COSTING GUIDELINES FOR TUBERCULOSIS INTERVENTIONS

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VALUE TB
ESTIMATING THE COSTS OF TB SERVICES
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ABBREVIATIONS

3HP	three months of once-weekly isoniazid and rifapentine
6H	isoniazid for six months
ACF	active case finding
ALT	alanine aminotransferase
ART	antiretroviral therapy
AST	aspartate aminotransferase (also known as SGOT)
BCG	Bacille Calmette-Guérin
BMI	body mass index
COPD	chronic obstructive pulmonary disease
CPI	consumer price index
CT	computed tomography
CXR	chest x-ray
DOTS	directly observed therapy, short-course
DR	drug-resistant
DS	drug-susceptible
DS-TB	drug sensitive tuberculosis
DST	drug susceptibility testing
ECG	electrocardiography
EPTB	extra-pulmonary tuberculosis
FLD	first-line drugs
FTE	full-time equivalent
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHCC	Global Health Cost Consortium
H	isoniazid
HCW	health care worker
HEU UCT	Health Economics Unit, University of Cape Town
HMIS	health management information system
HR	human resources
ICF	intensified case finding
IEC	information, education and communication
IGRA	interferon-gamma release assay
INH	isoniazid
IPD	inpatient department
IPT	isoniazid preventive therapy
KEMRI	Kenya Medical Research Institute
KEMRI-WT	Kenya Medical Research Institute Wellcome Trust
LAMP	loop-mediated isothermal amplification
LED	light-emitting diode
LF-LAM	lateral flow urine lipoarabinomannan assay

LJ	Lowenstein-Jensen
LPA	line probe assay
LSHTM	London School of Hygiene and Tropical Medicine
LTBI	latent tuberculosis infection
M-health	mobile-health
MCH	maternal and child health
MDR	multidrug-resistant (resistant to both rifampicin and isoniazid)
MDR-TB	multidrug resistant tuberculosis
MGIT	mycobacteria Growth Indicator Tube
NCDs	noncommunicable diseases
NGOs	non-governmental organizations
NTLP-P	National Tuberculosis, Leprosy and Lung Disease Program
NTP	National Tuberculosis Programme
OPD	outpatient department
PCF	passive case finding
PCR-DNA	polymerase chain reaction – deoxyribonucleic acid
PI	principal investigator
PMT	payment function
PPD	purified protein derivative
PTB	pulmonary tuberculosis
R	rifampicin
RBC	red blood cell
RBS	random blood sugar (also known as random blood glucose)
S	streptomycin
SGOT	serum glutamic-oxaloacetic transaminase (also known as AST)
SGPT	serum glutamic-pyruvic transaminase (also known as ALT)
SLD	second-line drugs
TB	tuberculosis
TST	tuberculin skin test (also known as PPD Mantoux test)
UHC	Universal Health Coverage
UNICEF	United Nations Children's Fund
USD	United States dollars
UV	ultraviolet
WBC	white blood cell
WHO	World Health Organization
XDR-TB	extensively drug resistant tuberculosis
Xpert® MTB/RIF	Xpert mycobacterium tuberculosis/rifampicin resistance
Z	Pyrazinamide
ZN	Ziehl-Neelsen

SECTION A. INTRODUCTION

BACKGROUND

Substantial progress has been made in the past decade to improve tuberculosis (TB) outcomes and control, particularly with the development and implementation of new diagnostic tests and treatment regimens *[1–3]*. Addressing the global TB epidemic is in line with the goals of Universal Health Coverage (UHC) to provide health care for all, without financial adversity. However, funding for TB still needs to be increased in order to reach global targets. Estimating the costs of TB interventions is an essential component to planning, prioritizing and managing the funding of TB services *[4]*.

The 'Reference Case for Estimating the Costs of Global Health Services and Interventions' *[5]* (referred to hereafter as the 'Reference Case') encourages consistent adherence to core principles when collecting data to estimate the costs of health services. As a guiding document, it also presents the different costing methodologies that can be utilized, indicating the strengths and weaknesses of each, and provides a set of principles to improve global health costing. In this set of guidelines, we draw on the Reference Case principles to outline the main steps for costing TB services. Researchers can develop specific protocols which draw from these steps depending on the purpose of their costing study. For example, cost methods may vary depending on the time available, size or scope of a study.

Throughout this document, we use the Value TB Study as an illustration of how a TB costing study can be undertaken. Value TB was funded by The Bill and Melinda Gates Foundation (https://datacompass.lshtm.ac.uk/817/). The purpose of the Value TB Study was to assess the service delivery costs of all TB interventions in five countries (Kenya, Ethiopia, India, Philippines and Georgia) in order to update current data and inform users of the cost data, such as modellers and policy makers. The primary aim of Value TB was to enable National Tuberculosis Programmes (NTPs) and their funders to allocate their resources, both to and within TB, in an efficient and fair way. We also include a set of costing instruments called the *Value TB Costing Tool Suite* (including Data Collection and Data Entry components) which can be adapted depending on the costing protocol developed. The complementary *Value TB Costing Tool Suite* can be found on the Global Health Cost Consortium (GHCC) and World Health Organization (WHO) websites (https://ghcosting.org/ and https://www.who.int/tb/publications/en/), and a detailed explanation of these tools can be found in **Appendix 8** of these guidelines.

AIM OF THE GUIDELINES

The aim of these guidelines is to provide a step-by-step guide for those who need to conduct primary data collection to estimate the cost of delivering TB interventions and produce a standard set of unit costs. These guidelines take the reader from protocol design to cost data analysis. They provide practical advice on how to collect cost data for specific chosen purposes, perform analysis and disseminate data. These guidelines do not cover how to assess cost savings for TB interventions over time, as the focus of the guidelines is the production of unit costs through a cost analysis rather than undertaking economic modelling. They also do not touch on assessing cost-effectiveness of programmes or interventions, or the analytics required to produce cost functions. Rather, they assist with the collection and estimation of a standard set of unit costs as this relates to making estimates of economics costs, setting budgets, financial planning, understanding TB programmes and responding to the introduction of new technologies as they emerge. Several guidelines have previously been developed for TB costing. This set of guidelines specifically updated and built on existing work by Floyd *[6–9]*.

Who should use these guidelines?

These guidelines are intended for experienced producers of cost data who may know less about how to cost TB services. This manual is TB-specific and allows costing work to be adapted to context and purpose. While this guidance can be used for those who have not costed health services previously, where this is the case we would advise using the Reference Case as a complementary resource *[5]*.

The primary user may be the **costing coordinator** based in the NTP, a primary investigator or a manager at a facility. For the co-ordinator of studies, particular reference should be made to **Section C – Study Design and Set Up**. **Section C** covers the necessary steps in establishing the study, including defining the purpose of the study, setting up a study team to perform the data collection and analysis, gaining ethical approval and establishing the study aims and objectives. This guidance is also designed to support **those collecting data in the field**. In this case, the focus should be on **Section D**, which highlights the important aspects in TB cost data collection, including understanding the production process, adapting the Data Collection Tool, mapping data sources and measuring resource use.

Structure of the guidelines

The guidelines are structured into the following stages in a costing study: **pre-data collection activities** (initial conceptualization, defining the interventions, setting up country links/selection of study partners, establishing country teams, study protocol formation and submission of protocol for ethical approval, training and piloting); **data collection** at the facility level (and the community level if required), data collection at above-facility level; and **post-data collection activities** (data analysis, preparation of reports, papers and a publicly accessible database, dissemination of data). Accordingly, the guidelines have the following four sections:

Section B: Defining the TB Interventions to be costed

This encompasses a brief overview of TB interventions, with additional detail in **Appendix 2**.

Section C: Study Design and Set Up

Section C focuses on study design aspects and how to set up a TB costing study, highlighting key steps in the process.

Section D: Data Collection: Resource and Service Use Measurement; Pricing and Valuation

Section D outlines the features of data collection and the production process, details costing approaches and provides an introduction to the *Value TB Costing Tool Suite*. These features include: the scope, methods, sampling, data sources, timing of data collection and adjustments to data.

Section E: Data Analysis, Presenting Results and Dissemination of Cost Data

Section E speaks to the data analysis stage where one assesses the unit costs that have been generated. It also addresses the need to look at the drivers of cost, variation in costs, sensitivity analyses one may want to undertake to assess uncertainty and how to disseminate this information effectively in a transparent manner to the users of TB unit costs.

Additionally, appendices can be found in the final section:

Section F: Appendices

Appendix 8 describes the corresponding *Value TB Costing Tool Suite*, how to make best use of these tools and how to adapt them to specific contexts.

Appendix 11 provides case studies to illustrate steps for learning how things are practically and pragmatically done when costing TB services.

SECTION B. DEFINING TB INTERVENTIONS

STANDARDIZED UNIT COSTS FOR TB INTERVENTIONS

In order to enable cross-country comparisons of TB costs and extrapolate costs across settings, it is important to develop a set of standardized unit costs for TB services. This was done as part of the GHCC, contained here in **Appendix 3** *[5]*. **Appendix 3** outlines the main TB intervention categories (under the heading *Intervention*), intervention details and standardized cost units that should be reported.

The main classes of intervention for TB are:

A. Vaccination (which includes Bacille Calmette-Guérin (BCG) Vaccination)

B. TB case detection and diagnosis, which includes the intervention types of passive, active and intensified case finding (PCF, ACF and ICF)

C. TB treatment

D. TB prevention

E. TB infection control

F. TB programme above site services (which comprises policy, planning, coordination and management for TB services)

Over time there may be further adoption of future technologies and thus interventions to be included, for instance if new vaccine candidates are developed.

To ensure comparability of costs, **Appendix 3** also provides details of different options for intervention implementation, including: an open field for any specific intervention modality (e.g. centralized, decentralized etc.), the technologies utilized for that particular intervention (such as first line treatment, or type of diagnostic), the delivery platform ownership and type (such as private facilities, public clinics and hospitals), and the population that is covered, for instance adults with pulmonary TB, HIV comorbidity or children (which can be further separated into demographic and clinical details). For TB treatment, the particular phase should be indicated (start-up, implementation, intensive or continuation). If a new intervention for TB care emerges and requires costing, it should be described in a similar manner (platform, population covered etc).

For each intervention, a standardized unit cost is presented (unit cost per recipient/person reached) in order to standardize the outputs of TB costing studies to provide comparability and generalizability. Further breakdowns of unit costs are indicated: an optional quality adjusted unit cost per recipient, and unit costs for the list of outputs required to deliver the intervention or services. The activity and other total cost breakdowns, input category breakdown and mandatory reported inputs are listed by intervention.

Fig. 1. Standard unit costs

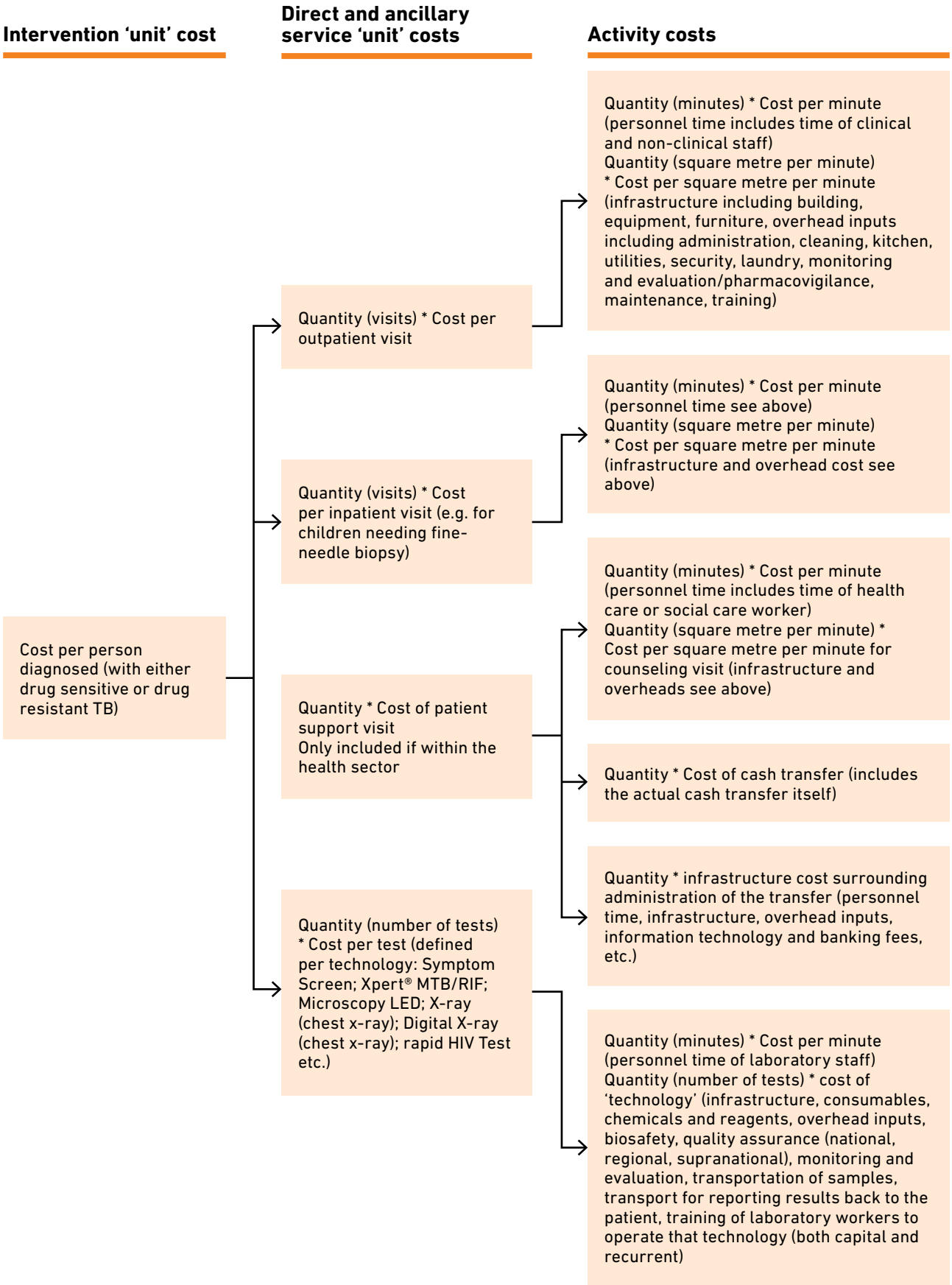


Figure 1 shows one diagrammatic example of a unit cost per recipient for PCF (from **Table 3**, **Appendix 2**). It explores the possible activities that make up the direct and ancillary unit costs in term the intervention unit cost.

When starting a costing study, it is important to describe the intervention and all the outputs and inputs required to produce the intervention (the production process). For example, in the instance of TB Treatment (**Table 1**), one would first define the intervention unit costs e.g. the Cost per person completing treatment for children with pulmonary TB having taken first line treatment in the context of a hospital delivering TB care). This intervention 'unit' cost can be broken down into the direct (mean cost per output) and ancillary (mean cost per additional output that supports the delivery of health services). The direct and ancillary service 'unit' costs can be further broken down into activity costs, which are the costs for each action required to provide services. The activity costs are in turn determined by the quantity of input multiplied by price (see **Table 3** in **Appendix 2**).

To cost an intervention, it is necessary to understand and describe this production process and build up the cost from the different components to ensure the cost is not biased. Much of the work of costing involves describing this detail, often together with TB service planners. For instance, for drug sensitive TB (DS-TB) treatment, one needs to include the cost of all the capital items/assets or providing outpatient visits (building, training, vehicle, equipment and furniture unit costs) to the recurrent cost per visit (overhead utility costs and staff costs). The cost per DS-TB treatment visit is then added to the diagnostic test cost per DS-TB treatment case and then the drug cost per DS-TB treatment case. To determine the total cost of treating a DS-TB case, the cost per visit would be multiplied by the average number of visits made added to the diagnostic test cost and drug costs multiplied by the number of tests performed and drugs received respectively. Generic descriptions of the TB interventions are given in **Appendix 2** which can be adapted as needed to define the interventions in the setting selected.

Table 1. Sample of Annex 3 from Reference Case *[5]* for TB treatment

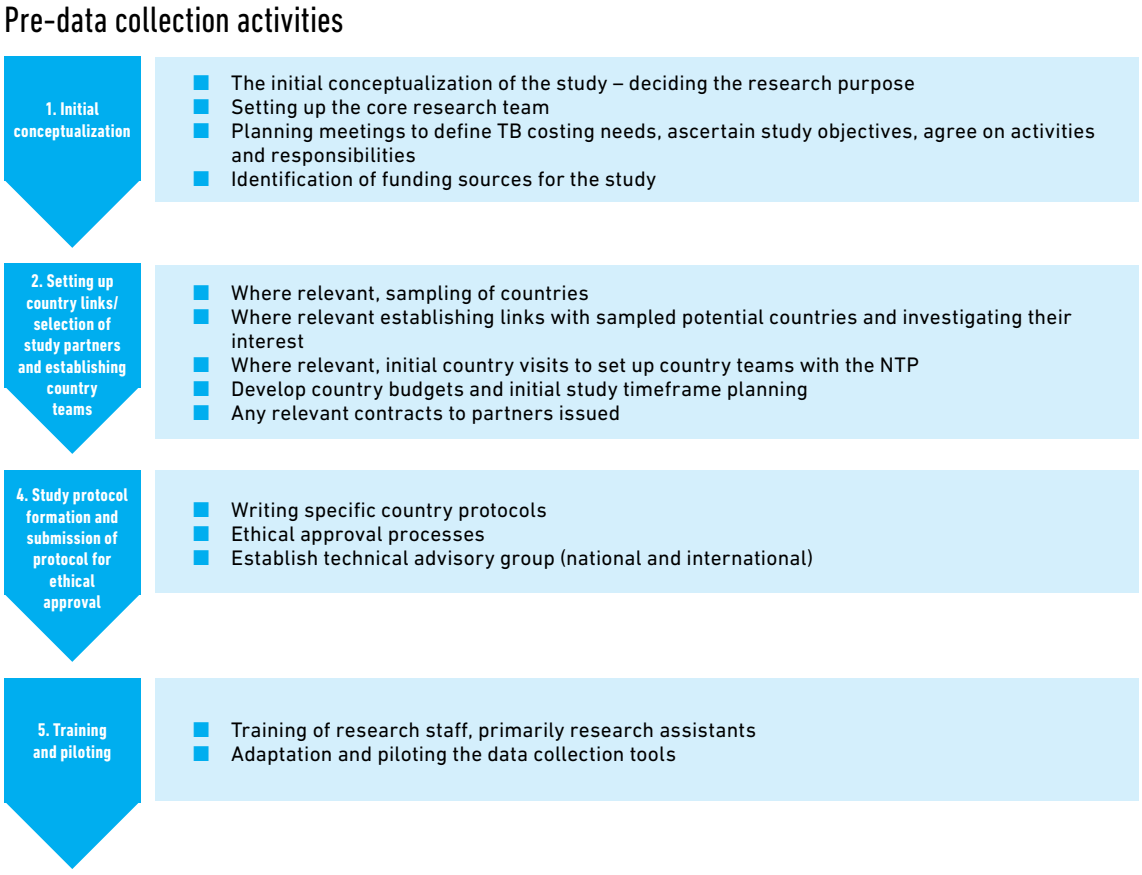
Intervention class	Intervention	Intervention Details	Phase	Technology	Platform (choose more than one only when necessary)	Population (choose more than one only when necessary)	STANDARD UNIT COST INTERVENTION (quality-adjusted unit cost)	STANDARD UNIT COST SERVICE DIRECT	STANDARD UNIT COST SERVICE ANCILLARY
TB treatment	TB Treatment	Treatment of active TB with observation and possibly patient support	Intensive Continuation	First-line treatment Retreatment Second-line treatment Third-line treatment Palliative care Monitoring tests (for status, adverse events and nutritional assessment) Follow up of defaulters M-health ART regimen if HIV+	Household Community Public facility Private facility Hospital general Hospital TB	Children Adults (HIV+, HIV-) Adults (pulmonary TB, EPTB) Adults (DS-TB, MDR-TB, pre-XDR-TB, XDR-TB)	Cost per treatment month DS-TB Cost per treatment month DR-TB Cost per treatment month MDR-TB Cost per treatment month pre-XDR-TB Cost per treatment month XDR-TB Cost per person treated Cost per treatment monitoring Cost per person completing treatment	Cost per outpatient visit Cost per inpatient bed-day Cost per DOT visit community Cost per DOT outpatient visit Cost per drug pick up visit Cost per community treatment visit Cost per microscopy Cost per other test Cost per DS-TB regimen Cost per short DR-TB regimen Cost per long DR-TB regimen	Cost per person month patient support Cost per person patient support Cost per patient support visit Cost per community event

SECTION C. STUDY OBJECTIVES AND SET-UP

Overview

This section addresses how to determine the broad objectives and scope of the costing study, as well as the study set up. It briefly describes the various steps with examples from recent costing studies with a focus on the study methodology and design. Depending on the aim of the study, the steps may take a different order than laid out here (in **Figures 2 and 3**). In practice a TB costing study involves the following pre-data collection activities.

Fig. 2. Example of activities for national costing study (example of Value TB)



Pre-data collection activities

1. Initial conceptualization

Initial conceptualization and defining the study team (three to six months)

1. The first step will be the initial conceptualization of the research purpose and scope as well as setting up the core research team who will oversee the study. Applications for funding may need to be made at this stage. If an external international study team is involved, this is the time to establish links in potential countries and investigate their interest.
2. The core research team should hold planning meetings to define TB costing needs, develop a study question, ascertain study aim and specific objectives, and agree on activities, roles and responsibilities of each of the members.

2. Setting up country links/ selection of study partners and establishing country teams

3. If a multi-country study is selected, at this stage researchers will need to collate global data so that sampling of countries can be undertaken (e.g. sampling of high TB burden countries by region).
4. Inclusion of study partners (NTP, local research group, other researchers, technical assistance support) should be considered. When funding is awarded, sub-contracts from the study lead to other partners may also be required, which may take additional time.

4. Study protocol formation and submission of protocol for ethical approval

Study protocol formation and submission of protocol for ethical approval (three to six months)

5. A protocol development workshop can be an effective platform to develop a common vision, establish the purpose of the costing and decide what is within (and out of) the study scope at the start of the costing study. Specific roles and responsibilities of the team members can be considered. Protocol development should be initiated, as well as proposed budget and timeline.
6. At this point, all relevant information that is available at the country level for TB services for the sampling frame for site selection should be collated.
7. Country adaptation of existing tools and inclusion of specific country protocols (standard operating procedures) is required.
8. Protocols need to be submitted in a timely manner for appropriate ethical approval. While an expedited review can be requested if no patient records will be used, with patient observation the process of review may take longer.
9. A technical advisory group (national and/or international) should be established to assist with decision-making and strategic direction.

5. Training and piloting

Training and piloting (two months)

10. Once ethical approval is given, a study pilot can be undertaken. Together with initial training, this process can take around two months. The analysis of the study pilot can help fine-tuning of generic tools (such as the *Value TB Costing Tool Suite*) and direct the data collection.
11. Throughout the process, training is necessary to familiarize data collectors with the tool, the purpose, scope and aim of the study.

INITIAL CONCEPTUALIZATION AND DEFINING THE STUDY TEAM

Overview

A costing study is initiated where a need for primary costing has been identified based on what the cost estimates are going to be used for, and the level of availability of existing cost data. There may be some cases where a country would not need a primary costing to be undertaken for instance if cost data already available is detailed, recent and of good enough quality for the required purpose (see Reference Case *[5]* for further details).

1. Understanding the purpose of the costing study

The first step in any costing study is to identify what the costs are needed for and defining the purpose of the TB costing study *[5]*. Costing can be done with a specific purpose in mind. For instance, costing could be applied if a new technology (e.g. loop-mediated isothermal amplification (LAMP)) is being rolled out and one wants to assess cost and cost-effectiveness in a particular setting (e.g. an urban district in the Republic of Congo). Alternately, the purpose for the study can be more general, for instance costing all TB interventions in a particular country (e.g. treatment costs in Yemen) to inform resource allocation between different TB interventions.

Methods used to estimate the cost of health interventions or 'costing' will depend on the purpose of the study. To reduce expenditures, any primary data-derived cost estimate ideally should be able to be used for multiple purposes. However, in practice, costing studies are often commissioned with a specific purpose in mind, and the methodological choices will be driven by that purpose. Each purpose may require different approaches to definition and measurement (i.e. the unit of the costs reported). There are several groupings of potential purposes that are outlined below.

A. Economic evaluation and/or priority setting

Certain cost estimates assess allocative efficiency of either single or multiple TB interventions. Allocative efficiency is achieved by maximizing health impact among different (competing) health care interventions within a given (restricted) health budget. There are various approaches and processes that help decision-makers assess allocative efficiency of investment in TB interventions. These include cost-effectiveness analysis and benefit cost analysis. Assessing the cost-effectiveness of alternative uses of resources is now recognized as a core piece of information for decisions around whether to invest in new technologies or set priorities across different strategies and interventions, and as part of the WHO TB guideline development. For example, cost-effectiveness can inform the design of health care benefit packages provided by governments or insurers. As many low-income countries move towards national insurance schemes, these assessments can estimate reimbursement levels.

B. Medium- and long-term financial planning, budget impact and resource requirements estimation

Cost estimates are also used to predict expenditures in the medium (three to five years) and longer term. Examples include using costs to inform budget impact

analyses and budgets for national strategic plans; support medium-term expenditure frameworks; develop financial plans for investment cases; and produce 'global price tags'. These analyses support national planning but can be used in both national and global fundraising efforts for increased investment in a specific global health area. For example, since 2009, the South African government has collected cost data to predict the medium- and long-term costs to the South African national public sector antiretroviral treatment (ART) programme, which was then used to advocate for increasing funding for ART.

C. Budgeting and price-setting

Cost data may also be useful to those planning both the incomes and expenditures of health providers (or funders). Costs can predict expenditures by specific budget holders and help to set prices for specific services. Budget settings would include annual programme budgeting by managers for routine health services, or a specific provider, or could refer to an investment case for a specific study or a funding application. For some organizations, such as insurance companies or private providers, budgets involve planning incomes, and prices for specific goods and services for the coming year and costs are core elements in this process.

D. Technical efficiency analyses

Costs can also be used to explore differences and drivers of technical efficiency between providers and/or modes of delivery (integrated services, platforms, level of decentralization, etc.) for health interventions or services. Technical efficiency analyses are usually conducted through the comparison or analysis of costs over multiple sites, or by comparing actual costs to benchmarks. Technical efficiency can be defined as assessing the best way of spending a given (limited) budget to produce a set of TB services. Cost data from studies that help to estimate technical efficiency can also help identify the minimum efficient scale of operation or providing insights into areas of efficient or inefficient practices. For example, WHO, the United Nations Children's Fund (UNICEF), and Gavi, the Vaccine Alliance, use unit cost data to identify and design efficient supply chain logistic systems in immunization activities.

For each of these purposes, there may be different theoretical and practical reasons that a certain type of cost or methodological approach is preferred. For example, where countries are moving towards UHC, the need to generate reimbursement rates and to understand the comparative value of new technologies (i.e., applying economic evaluation/and or priority setting) creates a demand for unit cost data that are comparable across diseases and health services, follow a standardized methodology, and reflect economic cost.

In contrast, cost data for technical efficiency studies may need larger sample sizes, have a different perspective, and need additional information about cost determinants collected to enable analysis. For the purposes of financial planning and resource requirement estimates, financial costs are generally needed rather than economic costs (see Principle 3 *[5]*), and disaggregation of prices and quantities in unit cost reporting is helpful. The Reference Case *[5]* explains which type of cost can be used for which purpose.

2. Establishing the research team

The core research team may be set up before, during, or after deciding the costing purpose. This is the group that will oversee the study, define the scope, and bear primary responsibility for applying for or sourcing funding for the study. The core research team will also develop a study question, plan study aims and objectives, decide what the study activities will entail and identify the roles and responsibilities of each team member. The core research team may be comprised of individuals in the country of interest or outside of the country or countries included in the study (as was the case with Value TB).

Careful consideration should be given to appropriate study team composition and roles and responsibilities. A range of skills sets may be required. For instance, the primary investigator will need experience in protocol writing, ethical applications, managing teams, TB and costing generally; those in the field doing the data collection should be organized, keep well-documented notes and records, be able to understand and disentangle different clinical TB procedures and processes, enquire and interview, and report back to the study co-ordinator. The study co-ordinator should have good oversight of the data collection process, and be able to provide additional guidance and training if needed and to identify any errors in data collection as they arise. Appendix 10 contains a sample terms of reference for the costing team.

BOX 1. SELECTING A STUDY TEAM FOR VALUE TB

Core Research Team

For Value TB, it was important to select individuals with extensive previous TB costing experience and a current interest in the field, to oversee the study to its completion. Three institutions were selected to be involved: the London School of Hygiene and Tropical Medicine (LSHTM); the Global TB Programme at WHO; and the Health Economics Unit, University of Cape Town (HEU UCT).

Setting up country links/selection of study partners and establishing country teams

At a country level, the NTP took responsibility for the TB costing, supported by the core team of seven researchers from the three institutions listed above. The NTP was responsible for selecting the principal investigator (PI) within the country (this role was given either to someone within the NTP with prior costing knowledge or to an external principal investigator (PI) from a consultancy or academic institution in the country with experience in TB costing such as a health economist). In Kenya, this PI role was shared between a senior member of the NTP (National Tuberculosis, Leprosy and Lung Disease Program (NTLP-P)) and a senior health economist and researcher at Kenya Medical Research Institute Wellcome Trust (KEMRI-WT).

The country PI formulated the country specific protocol (with input from the broader team) and ensured its timely submission to ethical committees. The PI supported by the NTP focal point for the study also communicated with public and private facilities to ensure that permission had been obtained, and that data collection would be welcome. Piloting and training were organized by both the country PI as well as the core research team.

The PI and NTP were responsible for assigning the remainder of the within-country research team, generally comprised of research assistants and data managers hired by the PI. Research assistants' main roles were data collection at the facilities and centrally (when data such as salary grades were not available at the facility) as well as data cleaning and some primary analysis. If a data manager was employed, his/her role was to manage incoming data and to ensure the quality of this data.

In addition to the core country team, a national advisory committee or task force was established to provide inputs in the initial stages as well as later stages of data analysis and dissemination. This task force met initially to discuss results, and were contacted regarding specific issues as needed.

An international advisory panel was also established, hosted by the WHO Task Force on Impact Measurement. The rest of the panel was made up of members (advisors and stakeholders) linked to the GHCC, as well as others who are involved in the economics of TB. The members comprise a mix of global agencies, TB economic modelers, NTP representatives and 'costing experts'. A 36-month duration of funding was applied for through the Bill and Melinda Gates Foundation.

When deciding an appropriate timeframe and timeline, planners should consider the trade-off between the number of staff hired and the amount of time needed for data collection. Generally, it takes a trained data collector one week to collect good quality TB cost data at a facility (this of course will vary based on the facility size, the way records are stored at the facility and the number of interventions to be costed at a given facility). However, as more staff are involved the role of a coordinator becomes even more crucial as facilities will be seen in parallel, and multiple data points will need to be checked for consistency and errors. With larger groups of data collectors, there may be a need for greater investment in ongoing training.

STUDY PROTOCOL FORMATION AND SUBMISSION OF PROTOCOL FOR ETHICAL APPROVAL

Overview

This section summarizes the main elements of a draft study protocol; a draft protocol outline is provided in Appendix 6. The protocol has been developed as part of the Value TB study which closely follows the Reference Case *[5]* as a guiding document. The Value TB study design and methodology can be applied in small (<10 sites) or large (>10 sites) costing studies.

Study protocols outline objectives, present the detailed study design, develop a timeline and budget. Objectives and scope are described below, with more detail on the methods used presented in **Section C**. The process should closely involve cost data users from the start, and ideally the initial draft of the protocol should be developed through a workshop to facilitate a participatory process. These initial stages can be time-consuming if starting from scratch. However, adapting the protocol in **Appendix 6** and associated *Value TB Costing Tool Suite* can accelerate the study design phase considerably.

1. Specifying the study objectives

The primary output from a costing study is a dataset of unit costs; this dataset should be constructed along the lines outlined in Annex 3 of the Reference Case and **Appendix 3**. For the Value TB study, the output was a nationally representative set unit costs (when feasible) for the delivery of TB interventions and services in five countries. The dataset should be eventually made available in a disaggregated form, as this facilitates future analysis and decision-making at the country level and by researchers. Breakdowns of data presented in Value TB include:

- prices and quantities of inputs by site;
- costs broken down by activity and level (service-level versus above-service level);
- economic and financial costs by provider/payer (i.e. The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) versus NTP-funded interventions/resources); and
- 'real world' and 'per protocol' costs where possible (see Principle 3).

BOX 2. STUDY OBJECTIVES

The XTEND study had the overall goal of understanding how Xpert® MTB/RIF should best be used under conditions of national roll-out by determining its effectiveness and cost-effectiveness and modelling these data to project the impact at a population level in South Africa.[a]

This goal required empirical costing in a 'real world' setting. The objective for the costing component of the XTEND project was therefore:

To estimate the unit cost per test and total costs per laboratory for Xpert® MTB/RIF and microscopy tests during Xpert® MTB/RIF roll-out.

[a] Vassall A, Siapka M, Foster N, Cunnama L, Ramma L, Fielding K, et al. Cost-effectiveness of Xpert MTB/RIF for tuberculosis diagnosis in South Africa: a real-world cost analysis and economic evaluation. The Lancet Global Health. 2017;5(7): e710-e719.

2. Perspective of the evaluation

These guidelines have been developed to guide costing of TB interventions from the perspective of the providers of health services. The provider perspective takes the point of view of the provision of services; the costs are those incurred by a hospital, clinic or TB facility providing the services. WHO has developed a 'Tuberculosis patient cost surveys' handbook which will guide the user in collecting patient costs relating to TB *[10]*. A patient perspective assesses the costs from the patients' perspective, and considers direct patient costs such as medical out-of-pocket payments or non-medical expenses (transport, relocation costs), as well as indirect costs which relate to productivity losses such as time off work. Some data can be easily collected at the same time or may include the same information, such as time with a healthcare provider, and so it can be worthwhile to include both the provider and patient perspective in a study (i.e. a societal perspective).

3. Site selection/sampling

There are several different approaches to sampling. Random sampling ensures that the sample is representative of the population it characterizes, i.e. that each individual in a population has an equal chance of being drawn. In order to obtain a random sample a sampling frame is necessary. A method for stratified random sampling using a sampling frame is described below. The strata are the subgroups that should be represented which should also be mutually exclusive. There are other non-random methods for sampling such as convenience and purposive. The advantage of convenience sampling is that selection is based on easy inclusion or willingness to participate, although this can introduce bias. Purposive sampling can be suitable if it is necessary to include something that is rare in the broader population (such as patients with extensively drug-resistant TB (XDR-TB)) but may not be desirable if more broad costing is being done (i.e. DS-TB pulmonary TB). In principle the sample size of a costing can be determine with a set precision in mind *[11]*.

Depending on the purpose of the cost estimation, the sampling frame may involve the selection of countries, geographical regions within countries, sites within regions, patients within sites, and different client groups. The purpose will also determine the most appropriate sampling method and size. For example, some financial planning processes will require the collection of data from different site types. For economic evaluation, the aim is usually to compare the 'intervention' with the 'comparator' and this will determine the method used. For the sampling process, the first step is to

synthesize information that is available at the country level for relevant TB services to outline the sampling frame (from which the eventual site selection is made).

Due to logistical challenges and budget constraints, most cost estimates in low- and middle-income countries have been typically conducted on a small number of sites or locations (<10), though in recent years, larger studies have emerged, particularly in HIV. Where large studies have occurred, they have demonstrated a high variation of costs, suggesting that the common practice of estimating costs on a small sample may produce highly unrepresentative results *[15]*. However, even if a few sites are selected, explicit consideration (and transparency) of the sampling frame and selection method can at least assist others apply cost estimates to other settings.

Depending on the structure of the health system in one's setting, developing the sampling frame will require determining where the interventions of interest take place. For instance, a screening for TB symptoms might take place in a clinic as an

BOX 3. SAMPLING IN LARGE (>10 FACILITIES) COSTING STUDY: EXAMPLE FROM VALUE TB SITE SELECTION/SAMPLING

Given the objective of the Value TB study (to assess the costs of all TB interventions in five countries in order to update current data and inform users of the cost data, such as modellers and policy makers), sampling was done on two levels.

The first level was to select countries based on five criteria: budget, study team capacity, data availability, representativeness and feasibility.

In terms of budget, the sample size for participating countries was agreed upon with the funder based on budgetary considerations. Data collection was budgeted to take place in five countries. Countries with the highest burden of TB, TB and HIV coinfection and multidrug-resistant TB (MDR-TB) were prioritized. Only one country with extensive hospitalization due to MDR-TB was selected and hospital costing was simplified due to the limited study team capacity and limited time.

To assess data availability among the countries of interest, published literature was mapped from the GHCC database (https://ghcosting.org/pages/data/ucsr/app/) by type of intervention. Countries were excluded where data were considered recent and sufficient.

Selecting a wide range of countries is helpful when only a few can be studied. In this case, rather than comparing randomly chosen countries, countries were selected to represent a range of income levels and geographical regions.

Finally, feasibility was considered when selecting the order in which countries were approached. Feasibility included both local NTP interest in the study and capacity to collaborate (on-going research platforms/ partnerships); both aspects are critical to ensure cost data produced is relevant and useful to countries so that it ultimately contributes to decision making processes.

The second level of sampling/selection took place within the five countries. Preliminary data was collected regarding the TB interventions offered at different facilities levels, population density of regions, and TB notifications etc.

The focus of the facility selection was to obtain a sample of facilities to estimate unit costs for a comprehensive set of TB interventions and, where feasible, to calculate a nationally representative unit cost. Again, budget played a role in the selection of 24–30 facilities per country. The selected facilities followed a standardized sampling strategy shared across the five countries. Three regions were purposively sampled to reflect a high, medium and low burden of TB respectively based on population size and cases of TB as well as urbanicity as a proxy for spread of facilities/accessibility of services.

A stratified random sampling approach was used to obtain a sample of facilities within the following strata: level of care, ownership (public, private), and diagnostic interventions available (availability of Xpert® MTB/RIF, microscopy and none) to ensure a representation of facilities in each stratum (facilities with very low volume of TB services were excluded). These strata were selected as they represent important determinants of cost variation. If a facility refused to take part in the study, a substitute facility from the same strata was selected from a 'substitution' list.

outpatient whereas a microscopy test would take place in a laboratory either at the clinic or peripherally.

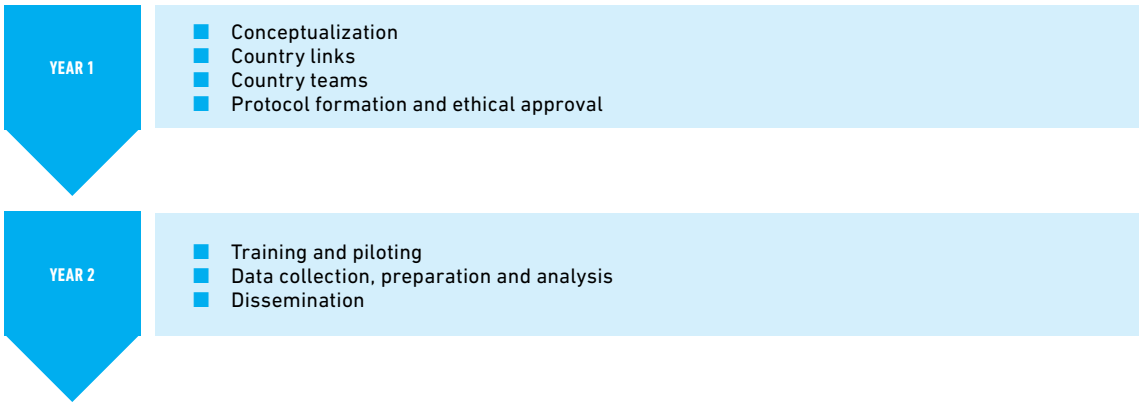
Consideration should also be given to how to access data for the target population and the epidemiological context in one's setting. For the intervention(s) being costed, coverage level or phase should be noted: the cost may differ if an intervention has just been piloted or is well-established.

4. Timeframe and budgeting

The costing study timeline is usually around six months or longer (**Figure 3**). Costing selected TB services in a smaller sample (less than 10 sites) should take less than a year. However, costing all TB services in a nationally representative sample (such as in the example of Value TB) using the current TB guidelines and *Value TB Costing Tool Suite* (described in **Appendix 8**) will take approximately one year.

The average budget for one Value TB country, for approximately 20 sites (taking around 12 months) was in the region of US$100 000 (excluding external technical support from core research team). This includes around a third for travel funds, training and meeting funds; and the rest for staff (two co-principal investigators spending 5% and 10% of their time respectively; a study co-ordinator working 10%; a data manager working 10%; and four research assistance/data collectors working 25% each for the year).

Fig. 3. Example of timeline for national costing study (example of Value TB)



5. Ethical consideration/approval

As costing work requires review of medical records and interviews with staff, costing studies require ethical approval. If a costing study is done alongside a larger existing study which already has such approval (such as a study collecting widespread epidemiological data on TB with a costing component), expedited ethical approval may be sought or, if the TB costing work is included in the existing study, this may be combined with the proposal sent for ethical approval. If a study is a stand-alone TB costing study, then ethical approval will need to be sought from all relevant parties. Ethical approval can take time to obtain depending on the setting and whether patient records or observation of patients during TB care are included (the ethical approval can take anywhere from one to six months). This needs to be considered when planning the overall study and timeline.

BOX 4. ETHICAL APPROVAL FOR VALUE TB

In the case of Value TB, ethical approval was obtained from the three institutions involved (LSHTM; Global TB Programme, WHO; Health Economics Unit UCT). In addition, ethical approval was granted by the medical ethical committees within the five relevant countries for instance in Kenya through the Kenya Medical Research Institute (KEMRI) and WHO African Regional Office. Permission to gain access to the selected facilities was requested in each of the five countries. In Kenya this was done by approaching the Ministry of Health at a County Level with a letter applying for entry (with letters of ethical approval attached), and then at a facility level through telephone communications with the facility managers stating that the relevant ethical approval and County Level permissions had been obtained. The NTPs were central to the facilitation of this process as well as to data collection teams accessing facilities.

SECTION D. DESIGNING DATA COLLECTION

UNDERSTANDING THE PRODUCTION PROCESS

In the costing approach, describing the outputs of interest (see **Tables 2 and 3**) allows planners to consider what needs to be estimated in terms of the cost per activity broken down into cost per output. Activities can occur at different platforms, for instance at health facilities, or as outreach, mobile or household visits.

The first step consists of establishing and defining the interventions that require costing. While the protocol will describe TB service delivery process as per country guidelines and the "generic" Data Collection Tool (from the *Value TB Costing Tool Suite*) will be adapted accordingly, data collectors will need to reassess the production process of each TB service at a given facility. Where interventions are placed will depend on the delivery mechanism and will vary by setting. For example, an intervention may be housed within the health system level, at different facility types, in the community, or in facilities such as non-governmental organizations (NGOs), or faith-based organizations.

At the facility level, possible TB interventions include: vaccination; TB case detection and diagnosis; PCF, ACF and ICF; TB treatment; TB prevention; TB infection control. Above the facility level, TB interventions include: development of strategic plans, programme reviews, national and regional meetings, surveys, management and information systems, supervision, procurement and supply chain management, transportation of specimens, advocacy, technical assistance, training, accreditation and quality assurance of laboratories, community media, information, education and communication (IEC) campaigns or any partnership activities (see **Appendix 2**).

For each intervention, data collectors will then need to understand the workflow of the 'facility' (health facility, laboratory, pharmacy, community outreach etc.) (see **Figure 4** and **Appendix 11**; Case Study 1 as examples). This entails asking questions and observing practices (how services are provided and by whom) and the structure of how the services are delivered. A good starting point is a discussion with the clinic manager or TB nurse or laboratory manager about the facility.

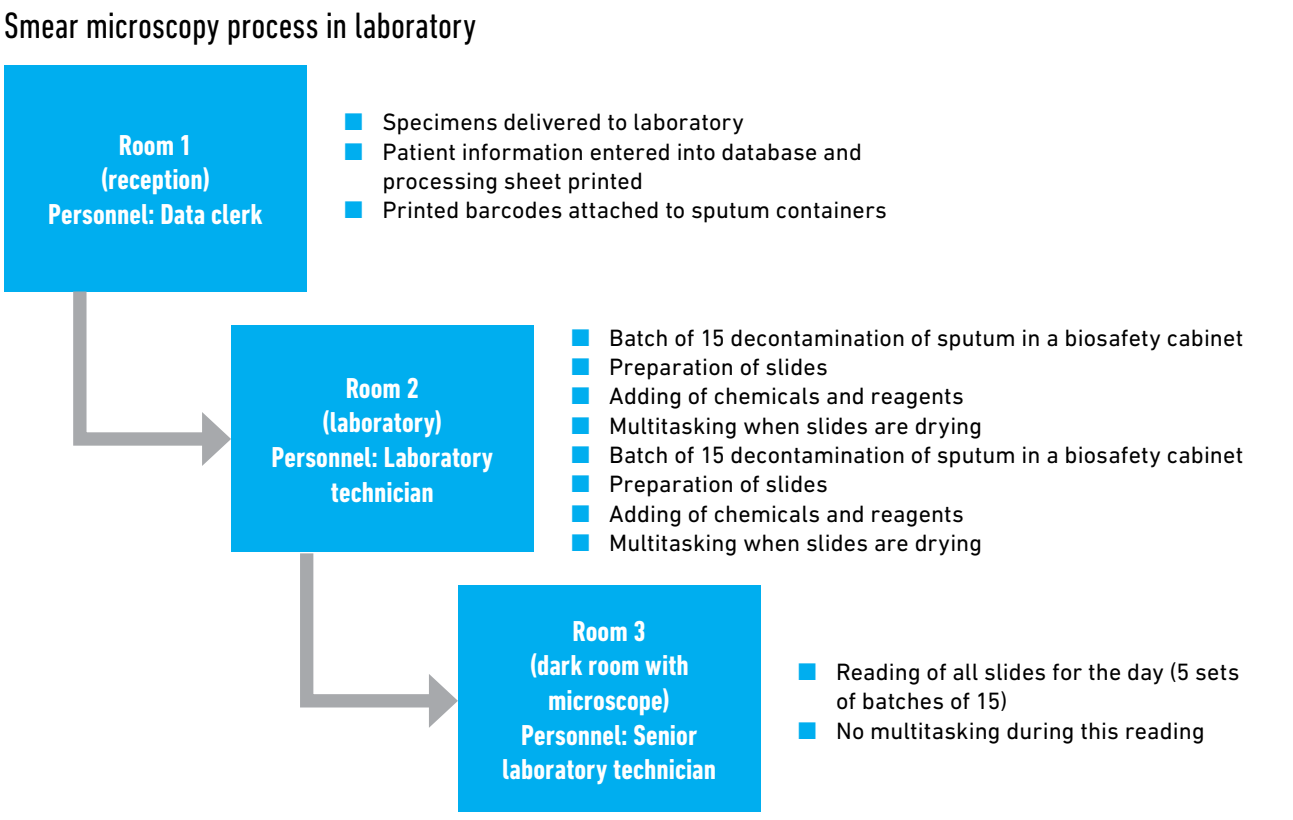
For instance, within a health facility at an introductory meeting questions could include:

- Where are patients seen?
- Is space shared between TB and other services?
- If TB and HIV care are integrated, how (ie. physically, temporally, clinically)?
- Are TB patients kept separate from other patients?
- Where do patients wait?
- Which staff attend to the patients?

- Is staff time shared between TB and other services (such as outpatient care, curative medicine, noncommunicable diseases (NCDs)/chronic care, maternal and child health, family planning, ART)?
- Which days are TB services offered (every day or only selected days)?
- Do patients make appointments or come on an ad hoc basis?
- How often do patients come for treatment?
- Do patients come with a treatment support partner, or can send one to collect medicine?
- Where are tests sent?
- What is the process for referring tests (do they send a letter with a patient, phone the laboratory/private facility)?
- How are results returned?
- Is transport or vehicles provided to staff or patients?
- How often has training occurred in the previous year?
- How many TB patients are seen on average in a day?

A process flow diagram can be helpful at this stage (often drawn immediately after the site visit) and this can then be used to validate the process by asking the staff to look at the diagram and confirm that it is accurate representation of what happens within the facility (see **Figure 4**). This is then used to ensure that all aspects are being costed and to better understand cost estimates within the context of the facility.

Fig. 4. Example of a process flow diagram for smear microscopy in a laboratory



Within a laboratory, it is useful to speak to the laboratory manager and to observe the tests being processed (which is slightly more straightforward as there are no patients present). Some laboratories keep standard operating procedures that record the diagnosis delivery process, which can then be verified through an interview with the laboratory manager who has an overview of TB diagnostic services.

This process of workflow mapping can help data collectors to identify inputs, or resources, which need to be measured. **Figure 5** shows the capital and recurrent inputs to consider at each level of the health system. The platform refers to the type

Fig. 5. Capital and recurrent inputs

Platform	Capital costs (input)	Recurrent costs (input)
Public health facilities (including TB Care, HIV care, Hospital general, Hospital TB) and laboratories **Private health facilities** (including TB Care, HIV care, Hospital general, Hospital TB) and laboratories	**Building space** Quantities: Size of department/ clinic/room/area/building Prices: Value if sold today	**Above service level cost** Quantities: Number of facilities served Prices: Expenditure on above service level activities such as NTP support, TB drug delivery
National TB Programme Ministry of Health Non-governmental organizations	**Vehicles (transportation)** Quantities: Number of vehicles Prices: Current market value of all vehicles	**Recurrent expenditure/ Overhead inputs** Quantities: Per facility Price: Annual expenditure
Households Community Mobile Prisons Schools (through health facility outreach)	**Equipment and furniture** Quantities: Inventory of equipment and furniture Prices: Current price/ replacement cost for the listed equipment and furniture	**Personnel (Staff costs)** Quantities: Staff time on task(s) measured using timesheets/ observation/interview Prices: Salaries/wages of staff
	Training (the effects of which will last more than one year) Quantities: Duration of training, number of participants trained, number of trainers Prices: Training fee per participant (venue, catering, training materials, training staff salaries, per diem)	**Supplies** Quantities: Quantity of consumables used Price: Annual expenditure/price of consumables etc
		Drugs Quantities: Number and type of drugs/regimen used Price: Current price of medication
		Diagnostic tests Quantities: Number and type of diagnostic tests/supplies used Price: Current price of diagnostic test/supplies
		Other This could include calibration of instruments, chemicals and reagents, administration of cash transfer, quality assurance,

of facility or structure (such as community outreach, visits at the household level, or schools) used to administer TB. The prices and quantities for both capital and recurrent inputs are outlined in **Figure 5** to illustrate which prices and quantities of items should be collected in the different platforms.

Mapping of interventions

After fully defining the interventions and classifying them according to the GHCC intervention definitions *[5]*, the available interventions and technologies in each facility level should be mapped. This will establish where the relevant interventions will be captured when conducting the costing at the facility. A new blank Data Collection Tool should be used for each facility (see **Appendix 8**).

The facility costing tool has been organized to capture the description of the health facility, followed by service utilization and overhead items. It also includes default lists of staff type, equipment, consumables, chemicals and reagents and drugs used in the TB interventions provided at the facility. The quantities and costs of each item can be inputted into these lists. Additional items can also be added to the lists.

Defining inputs

Another consideration involves which inputs need to be included in order to work out the unit cost from the provider perspective. The broad groupings are capital and recurrent categories with specific inputs in these categories (**Figure 5**). Depending on the platform costed, these can include capital (building space; vehicles (transportation); equipment and furniture; training (the effects of which will last more than one year) and recurrent inputs (recurrent expenditure/overhead inputs, personnel (staff costs) and supplies) that make up a visit cost. Input costs of diagnostic testing and medication (drugs) are added subsequently, as these are the most likely to change or need updating.

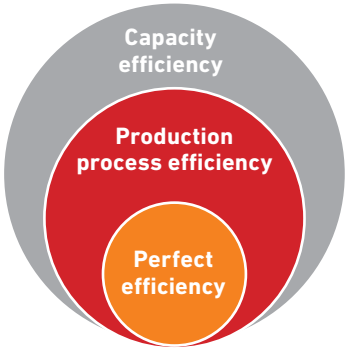
COSTING APPROACHES

There are a number of core principles laid out in the Reference Case on how to measure and value inputs. The two main (but complementary) approaches to estimating costs are bottom-up and top-down (see Principle 7 in the Reference Case *[5]*). Perfect efficiency as represented by guideline or normative costing in a system is rare in real health systems, and it is much more likely that the costs in the real world reflect some inefficiency both in capacity and production. In order to capture real world costs, we can use bottom-up costing of real world services to capture process inefficiency and top-down costing to also capture capacity inefficiency (see **Figure 6**). If both time and resources are available to the study team, both top-down and bottom-up should be undertaken in order to have a range of costs for most efficient practice (bottom-up) to a cost that includes inefficiency (top-down).

Bottom-up costing

Bottom-up is a detailed approach to costing which involves detailed measurement of all resources used in the provision of a specific health service or intervention. This involves the "ingredients" approach where all resources (i.e. inputs) utilized or consumed in the production of a service are costed separately. Bottom-up costing can

Fig. 6. Estimating efficiency



use interviews (as a minimum), time-in-motion style data collection, observation, or work sampling techniques of health providers. Methods of estimating building space, staff, equipment and furniture are detailed here, with further detail on all inputs provided in **Appendix 8**.

Estimating resource use

Estimating resources used requires assessing the quantities of inputs. This may be from routine data, patient file abstraction or alongside a study. The methods used to estimate the levels of inputs used in an intervention can bias estimates, and therefore should be reported. For instance, observation can be biased in that it may suffer from the Hawthorne effect of observation bias, where more efficient practice is presented due to an awareness of being studied. The methodological specification is to report the source of data, report the approach used to sample or fill missing data and justify why the approach was selected given the potential for bias caused by misreporting or incomplete data *[5]*.

Measurement and valuation of space

The size of all the buildings at the facility should be reported in square metres (m^2). The best-case scenario is if the facility has a record of the size in square metres or better still a map with the dimensions and floor plan. If this is unavailable, one of the following options for estimating the facility size can be used:

- value of the building, obtained by sourcing the current replacement value;
- original facility records inflated to the current value;
- insurance valuation of the building;
- tax forms for the building or government rate for stamp duty;
- cost of recent renovations;
- rental value from lease agreement;
- where total land space is known but building size is not, estimation of the proportion of land that the building occupies; or
- physical measurement of the space with a laser distance measurer or a tape measure or street mapping software (e.g. Google Earth).

Measurement of equipment and furniture

This is generally done through an itemized count or reliance on an existing detailed list per department.

Measurement of staff time

Calculation of quantities of staff time using a bottom-up approach can be assessed through either an observation or interview. This is calculated by multiplying the price of staff time per minute (derived from their cost of employment and the number of minutes they work for in a year) by the number of minutes for a TB service collected through either observation (ideal) or interview (as a minimum).

Valuing resources

Once all resources have been identified for each facility/place, these need to be quantified and valued. **Figure 4** illustrates how this could be done for both capital and recurrent costs. Examples of prices for different inputs have been given. If research costs are part of the intervention there may be a need to include these, however that is up to the judgement of the researcher. Data sources should be listed, for instance NTP under the Ministry of Health or TB clinical records etc.

Valuation, especially for economic costs, is important as it is a way of making unit costs comparable. Current prices for consumables, medical equipment may be obtained from the records kept by a facility or from a medical supplier. Pricing for furniture and equipment may be kept at a facility level or more likely will need to be requested from a furniture or medical equipment supplier. See the Reference Case *[5]* for further detail on exchange rates, discount rates, etc.

Estimation of total costs

Total costs are estimated through the multiplication of unit costs with the total utilization for the period of interest.

Top-down costing

The top-down approach is a more aggregative method which involves estimating the cost of delivering a TB service (e.g. a hospitalization for a TB patient) by using a national average figure or expenditure accounts from a facility. The top-down approach involves preferably the step-wise allocation of the facility expenditure by various departments (usually of a complex organization) to specific cost centres of interest. Criteria used to allocate shared resources should be explicit and reflect usage of each input. Where allocations have been made 'top-down', either to sites or within sites to services, or above-service delivery or overhead costs have been allocated, the criteria used and the relevant data sources of the allocation factors should be explained.

As indicated in previous work, one can cost resources within a laboratory through top-down methods *[13]*. The top-down approach utilizing expenditure for different cost centres, departments or inputs considers inefficiency. The example of staff time is given here, while more detail for other inputs is provided in **Appendix 8**.

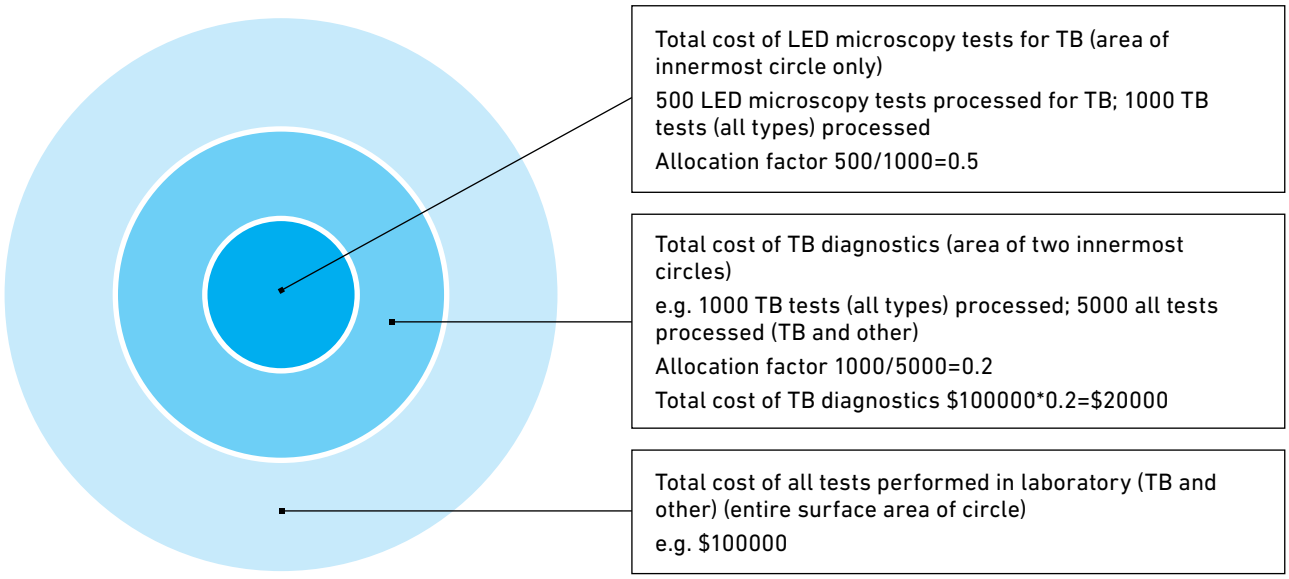
Measurement of staff time top-down

Top-down costing methods use the proportion of time for each TB output calculated from timesheets and the expenditure of facilities on TB services for staff (as derived from their cost of employment). Timesheets and interview may have an overestimation or underestimation of time being spent on tasks depending on staff ability to recall work practices and workload.

Valuing resources top-down

For salary information, facility expenditure and overhead costs (such as administration, cleaning, kitchen, utilities, security, laundry, monitoring and evaluation, pharmacovigilance, maintenance), information is often obtained from a central level, for instance the finance department of a Minstry of Health.

Fig. 7. Top-down allocation of costs within a laboratory



In a top-down costing of light emitting diode (LED) microscopy for TB diagnosis in a laboratory, the cost of the microscopy department would be separated from the total TB diagnostic costs for the laboratory using an allocation factor (such as the number of microscopy tests using LED divided by the total number of all TB tests processed in that laboratory multiplied by the total TB diagnostic cost for the laboratory). A separate allocation procedure may be needed to separate out the cost of processing TB diagnostic tests, if the cost of all diagnostic tests in the laboratory, TB-related and all others, are aggregated (see **Figure 7**). The allocation factor could be the total number of TB tests processed divided by the total number of all tests processed in the laboratory.

Table 2. Costing approaches

Activity and other total cost breakdowns	Outputs	Bottom-up costing (Cost category input breakdowns)	Top-down costing
Site-level direct service provision	Outpatient visit	Quantity (Q) (minutes) * Cost per minute (personnel time of clinical and non-clinical staff) Q (square metres per minute) * Cost per square metre per minute (infrastructure including building, equipment, furniture, vehicles; overhead inputs including administration, cleaning, kitchen, utilities, security, laundry, monitoring and evaluation/pharmacovigilance, maintenance and training)	Total expenditure for TB outpatient department/Number of TB outpatient visits
	Inpatient bed-day	Q (minutes) * Cost per minute (personnel time of clinical and non-clinical staff) Q (square metre per minute) * Cost per square metre per minute (infrastructure as above; overhead inputs as above)	Total expenditure for hospitalized TB/Number of TB inpatient visits
	Household visit	Q (minutes) * Cost per minute (personnel time, travel time cost) Q (minutes) * Cost per minute (overhead inputs including administration, security, monitoring and evaluation/ pharmacovigilance, transport and training)	Total expenditure for TB household visit team/Number of TB household visits
	Mobile clinic visit	Q (minutes) * Cost per visit per minute (personnel time; overhead inputs (e.g. cleaning, laundry, maintenance); vehicles, fuel and equipment)	Total expenditure for TB outreach care/Number of TB mobile clinic visits
	Triage (people living with human immunodeficiency virus (HIV), diabetes mellitus, chronic obstructive pulmonary disease (COPD), cancer or attending maternal and child health clinics)	Q (minutes) * Cost per minute (personnel time for clinical and non-clinical staff) Q (square metre per minute) * Cost per square metre per minute (infrastructure as above; overhead inputs as above)	Total expenditure for TB care (in HIV clinic+diabetes clinic+COPD+oncology clinic+ maternal and child health (MCH) clinic)/Number of clinic visits for TB care in HIV clinic+diabetes clinic+COPD+oncology clinic+ MCH clinic
	Diagnostic test (sample/ slide)[a]	Q (minutes) * Cost per minute (personnel time of laboratory staff) Q (tests) * Cost of 'technology' (infrastructure as above; consumables, chemicals and reagents; overhead inputs, and biosafety, quality assurance (national, regional, supranational), monitoring and evaluation, transportation of samples and results to patients, training of laboratory staff to operate that technology (both capital and recurrent))	Total expenditure for TB diagnostics/Number of TB tests performed
	Drugs[b]	...Q * Cost of drugs	Total expenditure for TB drugs/Number of TB drugs dispensed

Activity and other total cost breakdowns	Outputs	Bottom-up costing (Cost category input breakdowns)	Top-down costing
	Other technology[c]	...Q * Cost of other technology	Total expenditure of other technology (such as sputum screening)/Number of patients treated using other TB technology (such as sputum screens performed)
Site level ancillary service provision	Patient support provision per patient	Q (minutes) * Cost per minute (personnel time for health care or social care worker) Q (square metre per minute) * Cost per square metre per minute for counselling visit if within the health sector (infrastructure and overhead inputs as above) And/or Q * Cost of cash transfer (includes the actual cash transfer; infrastructure surrounding administration of the transfer (personnel time; infrastructure and overhead inputs as above; and information technology, banking fees, etc.)	Total expenditure of TB patient support/Number of TB patients supported
Site level and above-site level operational activities:	Programme management (national and regional meetings, partnership activities and technical assistance)	Q (minutes) * Cost per minute (personnel time of clinical and non-clinical staff participating and facilitators' time) Q (participants) * Cost per participant (venue, materials, catering, transport, accommodation)	Total expenditure of TB programme management/Number of TB national and regional meetings, partnership activities and technical assistance provided
	Supervision	Q (minutes) * Cost per minute (personnel time of clinical and non-clinical staff) Q (square metre per minute) * Cost per square metre per minute for supervisory visit (infrastructure including building, equipment, furniture; overhead inputs including administration, cleaning, kitchen, utilities, security, laundry, monitoring and evaluation/pharmacovigilance, maintenance and training)	Total expenditure of TB supervision/Number of TB staff supervised
	Management and information systems	Q (minutes) * Cost per minute (personnel time of clinical and non-clinical staff) Q (square metre per minute) * Cost per square metre per minute (supplies, infrastructure including building, equipment, furniture; overhead inputs including administration, cleaning, kitchen, utilities, security, laundry, monitoring and evaluation/pharmacovigilance, maintenance and training)	Total expenditure of management and information systems/ Number patients with TB
	Research, surveillance and surveys	Q (minutes) * Cost per minute (personnel time of clinical and non-clinical staff, patients, household or community members and survey administrators' time) Q (surveys per minute) * Cost per survey per minute (equipment, software, materials, transportation, security, training, building, utilities, administration, furniture, cleaning)	Total expenditure of TB research, surveillance and surveys/ Number patients with TB

Activity and other total cost breakdowns	Outputs	Bottom-up costing (Cost category input breakdowns)	Top-down costing
	Procurement and supply chain management		Total expenditure of TB procurement and supply chain management/Number patients with TB
	Community media/IEC/ mobilisation/advocacy	Q (minutes) * Cost per minute (personnel time of clinical and non-clinical staff; auxiliary staff, consultants and volunteers) Q (square metre per minute) * Cost per square metre per minute (venue, materials, catering, transport, accommodation; infrastructure and overhead inputs as above)	Total expenditure of TB community media, IEC, mobilisation, advocacy/Number patients with TB
	Training	Q (minutes) * Cost per minute (personnel time of clinical and non-clinical staff; auxiliary staff, consultants and volunteers) Q (square metre per minute) * Cost per square metre per minute (venue, materials, catering, transport, accommodation; infrastructure and overhead inputs as above)	Total expenditure of TB training/Number of staff trained
	Laboratory support (accreditation and quality assurance in laboratories)		Total expenditure for laboratory support/Number of tests performed

Adapted Annex 3 of the Reference Case *[5]*.
In this table the symbol "/" represents divided by.

THE STANDARDIZED *VALUE TB COSTING TOOL SUITE*

In conjunction with this set of guidelines, a generic *Value TB Costing Tool Suite* has been developed in Microsoft Excel spreadsheets with aligning instructions in Microsoft Word (see **Appendix 8**). The *Value TB Costing Tool Suite* encompasses all the aspects one needs to consider for costing a variety of TB interventions in any country setting, which should be adapted to specific country contexts.

The *Value TB Costing Tool Suite* consists of a list of all data required for costing (for submission to ethics), a Data Collection Tool (a unit cost generation tool), a separate Data Entry Tool, and draft informed consent forms. The rationale for having two instruments, one for data collection and one for unit cost generation stems from the need to simplify the data collection itself, leaving the data analyst to use the Data Entry Tool to clean data reported by research assistants/data collectors (through the Data Collection Tool) and to generate unit costs for the facility.

The Data Collection Tool can be used by research assistants to collect data for one facility. The tool will essentially allow recording of quantity and price data collected from the facility for each of the TB interventions that are present in a given facility. The Data Collection Tool collects the necessary bottom-up and top-down ingredients. In terms of bottom-up costing this relates to the prices and quantities. The quantities include time spent on tasks by health care workers, training, building space utilized for tasks, the equipment, drugs and supplies used etc. Prices include the prices for these items, the price of staff time per minute (derived from their cost of employment and the number of minutes they work for in a year), time spent on training, the price of space, equipment, drugs and supplies, etc. For top-down costing this relates to the expenditure of facilities on TB services on staff, training, buildings, equipment, drugs supplies, and the service statistics or utilization by patients (to work out the allocation to TB services).

The Data Entry Tool will be used by data analysts to clean and copy data from the Data Collection Tool, and generates unit costs and other intermediary results for a facility. The Data Entry Tool takes all these ingredients and produces unit costs of delivering each TB service using both bottom-up and top-down methodologies. For bottom-up this means taking the prices and quantities for all inputs (staff time, training, building space, equipment, drugs and supplies) and calculating the bottom-up unit costs. For top-down costing, this entails calculating the unit cost for all inputs (recurrent expenditure (overhead costs), staff time, training, building space, equipment, drugs and supplies) based on step-down accounting using allocations based on space or service statistics (as described in **Appendix 8**).

The *Value TB Costing Tool Suite* and accompanying instructions can easily be adapted to any costing of TB service delivery exercise. When submitting the protocol to the ethics review board, one can include a draft interview questionnaire and a list of the other types of data that are planned to be collected. Consent form sheets also need to be submitted to ethics – these will be required from all staff interviewed and providing data to the data collector. Samples of facility information and consent form sheets have been provided (see **Appendix 12**). Format and content that is appropriate or required for the setting as per local ethical guidelines should be used, but these samples can also be adapted for use in the setting.

BOX 5. THE ACCOMPANYING DATA COLLECTION INSTRUCTIONS INCLUDE THE FOLLOWING DOCUMENTS

- An observation guide assists the data collector in observation of a TB service.
- This guide will be used to estimate the bottom-up costing of an intervention and to populate the data collection and data entry bottom-up sheets for staff time, equipment utilization and supply consumption.
- Observation is considered as the gold-standard method to measure staff time.
- An interview guide will be used by data collectors to carry out interviews to staff providing TB, MDR or TB/HIV services in the health facility and staff working in the laboratory or radiology departments.
- The interviews, like observation, will provide the data collector with information on staff time, equipment utilization and supply consumption.
- Timesheets are another instrument to collect staff time.
- Timesheets are distributed to facility staff providing TB services at the beginning of the week of data collection at the facility and collected on the last day of data collection.
- The timesheets will capture the time spent on the 25 predefined TB related service outputs, non-TB services, administration and down time (lunch, break) over a few typical work days by various cadres of health professionals.
- The facility contact list collects participant names and contact information but is stored separately and securely at all times, ensuring no identifiable information can be linked to any data in the tools.
- Facility information sheets summarize the key features of the study and will be made available to staff interviewed.

What the *Value TB Costing Tool Suite* can do

The *Value TB Costing Tool Suite* has been organized to allow the collection of data and calculation of unit costs of TB service delivery at the facility level. It supports obtaining unit costs for both top-down and bottom-up costing, economic and financial cost approaches, different methodologies for measuring staff time (interviews, observations and timesheets) and disaggregated by key input categories.

The *Value TB Costing Tool Suite* allows costing in different platforms (such as outpatient and inpatient care and facility outreach services), but is currently limited to facility level (i.e. it does not allow for community-based costing). Above-facility cost data collection will need to be done using an additional data collection instrument which is currently under development.

What the *Value TB Costing Tool Suite* cannot do

Due to the comprehensive nature of the tools, certain components within TB interventions have been omitted so that the costing process remains feasible within a reasonable time frame. No unit costs have been derived for individual adverse events related to TB treatment or prevention nor are the list of monitoring tests required to identify these events entirely comprehensive. However, the current tool allows for the cost of inpatient care to capture some time spent treating the adverse drug reactions associated with anti-TB drugs. The most frequent adverse event monitoring tests have been included in the Tool Suite and can therefore be costed.

Adapting the *Value TB Costing Tool Suite* and mapping data sources

In drafting these guidelines and associated data collection instruments, efforts were made to ensure the specific costing's country context, scope and objectives can be

incorporated. The generic tool provided alongside this guide can be modified to the country context and there are four main steps in this adaptation process.

1. Defining the TB interventions that will be costed: this is done by the study team at the protocol development phase.
2. Defining the production process and potential data sources: this is done by the study team at the protocol development phase, but data collectors re-evaluate for each of the facilities during site visits.
3. Piloting: if a comprehensive range of TB interventions have been selected, then the piloting at a couple of facilities can take up to two weeks to complete. Once piloting has been undertaken, one must then adapt the tool to the country context.
4. Adaptation of the tools

Adapting the tools during the study pilot

During the piloting process, the research assistant(s) and team should endeavour to add as many of the context-specific and country appropriate service outputs, drug names, test procedures, service utilization labels, consumables supplies, staff titles, department or clinic names and other important labelling as possible.

SECTION E. DATA ANALYSIS, PRESENTING RESULTS AND DISSEMINATION OF COST DATA

Fig. 8. Post data collection activities

7. Post-data collection activities

- Commencement of data analysis and data analysis workshop (cross-country meeting)
- Preparation of reports, papers and a publicly accessible database
- Cross-country data analysis and write up
- Dissemination of findings at a country and international level
- Publicly share datasets
- Wrapping up the study and discussion about updating cost estimates managed by the NTPs going forward

Data analysis

The data analysis stage is an important stage in the costing process and resources (research staff and money) should be allocated for this. The main purpose is to take the prices and quantities collected at each of the facilities and at the level above facilities and produce both total costs and unit costs that meet the objectives of the study (see **Section C**). However, total and unit costs on their own have little value: it is important to think about the unique setting from which these costs are produced and situate them, providing information on the elements that appear to drive cost.

In addition, differences can be compared by subgroup, such as DS-TB, MDR-TB and XDR-TB. If the sample size is large enough, statistical differences between population/facility groups can be examined. Descriptive analyses can include assessing the average number of visits per patient for different patient groups/subgroup (such as pulmonary, EPTB, new and retreatment) and the breakdown for the different types of visit (diagnostic visit, treatment visit, treatment support, community treatment visits, inpatient bed-days etc). The cost per input (as well as mean, standard deviation, median and interquartile range) for different interventions can also be assessed and looked at by patient group/subgroup. For instance, assessing the cost for first-line treatment for different facilities broken up by input (diagnostic tests – Xpert® MTB/RIF, microscopy; treatment visits; inpatient bed-days etc). One can look at the variation within a country for the number of visits per patient for different visit type by health facility (the levels of care). The proportion for the inputs in a visit cost can also be evaluated through, for example, looking at the proportion spent on personnel; building space; furniture and equipment; or consumables/supplies. This can help in assessing the variability in efficiency. For instance, looking at the cost of smear microscopy in different levels of care broken down into inputs can illustrate where the highest amounts are being spent from both top-down and bottom-up points of view. Again, the unit cost per intervention can be assessed by platform and from both top-down and bottom-up approaches.

Econometric analysis can also be conducted on larger data sets to explore technical efficiency, extrapolate costs to other settings and understand the determinants of costs. These analyses are not outlined here, but please see Arinaminpathy et al., Silva et al. and Denysiuk et al. *[14–16]* for further reading on cost functions and other aspects.

Sensitivity analyses

Whenever doing a cost analysis, it is important to assess possible areas of bias. Sensitivity analyses are also crucial for looking at factors that may contribute to uncertainty in the unit cost estimates. Examples are altering the cost of medication (one can often use this information to inform at what threshold the cost could become affordable); the utilization rate (especially if the cost analysis was done during a start-up phase only); one could also alter the salary costs if task shifting could be likely in the future. This can be in the form of a one-way sensitivity analysis (univariate sensitivity analysis), where one alters one variable at a time, or a multi-way sensitivity analysis (multivariate sensitivity analysis) where one alters several factors at one time to see their combined effect on the cost estimates. Scenario analyses are helpful in looking at different approaches or options for the future. Techniques such probabilistic sensitivity analysis (PSA) can be used to look at uncertainty ranges in a cost analysis, where one initially assigns a probability range to the input data *[17–20]*.

Presenting results and dissemination of cost data

While it is important to tailor presentations to a specific audience, in general simple graphical presentation of data is best. Bar graphs can effectively compare costs across sites, with percentage breakdowns to visually indicate which components are the highest/lowest contributors. For policymakers, data should be presented in transparent and easy to digest format, so that they can make decisions about resource allocation to better combat TB. Audiences of health care workers will need the knowledge to be translated so that it can be practically applied in a work setting, for instance the expense of certain tests may mean that rationing is appropriate.

The limitations of the study should be identified and described. This includes inter alia interventions that have not been costed, where sample size was not sufficient, when above-facility costs were not assessed and adaptation of methods. The ability to generalize and its application should be explained. For example, is it only appropriate to generalize to other low- and middle-income settings, or, if the sample is not representative of the country, only to similarly sized facilities within other districts or within the country. Any conflicts of interest (i.e. involvement with developers or pharmaceutical companies) should be declared. This allows the reader and consumers of costs to be able to judge whether the research is independently undertaken or may suffer from bias. If a conflict of interest is not declared but exposed later, the reader may feel misled and the credibility of the work may be reduced.

An important part of the dissemination process is to translate the information into easily digestible knowledge which is appropriate for the audience. One example might be presentation applicable for National Strategic Plan costing. In addition, it is important to share feedback with those that were involved in the cost analysis, such as stakeholders, clinic and laboratory managers, members of the NTP and Ministry of Health/Departments of Health, funders, and other interested parties.

Wherever possible data should be openly accessible to the public such as on the GHCC. If work is published in journal articles, open access should be granted so that the information becomes a public good.

SECTION F. APPENDICES

APPENDIX 1. BASIC CONCEPTS AND TERMS IN COSTING

Cost is a general term that refers to the value of resources or inputs used to produce a good or service. This can refer to financial, economic, unit (or average) or other types of costs depending on the ingredients included. **TB costing** is the process of estimating the value of resources used for a TB service/intervention through identification, measurement and valuing of resources consumed by an intervention.

Costs generally relate to four areas where costs are incurred: the health sector (health care providers), other sectors (e.g. education or housing sector), patients and households costs of seeking care, and productivity losses *[21]*. This manual focuses on costing the resources used in the health sector. In this methodology, common costs to different interventions (shared costs) are identified so that double counting (where the costs are accounted for more than once making the cost seem higher than it actually is) does not take place. This highlights the importance of understanding what one is costing, how the health system (or part of the health system) works and the processes that are involved.

Costs are comprised of **quantities of resource** used and the unit costs or **prices** (referred to as the prices and quantities – P's and Q's). To estimate quantities, several techniques might have to be employed: this could include interviewing staff about the time that tasks take them, using timesheets, observing consultation time, or following patients through a facility. For prices, market price can be used. This could be estimated through the current replacement value for a piece of equipment, or the price paid for an item (adjusted to the relevant year). Where price data is unavailable (for example to value the cost of volunteer time), a **shadow price** can be estimated to reflect the value of these resources.

Economic costs reflect the full value of all resources utilized in producing a good or service, for example the value of all resources used in a TB intervention. Economic costs include all resources, whether paid for or not; volunteers or donated goods should be included.

An **opportunity cost** is the value of the benefits that are sacrificed due to making an alternate choice to provide a service (hence the resources are not available) *[21]*. **Resources** refer to monetary resources as well as staff time, building space and equipment etc. Another way of looking at this opportunity cost is the value or benefit that one could have had if one had made a different choice. Economic costs are sometimes referred to as opportunity costs since they represent resources actually consumed, preventing the opportunity to devote those resources to another purpose. For example, if resources are used for expanding an MDR-TB programme, those same resources cannot be used for additional infection control measures. The opportunity cost is the benefits of the additional infection control measures.

When it comes to **donated goods and services** (such as volunteered time or donated clinic space), assessing **economic costs** should include and value these costs so that if a programme was reproduced elsewhere, all the costs would be accounted for. This is one area where economic and financial costs differ.

Financial costs are the actual expenditures, or monetary amount paid (the price tag), which are distinctly different from economic costs which include opportunity cost *[22]*. These costs are not generalizable across settings, unless there is a similar payment structure.

Cost of health service provision is the cost of providing health care, for instance through TB interventions, but this cost does not cover the payments made by patients nor economic costs borne by households.

A costing can be done from the point of view of the **provider (health services)** or a **societal perspective**. In addition, a **patient perspective** assesses the costs from the point of view of the patients themselves and considers both the **direct patient costs** such as medical out-of-pocket payments or non-medical expenses (transport, relocation costs) as well as **indirect costs** which relate to **productivity losses** such as time off work. The provider perspective takes the point of view of the provision of services, so here the costs are those incurred by a hospital, clinic or TB facility providing the services. With a **societal perspective**, provider and patient costs (and any broader societal costs) are combined in a meaningful way to assess the overall cost of an intervention to both the patient and provider.

Health care costs from the provider perspective can be divided into capital and recurrent costs. **Capital costs** are one-time costs for items that have a useful life of over one year – such as buildings, vehicles, laboratory or medical equipment. Usually capital costs are outlaid at the beginning of a programme (see **Table 2** for a comprehensive list of TB capital and recurrent items), and do not vary per patient treated. These costs are defined according to useful life of potential use rather than purchase price alone. Capital costs should be amortized (annuitized) or depreciated to reflect the expected life years of capital inputs (for example a building could be expected to have a useful lifetime of 30 years). This means that the initial capital item investment (the amount paid for the capital item, or the current replacement value), which is usually fairly substantial once off cost, is shared over the expected lifetime of the item so that it can be realistically reflected in an annual cost *[22]*.

Economic and financial costs also differ in the valuation of capital items. When performing an economic costing, one would amortize capital costs (as described in **Appendix 8**) so that both capital and recurrent costs are presented in the same year and can be meaningfully combined. In a sense, one is taking the large capital outlay and representing how much it would cost to have that item for a single year, by spreading the cost over the useful lifetime of that item. An amortization table is included in **Appendix 5** and an explanation of how to calculate the amortized cost in **Box A** below and in **Appendix 8** using Microsoft Excel (under subheading Amortizing capital costs).

Recurrent or operating costs are the value of resources or inputs with useful lives of less than one year. These inputs can be purchased irregularly and include chemicals and reagents within a laboratory. Their costs can be recovered at any time for instance by buying fewer supplies the next month to lower costs or by task shifting between lay workers and professional nurses for TB screening.

BOX A. AMORTIZING CAPITAL COSTS

To combine capital and recurrent costs in a substantial way, capital cost should be amortized (annuitized) or depreciated to reflect the expected useful life years of capital inputs (for example, 30 years for buildings).

The amortization process to estimate the annual value of the capital assets, including buildings, equipment, furniture, vehicles and training, is described below:

Step 1: Estimate the life expectancy (estimated life years) of the capital item; this may be 30 years for a building, 10 years for laboratory equipment, two years for training, etc.

Step 2: Establish the current replacement value or 'price' of the capital item (see source of costs above).

Step 3: Use the amortization table in **Appendix 5** to identify the amortization factor based on the number of expected life years (or 'number of remaining years or useful life' in the first column) and the desired discount rate (1–19%), or use the payment (PMT) function (as is done in the tool).

Step 4: Divide the current replacement value by the amortization factor to arrive at the amortized cost. If a discount rate of 0% is selected, the current replacement value can be divided by the expected life years to provide the amortized cost (also called the annualized financial cost).

Worked example 1: amortizing a building price

Step 1	Building, estimated life expectancy of 30 years
Step 2	Current replacement value $300 000
Step 3	30 years at 3% discount rate = 19.60
Step 4	$300 000/19.60 = $15 306
Step 4 if discount rate of 0% is used, then divide by the number of years – i.e. 30 years in this case	$300 000/30 = $10 000

This annual equivalent cost of $15306 can then be used when calculating the cost of space. For instance, if 30% of the building is used exclusively for TB outpatient visits, then the estimated annual cost of space allocated for TB outpatient visits is $4592. If 100 outpatient TB visits are made in the year, then the cost per TB outpatient visit for space only is $45.92.

The economic (using standard and local discount rates) and financial costs then need to be allocated to the departments providing direct (outpatient, inpatient and community), support (laboratory and radiology) and indirect services (pharmacy, administration & management, and other overhead services). The proportion allocated to each department has already been completed based on the building space being costed.

Overhead costs are costs that are necessary to support services but are not directly part of providing patient care (further examples are given in **Appendix 8**). Integral overhead costs for a facility could consist of items such as administration, cleaning, kitchen, utilities, security, laundry, monitoring and evaluation, pharmacovigilance, maintenance and training (if the effects last for less than a year).

Above site level costs are items that are necessary for the functioning the health system as whole, such as the management of human resources, financial services, information technology, procurement and others. Steps should be taken to disentangle whether an **above service** item is better placed under overhead costs (at the site level) or above site level costs and ensure that the cost has only been costed under one of the two. Above site level structures are essential to the smooth functioning of TB (and other) services but may be challenging to allocate to the facility or service level as they generally aid many different facilities of various sizes and types of service provision.

Total cost is the entire cost of producing the service, which is made up of fixed and variable costs. **Fixed costs** do not vary with the level of output *[22]*, whereas **variable costs** vary directly with the level of output. **Total costs** can also be calculated through the addition of recurrent and capital costs, i.e. the sum of all the costs of an intervention.

Marginal cost is the additional cost to produce one extra unit (change in total cost when one extra unit is produced) *[22]*.

Unit costs or average costs (mean costs) are the total costs divided by the quantity (service/output), with output being measured in different ways (i.e. the cost per patient treated, the cost per test or the cost per patient retained).

Full costing assesses all the resources used in the intervention, including basic infrastructure, overhead inputs, etc., as opposed to incremental costing.

Incremental costing estimates the costs of adding or implementing an additional study or programme to existing services. It is useful when sound data of existing service cost is available, but difficult to generalize to other settings. It does not include the cost of existing services and is appropriate when the intervention being costed is not a major component of an organization's activities. Incremental costing will underestimate costs that are of a general administrative nature (such as overhead inputs). It is more difficult to generalize from incremental cost analyses, unless the prior level of existing services and infrastructure is clearly specified and understood. Defining incremental costs may be challenging unless the analyst has sound data on current health service delivery capacity.

A **cost function** reflects the underlying production function of a service and how inputs/factors of production are combined to produce a health service – in this case, TB service. It describes how cost varies with input prices, volume of service provision (scale), quality or other factors.

Real world costing is done as per actual implementation, as seen in health facilities. This contrasts with **guideline costing/normative best practice costing** which is done per national (or WHO) guidelines. In an ideal world, guideline costing and real-world costing would produce similar results, however in most cases it is likely that there will be deviations in the real-world costing (for instance practical changes to the guidelines).

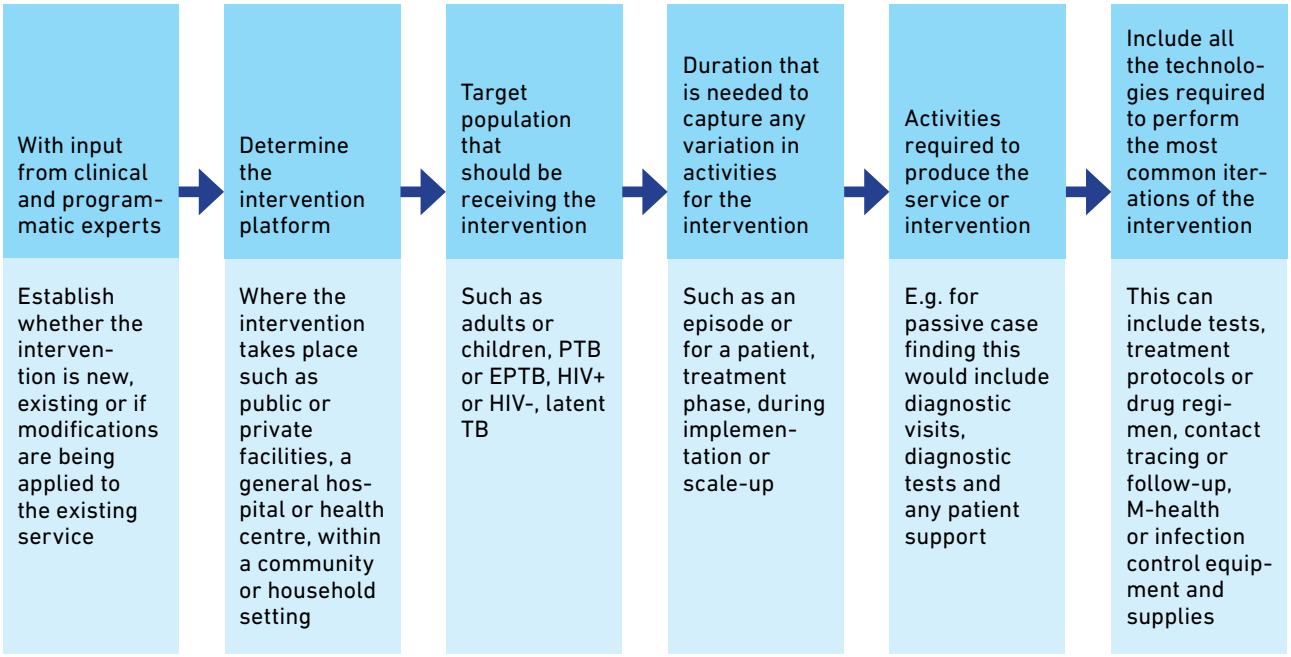
Two methods that are used in costing are **bottom-up** and **top-down costing**, although generally mixed methodology is used (a combination of both bottom-up and top-down costing). In essence, this refers to whether there are the time and resources needed to enter a facility and cost all the processes that are being undertaken within a facility or laboratory providing TB services (bottom-up costing), or whether if one has the appropriate information available that allows one to cost the services using a top-down approach (also known as gross costing or step-down accounting/costing). Both approaches have their limitations; however, Cunnama et al. 2016 recommend doing both as a gold standard, so that a range of costs can be produced, the lower limit representing the most efficient practice without regard for breaks, leave or suboptimal processing (bottom-up cost value). The upper limit represents a more inefficient and, in some ways, more realistic cost in terms of inclusion of leave, breaks, sub optimal processing speed and down time (top-down cost value). If the researcher has the resources (time and money) to perform both methodologies, then this is the recommended practice. Examples of these methodologies are given in **Appendix 8**.

APPENDIX 2. SPECIFIC TB INTERVENTIONS

Understanding the process of the intervention will help to establish which inputs are needed and what units will be costed. For example, inputs for costing an intervention in a clinic would differ from those used for costing in a laboratory setting. For this, it is necessary to describe the interventions (through national guideline review and consultation with experts) and how they are undertaken in the facility, laboratory, community or other setting (through time-motion studies, observation, work sampling or interviews).

To describe the TB intervention, one needs to have a clear understanding of the coverage in terms of what the intervention aims to achieve, whether that is defined by intervention specific targets or recent epidemiological data pertaining to the intervention (see **Figure 9**).

Fig. 9. Intervention flow chart



Vaccination

Vaccination for TB is used to prevent TB and currently includes the BCG vaccine for infants, children and young adults (between eight and eighteen years old). Treatment for adverse reactions has been included as part of the vaccination intervention.

TB case detection and diagnosis: Passive case finding

PCF is defined as detection of TB cases (screening and diagnosing of active and latent TB) reporting to public or private TB services in health facilities. The standard method of identifying people with TB is PCF, where individuals with TB symptoms present themselves at a health facility. A health worker assesses the person and orders a diagnostic test. Several technologies are available for PCF depending on the setting and patient attributes, including a verbal symptom screen, cough triage, sputum

induction, Xpert® MTB/RIF, (LED or Ziehl-Neelsen (ZN)) microscopy, culture (solid or liquid), film and digital x-ray, rapid HIV test, line probe assay for first (LPA-FLD) and second-line drugs (LPA-SLD), drug sensitivity testing (DST), LAMP, lateral flow urine lipoarabinomannan assay (LF-LAM), interferon-gamma release assay (IGRA) (where used for detection of latent TB infection (LTBI)), tuberculin skin test (TST, also known as Mantoux test or purified protein derivative (PPD) skin test), fine needle biopsy, bronchial and gastric lavage, and tests for extra-pulmonary TB (EPTB) (aspirates, computed tomography (CT) scan and ultrasound). Other tests include: HIV confirmatory test, cluster of differentiation 4 (CD4) count, erythrocyte sedimentation rate, total white blood cell count, full heamogram, aspartate aminotransferase (AST also known as serum glutamic-oxaloacetic transaminase (SGOT)), creatinine, creatinine clearance, glucose random blood sugar (RBS), lactic acid, lipase, thyroid stimulating hormone, body fluid analysis polymerase chain reaction – deoxyribonucleic acid (PCR-DNA) and electrocardiography (ECG). The population of concern includes both children and adults, irrespective of HIV status or TB strain. Costing should be conducted for the entire duration of the diagnostic visit, diagnostic test and patient support activity. PCF occurs in both public and private health facilities, but rarely occurs outside of the health facility or laboratory.

TB case detection and diagnosis: Intensified case finding

ICF detects potential active and latent TB cases among people living with HIV or diabetes or attending maternal and child health clinics or in other high-risk populations, receiving non-TB health care. Symptom screening, film or digital x-ray and Xpert® MTB/RIF are the main ICF technologies, but technologies used in PCF may also become part of the diagnostic algorithm for HIV positive adults, persons within high-risk groups (including people exposed to drug-resistant TB) attending health facilities, and children. Screening and diagnostic visits, diagnostic tests and patient support activities should be costed to obtain the unit cost of ICF.

TB case detection and diagnosis: Active case finding

ACF is defined as screening and diagnosing active and latent TB in those who are not in public health care (i.e. who are not detected passively). Generally, fewer technologies are used to detect cases actively, which include a verbal symptom screen, Xpert® MTB/RIF, microscopy (LED), film or digital X-ray, rapid HIV test, contract tracing, fine needle biopsy aspirates, CT scan or ultrasound. Other tests can include culture (solid or liquid), LPA, DST, IGRA, TST, and bronchial or gastric lavage. It can be conducted in private or public facilities, in mobile clinics, through outreach programmes such as to schools, prisons, or within the household. Target populations are household contacts (adults and children less than five and between five and eighteen years old), poor urban populations, prisoners, mobile populations, migrant populations, healthcare and other workers with an occupational risk of contracting TB. Any new ACF technologies should be costed during the start-up as well as the continued implementation for a patient or an episode. The activities included in ACF are the screening visits, diagnostic visits, diagnostic tests and all patient support services.

TB treatment

TB treatment includes all activities involved in treating patients with active TB, observation of treatment, patient support, restoring quality of life and productivity, preventing relapse or death, reducing transmission and preventing development and transmission of drug resistance. During the intensive and continuation phases of treatment, persons of all ages being treated for either DS-TB or DR-TB (mono-resistant, poly-drug resistant, Rifampicin resistant, MDR-TB, pre-XDR-TB or XDR-TB) can be treated within the household, the community, through outreach programmes, in public or private facilities, or at general or specialized TB hospitals. HIV-positive or negative patients with either pulmonary TB (PTB) or EPTB are included. In addition to the drugs for first-, second- and third-line treatment; retreatment, palliative care, monitoring tests for treatment response, adverse events, nutritional assessment, lost to follow-up tracing, ART regiment if HIV-positive and M-health are included in TB treatment.

TB prevention

TB prevention refers to screening and treatment to prevent latent and active TB (PTB and EPTB) amongst children and HIV-positive adults. Screening visits, treatment monitoring (including for breakthrough disease, adverse events, acquired drug resistance), visits occur in public or private facilities. The technologies for prevention of TB include symptom screening to rule out active TB, IGRA test or TST, as well as treatment protocols of isoniazid for six months (6H), lifelong isoniazid (H), three months of once-weekly isoniazid and rifapentine (3HP), or rifapentine only, ART regimen for HIV positive patients and cotrimoxazole prophylaxis.

TB infection control

Infection control for TB in environments such as health facilities, laboratories, congregate settings and households involves a combination of activities to minimise the risk of transmitting TB within these settings. Successful TB infection control includes early and fast diagnosis of TB, coupled with appropriate management of people with TB.

Within health facilities, in addition to the administrative controls to reduce diagnostic delays and prompt treatment initiation, infection control for patients, laboratory staff and health care workers includes the use of ventilation systems, laboratory biosafety systems, UV fixtures and personal protective equipment.

Congregate settings include hospital premises, prisons, refugee camps and schools. TB infection control in these settings must be coordinated with other sectors. Within households, TB infection prevention includes campaigns educating on behaviour and social change to minimize exposure. The delivery platforms include private and public health facilities, as well as facilities managed by international and national NGOs. Infection control can also occur in community-based activities and during outreach activities.

TB programme above site services: Above service costs

At the national level activities and technologies that contribute to the successful delivery of TB services include development of strategic plans, TB care guidance development or adaptation, programme reviews, national and regional meetings, surveys,

management and information systems, supervision, procurement and supply chain management, transportation of specimens, advocacy, technical assistance, training, accreditation and quality assurance of labs, community media or information, education and communication (IEC) campaigns or any partnership activities.

The delivery platforms for these activities and technologies are ministries of health, NTPs, reference laboratories, government and non-government research institutes, public health facilities, private health facilities and laboratories, regulatory bodies for food, drugs and health, NGOs, and bi- and multi-lateral partners, including WHO. Populations involved in these activities include health care workers, laboratory staff and management involved in TB or any support services.

Defining standard costs for each intervention

Table 3 was devised as part of the GHCC and Reference Case development. The table lists the interventions and a default and optional unit cost per recipient. The default unit cost per recipient is the one that makes the most sense in terms of standardising and using these costs for budgeting and modelling purposes. **Table 3** also lists the possible outputs as well as the direct and ancillary (supportive) unit costs per output.

Table 3. Defining standard unit costs for each intervention

Intervention	Unit cost per recipient	List of outputs	Unit cost per output direct	Unit cost per output ancillary
Vaccination	Default unit cost (required) *Cost per person vaccinated*	Outpatient visit Community visit	Cost per outpatient visit Cost per outpatient visit	Cost per person supported
Passive case finding	Default unit cost (required) *Cost per person diagnosed DS-TB* Quality adjusted unit cost per recipient (optional) *Cost per person diagnosed DR-TB* *Cost per TB case diagnosed*	Outpatient visit Inpatient bed-day Diagnostic test (sample/slide) Patient support provision per patient Above service outputs	Cost per outpatient visit Cost per inpatient visit Cost per test Cost per sample/slide	Cost per person supported
Intensified case finding	Cost per person screened Cost per person diagnosed Cost per TB case diagnosed	Patient screen Outpatient visit Inpatient bed-day Triage test Diagnostic test (sample/slide) Patient support provision	Cost per screen Cost per outpatient visit Cost per inpatient visit Cost per triage test Cost per diagnostic test Cost per sample/slide	Cost per patient support (per visit, screen or diagnosis)
Active Case Finding	Cost per person screened Cost per person diagnosed Cost per TB case diagnosed	Patient screen Outpatient visit Inpatient bed-day Triage test Diagnostic test (sample/slide) Patient support provision Community event	Cost per screen (different platforms and algorithms) Cost per outpatient visit Cost per inpatient visit Cost per mobile clinic visit Cost per household visit Cost per other visit Cost per triage test Cost per diagnostic test Cost per sample/slide	Cost per patient support (per visit, screen or diagnosis) Cost per community event
TB treatment	Cost per treatment month DS-TB Cost per treatment month MR-TB/ Cost per treatment month PDR-TB/ Cost per treatment month MDR-TB/ Cost per treatment month pre-XDR-TB/ Cost per treatment month XDR-TB Cost per person treated Cost per person completing treatment Cost per treatment monitoring	Outpatient visit Inpatient bed-day DOT visit community platform Monitoring test	Cost per outpatient visit Cost per inpatient bed-day Cost per DOT visit community Cost per microscopy Cost per other test Cost per DS-TB regimen Cost per short DR-TB regimen Cost per long DR-TB regimen	Cost per person patient support Cost per person month patient support Cost per patient support visit

Intervention	Unit cost per recipient	List of outputs	Unit cost per output direct	Unit cost per output ancillary
TB prevention	Cost per treatment month LTBI Cost per person treated LTBI Cost per person completing treatment LTBI	Outpatient visit Person screened Diagnostic test	Cost per outpatient visit Cost per screen Cost per test Cost per regimen	Cost per person month patient support Cost per person patient support Cost per patient support visit Cost per community event
TB infection control	Cost per facility Cost per laboratory			
TB programme above site services: Above service costs	If included in intervention then unit cost per recipient estimated by 1) multiplying each unit cost by unit (facility, district etc.) 2) if top-down cost dividing by an allocation formula per intervention, 3) divided by number of recipients	Advocacy campaign Training programme per facility Accreditation per laboratory Community mobilisation campaign per district		Programme management cost per region Programme management cost per district Cost of supervision per facility IT/software cost per national system Cost per surveillance study Cost of advocacy per district Cost of community campaign per district Cost of training per facility Cost of support per laboratory Cost of supply chain per region

Adapted annex 3 of the Reference Case[5]

APPENDIX 3. STANDARDIZED UNIT COSTS FOR TB INTERVENTIONS

This is taken from Annex 3 of the Reference Case *[5]*

Intervention class	Intervention	Intervention Details	Technology	Platform (choose more than one only when necessary)	Population (choose more than one only when necessary)	STANDARD UNIT COST INTERVENTION (quality-adjusted unit cost)	STANDARD UNIT COST SERVICE DIRECT	STANDARD UNIT COST SERVICE ANCILLARY
Vaccination	Vaccination	Vaccination to prevent TB	BCG vaccination alone BCG, plus treatments for adverse reactions: liver function, creatinine, serum potassium, thyroid stimulating hormone, audiometry, symptom screening for peripheral neuropathy (specify)	Community Mobile Private facility for profit (different facilities) Private facility not for profit (different facilities) Public facility (different departments) Public/private mix	Infants Children and young adult population (11–18 years)	Cost per person vaccinated	Cost per outpatient visit Cost per community visit	Cost per person supported

Intervention class	Intervention	Intervention Details	Technology	Platform (choose more than one only when necessary)	Population (choose more than one only when necessary)	STANDARD UNIT COST INTERVENTION (quality-adjusted unit cost)	STANDARD UNIT COST SERVICE DIRECT	STANDARD UNIT COST SERVICE ANCILLARY
TB case detection and diagnosis	Passive Case Finding	Screening and diagnosing **active and latent** TB in those who report to TB services with symptoms	Aspirates (EPTB) AST also known as SGOT Body fluid analysis PCR-DNA Bronchial lavage CD4 count Cough triage Creatinine Creatinine clearance CT scan (EPTB) Culture (solid media) Culture (liquid media) Digital x-ray DST – FLD (solid media) DST- SLD (solid media) DST – FLD (liquid media) DST – SLD (liquid media) ECG Erythrocyte sedimentation rate Fine needle biopsy Full heamogram Gastric lavage Glucose (RBS) HIV confirmatory test IGRAa Lactic Acid LAMP LF-LAM Lipase LPA – FLD LPA – SLD Microscopy (LED) Microscopy (ZN) Rapid HIV Test Sputum induction Symptom screen Thyroid stimulating hormone Total white blood cell count TST or PPD or Mantoux test Ultrasound (EPTB) Xpert® MTB/RIF X-ray film	Public facility (TB care) Private facility (TB care) May include clinic type (e.g. HIV, diabetes, MCH etc.)	Children Adults (HIV+, HIV-) Adults (pulmonary TB, EPTB) Adults (DS-TB, MDR-TB, pre-XDR-TB, XDR-TB)	Cost per person screened for TB Cost per person diagnosed TB Cost per TB case diagnosed	Cost per screening visit (different platforms and approaches) Cost per diagnostic visit Cost per other outpatient visit (by clinic where relevant) Cost per inpatient bed-day (e.g. for children needing fine needle biopsy) Cost per diagnostic test Cost per x-ray or radiology test	Cost per person or visit patient support (vouchers, cash or other) Cost per PPM activity Cost per person lost to follow-up tracing

Intervention class	Intervention	Intervention Details	Technology	Platform (choose more than one only when necessary)	Population (choose more than one only when necessary)	STANDARD UNIT COST INTERVENTION (quality-adjusted unit cost)	STANDARD UNIT COST SERVICE DIRECT	STANDARD UNIT COST SERVICE ANCILLARY
TB case detection and diagnosis	Intensified case finding	Detect potential **active and latent** TB among people living with HIV or in other high-risk populations receiving non-TB health care (diabetes, MCH clinics)	Aspirates (EPTB) Bronchial lavage CT scan (EPTB) Culture (solid media) Culture (liquid media) Digital x-ray DST (solid media) DST – FLD (liquid media) DST – SLD (liquid media) Fine needle biopsy Gastric lavage IGRA[a] LAMP LF-LAM LPA – FLD LPA – SLD Microscopy (LED) Microscopy (ZN) Rapid HIV Test Symptom Screen TST or PPD or Mantoux test Ultrasound (EPTB) Xpert® MTB/RIF X-ray film	Public facility (different departments) Private facility (different facilities)	Adults (HIV+) Other high-risk groups attending health facilities	Cost per person screened Cost per person diagnosed Cost per TB case diagnosed	Cost per screen (different platforms and approaches) Cost per outpatient visit Cost per inpatient bed-day Cost per triage test Cost per diagnostic test	Cost per person or visit patient support (vouchers, cash or other) Cost per PPM activity Cost per PAL activity Cost per person lost to follow-up tracing
TB case detection and diagnosis	Active Case Finding	Screening and diagnosing **active and latent** TB in those who are not in public health care	Aspirates (EPTB) Bronchial lavage Contact tracing CT scan (EPTB) Culture (solid) Culture (liquid) media Digital x-ray DST Fine needle biopsy Gastric lavage IGRA[a] LPA Microscopy (LED) Rapid HIV Test Symptom Screen TST or PPD or Mantoux test Ultrasound (EPTB) Xpert® MTB/RIF X-ray film	Household Mobile Prisons Schools (through health facility outreach)	Household contacts: Adults Children under 5 Children 5–18 Prisoners Poor urban populations (slums) Mobile and migrant populations Private providers Occupational groups (miners, health-care workers, etc.)	Cost per person screened Cost per person diagnosed Cost per TB case diagnosed	Cost per screen (different platforms and algorithms) Cost per outpatient visit Cost per inpatient bed-day Cost per mobile clinic visit Cost per community screening visit Cost per community diagnostic visit Cost per triage test Cost per diagnostic test	Cost per person or visit patient support (vouchers, cash or other) Cost per community event

Intervention class	Intervention	Intervention Details	Phase	Technology	Platform (choose more than one only when necessary)	Population (choose more than one only when necessary)	STANDARD UNIT COST INTERVENTION (quality-adjusted unit cost)	STANDARD UNIT COST SERVICE DIRECT	STANDARD UNIT COST SERVICE ANCILLARY
TB treatment	TB Treatment	Treatment of active TB with observation and possibly patient support	Intensive Continuation	First-line treatment Retreatment Second-line treatment Third-line treatment Palliative care Monitoring tests (for status, adverse events and nutritional assessment) Follow up of defaulters M-health ART regimen if HIV+	Household Community Public facility Private facility Hospital general Hospital TB	Children Adults (HIV+, HIV-) Adults (pulmonary TB, EPTB) Adults (DS-TB, MDR-TB, pre-XDR-TB, XDR-TB)	Cost per treatment month DS-TB Cost per treatment month DR-TB Cost per treatment month MDR-TB Cost per treatment month pre-XDR-TB Cost per treatment month XDR-TB Cost per person treated Cost per treatment monitoring Cost per person completing treatment	Cost per outpatient visit Cost per inpatient bed-day Cost per DOT visit community Cost per DOT outpatient visit Cost per drug pick up visit Cost per community treatment visit Cost per microscopy Cost per other test Cost per DS-TB regimen Cost per short DR-TB regimen Cost per long DR-TB regimen	Cost per person month patient support Cost per person patient support Cost per patient support visit Cost per community event

Intervention class	Intervention	Intervention Details	Technology	Platform (choose more than one only when necessary)	Population (choose more than one only when necessary)	STANDARD UNIT COST INTERVENTION (quality-adjusted unit cost)	STANDARD UNIT COST SERVICE DIRECT	STANDARD UNIT COST SERVICE ANCILLARY
TB prevention	TB Prevention	Treatment of latent TB	3HP 6H ART regimen if HIV+ Cotrimoxazole prophylaxis IGRA[a] Lifelong isoniazid Monitoring tests (breakthrough disease, adverse events and acquired drug resistance) Rifapentine TB screen to rule out active TST or PPD or Mantoux test	Public facility (HIV care) Public facility Private facility Hospital general Hospital TB	Children Adults (HIV+)	Cost per treatment month latent TB infection Cost per person treated latent TB infection Cost per person completing treatment latent TB infection	Cost per outpatient visit Cost per screen Cost per test Cost per regimen	Cost per person month patient support Cost per person patient support Cost per patient support visit Cost per community event
TB infection control	TB infection control	Administrative, environmental and personal protection to prevent infection in health facilities and laboratories	Administrative controls Biosafety in laboratories Environmental (ventilation, UV lights) Infection control for patients Protective equipment and supplies	Public facility Private facility Hospital general Hospital TB	Health care workers Patients Accompanying family or friend or supporter or DOT observer Laboratory staff	Cost per facility Cost per laboratory		Activity unit costs Costs per laboratory specification Cost of safety equipment Cost of personal protective equipment Cost of waste handling Cost per safety training Cost of codes and standard operating procedures

Intervention class	Intervention	Intervention Details	Technology	Platform (choose more than one only when necessary)	Population (choose more than one only when necessary)	STANDARD UNIT COST INTERVENTION (quality-adjusted unit cost)	STANDARD UNIT COST SERVICE DIRECT	STANDARD UNIT COST SERVICE ANCILLARY
TB policy, planning, coordination and management	TB policy, planning, coordination and management	Policy, planning, coordination and management for TB services	Development of strategic plans Programme reviews National meetings Regional meetings Supervision Management and information systems Surveys Procurement and supply chain management Advocacy Technical assistance Training Accreditation and quality assurance for laboratories Transport for specimens Community media Information, education and communication Partnership Activities	National TB programme Ministry of Health Public health facilities and laboratories Private health facilities and laboratories Non-governmental organizations	Health-care workers Laboratory staff Management	Cost per programme		Activity unit costs Costs per training Costs per software development Cost per event Cost per workshop Cost per supervisory visit Cost per item transported

TB: tuberculosis;
MTB: mycobacterium tuberculosis;
RIF: rifampicin;
LED: light-emitting diode;
ZN: Ziehl Neelsen;
HIV: human immunodeficiency virus;
CD4: cluster of differentiation 4;
LPA: line probe assay;
FLD: first-line drug;
SLD: second-line drug;
DST: drug-susceptibility testing;
LAMP: loop-mediated isothermal amplification;
LF-LAM: lateral flow urine lipoarabinomannan assay;
IGRA: interferon-gamma release assay;
TST: tuberculin skin test;
PPD: purified protein derivative;
AST: aspartate aminotransferase;
SGOT: serum glutamic-oxaloacetic transaminase;
RBS: random blood sugar;
PCR-DNA: polymerase chain reaction-deoxyribonucleic acid;
EPTB: extra-pulmonary tuberculosis;
CT: computed tomography;
ECG: electrocardiography;
MCH: maternal child health;
DS-TB: drug sensitive TB;
MDR-TB: multidrug-resistant;
Pre-XDR-TB: pre-extensively drug-resistant TB;
XDR-TB: extensively drug-resistant;
PPM: public-private mix;
PAL: practical approach to lung health;
M-health: mobile health;
ART: antiretroviral therapy;
DR-TB: drug resistant TB;
DOT: directly observed treatment;
6H: 6-month isoniazid;
3HP: once-weekly isoniazid-rifapentine for 12 weeks
UV: ultraviolet;

[a] IGRA is not recommended for detection of latent TB infection in WHO Guidelines but is being used in some settings.

APPENDIX 4. PRINCIPLES AND METHODS REPORTING CHECKLIST

This table is recommended by GHCC for reporting methods *[5]*. For a specific costing study, the "Options" column should be completed according to how the study was conducted.

Reference Case Checklist Items	Options
STUDY DESIGN AND SCOPE	
Principle 1 – The purpose of the study, the population, and the intervention and/or service/output being costed should be clearly defined.	
Purpose	
Purpose type:	Economic evaluation, Financial planning, Budget impact analysis, Efficiency analysis, Other
Relevance for health practice and/or policy decisions:	Free text
Aim of the cost analysis:	Free text
Intended user(s) of the cost estimate:	Free text
Intervention	
Main activities/technologies involved:	Free text
Target population:	As relevant: age, gender, geographical location, clinical indication
Coverage level:	Percentage of target population or sites
Delivery mechanism (e.g. health system level, facility type, ownership, etc.):	As relevant: level of health service, facility type
Epidemiological context (i.e. incidence/prevalence of disease)	As relevant: incidence and/or prevalence
Intervention	Describe production process (e.g. list main activities and key technologies involved in delivering the intervention)
Principle 2 – The perspective (extent of the resource use captured) of the cost estimation should be stated and justified relevant to purpose	
Study perspective (e.g. provider, health system, societal, household):	(Named) provider or societal, and list specific payers. State any stopping rules.
Principle 3 – The type of cost being estimated should be clearly defined, in terms of economic vs financial, real world vs guideline, and incremental vs full cost, and whether the cost is 'net of future cost', should be justified relevant to purpose.	
Defining the cost	
Economic vs. financial cost	Economic vs. financial cost
Real world' vs. guideline cost	Real world' vs. guideline cost
Full vs. incremental cost	Full vs. incremental cost
Net of future cost	Yes or No
Principle 4 – The 'units' in the unit costs for strategies, services and interventions should be defined, relevant for the costing purpose and generalizable	
List the unit costs used:	Choose from list of standardized unit costs
Describe any adjustments made to reflect the quality of service output:	Choose from list of standardized adjustments

Reference Case Checklist Items	Options
Principle 5 – The time horizon should be of sufficient length to capture all costs relevant to the purpose, and consideration should be given to disaggregating costs into separate time periods where appropriate.	
Time period	
Period type (start-up vs implementation):	Start-up, implementation or both
Time period:	Years and months
SERVICE AND RESOURCE USE MEASUREMENT	
Principle 6 – The scope of the inputs to include in the cost estimation should be defined and justified relevant to purpose	
Defining the scope	
Above service delivery costs included:	Yes or No
Costs of supporting change included:	Yes or No
Research costs included:	Yes or No
Unrelated costs included:	Yes or No
If incremental costs, assumptions made for existing capacity	Free text
Any exclusions other to scope:	Free text
Principle 7 – The methods for estimating the quantity of inputs should be described, including methods, data sources and criteria for allocating resources	
Describe the measurement of each input as either top-down or bottom-up	Top-down or bottom-up
Describe method to allocate human resources inputs	Observation, timesheets, work-sampling, interviews, other
Describe methods to allocated above site/overhead inputs	Method, criteria and data source for criteria
Describe the methods for excluding research costs:	Method, criteria and data source for criteria
Describe the methods for measuring other resources	Method and data source
Principle 8 – The sampling strategy used should be determined by the precision demanded by the costing purpose and designed to minimise bias	
Site/client selection process/criteria	
Describe geographic sampling (if applicable):	Frame and method
Describe site sampling (if applicable):	Frame and method
Describe patient sampling (if applicable):	Frame and method
Describe methods to calculate sample size:	Calculation
Principle 9 – The selection of the data source(s) and methods for estimating service use should be described, and potential biases reported in the study limitations.	
Identify the data source used to measure the units:	Case note extraction, patient interviews, provider interviews, routine information systems, claims data, other
Where relevant describe the sampling frame, method and size:	Free text
Describe any method used to fill missing data	Free text

Reference Case Checklist Items	Options
Principle 10 – Consideration should be given to the timing of data collection to minimize recall bias and, where relevant, the impact of seasonality and other differences over time	
The timing of data collection should be specified in the following ways:	
Timing of data collection (resource and service use)	Date of data collection
Prospective or retrospective	Prospective or retrospective
Longitudinal vs. cross-sectional data:	Longitudinal vs. cross-sectional data:
Where relevant recall period:	Months or weeks
VALUATION AND PRICING	
Principle 11 – The sources for price data should be listed by input, and clear delineation should be made between local and international price data sources, and tradeable and non-tradeable goods.	
Report the sources of price data by input:	Ministry of Health, local market etc.
Report inputs where local and international prices were used:	Local or international
Principle 12 – Capital costs should be appropriately annuitized or depreciated to reflect the expected life of capital inputs	
Describe the depreciation approach:	Straight line depreciation, amortization
Describe any discount rate used for capital goods:	Percentage
Report the expected life years of capital goods, and data sources:	Years and free text
Principle 13 – Where relevant an appropriate discount rate, inflation and exchange rates should be used, and clearly stated.	
Describe any discount rate used for future costs:	Percentage
Describe the reported currency year:	Currency and year
Describe any conversions made:	Exchange rate, source and year
Report the inflation type and rate used:	Percentage, GDP deflator/CPI, source
Principle 14 – The use and source of shadow prices for goods and for the opportunity cost of time should be reported	
Methods for valuing the following should be reported:	
Report methods for valuing volunteer time:	Free text
Report adjustments for input prices (donated or subsidised goods):	Free text
ANALYSING AND PRESENTING RESULTS	
Principle 15 – Variation in the cost of the intervention by site size/organization, sub-populations, or by other drivers of heterogeneity should be explored and reported.	
Describe any sub-groups or populations analysed	Free text
Describe any statistical methods used to establish differences in unit costs by sub-group	Free text
Describe any determinants of cost (model specification)	Free text
Describe any multivariate statistical methods used to analyse cost functions	Free text

Reference Case Checklist Items	Options
Principle 16 – The uncertainty associated with cost estimates should be appropriately characterized.	
Describe sensitivity analyses conducted	Free text
List possible sources of bias	Free text
Principle 17 – Cost estimates should be communicated clearly and transparently to enable decision-maker(s) to interpret and use the results.	
Limitations	
Limitations in the design, analysis, and results:	Free text
Aspects of the cost estimates that would limit generalizability of results to other constituencies:	Free text
Conflicts of interest	
All pecuniary and non-pecuniary interests of the study contributors:	Free text
All sources of funding that supported conduct of the costing:	Free text
Non-monetary sources of support for conduct of the costing:	Free text
Open access	
Dataset available	Yes or No

APPENDIX 5. AMORTIZATION TABLE

Use the number of expected life years (or 'number of remaining years or useful life' in the first column) and the desired discount rate (1–19%) to find the amortization factor.

n	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%	11%	12%	13%	14%	15%	16%	17%	18%	19%	20%
1	0.990	0.980	0.971	0.962	0.952	0.943	0.935	0.926	0.917	0.909	0.901	0.893	0.885	0.877	0.870	0.862	0.855	0.847	0.840	0.833
2	1.970	1.942	1.913	1.886	1.859	1.833	1.808	1.783	1.759	1.736	1.713	1.690	1.668	1.647	1.626	1.605	1.585	1.566	1.547	1.528
3	2.941	2.884	2.829	2.775	2.723	2.673	2.624	2.577	2.531	2.487	2.444	2.402	2.361	2.322	2.283	2.246	2.210	2.174	2.140	2.106
4	3.902	3.808	3.717	3.630	2.546	3.465	3.387	3.312	3.240	3.170	3.102	3.037	2.974	2.914	2.855	2.798	2.743	2.690	2.639	2.589
5	4.853	4.713	4.580	4.452	4.329	4.212	4.100	3.993	3.890	3.791	3.696	3.605	3.517	3.433	3.352	3.274	3.199	3.127	3.058	2.991
6	5.795	5.601	5.417	5.242	5.076	4.917	4.767	4.623	4.486	4.355	4.231	4.111	3.998	3.889	3.784	3.685	3.589	3.498	3.410	3.326
7	6.728	6.472	6.230	6.002	5.786	5.582	5.389	5.206	5.033	4.868	4.712	4.564	4.423	4.288	4.160	4.039	3.922	3.812	3.706	3.605
8	7.652	7.325	7.020	6.733	6.463	6.210	5.971	5.747	5.535	5.335	5.146	4.968	4.799	4.639	4.487	4.344	4.207	4.078	3.954	3.837
9	8.566	8.162	7.786	7.435	7.108	6.802	6.515	6.247	5.995	5.759	5.537	5.328	5.132	4.946	4.772	4.607	4.451	4.303	4.163	4.031
10	9.471	8.983	8.530	8.111	7.722	7.360	7.024	6.710	6.418	6.145	5.889	5.650	5.426	5.216	5.019	4.833	4.659	4.494	4.339	4.192
11	10.368	9.787	9.253	8.760	8.306	7.887	7.499	7.139	6.805	6.495	6.207	5.938	5.687	5.453	5.234	5.029	4.836	4.656	4.486	4.327
12	11.255	10.575	9.954	9.385	8.863	8.384	7.943	7.536	7.161	6.814	6.492	6.194	5.918	5.660	5.421	5.197	4.988	4.793	4.611	4.439
13	12.134	11.348	10.635	9.986	9.394	8.853	8.358	7.904	7.487	7.103	6.750	6.424	6.122	5.842	5.583	5.342	5.118	4.910	4.715	4.533
14	13.004	12.106	11.296	10.563	9.899	9.295	8.745	8.244	7.786	7.367	6.982	6.628	6.302	6.002	5.724	5.468	5.229	5.008	4.802	4.611
15	13.865	12.849	11.938	11.118	10.380	9.712	9.108	8.559	8.061	7.606	7.191	6.811	6.462	6.142	5.847	5.575	5.324	5.092	4.876	4.675
16	14.718	13.578	12.561	11.652	10.838	10.106	9.447	8.851	8.313	7.824	7.379	6.974	6.604	6.265	5.954	5.668	5.405	5.162	4.938	4.730
17	15.562	14.292	13.166	12.166	11.274	10.477	9.763	9.122	8.544	8.022	7.549	7.120	6.729	6.373	6.047	5.749	5.475	5.222	4.990	4.775
18	16.398	14.992	13.754	12.659	11.690	10.828	10.059	9.372	8.756	8.201	7.702	7.250	6.840	6.467	6.128	5.818	5.534	5.273	5.033	4.812
19	17.226	15.678	14.324	13.134	12.085	11.158	10.336	9.604	8.950	8.365	7.839	7.366	6.938	6.550	6.198	5.877	5.584	5.316	5.070	4.843
20	18.046	16.351	14.877	13.590	12.462	11.470	10.594	9.818	9.129	8.514	7.963	7.469	7.025	6.623	6.259	5.929	5.628	5.353	5.101	4.870
21	18.857	17.011	15.415	14.029	12.821	11.764	10.836	10.017	9.292	8.649	8.075	7.562	7.102	6.687	6.312	5.973	5.665	5.384	5.127	4.891
22	19.660	17.658	15.937	14.451	13.163	12.042	11.061	10.201	9.442	8.772	8.176	7.645	7.170	6.743	6.359	6.011	5.696	5.410	5.149	4.909
23	20.456	18.292	16.444	14.957	13.489	12.303	11.272	10.371	9.580	8.883	8.266	7.718	7.230	6.792	6.399	6.044	5.723	5.432	5.167	4.925
24	21.243	18.914	16.936	15.247	13.799	12.550	11.469	10.529	9.707	8.985	8.348	7.784	7.283	6.835	6.434	6.073	5.746	5.451	5.182	4.937
25	22.023	19.523	17.413	15.622	14.094	12.783	11.654	10.675	9.823	9.077	8.422	7.843	7.330	6.873	6.464	6.097	5.766	5.467	5.195	4.948
26	22.795	20.121	17.877	15.983	14.375	13.003	11.826	10.810	9.929	9.161	8.488	7.896	7.372	6.906	6.491	6.118	5.783	5.480	5.206	4.956
27	23.560	20.707	18.327	16.330	14.643	13.211	11.987	10.935	10.027	9.237	8.548	7.943	7.409	6.935	6.514	6.136	5.798	5.492	5.215	4.964
28	24.316	21.281	18.764	16.663	14.898	31.406	12.137	11.051	10.116	9.307	8.602	7.984	7.441	6.961	6.534	6.152	5.810	5.502	5.223	4.970
29	25.066	21.844	19.188	16.984	15.141	13.591	12.278	11.158	10.198	9.370	8.650	8.022	7.470	6.983	6.551	6.166	5.820	5.510	5.229	4.975
30	25.80	22.396	19.600	17.292	15.372	13.765	12.409	11.258	10.274	9.427	8.694	8.055	7.496	7.003	6.566	6.177	5.829	5.517	5.235	4.979

N=Number of remaining years of useful life

APPENDIX 6. PROTOCOL OUTLINE

Title of the study
Investigators and institutional affiliations
Abstract
Introduction/Background
Justification for the study/Purpose and study question
Null hypothesis
Objectives:

1. General objectives
2. Specific objectives

Study design and methodology:

1. Study site
2. Study populations
3. Sampling
4. Procedures
    a. Costing methods
    b. Interventions and unit costs
    c. Piloting and data collection

Perspective of the evaluation
Selecting a study team
Data management:

1. Data storage
2. Data analysis

Intellectual property
Time frame/Duration of the study:
Ethical consideration:

1. Human subjects
2. Informed consent
3. Confidentiality
4. Benefits and risks
5. Data sharing
6. Community engagement

Expected application of the results
References
Appendices:
Appendix 1: Summary budget
Appendix 2: Justification of budget
Appendix 3: Role of investigators
Appendix 4: Description of interventions

1. Vaccination intensified case finding
2. Active case finding
3. Passive case finding
4. Treatment of TB
5. Prevention (latent TB infection treatment)
6. Infection prevention control
7. TB policy, planning, coordination and management

Appendix 5: Facility information sheet
Appendix 6: Informed consent
Appendix 7: Curriculum vitae of each investigator

APPENDIX 7. EXAMPLES OF QUERIES AND COMMENTS FROM ETHICS COMMITTEES

1. What will happen if facilities do not agree to take part? Will you need to rerun your sample?
2. Could you add more information on the observations?
3. Special care needs to be given to ensure the anonymity of participants and to mitigate the risk that they are identifiable by their location/institution. Be careful about how you describe respondents to ensure that they cannot be identified by location/role. The sentence "Your questionnaire will not bear your names; this way your responses will be anonymous" is not always true if you reveal the respondents job title and hint at their location – colleagues/managers will know who has been interviewed and may be able to identify who said what.
4. In both the information sheet and consent form, it should be specified how the observation will be done, who and number of observers involved. Similarly, with the timesheet it should state in the consent form the actual period rather than saying 'over the period specified'.
5. In the information sheet, it states that participation is voluntary and that choosing to withdraw can be at any time without consequence. The committee suggest adding the commonly used 'without the need to give a reason'.
6. The committee thinks you should consider asking participants to initial the sentences indicating permission granted for different aspects of your research rather than ticking a box.
7. How will the data be aggregated? Since only 3–5 staff per facility will be interviewed, will there not be a risk of breach of confidentiality?
8. The approach and justification for the proposed sampling of health facilities is unclear. Please explain how the reference list of 25 was derived?
9. The information sheet/consent form states that they may be asked to complete a diary over the course of one week or allow researchers to observe them as they go about daily tasks. Is the observation for 1-day or 1-week? Please make that clear to the participant.
10. Kindly consider adding the study population in the title.
11. Please clarify whether both direct and indirect costs will be collected.
12. Indirect cost is an important cost driver for TB services, why was this not necessary in this study?
13. Three (3) regions Nairobi, Eastern and Western Kenya were selected due to high number of TB cases, but sampling table does not show the five other regions of Kenya to justify site selections. Please clarify.
14. Sampling of health facilities has been provided but the sample size determination has not been provided. Of the total 3690, you will randomly select 24 facilities, which translates to 20% margin of error which is quite low compared to traditional 5% margin of error which would need 350 health facilities with adequate power to generalize to the entire country: please provide a section for sample size determination and procedures and level of power needed for analysis.

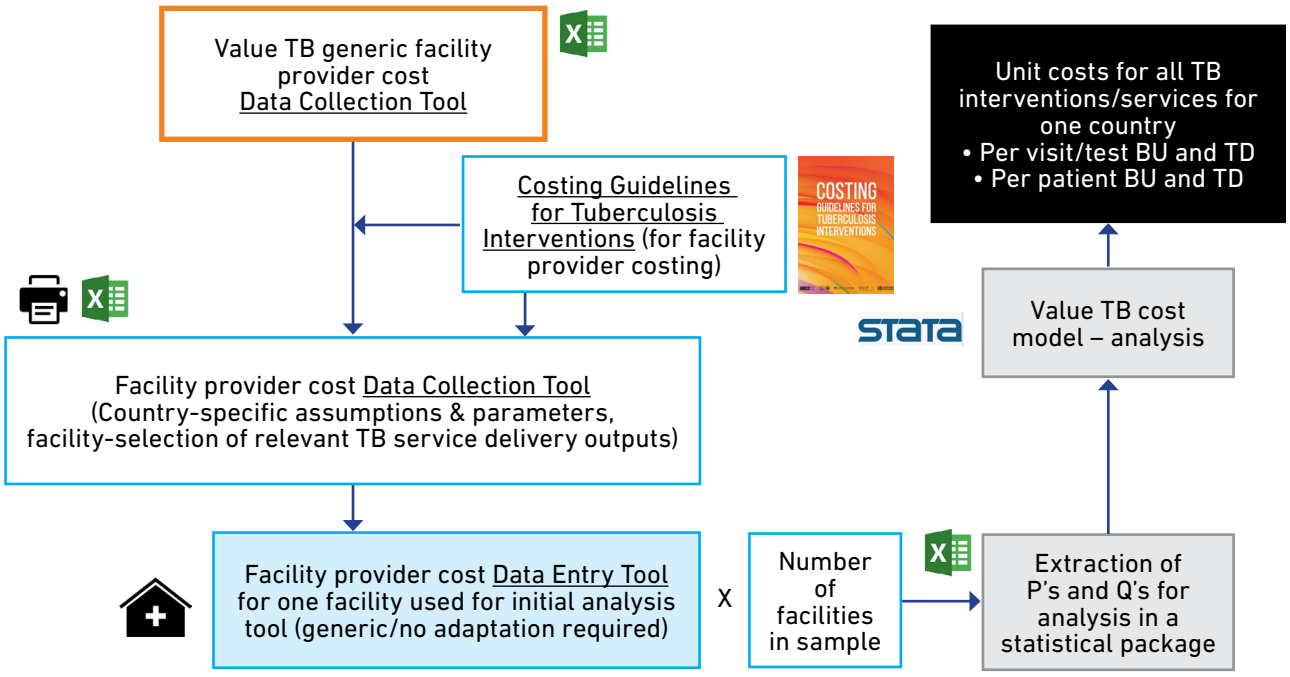
15. Please clarify the exclusion of prisoners as study subjects; the other facilities listed where the study may be conducted will also possibly have a mix of funding resource? Given also their close living conditions, the likelihood of TB infection is high.
16. Per protocol costs tend to over-estimate costs if the intervention is funded by donors and often deviate from real world costs, how will the study handle these variances? Please clarify.
17. Which econometric models/methods will be used in the analysis?
18. Given that you intend to observe health providers in the course of delivering service, please also [ensure] direct sensitization of the study activities to patients who will be present during that observation, through fliers, posters etc.
19. In the informed consent document, under "who has allowed…", please indicate the institution names rather than several national and international committees for added confidence.

APPENDIX 8. *VALUE TB COSTING TOOL SUITE*

This appendix details all the aspects included in the Value TB Data Collection Tool and the Data Entry Tool, providing instruction and some methodology. For ease of use, an image of each of the sheets is displayed for the different sections. The layout follows a thought process of how one might collect and enter data, however given the nature of costing the sequence of quantities and prices collected may vary.

DATA COLLECTION TOOL

Fig. 10a. The Value TB Costing Tool Suite (Data Collection Tool highlighted in orange)



The Data Collection Tool, used by data collectors, is described here (see Figure 10a). First, general instructions are given for the tool sheets. This is followed by an overview of how to use the generic unadapted tool to collect facility data for bottom-up and top-down unit costs calculation.

Types of sheets

- In the **Data Collection Tool**, there are five types of color-coded sheets.
- **Black sheets** are meant to help with the planning of the data collection and to acquire an understanding of the structure and processes within the facility.

- These sheets, in particular **Data collection planning 1** and **Data collection planning 2**, can be used during an introductory visit while one becomes familiar with the facility.
- Data should be entered into the yellow cells and nowhere else.
- The **blue sheets** are for data related to the facility, including identifying facility-specific service outputs, inventory of capital assets, building dimensions, overhead (recurrent and capital) costs and availability of above service level data.
- **Green sheets** are for prices for drugs, supplies, and equipment.
- The **grey sheets** relate to TB service utilization for the 20 standardized service outputs and at least 39 diagnostic and monitoring tests being costed, as well as the drug regimens and supplies used.
- The **red sheets** are for capturing quantities related to time for staff (assessed by observations, interviews and timesheets) and usage for equipment, supplies and vehicles (observation and interviews), which are inputs for both top-down and bottom-up costing.
- In the **red sheets** one would collect and enter the information on utilization within the health facility, such as the annual number of outpatient and community visits for TB-related services and for the entire facility.
- A breakdown is also provided for top-down and bottom-up relevant quantities. For example, for drugs, the top-down quantities refer to the total amount of each TB medication disbursed within the facility, while for the bottom-up quantities sampled usage by patients is collected.
- The template for staff-time interviews is used as one method to capture the quantity and allocation of staff time.
- The second method is that of weekly timesheet templates, also printable.
- During the detailed costing, these would be printed out or provided on electronic tablets to staff members at the beginning of the data collection week and collected at the end of the week.
- Total drug expenditure, which will enable top-down cost calculations later on, will be estimated based on the product of the total annual quantity of drugs disbursed at the facility by the unit price of the drugs.
- Similarly, bottom-up calculations will be performed based on the product of the drug prices and the average quantity per average patient for each TB treatment and prevention regimen by phase.
- The **instructions for Data Collection Tool often apply to the Data Entry Tool too**. This is because one collects the quantities (such as minutes observed, etc.) and prices in the **Data Collection Tool** and then transfers the pertinent information to the **Data Entry Tool**, where costs are allocated to departments and services and the unit costs are calculated.
- Throughout the data collection and **Data Entry Tools**, if an input cell is not applicable, it can be left blank or the cell can be changed to green (MS Excel 'Good' style).
- Do not enter NA or 0 in cells that are not applicable, as this may affect the calculations in the **Data Entry Tool**.

Adaptation of the tool to the context

In addition to default listings, there ispace to add as many of the context-specific and country appropriate service outputs, drug names, test procedures, service utilization labels, consumables supplies, staff titles, department or clinic names and other important labelling as possible, is provided in blue font in the non-yellow (un-highlighted) cells, such as in the column labelled 'Health care worker type' in the **Staff Salaries sheet (9)** or by including yellow highlighted cells where information can be typed in, such as the 'Name or description of supply' column in the **Price list-Supplies sheet (22)** of the **Data Collection Tool**.

Without adaptation, the generic Data Collection Tool allows the data collector to:

A. Plan for data collection

- As a guide for planning the data collection, it is estimated that a health centre would require two days, a large health centre or small hospital would require four days and a regional or tertiary hospital or reference laboratory would require two weeks.
- Sheets **Data collection planning 1 (4)** and **Data collection planning 2 (5)** can be used during an introductory visit while one becomes familiar with the facility.

Data collection planning 1

Interview Planning

INSTRUCTIONS: THIS SHEET IS OPTIONAL. It is intended to help you understand and plan your interviews and other data collection.
There is space to identify up to 4 locations (within the facility or community spaces) where each TB intervention type occurs, with the title of the corres
knowledge of TB service delivery.

Start date of data collection	dd/mm/yyyy	Start time of data collection	HH:MM
End date of data collection	dd/mm/yyyy	End time of data collection	HH:MM
Name of data collector			
Sheet complete (dropdown)		*If no, list missing data?*	

INTERVENTIONS						
Class	Type	**Intervention provided at or through facility?** [use dropdown]	**Location 1 of intervention** (facility or offsite) [use dropdown]	**Title of person(s) responsible for intervention**	**Location 2 of intervention** (facility or offsite) [use dropdown]	**Title of person(s) responsible for intervention**
VACCINATION	BCG vaccination					
TB CASE DETECTION AND DIAGNOSIS	Passive case finding					
	Intensified case finding - cough triage					
	Intensified case finding - screening					

- This is an optional sheet that has been developed to help with planning for data collection by noting the location and title of the contact person who can provide further information about each TB intervention type.
- Please be sure to only record the title of the contact person and not their name in this tool so that data protection and participant anonymity are ensured.
- If one would like to capture the name of the contact, please use the separate **facility contact workbook**, which should always be saved separately from the data, in a locked cabinet or with password protection.

- For each intervention, the user includes services/interventions that are happening both within the facility and in the community.
- Community visits (BCG vaccination, ACF and TB Treatment) can occur in various platforms.
- The user specifies the platforms where these TB services are offered through this health facility.
- These platforms should be specified and could include health clinics, health posts, community buildings, households, mobile clinics, schools, places of work, prisons or camps.
- The 'TB Screening, Diagnostic & Monitoring Tests' are for diagnosis of latent and active TB, and HIV, as well as monitoring of treatment for active TB.

Data collection planning 2

Checklist

INSTRUCTIONS: This checklist can be used to keep track of the various data needed and obtained from the different cadres of health staff in the departments applicable to this facility, not started, in progress or complete and is colour coded to reflect the status.
Please note, the list included is not exhaustive and additional rows can be added to the checklist to include more staff. Potential locations for data collection services provided there.

	Data collection activity/category [use dropdown]	Location in facility [use dropdown]	Sheet name	Start date of interview, observation or extraction
A.	**Staff time sheets**			
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	
			20.Staff time sheets	

- In addition, the user can also fill in a complementary sheet (**Data collection planning 2**) to organize the data collection by the data collection methodology (timesheets, interviews, observation, and extraction of service statistics, resource quantities, prices and overhead data).
- Each staff member or input can then be selected from a dropdown or is listed under the methodology type.
- The potential locations for the data and the corresponding data collection sheet are either listed or can be selected from a dropdown.
- In order to track the data collection progress, the start and end date, person responsible for obtaining the data and the status of the data can be completed as one proceeds.
- The dropdown options for the status column are: not started, in progress, completed and not applicable and each is colour-coded, so the status can be visually assessed at a glance.
- This checklist sheet is optional and intended to assist with the organization of the costing process.
- For various types of data needed for completing the tool, Appendix 8 provides potential sources (see page 31, Table 4.1 of WHO Guidelines for cost and cost-effectiveness analysis of tuberculosis control (2002))

Title page

VALUE-TB

Data collection tool for estimating unit costs of TB services

Project overview:

VALUE-TB is a three-year project, funded by the Bill and Melinda Gates Foundation, established to work with National Tuberculosis Programmes (NTPs) from high TB burden countries to collect unit cost data, using new standardised methods.
The included TB interventions are those that are most relevant for future local planning and resource requirement projections and have been jointly defined by the NTP and the VALUE-TB team.

There are two tools required to estimate the unit costs of TB services at the facility level: this Data Collection Tool and an accompanying Data Entry Tool. The data collection tool will be used by data collectors while at the facility to gather the required data. The data entry tool will be compiled by the study principal investigator or study coordinator to produce the calculated unit costs.

This cost data collection tool has been developed to estimate the unit costs of a comprehensive set of TB services from the providers' perspective. It is a facility-based tool that collects data needed to calculate the bottom-up and top-down, economic and financial costs of TB services offered at this facility.
Outpatient and community services linked to this facility will be costed. While the unit costs of TB related inpatient care are also calculated, this has not been done at the patient level. The estimated values may include time spent in hospital receiving treatment for adverse events but the additional costS of tests and drugs for TREATING adverse events has not been included so that the tool remains feasible within a reasonable amount of time.

The estimated time for data collection is approximately 1 week per facility, with data being collected from 20 to 30 public and private providers of TB services and interventions nationally.

Using this instument, financial and TB service records will be examined; all rooms and equipment used for TB will be listed; staff will be interviewed about their time spent on different activities; some activities will be observed; and price data will be collected, including supplies, equipment and salaries.

The cost data collected in this tool can further be used:

- for programme management, funding and planning
- to inform the estimates of the costs of TB services globally

March 8, 2019

Version 2.0

- This provides an overview of the study, outlining the aims of the study and the tool, as well as how the data can be used.
- The example of the Value TB study is used throughout this section.

Glossary

Glossary

AE	adverse events
ACF	active case finding
AFB	acid-fast bacilli
ALT	alanine aminotransferase (also known as SGPT)
AST	asparate aminotransferase (also known as SGOT)
BCG	bacille Calmette-Guérin
BSC	biosafety cabinet
BU	bottom-up cost estimation/allocation
BUN	blood urea nitrogen
CBC	complete blood count
CCC	comprehensive care clinic
CT	computed tomography
CXR	chest x-ray
DOTS	directly observed therapy, shortcourse
DR	drug-resistant
DS	drug-susceptible
DST	drug susceptibility testing
E	Ethambutol
ECG	electrocargiogram

- Defines the acronyms and abbreviations used within the tool.

Instructions

Instructions

1. This data collection tool is comprised of **black**, blue, grey, red and green sheets.
   Black sheets are designed to help plan the study but no data is collected here so the degree of utilisation of these sheets is up to you.
   Blue sheets capture captial and recurrent data for the facility.
   Grey sheets describe where and how TB services are delivered and how much.
   Red sheets relate to staff time.
   Green sheets are prices and expenditure.

2. The yellow cells are input cells where you need to enter data.
   Do not enter data anywhere else.

3. All sheets in this tool have been formated so that they can be printed and data collected on hard copies or entered electronically into the sheets.

4. Additional instructions for data collection is given in blue text throughout the tool.

5. Please use the "Notes" column to explain any values that are not in the spreadsheet, provide more detail on the source or method of calculation of the data, or anything else that you think would be of interest.

6. Optional sheets:

- Describes the colour-coding of the sheets and the cells in the tool and how they should be used.
- Instructions throughout the tool are in blue font, including in cells where data type or name is stated, and the blue font tells one how to input the data needed (e.g. [see dropdown]) or provides an example of the options (e.g. Culture – liquid media [e.g.: MB/Bact Alert, Bactec Mycobacteria Indicator Tube (MGIT) 960]).
- The data collection sheets have been formatted so they can be printed on A4 paper in either portrait or landscape orientation.
- If one finds that the printed documents are too small, the size of paper can be changed in the Page Layout tab of Excel and the scaling increased to allow the content to fill up the entire space.

B. Record data related to the facility including identifying facility-specific service outputs, inventory of capital assets, building dimensions, overhead (recurrent and capital) costs and availability of above service level data

Facility characteristics

Facility Characteristics

INSTRUCTIONS: on day 1 of data collection, meet with facility manager, briefly outline VALUE-TB background and objectives, obtain written informed consent. Then o characteristics and the population it serves. This sheet will be used to provide a description of the health facility and provide context when reporting results.

Start date of data collection	dd/mm/yyyy	Start time of data collection	HH:MM
End date of data collection	dd/mm/yyyy	End time of data collection	HH:MM
Name of data collector			
Country			
District name			
Town/city name			
Sheet completed [use dropdown]		0	

	Value	Source
Facility name		
Facility location/address 1		
Facility location/address 2		
Geography 1 - urbanicity [use dropdown]		
Geography 2		
Geography 3		

- Information about the geography where the facility is located includes whether that area is urban, rural or a mixture of the two.
- Local knowledge of potential drivers of costs is additional contextual information (e.g. socio-economic status of community) that can be included in the Geography 2 and Geography 3 cells.
- The size of all the buildings at the facility should be reported in square metres (m^2).
- The best-case scenario is if the facility has a record of the size in square metres or, better still. a map with the dimensions and floor plan.
- If this is unavailable see options for estimating the facility size in **Building space**.
- Operating hours for the entire facility and of **TB services** (regular hours of TB clinic) should be recorded by first indicating the days of the week that the facility is open and the services are provided, and then by inserting the total hours of operation of the facility and TB services during a seven day week.
- Please be sure to enter values for both the facility and TB services, even if they are the same.
- Total hospital beds (inpatient) should be reported for the entire hospital (all) as well as for DS-TB, MDR-TB and TB-HIV patients. Values should be reported for the same categories for day beds (outpatient), which may also be referred to as cots, gurneys or other name in different settings.
- Information about the TB services offered at that facility is being captured for treatment services, patient support during diagnosis or treatment, and community services provided through or to the facility.
- Additional service outputs relevant to the facility can be selected from dropdowns in the categories of visit and bed-day types; additional laboratory tests; additional radiology tests; and other TB services.
- Other TB services could include, but are not limited to, lost to follow-up tracing by a home visit, contact tracing, education or health talks, adherence or infection control.

Adaptation

If one requires an additional service output for any of these categories that is not already an option, please go to the Lists sheet at the end of the tool and enter the name of the service output in the yellow cells of the relevant category.

Building space

- The value of the building could be obtained by sourcing the current **replacement value** for a similar type of building and situation. This could be the value of rebuilding a clinic in an urban, peri-urban or rural area.
- An architect, structural engineer, centre for scientific and industrial research or construction company could be contacted to give a valuation of the facility.
- Alternatively, original facility records from when it was built, sourced from the facility administrative department or government records offices, could be used and inflated to arrive at the current value.

Building space

INSTRUCTIONS: Obtain or create map of each area with dimensions. Please ensure that there is no overlap of the dimensions of the spaces within each department or building; that is if the values for clinics, rooms or areas are not available, put values for the entire department.
If there are additional spaces within a department that are not included in the list, use the rows with 'other space' and change the name to match that space as used within the facility.
If a space is used for more than one output (e.g. LPA preparation and culture) then please list all outputs relevant to that space in the 'Notes' section.

Start date of data collection	dd/mm/yyyy	Start time of data collection	HH:MM
End date of data collection	dd/mm/yyyy	End time of data collection	HH:MM
Name of data collector			
Sheet completed [use dropdown]		*If no, list missing data?*	

	Owned, rented or donated [use dropdown]	Value if sold today (local currency)	OR Annual Rent (local currency)
Building - general information			

Name of department or clinic or room or area or building	Name of department/ clinic/ room/ area/ building in language of site	Size of department/ clinic/ room/ area/ building (m^2)	Percent of space used for TB (%)	Notes
Outpatient Department (OPD)				

- If these options are not available then one could look at the insurance valuation of the building, the cost per square metre (m^2) in that area (from commercial realtors, construction companies or the internet), tax forms for the building or government rate for stamp duty.
- If buildings have been recently renovated, then the cost can be inflated using the consumer price index (CPI) for the country.
- The rental value, if the facility or certain buildings within the facility have been rented, can be found in the lease agreement, sourced from the finance department within the facility or from the leasing agency.
- The size measurements should be in square metres (m^2).
- If perimeters are measured in feet, please convert to metres by multiplying by 0.305, then calculate the area, or convert square feet to m2 by multiplying by 0.093.
- Data for the MDR-TB clinic in the Outpatient Department (OPD) should be included only if there is a separate space for MDR-TB services within the facility.
- If the total land space is known but not the building size, then one option is to estimate the proportion land that the building resides on which can then be multiplied by the total size of the land (m^2) and the number of floors (if a multi-storey building is being costed).
- It is a good idea to ask if there is a map of the facility or draw a map. On this map note which rooms are dedicated to TB consultation, sputum collection, waiting, diagnostics, dispensing medication, other services, shared spaces (e.g. space that is used for both TB and HIV care).
- If space is shared, note if specific days are assigned to the room or how the time is divided.
- One can then physically measure the space with a laser distance measurer or a tape measure.
- The dimensions of the various areas may also be obtained from building plans or by estimating based on length of steps (if a step is on average one metre).
- Street mapping software (e.g. Google Earth) can also be used for land or external buildings; again, multiplying the measured size by the number of floors.

- One can then add these measurements to the map. This allows for repeatability in the future as the 'quantities' of the building will be known and mapped with measurements so one can then work out the space used if the room allocation changes i.e. the square meterage of the building.
- The size of the space is then calculated by multiplying the length by the breadth of the room resulting in the number of square metres.
- The total space of the facility can then be calculated by adding together all the rooms (or if it is a perfect square or rectangle one could calculate the total square meterage of the building by multiplying the length by the breadth).
- If TB services are provided in a designated space then the total space for TB would be calculated by adding space that the TB services utilize in metres squared (for example using a bottom-up approach, 3 rooms which are each $5m^2$=a total of $15m^2$ for TB services in a $100m^2$ facility).
- Do not include spaces that are no longer in use for instance if they are abandoned or derelict. However, 'empty space' should be included.
- In order to not double count, either fill in the total m^2 value for a department or the subsets, but not both.
- If the TB services do not occupy a designated area one could calculate the space used in top-down manner (described under the **data entry sheet**).
- If there are spaces at the facility where TB services are performed that have not been listed in the sheet, try to include the space (including m2 and proportion used for TB) in the most overarching department or room and make a note of the additional space that has been captured there (rather than adding a room).
- For example, to incorporate the size and percentage of space allocated TB for a consulting room for the laboratory doctor, that space can be included under 'Laboratory – main'.

Recurrent expenditure

Recurrent expenditure

INSTRUCTIONS: Data collected in this sheet should be for the ENTIRE FACILITY and downloaded/extracted from the facility expenditure records.
If disaggregated expenditure for a category (e.g. administrative, food, etc.) is not available, please enter the total value for that category in the row provided. Proportion of total D) can be used if the information is available.

Start date of data collection	dd/mm/yyyy	Start time of data coll
End date of data collection	dd/mm/yyyy	End time of data coll
Name of data collector		
Sheet completed [use dropdown]		*If no, list missing data*

	Recurrent overhead costs (ENTIRE FACILITY)	Annual expenditure (Local currency)	Notes *[Include HMIS code for easy verification, if*
Utilities	Water		
	Sewerage and sanitation		
	Electricity (light and heat)		
	Gas		
	Bio-safety disposal		
	Other		
	TOTAL UTILITIES		
unications	Internet		
	Telephone		
	Post		
	TV and radio		

- This usually relates to the running costs of the facility (i.e. clinic, hospital or laboratory) such as administration, kitchen, utilities (water, gas, heating, cooling, electricity), security, laundry, maintenance (of buildings, vehicles, furniture and equipment), cleaning, monitoring and evaluation/pharmacovigilance, mainte-

nance, training (such as in service training the effects of which potentially last less than one year) and quality assurance, etc.

- Supplies in the facility, such as gloves, masks, etc., can also be costed under recurrent overhead costs (for laboratories this has been described under diagnostic tests below). Other recurrent costs could include calibration of instruments, administration of cash transfers or similar expenditures.
- Infrastructure/resources jointly used or shared between different departments within a health system/programme or facility (such as administration, maintenance, transport, electricity, etc.) are known as **overhead inputs**.
- In a cost analysis, overhead inputs are allocated accordingly to various departments or activities. For example, inputs could be allocated to 'cost centres' (depends on how cost data are organized, and cost centres are defined).
- An allocation basis needs to be defined for allocating each input to various cost centres. For instance, some costs can be assigned directly to certain cost centres.
- If 'inpatient care' is a cost centre, then the line item 'laundry' could be allocated to that centre, using 'a patient day equivalent' as an allocation method.
- If 'maintenance' is a cost centre, then 'floor space utilized by department' could be a useful allocation method. Allocation of overhead inputs usually requires step down costing.
- It is important to note which costs have been considered overhead costs at the facility level (service level) and which costs are included in above service level costs, so that double counting does not take place.
- The easiest way to distinguish between overhead costs at the facility level and above service level costs, is to ascribe any operating costs to the facility level under overhead costs if they occur and are paid for by the facility.
- Overhead costs are often obtained through the finance office at a larger facility, facility records or through interviews with staff.

Transportation

Transportation

INSTRUCTIONS: Data is for transportation of TB specimens, supplies, drugs or results or transporting TB patients for diagnostics or tr
The sheet contains data to be sourced from the Finance and Human Resources Departments, as well as utilisation data.
Ensure both sections A (health facility or laboratory owned services) and B (courier services) are completed where relevant.

A Health Facility or Laboratory Owned Transport Service

				Ask FINANCE DEPA
				If own or donated current market v of all vehicles (local currency)
Vehicles	**Number of vehicles**	**Life expectancy (years)**	**Own, rent or donated**	
Ambulance				
Bicycle				
Motorcycle				
Small car				
Large car				
SUV				
Mini-van				
Van				
Mobile clinic				
Bus				
Other				

- Vehicles used by a facility, for instance vans used for transporting TB patients or mobile clinics, should be included as capital items.
- For vehicle current market (i.e. replacement) value, a vehicle with equivalent specifications can be used and derived by contacting local automotive dealers or visiting their websites
- Allocation to TB for each vehicle should be derived by asking the transportation manager or driver to estimate based on the time and/or mileage for TB services divided by total time and/or mileage.
- The percent of time spent on TB for Department 1 (column O) and Department 2 (column Q) should add up to 100%.
- ***Note:*** *if any services, such as* ***transportation or training****, are paid for by the NTP or NGOs but the benefit of the service is at the facility level, the costs still need to be included in this facility costing tool. For example, courier services paid for by the NTP are for samples for patients seen at the facility, so these costs need to be included in the facility tool.*

Training

Training

INSTRUCTIONS: Training data should be TB related, for staff of this facility.

Start date of data collection	dd/mm/yyyy	Start time of data collection	HH:MM
End date of data collection	dd/mm/yyyy	End time of data collection	HH:MM
Name of data collector			
Sheet completed [use dropdown]		*If no, list missing data?*	

	Name of training	Facility, or if offsite provide location	Training provider (institution or programme name)	Date of training	Duration (days)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					

- Costs of training are usually established through facility records or by estimating the cost of replicating a similar training (for example by looking at a venue cost, catering costs, facilitator hourly rates etc.).
- For training (which is considered a capital asset if the effects will last longer than a year), bottom-up costing requires obtaining the duration of training, number of staff trained, transportation and/or per diem costs, training materials used, number of facilitators/trainers and their qualifications.
- The top-down approach to training is to look at the expenditure on training for TB services and divide this by the staff that received the training.

- Data needs to be for all TB-related training for staff attached to this facility.
- Training fees are the amount paid for the training to occur, including costs for facilitators and any training material.
- Allocation of training costs to TB can be obtained by asking the person receiving the training (or another member of staff with this knowledge, e.g. their manager or TB focal person) about the total time (hours or days) spent on TB compared to the time for any other training topic.
- This information may also be obtained from training letters held in the Human Resources department or within the TB department.
- If training covers more than one service output, the training can be entered on multiple rows and allocated to the respective outputs based on the proportion for each.
- If the proportion is not known, these could be split. For example, a four-day training on TB outpatient and inpatient treatment can be entered as:

1. *TB treatment training | 4 | 10 | 200 | 25 | 100 | 0 | 100% | Outpatient diagnostic visit | 50%*
2. *TB treatment training | 4 | 10 | 200 | 25 | 100 | 0 | 100% | Outpatient treatment visit | 50%*

Above service level

Above Service Level Costs

INSTRUCTIONS: This sheet assesses the ease of access of above facility level cost data and is optional. If you do wish to collect this informatior

Start date of data collection	dd/mm/yyyy	Start time of data collection	HH:MM
End date of data collection	dd/mm/yyyy	End time of data collection	HH:MM
Name of data collector			
Sheet completed [use dropdown]		*If no, list missing data?*	

	TB processes - above service level costs	Type of support	Whom?
Support	What type of TB supervisory support do you receive from the *district health bureau/authority* ? How often?		
	What type of TB support do you receive from the National TB Programme? How often?		
	Do you receive TB support from other entities?		
	If yes, please describe the type of TB support and the frequency.		
Drugs	How often are TB drugs delivered to the facility?		
	Have there been any stock-outs of TB drugs in the last year?		
	If yes, describe frequency and circumstances of TB drugs stock-out.		

- The above service level costs are for activities that support the facility but are paid for by external sources such as the NTP (for instance, management of human resources, financial services, information technology, procurement and others).
- These above service level costs can be TB-specific (i.e. not shared such as training for health care workers on TB reporting standards) or shared between TB and other services (such as training for health care workers on general reporting standards).
- This would mean that training provided by the NTP for employees nationally would fall into above service level costs, whereas in service training (facility level training) would be considered an overhead or service level cost.

- Allocations of above service level are implemented in the **Data Entry Tool**.
- The data collection for above service level costs is done separately from the facility data collection.
- It involves approximately an additional week of data collection at the national, district or regional level.
- However, to guide the allocation of above service level costs to each facility, the data collector will complete the **Above service level** sheet which covers visits related to monitoring and supervision and drug procurement from national, regional or district levels.
- There are different ways to allocate above service level costs. The recommended approach is weighting based on the number of staff at each facility (**Figure 12**); equal weighting is not recommended.
- The shared above service level costs would need to be further allocated to TB services based on the utilization figures for the facility. In this tool, the above service level costs cover support from the NTP, other entities and delivery of medication

C. Record prices for drugs, supplies, and equipment

Equipment inventory

Inventory - equipment and furniture

INSTRUCTIONS: This should be a complete list of all equipment and furniture used in any of the TB service outputs. If there is more than one of a particular type of equipm the quantity in use at the facility for TB services.
Any additional equipment or furniture that is not already included in this sheet should be added to the bottom of the appropriate section.

Equipment name	Department	Clinic or room	Manufacturer [if applicable]	Model [if applicable]	% use for TB [eg. Based on TB tests/all tests performed by total numbers of machines]
Analytical balance					
Analytical balance (electronic) for DST					
Autoclave - horizontal					
Autoclave - vertical					
Autoclave (basic unit for media kitchen) - 1					
Autoclave (basic unit for media kitchen) - 2					
Autoclave (basic unit for media kitchen) - 3					
Autoclave (basic unit for media kitchen) - 4					
Automatic filling station					
AVR (for autoclave)					
BACTEC - starter kit					
BACTEC MGIT 320 System					
BACTEC MGIT 960 system					
BACTEC printer					

- The **Data Collection Tool** includes a default list (alphabetically ordered) of equipment used for TB care. Default categories are to be used in preference to adding new elements to the list given that there are automatized links within the tool.
- The equipment price list should be collected centrally and used for each facility. If the prices paid for the equipment are known, then (inflate using CPI if necessary and) convert to United States dollars (USD) using the exchange rate of that year.
- The standard and most appropriate value for the unit price is the replacement cost.
- Equipment and furniture that are used at the facility for **TB services**, for instance beds, tables, chairs, x-rays, biosafety cabinets etc., should be included as capital items.
- As the interest lies in the TB services only, any equipment that is not used for TB services should not be captured.

- The bottom-up approach to costing these items is by auditing/counting how many there are within the facility.
- The facility may keep a record of all the equipment and furniture; however, one will need to establish if these are used for TB services or not.
- It is often useful to note which rooms these items can be found in, on the map of the facility.
- A new line should be used for each piece of equipment or furniture, for instance if there are 10 chairs then 10 lines are used to enter information for these 10 chairs. The top-down approach would be to take lists of all the equipment and furniture (or expenditure of all the equipment and furniture)
- When estimating usage of equipment, the bottom-up approach is either through observation *or* interview, while timesheets are used for the top-down approach.
- Observation should be the default; if not possible, then collect equipment information via an interview. Keep good notes on things such as stockouts, broken equipment and overused equipment (i.e. estimated life years (ELY)=5 but used for 30 years) so that one can try to understand and explain cost variation.
- If equipment is broken but was used in the last year and will be fixed or replaced, then this should be costed. The same is true for equipment that has been purchased and has not yet been used but is planned to be used (for instance if training is pending).
- Derelict equipment that has broken down and will not be fixed should not be costed – if this has not been used in a year and is not expected to be used again, the item should not be costed.

Price list-drugs

Price List for Drugs

This sheet can be used to get prices on drugs from the facility or from a central source such as the Ministry of H

INSTRUCTIONS: **Please provide data for the yellow cells.** The unit price in local currency is for drugs that Standard drugs for TB treatment, prevention and palliative care have already been listed. Any additional

	Drug wastage factor		
	Transportation mark-up (within country), %	(1st-line drugs)	(2nd-line drugs)
	Drug name	**Product code (e.g. GDF)**	**Strength**
DRUGS: first-line -dose combination (combi-packs)	Rifampicin/Isoniazid, Dispersible tablet(s), Strip(s)	2-FDC/RH-75/50-(B)-84 (28x3)	FDC-child
	Rifampicin/Isoniazid, Film coated tablet(s), Blister(s)	2-FDC/RH-150/75-(B)-672	FDC-adult
	Rifampicin/Isoniazid, Film coated tablet(s), Blister(s)	2-FDC/RH-150/75-(B)-336	FDC-adult
	Rifampicin/Isoniazid/Ethambutol, Film coated tablet(s), Blister(s)	3-FDC/RHE-150/75/275-(B)-672	FDC-adult
	Rifampicin/Isoniazid/Pyrazinamide, Dispersible tablet(s), Blister(s)	3-FDC/RHZ-75/50/150-(B)-84 (28x3)	FDC-child
	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol, Film coated tablet(s), Blister(s)	4-FDC/RHZE-150/75/400/275-(B)-672	FDC-adult
	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol, Film coated tablet(s), Blister(s)	4-FDC/RHZE-150/75/400/275-(B)-336	FDC-adult
	Cat I & III Kit A, Film coated tablet(s), Blister(s)	PK-Cat I & III-A	

- Drug prices per drug delivered at the health facility are collected. 'Wastage of supplies' is also documented; this is an estimate of the percent of drugs thrown out, i.e. drugs expired or damaged, within the year.

- The unit price of many of the drugs on this list can be centrally sourced through the Ministry of Health, Central Stores, some government procurement agency or from the Stop TB Partnership's Global Drug Facility.
- If locally obtained prices are not available one can use international prices available through http://www.stoptb.org/assets/documents/gdf/drugsupply/GDFMedicinesCatalog.pdf as recommended by the Reference Case *[5]*.
- These values need only be obtained once and can be used for all facilities.
- For drugs that are not sourced internationally or are unique to a particular facility, e.g. if XDR treatment is only offered in one specialized facility, invoices or procurement records may need to be sourced at the facility level.
- The order size and price for the year should be collated and entered into columns G and H. The source of the quantity or price data or the vendor should be included in column K.

Price list-supplies

Price List for Supplies

This sheet can be used to get prices on supplies from the facility or from a central source such as the Minis

INSTRUCTIONS: The list of supplies is not exhaustive so please insert any additional supplies that ha supplies section.

	Name or description of supply	Unit of measure	Package amount or volume	Price per package (local currency)	F (
	0.5-10 µl tips				
	100-1000 µl pipette tips				
	100-1000 µl pipette tips				
	100-1000 µl pipette tips (Long tip)				
	10-100 µl tips				
	1-20 µl tips				
	1-200 µl pipette tips				
	1-200 µl tips				
	20-200 µl pipette tips				
	20-200 µl pipette tips				
	2ml standard reaction tube				
	Applicator stick (disposable)	box	20		
	BACTEC MGIT 960 AST transport rack – 445942.				
	BACTEC MGIT 960 Supplement Kit (100 tests, PANTA and OADC combined) Catalogue No: 245124				
	BACTEC MGIT 960 Supplement Kit (PANTA and OADC combined)	kit	100		

- The **Data Collection Tool** includes a default list (alphabetically ordered) of supplies used for TB care. Default categories are to be used in preference to adding new elements to the list.
- A price list for the supplies used at the facility may be centrally sourced, but it is likely that some supplies would have been obtained from a vendor directly through the facility.
- Multiple sources of data are acceptable.

Staff salaries

Staff Salaries

INSTRUCTIONS: 'TB Personnel' should list every staff member (direct and support) providing TB services within the facility.
For staff salaries, if gross values are not available, use net values and gather information on government (central and local) and other deduction type
If relevant, the type of health care worker (column C) can be modified to include the clinic or specialty of the health care worker.
Data for columns I to M should only be obtained if a timesheet is NOT obtained for that staff member (e.g. for all support personnel, phlebotomists,

Start date of data collection	dd/mm/yyyy	Start time of data collection	
End date of data collection	dd/mm/yyyy	End time of data collection	
Name of data collector			
Sheet completed [use dropdown]		*If no, list missing data?*	

Facility Staff	Health care worker category	Gross annual salary (local currency)	Gross annual benefits (local currency)	Total working hours per week	C
	Clinical, allied and auxiliary staff				
	Support and administrative staff				
	Total Staff				

- The list of staff should include any personnel involved in TB services, i.e. any staff who spend at least 10% of their time on TB or anyone with TB-specific tasks in their job description.
- The list is organized by direct service personnel, support personnel and volunteers. To provide clarity on where staff salaries should be allocated, one can append the location of the health care worker to their title (e.g. 'Nurse 2' can become 'Nurse 2 – ART clinic').
- The gross annual salary of each staff member should be provided. Staff salaries are often obtained through the finance office at a larger facility, facility records or through interviews with staff. It may necessary to approach a central finance office and human resources department separately to obtain the list of staff titles at a facility and the corresponding salaries.
- If gross salaries are not available, obtain the net (post deductions) value. Using an estimate of the proportion of income tax and other deductions relevant to the type of employee in the country, calculate the gross salary. For instance, if net annual salary for a nurse is $61,237 and the average income tax is 20%, with additional deductions averaging 9%, the gross salary would be ($61,237/(100-(20+9)%)) = $86,249.30.
- If it is not possible to collect the actual salary data for facilities based on the staff mix, an average salary can be used for a cadre of staff.
- Gross annual benefits should include housing and travel allowances, or payments, hazard or other incentive pay, and any other payments made to staff for their service to the facility.
- For staff working less than the full year of assessment (i.e. retiring, resigning or doing periodic work), the gross annual salary should be adjusted by the proportion of the year worked.
- Similarly, the working hours per week on average over the year should account for any time when the staff member was not working at the facility, by using the total hours worked for the year of assessment and finding the average hours per week across the entire year.
- The method used to measure staff time for each health care worker included in the study should be captured in column H.

- Specialized personnel providing direct services (e.g. phlebotomists, pharmacists, social workers, etc.) should be interviewed to provide an estimate of the proportion of time spent on TB, and how that time is split between various departments (e.g. outpatient and inpatient departments for social workers).
- ***Recommendation:*** *For staff, bottom-up costing is performed either through observation* ***or*** *interview; for top-down costing, timesheets are used. Observations, interviews and timesheets should be administered to at least one staff member per cadre in a big facility, however for small facilities, where perhaps there are only two staff members working on TB, both should be interviewed and given timesheets. There should be at least one bottom-up and one top-down estimate of staff time per service. However, if an observation or interview is impossible, one can use an assumption based on interviews at another facility, standard operating procedures or a demonstration of a process.*

D. Record TB service utilization for the 20 standardized service outputs and at least 39 diagnostic and monitoring tests being costed, as well as the drug regimens and supplies used

Service statistics

Service Statistics

INSTRUCTIONS: This sheets asks for summary facility data (C12-C31) as well as summary and disaggregated data for TB.
Service statistics data should be obtained from the head of the facility, head of the laboratory or radiology departments, head of respective clinic reports (HMIS).
TB treatment data can be extracted from the TB Register or annual or quarterly reports for TB.
Data should be collected only for service outputs performed at the facility or for community services performed by staff from this facility.
Please ensure that the metrics listed and period for the data collected matches that of the *Service outputs* of the '15.Service Description ' sheet.

Start date of data collection	dd/mm/yyyy	
End date of data collection	dd/mm/yyyy	
Name of data collector		
Sheet completed [use dropdown]		

	Year of data (latest financial or calendar year)		
	Unit	**Annual quantity - entire facility**	**Annual quantity - TB services only**
Section I: Health facility statistics	Outpatient visits		
	TB Clinic		
	MCH Clinic		
	Paediatric Clinic		
	HIV Clinic		
	Chronic Disease (diabetes) Clinic		
	Comprehensive Care Clinic		
	Inpatient beddays		
	Inpatient admissions		
	Laboratory tests (all labs)		
	Microbiology Lab - tests		
	Bacteriology Lab - tests		
	Laboratory: main (clinical path, incl haematology) - tests		
	Area for blood, serum, plasma collection - samples		

- Estimation of unit costs requires information on utilization which covers data on services received by patients in a facility, or about diagnostic tests processed in a laboratory.
- The figures needed vary depending on the unit cost to be calculated; however standard utilization data might be "Total number people initiating treatment for MDR-TB using the long regimen per year" or "Total number of inpatient bed-days for DS-TB treatment per year" or "Number of Xpert® MTB/RIF tests performed per year".
- These utilization data allow one to allocate costs if a top-down methodology is being utilized.

- Data will be collected for total facility and TB specific utilization data for the main departments ('Section I: Health facility statistics' – Outpatient, Inpatient, Laboratory and Radiology) within the facility, with some disaggregation by clinic or laboratory specialization. This service utilization data can be obtained from health management information system (HMIS or DHIS2), or other routinely reported TB data.
- Data will also be collected for TB service outputs only which can be populated using the WHO Global TB recording and reporting forms (https://apps.who.int/iris/bitstream/handle/10665/44840/9789241564465_eng.pdf?sequence=1) for the facility, except for the distinction between short and long MDR-TB treatment which is not always available from routine reporting. 'Section II: TB service statistics' is for TB service outputs only, within Section II, rows 29–37 can be populated using the WHO Global TB recording and reporting forms for the facility. Rows 39–55 should be obtained from disaggregated TB reports for the key facility departments, as well as community services provided through this facility
- It is important that the utilization data collected in this sheet is for the year of assessment of the study and matches the cost data being collected for the facility.
- If it is unavoidable that this criterion cannot be met at this facility and any of the data is not for the year of assessment, be sure to indicate this in the 'Notes' column of this sheet.
- The ideal is to collect information on the number of visits that actually occur at a facility based on the reporting done by the facility.
- However, if number of patients is known but not number of visits, it is then appropriate to calculate the number of visits using the average number of visits per patient = average #visits per patient * #patients.
- For test volume, if there are no records for the annual values, the head of the laboratory or equivalent personnel should be requested to estimate the total TB and all tests per week and then multiply this number by 52 to get the annual value. Present this figure to the person being interviewed and ask if this is a reasonable estimation.
- If there is missing data, the allocations (see **Data Entry Tool**) cannot be calculated, so this should be avoided as far as possible.

Service description

- The average number (quantity) of each service output required for each patient type (population, regimen and phase) is obtained by interviewing the TB head nurse or focal person or another member of staff with knowledge of TB service utilization. This is entered into the yellow cells (grey cells indicate where the service output is not applicable to that intervention).
- The gold standard here is to obtain the average per patient type by extracting the service utilization from patient records and calculating the average. However, if one does not have ethical approval to extract data from patient records or are unable to access them, the quantities should be obtained by interviewing the TB focal person or head nurse at the facility or an individual who has knowledge of the service utilization for the TB services at the facility.

Service Description

INSTRUCTIONS: Service description data for TB should be obtained from the TB Nurse in Charge within the TB clinic or anot
Data should be collected only for service outputs performed at the facility or by staff attached to the facility and is per pati

		QUANTITY PER PATIENT (visits, beddays or tests) for year of ass						
	INTERVENTION CLASS	VACCINATION						
	INTERVENTION TYPE	BCG Vaccination	Passive Case Finding				Intensified Ca	
	INTERVENTION POPULATIONS	Infant	Adult		Child		HIV+	
			PTB	EPTB	PTB	EPTB	PTB	EPTB
	REGIMEN							
	PHASE							
	Service output							
TB services	Outpatient vaccinations							
	Outpatient cough triage							
	Outpatient screening visit							
	Outpatient diagnostic visit							
	Outpatient visit type 1							
	Outpatient visit type 2							
	Outpatient visit type 3							
	Inpatient bed-day type 1							
	Inpatient bed-day type 2							
	Community vaccinations							
	Community screening visit							
	Community diagnostic visit							
	Community treatment visit							
	Community other visit							
	Community event							
	Lost to follow-up tracing per person on contact list (phone calls)							

- For the community vaccination visits, the total number of visits per year and the number of infants vaccinated in that year are needed (in rows 16 and 17, respectively). This will be used to calculate the average number of people vaccinated during a community vaccination visit and subsequently the cost per person vaccinated during a visit.
- Similarly, the total visits in the year of assessment and the total people screened are needed (rows 20 and 21) as inputs to calculate the cost per person screened.

Drug services

Drug Services

INSTRUCTIONS: In column E, provide the total annual quantity disbured for each TB drug prescribed at the facility. In the remaining cells (column
Data on TB drugs can be sourced from the TB register in the TB Clinic and TB prevention drug data from the clinics where those activities are perf
If a drug used at this facility is not included in the list, please included it at the bottom of the relevant section and add to the corresponding secti

					Quanti
			INTERVENTION CLASS (TREATMENT ONLY)		
			INTERVENTION POPULATIONS		
					PT
			REGIMEN		Ne
			PHASE	Total annual quantity disbursed for TB (in units)	Intensive
	Drug/pharmaceutical product	Product code	Unit of measure		
DRUGS: first-line use combination (combi-packs)	Rifampicin/Isoniazid, Dispersible tablet(s), Strip(s)	2-FDC/RH-75/50-(B)-84 (28x3)	Per pack/blister		
	Rifampicin/Isoniazid, Film coated tablet(s), Blister(s)	2-FDC/RH-150/75-(B)-672	Per pack/blister		
	Rifampicin/Isoniazid, Film coated tablet(s), Blister(s)	2-FDC/RH-150/75-(B)-336	Per pack/blister		
	Rifampicin/Isoniazid/Ethambutol, Film coated tablet(s), Blister(s)	3-FDC/RHE-150/75/275-(B)-672	Per pack/blister		
	Rifampicin/Isoniazid/Pyrazinamide, Dispersible tablet(s), Blister(s)	3-FDC/RHZ-75/50/150-(B)-84 (28x3)	Per pack/blister		
	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol, Film coated tablet(s), Blister(s)	4-FDC/RHZE-150/75/400/275-(B)-672	Per pack/blister		
	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol,	4-FDC/RHZE-150/75/400/275-	Per pack/blister		

- As with diagnostic tests, for TB drugs one needs to first understand how medication is dispensed in terms of location (clinic, hospital, outreach or mobile clinics etc.), frequency (daily (directly observed therapy, short-course (DOTS)), monthly, twice monthly, etc.), as well as who is involved in dispensing medication (pharmacist, doctor, nurse, community health care worker etc.).
- Following the methodology of the **Data Collection Tool**, the quantities to be entered should ideally be the actual average for all patients treated (for an episode of care). If this information is not available, include the protocol value for an average patient in the respective regimens.
- If the actual values are known, a note can state the protocol value.
- Only drug quantities for treatment that is happening at the facility should be entered. For example, if the hospital only does one week of intensive phase, then only include that one week's worth of drugs for the hospital costing.
- The drugs remaining to complete the treatment regimen should be included in the facility from which they are distributed, such as health centre or community facility.

E. Capturing quantities related to time for staff (assessed by observations, interviews and timesheets) and usage for equipment, supplies and vehicles (observation and interviews), which are inputs for both top-down and bottom-up costing

Staff time used for TB service delivery is captured using three different methods: interviews, observations and timesheets. The **Data Collection Tool** caters for a sheet per data collection method (Staff timesheets, Observations and Interviews).

Staff timesheets

DAY 1 -

Day (circle as appropriate) M / T / W / TH / F / SA / SU

Date (dd/mm/yyyy)

INSTRUCTIONS: in each box wirte the number of minutes spent on each activity.

Activities (in minutes)

Time	Outpatient vaccinations	Outpatient cough triage	Outpatient screenig visit	Outpatient diagnostic visit	Outpatient visit type 1	Outpatient visit type 2	Outpatient visit type 3	Inpatient bed-day type 1	Inpatient bed-day type 2	Community vaccinations	Community screening visit	Community diagnostic visit	Community treatment visit	Community other visit	Community event	Lost to follow-up tracing per person on contact list (phone)	Patient support during diagnosis (voucher, cash,
Quantity performed for entire day																	

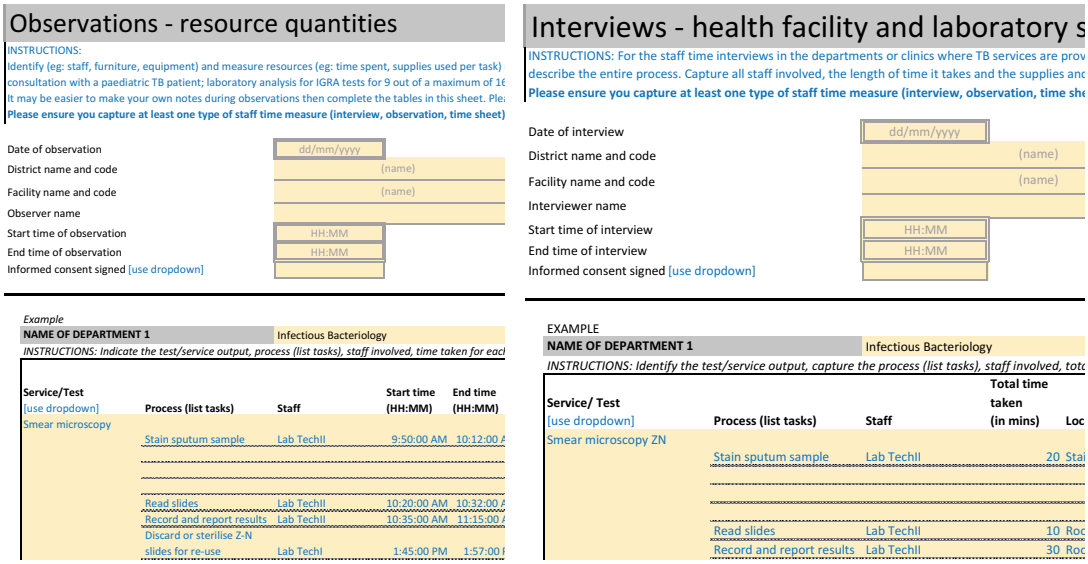
- When one understands the flow of the facility or laboratory then one can start to assess the staff time and costs.
- Personnel time could comprise the time of both clinical and non-clinical staff within clinics and hospitals (or different facility types), laboratory staff involved in TB technology, community health care workers involved in patient support and other TB services amongst others (see case study 3 as an example).
- The first step is to establish who is directly involved in TB services (such as a TB focal nurse) and who provides support to TB services (for instance an administrator or clinic manager).

- For the staff that are directly involved in TB services, data can be collected about the time they spend with patients in several different ways using bottom-up methods.
- One can observe the hands-on time they spend with TB patients, measuring with a stopwatch over the course of week to assess what proportion of their time is spent on TB tasks.
- The type of task should be defined before one starts measuring.
- This is useful if one is able to easily calculate all the other aspects of the costing from a bottom-up perspective. Because one can then calculate for instance the cost of treating one DS-TB case (in terms of staff time, TB drugs, TB diagnostics, capital costs (time that specific area of building space, furniture and equipment were used), portion of recurrent costs).
- Another bottom-up approach is to use work sampling, where a staff member is contacted (usually on a mobile phone) to ask what task they are currently busy with, in order to construct a picture of what tasks are being done and for how long.
- The proportion of time spent on TB tasks can inform this calculation. Hypothetically, 25% of a staff nurse's time might be spent diagnosing new drug-sensitive TB cases, while 35% of his time is spent following up DS-TB cases, 10% of his time was taken up with dispensing medication, 5% was spent on record-keeping, 5% on other TB management such as meetings relating to TB., and the remaining 20% of his time was spent on tasks unrelated to TB services. Considering the salary of the staff member (in this case staff nurse), the cost of time per task can be estimated from these percentages.
- Another way to work out the proportion of time taken for specific tasks is to ask staff to estimate how much time it takes for them to perform the task on average, and how many times they perform the task in a week. This is usually done through a mixture of giving the staff a timesheet to complete and interviewing/discussing with the staff member how long tasks actually take them.
- A top-down way of allocation staff time is to again estimate the amount of time spent on tasks, which could be done by weighting tasks based on utilization or workload. For instance, the allocation of time to DS-TB treatment by using the allocation of number of patients treated for DS-TB treatment over all TB cases.
    - For more precise estimates, the time spent on DS-TB patients could be estimated using one or more of the following methods.:
    - Firstly, timesheets could be completed by relevant staff for a relevant period of time (a month, or several months).
    - If the timesheets are returned incomplete, or certain estimates do not make sense, interviews could be conducted with staff members when they are asked how much of their time is spent seeing DS-TB patients in a particular day/week/month.
    - Lastly, a researcher could estimate the time spent with DS-TB patients by observing how the services are provided in a facility, and then timing those services that are relevant to these patients.
- Often, a combination of these approaches is necessary in order to get the best estimate possible.

Recommendations

- The data collector should provide verbal instructions on how to fill the timesheets.
- The health care worker (HCW) should fill in distributed physical timesheets where possible; if not possible, complete timesheets using interview format.
- Timesheet should be completed per cadre; however, if nurses perform different functions (such as only DS-TB and only MDR-TB) then one timesheet should be completed per function.
- If timesheets are absolutely not possible, estimate the proportion of staff time for the relevant service outputs.
- To determine which outputs are applicable to a particular health care worker, be guided by the bottom-up data (observations and interviews).
- Ensure that the total minutes per week in the timesheet add up to the working hours per week on average over the year when allocating minutes to the service outputs.
- ***Note:*** *The category 'break/lunch' should include any downtime when not working, even if that is because there were no TB patients or tests to perform.*

Observations and Interviews



This data collection sheet facilitates two types of observations:

A. identifying the resource – creating lists of staff, furniture, equipment and supplies used to provide TB services within a clinic or department (including laboratory); and

B. measuring the resources for each TB service output – i.e. time in minutes for staff and equipment, and quantities for supplies.

- Tables have been developed in the Observation and Interview sheets to allow data collection for five outputs in each of five facility departments.
- Additional data collection is likely needed to obtain at least one staff time measure for every service output, so the tables can be replicated to accommodate as many measurements as needed.

- The sheets have also been formatted so that, when printed, there is one table per sheet. This means that data can be collected either electronically (inputted directly into the **Data Collection Sheets**) or on hard copies (information recorded on the printed sheets of paper). Use whichever data collection method is best suited.
- When interviewing the doctor and/or nurse involved in TB inpatient services, ask if he or she can list other people (e.g. other clinicians) who are involved in this TB service and obtain interviews with these people where possible, or ask the ward nurse about their time spent on TB services (e.g. cleaners, porters, etc.).
- Because the staff cost component of the unit costs derived by each method will be compared during analysis (**Data Entry Tool**), please try to use all three methods to measure the staff time for each service output.
- Recognizing that this is not always possible, it is important that **at least one** methodology is applied to each service output. A supply wastage proportion assumption needs to be documented. Based on the experience of Value TB study, an examples of waste proportions used for Xpert® MTB/RIF was 3–5%.
- Informed consent forms need to be given to every person from whom data is collected by interviews, observations and timesheets and kept separately in a secure location. As a reminder within the tool, there is a drop down to indicate whether consent has been obtained.
- All staff time measures (interviews, observation and timesheets) should be given to at least one health care worker in each cadre of staff involved in every service output.
- It may sometimes not be possible to administer all three methods (interviews, observation and timesheets) to each health care worker, however, please ensure that each health care worker's time is measure by **at least** one method.
- Information on utilization within the health facility, such as the annual number of outpatient and community visits for TB-related services and for the entire facility, can be collected and entered in this sheet.
- A breakdown is also provided for top-down and bottom-up relevant quantities. For example, for drugs, the top-down quantities refer to the total amount of each TB medication disbursed within the facility, while for the bottom-up quantities sampled usage by patients is collected.
- The template for staff-time interviews is used as one method to capture the quantity and allocation of staff time.
- The second method is that of weekly timesheet templates, also printable.
- During the detailed costing, these would be printed out or provided on electronic tablets to staff members at the beginning of the data collection week and collected at the end of the week.
- An example of total staff time for a chest x-ray would be the staff time including taking the chest x-ray; reading, interpreting and noting results.

Supplies

Price List for Supplies

This sheet can be used to get prices on supplies from the facility or from a central s

INSTRUCTIONS: The list of supplies is not exhaustive so please insert any addit
Also ensure that this list matches the list in sheet '22.Price list-Supplies'.

	Name or description of supply	Annual expenditure (local currency)	% use for TB
	0.5-10 µl tips		
	100-1000 µl pipette tips		
	100-1000 µl pipette tips		
	100-1000 µl pipette tips (Long tip)		
	10-100 µl tips		
	1-20 µl tips		
	1-200 µl pipette tips		
	1-200 µl tips		
	20-200 µl pipette tips		
	20-200 µl pipette tips		
	2ml standard reaction tube		
	Applicator stick (disposable)		
	BACTEC MGIT 960 AST transport rack – 445942.		

- This datasheet includes on an exhaustive list of supplies (mostly laboratory supplies and infection control) used for TB services at a facility (with prices collected as mentioned above).
- For each supply category, the annual expenditure and percentage use for TB will be collected.
- 'Wastage of supplies' refers to the percent of supplies discarded (expired or thrown out).
- The value should be for the facility in question; if this value cannot be obtained, an estimated value for the country can be used.

Price list-equipment

Price List for Equipment and furniture

This sheet can be used to get prices of equipment from the facility or from a

INSTRUCTIONS: Please provide data for the yellow cells. The list of equi
for health facilities to provide TB services.
The unit price (local currency) should be used for any equipment purch
USD.

	Equipment or furniture name or description	Manufacturer
	Analytical balance	
	Analytical balance (electronic) for DST	
	Autoclave - horizontal	
	Autoclave - vertical	
	Autoclave (basic unit for media kitchen) - 1	
	Autoclave (basic unit for media kitchen) - 2	
	Autoclave (basic unit for media kitchen) - 3	
	Autoclave (basic unit for media kitchen) - 4	
	Automatic filling station	
	AVR (for autoclave)	
	BACTEC - starter kit	
	BACTEC MGIT 320 System	
	BACTEC MGIT 960 system	
	BACTEC printer	
	Balance (analytical)	
	Balance (precision)	
	Balance (precision) - electronic	
	Biosafety cabinet - 2 filters	

- The equipment price list should be collected centrally and used for each facility.
- The **Data Collection Tool**'s default equipment labels should be preserved.
- If the prices paid for the equipment are known, inflate using CPI and convert to USD using the exchange rate of that year.
- The standard and most appropriate value for the unit price is the replacement cost.

Lists

Drop-down lists

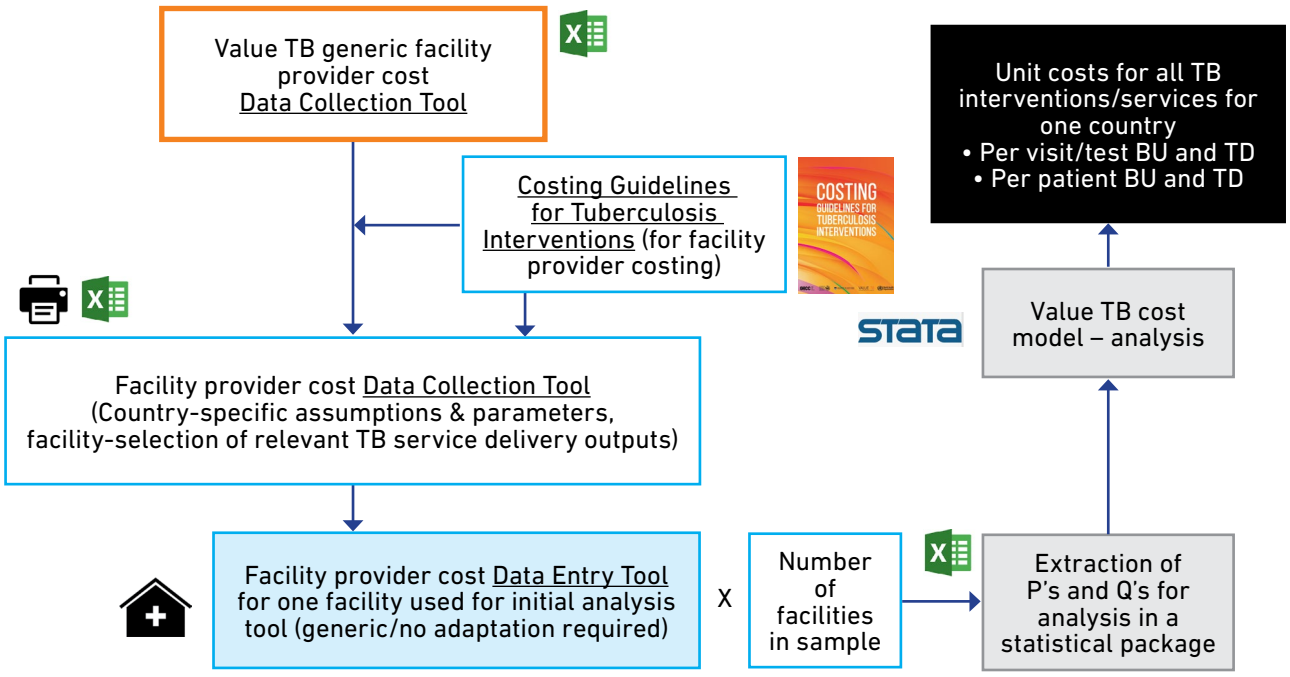
INSTRUCTIONS: Please DO NOT make changes to this sheet. This sheet should remain locked.

Country	Facility level	Geography
Ethiopia	Community health unit	Urban
India	Health post/dispensary	Rural
Kenya	Health centre	
Philippines	Primary (sub-county/district) hospital	
Georgia	Secondary (county/general) hospital	
	Tertiary (national/ teaching/ referral/ specialised) hospital	
	Basic laboratory (stand alone)	
	Basic laboratory (linked to facility)	
	Laboratory (full)	
	Reference laboratory	

- The Lists sheet provides the selections for the dropdowns used throughout the tool. Only enter relevant data in the yellow cells of this sheet, namely columns Q "Possible additional units" and R "Possible additional tests (lab and radiology)".
- Do not make any other edits to this sheet.
- This sheet asks for the time taken (in minutes) to collect all the data needed to complete the respective sheets in the **Data Entry Tool**, as well as time it takes to transfer data from the **Data Collection Tool** to the **Data Entry Tool**.
- To facilitate this documentation, several of the data collection sheets include space at the top to input the start and end dates and times for the data collection.
- Appreciating that in many instances the data collection for a sheet may not happen in one discrete time period, the dates and times included in some sheets are meant to be an aid in capturing this information.
- Complete times will likely also require piecing together time spent based on input from each data collector.
- A template for data collector timesheets has been included in the **Data Collection Tool** as a way to collect more detailed time information from each data collector.
- Using it is optional, but it may also be useful for the study to use it during the piloting stage as a way of estimating the time needed to for data collection in each facility.
- A pilot would take approximately a week and would test the tool adaption and data availability.

DATA ENTRY TOOL

Fig. 10a. The Value TB Costing Tool Suite (Data Collection Tool highlighted in orange)



The next section is an overview of the (generic/unadapted) Data Entry Tool (see Figure 10b), which is used for data analysis at the facility level to generate bottom-up and top-down unit costs. When clean and finalised, Data Entry Tools for each of the facilities should be safely stored and shared with study investigators for pooled analysis.

- The **Data Entry Tool**, used by data analysts, aims to distill the information from the **Data Collection Tool** and to generate unit cost per patient per output, top-down and bottom-up (Appendix 9). It also allows users to drill down into the cost components of a unit cost. It gives the data analyst the opportunity to clean and review the data collected and review the ingredients and method to calculate unit costs.
- Practically, the **Data Entry Tool** (provided in Excel) has calculations and links which summarize the cost data by service outputs in capital and recurrent categories ('Dataset output') and intervention type by TB services, laboratory and radiology tests ('Dataset patient'). These datasets can be explored in Excel or exported into software such as STATA or RStudio for pooled analysis.

BOX B. TRANSFERRING DATA FROM DATA COLLECTION TOOL TO DATA ENTRY TOOL: THE PROCESS

Data should be transferred from the data collection to the data entry sheets by pasting the *Values* or *Values & Number Formatting* only. This will ensure that the cell format is not changed and that there are no links to other files. Do not enter data in any non-yellow cells or make any edits to this sheet as it provides the selections for the dropdowns used throughout the tool.

Identical sheets in **Data Collection and Data Entry Tools** are listed here and mere copying (as described above) is sufficient. Ensure that any edits or additions made to the lists are replicated (with the same spelling and order).

Drop-down lists

INSTRUCTIONS: Please DO NOT make changes to this sheet. This sheet should remain locked.

Country	Facility level	Geography
Ethiopia	Community health unit	Urban
India	Health post/dispensary	Rural
Kenya	Health centre	
Philippines	Primary (sub-county/district) hospital	
Georgia	Secondary (county/general) hospital	
	Tertiary (national/ teaching/ referral/ specialised) hospital	
	Basic laboratory (stand alone)	
	Basic laboratory (linked to facility)	
	Laboratory (full)	
	Reference laboratory	

General information

- The sheets for collecting information about the facility, including capital assets (buildings, equipment, furniture, vehicles and training) and recurrent costs (staff and other expenditure) are in **blue**, while price lists for drugs, equipment and supplies are colour-coded in **green**.
- Service utilization data are in **light grey** and calculation sheets are in **orange**. Data should not be inputted into these orange sheets as they calculate unit costs and generate results.
- There is an additional **yellow** sheet that should be used for capturing the time taken by data collectors to perform the data collection.
- Title page, Glossary and Instructions sheets are similar to those in the **Data Collection Tool**, but the instructions have been adapted to give guidance on how to use the **Data Entry Tool**.

Title page

VALUE-TB

Data entry and calculation tool for estimating unit costs of TB services in COUNTRY A

Project overview:

VALUE-TB is a three-year project, funded by the Bill and Melinda Gates Foundation, established to work with National Tuberculosis Programmes (NTPs) from high TB burden countries to collect unit cost data, using new standardised methods.

The included TB interventions are those that are most relevant for future local planning and resource requirement projections and have been jointly defined by the NTP and the VALUE-TB team.

There are two tools required to estimate the unit costs of TB services at the facility level: this is the Data Entry Tool, which accompanies the data collection tool. The data collection tool was used first by data collectors at the facility to gather the required data. Then this Data Entry Tool should be compiled by the study principal investigator or study coordinator to produce the calculated unit costs.

This cost Data Entry Tool has been developed to estimate the unit costs of a comprehensive set of TB services from the providers' perspective. Once the data from the data collection tool have been entered into the relevant sheet in this tool, unit costs are produced for bottom-up and top-down as well as economic and financial costs of the TB services offered at this facility.

The estimated time for transferring data from the data collection tool into this Data Entry Tool, including data management of the sheets and validation of the calculations, is 1 day for smaller facilities and up to 3 days for larger facilities.

The cost data collected in this tool can further be used:

- for programme management, funding and planning
- to inform the estimates of the costs of TB services globally

March 13, 2019

Version 2.0

- This provides an overview of the Value TB study, outlining the aims of the study and the tool, as well as how the data can be used.

Glossary

Glossary

AE	adverse events
ACF	active case finding
AFB	acid-fast bacilli
ALT	alanine aminotransferase (also known as SGPT)
AST	asparate aminotransferase (also known as SGOT)
BCG	bacille Calmette-Guérin
BSC	biosafety cabinet
BU	bottom-up cost estimation/allocation
BUN	blood urea nitrogen
CBC	complete blood count
CCC	comprehensive care clinic

- The glossary defines the acronyms and abbreviations used within the tool.

Instructions

Instructions

1. One data entry workbook should be used for each facility being costed.

2. The **black**, **blue**, grey and **green** sheets are for inputting data collected in the data collection tool. The **yellow** sheet is for capturing the time it takes to collect all the cost data, including transfering the entry sheets.

- Instructions describe the colour-coding of the sheets and the cells in the tool, and how they should be used.

Parameters

Parameter Assumptions

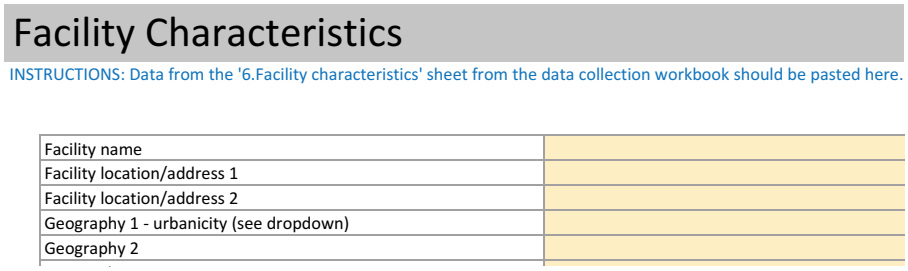
INSTRUCTIONS: Validate the values; then lock the entire sheet

Parameter name	Value	Source
Year of assessment		*Latest financial or calendar year*
No. of months evaluated	12	Assumption
No. of days in a month	30	Assumption
No. of weeks in a month	4.348214286	Julian calender
No. of weeks in a year	52	Assumption

- This sheet contains key data on the year of assessment, country name, factors for valuing assets and prices (e.g. useful life, discount rates, exchange rates, monthly minimum wage, etc). There are also factors for converting measures of time to common units (e.g. minutes in an hour, average days in a month, etc.).
- The source of all the data needs to be provided, whether it is from a specific agency, website, established methodology or an assumption.
- The 'useful life' values (**Data Collection Tool**, column G for both Price List-Equipment and Equipment Inventory) can be obtained from WHO CHOICE or **Parameters** of the **Data Entry Tool** for different sizes of equipment.
- The country in which this tool is being used (Title Page, cell M3) will be updated when the country name has been included in the **Parameters** sheet (cell C16).

- Values in this sheet should only be entered once for a particular country. Once this has been done, no edits should be made to this data and the tool can then be replicated for all facilities with the same parameter data. To ensure the sheet is not edited, it should be locked: [Review tab>Protect Sheet (in the Changes menu)>'Select locked cells' should be ticked>select 'OK'].

Facility characteristics



Facility Characteristics

INSTRUCTIONS: Data from the '6.Facility characteristics' sheet from the data collection workbook should be pasted here.

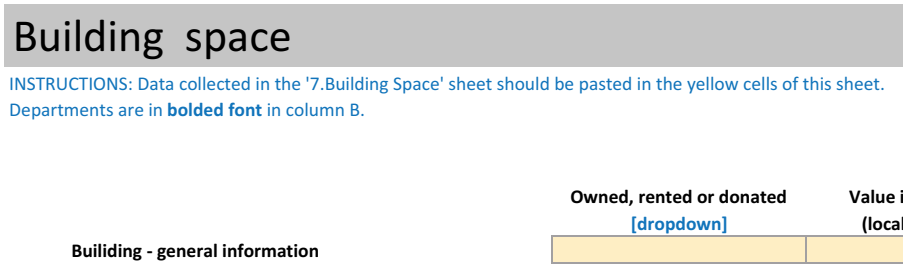
Facility name	
Facility location/address 1	
Facility location/address 2	
Geography 1 - urbanicity (see dropdown)	
Geography 2	

- The values from the data collection **Facility Characteristics** should be copied and pasted into this **Data Entry Tool**.
- Do not transfer data from the source, year of data or notes cells in the **Data Collection Tool**.
- Ensure that the dropdown selections for the additional service output types have been selected properly.

A. Reviewing completed sheets

The following review and calculations for unit cost generation will be performed using the **Data Entry Tool**. This section of the guidelines will cover **(A) reviewing completed sheets** and **(B) generation of unit costs** using the associated **Data Entry Tool**.

Building space



Building space

INSTRUCTIONS: Data collected in the '7.Building Space' sheet should be pasted in the yellow cells of this sheet.
Departments are in **bolded font** in column B.

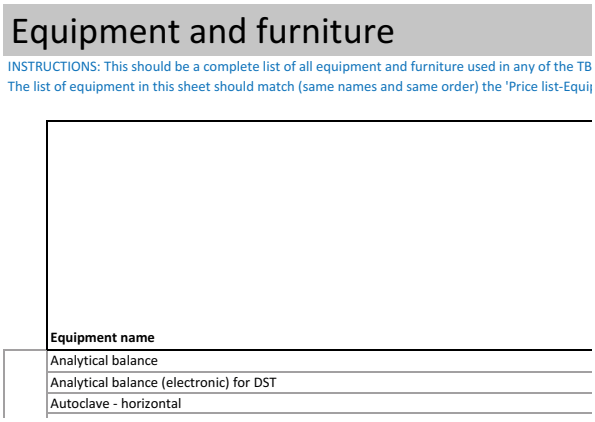
	Owned, rented or donated [dropdown]	Value i (local
Builiding - general information		

Amortizing capital costs:

- Check the calculations for the annualized economic and financial costs, as well as the allocations of the building costs to the direct, support and indirect facility departments (see **Box A**).
- The useful life years of the building (from **Parameters**) feeds into the calculation for 'Annualized economic costs (local currency)' taking the standard discount rate (from **Parameters**),'Value if sold today (local currency)', and useful life years of the building, and running a PMT function which calculates the annualized/amortized amount.

- The same calculation is done for the local discount rate (from the *Parameters* sheet).
- There are check cells in column AO, which ensure that the proportion of building space allocated to each department adds up to 100%. If this is not the case, 'ERROR' will be returned in the check cell and the department allocations need to be amended.

Equipment top-down



Equipment and furniture

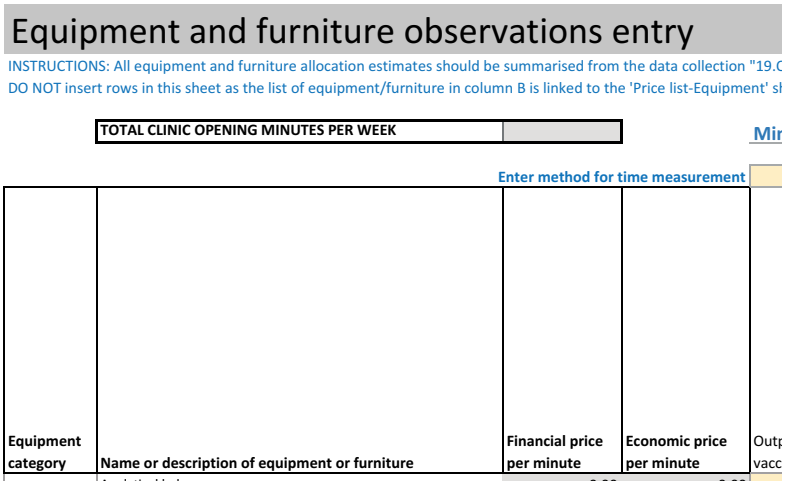
INSTRUCTIONS: This should be a complete list of all equipment and furniture used in any of the TB
The list of equipment in this sheet should match (same names and same order) the 'Price list-Equi

	Equipment name
	Analytical balance
	Analytical balance (electronic) for DST
	Autoclave - horizontal

Equipment time (top-down) calculation:

- The proportion of time for each relevant TB service output should be calculated using service statistics for that particular output divided by the service statistics for all tests (outputs) performed using that piece of equipment. If the tests (outputs) performed by that piece of equipment are not known, all tests in the lab can be used.
- Using a top-down approach, the expenditure of all the equipment and furniture are allocated to TB services using an allocation factor (for instance, number of TB tests processed divided by the total number of tests processed in a laboratory).
- If the equipment was used for more than three service outputs, information can be entered for the same piece of equipment on two separate rows, ensuring that the percent usage for TB has been split between the two rows.
- The values in columns I, K and M should total 100%.

Equipment BU



Equipment and furniture observations entry

INSTRUCTIONS: All equipment and furniture allocation estimates should be summarised from the data collection "19.C
DO NOT insert rows in this sheet as the list of equipment/furniture in column B is linked to the 'Price list-Equipment' sh

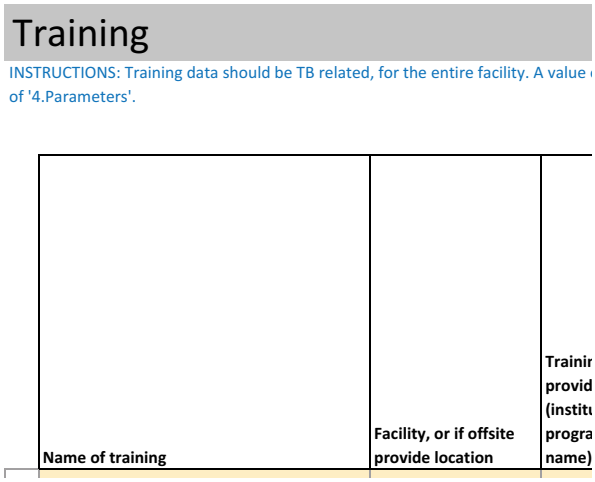
TOTAL CLINIC OPENING MINUTES PER WEEK		Mir
	Enter method for time measurement	

Equipment category	Name or description of equipment or furniture	Financial price per minute	Economic price per minute	Outp vacc

Equipment time (bottom-up) calculation:

- From the observations and/or interviews performed during data collection, enter the quantity of time (in minutes) that the relevant pieces of equipment were used to perform each service output.
- The method used to measure the time each piece of equipment was utilized for each service output needs to be selected.
- It is possible to select a combination of observation and interview in cases where observation of the entire service was not possible because of ethical issues or if the entire service did not naturally occur during the data collection period.

Training



Training

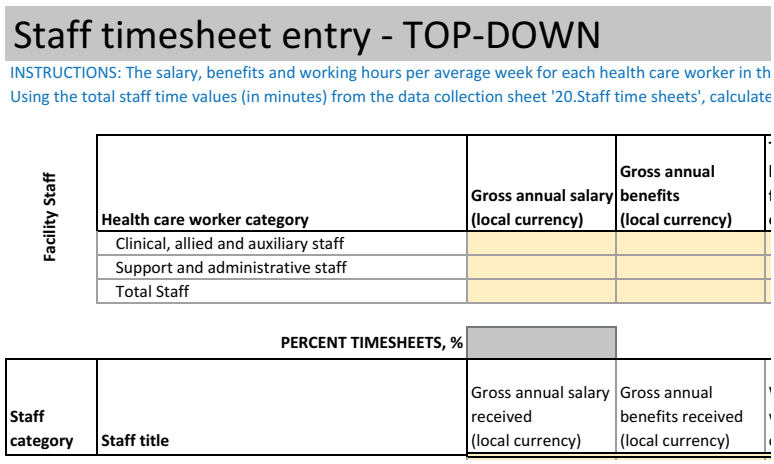
INSTRUCTIONS: Training data should be TB related, for the entire facility. A value
of '4.Parameters'.

Name of training	Facility, or if offsite provide location	Trainir provid (institu progra name)

Allocate training across departments:

- After copying data from **Data collection**, check that the correct proportions and service outputs appear in the relevant department and service output allocation boxes to the right of the sheet.

Staff top-down



Staff timesheet entry - TOP-DOWN

INSTRUCTIONS: The salary, benefits and working hours per average week for each health care worker in th
Using the total staff time values (in minutes) from the data collection sheet '20.Staff time sheets', calculate

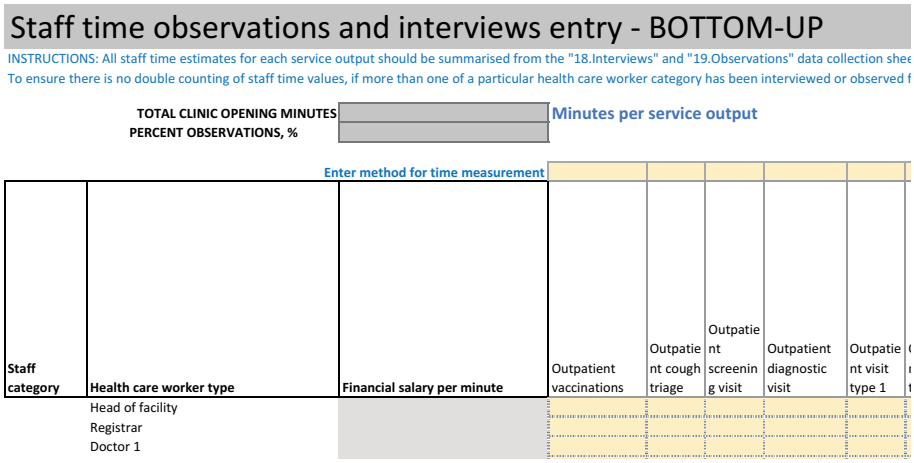
Facility Staff	Health care worker category	Gross annual salary (local currency)	Gross annual benefits (local currency)
	Clinical, allied and auxiliary staff		
	Support and administrative staff		
	Total Staff		

		PERCENT TIMESHEETS, %	
Staff category	Staff title	Gross annual salary received (local currency)	Gross annual benefits received (local currency)

Review automatically calculated proportions of health care worker time spent on each service output – top-down method:

- For staff performing TB services within a cadre who were not given timesheets, one can assume their time distribution is the same as the staff member within that cadre (in the same department or clinic) who did complete a timesheet. Therefore, the minutes per week for each service output should be duplicated from the timesheet collected for the staff member within that cadre at the facility. In this situation, the top-down staff time measurement method will also be 'timesheet'.
- The top-down method will be 'interview' if the timesheet was completed by sitting with the staff member and asking them how they spend their time over a specific period of time.
- For support and administrative staff, top-down measurement is likely to be based on 'assumption', where their total working hours per week can be allocated to TB versus non-TB services by using service statistics.
- For example, for a driver attached to the facility, time allocated to 'Other overhead services' can be allocated by ((TB outpatient visits + TB inpatient bed-days)/(total facility outpatient visits + total facility inpatient bed-days)) * total minutes worked per week. The remaining minutes in their work week should be allocated to 'Non-TB services'.
- At the end of the staff categories "clinical, allied and auxiliary staff" and "support and administrative staff", there is space to include the title of 15 and 10 additional staff members, respectively. This has been indicated in blue font.
- Only change text in the cells with blue font in column B.
- This sheet contains the original list of health care workers used throughout the tool.
- The list in **Staff BU** has been linked to the list in this sheet.

Staff BU



Staff time observations and interviews entry - BOTTOM-UP

INSTRUCTIONS: All staff time estimates for each service output should be summarised from the "18.Interviews" and "19.Observations" data collection shee
To ensure there is no double counting of staff time values, if more than one of a particular health care worker category has been interviewed or observed f

TOTAL CLINIC OPENING MINUTES		Minutes per service output	
PERCENT OBSERVATIONS, %			

			Enter method for time measurement					
Staff category	Health care worker type	Financial salary per minute	Outpatient vaccinations	Outpatient cough triage	Outpatient screening visit	Outpatient diagnostic visit	Outpatient visit type 1	
	Head of facility							
	Registrar							
	Doctor 1							

Review automatically calculated the proportion of health care worker time spent on each service output – bottom-up method:

- The minutes per service output should be entered based on observations or interviews performed for each service output at the facility.

- Only enter values for the person(s) who actually perform the job.
- Be sure to select the method used for staff time measurement for each output in row 6.
- The list of healthcare workers is linked to the list of staff in the **Staff top-down** sheet.
- Check that the correct value for 'financial salary per minute' appears for the corresponding health care worker from the **Staff sheet**.

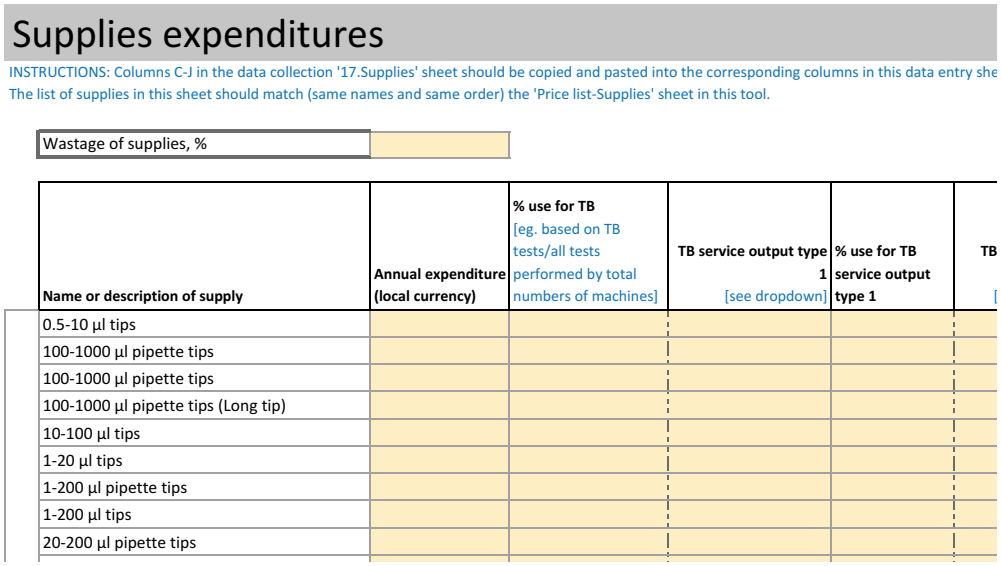
Review drug quantities:

The analyst will review:

— Total annual quantity disbursed for TB (in units) (**Data Entry Tool** – **Drugs top-down**)

— Average number of drugs per patient (**Data Entry Tool** – **Drugs bottom-up**)

Supplies top-down



Supplies expenditures

INSTRUCTIONS: Columns C-J in the data collection '17.Supplies' sheet should be copied and pasted into the corresponding columns in this data entry she
The list of supplies in this sheet should match (same names and same order) the 'Price list-Supplies' sheet in this tool.

Wastage of supplies, %	

Name or description of supply	Annual expenditure (local currency)	% use for TB [eg. based on TB tests/all tests performed by total numbers of machines]	TB service output type 1 [see dropdown]	% use for TB service output type 1	TB [
0.5-10 µl tips					
100-1000 µl pipette tips					
100-1000 µl pipette tips					
100-1000 µl pipette tips (Long tip)					
10-100 µl tips					
1-20 µl tips					
1-200 µl pipette tips					
1-200 µl tips					
20-200 µl pipette tips					

Review supplies quantities (top-down) and allocation of office and general supplies:

- In the method embedded in the **Data Entry Tool**, 100% of 'Office supplies' and 'General supplies' have been allocated to 'Admin & Management' and 'Other Overhead', respectively.
- Ensure that the proportions for each category of supplies is accurate and that the economic costs have been properly allocated.
- All other supplies ('Medical supplies' and 'Chemicals and reagents') have been allocated to the service outputs identified during observations or interviews.
- Do a spot check to ensure that the service outputs and proportions for each supply item with data is being pulled into the correct department and service output cost calculation.

Supplies BU

Supplies observation entry

INSTRUCTIONS: All supply allocation estimates should be summarised from the data collection "18.Interviews" and "19.Observations" sheets, and entered into this input she
The list of supplies in this sheet should match (same names and same order) the 'Price list-Supplies' sheet in this tool.

			Quantity (units) per service output								
	Method of quantity measurement										
Type of supply	Name or description of supply	Price per unit	Outpatient vaccinations	Outpatient cough triage	Outpatient screening visit	Outpatient diagnostic visit	Outpatient visit type 1	Outpatient visit type 2	Outpatient visit type 3	Inpatient bed-day type 1	Inpatient bed-day type 2
General supp	Rinse aid for dish washer	0.00									
	Salt for dish washer	0.00									
	Silica gel (for desiccator)	0.00									
	Spatula	0.00									
	Styro box	0.00									
	Surface cleaner	0.00									

Complete supplies bottom-up calculations:

- From the observations and/or interviews performed during data collection, enter the quantity of each supply (in units) that was utilized for each service output.
- The analyst selects whether these quantitates have been obtained by observation, interview or a mixture of the two.
- This value is applicable to all the supply quantity values obtained for the entire facility.
- Selection of the method should be based on whether the majority of values were obtained by observation (select 'Observation'), interview (select 'Interview') or about equal (select 'Mix').
- For the 'Mix' method, the default in the tool is 50% observation to 50% interview but this can be changed by varying the 'Time measurement allocation for 'Mix' method' in cell C24 of the **Parameters** sheet.
- Do a spot check that the price per unit for each supply is being pulled in correctly from **Price list-supplies** and that the calculation for the cost of supplies for each output is being applied to the correct quantity.

Review drug, supplies and equipment prices

In this tool, drugs used to treat adverse events have not been included in the unit costs.

Data collection time

(Optional) Review data collection time if one wishes to analyse the time invested in the costing study itself and use the evidence to inform the data collection.

- This sheet asks for the time taken (in minutes) to collect all the data needed to complete the respective sheets in the **Data Entry Tool** as well as time it takes to transfer data from the **Data Collection Tool** to the **Data Entry Tool**.
- To facilitate documentation, several of the data collection sheets include space at the top to input the start and end dates and times for the data collection.

Data Collection time

INSTRUCTIONS: Report the time taken, in minutes, to collect all the data in each sheet listed below. Also include the time taken to transfer from data collection to date entry tool.

Start date:
End date:

Sheet name	Collected for this facility (see dropdown)	Time taken to complete data collection (in minutes)
4.Parameters		
5.Facility Characteristics		
6.Building Space		
7a.Building		
7b.Building BU		
8.Transport		
9.Training		
10a.Staff TD		
10b.Staff BU		
11.Recurrent Other		
12a.Drugs TD		
12b.Drugs BU		

- Appreciating that in many instances the data collection for a sheet may not happen in one discrete time period, the dates and times included in some sheets are meant to be an aid in capturing this information.
- Complete times will likely also require piecing together time spent based on input from each data collector.
- A template for data collector timesheets has been included in the **Data Collection Tool** as a way to collect more detailed time information from each data collector. Using it is optional, but it may also be useful for the study to use it during the piloting stage as a way of estimating the time needed to for data collection in each facility.
- A pilot study would take approximately a week and would test the tool adaption and data availability.

Service statistics

Service Statistics and Allocation Keys

INSTRUCTIONS: Copy and paste data from the '14.Service Statistics' sheet in the data collection tool.

Year of data (latest financial or calendar year)

	Unit	Annual quantity - entire facility	Annual quantity - TB services only
Section I: Health facility statistics	Outpatient visits		
	TB Clinic		
	MCH Clinic		
	Paediatric Clinic		
	HIV Clinic		
	Chronic Disease (diabetes) Clinic		
	Comprehensive Care Clinic		
	Inpatient beddays		
	Inpatient admissions		
	Laboratory tests (all labs)		
	Microbiology Lab - tests		
	Bacteriology Lab - tests		
	Laboratory: main (clinical path, incl haematology) - tests		
	Area for blood, serum, plasma collection - samples		
	Area for sputum sample collection - samples		
	Area for AFB and GeneXpert - tests		

Review service statistics and allocations of main cost components in the unit costs.

- The **Data Entry Tool** will generate automatic calculations, but the analyst will be making choices in the two options available for allocation keys depending on data available at the facility.

- Here is a description of the allocation of all the main cost categories (i.e. space, equipment, staff time, drugs, transport).
- It will be followed by a description of its implementation in the **Data Entry Tool** through sheets on **Service statistics**, **Summary top-down** and **Summary bottom-up**.

Description of cost components allocations

Space

- For comprehensive care clinics in OPD where services are integrated, such as TB screening for all patients with HIV, questions could address the proportion of time spent screening for TB (or work out the proportion based on number of minutes for screening/total time for HIV consultation) and use this time to allocate a portion of the space (i.e. incorporate time where spaces are shared, with the assumption that visits take the same amount of time).
- The top-down allocation is calculated using TB visits over total clinic headcount multiplied by the total building space (for example TB visits/total clinic headcount*total building space (500/5000)*100m^2=10m^2).

BOX C. ALLOCATION FOR SPACE

Ideal: measure bottom-up space directly – i.e. the proportion of space used for a service

If direct measurement is not possible, use visits for the allocation or ask staff who use the space to estimate the proportion for TB versus non-TB services

For general OPD, recommended allocation = total TB outpatient visits/total outpatient visits

For MCH in OPD where BCG vaccination and screening occurs, the recommended allocation = (total BCG vaccine visits + total TB screening visits)/total MCH OP visits

For inpatient department (IPD), recommended allocation = total TB inpatient bed-days/total department inpatient bed-days

For laboratory or radiology departments, recommended allocation = total TB tests/total department tests

BOX D. ALLOCATION FOR EQUIPMENT

To allocate equipment cost to TB service:

Ideal: use the number of tests to calculate the allocation. If one knows which tests the equipment is used for, denominator=sum of those test numbers; if one does NOT know which tests it is used for, denominator=all tests in that laboratory (i.e. microscope: used for ZN/Malaria/Stool testing only)

EXCEPT: for equipment for culture and DST tests, including MGIT, incubator, Xpert® MTB/RIF if also used for HIV, influenza, etc. testing. Here time can be included in the calculation.

Observation should be the default; if not available then use **interview data**. For instance, if MDR-TB testing is not done frequently then interview data may be the only option. It is also possible to ask for a demonstration which can be observed.

BOX E. ALLOCATION FOR STAFF TIME USING A TOP-DOWN MEASUREMENT METHOD

Ideal: Staff timesheets for at least one cadre of health care worker performing each TB service output. Based on the total time spent on each output, the proportion of time for each TB output will be calculated in the **Data Entry Tool**.

Alternatives: For direct service personnel without timesheets, the assumption is that the proportion of time spent on TB should be the same as other personnel in that cadre of health professional. For example, if timesheets were collected for one doctor, nurse and nursing assistant, but there are additional doctors, nurses and nursing assistants providing TB services in the facility, it can be assumed that the timesheet values for "doctor 1" can be used for "doctor 2" and "doctor 3" as well. The same assumptions will also apply for the other cadres.

For support staff, the head of facility or registrar, the proportion of time for TB is estimated (**assumption**) based on the total TB outpatient visits divided by the total facility outpatient visits:

— *% time for TB (support staff, facility head, registrar) = total TB outpatient visits/total outpatient visits for facility*

For head of laboratory, radiology and the inpatient department, use laboratory tests, radiology tests and bed-days, respectively.

— *% time for TB (laboratory head) = total TB laboratory tests/total laboratory tests in facility*

— *% time for TB (radiology head) = total TB radiology tests/total radiology tests in facility*

— *% time for TB (inpatient department head) = total TB bed-days/total bed-days for facility*

Specialized personnel providing direct services (e.g. phlebotomists, pharmacists, social workers, etc.) should be interviewed to provide an estimate of the proportion of time spent on TB, and of that time, how it is split between various departments (e.g. outpatient and inpatient departments for social workers).

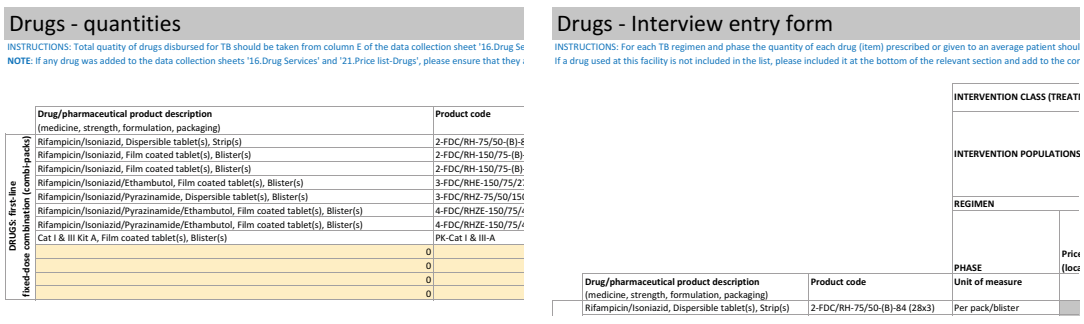
Other options: If one cannot measure directly, then use service statistics for the allocation. If the health care worker provides outpatient services, estimate using number of TB outpatient visits/Total outpatient visits. If the health care worker provides both outpatient and inpatient services, estimate using number of TB outpatient visits+TB inpatient bed-days/Total outpatient visits+Total inpatient bed-days

BOX F. ALLOCATION FOR STAFF TIME USING A BOTTOM-UP MEASUREMENT METHOD

Ideal: Number of hours measured directly, and proportion of time spent on each task will be calculated in the **Data Entry Tool**

Alternatives: a rough estimate given by the staff interviewed, or the percentage time for TB (%)= Department 1+ 2.

Drugs top-down and Drugs bottom-up



Drugs - quantities

INSTRUCTIONS: Total quatity of drugs disbursed for TB should be taken from column E of the data collection sheet '16.Drug Se

NOTE: If any drug was added to the data collection sheets '16.Drug Services' and '21.Price list-Drugs', please ensure that they

	Drug/pharmaceutical product description (medicine, strength, formulation, packaging)	Product code
DRUGS: first-line fixed-dose combination (combi-packs)	Rifampicin/Isoniazid, Dispersible tablet(s), Strip(s)	2-FDC/RH-75/50-(B)-8
	Rifampicin/Isoniazid, Film coated tablet(s), Blister(s)	2-FDC/RH-150/75-(B)-
	Rifampicin/Isoniazid, Film coated tablet(s), Blister(s)	2-FDC/RH-150/75-(B)-
	Rifampicin/Isoniazid/Ethambutol, Film coated tablet(s), Blister(s)	3-FDC/RHE-150/75/2
	Rifampicin/Isoniazid/Pyrazinamide, Dispersible tablet(s), Blister(s)	3-FDC/RHZ-75/50/15
	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol, Film coated tablet(s), Blister(s)	4-FDC/RHZE-150/75/4
	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol, Film coated tablet(s), Blister(s)	4-FDC/RHZE-150/75/4
	Cat I & III Kit A, Film coated tablet(s), Blister(s)	PK-Cat I & III-A
	0	
	0	
	0	
	0	

Drugs - Interview entry form

INSTRUCTIONS: For each TB regimen and phase the quantity of each drug (item) prescribed or given to an average patient shoul

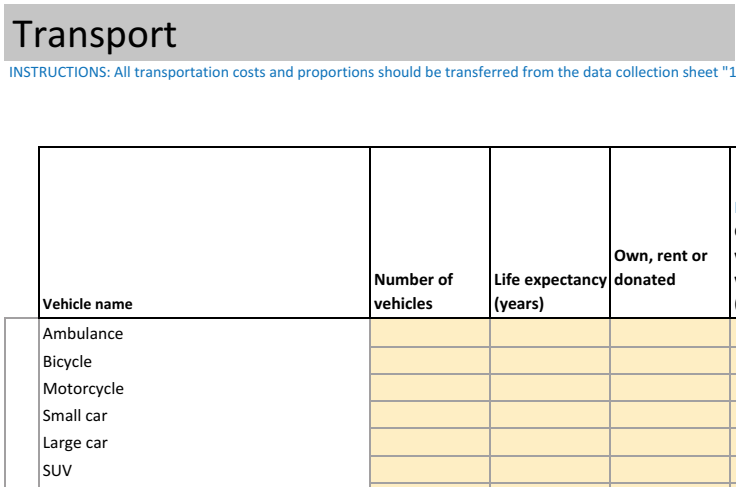
If a drug used at this facility is not included in the list, please included it at the bottom of the relevant section and add to the cor

	INTERVENTION CLASS (TREATI	
	INTERVENTION POPULATIONS	
	REGIMEN	
	PHASE	Price (loca
Drug/pharmaceutical product description (medicine, strength, formulation, packaging)	Product code	Unit of measure
Rifampicin/Isoniazid, Dispersible tablet(s), Strip(s)	2-FDC/RH-75/50-(B)-84 (28x3)	Per pack/blister

- Top-down drug cost is estimated as the total annual quantity of drugs disbursed at the facility by the unit price of the drugs.
- Top-down costing would involve looking at the expenditure of TB medication divided by the number of patients taking the medication.
- This would usually involve step down accounting methods or allocation to move from an aggregate value to disaggregated costs for different regimens or individual drugs.

- Similarly, to cost diagnostic tests one may need to allocate the cost of TB drugs from the expenditure of all drugs in a facility, and then further allocate costs to specific TB regimens i.e. first-line, retreatment, second-line and third-line treatment.
- Bottom-up drug cost is calculated as the product of the drug prices and the average quantity per average patient for each TB treatment and prevention regimen by phase.
- For a bottom-up costing, one would look at the patient TB drug usage.
- For smaller facilities, this may include abstraction of all the patients' medication records; for larger facilities a sample of patient records might be used.
- Together with a price list for TB medication, one could calculate the average cost of TB medication (e.g. first-time treatment) for a relevant amount of time, for instance per month or per annum.

Transport



Transport

INSTRUCTIONS: All transportation costs and proportions should be transferred from the data collection sheet "1

Vehicle name	Number of vehicles	Life expectancy (years)	Own, rent or donated
Ambulance			
Bicycle			
Motorcycle			
Small car			
Large car			
SUV			

- Care should be taken that transport is captured either in overhead costs; or above service level costs or in vehicle costs (capital costs), and that it is not double counted.
- The 'Life expectancy (years)' needs to be provided for each vehicle being costed in this sheet.
- If there is no locally specific value, be sure to include the value provided in **Parameters**.

Recurrent other

- The proportion of recurrent costs allocated to TB services has been calculated using service statistics for outpatient visits (TB outpatient visits/total facility outpatient visits).
- In a cost analysis, overhead inputs are allocated accordingly to various departments or activities. Inputs could be allocated to 'cost centres' (depending on how cost data are organized, and cost centres are defined).
- An allocation basis needs to be defined for allocating each input to various cost centres. For instance, some costs can be assigned directly to certain cost centres.

Other recurrent expenditures

INSTRUCTIONS: Annual expenditure from the '10.Recurrent Expenditure' data collection s

	Recurrent overhead costs (ENTIRE FACILITY) - disaggregated
Utilities	Water
	Sewerage and sanitation
	Electricity (light and heat)
	Gas
	Bio-safety disposal
	Other
	TOTAL UTILITIES
ations	Internet
	Telephone

- If 'inpatient care' is a cost centre, then the line item 'laundry' could be allocated to that centre, using 'a patient day equivalent' as an allocation method.
- If 'maintenance' is a cost centre, then 'floor space utilized by department' could be a useful allocation method.
- Allocation of overhead inputs usually requires step down costing.

Service description

Service Description

INSTRUCTIONS: The data from the '15.Service Description' sheet in the data collection tool sh

	Quantity per patient (visits		
INTERVENTION CLASS	VACCINATION		
INTERVENTION TYPE	BCG Vaccination	Passive Ca	
INTERVENTION POPULATIONS	Infant	Adult	
		PTB	EPTB
REGIMEN			

- The values in cells C13 to CE84 of **Service Description** should be copied and pasted into C14 to CE85 of this **Data Entry Tool**.

Price list-drugs

Price List for Drugs

This sheet can be used to get prices on drugs from the facility or from a central source such as the Ministry of

INSTRUCTIONS: Copy and paste data from the '21.Price list-Drugs' sheet in the data collection tool into
Please enter a transportation and logistics mark-up for the facility.

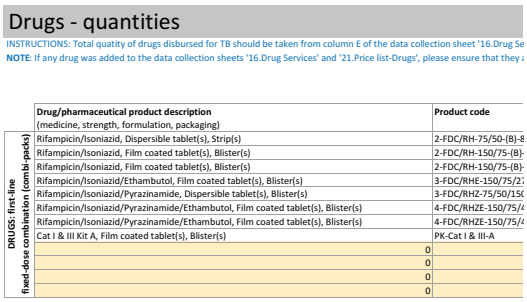
	First-line drugs	Second-line drugs
Transportation mark-up (within country), %		

Drug/pharmaceutical product description (medicine, strength, formulation, packaging)	Product code (eg GDF)	Unit of measure
Rifampicin/Isoniazid, Dispersible tablet(s), Strip(s)	2-FDC/RH-75/50-(B)-84 (28x3)	Per pack/blister
Rifampicin/Isoniazid, Film coated tablet(s), Blister(s)	2-FDC/RH-150/75-(B)-672	Per pack/blister

- The transportation mark-up values for first-line and second-line drugs are linked to the formulae in column N.

- Check that the list of drugs is being linked to the correct mark-up value based on which regimen they are used for.
- Also do a spot check of the calculations of the unit prices and costs per tablet/dose (local currency and USD) to ensure values from different rows are not being pulled in.
- In this tool, drugs used to treat adverse events have not been included in the unit costs.
- If this data is easily available and one does not wish to lose it, one can enter them in the 'DRUGS: vaccines' section (rows 160–165).

Drugs top-down and Drugs bottom-up

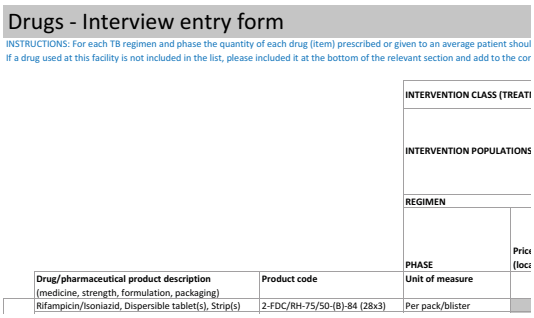


Drugs - quantities

INSTRUCTIONS: Total quatity of drugs disbursed for TB should be taken from column E of the data collection sheet '16.Drug Se

NOTE: If any drug was added to the data collection sheets '16.Drug Services' and '21.Price list-Drugs', please ensure that they a

	Drug/pharmaceutical product description (medicine, strength, formulation, packaging)	Product code
DRUGS: first-line fixed-dose combination (combi-packs)	Rifampicin/Isoniazid, Dispersible tablet(s), Strip(s)	2-FDC/RH-75/50-(B)-8
	Rifampicin/Isoniazid, Film coated tablet(s), Blister(s)	2-FDC/RH-150/75-(B)-
	Rifampicin/Isoniazid, Film coated tablet(s), Blister(s)	2-FDC/RH-150/75-(B)-
	Rifampicin/Isoniazid/Ethambutol, Film coated tablet(s), Blister(s)	3-FDC/RHE-150/75/2
	Rifampicin/Isoniazid/Pyrazinamide, Dispersible tablet(s), Blister(s)	3-FDC/RHZ-75/50/150
	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol, Film coated tablet(s), Blister(s)	4-FDC/RHZE-150/75/4
	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol, Film coated tablet(s), Blister(s)	4-FDC/RHZE-150/75/4
	Cat I & III Kit A, Film coated tablet(s), Blister(s)	PK-Cat I & III-A
	0	
	0	
	0	
	0	



Drugs - Interview entry form

INSTRUCTIONS: For each TB regimen and phase the quantity of each drug (item) prescribed or given to an average patient shoul

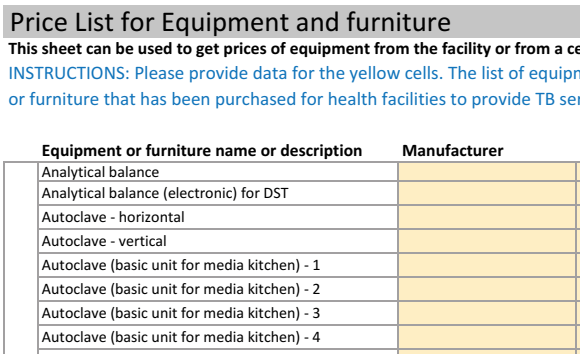
If a drug used at this facility is not included in the list, please included it at the bottom of the relevant section and add to the cor

	INTERVENTION CLASS (TREATI
	INTERVENTION POPULATIONS
	REGIMEN
PHASE	Price (loca

Drug/pharmaceutical product description (medicine, strength, formulation, packaging)	Product code	Unit of measure	
Rifampicin/Isoniazid, Dispersible tablet(s), Strip(s)	2-FDC/RH-75/50-(B)-84 (28x3)	Per pack/blister	

- Ensure that any edits or additions made to this sheet are replicated (with the same spelling and order) in **Drugs top-down** and **Drugs bottom-up** sheets.

Price list-equipment



Price List for Equipment and furniture

This sheet can be used to get prices of equipment from the facility or from a ce

INSTRUCTIONS: Please provide data for the yellow cells. The list of equipn

or furniture that has been purchased for health facilities to provide TB ser

	Equipment or furniture name or description	Manufacturer
	Analytical balance	
	Analytical balance (electronic) for DST	
	Autoclave - horizontal	
	Autoclave - vertical	
	Autoclave (basic unit for media kitchen) - 1	
	Autoclave (basic unit for media kitchen) - 2	
	Autoclave (basic unit for media kitchen) - 3	
	Autoclave (basic unit for media kitchen) - 4	

- Vehicles, equipment and furniture costs can be found in the facility records and inflated to the costed year, or by contacting local medical and furniture supplies for prices.

Price list-supplies

Price list for Supplies

INSTRUCTIONS: Any additional supplies that are not alread

Name or description of supply
0.5-10 µl tips
100-1000 µl pipette tips
100-1000 µl pipette tips
100-1000 µl pipette tips (Long tip)
10-100 µl tips
1-20 µl tips
1-200 µl pipette tips
1-200 µl tips
20-200 µl pipette tips

- Check that the calculations for the unit prices (local currency and USD) are not pulling values from different rows.

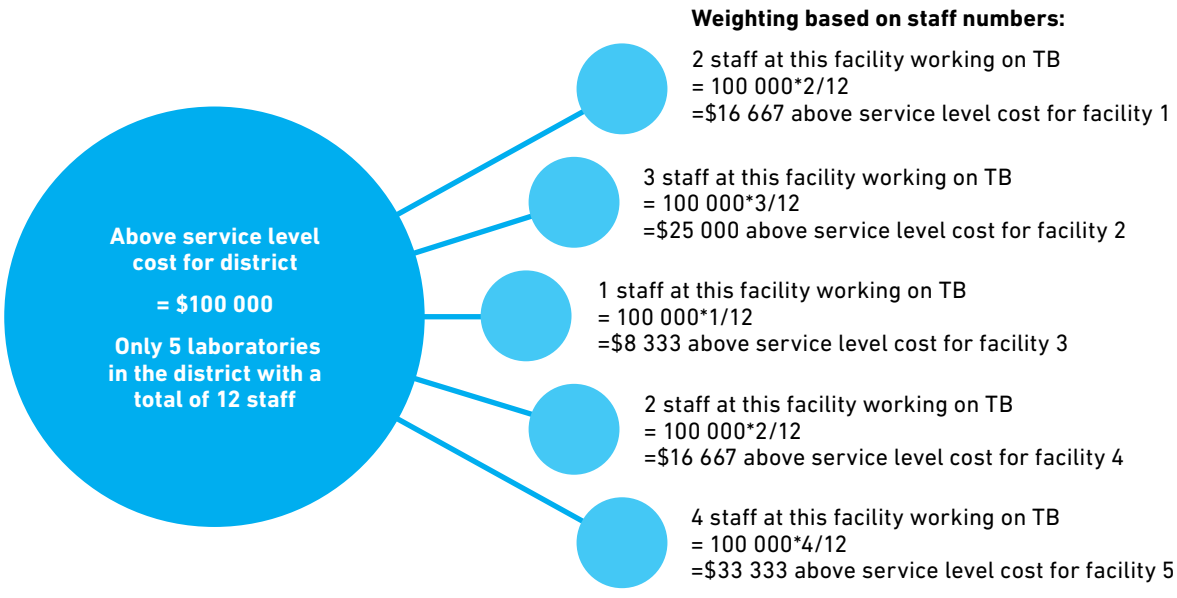
Notes

Notes or outstanding issues

	Sheet name	Outstanding data or question

- Any questions, unresolved issues or queries about unit cost values can be listed in this sheet.
- This provides one central place to store this information for each facility and incorporates the contact and resolution.

Figure 11. Shared above service level costs



B. Generation of unit costs

Service statistics caters for some these allocation calculations

Service Statistics and Allocation Keys

INSTRUCTIONS: Copy and paste data from the '14.Service Statistics' sheet in the data collection tool.

	Year of data (latest financial or calendar year)	
Section I: Health facility statistics	**Unit**	**Annual quantity - entire facility**
	Outpatient visits	
	TB Clinic	
	MCH Clinic	
	Paediatric Clinic	
	HIV Clinic	
	Chronic Disease (diabetes) Clinic	
	Comprehensive Care Clinic	
	Inpatient beddays	
	Inpatient admissions	
	Laboratory tests (all labs)	
	Microbiology Lab - tests	
	Bacteriology Lab - tests	
	Laboratory: main (clinical path, incl haematology) - tests	
	Area for blood, serum, plasma collection - samples	
	Area for sputum sample collection - samples	
	Area for AFB and GeneXpert - tests	
	Area for biopsy - tests	

- The percent allocation of healthcare worker time spent on TB directly is calculated from the timesheets, adding together the values by facility department (Outpatient, Inpatient, Community, Other TB, Admin & Management, Other Overhead and Pharmacy).
- It then allocates a proportion of the total for each department to the service outputs provided in that department, then allocates to each department based on the proportion of time spent on TB in the entire facility.
- It estimates the number of minutes for all TB services, i.e. minutes per service (derived from either observation or interview) * number of each TB service output.
- The tool then allocates a proportion of the services within the relevant department to each service output type in that department.
- It provides the size of the facility departments allocated to TB services and column M then calculates the proportion of all facility space used for TB by department.
- It calculates the proportion of services utilized for each service output within each facility departments.
- The 'Drug wastage factor' is documented
- The human resources bottom-up to top-down (HR bottom-up/top-down) capacity adjustment factor documents what proportion of the top-down estimate of staff time use is equivalent to the bottom-up estimate of staff time use.

Capacity adjustment factor

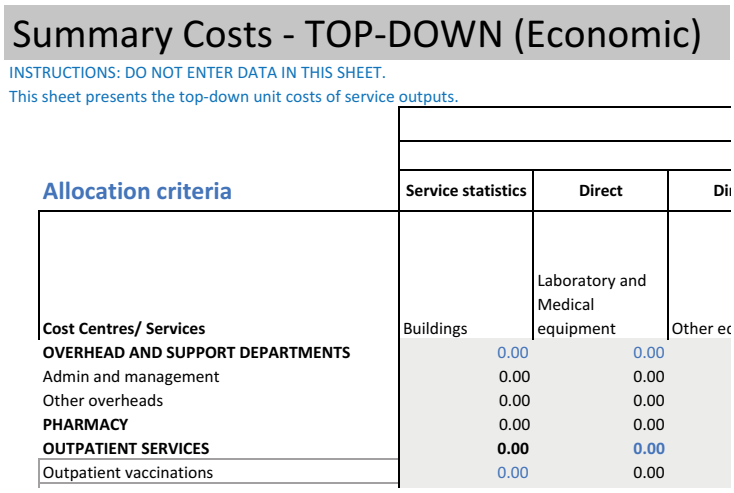
- The **HR BU/TD capacity adjustment factor, automatically generated in the Data Entry Tool**, tells us what proportion of the top-down estimate of staff time use is equivalent to the bottom-up estimate of staff time use.
- The numerator is the total hours per week estimated using the bottom-up approach for all TB services in the facility = [(Total minutes in the year for all TB services) + (an administration factor for admin & management, other overhead and pharmacy costs), converted to hours per week].

- The denominator is the total hours per week estimated using the top-down approach for all TB services in the facility = (total working hours per week over the year for staff included in the study * proportion of their working hours per week over the year allocated to TB) * 80%.
- If **HR bottom-up/top-down capacity adjustment factor <1**, the bottom-up estimates are lower than the top-down estimates.
- If **HR bottom-up/top-down capacity adjustment factor >1**, the top-down estimates are lower than the bottom-up estimates.

Summary bottom-up, Summary top-down, Patient top-down, Patient bottom-up Results (automatized in Data Entry Tool): unit cost generation:

- **Summary top-down**, **Summary bottom-up**, and **Patient bottom-up** sheets show intermediate results. They are auto-populated and do not need the analyst to do anything, as the formulae generate unit costs for the facility.
- The bottom-up approach to costing these items is by auditing/counting how many there are within the facility.
- The allocation of these costs to TB services is standardized within the sheets. First estimation is done through output (i.e. visits) and then cost per patient is estimated in the **Patient top-down** and **Patient bottom-up** sheets.
- This sheet calculates the bottom-up unit costs for an average patient by pulling in the service output bottom-up unit costs (from **Summary bottom-up**) and the quantities of each output per patient **Service description**.
- To check the sheet, do a spot check to ensure the formulae are pulling in the correct values and that there are no missing or error values due to missing unit cost or quantity data.
- The top-down approach would list all the equipment and furniture (or expenditure of all the equipment and furniture) and allocate these to TB services using a standardized allocation factor specific to the different inputs.
- This sheet multiplies the top-down unit costs of the service outputs (from **Summary top-down**) by the quantity of each service output (from **Service description**) for an average patient for each of the populations and regimen within each intervention type.
- The patient costs are also provided by phase of treatment and includes the costs of drugs specific to the regimen and phase.
- To check the results in this sheet, the analyst will do a spot check to ensure the cells contain the correct values and that there are no missing or error values due to missing unit cost or quantity data.

Summary top-down



Summary Costs - TOP-DOWN (Economic)

INSTRUCTIONS: DO NOT ENTER DATA IN THIS SHEET.
This sheet presents the top-down unit costs of service outputs.

Allocation criteria	Service statistics	Direct	Di
Cost Centres/ Services	Buildings	Laboratory and Medical equipment	Other ec
OVERHEAD AND SUPPORT DEPARTMENTS	0.00	0.00	
Admin and management	0.00	0.00	
Other overheads	0.00	0.00	
PHARMACY	0.00	0.00	
OUTPATIENT SERVICES	**0.00**	0.00	
Outpatient vaccinations	0.00	0.00	

Total costs for TB services are allocated for different input categories: The allocation criteria for the input categories comprising the unit costs is indicated.

A stepped approach has been used to obtain the unit costs for each cost centre and service output:

1. (columns C–S): costs are initially pulled in from the departments for the equipment/furniture, training, staff, and supplies input categories.

   For the remaining inputs, the costs are allocated based on the criteria indicated in row 5. For example, for 'Building space' (column C), the total economic costs allocated to each department are pulled in from **Buildings space**, then within each department these costs are allocated to each service output using the services statistics allocation keys in **Service statistics** (column I).

   The same process is repeated for vehicles; other (non-medical) supplies; capital maintenance; utilities; fuel and other recurrent transport (including maintenance and courier services); food (including food services), supplements; including food services; and other recurrent.

   The costs of drugs have not been included in the summary sheets but pulled in to the **Patient top-down** sheet.

2. (columns T–AJ): administration and management, other overhead and pharmacy costs (columns C–S) are allocated to each department based on the TB versus total facility service utilization. Then these department costs are allocated based on the quantity of service outputs provided in that department for the year.

3. (columns AK-BA): direct costs (columns C–S) and administration and management, other overhead and pharmacy costs (columns T–AJ) are summed.

4. (column BB): 'unit' or service output quantities are pulled in from **Service statistics**.

5. (columns BC–BS): the unit costs are calculated by dividing the total unit costs (columns AK–BA) for each service output by the total units for each service output.

6. (column BT): total unit cost for each service output is obtained by adding the unit cost for each input.

- There are check cells in row 92 of this sheet.

- If the values in this row do not match that of the summary values in rows 90 and 91, check the calculations and values in the preceding cells and related sheets for errors such as missing data or broken links.
- The unit costs of the service outputs and the summary costs for each input should be reviewed to assess reasonableness of the calculated values with respect to the local context and cost composition.

Summary bottom-up

Summary Costs - BOTTOM-UP (Economic)

INSTRUCTIONS: DO NOT ENTER DATA IN THIS SHEET.
This sheet presents the bottom-up unit costs of service outputs.

	DIRECT UNIT COS			
Allocation criteria	Direct	Direct	Direct	
Cost Centres/ Services	Laboratory and Medical equipment	Other equipment	Furniture	C
OVERHEAD AND SUPPORT DEPARTMENTS				
Admin and management				
Other overheads				
PHARMACY				
OUTPATIENT SERVICES	0.00	0.00	0.00	
Outpatient vaccinations	0.00	0.00	0.00	
Outpatient cough triage	0.00	0.00	0.00	
Outpatient screening visit	0.00	0.00	0.00	
Outpatient diagnostic visit	0.00	0.00	0.00	
Outpatient visit type 1	0.00	0.00	0.00	
Outpatient visit type 2	0.00	0.00	0.00	

Total Unit Cost for each service output – bottom-up approach: Step 1 for this sheet is an additional step. The subsequent steps follow a similar approach to that of steps 1–6 of the **Summary top-down** sheet.

1. (columns C–J): For each service output, the direct unit costs obtained from the bottom-up methods of data collection (observation or interview) are pulled in directly for the equipment, staff and supplies input categories (sheets 7b on *Equipment BU*, 10b on **Staff bottom-up** and 13b on **Supplies bottom-up**, respectively).
2. (columns K–AA):
   a. For the input categories that were not measured using a bottom-up approach, the top-down values (**Summary top-down**, columns C–S) are multiplied by the **HR bottom-up/top-down capacity adjustment factor**
   b. For inputs the equipment, staff and supplies inputs, the direct unit costs are multiplied by the total unit quantity for each service output. The unit cost for the department is the sum of the unit costs for the service outputs provided in that department.
3. (columns AB–AR): the admin & management, other overhead and pharmacy costs (columns K–AA) are allocated to each department based on the TB versus total facility service utilization. Then these department costs for each service output are allocated based on the quantity of the service outputs provided in that department for the year.

4. (columns AS–BI): direct costs (columns K–AA) and admin & management, other overhead and pharmacy costs (columns AB–AR) are summed.
5. (column BJ): 'unit' or service output quantities are pulled in from **Service statistics**.
6. (columns BK–CA) – the Unit Costs for each service output is calculated by dividing the total unit costs (columns AK–BA) for that output by the total units (quantity).
7. (column CB): Total Unit Cost for each service output is obtained by adding the unit cost for each input.

- There are check cells in row 92 of this sheet.
- If the values in this row do not match that of the Summary values in rows 90 and 91, check the calculations and values in the preceding cells and related sheets for errors such as missing data or broken links.
- The unit costs of the service outputs and the summary costs for each input should be reviewed to assess reasonableness of the calculated values with respect to the local context and cost composition.

Patient top-down

Cost per patient - TOP-DOWN

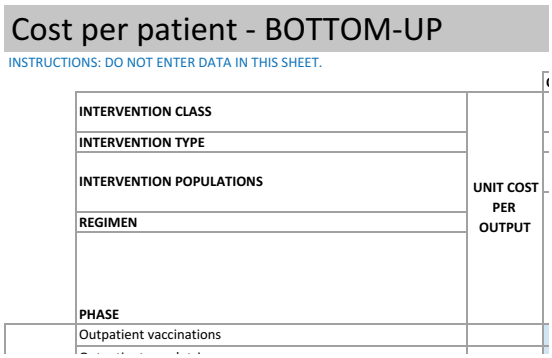
INSTRUCTIONS: DO NOT ENTER DATA IN THIS SHEET.

			QUANTITY PER PATIENT (visits, beddays or tests) for year of			
	INTERVENTION CLASS		VACCINATION			
	INTERVENTION TYPE		BCG Vaccination	Passive Case Finding		
	INTERVENTION POPULATIONS		Infant	Adult		Chil
				PTB	EPTB	PTB
	REGIMEN	UNIT COST PER OUTPUT				
	PHASE					
	Outpatient vaccinations		-	-	-	-
	Outpatient cough triage		-	-	-	-
	Outpatient screening visit		-	-	-	-

Calculate unit cost for an average patient – top-down:

- This sheet multiplies the top-down unit costs of the service outputs (from **Summary top-down**) by the quantity of each service output (from **Service description**) for an average patient for each of the populations and regimen within each intervention type.
- The patient costs are provided by phase of treatment and include the costs of drugs specific to the regimen and phase.
- To check the sheet, do a spot check to ensure the formulae are pulling in the correct values and that there are no missing or error values due to missing unit cost or quantity data.

Patient bottom-up



Cost per patient - BOTTOM-UP

INSTRUCTIONS: DO NOT ENTER DATA IN THIS SHEET.

INTERVENTION CLASS	UNIT COST PER OUTPUT
INTERVENTION TYPE	
INTERVENTION POPULATIONS	
REGIMEN	
PHASE	
Outpatient vaccinations	

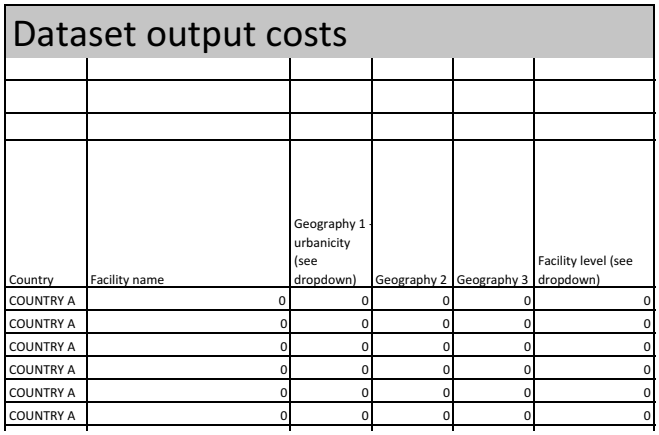
Calculate unit cost for an average patient – bottom-up:

- This sheet calculates the bottom-up unit costs for an average patient by pulling in the service output bottom-up unit costs (from **Summary bottom-up**) and the quantities of each output per patient (**Service description**).
- To check the sheet, do a spot check to ensure the formulae are pulling in the correct values and that there are no missing or error values due to missing unit cost or quantity data.

Datasets are produced per facility

- Each data set from a facility will be analysed with traditional statistical packages to meet the study objectives.

Dataset output



Dataset output costs

Country	Facility name	Geography 1 - urbanicity (see dropdown)	Geography 2	Geography 3	Facility level (see dropdown)
COUNTRY A	0	0	0	0	0
COUNTRY A	0	0	0	0	0
COUNTRY A	0	0	0	0	0
COUNTRY A	0	0	0	0	0
COUNTRY A	0	0	0	0	0
COUNTRY A	0	0	0	0	0

- This sheet contains the unit costs of all the service outputs presented by inputs.
- The quantities and prices of building space and staff time have also been presented for each service output.
- They are presented in a dataset format to allow for easy uploading into statistical software and for publication in the GHCC database.

Dataset patient

Dataset patient costs						
Country	Facility name	Geography (see dropdown)	Facility level (see dropdown)	Ownership (see dropdown)	Size (approximate) of facility buildings (m^2)	Total hospital beds (inpatient)
COUNTRY A	0	0	0	0	0	(all)
COUNTRY A	0	0	0	0	0	(all)
COUNTRY A	0	0	0	0	0	(all)
COUNTRY A	0	0	0	0	0	(all)
COUNTRY A	0	0	0	0	0	(all)

- This sheet contains the unit costs for each patient receiving vaccination, TB case detection and diagnosis, TB treatment and TB prevention by the service outputs.
- Both the top-down and bottom-up costing approaches are presented, along with financial and economic costs.
- Intervention class, type, populations, regimen and phase for both top-down and bottom-up costing approaches, as well as the financial and economic costs, are calculated.

APPENDIX 9. NON-EXHAUSTIVE LIST OF UNIT COST PER PATIENT PER OUTPUT, TOP-DOWN AND BOTTOM-UP GENERATED BY THE DATA ENTRY TOOL

ALT also known as SGPT

Aspirates (EPTB)

AST also known as SGOT

Body fluid analysis PCR-DNA (children)

Bronchial lavage (children)

CD4 count

Creatinine

Creatinine clearance

Culture (liquid media) [e.g.: MB/Bact Alert, Bactec MGIT 960]

Culture (solid medium) [e.g.: Lowenstein-Jensen, Ogawa or Stonebrink]

Digital x-ray

DST – FLD (liquid media) (isoniazid, rifampicin, ethambutol, streptomycin)

DST – FLD (solid media) (isoniazid, rifampicin, ethambutol, streptomycin)

DST – SLD (liquid media) (fluoroquinolone injectables)

DST – SLD (solid media) (fluoroquinolone injectables)

ECG

Erythrocyte sedimentation rate

Fine needle biopsy (children)

Full haemogram (red blood cell, white blood cell and platelet tests)

Gastric lavage (children)

Glucose (RBS)

HIV confirmatory test

HIV rapid test

IGRA

Lactic acid

LAMP

LF- LAM (rapid antibody or antigen detection tests for TB)

Lipase

LPA – FLD

LPA – SLD

Microscopy (ZN)

Sputum induction

Thyroid stimulating hormone

Total white blood cell count

TST or PPD or Mantoux test

X-ray (film)

Xpert® MTB/RIF

Community diagnostic visit

Community event

Community other visit

Community screening visit

Community treatment visit

Community vaccinations (BCG vaccination)

Inpatient bed-day

Lost to follow-up tracing (using phone calls)

Outpatient cough triage

Outpatient diagnostic visit

Outpatient screening visit

Outpatient vaccinations (BCG vaccination)

Outpatient visit

Patient support during diagnosis

Patient support during treatment

APPENDIX 10. TERMS OF REFERENCE FOR THE STUDY TEAM

The below terms of reference are an example taken from the Value TB Study.

DATA COLLECTION TEAM DUTIES AND QUALIFICATIONS

It is anticipated that cost data will be collected from between 15–25 providers of TB services and interventions nationally (both health facilities and laboratories). The data collection process involves visits to each site lasting between 1–3 days depending on the size and type of provider. The data collection instrument will examine financial and TB service records. In addition, all rooms and equipment used for TB will be listed. Finally, staff will be interviewed about their time spent on different activities. In some cases, activities will be observed. In addition, data collectors will need to collect data on local prices of salaries, supplies and equipment costs. The data collection process will be piloted in a small number of sites in the first instance (in approximately 2 sites). This will be followed by a detailed costing in approximately 5 sites. All data will be entered electronically into mobile phones or tablets.

The study team will comprise of the VALUE-TB principal investigator (PI) and local PI (hereafter referred to as 'VALUE-TB PI' and 'PI' respectively) who will jointly lead the study. Due to the large scale of the study, it is envisaged that at least 2 research assistants will be required over a period of one year, with a local consultant or member of the National TB Programme (NTP) in a supervisory role (PI). It is expected that these 2 research assistants would each collect data from approximately 15–25 facilities over a period of one year (working full time for 40 hours a week, with approximately 1 week per facility).

Roles/responsibilities of the NTP

a. Work with the VALUE-TB team to identify local consultants. Specifically, the NTP should identify an appropriate local PI and a data collection/analysis team.

ba. Work with the VALUE-TB team to design the study protocol so that it meets local needs.

c. Host workshops to train data collectors, provide logistical support, and facilitate access to providers to enable data collection activities including retrieving salary and expenditure data.

d. Support the process of local ethics submission and provide local oversight for the study.

e. Attend and contribute to a data analysis workshop in Geneva.

f. Facilitate dissemination of key findings and aid translation of research into policy.

g. Contribute and where relevant lead the write up of results.

Country Principal Investigator (PI) (approximately half time position, 0.5 FTE over 1 year)

Each national VALUE TB provider cost collection should have a designated principal investigator (PI). More than one PI can also be nominated. The PI(s) should be a senior

person from the Ministry of Health and/or the contracted external organization who has both TB experience and experience in overseeing and managing research or health facility-based data collection. The PI assumes overall responsible for all data collection activities and is a nominated person on the protocol and in any ethics committee applications.

If no data collection manager is assigned then the day-to-day management of the cost collection is the responsibility of the PI. This entails managing the implementation of the cost collection. If possible, this person should be actively involved in the design of the study. The PI supervises the work of research assistants who collect the data. For this to happen, there needs to be close collaboration between the PI and the research assistants in the field via either direct supervision or regular reports from the staff or online cost collection tool that allow for quality control.

If no data manager is assigned then the PI is responsible for flagging quality data issues periodically and managing the data collected by research assistants. This person should have some expertise in data management for cost collection or public health research and prior experience in managing data would be highly beneficial. The majority of countries will collect data in an online tool. If this is the case, the PI should be familiar with the online data collection system and should be able to troubleshoot and rectify any data collection problems.

Roles and responsibilities

- Oversees the development of the research protocol and ethical clearance
- Acts as a liaison person for communication with partners and stakeholders outside the data collection team, with staff from the NTP, the public health service, local research institutions and other government departments. Manages funding for the data collection and funding reports, ensuring that funds are managed according to national procedures
- Assembles the data collection team that has all the expertise needed to design, implement, and analyse the TB provider cost data
- Liaises with the research assistants on a frequent basis and oversees their work
- Maintains and ensures the quality of the study's conduct and writes the final study report and ensures that it is disseminated to the key stakeholders identified during the stakeholder analysis
- *Convenes jointly with NTP the dissemination of results with stakeholders (health and non-health)*
- Establishes contact with facilities sampled for the study and facilitates the welcoming of the research assistant and the key information providers within each facility.
- Oversees the day-to-day management of the data collection
- Assists in the design of the data collection together with the VALUE TB PI
- Adapts training manual and cost collection materials
- Prepares standard operating procedures
- Trains research assistants before data collection and provides retraining if mid-term review identifies such a need

- Supervises the work of data collection research assistants through on-site visits or through periodic reports
- Monitors the operational implementation of the data collection
- Flags data quality issues periodically (i.e. every two weeks) to VALUE TB PI and completes regular data management reports
- Adapts the electronic data collection instrument (with validation by VALUE TB PI) in an effective and feasible manner to support the cost collection
- Coordinates data management activities for the cost collection: receiving, batching, cleaning, and merging data from different sources (e.g. NTP regarding prices vs data collection for diagnostic tools)
- Is responsible for the validation of double-entered data files
- Ensures that data are properly stored and backed up
- Checks validated data files regularly (weekly if electronic) for systematic errors (cleaning)
- Prepares database to be ready for analysis and data entry screens
- Contributes to the analysis of results

Key tasks

- Adapts and develops the protocol as per methodology developed by VALUE TB team and with input from the VALUE TB PI, NTP and National Technical Advisory Group (as needed)
- Drafts letter with the NTP manager (and WHO) addressed to facilities involved in the study to communicate the purpose of the study and request facility managers to share the information requested by the research assistant (which may be listed in the letter)
- Ensures that cost data collection and analysis are conducted according to the protocol and the plan
- Discusses any problems encountered during the data collection, and then proposes and decides on feasible solutions, in collaboration with the data collection team and the technical advisory group (if needed)
- Endorses the TB provider cost results
- Translates study results into policy recommendations
- Engages with NTP for results dissemination
- Coordinates overall implementation of cost collection in the field
- Plans the field implementation and required training, including preparation of training materials as appropriate
- Contacts and coordinates with local authorities
- Ensures quality assurance processes are implemented according to the protocol
- Supervises implementation in the health facilities and laboratories
- Plans and co-ordinates data collection monitoring visits comprising all partners involved in data collection implementation

- Oversees the provision of supplies and required materials
- Involved in the analysis of the results
- Organizes the writing of activity reports and the final report
- Plans the detailed budget of the cost collection and periodically reports to funders on funds utilization (as per contract)
- Provide any logistic support for the cost collection team
- Arrange pilot-testing and its evaluation
- Liaise with local officials in the health care facilities and laboratories (during pre-cost collection visits and actual field work)
- Report without delay any major problems in preparation, execution or data management of the cost collection

Qualifications

- Preferably at least 5 years of managerial experience in the field of public health preferably with costing or health economics experience
- Strong managerial skills, including being able to delegate tasks
- Extensive knowledge of TB management including the context in which the data is being collected
- Knowledge of laboratory and facility-based costing
- Working within or having access to an organization that has an infrastructure that can support
- Facility-based costing in the field

Research assistants (2 FTE over 1 year may cover 15–25 facilities each)

The research assistants will be based at the health facilities and laboratories for a period of one week per facility and will conduct the data collection mostly regarding quantities of resources used in TB prevention, diagnosis and care. They will need to be employed for the cost collection and cleaning periods and may or may not need to be full time depending. The research assistants should have good social and communication skills and should be thoroughly trained in costing techniques and the Data Collection Tools. The research assistants should also have the ability to manage technology if the online Data Collection Tool is used.

Roles and responsibilities

- Carries out interviews with TB providers with due respect for privacy and confidentiality
- Analyses client registers, financial records, pharmacy/laboratory records, and other TB-related documentation and extracts required information from them
- Enters, manages, and keeps economic data collected from the field
- Participates in data cleaning and analysis with support from the PI
- Communicates promptly with study coordinator on any bottlenecks arising (technical or managerial)

Qualifications

- Prior experiences in cost collection desirable
- Demonstrated good computer skills in Microsoft Excel and Word packages
- Good knowledge of the Kenyan health system
- Fluent in the local language spoken in the cluster or health facility
- Good administration and organizational skills
- Well-developed social and communication skills, particularly with regards to staff
- Prior experience in undertaking field work for public health research or facility based costing

Technical advisory group

The technical advisory group advises the PI on all technical aspects of the cost collection and also on issues such as the cost collection approval and acceptance process. It provides technical input (statistical, epidemiological and health economics) into all activities for which the PI is responsible and consists of experts in these fields. Collaboration with the technical advisory group is substantial during the design and adaptation of the protocol, but ad-hoc during actual data collection. Members of the technical advisory group perform these activities on a part-time basis. Their workload will be different in different phases of the survey, ranging from ad hoc meetings during the implementation to more intensive involvement during the design or the analysis phase. The technical advisory group may include international experts. The suggested composition of the national technical advisory group and terms of reference are provided below.

In the initial stages, for the purpose of the generic TB provider cost collection instrument and guidelines and to ensure consistency across cost collection conducted in different countries with a common methodology, there will also be an international technical advisory group which will be coordinated by the VALUE TB Team. Involvement of the international advisory group will also be more substantial when supporting the translation of results into policy recommendation and the dissemination of results. Data will become part of the GHCC data repository after dissemination. This is an open access database which can be freely accessed. The purpose of this sharing is to enable cost to be generalized to other settings where unit costs are not yet available.

Composition of national technical advisory group

- Social scientist/epidemiologist/survey expert
- Health economist/analyst
- Statistician or data analyst
- International development agencies
- Private sector
- Civil society
- Health insurance
- WHO Country Office

Terms of reference for the national tuberculosis advisory group

- Advise on the cost collection
- Advise on the design, pre-testing and production of costing materials (e-survey instrument design, SOP revision, etc.)
- Provide technical assistance during training and pilot-testing
- Provide ad-hoc advice to data collection co-ordinator during cost collection implementation based on preliminary data analysis, monitoring missions
- Support local data manager and PI in analysis of results
- Provide feedback on interpretation of results, results dissemination strategy, and policy implications and follow-up

OTHER POTENTIAL TEAM MEMBERS

Data collection co-ordinator

The day-to-day management of the cost collection is the responsibility of the data collection co-ordinator who may be a Ministry of Health staff member or someone from an external organization. The data collection co-ordinator should report to the PI. The main work of the data collection co-ordinator is managing the implementation of the cost collection. If possible, this person should be actively involved in the design of the study.

The data collection co-ordinator supervises the work of research assistants who collect the data. For this to happen, there needs to be close collaboration between the data collection co-ordinator and the research assistants in the field via either direct supervision or regular reports from the staff or online cost collection tool that allow for quality control. The work of the data collection co-ordinator can be substantial, and the position may need to be half time or more.

Roles and responsibilities

- Establishes contact with facilities sampled for the study and facilitates the welcoming of the research assistant and the key information providers within each facility.
- Oversees the day-to-day management of the data collection
- Assists in the design of the data collection
- Adapts training manual and cost collection materials
- Prepares standard operating procedures
- Trains research assistants before data collection and provides retraining if mid-term review identifies such a need
- Supervises the work of data collection research assistants through on-site visits or through periodic reports
- Monitors the operational implementation of the survey

Key tasks

- Coordinates overall implementation of cost collection in the field
- Plans the field implementation and required training, including preparation of training materials as appropriate
- Together with the PI, contacts and coordinates with local authorities
- Ensures quality assurance processes are implemented according to the protocol
- Supervises implementation in the health facilities and laboratories
- Plans and co-ordinates data collection monitoring visits comprising all partners involved in data collection implementation
- Oversees the provision of supplies and required materials
- Involved in the analysis of the results
- Organizes the writing of activity reports and the final report
- Plans the detailed budget of the cost collection and periodically reports to funders on funds utilization (as per contract)
- Provide any logistic support for the cost collection team
- Arrange pilot-testing and its evaluation
- Liaise with the PI on a regular basis, and provide the PI with updates
- Liaise with local officials in the health care facilities and laboratories (during pre-cost collection visits and actual field work)
- Report without delay any major problems in preparation, execution or data management of the cost collection

Qualifications

- Preferably at least 3 years of research experience in the field of public health
- Strong managerial and coordination skills
- Knowledge of public health research and health economics
- Knowledge of TB
- Expertise in field work
- Experience in planning and conducting cost data collection or health facility data collection

Data manager

The data manager is responsible for flagging quality data issues periodically to data collection co-ordinator and managing the data collected by research assistants. This person should have some expertise in data management for cost collection or public health research and prior experience in managing data would be highly beneficial. The majority of countries will collect data in an online tool. If this is the case, the data manager should be familiar with the online data collection system and should be able to troubleshoot and rectify any data collection problems. Depending on the composition of the data collection team, the data manager will usually report to the PI or the data collection co-ordinator.

Roles and responsibilities

- Flags data quality issues periodically (i.e. daily/bi-weekly) to PI and completes regular data management reports
- Adapts the electronic data collection instrument (with supervision from PI and validation by VALUE TB PI) in an effective and feasible manner to support the cost collection
- Coordinates data management activities for the cost collection: receiving, batching, cleaning, and merging data from different sources (e.g. NTP regarding prices vs data collection for diagnostic tools)
- Is responsible for the validation of double-entered data files
- Ensures that data are properly stored and backed up
- Checks validated data files regularly for systematic errors (cleaning)
- Prepares database to be ready for analysis and data entry screens
- Contributes to the analysis of results (led by PI)
- Liaises with the data collection co-ordinator on a regular basis
- Reports without delay any problems encountered in data management

Qualifications

- Proven experience in leading and motivating teams
- Proven extensive experience with health facility based costing or public health research
- Experience in analysing data to provide summary statistics
- Experience in troubleshooting data collection problems including the identification of systematic entry and ad hoc errors
- Good administrative skills including maintenance of adequate documentation for costing or public health research

APPENDIX 11. THREE CASE STUDIES

CASE STUDY 1: DESCRIPTION OF WORK FLOW WITHIN A KENYAN CLINIC

Here is an example of a peri-urban clinic that was visited for a morning to understand the workflow and flow of patients.

This clinic is situated in the outskirts of Nairobi on a dirt road (with potholes and stones) with market stalls on either side of the road. There are gates to the clinic that stand open and are opened further by unarmed security for cars. The area is described by the clinic staff as a township and 'shanty' (area of informal housing).

The main clinic is a brick and concrete structure with grass outside and a covered outdoor waiting area. The small laboratory is housed in a shipping container with wide windows and no running water. Lights are on in the corridor. Posters are stuck on the walls with health messages, a staff list, diagnostic algorithms etc.

Patients wait in a separate area outside under a shelter (roof that protects them from the sun and rain). The TB clinic is situated in the main clinic building in room that is accessed from a separate door. The HIV services are provided in a room diagonally across from the TB room and one can see inside when the doors are open. The patients hand the staff their yellow TB patient cards through the open windows (through burglar bars). Staff speak to the patient (in Kiswahili) through the open window. The TB nurse (deputy in charge (the in-charge sister was absent from the clinic this particular morning)) checks the TB register and patient card. The patient enters the facility and is weighed in the passageway by a staff member. The patient sits on a chair a metre away from the TB nurse. Two counsellors are also involved in TB services (however were not present on the initial visit to this facility). A separate patient costing study (led by WHO) is underway at the facility and a data collector was present in the TB clinic room.

Patients are given their anti-tuberculosis medication weekly from pre-packed boxes which have a unique identifier (patient initiation date) written on the side of the box. Boxes are stored on a shelf in the consultation room. The pre-packaging is done a central public dispensary. Treatment is observed (daily) at home by a treatment support partner or by a community health care worker. Nutrition packages (maize flour and peanut butter) are given if a patient's body mass index (BMI) is below a threshold of 18. Masks are used when initiating a patient (although this was not observed as no new patients were seen).

A small laboratory is situated outside with two laboratory technicians (only one was present). Microscopy specimens are decontaminated, the slides are prepared and are then read under an electron microscope (two are available). There is a decontamination hood (biosafety cabinet) in the corner with an extraction fan. This was not working but was due to be repaired shortly.

If the TB nurse requests an Xpert® MTB/RIF or culture (DST, LPA etc.) then specimens are sent to a nearby facility or reference laboratory respectively. MDR-TB services are offered at the clinic however there are very few cases (the TB nurse had attended one patient in the recent past). This patient was asked to come to the clinic in the afternoon when fewer patients were present and the sister made home visits if the patient was too sick to attend the clinic (going on foot) to limit exposure. Children are treated for TB in the facility. In the surrounding area, 20 community health care workers are assigned to make home visits to patients (with external funding).

CASE STUDY 2: DATA COLLECTION IN A HOSPITAL LABORATORY IN ROMANIA

To obtain the quantities, specifications and some costs for consumables, chemical, reagents and equipment used to analyse sputum smear (Ziehl Neelsen (ZN)) and culture Lowenstein-Jensen (LJ) samples for TB, a detailed interview was conducted with the senior microbiologist who performed the tests.

The quantities were provided by the microbiologist during the interview and confirmed by observation of the analysis processes. The ZN and LJ samples were prepared for analysis in batches of 10, so observation of the analysis process occurred by returning to the laboratory two days later when there were sufficient samples.

Test-specific capital costs, primarily the equipment used in analysing the ZN and LJ tests, were determined by annualising the value of the equipment. This included the purchase price when obtained or the current market value, which was divided by the life expectancy of the equipment (at a 3% discount rate). The annual cost of maintenance was added to this value. The mean capital cost per test utilizing each piece of equipment was calculated by dividing the total annualized cost of each piece of equipment by the annual number of tests performed.

To obtain recurrent (utilities, insurance, linens and soft inventory, sterilization, cleaning, security and general office supplies) and capital (value of buildings and land, furniture, computers, general non-medical equipment and vehicles) overhead costs an interview was conducted with the financial director of the hospital during the following week. For salary and benefits information, the HR manager was called into the interview by the financial director and provided this personnel information, which was already available from an annual HR report. Additional overhead costs that were not readily available in pre-existing reports or in electronic files were later obtained by sending spreadsheets with the information required, for completion by the financial director.

The mean overhead costs per ZN and LJ tests were calculated by multiplying these annual overhead costs by the proportion of the square footage of the respective laboratories spaces which were on two different floors of the hospital wing. This was then divided by the total annual number of sputum samples analysed by ZN and LJ tests for each respective laboratory space. While the square footage of the hospital wing with the laboratories was provided by surveyor reports from the financial director, the space where the respective tests were performed was measured using a tape measure. The annual number of tests performed in each laboratory was obtained from the senior microbiologist.

CASE STUDY 3: PERSONNEL TIME IN INDONESIA

The staff costs associated with IGRA tests in Indonesia were calculated by conducting interviews with the resident doctors who drew blood from patients in the clinic and time-motion studies to observe the laboratory technicians performing the analysis in an immunology laboratory.

The resident doctors were interviewed about the patient flow in the clinic. They were asked to estimate the time taken for the full patient consultation as well as the IGRA specific activities (talking to patient about the test and taking the blood) for a single patient. Data on the total time worked per month, the volume of patients seen at the

clinic and the number of patients receiving an IGRA test was obtained from the doctor in charge of the clinic.

For the immunology laboratory, the laboratory doctor was contacted and briefed on the objectives and methodology of the study which sought to determine the unit costs of screening and diagnostic tests for TB at a teaching hospital in West Java, Indonesia. Through the laboratory doctor, an appointment was made to meet with the two laboratory technicians who performed analysis of the blood samples. During this meeting, the technicians were also briefed on the objectives and costing methodology of the study. They explained the work flow of the analysis and the equipment used as well as some of the challenges of IGRA tests, particularly with maintaining the quality of the blood sample when collecting the blood from patients, during transportation and in the laboratory. They were then asked to participate in a time-motion study to capture the time taken for each task as well as details of the consumables, chemicals and reagents used. Since the IGRA test was new to the facility (implemented within the last year) the volume of samples was inconsistent and insufficient for daily analysis. Therefore, the analysis was done in batches, usually at the end of the week, and the time-motion study was scheduled for the following Friday.

On the day of the time-motion study the technicians were asked to review a diagram of the sample workflow and a list of the IGRA relevant equipment, consumables, chemicals and reagents that had been created after the initial meeting. Edits were made to the workflow and lists as needed. Each task was numbered sequentially. For the time-motion study data collection, the observer sat in a corner of the laboratory that provided a clear view of the processes involved in the analysis of the samples. As the technicians performed each task, the digital stopwatch on the observer's phone was used to capture the time of each task by taking the lap time and notes were made about the activities in each task as well as the equipment and consumables used. The entire process for analysis was timed and annotated without interacting with the technicians. Waiting time and recording of results were also included in the time-motion study. After the study, the technician was again asked to review the workflow as well as fill in any gaps with respect to the process or equipment, consumables, chemicals or reagents.

The time-motion study was repeated the following Friday, but with a more junior technician. An average of the time taken to perform analysis on an IGRA test was used for the unit costs calculation.

Note 1: Before approaching any of the clinicians or laboratory staff the approval letters from the ethics review committee and permission letters were forwarded to the persons in charge of the clinic and laboratory.

Note 2: The time taken for administration of the samples (when samples were delivered to the laboratory, and storage and disposal after analysis) was obtained by interviewing the laboratory doctor and technicians. It was not possible to include this in the time-motion study as these processes did not happen at the same time as the analysis.

APPENDIX 12. INFORMED CONSENT TEMPLATES

Information Sheet

NAME OF INSTITUTION

Study Title: Costing the delivery of tuberculosis services in country name from a health systems' perspective

Lay Title: Examining how much it costs to deliver tuberculosis services in country name

Lead institutions	Investigator
Other Institutions	

Who is carrying out this study and what is this study about?

This study is being carried out by name of lead institution with the Ministry of Health's National Tuberculosis Programme, in collaboration with collaborator name (Principal Investigator).

(Briefly describe lead institution).

Our researchers are visiting health facilities providing services for Tuberculosis (TB), to estimate the costs of providing these services. The aim of this research is to provide a comprehensive set of unit costs for TB services in country name. This cross-sectional survey involves (insert number of facilities) healthcare facilities in country name sampled from private (for-profit and non-profit) and public facilities of different service levels. Your facility is one of those selected through a two-stage stratified cluster sampling process. The study will involve interviews with key staff members (between three and five individuals) in your facility, document reviews, observations and timesheets filled in by some of these staff members.

Why do you want to talk to the staff and what does it involve?

This study would involve key members of clinical staff. We would like to ask a number of questions about the running costs of providing TB services, the activities that the staff are involved in with regards to TB care, and how much time is taken up by each activity.

If you agree to participate in this research, *trained research assistants will perform* the following:

- We will ask some questions about the clinical staff's knowledge and experiences with managing patients with TB, the training and supervision that they have received, and the challenges that they encountered while managing TB.
- In order to value the type and quantities of inputs used in the staff's daily clinical duties, we will review your facility's project reports, financial and expenditure records, with the consent of the facility in-charge.

- We would also like to observe the staff as they carry out their daily clinical duties, in order to understand how much time in general it takes to conduct these activities. The observations will involve being present at the facility and observing and making notes about the conduct of various TB services provided. We will not be present during patient consultations but will record the length of time of the consultation by observing from a common area adjacent to the consultation area.
- We would also like the staff to complete a timesheet that covers their activities during their working hours over the period of one week in order to have information on time spent on various activities.

Are there any risks or disadvantages to participation?

There is no major risk in participating in this study. The interview will take about 60 minutes, while the observations will be conducted over a working day. We will not record the interview or the observations, but we will take detailed notes. All responses and observations will be treated confidentially.

The study participants may be uncertain whether they have the correct answers to some of the questions and this may make them feel uncomfortable. The participants are free to refuse to answer any questions.

Are there any advantages to participation?

There are no individual benefits to taking part. In talking to us however, the study participants will directly help the National Tuberculosis Programme improve its services, and will help to plan its spending over the medium term. The overall data collected may also help National TB Programmes in other countries estimate the costs of their TB services, and plan better for their resources.

Who will have access to the information obtained?

All of our documents are stored securely in locked cabinets and on password protected computers. The interview will not bear any names; this way the responses will be anonymous. Information on the workload and typical resources used in the process of providing TB services will be aggregated into a total estimate of the unit cost per TB episode.

The knowledge gained from this research will be shared in summary form, without revealing individuals' identities, with all participating facilities, the NTP and collaborating institutions, and the wider scientific community, for instance through policy briefs and scientific publications.

In order to carry out this study, we will also share anonymized individual information we collect or generate with the Global Health Cost Consortium (GHCC) in ways that do not reveal individual participants' identities. The cost data from this project will be incorporated in the web-based GHCC platform to improve extrapolations of cost across settings undertaken by the GHCC.

Who has allowed this research to take place?

All research has to be approved before it begins by several institutional, national and international committees who look carefully at planned work. They must agree that the research is important, relevant to country name and follows nationally and

internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What will happen if I refuse to participate?

All participation in research is voluntary. The staff are free to decide if they want to take part or not. If they do agree to participate, they can change their mind at any time without any consequences and without the need to give a reason.

What if I have any questions?

You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Name, address, and contact information of lead at the research institute xxx, Telephone: +xxx, Email: xxx@yyy.com

If you want to ask someone independent anything about this research, please contact:

Name, address, and contact information of the ethics lead at the research institute xxx, Telephone: +xxx, Email: xxx@yyy.com

Informed Consent Forms

NAME OF INSTITUTION

Study Title: Costing the delivery of tuberculosis services in country name from a health systems' perspective

Lay Title: Examining how much it costs to deliver tuberculosis services in country name

Lead institutions	Investigator
Other Institutions	

Who is carrying out this study and what is this study about?

This study is being carried out by name of lead institution with the Ministry of Health's National Tuberculosis Programme, in collaboration with collaborator name (Principal Investigator).

(Briefly describe lead institution).

Our researchers are visiting health facilities providing services for Tuberculosis (TB), to estimate the costs of providing these services. The aim of this research is to provide a comprehensive set of unit costs for TB services in country name. This cross-sectional survey involves (insert number of facilities) healthcare facilities in country name sampled from private (for-profit and non-profit) and public facilities of different service levels. Your facility is one of those selected through a two-stage stratified cluster sampling process. The study will involve interviews with key staff members (between 3 and 5 individuals) in your facility, document reviews, observations and timesheets filled in by some of these staff members.

Why do you want to talk to me and what does it involve?

As a key member of staff, we would like to ask you a number of questions about the running costs of providing TB services, the activities that are you are involved in, and how much of your time is taken up by each activity.

If you agree to participate in this research, *trained research assistants will perform* the following:

- We will ask some questions about your knowledge and experiences with managing patients with TB, the training and supervision that you have received, and the challenges that you encountered while managing TB.
- In order to value the type and quantities of inputs used in your daily clinical duties, we will review your facility's project reports, financial and expenditure records, with your consent.
- We would also like to observe you as you carry out your daily clinical duties, in order to understand how much time in general it takes you to conduct these activities. *The observations will involve being present at the facility and observing and making notes about the conduct of various TB services provided. We will not be present during*

patient consultations but record the length of time of the consultation by observing from a common area adjacent to the consultation area.

- We would also like to ask you to complete a timesheet that covers your activities during your working hours over the period of one week.

Are there any risks or disadvantages to me of taking part?

There are no major risks in participating in the study. The interview will take about 60 minutes, while the observations will be conducted over a working day. We will not record the interview or the observations, but we will take detailed notes. All responses and observations will be treated confidentially.

You may be uncertain whether you have the correct answers to some of the questions to be asked and this may make you feel uncomfortable. You are free to refuse to answer any questions. However, in order to have good results from the study, it is important that you try to answer all questions correctly.

Are there any advantages to me of taking part?

There are no individual benefits to taking part. In talking to us however, you will directly help the National Tuberculosis Programme improve its services, and will help to plan its spending over the medium term. The overall data collected may also help National TB Programmes in other countries estimate the costs of their TB services, and plan better for their resources.

Who will have access to the information I give?

All of our documents are stored securely in locked cabinets and on password protected computers. Your questionnaire will not bear your names; this way your responses will be anonymous. Information on your workload and typical resources used in the process of providing TB services will be aggregated into a total estimate of the unit cost per TB episode.

The knowledge gained from this research will be shared in summary form, without revealing individuals' identities, with all participating facilities, the NTP and collaborating institutions, and the wider scientific community, for instance through policy briefs and scientific publications.

In order to carry out this study, we will also share anonymized individual information we collect or generate with the Global Health Cost Consortium (GHCC) in ways that do not reveal individual participants' identities. The cost data from this project will be incorporated in the web-based GHCC platform to improve extrapolations of cost across settings undertaken by the GHCC.

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What will happen if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree to participate, you can change your mind at any time without any consequences and without the need to give a reason.

What if I have any questions?

You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Name, address, and contact information of lead at the research institute xxx, Telephone: +xxx, Email: xxx@yyy.com

If you want to ask someone independent anything about this research, please contact:

Name, address, and contact information of the ethics lead at the research institute xxx, Telephone: +xxx, Email: xxx@yyy.com

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CONSENT FORM

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. *Please write your initials next to each of the following three statements to provide consent*.

_____ Yes, I agree for the interview/discussion to be conducted

_____ Yes, I agree to take part in the observational research

_____ Yes, I agree to fill in a working timesheet over one week

I understand that I can change my mind at any stage and it will not affect me in any way.

Signature: Date:

Participant/guardian name: Time:

(please print name)

[Following section is recommended where verbal consent is obtained, and must be signed by person undertaking informed consent.]

I have followed the study's standard operating procedure to obtain consent from the participant. S/he appeared to understand the nature and purpose of the study and consents to participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: Date:

Designee/investigator's name: Time:

(please print name

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