Supplementary File 1 - Global Evaluation Framework

The global framework presented in this document highlights the general strategy for needs assessment, monitoring and evaluation for the four target countries in this project. The global framework is designed to align with Medtronic Philanthropy's Continuum of Care. Through systematic data collection and analysis, we aim to provide the most reliable information to support the program implementation process and offer meaningful insights into understanding the best practice in non-communicable disease (NCD) interventions specifically cardiovascular disease (CVD) and diabetic care. While the global framework serves as a skeleton for the study design, specific adjustment will be made in each country to tailor the framework to local settings.

1. Needs assessment

The goal of the needs assessment is to identify barriers along the Continuum of Care which prevent care seeking by patients, their proper diagnosis and the subsequent management of CVD and diabetes. A mixed methods approach will be adopted in which both quantitative and qualitative data will be collected to capture the different types of needs, barriers and opportunities. In order to identify these barriers within each community, it will be necessary to collect all relevant and available data within those settings, as well as other existing data that could provide additional information on barriers to care. Specifically, primary data collection will target three major aspects of the health system, namely demand side (ie the patients perspective), supply side (the provider/system perspective) and the context. Table 1 summarizes the purposes, content and data collection methods for the three aspects.

	Demand side	Supply side	Context
Purpose	To understand the needs and barriers in seeking care, proper diagnosis and treatment amongst the general population	To assess the quality, capacity and barriers in the provision of care	To capture existing physical environment, systems and policies

Content	1. Sociodemographic
	2. Risk factors
	3. Knowledge, Attitudes and Practices (KAP)
	4. Care seeking behavior
	5. Medical history
	6. Physical examination
	7. Personal and cultural beliefs
	8. Awareness and participation at activities organized by local NGO/CBO.)
		1. Facility mapping
		2. Facility capacities:
		   a. Human resources
		   b. Infrastructure
		   c. Services
		3. Front-line health workers experience and perspective
		4. Community-based organizations (awareness raising, for example, happens at the NGO/CBO level – outside of facility.)
			1. Built environment
			2. Existing health programs and policies – some related to NCDs

Data collection method	Quantitative	Quantitative	Qualitative:

	1. Household + individual survey
	Qualitative
	2. Focus groups with:
	  a. individuals from different sociodemographic background
	  b. Patient groups
	  c. Community leaders
	  d.
		1. Facility assessment survey (private, governmental and non-governmental facilities)
		Qualitative
		2. In-depth interview with front-line health workers on pressing challenges
		3. In –depth interviews and/or focus groups with facility-level providers of care (nurses, physicians, administrators and CBO representatives)
			1. Observation of community environment
			2. Focus group discussion of community members
			3. Interview with local stakeholders and document review of existing programs and policy

1.1 Demand side

As shown in the table, demand side data collection will consist of both quantitative and qualitative data collections. Quantitative data will primarily be collected through a household survey, which will focus on information such as sociodemographic background, risk factors assessment, basic knowledge, attitudes and practices (KAP) regarding symptoms and treatment of CVD and diabetes, health seeking behavior, medical history and physical examination. The data collected from the household survey will be used for the following purposes:

1. Estimate prevalence of disease, risk and coverage of health services in the community
2. Classify population needs according to four specific categories (see subsequent section for details)
3. Identify systematic differences in disease prevalence, risk and health seeking practice among different sociodemographic groups

The estimation of disease and risk factors prevalence as well as health services coverage is critical for understanding the population-level burden and the overall level of accessibility to health services. This information can help determine the scope and set realistic targets for subsequent interventions.

In addition to deriving general prevalence estimates, based on the information obtained from the household survey, population will be classified according to four unique needs categories (See Figure 1). Category 1 refers to population who have NCD. They are aware of their condition and are under treatment. This group of population has already entered the health system. Their needs, therefore, would mainly relate to ensuring they are receiving the appropriate treatment for their condition, they are adhering to their treatment protocol and that they have remained in the health system, with the ultimate goal of achieving the best health outcomes, given their condition. Given that this group is the most advanced along the Continuum of Care, they will provide valuable information for understanding factors which facilitate their positive health-seeking behavior. Category 2 refers to the population who have been diagnosed with a NCD, are aware of their condition(s) but are not being treated. This sub-group of the population has entered the health system (entered for diagnosis); however, they have not remained in the system for treatment. To improve outcomes for this group, the first concern would be the promotion of treatment-seeking behavior. Category 3 refers to the population who have a NCD, but

do not know that they have the condition and are not being treated for it. This group has not received any diagnosis nor treatment for their NCD. To ultimately improve outcomes in this group interventions would primarily (at least initially) focus on the promotion of diagnosis-seeking and subsequently treatment-seeking behavior. Finally, category 4 refers to population who do not currently have an NCDs. For this group, the prevention of future disease would be the main goal of any intervention. This classification scheme is tightly linked to the Continuum of Care (see Figure 2). By identifying the proportion of population falling into each category, we will be able to systematically determine aspects along the Continuum which has the most pressing needs for interventions. Furthermore, as it will be explained in later sections, this classification scheme will also be applied in the monitoring and evaluation phase to classify intervention programs and to facilitate the development and adaptation of appropriate M&E indicators and strategy.

Figure 1: Four categories of needs
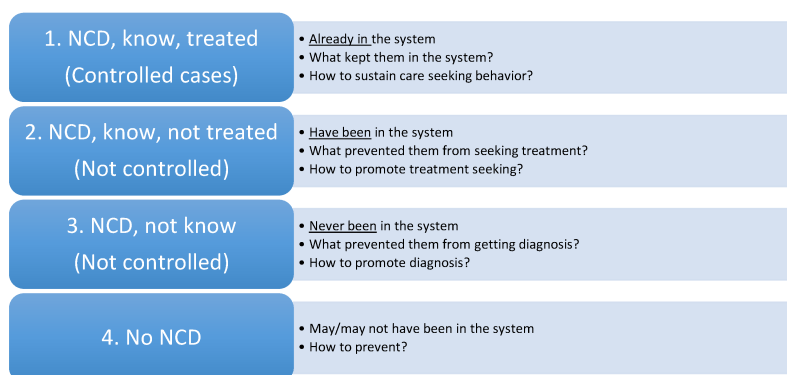
Figure 2: Mapping four categories of need on Continuum of Care
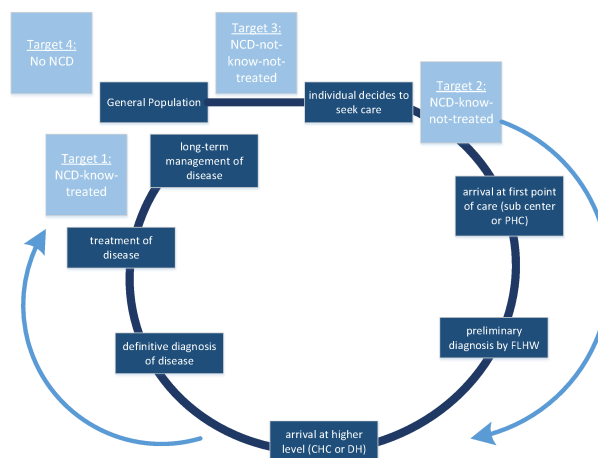
Finally based on the population side data, analysis will be carried out to identify systematic differences in disease prevalence, risk factors and health seeking practices among different sociodemographic (or cultural, depending on what is relevant in each setting) groups. This analysis will reveal underserved groups which are particularly prone to NCD and related risk factors, yet have limited access to health

services. During the qualitative data collection phase, focus group discussions will be conducted targeting the different sociodemographic groups to obtain a deeper understanding of the personal perception, experience and cultural belief, which may have influenced their attitude and practice.

Qualitative data will be collected primarily through separate focus group discussions with 3 different target groups of participants. The first group of participants is the general population. Based on the results from the household survey, we will invite participants with different sociodemographic background. The discussion topics for this group include participants' definition of health needs, current practice and perceived barriers in seeking health care and beliefs in medical practices and quality of care available to them. The findings here will be interpreted alongside with results from household survey to elucidate systematic differences in disease prevalence and health-seeking behavior across groups. The second group of participants are patients. The discussion topic for this group include current health seeking practice, factors which promote or hinder health-seeking behavior, their perceived issues in the existing health services. Finally, the last group of participants is community leaders. This group of participants will offer the viewpoints of policy-makers. In particularly, the discussion topics include their perception of community health needs, their assessments of the strengths and limitations of existing health care system and their thoughts on future programs and policy. Data from the various focus groups will be analyzed and interpreted both separately, to obtain the unique perspectives of different population, and collectively, to compare and contrast the different viewpoints. In particular, by comparing the responses of the community leaders with those of general population and patients, we will be able to identify potential discrepancy between policy planning and population needs and expectations. Details of the qualitative data collection and analysis are still pending and will be finalized by the prospective qualitative researcher.

1.2 Supply side

Supply side data collection will involve a facility mapping, facility assessment survey and interviews. A comprehensive facility mapping will first be carried out to catalog the types and location of existing health facilities – public and private. Subsequently, a facility assessment survey will be conducted in selected health facilities. Quantitative data will be collected for the following aspects: Human resources, financial resources, infrastructure, infection control, types of services, health service statistics, mortality and morbidity. Similar to the demand side data collection, in addition to quantitative data, qualitative data will also be collected. Specifically, structured or semi-structured interviews will be carried out with frontline health workers including facility directors, physicians, nurses, EMS respondents and community health workers. The goal of these interviews is to understand their experience with patients, their perspective on community health needs as well as challenges they encountered. Findings from these data will help determine gaps in existing health delivery system which are in needs of strengthening and support.

1.3 Context

To obtain a holistic picture of needs, information regarding the context will also be collected. Data collection regarding the context will be primarily qualitative in nature with the focus on physical environment, programs and policies. Specifically, observation will be carried out to gather data on the built environment of the community, for example residential density, the presence of gathering space and paved roads, the availability of space for physical activity (including sidewalks, parks, open spaces), the availability of other key health services, and healthy and nutritious foods, etc.. Give that constraints

in physical environment can be a barrier to health service access, by assessing the built environment, we will identify objective issues which may have hinder the existing health service delivery. To understand the landscape of existing programs and policies, detailed document review and interview with local stakeholders will be carried out. The duration, target and objectives of *all* the health-related programs and policies will be mapped out. This include both governmental and non-governmental efforts which may or may not be directly related to CVD and diabetes. The goals are to first understand where the emphasis is placed in existing programs; second, to identify existing policy gaps; third, to document ongoing programs which may potentially interact or confound our subsequent intervention implementation and evaluation analysis.

1.4 Country adaptation

All data collection tools will be properly adapted to fit the needs and situation of each country. Questionnaire and protocols will be translations will be carried out forward and backward by two independent translators to ensure conceptual and cultural equivalence is achieved. Inputs will be solicited from the local partner to determine the appropriateness of each questions and data collection procedure. Site specific findings from the needs assessment will be presented to MP and implementation partners along with the results literature review on effective interventions to facilitate the selection and design of local intervention strategies.

2. Monitoring

2.1 Overview

Monitoring will be conducted throughout program implementation. There are two major goals of monitoring: 1) provide timely information for implementation partners on the progress of program execution 2) accumulate longitudinal information for evaluation of program impact. Given the potential diversity in the programs being implemented, to achieve consistency and quality of monitoring and evaluation, the following strategy will be adopted (see Figure 3). First, according to their objectives, programs will be classified following the four needs categories previously mentioned. Second, according to their implementation content, programs will be further classified into four interventions categories: patients' empowerment, health-system strengthening, technology upgrades, and policy reform. The two levels of categorization will yield a total of 16 unique combination of intervention type (see Figure 4). Third, according to the resulting classification, a specific set of indicators will be chosen for monitoring. Finally, a universal protocol for monitoring and evaluation protocol will be applied.

Figure 3: Overview of monitoring and evaluation strategy
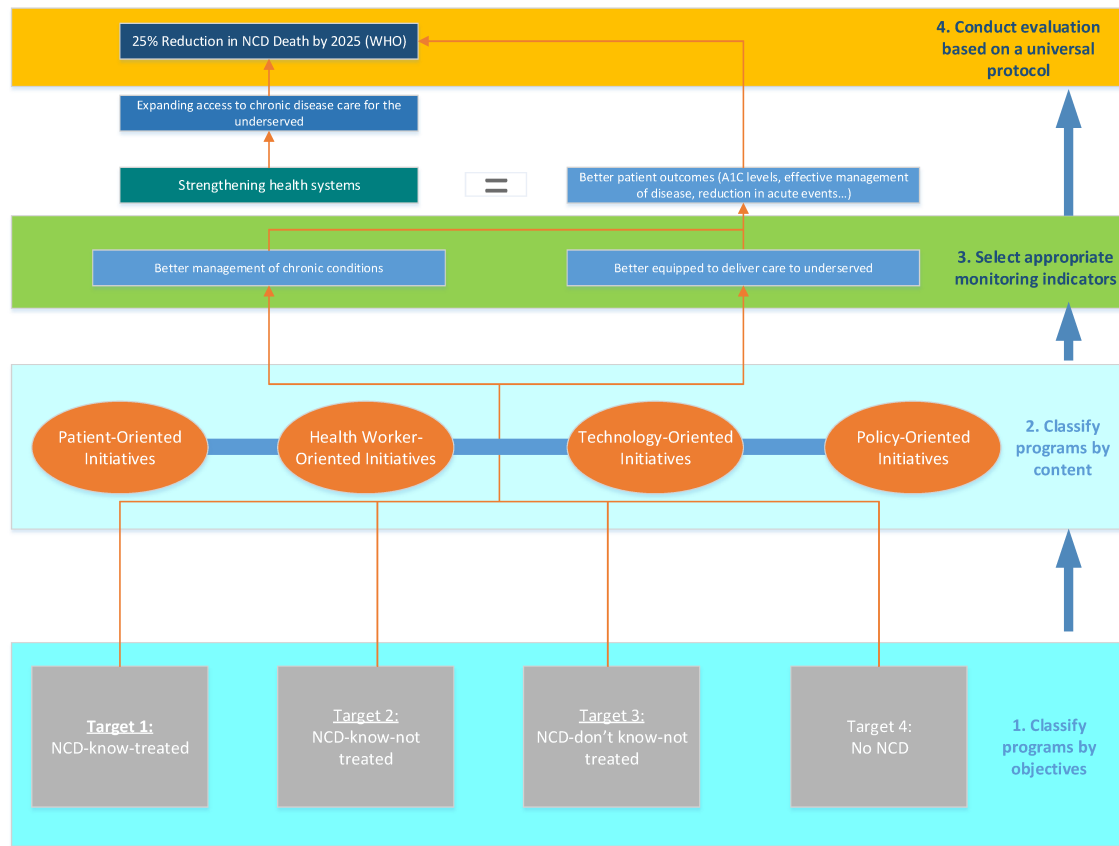
Figure 4: Sixteen unique intervention categorization and examples

	Intervention Categories	Examples of interventions	Examples of Outcome Indicators
Target 1: NCD-know-treated	Patient-Oriented Interventions	Patient support network	Improved psychosocial status of patients
	Health Worker-Oriented Interventions	Improve efficiency of treatment delivery	Reduced wait time
	Technology-Oriented Interventions	Mobile reminder	Improved treatment adherence
	Policy-Oriented Interventions	Inclusion of NCD in UHC planning	Improved service integration
Target 2: NCD-know-not treated	Patient-Oriented Interventions	Education campaign to raise awareness of importance of treatment	Improved KAP
	Health Worker-Oriented Interventions	Equip FLHW to provide consultation on treatment	Increased number of consultation
	Technology-Oriented Interventions	Availability of generic and affordable drugs	Reduced cost
	Policy-Oriented Interventions	Streamline referral services	Improved number of patients treated
Target 3: NCD-don't know-not treated	Patient-Oriented Interventions	Education campaign to raise awareness of importance of diagnosis	Improved KAP
	Health Worker-Oriented Interventions	Equip FLHW to provide screening services on routine health visits	Increased number of screening
	Technology-Oriented Interventions	Adoption of more efficient testing/ screening procedure	Increased number of screening
	Policy-Oriented Interventions	Mandate the provision of screening for population age 45+	Increased number of screening
Target 4: No NCD	Patient-Oriented Interventions	Education campaign to raise awareness of risk factors	Improved KAP
	Health Worker-Oriented Interventions	Equip FLHW to provide consultation on smoking cessation, healthy diet etc.	Increased number of consultation on healthy behavioral pratice
	Technology-Oriented Interventions	Mobile technology for monitoring diet an living habits	Reduced harmful behaviors
	Policy-Oriented Interventions	Policy ban on smoking in public area	Reduced harmful behaviors

2.2 Indicators

The indicators to be included in the monitoring aim to capture five key domains namely input, process, output, outcomes and impact. Table 2 provides a summary of potential monitoring indicators. Input indicators aim to capture the resources including human, financial, physical resources entered into the program. Process indicators aim to capture the features of program execution such as duration, content, activities (number of individuals contacted/ reached, etc.). Output indicators aim to capture productivity of a program such as target population reached, development of a product or formulation of documents. Outcome indicators aim to capture the results of the output. Of specific interest to this study are outcome such as changes in efficiency along the continuum of care, changes in KAP, changes in service coverage and changes in prevalence of risk factors. Finally, impact indicators aim to capture the ultimate impact of these interventions on health outcomes. In this case, changes in the incidence of CVD and diabetes, changes in the management and control of CVD and diabetes, and potentially changes in mortality related to these diseases.

Note that only a limited set of indicators are presented in the table. The final indicators used for monitoring will depend on the type of program being evaluated. In particular, the indicators for process and outputs will differ by programs. For instance, the relevant process indicators for a program which intends to improve the KAP of patients through outreach would be the time and content of outreach. The relevant output indicators would be, for instance, the number of patients reached. In contrast, the relevant process indicators for program which intends to improve hospital guidelines for treating CVD would be the steps by which the guideline was developed. The relevant output indicators would be the

document of the guidelines. While process and output indicators may differ across programs, we anticipate that the same set of input, outcome and impact indicators will be used across all programs. The rationale is that, given that all programs are expected to have human, financial and physical resource components, the same set of indicators would be applicable. Although different programs may have different goals and targets, the same set of outcome indicators will likely be used to capture both intentional and unintentional outcomes. Since the shared goal of all programs is to improve health outcomes related to CVD and diabetes, all programs should be evaluated based on the same health impact indicators.

Table 2: Summary of indicators for monitoring

Domains	Items	Indicators
1. Inputs	• Financial	• Expenses • Direct and indirect costs
	• Personnel number and characteristics	• Number of staff, hours, education/training, age, gender
	• Facilities	• Accessibility, technological capability, managerial capacity operation schedule
	• Location	• Geographical scope, catchment area characteristics
2. Process	• Duration	• Date intervention started/ended
	• Nature of activities	• How training was carried out • How products were developed
	• Strategies for identifying targets	• Types of contacts • Incentives used • Means of recruitment
	• Management	• Overall organization, management and implementation structure
3. Outputs	• People reached (CHWs, patients, general population)	• Number of people reached • Program participants • Staff trained
	• Characteristics of people reached	• Characteristics of people reached compared with target population (is the program reaching the intended target?)
	• Products	• Number of meetings, courses, advertisements, content of activities, new diagnostic tools
	• Documents	• Completed guidelines, protocol, training manual

4. Outcomes	• Changes in efficiency in the continuum of care	• Drop-off rate between at risk and seeking care groups
		• Drop-off rate between contact to long term management
		• Adherence rate
	• Changes in risk factors	• Prevalence of exposure to risks
	• Coverage	• Rate of utilization of services
	• KAP	• Ability to identify symptoms and channels for health care
		• Rate of routine check-up, follow-up
	• Patient empowerment	• Level of satisfaction with health services
		• Ease of access to information and resources
		• Level of aftercare support
5. Impact	• Impact from improvement in treatment/ quality of care	• Prevalence of controlled NCDs
		• Premature mortality rate attributable to NCDs (2025 goal)
	• Impact from improvement in risk factor management	• Incidence of NCDs

2. Global Timeline for Needs Assessment, Monitoring and Evaluation

Below is the overall timeline for the development and implantation of the project components described above.

	2014	2015	2016	2017	2018
Framework Development	All sites				
Needs Assessment	India, US, Brazil and South Africa				
Intervention Monitoring		India, US, Brazil and South Africa			
Impact Evaluation				India, US, Brazil and South Africa	

2.3 Data collection & quality

Quantitative data for monitoring and evaluation will be collected using an electronic system developed at IHME. The system has proven to work reliably in low-resource and in low-connectivity settings.

Weekly data verification will be carried out to highlight major issues, quickly, without slowing down data collection to an inefficient level. During the data collection process, IHME team will work closely with in-country partners to verify in-coming data and provide prompt feedback when issues or questions arise. Finally, using electronic data collection and statistical software, IHME will generate reports and present results of specific indicators on the dashboard system to demonstrate the quality of the data and provide precise instructions back to the field teams on what needs to be done to improve it.

2.4   Country adaptation

Similar to the needs assessment, all data collection tools will be systematically adapted to fit the needs and situation of each country. Inputs will be solicited from the Medtronic, Abt and local partners to ensure the appropriate monitoring indicators were chosen. In addition, to facilitate the implementation process, reporting plan and the dashboard system will be catered to the specific needs and expectation of the various partners.

3.   Evaluation

3.1   Overview

Evaluation consists of two major parts, namely process evaluation and impact evaluation. Figure 5 shows a schematic diagram of the monitoring components relevant to each part of the evaluation.

Figure 5: Schematic diagram of monitoring and evaluation components
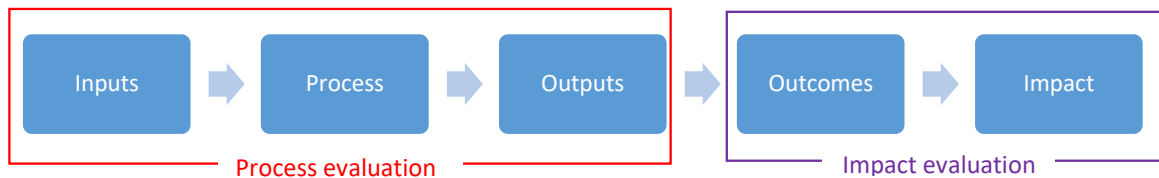
Process evaluation is closely tied to the monitoring process. It aims to assess program scale-up, document program implementation and assess whether the program met its targets outputs. The key questions include:

- o Is the program implemented as designed?

- o How partnership differ across countries and projects and how it influences program implementation?

- o Can the operations be more efficient?

- o Are the benefits getting to those intended?

- o What are the costs and how are they accounted for?

On the other hand, impact evaluation aims to derive causal inferences about the health outcomes of a program on a target population. The key questions include:

- o   Are the beneficiaries of the program experiencing improvement in health?

- o   Is the program achieving the target outcomes within the community?

3.2 Approaches

Process evaluation will primarily be descriptive in nature. We will compare the targeted and actual input, process and outputs to capture potential discrepancy between program planning and execution, hence identify implementation flaws. We will also compare implementation process of programs which are similar in nature. This particular analysis will highlight programs' efficiency and productivity relative to each other.

Impact evaluation will utilize statistical inference techniques. It will focus on changes in health outcomes at two levels namely individual level (program participants) and community level. For individual level analyses, comparisons will be made to detect differences in the incidence/prevalence of diseases and risk factors, management of NCD for those who have them, and NCD-related mortality between groups with and without intervention. To ensure the rigor of the analysis, matching algorithm will be applied such that the basic sociodemographic characteristics of two groups are comparable. For community level analyses, we will aim to detect longitudinal changes in the incidence of disease and risk factors, management of the disease among those who have it, and mortality over the course of the program implementation. We anticipate that a dose-response analysis will be applied to examine the association between exposure or intensity of intervention and the targeted health outcomes.

3.3 Potential challenges

There are several challenges which may limit the capacity of the current evaluation framework in determining the impact of intervention programs. First, given that programs may not be implemented in a randomized fashion, drawing definitive causal inferences between programs and outcomes might be challenging. Second, given that different programs may be carried out simultaneously by different CBO, teasing out the unique contribution of each program may not be feasible. Third, there may be other existing programs funded by the government (local, state or national) or NGOs addressing the same health issue. The presence of these programs can interact and confound the impact of programs funded by Medtronic Philanthropy. Finally, the duration of implementation and evaluation are relatively brief. It is possible that the impact of some of the intervention may take longer to realize than the duration of the program.