PROGRAM REPORT

APRIL 2020

Secure The Future Multinational Lung Cancer Control Program (MLCCP)

Bristol-Myers Squibb Foundation

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 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: Bristol-Myers Squibb, Secure The Future - Multinational Lung Cancer Control Program (MLCCP) (2020), Access Observatory Boston, US 2020 (online) available from www.accessobservatory.org

Program Description

Program Overview

1 Program Name

Secure The Future - Multinational Lung Cancer Control Program (MLCCP)

2 Diseases program aims to address

- Cancer (Lung cancer registries)

3 Beneficiary population

- General population

4 Countries

- South Africa
- Swaziland
- Tanzania
- Kenya

5 Program start date

October 01, 2017.

6 Anticipated program completion date

March 31, 2019.

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8 Program summary

Globally, there are approximately 1.8 million new cases of lung cancer per year.[1] Lung Cancer accounts for highest cancer-related mortality globally. Despite this, many African countries lack information regarding the epidemiology of lung cancer and its control. There is also the compounding heavy burden of comorbidities in Sub-Saharan Africa, including HIV and TB. This is the first proposal of a collaboration between 4 African countries on lung cancer across the continent. We propose to develop a lung cancer control program in the specified regions of the four participating countries with emphasis on improvement of access to early diagnostics and addressing the barriers to optimal outcomes.

Contextual introduction:
This is a multinational study covering four countries in sub-Saharan Africa. However, this proposal is mainly focusing on the KwaZulu-Natal (KZN) study sites in South Africa, in line with the federal system arrangement as proposed by the funder: Bristol-Myers Squibb Foundation (BMSF). Therefore, information pertaining to the other three (Kenya, Swaziland and Tanzania) participating countries may not be of sufficient detail.

a. Goal:
The goal of the MLCCP is to improve access to early diagnostic services for lung cancer by addressing the barriers of cancer care through working with communities and the Ministries of Health in the identified regions in the four countries with a potential for scale-up.

b. Project Scope:
The project will span three years and will involve a mix of interventions and evaluations (2 years for South Africa). The overall methodological approach is one of pragmatic studies. Pragmatic studies, as opposed to explanatory trials, seek to answer a research question in the context of usual clinical practice, without requiring extraordinary additional changes.

(continued on next page)

8 Program summary cont.

They have the advantages of being easier to conduct in real-world conditions, and they apply the research question to generalized populations as opposed to explanatory trials, where the intervention is applied in optimal conditions, to highly selected and controlled population.[2,3]

The scope of the overall multinational project covers the following:

1. Assessing the readiness of the health system to prevent and control lung cancers.
2. Identify pathways of care of lung cancer.
3. Identify the enablers to achieving earlier diagnosis.
4. Strengthen hospital-based cancer surveillance/registries.

However, there are some country differences in the manner in which the project will be implemented in each country. For example, in South Africa the project will cover the following four sub-projects:

Project 1: Raising awareness on lung cancer in the communities of KwaZulu-Natal, South Africa and evaluating the impact of oncological services on cancer among the three hospitals in KwaZulu-Natal.

Project 2: To conduct a needs assessment in order to identify facilitators and barriers to lung cancer patient access, referral, diagnosis and treatment in the study settings.

Project 3: Assessing the risk factors associated with lung cancer in the study settings.

Project 4: Assessing the factors determining progressive utilization of palliative care services by patients with cancer (at public and private sectors).

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	Raising awareness on lung cancer in the communities of KZN, South Africa.
Planning	The Program has a series of research questions related to lung cancer burden, risk factors, KAPB, patient pathway and access to care, support and services. This information will inform interventions and also policy and programs by relevant governments.
Mobilization	Community and leadership mobilization to support interventions.

Strategy 2: Health Service Strengthening

ACTIVITY	DESCRIPTION
Training	Strengthen hospital-based cancer surveillance/ registries through trainings. Skills and Capacity Building: The Project aims to result in more than 20 post graduates degrees from young researchers involved involved as Co-PIs or research assistants; 5 PhDs are expected and 15 Masters Degrees across countries. We have adopted a unique strategy of utilizing the program and grants to add to the body of knowledge, improve experts in the topics and fields, improve academic achievement and groom young researchers.
Infrastructure	Improving Bio-banking in Kenya and Tanzania.
Technology	Introducing electronic Data collection and management.

Strategy 3: Health Service Delivery

ACTIVITY	DESCRIPTION
Diagnosis	Strengthening the link and sharing resources utilizing tele medicine especially for radiology Mobile X-Ray units deployed in communities.

Program Strategies & Activities

9 Strategies and activities, cont.

ACTIVITY	DESCRIPTION
Treatment	Kenya and Tanzania partner are fully fledged oncology and radio therapy centers and will treat patients according to existing standard of care.
Retention	Psycho-social support components as well and enhanced palliative care.

10 Strategy by country

STRATEGY	COUNTRY
Community Awareness and Linkage to Care	Kenya, Swaziland, Tanzania, South Africa
Health Service Strengthening	Kenya, Tanzania, Swaziland, South Africa
Health Service Delivery	Kenya, South Africa, Swaziland, Tanzania

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Bristol-Myers Squibb	Sponsor and funder.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Bristol-Myers Squibb Foundation	Sponsor and funder. https://www.bms.com/about-us/responsibility/bristol-myers-squibb-foundation.html	Private
Kenya Ministry of Health	Kenyan Ministry of Health: In all countries the partners have signed MOUs with provincial and/or national governments to provide services. All the projects are undertaken by Teaching and Referral hospitals, Academic Institutions which are extensions of government and public health care provision. The Ministries of Health are also involved in providing ethical approval especially as these project have strong research components. http://www.health.go.ke/	Public
Swaziland Ministry of Health	Swaziland Ministry of HealthIn all countries the partners have signed MOUs with provincial and/or national governments to provide services. All the projects are undertaken by Teaching and Referral hospitals, Academic Institutions which are extensions of government and public health care provision. In case of Swaziland by the Ministry of Health, National cancer registry. The Ministries of Health are also involved in providing ethical approval especially as these project have strong research components. http://www.gov.sz/index.php?option=com_content&view=article&id=267&Itemid=403	Public
Tanzania Ministry of Health	Tanzanian Ministry of Health: Ministry of Health: In all countries the partners have signed MOUs with provincial and/or national governments to provide services. All the projects are undertaken by Teaching and Referral hospitals, Academic Institutions which are extensions of government and public health care provision. The Ministries of Health are also involved in providing ethical approval especially as these project have strong research components. http://www.moh.go.tz/en/	Public
KwaZulu Natal Non-Communicable Diseases Directorate	To develop and implement a sustainable, coordinated, integrated and comprehensive health system at all levels, based on the Primary Health Care approach through the District Health System, to ensure universal access to health care http://www.kznhealth.gov.za/health.asp	Public

Companies, Partners & Stakeholders

12 Funding and implementing partners, cont.

South Africa Ministry of Health	South African Ministry of Health: Ministry of Health: In all countries the partners have signed MOUs with provincial and/or national governments to provide services. All the projects are undertaken by Teaching and Referral hospitals, Academic Institutions which are extensions of government and public health care provision. The Ministries of Health are also involved in providing ethical approval especially as these project have strong research components. http://www.health.gov.za/	Public

13 Funding and implementing partners by country

PARTNER	COUNTRY
Bristol-Myers Squibb Foundation	Kenya, South Africa, Swaziland, Tanzania
Kenya Ministry of Health	Kenya
Swaziland Ministry of Health	Swaziland
Tanzania Ministry of Health	Tanzania
KwaZulu Natal Non-Communicable Diseases Directorate	South Africa
South Africa Ministry of Health	South Africa

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT
Government	Kenyan Ministry of Health: In all countries the partners have signed MOUs with provincial and/or national governments to provide services. All the projects are undertaken by Teaching and Referral hospitals, Academic Institutions which are extensions of government and public health care provision. The Ministries of Health are also involved in providing ethical approval especially as these project have strong research components. Raising awareness on lung cancer in the communities. Community and leadership mobilization to support interventions.
NGO	Community and leadership mobilization to support interventions.
Local Hospitals / Health Facilities	Strengthen hospital-based cancer surveillance/ registries through trainings. Skills and Capacity Building: The Project aims to result in more han 20 post graduates degrees from young researchers involved involved as Co-PIs or research assistants; 5 PhDs are expected and 15 Masters Degrees across countries. We have adopted a unique strategy of utilizing the program and grants to add to the body of knowledge, improve experts in the topics and fields, improve academic achievement and groom young researchers. Improving Bio-banking in Kenya and Tanzania.

Local Context, Equity & Sustainability

15 Local health needs addressed by program

Lung cancer is the most common cancer worldwide, and disproportionately affects developing countries where over 58% of cases occur. This however is in sharp contrast with low incidence rates of lung cancers reported in Africa (7.7 per 100,000 in men and 2.6 per 100,000 in women, respectively).[4] This apparently low burden of lung cancers in the context of critical lack of accurate data, likely reflects enormous underestimations of the true burden, considering the high prevalence in the African setting of some major risk factors for lung cancer,[5] such as pulmonary tuberculosis and HIV infection. Indeed, most African countries lack nationwide or regional population-based cancer registries, and have no reliable source of mortality data.[4,6]

The epidemiology of lung cancer is largely unknown in Africa, reflecting until recently, the low priority given to cancer and non-communicable diseases (NCDs) research in this setting. In most African settings, there is low cancer awareness, uncoordinated or absent screening services, late cancer diagnoses, when therapeutic solutions, where available, are less likely to be effective.[7] In addition, cultural beliefs in these settings influence health seeking behavior, with patients with warning signs and those with clinical signs suggestive of cancer or diagnosed with cancer resorting to alternative medicine either preferentially, or in parallel with modern medicine.[7] For example, the number of lung cancer cases reported from 2 of the collaborating centers (Eldoret in Kenya and Mwanza in Tanzania), over the preceding period was extremely small, for Eldoret-Kenya only 53 cases 2011-2014 and for Mwanza 69 cases over 5 years. All these factors have contributed to lack of a true burden estimation in this region, which this program will address.

a How needs were assessed

[No response provided]

b Formal needs assessment conducted

[No response provided]

16 Social inequity addressed

Yes. Globally, there are approximately 1.8 million new cases of lung cancer per year. Lung cancer accounts for highest cancer-related mortality globally. Despite this, many African countries lack information regarding the epidemiology of lung cancer and its control. There is also the compounding heavy burden of comorbidities in Sub-Saharan Africa, including HIV and TB. This is the first proposal of a collaboration between 4 African countries on lung cancer across the continent. We propose to develop a lung cancer control program in the specified regions of the four participating countries with emphasis on improvement of access to early diagnostics and addressing the barriers to optimal outcomes.

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

Collaboration, involvement and participatory approaches have been the key to our Program. The KZN Non-communicable Diseases Directorate, Research directorate, and CEOs of the health facilities are in support of the Program. Local policies, practices and law has been taken into consideration. The Program is in line with the country policies.

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 response provided]

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

Wish to leave blank at this time.

Additional Program Information

24 Additional program information

Not at this time. The program was only recently launched, so perhaps when more data/information is available, it can be further reported upon.

25 Access Accelerated Initiative participant

Yes.

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

Yes.

Resources

1. World Cancer Research Fund International. (n.d.) Lung cancer statistics. Retrieved from https://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/lung-cancer-statistics.
2. Ford, I,, & Norrie, J. (2016). Pragmatic Trials. New England Journal of Medicine. 375, 454-463.DOI: 10.1056/NEJMra1510059
3. Patsopoulos, N. A. (2011). A pragmatic view on pragmatic trials. Dialogues in Clinical Neuroscience, 13(2), 217–224.
4. Ferlay et al., 2015. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. Int J Cancer. 136(5):E359-86. doi: 10.1002/ijc.29210. Epub 2014 Oct 9.
5. Siegel, K., Naishadham, D., and Jemal, A. (2012). Cancer statistics, 2012. CA: A Cancer Journal for Clinicians, 62 (1), 10-29.
6. Joubert, J., Rao, C., Bradshaw, D., Dorrington, R. E., Vos, T., & Lopez, A. D. (2012). Characteristics, availability and uses of vital registration and other mortality data sources in post-democracy South Africa. Global Health Action, 5, 10.3402/gha.v5i0.19263. http://doi.org/10.3402/gha.v5i0.19263
7. Nanguzgambo, A. B., Razack, R., Louw, M., Bolliger, C. T. (2011). Immunochemistry and lung cancer: Application in diagnosis, prognosis and targeted therapy. Oncology, 80, 247-256

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 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.