly to the overall economic impact of the condition.
- The health costs of treating the complications of Diabetes account for over 50% of the direct health costs of Diabetes.
- This relates both to direct costs, for which the costs of hospitalisation for diabetes complications are a major driver.
- Diabetes complications, as frequent causes of disability, premature mortality, and absence from work due to sickness, are important drivers of indirect costs.
- The early detection and improved management of diabetes complications will have benefits not only for the individuals with Diabetes but also for the wider health economy.

REFERENCES

Page No.	Topic	Reference
1.	What is Diabetes, and the types of Diabetes	Module for ASHA on Non-Communicable Diseases
2.	Difference between type 1 and type 2 diabetes	ICMR guidelines for Management of Type 2 Diabetes 2018
2.	Other types of Diabetes	IDF Diabetes Atlas 2019
3.	Prevalence of Diabetes in India	IDF Diabetes Atlas 2019
4.	Risk factors for type 2 diabetes	Module for ASHA on Non-Communicable Diseases
5.	Signs and symptoms of type 2 diabetes	Module for ASHA on Non-Communicable Diseases, IDF Diabetes Atlas 2019
5.	Prevention and control of type 2 diabetes	Reading material for ASHA (book no.8)
6.	Blood glucose estimation	Module for ASHA on Non-Communicable Diseases
7.	Role of ASHA in population-based screening	Training module for Medical Officers for Prevention, Control and Population-Level Screening of Hypertension, Diabetes, and Common Cancer
11.	Management of Diabetes	Training module for Medical Officers, ICMR guidelines for Management of Type 2 Diabetes 2018
12.	Diabetes patient education and diet counselling, Follow-up	Training module for Medical Officers for Prevention, Control and Population-Level Screening of Hypertension, Diabetes, and Common Cancer
15.	Continuity of care	Operational guidelines: Prevention, Screening and Control of Non-Communicable Diseases
16.	Checklist for Diabetes Complications	Operational guidelines: Prevention, Screening and Control of Non-Communicable Diseases
16.	Diabetes complications and Management, Economic impact	IDF Diabetes Atlas 2019, ICMR guidelines for Management of Type 2 Diabetes 2018

ANNEXURE I- Community-Based Assessment Checklist (CBAC) for Early Detection of Non-Communicable Diseases

General Information	
Name of ASHA	Village
Name of ANM	Sub Centre
PHC	Date
Personal Details	
Name	Any Identifier (Aadhar Card, UID, Voter ID)
Age	RSBY beneficiary: (Y/ N) _____
Sex	Telephone No.
Address	

Part A: Risk Assessment			
Question	**Range**	**Circle any**	**Write score**
1. What is your age? (incomplete years)	30-39 years	0	
	40-49 years	1	
	≥ 50 years	2	

smokeless products such as Gutka or Khaini?				
	Used to consume in the past / Sometimes now		1	
	Daily		2	
3. Do you consume alcohol daily?	No		0	
	Yes		1	
4. Measurement of waist (in cm)	Female	Male		
	<80 cm	<90 cm	0	
	80-90 cm	90-100 cm	1	
	>90 cm	>100 cm	2	
5. Do you undertake any physical activities for a minimum of 150 minutes a week?	Less than 150 minutes a week		0	
	At least 150 minutes a week		1	
6. Do you have a family history (any one of your parents or siblings) of high blood pressure, Diabetes, and heart disease?	No		0	
	Yes		2	
Total Score				

A score above 4 indicates that the person may be at risk for these NCDs and needs to be prioritised for attending the weekly NCD day

ANNEXURE II: Steps of Waist Circumference Measurement

Tool

- Non-stretchable flexible measuring tape

Important point to keep in mind

- WC should be taken in a standing posture

Process steps

- Remove any layers of clothing blocking the waist. If the individual is unwilling to remove clothing, the measurement can be taken over the thinnest layer of clothing.
- The individual stands straight, looking in front with the abdomen (stomach) relaxed, arms at their sides, and their feet close together (about 12- 15 cm) with their weight equally distributed across both feet.
- You will stand in front, facing the subject. Find the midpoint between the lowest rib / bony point in front and the top of the hip bone in back. Waist circumferences can also be measured across the umbilical line (at the navel).
- The person should be asked to breathe normally. At the time of the measurement, she/he asked to breathe out gently.
- Place the tape firmly in a horizontal position, making sure the measuring tape is parallel to the floor and not folded or twisted.
- Record the reading at the end of the normal expiration/breathing.
- The tape should be loose enough to allow one finger to be placed between the tape and the person's body, but the tape should fit firmly but comfortably around the waist. The tape should not squeeze the skin.

- Look at the place on the tape where the zero end meets the other end of the tape measure. The location of this meeting point is the waist measurement.
- Record the measurement in cms to the nearest 0.0 or 0.5 cm in the individual's card or your register. Example: If the exact measurement is 85.7 cm, record it as 85.5 cm; if it is 85.9 cm, record the reading as 86 cm.

1800 Calorie Chart

Time	Diet Menu	Quantity
6:00 to 7:00 am	Coffee or Tea or Milk (Without Sugar)	1 cup
8:00 to 9:00 am	Idlis or	4 with Chutney or Sambar
	Chapathis or	4 with curry
	Dosas	2 with Chutney or Sambar
10:30 to 11:00 am	Lime or Tomato Juice (Without Sugar) or	1 glass
	Buttermilk or	1 glass
	Vegetable salad or	1 plate
	Vegetable soup	1 bowl
1:00 to 2:00 pm	Rice	1.5 katoris
	Sambar or Rasam with Vegetables (Green Leafy, Salad, other vegetables)	1 bowl
	Skimmed Milk/Buttermilk	1 cup
	Whole Grams(Bengal or Green Gram or Cow Pea or Rajma) OR	1 katori/day
	Fish/Chicken	100 gm (Twice a week)
	Whole Grams(Bengal or Green Gram or Cow Pea or Rajma) +	1/4 katori
	+ Whole Egg	Weekly once
	Mutton	100 gm (weekly once)
	Egg White	1 daily
3:00 to 4:00 pm	Whole Wheat Bread (with gram/dal/ vegetable filling) OR	2 slices
	Wheat Rava Khichdi or Rice Flakes or Upma or Any Dal/Gram preparation	1 katori
	Coffee or Tea or Milk (Without Sugar)	1 cup
5:00 to 6:00	Fruit as Advised	1 portion
8:00 to 9:00 pm	Same as Lunch except	
	Chapatis	3
	Dal & Vegetables	2 Katoris each
	Skimmed Milk/Buttermilk	1/2 cup

2000 Calorie Chart

Time	Diet Menu	Quantity
6:00 to 7:00 am	Coffee or Tea or Milk (Without Sugar)	1 cup
8:00 to 9:00 am	Idlis or	5 with Chutney or Sambar
	Chapathis or	5 with curry
	Dosas	3 with Chutney or Sambar
10:00 to 10:30 am	Toned Milk (Without Sugar)	1 cup
10:30 to 11:00 am	Lime or Tomato Juice (Without Sugar) or	1 glass
	Buttermilk or	1 glass
	Vegetable salad or	1 plate
	Vegetable soup	1 bowl
1:00 to 2:00 pm	Rice	3 katoris
	Sambar or Rasam with Vegetables (Green Leafy, Salad, other vegetables)	1 bowl
	Skimmed Milk/Buttermilk	1 cup
	Whole Grams (Bengal or Green Gram or Cow Pea or Rajma) OR	1 katori/day
	Fish/Chicken	100 gm (Twice a week)
	Whole Grams (Bengal or Green Gram or Cow Pea or Rajma) +	1 katori
	+ Whole Egg	Weekly once
	Mutton	100 gm (weekly once)
	Egg White	1 daily
3:00 to 4:00 pm	Whole Wheat Bread (with gram/dal/ vegetable filling) OR	2 slices
	Wheat Rava Khichdi or Rice Flakes or Upma or Any Dal/Gram preparation	1 katori
	Coffee or Tea or Milk (Without Sugar)	1 cup
5:00 to 6:00	Fruit as Advised	1 portion
8:00 to 9:00 pm	Same as Lunch except	
	Chapatis	5
	Dal & Vegetables	2 Katoris each
	Skimmed Milk/Buttermilk	1/2 cup

Bed time	Toned Milk (Without Sugar)	1 cup



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Curriculum Vitae

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Professional Summary

Public health researcher and practitioner with over a decade of experience leading community health worker (CHW)-delivered interventions, AI applications for healthcare screening, and capacity-building programmes for non-communicable diseases (NCDs) across India and other low- and middle-income countries (LMICs). PhD candidate at Maastricht University and current Hubert H. Humphrey Fellow at Virginia Commonwealth University, with a Non-Resident Senior Fellowship at the Atlantic Council, contributing to AI Connect III, a Government of Canada-funded programme that builds AI governance capacity among LMIC policymakers. Author of 16 peer-reviewed publications in journals including JCO Global Oncology, Medicine, and JMIR Research Protocols. As Director of Public Health at PRASHO Foundation, leads a 25-member team that designs and delivers competency-based training programmes for diabetes, hypertension, and cervical and oral cancer screening. Distinct expertise at the intersection of CHW-led service delivery, evidence-based public health, and AI/digital health governance in resource-constrained settings.

Education

Hubert H. Humphrey Fellowship at Virginia Commonwealth University (VCU) (August 2025 - June 2026)

Fulbright-sponsored fellowship focusing on public health leadership, global health governance, and AI applications in healthcare. Engaged in coursework, professional affiliations with Atlantic Council, Dialogue at the Global Leadership Forum and attended the American Public Health Association (APHA) and Association of Community Health Worker Educators (ACDES) conferences, and collaborative research initiatives.

PhD Student at Maastricht University (February 2019 - September 2026)

Thesis: Evaluation of competency-based training of minimally trained health workers in type 2 diabetes mellitus for improving diabetes management in rural communities. Expected completion by September 2026.

M.A. in Social Entrepreneurship - Tata Institute of Social Sciences (2012-2014)

CGPA: 8.2 on a scale of 10. Thesis: Socioeconomic rehabilitation of the differently abled via their employment.

B.D.S. - Bapuji Dental College & Hospital, Davangere, Rajiv Gandhi University of Health Sciences, Karnataka (2006-2011)

Work Experience

Non-Resident Senior Fellow, Atlantic Council (January 2026 – April 2026)

- Contributed as subject-matter expert to AI Connect III, the Atlantic Council's flagship capacity-building programme, funded by the Government of Canada, designed to train policymakers from low- and middle-income countries (LMICs) in artificial intelligence and AI governance
- Authored and revised six AI governance case studies (CS1–CS6) spanning health triage, smart grid, urban data governance (Sidewalk Toronto), and climate AI, each anchored to LMIC policy contexts and verified against peer-reviewed and institutional sources
- Established a verified-sources protocol for the case study suite, eliminating fabricated and defunct references and strengthening reference integrity across the curriculum
- Brought a public health and Global South lens to curriculum design, helping advance equity-centred AI governance frameworks for adoption across LMIC policy environments

Director - Public Health, Pragyaan Sustainable Health Outcomes (PRASHO) Foundation (January 2024 - Present)

- Provide mentorship and leadership to a 25-member public health team
- Design and deliver competency-based skilling programs in physical and virtual formats for community health workers (CHWs) in diabetes, hypertension, cervical cancer, and oral cancer screening
- Develop research protocols (13 protocols developed in the past year)
- Secure funding through grant applications (8 out of 9 grants secured in the past year)

Senior Research Associate - Indian Institute of Public Health Hyderabad (June 2020 - December 2024)

Led multiple high-impact research projects:

- **I-HOPE Project**: Implementation research for diabetes and diabetic retinopathy management
- **SEVA Operational Research Project**: Capacity building for eye hospitals across India and Nepal
- **ASCO AI Cervical Cancer Screening Project**: Development and validation of AI-assisted visual inspection tools
- **DST Smartphone Project**: Principal Investigator for digital health intervention

Key Responsibilities:

- Design and implement epidemiological studies in diabetes, eye care, and cancer
- Lead multidisciplinary teams in day-to-day operations
- Design and implement capacity-building training for field workers
- Conduct data collection, cleaning, and analysis
- Build networks with government stakeholders
- Conduct qualitative research and process evaluations
- Develop and implement Monitoring & Evaluation frameworks

Research Fellow - Pushpagiri Eye Institute (August 2019 - June 2020)

Coordinated Operational Research capacity-building program between 4 eye hospitals across India and Nepal with IIPHH, supported by SEVA International:

Facilitated online training sessions between IIPHH guides and partner institutions

- Coordinated workshops between IIPHH, SEVA, and partner hospital teams
- Provided administrative and technical assistance to research teams
- Prepared progress reports and documentation

Research Fellow - Indian Institute of Public Health Hyderabad (April 2018 - August 2019)

Worked on diabetic retinopathy (DR) project focused on reducing avoidable blindness:

- Contributed to national policy framework on diabetic retinopathy
- Implemented and monitored digital diabetic helpline operations (toll-free service for Telangana & Andhra Pradesh)
- Established 6 peer support groups across Maharashtra and Gujarat
- Developed curriculum for peer support group delivery
- Coordinated DR program implementation in Goa and Gujarat
- Managed project data and monitoring & evaluation
- Prepared monthly progress reports for Queen Elizabeth Diamond Jubilee Trust (QEDJT)
- Published 4 peer-reviewed articles in Indian Journal of Ophthalmology special edition

Founder & Director - Rovnost Healthcare (February 2016 - Present)

Founded m-Health social enterprise strengthening health systems and improving healthcare accessibility in rural Karnataka and Telangana:

- Developed strategy, design thinking, and operations

- Designed and delivered health worker training modules
- Developed digital smartphone application for tele-consultations
- Established village clinics
- Developed e-prescription and patient flow mechanisms optimised for low-bandwidth rural environments
- Designed and implemented monitoring & evaluation framework
- Led fundraising, community engagement, and awareness campaigns

Monitoring & Evaluation Coordinator - Public Health Foundation of India, Delhi (December 2014 - February 2016)

Coordinated Certificate Course in Management of Thyroid Disorders (CCMTD), a collaboration between PHFI and Chellaram Diabetes Institute supported by GSK:

- Trained over 1,500 physicians across 25 centers in India
- Designed similar programs for Gujarat and Madhya Pradesh governments (50 centers)
- Planned, developed, and implemented M&E modalities
- Negotiated contracts and provided technical assistance
- Supervised professional and technical staff
- Led external and internal monitoring teams
- Conducted surveillance and site reviews across 25 centers monthly
- Developed and implemented program policies and procedures
- Engaged stakeholders and resolved conflicts

Publications

1. ***Gudlavalleti AG**, Kamalakannan S, Vanbelle S S, Gudlavalleti VSM, Schaper NC, Babu GR**, Schayck OCV**.* Training Community Health Workers for Diabetes Management in Low- and Middle-Income Countries: Systematic Review. JMIR Diabetes. 2026 Jun 10;11:e84508. doi: 10.2196/84508. PMID: 42269165; PMCID: PMC13252886

2. Ali S, Murthy GVS, Bassett KL, Reddy P, Judson K, Gilbert SS, Patra A, **Gudlavalleti AG**, Mahapatra D, Pant H, Dakhwa P, Jameel S, Pandey SP, Tetali S, Chaudhuri S, Imandi S, Kamalakannan S. Building Capacity in Institutional Operational Research in Low-Resource Settings: Protocol for an Implementation Research Study. *JMIR Res Protoc*. 2026 Apr 13;15:e84284. doi: 10.2196/84284. PubMed PMID: 41983623; PubMed Central PMCID: PMC13081132.

3. **Poli UR, Gudlavalleti AG**, Bharadwaj YJ, Pant HB, Agiwal V, Murthy GVS. Development and Clinical Validation of Visual Inspection With Acetic Acid Application-Artificial Intelligence Tool Using Cervical Images in Screen-and-Treat Visual Screening for Cervical Cancer in South India: A Pilot Study. *JCO Glob Oncol*. 2024 Dec;10:e2400146. doi: 10.1200/GO.24.00146. Epub 2024 Dec 12. PubMed PMID: 39666915; PubMed Central PMCID: PMC11684514.

4. **Gudlavalleti AG**, Babu GR, Kamalakannan S, Murthy GVS, Schaper NC, van Schayck OCP. Training of Community Health Workers in Diabetes Lead to Improved Outcomes for Diabetes Screening and Management in Low- and Middle-Income Countries: Protocol for a Systematic Review. *JMIR Res Protoc*. 2024 Aug 21;13:e57313. doi: 10.2196/57313. PubMed PMID: 39167436; PubMed Central PMCID: PMC11375384.

5. **Gudlavalleti AG**, Babu GR, Agiwal V, Murthy GVS, Schaper NC, van Schayck OCP. Undesirable Levels of Practice Behaviours and Associated Knowledge amongst

Community Health Workers in Rural South India Responsible for Type 2 Diabetes Screening and Management. *Int J Environ Res Public Health*. 2024 Apr 28;21(5):562. doi: 10.3390/ijerph21050562. PMID: 38791775; PMCID: PMC11121515.

6. Shrestha M, Bhandari G, Kamalakannan S, Murthy GVS, Rathi SK, **Gudlavalleti AG**, Agiwal V, Pant H, Pandey B, Ghimire R, Ale D, Kayastha S, Karki R, Chaudhary DS, Byanju R; Operational Research Capacity Building Study Group. Evaluating the Effectiveness of Interventions to Improve the Follow-up Rate for Children With Visual Disabilities in an Eye Hospital in Nepal: Nonrandomized Study. *JMIR Pediatr Parent*. 2023 Feb 23;6:e43814. doi: 10.2196/43814. PMID: 36821366; PMCID: PMC9999261.

7. Gilbert SS, Murthy G, Bassett KL; Operational Research Capacity Building Study Group. Building local capacity in operational research: a case study in Nepal and India. *Community Eye Health*. 2022;35(117):14-16. Epub 2023 Jan 30. PMID: 37007828; PMCID: PMC10061251.

8. Sabherwal S, Chinnakaran A, Sood I, Garg GK, Singh BP, Shukla R, Reddy PA, Gilbert S, Bassett K, Murthy GVS. Effect of Door-to-Door Screening and Awareness Generation Activities in the Catchment Areas of Vision Centers on Service Use: Protocol for a Randomized Experimental Study. *JMIR Res Protoc*. 2021 Nov 4;10(11):e31951. doi: 10.2196/31951. PubMed PMID: 34734839; PubMed Central PMCID: PMC8603175.

9. Shrestha M, Bhandari G, Rathi SK, **Gudlavalleti AG**, Pandey B, Ghimire R, Ale D, Kayastha S, Chaudhary DS, Byanju R. Improving the Follow-up Rate for Pediatric Patients (0-16 years) of an Eye Hospital in Nepal: Protocol for a Public Health Intervention Study. *JMIR Res Protoc*. 2021 Oct 8;10(10):e31578. doi: 10.2196/31578. PubMed PMID: 34521615; PubMed Central PMCID: PMC8538025.

10. **Gudlavalleti AG**, Babu GR, van Schayck OCP, Schaper NC, Lewis MG, Murthy GVS. Evaluation of competence training for the minimally trained health worker in type 2 diabetes: A cluster randomized controlled trial. *Medicine (Baltimore)*. 2020 Oct 30;99(44):e22959. doi: 10.1097/MD.0000000000022959. PubMed PMID: 33126364; PubMed Central PMCID: PMC7598789.

11. Mukpalkar S, Gilbert C, Murthy GVS, **Gudlavalleti AG**, Batchu T, Edla S, Hebrew V, Vemulapalli L, Janagama H, Shukla R, Bala VMS, Yamarthi P, Pendyala S, Puppala A. 1800 121 2096 Diabeteshelp - A toll free helpline for people with diabetes. *Indian J Ophthalmol*. 2020 Feb;68(Suppl 1):S100-S102. doi: 10.4103/ijo.IJO_1819_19. PubMed PMID: 31937742; PubMed Central PMCID: PMC7001186.

12. **Gudlavalleti AG**, Gilbert C, Shukla R, Gajiwala U, Shukla A, Murthy GVS, Batchu T, Mukpalkar S, Bala Vidyadhar MS, Sheikh A. Establishing peer support groups for diabetic retinopathy in India: Lessons learned and way ahead. *Indian J Ophthalmol*. 2020 Feb;68(Suppl 1):S70-S73. doi: 10.4103/ijo.IJO_1928_19. PubMed PMID: 31937735; PubMed Central PMCID: PMC7001185.

13. Gilbert C, Shukla R, Murthy GVS, Santosha BVM, **Gudlavalleti AG**, Mukpalkar S, Yamarthi P, Pendyala S, Puppala A, Edla S, Batchu T. Retinopathy of prematurity: Overview and highlights of an initiative to integrate prevention, screening, and management into the public health system in India. *Indian J Ophthalmol*. 2020 Feb;68(Suppl 1): S103-S107. doi: 10.4103/ijo.IJO_2080_19. PubMed PMID: 31937743; PubMed Central PMCID: PMC7001169.

14. Malladi BVS, Iyer GK, Murthy GVS, Gilbert C, Shukla R, **Gudlavalleti AG**, Yamarthi P, Mukpalkar S. Establishing support groups to support parents of preterm babies with retinopathy of prematurity: A pilot study. *Indian J Ophthalmol*. 2020 Feb;68(Suppl

1):S128-S130. doi: 10.4103/ijo.IJO_1818_19. PubMed PMID: 31937748; PubMed Central PMCID: PMC7001163.

15. Murthy GVS, Gilbert C, Shukla R, Bala V, **Anirudh GG**, Mukpalkar S, Yamarthi P, Pendyala S, Puppala A, Supriya E, Batchu T. Overview and project highlights of an initiative to integrate diabetic retinopathy screening and management in the public health system in India. *Indian J Ophthalmol*. 2020 Feb;68(Suppl 1): S12-S15. doi: 10.4103/ijo.IJO_1964_19. PubMed PMID: 31937722; PubMed Central PMCID: PMC7001184.

16. Bhalla S, Monga D, Soni T, **Gaurang A**, Deshpande SR, Bhatt A, Prabhakaran D, Unnikrishnan AG. Competency Education of Primary Care Physicians in Management of Thyroid Disorders: Implementation Experiences from a Pan India Certificate Course. *Thyroid*. 2016 Dec;26(12):1807-1808. doi: 10.1089/thy.2016.0416. Epub 2016 Nov 28. PubMed PMID: 27758136.

Certifications

- CITI Program - Social and Behavioral Research Ethics (2024)
- Global Health Network - Clinical Research Operations for Study Coordinators Course (100% score, January 2023)
- Global Health Network - Ethics Review of Social Research on Health-Related Topics (100% score, January 2023)
- Global Health Network - ICH Good Clinical Practice Course (100% score, January 2023)
- Seva Foundation, LAICO, and Ophthalmology Foundation - EyeExcel 2.0 Workshop (June 2021)

- IIPH Hyderabad - Public Health Planning for Hearing Impairment Course (December 2020)
- CMC Vellore - Online Workshop in Systematic Reviews (October 2020)

Professional Affiliations

- Member, American Public Health Association (APHA)
- Member, Association of Community Health Worker Educators (ACDES)
- Humphrey Fellow Alumni Network

Awards and Honours

- **Hubert H. Humphrey Fellowship** - Selected as Fulbright Humphrey Fellow at Virginia Commonwealth University (2025-2026)
- **DBS-NUS Social Venture Challenge Asia 50** - Selected as one of 50 most promising social entrepreneurs across Asia by Development Bank of Singapore; invited to DBS SE 50 summit (October 2018)
- **School for Social Entrepreneurs (SSE) India** - Chosen as one among 20 future leaders/social entrepreneurs by PwC India for SSE second cohort (April 2017 - February 2018)
- **Deshpande Foundation Sandbox Event Winner** - Won social entrepreneurship competition (September 2017)

Conference Presentations and Academic Activities

- Presenter, Global Leadership Forum, Washington DC (October 2025)
- Presenter, Home Country Presentation on India’s Public Health Landscape, Humphrey Fellowship Program (2025)

- Guest Lecturer, Community Health Worker Practice and Training, VCU School of Public Health (2025-2026)

Media Mentions

- Deutsche Welle (DW): "India: COVID unaffordable health care" (July 5, 2021) - https://www.dw.com/en/india-covid-unaffordable-health-care/a-58162810
- TV9 News: "Unlocking: How to avoid mistakes that led to the second wave of COVID-19" (June 5, 2021) - https://tv9news.com/health/covid-19/unlocking-how-to-avoid-mistakes-that-led-to-the-second-wave-of-covid-19-35702.html

Skills and Competencies

Research and Technical Skills

- Epidemiological study design and implementation
- Quantitative and qualitative research methods
- Data collection, cleaning, and statistical analysis (STATA proficiency)
- Systematic review methodology
- Protocol development for clinical and implementation research
- Monitoring and Evaluation framework development
- CONSORT and other research reporting guidelines

Leadership and Management

- Team building, mentoring, and capacity development
- Strategic planning and organizational development
- Stakeholder engagement and network building
- Grant writing and fundraising

- Financial reporting and compliance management
- Cross-cultural collaboration and international partnerships

Public Health and Clinical

- Community health worker training and competency assessment
- Diabetes and diabetic retinopathy screening and management
- Cervical cancer screening (VIA methods)
- AI applications in healthcare screening
- Digital health and telemedicine platforms
- Health systems strengthening
- Task-shifting and task-sharing strategies

Teaching and Training

- Curriculum development for competency-based education
- Online and face-to-face teaching delivery
- Learning Management System (LMS) design and management
- Workshop facilitation
- Educational content development

Technology and Innovation

- Artificial Intelligence for healthcare applications
- Digital health platform development
- Health informatics
- Low-bandwidth technology optimization

- E-prescription systems

Additional Competencies

- Ability to work in resource-constrained settings
- Strong relationship building across diverse stakeholder groups
- Policy analysis and advocacy
- Community engagement and grassroots innovation

Languages

- English (Fluent)
- Hindi (Fluent)
- Telugu (Native)
- Kannada (Conversational)

SUMMARY

Type 2 diabetes has become one of India's most urgent public health challenges, heavily impacting rural populations who face difficulties related to distance, cost, and a shortage of trained health personnel. India's community health workers, known as Accredited Social Health Activists, are officially tasked with diabetes screening, referral, and follow-up. However, evidence consistently reveals gaps between their assigned roles and the training they receive to carry them out.

This dissertation investigates whether a structured, competency-based training programme can bridge that gap. It methodically progresses from a baseline assessment to identify gaps in health workers' knowledge and practice, through a systematic review of similar training outcomes elsewhere, to a cluster-randomised trial assessing a specially designed programme within the government's non-communicable disease framework in rural Telangana. The work demonstrates that trained workers identify and refer substantially more people for diabetes and diabetic retinopathy care than those working under standard conditions, and that these gains are achievable using existing health-system structures. Together, the studies make the case for task-shifting as an affordable, scalable route to earlier diabetes detection in low-resource settings.

ABOUT THE AUTHOR

Dr. Anirudh Gaurang Gudlavalleti holds both a bachelor's in dentistry and a master's in social entrepreneurship. A Fulbright alumnus, he completed his Hubert Humphrey Fellowship in 2026 and serves as the Director of Public Health at Pragyaan Sustainable Health Outcomes Foundation.

His work focuses on using technology and training community health workers to diagnose and treat diabetes, cancers, and eye diseases in Indian villages. He has received grants to develop a prototype AI-driven cancer screening tool. In 2018, DBS Bank named him one of Asia's fifty top social entrepreneurs.

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