

A Proposed Evaluation Plan for the Diabetes Prevention and Control Program: A Concept Paper

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Abstract

Introduction: India is projected to be the diabetes capital by the next decade, and Asians are predisposed to central obesity and visceral adiposity which puts them at additional risk for diabetes. **Materials and Methods:** The proposed evaluation plan draws reference from the non-communicable disease prevention and control program, implemented by the Karnataka Health Systems Development & Reforms Project (KHSDRP), Directorate of Health Services, Government of Karnataka (GoK) in collaboration with the World Bank, New Delhi, during the period 2012 to 2016. This evaluation will be conducted by an external agency in consultation with the Medical Officer/Investigator. **Results:** The relevant reports will officially benefit the District Program Officer and District Health Officer of Davangere and Dakshina kannda districts, Karnataka, India, where the program is being implemented. **Conclusion:** The results of this plan will benefit health promotion planning by the Health Department including building of community advocacy for the promotional initiatives.

Keywords: Behavior change, diabetes program, health promotion, logic model

BACKGROUND AND STATEMENT OF NEED

With aging, the disease burden shifts toward noncommunicable diseases (NCDs),¹ which can threaten the health condition of this age-group. (The World Health Organization [WHO] defines noncommunicable diseases as including chronic disease [principally cardiovascular disease, diabetes, cancer, and asthma/chronic respiratory disease], injuries, and mental health. This does not include all chronic diseases, such as those of an infectious nature [HIV or AIDS, for instance].) In India, aging occurs without the social changes such as improved living conditions, better nutrition, wealth gains, and better access to health services, which accompanied aging, decades ago in most developed countries.

India is at the crossroads. Over half of the disease burden (62%, including injuries)^[1] is now attributable to NCDs, and therefore comprises a larger share than communicable diseases, maternal and child health issues, and nutritional

causes combined together. Decades ago, a similar pattern was found in high-income countries.

NCDs by definition are chronic in nature and require treatment over a much longer period than acute communicable diseases. Currently in our country, reforms are under progress to address health financing issues. Presently, a high fraction of healthcare costs are borne by patients through out-of-pocket expenditure or through government-sponsored health insurance for tertiary surgical care or private insurance subscribed by a small proportion of the population. This is likely to weigh heavily on those unable to afford high levels of health care.

Among all the NCDs, diabetes mellitus (DM) affects the quality of life to a greater extent. Uncontrolled diabetes has debilitating implications on end organs (heart, kidney,

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Table 1: Logic model (Noncommunicable Disease Prevention and Control Project—Diabetes Component)

SI. No.	DOMAINS	INPUT		PROCESS	OUTPUT
		RESOURCES	ACTIVITIES*		
	<i>frequency of evaluation and source of data</i>	<i>done at the initiation of project</i>			
1	Formative research	Contracting with private institutions for conducting needs assessment in public healthcare facilities, where the Project will be implemented	Visit to all the healthcare facilities for conducting needs assessment and focus group discussions	Project staff monitoring the assessment visits of the health facilities and discussion events	Identifying gaps in the health facility towards which logistic support can be addressed. Finding social barriers for uptake of the Project.
	<i>frequency of evaluation and source of data</i>	<i>done at the initiation of project and after one year (for attrition issues)</i>		<i>done two months after the initiation of the Project by conducting surveys</i>	<i>done three months after the initiation of the Project by conducting surveys</i>
2	Enumeration / Awareness Generation	Nominating enumerators and community mobilizers from the existing staff Printing of IEC materials and tools for BCC such as identifying physical instructors in the community Sanctioning of incentives by the Health Department through the loans received from the World Bank	Training of all the enumerators and community mobilizers at the District level hospital Adequate distribution of publicity (IEC) materials to all health facilities, Implementation of behavior change (BCC) strategies in the communities. Incentives provided to all the enumerators Total enumeration of the capital population, 25% of the Community mobilized for undergoing screening services	Assessing knowledge of a sample of beneficiaries regarding NCDs, and their attitude towards inculcating lifestyle changes Total number of meetings convened between the health workers and community groups No. of working hours of health system staff utilized for NCD program viz..Medical officer, Staff nurse, health worker, No. of working hours of NCD Program administrative staff members viz..Management officer, Coordinator utilized for NCD program No. of working hours of community resources (self-help groups) utilized for NCD Project No. of meetings held with schools/ workplaces	Assessing community (using sampling method) awareness regarding utilization of screening services No. of Schools/ Workplaces implementing the guidelines regarding lifestyle practice, provided by the NCD Project
	<i>frequency of evaluation and source of data</i>	<i>done at the initiation of project and after one year (for attrition issues)</i>		<i>done annually</i>	<i>done bi-annually using data from the health reporting system</i>
3	Screening	Recruitment of staff for health centers which are deficient in manpower Purchase and supply of all items & consumables for all the health centers Upgradation of infrastructure for providing screening services	Training of staff at County (District-level) hospital: i) Medical Officer ii) Staff Nurse iii) Health workers iv) Lab technician Contracting with agencies for annual maintenance	Proportion of the eligible population who have accessed healthcare 25% improvement of knowledge regarding NCDs among health workers, 90% change in attitude among health workers, who are advocating the screening services	Prevalence proportion of beneficiaries who have been screened / tested Total number of Supportive supervisory visits done for health workers

Table 1: Continued

SI. No.	DOMAINS	INPUT		PROCESS	OUTPUT
		RESOURCES	ACTIVITIES*		
4	Diagnosis	Enrolling all Consultants for CME programs, to provide updated information on tertiary care	No. of continued medical education (CME) programs conducted Cost effective delivery of services to all the patients	Proportion diagnosed (of the total screened, comparing the rates with existing morbidity) Proportion of items (equipments, instruments) serviced under maintenance contract Proportion of health facilities sending reports on time	Prevalence proportion of diabetes, diagnosed over the last six months
5	Treatment & follow-up	Establishing effective demand-supply chain for supply of drugs and consumables Enrolling all impoverished individuals under Government sponsored subsidized insurance scheme	Determining linkages to care through empanelled hospital network Health worker assisted patient navigation to higher healthcare centers, for necessary surgical interventions	Proportion on treatment (of both the incident and prevalent cases) Total number of counseling sessions on lifestyle change conducted Reliability of Health management information system	Compliance to treatment, adherence to follow-up & referral linkages Proportion of functional referral pathways % effective linkage with health insurance scheme % patients provided treatment as per the NCD program guideline

*Home based and palliative care activities have not been included

nerves, and nervous system), compounding the existing predisposition of Asians to the development of diabetes.

Globally, one in two adults with diabetes is unrecognized. One in five people with diabetes is older than 65 years. Of global health expenditure, 10% is spent on diabetes management. Three in four people with diabetes live in low- and middle-income countries. Two in three people with diabetes live in urban areas. One in six live births is affected by hyperglycemia in pregnancy, 84% of which have gestational diabetes. Two in three people with diabetes live in urban areas. One in 13 adults (20–79 years) has impaired glucose tolerance. The global prevalence of diabetes is 10.8% in urban areas and 7.2% in rural areas. One death in every 8s is contributed by diabetes.^[2] India has >65 million patients with diabetes.^[3] As against the incidence studies for type 1 diabetes, prevalence studies are more commonly conducted in type 2 diabetes. In India, >96% of the diabetics are type 2 in nature.^[3] Recent increase in the prevalence rate of diabetes, correlates with rapid transformation of society, from traditional to modern lifestyles. The epidemiological data collected from diabetes control programs can be used to evolve prudent strategies best suited for our socioeconomic situation.

In India, a majority of patients accessing care at the public sector health facilities belong to the lower socioeconomic status (comprising >2/3 of the population).^[4] Private health facilities, which claim to provide effective diabetes care, come at a cost, which patients need to pay out of pocket (viz. physician consultation, procedures, and

investigations). Although first-line antidiabetic drugs are cost-effective, higher line of treatment will be a burden on these patients who lack private insurance. Public sector insurance covers below poverty line families, and is applicable only for hospitalized patients and not for outpatient care or prescription drugs. Hence, this project was conceptualized to fill the necessary gaps for DM management at the public sector health facilities in the two pilot districts.

PROPOSAL (PROJECT) TO ADDRESS THIS ISSUE

The Diabetes control project was launched as a component of the larger NCD Prevention and Control Program (NPCDCS), wherein advocacy for screening services was built through publicity activities (information, education, and communication—IEC) and lifestyle promotion through behavior change communication (BCC) methods. It was planned to conduct publicity activities using educational and audiovisual material, and behavior change activities using role-plays and practice of yoga at schools, workplaces, and community gatherings.^[4] Also, this program provides logistic support to the already existing healthcare systems in the medical facility, where screening and diagnosis of DM will be conducted. During 2012, NPCDCS was being implemented in five districts of Karnataka State.

The proposed evaluation plan draws reference from the Karnataka Health Systems Development and Reforms Project (KHSDRP), Directorate of Health Services,

Table 2: Logic model for outcome and impact assessment

Sl. no.	Domains	Outcome			Impact
		Short term	Intermediate	Long term	
	Frequency of evaluation and source of data	Done every 6 months after project initiation using HMIS	Done annually using HMIS	Done at the end of the project period of 2 years using HMIS	Done at the end of 5 years using HMIS
1	Formative research	Logistic procurement of major items for filling gaps in the health facilities	Targeted behavioral interventions for improving the uptake of the project	Advocacy for lifestyle changes and utilization of screening programs	Improving quality of health care at the facility level and inculcating healthy behaviors in the community
2	Enumeration/ awareness generation			20% reduction in the prevalence of tobacco/alcohol intake 25% of the population have adopted behavior change, viz. good physical activity 25% of the population avoids consumption of foods rich in saturated fats, trans fats, free sugars and excess salt.	10% reduction in the prevalence of diabetes 10% reduction in prevalence of obesity
3	Screening	10% change in the proportion of individuals screened compared with previous 6 months	Equitable access to screening services for at least 50% of the population	Sustainable logistic supply chain systems for maintaining the screening activities in all the health centers	
4	Diagnosis	Availability of diagnostic services at all health centers in the two counties (districts)	Delivery system for drugs and lab services to all the diagnosed individuals	25% increase in newly diagnosed diabetes cases. Availability of basic drugs and lab facilities for >90% of prevalent cases, in the health facilities	Equitable access to DM-related health care for all needy patients in public health facilities
5	Treatment and follow-up		No. of diagnosed cases with the disease (DM) under control, and those responded to therapy for end organ complications	25% increase in cases with controlled diabetes status 25% increase in adherence to treatment and compliance to follow-up regimen	Increase in median survival period of 50% diabetics 25% reduction in diabetes-specific mortality rate

HMIS = Health Management Information System, DM = diabetes mellitus

Government of Karnataka (GoK), which is being implemented in collaboration with the World Bank, New Delhi. The NCD program of KHSDRP was pilot tested in two other districts (Davangere and Dakshina Kannada) of Karnataka State during the period 2012–16, and has minor methodological changes when compared with NPCDCS.

NPCDCS was implemented at the subcenter (SC) level, by mobilizing beneficiaries for screening camps. The primary health center (PHC) was bypassed, by referring patients to the community health center and taluk/district hospitals. The focus was on the biological component. However, in the KHSDRP Project, beneficiaries are mobilized for screening services to the PHC. This builds advocacy for accessing care. The behavioral component received equal emphasis in the project when compared with the biological component. Capacity building of the public sector healthcare system in the chosen two districts, was facilitated through the KHSDRP Project by hiring additional manpower, technical training,

behavior change initiatives, procuring drugs and items, streamlining supply chain logistics, and incentivizing patient navigation.

Although this proposal's focus is on the diabetes component, hypertension and cervical cancer were the two other diseases included in the KHSDRP Project. The eligible population comprised individuals older than 30 years, as type II diabetes is more common in this age-group. Screening for type I diabetes in younger age-group was not included in this project. The overall methodology for this project was advised by World Bank, based on the best practices being implemented in their supported projects across the globe.

The management of diabetes in our country, hitherto restricted to symptom-based diagnosis and treatment, received an impetus through the NPCDCS Program, which advocated the screening of healthy individuals for early diagnosis and treatment. Until the launch of this program, the community perceived screening services as a burden, which could rather be avoided and not a privilege, which needs to be sought.

Table 3: Utility of evaluation information to the stakeholders

Sl. no.	Stakeholders	Relevance of evaluation
1	Community	Provides a sense of security, which enables uptake of healthy behavior, including accessing screening services and conforming to treatment regimen
2	Leaders of community associations	Enable planning the plugging of gaps in the management of diabetes, and address issues regarding uptake of healthy behaviors
3	Healthcare personnel of the public sector facility	Plan for alternate avenues in community mobilization and behavior change initiatives, including their capacity to manage diabetes
4	Directorate of Health Services (Health Department)	Addressing lack of resources, including manpower, logistics, and funds
5	Ministry of Health and Family Welfare, Govt. of India	Cost-benefit analysis of implementing the Diabetes Project in the community, and appropriate allocation of financial budget for health promotional activities

KHSDRP diabetes project goals and objectives are as follows:

Goals

1. To bring behavioral changes in the community for addressing the impending epidemic of diabetes in the two pilot counties (districts)
2. To comprehensively address the biologic issues at the health facilities for managing the burden of diabetes among the community of the selected districts

Objectives

1. To assess and reduce (by at least 10%) the prevalence of modifiable risk factors for diabetes such as diet, physical activity, and stress among the capital population (primordial prevention)
2. To assist in preventing the onset of diabetes by promoting risk reduction and enhancing healthy lifestyle among >50% of the population (primary prevention)
3. To promote early detection among >90% of diabetics and provision of free treatment to all the patients at the public health facility (secondary prevention)
4. To prevent diabetes-related complications among >95% diabetics, and promote achievement of optimum levels of health for all patients (tertiary prevention)

The KHSDRP project activities are listed in the logic model [Table 1], including recruitment, training, IEC/BCC activities, community mobilization, distribution of incentives, health care at the facility, establishing referral pathways, and patient navigation. The project was designed for a period of 2 years and is bifurcated into the following:

1. “Behavioral component,” which addresses issues regarding creating community awareness regarding NCDs, bringing in behavioral change and building advocacy for screening services
2. “Biologic component” for improving care for NCDs at the public sector health facilities and establishing referral linkages

EVALUATION QUESTIONS AND DESIGN

Nonexperimental design will be planned, and data will be gathered from surveys (primary data) and health reporting

system (Health Management Information System—HMIS) (secondary data). The focus of this evaluation report is on activities such as creating awareness of DM, bringing lifestyle changes, strengthening screening services, and implementing diagnostic and treatment activities. Impact evaluation is not covered in this report, as 2 years is a short time for bringing a holistic change through the project. All of these issues are mentioned in the logic model.

1. Process evaluation questions:

- a. Have all public sector health facilities in the two districts been assessed for needs?
- b. Have focus group discussions been convened?
- c. Have all the beneficiaries (>30 year olds) in the capital population been enumerated, and screening process been advocated to them?
- d. Are the beneficiaries actively participating in the screening activity, following the roll out of the project?
- e. Are standard procedures being followed by the physician/staff nurse/laboratory technician for diagnosis/assessment/profiling of patients in the medical facility?

2. Process measures which would be gathered and why?

- a. Number of health facilities assessed for needs, and number of focus group discussions conducted to deliberate the social barriers for accessing care
- b. Number of meetings convened between the health workers and community groups/schools/workplaces, which will give an estimate of the advocacy activities
- c. Exit survey of beneficiaries regarding lifestyle changes and screening activities at the health center, which will enable the assessment of their awareness regarding the program
- d. Proportion of the eligible population who have been screened after 6 months of program initiation, which will provide a measure of the community mobilization activities

3. Outcome evaluation questions:

Short term:

- a. Has logistic procurement of major items been completed?
- b. Has there been a significant increase in the outpatient numbers at public sector health facilities who were screened/diagnosed with DM?

c. Are diagnosed patients adherent to treatment regimen?

Intermediate term:

- a. Have community advocacy activities been effective in mobilizing the community for screening activities?
- b. Have the interventions at public sector health facilities been cost-effective in offsetting out-of-pocket expenditure for accessing DM-related care in private facilities?
- c. What proportion of patients is compliant to follow-up regimen?

Long term:

- a. Have behavior change communication methods been effective in the community?
 - b. Is there a reduction in the prevalence of tobacco/ alcohol consumption among the capital population?
 - c. Has the logistic supply chain system (for drugs and consumables) for facilities been effective?
 - d. Has there been an increase in detection of incident cases of DM, when compared with the rates of previous years?
 - e. Are the referrals being navigated (with or without the accompanying health worker) as per the linkage pathways?
4. Outcome measures which would be gathered and why?
- a. Periodical (biannual) audit of the health facilities will enable identification of gaps in logistic supply (items and consumables),
 - b. Audit of health center reports of previous years will enable trend analysis of DM morbidity with the current rates of the existing HMIS
 - c. Field-based survey to assess the behavioral changes in the community, prevalence of DM, decrease in consumption of tobacco/alcohol, and obesity rates
 - d. Number of supportive supervisory visits conducted will assess the work efficiency of outreach health workers and hospital healthcare staff
 - e. Facility-based exit survey of diagnosed patients regarding drug supply and laboratory investigations will enable the assessment of logistic supply chain systems. Such surveys will also enable the assessment of cost-effective treatment, adherence to treatment regimen, compliance to follow-up, and effectiveness of referral linkage pathways
5. Others measures, which would be acceptable:
- a. Audit of medical and surgical interventions conducted on beneficiaries at the tertiary health center, diagnosed through the program, will enable assessing the validity of referral pathways, linkage with health insurance scheme, and delivery of treatment as per the protocol.
6. Strengths and limitations of the chosen measures:
- a. *Strengths:* Primary data elicited from surveys will provide an estimate of publicity measures, uptake of the program by beneficiaries, and implementation

activities. Secondary data from HMIS will estimate the efficiency of activities such as screening, diagnosis, therapeutics, biochemical assessment, referrals, and benefits of general insurance.

- b. *Limitations:* As World Bank is the external funding agency for the project, a target-based approach toward all of the programmatic activities within a specified time frame of 2 years could potentially lead to duplication of secondary data. With the pretext of meeting the given targets, the cumulative data reported could be inappropriately increased without the beneficiaries being truly screened.

Outcome and impact assessment

Table 2 depicts that the long-term outcome assessment is done at the end of 2-year period, through existing health reporting system, special (exit), and population-based surveys. Utilizing data from the health reporting system, short-term assessment will be done every 6 months of the project and intermediate assessment at the end of each year. Impact assessment is done at the end of 5 years, by which time the project objectives would have been imbibed into the National Program (NPCDCS).

The following drugs were planned for procurement through the Karnataka State Drug Logistic and Warehousing Society. Drug pricing and procurement will be as per the government guidelines.

1. Tablet metformin SR (500 and 1000 mg)
2. Tablet glimepiride (1 mg)
3. Tablet glibenclamide (5 mg)
4. Injection premixed insulin (30/70 mg)

The learning outcomes from this project as shown in Table 3 will be imbibed into the ongoing NPCDCS Program, after March 2016. By this time, World Bank funding for KHSDRP Project would have stopped, and NPCDCS will be expanded to all the districts of Karnataka State.

This report enlists the project implementation activities and identifies potential areas for improvement in the delivery of the program. The logic model discusses the outline of programmatic activities and flow of events. The evaluation design will establish whether goals and objectives of the project are being accomplished.

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Conflicts of interest

There are no conflicts of interest.

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