PROGRAM REPORT

APRIL 2020

Tshwane Insulin Project (TIP)

Eli Lilly

Submitted as part of Access Accelerated

Access Observatory

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The information in this report has been submitted by the company concerned to the Access Observatory at Boston University. The information will be updated regularly. For more information about the Observatory go to www.accessobservatory.org

Program Description

Program Overview

1 Program Name

Tshwane Insulin Project (TIP)

2 Diseases program aims to address

- Diabetes: Type 2
- Cardiovascular Disease: Hypertension
- General Non-communicable disease care (Health system): Non-Communicable Disease Care, General
- Other NCD: Dyslipidemia

3 Beneficiary population

- Age Group: 18-70 years
- Gender: All genders
- Special Populations: People with low income, Urban populations

4 Countries

- South Africa

5 Program start date

January 3, 2019

6 Anticipated program completion date

August 30, 2024

7 Contact person

Prof Paul Rheeder (Paul.Rheeder@up.ac.za)

8 Program summary

The Tshwane Insulin Project (TIP) is a partnership between the University of Pretoria and Lilly Global Health Partnership with the support of the South African National Department of Health, Gauteng Province and the City of Tshwane. The project was officially launched on the 19th of September 2018 in Pretoria, South Africa. However, actual implementation of the project started in January 2019.

TIP is a translational research program of a duration of 5 years that will focus on diabetes care and management at primary care level in the Tshwane District. The aim of the project is to optimise the control of blood glucose, blood pressure and lipids in people with type 2 diabetes. The goal is to develop evidence-based interventions adapted to the South African health system.

The Tshwane District is situated in the northern part of Gauteng Province in South Africa. Tshwane District is divided into seven sub-districts or health regions. It has a population of about 3,500,000. The district has a total of 68 health facilities that are managed by the City of Tshwane (local government) and the Gauteng Department of Health (provincial government). In South Africa, the majority of population who access health care through public health facilities are medium to low-income. They often do not have private medical insurance and rely on public primary care services that are free of charge.

The implementation of the project will be done in 5 phases:

- Phase I: Identification of challenges and opportunities for insulin use in primary care;
- Phase II: Review of the legal and policy framework for insulin use in primary care;
- Phase III: Exploratory trial to test a new model of care to facilitate initiation and titration of insulin;
- Phase IV: Stepped wedge cluster randomised trial;
- Phase V: Implementation of the model of care into routine care.

Program Overview

8 Program summary cont.

Each phase has specific objectives that can be summarised as follows:

#1: To identify the barriers and opportunities for insulin initiation and titration at primary care level in the Tshwane District from both patients and healthcare providers' perspective.

#2: To investigate the gaps and missed opportunities in the management of people with type 2 diabetes at primary care level in the Tshwane District.

#3: To conduct a critical review of current policy guidelines, relevant legislation and clinical practice on the initiation and titration of insulin in South Africa.

#4: To design and evaluate a novel model of care that facilitates insulin initiation and titration in primary care clinics in the Tshwane District.

Various activities will be conducted to achieve the program objectives including a Knowledge, Attitudes and Practices Survey, an audit of medical records, an interview of role players, a document analysis and a pilot study. During the course of the project, there will be various training workshops with health professionals and various engagement meetings with stakeholders.

The success of the project requires a strong collaboration with key partners including the South African National Department of Health as well as the local authorities which are Gauteng Province and City of Tshwane. The support of the partners will allow for the integration within the health system of the interventions developed through the project.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Health Service Strengthening

ACTIVITY	DESCRIPTION
Training	Diabetes management workshops will be held to train health professionals involved in diabetes, hypertension and lipid care as well as in the intervention to initiate and titrate insulin. A curriculum will be developed to ensure that all health professionals involved in the proposed model of care have similar messages to share with patients. The aim of the training is to ensure that the primary care doctor/nurse/community health worker teams have the knowledge, systems, supports and confidence to work collaboratively with participating patients to start insulin and to do adequate follow-up. The training session will cover evidence and rationale for insulin use, how to motivate patients and deal with common patient-level barriers to insulin initiation, initiating and titrating basal insulin and prandial insulin.
Technology	In South Africa, like anywhere in the world, there are very few diabetes specialists. Further, those specialists are based in referral hospitals. The majority of people with type 2 diabetes access care at their local clinic and are seen by a nurse and/or a general practitioner. With remote technical assistance and mentorship, the health professionals at the local clinic will be able to benefit from the knowledge and expertise of the diabetes specialists. Support and mentorship will be provided to primary care doctors and professional nurses by diabetes specialists recruited for the study. A mobile app called Vula Mobile will be used to facilitate communication between the healthcare professionals. The use of electronic scripting will also be explored.
Human Resources for Health	An innovative aspect of this project is the use of community health workers (CHWs) to provide diabetes management and care. CHWs will be trained to identify signs and symptoms of diabetes, to identify signs and symptoms of hyperglycaemia and hypoglycaemia, as well as what to do in case of hypoglycaemia, and to deliver health talks on healthy lifestyle (diet and exercise) to people living with diabetes. They will visit patients that would have been initiated on insulin in their homes. During home visits, the CHWs will focus on health promotion, blood glucose monitoring and treatment compliance. They will reinforce the messages that patients would have received during clinic visits and this will lead to better education and empowerment of patients.

Program Strategies & Activities

9 Strategies and activities

Strategy 2: Health Service Delivery

ACTIVITY	DESCRIPTION
Treatment	The project goal is to facilitate and improve insulin initiation and titration for insulin-requiring type 2 diabetes patients. This will be achieved through the development and implementation of a new model of care that will involve doctors, nurses and community health workers. The model of care consists of 3 distinct levels: 1. the home of the person with type 2 diabetes. 2. the local primary care clinic. 3. a virtual level represented by the diabetes specialist accessible through a mobile application.
Retention	The use of community health workers (CHWs) will improve the retention in care of people with type 2 diabetes. The CHWs will conduct home visits and they will enforce patient adherence to treatment and compliance with clinic appointments. The CHWs will act as linkage officers to ensure that people with type 2 diabetes remain in care.

Strategy 3: Regulation & Legislation

ACTIVITY	DESCRIPTION
Advocacy	A component of the project is to review the legal and policy framework in order to identify ways to improve insulin initiation and titration at the primary care level. Moreover, during the course of the project, there will be various engagements with role players and stakeholders on numerous platforms to ensure the buy-in for the project but also to advocate for better management of people with type 2 diabetes in an environment constrained by competing priorities such as infectious diseases.

10 Strategy by country

STRATEGY	COUNTRY
Health Service Strengthening	South Africa
Health Service Delivery	South Africa
Regulation & Legislation	South Africa

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Eli Lilly and Company	Eli Lilly and Company is providing the funds necessary to implement the program.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
University of Pretoria	University of Pretoria is the implementing partner. Various departments of the university are involved in the program including Internal Medicine, School of Health Systems and Public Health, Family Medicine, Human Nutrition, and Sport Sciences. https://www.up.ac.za/	Public

Companies, Partners & Stakeholders

13 Funding and implementing partners by country

PARTNER	COUNTRY
University of Pretoria	South Africa

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	REQUESTED OR RECEIVED FROM STAKEHOLDER
Government	The Tshwane Insulin Project (TIP) is receiving support from the South African National Department of Health as well as provincial, Gauteng Province, and local authorities, city of Tshwane. This support is important as the project aims at developing interventions that will be implemented within the South African health system and scalable to the entire country. An Advisory Board which includes representatives from the provincial and local authorities has been established to oversee the implementation of the project and provide guidance.	Infrastructure: No Human Resources: Yes Funding: No Monitoring or Oversight: Yes Other resource: No
Other	Patient organisations will be involved to ensure that the interests of people with type 2 diabetes are at the centre of the project activities.	---

Local Context, Equity & Sustainability

15 Local health needs addressed by program

Increasing urbanisation and rising unhealthy lifestyle risk factors are contributing to a growing diabetes epidemic in South Africa. According to the 2017 International Diabetes Federation (IDF) estimates, there were 1.826 (1.071-3.638) million adults (20-79 years) with diabetes in South Africa; the national prevalence was 5.4% (3.2-10.8).[1]

In South Africa, diabetes was the second most common natural cause of death in 2016, being responsible for 5.5% deaths in both males and females. However, diabetes was the leading cause of death amongst females with 7.2% deaths.[2] Furthermore, diabetes is an important direct and indirect cause of burden in South Africa in terms of deaths, loss of healthy life years and disability.

Type 2 diabetes mellitus is a progressive disease with a gradual decline in beta cell function of the pancreas with deterioration in glycaemic control with time and increased associated risk of microvascular and macrovascular complications. The progressive nature of type 2 diabetes necessitates step titration of therapy from diet and lifestyle to oral antidiabetic drugs combination often culminating in insulin and other therapies being required.

Between 5 to 10 years after diagnosis, approximately 50% of people with type 2 diabetes will require insulin injections because of the progressive nature of the disease and despite the use of oral agents.[3]

In South Africa, most people with type 2 diabetes access diabetes care at their local clinic. Local clinics are mostly manned by professional nurses. However, currently, nurses are unable to initiate or titrate insulin for requiring type 2 patients. The current guidelines recommend a referral of insulin-requiring patients to a doctor for initiation which often leads to delays and other issues. Moreover, clinical intertia as well as psychological insulin resistance have been described in South Africa as contributing factors to poor levels of insulin initiation for people with type 2 diabetes leading to poor clinical outcomes.

The Tshwane Insulin Project proposes to address an existing gap between research evidence which demonstrates the effectiveness of insulin in people with diabetes and the actual use of insulin therapy in the real-world including primary care. The project will developed interventions suitable to the South African environment taking into considerations issues of organisation of care as well as shortage of health professionals, but leveraging on available resources both human with the community health workers and material with the use of information technology.

a How needs were assessed

A formal need assessment was not conducted as part of the Tshwane Insulin Project. However, the University of Pretoria conducted an evaluation of diabetes care at primary care level in the Tshwane District in South Africa in 2014. It was found that glycaemic control was poor and less than 30% of patients recorded an HbA1c <7%. This means that according to national diabetes guidelines, 70% of people with type 2 diabetes who receive care at primary level are poorly controlled. Furthermore, among the poorly controlled patients, those who were on insulin had the worst clinical outcomes. Those findings pointed to the need for an intervention.

b Formal needs assessment conducted

No.

16 Social inequity addressed

No

Local Context, Equity & Sustainability

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

POLICY, PRACTICE, LAW	APPLICABLE TO PROGRAM	DESCRIPTION OF HOW IT WAS TAKEN INTO CONSIDERATION
National regulations	No	N/A
Procurement procedures	No	N/A
Standard treatment guidelines	Yes	The "Standard Treatment Guidelines and Essential Medicines List of South Africa". The "Management of type 2 diabetes in adults at primary care level (January 2014)".
Quality and safety requirements	No	N/A
Remuneration scales and hiring practices	No	N/A
Other, please specify	No	N/A

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

A dedicated project team has been appointed with a project manager, a nurse coordinator and field researchers (nurses and clinical associates). The project team is responsible to implement the research programme and conduct planned activities. With a full-time dedicated team, the project will minimise the involvement of local human resources in program implementation. The local human resources will receive training from the project and that will help them to improve service delivery and the provision of diabetes management and care to people with type 2 diabetes.

Local Context, Equity & Sustainability

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

Yes.

TYPE	COMMERCIAL NAME	INTERNATIONAL NON-PROPRIETARY NAME AND/OR INN
Device	—	Blood glucose meters
Medicine	—	Insulin
Device	—	Glucose test strips

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

Yes

- Blood glucose meters.

- Glucose test strips: These will be compatible with the ones that are used in the public health sector in South Africa. The project team still has to decide which brands to purchase. However, the idea is to get brands that could be affordable in the South African public health context.

- Insulin: The project team will purchase the insulin from local providers with the funds received from Eli Lilly. The insulin will probably be Protaphane (human insulin) as it is the one that patients would normally receive from the clinic pharmacy.

21 Health technologies are covered by local health insurance schemes

Yes. Blood glucose meters, glucose test strips, insulin.

22 Program provides medicines listed on the National Essential Medicines List

Yes. Insulin.

23 Sustainability plan

During the design of the project, the sustainability of the intervention was foremost in the minds of the researchers. As a result, Phase V of the project is dedicated to the implementation of the intervention into routine care. During Phase V, the project team will focus on providing technical assistance to health authorities and health professionals to ensure the sustainability of the intervention. Further measures taken to ensure sustainability are:

- a review of the legal and policy framework to make recommendations to health authorities where needed,

- the use of available human resources at the health facilities,

- the rolling out of training workshops for health professionals,

- the organisation of stakeholder meetings throughout the implementation of the project,

- an alignment with existing diabetes management guidelines,

- an involvement of local authorities in the implementation of the project through the Advisory Board.

Additional Program Information

24 Additional program information

[No response provided]

a Potential conflict of interest discussed with government entity

No

25 Access Accelerated Initiative participant

Yes

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

Yes

Resources

1 International Diabetes Federation. IDF Diabetes Atlas, 2017.

2 Statistics South Africa. Mortality and causes of death in South Africa, 2016: Findings from death notification. Pretoria, South Africa: Statistics South Africa, 2018.

3 Hanefeld M. Use of insulin in type 2 diabetes: What we learned from recent clinical trials on the benefits of early insulin initiation. Diabetes & Metabolism. 2014;40(6):391-9.

Program Indicators

Not yet available for this program.

Program Documents

Program Documents

1. Tshwane Insulin Project-Developing TIPS for an optimal glucose control. Program flyer. Available at: https://bit.ly/tshwane

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 are 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.