

APRIL 2018

SMARThealth Extend

Pfizer Foundation

Submitted as part of Access Accelerated

Contents

| | |
|--|----|
| Program Description | 3 |
| Program Overview | 4 |
| Program Strategies & Activities | 6 |
| Companies, Partners & Stakeholders | 8 |
| Local Context, Equity & Sustainability | 10 |
| Additional Program Information | 12 |
| Resources | 13 |
| Program Indicators | 14 |
| Appendix | 15 |

The information in this report has been submitted by the company concerned to the Access Observatory as part of its commitment to Access Accelerated. The information will be updated regularly. For more information about the Access Observatory go to www.accessobservatory.org

The information contained in this report is in the public domain and should be cited as: Pfizer, SMARThealth Extend (2018), Access Observatory Boston, US 2018 (online) available from www.accessobservatory.org

Program Description

Program Overview

1 Program Name

SMARThealth Extend

2 Diseases program aims to address

- Cardiovascular disease (Hypertension; Cardiovascular Disease, General)

3 Beneficiary population

- Adults > 39 years

4 Countries

- India
- Indonesia

5 Program start date

January 1, 2016

6 Anticipated program completion date

April 30, 2018

7 Contact person

Claire Maguire (claire.maguire@pfizer.com)

8 Program summary

Cardiovascular disease (CVD) is one of the major causes of morbidity and premature mortality in many low and middle income countries, including India and Indonesia. It is estimated that 20% of Indonesian adults between 41-50 years and around 70% of those aged 51-60 years are at high risk of CVD. Furthermore, two-thirds of those at risk are not receiving appropriate treatment. The situation is similar for India, where recent data from rural Andhra Pradesh shows that almost 17% of the adult population are at high short-term risk of CVD and the vast majority of these individuals are not receiving any preventive drug therapy whatsoever. Despite the availability of evidence-based guidelines for the prevention of CVD, the use of simple, affordable preventive treatments such as smoking cessation strategies, medications to control hypertension and cholesterol is very low in these regions. In addition to population-wide measures, efforts need to be directed to identify individuals at high cardiovascular risk and to offer interventions to lower that risk. In the context of limited resources, prioritizing patients at high risk of heart attack or stroke for blood pressure (BP) lowering treatment is the most effective and cost-efficient approach to risk reduction. This is in line with the national primary healthcare guidelines in both countries.

Despite this, use of BP lowering treatments for CVD risk reduction in rural India and Indonesia is limited, even when low-cost medications are available in the primary healthcare formularies. This is where the SMART (Systematic Medical Appraisal Referral and Treatment) health, an android-based technology platform, aims to deliver low-cost, high-quality healthcare through the existing government-funded primary healthcare system. SMARThealth Extend proposes to test an innovative, multifaceted intervention that draws on three elements: capacity strengthening of primary care doctors and non-physician health workers (NPHW); development of a mobile device-based clinical decision support system (CDSS) for use by these healthcare providers; and integration of this system within the existing public primary healthcare sector. The study tries to address the existing gaps (both manpower and technology) in the primary health care system by using an android application for measuring the CVD risk of adults between

8 Program summary cont.

40-85 years of age through household screening by trained non-physician healthcare workers (ASHAs in India and Cadres in Indonesia). Based on the analysis of patient data by the app, the NPHW can recommend preventive measures, such as behavioural changes relating to tobacco use, physical activity and diet, as well as refer those at high risk to physicians at the primary healthcare facility.

The physician at the facility also manages high risk patients with the support of the CDSS, by reinforcing behavioural change messages and prescribing preventive medications. The prime objective of the intervention is the risk reduction for CVD through optimal management of risk factors, utilizing methods to strengthen the existing public healthcare system. The aim of this demonstration project is to determine whether the SMARThealth platform can be appropriately and rapidly customized and implemented in two large rural communities (in the Indonesian province of East Java and the northern Indian state of Haryana). Mixed methods evaluation will be used to assess feasibility, acceptability, scalability and sustainability in both the sites while in Indonesia, an additional evaluation of effectiveness will be undertaken.

The data collection is ongoing and the study is expected to be completed by May 2018. The intervention includes the following activities: 1. Holding community meetings to raise awareness in the population about CVD and its risk factors. 2. Conducting household visits to screen the population for CVD risk factors. 3. Provision of training of non-physicians health workers (NPHW) and physicians. 4. Implementation of a mHealth screening tool for CVD risk assessment and decision support for health care providers.^{1,2,3}

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

| ACTIVITY | DESCRIPTION |
|---------------|--|
| Planning | The non-physician healthcare workers (NPHW – ASHA in India, Kaders and/or nurses in Indonesia) plan the dates for the monthly local gathering at the sub-centers with the local community. |
| Communication | Community meetings with group sessions to provide education on CVD, management and control of CVD risk factors, including advice on tobacco cessation, physical activity and nutrition. |
| Technology | The SMARThealth platform is used to raise awareness on CVD risk factors through the use of A-V media. This is embedded within the decision support system, such that NPHW can direct specific education (e.g. tobacco cessation) to individuals with these risk factors. |

Strategy 2: Health Service Strengthening

| ACTIVITY | DESCRIPTION |
|------------|--|
| Training | A number of District Health Administration officials trained in Cardiovascular diseases and its management using technology. Training of NPHW and PHC doctor in CVD risk and its management, as well as the use of the SMARThealth digital platform. |
| Technology | The SMARThealth technology platform has been modified for relevance to the local health system context. |
| Funding | Funding provided to ensure the availability of essential CVD preventive medications in Indonesia only. |

9 Strategies and activities

Strategy 3: Health Service Delivery

| ACTIVITY | DESCRIPTION |
|-----------|---|
| Screening | Household visits to identify individuals at high CVD risk by a NPHW, using the SMARThealth decision support systems. |
| Diagnosis | Identification of individuals at high CVD risk by the NPHW with delivery of lifestyle advice and referral to nurses and doctors |
| Treatment | Referral of high risk patients to nurses and/or physicians for consideration of drug therapy. The SMARThealth system provides decision support for drug prescription. |
| Retention | The SMARThealth system provides decision support for follow-up of patients, including priority-listing of high risk patients for NPHW to follow-up in the community. |

10 Strategy by country

| STRATEGY | COUNTRY |
|---|-------------------|
| Community Awareness and Linkage to Care | India, Indonesia. |
| Health Service Strengthening | India, Indonesia. |
| Health Service Delivery | India, Indonesia. |

Companies, Partners & Stakeholders

11 Company roles

| COMPANY | ROLE |
|-------------------|---|
| Pfizer Foundation | The Pfizer Foundation, through a donor advised fund at Give2Asia, provided grant funding to The George Institute for Global Health to support implementation of this program. The George Institute is leading the project and they are responsible for the design, management and evaluation of the project. The Pfizer Foundation is a charitable organization established by Pfizer Inc. It is a separate legal entity from Pfizer Inc. with distinct legal restrictions. |

12 Funding and implementing partners

| PARTNER | ROLE/URL | SECTOR |
|--|---|-----------|
| George Institute for Global Health | The George Institute for Global Health, through its offices in Hyderabad and Sydney, is providing high-level project oversight / management and logistical support for the project. The George Institute will take primary responsibility for data analysis and the development of study reports. www.georgeinstitute.org | Voluntary |
| Brawijaya University, Malang, Indonesia | Facilitating access with key stakeholders, local project management in Indonesia. https://ub.ac.id/ | Public |
| District Health Administration, Jhajjar District, Haryana, India | Assistance with access to healthcare providers and facilities in India. | Public |
| District Health Agency, Malang, Indonesia | Assistance with access to healthcare providers and facilities in Indonesia. | Public |
| Pt. BD Sharma University of Health Sciences and PGIMS Rohtak, Haryana, India | Facilitating access to key stakeholders, local project management in India. http://uhsr.ac.in/ | Public |

13 Funding and implementing partners by country

| PARTNER | COUNTRY |
|--|-----------|
| Brawijaya University, Malang, Indonesia | Indonesia |
| District Health Agency, Malang, Indonesia | Indonesia |
| District Health Administration, Jhajjar District, Haryana, India | India |
| Pt. BD Sharma University of Health Sciences and PGIMS Rohtak, | India |

14 Stakeholders

| STAKEHOLDER | DESCRIPTION OF ENGAGEMENT |
|---------------------------------------|--|
| Government | The local district health administration in both Indonesia and India were the chief implementers of the program. |
| Local Hospitals/ Health Facilities | The local health universities supported the implementation of the program. |

Local Context, Equity & Sustainability

15 Local health needs addressed by program

The program aligns to the non-communicable diseases national health programs in both countries.

INDONESIA: The delivery of care for non-communicable diseases including cardiovascular diseases is an integral component of the primary health in the public health delivery system in Indonesia. There have been significant increases in the rates of non-communicable diseases in the country in the recent past. The current project is in line with the delivery of care for non-communicable diseases through early identification and management of high risk cases as stated by the national health program in Indonesia. The SMARThealth program was developed in India and was adapted and implemented in Indonesia with support and collaboration of a local medical university (Brawijaya University) and local district health administration in Malang.

The University has close ties with the local district health board on a range of ongoing projects. For adaption of the program, multiple meetings were held with key stakeholders including the Malang district health administration, healthcare providers, and relevant local professional associations. Additionally, a key component of the project was a detailed health system assessment to identify enablers and challenges for incorporation of such a platform to the existing health system. Inputs from this health system assessment provided insights into how the program could integrate into the system without disrupting current routine service delivery.

INDIA: India has a National Program for Prevention and Control of Cancer, Diabetes, CVD and Stroke (NPCDCS) under which early identification and management of non-communicable diseases (NCDs) is an integral component. In addition, the recently launched Digital India Campaign encourages use of technology, especially mobile and internet technology, for enhancing the reach and effectiveness of healthcare delivery in India. The Ministry of Health and Family Welfare in India also has launched several initiatives for maternal and child health, tuberculosis management and other programs for enhancing use of digital technology in healthcare delivery.

For the extension of the SMARTHealth Program to Haryana, India, a local implementing partner was identified as a medical university – Pt. B D Sharma PGIMS, Rohtak. The University has close ties with the local State and district health administration for various projects. Multiple meetings were held with stakeholders including the Jhajjar District Health Authorities to ascertain the way forward for the inclusion of such a clinical decision support system based smartphone application into the existing public health delivery system in Jhajjar District, Haryana.

16 Social inequity addressed

The projects focus on rural communities which have inequitable access to high quality healthcare in both countries.

17 Local policies, practices, and laws considered during program design

Local health district administration and health universities are collaborators for the implementation of this project. A detailed health system assessment identified local regulations for management of NCDs and the program was adapted to suit the local needs without changing the existing care delivery pathways. For clinical decision systems, local cardiologists were consulted and local referral and management protocols were followed.

18 How program meets or exceeds local standards

[No response provided].

19 Program provides health technologies (medical devices, medicines, and vaccines)

Yes.

20 Health technologies are part of local standard treatment guidelines

No.

During the intervention, health workers in Haryana, India used the Blue-tooth enabled automated blood pressure machines (Sphygmomanometers). These machines automatically transferred the readings into the tablet device thereby reducing data entry errors.

21 Health technologies are covered by local health insurance schemes

No.

The use of the technology is not for direct patient use but is used by the health system.

22 Program provides medicines listed on the National Essential Medicines List

Yes.

23 Sustainability plan

For Indonesia:

- Gaps in the NCD care by local health government identified with the support of the health system.
- The district health administration have indicated willingness to consider improvement in the delivery of health care to the communities.
- No digitization of the data yet so an opportunity to develop open source software for interoperability.
- Staff training
- Essentials drugs list being used
- Minimum disruption of routine healthcare delivery in public health system.

For India:

- Digital India Campaign where use of technology is encouraged
- Already field staff in government health system using smartphones and tablets
- The platform uses open source software which is interoperable as per government regulations
- Staff training
- Essentials drugs list being used
- Minimum disruption of routine healthcare delivery in public health system.

Additional Program Information

24 Additional program
information

[No response provided].

25 Access Accelerated Initiative
participant

Yes.

26 International Federation
of Pharmaceutical Manufacturers
& Associations (IFPMA)
membership

Yes.

Resources

1. Maharani, A. and G. Tampubolon, Unmet needs for cardiovascular care in Indonesia. PLoS One, 2014. 9(8): p. e105831.
2. National Programme for Prevention and Control of Diabetes, Cardiovascular Disease and Stroke - A manual for medical officer. 2008.
3. Praveen, D., et al., A multifaceted strategy using mobile technology to assist rural primary healthcare doctors and frontline health workers in cardiovascular disease risk management: protocol for the SMARTHealth India cluster randomised controlled trial. Implement Sci, 2013. 8: p. 137.

Program Indicators

Not yet available for this program

Appendix

This program report is based on the information gathered from the Access Observatory questionnaire below.

Program Description

PROGRAM OVERVIEW

1 Program Name

2 Diseases program aims to address:

Please identify the disease(s) that your program aims to address (select all that apply).

3 Beneficiary population

Please identify the beneficiary population of this program (select all that apply).

4 Countries

Please select all countries that this program is being implemented in (select all that apply).

5 Program Start Date

6 Anticipated Program Completion Date

7 Contact person

On the public profile for this program, if you would like to display a contact person for this program, please list the name and email address here (i.e. someone from the public could email with questions about this program profile and data).

8 Program summary

Please provide a brief summary of your program including program objectives (e.g., the intended purposes and expected results of the program; if a pilot program, please note this). Please provide a URL, if available. Please limit replies to 750 words.

PROGRAM STRATEGIES & ACTIVITIES

9 Strategies and activities

Based on the BUSPH Taxonomy of Strategies, which strategy or strategies apply to your program (please select all that apply)?

10 Strategy by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g. some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have selected from above (program strategies), please identify which country/countries these apply.

COMPANIES, PARTNERS AND STAKEHOLDERS

11 Company roles

Please identify all pharmaceutical companies, including yours, who are collaborating on this program:

What role does each company play in the implementation of your program?

12 Funding and implementing partners

Please identify all funding and implementing partners who are supporting the implementation of this program (Implementing partners is defined as either an associate government or non-government entity or agency that supplements the works of a larger organization or agency by helping to carry out institutional arrangements in line with the larger organization's goals and objectives.)

a. What role does each partner play in the implementation of your program? Please give background on the organization and describe the nature of the relationship between the organization and your company. Describe the local team's responsibilities for the program, with reference to the program strategies and activities. (response required for each partner selected).

b. For each partner, please categorize them as either a Public Sector, Private Sector, or Voluntary Sector partner. (Public Sector is defined as government; Private Sector is defined as A business unit established, owned, and operated by private individuals for profit, instead of by or for any government or its agencies. Generation and return of profit to its owners or shareholders is emphasized; Voluntary Sector is defined as Organizations whose purpose is to benefit and enrich society, often without profit as a motive and with little or no government intervention. Unlike the private sector where the generation and return of profit to its owners is emphasized, money raised or earned by an organization in the voluntary sector is usually invested back into the community or the organization itself (ex. Charities, foundations, advocacy groups etc.))

c. Please provide the URL to the partner organizations' webpages

13 Funding and implementing partners by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g., some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have selected from above (funding and implementing partners), please identify which country/countries these apply.

14 Stakeholders

Please describe how you have engaged with any of these local stakeholders in the planning and/or implementation of this program. (Stakeholders defined as individuals or entities who are involved in or affected by the execution or outcome of a project and may have influence and authority to dictate whether a project is a success or not (ex. Ministry of Health, NGO, Faith-based organization, etc.). Select all that apply.

Government, please explain

Non-Government Organization (NGO), please explain

Faith-based organization, please explain

Commercial sector, please explain

Local hospitals/health facilities, please explain

Local universities, please explain

Other, please explain

LOCAL CONTEXT, EQUITY & SUSTAINABILITY

15 Local health needs addressed by program

Please describe how your program is responsive to local health needs and challenges (e.g., how you decided and worked together with local partners to determine that this program was appropriate for this context)?

16 Social inequity addressed

Does your program aim to address social inequity in any way (if yes, please explain). (Inequity is defined as lack of fairness or justice. Sometime 'social disparities,' 'structural barriers' and 'oppression and discrimination' are used to describe the same phenomenon. In social sciences and public health social inequities refer to the systematic lack of fairness or justice related to gender, ethnicity, geographical location and religion. These unequal social relations and structures of power operate to produce experiences of inequitable health outcomes, treatment and access to care. Health and social programs are often designed with the aim to address the lack of fairness and adjust for these systematic failures of systems or policies.*)

*Reference: The definition was adapted from Ingram R et al. Social Inequities and Mental Health: A Scoping Review. Vancouver: Study for Gender Inequities and Mental Health, 2013.

17 Local policies, practices, and laws considered during program design

How have local policies, practices, and laws (e.g., infrastructure development regulations, education requirements, etc.) been taken into consideration when designing the program?

18 How program meets or exceeds local standards

Is there anything else that you would like to report on how your program meets or exceeds local standards?

19 Program provides health technologies

Does your program include health technologies (health technologies include medical devices, medicines, and vaccines developed to solve a health problem and improve quality of lives)? (Yes/No)

20 Health technology(ies) are part of local standard treatment guidelines

Are the health technology(ies) which are part of your program part of local standard treatment guidelines? (Yes/No) If not, what was the local need for these technologies?

21 Health technologies are covered by local health insurance schemes

Does your program include health technologies that are covered by local health insurance schemes? (Yes/No) If not, what are the local needs for these technologies?

22 Program provides medicines listed on the National Essential Medicines List

Does your program include medicines that are listed on the National Essential Medicines List? (Yes/No) If not, what was the local need for these technologies?

23 Sustainability plan

If applicable, please describe how you have planned for sustainability of the implementation of your program (ex. Creating a transition plan from your company to the local government during the development of the program).

ADDITIONAL PROGRAM INFORMATION

24 Additional program information

Is there any additional information that you would like to add about your program that has not been collected in other sections of the form?

25 Access Accelerated Initiative participant

Is this program part of the Access Accelerated Initiative? (Yes/No)

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Is your company a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)? (Yes/No)

Program Indicators

INDICATOR DESCRIPTION

27 List of indicator data to be reported into Access Observatory database

For this program, activities, please select all inputs and impacts for which you plan to collect and report data into this database.

28 Data source

For this indicator, please select the data source(s) you will rely on.

29 Frequency of reporting

Indicate the frequency with which data for this indicator can be submitted to the Observatory.

30 Data collection

- Responsible party: For this indicator, please indicate the party/parties responsible for data collection.
- Data collection — Description: Please briefly describe the data source and collection procedure in detail.
- Data collection — Frequency: For this indicator, please indicate the frequency of data collection.

31 Data processing

- Responsible party: Please indicate all parties that conduct any processing of this data.
- Data processing — Description: Please briefly describe all processing procedures the data go through. Be explicit in describing the procedures, who enacts them, and the frequency of processing.
- Data processing — Frequency: What is the frequency with which this data is processed?

32 Data validation

Description: Describe the process (if any) your company uses to validate the quality of the data sent from the local team.

33 Challenges in data collection and steps to address challenges

Please indicate any challenges that you have in collecting data for this indicator and what you are doing to address those challenges.