BMJ Open

UDAY: Protocol of a Comprehensive Diabetes and Hypertension Prevention and Management Program in India

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-015919
Article Type:	Protocol
Date Submitted by the Author:	12-Jan-2017
Complete List of Authors:	Mohan, Sailesh; Public Health Foundation of India Jarhyan, Prashant; Public Health Foundation of India Ghosh, Shreeparna; Public Health Foundation of India Srinivasapura Venkateshmurthy, Nikhil; Public Health Foundation of India Gupta, Ruby; Public Health Foundation of India Rana, Ritu; Population Services International India Malhotra, Cheena; Project Hope India Rao, Bhaskara; MaxCure Hospital Kalra, Sanjay; Bharti Hospital Karnal Tandon, Nikhil; All India Institute of Medical Sciences, Reddy, KS; Public Health Foundation of India Prabhakaran, Dorairaj; Public Health Foundation of India
Primary Subject Heading:	Epidemiology
Secondary Subject Heading:	Diabetes and endocrinology, Health services research, Public health, Cardiovascular medicine
Keywords:	Hypertension < CARDIOLOGY, General diabetes < DIABETES & ENDOCRINOLOGY, EPIDEMIOLOGY

UDAY: Protocol of a Comprehensive Diabetes and Hypertension Prevention and Management Program in India

Authors: Sailesh Mohan, [1] Prashant Jarhyan, [1] Shreeparna Ghosh, [1] Nikhil Srinivasapura Venkateshmurthy , [1] Ruby Gupta, [1] Ritu Rana, [2] Cheena Malhotra, [3] Bhaskara Rao, [4] Sanjay Kalra, [5] Nikhil Tandon, [6] K. Srinath Reddy, [1] Dorairaj Prabhakaran[1]

[1] Public Health Foundation of India, Gurgaon, India

[2] Population Services International, Delhi, India

[3] Project HOPE, Delhi, India

[4] Manipal Hospitals, Visakhapatnam, India

[5] Bharti Hospital, Karnal, India

[6] All India Institute of Medical Sciences, Delhi, India

Corresponding author
Dr. Sailesh Mohan
Senior Research Scientist and Associate Professor
Public Health Foundation of India
Email:smohan@phfi.org

Abstract

Introduction
Diabetes and hypertension are two leading noncommunicable conditions, which are sub-optimally managed in India. Thus, innovative comprehensive approaches that can concomitantly improve their detection, prevention and control are warranted.

Methods and analysis
UDAY, a 5-year initiative aims to reduce the risk of diabetes and hypertension and improve management by implementing a comprehensive intervention program in the two selected study sites, Sonipat and Visakhapatnam (Vizag). It has a pre-post evaluation design with representative cross-sectional surveys before and after intervention. Within these two sites, urban and rural sub-sites each with a total population of approximately 1, 00,000 people each were selected and a baseline and post intervention assessment will be conducted deploying 5 surveys (among general population, patients, healthcare providers including physicians and pharmacists, health facilities) which will determine: the knowledge levels about diabetes and hypertension, the proportion treated and controlled; the patient knowledge and self-management skills; healthcare providers' management practices; the level of access and barriers to obtaining care.
The interventions will include: tailored health promotion for improving public knowledge; screening of adults aged ≥ 30 years for identifying those at high risk of diabetes and/or hypertension for linkage to the healthcare system; patient education using technology enabled community health workers, geographic information system (GIS) based mapping of the communities, healthcare provider training on management guidelines, community based diabetes registry and; advocacy to improve access to healthcare. The baseline surveys have been completed, the study areas mapped using GIS and the interventions are being implemented. UDAY is expected to increase over baseline the levels of: public knowledge about diabetes and hypertension; those treated and controlled; patient self-management skills; the use of guideline based management by providers and; access to healthcare, leading to improved health outcomes and inform development of a India relevant chronic care model.

Ethics and dissemination
Ethical clearance for conduct of the study was obtained from the Institutional Ethics Committee (IEC) of the Public Health Foundation of India. The findings will be targeted primarily at public health policymakers and advocates, but will be disseminated widely through other mechanisms including conference presentations and peer-reviewed publications, as well as to the participating communities.

Strengths and limitations of this study

- Unique large community based study in geographically and culturally diverse "real world" settings in India for improving prevention and control of diabetes and hypertension.
- Employs a comprehensive multi-level, multi component intervention approach to target the general population, patients, providers and to strengthen the health system for improving prevention and control of diabetes and hypertension.

- Concomitantly addresses detection, prevention and management of both diabetes and hypertension.
- Extensively leverages mobile technology to enable health workers in task sharing as well as for electronic data capture.
- Quasi experimental design with complex intervention may hinder attribution of specific effect to individual intervention components.

Introduction

Non-communicable Diseases (NCDs) are currently the leading cause of preventable death and disability in India, accounting for two out of every three deaths [1]. Among NCDs, the prevalence of type-2 diabetes mellitus (DM) and hypertension have been rising rapidly. Currently there are about 69 million people with diabetes, a figure that is projected to further increase to a staggering 124 million by 2040 [2]. The number of individuals with hypertension is projected to increase to 214 million by 2030 from 118 million in 2000 [3,4]. Furthermore, diabetes and hypertension are important risk factors for both the major forms of cardiovascular disease [CVD (coronary heart disease and stroke)], highly prevalent and attributable to nearly half of all the deaths from NCDs [4].

Despite the availability of proven and effective treatments, diabetes as well as hypertension detection and control rates are abysmally low in India with blood pressure control among those with diabetes being even more sub-optimal, with a huge gap between detection and adequate treatment [1,3,4]. Thus, there is great potential and opportunity to reduce the rising burden of diabetes and hypertension as well as the associated vascular risk in India through concomitantly improving their detection, prevention and control.

To address this huge gap in the prevention and management of both these conditions we are undertaking a 5-year initiative entitled “UDAY” (meaning dawn in *Sanskrit*) in epidemiologically

transitioning communities, that aims to reduce the risk of diabetes and hypertension and concomitantly improve the management of either conditions by implementing a comprehensive community based innovative intervention program in the two geographically and culturally distinct study sites, Sonipat (Haryana, North India) and Visakhapatnam or Vizag (Andhra Pradesh, South India). This paper describes the design and methods of UDAY- A Comprehensive Diabetes and Hypertension Prevention and Management Program In India.

Methods

Study design

UDAY has a pre-post evaluation design with representative cross sectional surveys before (in year one at baseline, pre-intervention) and after the intervention (in year 5). The main research question is: whether a multi-component, multi-level, cost-effective, comprehensive intervention program will improve the prevention, detection and optimal management of diabetes and hypertension in the two selected study sites. Ethical clearance for conduct of the study was obtained from the Institutional Ethics Committee (IEC) of the Public Health Foundation of India.

At baseline, in year one, 5 surveys were conducted among the general population, among patients, among healthcare providers including physicians and pharmacists and in health facilities to guide intervention development and impact assessment. Similar assessment is planned after the intervention, in year 5.

The specific objectives these assessments are to:

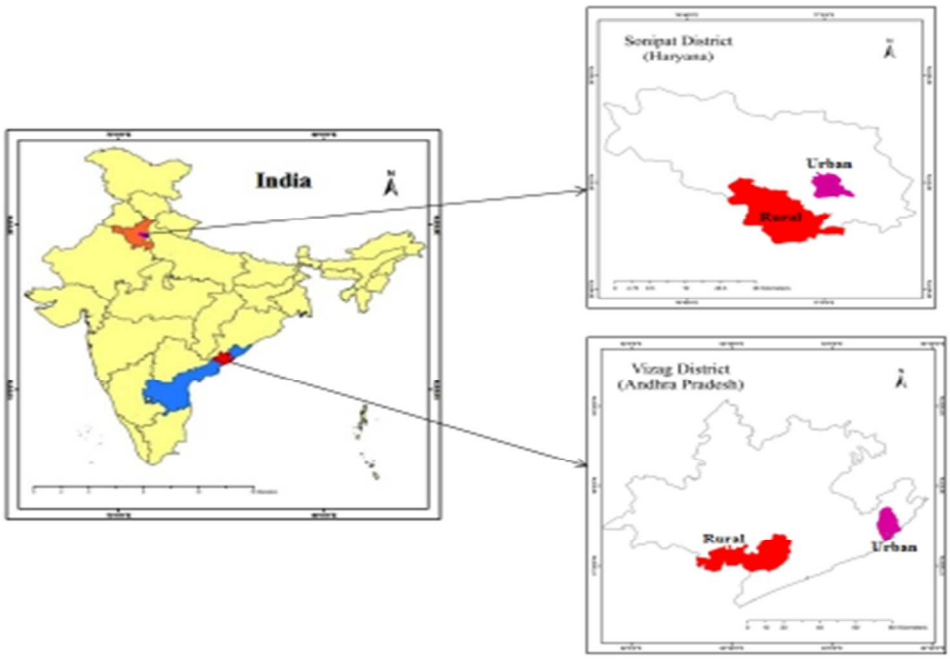
1. Determine the prevalence, awareness, the knowledge levels about diabetes and hypertension, the proportion treated and controlled among a representative sample (n=12000) of adults aged ≥ 30 years in the selected study areas. (Population survey)
2. Determine the patient knowledge levels and self-management skills among a convenience sample (n=400) of those diagnosed with diabetes and hypertension in the selected study areas. (Patient survey)
3. a) Determine healthcare providers' (physicians) knowledge and practices related to diabetes and hypertension management among a convenience sample (n=50) of healthcare providers' in the selected study areas.

   b) Determine pharmacists' knowledge related to diabetes and hypertension and dispensing practices among a convenience sample of pharmacists (n=350) (Provider survey)
4. Determine the level of access and potential barriers to diabetes and hypertension care provided by the public healthcare system in the selected study areas (n=50). (Facility survey)
5. Determine the cost-effectiveness of the intervention program in improving diabetes and hypertension treatment and management outcomes in the study areas. (Using population survey, GIS data and project implementation data)

Study sites

We are undertaking this comprehensive diabetes prevention and management program in two epidemiologically transitioning areas located in Sonipat in Haryana and Vizag in Andhra Pradesh (Figure 1).

Figure 1: Study sites



We defined the areas and their sub-areas using the following terminology:

- Sites – a bounded geographic area within which we have defined distinct rural and urban sub-sites for the study. Each site has been defined such that it contains approximately 2,00,000 people. Sonipat and Vizag are each a site.
- Sub-sites – within each site, we have defined one rural and one urban sub-site for study. Each sub-site is geographically bounded, and contains a population of

approximately 1,00,000. Within Sonipat and Vizag, we have defined two sub-sites each (rural and urban).

- Total project – the total project is the summation of the two sites, including the four sub-sites (two sub-sites within each site). Therefore the total population under the study is approximately 4,00,000.

Sample for the population survey

We based our sample size calculation on the prevalence of diabetes, which has a lower prevalence than hypertension, in previously reported studies in India. Anticipating a response rate of 85 % with a design effect factor of 1.5 (to account for cluster sampling, and a confidence level of 1.96, the sample size estimates were generated for males and females in three age strata (30-49, 50-69, 69 and above) in each setting (urban, rural). About 2968 subjects was estimated to be required per urban sub-site (Sonipat and Vizag) and 2942 subjects per rural sub-site (Sonipat and Vizag). The total estimated sample was 11820, which was increased to 12000 to obtain equal samples in both urban and rural areas. Sample weights were generated for estimating the prevalence of diabetes, hypertension and related cardiometabolic risk factors at the district level.

Survey sampling and participant selection

Population survey

Two representative population based cross sectional surveys with independent samples and identical methodologies at baseline and at the end of intervention will be conducted, that will provide estimates of the burden and changes in the prevalence of diabetes, hypertension, and related cardiometabolic risk factors. In addition, those recruited for the first survey at baseline

(which has been completed), will be followed up as a cohort to estimate the incidence of new cardio-metabolic (CMD) risk factors, disease, healthcare utilization, diabetes and hypertension related morbidity and mortality.

The first population survey (baseline survey) was done among a representative sample of adults aged ≥ 30 years residing in the selected study areas of Sonipat and Vizag. Inclusion criteria – a) adults aged ≥ 30 years residing in the sampled urban and rural areas of Sonipat and Vizag respectively. b) willing to participate and provide informed consent.
We excluded individuals who were unwilling to provide informed consent and those with serious chronic illnesses [such as that of the liver (cirrhosis), kidneys (renal failure) or malignancies], pregnant women.

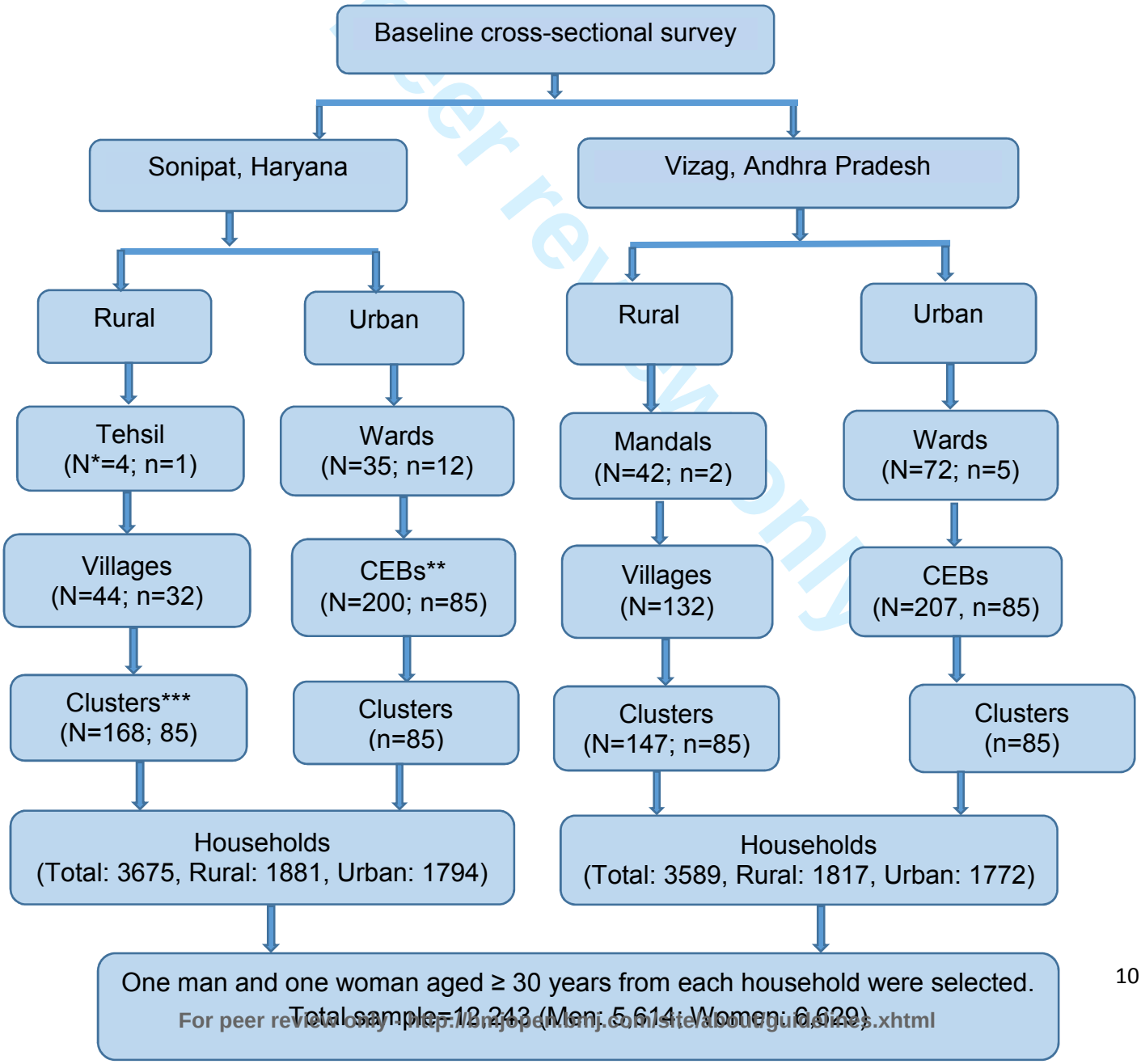
For the baseline survey, a multistage random sampling technique was deployed to obtain a representative sample of adults aged ≥30 years, using data from the most recent census of 2011. In addition, a manual enumeration and mapping of all households and structures was conducted in all the study areas [all census enumeration blocks (CEBs) in urban areas and villages in rural], to identify households and structures constructed since the last census (Table 1). CEBs are considered as the primary sampling unit in urban areas and villages in the rural areas respectively. On average, about 100-125 households with a population of 650-700 persons would generally constitute a CEB. This enabled a complete sampling frame for the selection of households for the survey and thus provided an equal chance of selection to each household. Besides, it also helped identify potential recipients of the intervention program (i.e., adults aged ≥30 years) in the study sites.

In each sub-site, 85 clusters were randomly selected (urban Sonipat: 85/200 CEBs, urban Vizag: 85/207 CEBs and rural Sonipat: 85/168 clusters, rural Vizag: 85/147 clusters) according to probability proportional to size (Figure 2). In rural sub-sites, bigger villages were divided into clusters with 75 to 300 households. From each cluster in the urban and rural sub-sites, 18 to 25 households were randomly selected and 1 eligible male and female were selected randomly within each household using Kish table. In Sonipat district, 3675 households participated in baseline survey (rural: 1881, urban: 1794) with total being 6208 participants (rural: 3104, urban: 3104). In Vizag district, 3589 households (rural: 1817, urban: 1772) participated in the baseline survey with total being 6035 participants (rural: 3069, urban: 2966). Thus, we had 12000 individuals from both urban and rural areas of North and South India.

Table 1: Manual enumeration of study areas

Study site	Structures	Households	Population ≥30 years	Total population (census 2011)
Sonipat urban sub-site	24408	20406	41981	102292
Sonipat rural sub-site	28813	17283	40850	100935
Vizag urban sub-site	16888	39504	70735	153721
Vizag rural sub-site	33799	30817	59540	121209

Figure 2: Sample selection for the baseline survey



*N=total, n=number selected

**CEB=Census Enumeration Block

***Cluster = In urban sub-site clusters comprise CEBs, in rural sub-site bigger villages were split into 2 or 3 clusters with sizes of 75-300 households.

Data collection for the population survey

For the baseline survey, trained health workers visited the selected participants at their homes. Written informed consent was sought and obtained from the selected individuals prior to data collection and a unique identification number was assigned. For each participant, data collection comprised an interviewer administered questionnaire, a brief physical examination (height, weight, waist circumference, hip circumference, blood pressure, body fat percentage), blood and urine collection as detailed below.

Information on demographics, socio-economic characteristics, behavioral risk factors (tobacco use, alcohol use, diet and physical inactivity), family history of various NCDs, female reproductive history, general awareness about diabetes and hypertension, risk factors, prevention, symptoms and diagnosis, complications, treatment and management, medical history of NCDs [diabetes, hypertension, coronary artery disease (CAD), myocardial infraction (MI), stroke, heart failure, chronic kidney disease (CKD), peripheral vascular disease (PVD), chronic obstructive pulmonary disease (COPD), asthma], quality of life, mental health, social support, cost of healthcare and healthcare utilization was collected using a tablet based application (Table 2).

Body measurements such as height, weight, waist and hip circumferences, blood pressure and body fat measurement by bio impedance using TANITA were also obtained using standardized equipment.

Bio-samples (fasting blood and morning urine) were collected for the laboratory estimation of fasting plasma glucose, glycated hemoglobin (HbA1c), lipids, serum creatinine, urea, urine microalbumin and urine creatinine. We have also stored the bio samples for future analysis of emerging biomarkers and genetics.

Table 2: Summary of indicators, measures, methods and instruments for baseline survey

Indicators	Measures	Methods	Instruments
Demographics and socio-economic characteristics	Age, sex, marital status, religion, education, income, occupation, contact details, and household assets	Questionnaires	Centre for cArdio-metabolic Risk Reduction in South Asia(CARRS) Surveillance Study [5] Establishment of Sentinel Surveillance System for CVD in Indian Industrial Populations (Sentinel Surveillance Study) [6] National Family Health Survey, 2005-06 [7]
Behavioral risk factors	Tobacco use Alcohol use Physical activity Dietary habits	Questionnaire Questionnaire Questionnaire	CARRS, Sentinel Surveillance Study Global Physical Activity Questionnaire (GPAQ-2) [8] CARRS,INTERHEART Study[9]
Family history	Prevalence of cardiometabolic diseases (CMDs) among family	Questionnaire	CARRS

	members related to participants, mortality		
Female reproductive history	Menarche/ gestational history, menopause (surgical / physiological / whether on hormone replacement therapy) / contraception	Questionnaire	CARRS
Awareness and knowledge	General awareness about diabetes and hypertension, risk factors, prevention, symptoms and diagnosis, complications, treatment and management	Questionnaire	CARRS
Physiological and biochemical risk factors	Hypertension	Blood pressure measurements	Standardized method (American Heart Association) and validated instrument (certified by British Hypertensive Society and Association for the Advancement of Medical Instrumentation) Standardized across both the sites
	Diabetes	Laboratory estimation of fasting plasma glucose, glycated hemoglobin (HbA1c)	Standardized across both the sites
	Dyslipidemia	Laboratory	

		estimation of serum total cholesterol, low density lipoprotein cholesterol, very low density lipoprotein cholesterol, high density lipoprotein cholesterol, triglycerides	Standardized across both the sites
	Obesity	Anthropometry (height, weight, waist and hip circumferences, body fat	Standard procedures based on National Health And Nutrition Examination Survey-III with instruments used in epidemiological studies on South Asian population
Medical history	Chronic kidney disease	Serum creatinine, urea, urine microalbumin and urine creatinine	Standardized across both the sites
	Stroke, myocardial infraction, Congestive heart failure, Chronic stable angina	Questionnaires including medical history	Rose Angina, CARRS
Treatment history, health services, quality of care and health care costs	Awareness and risk factor control	Questionnaire	CARRS
	Access to health care services, utilization of		

	services, health insurance coverage, costs of treating CMDs and their risk factors		
Prevalence	COPD and asthma	Questionnaire	NHANES III and present standards of the American Thoracic Society (ATS)
Health related Quality of Life	Mobility, self-care, usual activities, pain/discomfort, anxiety/depression (related to CMDs and risk factors)	Questionnaire	European Quality of Life 5 Dimensions questionnaire (EQ-5D-3L) [10]
Mental health	Depression	Questionnaire	Modified from Patient Health Questionnaire 9 (PHQ-12) [11]
Social well-being	Social support	Questionnaire	Developed for UDAY

Data collection for the patient survey

Trained research staff visited health facilities located in the aforementioned selected study areas and approached those with a diagnosis of diabetes and/or hypertension. Written informed consent was sought and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire (Table 3).

The patient survey was done among a convenience sample of 400 patients having diabetes and/or hypertension attending health facilities and residing in the selected study areas of Sonipat and Vizag.

Inclusion criteria: We included patients with diabetes and or hypertension residing/attending health facilities in the sampled urban and rural areas of Sonipat and Vizag respectively and were willing to participate and provide informed consent.

Exclusion criteria: We excluded those unwilling to provide informed consent.

Table 3: Summary of indicators, measures, methods and instruments for the patient survey

Indicators	Measures	Methods	Instruments
Demographics and socio-economic characteristics	Age, sex, education, income, occupation, contact details	Questionnaires	CARRS Sentinel Surveillance Study
Behavioral risk factors	Tobacco use Alcohol use	Questionnaire	CARRS, Sentinel Surveillance Study
Awareness and knowledge of diabetes and hypertension	Awareness of risk factors, symptoms and diagnosis, cut-off levels for diagnosis, complications, treatment and management	Questionnaire	Developed for UDAY
Diabetes and hypertension related medical history	Diagnosis, health care utilization, control, self-management practices, complications, comorbidities, and treatment adherence	Questionnaire	Developed for UDAY
Health related Quality of Life	Mobility, self-care, usual activities, pain/discomfort, anxiety/depression (related to CMDs and risk factors)	Questionnaire	European Quality of Life 5 Dimensions questionnaire (EQ-5D-3L)
Mental health	Depression	Questionnaire	Modified from Patient Health Questionnaire 9 (PHQ-12)
Social well-being	Social support	Questionnaire	Developed for UDAY

Healthcare utilization	Hospital visits in the past 12 months and health care expenditure	Questionnaire	CARRS

Data collection for the provider surveys

Trained research staff visited health facilities located in the aforementioned selected study areas and approached healthcare providers (physicians and pharmacists). Written informed consent was sought and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire (Table 4).

The physician survey was done among a convenience sample of 50 physicians working in the health facilities located in the selected study areas of Sonipat and Vizag.

Inclusion criteria: We included physicians working in health facilities located in the sampled urban and rural areas of Sonipat and Vizag respectively and were willing to participate and provide informed consent.

Exclusion criteria: Those unwilling to provide informed consent were excluded.

The pharmacist survey was conducted among 350 pharmacists by trained research staff in the aforementioned selected study areas. Written informed consent was sought and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire.

Inclusion criteria: We included pharmacists who were located in the sampled urban and rural areas of Sonipat and Vizag respectively, dispensing medicines for diabetes and hypertension, were willing to participate and provide informed consent.

Exclusion criteria: Those not dispensing medicines for diabetes and hypertension and unwilling to provide informed consent were excluded.

Table 4: Summary of indicators, measures, methods and instruments for the provider survey (physicians)

Indicators	Measures	Methods	Instruments
Socio-demographic details	Age, gender, qualification, years of practice, patient load, training in diabetes and hypertension management	Questionnaire	Developed for UDAY
Knowledge and practice pertaining to diabetes and hypertension diagnosis and evaluation of complications	Signs and symptoms, diagnosis and cut-off levels for diagnosis, evaluation for complications	Questionnaire	Developed for UDAY
Treatment practices for diabetes and hypertension	Lifestyle modifications, prevention and management of complications, names of medicines prescribed commonly	Questionnaire	Developed for UDAY

Data collection for the health facility survey

Permission was sought and obtained from respective district medical/health officers prior to data collection and data collection comprised an interviewer administered questionnaire (Table

5). Trained research staff visited public healthcare facilities located in the aforementioned selected study areas and approached the person/ medical officer in charge.

The facility survey was done in 50 public healthcare facilities (sub-centres, primary and community health centres, taluk/district/tertiary hospitals) situated in the selected study areas of Sonipat and Vizag.

Table 5: Summary of indicators, measures, methods and instruments for the health facility survey

Indicators	Measures	Methods	Instruments
Coverage statistics	Types of services offered, number of hours and days services provided per week, population covered, average daily outpatient department (OPD) attendance, number of beds available, status of National program for control and prevention of diabetes, cardiovascular disease and stroke (NPCDCS) implementation	Questionnaire	Adapted from Service Availability and Readiness Assessment tool (SARA) of the World Health Organization
Recommended manpower list	Numbers working at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended numbers and reasons for lack of recommended personal. Additional manpower required	Checklist, questionnaire	Adapted from Indian Public Health Standards, (IPHS) and SARA

	for NCDs		
Recommended medication list	Availability of medicines at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended medicines and reasons for lack for recommended medicines. Additional medicines required for NCDs	Checklist, questionnaire	Adapted from IPHS and SARA
Recommended equipment list	Numbers of equipment available at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended equipment and their functional status. Additional equipment required for NCDs	Checklist, questionnaire	Adapted from IPHS and SARA
Recommended investigative services list	Investigative services available at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended services and reasons for their unavailability. Additional investigative services required	Checklist, questionnaire	Adapted from IPHS and SARA

	for NCDs		
Recommended activities list	Frequency of recommended activities conducted and methods of conducting at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres for current diagnosis, treatment and health promotion. Reasons for not conducting the activities	Checklist, questionnaire	Adapted from IPHS and SARA
Availability of national guidelines and training of healthcare providers	Availability of national guidelines for diagnosis and management of diabetes, hypertension and CVD and training of healthcare providers in the facility to diagnose and manage diabetes, hypertension and CVD	Questionnaire	Adapted from IPHS and SARA

Bio-sample collection and storage

Blood samples (in fasting state) were collected in plain, fluoride and EDTA vacutainers (Becton & Dickinson, USA) by trained phlebotomists in households or in camps arranged close to the households. Samples for estimation for blood glucose were kept in ice and transferred to laboratories within 2 hours of sample collection and immediately centrifuged. Samples were centrifuged at 2500 rpm for 15 minutes and serum / plasma were transferred into the cryo-vials which were stored in 20^0C immediately. Buffy coat from EDTA vacutainers were separated and stored into cryo-vials for DNA extraction. Red blood cells were washed thrice with normal

saline and were stored for analysis of fatty acids in future. First early morning voided urine was collected from the participants and has been stored in deep freezer for future analysis of metabolites. All these samples were transported to the biochemistry laboratory at the Public Health Foundation of India (PHFI) in dry-ice on the day of collection from Sonipat and Vizag, where they were stored at -80^{0}C.

All clinical chemistry parameters were analyzed on autoanalyzer Cobas 311 using reagents from Roche Diagnostics, Switzerland. Glucose was estimated using Hexokinase method, cholesterol by enzymatic cholesterol oxidase method, triglycerides by GPO-PAP method & HDL and LDL by direct method, AST & ALT was estimated according to IFCC without pyridoxal phosphate, bilirubin total by Diazonium ion method, bilirubin direct by Diazo with sulphanilic acid method, urea by kinetic method, creatinine by Jaffe's method, and urinary microalbumin using immuno turbidimetric method. HbA1c was assayed by hplc method using reagents from Bio-Rad Laboratories, Hercules, CA.

Two levels of internal controls were run with every batch of samples. The intra assay and inter assay coefficient of variation for all the parameters were <3% and <5 % respectively.

The biochemistry laboratory is part of External Quality Assurance program from RIQAS for clinical chemistry parameters and HbA1c assay.

Geographical Information System (GIS) based mapping of study households and neighborhood built environment

All households as well as the study areas, including various points of interest as indicated below were geocoded using GIS mapping. This will be used to comprehensively assess the built environment and its impact on diabetes hypertension and risk factors. GIS based

techniques will be employed to study the association between built environment (BE) features and diabetes, hypertension and related risk factors.

Specially trained field staff visited all participant households and used handheld Garmin ™ GPS receivers to capture GPS locations of the households. The captured GPS coordinates were verified using Google Earth to see if the locations matched the actual locations.

Table 6 below shows the built environment features from the study areas that were located and mapped.

Table 6: Characteristics of the built environment in study sites

Environment features	Points of interest	N	Sonipat	Vizag
Healthcare facilities	Government hospitals	64	36	28
	Private hospitals & clinics	228	147	81
	Registered medical practitioners and unqualified practitioners	220	195	25
	Other health professionals	120	115	3
	Pharmacies	337	224	113
	Medical laboratories	46	30	16
Food outlets	Hotels	162	4	161
	Restaurants	33	10	23
	Small eateries	97	40	57
	Provision / department stores	313	196	117
	Fruit / vegetable / juice outlets	254	36	218
	Meat / fish shops	128	24	104
	Public distribution system (ration)shops	52		52

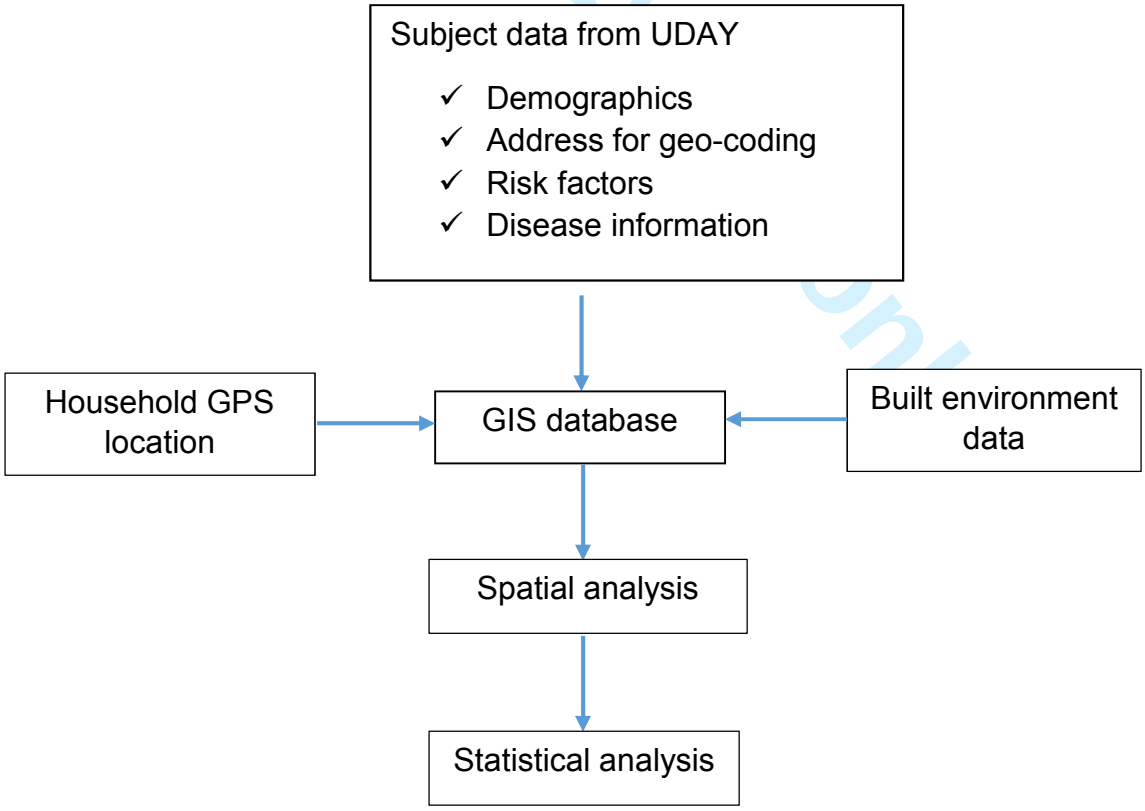
	Milk outlets Bakeries/ sweet shops	126 106	344 56	122 50
Tobacco outlets	Pan shop	713	17	696
Alcohol outlets	Authorized government outlets Unauthorized alcohol outlets	45 100	31	14 100
Recreational facilities	Parks Walking tracks Play grounds Fitness / yoga centers	91 6 50 10	62 43 6	29 6 7 4
Other	Anganwadis, schools, temples etc.	633	124	509

Household GPS locations and neighborhood BE features were integrated with participant data collected as part of the baseline data collection. An overview of the GIS mapping is provided in Figure 3. Area boundaries were obtained from government records and digitized. All spatial data was integrated into a spatial database and ArcGIS ™ software will be used to carry out following spatial analysis methods.

- Distance calculations: distance between participant households and features of interest such as health care facilities, food and alcohol outlets, parks etc. and their association between CMD and risk factors.
- Spatial aggregation: Aggregation of features such as number of food outlets, parks etc. in the neighbourhood and relationship with CMD and risk factors.

- Clustering: Identify clustering of CMD and risk factors (hotspots) and determine if disease clusters are of sufficient geographic size and concentration to have not occurred by chance.
- Spatial smoothing and interpolation: Used to derive a spatial surface from sampled data points (filling in where data are unobserved) or to smooth across polygons (aggregate data) to create more robust estimates.
- Spatial regression: Use of Spatial regression methods such as Geographically weighted regression (GWR) to further understand the relationship between built environment and CMD risk factors as standard statistical regression models, which assume independence of the observations, are not appropriate for analysing spatially dependent data.

Figure 3: GIS mapping overview

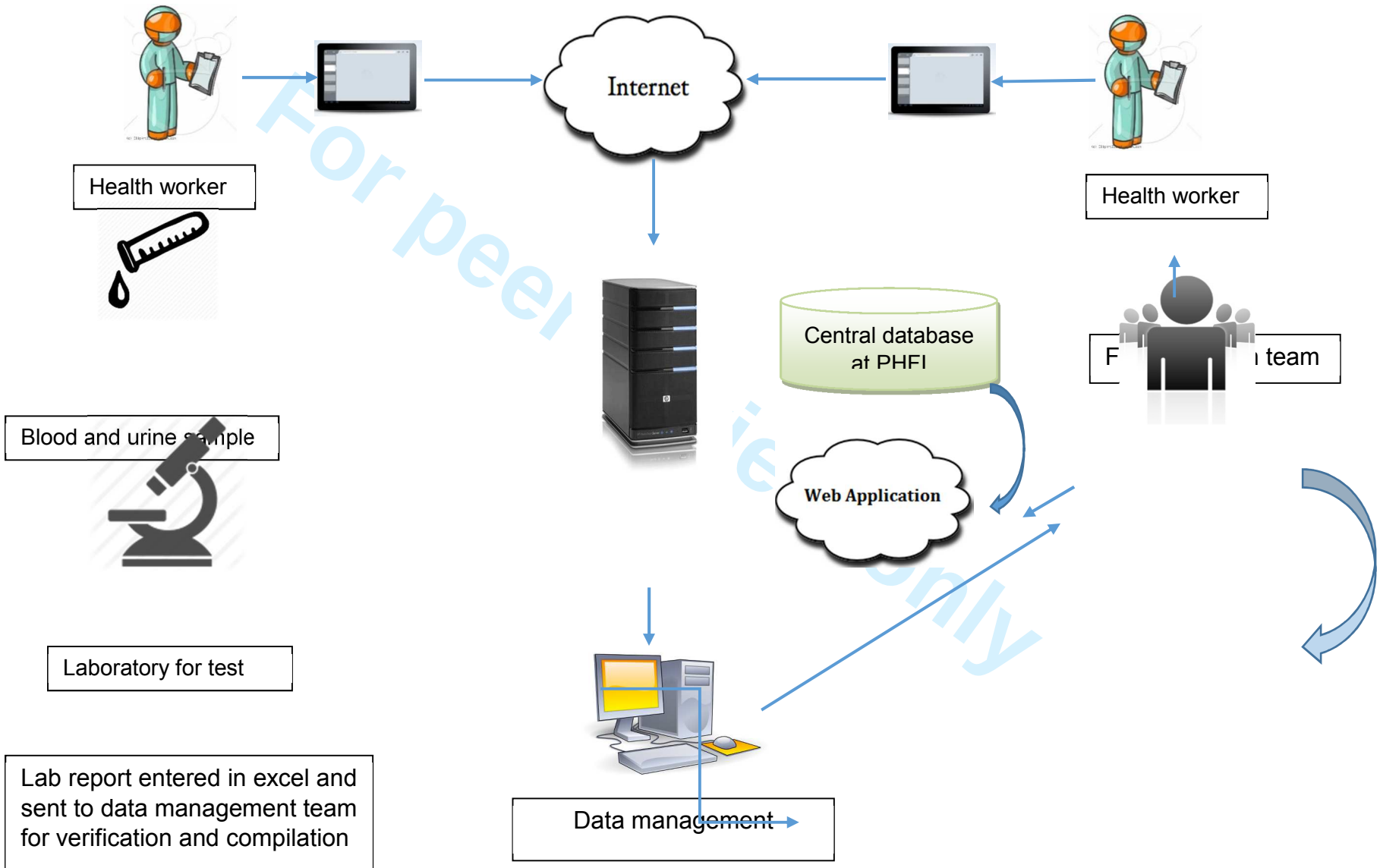


Data management

Data were collected in electronic format using customized android based software on a tablet platform and uploaded to server on a real time basis (Figure 4). For ensuring quality control, all validation, range and logical checks were in-built in the software. Error reports were generated bi-weekly and sent to the study sites for rectification. Errors were checked against completion of the questionnaire, identifiers and adherence to the sampling strategy of interviews (only one man and one woman from single household).

Further, site research teams identified any other issues and reported to centralized team for the corrections. Data correction took place concomitantly with the conduct of the baseline survey. Similarly, bio-sample reports were matched with participant questionnaires and the final data was locked after all matching, and rectification of errors.

Figure 4: Data collection and management pathway



Analysis plan

Data were entered into a database designed specifically for the project, housed at PHFI and accessible only to investigators and designated study staff. Data will be analysed using Stata/SE version 10.1 for windows software. Descriptive statistics will be done and the data expressed as frequencies and percentages for categorical variables and means and standard deviations for normally distributed continuous variables or inter-quartile ranges otherwise. Differences between gender groups, age groups, socio-economic groups, study sites, time periods and individual hypotheses will be tested using appropriate analytical statistical tests (Chi-square tests for categorical variables, t-tests continuous variables, multiple linear regression for continuous variables, and multiple logistic regression for categorical variables). Stratified analysis will be done to assess for potential confounding and effect modification by other variables. A p-value of < 0.05 will be considered to indicate statistical significance. Multi-level modelling will be undertaken by clusters and households as potential levels.

Intervention program

We propose to implement a priority set of synergistic innovative ecosystem interventions (Figure 5, Table 7), with the overarching goal to prevent, detect, reduce the risk of diabetes and hypertension and to improve the treatment and management of individuals with either of the conditions in the study sites. We hypothesize (Figure 6) that education of the public on diabetes, hypertension and related risks will lead to increased self-referral and prevention, while education of the healthcare providers will promote opportunistic screening for diabetes, hypertension and related risks, and

purposeful implementation of evidence based diagnostic (to screen, stratify by risk) and management guidelines (to initiate appropriate therapy).

Figure 5: Priority interventions in UDAY

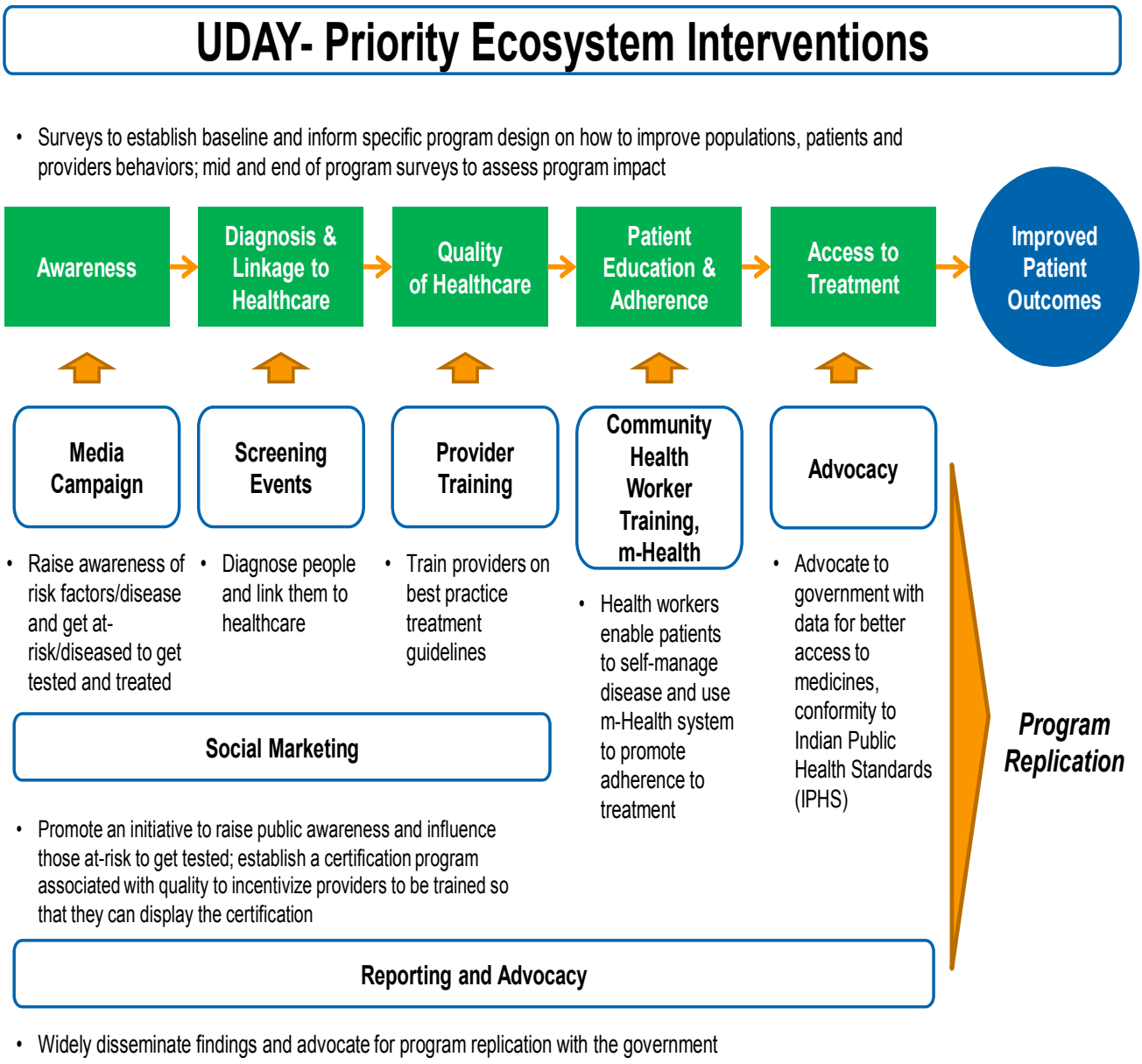
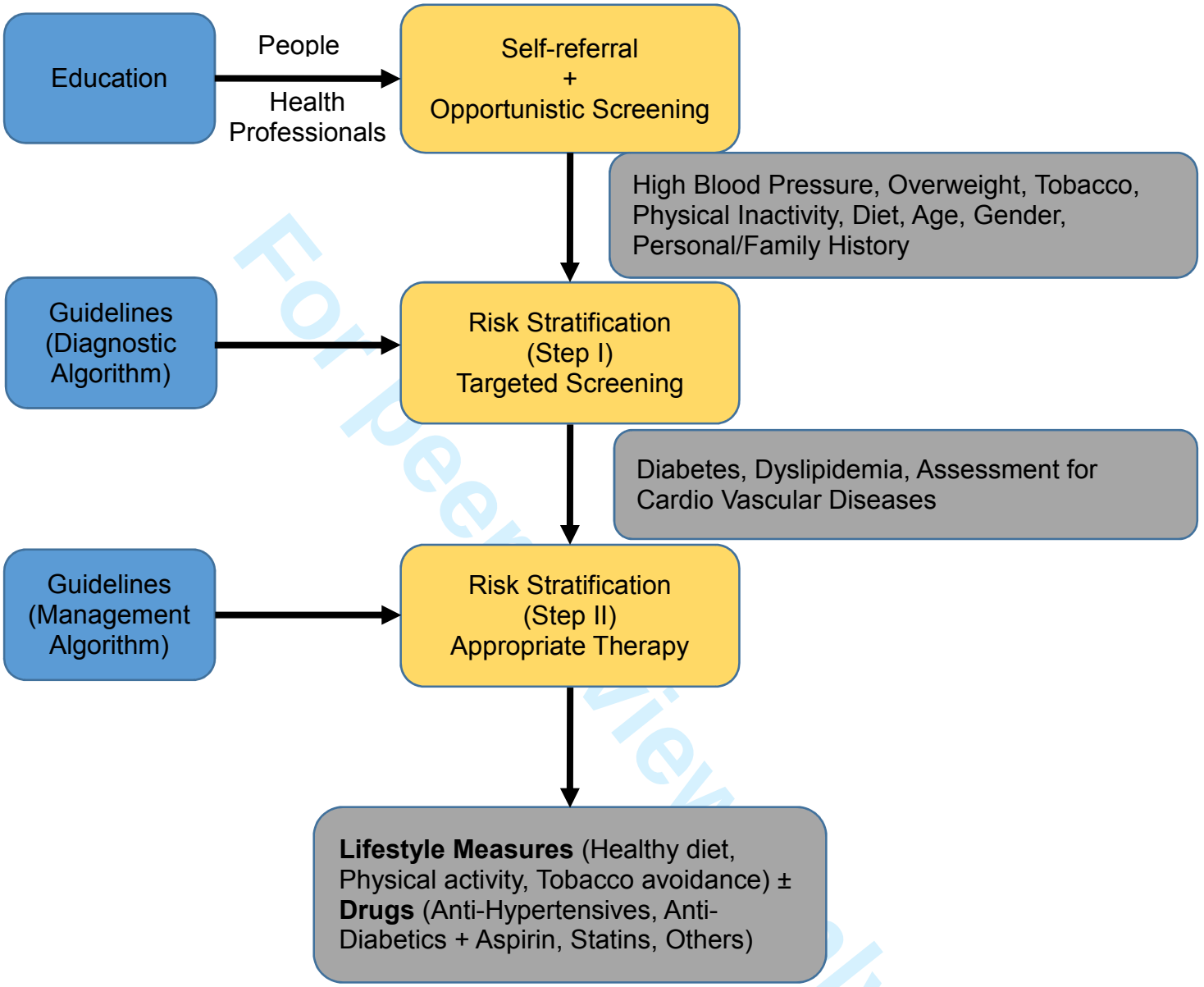


Figure 6: Intervention framework



Following the baseline assessments a comprehensive intervention program is being currently implemented. The intervention components includes:

1. tailored health promotion using social marketing approaches for increasing public awareness and promoting population risk factor modification and reduction;

2. community based screening of all adults aged ≥ 30 years for identifying those at high risk of diabetes and/or hypertension or with disease to link to the healthcare system leveraging task-sharing approaches utilizing technology enabled health workers;
3. patient education using technology enabled health workers,
4. healthcare provider training on evidence based management guidelines,
5. implementation of a quality improvement program and diabetes registry and;
6. advocacy with governments and other stakeholders to improve access to healthcare.

It is expected that the comprehensive interventions will increase over baseline the levels of: public awareness and knowledge about diabetes and hypertension; those aware, diagnosed, treated and controlled to recommended targets; the use of guideline based management by providers leading to improved health outcomes and access to healthcare for people living with diabetes and hypertension in India as well as provide a model of healthcare which is low-cost, community based and context relevant in a milieu of rapid rise in these chronic conditions.

Table 7: Innovations in UDAY

Intervention domain	Approach	Target
Prevention, early detection and referral	Culturally tailored health promotion, screening	400,000 population
Capacity building, task shifting of healthcare providers	CME, short trainings, distance learning, QIP	Healthcare providers
Early diagnosis and prevention of complications	Registry	10,000 patients

m-health system	Electronic data system +DSS	Adult population
Electronic data capture	Tablet based surveys	12,000
Spatial and built environment assessment	GIS mapping	All study areas
Improved access to medicines by social marketing initiatives	Improving quality of services	300 pharmacists
Culturally tailored patient education and networks for enabling self-care	Utilizing health workers	Patients

Discussion

UDAY is one of the largest community based intervention studies established in India to implement and evaluate a multi-component, multi-level, cost-effective, comprehensive intervention program to concomitantly improve the prevention, detection and optimal management of diabetes and hypertension, which together constitute the leading NCDs in India. Their high and rising burden coupled with huge healthcare costs underlines the need for cost-effective community based approaches supplemented by measures to strengthen the health system to address both these NCDs effectively as envisaged in UDAY.

Individuals with diabetes or hypertension often require similar lifestyle therapy (healthy diet, physical activity, smoking cessation) and similar long-term drug therapy for prevention of complications (cholesterol and glucose lowering drugs, aspirin, ACE inhibitors and other blood pressure lowering drugs). Proven lifestyle interventions which can prevent the onset of diabetes (healthy diet and physical activity) are similar to those proven to reduce the risk of developing hypertension, coronary heart disease or stroke. The strategic approaches and operational elements for prevention and control of

diabetes hypertension and CVD are thus similar or closely interlinked, whether it is primordial prevention (preventing the acquisition of risk factors in the first place), primary prevention (preventing onset of disease by reducing risk factors which are elevated) or secondary prevention (reducing the risk of complications after the onset of disease). Further, hypertension is easily measurable, diagnosable and treatable with effective medications and additionally in community settings, it provides an easy entry point to diagnose and manage chronic illness such as diabetes and CVD which involve long-term continued care. Synergies in management of both can lead to improved health outcomes, cost savings, better use of scare human and financial resources. Despite the availability of effective and affordable therapies both pharmacological and non-pharmacological, the management of both diabetes and hypertension India is suboptimal in rural as well as urban settings with typical control rates between 10-15%. Multiple reasons are attributed to this inadequate levels of control and failure to attain treatment targets. These include the largely asymptomatic nature of diabetes and hypertension coupled with low awareness, inadequate access to the healthcare system, delays in diagnosis, lack of targeted screening practices as well as poor adherence to prescribed medications and complexities associated with taking multiple medications. Further, even among those with established diabetes and CVD, the use of proven lifesaving therapies for secondary prevention is sub-optimal. The intervention framework in UDAY takes into account these impeding factors and the interventions proposed endeavors to address all of these better prevention and control. In addition, a unique prospective community and hospital based registry program with implementation of quality improvement program comprising an electronic decision support system with evidence based guidelines for management will provide the opportunity to assess

clinical practice patterns, quality of care, and partner healthcare providers' in improving management. Further, the community based cohorts established will not only facilitate tracking of the trends in risk factors and diseases in rapidly transitioning populations in India, but also serve as well characterized population platforms for embedding and evaluating new research questions of public health relevance in combating the rise of NCDs. Notably, a unique strength of UDAY besides occurring in a developing country setting where there are limited community based projects, in comparison to various other community based projects conducted in both developed and developing countries, which have either addressed prevention or management of select chronic conditions, is that UDAY aims to address both prevention and management of concurrently and comprehensively.

It is anticipated that the results obtained from the study will inform policy makers on the most appropriate community and health system based approaches that are effective in stemming the rising burden of diabetes and hypertension in India and countries with similar challenges.

Appendix

Sonipat district in the state of Haryana, is north of India's capital city Delhi. It covers an area of 2,122 sq. km and has a population of 1,450,001 (Census 2011). The district has 4 tehsils (sub-districts), namely Gohana, Ganaur, Sonipat and Kharkhoda. Among these, we selected Sonipat tehsil as the urban sub-site and Kharkhoda as the rural sub-site.

Vizag district is one of the north eastern coastal district in the state of Andhra Pradesh and lies in proximity to the Bay of Bengal. It covers an area of 11,161 sq. km and has a population of 4,290,589 (Census 2011). Vizag district has 43 mandals (sub-districts) comprising 4 urban mandals and 39 rural mandals. Among these, we selected Vizag as the urban sub-site and Makavarapalem and Nathavaram as the rural sub-site.

Data sharing and Contributorship statement

Data will be available to the study investigators only. De-identified data can be shared with other researchers based on specific request to the publication sub-committee of the project with potential research questions to be examined.

Sailesh Mohan, K. Srinath Reddy, Dorairaj Prabhakaran and Nikhil Tandon conceived the study. Sailesh Mohan wrote the first draft of the manuscript. Prashant Jarhyan, Shreeparna Ghosh, Nikhil Srinivasapura Venkateshmurthy, Ritu Rana, Cheena Malhotra, Ruby Gupta, Bhaskara Rao and Sanjay Kalra wrote specific sections of the manuscript as well as contributed to the design and implementation of the study. Bhaskara Rao and Sanjay Kalra also coordinate the activities in the study sites and provide technical support. Sailesh Mohan, Shreeparna Ghosh, Prashant Jarhyan, and Nikhil Srinivasapura Venkateshmurthy contributed to the collection and assembly of

data. All authors provided input into the study design, as well as provided critical intellectual input for revision of the manuscript and approved the final version of the manuscript.

Acknowledgements

The UDAY project is led by the Public Health Foundation of India, Gurgaon, India in collaboration with Population Services International, India and Project HOPE. We acknowledge the contributions of the field and research staff of the project. The funder has no role in the design, implementation, and evaluation of the project as well as in the writing of this paper. All contents of this paper are solely the responsibility of the authors.

Funding source

It is supported by an unrestricted educational grant from Eli Lilly and Company under the Lilly NCD Partnership Program.

Disclaimer

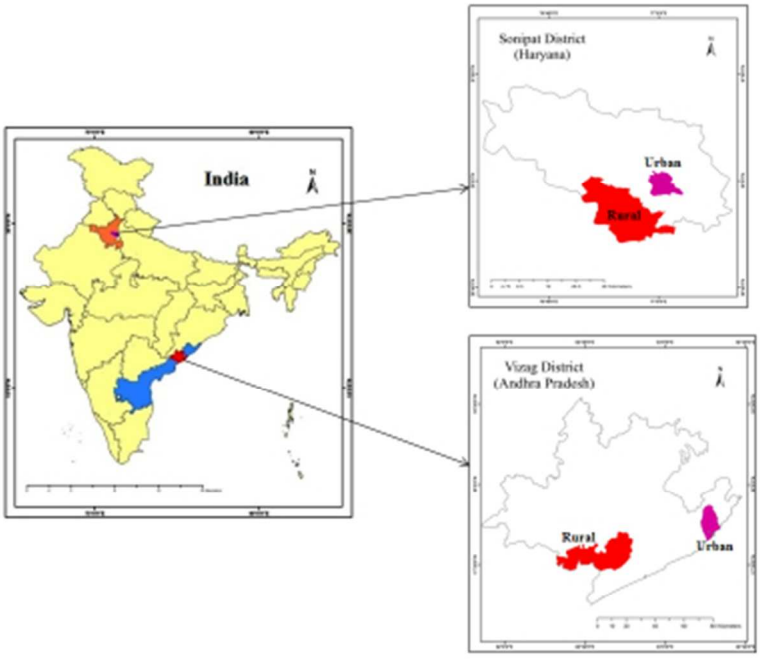
The funding agency had no role in the design, conduct or analysis of the study, and no role in the decision to submit the protocol for publication.

Conflicts of interest

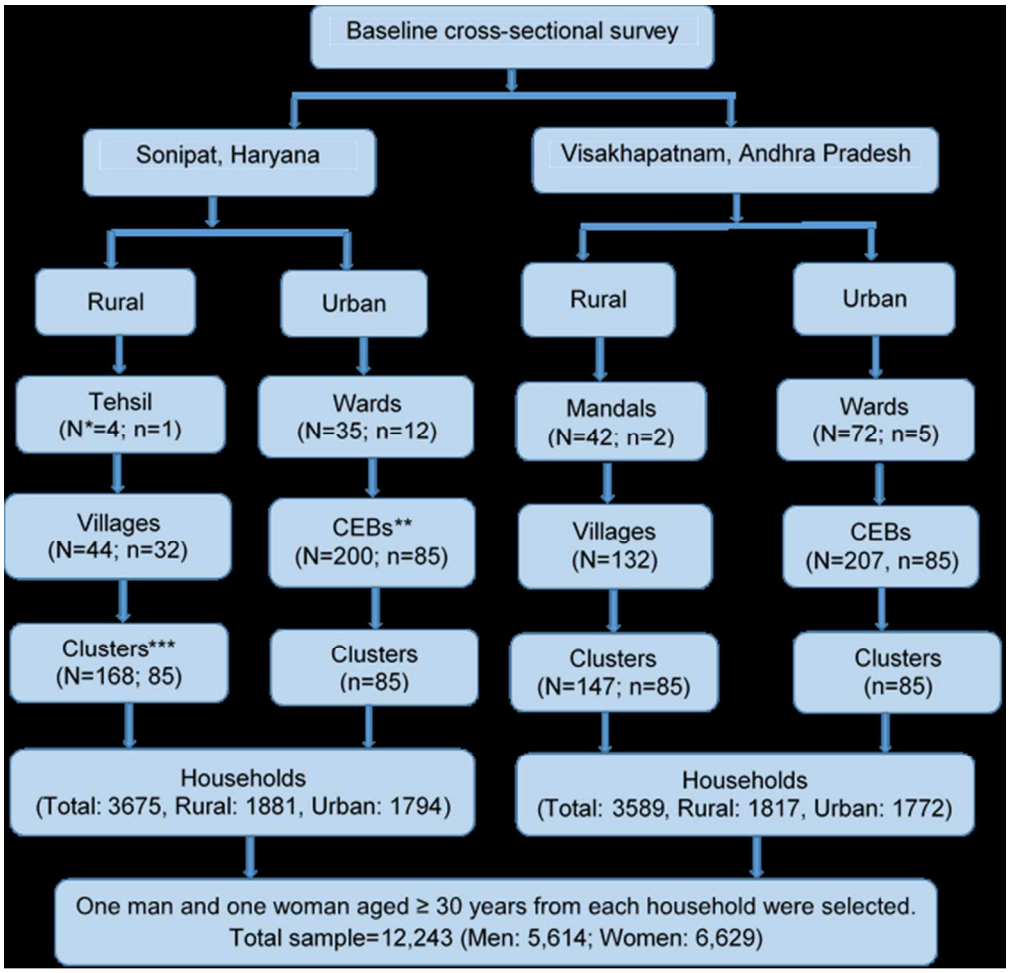
None declared

References

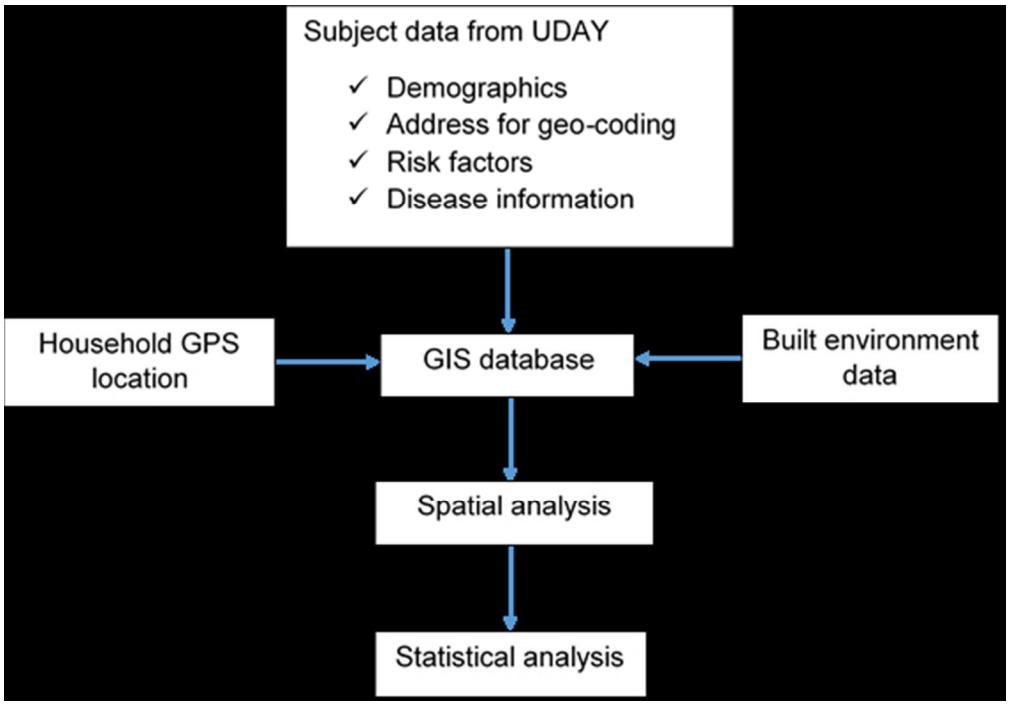
1. National Multisectoral Action Plan for Prevention and Control of NCDs in India. World Health Organization (WHO) Country Office for India, New Delhi, 2013.
2. International Diabetes Federation. IDF Diabetes Atlas, 7th edition. 7th ed. Brussels, Belgium: International Diabetes Federation, 2015.
3. Reddy KS, Shah B, Varghese C, et al. Responding to the threat of chronic diseases in India. Lancet 2005; 366:1744-49.
4. Mohan S, Koller T.Hypertension and related comorbidities in India: Implications for the health system. World Health Organization (WHO) Country Office for India, New Delhi, 2013.
5. Nair M, Ali MK, Ajay VS, et al. CARRS Surveillance study: design and methods to assess burdens from multiple perspectives. BMC Public Health 2012;12:701.
6. Reddy KS, Prabhakaran D, Chaturvedi V, et al. Methods for establishing a surveillance system for cardiovascular diseases in Indian industrial populations. Bull World Health Organ 2006; 84:461-69.
7. International Institute for Population Sciences (IIPS) and Macro International. 2007. National Family Health Survey (NFHS-3), 2005–06: India: Volume II.Mumbai: IIPS.
8. World Health Organization. Global Physical Activity Questionnaire (GPAQ) Analysis Guide: World Health Organization. Available at: http://www.who.int/chp/steps/resources/GPAQ_Analysis_Guide.pdf (Assessed 15 December 2015)
9. Yusuf S, Hawken S, Ounpuu S, et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. Lancet 2004; 364:937-52.
10. EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy 1990; 16:199–208.
11. Poongothai S, Pradeepa R, Ganesan A, et al. Reliability and validity of a modified PHQ9 item inventory (PHQ12) as a screening instrument for assesing depression in Asian Indians (CURES—65). J Assoc Physicians India 2009; 57: 147–52.



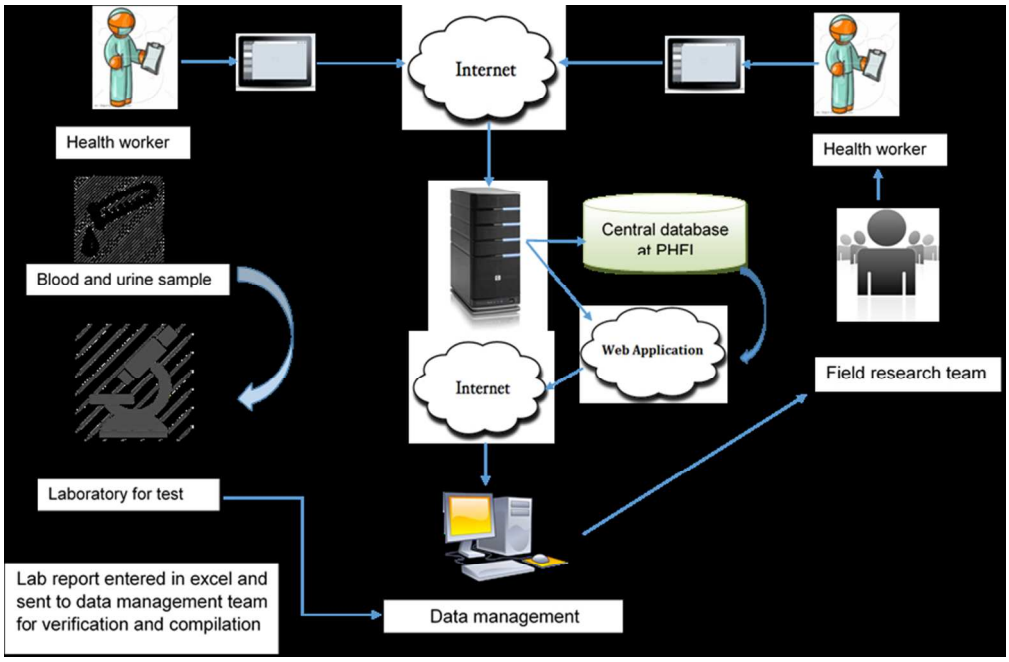
40x30mm (300 x 300 DPI)



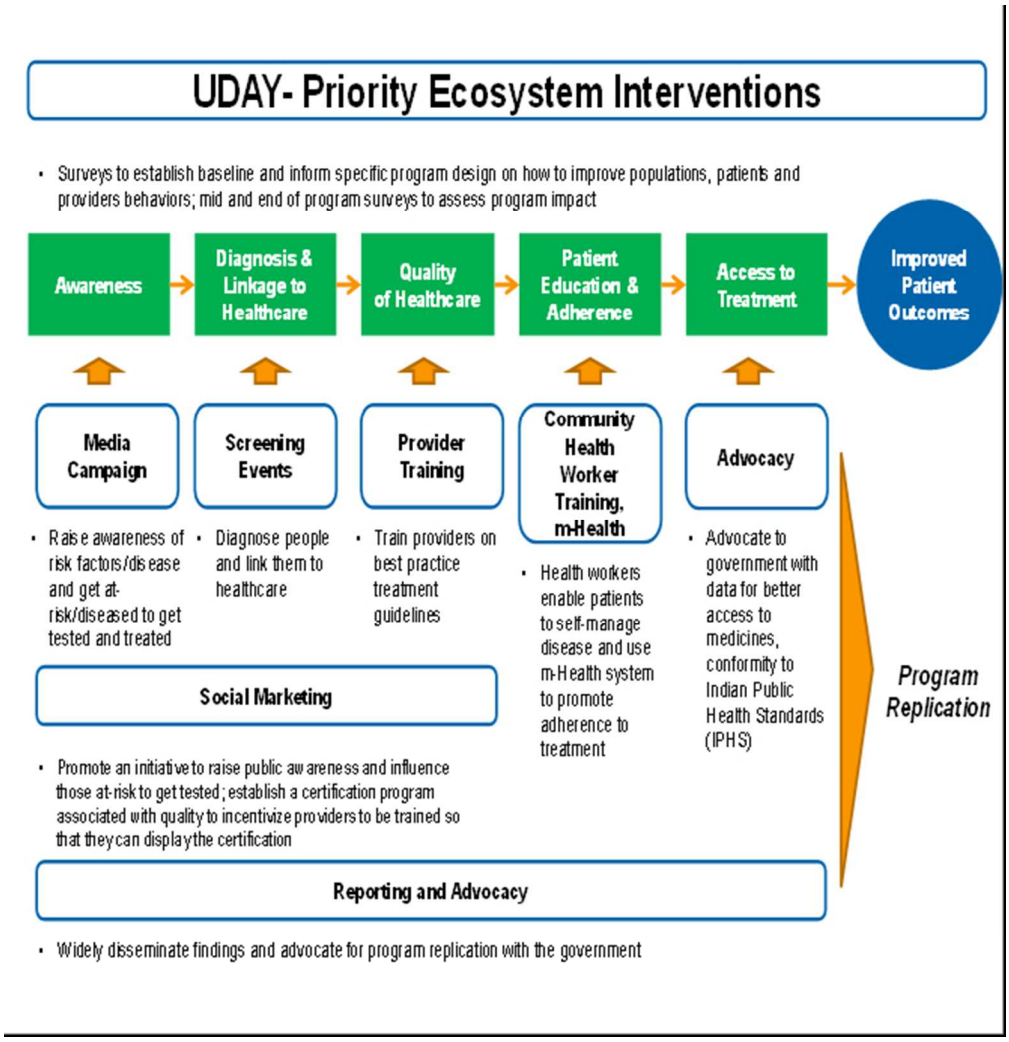
56x54mm (300 x 300 DPI)



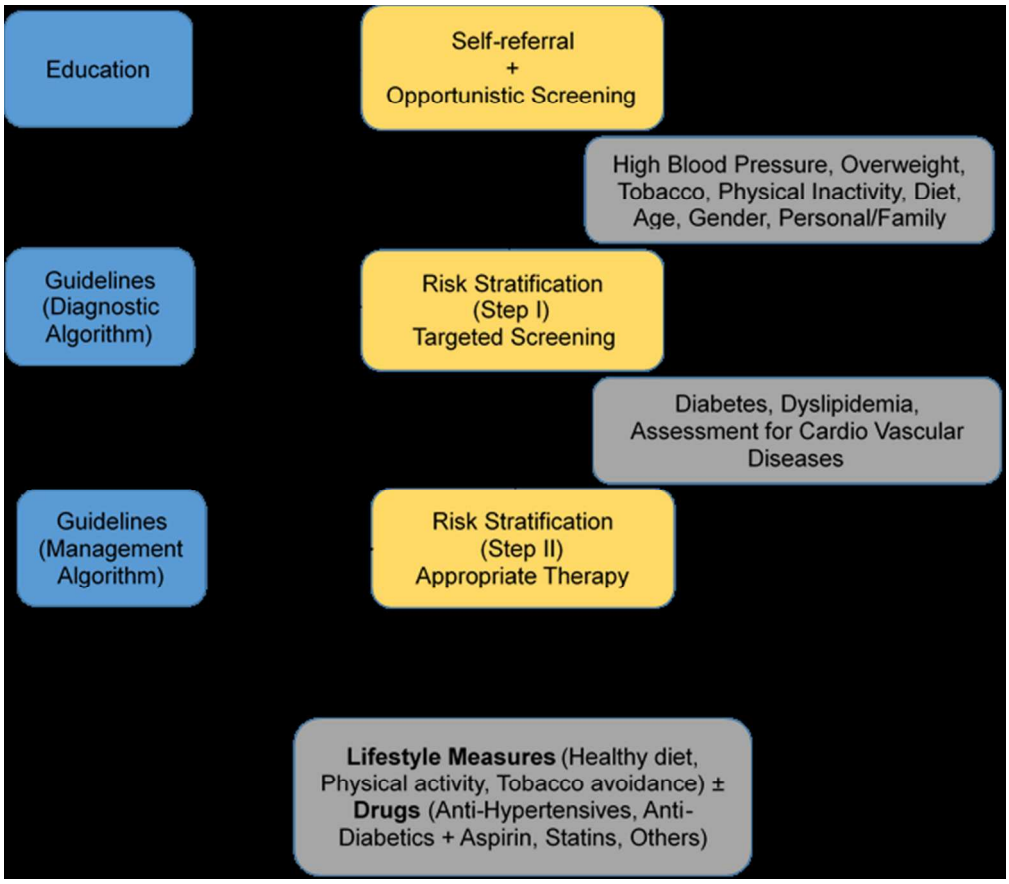
48x33mm (300 x 300 DPI)



74x48mm (300 x 300 DPI)



56x58mm (300 x 300 DPI)



57x50mm (300 x 300 DPI)

BMJ Open

UDAY: Protocol of a Comprehensive Diabetes and Hypertension Prevention and Management Program in India

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-015919.R1
Article Type:	Protocol
Date Submitted by the Author:	01-Aug-2017
Complete List of Authors:	Mohan, Sailesh; Public Health Foundation of India Jarhyan, Prashant; Public Health Foundation of India Ghosh, Shreeparna; Public Health Foundation of India Srinivasapura Venkateshmurthy, Nikhil; Public Health Foundation of India Gupta, Ruby; Public Health Foundation of India Rana, Ritu; Population Services International India Malhotra, Cheena; Project Hope India Rao, Bhaskara; MaxCure Hospital Kalra, Sanjay; Bharti Hospital Karnal Tandon, Nikhil; All India Institute of Medical Sciences, Reddy, KS; Public Health Foundation of India Prabhakaran, Dorairaj; Public Health Foundation of India
Primary Subject Heading:	Epidemiology
Secondary Subject Heading:	Diabetes and endocrinology, Health services research, Public health, Cardiovascular medicine
Keywords:	Hypertension < CARDIOLOGY, General diabetes < DIABETES & ENDOCRINOLOGY, EPIDEMIOLOGY

UDAY: Protocol of a Comprehensive Diabetes and Hypertension Prevention and Management Program in India

Authors: Sailesh Mohan, [1] Prashant Jarhyan, [1] Shreeparna Ghosh, [1] Nikhil Srinivasapura Venkateshmurthy , [1] Ruby Gupta, [1] Ritu Rana, [2] Cheena Malhotra, [3] Bhaskara Rao, [4] Sanjay Kalra, [5] Nikhil Tandon, [6] K. Srinath Reddy, [1] Dorairaj Prabhakaran[1]

[1] Public Health Foundation of India, Gurgaon, India

[2] Population Services International, Delhi, India

[3] Project HOPE, Delhi, India

[4] Manipal Hospitals, Visakhapatnam, India

[5] Bharti Hospital, Karnal, India

[6] All India Institute of Medical Sciences, Delhi, India

Corresponding author
Dr. Sailesh Mohan
Additional Professor
Public Health Foundation of India
Email:smohan@phfi.org

Abstract

Introduction
Diabetes and hypertension are two leading noncommunicable conditions, which are sub-optimally managed in India. Thus, innovative comprehensive approaches that can concomitantly improve their detection, prevention and control are warranted.

Methods and analysis
UDAY, a 5-year initiative aims to reduce the risk of diabetes and hypertension and improve management by implementing a comprehensive intervention program in the two selected study sites, Sonipat and Visakhapatnam (Vizag). It has a pre-post evaluation design with representative cross-sectional surveys before and after intervention. Within these two sites, urban and rural sub-sites each with a total population of approximately 1, 00,000 people each were selected and a baseline and post intervention assessment will be conducted deploying 5 surveys [among general population (including body measurements or bio-samples), patients, healthcare providers including physicians and pharmacists, health facilities] which will determine: the knowledge levels about diabetes and hypertension, the proportion treated and controlled; the patient knowledge and self-management skills; healthcare providers' management practices; the level of access and barriers to obtaining care.
The interventions will include: tailored health promotion for improving public knowledge; screening of adults aged ≥ 30 years for identifying those at high risk of diabetes and/or hypertension for linkage to the healthcare system; patient education using technology enabled community health workers, geographic information system (GIS) based mapping of the communities, healthcare provider training on management guidelines, community based diabetes registry and; advocacy to improve access to healthcare. The baseline surveys have been completed, the study areas mapped using GIS and the interventions are being implemented. UDAY is expected to increase over baseline the levels of: public knowledge about diabetes and hypertension; those treated and controlled; patient self-management skills; the use of guideline based management by providers and; access to healthcare, leading to improved health outcomes and inform development of a India relevant chronic care model.

Ethics and dissemination
Ethical clearance for conduct of the study was obtained from the Institutional Ethics Committee (IEC) of the Public Health Foundation of India. The findings will be targeted primarily at public health policymakers and advocates, but will be disseminated widely through other mechanisms including conference presentations and peer-reviewed publications, as well as to the participating communities.

Strengths and limitations of this study

- Unique large community based study in geographically and culturally diverse "real world" settings in India for improving prevention and control of diabetes and hypertension.
- Employs a comprehensive multi-level, multi component intervention approach to target the general population, patients, providers and to strengthen the health system for improving prevention and control of diabetes and hypertension.

- Concomitantly addresses detection, prevention and management of both diabetes and hypertension.
- Extensively leverages mobile technology to enable health workers in task sharing as well as for electronic data capture.
- Quasi experimental design with complex intervention may hinder attribution of specific effect to individual intervention components.

Introduction

Non-communicable Diseases (NCDs) are currently the leading cause of preventable death and disability in India, accounting for two out of every three deaths [1]. Among NCDs, the prevalence of type-2 diabetes mellitus (DM) and hypertension have been rising rapidly. Currently there are about 69 million people with diabetes, a figure that is projected to further increase to a staggering 124 million by 2040 [2]. The number of individuals with hypertension is projected to increase to 214 million by 2030 from 118 million in 2000 [3,4]. Furthermore, diabetes and hypertension are important risk factors for both the major forms of cardiovascular disease [CVD (coronary heart disease and stroke)], highly prevalent and attributable to nearly half of all the deaths from NCDs [4].

Despite the availability of proven and effective treatments, diabetes as well as hypertension detection and control rates are abysmally low in India with blood pressure control among those with diabetes being even more sub-optimal, with a huge gap between detection and adequate treatment [1,3,4]. Thus, there is great potential and opportunity to reduce the rising burden of diabetes and hypertension as well as the

associated vascular risk in India through concomitantly improving their detection, prevention and control.

To address this huge gap in the prevention and management of both these conditions we are undertaking a 5-year initiative entitled “UDAY” (meaning dawn in *Sanskrit*) in epidemiologically transitioning communities, that aims to reduce the risk of diabetes and hypertension and concomitantly improve the management of either conditions by implementing a comprehensive community based innovative intervention program in the two geographically and culturally distinct study sites, Sonipat (Haryana, North India) and Visakhapatnam or Vizag (Andhra Pradesh, South India). This paper describes the design and methods of UDAY- A Comprehensive Diabetes and Hypertension Prevention and Management Program In India.

Methods

Study design

UDAY has a pre-post evaluation design with representative cross sectional surveys before (in year one at baseline, pre-intervention) and after the intervention (in year 5). The main research question is: whether a multi-component, multi-level, cost-effective, comprehensive intervention program will improve the prevention, detection and optimal management of diabetes and hypertension in the two selected study sites. Ethical clearance for conduct of the study was obtained from the Institutional Ethics Committee (IEC) of the Public Health Foundation of India.

We selected a pre-post evaluation design due to the following reasons. We wanted to evaluate if multi-component interventions delivered at multiple levels in a

comprehensive manner can improve outcomes. Further, we also wanted to understand and examine the operational part of the program implementation to gain insights into underpinning factors behind success or failure that can inform possible replication and scale up in the future. The options for an implementation study of this nature with process outcomes are either a pre-post design or quasi-experimental design or step wedge design. We deemed a step wedge to be too complicated for this evaluation and given that quasi experimental design would not have enough power to decipher real differences, we chose a pre-post design. This was also aimed at cutting down costs. At baseline, in year one, 5 surveys were conducted among the general population, among patients, among healthcare providers including physicians and pharmacists and in health facilities to guide intervention development and impact assessment. Similar assessment is planned after the intervention, in year 5.

The specific objectives these assessments are to:

1. Determine the prevalence, awareness, the knowledge levels about diabetes and hypertension, the proportion treated and controlled among a representative sample (n=12000) of adults aged ≥ 30 years in the selected study areas. (Population survey)
2. Determine the patient knowledge levels and self-management skills among a convenience sample (n=400) of those diagnosed with diabetes and hypertension in the selected study areas. (Patient survey)
3. a) Determine healthcare providers' (physicians) knowledge and practices related to diabetes and hypertension management among a convenience sample (n=50) of healthcare providers' in the selected study areas.

b) Determine pharmacists' knowledge related to diabetes and hypertension and dispensing practices among a convenience sample of pharmacists (n=350) (Provider survey)

4. Determine the level of access and potential barriers to diabetes and hypertension care provided by the public healthcare system in the selected study areas (n=50). (Facility survey)
5. Determine the cost-effectiveness of the intervention program in improving diabetes and hypertension treatment and management outcomes in the study areas. (Using population survey, GIS data and project implementation data)

Study sites

We are undertaking this comprehensive diabetes prevention and management program in two epidemiologically transitioning areas located in Sonipat in Haryana and Vizag in Andhra Pradesh (Figure 1, supplementary file).

Figure 1: Study sites (insert here)

We defined the areas and their sub-areas using the following terminology:

- Sites – a bounded geographic area within which we have defined distinct rural and urban sub-sites for the study. Each site has been defined such that it contains approximately 2,00,000 people. Sonipat and Vizag are each a site.
- Sub-sites – within each site, we have defined one rural and one urban sub-site for study. Each sub-site is geographically bounded, and contains a population of

approximately 1,00,000. Within Sonipat and Vizag, we have defined two sub-sites each (rural and urban).

- Total project – the total project is the summation of the two sites, including the four sub-sites (two sub-sites within each site). Therefore the total population under the study is approximately 4,00,000.

Intervention program

We propose to implement a priority set of synergistic innovative ecosystem interventions (Figure 2, Table 1), with the overarching goal to prevent, detect, reduce the risk of diabetes and hypertension and to improve the treatment and management of individuals with either of the conditions in the study sites. We hypothesize (Figure 3) that education of the public on diabetes, hypertension and related risks will lead to increased self-referral and prevention, while education of the healthcare providers will promote opportunistic screening for diabetes, hypertension and related risks, and purposeful implementation of evidence based diagnostic (to screen, stratify by risk) and management guidelines (to initiate appropriate therapy).

Figure 2: Priority interventions in UDAY (insert here)

Table 1: Innovations in UDAY

Intervention domain	Approach	Target
Prevention, early detection and referral	Culturally tailored health promotion, screening	400,000 population
Capacity building, task	CME, short trainings,	Healthcare providers

shifting of healthcare providers	distance learning, QIP	
Early diagnosis and prevention of complications	Registry	10,000 patients
m-health system	Electronic data system +DSS	Adult population
Electronic data capture	Tablet based surveys	12,000
Spatial and built environment assessment	GIS mapping	All study areas
Improved access to medicines by social marketing initiatives	Improving quality of services	300 pharmacists
Culturally tailored patient education and networks for enabling self-care	Utilizing health workers	Patients

Figure 3: Intervention framework (insert here)

Following the baseline assessments a comprehensive intervention program is being currently implemented. The intervention components includes:

1. tailored health promotion using social marketing approaches for increasing public awareness and promoting population risk factor modification and reduction;
2. community based screening of all adults aged ≥ 30 years for identifying those at high risk of diabetes and/or hypertension or with disease to link to the healthcare system leveraging task-sharing approaches utilizing technology enabled health workers;
3. patient education using technology enabled health workers,
4. healthcare provider training on evidence based management guidelines,
5. implementation of a quality improvement program and diabetes registry and;

6. advocacy with governments and other stakeholders to improve access to healthcare.

It is expected that the comprehensive interventions will increase over baseline the levels of: public awareness and knowledge about diabetes and hypertension; those aware, diagnosed, treated and controlled to recommended targets; the use of guideline based management by providers. Detailed outcome assessment metrics is provided in table 2. This is anticipated to improve health outcomes and access to healthcare for people living with diabetes and hypertension in India as well as provide a model of healthcare which is low-cost, community based and context relevant in a milieu of rapid rise in these chronic conditions.

Table 2: Assessment of intervention outcomes

Indicator	**Target Population**	**Metric**	**Evaluation Methodology**
1. Patient outcomes	Diabetes and hypertension patients	% implementing lifestyle change (meet the recommended levels of physical activity, and intend to and/or implement dietary changes)	Baseline and endline surveys, diabetes registry
		% engaging in self-monitoring/testing	Baseline and endline surveys, diabetes registry
		% increase in correct self-management practices	Baseline and endline surveys, diabetes registry
		% increase in knowledge on diabetes and hypertension	Baseline and endline surveys, diabetes registry

		% of patients on treatment, whose diabetes, hypertension is successfully controlled, i.e., HbA1C≤ 7% / BP ≤130/80 mm Hg	Baseline and endline surveys, diabetes registry
2. Awareness and knowledge about diabetes and hypertension	General population	% increase in knowledge of diabetes, hypertension and their risk factors	Baseline and endline surveys
		% increase in detection rate and in seeking healthcare	Baseline and endline surveys, screening program
		% implementing lifestyle change (meet the recommended levels of physical activity, and intend to and/or implement dietary changes)	Baseline and endline surveys, screening program
		% exposed to health promotion campaign	Baseline and endline surveys, screening program
3. Provider knowledge and practices	Physicians, other health workers	# who participate in training programs	Training participation data
		% increase in knowledge related to diabetes and hypertension management	Baseline and endline surveys of providers, diabetes registry
		% increase in practices related to diabetes and hypertension management and providing lifestyle advice	Baseline and endline surveys of providers, diabetes registry
	Pharmacists	% of pharmacists who identify people at risk of and with diabetes, hypertension	Baseline and endline surveys of providers
		% increase in pharmacists dispensing and filling prescriptions correctly	Baseline and endline surveys of providers, diabetes registry
4. Program cost-effectiveness	Diabetes patients	Cost per diabetic patient treated to recommended target	Baseline and endline surveys of patients, program cost data, diabetes registry
		% reduction in out of pocket expenditure	Baseline and endline surveys of patients, diabetes registry
	General population	Cost per diabetes case identified	Surveys, screening program, program cost data

5. Access to treatment	Healthcare system	Improvements in access to and availability of medications	Baseline and endline surveys of patients, facility survey, diabetes registry
		% increase in the proportion patients who report that medicines are easily available	Baseline and endline surveys of patients, facility survey, diabetes registry
		% reduction in stock outs of medicines	Baseline and endline surveys of patients, facility survey, diabetes registry
		Adherence to IPHS guidelines on drugs, services	Facility survey, diabetes registry

Intervention development

We used evidence based interventions and leveraged the results from the baseline surveys (population, patient, facility and providers) to develop and refine the interventions, which were subsequently piloted. For example, from population survey we found that there were differences in the awareness of risk factors for developing diabetes/hypertension across rural/urban areas and the two study sites in North and South India. Therefore, taking this into cognizance, we designed the tailored health promotion program and messages to be delivered by trained health workers ti increase awareness about the risk factors. Facility and providers' surveys helped us to design the training programs for training healthcare providers as well as to conduct advocacy to improve access to the health system. Similarly, findings from the patients' survey helped us to focus the training of health workers on building self-management skills of people with diabetes/hypertension and for developing patient networks.

Sample for the population survey

We based our sample size calculation on the prevalence of diabetes, which has a lower prevalence than hypertension, in previously reported studies in India. Anticipating a response rate of 85 % with a design effect factor of 1.5 (to account for cluster sampling, and a confidence level of 1.96, the sample size estimates were generated for males and females in three age strata (30-49, 50-69, 69 and above) in each setting (urban, rural). About 2968 subjects was estimated to be required per urban sub-site (Sonipat and Vizag) and 2942 subjects per rural sub-site (Sonipat and Vizag). The total estimated sample was 11820, which was increased to 12000 to obtain equal samples in both urban and rural areas. Sample weights were generated for estimating the prevalence of diabetes, hypertension and related cardiometabolic risk factors at the district level.

Survey sampling and participant selection

Population survey

Two representative population based cross sectional surveys with independent samples and identical methodologies at baseline and at the end of intervention will be conducted, that will provide estimates of the burden and changes in the prevalence of diabetes, hypertension, and related cardiometabolic risk factors. In addition, those recruited for the first survey at baseline (which has been completed), will be followed up as a cohort to estimate the incidence of new cardio-metabolic (CMD) risk factors, disease, healthcare utilization, diabetes and hypertension related morbidity and mortality.

The first population survey (baseline survey) was done among a representative sample of adults aged ≥ 30 years residing in the selected study areas of Sonipat and Vizag. Inclusion criteria – a) adults aged ≥ 30 years residing in the sampled urban and rural areas of Sonipat and Vizag respectively. b) willing to participate and provide informed consent.

We excluded individuals who were unwilling to provide informed consent and those with serious chronic illnesses [such as that of the liver (cirrhosis), kidneys (renal failure) or malignancies], pregnant women.

For the baseline survey, a multistage random sampling technique was deployed to obtain a representative sample of adults aged ≥30 years, using data from the most recent census of 2011. In addition, a manual enumeration and mapping of all households and structures was conducted in all the study areas [all census enumeration blocks (CEBs) in urban areas and villages in rural], to identify households and structures constructed since the last census (Table 3). CEBs are considered as the primary sampling unit in urban areas and villages in the rural areas respectively. On average, about 100-125 households with a population of 650-700 persons would generally constitute a CEB. This enabled a complete sampling frame for the selection of households for the survey and thus provided an equal chance of selection to each household. Besides, it also helped identify potential recipients of the intervention program (i.e., adults aged ≥30 years) in the study sites.

In each sub-site, 85 clusters were randomly selected (urban Sonipat: 85/200 CEBs, urban Vizag: 85/207 CEBs and rural Sonipat: 85/168 clusters, rural Vizag: 85/147 clusters) according to probability proportional to size (Figure 4). In rural sub-sites, bigger

villages were divided into clusters with 75 to 300 households. From each cluster in the urban and rural sub-sites, 18 to 25 households were randomly selected and 1 eligible male and female were selected randomly within each household using Kish table. In Sonipat district, 3675 households participated in baseline survey (rural: 1881, urban: 1794) with total being 6208 participants (rural: 3104, urban: 3104). In Vizag district, 3589 households (rural: 1817, urban: 1772) participated in the baseline survey with total being 6035 participants (rural: 3069, urban: 2966). Thus, we had 12000 individuals from both urban and rural areas of North and South India.

Table 3: Manual enumeration of study areas

Study site	Structures	Households	Population ≥30 years	Total population (census 2011)
Sonipat urban sub-site	24408	20406	41981	102292
Sonipat rural sub-site	28813	17283	40850	100935
Vizag urban sub-site	16888	39504	70735	153721
Vizag rural sub-site	33799	30817	59540	121209

Figure 4: Sample selection for the baseline survey (insert here)

*N=total, n=number selected

**CEB=Census Enumeration Block

***Cluster = In urban sub-site clusters comprise CEBs, in rural sub-site bigger villages were split into 2 or 3 clusters with sizes of 75-300 households.

Data collection for the population survey

For the baseline survey, trained health workers visited the selected participants at their homes. Written informed consent was sought and obtained from the selected individuals prior to data collection and a unique identification number was assigned. For each participant, data collection comprised an interviewer administered questionnaire, a brief physical examination (height, weight, waist circumference, hip circumference, blood pressure, body fat percentage), blood and urine collection as detailed below.

Information on demographics, socio-economic characteristics, behavioral risk factors (tobacco use, alcohol use, diet and physical inactivity), family history of various NCDs, female reproductive history, general awareness about diabetes and hypertension, risk factors, prevention, symptoms and diagnosis, complications, treatment and management, medical history of NCDs [diabetes, hypertension, coronary artery disease (CAD), myocardial infraction (MI), stroke, heart failure, chronic kidney disease (CKD), peripheral vascular disease (PVD), chronic obstructive pulmonary disease (COPD), asthma], quality of life, mental health, social support, cost of healthcare and healthcare utilization was collected using a tablet based application (Table 4).

Body measurements such as height, weight, waist and hip circumferences, blood pressure and body fat measurement by bio impedance using TANITA were also obtained using standardized equipment.

Bio-samples (fasting blood and morning urine) were collected for the laboratory estimation of fasting plasma glucose, glycated hemoglobin (HbA1c), lipids, serum creatinine, urea, urine microalbumin and urine creatinine. We have also stored the bio samples for future analysis of emerging biomarkers and genetics.

Table 4: Summary of indicators, measures, methods and instruments for baseline survey

Indicators	Measures	Methods	Instruments
Demographics and socio-economic characteristics	Age, sex, marital status, religion, education, income, occupation, contact details, and household assets	Questionnaires	Centre for cArdio-metabolic Risk Reduction in South Asia(CARRS) Surveillance Study [5] Establishment of Sentinel Surveillance System for CVD in Indian Industrial Populations (Sentinel Surveillance Study) [6] National Family Health Survey, 2005-06 [7]
Behavioral risk factors	Tobacco use Alcohol use	Questionnaire	CARRS, Sentinel Surveillance Study
	Physical activity	Questionnaire	Global Physical Activity Questionnaire (GPAQ-2) [8]
	Dietary habits	Questionnaire	CARRS,INTERHEART Study[9]
Family history	Prevalence of cardiometabolic diseases (CMDs) among family members related to participants, mortality	Questionnaire	CARRS
Female	Menarche/	Questionnaire	CARRS

reproductive history	gestational history, menopause (surgical / physiological / whether on hormone replacement therapy) / contraception		
Awareness and knowledge	General awareness about diabetes and hypertension, risk factors, prevention, symptoms and diagnosis, complications, treatment and management	Questionnaire	CARRS
Physiological and biochemical risk factors	Hypertension	Blood pressure measurements	Standardized method (American Heart Association) and validated instrument (certified by British Hypertensive Society and Association for the Advancement of Medical Instrumentation) Standardized across both the sites
	Diabetes	Laboratory estimation of fasting plasma glucose, glycated hemoglobin (HbA1c)	Standardized across both the sites
	Dyslipidemia	Laboratory estimation of serum total cholesterol, low	Standardized across both the

		density lipoprotein cholesterol, very low density lipoprotein cholesterol, high density lipoprotein cholesterol, triglycerides	sites
	Obesity	Anthropometry (height, weight, waist and hip circumferences, body fat	Standard procedures based on National Health And Nutrition Examination Survey-III with instruments used in epidemiological studies on South Asian population
Medical history	Chronic kidney disease	Serum creatinine, urea, urine microalbumin and urine creatinine	Standardized across both the sites
	Stroke, myocardial infraction, Congestive heart failure, Chronic stable angina	Questionnaires including medical history	Rose Angina, CARRS
Treatment history, health services, quality of care and health care costs	Awareness and risk factor control Access to health care services, utilization of services, health insurance	Questionnaire	CARRS

	coverage, costs of treating CMDs and their risk factors		
Prevalence	COPD and asthma	Questionnaire	NHANES III and present standards of the American Thoracic Society (ATS)
Health related Quality of Life	Mobility, self-care, usual activities, pain/discomfort, anxiety/depression (related to CMDs and risk factors)	Questionnaire	European Quality of Life 5 Dimensions questionnaire (EQ-5D-3L) [10]
Mental health	Depression	Questionnaire	Modified from Patient Health Questionnaire 9 (PHQ-12) [11]
Social well-being	Social support	Questionnaire	Developed for UDAY

Data collection for the patient survey

Trained research staff visited health facilities located in the aforementioned selected study areas and approached patients attending outpatient section of the health facilities and identified those with the diagnosis of diabetes and/or hypertension based on their prescription note for participating in the study. Written informed consent was sought and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire (Table 5).

The patient survey was done among a convenience sample of 400 patients having diabetes and/or hypertension attending health facilities and residing in the selected study areas of Sonipat and Vizag.

Inclusion criteria: We included patients with diabetes and or hypertension residing/attending health facilities in the sampled urban and rural areas of Sonipat and Vizag respectively and were willing to participate and provide informed consent.

Exclusion criteria: We excluded those unwilling to provide informed consent.

Table 5: Summary of indicators, measures, methods and instruments for the patient survey

Indicators	Measures	Methods	Instruments
Demographics and socio-economic characteristics	Age, sex, education, income, occupation, contact details	Questionnaires	CARRS Sentinel Surveillance Study
Behavioral risk factors	Tobacco use Alcohol use	Questionnaire	CARRS, Sentinel Surveillance Study
Awareness and knowledge of diabetes and hypertension	Awareness of risk factors, symptoms and diagnosis, cut-off levels for diagnosis, complications, treatment and management	Questionnaire	Developed for UDAY
Diabetes and hypertension related medical history	Diagnosis, health care utilization, control, self-management practices, complications, comorbidities, and treatment adherence	Questionnaire	Developed for UDAY
Health related Quality of Life	Mobility, self-care, usual activities,	Questionnaire	European Quality of Life 5 Dimensions

	pain/discomfort, anxiety/depression (related to CMDs and risk factors)		questionnaire (EQ-5D-3L)
Mental health	Depression	Questionnaire	Modified from Patient Health Questionnaire 9 (PHQ-12)
Social well-being	Social support	Questionnaire	Developed for UDAY
Healthcare utilization	Hospital visits in the past 12 months and health care expenditure	Questionnaire	CARRS

Data collection for the provider surveys

Trained research staff visited health facilities located in the aforementioned selected study areas and approached healthcare providers (physicians and pharmacists). Written informed consent was sought and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire (Table 6).

The physician survey was done among a convenience sample of 50 physicians working in the health facilities located in the selected study areas of Sonipat and Vizag.

Inclusion criteria: We included physicians working in health facilities located in the sampled urban and rural areas of Sonipat and Vizag respectively and were willing to participate and provide informed consent.

Exclusion criteria: Those unwilling to provide informed consent were excluded.

The pharmacist survey was conducted among 350 pharmacists by trained research staff in the aforementioned selected study areas. Written informed consent was sought

and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire.

Inclusion criteria: We included pharmacists who were located in the sampled urban and rural areas of Sonipat and Vizag respectively, dispensing medicines for diabetes and hypertension, were willing to participate and provide informed consent.

Exclusion criteria: Those not dispensing medicines for diabetes and hypertension and unwilling to provide informed consent were excluded.

Table 6: Summary of indicators, measures, methods and instruments for the provider survey (physicians)

Indicators	Measures	Methods	Instruments
Socio-demographic details	Age, gender, qualification, years of practice, patient load, training in diabetes and hypertension management	Questionnaire	Developed for UDAY
Knowledge and practice pertaining to diabetes and hypertension diagnosis and evaluation of complications	Signs and symptoms, diagnosis and cut-off levels for diagnosis, evaluation for complications	Questionnaire	Developed for UDAY
Treatment practices for diabetes and hypertension	Lifestyle modifications, prevention and management of	Questionnaire	Developed for UDAY

	complications, names of medicines prescribed commonly		

Data collection for the health facility survey

Permission was sought and obtained from respective district medical/health officers prior to data collection and data collection comprised an interviewer administered questionnaire (Table 7). Trained research staff visited public healthcare facilities located in the aforementioned selected study areas and approached the person/ medical officer in charge.

The facility survey was done in 50 public healthcare facilities (sub-centres, primary and community health centres, taluk/district/tertiary hospitals) situated in the selected study areas of Sonipat and Vizag.

Table 7: Summary of indicators, measures, methods and instruments for the health facility survey

Indicators	Measures	Methods	Instruments
Coverage statistics	Types of services offered, number of hours and days services provided per week, population covered, average daily outpatient department (OPD) attendance, number of beds available, status of National program	Questionnaire	Adapted from Service Availability and Readiness Assessment tool (SARA) of the World Health Organization

	for control and prevention of diabetes, cardiovascular disease and stroke (NPCDCS) implementation		
Recommended manpower list	Numbers working at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended numbers and reasons for lack of recommended personal. Additional manpower required for NCDs	Checklist, questionnaire	Adapted from Indian Public Health Standards, (IPHS) and SARA
Recommended medication list	Availability of medicines at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended medicines and reasons for lack for recommended medicines. Additional medicines required for NCDs	Checklist, questionnaire	Adapted from IPHS and SARA
Recommended equipment list	Numbers of equipment available at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended	Checklist, questionnaire	Adapted from IPHS and SARA

	equipment and their functional status. Additional equipment required for NCDs		
Recommended investigative services list	Investigative services available at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended services and reasons for their unavailability. Additional investigative services required for NCDs	Checklist, questionnaire	Adapted from IPHS and SARA
Recommended activities list	Frequency of recommended activities conducted and methods of conducting at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres for current diagnosis, treatment and health promotion. Reasons for not conducting the activities	Checklist, questionnaire	Adapted from IPHS and SARA
Availability of national guidelines and training of healthcare providers	Availability of national guidelines for diagnosis and management of diabetes, hypertension and CVD and training of healthcare providers in the	Questionnaire	Adapted from IPHS and SARA

	facility to diagnose and manage diabetes, hypertension and CVD		

Bio-sample collection and storage

Blood samples (in fasting state) were collected in plain, fluoride and EDTA vacutainers (Becton & Dickinson, USA) by trained phlebotomists in households or in camps arranged close to the households. Samples for estimation for blood glucose were kept in ice and transferred to laboratories within 2 hours of sample collection and immediately centrifuged. Samples were centrifuged at 2500 rpm for 15 minutes and serum / plasma were transferred into the cryo-vials which were stored in 20^0C immediately. Buffy coat from EDTA vacutainers were separated and stored into cryo-vials for DNA extraction. Red blood cells were washed thrice with normal saline and were stored for analysis of fatty acids in future. First early morning voided urine was collected from the participants and has been stored in deep freezer for future analysis of metabolites. All these samples were transported to the biochemistry laboratory at the Public Health Foundation of India (PHFI) in dry-ice on the day of collection from Sonipat and Vizag, where they were stored at -80^0C.

All clinical chemistry parameters were analyzed on autoanalyzer Cobas 311 using reagents from Roche Diagnostics, Switzerland. Glucose was estimated using Hexokinase method, cholesterol by enzymatic cholesterol oxidase method, triglycerides by GPO-PAP method & HDL and LDL by direct method, AST & ALT was estimated according to IFCC without pyridoxal phosphate, bilirubin total by Diazonium ion method,

bilirubin direct by Diazo with sulphanilic acid method, urea by kinetic method, creatinine by Jaffe's method, and urinary microalbumin using immuno turbidimetric method. HbA1c was assayed by hplc method using reagents from Bio-Rad Laboratories, Hercules, CA.

Two levels of internal controls were run with every batch of samples. The intra assay and inter assay coefficient of variation for all the parameters were <3% and <5 % respectively.

The biochemistry laboratory is part of External Quality Assurance program from RIQAS for clinical chemistry parameters and HbA1c assay.

Evaluation of cost-effectiveness

This will be evaluated by assessing the costs and benefits of the multi-component, multi-level comprehensive interventions in improving diabetes related health outcomes. Data on healthcare utilization and costs, as well as that of out of pocket expenditure will be collected in the baseline and end line surveys. In addition, data on direct costs including the cost of personnel, provider training, medications, lab tests and supplies, screening, outpatient visits, and costs related to the social marketing campaign will be obtained during the implementation process. The total costs entailed to identify a person with diabetes as well as to appropriately treat that person to recommended targets based on guidelines will be measured. In addition, we will model the costs accrued from the use of drugs and other related interventions, based on results of other such comprehensive programs and do a comparison to assess effectiveness. Based on the aforesaid indicators, we will develop a comprehensive cost-effectiveness model to assess the overall program effectiveness.

Geographical Information System (GIS) based mapping of study households and neighborhood built environment

All households as well as the study areas, including various points of interest as indicated below were geocoded using GIS mapping. This will be used to comprehensively assess the built environment and its impact on diabetes hypertension and risk factors. GIS based techniques will be employed to study the association between built environment (BE) features and diabetes, hypertension and related risk factors.

Specially trained field staff visited all participant households and used handheld Garmin ™ GPS receivers to capture GPS locations of the households. The captured GPS coordinates were verified using Google Earth to see if the locations matched the actual locations.

Table 8 below shows the built environment features from the study areas that were located and mapped.

Table 8: Characteristics of the built environment in study sites

Environment features	Points of interest	N	Sonipat	Vizag
Healthcare facilities	Government hospitals	64	36	28
	Private hospitals & clinics	228	147	81
	Registered medical practitioners and unqualified practitioners	220	195	25
	Other health professionals	120	115	3
	Pharmacies	337	224	113

	Medical laboratories	46	30	16
Food outlets	Hotels	162	4	161
	Restaurants	33	10	23
	Small eateries	97	40	57
	Provision / department stores	313	196	117
	Fruit / vegetable / juice outlets	254	36	218
	Meat / fish shops	128	24	104
	Public distribution system (ration)shops	52		52
	Milk outlets	126	344	122
	Bakeries/ sweet shops	106	56	50
Tobacco outlets	Pan shop	713	17	696
Alcohol outlets	Authorized government outlets	45	31	14
	Unauthorized alcohol outlets	100		100
Recreational facilities	Parks	91	62	29
	Walking tracks	6		6
	Play grounds	50	43	7
	Fitness / yoga centers	10	6	4
Other	Anganwadis, schools, temples etc.	633	124	509

Household GPS locations and neighborhood BE features were integrated with participant data collected as part of the baseline data collection. An overview of the GIS mapping is provided in Figure 5. Area boundaries were obtained from government

records and digitized. All spatial data was integrated into a spatial database and ArcGIS ™ software will be used to carry out following spatial analysis methods.

- Distance calculations: distance between participant households and features of interest such as health care facilities, food and alcohol outlets, parks etc. and their association between CMD and risk factors.
- Spatial aggregation: Aggregation of features such as number of food outlets, parks etc. in the neighbourhood and relationship with CMD and risk factors.
- Clustering: Identify clustering of CMD and risk factors (hotspots) and determine if disease clusters are of sufficient geographic size and concentration to have not occurred by chance.
- Spatial smoothing and interpolation: Used to derive a spatial surface from sampled data points (filling in where data are unobserved) or to smooth across polygons (aggregate data) to create more robust estimates.
- Spatial regression: Use of Spatial regression methods such as Geographically weighted regression (GWR) to further understand the relationship between built environment and CMD risk factors as standard statistical regression models, which assume independence of the observations, are not appropriate for analysing spatially dependent data.

Figure 5: GIS mapping overview (insert here)

Data management

Data were collected in electronic format using customized android based software on a tablet platform and uploaded to server on a real time basis (Figure 6). For ensuring quality control, all validation, range and logical checks were in-built in the software. Error reports were generated bi-weekly and sent to the study sites for rectification. Errors were checked against completion of

the questionnaire, identifiers and adherence to the sampling strategy of interviews (only one man and one woman from single household).

Further, site research teams identified any other issues and reported to centralized team for the corrections. Data correction took place concomitantly with the conduct of the baseline survey. Similarly, bio-sample reports were matched with participant questionnaires and the final data was locked after all matching, and rectification of errors.

Figure 6: Data collection and management pathway (insert here)

Analysis plan

Data were entered into a database designed specifically for the project, housed at PHFI and accessible only to investigators and designated study staff. Data will be analysed using Stata/SE version 10.1 for windows software. Descriptive statistics will be done and the data expressed as frequencies and percentages for categorical variables and means and standard deviations for normally distributed continuous variables or inter-quartile ranges otherwise. Differences between gender groups, age groups, socio-economic groups, study sites, time periods and individual hypotheses will be tested using appropriate analytical statistical tests (Chi-square tests for categorical variables, t-tests continuous variables, multiple linear regression for continuous variables, and multiple logistic regression for categorical variables). Stratified analysis will be done to assess for potential confounding and effect modification by other variables. A p-value of < 0.05 will be considered to indicate statistical significance. Multi-level modelling will be undertaken by clusters and households as potential levels.

Discussion

UDAY is one of the largest community based intervention studies established in India to implement and evaluate a multi-component, multi-level, cost-effective, comprehensive intervention program to concomitantly improve the prevention, detection and optimal management of diabetes and hypertension, which together constitute the leading NCDs in India. Their high and rising burden coupled with huge healthcare costs underlines the need for cost-effective community based approaches supplemented by measures to strengthen the health system to address both these NCDs effectively as envisaged in UDAY.

Most of the evidence on community interventions for chronic NCDs are from developed countries [12-13]. In the last two decades some evidence has emerged from developing countries as well but not quite commensurate to the disproportionate burden borne by them (80% NCD mortality) [14-15].This is due to several reasons including resources to conduct such large projects as well as the technical capacity [14,15]. However, available information indicates that results are likely better in developing countries (e.g. Isfahan Healthy Heart Program in Iran, diabetes prevention programs in China and India) [14-16]. We have taken into account findings of such prior research and attempted to address the reported gaps by adding relevant elements to the design of our study. For instance, most such intervention programs have entailed community based interventions (largely targeting lifestyle modification) but have not had active healthcare system and advocacy interventions as proposed in our study. In addition, many of the diabetes prevention programs have targeted high risk groups and not the general free living population as envisaged in this program. Further, we have used several innovations (see table 1) including task shifting/sharing of care to non-physician health workers by the extensively leveraging low-cost m-health technology to enable

and empower them to screen and deliver interventions as well as physicians to treat patients as per evidence based algorithms. We have also used GIS mapping to characterize the sites, built environment, healthcare facilities and providers to examine the influence of built environment on diabetes/hypertension and their risks factors as well as care pathways that patients undertake, in order to deliver interventions in a more focused way. In addition, we have built in extensive stakeholder and community engagement in the study implementation which should aid in improving acceptability and buy in for the intervention program.

Further, the community based cohorts established will not only facilitate tracking of the trends in risk factors and diseases in rapidly transitioning populations in India, but also serve as well characterized population platforms for embedding and evaluating new research questions of public health relevance in combating the rise of NCDs.

Notably, a unique strength of UDAY besides occurring in a developing country setting where there are limited community based projects, in comparison to various other community based projects conducted in both developed and developing countries, which have either addressed prevention or management of select chronic conditions, is that UDAY aims to address both prevention and management of concurrently and comprehensively.

However, the study has some limitations. Firstly, we used a pre-post study design for evaluating the effect of our interventions. Though, a randomized controlled trial is a better design to evaluate the effectiveness of interventions, providing a higher level of evidence than a pre-post design, to study the effect of multi-component interventions delivered at multiple levels in a comprehensive manner in a large population over a vast geographic area, we considered the pre-post design as more appropriate for our study.

Further, we also wanted to understand and examine the operational part of the program implementation to gain insights into underpinning factors behind success or failure that can inform possible replication and scale up in the future.

Secondly, our study does not include controls for the comparison. Given the size of the population covered by the interventions, we would have had to recruit control communities of similar size and numbers, which wasn't feasible from an implementation and resources availability point of view. However, our baseline and end line surveys that evaluate the impact are done on independent random samples of the population, which should provide robust data regarding potential changes over baseline in the levels of: public awareness and knowledge about diabetes and hypertension; those aware, diagnosed, treated and controlled to recommended targets; the use of guideline based management by providers leading to improved health outcomes and access to healthcare for people living with diabetes and hypertension in India. In addition, we will be comparing our results with ongoing national survey data on NCDs and their risk factors (National Family Health Survey, Annual Health Survey, District Level Household Survey) as well as a New National NCD survey which is being implemented currently. This will help assess secular trends and evaluate our findings in conjunction with such trends if any. Also we did not account for the regression to the mean as there would be at least some people both in the end line and baseline. We will do sensitivity analysis to explore this bias.

Thirdly, one of the major interventions of our program is to implement a community based screening, follow-up and educational program through health workers. We specifically hired and trained health workers to implement this interventional component, which might add to the cost of implementing a community based diabetes and

hypertension prevention and management program. However, the additional cost of is likely to be minimal as indicated by previous modelling estimates of training and using health workers.

Fourthly, we are using multi-component interventions at multiple levels (health promotion campaigns, health workers led home based screening, follow-up and education, training of healthcare providers, registry for facility based improvement in quality of care, patient networks and advocacy to strengthen the health system) which makes it difficult to evaluate the individual contribution of each intervention. However, the purpose is to deliver it in a comprehensive manner to improve outcomes, which to our knowledge has hitherto not been implemented in similar settings, and not to tease out impact of individual interventions in a milieu where many individuals have elevations of multiple NCD risk factors and suffer often from co-morbid conditions that require to be addressed comprehensively.

It is anticipated that the results obtained from the study will inform policy makers on the most appropriate community and health system based approaches that are effective in stemming the rising burden of diabetes and hypertension in India and countries with similar challenges.

Data sharing and Contributorship statement

Data will be available to the study investigators only. De-identified data can be shared with other researchers based on specific request to the publication sub-committee of the project with potential research questions to be examined.

Sailesh Mohan, K. Srinath Reddy, Dorairaj Prabhakaran and Nikhil Tandon conceived the study. Sailesh Mohan wrote the first draft of the manuscript. Prashant Jarhyan, Shreeparna Ghosh, Nikhil Srinivasapura Venkateshmurthy, Ritu Rana, Cheena Malhotra, Ruby Gupta, Bhaskara Rao and Sanjay Kalra wrote specific sections of the manuscript as well as contributed to the design and implementation of the study. Bhaskara Rao and Sanjay Kalra also coordinate the activities in the study sites and provide technical support. Sailesh Mohan, Shreeparna Ghosh, Prashant Jarhyan, and Nikhil Srinivasapura Venkateshmurthy contributed to the collection and assembly of data. All authors provided input into the study design, as well as provided critical intellectual input for revision of the manuscript and approved the final version of the manuscript.

Acknowledgements

The UDAY project is led by the Public Health Foundation of India, Gurgaon, India in collaboration with Population Services International, India and Project HOPE. We acknowledge the contributions of the field and research staff of the project. The funder has no role in the design, implementation, and evaluation of the project as well as in the writing of this paper. All contents of this paper are solely the responsibility of the authors.

Funding source

It is supported by an unrestricted educational grant from Eli Lilly and Company under the Lilly NCD Partnership Program.

Disclaimer

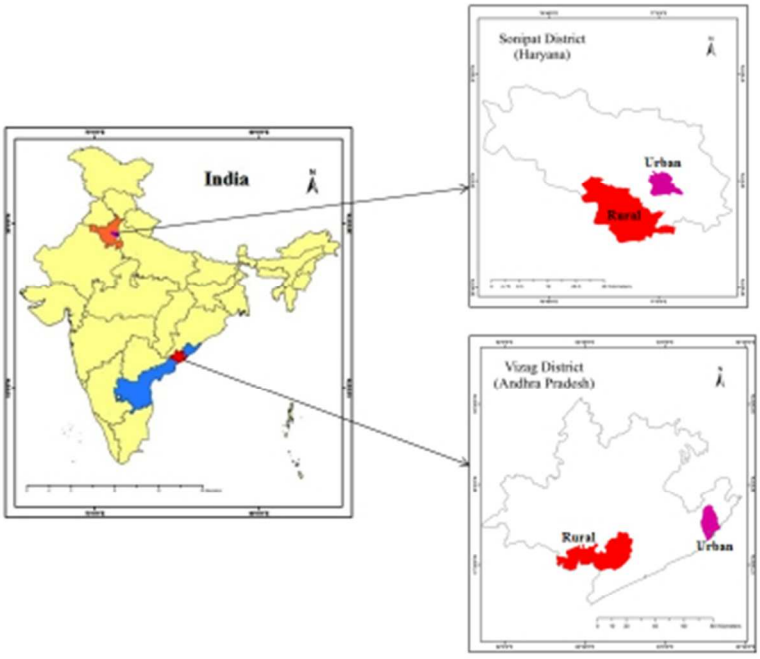
The funding agency had no role in the design, conduct or analysis of the study, and no role in the decision to submit the protocol for publication.

Conflicts of interest

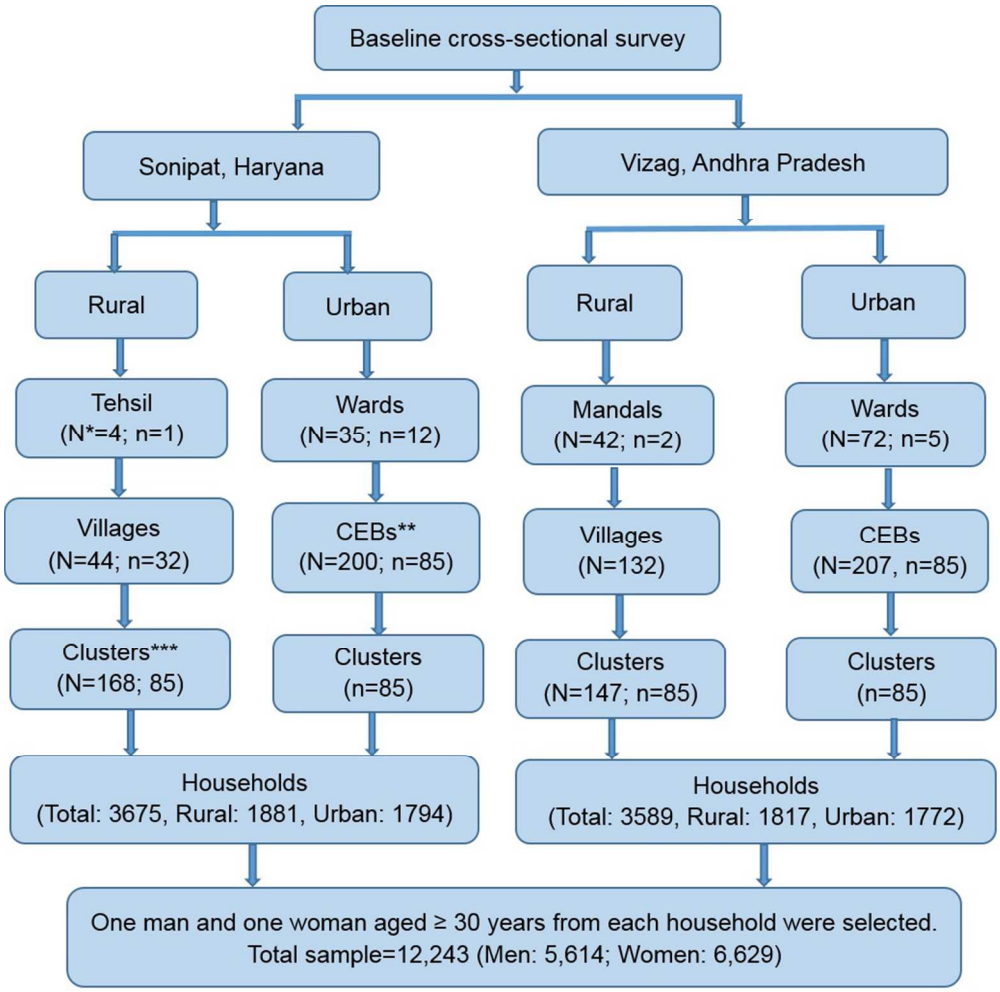
None declared

References

1. National Multisectoral Action Plan for Prevention and Control of NCDs in India. World Health Organization (WHO) Country Office for India, New Delhi, 2013.
2. International Diabetes Federation. IDF Diabetes Atlas, 7th edition. 7th ed. Brussels, Belgium: International Diabetes Federation, 2015.
3. Reddy KS, Shah B, Varghese C, et al. Responding to the threat of chronic diseases in India. Lancet 2005; 366:1744-49.
4. Mohan S, Koller T.Hypertension and related comorbidities in India: Implications for the health system. World Health Organization (WHO) Country Office for India, New Delhi, 2013.
5. Nair M, Ali MK, Ajay VS, et al. CARRS Surveillance study: design and methods to assess burdens from multiple perspectives. BMC Public Health 2012;12:701.
6. Reddy KS, Prabhakaran D, Chaturvedi V, et al. Methods for establishing a surveillance system for cardiovascular diseases in Indian industrial populations. Bull World Health Organ 2006; 84:461-69.
7. International Institute for Population Sciences (IIPS) and Macro International. 2007. National Family Health Survey (NFHS-3), 2005–06: India: Volume II.Mumbai: IIPS.
8. World Health Organization. Global Physical Activity Questionnaire (GPAQ) Analysis Guide: World Health Organization. Available at: http://www.who.int/chp/steps/resources/GPAQ_Analysis_Guide.pdf (Assessed 15 December 2015)
9. Yusuf S, Hawken S, Ounpuu S, et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. Lancet 2004; 364:937-52.
10. EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy 1990; 16:199–208.
11. Poongothai S, Pradeepa R, Ganesan A, et al. Reliability and validity of a modified PHQ9 item inventory (PHQ12) as a screening instrument for assesing depression in Asian Indians (CURES—65). J Assoc Physicians India 2009; 57: 147–52.
12. Berra K, Franklin B, Jennings C. Community-Based Healthy Living Interventions. Prog Cardiovasc Dis 2017; 59:430-439.
13. Puska P. Why Did North Karelia-Finland Work? Is it Transferrable? Glob Heart 2016; 11:387-391.
14. Sarrafzadegan N1, Kelishadi R, Esmaillzadeh A, Mohammadifard N, Rabiei K, Roohafza H, Azadbakht L, Bahonar A, Sadri G, Amani A, Heidari S, Malekafzali H. Do lifestyle interventions work in developing countries? Findings from the Isfahan Healthy Heart Program in the Islamic Republic of Iran. Bull World Health Organ 2009;87:39-50.
15. Harati H, Hadaegh F, Momenan AA, Ghanei L, Bozorgmanesh MR, Ghanbarian A, Mirmiran P, Azizi F. Reduction in incidence of type 2 diabetes by lifestyle intervention in a middle eastern community. Am J Prev Med 2010; 38:628-636.
16. Rawal LB, Tapp RJ, Williams ED, Chan C, Yasin S, Oldenburg B. Prevention of type 2 diabetes and its complications in developing countries: a review. Int J Behav Med. 2012; 19:121-33.



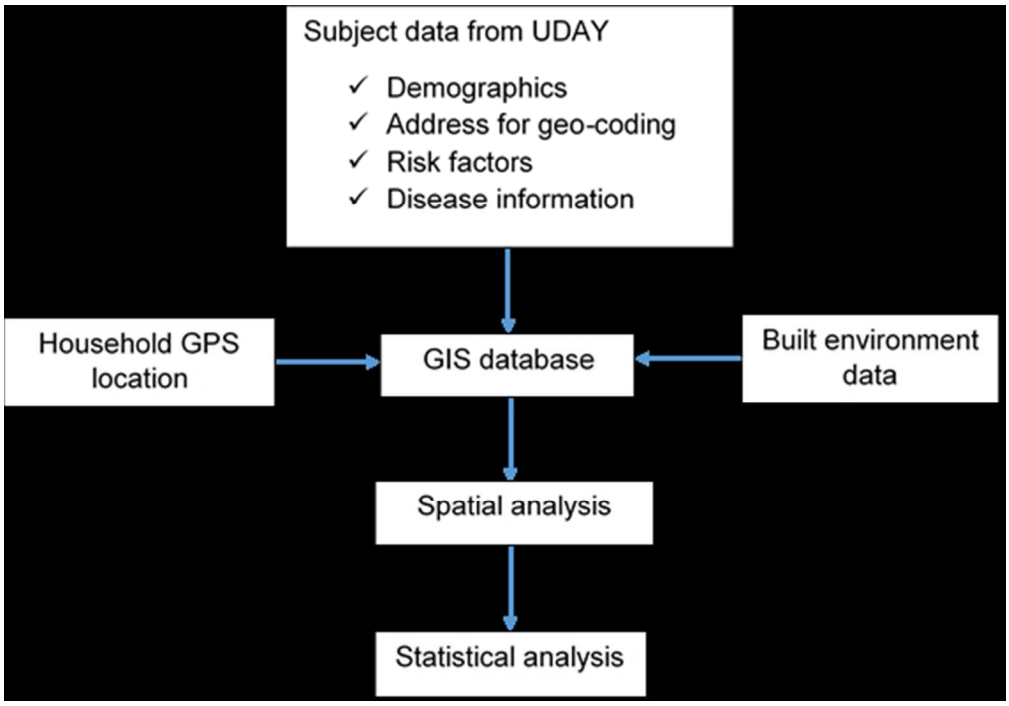
40x30mm (300 x 300 DPI)



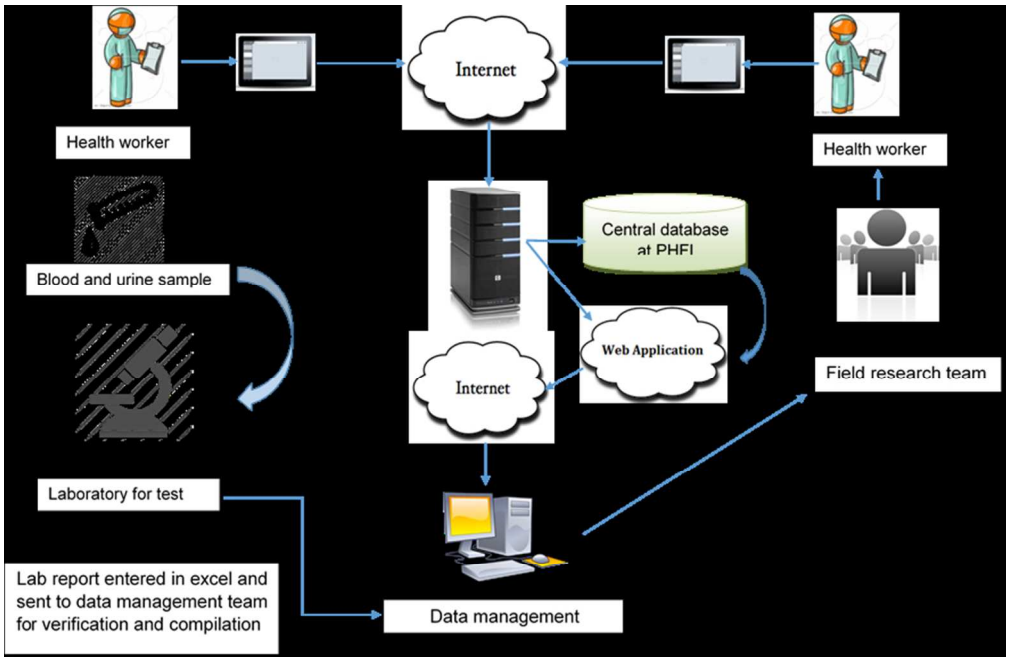
*N=total, n=number selected

**CEB=Census Enumeration Block

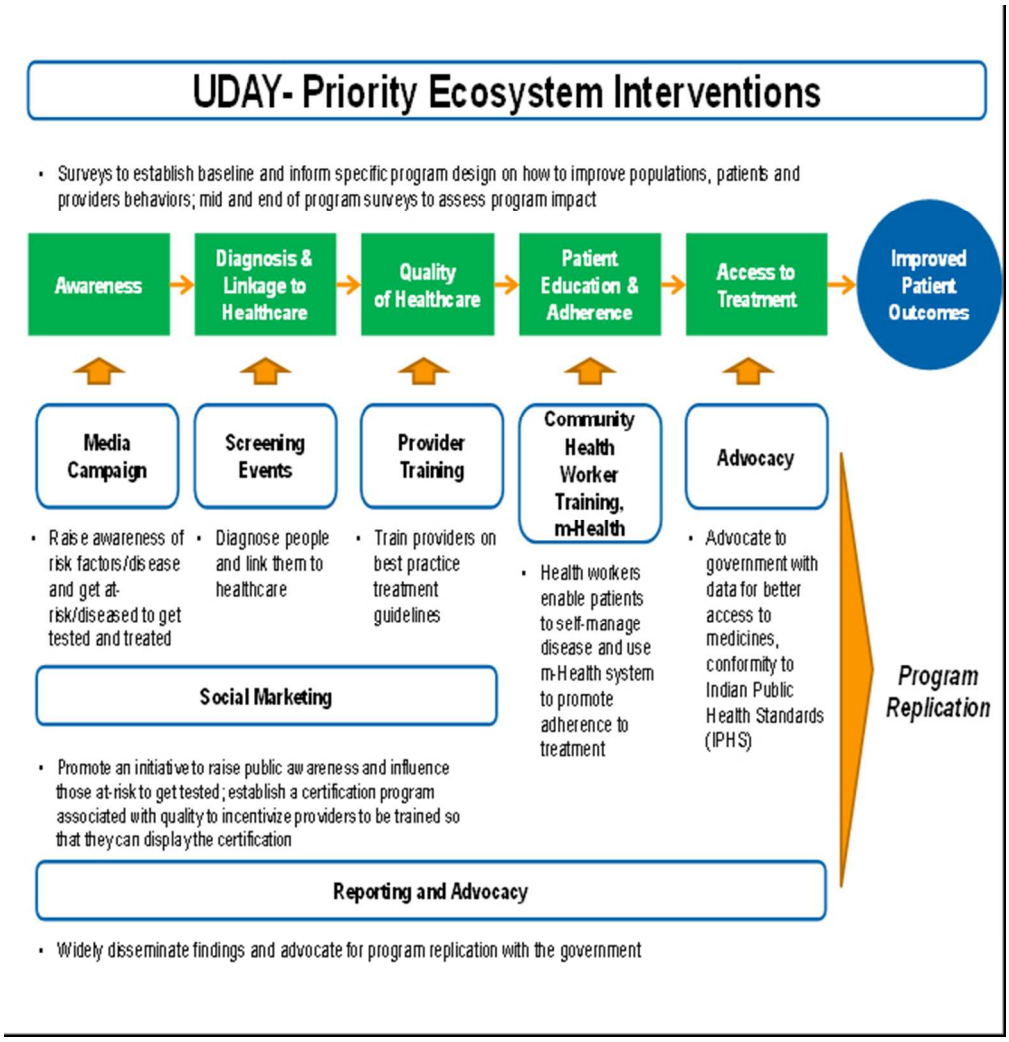
***Cluster = In urban sub-site clusters comprise CEBs, in rural sub-site bigger villages were split into 2 or 3 clusters with sizes of 75-300 households.



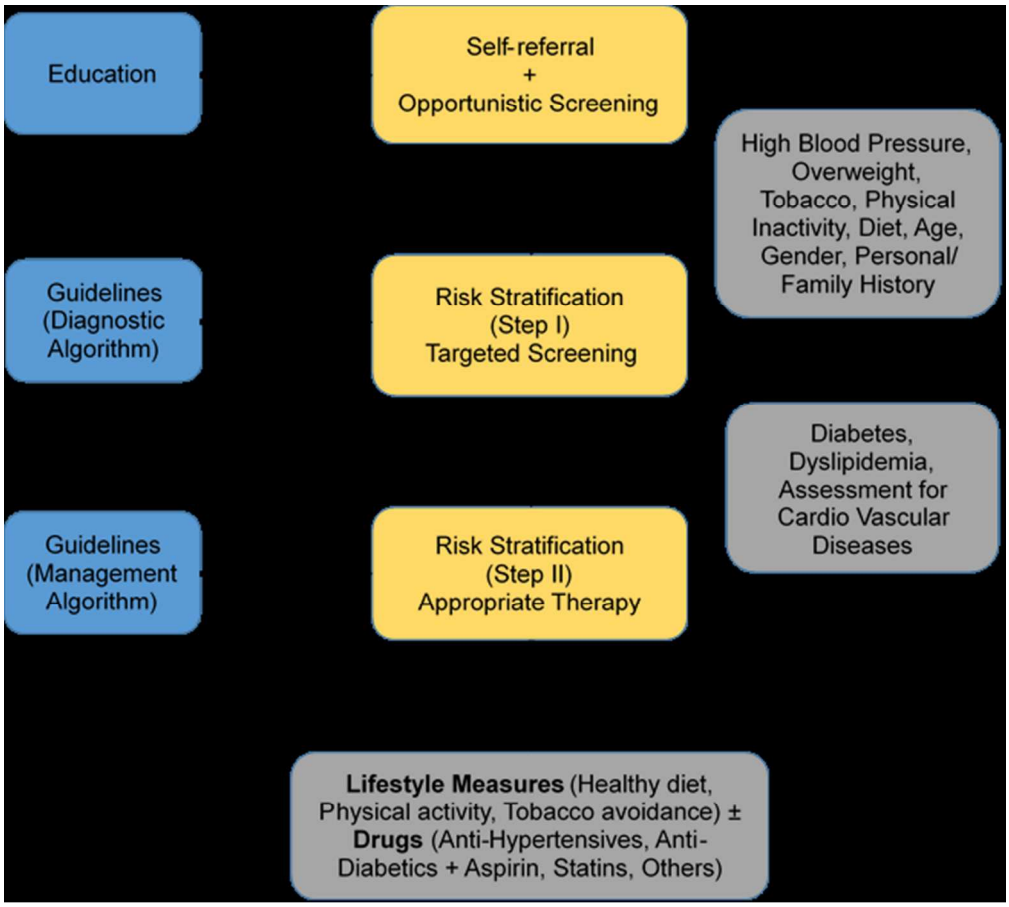
48x33mm (300 x 300 DPI)



74x48mm (300 x 300 DPI)



56x58mm (300 x 300 DPI)



55x49mm (300 x 300 DPI)

Supplementary file

Sonipat district in the state of Haryana, is north of India's capital city Delhi. It covers an area of 2,122 sq. km and has a population of 1,450,001 (Census 2011). The district has 4 tehsils (sub-districts), namely Gohana, Ganaur, Sonipat and Kharkhoda. Among these, we selected Sonipat tehsil as the urban sub-site and Kharkhoda as the rural sub-site.

Vizag district is one of the north eastern coastal district in the state of Andhra Pradesh and lies in proximity to the Bay of Bengal. It covers an area of 11,161 sq. km and has a population of 4,290,589 (Census 2011). Vizag district has 43 mandals (sub-districts) comprising 4 urban mandals and 39 rural mandals. Among these, we selected Vizag as the urban sub-site and Makavarapalem and Nathavaram as the rural sub-site.

BMJ Open

UDAY: Protocol of a Comprehensive Diabetes and Hypertension Prevention and Management Program in India

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-015919.R2
Article Type:	Protocol
Date Submitted by the Author:	06-Oct-2017
Complete List of Authors:	Mohan, Sailesh; Public Health Foundation of India Jarhyan, Prashant; Public Health Foundation of India Ghosh, Shreeparna; Public Health Foundation of India Srinivasapura Venkateshmurthy, Nikhil; Public Health Foundation of India Gupta, Ruby; Public Health Foundation of India Rana, Ritu; Population Services International India Malhotra, Cheena; Project Hope India Rao, Bhaskara; MaxCure Hospital Kalra, Sanjay; Bharti Hospital Karnal Tandon, Nikhil; All India Institute of Medical Sciences, Reddy, KS; Public Health Foundation of India Prabhakaran, Dorairaj; Public Health Foundation of India
Primary Subject Heading:	Epidemiology
Secondary Subject Heading:	Diabetes and endocrinology, Health services research, Public health, Cardiovascular medicine
Keywords:	Hypertension < CARDIOLOGY, General diabetes < DIABETES & ENDOCRINOLOGY, EPIDEMIOLOGY

UDAY: Protocol of a Comprehensive Diabetes and Hypertension Prevention and Management Program in India

Authors: Sailesh Mohan, [1] Prashant Jarhyan, [1] Shreeparna Ghosh, [1] Nikhil Srinivasapura Venkateshmurthy , [1] Ruby Gupta, [1] Ritu Rana, [2] Cheena Malhotra, [3] Bhaskara Rao, [4] Sanjay Kalra, [5] Nikhil Tandon, [6] K. Srinath Reddy, [1] Dorairaj Prabhakaran[1]

[1] Public Health Foundation of India, Gurgaon, India

[2] Population Services International, Delhi, India

[3] Project HOPE, Delhi, India

[4] Manipal Hospitals, Visakhapatnam, India

[5] Bharti Hospital, Karnal, India

[6] All India Institute of Medical Sciences, Delhi, India

Corresponding author
Dr. Sailesh Mohan
Additional Professor
Public Health Foundation of India
Email:smohan@phfi.org

Abstract

Introduction
Diabetes and hypertension are two leading noncommunicable conditions, which are sub-optimally managed in India. Thus, innovative comprehensive approaches that can concomitantly improve their detection, prevention and control are warranted.

Methods and analysis
UDAY, a 5-year initiative aims to reduce the risk of diabetes and hypertension and improve management by implementing a comprehensive intervention program in the two selected study sites, Sonipat and Visakhapatnam (Vizag). It has a pre-post evaluation design with representative cross-sectional surveys before and after intervention. Within these two sites, urban and rural sub-sites each with a total population of approximately 1, 00,000 people each were selected and a baseline and post intervention assessment will be conducted deploying 5 surveys [among general population (including body measurements or bio-samples), patients, healthcare providers including physicians and pharmacists, health facilities] which will determine: the knowledge levels about diabetes and hypertension, the proportion treated and controlled; the patient knowledge and self-management skills; healthcare providers' management practices; the level of access and barriers to obtaining care.
The interventions will include: tailored health promotion for improving public knowledge; screening of adults aged ≥ 30 years for identifying those at high risk of diabetes and/or hypertension for linkage to the healthcare system; patient education using technology enabled community health workers, geographic information system (GIS) based mapping of the communities, healthcare provider training on management guidelines, community based diabetes registry and; advocacy to improve access to healthcare. The baseline surveys have been completed, the study areas mapped using GIS and the interventions are being implemented. UDAY is expected to increase over baseline the levels of: public knowledge about diabetes and hypertension; those treated and controlled; patient self-management skills; the use of guideline based management by providers and; access to healthcare, leading to improved health outcomes and inform development of a India relevant chronic care model.

Ethics and dissemination
Ethical clearance for conduct of the study was obtained from the Institutional Ethics Committee (IEC) of the Public Health Foundation of India. The findings will be targeted primarily at public health policymakers and advocates, but will be disseminated widely through other mechanisms including conference presentations and peer-reviewed publications, as well as to the participating communities.

Strengths and limitations of this study

- Unique large community based study in geographically and culturally diverse "real world" settings in India for improving prevention and control of diabetes and hypertension.
- Employs a comprehensive multi-level, multi component intervention approach to target the general population, patients, providers and to strengthen the health system for improving prevention and control of diabetes and hypertension.

- Concomitantly addresses detection, prevention and management of both diabetes and hypertension.
- Extensively leverages mobile technology to enable health workers in task sharing as well as for electronic data capture.
- Quasi experimental design with complex intervention may hinder attribution of specific effect to individual intervention components.

Introduction

Non-communicable Diseases (NCDs) are currently the leading cause of preventable death and disability in India, accounting for two out of every three deaths [1]. Among NCDs, the prevalence of type-2 diabetes mellitus (DM) and hypertension have been rising rapidly. Currently there are about 69 million people with diabetes, a figure that is projected to further increase to a staggering 124 million by 2040 [2]. The number of individuals with hypertension is projected to increase to 214 million by 2030 from 118 million in 2000 [3,4]. Furthermore, diabetes and hypertension are important risk factors for both the major forms of cardiovascular disease [CVD (coronary heart disease and stroke)], highly prevalent and attributable to nearly half of all the deaths from NCDs [4].

Despite the availability of proven and effective treatments, diabetes as well as hypertension detection and control rates are abysmally low in India with blood pressure control among those with diabetes being even more sub-optimal, with a huge gap between detection and adequate treatment [1,3,4]. Thus, there is great potential and opportunity to reduce the rising burden of diabetes and hypertension as well as the

associated vascular risk in India through concomitantly improving their detection, prevention and control.

To address this huge gap in the prevention and management of both these conditions we are undertaking a 5-year initiative entitled “UDAY” (meaning dawn in *Sanskrit*) in epidemiologically transitioning communities, that aims to reduce the risk of diabetes and hypertension and concomitantly improve the management of either conditions by implementing a comprehensive community based innovative intervention program in the two geographically and culturally distinct study sites, Sonipat (Haryana, North India) and Visakhapatnam or Vizag (Andhra Pradesh, South India). This paper describes the design and methods of UDAY- A Comprehensive Diabetes and Hypertension Prevention and Management Program In India.

Methods

Study design

UDAY has a pre-post evaluation design with representative cross sectional surveys before (in year one at baseline, pre-intervention) and after the intervention (in year 5). The main research question is: whether a multi-component, multi-level, cost-effective, comprehensive intervention program will improve the prevention, detection and optimal management of diabetes and hypertension in the two selected study sites. Ethical clearance for conduct of the study was obtained from the Institutional Ethics Committee (IEC) of the Public Health Foundation of India.

We selected a pre-post evaluation design due to the following reasons. We wanted to evaluate if multi-component interventions delivered at multiple levels in a

comprehensive manner can improve outcomes. Further, we also wanted to understand and examine the operational part of the program implementation to gain insights into underpinning factors behind success or failure that can inform possible replication and scale up in the future. The options for an implementation study of this nature with process outcomes are either a pre-post design or quasi-experimental design or step wedge design. We deemed a step wedge to be too complicated for this evaluation and given that quasi experimental design would not have enough power to decipher real differences, we chose a pre-post design. This was also aimed at cutting down costs. At baseline, in year one, 5 surveys were conducted among the general population, among patients, among healthcare providers including physicians and pharmacists and in health facilities to guide intervention development and impact assessment. Similar assessment is planned after the intervention, in year 5.

The specific objectives these assessments are to:

1. Determine the prevalence, awareness, the knowledge levels about diabetes and hypertension, the proportion treated and controlled among a representative sample (n=12000) of adults aged ≥ 30 years in the selected study areas. (Population survey)
2. Determine the patient knowledge levels and self-management skills among a convenience sample (n=400) of those diagnosed with diabetes and hypertension in the selected study areas. (Patient survey)
3. a) Determine healthcare providers' (physicians) knowledge and practices related to diabetes and hypertension management among a convenience sample (n=50) of healthcare providers' in the selected study areas.

b) Determine pharmacists' knowledge related to diabetes and hypertension and dispensing practices among a convenience sample of pharmacists (n=350) (Provider survey)

4. Determine the level of access and potential barriers to diabetes and hypertension care provided by the public healthcare system in the selected study areas (n=50). (Facility survey)
5. Determine the cost-effectiveness of the intervention program in improving diabetes and hypertension treatment and management outcomes in the study areas. (Using population survey, GIS data and project implementation data)

Study sites

We are undertaking this comprehensive diabetes prevention and management program in two epidemiologically transitioning areas located in Sonipat in Haryana and Vizag in Andhra Pradesh (Figure 1, supplementary file).

Figure 1: Study sites (insert here)

We defined the areas and their sub-areas using the following terminology:

- Sites – a bounded geographic area within which we have defined distinct rural and urban sub-sites for the study. Each site has been defined such that it contains approximately 2,00,000 people. Sonipat and Vizag are each a site.
- Sub-sites – within each site, we have defined one rural and one urban sub-site for study. Each sub-site is geographically bounded, and contains a population of

approximately 1,00,000. Within Sonipat and Vizag, we have defined two sub-sites each (rural and urban).

- Total project – the total project is the summation of the two sites, including the four sub-sites (two sub-sites within each site). Therefore the total population under the study is approximately 4,00,000.

Intervention program

We propose to implement a priority set of synergistic innovative ecosystem interventions (Figure 2, Table 1), with the overarching goal to prevent, detect, reduce the risk of diabetes and hypertension and to improve the treatment and management of individuals with either of the conditions in the study sites. We hypothesize (Figure 3) that education of the public on diabetes, hypertension and related risks will lead to increased self-referral and prevention, while education of the healthcare providers will promote opportunistic screening for diabetes, hypertension and related risks, and purposeful implementation of evidence based diagnostic (to screen, stratify by risk) and management guidelines (to initiate appropriate therapy).

Figure 2: Priority interventions in UDAY (insert here)

Table 1: Innovations in UDAY

Intervention domain	Approach	Target
Prevention, early detection and referral	Culturally tailored health promotion, screening	400,000 population
Capacity building, task	CME, short trainings,	Healthcare providers

shifting of healthcare providers	distance learning, QIP	
Early diagnosis and prevention of complications	Registry	10,000 patients
m-health system	Electronic data system +DSS	Adult population
Electronic data capture	Tablet based surveys	12,000
Spatial and built environment assessment	GIS mapping	All study areas
Improved access to medicines by social marketing initiatives	Improving quality of services	300 pharmacists
Culturally tailored patient education and networks for enabling self-care	Utilizing health workers	Patients

Figure 3: Intervention framework (insert here)

Following the baseline assessments a comprehensive intervention program is being currently implemented. The intervention components includes:

1. tailored health promotion using social marketing approaches for increasing public awareness and promoting population risk factor modification and reduction;
2. community based screening of all adults aged ≥ 30 years for identifying those at high risk of diabetes and/or hypertension or with disease to link to the healthcare system leveraging task-sharing approaches utilizing technology enabled health workers;
3. patient education using technology enabled health workers,
4. healthcare provider training on evidence based management guidelines,
5. implementation of a quality improvement program and diabetes registry and;

6. advocacy with governments and other stakeholders to improve access to healthcare.

It is expected that the comprehensive interventions will increase over baseline the levels of: public awareness and knowledge about diabetes and hypertension; those aware, diagnosed, treated and controlled to recommended targets; the use of guideline based management by providers. Detailed outcome assessment metrics is provided in table 2. This is anticipated to improve health outcomes and access to healthcare for people living with diabetes and hypertension in India as well as provide a model of healthcare which is low-cost, community based and context relevant in a milieu of rapid rise in these chronic conditions.

Table 2: Assessment of intervention outcomes

Indicator	**Target Population**	**Metric**	**Evaluation Methodology**
1. Patient outcomes	Diabetes and hypertension patients	% implementing lifestyle change (meet the recommended levels of physical activity, and intend to and/or implement dietary changes)	Baseline and endline surveys, diabetes registry
		% engaging in self-monitoring/testing	Baseline and endline surveys, diabetes registry
		% increase in correct self-management practices	Baseline and endline surveys, diabetes registry
		% increase in knowledge on diabetes and hypertension	Baseline and endline surveys, diabetes registry

		% of patients on treatment, whose diabetes, hypertension is successfully controlled, i.e., HbA1C≤ 7% / BP ≤130/80 mm Hg	Baseline and endline surveys, diabetes registry
2. Awareness and knowledge about diabetes and hypertension	General population	% increase in knowledge of diabetes, hypertension and their risk factors	Baseline and endline surveys
		% increase in detection rate and in seeking healthcare	Baseline and endline surveys, screening program
		% implementing lifestyle change (meet the recommended levels of physical activity, and intend to and/or implement dietary changes)	Baseline and endline surveys, screening program
		% exposed to health promotion campaign	Baseline and endline surveys, screening program
3. Provider knowledge and practices	Physicians, other health workers	# who participate in training programs	Training participation data
		% increase in knowledge related to diabetes and hypertension management	Baseline and endline surveys of providers, diabetes registry
		% increase in practices related to diabetes and hypertension management and providing lifestyle advice	Baseline and endline surveys of providers, diabetes registry
	Pharmacists	% of pharmacists who identify people at risk of and with diabetes, hypertension	Baseline and endline surveys of providers
		% increase in pharmacists dispensing and filling prescriptions correctly	Baseline and endline surveys of providers, diabetes registry
4. Program cost-effectiveness	Diabetes patients	Cost per diabetic patient treated to recommended target	Baseline and endline surveys of patients, program cost data, diabetes registry
		% reduction in out of pocket expenditure	Baseline and endline surveys of patients, diabetes registry
	General population	Cost per diabetes case identified	Surveys, screening program, program cost data

5. Access to treatment	Healthcare system	Improvements in access to and availability of medications	Baseline and endline surveys of patients, facility survey, diabetes registry
		% increase in the proportion patients who report that medicines are easily available	Baseline and endline surveys of patients, facility survey, diabetes registry
		% reduction in stock outs of medicines	Baseline and endline surveys of patients, facility survey, diabetes registry
		Adherence to IPHS guidelines on drugs, services	Facility survey, diabetes registry

Intervention development

We used evidence based interventions and leveraged the results from the baseline surveys (population, patient, facility and providers) to develop and refine the interventions, which were subsequently piloted. For example, from population survey we found that there were differences in the awareness of risk factors for developing diabetes/hypertension across rural/urban areas and the two study sites in North and South India. Therefore, taking this into cognizance, we designed the tailored health promotion program and messages to be delivered by trained health workers ti increase awareness about the risk factors. Facility and providers' surveys helped us to design the training programs for training healthcare providers as well as to conduct advocacy to improve access to the health system. Similarly, findings from the patients' survey helped us to focus the training of health workers on building self-management skills of people with diabetes/hypertension and for developing patient networks.

Sample for the population survey

We based our sample size calculation on the prevalence of diabetes, which has a lower prevalence than hypertension, in previously reported studies in India. Anticipating a response rate of 85 % with a design effect factor of 1.5 (to account for cluster sampling, and a confidence level of 1.96, the sample size estimates were generated for males and females in three age strata (30-49, 50-69, 69 and above) in each setting (urban, rural). About 2968 subjects was estimated to be required per urban sub-site (Sonipat and Vizag) and 2942 subjects per rural sub-site (Sonipat and Vizag). The total estimated sample was 11820, which was increased to 12000 to obtain equal samples in both urban and rural areas. Sample weights were generated for estimating the prevalence of diabetes, hypertension and related cardiometabolic risk factors at the district level.

Survey sampling and participant selection

Population survey

Two representative population based cross sectional surveys with independent samples and identical methodologies at baseline and at the end of intervention will be conducted, that will provide estimates of the burden and changes in the prevalence of diabetes, hypertension, and related cardiometabolic risk factors. In addition, those recruited for the first survey at baseline (which has been completed), will be followed up as a cohort to estimate the incidence of new cardio-metabolic (CMD) risk factors, disease, healthcare utilization, diabetes and hypertension related morbidity and mortality.

The first population survey (baseline survey) was done among a representative sample of adults aged ≥ 30 years residing in the selected study areas of Sonipat and Vizag. Inclusion criteria – a) adults aged ≥ 30 years residing in the sampled urban and rural areas of Sonipat and Vizag respectively. b) willing to participate and provide informed consent.

We excluded individuals who were unwilling to provide informed consent and those with serious chronic illnesses [such as that of the liver (cirrhosis), kidneys (renal failure) or malignancies], pregnant women.

For the baseline survey, a multistage random sampling technique was deployed to obtain a representative sample of adults aged ≥30 years, using data from the most recent census of 2011. In addition, a manual enumeration and mapping of all households and structures was conducted in all the study areas [all census enumeration blocks (CEBs) in urban areas and villages in rural], to identify households and structures constructed since the last census (Table 3). CEBs are considered as the primary sampling unit in urban areas and villages in the rural areas respectively. On average, about 100-125 households with a population of 650-700 persons would generally constitute a CEB. This enabled a complete sampling frame for the selection of households for the survey and thus provided an equal chance of selection to each household. Besides, it also helped identify potential recipients of the intervention program (i.e., adults aged ≥30 years) in the study sites.

In each sub-site, 85 clusters were randomly selected (urban Sonipat: 85/200 CEBs, urban Vizag: 85/207 CEBs and rural Sonipat: 85/168 clusters, rural Vizag: 85/147 clusters) according to probability proportional to size (Figure 4). In rural sub-sites, bigger

villages were divided into clusters with 75 to 300 households. From each cluster in the urban and rural sub-sites, 18 to 25 households were randomly selected and 1 eligible male and female were selected randomly within each household using Kish table. In Sonipat district, 3675 households participated in baseline survey (rural: 1881, urban: 1794) with total being 6208 participants (rural: 3104, urban: 3104). In Vizag district, 3589 households (rural: 1817, urban: 1772) participated in the baseline survey with total being 6035 participants (rural: 3069, urban: 2966). Thus, we had 12000 individuals from both urban and rural areas of North and South India.

Table 3: Manual enumeration of study areas

Study site	Structures	Households	Population ≥30 years	Total population (census 2011)
Sonipat urban sub-site	24408	20406	41981	102292
Sonipat rural sub-site	28813	17283	40850	100935
Vizag urban sub-site	16888	39504	70735	153721
Vizag rural sub-site	33799	30817	59540	121209

Figure 4: Sample selection for the baseline survey (insert here)

*N=total, n=number selected

**CEB=Census Enumeration Block

***Cluster = In urban sub-site clusters comprise CEBs, in rural sub-site bigger villages were split into 2 or 3 clusters with sizes of 75-300 households.

Data collection for the population survey

For the baseline survey, trained health workers visited the selected participants at their homes. Written informed consent was sought and obtained from the selected individuals prior to data collection and a unique identification number was assigned. For each participant, data collection comprised an interviewer administered questionnaire, a brief physical examination (height, weight, waist circumference, hip circumference, blood pressure, body fat percentage), blood and urine collection as detailed below.

Information on demographics, socio-economic characteristics, behavioral risk factors (tobacco use, alcohol use, diet and physical inactivity), family history of various NCDs, female reproductive history, general awareness about diabetes and hypertension, risk factors, prevention, symptoms and diagnosis, complications, treatment and management, medical history of NCDs [diabetes, hypertension, coronary artery disease (CAD), myocardial infraction (MI), stroke, heart failure, chronic kidney disease (CKD), peripheral vascular disease (PVD), chronic obstructive pulmonary disease (COPD), asthma], quality of life, mental health, social support, cost of healthcare and healthcare utilization was collected using a tablet based application (Table 4).

Body measurements such as height, weight, waist and hip circumferences, blood pressure and body fat measurement by bio impedance using TANITA were also obtained using standardized equipment.

Bio-samples (fasting blood and morning urine) were collected for the laboratory estimation of fasting plasma glucose, glycated hemoglobin (HbA1c), lipids, serum creatinine, urea, urine microalbumin and urine creatinine. We have also stored the bio samples for future analysis of emerging biomarkers and genetics.

Table 4: Summary of indicators, measures, methods and instruments for baseline survey

Indicators	Measures	Methods	Instruments
Demographics and socio-economic characteristics	Age, sex, marital status, religion, education, income, occupation, contact details, and household assets	Questionnaires	Centre for cArdio-metabolic Risk Reduction in South Asia(CARRS) Surveillance Study [5] Establishment of Sentinel Surveillance System for CVD in Indian Industrial Populations (Sentinel Surveillance Study) [6] National Family Health Survey, 2005-06 [7]
Behavioral risk factors	Tobacco use Alcohol use	Questionnaire	CARRS, Sentinel Surveillance Study
	Physical activity	Questionnaire	Global Physical Activity Questionnaire (GPAQ-2) [8]
	Dietary habits	Questionnaire	CARRS,INTERHEART Study[9]
Family history	Prevalence of cardiometabolic diseases (CMDs) among family members related to participants, mortality	Questionnaire	CARRS
Female	Menarche/	Questionnaire	CARRS

reproductive history	gestational history, menopause (surgical / physiological / whether on hormone replacement therapy) / contraception		
Awareness and knowledge	General awareness about diabetes and hypertension, risk factors, prevention, symptoms and diagnosis, complications, treatment and management	Questionnaire	CARRS
Physiological and biochemical risk factors	Hypertension	Blood pressure measurements	Standardized method (American Heart Association) and validated instrument (certified by British Hypertensive Society and Association for the Advancement of Medical Instrumentation) Standardized across both the sites
	Diabetes	Laboratory estimation of fasting plasma glucose, glycated hemoglobin (HbA1c)	Standardized across both the sites
	Dyslipidemia	Laboratory estimation of serum total cholesterol, low	Standardized across both the

		density lipoprotein cholesterol, very low density lipoprotein cholesterol, high density lipoprotein cholesterol, triglycerides	sites
	Obesity	Anthropometry (height, weight, waist and hip circumferences, body fat	Standard procedures based on National Health And Nutrition Examination Survey-III with instruments used in epidemiological studies on South Asian population
Medical history	Chronic kidney disease	Serum creatinine, urea, urine microalbumin and urine creatinine	Standardized across both the sites
	Stroke, myocardial infraction, Congestive heart failure, Chronic stable angina	Questionnaires including medical history	Rose Angina, CARRS
Treatment history, health services, quality of care and health care costs	Awareness and risk factor control Access to health care services, utilization of services, health insurance	Questionnaire	CARRS

	coverage, costs of treating CMDs and their risk factors		
Prevalence	COPD and asthma	Questionnaire	NHANES III and present standards of the American Thoracic Society (ATS)
Health related Quality of Life	Mobility, self-care, usual activities, pain/discomfort, anxiety/depression (related to CMDs and risk factors)	Questionnaire	European Quality of Life 5 Dimensions questionnaire (EQ-5D-3L) [10]
Mental health	Depression	Questionnaire	Modified from Patient Health Questionnaire 9 (PHQ-12) [11]
Social well-being	Social support	Questionnaire	Developed for UDAY

Data collection for the patient survey

Trained research staff visited health facilities located in the aforementioned selected study areas and approached patients attending outpatient section of the health facilities and identified those with the diagnosis of diabetes and/or hypertension based on their prescription note for participating in the study. Written informed consent was sought and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire (Table 5).

The patient survey was done among a convenience sample of 400 patients having diabetes and/or hypertension attending health facilities and residing in the selected study areas of Sonipat and Vizag.

Inclusion criteria: We included patients with diabetes and or hypertension residing/attending health facilities in the sampled urban and rural areas of Sonipat and Vizag respectively and were willing to participate and provide informed consent.

Exclusion criteria: We excluded those unwilling to provide informed consent.

Table 5: Summary of indicators, measures, methods and instruments for the patient survey

Indicators	Measures	Methods	Instruments
Demographics and socio-economic characteristics	Age, sex, education, income, occupation, contact details	Questionnaires	CARRS Sentinel Surveillance Study
Behavioral risk factors	Tobacco use Alcohol use	Questionnaire	CARRS, Sentinel Surveillance Study
Awareness and knowledge of diabetes and hypertension	Awareness of risk factors, symptoms and diagnosis, cut-off levels for diagnosis, complications, treatment and management	Questionnaire	Developed for UDAY
Diabetes and hypertension related medical history	Diagnosis, health care utilization, control, self-management practices, complications, comorbidities, and treatment adherence	Questionnaire	Developed for UDAY
Health related Quality of Life	Mobility, self-care, usual activities,	Questionnaire	European Quality of Life 5 Dimensions

	pain/discomfort, anxiety/depression (related to CMDs and risk factors)		questionnaire (EQ-5D-3L)
Mental health	Depression	Questionnaire	Modified from Patient Health Questionnaire 9 (PHQ-12)
Social well-being	Social support	Questionnaire	Developed for UDAY
Healthcare utilization	Hospital visits in the past 12 months and health care expenditure	Questionnaire	CARRS

Data collection for the provider surveys

Trained research staff visited health facilities located in the aforementioned selected study areas and approached healthcare providers (physicians and pharmacists). Written informed consent was sought and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire (Table 6).

The physician survey was done among a convenience sample of 50 physicians working in the health facilities located in the selected study areas of Sonipat and Vizag.

Inclusion criteria: We included physicians working in health facilities located in the sampled urban and rural areas of Sonipat and Vizag respectively and were willing to participate and provide informed consent.

Exclusion criteria: Those unwilling to provide informed consent were excluded.

The pharmacist survey was conducted among 350 pharmacists by trained research staff in the aforementioned selected study areas. Written informed consent was sought

and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire.

Inclusion criteria: We included pharmacists who were located in the sampled urban and rural areas of Sonipat and Vizag respectively, dispensing medicines for diabetes and hypertension, were willing to participate and provide informed consent.

Exclusion criteria: Those not dispensing medicines for diabetes and hypertension and unwilling to provide informed consent were excluded.

Table 6: Summary of indicators, measures, methods and instruments for the provider survey (physicians)

Indicators	Measures	Methods	Instruments
Socio-demographic details	Age, gender, qualification, years of practice, patient load, training in diabetes and hypertension management	Questionnaire	Developed for UDAY
Knowledge and practice pertaining to diabetes and hypertension diagnosis and evaluation of complications	Signs and symptoms, diagnosis and cut-off levels for diagnosis, evaluation for complications	Questionnaire	Developed for UDAY
Treatment practices for diabetes and hypertension	Lifestyle modifications, prevention and management of	Questionnaire	Developed for UDAY

	complications, names of medicines prescribed commonly		

Data collection for the health facility survey

Permission was sought and obtained from respective district medical/health officers prior to data collection and data collection comprised an interviewer administered questionnaire (Table 7). Trained research staff visited public healthcare facilities located in the aforementioned selected study areas and approached the person/ medical officer in charge.

The facility survey was done in 50 public healthcare facilities (sub-centres, primary and community health centres, taluk/district/tertiary hospitals) situated in the selected study areas of Sonipat and Vizag.

Table 7: Summary of indicators, measures, methods and instruments for the health facility survey

Indicators	Measures	Methods	Instruments
Coverage statistics	Types of services offered, number of hours and days services provided per week, population covered, average daily outpatient department (OPD) attendance, number of beds available, status of National program	Questionnaire	Adapted from Service Availability and Readiness Assessment tool (SARA) of the World Health Organization

	for control and prevention of diabetes, cardiovascular disease and stroke (NPCDCS) implementation		
Recommended manpower list	Numbers working at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended numbers and reasons for lack of recommended personal. Additional manpower required for NCDs	Checklist, questionnaire	Adapted from Indian Public Health Standards, (IPHS) and SARA
Recommended medication list	Availability of medicines at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended medicines and reasons for lack for recommended medicines. Additional medicines required for NCDs	Checklist, questionnaire	Adapted from IPHS and SARA
Recommended equipment list	Numbers of equipment available at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended	Checklist, questionnaire	Adapted from IPHS and SARA

	equipment and their functional status. Additional equipment required for NCDs		
Recommended investigative services list	Investigative services available at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended services and reasons for their unavailability. Additional investigative services required for NCDs	Checklist, questionnaire	Adapted from IPHS and SARA
Recommended activities list	Frequency of recommended activities conducted and methods of conducting at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres for current diagnosis, treatment and health promotion. Reasons for not conducting the activities	Checklist, questionnaire	Adapted from IPHS and SARA
Availability of national guidelines and training of healthcare providers	Availability of national guidelines for diagnosis and management of diabetes, hypertension and CVD and training of healthcare providers in the	Questionnaire	Adapted from IPHS and SARA

	facility to diagnose and manage diabetes, hypertension and CVD		

Bio-sample collection and storage

Blood samples (in fasting state) were collected in plain, fluoride and EDTA vacutainers (Becton & Dickinson, USA) by trained phlebotomists in households or in camps arranged close to the households. Samples for estimation for blood glucose were kept in ice and transferred to laboratories within 2 hours of sample collection and immediately centrifuged. Samples were centrifuged at 2500 rpm for 15 minutes and serum / plasma were transferred into the cryo-vials which were stored in 20^0C immediately. Buffy coat from EDTA vacutainers were separated and stored into cryo-vials for DNA extraction. Red blood cells were washed thrice with normal saline and were stored for analysis of fatty acids in future. First early morning voided urine was collected from the participants and has been stored in deep freezer for future analysis of metabolites. All these samples were transported to the biochemistry laboratory at the Public Health Foundation of India (PHFI) in dry-ice on the day of collection from Sonipat and Vizag, where they were stored at -80^0C.

All clinical chemistry parameters were analyzed on autoanalyzer Cobas 311 using reagents from Roche Diagnostics, Switzerland. Glucose was estimated using Hexokinase method, cholesterol by enzymatic cholesterol oxidase method, triglycerides by GPO-PAP method & HDL and LDL by direct method, AST & ALT was estimated according to IFCC without pyridoxal phosphate, bilirubin total by Diazonium ion method,

bilirubin direct by Diazo with sulphanilic acid method, urea by kinetic method, creatinine by Jaffe's method, and urinary microalbumin using immuno turbidimetric method. HbA1c was assayed by hplc method using reagents from Bio-Rad Laboratories, Hercules, CA.

Two levels of internal controls were run with every batch of samples. The intra assay and inter assay coefficient of variation for all the parameters were <3% and <5 % respectively.

The biochemistry laboratory is part of External Quality Assurance program from RIQAS for clinical chemistry parameters and HbA1c assay.

Evaluation of cost-effectiveness

This will be evaluated by assessing the costs and benefits of the multi-component, multi-level comprehensive interventions in improving diabetes related health outcomes. Data on healthcare utilization and costs, as well as that of out of pocket expenditure will be collected in the baseline and end line surveys. In addition, data on direct costs including the cost of personnel, provider training, medications, lab tests and supplies, screening, outpatient visits, and costs related to the social marketing campaign will be obtained during the implementation process. The total costs entailed to identify a person with diabetes as well as to appropriately treat that person to recommended targets based on guidelines will be measured. In addition, we will model the costs accrued from the use of drugs and other related interventions, based on results of other such comprehensive programs and do a comparison to assess effectiveness. Based on the aforesaid indicators, we will develop a comprehensive cost-effectiveness model to assess the overall program effectiveness.

Geographical Information System (GIS) based mapping of study households and neighborhood built environment

All households as well as the study areas, including various points of interest as indicated below were geocoded using GIS mapping. This will be used to comprehensively assess the built environment and its impact on diabetes hypertension and risk factors. GIS based techniques will be employed to study the association between built environment (BE) features and diabetes, hypertension and related risk factors.

Specially trained field staff visited all participant households and used handheld Garmin ™ GPS receivers to capture GPS locations of the households. The captured GPS coordinates were verified using Google Earth to see if the locations matched the actual locations.

Table 8 below shows the built environment features from the study areas that were located and mapped.

Table 8: Characteristics of the built environment in study sites

Environment features	Points of interest	N	Sonipat	Vizag
Healthcare facilities	Government hospitals	64	36	28
	Private hospitals & clinics	228	147	81
	Registered medical practitioners and unqualified practitioners	220	195	25
	Other health professionals	120	115	3
	Pharmacies	337	224	113

	Medical laboratories	46	30	16
Food outlets	Hotels	162	4	161
	Restaurants	33	10	23
	Small eateries	97	40	57
	Provision / department stores	313	196	117
	Fruit / vegetable / juice outlets	254	36	218
	Meat / fish shops	128	24	104
	Public distribution system (ration)shops	52		52
	Milk outlets	126	344	122
	Bakeries/ sweet shops	106	56	50
Tobacco outlets	Pan shop	713	17	696
Alcohol outlets	Authorized government outlets	45	31	14
	Unauthorized alcohol outlets	100		100
Recreational facilities	Parks	91	62	29
	Walking tracks	6		6
	Play grounds	50	43	7
	Fitness / yoga centers	10	6	4
Other	Anganwadis, schools, temples etc.	633	124	509

Household GPS locations and neighborhood BE features were integrated with participant data collected as part of the baseline data collection. An overview of the GIS mapping is provided in Figure 5. Area boundaries were obtained from government

records and digitized. All spatial data was integrated into a spatial database and ArcGIS ™ software will be used to carry out following spatial analysis methods.

- Distance calculations: distance between participant households and features of interest such as health care facilities, food and alcohol outlets, parks etc. and their association between CMD and risk factors.
- Spatial aggregation: Aggregation of features such as number of food outlets, parks etc. in the neighbourhood and relationship with CMD and risk factors.
- Clustering: Identify clustering of CMD and risk factors (hotspots) and determine if disease clusters are of sufficient geographic size and concentration to have not occurred by chance.
- Spatial smoothing and interpolation: Used to derive a spatial surface from sampled data points (filling in where data are unobserved) or to smooth across polygons (aggregate data) to create more robust estimates.
- Spatial regression: Use of Spatial regression methods such as Geographically weighted regression (GWR) to further understand the relationship between built environment and CMD risk factors as standard statistical regression models, which assume independence of the observations, are not appropriate for analysing spatially dependent data.

Figure 5: GIS mapping overview (insert here)

Data management

Data were collected in electronic format using customized android based software on a tablet platform and uploaded to server on a real time basis (Figure 6). For ensuring quality control, all validation, range and logical checks were in-built in the software. Error reports were generated bi-weekly and sent to the study sites for rectification. Errors were checked against completion of

the questionnaire, identifiers and adherence to the sampling strategy of interviews (only one man and one woman from single household).

Further, site research teams identified any other issues and reported to centralized team for the corrections. Data correction took place concomitantly with the conduct of the baseline survey. Similarly, bio-sample reports were matched with participant questionnaires and the final data was locked after all matching, and rectification of errors.

Figure 6: Data collection and management pathway (insert here)

Analysis plan

Data were entered into a database designed specifically for the project, housed at PHFI and accessible only to investigators and designated study staff. Data will be analysed using Stata/SE version 10.1 for windows software. Descriptive statistics will be done and the data expressed as frequencies and percentages for categorical variables and means and standard deviations for normally distributed continuous variables or inter-quartile ranges otherwise. Differences between gender groups, age groups, socio-economic groups, study sites, time periods and individual hypotheses will be tested using appropriate analytical statistical tests (Chi-square tests for categorical variables, t-tests continuous variables, multiple linear regression for continuous variables, and multiple logistic regression for categorical variables). Stratified analysis will be done to assess for potential confounding and effect modification by other variables. A p-value of < 0.05 will be considered to indicate statistical significance. Multi-level modelling will be undertaken by clusters and households as potential levels.

Discussion

UDAY is one of the largest community based intervention studies established in India to implement and evaluate a multi-component, multi-level, cost-effective, comprehensive intervention program to concomitantly improve the prevention, detection and optimal management of diabetes and hypertension, which together constitute the leading NCDs in India. Their high and rising burden coupled with huge healthcare costs underlines the need for cost-effective community based approaches supplemented by measures to strengthen the health system to address both these NCDs effectively as envisaged in UDAY.

Most of the evidence on community interventions for chronic NCDs are from developed countries [12-13]. In the last two decades some evidence has emerged from developing countries as well but not quite commensurate to the disproportionate burden borne by them (80% NCD mortality) [14-15].This is due to several reasons including resources to conduct such large projects as well as the technical capacity [14,15]. However, available information indicates that results are likely better in developing countries (e.g. Isfahan Healthy Heart Program in Iran, diabetes prevention programs in China and India) [14-16]. We have taken into account findings of such prior research and attempted to address the reported gaps by adding relevant elements to the design of our study. For instance, most such intervention programs have entailed community based interventions (largely targeting lifestyle modification) but have not had active healthcare system and advocacy interventions as proposed in our study. In addition, many of the diabetes prevention programs have targeted high risk groups and not the general free living population as envisaged in this program. Further, we have used several innovations (see table 1) including task shifting/sharing of care to non-physician health workers by the extensively leveraging low-cost m-health technology to enable

and empower them to screen and deliver interventions as well as physicians to treat patients as per evidence based algorithms. We have also used GIS mapping to characterize the sites, built environment, healthcare facilities and providers to examine the influence of built environment on diabetes/hypertension and their risks factors as well as care pathways that patients undertake, in order to deliver interventions in a more focused way. In addition, we have built in extensive stakeholder and community engagement in the study implementation which should aid in improving acceptability and buy in for the intervention program.

Further, the community based cohorts established will not only facilitate tracking of the trends in risk factors and diseases in rapidly transitioning populations in India, but also serve as well characterized population platforms for embedding and evaluating new research questions of public health relevance in combating the rise of NCDs.

Notably, a unique strength of UDAY besides occurring in a developing country setting where there are limited community based projects, in comparison to various other community based projects conducted in both developed and developing countries, which have either addressed prevention or management of select chronic conditions, is that UDAY aims to address both prevention and management of concurrently and comprehensively.

However, the study has some limitations. Firstly, we used a pre-post study design for evaluating the effect of our interventions. Though, a randomized controlled trial is a better design to evaluate the effectiveness of interventions, providing a higher level of evidence than a pre-post design, to study the effect of multi-component interventions delivered at multiple levels in a comprehensive manner in a large population over a vast geographic area, we considered the pre-post design as more appropriate for our study.

Further, we also wanted to understand and examine the operational part of the program implementation to gain insights into underpinning factors behind success or failure that can inform possible replication and scale up in the future.

Secondly, our study does not include controls for the comparison. Given the size of the population covered by the interventions, we would have had to recruit control communities of similar size and numbers, which wasn't feasible from an implementation and resources availability point of view. However, our baseline and end line surveys that evaluate the impact are done on independent random samples of the population, which should provide robust data regarding potential changes over baseline in the levels of: public awareness and knowledge about diabetes and hypertension; those aware, diagnosed, treated and controlled to recommended targets; the use of guideline based management by providers leading to improved health outcomes and access to healthcare for people living with diabetes and hypertension in India. In addition, we will be comparing our results with ongoing national survey data on NCDs and their risk factors (National Family Health Survey, Annual Health Survey, District Level Household Survey) as well as a New National NCD survey which is being implemented currently. This will help assess secular trends and evaluate our findings in conjunction with such trends if any. Also we did not account for the regression to the mean as there would be at least some people both in the end line and baseline. We will do sensitivity analysis to explore this bias.

Thirdly, one of the major interventions of our program is to implement a community based screening, follow-up and educational program through health workers. We specifically hired and trained health workers to implement this interventional component, which might add to the cost of implementing a community based diabetes and

hypertension prevention and management program. However, the additional cost of is likely to be minimal as indicated by previous modelling estimates of training and using health workers.

Fourthly, we are using multi-component interventions at multiple levels (health promotion campaigns, health workers led home based screening, follow-up and education, training of healthcare providers, registry for facility based improvement in quality of care, patient networks and advocacy to strengthen the health system) which makes it difficult to evaluate the individual contribution of each intervention. However, the purpose is to deliver it in a comprehensive manner to improve outcomes, which to our knowledge has hitherto not been implemented in similar settings, and not to tease out impact of individual interventions in a milieu where many individuals have elevations of multiple NCD risk factors and suffer often from co-morbid conditions that require to be addressed comprehensively.

It is anticipated that the results obtained from the study will inform policy makers on the most appropriate community and health system based approaches that are effective in stemming the rising burden of diabetes and hypertension in India and countries with similar challenges.

Data sharing and Contributorship statement

Data will be available to the study investigators only. De-identified data can be shared with other researchers based on specific request to the publication sub-committee of the project with potential research questions to be examined.

Sailesh Mohan, K. Srinath Reddy, Dorairaj Prabhakaran and Nikhil Tandon conceived the study. Sailesh Mohan wrote the first draft of the manuscript. Prashant Jarhyan, Shreeparna Ghosh, Nikhil Srinivasapura Venkateshmurthy, Ritu Rana, Cheena Malhotra, Ruby Gupta, Bhaskara Rao and Sanjay Kalra wrote specific sections of the manuscript as well as contributed to the design and implementation of the study. Bhaskara Rao and Sanjay Kalra also coordinate the activities in the study sites and provide technical support. Sailesh Mohan, Shreeparna Ghosh, Prashant Jarhyan, and Nikhil Srinivasapura Venkateshmurthy contributed to the collection and assembly of data. All authors provided input into the study design, as well as provided critical intellectual input for revision of the manuscript and approved the final version of the manuscript.

Acknowledgements

The UDAY project is led by the Public Health Foundation of India, Gurgaon, India in collaboration with Population Services International, India and Project HOPE. We acknowledge the contributions of the field and research staff of the project. The funder has no role in the design, implementation, and evaluation of the project as well as in the writing of this paper. All contents of this paper are solely the responsibility of the authors.

Funding source

It is supported by an unrestricted educational grant from Eli Lilly and Company under the Lilly NCD Partnership Program.

Disclaimer

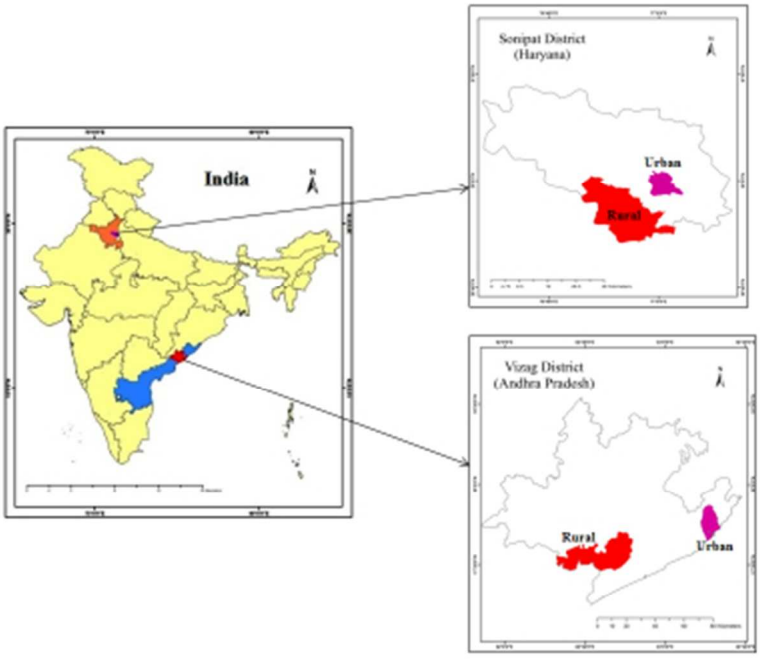
The funding agency had no role in the design, conduct or analysis of the study, and no role in the decision to submit the protocol for publication.

Conflicts of interest

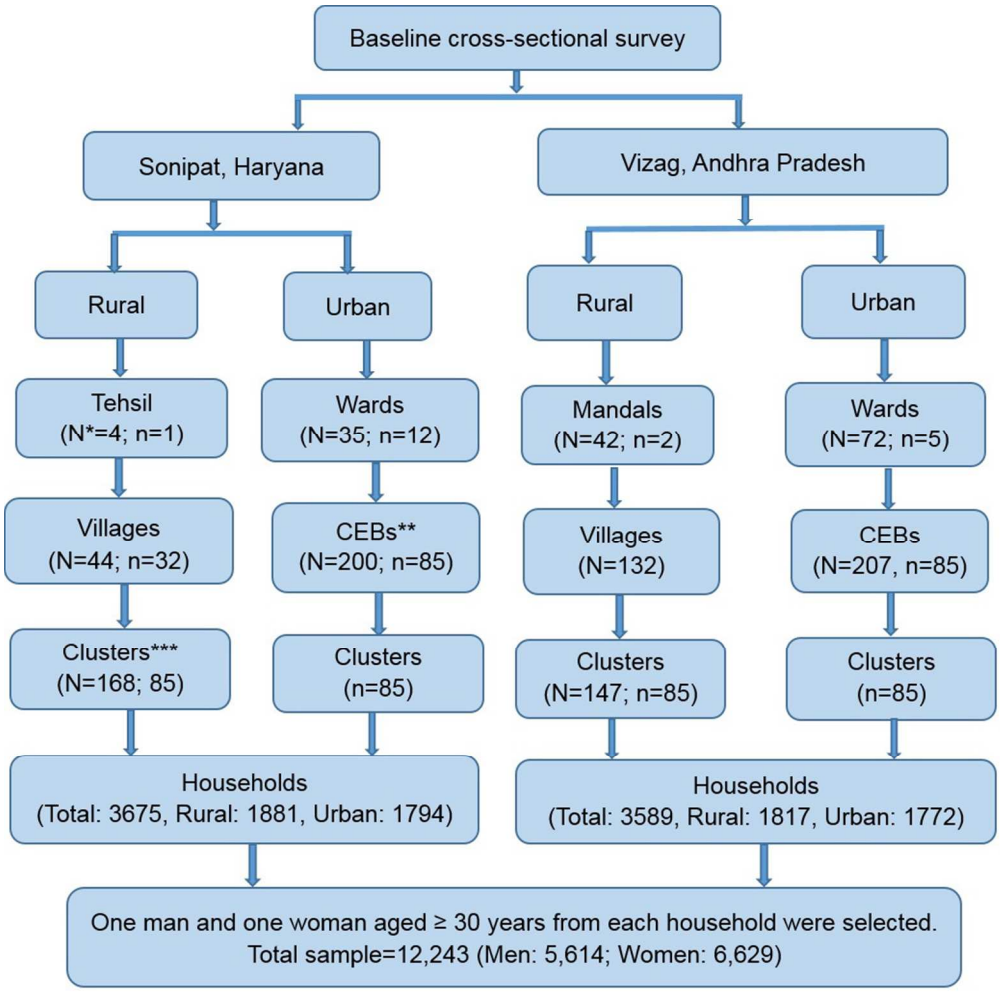
None declared

References

1. National Multisectoral Action Plan for Prevention and Control of NCDs in India. World Health Organization (WHO) Country Office for India, New Delhi, 2013.
2. International Diabetes Federation. IDF Diabetes Atlas, 7th edition. 7th ed. Brussels, Belgium: International Diabetes Federation, 2015.
3. Reddy KS, Shah B, Varghese C, et al. Responding to the threat of chronic diseases in India. Lancet 2005; 366:1744-49.
4. Mohan S, Koller T.Hypertension and related comorbidities in India: Implications for the health system. World Health Organization (WHO) Country Office for India, New Delhi, 2013.
5. Nair M, Ali MK, Ajay VS, et al. CARRS Surveillance study: design and methods to assess burdens from multiple perspectives. BMC Public Health 2012;12:701.
6. Reddy KS, Prabhakaran D, Chaturvedi V, et al. Methods for establishing a surveillance system for cardiovascular diseases in Indian industrial populations. Bull World Health Organ 2006; 84:461-69.
7. International Institute for Population Sciences (IIPS) and Macro International. 2007. National Family Health Survey (NFHS-3), 2005–06: India: Volume II.Mumbai: IIPS.
8. World Health Organization. Global Physical Activity Questionnaire (GPAQ) Analysis Guide: World Health Organization. Available at: http://www.who.int/chp/steps/resources/GPAQ_Analysis_Guide.pdf (Assessed 15 December 2015)
9. Yusuf S, Hawken S, Ounpuu S, et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. Lancet 2004; 364:937-52.
10. EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy 1990; 16:199–208.
11. Poongothai S, Pradeepa R, Ganesan A, et al. Reliability and validity of a modified PHQ9 item inventory (PHQ12) as a screening instrument for assesing depression in Asian Indians (CURES—65). J Assoc Physicians India 2009; 57: 147–52.
12. Berra K, Franklin B, Jennings C. Community-Based Healthy Living Interventions. Prog Cardiovasc Dis 2017; 59:430-439.
13. Puska P. Why Did North Karelia-Finland Work? Is it Transferrable? Glob Heart 2016; 11:387-391.
14. Sarrafzadegan N1, Kelishadi R, Esmaillzadeh A, Mohammadifard N, Rabiei K, Roohafza H, Azadbakht L, Bahonar A, Sadri G, Amani A, Heidari S, Malekafzali H. Do lifestyle interventions work in developing countries? Findings from the Isfahan Healthy Heart Program in the Islamic Republic of Iran. Bull World Health Organ 2009;87:39-50.
15. Harati H, Hadaegh F, Momenan AA, Ghanei L, Bozorgmanesh MR, Ghanbarian A, Mirmiran P, Azizi F. Reduction in incidence of type 2 diabetes by lifestyle intervention in a middle eastern community. Am J Prev Med 2010; 38:628-636.
16. Rawal LB, Tapp RJ, Williams ED, Chan C, Yasin S, Oldenburg B. Prevention of type 2 diabetes and its complications in developing countries: a review. Int J Behav Med. 2012; 19:121-33.



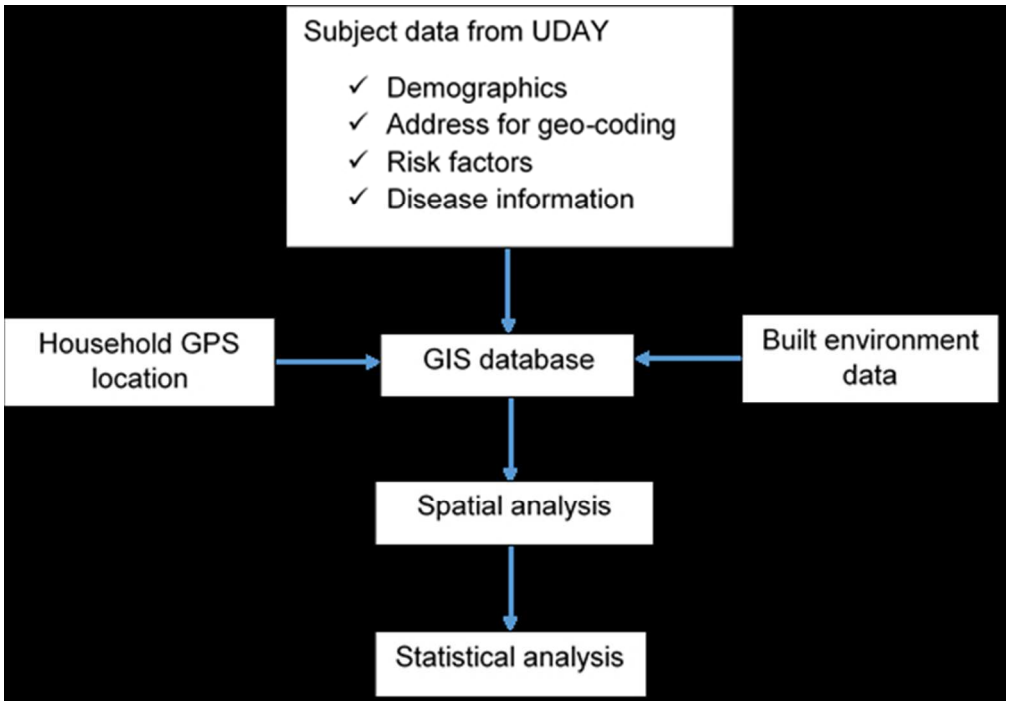
40x30mm (300 x 300 DPI)



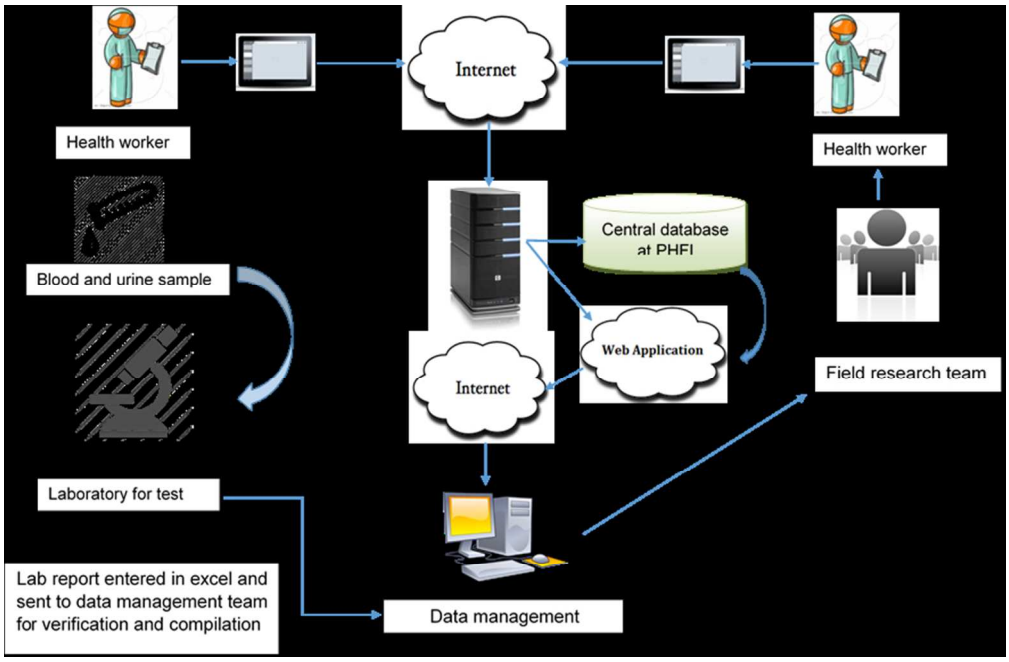
*N=total, n=number selected

**CEB=Census Enumeration Block

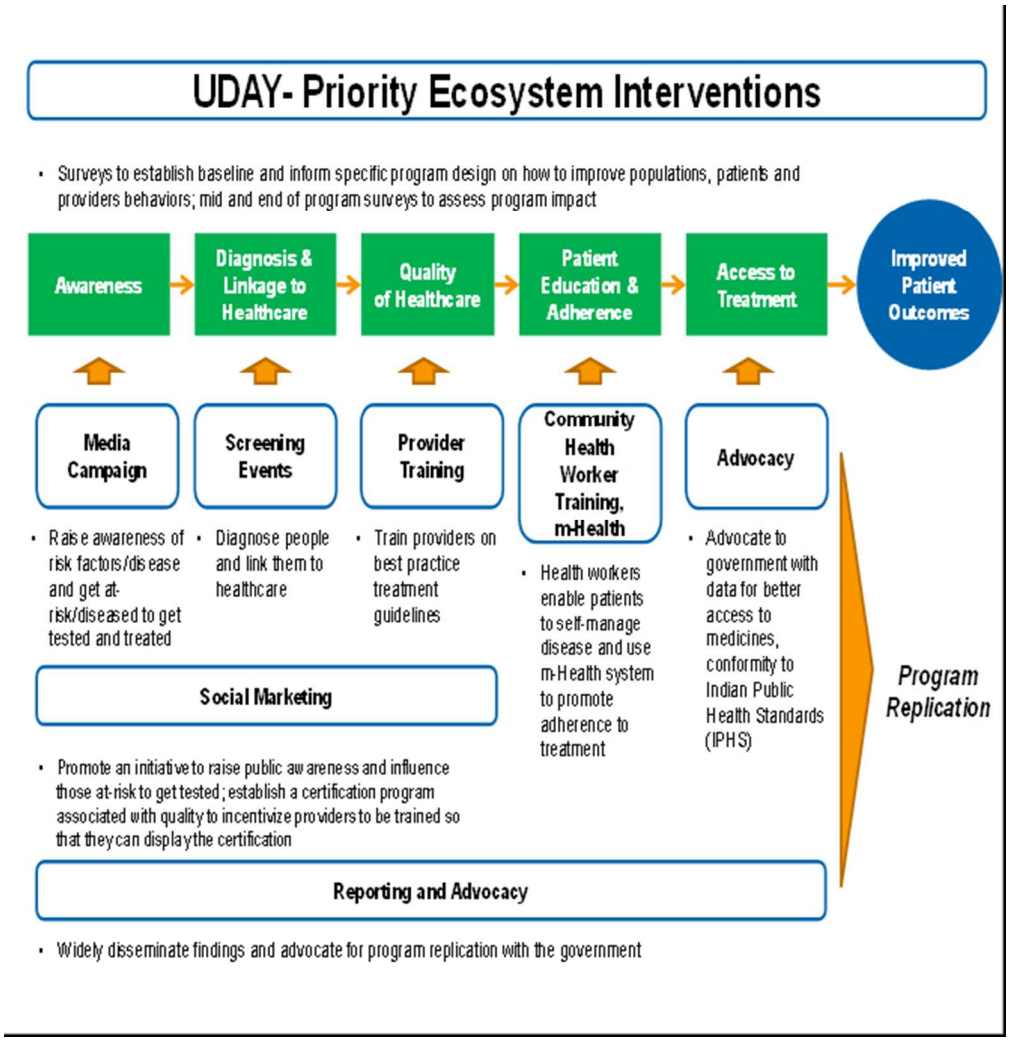
***Cluster = In urban sub-site clusters comprise CEBs, in rural sub-site bigger villages were split into 2 or 3 clusters with sizes of 75-300 households.



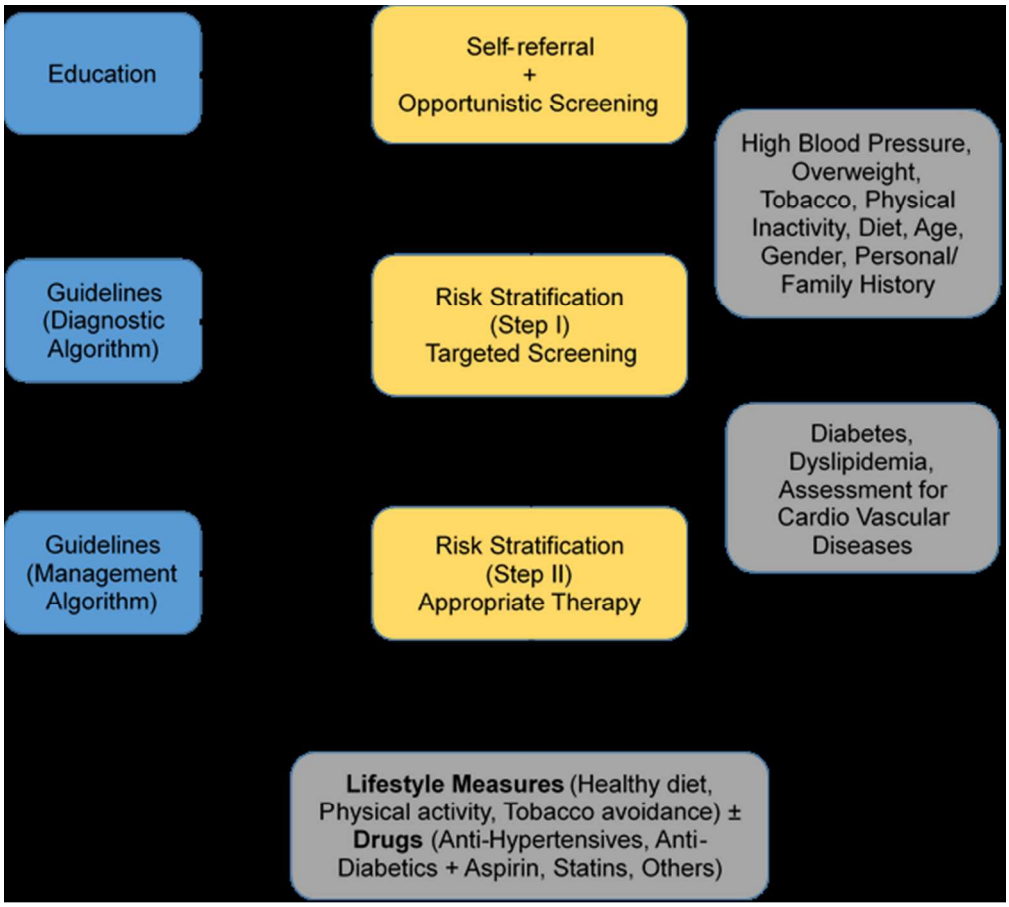
48x33mm (300 x 300 DPI)



74x48mm (300 x 300 DPI)



56x58mm (300 x 300 DPI)



55x49mm (300 x 300 DPI)

Supplementary file

Sonipat district in the state of Haryana, is north of India's capital city Delhi. It covers an area of 2,122 sq. km and has a population of 1,450,001 (Census 2011). The district has 4 tehsils (sub-districts), namely Gohana, Ganaur, Sonipat and Kharkhoda. Among these, we selected Sonipat tehsil as the urban sub-site and Kharkhoda as the rural sub-site.

Vizag district is one of the north eastern coastal district in the state of Andhra Pradesh and lies in proximity to the Bay of Bengal. It covers an area of 11,161 sq. km and has a population of 4,290,589 (Census 2011). Vizag district has 43 mandals (sub-districts) comprising 4 urban mandals and 39 rural mandals. Among these, we selected Vizag as the urban sub-site and Makavarapalem and Nathavaram as the rural sub-site.

BMJ Open

UDAY: Protocol of a Comprehensive Diabetes and Hypertension Prevention and Management Program in India

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-015919.R3
Article Type:	Protocol
Date Submitted by the Author:	20-Nov-2017
Complete List of Authors:	Mohan, Sailesh; Public Health Foundation of India Jarhyan, Prashant; Public Health Foundation of India Ghosh, Shreeparna; Public Health Foundation of India Srinivasapura Venkateshmurthy, Nikhil; Public Health Foundation of India Gupta, Ruby; Public Health Foundation of India Rana, Ritu; Population Services International India Malhotra, Cheena; Project Hope India Rao, Bhaskara; MaxCure Hospital Kalra, Sanjay; Bharti Hospital Karnal Tandon, Nikhil; All India Institute of Medical Sciences, Reddy, KS; Public Health Foundation of India Prabhakaran, Dorairaj; Public Health Foundation of India
Primary Subject Heading:	Epidemiology
Secondary Subject Heading:	Diabetes and endocrinology, Health services research, Public health, Cardiovascular medicine
Keywords:	Hypertension < CARDIOLOGY, General diabetes < DIABETES & ENDOCRINOLOGY, EPIDEMIOLOGY

UDAY: Protocol of a Comprehensive Diabetes and Hypertension Prevention and Management Program in India

Authors: Sailesh Mohan, [1] Prashant Jarhyan, [1] Shreeparna Ghosh, [1] Nikhil Srinivasapura Venkateshmurthy , [1] Ruby Gupta, [1] Ritu Rana, [2] Cheena Malhotra, [3] Bhaskara Rao, [4] Sanjay Kalra, [5] Nikhil Tandon, [6] K. Srinath Reddy, [1] Dorairaj Prabhakaran[1]

[1] Public Health Foundation of India, Gurgaon, India

[2] Population Services International, Delhi, India

[3] Project HOPE, Delhi, India

[4] Manipal Hospitals, Visakhapatnam, India

[5] Bharti Hospital, Karnal, India

[6] All India Institute of Medical Sciences, Delhi, India

Corresponding author
Dr. Sailesh Mohan
Additional Professor
Public Health Foundation of India
Email:smohan@phfi.org

Abstract

Introduction
Diabetes and hypertension are two leading noncommunicable conditions, which are sub-optimally managed in India. Thus, innovative comprehensive approaches that can concomitantly improve their detection, prevention and control are warranted.

Methods and analysis
UDAY, a 5-year initiative aims to reduce the risk of diabetes and hypertension and improve management by implementing a comprehensive intervention program in the two selected study sites, Sonipat and Visakhapatnam (Vizag). It has a pre-post evaluation design with representative cross-sectional surveys before and after intervention. Within these two sites, urban and rural sub-sites each with a total population of approximately 1, 00,000 people each were selected and a baseline and post intervention assessment will be conducted deploying 5 surveys [among general population (including body measurements or bio-samples), patients, healthcare providers including physicians and pharmacists, health facilities] which will determine: the knowledge levels about diabetes and hypertension, the proportion treated and controlled; the patient knowledge and self-management skills; healthcare providers' management practices; the level of access and barriers to obtaining care.
The interventions will include: tailored health promotion for improving public knowledge; screening of adults aged ≥ 30 years for identifying those at high risk of diabetes and/or hypertension for linkage to the healthcare system; patient education using technology enabled community health workers, geographic information system (GIS) based mapping of the communities, healthcare provider training on management guidelines, community based diabetes registry and; advocacy to improve access to healthcare. The baseline surveys have been completed, the study areas mapped using GIS and the interventions are being implemented. UDAY is expected to increase over baseline the levels of: public knowledge about diabetes and hypertension; those treated and controlled; patient self-management skills; the use of guideline based management by providers and; access to healthcare, leading to improved health outcomes and inform development of a India relevant chronic care model.

Ethics and dissemination
Ethical clearance for conduct of the study was obtained from the Institutional Ethics Committee (IEC) of the Public Health Foundation of India. The findings will be targeted primarily at public health policymakers and advocates, but will be disseminated widely through other mechanisms including conference presentations and peer-reviewed publications, as well as to the participating communities.

Strengths and limitations of this study

- Unique large community based study in geographically and culturally diverse "real world" settings in India for improving prevention and control of diabetes and hypertension.
- Employs a comprehensive multi-level, multi component intervention approach to target the general population, patients, providers and to strengthen the health system for improving prevention and control of diabetes and hypertension.

- Concomitantly addresses detection, prevention and management of both diabetes and hypertension.
- Extensively leverages mobile technology to enable health workers in task sharing as well as for electronic data capture.
- Quasi experimental design with complex intervention may hinder attribution of specific effect to individual intervention components.

Introduction

Non-communicable Diseases (NCDs) are currently the leading cause of preventable death and disability in India, accounting for two out of every three deaths [1]. Among NCDs, the prevalence of type-2 diabetes mellitus (DM) and hypertension have been rising rapidly. Currently there are about 69 million people with diabetes, a figure that is projected to further increase to a staggering 124 million by 2040 [2]. The number of individuals with hypertension is projected to increase to 214 million by 2030 from 118 million in 2000 [3,4]. Furthermore, diabetes and hypertension are important risk factors for both the major forms of cardiovascular disease [CVD (coronary heart disease and stroke)], highly prevalent and attributable to nearly half of all the deaths from NCDs [4].

Despite the availability of proven and effective treatments, diabetes as well as hypertension detection and control rates are abysmally low in India with blood pressure control among those with diabetes being even more sub-optimal, with a huge gap between detection and adequate treatment [1,3,4]. Thus, there is great potential and opportunity to reduce the rising burden of diabetes and hypertension as well as the

associated vascular risk in India through concomitantly improving their detection, prevention and control.

To address this huge gap in the prevention and management of both these conditions we are undertaking a 5-year initiative entitled “UDAY” (meaning dawn in *Sanskrit*) in epidemiologically transitioning communities, that aims to reduce the risk of diabetes and hypertension and concomitantly improve the management of either conditions by implementing a comprehensive community based innovative intervention program in the two geographically and culturally distinct study sites, Sonipat (Haryana, North India) and Visakhapatnam or Vizag (Andhra Pradesh, South India). This paper describes the design and methods of UDAY- A Comprehensive Diabetes and Hypertension Prevention and Management Program In India.

Methods

Study design

UDAY has a pre-post evaluation design with representative cross sectional surveys before (in year one at baseline, pre-intervention) and after the intervention (in year 5). The main research question is: whether a multi-component, multi-level, cost-effective, comprehensive intervention program will improve the prevention, detection and optimal management of diabetes and hypertension in the two selected study sites. Ethical clearance for conduct of the study was obtained from the Institutional Ethics Committee (IEC) of the Public Health Foundation of India.

We selected a pre-post evaluation design due to the following reasons. We wanted to evaluate if multi-component interventions delivered at multiple levels in a

comprehensive manner can improve outcomes. Further, we also wanted to understand and examine the operational part of the program implementation to gain insights into underpinning factors behind success or failure that can inform possible replication and scale up in the future. The options for an implementation study of this nature with process outcomes are either a pre-post design or quasi-experimental design or step wedge design. We deemed a step wedge to be too complicated for this evaluation and given that quasi experimental design would not have enough power to decipher real differences, we chose a pre-post design. This was also aimed at cutting down costs. At baseline, in year one, 5 surveys were conducted among the general population, among patients, among healthcare providers including physicians and pharmacists and in health facilities to guide intervention development and impact assessment. Similar assessment is planned after the intervention, in year 5.

The specific objectives these assessments are to:

1. Determine the prevalence, awareness, the knowledge levels about diabetes and hypertension, the proportion treated and controlled among a representative sample (n=12000) of adults aged ≥ 30 years in the selected study areas. (Population survey)
2. Determine the patient knowledge levels and self-management skills among a convenience sample (n=400) of those diagnosed with diabetes and hypertension in the selected study areas. (Patient survey)
3. a) Determine healthcare providers' (physicians) knowledge and practices related to diabetes and hypertension management among a convenience sample (n=50) of healthcare providers' in the selected study areas.

b) Determine pharmacists' knowledge related to diabetes and hypertension and dispensing practices among a convenience sample of pharmacists (n=350) (Provider survey)

4. Determine the level of access and potential barriers to diabetes and hypertension care provided by the public healthcare system in the selected study areas (n=50). (Facility survey)
5. Determine the cost-effectiveness of the intervention program in improving diabetes and hypertension treatment and management outcomes in the study areas. (Using population survey, GIS data and project implementation data)

Study sites

We are undertaking this comprehensive diabetes prevention and management program in two epidemiologically transitioning areas located in Sonipat in Haryana and Vizag in Andhra Pradesh (Figure 1, supplementary file).

Figure 1: Study sites (insert here)

We defined the areas and their sub-areas using the following terminology:

- Sites – a bounded geographic area within which we have defined distinct rural and urban sub-sites for the study. Each site has been defined such that it contains approximately 2,00,000 people. Sonipat and Vizag are each a site.
- Sub-sites – within each site, we have defined one rural and one urban sub-site for study. Each sub-site is geographically bounded, and contains a population of

approximately 1,00,000. Within Sonipat and Vizag, we have defined two sub-sites each (rural and urban).

- Total project – the total project is the summation of the two sites, including the four sub-sites (two sub-sites within each site). Therefore the total population under the study is approximately 4,00,000.

Intervention program

We propose to implement a priority set of synergistic innovative ecosystem interventions (Figure 2, Table 1), with the overarching goal to prevent, detect, reduce the risk of diabetes and hypertension and to improve the treatment and management of individuals with either of the conditions in the study sites. We hypothesize (Figure 3) that education of the public on diabetes, hypertension and related risks will lead to increased self-referral and prevention, while education of the healthcare providers will promote opportunistic screening for diabetes, hypertension and related risks, and purposeful implementation of evidence based diagnostic (to screen, stratify by risk) and management guidelines (to initiate appropriate therapy).

Figure 2: Priority interventions in UDAY (insert here)

Table 1: Innovations in UDAY

Intervention domain	Approach	Target
Prevention, early detection and referral	Culturally tailored health promotion, screening	400,000 population
Capacity building, task	CME, short trainings,	Healthcare providers

shifting of healthcare providers	distance learning, QIP	
Early diagnosis and prevention of complications	Registry	10,000 patients
m-health system	Electronic data system +DSS	Adult population
Electronic data capture	Tablet based surveys	12,000
Spatial and built environment assessment	GIS mapping	All study areas
Improved access to medicines by social marketing initiatives	Improving quality of services	300 pharmacists
Culturally tailored patient education and networks for enabling self-care	Utilizing health workers	Patients

Figure 3: Intervention framework (insert here)

Following the baseline assessments a comprehensive intervention program is being currently implemented. The intervention components includes:

1. tailored health promotion using social marketing approaches for increasing public awareness and promoting population risk factor modification and reduction;
2. community based screening of all adults aged ≥ 30 years for identifying those at high risk of diabetes and/or hypertension or with disease to link to the healthcare system leveraging task-sharing approaches utilizing technology enabled health workers;
3. patient education using technology enabled health workers,
4. healthcare provider training on evidence based management guidelines,
5. implementation of a quality improvement program and diabetes registry and;

6. advocacy with governments and other stakeholders to improve access to healthcare.

It is expected that the comprehensive interventions will increase over baseline the levels of: public awareness and knowledge about diabetes and hypertension; those aware, diagnosed, treated and controlled to recommended targets; the use of guideline based management by providers. Detailed outcome assessment metrics is provided in table 2. This is anticipated to improve health outcomes and access to healthcare for people living with diabetes and hypertension in India as well as provide a model of healthcare which is low-cost, community based and context relevant in a milieu of rapid rise in these chronic conditions.

Table 2: Assessment of intervention outcomes

Indicator	Target Population	Metric	Evaluation Methodology
1. Patient outcomes	Diabetes and hypertension patients	% implementing lifestyle change (meet the recommended levels of physical activity, and intend to and/or implement dietary changes)	Baseline and endline surveys, diabetes registry
		% engaging in self-monitoring/testing	Baseline and endline surveys, diabetes registry
		% increase in correct self-management practices	Baseline and endline surveys, diabetes registry
		% increase in knowledge on diabetes and hypertension	Baseline and endline surveys, diabetes registry

		% of patients on treatment, whose diabetes, hypertension is successfully controlled, i.e., HbA1C≤ 7% / BP ≤130/80 mm Hg	Baseline and endline surveys, diabetes registry
2. Awareness and knowledge about diabetes and hypertension	General population	% increase in knowledge of diabetes, hypertension and their risk factors	Baseline and endline surveys
		% increase in detection rate and in seeking healthcare	Baseline and endline surveys, screening program
		% implementing lifestyle change (meet the recommended levels of physical activity, and intend to and/or implement dietary changes)	Baseline and endline surveys, screening program
		% exposed to health promotion campaign	Baseline and endline surveys, screening program
3. Provider knowledge and practices	Physicians, other health workers	# who participate in training programs	Training participation data
		% increase in knowledge related to diabetes and hypertension management	Baseline and endline surveys of providers, diabetes registry
		% increase in practices related to diabetes and hypertension management and providing lifestyle advice	Baseline and endline surveys of providers, diabetes registry
	Pharmacists	% of pharmacists who identify people at risk of and with diabetes, hypertension	Baseline and endline surveys of providers
		% increase in pharmacists dispensing and filling prescriptions correctly	Baseline and endline surveys of providers, diabetes registry
4. Program cost-effectiveness	Diabetes patients	Cost per diabetic patient treated to recommended target	Baseline and endline surveys of patients, program cost data, diabetes registry
		% reduction in out of pocket expenditure	Baseline and endline surveys of patients, diabetes registry
	General population	Cost per diabetes case identified	Surveys, screening program, program cost data

5. Access to treatment	Healthcare system	Improvements in access to and availability of medications	Baseline and endline surveys of patients, facility survey, diabetes registry
		% increase in the proportion patients who report that medicines are easily available	Baseline and endline surveys of patients, facility survey, diabetes registry
		% reduction in stock outs of medicines	Baseline and endline surveys of patients, facility survey, diabetes registry
		Adherence to IPHS guidelines on drugs, services	Facility survey, diabetes registry

Intervention development

We used evidence based interventions and leveraged the results from the baseline surveys (population, patient, facility and providers) to develop and refine the interventions, which were subsequently piloted. For example, from population survey we found that there were differences in the awareness of risk factors for developing diabetes/hypertension across rural/urban areas and the two study sites in North and South India. Therefore, taking this into cognizance, we designed the tailored health promotion program and messages to be delivered by trained health workers ti increase awareness about the risk factors. Facility and providers' surveys helped us to design the training programs for training healthcare providers as well as to conduct advocacy to improve access to the health system. Similarly, findings from the patients' survey helped us to focus the training of health workers on building self-management skills of people with diabetes/hypertension and for developing patient networks.

Sample for the population survey

We based our sample size calculation on the prevalence of diabetes, which has a lower prevalence than hypertension, in previously reported studies in India. Anticipating a response rate of 85 % with a design effect factor of 1.5 (to account for cluster sampling, and a confidence level of 1.96, the sample size estimates were generated for males and females in three age strata (30-49, 50-69, 69 and above) in each setting (urban, rural). About 2968 subjects was estimated to be required per urban sub-site (Sonipat and Vizag) and 2942 subjects per rural sub-site (Sonipat and Vizag). The total estimated sample was 11820, which was increased to 12000 to obtain equal samples in both urban and rural areas. Sample weights were generated for estimating the prevalence of diabetes, hypertension and related cardiometabolic risk factors at the district level.

Survey sampling and participant selection

Population survey

Two representative population based cross sectional surveys with independent samples and identical methodologies at baseline and at the end of intervention will be conducted, that will provide estimates of the burden and changes in the prevalence of diabetes, hypertension, and related cardiometabolic risk factors. In addition, those recruited for the first survey at baseline (which has been completed), will be followed up as a cohort to estimate the incidence of new cardio-metabolic (CMD) risk factors, disease, healthcare utilization, diabetes and hypertension related morbidity and mortality.

The first population survey (baseline survey) was done among a representative sample of adults aged ≥ 30 years residing in the selected study areas of Sonipat and Vizag. Inclusion criteria – a) adults aged ≥ 30 years residing in the sampled urban and rural areas of Sonipat and Vizag respectively. b) willing to participate and provide informed consent.

We excluded individuals who were unwilling to provide informed consent and those with serious chronic illnesses [such as that of the liver (cirrhosis), kidneys (renal failure) or malignancies], pregnant women.

For the baseline survey, a multistage random sampling technique was deployed to obtain a representative sample of adults aged ≥30 years, using data from the most recent census of 2011. In addition, a manual enumeration and mapping of all households and structures was conducted in all the study areas [all census enumeration blocks (CEBs) in urban areas and villages in rural], to identify households and structures constructed since the last census (Table 3). CEBs are considered as the primary sampling unit in urban areas and villages in the rural areas respectively. On average, about 100-125 households with a population of 650-700 persons would generally constitute a CEB. This enabled a complete sampling frame for the selection of households for the survey and thus provided an equal chance of selection to each household. Besides, it also helped identify potential recipients of the intervention program (i.e., adults aged ≥30 years) in the study sites.

In each sub-site, 85 clusters were randomly selected (urban Sonipat: 85/200 CEBs, urban Vizag: 85/207 CEBs and rural Sonipat: 85/168 clusters, rural Vizag: 85/147 clusters) according to probability proportional to size (Figure 4). In rural sub-sites, bigger

villages were divided into clusters with 75 to 300 households. From each cluster in the urban and rural sub-sites, 18 to 25 households were randomly selected and 1 eligible male and female were selected randomly within each household using Kish table. In Sonipat district, 3675 households participated in baseline survey (rural: 1881, urban: 1794) with total being 6208 participants (rural: 3104, urban: 3104). In Vizag district, 3589 households (rural: 1817, urban: 1772) participated in the baseline survey with total being 6035 participants (rural: 3069, urban: 2966). Thus, we had 12000 individuals from both urban and rural areas of North and South India.

Table 3: Manual enumeration of study areas

Study site	Structures	Households	Population ≥30 years	Total population (census 2011)
Sonipat urban sub-site	24408	20406	41981	102292
Sonipat rural sub-site	28813	17283	40850	100935
Vizag urban sub-site	16888	39504	70735	153721
Vizag rural sub-site	33799	30817	59540	121209

Figure 4: Sample selection for the baseline survey (insert here)

*N=total, n=number selected

**CEB=Census Enumeration Block

***Cluster = In urban sub-site clusters comprise CEBs, in rural sub-site bigger villages were split into 2 or 3 clusters with sizes of 75-300 households.

Data collection for the population survey

For the baseline survey, trained health workers visited the selected participants at their homes. Written informed consent was sought and obtained from the selected individuals prior to data collection and a unique identification number was assigned. For each participant, data collection comprised an interviewer administered questionnaire, a brief physical examination (height, weight, waist circumference, hip circumference, blood pressure, body fat percentage), blood and urine collection as detailed below.

Information on demographics, socio-economic characteristics, behavioral risk factors (tobacco use, alcohol use, diet and physical inactivity), family history of various NCDs, female reproductive history, general awareness about diabetes and hypertension, risk factors, prevention, symptoms and diagnosis, complications, treatment and management, medical history of NCDs [diabetes, hypertension, coronary artery disease (CAD), myocardial infraction (MI), stroke, heart failure, chronic kidney disease (CKD), peripheral vascular disease (PVD), chronic obstructive pulmonary disease (COPD), asthma], quality of life, mental health, social support, cost of healthcare and healthcare utilization was collected using a tablet based application (Table 4).

Body measurements such as height, weight, waist and hip circumferences, blood pressure and body fat measurement by bio impedance using TANITA were also obtained using standardized equipment.

Bio-samples (fasting blood and morning urine) were collected for the laboratory estimation of fasting plasma glucose, glycated hemoglobin (HbA1c), lipids, serum creatinine, urea, urine microalbumin and urine creatinine. We have also stored the bio samples for future analysis of emerging biomarkers and genetics.

Table 4: Summary of indicators, measures, methods and instruments for baseline survey

Indicators	Measures	Methods	Instruments
Demographics and socio-economic characteristics	Age, sex, marital status, religion, education, income, occupation, contact details, and household assets	Questionnaires	Centre for cArdio-metabolic Risk Reduction in South Asia(CARRS) Surveillance Study [5] Establishment of Sentinel Surveillance System for CVD in Indian Industrial Populations (Sentinel Surveillance Study) [6] National Family Health Survey, 2005-06 [7]
Behavioral risk factors	Tobacco use Alcohol use	Questionnaire	CARRS, Sentinel Surveillance Study
	Physical activity	Questionnaire	Global Physical Activity Questionnaire (GPAQ-2) [8]
	Dietary habits	Questionnaire	CARRS,INTERHEART Study[9]
Family history	Prevalence of cardiometabolic diseases (CMDs) among family members related to participants, mortality	Questionnaire	CARRS
Female	Menarche/	Questionnaire	CARRS

reproductive history	gestational history, menopause (surgical / physiological / whether on hormone replacement therapy) / contraception		
Awareness and knowledge	General awareness about diabetes and hypertension, risk factors, prevention, symptoms and diagnosis, complications, treatment and management	Questionnaire	CARRS
Physiological and biochemical risk factors	Hypertension	Blood pressure measurements	Standardized method (American Heart Association) and validated instrument (certified by British Hypertensive Society and Association for the Advancement of Medical Instrumentation) Standardized across both the sites
	Diabetes	Laboratory estimation of fasting plasma glucose, glycated hemoglobin (HbA1c)	Standardized across both the sites
	Dyslipidemia	Laboratory estimation of serum total cholesterol, low	Standardized across both the

		density lipoprotein cholesterol, very low density lipoprotein cholesterol, high density lipoprotein cholesterol, triglycerides	sites
	Obesity	Anthropometry (height, weight, waist and hip circumferences, body fat	Standard procedures based on National Health And Nutrition Examination Survey-III with instruments used in epidemiological studies on South Asian population
Medical history	Chronic kidney disease	Serum creatinine, urea, urine microalbumin and urine creatinine	Standardized across both the sites
	Stroke, myocardial infraction, Congestive heart failure, Chronic stable angina	Questionnaires including medical history	Rose Angina, CARRS
Treatment history, health services, quality of care and health care costs	Awareness and risk factor control Access to health care services, utilization of services, health insurance	Questionnaire	CARRS

	coverage, costs of treating CMDs and their risk factors		
Prevalence	COPD and asthma	Questionnaire	NHANES III and present standards of the American Thoracic Society (ATS)
Health related Quality of Life	Mobility, self-care, usual activities, pain/discomfort, anxiety/depression (related to CMDs and risk factors)	Questionnaire	European Quality of Life 5 Dimensions questionnaire (EQ-5D-3L) [10]
Mental health	Depression	Questionnaire	Modified from Patient Health Questionnaire 9 (PHQ-12) [11]
Social well-being	Social support	Questionnaire	Developed for UDAY

Data collection for the patient survey

Trained research staff visited health facilities located in the aforementioned selected study areas and approached patients attending outpatient section of the health facilities and identified those with the diagnosis of diabetes and/or hypertension based on their prescription note for participating in the study. Written informed consent was sought and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire (Table 5).

The patient survey was done among a convenience sample of 400 patients having diabetes and/or hypertension attending health facilities and residing in the selected study areas of Sonipat and Vizag.

Inclusion criteria: We included patients with diabetes and or hypertension residing/attending health facilities in the sampled urban and rural areas of Sonipat and Vizag respectively and were willing to participate and provide informed consent.

Exclusion criteria: We excluded those unwilling to provide informed consent.

Table 5: Summary of indicators, measures, methods and instruments for the patient survey

Indicators	Measures	Methods	Instruments
Demographics and socio-economic characteristics	Age, sex, education, income, occupation, contact details	Questionnaires	CARRS Sentinel Surveillance Study
Behavioral risk factors	Tobacco use Alcohol use	Questionnaire	CARRS, Sentinel Surveillance Study
Awareness and knowledge of diabetes and hypertension	Awareness of risk factors, symptoms and diagnosis, cut-off levels for diagnosis, complications, treatment and management	Questionnaire	Developed for UDAY
Diabetes and hypertension related medical history	Diagnosis, health care utilization, control, self-management practices, complications, comorbidities, and treatment adherence	Questionnaire	Developed for UDAY
Health related Quality of Life	Mobility, self-care, usual activities,	Questionnaire	European Quality of Life 5 Dimensions

	pain/discomfort, anxiety/depression (related to CMDs and risk factors)		questionnaire (EQ-5D-3L)
Mental health	Depression	Questionnaire	Modified from Patient Health Questionnaire 9 (PHQ-12)
Social well-being	Social support	Questionnaire	Developed for UDAY
Healthcare utilization	Hospital visits in the past 12 months and health care expenditure	Questionnaire	CARRS

Data collection for the provider surveys

Trained research staff visited health facilities located in the aforementioned selected study areas and approached healthcare providers (physicians and pharmacists). Written informed consent was sought and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire (Table 6).

The physician survey was done among a convenience sample of 50 physicians working in the health facilities located in the selected study areas of Sonipat and Vizag.

Inclusion criteria: We included physicians working in health facilities located in the sampled urban and rural areas of Sonipat and Vizag respectively and were willing to participate and provide informed consent.

Exclusion criteria: Those unwilling to provide informed consent were excluded.

The pharmacist survey was conducted among 350 pharmacists by trained research staff in the aforementioned selected study areas. Written informed consent was sought

and obtained from the individuals prior to data collection and data collection comprised an interviewer administered questionnaire.

Inclusion criteria: We included pharmacists who were located in the sampled urban and rural areas of Sonipat and Vizag respectively, dispensing medicines for diabetes and hypertension, were willing to participate and provide informed consent.

Exclusion criteria: Those not dispensing medicines for diabetes and hypertension and unwilling to provide informed consent were excluded.

Table 6: Summary of indicators, measures, methods and instruments for the provider survey (physicians)

Indicators	Measures	Methods	Instruments
Socio-demographic details	Age, gender, qualification, years of practice, patient load, training in diabetes and hypertension management	Questionnaire	Developed for UDAY
Knowledge and practice pertaining to diabetes and hypertension diagnosis and evaluation of complications	Signs and symptoms, diagnosis and cut-off levels for diagnosis, evaluation for complications	Questionnaire	Developed for UDAY
Treatment practices for diabetes and hypertension	Lifestyle modifications, prevention and management of	Questionnaire	Developed for UDAY

	complications, names of medicines prescribed commonly		

Data collection for the health facility survey

Permission was sought and obtained from respective district medical/health officers prior to data collection and data collection comprised an interviewer administered questionnaire (Table 7). Trained research staff visited public healthcare facilities located in the aforementioned selected study areas and approached the person/ medical officer in charge.

The facility survey was done in 50 public healthcare facilities (sub-centres, primary and community health centres, taluk/district/tertiary hospitals) situated in the selected study areas of Sonipat and Vizag.

Table 7: Summary of indicators, measures, methods and instruments for the health facility survey

Indicators	Measures	Methods	Instruments
Coverage statistics	Types of services offered, number of hours and days services provided per week, population covered, average daily outpatient department (OPD) attendance, number of beds available, status of National program	Questionnaire	Adapted from Service Availability and Readiness Assessment tool (SARA) of the World Health Organization

	for control and prevention of diabetes, cardiovascular disease and stroke (NPCDCS) implementation		
Recommended manpower list	Numbers working at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended numbers and reasons for lack of recommended personal. Additional manpower required for NCDs	Checklist, questionnaire	Adapted from Indian Public Health Standards, (IPHS) and SARA
Recommended medication list	Availability of medicines at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended medicines and reasons for lack for recommended medicines. Additional medicines required for NCDs	Checklist, questionnaire	Adapted from IPHS and SARA
Recommended equipment list	Numbers of equipment available at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended	Checklist, questionnaire	Adapted from IPHS and SARA

	equipment and their functional status. Additional equipment required for NCDs		
Recommended investigative services list	Investigative services available at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres against recommended services and reasons for their unavailability. Additional investigative services required for NCDs	Checklist, questionnaire	Adapted from IPHS and SARA
Recommended activities list	Frequency of recommended activities conducted and methods of conducting at District Hospitals, Community Health Centres, Primary Health Centres and Sub-centres for current diagnosis, treatment and health promotion. Reasons for not conducting the activities	Checklist, questionnaire	Adapted from IPHS and SARA
Availability of national guidelines and training of healthcare providers	Availability of national guidelines for diagnosis and management of diabetes, hypertension and CVD and training of healthcare providers in the	Questionnaire	Adapted from IPHS and SARA

	facility to diagnose and manage diabetes, hypertension and CVD		

Bio-sample collection and storage

Blood samples (in fasting state) were collected in plain, fluoride and EDTA vacutainers (Becton & Dickinson, USA) by trained phlebotomists in households or in camps arranged close to the households. Samples for estimation for blood glucose were kept in ice and transferred to laboratories within 2 hours of sample collection and immediately centrifuged. Samples were centrifuged at 2500 rpm for 15 minutes and serum / plasma were transferred into the cryo-vials which were stored in 20^0C immediately. Buffy coat from EDTA vacutainers were separated and stored into cryo-vials for DNA extraction. Red blood cells were washed thrice with normal saline and were stored for analysis of fatty acids in future. First early morning voided urine was collected from the participants and has been stored in deep freezer for future analysis of metabolites. All these samples were transported to the biochemistry laboratory at the Public Health Foundation of India (PHFI) in dry-ice on the day of collection from Sonipat and Vizag, where they were stored at -80^0C.

All clinical chemistry parameters were analyzed on autoanalyzer Cobas 311 using reagents from Roche Diagnostics, Switzerland. Glucose was estimated using Hexokinase method, cholesterol by enzymatic cholesterol oxidase method, triglycerides by GPO-PAP method & HDL and LDL by direct method, AST & ALT was estimated according to IFCC without pyridoxal phosphate, bilirubin total by Diazonium ion method,

bilirubin direct by Diazo with sulphanilic acid method, urea by kinetic method, creatinine by Jaffe's method, and urinary microalbumin using immuno turbidimetric method. HbA1c was assayed by hplc method using reagents from Bio-Rad Laboratories, Hercules, CA.

Two levels of internal controls were run with every batch of samples. The intra assay and inter assay coefficient of variation for all the parameters were <3% and <5 % respectively.

The biochemistry laboratory is part of External Quality Assurance program from RIQAS for clinical chemistry parameters and HbA1c assay.

Evaluation of cost-effectiveness

This will be evaluated by assessing the costs and benefits of the multi-component, multi-level comprehensive interventions in improving diabetes related health outcomes. Data on healthcare utilization and costs, as well as that of out of pocket expenditure will be collected in the baseline and end line surveys. In addition, data on direct costs including the cost of personnel, provider training, medications, lab tests and supplies, screening, outpatient visits, and costs related to the social marketing campaign will be obtained during the implementation process. The total costs entailed to identify a person with diabetes as well as to appropriately treat that person to recommended targets based on guidelines will be measured. In addition, we will model the costs accrued from the use of drugs and other related interventions, based on results of other such comprehensive programs and do a comparison to assess effectiveness. Based on the aforesaid indicators, we will develop a comprehensive cost-effectiveness model to assess the overall program effectiveness.

Geographical Information System (GIS) based mapping of study households and neighborhood built environment

All households as well as the study areas, including various points of interest as indicated below were geocoded using GIS mapping. This will be used to comprehensively assess the built environment and its impact on diabetes hypertension and risk factors. GIS based techniques will be employed to study the association between built environment (BE) features and diabetes, hypertension and related risk factors.

Specially trained field staff visited all participant households and used handheld Garmin ™ GPS receivers to capture GPS locations of the households. The captured GPS coordinates were verified using Google Earth to see if the locations matched the actual locations.

Table 8 below shows the built environment features from the study areas that were located and mapped.

Table 8: Characteristics of the built environment in study sites

Environment features	Points of interest	N	Sonipat	Vizag
Healthcare facilities	Government hospitals	64	36	28
	Private hospitals & clinics	228	147	81
	Registered medical practitioners and unqualified practitioners	220	195	25
	Other health professionals	120	115	3
	Pharmacies	337	224	113

	Medical laboratories	46	30	16
Food outlets	Hotels	162	4	161
	Restaurants	33	10	23
	Small eateries	97	40	57
	Provision / department stores	313	196	117
	Fruit / vegetable / juice outlets	254	36	218
	Meat / fish shops	128	24	104
	Public distribution system (ration)shops	52		52
	Milk outlets	126	344	122
	Bakeries/ sweet shops	106	56	50
Tobacco outlets	Pan shop	713	17	696
Alcohol outlets	Authorized government outlets	45	31	14
	Unauthorized alcohol outlets	100		100
Recreational facilities	Parks	91	62	29
	Walking tracks	6		6
	Play grounds	50	43	7
	Fitness / yoga centers	10	6	4
Other	Anganwadis, schools, temples etc.	633	124	509

Household GPS locations and neighborhood BE features were integrated with participant data collected as part of the baseline data collection. An overview of the GIS mapping is provided in Figure 5. Area boundaries were obtained from government

records and digitized. All spatial data was integrated into a spatial database and ArcGIS ™ software will be used to carry out following spatial analysis methods.

- Distance calculations: distance between participant households and features of interest such as health care facilities, food and alcohol outlets, parks etc. and their association between CMD and risk factors.
- Spatial aggregation: Aggregation of features such as number of food outlets, parks etc. in the neighbourhood and relationship with CMD and risk factors.
- Clustering: Identify clustering of CMD and risk factors (hotspots) and determine if disease clusters are of sufficient geographic size and concentration to have not occurred by chance.
- Spatial smoothing and interpolation: Used to derive a spatial surface from sampled data points (filling in where data are unobserved) or to smooth across polygons (aggregate data) to create more robust estimates.
- Spatial regression: Use of Spatial regression methods such as Geographically weighted regression (GWR) to further understand the relationship between built environment and CMD risk factors as standard statistical regression models, which assume independence of the observations, are not appropriate for analysing spatially dependent data.

Figure 5: GIS mapping overview (insert here)

Data management

Data were collected in electronic format using customized android based software on a tablet platform and uploaded to server on a real time basis (Figure 6). For ensuring quality control, all validation, range and logical checks were in-built in the software. Error reports were generated bi-weekly and sent to the study sites for rectification. Errors were checked against completion of

the questionnaire, identifiers and adherence to the sampling strategy of interviews (only one man and one woman from single household).

Further, site research teams identified any other issues and reported to centralized team for the corrections. Data correction took place concomitantly with the conduct of the baseline survey. Similarly, bio-sample reports were matched with participant questionnaires and the final data was locked after all matching, and rectification of errors.

Figure 6: Data collection and management pathway (insert here)

Analysis plan

Data were entered into a database designed specifically for the project, housed at PHFI and accessible only to investigators and designated study staff. Data will be analysed using Stata/SE version 10.1 for windows software. Descriptive statistics will be done and the data expressed as frequencies and percentages for categorical variables and means and standard deviations for normally distributed continuous variables or inter-quartile ranges otherwise. Differences between gender groups, age groups, socio-economic groups, study sites, time periods and individual hypotheses will be tested using appropriate analytical statistical tests (Chi-square tests for categorical variables, t-tests continuous variables, multiple linear regression for continuous variables, and multiple logistic regression for categorical variables). Stratified analysis will be done to assess for potential confounding and effect modification by other variables. A p-value of < 0.05 will be considered to indicate statistical significance. Multi-level modelling will be undertaken by clusters and households as potential levels.

Discussion

UDAY is one of the largest community based intervention studies established in India to implement and evaluate a multi-component, multi-level, cost-effective, comprehensive intervention program to concomitantly improve the prevention, detection and optimal management of diabetes and hypertension, which together constitute the leading NCDs in India. Their high and rising burden coupled with huge healthcare costs underlines the need for cost-effective community based approaches supplemented by measures to strengthen the health system to address both these NCDs effectively as envisaged in UDAY.

Most of the evidence on community interventions for chronic NCDs are from developed countries [12-13]. In the last two decades some evidence has emerged from developing countries as well but not quite commensurate to the disproportionate burden borne by them (80% NCD mortality) [14-15].This is due to several reasons including resources to conduct such large projects as well as the technical capacity [14,15]. However, available information indicates that results are likely better in developing countries (e.g. Isfahan Healthy Heart Program in Iran, diabetes prevention programs in China and India) [14-16]. We have taken into account findings of such prior research and attempted to address the reported gaps by adding relevant elements to the design of our study. For instance, most such intervention programs have entailed community based interventions (largely targeting lifestyle modification) but have not had active healthcare system and advocacy interventions as proposed in our study. In addition, many of the diabetes prevention programs have targeted high risk groups and not the general free living population as envisaged in this program. Further, we have used several innovations (see table 1) including task shifting/sharing of care to non-physician health workers by the extensively leveraging low-cost m-health technology to enable

and empower them to screen and deliver interventions as well as physicians to treat patients as per evidence based algorithms. We have also used GIS mapping to characterize the sites, built environment, healthcare facilities and providers to examine the influence of built environment on diabetes/hypertension and their risks factors as well as care pathways that patients undertake, in order to deliver interventions in a more focused way. In addition, we have built in extensive stakeholder and community engagement in the study implementation which should aid in improving acceptability and buy in for the intervention program.

Further, the community based cohorts established will not only facilitate tracking of the trends in risk factors and diseases in rapidly transitioning populations in India, but also serve as well characterized population platforms for embedding and evaluating new research questions of public health relevance in combating the rise of NCDs.

Notably, a unique strength of UDAY besides occurring in a developing country setting where there are limited community based projects, in comparison to various other community based projects conducted in both developed and developing countries, which have either addressed prevention or management of select chronic conditions, is that UDAY aims to address both prevention and management of concurrently and comprehensively.

However, the study has some limitations. Firstly, we used a pre-post study design for evaluating the effect of our interventions. Though, a randomized controlled trial is a better design to evaluate the effectiveness of interventions, providing a higher level of evidence than a pre-post design, to study the effect of multi-component interventions delivered at multiple levels in a comprehensive manner in a large population over a vast geographic area, we considered the pre-post design as more appropriate for our study.

Further, we also wanted to understand and examine the operational part of the program implementation to gain insights into underpinning factors behind success or failure that can inform possible replication and scale up in the future.

Secondly, our study does not include controls for the comparison. Given the size of the population covered by the interventions, we would have had to recruit control communities of similar size and numbers, which wasn't feasible from an implementation and resources availability point of view. However, our baseline and end line surveys that evaluate the impact are done on independent random samples of the population, which should provide robust data regarding potential changes over baseline in the levels of: public awareness and knowledge about diabetes and hypertension; those aware, diagnosed, treated and controlled to recommended targets; the use of guideline based management by providers leading to improved health outcomes and access to healthcare for people living with diabetes and hypertension in India. In addition, we will be comparing our results with ongoing national survey data on NCDs and their risk factors (National Family Health Survey, Annual Health Survey, District Level Household Survey) as well as a New National NCD survey which is being implemented currently. This will help assess secular trends and evaluate our findings in conjunction with such trends if any. Also we did not account for the regression to the mean as there would be at least some people both in the end line and baseline. We will do sensitivity analysis to explore this bias.

Thirdly, one of the major interventions of our program is to implement a community based screening, follow-up and educational program through health workers. We specifically hired and trained health workers to implement this interventional component, which might add to the cost of implementing a community based diabetes and

hypertension prevention and management program. However, the additional cost of is likely to be minimal as indicated by previous modelling estimates of training and using health workers.

Fourthly, we are using multi-component interventions at multiple levels (health promotion campaigns, health workers led home based screening, follow-up and education, training of healthcare providers, registry for facility based improvement in quality of care, patient networks and advocacy to strengthen the health system) which makes it difficult to evaluate the individual contribution of each intervention. However, the purpose is to deliver it in a comprehensive manner to improve outcomes, which to our knowledge has hitherto not been implemented in similar settings, and not to tease out impact of individual interventions in a milieu where many individuals have elevations of multiple NCD risk factors and suffer often from co-morbid conditions that require to be addressed comprehensively.

It is anticipated that the results obtained from the study will inform policy makers on the most appropriate community and health system based approaches that are effective in stemming the rising burden of diabetes and hypertension in India and countries with similar challenges.

Data sharing and Contributorship statement

Data will be available to the study investigators only. De-identified data can be shared with other researchers based on specific request to the publication sub-committee of the project with potential research questions to be examined.

Sailesh Mohan, K. Srinath Reddy, Dorairaj Prabhakaran and Nikhil Tandon conceived the study. Sailesh Mohan wrote the first draft of the manuscript. Prashant Jarhyan, Shreeparna Ghosh, Nikhil Srinivasapura Venkateshmurthy, Ritu Rana, Cheena Malhotra, Ruby Gupta, Bhaskara Rao and Sanjay Kalra wrote specific sections of the manuscript as well as contributed to the design and implementation of the study. Bhaskara Rao and Sanjay Kalra also coordinate the activities in the study sites and provide technical support. Sailesh Mohan, Shreeparna Ghosh, Prashant Jarhyan, and Nikhil Srinivasapura Venkateshmurthy contributed to the collection and assembly of data. All authors provided input into the study design, as well as provided critical intellectual input for revision of the manuscript and approved the final version of the manuscript.

Acknowledgements

The UDAY project is led by the Public Health Foundation of India, Gurgaon, India in collaboration with Population Services International, India and Project HOPE. We acknowledge the contributions of the field and research staff of the project. The funder has no role in the design, implementation, and evaluation of the project as well as in the writing of this paper. All contents of this paper are solely the responsibility of the authors.

Funding source

It is supported by an unrestricted educational grant from Eli Lilly and Company under the Lilly NCD Partnership Program.

Disclaimer

The funding agency had no role in the design, conduct or analysis of the study, and no role in the decision to submit the protocol for publication.

Conflicts of interest

None declared

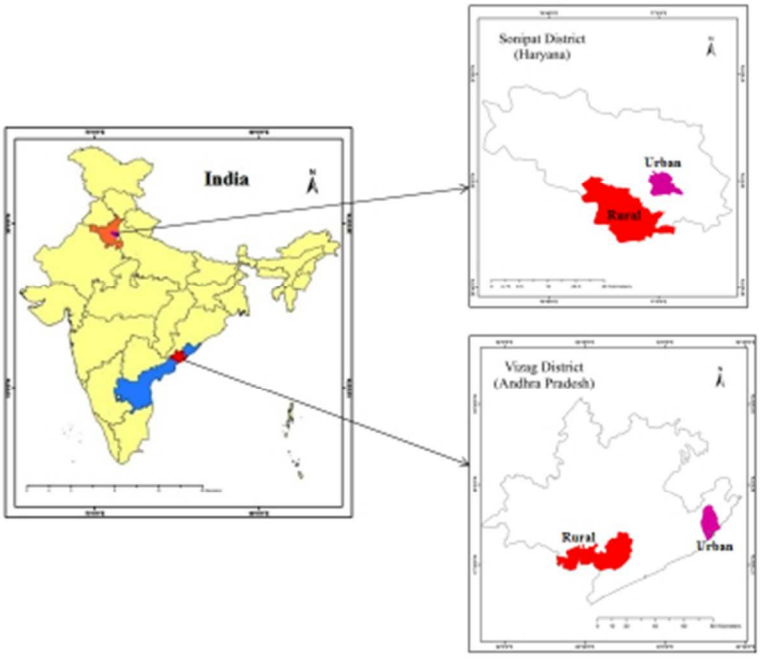
Ethics and dissemination

Ethical clearance for conduct of the study was obtained from the Institutional Ethics Committee (IEC) of the Public Health Foundation of India. The findings will be targeted primarily at public health policymakers and advocates, but will be disseminated widely through other mechanisms including conference presentations and peer-reviewed publications, as well as to the participating communities.

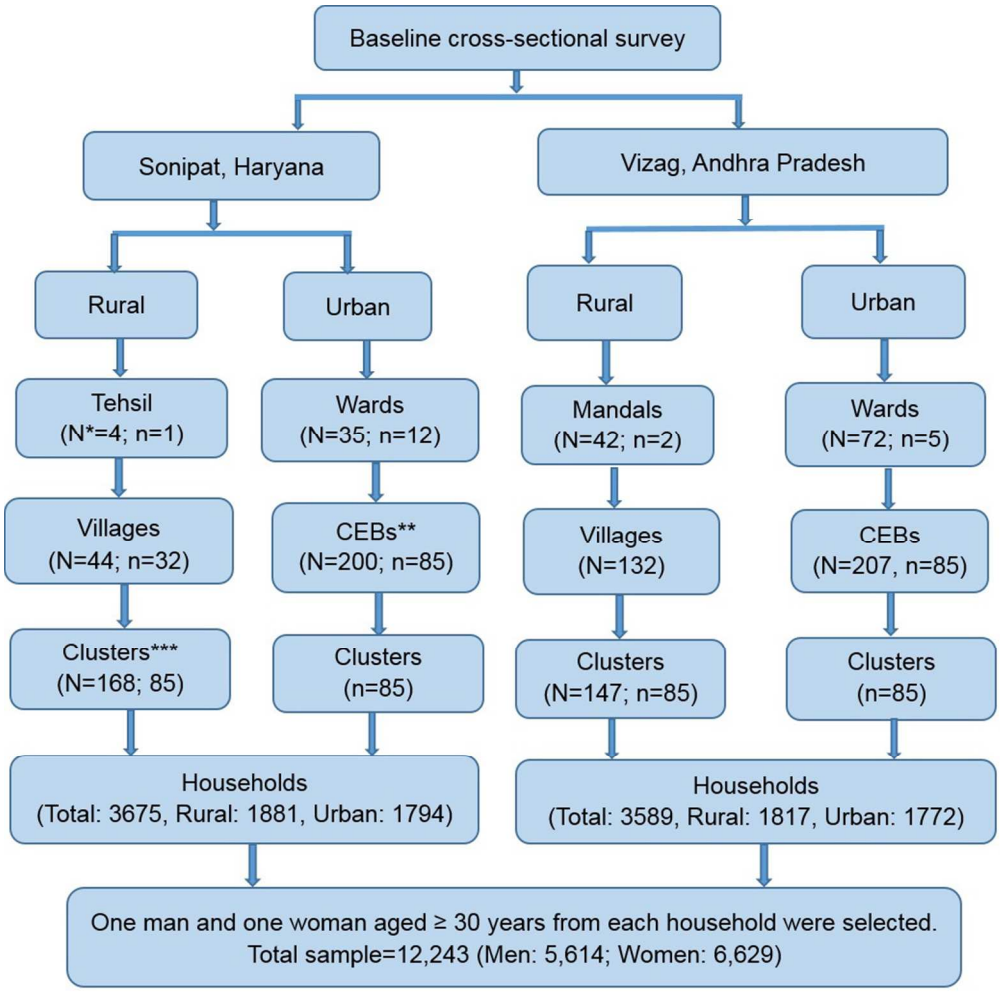
References

1. National Multisectoral Action Plan for Prevention and Control of NCDs in India. World Health Organization (WHO) Country Office for India, New Delhi, 2013.
2. International Diabetes Federation. IDF Diabetes Atlas, 7th edition. 7th ed. Brussels, Belgium: International Diabetes Federation, 2015.
3. Reddy KS, Shah B, Varghese C, et al. Responding to the threat of chronic diseases in India. Lancet 2005; 366:1744-49.
4. Mohan S, Koller T.Hypertension and related comorbidities in India: Implications for the health system. World Health Organization (WHO) Country Office for India, New Delhi, 2013.
5. Nair M, Ali MK, Ajay VS, et al. CARRS Surveillance study: design and methods to assess burdens from multiple perspectives. BMC Public Health 2012;12:701.
6. Reddy KS, Prabhakaran D, Chaturvedi V, et al. Methods for establishing a surveillance system for cardiovascular diseases in Indian industrial populations. Bull World Health Organ 2006; 84:461-69.
7. International Institute for Population Sciences (IIPS) and Macro International. 2007. National Family Health Survey (NFHS-3), 2005–06: India: Volume II.Mumbai: IIPS.
8. World Health Organization. Global Physical Activity Questionnaire (GPAQ) Analysis Guide: World Health Organization. Available at: http://www.who.int/chp/steps/resources/GPAQ_Analysis_Guide.pdf (Assessed 15 December 2015)
9. Yusuf S, Hawken S, Ounpuu S, et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. Lancet 2004; 364:937-52.
10. EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy 1990; 16:199–208.
11. Poongothai S, Pradeepa R, Ganesan A, et al. Reliability and validity of a modified PHQ9 item inventory (PHQ12) as a screening instrument for assesing depression in Asian Indians (CURES—65). J Assoc Physicians India 2009; 57: 147–52.
12. Berra K, Franklin B, Jennings C. Community-Based Healthy Living Interventions. Prog Cardiovasc Dis 2017; 59:430-439.
13. Puska P. Why Did North Karelia-Finland Work? Is it Transferrable? Glob Heart 2016; 11:387-391.
14. Sarrafzadegan N1, Kelishadi R, Esmaillzadeh A, Mohammadifard N, Rabiei K, Roohafza H, Azadbakht L, Bahonar A, Sadri G, Amani A, Heidari S, Malekafzali H. Do lifestyle interventions work in developing countries? Findings from the Isfahan Healthy Heart Program in the Islamic Republic of Iran. Bull World Health Organ 2009;87:39-50.

15. Harati H, Hadaegh F, Momenan AA, Ghanei L, Bozorgmanesh MR, Ghanbarian A, Mirmiran P, Azizi F. Reduction in incidence of type 2 diabetes by lifestyle intervention in a middle eastern community. Am J Prev Med 2010; 38:628-636.
16. Rawal LB, Tapp RJ, Williams ED, Chan C, Yasin S, Oldenburg B. Prevention of type 2 diabetes and its complications in developing countries: a review. Int J Behav Med. 2012; 19:121-33.



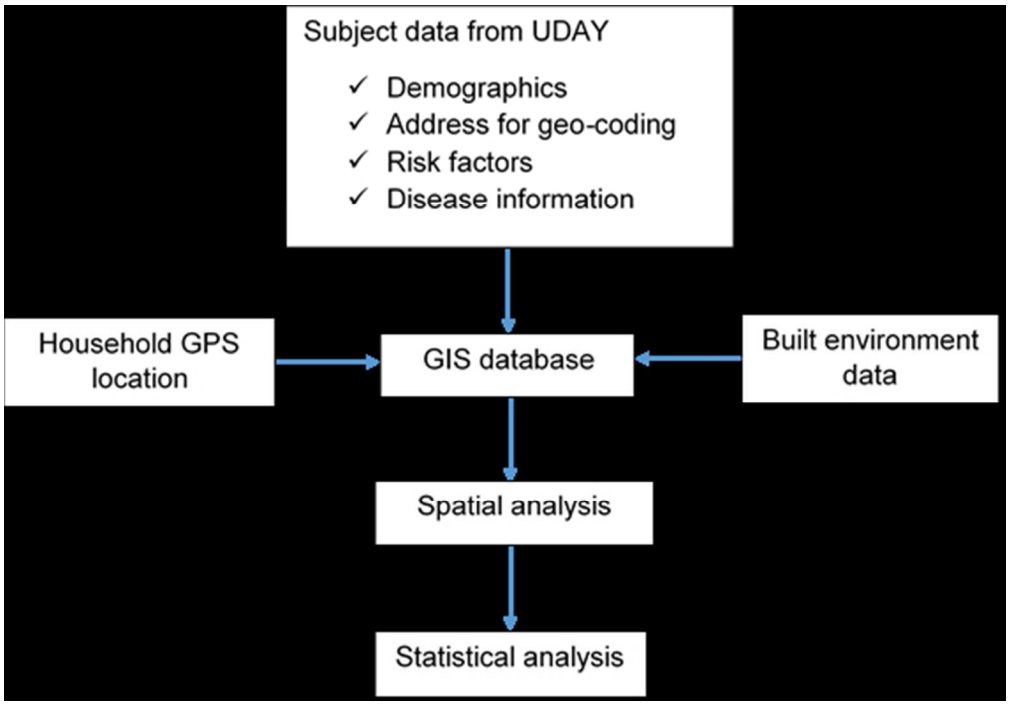
40x30mm (300 x 300 DPI)



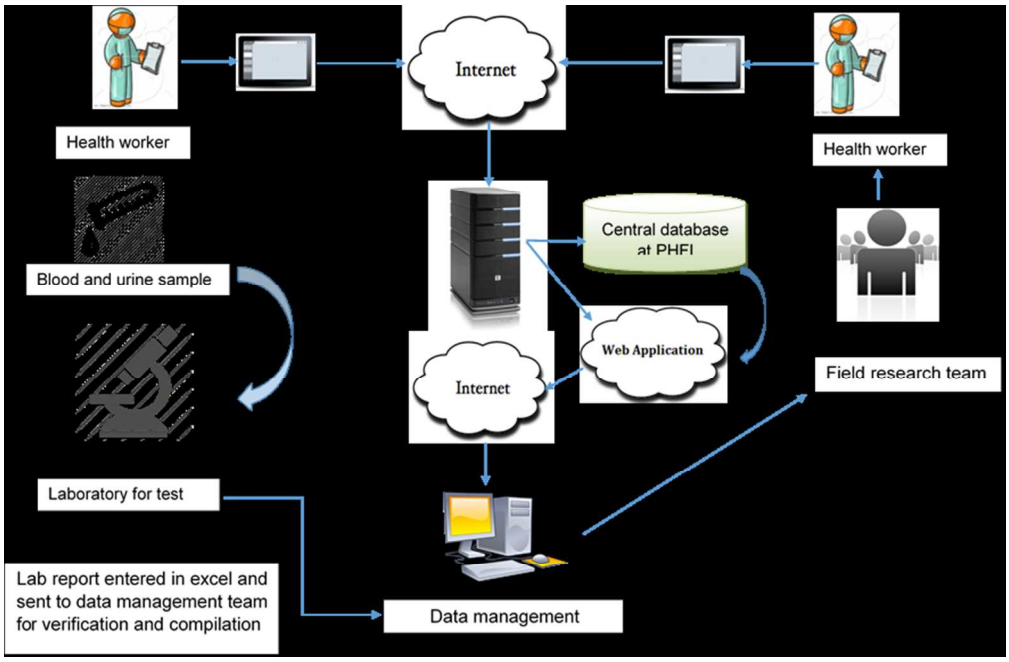
*N=total, n=number selected

**CEB=Census Enumeration Block

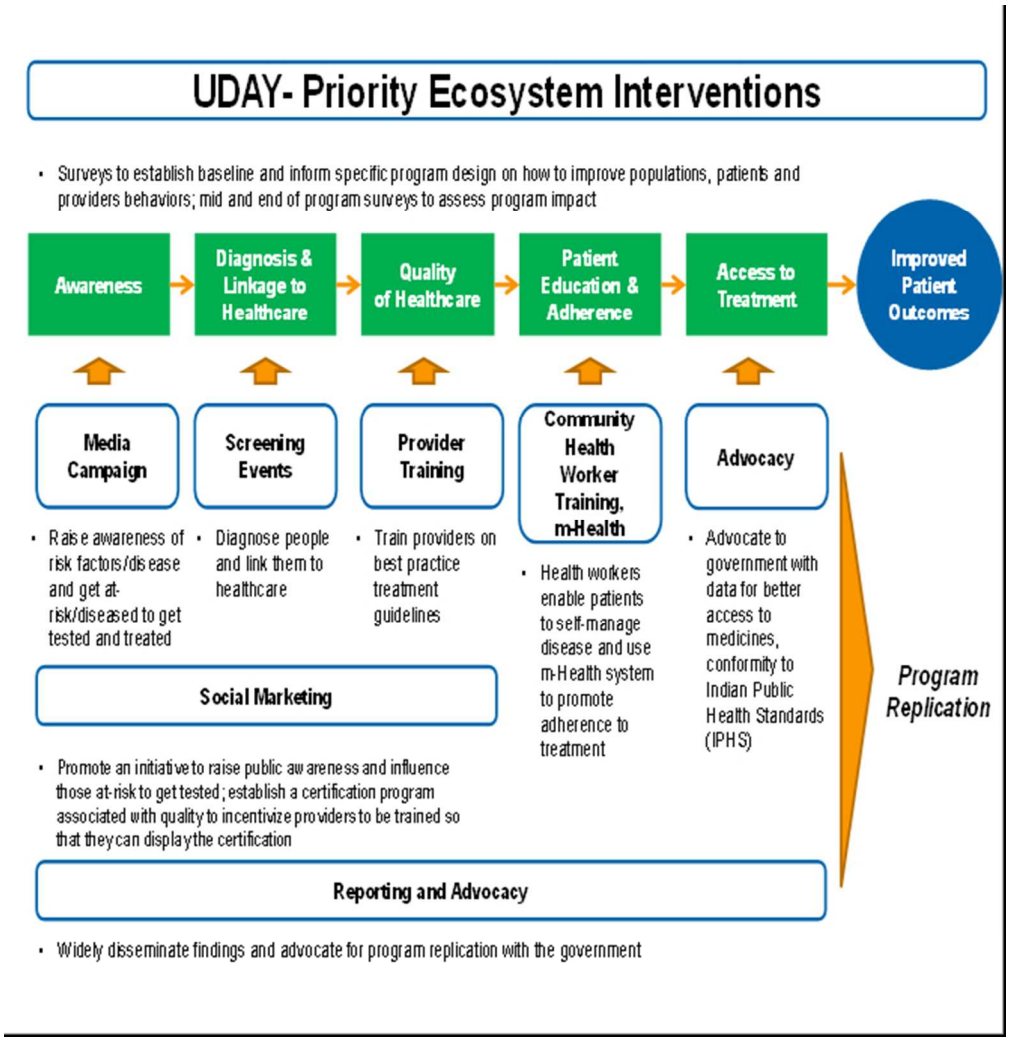
***Cluster = In urban sub-site clusters comprise CEBs, in rural sub-site bigger villages were split into 2 or 3 clusters with sizes of 75-300 households.



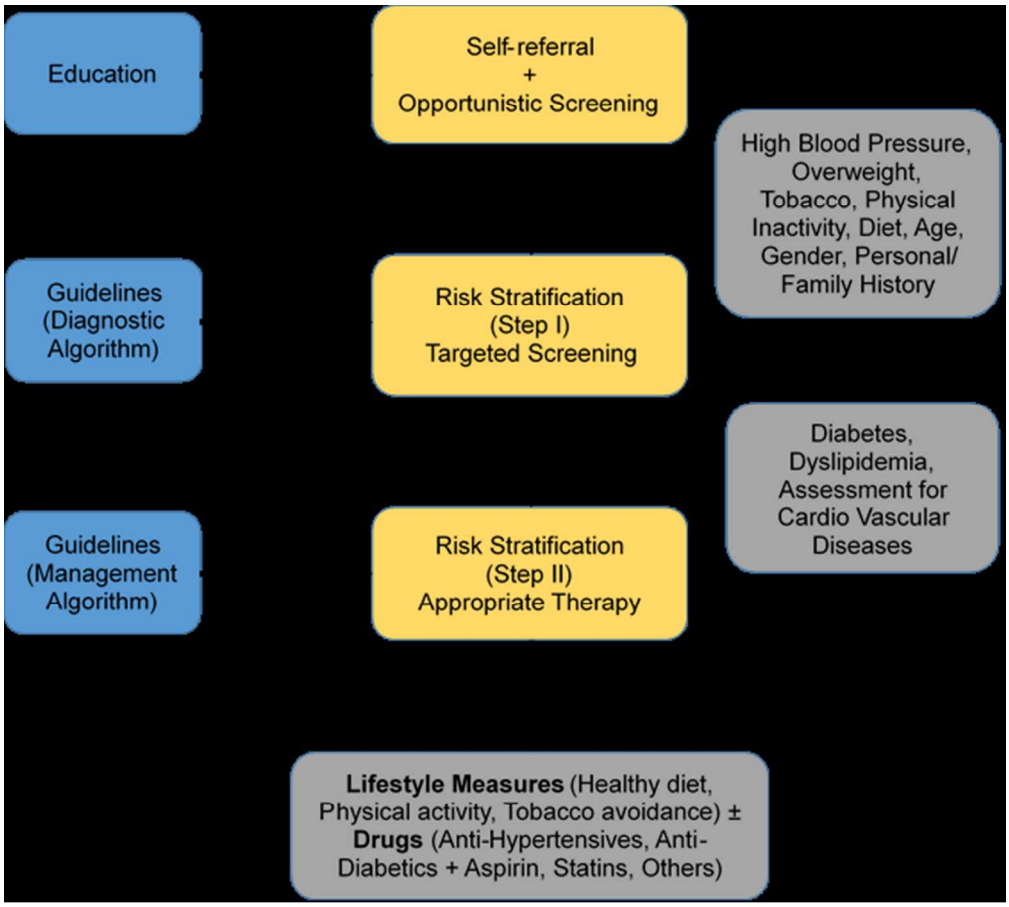
48x33mm (300 x 300 DPI)



74x48mm (300 x 300 DPI)



56x58mm (300 x 300 DPI)



55x49mm (300 x 300 DPI)

Supplementary file

Sonipat district in the state of Haryana, is north of India's capital city Delhi. It covers an area of 2,122 sq. km and has a population of 1,450,001 (Census 2011). The district has 4 tehsils (sub-districts), namely Gohana, Ganaur, Sonipat and Kharkhoda. Among these, we selected Sonipat tehsil as the urban sub-site and Kharkhoda as the rural sub-site.

Vizag district is one of the north eastern coastal district in the state of Andhra Pradesh and lies in proximity to the Bay of Bengal. It covers an area of 11,161 sq. km and has a population of 4,290,589 (Census 2011). Vizag district has 43 mandals (sub-districts) comprising 4 urban mandals and 39 rural mandals. Among these, we selected Vizag as the urban sub-site and Makavarapalem and Nathavaram as the rural sub-site.