Protocol for the Costing of MALTEM in Magude District, Mozambique

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Version 03: June 29th, 2015

ABREVIATIONS

ANC ï antenatal care BMGF - Bill & Melinda Gates Foundation

CISM- Manhiça Health Research Centre

DHS ï Demographic and Health Survey

GDP - Gross Domestic Product

IPTp - Intermittent Preventive Treatment for Pregnant women

IRS - Indoor Residual Spraying

ITNs - insecticide treated nets

MALTEM- Mozambican Alliance Towards the Elimination of Malaria

MDA- Mass Drug Administration

MISAU - Mozambican Ministry of Health

MOH ï Ministry of Health

NMCP ï National Malaria Control Program

OR - Operational Research

RDT- Rapid Diagnostic Test

SUMMARY

A crucial element for the successful completion of MALTEM program and its potential scale up is the development of a fully costed, targeted, evidence-based elimination plan for Southern Mozambique. Conducting cost analyses alongside program implementation will provide useful information on the sustainability and affordability of the approaches to malaria elimination as well as be used to estimate the comparative cost-effectiveness of different strategies.

This study will estimate costs associated with malaria elimination activities in the district of Magude and will model these costs, in accordance to economic theory principles, to the whole South of the country. These costs will be compared with malaria control costs to identify potential savings of resources associated with malaria elimination, in the medium/long run. In addition to costs, it is fundamental to reply to the following questions: Is malaria elimination (by comparing the costs of malaria elimination vs. costs of malaria control activities implementation and estimating the quantity and value of additional resource requirements to achieve malaria elimination), financially affordable and sustainable over the next 10 years?

This study includes an estimate of the affordability and of financial sustainability of malaria elimination.

BACKGROUND/RATIONALE

Mozambique is one of the 10 highest-malaria burden countries in the world, with parasite prevalence ranging from 3 to more than 50%. Although large drops in transmission can be achieved in a limited timeframe, indoor residual spraying and case management alone are not sufficient to attain elimination (Okumu et al, 2011). Based on this evidence, MALTEM program will provide technical, operational and financial support to design and scale up new strategies for the Mozambican National Malaria Control Program (NMCP) to achieve elimination in Maputo and significantly decrease malaria transmission rates in Gaza and Inhambane provinces by 2020.

Within this context, a rigorous costing analysis needs to be carried out in order to assess the viability of MALTEM strategies and guarantee the financial sustainability of the project. Moreover, modelling approaches will be used in order to estimate the economic benefits of malaria elimination in Southern Mozambique, including not only the direct health impact, but the economic and social benefits.

In order for these cost analyses to be comparable and global lessons to be drawn, it is important for costing methods and definition to be consistent across the various country-level studies focused on malaria elimination that are taking place. As a consequence, the costing of MALTEM program is based on the economic evaluation approach methods that the BMGF funded malaria elimination studies used in different countries, which are compiled in a report (Levin A).

OBJECTIVES

General objective

To generate information on the financial sustainability and affordability associated with malaria elimination in Mozambique that could be used by policymakers in taking decisions

Specific objectives

1. To estimate the cost of achieving malaria elimination through the strategies tested in MALTEM program.
2. To estimate the cost of continuing with the **standard activities for malaria control** (including prevention and treatment) in the district of Magude.
3. To assess the **affordability** of achieving malaria elimination beyond the district of Magude, by comparing the costs of malaria elimination vs. costs of malaria control activities implementation and estimating the quantity and value of additional resource requirements to achieve malaria elimination.
4. To estimate malaria elimination **financial sustainability**.

METHODS

Study Area:

The malaria elimination plan will take place in Magude District, on the North-Western area of Maputo Province, Southern Mozambique. Magude District borders with the district of Massingir (Gaza Province), in the North, Manhiça District and the province of Gaza (Chokwe and Bilene Districts) on the East, Moamba District in the South, and the South African Kruger National Park on the West. It has an area of 6,961 km2, with approximately 60,000 individuals and 11,408 family compounds. The district has seven health facilities with a total of 43 beds (1.65 beds per 1,000 inhabitants) and reported 20,000 malaria cases per 100,000 population at risk in 2012.

Manhiça district will be used as a comparator area for the analysis of the interventions and variables of interest. Manhiça, located 80km north of the capital, Maputo, is a semi-rural area, with a population of 165.497 habitants. As of 2013, malaria remains one of the main causes of under-five morbidity and mortality in the district.

Study Design: This study consists of collecting administrative data (expenses data associated with the elimination of malaria in the district of Magude) and in extrapolating this information, though a predefined model, beyond the district. In addition, the study consists in elaborating information on the costs of malaria control also from administrative sources (e.g. documents of the National Malaria Control Program) and from estimates already published referring to the district of Manhiça.

Study Population: This study does not include the collection of data from the population as both administrative and data published in scientific journals will be used. However, the study refers to the population of the district of Magude (all the population, including children and adults) and the whole country population in component of extrapolation of the estimates to the national level.

Timing and duration of the study: The study will start in July 2015 and will end just after the finalization of elimination activities, including post-elimination, in the district of Magude**.** Only at the end of these activities it will be possible to identify all the costs associated with malaria elimination.

Data Collection and Management: This study does not include individual level data collection. Only administrative data will be collected from the administration department of the CISM, from documents of the ministries and of the national malaria control program and from published sources. Data collected will be organised in Excel spreadsheets.

Data analysis: Data analysis will be performed in Excel spreadsheets. Simulations for probabilistic sensitivity analysis will be performed in Visual Basic within Excel.

Ethics clearance:

The protocol, consent forms and questionnaires will be approved by the CISM Institutional Ethics Review Board, National Ethics Committee of Mozambique and the Ethics Committee of the Hospital Clínic of Barcelona before its implementation.

Confidentiality:

All information on individuals will remain confidential and be shared only by the study team. Unique identifiers will be used for computer-based data entry. In all cases, the principal investigator will ensure that the completed identification code list are kept in locked files.

METHODOLOGY SPECIFICATION by OBJECTIVE

The following section outlines the main approaches that will be used when defining and implementing the costing processes for each of the objectives outlined in the previous section, as well as the economic models of reference, key sources and indicators that will be taken into consideration.

Objective 1: full cost analysis of achieving elimination

A micro-costing approach (also called ingredient or bottom-up) will be applied (Gold M, et al, 1996) as suggested by the BMGF for the estimated of costs of malaria. To conduct this type of costing, the resources used for every activity (*a*) carried out for malaria elimination will be identified and a unit cost will be attached to each resource within each activity. Activities (*a*) will be: pulverization, mass drug administration, epidemiological and entomological surveillance and monitoring, etc The quantity of each resource (*Q*i) will be multiplied by their unit costs (*P*i) for each activity. Resources (*i)* will be: human resources (e.g. health workers involved in mass drug administration); drug and other medical costs; transportation costs, etc. Capital costs will be also taken into account (e.g. cars) and annualized. Total costs associated with malaria elimination activities (T_{me}) at time *t* will be $T_{me} = \sum_{a} \sum_{i} (Q_i * P_i) * \frac{1}{(1+r)^t}$ where *r* is the interest rate (which will allow to discount future costs) and *t* is time in years. The costing will build on an existing model used for estimate the costs of malaria elimination activities in Lihir Islands (Alonso S, Sicuri E, 2014).

Information on activities and on Qi and Pi per each activity will be mainly taken from documents and information on MALTEM, particularly from the expenses budget. A strict collaboration with the administration department of the CISM will allow to record in the most precise possible way, all the quantities and the unit costs associated for each of the activities undertaken as part of the MDA and of the other elimination activities. Resources for each activity will be recorded in the expenses budget, no matter the entity that pays (the CISM, the MoH or the NCMP). However, information on the entity that covers the expenses will be also recorded. Both Qi and Pi, for each

resource, will be discussed with the MALTEM team to evaluate if and at which extent the values are study specific or can be extrapolated beyond the MALTEM study. As an example, the cost of drugs used for MDA can be higher in the context of the study compared with the cost of same drugs as part of a wide health programme in which international buyers (such as the Global Fund) negotiate either with international importers or directly with the producer. The uncertainty of parameters such as drug costs will be managed through probabilistic sensitivity analysis (see below). In addition, from the MALTEM expenses budget, costs associated with research and not directly with the implementation of the elimination strategy, will be withdrawn.

Overhead costs (=costs that are general for the institution and not directly imputable to malaria elimination activities only) will be also recorded and imputed following step-down allocation criteria (Conteh et al, 2004).

Further sources will be the following:

- International drug price guide: https://www.msh.org/blog/2013/07/08/new-international-drug-price-indicator-guide-now-available
- Global fund drug procurement prices: http://www.theglobalfund.org/en/procurement/pqr/

Other fundamental references for costing will be a previous costing of malaria elimination (Sabot et al, 2010) as well as a paper under revision of Kim et al (upcoming). Although the latter is not focused on malaria but on onchocercasis, the methodology used can be easily adapted to malaria elimination**.**

Financial vs. economic costs

Costs will be split into financial and economic (see table 1) (Philips M, et al, 1993). We define financial costs as the value of those resources that imply a monetary manifestation. The estimate of these costs provides an indepth understanding of money flows and of who is in charge of payments. They provide an overview of the financial resources required for the intervention, the extent to which budgets have been actually utilized, the relative inputs of the key contributors and the relative significance of foreign exchange and local currency demands. Economic costs measure the value of all resources employed in the intervention (both monetary and non-monetary). For example, volunteer work used in malaria elimination activities (eg: community health workers) will be treated as an economic cost but not as a financial cost. The current analysis takes an economic and health system perspective and thus, aims at estimating not only the financial costs but also the economic ones (UNAIDS, 2000).

Table 1. Financial Costs vs. Economic Costs

	Financial Costs	**Economic Costs**
Description	Expenditure on the intervention (the usual lay use of the term 'cost')	Value of the opportunities lost in employing resource in the intervention
Costs included	Inputs purchased	All resources employed in the intervention, including voluntary labour
		Excludes money transfers which do not reflect resource consumption
Valuation	Market price of purchased goods	Shadow prices are employed if market prices do not reflect the opportunity cost of resources.
Perspective	Can be any defined individual or organization	Usually a societal perspective. Ideally consumer costs should also be included (eg the time or money employed in adopting control measures)
Purpose	Shows the funds required to cover costs and whether the intervention is affordable	Shows (together with measures of effectiveness) whether the intervention is efficient

Main Steps for costing analysis

- Identify the different working units within the project (i.e. entomology, epidemiology, health economics, M&E, research, advocacy, administration, operations)
- Define the main activities to be costed under each working unit (i.e. Supervision, training, staff, surveillance, , mass drug administration, etc.) as well as those that are transversal across units
- Identify the costing inputs that are needed to cost each activity
- For each costing input, identify the specific data requirements as well as main data sources (table 2)
- Define the costing outputs and indicators that will be obtained from the costing process. The costing indicators are usually aligned with the objectives of the project, so they are better defined and classified by intervention (i.e. case management, MDA, IRS) (table 3)

Table 2. Costing inputs

Inputs	Data Requirements	Sources for unit costs (pi)
Salary	Gross salary plus benefits Working days per year Number of hours worked per day % time spent on malaria elimination activities	Government records NGO personnel records
Worker per diems	Per diem by type of community health worker and location	Government records NGO personnel records
Commodities	RDTs Drugs ITNs	Essential drug lists Government procurement lists International price lists
Supplies	Insecticides Mobile phone talk time Blood Slides and other lab resources Stationery	Essential drug lists Government procurement lists International price lists Local price surveys
Transportation	Fuel Maintenance Travel Allowance for outreach	Government records NGO records
Print Items	Printing of brochures Radio and Television spots	Local price surveys
Equipment	Microscopes Vehicles Compression sprayers Personal protective equipment Mobile phones	Essential drug lists Government procurement lists International price lists

Cost projection

The process for eliminating malaria has different phases (control, pre-elimination, elimination and prevention of reintroduction), and each phase is defined by a set of specific programme interventions. We expect that the first years the elimination plan will require important resources compared to the malaria control plan, but after the elimination plan is completed, costs will shrink sharply, while expenditures for malaria control plan might remain stable across years.

Costing the MALTEM study will correspond to estimating the cost of achieving the elimination of malaria if the campaign is successful and then the post-elimination phases. However, in the case that malaria will not be eliminated, the costing model will include a projection of how many additional resources and relative costs, achieving malaria elimination will imply. On one side, epidemiologists, clinicians and other researchers of the study will help drawing different scenarios on how malaria transmission and incidence might progress over time. On the other side, they will help

identifying which and the magnitude of the lack of resources that impede the achievement of the full elimination. The interventions will then be costed and projected in time according to different scenarios drawn in strict collaboration with the MALTEM team.

Table 3. Costing outputs by intervention

Intervention	**Output indicator**	**Cost per output indicator**
Case management	*Patient diagnosed* *Patient diagnosed and treated (Should reflect outpatient treatment, diagnosis and cost of medicines)* *Uncomplicated case treated* *Severe case treated*	*Cost per patient diagnosed* *Cost per patient diagnosed and treated (Should reflect outpatient treatment, diagnosis and cost of medicines)* *Cost per uncomplicated case treated* *Cost per severe case treated* *Total cost of case management*
ITNs	ITNs distributed (total and delivery cost only) Treated net/year Person protected per year	Cost per ITN distributed (total and delivery cost only) Cost per treated net/year Cost per person protected per year Total cost of ITN distribution
IRS	Sprayed room Spray round per person Person protected per year	Cost per sprayed room Cost per spray round per person Cost per person protected per year Total Cost of IRS program
Mass drug administration or mass testing and treatment using RDTs and ACTs	Person tested per round Person treated per round	Cost per person tested per round Cost per person treated per round Cost per person living in the area Total cost per mass drug administration or mass testing and treatment

Objective 2: costs of continuing with the standard activities for malaria control (including prevention and treatment)

Continuing with the current control malaria activities is the alternative strategy that may be implemented in the Magude district instead of elimination. These costs will be estimated based on the assumption that malaria may be eliminated even without

implementing malaria elimination specific activities, thus through control activities only. However, time taken to eliminate malaria under control activities will be longer than time necessary under elimination activities. Costing malaria control activities will be a key piece of information for the estimate of the benefits (=cost savings) consequent to the elimination of malaria in the area. Resources needed for malaria control (including prevention and treatment) will be estimated based on the baseline malaria information from the district (prevalence, incidence) and the demographic information (how many children, how many pregnant women, etc). Resources and costs associated with the prevention and treatment of malaria under the malaria control scenario (IPTp, ITNs, treatment with ACTs, etc) will be done based on previous estimates in a neighboring area (Sicuri E et al, 2010; Conteh L et al, 2010; Chase C et al, 2009).

- Prevention costs

Annual costs will include the costs of providing IPTp at every ANC visit during pregnancy (as recommended by the WHO) to pregnant women. The average number of ANC visits will be derived from most recent Demographic and Health Survey in the country. The number of pregnant women, per year, will be derived from the information from the census in Magude. The cost of ITNs will be equal to 1 ITN given each to each pregnant woman plus the estimated costs of ITNs delivery.

Annual costs for IRS will be estimated based on information from the Government, in terms of quantity of resources used, number of times the strategy is implemented per year in the district and unit costs.

- Treatment costs

The number of treatments per year will be derived from the malaria cross section of Magude and from the census carried out in the district.

Control activities, both prevention and control, will be assumed to be performed according to different scenarios, according to the number of years needed to eliminate malaria even just by carrying out control activities:

1. Malaria eliminated in 10 years;
2. Malaria eliminated in 20 years;
3. Malaria eliminated in 30 years.

Objective 3: affordability of achieving malaria elimination beyond the district of Magude

Scaling-up model

The costing model estimated for the Magude district will be scaled up to the South of the country initially and to the whole country in order to assess the potential resources needed if malaria elimination interventions would be extended. There is growing evidence of scale variation among the costs of health interventions, so average costs may become larger or smaller as the volume of services expands. Thus, economic frameworks examining costs and variation by scale will be considered as reference and used for the analysis (Bishai D et al, 2006; Kumanarayake L, 2008; John B et al, 2005).

Costs of scaling up will be derived from the costs of malaria elimination in Magude. Key parameters of the costs evaluated for the elimination activities in Magude will be changed and translated into specific parameters for other areas. As an example, should elimination activities be carried out in a bigger and more populated district with the same level of malaria as Magude, higher transportation costs will be incurred; a higher number of community health workers for drug administration will be needed, and so on.

In addition to an analysis of how parameters can change when a local to a larger level, the costs of scaling up will be guided also from standard economic theory, as it has been done already for HIV/AIDS (Alistar et al, 2012). More specifically, we will base our estimates on a production function in which the output is the number of malaria cases averted (or the intensity of malaria, measured in terms of incidence or prevalence) (Q) and the inputs are the resources used to achieve a certain level of Q, summarized in quantity of labour (L) and quantity of capital (K). Labour is given by the quantity of human resources involved in malaria elimination activities and K will be the capital goods (cars, durable goods) and supplies. The shape of the production function will be analyzed from data collected in Magude. This will be done through parameterization of a few potential functional forms for the production function (Annabi N et al, 2006).

Should the shape of the function be a standard one (Cobb-Douglas) this will the equation (functional form):

$$Q=f(K,L)=K^{\breve{U}}*L^{1-\breve{U}}$$

where Ŭ is a factor determining the productivity of the production process. Ŭ is a key parameter in this analysis as it determines how much input (L and K) is necessary to

achieve the desired level of Q. We will assume Ŭ to be constant for the whole country and at different levels of the analysis of scale-up, meaning that labour and capital have the same productivity in Mozambique in different areas of the country and both at local and national level. This parameter will be estimated based on the resources used and the outputs achieved in the malaria elimination programme in Magude.

In a context of malaria elimination the desired number of cases or other measures of malaria should be either zero or close to zero; thus Q (number of cases averted) will take different values at different scales (local, regional, national).

Total costs (TC) will be given by pk*K + pl*L, where pk is the unit cost of capital and pl is the unit cost of labour.

Costs associated with the scale up of malaria elimination activities, will be based on the following assumed constrained objective function:

Min (pk*K + pl*L)

s.t. Q=N where N would bring the number of cases down to zero.

meaning that the objective function is to minimize the costs associated with malaria elimination subject to the output (number of malaria cases averted) be equal to a number that would allow to have zero malaria cases.

The analysis of this minimization problem will provide a costing function that will allow to measure costs consequent to extend malaria elimination activities to larger scale (with higher levels of both input parameters K and L).

Objective 4: malaria elimination financial sustainability

The analysis will provide estimates of the financial requirements to sustain the project in time but also an assessment of the probability of meeting these requirements. Financial sustainability in time is crucial for the high risk of failure associated with malaria elimination. If the first strategies employed should not work, despite the high costs, new strategies will need to be implemented, implying strong need of constant levels of investment in time.

To assess financial sustainability, the total costs of scaling up to either to the south or to the whole country will be compared with several budget indicators describing the availability of financial resources in the country:

1. The total annual governmental health budget;
2. The total annual governmental budget for malaria and for other major diseases
3. The total annual GDP in the country and its composition;
4. The total amount of aid received for health and overall.

The comparison between the total costs of eliminating malaria and these figures will provide an idea of the availability of resources and of the gaps in resources available versus the financial needs.

Probabilistic Sensitivity Analysis

Uncertainty about costs and some variables (interest rate, inflation, taxes, etc.) across time needs to be taken into account and Probabilistic Sensitivity Analysis (PSA) has become one of the most important tools to capture it. To this end, program costs as well as important economic variables, would be considered as deterministic estimations with a certain value but will be modelled in order to reflect their exposure to random and external events that affect them, in an unpredictable way. In this way, probabilistic sensitivity analysis provides a useful technique to quantify the level of confidence that a decision-maker has in the conclusions of an economic evaluation.

Probabilistic sensitivity analysis will be carried out by assigning to the parameters included in the model a probability distribution (Briggs et al, 2012). Monte Carlo simulations will allow obtaining results (costs) with 95% confidence intervals.

WORK PLAN

	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Development of protocols													
Preparation and data collection (pre-post MDA)													
Data management and analysis													
Study completed (1st phase)													
Study completed (2nd phase)													
Results dissemination													

BUDGET

Item	Total (in USD)
Field data supervisor cost	**3.000**
Office Material	**1.500**
Transport and fuel (field work activities)	**2.500**
Publication costs	**5.000**
Communications	**500**
Data entry and analysis	**5.000**
Total direct costs	**17.500**

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