PROGRAM REPORT

APRIL 2020

SPARSH Healthline

Merck Sharp & Dohme

Submitted as part of Access Accelerated

Access Observatory

Contents

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

Program Description

Program Overview

1 Program Name

SPARSH Healthline

2 Diseases program aims to address

- Diabetes (Type 2)

3 Beneficiary population

- General population

4 Countries

- India

5 Program start date

October 02, 2009

6 Anticipated program completion date

Completion date not specified.

7 Contact person

[No response provided]

8 Program summary

Merck Sharp & Dohme (MSD) Pharmaceuticals created SPARSH HEALTHLINE in 2008. SPARSH (which means "Touch" in Hindi) is a telephone-based complementary diabetes management patient support program for patients who have been prescribed Januvia (Sitagliptin)/Janumet (Sitagliptin – Metformin HCL)/Janumet XRCP (Sitagliptin – Metformin HCL extended release) by their treating physician. ALL PHYSICIANS in both the private and public sector who wish to enroll patients in the program are free to do so. The only qualifying criteria is that the patient should be prescribed JANUVIA/JANUMET/JANUMET XRCP.
The objective of the program is to help improve patient's diabetes control and health outcomes via counseling them on understanding of the disease and its management, self-management of diet, exercise and other lifestyle changes and adherence and compliance to prescribed treatment plan.
PROGRAM DETAILS:
This program supports 12 commonly spoken languages (English, Hindi, Marathi, Gujarati, Bengali, Oriya, Assamese, Punjabi, Malayalam, Tamil, Telugu, and Kannada). Counselors engage with patients over the phone to provide diabetes management education and guidance on diet, exercise, monitoring, medication adherence and other lifestyle changes. All counselors have a background in science or life sciences (i.e. all have graduate or post-graduate degree). SPARSH uses a call schedule to engage patients; counselors make a call each week to newly enrolled patients for 4 weeks, then a call each month for 10 months, then a call every two months for one year, followed by a call each quarter while the patient continues to take Januvia/Janumet/Janumet XRCP as prescribed by his/her physician. Patients can access a counselor through tele-services provided 7 days per week from 8am to 8pm., and receive support through education literature, the SPARSH website and multi-lingual text messages.
The key elements of support at SPARSH are:
• Counseling: Care counselors provide counseling support to patients, which prepares and motivates the patient to participate actively in diabetes management.
• Disease education: Counselors provide customized education to patients on topics that explain the disease and its consequences, providing tips on effective participation in therapy. These resources are complemented with reading material, dispatched to the patient in his/her preferred language, and a diabetes education and life-style support website, http://www.sparshmsd.com . Patients also receive

Program Overview

8 Program summary cont.

tips and alerts about diabetes management through text messages in their preferred language.
• Life-style support, including customized diet plans: MSD SPARSH provides advice on lifestyle including foot- care, hypoglycemia management, sick-day management, among others. It has a unique diet software for the diverse populations in India, which includes a data base of 700 recipes that follow the principles of Medical Nutrition Therapy.
• Progress monitoring: Counselor's monitor patient progress on various lifestyle behaviors and overall diabetes management using a systematic monitoring system thus motivating them to adopt/achieve optimal self-care behaviours.
• Information sharing with physicians: Treating physicians can view the status of their patients, their reports and progress at the Doctor Portal hosted on http://www.sparshforpatients.com/doctor/index.jsp
Training sales force to effectively communicate the program merits to health care providers in addition to regular brand promotion which includes the pill plus program benefit/value offered to such patients.
All the services offered by the program are provided completely free to patients.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	Phone counselling and education of patients through regular calls and text messages.
Other	Training sales force to effectively communicate the program merits to health care providers.

Strategy 2: Health Service Strengthening

ACTIVITY	DESCRIPTION
Training	Training of counselors on the disease, life style management, customer relationship management software and counseling skills.
Technology	Use of CRM on Demand to manage patient records, preferences and services and for efficient delivery of services. Automated and health care provider (HCP) specific patient reports on participation, progress and blood sugar values.

Strategy 3: Health Service Delivery

ACTIVITY	DESCRIPTION
Treatment	Lifestyle support, including nutrition and exercise regimens, disease education, and information sharing with physicians.
Retention	Treatment progress monitoring and counseling. By supporting patients and educating them on the importance of complying with treatment, SPARTA helps keep patients on therapy.

10 Strategy by country

STRATEGY	COUNTRY
Community Awareness and Linkage to Care	India
Health Service Strengthening	India
Health Service Delivery	India

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
MSD	MSD Pharmaceuticals Pvt Ltd (India) is the sole sponsor for this program and also oversees the execution by a 3rd party vendor.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Portea Medical	Portea Medical is a leading home care service provider which provides a broad spectrum of healthcare services ranging from nursing support to medication refills, patient assistance program and chronic disease management. Portea Medical is responsible for managing the complete operations of the program such as hiring and training of resources, providing counseling support to patients, monitoring execution of the program as per the standard operating procedure, capturing relevant information, tracking patient progress and providing performance reports and program analytics as required. www.portea.com	Private

13 Funding and implementing partners by country

PARTNER	COUNTRY
Porteoa Medical	India

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT
Other	MSD India has engaged with the local Healthcare Providers (HCPs) to encourage them to enroll patients with Type 2 Diabetes on MSD's marketed drugs on the program. HCPs from both private as well as public healthcare institutions can utilize this service for their patients. Any HCP prescribing Januvia/Janumet/Janumet XRCP to his patients, may recommend the program to such patients; however, HCPs with predominant diabetes practice and those covered by the sales team for drug promotion are the ones preferred.

Local Context, Equity & Sustainability

15 Local health needs addressed by program

India has a huge diabetes burden with approximately 67 million people affected.[1] It is a chronic condition necessitating continued medical care and patient self-management education to reduce or prevent acute and long-term complications.[2] According to Wangnoo et al. (2013), ".. health systems in India have not kept pace in evolving mechanisms to tackle diabetes effectively and the result is reflected in the sheer number (50-60%) of people with diabetes who do not achieve the glycemic target of glycated hemoglobin (HbA1c) below 7%, as reported in the limited studies available on diabetes care in India."[2] In order for diabetes management to be effective, diabetes care awareness is needed. But poor glycemic control in Indians with diabetes is associated to low awareness and education of diabetes and its complications.[2] This is also supported by Wangnoo et al. (2013), who reports that "in India a substantial percentage of patients are unaware of diabetes condition (~25%), risk factors (obesity and physical inactivity) and secondary complications of diabetes (~60%). Further, almost half of the patients are unaware that good glycemic control would help to avoid complications related to diabetes. In a study… only 10.3% of patients reported receiving diabetes self-management education [and] 20-30% respondents reported not being up-dated about new information and developments on diabetes."

India has a shortage of trained diabetes educators, which leaves the burden of educating patients to physicians,[2] making education an inconsistent activity. According to Wangnoo et al. (2013) "Diabetes management requires significant modifications in patient life-styles; new patterns of behavior and thought must be integrated into their everyday life and adherence to these patterns must be consistent. Effective monitoring of adherence to therapeutic measures by patients is needed to keep doctors informed of the on-ground behavior patterns of the patient."[2] To achieve this, a team based approach to diabetes care is necessary to handle the complex nature of diabetes care modalities. A patient-centric approach to diabetes care must be sensitive to patient needs and avoid placing an undue burden of therapy on the patient.[2] In this model, the physician provides oversight of the disease management process, while customization of therapy is built through the care team. Keeping this in mind, MSD SPARSH Healthline was conceptualised in 2008 to compliment the physicians' effort to help patients manage their diabetes well through a structured, consistent and personalised intervention.

a How needs were assessed

[No response provided]

b Formal needs assessment conducted

[No response provided]

16 Social inequity addressed

The knowledge and awareness of diabetes in India has been found to increase with increasing education.[3] This program provides diabetes education to all enrolled patients helping to bridge the gap in the knowledge of diabetes between the educated and uneducated. Additionally, the program addresses the global inequity in knowledge of diabetes management between India and high-income countries. Similarly, SPARSH improves access to diabetes management information by providing support in 11 commonly spoken Indian languages in addition to English and using telephone as a medium of engagement, thus addressing the inequity of information access between educated and the uneducated population.

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

The execution of the program is in line with local laws and policies. Patient privacy, telecom guidelines and such other policies are abided by to ensure compliant implementation of the program.

18 How diversion of resources from other public health priorities are avoided

[No response provided]

Local Context, Equity & Sustainability

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

No.

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

N/A.

21 Health technologies are covered by local health insurance schemes

N/A.

22 Program provides medicines listed on the National Essential Medicines List

N/A.

23 Sustainability plan

The program is a company sponsored program with the objective of providing 'pill plus diabetes management' benefit to patients on MSD marketed drugs. There is no transition plan to government or any other local body.

Additional Program Information

24 Additional program information

[No response provided]

a Potential conflict of interest discussed with government entity

[No response provided]

25 Access Accelerated Initiative participant

Yes.

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

Yes.

Resources

1. Vashist SK, Luong JHT. Concluding Remarks. In: Vashist SK, Luong JHT. Point-of-care Glucose Detection for Diabetic Monitoring and Management. CRC Press; 2017.2.

2. Wangnoo SK, Maji D, Das AK, et al. Barriers and solutions to diabetes management: An Indian perspective. Indian Journal of Endocrinology and Metabolism. 2013;17(4):594-601. doi:10.4103/2230-8210.113749.

3. Mohan D, Raj D, Shanthirani CS, Datta M, Unwin NC, Kapur A, Mohan V. Awareness and knowledge of diabetes in Chennai-the Chennai urban rural epidemiology study [CURES-9]. Japi. 2005 Apr 1;53:283-7.

Program Indicators

Not yet available for this program.

Program Documents

Program Documents

1. Wangnoo SK, Maji D, Das AK, et al. Barriers and solutions to diabetes management: An Indian perspective. Indian Journal of Endocrinology and Metabolism. 2013;17(4):594-601. doi:10.4103/2230-8210.113749. Available at: http://www.ijem.in/article.asp?issn=2230-8210;year=2013;volume=17;issue=4;spage=594;epage=601;aulast=Wangnoo

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 you 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 you 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)?

a How were needs assessed

b Was a formal need assessment conducted

(Yes/No) If yes, please upload file or provide URL.

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 diversion of resources from other public health priorities is avoided

Please explain how the program avoids diverting resources away from other public health priorities? (e.g. local human resources involved in program implementation diverted from other programs or activities).

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?

a Potential conflict of interest discussed with government entity

Have you discussed with governmental entity potential conflicts of interest between the social aims of your program and your business activities? (Yes/No) If yes, please provide more details and the name of the government entity.

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

a. Responsible party: For this indicator, please indicate the party/parties responsible for data collection.

b. Data collection — Description: Please briefly describe the data source and collection procedure in detail.

c. Data collection — Frequency: For this indicator, please indicate the frequency of data collection.

31 Data processing

a. Responsible party: Please indicate all parties that conduct any processing of this data.

b. 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.

c. 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.