



FINAL REPORT

Primary Healthcare Financing Proposal

**Financing Novel Diabetes Prevention and
Management Models**

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1. BACKGROUND	3
2. DELIVERY MODELS	3
2.1 COMMUNITY HEALTH WORKER (CHW)-BASED MODEL	4
2.2 TELEMEDICINE-BASED MODEL	6
2.3 TELEMEDICINE-EQUIPPED MOBILE MEDICAL UNIT-BASED MODEL (MMU)	9
3. METHODOLOGY	11
3.1 Cost of the delivery models	11
3.2 Cost-effectiveness analysis	15
3.3.3 Probabilities	17
3.4 Disability weights	21
3.5 Cost of drugs, cost of annual, post-event care data	21
3.6 Thresholds	23
3.7 Ethics Approval	24
4. RESULTS	25
4.1 COST RESULTS	25
4.2 COST-EFFECTIVENESS	26
4.2.1 CHW-BASED VS. STATUS QUO	26
4.2.2 TMU VS. STATUS QUO	26
4.2.3 MMU VS. STATUS QUO	28
5. Discussion and Conclusion	29
6. REFERENCES	31
7. ANNEXURES	32

1. Background

Non-communicable diseases (NCDs) such as diabetes, hypertension, cardiovascular diseases account for more than 60% of all deaths in India and an annual loss of 5-10% of its GDP. [1-3] The key drivers of the growing NCD burden in India include delayed diagnosis and out-of-pocket (OOP) expenditure for healthcare; thereby, missing the opportunity for timely care. [4-6] Currently, the care for NCDs in India is predominantly borne out of pocket with some financial protection from hospitalization through government insurance schemes. For these reasons, there is an underutilization of care for NCD management, leading to an escalation of disease, emergency health incidents, and increased out of pocket spending on hospitalizations. Without robust preventive and primary care, the rising burden of NCDs may render many of the tertiary care schemes financially unsustainable.

While the growing interest among policymakers to bring NCDs on the forefront of national policy is promising, the public health system in low and middle-income countries lacks the expertise and is burdened with the handling of infectious diseases and infant and maternal mortality. [7] Also, studies have reported that the previous publicly funded insurance scheme such as RSBY (Rashtriya Suraksha Bima Yojna, Aarogyasri Health Insurance Scheme) failed in reducing out-of-pocket expenditure of its beneficiaries. [8]

On the flip side, the private sector has implemented innovative models that harness health systems and address some of the gaps in public sector delivery. [9] But, this sector does not have the incentives to manage disease proactively.

India, like other low and middle-income countries, has a mixed health system with a large fraction of patients going to private sectors. And, most of the patients do not identify the public sector as a provider for treatment of NCDs. Hence, in these landscapes, it seems intuitive that public-private engagement models--where the health services are financed by the public sector with provisioning of the services by the private sector-- can effectively address the rising NCD burden. Evidence indicates that such models can reduce provider fragmentation, create incentives for quality, provide subsidies for targeted populations and high impact interventions, and use technologies that expand access and improve quality. [10]

In these mixed-health systems, where there is lack of information on the financial viability of large-scale diabetes prevention programs, we aim to identify existing models of public-private engagement in India and understand how these can effectively operationalize the current mixed health systems to reduce health systems costs over the long term.

In this study, we aim to assess the cost-effectiveness of implementing existing or potential public-private engagement models for diabetes prevention and management aimed at low-income populations in urban and rural areas of India.

2. Delivery models

Based on literature review, and interactions with healthcare organizations and policymakers, we identified three delivery models on chronic disease management for a detailed study and cost analysis: community health worker (CHW) based, telemedicine based, and mobile medical van based models.

For the delivery models, we analysed ongoing and past exemplary programs with potential to scale at national level. The choice of these programs was based on their integrated care coordination system, accessible care provision, intensive training of the frontline health workers, follow up care, and referral linkages; factors pertinent to provide long-term effective care for NCDs. [11] Additionally, we considered some other factors including the relative strength of their proven impact, years of operations, and the potential feasibility of scaling them up at the national or state levels. All three programs provided primary care for diabetes to low-income groups in different settings and geographies in India. We adopted a case research methodology for the detailed analysis of the three delivery models.

2.1 Community Health Worker (CHW)-based Model

As our first model, we analysed an ongoing CHW-based program which provides proactive and continuous care for management of NCDs to low-income families. Founded in 2014 after the founders won the prestigious Hult Prize, the program has impacted more than 70,000 people since. Presently, it manages the health of over 2,000 users. The program is operational in urban slums and their surrounding neighbourhoods. The catchment population comprises individuals working as drivers, daily-wage earners, domestic helpers, vendors and self-employed professionals in the unorganised sector of the economy. The average family income of its beneficiaries ranges between INR 15,000—INR 30,000 per month. The program aims at improving the diagnosis and management of NCDs through: (i) trained and certified community health workers, and (ii) an integrated proprietary technology platform.

2.1.1 Community Health Workers

CHWs are trusted female members of the community with at least secondary school education who are interested in welfare services. CHWs are selected through community referrals and typically serve the community they come from. A recruitment test is conducted to assess their knowledge on health, basic reasoning, communication skills and behavioural skills. Upon recruitment, they are trained and certified under the program. Each CHW covers an area with a population of roughly 5,000 people, and performs a range of clinical, behavioural and operational tasks to achieve the goal of managing the health of the users in her catchment area.

CHWs undergo rigorous training by the program training team led by a clinician on patient care management, use of the CHW application, and operational and behavioural protocols. They are trained to assess clinical presentation and risk factors, education of users, principles of management, recordkeeping, and referral scheme for users with hypertension and/or diabetes. The training methods include formal lectures, demonstration, discussions, practical sessions, role-playing, post-training evaluation and continuous refresher training sessions.

2.1.1.1 Performance management of CHWs

The program uses a combination of financial (e.g. incentives) and non-financial methods (e.g. recognition) to ensure good performance of the CHWs. Their performance is measured on two key aspects: operational efficiency (number of follow up visits conducted per month) and clinical outcomes of the user.

Operational Efficiency: A web-based dashboard displays multiple live indicators of CHWs' operational performance in real time. These include the number of patient touches, the number of repeat user visits per month, and the number of new enrolments. The dashboard and the reports are scrutinised regularly by field executives, each of whom monitors a maximum of 10 CHWs.

Clinical Performance Monitoring: CHWs are evaluated based on the conversion of their respective users from a high-risk category to a low-risk category over a period of time. This would depend on the nature of follow ups and counselling provided to the users.

2.1.2 Empanelment of doctors

The program applies stringent evaluation criteria before empanelling the doctors in their network. Some of the key aspects are reviewing their qualification and certifications, checking their reputation within the community through informal interviews with key community members, assessing the hygiene of the premises by making physical visits to their clinic to assess the approachability and hygiene of the premises and ensuring their consent on the guidelines laid out by the program such as prescribing of generic medicine, avoiding unnecessary diagnostic tests, etc.

2.1.3 Integrated proprietary technology platform

An integrated technology proprietary platform supports the CHWs in delivering personalised care services at scale. These include health screening, doctor consultation, diagnostics, and medication through the following modules:

CHW Module: Each CHW is provided with a Doc-in-a-Bag™ that contains point-of-care diagnostic devices and a tablet-based module that assists them to perform doorstep health screening, inform users about their risk profile, deliver appropriate counselling, manage work schedules to meet the required targets, and coordinate appointments with doctors and other providers for the user. In case a user does not own a smartphone, CHW can use this module to book an appointment with the appropriate service providers (e.g. doctor, nutritionists, lab technician, etc.) and also help them with the video consultation if required.

User Module: The user module (mobile & web) provides information to individuals about their own health and facilitates effective self-management of the disease. The users can access their electronic health records (EHRs), view analytics on their health indicators, and follow associated recommendations (e.g. repeat doctor visits, medication reminders, etc.). They can use the app to interact with doctors and health coaches, take video consultation with doctors/nutritionists, book diagnostic tests at the labs or order drugs from pharmacies.

Provider Module: The provider module is a customised interface created for each of the multiple providers such as general physicians, specialists, diagnostic providers, and dieticians that manage health of the users. This application allows for seamless information-sharing on user health profiles across provider networks. For example, the doctor web application assists doctors in seeing EHRs, entering e-prescriptions during physical or virtual consultation, and enables communication with CHWs.

2.1.4 Healthcare Services

The program undertakes various activities to enable early identification of individuals who are at risk for NCDs and to provide convenient and continuous care for managing NCDs over a long term.

2.1.4.1 Health Screening (Case Finding) at the doorstep

CHWs provide free screening to the population in their community and identify users at risk of diabetes, hypertension, and obesity through door-to-door surveys and camps. Each CHW is equipped with a point-of-care diagnostic kit called Doc-in-a-Bag™ that includes a tablet-based module — CHW Module. CHW uses Doc-in-a-Bag™ to measure users' health parameters (anthropometric and blood sugar) and enters this data directly into the tablet. During screening, data is also collected on various other parameters such as demographics, previous medical history of self and family, and chief complaints (e.g. dizziness, dry tongue, nocturia, heartache, numbness and/or tingling sensation in limbs). The program's proprietary inbuilt algorithm uses this data and stratifies users into high and low risk for

hypertension, diabetes, and obesity. This aids CHWs in making various levels of on-the-spot recommendations such as referrals to doctors, change of diet plans, etc., and accordingly, an appropriate disease management plan is recommended to the users. A simple algorithm is also used to colour-code values entered for each parameter that help CHWs to easily understand the extent of severity for various diseases.

The technology platform helps in keeping track of timelines for the next-planned activities, personalised for each screened user. High-risk users undergo a second screening. In the second screening, fasting blood glucose and additional readings of blood pressure are measured for cases at high risk of diabetes and hypertension, respectively. Once found to be at high risk again during the second screening, they are counselled and referred to a doctor within the program empanelled network or partner government health centre for confirmation of diagnosis and treatment. High-risk users who receive a confirmed diagnosis from the doctor are encouraged to enroll into a monthly subscription-based *disease management plan* (USD 1.5/month). The core services of the plan are then made accessible to the interested users at a single, all-inclusive price at the time of enrollment and successive monthly subscription. At-risk users are counselled for necessary diet and lifestyle modifications to prevent the onset of chronic conditions. They are counselled to get a quarterly screening to monitor their progress. Low-risk users are advised to enroll for periodic (bi-annual) screenings.

2.1.4.2 Case Management

Clinical Care Coordination: CHWs guide the user to the appropriate healthcare provider(s) at regular intervals. The program provider network has registered and certified providers who are connected through technology (provider apps) to ensure coordinated care to users.

Continuous Care Management at doorstep: CHWs act as health coaches to support the users in disease management. They make periodic follow up visits to the users' households to monitor and measure their health parameters, perform standard screening assessments based on the user care plan (e.g. diabetic foot examination), ensure diet and medication compliance, and facilitate referral to the provider network, if and when required. The users are provided with a diet and medicine compliance calendar that records their adherence to diet and medication on a monthly basis. They also counsel users, in the local language, to manage and control lifestyle-related risk factors such as obesity, tobacco consumption, physical inactivity, and unhealthy diet. All health education sessions are conducted privately by CHWs with each enrolled user and one family member.

2.2 Telemedicine-based Model

As our second model, we analysed an ongoing telemedicine-based program which provides holistic primary care services with an integrated online-offline presence in order to service the rural population founded in 2014. The programme follows the hub-and-spoke model, but unlike conventional models, the program has its own chain of spokes i.e. e-clinics in rural Rajasthan, Haryana, and Madhya Pradesh in India. The catchment population comprises unemployed individuals (24.6%), self-employed or shop owners (27%), and those working in the organised or unorganised sectors of the economy (13.5%). The average family income of its 40% beneficiaries is less than INR 20,000 per month. The key features of this telemedicine model are:

- i. e-clinics staffed with trained nurses to control environment at patient end and provide high-quality care throughout the visit;
- ii. technology-enabled platform that optimises the complete process, including queue management, suggestions to correct doctor prescriptions, doctor workload management, and patient record management for better patient experience.

Since its inception, the program has touched over 750,000 people and provided online consultation to over 150,000 patients via 25 e-clinics. Over 40,000 of incoming patients were treated for NCDs. The program partners with doctors/hospitals in the nearby cities to provide medical consultation services

and adopts a variable cost model at the doctor end (where doctors are compensated on a per-consultation basis) and thereby reducing the fixed cost per clinic (as compared to traditional models of hiring a dedicated doctor/clinic).

2.2.1 e-Clinics

Each e-clinic caters to 20,000 to 25,000 population across 20-25 villages in the catchment area. Each e-doctor clinic is a centre furnished with a laptop, a television to view the doctor during consultation, a web camera for the patient, internet connection, and a printer, along with external speakers. This technical setup is accompanied by clinical equipment for the facility (weighing machine, glucometer, and sphygmomanometer, etc.). All e-clinics are staffed with certified and trained in-house nurses from the local community who act as the first point of contact with the walk-in patient. The nurses are trained to deliver protocol-based high-quality standardised healthcare that addresses specific patient needs. The patients are treated over teleconsultation by qualified medical doctors/specialists during 9 am to 6 pm for six days a week. Medicines are provided through partnered/owned local pharmacies. Blood and urine sample collection facilities are also available at all clinics from where the samples are transported to the nearest diagnostic labs for testing.

2.2.2 Technology platform

The program uses a proprietary software technology that enables online consultation and treatment via an assisted tele-medicine model. The platform includes web-based and mobile applications.

The program's technology platform guides and closely monitors the doctors to ensure optimal quality in care provided. Most doctors provide online consultation from their clinics/homes, thus utilising the excess capacity of doctors. The technology platform, with features like automatic doctor selection, smart triaging system (to ensure optimal utilisation of resources), and queue management system, provides for better patient experience. The technology is supported by a Clinical Decision Support System (CDSS) which ensures proper and standardised care to the patients. Below are the multiple functionalities of the platform:

- Patient registration
- Automatic doctor routing depending on patient load, illness and doctor availability
- Prescription generator using digital signature
- Pricing systems
- Outreach and marketing activity tracker
- Patient review information
- Data analytics for better clinical and operational outcomes
- Technology platform for structured patient history and triaging: The technology platform reduces the chances of human error in the process, right from patient registration, case history to prescription-making. All the important fields such as list of medicines, standard doses, and symptoms are entered by selecting options from the drop-down menus.
- Inventory control: Reduces the situation of stock-out at centres
- Prescription validation systems: Various validation checks such as default dosages, identification of high-risk cases, etc. are in-place. The prescription generated by the nurse appears on the doctor's mobile app who checks the accuracy of the prescription and approves the same.
- Database for patient records that can be tracked and monitored for clinical outcomes, clinical follow ups (if required), post-visit counselling and service quality
- Enables prompt and effective referral services to medical college-associated hospitals from both the public and the private sectors to the patients who need secondary or tertiary levels of care

Nurses app Each nurse is provided a laptop with an inbuilt application that assists them to perform health screening, enter patient records, coordinate appointments with doctors and other providers,

deliver appropriate counselling, and manage work schedules to meet the required targets. In addition, the app also allows the nurses to monitor the door-to-door and camps registrations. Nurses can also maintain/ update drug inventory through this app.

Provider app The provider module is a customised interface created for each of the multiple providers such as general physicians and specialists that manage health of the patients. This application allows for seamless information-sharing on patient's health profiles across provider networks. For example, the doctor web application assists the doctors in seeing EHRs, entering e-prescriptions during teleconsultation, and to communicate with their patients and nurses.

2.2.3 Healthcare Services

2.2.3.1 Community outreach (Case Finding)

For each clinic, there is one CHW, either men or women, from the local community. CHWs provide free screening to the population in their community and identify users with malnutrition or those at risk of diabetes and hypertension, and other conditions through door-to-door surveys and camps. Each CHW is equipped with a point-of-care diagnostic kit, to measure users' health parameters (vitals, anthropometrics and blood sugar), screens 10-12 households per day. On identifying users at-risk of a disease, CHW counsels them about the disease condition using tailor made content, in local language, around health issues and nutrition to educate users to proactively respond to the symptoms and danger signs requiring medical attention. Users are also counselled to visit the e-clinics for a doctor's consultation. They are provided with a referral card which allows them to get a free consultation at the e-clinic during their first visit.

CHWs also conduct community meetings using traditional media along with digital resources such as videos and audio messages together. CHWs are paid an honorarium/incentive for each assigned task.

2.2.3.2 Case management

The e-clinics operated by qualified and trained nurses assist incoming patients in having a real-time consultation with a qualified doctor over an audio-video interface backed by the program's proprietary technology platform.

There are four types of patients visiting the e-doctor clinics vis-à-vis new patients, new patients referred by CHWs after community screening, follow up patients (patients asked to consult with the doctor for their condition within a suggested time frame), over-the-counter patients (patients who are managed by the nurse e.g. wound-dressing, etc). Upon arriving, all incoming patients are met by the nurse who engages with the patients in their local dialect. The nurse records the necessary medical information relevant to the patient such as chief complaints, medical history against a unique patient identifier. Data is also collected on various other parameters such as demographics, socio-economic status, etc. They then measure vital signs and anthropometrics using medical devices. Their records and measurements are electronically captured, stored and retrieved using a password-protected web application. Once the nurse has gathered the data, a face-to-face consultation through video conferencing in real time with a doctor is set up.

Upon recording the patient's medical history and chief complaints, the doctor creates a prescription on the web application that is digitally signed and printed at the e-clinic. After consultation, the patients are counselled by the nurses and doctors on the disease: complications and progression. Finally, this prescription is retrieved at the program owned pharmacy or a partner pharmacy co-located within the clinic. The patient is charged a nominal fee that covers the consultation, diagnostics and medicine costs.

All patients are mandatorily required to be treated by teleconsultation to remove subjectivity in screening of the patients by the nurse at the centre. The nurse-assisted telemedicine approach combines critical human touch (via physically-present nurse) with digital connectivity (online doctor).

To ensure treatment compliance post consultation, patients are given regular reminders on the available digital communication channels such as WhatsApp. For patients who do not own smartphones or are not well versed with the technology, reminders are given over a phone call by the nurses.

2.3 Telemedicine-equipped Mobile Medical Unit-based Model (MMU)

As our third model, we analysed a MMU-based program which provided community-based screening and management of diabetes in rural areas through a combination of telemedicine and personalised care. Established in 2006, the program was supported by the World Diabetes Foundation (Denmark) and the Indian Space Research Organisation (ISRO) in Bengaluru, India. The program was undertaken in a cluster of 42 villages of Chunampet in the Kancheepuram district of Tamil Nadu, India. During the four years of its operation in 2007-2010, the program touched 27,000 people and actively managed over 1,001 patients with diabetes.

The program aimed at improving the diagnosis and management of diabetes through (i) non-physician and CHWs, and (ii) a telemedicine-equipped mobile medical van.

2.3.1 Field workers

Village Health Workers (VHWs), both men and women, are trusted members of the community with high-school qualification. VHWs were selected through referrals from the community. Upon recruitment, they were trained and certified by the program. The VHWs underwent an intensive 15-day training, with further retraining every six months. Some VHWs underwent frequent retraining based on their performance. The training was conducted by the program training team led by a clinician. The VHWs were trained to assess the clinical presentation and risk factors, recordkeeping, and referral scheme for individuals screened as at risk of diabetes.

The program also recruited lab technicians with diplomas or certificate courses in Medical Laboratory and Testing or Nursing. Like VHWs, lab technicians were also selected through referrals from the community. Upon recruitment, each lab technician underwent intensive XX-day training on collecting venous blood samples in the telemedicine van and to take digital retinal photographs, echocardiograms, Doppler images, and biothesiometry measurements for assessment of various diabetes complications.

2.3.2 Telemedicine-equipped mobile medical unit

The MMU van covered one to two villages per day, on one-shift basis. The frequency of the van was planned as per the number of individuals screened as at risk of diabetes from door-to-door screening. Villages with more at risk individuals were more frequently visited by the van as compared to others with a lesser number of at risk individuals.

The van, capable of providing primary health care (PHC) services, was established within an air-conditioned, generator-supported Volvo bus (sized 18 by 8 sq. ft., wheelbase 2286 mm). The van was also equipped with a digital retinal camera, a slit lamp, computerised electrocardiogram (ECG), Doppler imaging, and biothesiometry. It included videoconferencing equipment with a television screen, facilities for blood sampling, along with computers, a laser printer, and basic furniture. The design included a registration area, teleconsultation area, examination area, and a laboratory. The van was staffed with one VHW, one lab technician, and a driver. On an average, the van accommodated two patients in addition to the clinic staff. The remaining patients often had to wait outside. Information from the telemedicine van was transmitted to the tertiary care centre in Chennai through a small aperture terminal satellite.

During the program's operational years, every morning, the driver of the medical van met with the 15 VHWS and the lab technician at the overnight parking facility outside Chunampet rural diabetes centre (*details below*) and drove to the scheduled site (*village*) for the day. At the peripheral sites, the van was parked at commonplace where it was visible and easily accessible to the patients.

2.3.3 Rural diabetes centre

The rural diabetes centre was built in Chumanpet, in proximity to the 42 intervention villages, to provide follow up care for early complications of diabetes to people screened and referred from the van. Additionally, the centre was providing diabetes screening and follow up care to the people in proximity to that location even if they were not a part of the program. The centre was manned by physicians and paramedical staff who were recruited locally. Low-cost generic antidiabetic drugs (both tablets and insulin) were available at the centre. The patients were provided treatment for free if they could not afford to pay. Those with advanced complications of diabetes were referred to the main hospital in Chennai for their treatment.

2.3.4 Healthcare Services

The program undertakes various activities to enable early identification of individuals who are at risk for NCDs and to provide convenient and continuous care for managing NCDs over a longer term.

2.3.4.1 Door-to-door survey (Case Finding)

VHWS conducted a door-to-door diabetes screening at all selected villages (15 VHWS/village) using a handheld glucometer and a structured questionnaire, which included details on demographic and socioeconomic characteristics, health behaviour, knowledge of diabetes and its complications, health status and medical history of the subjects and their families, perception of health, diet, and physical activity. VHWS also measured and recorded anthropometric and blood pressure (in the sitting position in the right arm to the nearest 1 mm Hg). Two blood pressure readings were taken five minutes apart, and the mean of the two was taken as the final reading. The individuals with self-reported diabetes (diagnosed by a physician and on antidiabetic drugs) were identified during data collection of medical history. Individuals who did not report previous history of diabetes, underwent the screening for diabetes. Those with FPG $\geq$ 126 mg/dl ($\geq$ 7 mmol/L) were identified as at risk of diabetes and were referred to the mobile van for a second confirmatory test.

VHWS also provided a mass-scale diabetes awareness program. Various modalities were used to spread diabetes awareness such as family and self-help groups, performing arts, peer-group support, and one-on-one sessions. Self-help groups were trained in the preparation of low-cost recipes for balanced nutrition using locally-sourced food, including fruits and vegetables. Information, education and communication material was distributed regarding adopting a healthy lifestyle. In keeping with local traditions, puppet shows, skits on diabetes, awareness programs for teachers, and diet exhibitions on healthy nutrition for school children and pregnant women were presented. On occasions such as World Diabetes Day, walks for children and special programs on healthy living were organised. Finally, farmers and housewives were taught to grow nutritious vegetables.

2.3.4.2 Mobile van screening for diabetes complications (Case Finding)

Individuals screened as at risk of diabetes by FBG and those with self-reported diabetes underwent screening for diabetes-related complications in the mobile van. Newly identified at-risk individuals were subjected to a 75g oral glucose tolerance test (OGTT) (using venous blood) to confirm the diagnosis. Glycemic control of self-reported diabetes individuals was assessed using hemoglobin A1c.

In addition to the diabetes confirmation, the incoming individuals were screened for several other complications such as retinopathy, neuropathy, and microalbuminuria. These complications were not in the purview of the project's analysis and hence are not discussed in details here.

2.3.4.3 Rural diabetes centre (Case Management)

Newly diagnosed and self-reported individuals with diabetes who were identified through the screening program (door-to-door or mobile van) were referred to a local rural diabetes centre for follow up care. Self-reported diabetes subjects were reassessed for their glucose level using HA1c on their first follow up visit and repeated after one year. Similarly, OGTT was done at the same frequency for newly diagnosed people with diabetes. Electrocardiograms were performed and were interpreted by the onsite diabetologist, who was available for consultation at the local centre six days a week. The follow up care included treatment and monitoring of development of diabetes complications. Individuals requiring laser treatment or patients with advanced diabetic foot, heart or kidney complications requiring further treatment or surgical treatment were referred to the diabetes hospital in Chennai.

3. Methodology

In this study, we sought to compare the cost-effectiveness associated with screening and prevention of diabetes through different delivery models with status-quo (care currently available to the population). The cost of care for each program differed depending on their operational models. Therefore, we collected clinical, operational, and cost data for each program in an attempt to assess the health benefits and healthcare cost reduction associated with different screening and management strategies (**Figure 1**).

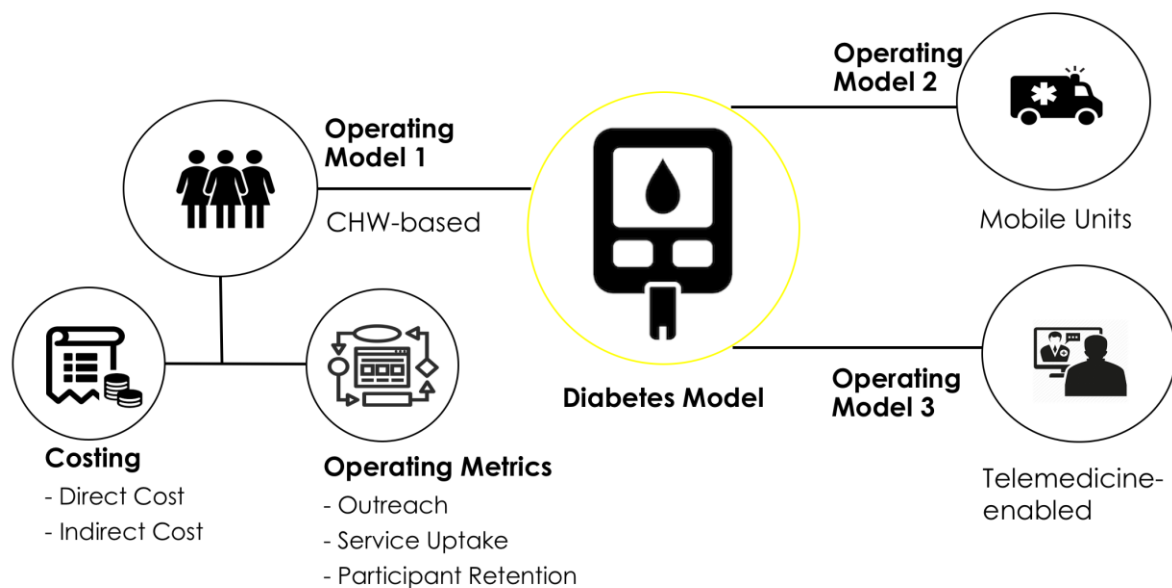


Figure 1: Program data collection approach

3.1 Cost of the delivery models

3.1.1 Costing approach

We conducted a costing exercise for the models under consideration for both the prevention and treatment of diabetes and related complications. This allowed for a comparative study of the models. We calculated the cost per unit of providing health service from a healthcare provider perspective. We adopted an activity-based costing (ABC) approach in the study. ABC is a standard approach that identifies the activities in an organisation and assigns a cost to each activity that goes into overall service or production.

We investigated the cost-driving activities and the time and resource consumption per unit of an activity under this approach. We identified two main activities - screening of an eligible individual and follow-

ups of the enrolled patients in the program after the diagnosis. We identified different cost centres in the CHW, TMU, and MMU models. The most common identified cost centres were personnel cost, capacity-building, consumables, digital equipment, furniture and appliances, infrastructure, and software costs. We identified the relevant cost drivers and various cost components for the diabetes screening method and classified them into direct and indirect costs. Direct costs consist of the expenses of items and services exclusively related to providing the screening services at the facility and community level. It includes the cost of consumables (glucometer, cotton swabs, lancet, glucose test strips, etc.) and personnel costs such as frontline staff salaries. Indirect costs, which were not directly attributed to diabetes management, include multi-program staff salaries, capacity-building training of the recruited staff, depreciation and maintenance costs of medical and office equipment and vehicles, general medical and office supplies (e.g., stationary, syringes, etc.), cost of utilities, rent, and maintenance of physical infrastructure.

3.1.1.1 CHW-based model

The outreach activities in the healthcare delivery structure under CHW model consisted of screening in the communities and follow up of the enrolled patients in the program. We segregated the costs under different cost centres into screening and follow up visit costs. We further classified these costs into direct and indirect costs. Direct costs comprised the expenses directly related to providing the healthcare service to the patients. It included the salaries of field staff and consumables such as test strips, lancet, and cotton swabs. Indirect costs included administrative staff salaries, staff training costs, infrastructure rent, cost of furniture and appliances, maintenance, and software costs.

Under the personnel cost in the CHW-based model, we collected salary and time data of the program staff at different levels, e.g. management, field, office, etc. We collected the data on staff salary, number of employees, working days in a year, and time proportion to diabetes-related activities of each employee under this model. The total salary cost was further allocated between the screening and the follow up visits based on the volume of activities achieved in the reference period (Table 1). The salary cost of employees under screenings and follow up segments was summed and divided by the total number of screenings and follow ups conducted in the reference period to calculate the per unit personnel cost. Except for CHWs, we considered the salary of all other employees under indirect costs. Per-unit personnel cost of a CHW, which is the direct personnel cost, was calculated by an average time spent on completing one screening and the follow up multiplied by per-hour salary of a CHW.

CHWs were trained once every month during the program period. In the selected reference period of one year, there were 12 training sessions of all CHWs in the program. To calculate the per-unit training cost, we took the diabetes-related proportion of the total cost and divided it by the total number of screenings and follow ups. Digital tablet purchasing cost and maintenance changes were first proportionately allocated to diabetes-specific activities and were divided further across activities based on activity volume. We divided the cost of glucometer across activities based on activity volume. The per-unit cost of consumables such as cotton swabs, test strip, and lancet was multiplied by their volume used, and was further allocated between the screening and follow up activities. The cost of IEC materials, software subscription, website maintenance, and promotions that occurred during the reference period were allocated across screenings and follow up activities. The cost of office furniture, appliances, and infrastructure rents were considered under institutional overheads.

We adopt two different methods of cost allocation across the screening and follow up activities. Under the CHW-based model, indirect costs were allocated based on the volume of activities and proportion of each activity out of the total number of activities. Direct medical costs were allocated based on further division across the number of diseases a model manages. We estimated the time spent on the

screening and following up with a patient based on actual time taken for each of these activities by CHW. We further allocated the salary over the activities in proportion to the time taken under the activities. Direct personnel cost was allocated based on time and salary required to achieve per unit of activity. We allocated the indirect costs over the screening and follow ups based on their volume in the reference period. **Table 1** describes the time allocation between the activities under the CHW model.

Coverage of the program		Allocation across activities		
Activities	Numbers	% of Activity Volume	% Allocation to Diabetes	% Allocation between Activities
Number of Screenings	33,057	76.32	50.00	38.16
Number of follow-ups	10,259	23.68	50.00	11.84
Total Number of Activities	43,316	100.00	-	-

Table 1: Summary of Coverage and Time Allocation between the Screening and follow ups under the CHW Model

*Screening includes checkup of hypertension, diabetes, and height-weight measurements, etc.

3.1.1.2 TMU model

TMU model operated through a chain of e-clinics at different locations in Rajasthan and Haryana, which served the rural population in their respective catchment areas. Each e-clinic was staffed by a trained nurse and outreach executive officers to manage field-related activities and routine coordination with patients. The e-clinics were empanelled with in-house doctors for consultations and referral services. On top of that, this model owned one head office to manage the operations of the program.

The cost centres under this model were personnel cost, capacity-building, infrastructure, furniture and appliances, consumables and equipment, software costs and institutional overheads. We collected the data on the cost incurred to run and maintain an e-clinic. It covered the salary of nurses and outreach executive officers, their proportional time spent on diabetes-specific activities, consumables cost, and the total number of screening and follow up conducted in the reference period. Personnel costs under this model were the actual salary of staff under the management, program support staff, front line staff. Except for the salary of the front line, the salaries of all other employees were considered under indirect personnel costs. The cost incurred in the training of the staff was deemed to be an indirect cost. The direct cost of consumables consisted of the cost of glucometer, cotton swabs, lancet, and test strips.

The program used a proprietary software technology that enables online consultation and treatment via an assisted telemedicine model. The platform included web-based applications and mobile applications for the nurse and the provider. The cost occurred on the development and maintenance of these apps was considered under indirect costs and was allocated over the screenings and follow up activities based on their proportionate volume. We considered the infrastructure rent and maintenance costs under indirect costs as institutional overheads. The yearly expenses incurred in water, electricity, stationary, telephone and internet bills, and audit expenses, etc. were also considered under institutional overheads. The overhead costs of all the e-clinics and head office under this model were taken under this cost center. The cost data on furniture and appliances of e-clinics and head office were taken and calculated under this costing. We allocated the costs under different cost centers over the number of diseases which the program manages, and further allocated between diabetes-specific activities. The TMU program coverage and allocation method across activities is presented in **Table 2**.

Coverage of the Program	Allocation Across Activities
-------------------------	------------------------------

Activities	Number s	% of Activity Volume	% Allocation to Diabetes	% Allocation Between Activities
Total Footfall at 25 e-clinics	26000	-	-	-
Number of diabetes screenings in one year of the study period	3215	81.87	12.37	10.12
Number of people diagnosed as diabetic	330	-	-	-
Number of diabetes follow-ups in one year of the study period	712	18.13	-	2.24
Total number of diabetes related activities in year of the Study Period	3927	100.00	-	-

Table 2: Summary of Coverage and Time Allocation between the Screening and follow ups under the TMU Model

3.1.1.3 MMU Model

The MMU based model provided community-based screening and management of diabetes in rural areas through a combination of telemedicine and personalised care. The program flow started from door-to-door screenings by VHWs in 42 villages. Data on salaries of a VHW, average working hours and total working days in a year, average time required to complete one door-to-door visit, average number of households reached in a day by VHWs, travel cost to the target village on daily basis, cost of consumables, etc. were collected to calculate the per-unit screening cost. The purchasing cost of the van, average years the van can function, per day running and maintenance cost, and personnel costs in the van were considered under the screening costs. Van personnel included a lab technician, driver, optometrist, ECG technician, and a biothesiometry technician. Except for the lab technician, salaries of all other van personnel were considered under indirect personnel costs. Those who were found diabetic during the initial screening were tested again for glucose tolerance (OGTT) and HbA1c in the telemedicine van. The cost of these tests was considered under direct medical cost of consumables along with other consumables used in door-to-door screenings.

We calculated the costs till the follow up care level and excluded the costs incurred in screenings for the complication of diabetes. Patients with diagnosed diabetes during door-to-door screenings received follow up care at the rural health clinic. We collected the data on salaries of staff at the rural health clinic, infrastructure cost, consumables, overheads, etc. to calculate the per-unit follow up cost. We collected the salary data of program staff which included management, finance, IT related staff. The salary cost of program level staff was considered under indirect personnel cost and was allocated across activities based on activity volume. We collected the data on expenses incurred under IEC materials, software, website development and maintenance during the program period. The total software and website costs were divided by the total number of activities and was allocated across activities based on activity volume. The coverage of the program and time allocation across activities is given in table 3.

Coverage of the Program		Allocation across activities	
Activities	Number s	% of Activity Volume	% Allocation between activities
Number of Diabetes D2D Screenings in a year	7800	88.63	-
Total Number of Follow-ups at Rural Healthcare Center (RHC)	6300	-	-
Total Number Follow-ups of Diabetic Patients at RHC Who were D2D Screened	1001	11.37	15.89
Total Number of Activities	8801	-	-

Table 3: Summary of Coverage and Time Allocation between the Screening and follow ups under the MMU Model

3.2 Modelling approach

We developed a cohort-based Markov model to estimate costs and disability-adjusted life years over a period of 20 years with a cycle time of one month. We ran the model for 8 age- and sex-stratified cohorts: men and women aged 50, 55, 60 and 65 years, and each cohort consisted of 10,000 individuals. The diabetes prevalence and smoking behaviour for each cohort was derived from existing studies [12, 13]. We conducted the analysis from the perspective of the government as a payor that allocates a budget for such intervention, and the outcome measure was incremental cost per DALY averted (represented as incremental cost effectiveness ratio or ICER). The model was developed using R and TreeAge software (TreeAge Inc, Williamstown, MA).

Every individual faced a risk of either Myocardial Infarction or Stroke (together termed as CVDs). Within each cohort, an individual with no history of diabetes had a lower risk of a CVD event compared to an individual with diabetes. Similarly, an individual with diabetes having controlled FBG level (<7 mmol/L) had a lower risk of CVD event compared to an individual with uncontrolled FBG (≥ 7 mmol/L). After a CVD event, the individual might either die within the first month (fatal CVD event), or stay alive (non-fatal CVD event). Individuals with a CVD history have a higher risk of death compared to the individuals without CVDs. We also model the occurrence of non-CVD-related deaths among individuals.

Each cohort was characterised by individuals with distinct health profiles. Health profiles were defined based on the following components: whether the individuals' status is known (as a result of either previous screening or symptom-based case finding) or unknown, whether the individual with known status is on previous treatment. The model then tracked cohorts who were at risk of diabetes complications with regards to their health profile. Each cohort had individuals with controlled FBG and uncontrolled FBG at baseline. Therefore, all individuals within each cohort started the first cycle in either of the two states i.e. controlled or uncontrolled FBG. Individuals who start at controlled FBG state may stay in this state or progress to the corresponding Markov states during the next cycles based on their risks. We modelled five health states for the analysis: Well (Healthy and Diabetic), CVD event (MI or stroke), alive with stroke, alive with MI and death. The possible transitions are illustrated in **Figure 2**. Diabetic individuals are considered in the well state and could either have controlled or uncontrolled blood sugar levels. The transition of diabetic individuals from controlled to uncontrolled blood sugar is provided in Table 2.

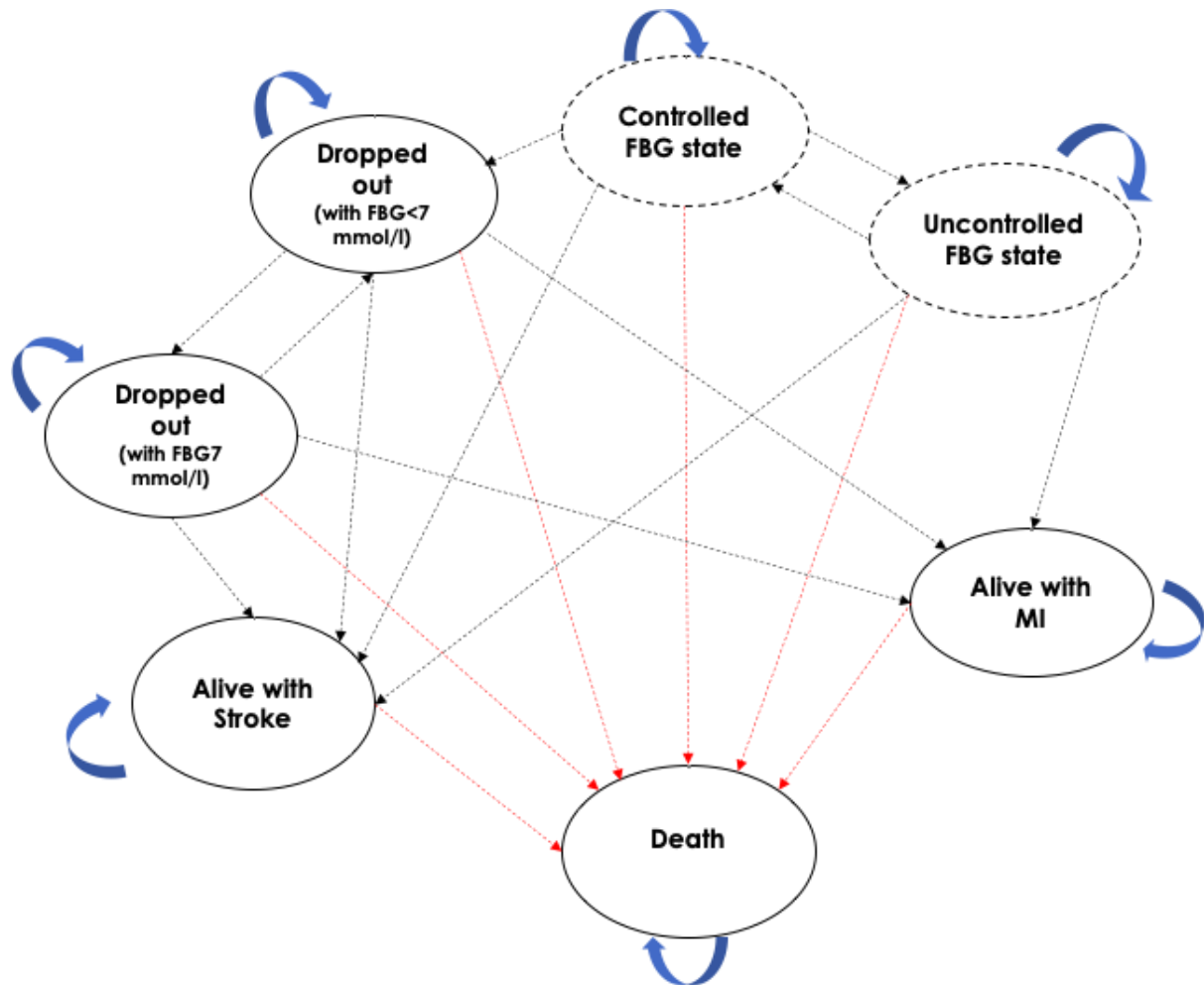


Figure 2: Markov state-transition model

3.2.2 Strategies modeled

Using a Markov model simulation, we compared the cost-effectiveness of status-quo with each of the three models under analysis. The delivery models were defined based on the cases studied and were then developed. The differences in the models were on various parameters such as program cost per patient, coverage of the model, affordability of treatment, population profile, and more. These underlying differences lead to varying degrees of the target population's knowledge of diabetic status, treatment initiation, and treatment continuation.

Status-quo: This represented a scenario where there was no active diabetes screening and management in the community and people sought care in the public/private health sector. The population in this arm comprised healthy individuals and those with diabetes (8%). Among individuals with diabetes, 42.5% sought care from the existing public/private sector while remaining 57.5% either refused to seek care or were unaware of their diabetic status. [14] Based on data from one of the organizations we studied, among those who sought treatment, 30.2% of the individuals had glycemic control. These estimates are conservative in our study as other trials in India suggest a lower proportion with controlled FBG. [15, 16, 17] For individuals who refused to seek care, we assumed 100% had uncontrolled FBG at baseline. For a healthy population, we assumed that 100% had controlled FBG at baseline.

Based on existing literature, we considered the proportion of individuals among those treated (routine care) with controlled sugar as 21%. The transition probabilities were calculated under this assumption of steady state probability.

CHW model: From 2015-2017, CHWs under the program screened 51,126 individuals, which contributed to 2% of the outreach population under the program. Of those screened, 51% were found at risk of diabetes. Among those screened as at-risk, 32% had a previous history of disease and 30% were seeking treatment for the same. Almost one-third (29%) of those on previous treatment enrolled for the *disease management plan* and 71% continued to seek treatment from their existing provider (i.e. sought routine care). Similarly, among those with previous history and not seeking previous treatment, 12% enrolled on the plan while 82% refused to seek care. It was observed that 30% of the individuals on previous treatment who enrolled on the plan had controlled FBG at baseline. For individuals who sought routine care, the fraction with controlled or uncontrolled FBG at baseline was assumed to be the same as that for status-quo arm.

Of the total screened, 68% individuals were diagnosed with diabetes under the program. Among these, 3% enrolled on the *disease management plan*, 24% chose to seek care from other providers (i.e. routine care), and 73% refused to seek care. It was observed that 30.2% of the newly diagnosed individuals had controlled FBG at baseline. For individuals who sought routine care or refused care, the fraction with controlled and uncontrolled FBG at baseline was assumed to be the same as that for status-quo arm.

TMU model: From July 2019 to 2020, 3,542 walk-in individuals sought teleconsultation under the program. Of these, 1,118 were diagnosed with diabetes or were at risk of developing diabetes-related complications. Of the total walk-ins with diabetes, 332 individuals continued on the program for diabetes management. It was observed that 29% of the individuals on previous treatment, who enrolled on the plan, had controlled FBG at baseline. For individuals seeking routine care or refused care, the fraction with controlled or uncontrolled FBG at baseline was assumed to be the same as that for status-quo arm. We considered no dropouts from the program once enrolled since the quality of care provided was better, and the cost of care was lower than routine care.

MMU model: From 2007-2010, VHWs under the program screened 23,380 individuals, which contributed to 86.5% of the outreach population under the program. Of those screened, 3.42% had a previous history of disease (defined as self-reported). All self-reported individuals stayed with the program for diabetes management.

Of the total screened, 1.4% individuals were diagnosed with diabetes under the program. Among these, 58.5% stayed with the program for diabetes management and 41.5% refused to seek care. It was observed that XX% of the newly diagnosed individuals had controlled FBG at baseline. For individuals who sought routine care, the fraction with controlled or uncontrolled FBG at baseline was assumed to be the same as that for status-quo arm.

3.3 Probabilities

3.3.1 Transition Probabilities

3.3.3.1 Clinical effectiveness

We characterised each model by estimating the probability of an individual to have either controlled or uncontrolled FBG concentration. These probabilities were conditional on having FBG as either controlled or uncontrolled in the previous month. **Table 4** is an illustrative example of capturing the clinical effectiveness of each model.

Previous\Current	Controlled FBG (C_t)	Uncontrolled FBG (U_t)
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Controlled FBG (C_{t-1})	Prob ($C_t C_{t-1}$)	Prob ($U_t C_{t-1}$)
Uncontrolled FBG (U_{t-1})	Prob ($C_t U_{t-1}$)	Prob ($U_t U_{t-1}$)

Table 4: Illustrative example to characterize each model based on clinical effectiveness

The probability of having controlled sugar levels conditional to the status in the previous month is provided below (**Table 5**). The probability values for each model were calculated using their clinical data in STATA 15.0.

	Prob ($C_t C_{t-1}$)	Prob ($U_t C_{t-1}$)	Prob ($C_t U_{t-1}$)	Prob ($U_t U_{t-1}$)
Refuse Care or Not aware	0	1	0	1
Routine Care	0.302	0.698	0.185	0.815
CHW Care	0.66	0.34	0.16	0.84
TMU Care	0.569	0.431	0.27	0.73
MMU Care				

Table 5: Transition probabilities for the different models

3.3.3.2 Risk of a CVD Event

The risk of a CVD event was determined using algorithms based on the World Health Organization/ International Society for Hypertension (WHO/ISH) risk laboratory-based charts for India under South Asian. [18] The chart provides the 10y probability of CVD based on age, sex, smoking status, level of blood cholesterol, BP, and absence or presence of diabetes. We converted the 10y probabilities to monthly probability of the CVD event assuming a constant hazard over the 10-year period. [19] We calculated the risk of a CVD event for each cohort in the model, every five years, to incorporate the effect of increase in age. (**Table 6**).

Age group	Men		Women	
	Non-smoker	Smoker	Non-Smoker	Smoker
50-54	0.09	0.14	0.07	0.14
55-59	0.11	0.17	0.09	0.17
60-64	0.14	0.20	0.12	0.19
65-69	0.17	0.24	0.15	0.22

Table 6: 10y risk of CVD among people with diabetes (in %)

The occurrence of MI upon a CVD event (**Table 7**) was calculated by averaging the observed ratio of incidence of MI in the GBD 2017 study during 2012-17 for each age group. [20] For example, the MI to Stroke CVD ratio in males of age group 50-54 years was calculated to be 0.517.

Age group	Men	Women
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50-54	0.517	0.421
55-59	0.547	0.456
60-64	0.578	0.5035
65-69	0.599	0.5435

Table 7: Age and sex-specific probability proportion of MI to Stroke upon CVD event

3.3.3.3 Risk of Myocardial Infarction (MI) among people with diabetes

The risk of MI was calculated separately for people with diabetes having FBG <7 mmol/L at baseline and for those with FBG ≥7 mmol/L.

The risk of non-fatal MI in people having diabetes with FBG ≥7 mmol/L (**Table 8**) was derived by multiplying the monthly CVD risk with the ratio of MI upon CVD (equation 2).

$$Eq\ 2: Risk\ of\ MI_{(FBG \geq 7\ mmol/L)} = CVD_{(monthly\ risk)} \times MI_{(proportion\ of\ CVD)}$$

The risk of non-fatal MI in people having diabetes with FBG <7 mmol/L (**Table 8**) was derived from HR based on a meta-analysis of 102 prospective studies. [21] The meta-analysis study estimated HR of 1.61 for non-fatal MI in people with diabetes and FBG <7 mmol/L as compared to people with no history of diabetes and FBG concentration of 3.9-5.59 mmol/L at baseline (equation 3).

$$Eq.\ 3: Risk\ of\ MI_{(FBG < 7\ mmol/L)} = \frac{Risk\ of\ MI_{(FBG \geq 7\ mmol/L)}}{HR\ MI_{(FBG < 7\ mmol/L)}}$$

Age group	Men				Women			
	Non-Smoker		Smoker		Non-Smoker		Smoker	
	FBG <7 mmol/L	FBG ≥7mmol/L	FBG <7 mmol/L	FBG ≥7 mmol/L	FBG <7 mmol/L	FBG ≥7 mmol/L	FBG <7 mmol/L	FBG ≥7 mmol/L
50-54	0.028	0.041	0.044	0.065	0.017	0.025	0.036	0.053
55-59	0.036	0.053	0.058	0.085	0.024	0.036	0.048	0.071
60-64	0.050	0.073	0.073	0.107	0.037	0.054	0.060	0.088
65-69	0.063	0.093	0.093	0.137	0.050	0.074	0.077	0.112

Table 8: Age and gender-specific probabilities of MI (in %)

3.3.3.4 Risk of Myocardial Infarction (MI) among healthy people with no history of diabetes

The risk of non-fatal MI in people with no history of diabetes (FBG <7 mmol/L) (**Table 9**) was derived from absolute risk and an estimated HR of 2.36, as applicable for non-fatal MI in people having diabetes with FBG ≥7 mmol/L (equation 4).

$$Eq\ 4: Risk\ of\ MI_{(healthy)} = \frac{Risk\ of\ MI_{(FBG \geq 7\ mmol/L)}}{HR\ MI_{(FBG \geq 7\ mmol/L)}}$$

Age group	Men		Women	
	Non-Smoker	Smoker	Non-Smoker	Smoker
	FBG <7 mmol/L	FBG <7 mmol/L	FBG <7 mmol/L	FBG <7 mmol/L
50-54	0.017	0.028	0.011	0.022
55-59	0.022	0.036	0.015	0.030

60-64	0.031	0.046	0.023	0.037
65-69	0.039	0.058	0.031	0.048

Table 9: Age and gender-specific probabilities of MI among people with no history of diabetes (in %)

3.3.3.5 Risk of Stroke among people with diabetes

Similar to the risk of MI, the risk of stroke was also calculated separately for people having diabetes with FBG <7 mmol/L at baselines and for those with FBG ≥7 mmol/L. The risk of non-fatal stroke in people having diabetes with FBG ≥7 mmol/L (**Table 10**) was derived by subtracting RR of MI in people having diabetes with FBG ≥7 mmol/L from the monthly CVD risk (equation 5).

$$\text{Eq. 5: Risk of Stroke}_{(\text{FBG} \geq 7 \text{ mmol/L})} = \text{Risk of CVD}_{(\text{monthly})} - \text{Risk of MI}_{(\text{FBG} \geq 7 \text{ mmol/L})}$$

For our analysis, we assumed the HR of non-fatal MI and non-fatal stroke to be equal. Therefore, the risk of non-fatal stroke in people having diabetes with FBG <7 mmol/L (**Table 10**) was also derived from the estimated HR of 1.61 and the risk of non-fatal stroke among people with no history of diabetes (equation 6).

$$\text{Eq. 6: Risk of Stroke}_{(\text{FBG} < 7 \text{ mmol/L})} = \text{Risk of Stroke}_{(\text{healthy})} \times \text{HR Stroke}_{(\text{FBG} < 7 \text{ mmol/L})}$$

Age group	Men				Women			
	Non-Smoker		Smoker		Non-Smoker		Smoker	
	FBG <7 mmol/L	FBG ≥7 mmol/L	FBG <7 mmol/L	FBG ≥7 mmol/L	FBG <7 mmol/L	FBG ≥7 mmol/L	FBG <7 mmol/L	FBG ≥7 mmol/L
50-54	0.026	0.038	0.041	0.061	0.024	0.035	0.050	0.073
55-59	0.030	0.044	0.048	0.070	0.029	0.043	0.058	0.084
60-64	0.036	0.053	0.053	0.078	0.036	0.053	0.059	0.087
65-69	0.042	0.062	0.062	0.092	0.042	0.062	0.064	0.094

Table 10: Age and gender-specific probabilities of stroke (in %)

3.3.3.6 Risk of Stroke among people without diabetes

The risk of non-fatal stroke in people with no history of diabetes (FBG <7 mmol/L) (**Table 11**) was derived from the risk and the estimated HR (of 2.36) of non-fatal MI in people having diabetes with FBG ≥7 mmol/L (equation 7).

$$\text{Eq 7: Risk of MI}_{(\text{healthy})} = \frac{\text{Risk of MI}_{(\text{FBG} \geq 7 \text{ mmol/L})}}{\text{HR MI}_{(\text{FBG} \geq 7 \text{ mmol/L})}}$$

Age group	Men		Women	
	Non-Smoker	Smoker	Non-Smoker	Smoker
	FBG <7 mmol/L	FBG <7 mmol/L	FBG <7 mmol/L	FBG <7 mmol/L
50-54	0.016	0.026	0.015	0.031
55-59	0.019	0.030	0.018	0.036
60-64	0.022	0.033	0.022	0.037
65-69	0.026	0.039	0.026	0.040

Table 11: Age and gender-specific probabilities of stroke among people with no history of diabetes (in %)

3.3.3.7. Risk of death post CVD event

Post CVD event, an individual can experience fatality within the first month, also known as a fatal CVD event. If the individual survives the first month post the CVD event, s/he experiences a higher risk of death compared to the risk of all-cause death among individuals in Healthy state. We calibrated the values for risk of death post MI or stroke such that the model-estimated mortality matches the observed mortality of death in 2017 from the GBD 2017 study. [20] We present the calibrated monthly probability of death in **Tables 12 and 13**.

Age group	Women		Men	
	MI	Stroke	MI	Stroke
50-54	0.0132		0.0330	
55-59	0.0188	0.1188	0.0470	0.1262
60-64	0.0188		0.0470	
65-69	0.0356		0.0890	

Table 12: Age and sex-specific 30-day probability of death after myocardial infarction and stroke

Age group	Women		Men	
	MI	Stroke	MI	Stroke
50-54	0.002155	0.001456	0.005786	0.002398
55-59	0.002562	0.001622	0.006085	0.003196
60-64	0.002969	0.001747	0.006085	0.003894
65-69	0.003317	0.002120	0.006980	0.005288

Table 13: Age and sex-specific monthly probability of death for non-fatal myocardial infarction and stroke

3.3.3.8 Risk of a non-CVD Death

The probability of all-cause deaths for India was retrieved from WHO's Global Health Data repository. [22] Further, the proportion of non-CVD deaths to all-cause deaths was determined by annual death data from GBD 2017 across 2012-17. [20] We, thus, calculated the monthly probability of non-CVD deaths in India (**Table 14**).

Age group	Female*	Male*
50-54	0.000381-0.000389	0.000568-0.000579
55-59	0.000544-0.000554	0.000834-0.000849
60-64	0.001013-0.001026	0.001224-0.001245
65-69	0.001658-0.001679	0.002029-0.002058

Table 14: Age and sex-specific 30-day probability of death after myocardial infarction and stroke

3.4 Disability weights

We calculated DALYs using disability weight values from the Global Burden of Disease Study (**Table 15**). [23] We included only the health loss and did not include any wage or productivity loss.

3.5 Cost of drugs, cost of annual, post-event care data

3.5.1 Cost of diabetes medication

In our model, we simulated the triple-therapy treatment for glycemic control, recommended when combination of a glucose-lowering drug with metformin is not sufficiently effective to reach or maintain the HbA1c target. [24] This option was chosen because almost half of the individuals who joined either of the program had previous history of diabetes i.e. they switched from their previous provider to join the intervention, presumably due to unsatisfactory health outcomes. This could mean that they found their previous treatment to be ineffective in controlling their blood glucose. In addition, the median FBG

at baseline among all participants across models was found to be more than 126 mg/dl: CHW, 141.5 mg/dl (110.0, 205.0); and TMU, 153.0 mg/dl (125.0, 190.0). The data was not available for the MMU model. We modelled the cost for metformin 500 mg daily, sulfonylurea gliclazide 80 mg daily, and NPH insulin with a dose of 0.5 IU/kg body weight to simulate the typical dose required to achieve A1c target of <7% (**Table 15**).

3.5.2 Cost of CVD medication

We simulated the following recommended treatments: statin treatment with simvastatin 20 mg and blood pressure-lowering agents (Aspirin 50 mg, Atenolol 50 mg; Lisinopril 10 mg) (**Table 15**). We assumed 50% of patients were on a single dosage regimen, and the remaining proportion were on double dosage [25].

3.5.3 Cost of post-event care (service cost)

The cost of acute CVD care included consultation, hospital room costs, procedures, and medication, and the cost of chronic CVD care included outpatient consultation cost and chronic medication cost. The values were based on data from WHO CHOosing Interventions that are Cost-Effective (WHO-CHOICE) [26], and calculated by a previous cost-effectiveness study by Lin et al. [25] All individuals with chronic CVD incurred CVD medication costs (**Table 15**).

Drug costs for therapy were based on per-unit buyer cost estimates from the International Drug Price Indicator Guide, [27] and assay and service cost data based on published literature. We expressed all costs in 2019 US dollars. All costs were scaled to the year 2020 with an inflation factor of 3%.[28]

Input Indicators	
Disability weights	
MI event	0.432
Stroke event	0.57
Living with history of MI	0.08
Living with history of stroke	0.135
Deceased	1
Cost Parameters (\$)	
Cost of CVD medication (\$)	
Retail cost per 1.5 pill of Aspirin 75 mg (dose 1.5/day)	0.0057
Retail cost per 1.5 pill of Atenolol 50 mg (dose 1.5/day)	0.036

Retail cost per 1.5 pill retail cost of Simvastatin 20 mg (dose 1.5/day)	0.3
Retail cost per 1.5 pill of Lisinopril 10 mg	0.255
Cost of diabetes medication (\$)	
Retail cost per pill of Metformin 1000 mg/person/month	0.69
Retail cost per pill of Gliclazide 80 mg/person/month	1.43
Retail cost per pill of NPH insulin + supplies*/person/month	28.02
Cost of medical care (\$)	
Cost of MI acute care/event	664.35
Cost of MI post-event annual care/person/month	6.78
Cost of stroke acute care/event	909.49
Cost of stroke post-event annual care/person/month	68.24
Cost of HbA1c testing, monitoring, and drug titration	9.01
Discount Rate (monthly)	0.0025

Table 15: Disability and cost input

MI=Myocardial Infarction, NPH insulin=Neutral Protamine Hagedorn insulin

3.6 Thresholds

We used country-specific gross domestic product (GDP) per-capita threshold as per WHO guidelines [29] to interpret the ICER for all interventions evaluated in this review, as listed below.

- Highly cost-effective: $ICER < 1 \times \text{GDP per capita per DALY averted}$
- Cost-effective: $1-3 \times \text{GDP per capita per DALYs averted}$
- Not cost-effective: $ICER > 3 \times \text{GDP per capita per DALYs averted}$

Interventions that result in a negative incremental health effect were regarded as dominated strategy and no ICER was reported. Interventions with negative incremental cost and positive incremental health effects were regarded as dominant strategy. ICER was not reported for either dominated or dominant strategies. We considered India's per-capita GDP at US \$2338 based on International Monetary Fund projections for 2020.

3.7 Ethics Approval

The ethics approval (ISB-IRB 2020-06) for the analysis was obtained from the Institutional Review Board at Indian School of Business. We followed the CHEERS guidelines for conducting the cost-effectiveness study.

4. Results

4.1 Cost results

The total cost (in INR) of the different models at their current scale of operations is provided in **Table 16**. The CHW based model screened 3,3057 individuals in a year in the study reference period and conducted 10,259 follow-up visits to those who enrolled in the plan. The screenings accounted for 76.32% and follow-up 23.68% of the total activities (**Table 1**). As the CHW model manages both hypertension and diabetes at an equal scale, 50% time was allocated to calculate costs specific to diabetes. The proportion cost to diabetes under each cost center is given in **Table 16**. In the TMU model, there were only 3,542 diabetes screenings conducted in e-clinics in one year of the study reference period. Of those diagnosed with diabetes continued to seek follow-up care from e-clinics accounting to a total of 712 follow-up visits. Under, TMU model screenings accounted for 83.26% and follow-ups 16.74% of the total number of activities. Of the total walk-in patients, 13.62% contributed to those who sought diabetes related care. Further, costs under different cost centers (described above in section 3.1.1) were proportionally calculated based on this and are presented in **Table 16**. Segregation of costs under screenings and follow-ups was done based on the volume of each activity. Across models, we observed that the personnel cost contributed to the largest fraction of the total cost, ranging 65% to 78%. Whereas, costs under capacity building, consumables, and furniture and appliances contributed to the smallest fraction of the total cost.

Cost Centers	CHW		TMU		MMU
	Screening (N=33057)	Follow-up (N=10259)	Screening (N=3542)	Follow-up (N=712)	Screening (N=7800)
Personnel Cost	3730535	861812	2134143	472631	2171465
Capacity Building	549475	170525	28346	6277	10000
Infrastructure	-	-	309777	68604	543750
Office Furniture and Appliances	-	-	63788	14127	-
Consumables and Digital Equipment	256981	79752	26144	5790	296790
IEC and Software Costs	37882	12618	71042	32835	4431
Institutional Overheads	686231	168706	104373	23115	306900
Total Cost (INR)	5,261,103	1,293,414	2,737,612	623,379	3,333,336

Table 16. Cost Centers and Total Costs of Healthcare Delivery under Selected Models

We also determined the unit cost of each model under the assumption that each model achieved 30,000 screenings in a year. The cost for screening and follow-up were separated into direct and indirect costs, and the values in INR are provided in **Table 17**. Compared to the CHW and MMU model, the direct personnel cost (which includes the cost of healthcare providers) was highest for TMU. This is because TMU was the only model which had doctors on their payroll. Doctors empanelled with TMU model, had to be online on the platform for 20% of their work time daily. This was done to ensure quality services. Compared to the TMU and MMU model, CHW model had the highest per unit capacity building cost. This is because the model held refresher training for it's CHWs on a monthly basis. Unlike TMU and MMU models, the CHW model didn't have any physical infrastructure and thus had the lowest per unit screening cost. Per unit cost of consumables and digital equipment was highest for the MMU model. The cost details under each component across all the three models is provided in **Annexure Table 1**.

Cost Centres	CHW				TMU				MMU	
	Screening		Follow-up		Screening		Follow-up		Screening	
	Direct Costs	Indirect Costs	Direct Costs	Indirect Costs	Direct Costs	Indirect Costs	Direct Costs	Indirect Costs	Direct Costs	Indirect Costs

Personnel Cost	54.91	63.24	26.07	63.24	173.87	24.00	244.16	33.70	74.20	9.44
Capacity Building	0.00	40.00	0.00	40.00	0.00	0.88	0.00	1.24	1.11	0.00
Infrastructure	0.00	0.00	0.00	0.00	0.00	16.78	0.00	23.56	72.50	0.00
Consumables and Digital Equipment	6.09	4.25	6.09	4.25	0.78	0.00	1.09	0.00	214.58	0.00
Office Furniture and Appliances	0.00	0.00	0.00	0.00	0.00	3.91	0.00	5.50	0.00	0.00
IEC and Software Costs	0.00	1.26	0.00	1.26	1.06	2.04	12.37	2.87	0.00	0.15
Institutional Overheads	0.00	25.46	0.00	21.14	0.00	6.61	0.00	9.28	0.00	45.02
Per-Unit Cost	61.00	134.21	32.15	129.88	175.70	54.21	257.62	76.13	362.39	54.61
Unit Cost – Direct + Indirect (INR)	195.21		162.04		229.92		333.75		417	

Table 17. Cost centres and per unit healthcare delivery costs under selected models

4.2 Cost-effectiveness

4.2.1 CHW-based vs. Status quo

Over 20 years, the CHW model was not cost-effective across all cohorts (**Table 18**). Across all cohorts, the CHW model resulted in fewer DALYs. Among 50 year old males, 0.0043% DALYs were averted whereas among 65 years old males, 0.0031% DALYs were averted. The ICERs improved as the age of the cohort increased with 50 year old females with ICER of \$245,361 and 65 year old females with ICER of \$144,675. The costs and DALYs are plotted across the cohorts in Figure 3.

Sex	Age	Incremental Cost (%)	DALYs Averted (%)	ICER (\$ / DALYs Averted)
F	50	1.890	0.0043	245361
F	55	1.581	0.0035	198537
F	60	1.382	0.0030	161861
F	65	1.292	0.0027	144675
M	50	1.435	0.0053	159820
M	55	1.239	0.0042	138504
M	60	1.124	0.0035	122458
M	65	1.060	0.0031	112483

Table 18: Costs and health outcomes comparing CHW model with status quo associated across 8 cohorts from 2020-40.

4.2.2 TMU vs. Status quo

Over 20 years, the TMU model was not cost-effective across all cohorts (**Table 19**). Across all cohorts, the TMU model resulted in fewer DALYs. Among 50 year old males, 0.0047% DALYs were averted whereas among 65 years old males, 0.0028% DALYs were averted. The ICERs improved as the age of the cohort increased with 50 year old females with ICER of \$104,841 and 65 year old females with ICER of \$61,371.

Sex	Age	Increment Cost (%)	DALYs Averted (%)	ICER
F	50	0.735	0.0039	104841

F	55	0.615	0.0033	83114
F	60	0.538	0.0028	67890
F	65	0.503	0.0025	61371
M	50	0.558	0.0047	70625
M	55	0.482	0.0038	60096
M	60	0.438	0.0031	52779
M	65	0.413	0.0028	48786

Table 19: Costs and health outcomes comparing TMU model with status quo associated across 8 cohorts from 2020-40.

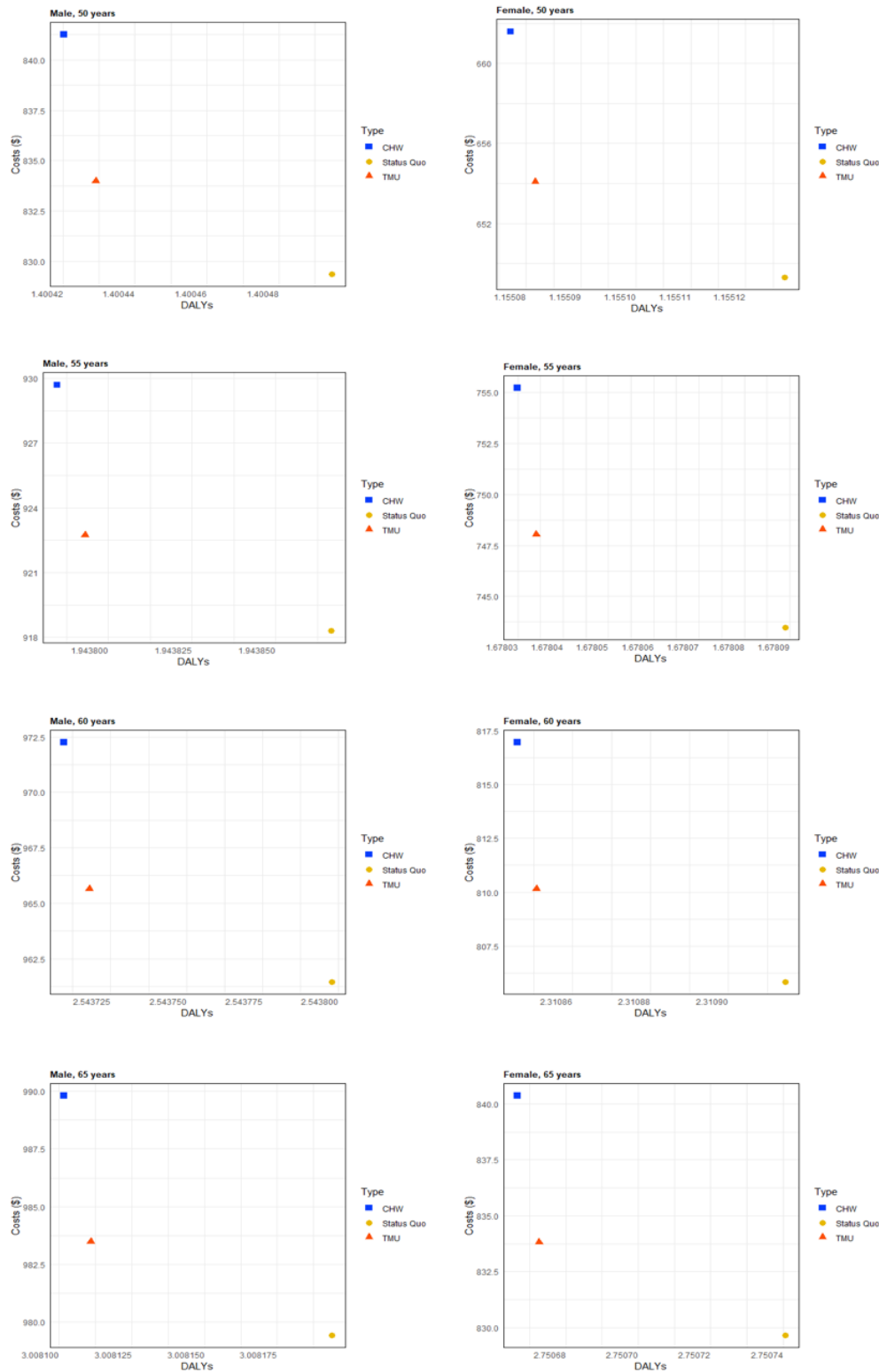


Figure 3: Comparison of costs and DALYs incurred per person across the three models for the different cohorts.

5. Discussion and Conclusion

In the study, we aimed to understand three delivery models for improving diabetes care, and determine if the models were cost-effective in improving health outcomes. We studied three models of providing care, based on ongoing or completed pilot initiatives undertaken in India. The first model (CHW model) leveraged community health workers to provide door-to-door screening for diabetes, and offered a diabetes management program to those screened as diabetes. In the second model (TMU model), e-clinics were set up to provide screening and care to any individual visiting the clinic. The consultation services were provided through teleconsultation. The third model (MMU model) provided door-to-door screening services through mobile units, and provided follow-up care to diabetic patients through rural diabetes centres.

We find that the CHW model was not cost-effective across cohorts. While the model improved health outcomes, the high screening and follow-up cost makes it not-effective, with the lowest ICER value of \$112,483 among males aged 65 years old. Though the model increases status awareness among individuals who were previously unaware, more than 70% of such individuals did not pursue diabetes care, and thus the benefit of increased screening is very marginal. For example, in our sensitivity analysis, with 8% coverage of screening rather than current 2%, the ICERs didn't improve. Also, the model has very poor retention of patients on the plan, and thus the quality of care obtained by the patients remains almost the same. In our sensitivity analysis, when we considered no one drops out from the disease management plan, the ICERs improved by 25%, but still was not cost-effective with an ICER of above \$90,000 for all cohorts. The underlying reason for poor ICERs is that the disease management plan increases the proportion of individuals with controlled blood glucose marginally, with the routine care at 21% of individuals with glycemic control and CHW-care at 28%. This could be because most individuals who enrolled in the CHW program had a previous history of diabetes with a larger fraction having uncontrolled FBG. This could imply that individuals enrolling in the CHW program were sicker compared to those soughting routine care.

Over 20 years, the TMU model was not cost-effective across cohorts. The model improved health outcomes across all cohorts, but the ICERs were consistently higher than the cost-effective threshold of \$6,600 / DALY averted. The 65 year old Male cohort had the lowest ICER of \$48,766. The model has no dropouts and is better at controlling blood glucose of individuals enrolled in the plan. The long-term proportion of patients with controlled blood glucose was estimated at 38.5%. Similar to the CHW model, the TMU model has low coverage of 1.7% only. In our sensitivity analysis of increased coverage of 8%, the ICERs improved marginally, but remained not cost-effective. The incremental cost observed for the TMU model was lower due to the lower follow-up cost for patients. While the cost incurred by the intervention is higher than the CHW model, it covers doctor consultation as well, and thus reduces the costs incurred by the patients beyond the program. This is the underlying reason for a better cost-effectiveness of the TMU model compared to the CHW model.

It is important to note that while the interventions are not cost-effective, they hold promise. Both the CMU and TMU model improve health outcomes and can be worth pursuing if we can either reduce the cost of intervention or improve the health outcomes further. The cost of medication for diabetes are out-of-pocket expenditures, and could be an important reason for discontinuation of treatment. [30] If such costs are covered by an external payor such as an insurance program, the health outcomes could improve further. Also, the model coverage needs to be improved to get a greater number of individuals under treatment. This would require both financial and operational support for the implementers. A government agency can fulfill both the roles as it can reduce the out-of-pocket expenditure for patients, and help the models reach scale. Further, these models can then be implemented within the ambit of public health infrastructure to improve health outcomes among patients accessing care at public health facilities. As India moves towards universal health coverage through the Ayushman Bharat initiative, the expenditure of the government exchequer is poised to increase. With a growing disease burden in

India, without preventive care, the expenditure will increase with time as well. Both the CHW and TMU model lead to a reduction in CVD expenditure. If the involvement of a payor can further reduce out-of-pocket expenditure, it will improve healthcare equity as well.

Our study has limitations. Due to paucity of data, we didn't model the risk of complications such as nephropathy, retinopathy and other microvascular complications. Inclusion of such events would improve the cost-effectiveness of the models but it is unlikely to make them cost-effective as cardiovascular complications comprise more than 75% of the complication events due to diabetes [31]. We estimated the transition probabilities for routine care under the assumption that the transitional probability of individuals with diabetes is the same as that observed among individuals when enrolled in the CHW model. The assumption might not hold true if the characteristics of the individuals with diabetes is different than those enrolling in CHW care. Also, we didn't consider any side effects of diabetes care, and the resulting discontinuation of care. Based on existing literature, we did not consider it to affect our results. Further, we do not incorporate the heterogeneity in ability of patients to control blood glucose based on duration of unknown diabetes, and the duration of treatment they have been on. This was difficult to calculate given the short time horizon of the interventions we studied. Moreover, the interventions did not capture the course of action of patients who chose to drop out of the program, and thus we had to assume the future progression of drop out patients based on care provided in the status quo.

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7. Annexures

Cost Centers	CHW				TMU				TMU-MMU			
	Screening		Follow-up		Screening		Follow-up		Screening		Follow-up	
	Direct Costs	Indirect Costs	Direct Costs	Indirect Costs	Direct Costs	Indirect Costs	Direct Costs	Indirect Costs	Direct Costs	Indirect Costs	Direct Costs	Indirect Costs
Personnel Cost Management												
Managing Director	-	18.38	-	18.38	-	4	-	5	-	-	-	-
Operations Manager	-	26.47	-	26.47	-	-	-	-	-	-	-	-
Marketing Manager	-	7.35	-	7.35	-	-	-	-	-	-	-	-

Division Manager	-	-	-	-	-	1	-	1
Mission Control Executive	-	-	-	-	-	10	-	13
Admin Staff	-	-	-	-	-	1	-	1
Finance Staff	-	-	-	-	-	3	-	4
Medical Staff								
Nurse	-	-	-	-	95	-	134	-
Doctor	-	-	-	-	79	-	110	-
Field Staff								
CHW	46	-	17.3	-	-	-	-	-
Field Executive	8.76	-	8.76	-	-	-	-	-
Outreach Executive								
Officer	-	-	-	-	-	7	-	10
Office staff								
Receptionist	-	3.68	-	3.73	-	-	-	-
Peon	-	2.45	-	2.48	-	-	-	-
IT/Finance/Others								
Data Analyst	-	4.90	-	4.97	-	-	-	-
Total Cost	54.76	63.23	26.06	63.38	174.00	24	244.00	34.00
Capacity Building								
Training of CHWs	-	40.00	-	40.00	-	-	-	-
Training of Nurse	-	-	-	-	-	0.9	-	1.2
Training of Doctors	-	-	-	-	-	-	-	-
Total Cost	0.00	40.00	0.00	40.00	0.00	0.90	0.00	1.20
Infrastructure								
Rents of Head Office, E- Clinics, Pharmacies	-	-	-	-	-	16.78	-	23.56
Office Furniture and Appliances	-	-	-	-	-	3.91	-	5.50
Total Cost	0.00	0.00	0.00	0.00	0.00	20.69	0.00	29.06
Consumables and Digital Equipment								
Digital Tablet	-	4.25	-	4.25	-	-	-	-
Cotton Swabs	0.44	-	0.44	-	0.06	-	0.06	-
Test Strip	4.41	-	4.41	-	0.57	-	0.57	-
Lancet	0.74	-	0.74	-	0.09	-	0.13	-
Glucometer	0.50	-	0.50	-	0.06	-	0.08	-
Total Cost	6.09	4.25	6.09	4.25	0.78	0.00	0.83	0.00
IEC and Software Costs								
Diet Chart	-	-	-	-	0.00	-	9.49	-
Branding Chart	-	-	-	-	1.59	-	1.00	-
Flip Chart	-	-	-	-	0.00	-	1.87	-
IEC materials	-	0.01	-	0.01	-	-	-	-
Software subscription cost	-	1.26	-	1.26	-	-	-	-
Website and maintenance cost	-	-	-	-	-	1.88	-	2.65
Promotional cost	-	-	-	-	-	0.16	-	0.22
Total Cost	0.00	1.27	0.00	1.27	1.59	2.04	12.37	2.87
Institutional Overheads	0.00	25.50	0.00	21.13	0.00	7	0.00	9
Per-Unit Costs of Healthcare Service Delivery								
Unit Cost	60.85	134.25	32.15	130.03	176.36	54.63	257.20	76.13
Unit Cost – Direct + Indirect		195.10		162.18		230.99		333.33

Table 1. Per Unit Healthcare Delivery Costs under Selected Models

7.2 Supplementary Results for comparing the models

7.2.1 Reduction in CVD expenditure for CHW-based vs Status Quo model

Sex	Age	Reduction in CVD Cost (in %)
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F	50	0.024
F	55	0.023
F	60	0.022
F	65	0.022
M	50	0.022
M	55	0.022
M	60	0.021
M	65	0.021

7.2.2 CHW-based vs Status-Quo under no dropouts

Sex	Age	Incremental Cost	DALYs Averted	ICER
F	50	0.036%	0.0017%	198625.6
F	55	0.030%	0.0015%	160737.1
F	60	0.027%	0.0013%	131337.6
F	65	0.026%	0.0012%	117836.2
M	50	0.032%	0.0018%	129458.4
M	55	0.027%	0.0015%	112298.4
M	60	0.024%	0.0013%	99361.5
M	65	0.023%	0.0012%	91530.4

7.2.3 CHW-based vs Status-Quo under 8% coverage

Sex	Age	Increment Cost	DALYs Averted	ICER
F	50	1.944%	0.0055%	198366.1
F	55	1.625%	0.0045%	160527.7
F	60	1.420%	0.0038%	131166.9
F	65	1.327%	0.0034%	117683.1
M	50	1.474%	0.0068%	129291.6
M	55	1.272%	0.0054%	112154.1
M	60	1.154%	0.0044%	99234.0
M	65	1.087%	0.0039%	91413.0

7.2.4 TMU-based vs Status-Quo under 8% coverage

Sex	Age	Increment Cost	DALYs Averted	ICER
F	50	3.258%	0.0178%	102924.2
F	55	2.727%	0.0148%	81600.7
F	60	2.387%	0.0125%	66658.7
F	65	2.233%	0.0112%	60260.6
M	50	2.475%	0.0211%	69353.2
M	55	2.139%	0.0171%	59018.6
M	60	1.944%	0.0142%	51835.5
M	65	1.834%	0.0125%	47915.8