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Community Control of Hypertension and Diabetes (CoCo-HD) program in the Indian states of Kerala and Tamil Nadu: a study protocol for a type 3 hybrid trial

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Abstract

Introduction India grapples with a formidable health challenge, with an estimated 315 million adults afflicted with hypertension and 100 million living with diabetes mellitus. Alarming statistics reveal rates for poor treatment and control of hypertension and diabetes. In response to these pressing needs, the Community Control of Hypertension and Diabetes (CoCo-HD) program aims to implement structured lifestyle interventions at scale in the southern Indian states of Kerala and Tamil Nadu.

Aims This research is designed to evaluate the implementation outcomes of peer support programs and community mobilisation strategies in overcoming barriers and maximising enablers for effective diabetes and hypertension prevention and control. Furthermore, it will identify contextual factors that influence intervention scalability and it will also evaluate the program's value and return on investment through economic evaluation.

Methods The CoCo-HD program is underpinned by a longstanding collaborative effort, engaging stakeholders to co-design comprehensive solutions that will be scalable in the two states. This entails equipping community health workers with tailored training and fostering community engagement, with a primary focus on leveraging peer supportat scale in these communities. The evaluation will undertake a hybrid type III trial in, Kerala and Tamil Nadu states, guided by the Institute for Health Improvement framework. The evaluation framework is underpinned by the application of three frameworks, RE-AIM, Normalisation Process Theory, and the Consolidated Framework for Implementation Research. Evaluation metrics include clinical outcomes: diabetes and hypertension control rates, as well as behavioural, physical, and biochemical measurements and treatment adherence.

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Discussion The anticipated outcomes of this study hold immense promise, offering important learnings into effective scaling up of lifestyle interventions for hypertension and diabetes control in low- and middle-income countries (LMICs). By identifying effective implementation strategies and contextual determinants, this research has the potential to lead to important changes in healthcare delivery systems.

Conclusions The project will provide valuable evidence for the scaling-up of structured lifestyle interventions within the healthcare systems of Kerala and Tamil Nadu, thus facilitating their future adaptation to diverse settings in India and other LMICs.

Keywords Diabetes, Hypertension, Scale-up, India, Structured lifestyle intervention, Peer support groups

Introduction

The burden of non-communicable diseases (NCDs) continues to rise in India. Globally, India had the highest number of people with cardiometabolic diseases in 2021: type 2 diabetes at 100 million, and hypertension at 315 million. The overall weighted prevalence of diabetes was 11.0%, and hypertension was 35.5% in 2016 [1]. The broader societal and economic impacts arising from this situation in India are now very substantial, with $3.55 trillion in productivity loss predicted by 2030 [2]. It is now critical for India's health system to adopt explicit preventive and control strategies to address this problem.

It has been very challenging for state governments in India to control diabetes and hypertension, and the recent COVID-19 pandemic has exacerbated this further. About 59% of people with diabetes and 45% of people with hypertension in India are receiving treatment. Of these, 65% of people with diabetes and 52% of people with hypertension achieved control [3, 4]. As in most other LMIC settings, the efforts to improve outcomes for hypertension and diabetes in India are still mostly facility-based and curative. To address the issue, the Governments of Kerala and Tamil Nadu are implementing India's comprehensive 'National Program for Prevention & Control of Non-Communicable Diseases (NP-NCD), including programs such as Patient Support Groups (PSG) and *Makkalai Thedi Maruthuvam* ("drugs on doorsteps"), to combat NCDs. PSGs involve a community-based intervention to strengthen community-level efforts for better NCD control. The *Makkalai Thedi Maruthuvam* scheme screens those over 45 years and those with disabilities through routine door-to-door check-ups to detect NCDs [5].

The original Kerala Diabetes Prevention Program (K-DPP) was an evidence-based program that was carefully adapted from the Good Ageing in Lahti (GOAL) Lifestyle Implementation Trial in Finland [6] based on the earlier Finnish Diabetes Prevention Study [7] and the US Diabetes Prevention Program. It was conducted as a cluster-randomised controlled trial in the Trivandrum district of Kerala in 2012–2014 [8]. This trial demonstrated that lifestyle interventions involving community engagement, mobilisation, and peer support can significantly improve cardiovascular risk factors and health-related quality of life (QoL) [9]. Furthermore, it was adapted for broader implementation in Kerala in collaboration with the *Kudumbashree Mission* [10]. This approach to diabetes prevention has been recently adapted for improving the management of diabetes and hypertension along with other evidence-based programs in India, including the Control of Hypertension in Rural India (CHIRI) program for hypertension control, involving ASHA workers in three rural communities in India [11].

By integrating findings from these and other community-based trials in India and by leveraging the two states' recent initiatives, this study now aims to create a scalable program model – called Community Control of Hypertension and Diabetes (CoCo-HD) - that aims to improve both behavioural and clinical outcomes related to hypertension and diabetes [11]. Currently, there is limited evidence about how to do this beyond research trials and at scale.

Objectives

1. Evaluate the implementation outcomes of a peer support program and community mobilisation strategy to improve the control of diabetes and hypertension.
2. Identify and address contextual factors within the community and health systems that act as enablers and barriers to scale-up in Kerala and Tamil Nadu.
3. Determine the program's value and return on investment by assessing program cost and cost-effectiveness in Kerala and Tamil Nadu.

Study methods

Study context The study is being conducted in the Southern states of India, specifically Kerala and Tamil Nadu, chosen based on local evidence highlighting significant gaps in care [3, 4]. According to recent data from the Indian Council of Medical Research–India Diabetes (ICMR-INDIAB) study, Kerala, with an estimated population of 35 million (with an average population size per district of about 2.5 million), exhibits a diabetes prevalence

of 25.5%, significantly higher than the national prevalence of 11.4%, alongside a hypertension prevalence of 47.6% (compared to the national prevalence of 35.5%). Meanwhile, Tamil Nadu, with an estimated total population of 72 million, reports a diabetes prevalence of 14.4% and a hypertension prevalence of 38.3% among adults [12].

For the implementation of the CoCo-HD program, we selected two districts in Tamil Nadu: Villupuram with a population size of about 2.2 million, and Cuddalore with an estimated population size of about 2.7 million. Conversely, in Kerala, the intervention will be carried out across all 14 districts, as decided by the state government to ensure comprehensive coverage.

Scale-up approach The total study period will be four years and will be conducted in three stages (summarized in Fig. 1 below).

In the first stage, the two research teams from the National Institute of Epidemiology (NIE) and Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) have worked in close collaboration with state health departments of Tamil Nadu and Kerala, respectively, other relevant stakeholders in the respective states, in the co-design of the program. The advisory board of the program, chaired by the Director General of the Indian Council for Medical Research, guided the development of the program. Through various technical consultations with state health departments and using the lessons learned from K-DPP and other related programs, the team developed the broad components of the program.

In the second stage, we are co-designing context-specific implementation strategies. The co-design process involves a range of stakeholders. The stakeholders in this process are people with hypertension and diabetes in the community, residents of the included community, CHWs, primary health centre care providers, including doctors, and district program officials. We are conducting a series of consultations and technical discussions with the above stakeholders. We are visiting the community to observe the community-level activities. We are performing formative assessments to understand the needs and contextual factors associated with implementing the Peer Support Group (PSG) intervention. The target population for this assessment are people with hypertension and diabetes, community residents, and CHWs. We are prioritising the strategies using the APEASE (Acceptability, Practicability, Effectiveness, Affordability, Side-effects, Equity) criteria [13].

In the third stage, the intervention model will be implemented and evaluated in both states. We will conduct a baseline assessment of the control status of individuals with diabetes and hypertension before implementing the intervention model at community-level using CHWs. After 12 months of intervention delivery, we will evaluate implementation and effectiveness outcomes. In the fourth stage, we will propose refinements in the delivery

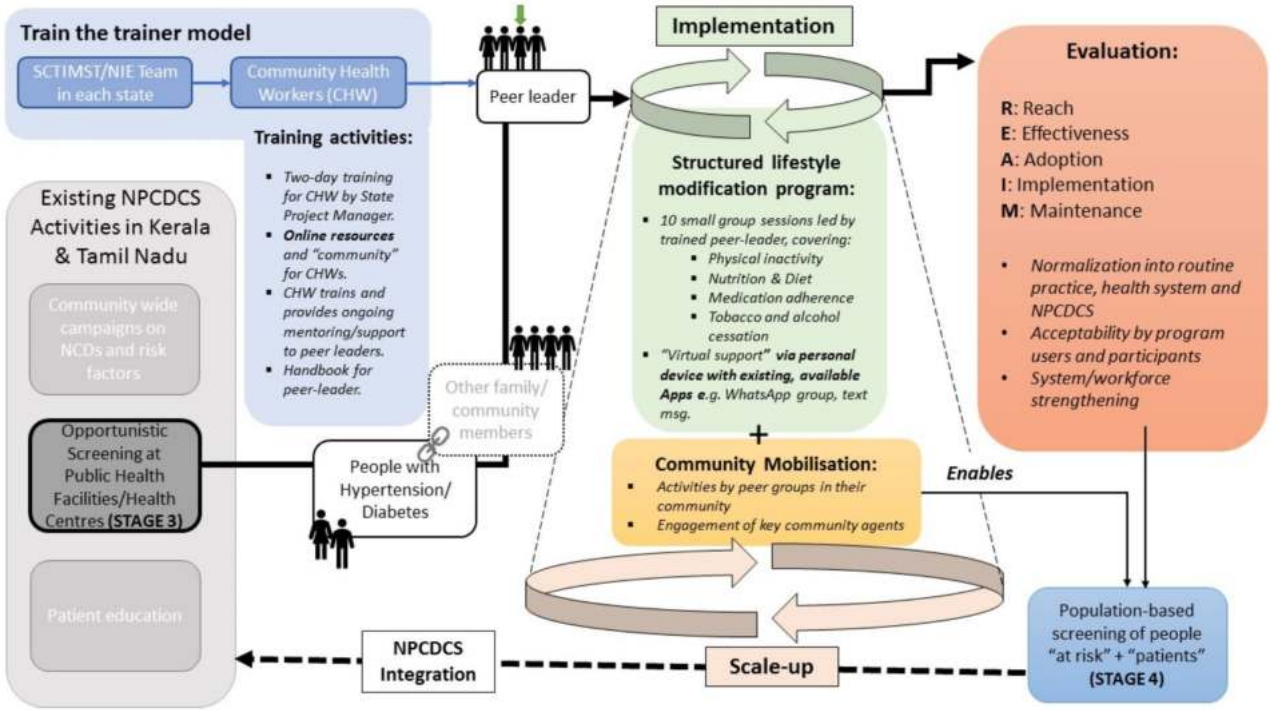

Fig. 1 Multi-level program delivery and iterative evaluation model

of the program at scale, based on the learnings from the evaluation.

Needs assessment and development of the program

This goal-based intervention program focuses on adopting a healthy lifestyle and self-care behaviours related to improving hypertension and diabetes control. Individual-level goals for the components such as physical activity (PA), healthy diet, blood pressure/sugar control, body weight, and medication adherence will be set through a co-design approach in collaboration with the health system.

Training material is being developed for CHWs/Mid-Level Service Providers (MLSPs) to deliver community-based interventions for PSGs. We are reviewing the existing training materials and program guidelines in each state in developing the specific training material. Input has been received from subject matter experts, healthcare providers, and relevant stakeholders on the content, applicability, and suitability to the local context.

The training materials incorporate visualisation, information on disease, medication adherence, treatment outcomes, community mobilisation skills, and conducting PSG sessions. In addition to the training material, role specifications are being developed for CHWs to deliver the intervention. To facilitate the program delivery, we will also develop job aid that will consist of activities and discussion topics to be delivered through PSG sessions.

Implementation of CoCo-HD program

Intervention PSGs will be formed with two PLs, one male and one female, to organize PSG session, faciliate dialogues and support within a group. Trained CHWs or MLSPs will deliver the structured intervention in the PSG sessions. These sessions will be conducted once a month per PSG. In a year, we aim to conduct 12–15 sessions, each lasting 60–90 min. There will be group discussions and group activities as part of each session. Each PSG will consist of 20–25 individuals with 10–14 individuals having hypertension and diabetes in Tamil Nadu and Kerala, respectively. Emphasis on medication adherence, lifestyle modification, and peer support will be delivered in the sessions to improve the control of hypertension and diabetes. Two peer leaders (PLs) will be selected among the individuals with hypertension and diabetes. The PLs will support the CHWs/MLSPs in conducting these sessions. The PSGs will also have their own WhatsApp groups to connect, interact, and share experiences.

Training for MLSPs in Kerala The project team will conduct a two-day training program for MLSPs with 60–70 participants in each training group. The training will be conducted at the district level using customised study modules. During district-level meetings, the medical officers will be briefed about the program components and how they can support their implementation and evaluation. In coordination with the state health departments, continuous technical support will be provided to the district medical officers and MLSPs by the project teams.

Training of trainers in Kerala The Kerala project team will initiate the training of selected MLSPs as trainers in all 14 districts They will introduce the pedagogy in 2–3 training sessions where the participants will get the opportunity to get involved in training under the supervision of the research team. Our research team will formally evaluate each trainer, and a graduation certificate will be issued upon completing the training. The graduated trainers will be officially inducted into the training team and conduct further training sessions within their respective districts.

Training of trainers in Tamil Nadu This has involved a comprehensive needs assessment and evaluation which will be based on the Analysis, Design, Development, Implementation, and Evaluation (ADDIE) standards. Adopting the Training of Trainers model, our implementation team will prepare Program Officers, Medical Officers, Senior Staff Nurses, and selected CHWs to ensure effective scale-up. These trained trainers will then conduct training sessions for CHWs across the districts. Additionally, facilitator manuals for trainers and training manuals for participants will be developed to maintain training quality.

Training of PLs in Kerala The CHWs/MLSPs will select and train the PLs. The training component will impart skills of group facilitation, communication, goal setting, and monitoring of lifestyle change. The MLSPs and PLs will receive a handbook of procedures to follow. The manual will highlight the roles and describe the contents of each session and the procedures they need to follow during the sessions to achieve the behavioural targets. The list of training and intervention materials for the program are shown in Table 1 below.

Evidence-based interventions The CoCo-HD program will implement evidence-based structured lifestyle interventions that will improve (1) the awareness, knowledge, and skills of people with diabetes and hypertension on disease management; (2) participation in PA; (3) the consumption of healthy eating and salt reduction; (4) medication adherence and self-management of disease; and (5) early detection and management of complications.

Implementation strategies The CoCo-HD program implementation strategy has three elements. The first comprises PSG sessions and activities led by trained PLs and facilitated by CHWs/MLSPs. These will focus on PA,

Table 1 List of training and intervention materials for the CoCo-HD program

SN	Type	Purpose	Users
1	Training materials and manuals	Guide the training of CHWs/MLSPs on the intervention and its implementation.	Trainers & CHWs/MLSPs; supervisors
2	Job Aids	Assist the CHWs in the facilitation of PSG sessions and activities.	CHWs & PLs in Tamil Nadu
3	Flipbooks	Directs CHWs to explain lifestyle modification to patients in a pictorial format	PLs & participants in Tamil Nadu
4	Standard operating procedures	Standardise the process of conducting patient group sessions	CHWs & PLs in Tamil Nadu
5	Participant Handbook and Factsheets	Guides participants and PLs to set, monitor, and evaluate goals. It also includes essential information about the selected topics for people with diabetes and hypertension.	PLs & participants
6	Monitoring checklists	To document measurements of fasting blood sugar (FBS), blood pressure, waist circumference, and medication adherence; and adoption of lifestyle modification measures; also includes provisions to monitor and record attendance and key parameters about the sessions.	CHWs/MLSPs

nutrition, diet, medication adherence, and tobacco and alcohol cessation. The second will be virtual support to CHWs/MLSPs and PLs via personal devices with existing, available apps, e.g., WhatsApp group, text message, etc. The third element will consist of supportive interventions such as monitoring blood pressure, blood glucose, waist circumference, body mass index (BMI), and medication adherence. Regular feedback on structured lifestyle modification (SLM) strategies and goals will be provided to the participants based on the values of the above measurements. The project teams in the two states will provide support in the implementation of these strategies.

Formation of PSGs CHWs (Women health volunteers (WHV), Health Inspector, Block Health Supervisors, and Village Health Nurses)/MLSPs will identify the patients from the respective area; pre-inform the patients before the day of PSG, mobilise the patient to the venue, and facilitate the PSG. Two PLs will be selected from among the participants in each PSG. We will explore the usage of digital health interventions to improve the engagement of participants in PSGs.

Peer group sessions The CHWs/MLSPs will choose a suitable venue and time each month. CHWs/MLSPS will deliver the structured intervention in the PSG sessions. Each session will have (1) a brief education by CHWs/MLSPs on a particular topic; (2) repetitive slogans; (3) group discussion about the planned topics with the use of case scenarios, myths, and facts on disease process and secondary prevention; (4) at least one group PA session; (5) measurement and documentation in follow-up register; and (6) a gift or appreciation expressed to a patient who has exhibited better control. These sessions will be conducted once a month. We will aim to conduct 12 sessions in a year. The participants will receive a factsheet on myths and facts about hypertension and diabetes. A participant card will be maintained for each participant in which monthly participation details, blood pressure, body weight, waist circumference, and random capillary blood sugar will be recorded by the CHWs/MLSPs in each session.

Table 2 List of topics to be covered in the PSG sessions

PSG topic	Tamil Nadu	Kerala
Introductory session	√	√
Preparatory phase	√	√
Goal setting	√	√
Diabetes and Hypertension		√
Healthy eating and salt reduction	√	√
Physical Activity	√	√
Tobacco and alcohol	√	√
Medication adherence	√	√
diabetes and hypertension complications	√	√
Mental Health and the importance of sleep	√	
Self-monitoring and self-care	√	√
Insulin		√
Community resources	√	√
Goal review and planning for maintenance	√	

The topics for the PSG sessions, as co-developed and agreed with the respective state health are shown in Table 2 below. As outlined in the table, the topics for PSG sessions co-designed with the state health departments of the two states are similar except for inclusion of a topic on mental health and sleep in Tamil Nadu and Insulin in Kerala.

While the contents of the intervention are largely the same between the two states, the implementation strategies will be context-specific. Accordingly, we will tailor our implementation strategies to the specific contexts of the two states. Table 3 summarises the contextualisation of the implementation strategies in the two states.

Evaluation of CoCo-HD program

Study design We will u undertake a hybrid type III trial focusing on implementation outcomes. Given that the CoCo-HD program is a scale-up of evidence-based lifestyle interventions, this is the most appropriate design.

Table 3 Contextualization of implementation strategies of the CoCo-HD program

Implementation strategies	Tamil Nadu	Kerala
Training of CHWs		
The actor	ICMR-NIE team and District Program Officers/ Medical Officers	SCTIMST team and District Programme Officers + ToT by selected MLSPs for further training under supervision.
The action	Face-to-face training	Face-to-face + online
Action target	MLSP and WHV	MLSPs in the entire state of Kerala
Temporality	August 2023 – Sept 2023	December 2023 – March 2024
Dose	2 days (1 + 1); 6 h/ day	1.5 days; 6 + 3 h
Outcome	Improved knowledge and skills in conducting PSG sessions	Empowered MLSPs in leading Peer group sessions in a structured and organized manner.
Justification	Training of the trainers and cascading to CHWs has been proven to be effective	A hybrid approach of face-to-face and online training mode is the preferred approach of the state health department.
PSG Sessions		
The actor	MLHP and WHV	MLSPs
The action	Conducting PSG sessions and activities: Repetitive slogan Special topic Activities Measurements	Conducting PSG Sessions and activities: Set and review of goals Discussion on the core topics Initiate activities specific to the concerned sessions Plan for the forthcoming session Conduct study-specific measurements
Action target	People with diabetes and hypertension	People with diabetes and hypertension
Temporality	Oct 2023 – Sept 2024	December 2023 – March 2025 (As the implementation is conceived in a phased manner across the state, with concurrent training and initiation of implementation overlapping).
Dose	12 sessions; 60–90 min	12 sessions; 60–90 min
Outcome	Medication compliance, Achieve treatment targets of hypertension (Blood pressure control) and diabetes (Blood sugar control)	Improved adoption of self-care practices. Improved medication adherence. Weight and waist circumference reduction. Improvement in consumption of fruits and vegetables. Reduction in daily salt use. Improved control rates of hypertension and diabetes.
Justification	Monthly sessions have been used and proven to be effective in other settings.	Monthly sessions have been used and proven to be effective in other settings.
Community engagement activities		
The actor	MLHP and WHV	MLSPs, Medical Officers and Supervisors
The action	Community Mobilisation during outreach activities, Information, Education, Communication (IEC) Provisions, Advertisements such as announcements, elevation of banners/posters, Peer Selection, and Reminders	Activities to engage and ensure more community participation in building awareness of the need for lifestyle modifications.
Action target	People with diabetes and hypertension and the community	Adults of all age groups
Temporality	18 months	18 months
Dose	Monthly once	One session: In a phased manner
Outcome	Community sessions conducted	Improved community awareness. Improved readiness to participate in structured lifestyle modification intervention sessions.
Justification	Community engagement is critical for effectively implementing PSG sessions and activities.	Community engagement will improve the acceptability of MLSPs and PSG in managing hypertension and diabetes.

Pre-post design (baseline and end-line assessments) with a mixed-method approach will be used to evaluate implementation outcomes. A template for the Intervention Description and Replication (TIDR) checklist will be used to describe the intervention's structure [14].

Study population The CoCo-HD program is developed on the background of both states putting major emphasis on diabetes and hypertension control and how they are planning to addressthese public health issues, especially following Covid-19. Both states have issued a Government Order regarding the details of the CoCo-HD program. In line with this, Individuals diagnosed with diabetes and hypertension by the health systems of Tamil Nadu and Kerala will be our target population.

Inclusion criteria

- Individuals with diabetes and hypertension irrespective of gender.
- Aged 18 years and above.
- Residents of selected study districts for at least one year.

Exclusion criteria

- Individuals with terminal, debilitating illnesses will be excluded due to differences in their care-seeking behavior, treatment outcomes, and low possibility of participating in the proposed intervention.
- Individuals who were bedridden due to illness.

Operational definitions

Based on the NP-NCD, we define key terms as follows:

People with diabetes Anyone aged 18 years and above reported FBS≥126 mg/dl & PPBS≥200 mg/dl or receiving medication for diabetes.

People with hypertension Anyone aged 18 years and above with Systolic BP≥140 mm Hg or Diastolic BP≥90 mm Hg on two different occasions or receiving medication for hypertension.

Control of blood pressure Hypertensive patients who achieved systolic blood pressure less than 140 mm Hg and diastolic blood pressure less than 90 mm Hg.

Control of blood glucose DM patients who achieved FBS less than 126 mg/dl.

Regular follow-up An individual registered for hypertension, diabetes, or both treatments with the State Government health facilities and visited the Primary Health Centre at least once in the previous three months at the time of reporting (as per the guideline, NP-NCD) [11].

Study participant selection and sampling technique One administrative block will be selected randomly from each district of Tamil Nadu. Administrative blocks are geographical divisions under each district (coverage of population). We will select health sub-centres in each block by a multi-stage cluster random sampling along with probability proportional to the size of hypertension and diabetes patients from population-based screening registers.

Health sub-centres are the first point of contact of the public primary care system, which caters to a population of 3,000 to 5,000 on average. Each health sub-centre is operated by a CHW who maintains the line list of individuals diagnosed with diabetes and hypertension in their catchment area. The CHWs will select 20–25 individuals with diabetes, hypertension, or both from their line list.

In Kerala, all health sub-centres under the public health care system where MLSPs are posted will be included in the study. The MLSPs in Kerala are trained nurses. Approximately 4,400-4,500 MLSPs are posted in health sub-centres across Kerala. Each MLSP will form a PSG with at least 10 participants (maximum 15) as per inclusion criteria. Participants are patients with hypertension, diabetes, or both residing in the respective health sub-centre area. Approximately 40,000–45,000 people will participate in the PSG intervention across Kerala.

Sample size estimation In estimating the sample size, we have considered multiple factors. The baseline control rates of hypertension and diabetes are 34% and 40%, respectively. To detect 20% improvements in both by the end of the program (12 months), these baseline control rates need to increase to 41% and 48%, respectively. We used the diabetes control rate in the power calculations as it provides a higher power. For those measured, the evaluation component will have 90% power to detect relative improvement of over 20% (ICC=0.05, cluster size=100, number of clusters=82, alpha=0.05). This will lead to an estimated 4,100 participants (100 participants each in 41 separate sub-centers) for Tamil Nadu.

In Kerala, the intervention component will be integrated with routine service delivery at the health sub-centre level. Our implementation model, with 40,000–50,000 participants from over 4,000 health sub-centres, will have more than 90% power to detect even an incremental increase in control rates (5%) in the pre-post evaluation.

Evaluation of implementation outcomes We will use RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance). The RE-AIM dimensions of the CoCo-HD program evaluation will be computed from the data collected at community levels by CHWs. RE-AIM dimensions and indicators are summarized in Table 4 below.

Outcome measures

Individual level outcomes The primary outcome measures among the included individuals will be the proportion of individuals participating in the PSGs who achieve adequate control of blood pressure and FBS. CHWs will document the proportion of individuals who visited health facilities for regular follow-up. The proportion/actual number of individuals who participated in the peer group sessions will be documented and analysed. Other secondary outcome measures include behavioural vari-

Table 4 RE-AIM dimensions & indicators for CoCo-HD program evaluation

SN	Dimensions	Key indicators
1	Reach	Tamil Nadu: The proportion of people with diabetes and hypertension enrolled in PSG in their respective communities. The proportion of CHWs trained on CoCo-HD program delivery. Kerala: Number of individuals with hypertension /diabetes or both approached and enrolled in the PSG; number of PSGs with a minimum of 10 participants; proportion or the number of individuals in absolute terms dropped-out from the PSG. The qualitative reach dimension will identify the influence of personal and contextual factors that contributed to the participation and non-participation in the intervention, the question of *Why* and *Why not*.
2	Effectiveness	The proportion of people with diabetes and hypertension who achieved adequate control of blood pressure and blood glucose at the end of the intervention. The proportion of people with diabetes and hypertension who attended at least five PSG sessions. Qualitatively, we will explore factors that affected the effectiveness of the intervention from the perspectives of the provider and the beneficiaries, and whether they find the outcome of the intervention meaningful.
3	Adoption	The proportion of people with diabetes and hypertension who have set at least one lifestyle goal. The proportion of CHWs/MLSPs who facilitated PSGs as part of the community health program. The proportion of CHWs/MLSPs who conducted at least nine (75%) PSG sessions. Qualitatively, we will explore the system factors that influence the adoption of PSG interventions and the enabling and challenging factors towards the adoption or initiation of the implementation.
4	Implementation	The proportion of PSG sessions and activities delivered per the protocol. The proportion of PSG members who attended all 12 sessions. Qualitatively, we will explore adaptations and modifications in the intervention delivery.
5	Maintenance	The proportion of people with diabetes and hypertension who maintained blood pressure and blood glucose within recommended ranges for six months after intervention. The proportion of PSGs who meet monthly after six months of intervention. The proportion of health sub-centres included in the study where the PSG intervention became part of routine care. Qualitatively, we will explore factors that facilitated the institutionalisation of PSG interventions in the routine management of hypertension and diabetes in the health sub-centres. At the individual-level, we will explore reasons for adherence and non-adherence to the intervention six months after implementation of the PSG.

ables (tobacco use, alcohol use, diet, PA, sedentary behaviour) and physical measurements (weight, waist, blood pressure) that will be collected using structured questionnaires at baseline and end-line.

Program level outcomes Glasgow's RE-AIM framework [15] will be used to evaluate the implementation outcomes of the program.

Data collection methods We will train CHWs through the trainer of trainers' model for measuring physical parameters and behavioural patterns of the individuals registered and followed up in the PSGs. CHWs will record the measurements and attendance in the PSG on the information system adopted by the state health department. Everyone in a PSG will receive a participant card where measurements will be recorded during the PSG. Data recorded at baseline, monthly observations, and at end evaluation will be converted into digital records for analysis.

The research team will train the MLSPs in data collection, including physical and behavioural measurements. The date will be entered manually during or after each PSG session into a monitoring and evaluation booklet maintained by the MLSPs and in the participant's handbook. Data collected at baseline, regular intervals, and at the end of sessions will be transferred to a digital platform with access to the concerned stakeholders at the state health department and the research team.

The data elements to be collected at baseline and follow-up assessments will include sociodemographic characteristics, medical history/chronic conditions, Lifestyle/behavioral factors [Diet, physical activity, tobacco use, alcohol use, sleep], medication adherence (using Morisky scale), Health service utilisation (short version), health-related quality of life (EQ-5D-5 L), and biochemical and anthropometric measurements (FBS, Blood pressure, waist circumference, BMI). In addition, PSG Monitoring data and unit costs of the intervention & health services will be collected at regular intervals throughout the program.

Assessing contextual factors – enablers and barriers

We will explore contextual factors, such as those within the health system and at the participant-level, that facilitate or hinder the implementation and scale-up of the program.

The research team will conduct semi-structured, in-depth interviews, key informant interviews, and focus group discussions (FGDs) with multiple stakeholders such as PSG participants, patients who did not show interest in participation in PSG interventions, dropped-out participants, MLSPs, the medical officers at primary health centres, other cadres of non-physician health workers, and the district health program managers during the implementation of the CoCo-HD program. The tools for the study will be conceived in an inductive manner with necessary iterations and corrections made as

required. The queries in the qualitative research tools will be sequenced inductively to understand the perspectives about factors that act as enablers and barriers at different implementation phases. The interview guide, which has been built inductively, will be extended to the constructs of identified frameworks in implementation research, such as NPT, CFIR [16], and components of RE-AIM [17].

Key questions The identification of enablers and barriers to implementation will be guided by the CFIR [16]. Using CFIR, we will formulate key questions on five domains of contextual factors that affect program implementation: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process of implementation.

Enablers and barriers to further scaling-up of the program are based on NPT. NPT focuses on what groups or individuals do, rather than what they believe [18]. NPT provides a framework to understand how interventions are implemented, embedded, and integrated in healthcare settings [19]. By focusing on the interactions between contexts, actors, practices, and procedures, NPT can help facilitate the exploration of translational gaps between evidence, policy, and practice [20]. We have operationalised the constructs and sub-constructs of NPT for the evaluation of the CoCo-HD program in Table 5 as follows:

Study informants To explore enablers and barriers to implementation of the CoCo-HD program from the health system, community, and participants' perspective, our research team will select informants from five categories of respondents: (1) participants (people with diabetes and hypertension); (2) PLs; (3) CHWs (MLSPs, WHVs, and health inspects); (4) District Medical Officers and District Programme Managers; and (5) Health Program managers, State level stakeholders, and policymakers.

Data collection methods We will conduct in-depth interviews and FGDs to identify barriers and facilitators of implementing the CoCo-HD program in the two states. The information saturation will determine the final number of in-depth interviews and FGDs. However, we will aim to conduct at least three 18–20 in-depth interviews with participants (including participants who continued and discontinued participation in the PSGs), 14–17 key informant interviews with MLSPs (including MLSPs providing interventions in different contexts; e.g. Rural, urban, coastal, terrain, etc.), 6–7 key informant interviews

Table 5 Operationalisation of NPT constructs & sub-constructs for the CoCo-HD program

SN	Constructs	Operationalisation of the CoCo-HD program
1	Coherence (What is the process?) Data source: In-depth interviews and FGDs	Definition: Enablers and barriers of how various actors make sense, had an explicit knowledge and understanding of the program and its associated elements when initiating the intervention. Experience by the actors (CHWs/MLSPs, Peer supporters, participants) who found it valuable to them and agreed to the usefulness and purpose of the CoCo-HD program. Key questions: How does the program *differ* from current practice? How does the program *fit* with current practice? To what extent do various actors *share* a common understanding of the program? What are the perceived benefits of the program to patients and the health system? What are factors inhibit the routine practice of the CoCo-HD program?
2	Cognitive participation (*Who performs the process?)* Data source: IDI and FGDs	Definition: Enablers and barriers of buy-in, engagement, and commitment of the various actors in implementing the CoCo-HD program. Key questions: To what extent have the various actors *bought* into it? To what extent have the various actors *engaged* with it? To what extent have the various actors *committed* to it? To what extent have the various actors *legitimized* it? To what extent have the various actors supported the program over time?
3	Collective action (*How does the process get performed?)* Data source: IDI and FGDs	Definition: Enablers and barriers to implementing and *integrating* the intervention into the health system. Key questions: What health system *resources* have been allocated to the program? How was the program *operationalised* during implementation in the existing context? Are there clear definitions of the *roles and responsibilities*? To what extent did the program get integrated into community health?
4	Reflexive monitoring (*How is the process understood?)* Data source: IDI and FGDs	Definition: Enablers and barriers of formal and informal monitoring of the progress, benefits, and costs of the intervention by the various actors. How did the actors evaluate the program and its supportive tools, either individually or collectively? Key questions: How much feedback did the various actors provide during the program's implementation? What are the various actors' judgments about the *effectiveness* and *usefulness* of the program? What are the various actors' judgments about the *costs* and *benefits* of the program? What are the *suggestions* to modify/improve the program?

medical officers and district program managers, and 2–3 key informant interviews with each of state-level implementing officers, policymakers, and other Gatekeepers.

Economic evaluation of the CoCo-HD program

The economic evaluation of the CoCo-HD program will assess the cost of the interventions and estimate the program's cost-effectiveness to draw inferences about the returns on investment associated with scale-up.

Costs of interventions

Estimation of costs of interventions The cost analysis will assess the (added) costs of integrating the intervention into ongoing government delivery systems (such as NCD clinics, primary health centres, and sub-centres). These will include costs of adaptation of the intervention, training activities, structured lifestyle programs, and community engagement activities.

Variation of costs across contexts The costing analysis will also explore how costs are likely to vary between the two states, and within the states based on geographic areas (rural versus urban), the categories of health workers and peers involved, and any economies of scale and scope that might occur with program scale-up. The scale-up costs will be adjusted for variations across geographical settings and population groups.

Data sources for unit costs Our data sources for unit costs of the major activities will include program accounts/registers, financial accounts data from government departments in the two states, global data (e.g., WHO-CHOICE estimates for the region), and evidence from previous studies in Kerala and Tamil Nadu.

Estimation of cost-effectiveness

In this pre-post evaluation, the costs of implementing the intervention as described above plus any changes in the costs of healthcare service use (relative to baseline), including both public subsidies and out-of-pocket expenses during the intervention period, will be used to capture the incremental costs of the intervention. Data on follow-up, outpatient visits, admission, and days lost due to illness will be collected at baseline and follow-up using the main questionnaire. We will estimate the costs of these outcomes using unit costs from the health system and international estimates. We will compute the change in costs of these outcomes between baseline and follow-up to estimate any cost savings associated with the implementation of the program.

Outcomes will be reported as Quality-Adjusted Life-Years (QALYs) gained measured with EQ-5D-5 L converted into an index score using time-trade-off-based weights from the Indian population [21]. The EQ-5D-5 L comprises five dimensions: mobility, self-care, usual activities, pain, discomfort, and anxiety/depression. Each dimension has five levels of response categories ranging from 'no problems' to 'severe problems.' The QALYs will combine time lived and QoL into a single index number where '1' corresponds to 1 year of full health and '0' corresponds to being dead. We will estimate the program's cost effectiveness as the ratio of program costs per participant to changes in QoL between baseline and follow-up assessments.

Data management and analysis The collection of baseline data, monthly monitoring data, and follow-up data will be led by NIE and SCTIMST in collaboration with the state health departments of Tamil Nadu and Kerala. The original data will be owned by and stored in the state health departments as per their respective data management standards. Based on data sharing agreements with the respective state health departments, de-identified data will be shared to the collaborating research institutions. We will apply the following methods in the analysis of data.

Evaluation of outcomes Using R programming, we will employ descriptive statistics, paired t-test, and repeated measure ANOVA to examine the changes in outcome variables between baseline and follow-up assessments. Mixed-effects models will be used to assess the program's effects on diabetes and hypertension control, lifestyle factors, and medication adherence. The model will include the participants' baseline status of blood glucose and blood pressure, medical treatment, participation in PSG interventions, and other behavioural characteristics. For monthly monitoring data, we will apply a time-series analysis to describe trends in blood glucose, blood pressure, waist circumference and BMI across the 12 months. Any skewed continuous outcome variable may be transformed before fitting this model. RE-AIM indicators will be described using adjusted proportions.

Identification of contextual factors After transcription and translation of scripts from qualitative techniques, we will use Nvivo 14 to code, sort and summarize the data. We will develop a coding algorithm based on the constructs and sub-constructs of CFIR and NPT to code the same. Key findings on barriers and enablers will be presented based on the dimensions of NPT and CFIR.

Economic evaluation We will collect data on program costs, direct costs (for health service utilisation, medications, and diagnostics), and indirect costs (loss of wages due to illness, transportation, food, and accommodation costs to seek health care). Unit costs for these components will be obtained from State Health Departments, National

and International estimates, and previous studies. Cost-effectiveness analysis will be conducted from a health system perspective. Incremental Cost-Effectiveness Ratios [22] will be estimated by dividing the program+direct costs with the changes in QALYs between baseline and follow-up. All adjusted measures will be estimated using a generalised estimating equation gamma regression model for repeated measures. Sensitivity analyses will use different assumptions concerning program effectiveness, service delivery costs, and discount rates.

Discussion

The findings of this study will inform the future scale-up of community-based structured lifestyle interventions in in India and other LMIC to improve the control of hypertension and diabetes in LMICs by generating strong evidence on implementation outcomes and identifying the contextual factors that affect the scaling up of the interventions. It will also determine the costs and cost-effectiveness of the program. We will disseminate these findings and learnings to the State and National Government policymakers to inform future policy recommendations and public health action. One of the limitations of this research is that we will not be able to assess directly the community-level control of hypertension and diabetes. Since we are identifying individuals who are already diagnosed with hypertension and diabetes, we will not have access to data regarding the total number of people with diabetes and hypertension in the community, nor their control rates.

Abbreviations

ADDIE	Analysis, Design, Development, Implementation, and Evaluation
BMI	Body Mass Index
CFIR	Consolidated Framework for Implementation Research
CHIRI	Control of Hypertension in Rural India
CHW	Community Health Worker
CoCo-HD	Community Control of Hypertension and Diabetes
FBS	Fasting Blood Sugar
FGD	Focus Group Discussion
GOAL	Good Ageing in Lahti
K-DPP	Kerala Diabetes Prevention Program
LMIC	Low- and Middle-Income Country
MLSP	Mid-Level Service Provider
NCD	Non-Communicable Disease
NP-NCD	National Program for Prevention & Control of Non-Communicable Diseases
NPT	Normalisation Process Theory
PA	Physical Activity
PL	Peer Leader
PSG	Peer Support Group
QALY	Quality-Adjusted Life-Year
QoL	Quality of Life
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance
SLM	Structured Lifestyle Modification
TIDR	Template for the Intervention Description and Replication
WHV	Women Health Volunteers

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Author contributions

GP, PJ, KRT, TH and BO wrote the first version of the manuscript. Other authors made substantial contributions. All authors have read and approved the final version of the manuscript for submission.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethical considerations

The study was approved by the Institutional Human Ethics Committee of the National Institute of Epidemiology [ID: NIE/IHEC/2010-02], the Institutional Ethics Committee of the Shree Chitra Tirunal Institute of Medical Sciences and Technology, Thiruvananthapuram [ID: SCT/IEC/1423/SEPTEMBER-2019] and the Ethics Committee of the University of Melbourne [ID: 1955651]. The research has also obtained ethics clearance from Alfred Health [ID: 465/21]. Written informed consent will be obtained from the study participants. The project was also approved by India's national Health Ministry Screening Committee (HMSC) based on ICMR Guidelines. Written informed consent will be obtained from those participants from whom additional information is to be collected.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Discovery, development, and deployment of a user-centered point-of-care digital information system to treat and track hypertension and diabetes patients under India Hypertension Control Initiative 2019–2022, India

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Abstract

Background: Hypertension affects 28.5% of Indians aged 18–69. Real-time registration and follow-up of persons with hypertension are possible with point-of-care digital information systems. We intend to describe herein the experiences of discovering, developing, and deploying a point-of-care digital information system for public health facilities under the India Hypertension Control Initiative.

Methods: We have adopted an agile and user-centered approach in each phase in selected states of India since 2017. A multidisciplinary team adopted a hybrid approach with quantitative and qualitative methods, such as contextual inquiries, usability testing, and semi-structured interviews with healthcare workers, to document and monitor utility and usability.

Results: During the discovery phase, we adopted a storyboard technique to understand the requirement of a digital information system. The participatory approach in discovery phase co-designed the information system with the nurses and doctors at Punjab state of India. Simple, which is the developed information system, has a front-end Android mobile application for healthcare workers and a backend dashboard for program managers. As of October 2022, over 24,31,962 patients of hypertension and 8,99,829 diabetes were registered in the information system of 10,017 health facilities. The median duration of registering a new patient was 50 seconds, and for recording a follow-up visit was 14 seconds in the app. High satisfaction was reported in 100 app users' quarterly interviews.

Conclusion: Simple was implemented by administering a user-centered approach and agile techniques. It demonstrated high utility and usability among users, highlighting the benefits of a user-centered approach for effective digital health solutions.

Keywords

Hypertension, digital information system, India Hypertension Control Initiative, Simple app

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Introduction

Non-communicable diseases (NCDs) contributed 1.62 billion disability-adjusted life years (DALYs) in 2019.[1] It increased from 43.2% in 1990 to 63.8% in 2019. Each year, nearly 17 million premature deaths occur due to NCDs. Most of these premature deaths occur at low- and middle-income countries.[2] Metabolic risk factors increase the risk of NCDs. Among the risk factors, 19% of global deaths are attributed to elevated blood pressure (i.e. hypertension). The prevalence of hypertension is higher in low-income and middle-income countries than in high-income countries.[3]

The prevalence of hypertension in India among the age group of 18 to 69 years is 28.5%. India has approximately 220 million people with hypertension, of which 12.6% have controlled blood pressure.[4] A poor blood pressure control status leads to unfavorable cardiovascular mortality and morbidity, such as myocardial infarction and stroke. Therefore, the treatment of hypertension requires lifelong follow-up and monitoring for better control and prevention of unfavorable health outcomes. The World Health Organization (WHO) recommended the HEARTS package with core strategies to improve blood pressure treatment and control.[5] One of the strategies in the HEARTS package is regular monitoring of patients on treatment for blood pressure control. The WHO pharmacological treatment guideline released in 2021[6] recommends a monthly follow-up of patients until they achieve control.

Public sector healthcare facilities cater to many patients with hypertension due to the high burden of the disease. Since people with hypertension require lifelong treatment and follow-up, the volume of information handled is huge.[7] Recording, analyzing, and reviewing such large data require a stable information system. Relying on a pen and paper information system to handle large data is time-consuming and requires a large number of human resources. Besides monitoring patient data monthly, generating program indicators is crucial for successful implementation and outcome of the disease control program.[8] Sufficient evidence supports the fact that data-driven decisions in public health programs produce effective outcomes.[9] Thus, a stable, simple, reliable, and swift digital information system is essential to monitor and manage hypertension control programs.

Understanding NCDs as a public health problem, the government of India has adopted the "25 by 25" goal, which aims to reduce premature mortality due to NCDs by 25% by 2025. One of the nine voluntary targets includes reducing the high BP by 25% by 2025. The Ministry of Health & Family Welfare, Indian Council of Medical Research, State Governments, and WHO-India jointly launched the India Hypertension Control Initiative (IHCI) in November 2017. Details about the strategies of early outcomes have also been published.[10]

The IHCI aims to accelerate progress toward the government of India's NCD target by supplementing and intensifying evidence-based strategies to strengthen the building blocks of hypertension management and control.

Deploying a robust information system is a key strategy of the IHCI. We designed a digital information system in the IHCI, called Simple.[11] Simple is a fast, free, open-source digital information system with an Android application and a secured web-based dashboard. In Simple, healthcare workers record every hypertension patient's visit, and program managers receive daily reports to monitor progress.

An information system is a day-to-day tool for a busy healthcare worker. To be useful, an information system must have utility and a high level of usability. Utility refers to the system that provides the features that the users need, while usability refers to how easy the system's features are to use in practice in a complex healthcare environment.[12] In principle, usability and utility evaluation at all stages and as a continuous exercise during information system building is recommended. Traditionally analytical models[13,14] of the evaluation of usefulness of an information system involves inputs by subject matter professionals. Involving end-users for such evaluation, called empirical models,[13] is the user-centered approach for creating software.

We adopted a user-centered design (UCD) approach with an agile development model for the discovery, development, and deployment of the Simple information system. The UCD improves the uptake and impact of a digital health intervention in a health ecosystem.[15–18] The UCD approach involves the system users during discovery and repeatedly in the development and post-deployment processes. Thus, the viewpoint of the users and their needs is adopted into the information system.

In this manuscript, we documented the development process of a digital information system for tracking hypertension and diabetes patients in the primary healthcare setting of India using a user-centered design approach with agile methodology. We aim to share our experiences of how we designed, developed, and deployed a highly usable digital information system.

Methods

We adopted various methods (Table 1) in the discovery, development, and deployment phases over the period of November 2017 to June 2022. The discovery phase consisted of understanding the healthcare workers and their work environment. In this phase, we identified the need of a digital information system for a hypertension control program. The development phase consisted of priming the design of the information system and technical development. The implementation of the developed application for real-world usage occurred in the deployment phase.

Table 1. Overview of the methods employed in the Simple app design and implementation, 2017–2022.

Phase	Qualitative	Quantitative
Discovery	• Discovery interviews • Storyboarding • Co-creation • Contextual inquiry (mixed)	• Contextual inquiry (mixed)
Development	• Usability test • User interviews • A/B testing	
Deployment	• User interviews • Pulse check interviews (mixed)	• User analytics • Pulse check interviews (mixed)

The development and deployment phases are a continuous iterative process where frequent cyclical steps of development, system refining, and deployment happen throughout. Under the UCD approach, we adopted generative[19–21] and evaluative methods during the three phases. We will explain the methods adopted in each phase in detail as follows:

Discovery phase

In this phase, we focused on the need for an information system for the hypertension control program and understanding the user work environment. We started the discovery of Simple in 2017 in a one-week "Design Sprint," a UCD method first developed at Google.[22] We used a graphics editing and user interface design app to build the prototypes and designs of Simple. A team of experts comprising epidemiologists, public health professionals, designers, and developers ideated and created a prototype in 1 week. With the prototype, we implemented a set of qualitative methods with Indian healthcare workers to validate the initial ideation and learn more about the needs from the field. The "Design Sprint" provided confidence in the basic concept to move forward with the project; hence, we initiated a discovery phase.

The generative exploratory methods,[19–21,23–25] namely, discovery interviews,[26,27] storyboarding,[28,29] co-creation[30] technique, and contextual inquiry[31–33] were used in the user-experience study for the Simple app.

1. Contextual inquiry involved observation of users in-depth while performing their regular tasks in their natural setting (i.e. a healthcare facility) to gain a strong understanding of their work practice and behavior. Contextual inquiry, a qualitative ethnographic technique, attempts to obtain and understand the product users' context by employing investigators in the user environment through participatory observation sessions.
2. Discovery interviews were conducted with stakeholders, wherein the problem to be solved was understood further, and study questions were formed. These interviews were conducted in the field as well as telephonically. Based on the discovery interviews, we observed the workflows of a typical staff nurse in a public health facility. We documented the pattern of concerns if they use an Android app concurrent with their work.
3. Storyboarding is the technique we adopted to communicate the concerns of a healthcare worker using an app to developers, designers, and product managers. Storyboarding is a visual, data-driven technique that illustrates the key parts of the user journey, which helps us to anchor many design decisions. The technique generated a deeper understanding within the internal team to sensitize them to the real-world challenges healthcare workers face.
4. Co-creation is a technique where we used low-fidelity paper prototypes to design solutions along with future app users. We involved the healthcare workers to refine the prototype of Simple designed by us. Co-creation involved a design-thinking iterative process such that we can document the constraints, workflows, processes, and services delivered in the healthcare worker environment.

Development phase

At the end of the discovery phase, we understood the requirements. In the Design Sprint, the needs were refined to design the prototype. The designers and engineers jointly identified the appropriate platform and program language for the app and dashboard. The development of the application was started, and the deployment of the tested application was implemented. However, when a new feature was introduced in Simple, we re-started with the discovery and proceeded to development and deployment. Development and deployment are cyclical, iterative processes. This continuous feedback for iterative development and deployment is called the agile development method.[34] The agile software development method is a time-bound, iterative approach to software delivery that builds software incrementally from the start of the project instead of trying to deliver all at once.[35] We obtained feedback from the end users with evaluative methods that included qualitative app assessments.

We adopted a hybrid mixed-method technique, called usability tests,[36–39] and qualitative methods, such as user interviews[40] and A/B testing[41–44] in the development phase.

1. Usability testing: In usability testing, we observed users during regular clinical care and asked participants to

perform tasks (i.e. task analysis). The observed and explicit verbal feedback during the completion of tasks was documented. Usability testing helped us improve the design, address pain points, and learn more about the users' perspectives on the app. Usability testing was done with the users to evaluate the efficacy, efficiency, and user satisfaction. Multiple new features of the app underwent usability tests with at least five participants. To identify usability issues, it is recommended to interview at least five users during the evaluation.[45–47] We conducted 30 usability tests for different features in four selected project districts in India.

2. User interviews: We adopted qualitative user interviews among Simple users to identify the reasons for the low uptake of any specific feature and address the user issues to improve usage. A set of questions was asked, targeting the context after establishing rapport with the participant. Each user interview lasted 20–30 min. Prior to 2020, we often conducted user interviews in-person, but due to COVID-19, we conducted remoted user interviews by telephone to healthcare workers.

Deployment phase

After deployment, we continued an iterative process to steadily improve the application's performance. We adopted qualitative methods, such as user interview[40] and diary studies,[48–50] as well as quantitative methods, such as user analytics. Pulse interviews, which are a mixed method, were adopted in the post-deployment phase.

1. User interviews: As explained in the development phase, we conducted user interviews with a specific study question on a specific context (e.g. usage of multiple information systems to register hypertension patients). User interviews are longer (45 minutes–1 hour) qualitative interviews conducted with Simple users post-deployment to identify how Simple affected their workflow and decision-making.
2. Diary studies: Diary studies require users to longitudinally self-report data of their experiences and pain points. We obtained self-reported user log data about their experiences in using the app. We told the users to answer six simple questions related to new app features that they use daily. We contacted the users every day for 1 week with the same set of six questions and recorded their responses. Thus, we observed whether or not a new feature was supportive of the users' day-to-day work and affected the app performance.
3. User analytics: We used a business intelligence tool called, Mixpanel, to monitor the user analytics recorded from the Simple application. We monitored the app health and specific indicators, such as the median time taken to register newly diagnosed patients, time taken to record a follow-up visit of a previously registered patient, and monthly trend of patient registration.
4. Pulse check interviews: These mixed-method interviews were conducted in regular intervals of shorter duration. These qualitative interviews were conducted in loop with the user analytics (explained later). User analytics generated alerts on the low uptake of a specific feature of Simple, which was clarified in the pulse check interviews. We also utilized the opportunity to gain suggestions on the features of Simple. During the pulse check interview, we conducted user-satisfaction surveys of the overall functionality of the app among the Simple users using a Likert scale.

Human ethics consideration

We obtained approval from the Institutional Human Ethics Committee of the ICMR-National Institute of Epidemiology, India (NIE/IHEC/201709-02). We obtained a written informed consent from all the participants before initiating the interview and maintained their confidentiality.

Data analysis

A quantitative analysis was employed in the usability metrics, Likert scale surveys, and user analytics that provided measurable indicators for app performance and user satisfaction. The time taken to register newly diagnosed patients, record a follow-up visit of a previously registered patient, and monthly trend of patient registration were expressed in median and interquartile ranges. User analytics from Mixpanel underwent a time-series analysis to identify the usage trends.

Thematic analysis was applied to the qualitative data obtained from the discovery interviews, usability testing, and post-deployment user interviews, revealing recurring patterns and insights. Coding techniques were used.

Results

We hereby document our observations and findings in each phase of building the Simple information system by adopting the UCD approach.

The Simple information system (https://www.simple.org) was designed to register and perform a follow-up on people with hypertension or diabetes. It has a front-end Android application and a web-based desktop application. The Android application enables the health worker at the facility to manage the data of diagnosed hypertension and diabetes patients. The web-based application has a dashboard of the data collected through the Android application and generates various reports, including treatment outcomes.

We explain herein the findings observed in the iterative discovery, development, and deployment phases of the Simple information system.

The discovery phase included observations and interactions with health care workers to understand their workflow, tasks performed in hypertension and diabetes care, and contextual factors related to the setting.

We explain below one of the methods adopted in the discovery phase using an example of nurse workflow mapping.

Discovery phase

Applying the generative methods, we mapped the work of a staff nurse and the patient flow in a primary healthcare facility. Based on our observation, a typical staff nurse works in a day between 9 a.m. and 3 p.m. There was much dynamicity in her work pattern in terms of the blood pressure measurement in a number of patients and record in the registers. A typical NCD staff nurse workflow (Figure 1) peaks between 9 a.m. and 12 p.m. with a greater number of patients waiting. There were also fluctuations in the number of patients they counseled.

In addition to the workflow of a staff nurse, we mapped the patient movement, data entry process, and description of the wait time based on the observation at the small and large facilities as per the number of patients being consulted every day (Figure. 2.)

Storyboarding

Based on our field visits and experiences from the simulation clinic, we adopted a visual, data-driven storyboard technique that illustrates a healthcare worker workflow in a typical public health facility. We assumed a staff nurse of a PHC as part of our storyboard technique since they represented the majority of app users. Storyboarding is a visual narrative of an end-to-end story of how a staff nurse hears about the Simple app for the first time, their thoughts on using the app in their workflow, and how they would teach a colleague to use Simple. This narrative focused on using an app and encompassed the user's workflow. We sketched the key moments of the healthcare workers where we brought in facts from the user interviews and observations. We sketched the 11 key moments that reflected the healthcare workers' experience. In each moment, we listed a healthcare worker's concern observed in our field visits and user interviews (Figure 3). We published our storyboard on our documentation site and printed out each frame. For the developers, the storyboard really helped build empathy with healthcare workers and provided them with real context. The storyboard was a reference for the app we were building and how it would affect healthcare workers. As a tool, the storyboard fostered the participation of all stakeholders in the information system design process and helped us all to make better, user-centered decisions.

The following were the key reflections of the storyboarding:

1. The app is one of the several tools a health worker uses in a busy clinic of anxious patients.
2. Healthcare workers will have little attention on the app; hence, it should be easy to use with less duplication of effort.

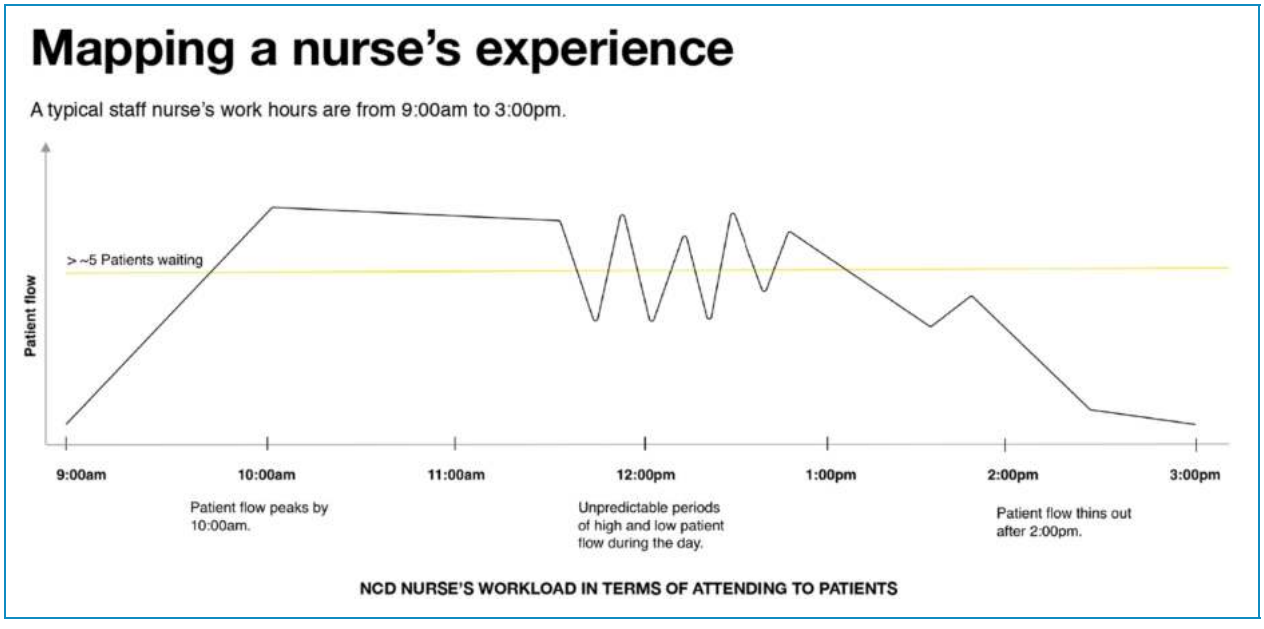

Figure 1. Nurse's workflow on a typical day in a primary care government health facility in India in 2019.

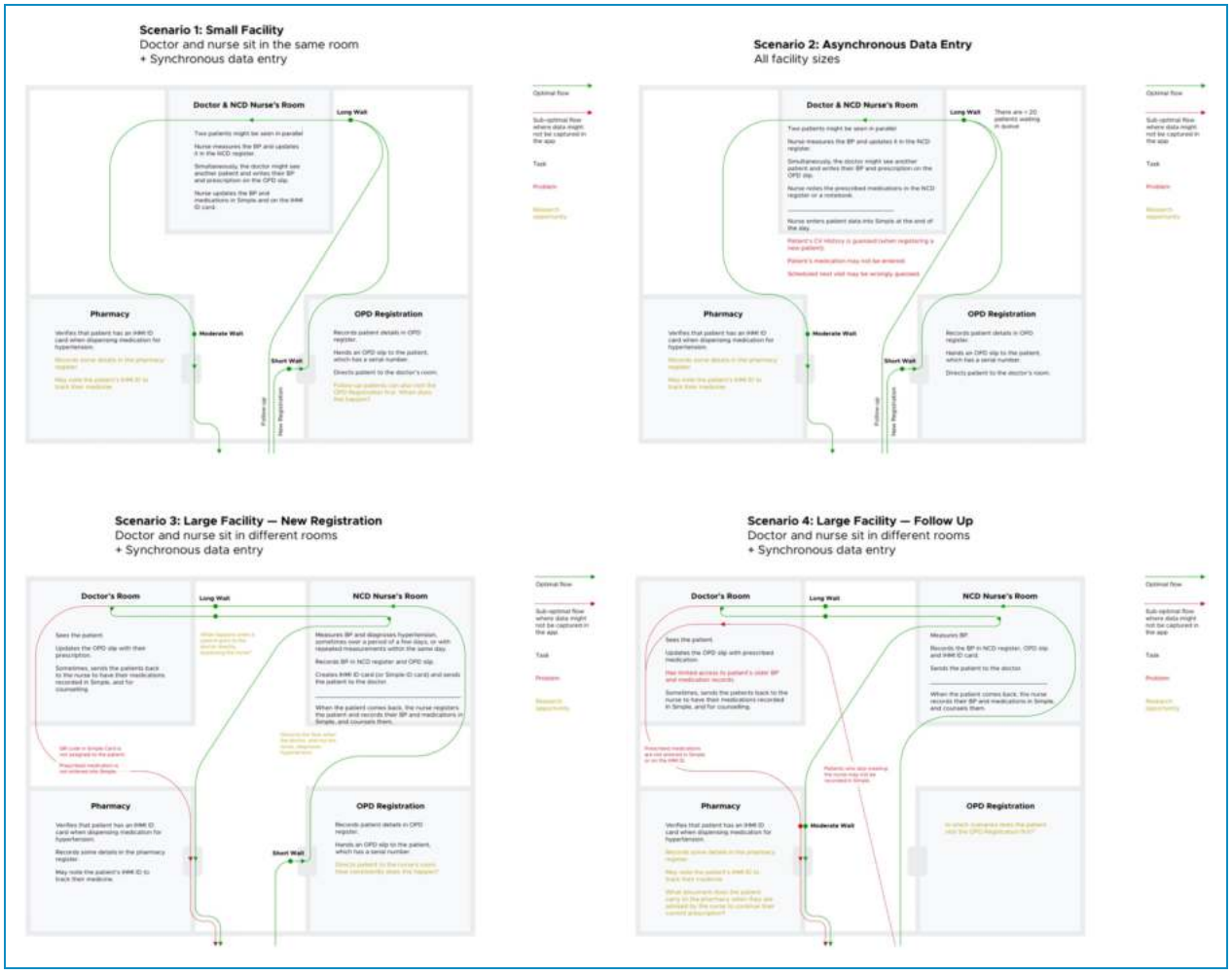

Figure 2. Patient flow in different primary care government health facilities in India in 2019.

3. It is challenging to navigate the patient data through the combination of prescription slips, patient ID cards, and mobile device.

Simulated clinic

Following the story boarding, we simulated a clinic and conducted roleplaying as staff nurse, doctors, and patients to understand how a digital information system could affect a busy clinic. Simulated clinics helped the implementation and tech team to understand the challenges of using them in public health facilities. The detailed plan and tasks of our simulation clinic are explained in the Supplemental material.

Co-creation

Co-creation, a participatory design technique, was centered around the voice of the healthcare worker and included them during the design process. We roughly sketched our app and chose a few designs to be taken to the field. We took prints of our designs on paper, called paper prototypes (Figure 4). We visited the health facilities and asked the staff nurses to pick which paper prototype design idea they find interesting and documented the reason. We asked each healthcare worker to pick their three favorite design ideas and explain their choices. These explanations were the key to the whole co-creation process. Some of their explanations are as follows:

> "I absolutely need this (an idea), no one appreciates our hard work, this is so motivating,'' "Oh! Stock of medicines? How will you get this?" (Staff nurse X, Health facility Y)

> "Oh! Can you show me daily updates? This will be super helpful in cross-checking if everything is updated." (Staff nurse X, Health facility Y)

We observed some suggestions for improvement in our design ideas, few examples are as follows:

Figure 3. Storyboard illustrating a typical day of a staff nurse in a government primary health center in India in 2019.

> "Could we see a list of patients who missed a follow-up visit?" (Staff nurse A, Health facility B)

> "Can we add a list of patients who we called but who never came for a follow-up?" (Staff nurse AY, Health facility BX)

Some of the key lessons we learnt from co-creation were.

1. Paper prototypes helped us focus the healthcare workers' attention on the content, not the design.
2. The low-fidelity paper prototypes also set the bar low; thus, nurses felt comfortable criticizing the ideas.
3. Since they chose from many ideas, there was no pressure to be right or wrong. Thus, nurses and doctors felt involved in the decision-making process behind an app they use daily.
4. Paper prototypes effectively shifted their mindset to imagine scenarios and creatively suggested how the Simple app could improve their work life.

Development phase

Based on the discovery phase, we identified the field requirement, context of the user (healthcare workers), and role of the Simple information system over the work environment. Designers liaised with the developers to build the Simple information system.

Usability test

We conducted 31 tests to determine whether or not a newly introduced feature was understood correctly and documented any apprehension on the new feature. One of the usability tests on a feature of listing overdue patients to visit the health facility is explained in this section. The overdue tab in the Simple app lists patients who missed their visit to the health facility. We provided the option to the user to call the patient and mark the outcome of the call. Based on the outcome of the call, the patient was categorized as pending to call, agreed to visit, reminded to call later, removed from the list, and had no visit in 1 year. We introduced a search bar and sections on the abovementioned categories in the overdue tab. We spoke to five users from four districts of different states to evaluate their responses on introducing this feature. All five users were clear about the meaning of the categories and functionality of the categories.

Figure 4. Process of preparing and selecting paper prototype design ideas in building the Simple information system, 2017–2022. *From left: Designing the app layout by hand, making paper prototype design and selecting the prototype.*

> "All patients should be downloaded, not just patients who are yet to be called. Because these lists are shared with ANMs etc, and they will need an extensive list". (Staff nurse XN, Facility YM)

All five users expected all patient names to be downloaded, regardless of their category. Most users preferred the new improvement in the design with a search bar and the categories for overdue patients (Figure 5)

Usability testing helped us understand and make decisions on the key features of Simple, such as QR code-based patient retrieval and inclusion of overdue list with call facility.

Like app improvement, we introduced a new navigation system in the Simple dashboard. We evaluated the new feature of the dashboard among five dashboard users who were program managers supporting the hypertension control program in their respective states. We obtained feedback on the existing dashboard design and functionality. Four out of five users could use the existing dashboard design comfortably. However, they all reported certain concerns: repetition of the content across the dashboard, difficulty navigating the reports section, and lack of training materials for dashboard users and their restrictions to visualize the data based on their roles. We found a 3.4 out of five satisfaction score of the existing dashboard (Figure 6), where the responses were recorded in a 1–5 Likert scale (1—very dissatisfied and 5—very satisfied). We improvised the concerns expressed by the users in our new design. We shared the new dashboard design prototype through a link to the five users. All five users found navigation easier in the newer dashboard design and unanimously preferred the new one over the existing one.

> "I will definitely prefer this over the current dashboard. It feels easier to use - I was able to find information more quickly." (Program manager A, District B)

All five users found downloading line lists to be a very useful feature. Identifying the facility/administrative block toggle button was not immediately apparent to three users. This limited their overall experience and did not allow them to explore the newly introduced design fully. Users opined a score of 4.3 out of five for the new design.

As part of usability testing, we provided tasks to the users on specific scenarios related to the dashboard. Users were asked a series of quick questions related to the navigation of the dashboard. Some of the questions and their responses were mentioned in Panel #4.

All five users could easily identify the facilities registering hypertension patients. Except for one, four users could complete the task within 5 seconds of finding the facility registering hypertension patients using Simple. While displaying the number of facilities using the Simple app, three out of five users opined to view the denominators of each facility type.

We also documented the suggestions related to the dashboard from the users:

> "If a peripheral health centre is not implementing the program, it is relatively better than a larger health facility not implementing the program. If we are able to find out if a large facility is not implementing the program, we can draw our focus to resolving this issue." (Program manager, District Y)

Usability testing helped us corroborate the users' interaction with the dashboard and obtain their suggestions for improvement.

User interviews

During the development, we obtained feedback from healthcare workers on the developed features through user interviews. We conducted 11 rounds of user interviews in the development phase for various functionalities and features of the system. One of the features we introduced

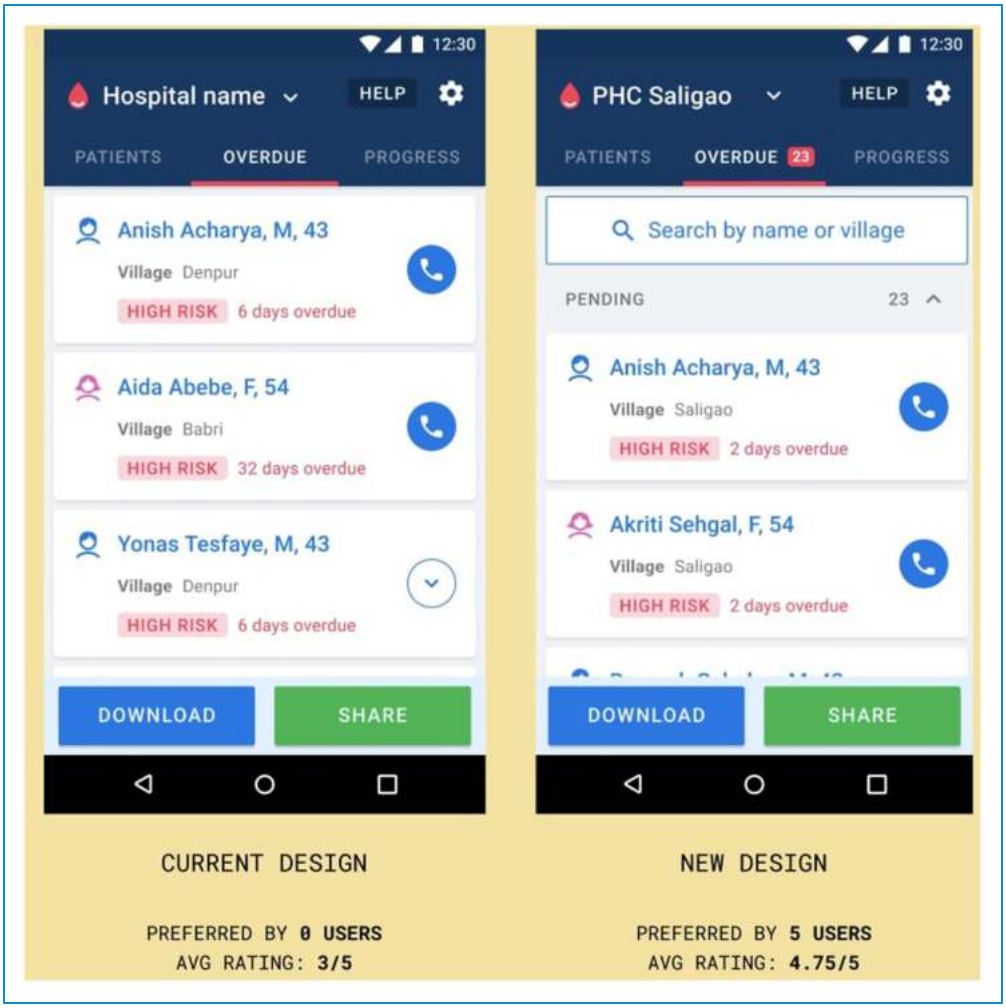

Figure 5. Improvements in a feature of Simple with its rating by users.

was the instant search of patients in the Simple app instead of typing the full name or phone number. We interviewed five users in three districts of various states to evaluate their experience with the instant search and understand its influence on the user's work speed. Four of five users shared that instant search had positively affected their work as it helped reduce the time to search for patients. None reported delay in loading results. One of the users opined:

> "Earlier, we spent much time entering the patient's full name and then hitting 'Next' to see a patient list. Now, it automatically appears as we type out a few letters. This has made our work faster." (Staff nurse XA, facility YB)

One user shared that if they accidentally entered after the patient's name, it affected the search results, as was also considered during instant search. Three of five users shared that the overall performance of the app had improved after the recent app updates. We received a suggestion of a keyboard up screen whenever adding details to register a patient, such that this nudge mandated the user to complete the patient details.

A/B testing

While designing the dashboard on the selection of the report output, we did A/B testing with five public health managers. We compared two report concepts and obtained their feedback on which concept was useful. We did a card-by-card analysis of the key reports to be displayed in the dashboard. Regarding the implementation status of the program, four out of five program officers reported Concept A as self-explanatory and appealing. All five program officers opined on the facility's requirement of the break-up of indicators. With respect to the registration status, Concept A was preferred by four out of five officers. One of the officers suggested that adding a comparison of the registration status among districts within a state was useful.

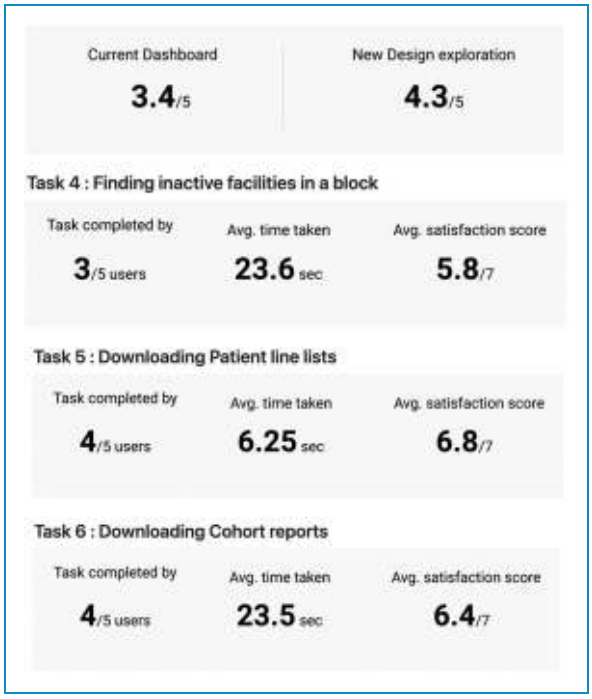

Figure 6. Tasks provided to the users in usability testing for the Simple dashboard, India Hypertension Control Initiative 2021.

> "We can show officials that with similar conditions, this district's coverage is at 15%. We can learn from the top district what they're doing well." (Program officer D, District E)

Three out of five officers suggested re-ordering information on the cards into 1) estimated hypertension population, 2) total registered patients, and 3) patients under care.

> "In one picture, the district official should know what the contribution of each block towards the coverage. Coverage status is an important indicator." (Program officer B, District C)

While we obtained views on the report card on the blood pressure control status, there were differences in how it was visualized.

> "During the district progress meeting, I'll need to show the bar graphs that display month-on-month progress. However, in review meetings and field visits, the maps will be useful since it highlights the block's control rate." (Program officer Y, District Z)

Simple was built with the Fast Healthcare Interoperability Resources (FHIR) standard. The FHIR standard is a set of guidelines for exchanging health information across health information systems.

Android application features

The Simple android application has four main features: patient tab, overdue patient list tab, progress tab, and drug stock reporting.

1. On the patient's tab: Users register a new patient with a QR code card linkage. At the time of registration, the user could record the age, address, phone number, diagnosis, co-morbid conditions, blood pressure reading, blood sugar values, and drugs prescribed. Patient follow-up is also done on the patient's tab by scanning the QR code or manually searching the patient by name or phone number. During the follow-up, it is enough for the user to record the blood pressure or blood sugar values and update the drugs prescribed.
2. Overdue patient's tab: Patients who did not visit the due date at the registered health facility are listed here with the number of days overdue.
3. Progress tab: The progress of registrations and follow-up daily, monthly, and yearly are summarized. Patient's treatment outcome reports about the proportion of patients under controlled, uncontrolled, and missed visits are listed here.
4. Drug stock reporting: In the progress tab, a featured button is placed to enter the details of drug stock at the end of every month by each facility.

Dashboard features

The Simple dashboard has five main sections: Reports, Facility comparison trends, Drug stock, Overdue patients, and Administrative tools.

1. Reports: The user could visualize the program indicators, such as monthly registered patients, proportion of patients under controlled, uncontrolled, and missed visits. Quarterly and monthly cohort reports on the treatment outcomes of patients under care could be visualized. Users could drilldown the reports by district, block, and facility level.
2. Facility trends: The user could visualize and compare the facilities on its performance based on the treatment outcomes. Users could identify the facilities requiring additional support and attention to improve the treatment outcomes of their patients.
3. Drug stock report: Tracking of drug stock by facility, block, and district for hypertension and diabetes is viewed by users; based on the number of registered users, the number of patient days the drug stock could be observed for better planning in drug logistics.
4. Overdue patients: This section captures and displays patients who are overdue by block and facility. Users could download the list of overdue patients under this section to follow-up either in field or through phone.

5. Administrative tools: Managing the users of the Android application and other access of dashboard users is done in this section. Apart from user approval, managing the medication list, adding facilities, and bulk import of patients could be done using the admin tools. Users can access the training resources and materials under this section.

Deployment phase

We adopted the iterative deployment and development processes to obtain feedback on the overall app performance and specific features. This enabled us to document how the application responded to field conditions when introducing a new update or feature.

Pulse check interviews. We regularly reached out to the users (healthcare workers) at regular intervals to understand their pressing issues with the app, the features they like the most, and other field needs related to the app. Due to CoViD-19, we reached out to the users via telephone. We conducted 15 pulse check interviews with the healthcare workers. Each interview lasted for an average of 15 minutes.

In a pulse interview conducted in February 2022 among five Simple users, the average user satisfaction rating was 4.2 out of 5 on the app's overall functionality (Figure 7). We adopted 3 as the lowest and 5 as the maximum score on the user satisfaction scale. After introducing an instant search feature, none reported that it slowed down the app's performance. All opined it was easy to search for the patient. The users provided recommendations on the design of the overdue list. Three out of five users were concerned on the time-consuming process of securing calls from the app.

As of October 2022, over 24,31,962 hypertension and 8,99,829 diabetes patients had already been registered in the information system of 10,017 health facilities across India. We found that the median duration of entering a new patient visit in the app was 78 seconds, and a follow-up patient visit was 14 seconds.

The usability five-point scoring on user satisfaction derived a 4.3 score for the dashboards. Four out of five random users completed the task of downloading the patient line list and cohort reports from the dashboards. When testing the user satisfaction among the app users (i.e. seven out of eight times), the average satisfaction score remained above 4 out of 5.

In October 2022, the median duration of registering a new patient into the app was 50 seconds, and recording a follow-up visit took 14 seconds. Over the last 2 years, quarterly short interviews with 100 app users indicated that seven out of eight times, the average satisfaction score remained above 4 out of 5. Usability tests of Simple dashboard designs with five dashboard users derived a 4.3 score on a five-point scale. Testing also found that four out of five test participants completed the tasks of downloading patient line lists and cohort reports satisfactorily.

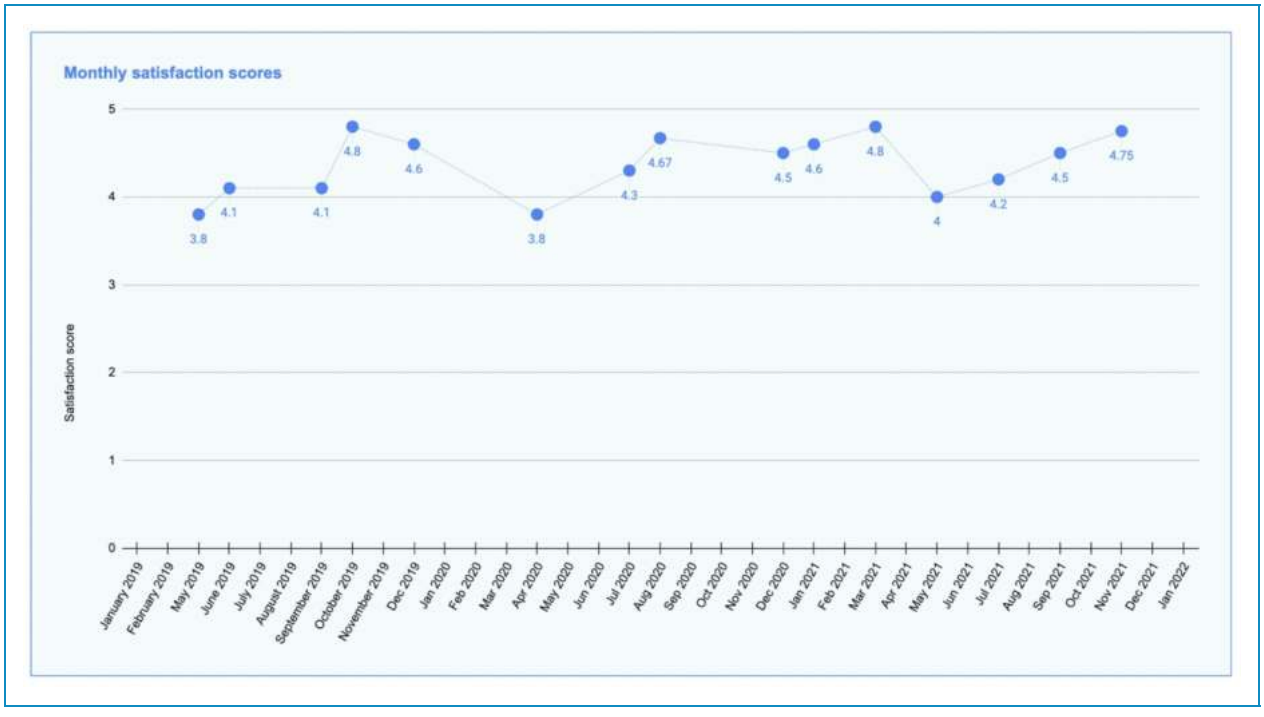

Figure 7. Satisfaction score by the users by time on the overall performance of the Simple app, 2017–2022.

Discussion

We designed, developed, and deployed a point-of-care application, called the Simple app, to improve hypertension and diabetes management in the government health facilities of India. We observed that the health workforce utilized well the Simple information system with high usability. The health workers were satisfied and completed the task while providing patient care. Simple operates with the best industrial standards, including offline-first application, free open-source software, compatibility with FHIR standards, and user-centered development standards.

Of the various non-communicable diseases, the burden of hypertension and diabetes is very high in India. We could not identify any literature documenting the experience of deploying a real-time information system at scale in a public health program in low-resource settings. Hence, we need to consider the scale and volume of patients while designing the information system. If we take the example of hypertension in India, it is the most common condition for which the adult population may seek treatment in primary care. Nearly 200 million people with hypertension live in India. As per recent estimates, only 14.5% of people with hypertension are under treatment.[4] Therefore, there are 29 million people under treatment whose care must be monitored regularly to avoid premature deaths. Assuming 50% of these patients are under care in government health facilities, nearly 15 million people with hypertension visits must be recorded to monitor their care and outcome. This will continue to increase every year. Even if they visit at least three times per year, then every year, the data of nearly 45 million visits will be recorded by any means of information system. For every patient, if only three details (e.g. blood pressure, data of visits, and drugs prescribed) are recorded, then 135 million data points for every year are recorded for 15 million patients visiting government health facilities. This data will need to be recorded every year until their lifetime. Assuming 20 years of visit, there will be nearly 400 million data points. The abovementioned estimates are for hypertension alone. Adding data generated from diabetes patients' visit increases the size much more. The information system is expected to convert data to useful information to track key indicators, such as proportion of registered patients under regular care and proportion of patients under care who achieved treatment goals (e.g. proportion under control at the facility, district, state, and national levels). The same has been mentioned by the WHO guidance document on monitoring the framework of NCDs.[51] A robust digital information system is a necessity to generate basic information from the generated data of such size over a period of time. Health workers at the ground level enter these data during patient visits at each time. Therefore, data accuracy is largely driven by the user's acceptance.

We designed and developed Simple considering the health care providers working at government health facilities. We utilized techniques and methods to identify the user requirement, experience, and usability of our digital information system, Simple. These techniques are collectively called user-centered design or approach. They are well utilized in non-health industry products, especially digital products, to improve the user experience and utilization. Spotify is a music-streaming industry with 205 million active subscribers across the globe. It invested well in user research mixed methods and improvised their products.[52] Airbnb is a digital platform that connects individuals requiring accommodation as a guest to hosts offering their accommodation for rent. Airbnb adopted experience designing to tell the story of a customer at each moment and the ideal outcome in a technique, called storyboarding. The project, called "Snow White," listed the emotional moments a customer experiences in their platform.[53] Both examples provide insight into harnessing UCD methods to improve usability and user experience. We adopted these user experience methods and storyboarding techniques in designing and developing the information system.

User experience study

Multiple factors play a role in determining the usage of a digital health application in a real-world health setting. In delivering medical care to people with hypertension and diabetes, digital health is a tool for improving the quality of care. Implementing a digital health application is a complex intervention with multiple components and contextual factors.[54] We adopted user experience study methods to understand the contextual factors that enable or halt the usage of a digital health application.[55–57]The user experience study methods were conducted in an iterative discovery, development, and deployment phase cycle. The key user considerations during these phases were captured to improve the usability of the Simple application.

Agile

Traditional project management techniques in software development, such as the waterfall model,[58,59] depend on stepwise development, completely specifying the requirements, designing, and testing the system. Anticipating requirements in advance through expert input and developing a tool that delivers for healthcare workers sounds enticing. However, it still misses the key pragmatic needs of users in the field. The uncertainty and variability nature of a dynamic healthcare environment limits the usage of the waterfall method. Therefore, we adopted the agile technique with UCD throughout the development cycles. Iterative development not only helped us come up with a user-centered application, but also provided us with the opportunity to understand the field functionality of the

application. The implementation of the agile method in digital health interventions brought an effective user-centered design.[22,60]

User-centered development

In developing the application, we harnessed methods, such as co-designing and user interviews, to deploy a user-centered point-of-care digital health application. The end users' views and perspectives played a larger role in the interface and, most importantly, in the operational aspect of the end product. User-centered development is considered as one of the best software development practices. As per health design thinking, the UCD plays a significant role in the functional design of equipment, product, or service.[61–63] The user-centered design, aka human-centered design, is a process where users are involved collaboratively and inclusively.[64] The inclusiveness of users in the development brought the context of using Simple in a busy clinic.

Usability

Ample evidence in the literature supports that poor usability of the health information system is a crucial factor linked to failure.[65–68] Our usability evaluation of the application and the specific features clarified our stand on how to keep the features minimal and maximize functionality. Usability testing is considered as the best industrial practice to improve user experience.[37,69,70] The best usable product level up from a minimally viable product to a maximum lovable product by the users. The practice of usability testing in digital health is to be considered a mandate. A well-usable digital health product improves efficiency and saves lives compared to any other IT applications.

With a high proportion of hypertension and diabetes in India, detecting, treating, and performing a follow-up of patients at primary care comprise a low-cost, rapid, and reliable intervention.[71] Therefore, providing a reliable information system in primary care is crucial for two main reasons, that is, patient monitoring during follow-up and program monitoring in achieving outcomes. The provision of real-time feedback about the treatment adherence by patients and the monitoring of patient cohorts by facility or geography to achieve the program outcomes in real time are critical.[72]

Exercising UCD methods require dedicated teams to design, program, and support end-users. We did not study the scalability of our development strategy, which is one of the major limitations of our study. Although we observed a within-group change in the usage behavior of the Simple information system, we did not compare it with another information system to determine the effectiveness in registering and perfroming a follow-up with the patients. This is another limitation of our study.

Conclusion

Our experience documented the advantages of designing, developing, and deploying a highly usable and user-friendly mobile application to achieve program outcomes. Agile methodology and user-centered design supported well the successful implementation of a digital health application in busy health facilities. We recommend that digital health practitioners utilize UCD product or service development methods. Our study also suggests that digital health researchers must explore the determinants of using an information system in the public health context. Transdisciplinary knowledge exchange activities could facilitate conversations between public health researchers and digital health, bringing better digital health applications.

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