

PrEP COSTING GUIDELINES

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LIST OF ACRONYMS

3TC	Lamivudine
AGYW	Adolescent Girls and Young Women
AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Aminotransferase
ART	Antiretroviral Therapy
ARV	Antiretroviral
AST	Aspartate Aminotransferase
CDC	Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CI	Confidence Interval
DIC	Drop-In Center
ELISA	Enzyme-Linked Immunosorbent Assay
FTC	Emtricitabine (Brand Name Emtriva)
FSW	Female Sex Worker
GDP	Gross Domestic Product
GBV	Gender-Based Violence
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GHCC	Global Health Cost Consortium
GOT	Glutamic-Oxaloacetic Transaminase
GPT	Glutamate-Pyruvate Transaminase
HBV	Hepatitis B Virus
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C
HIV	Human Immunodeficiency Virus
HMIS	Health Monitoring and Information Systems
HTC	HIV Testing and Counseling
iDSI	International Decision Support Initiative
IEC	Information, Education, and Communication
ICER	Incremental Cost-Effectiveness Ratio
ITPrEP	WHO Implementation Tool for Pre-Exposure Prophylaxis of HIV Infection
LCD	Liquid Crystal Display
LSHTM	London School of Hygiene & Tropical Medicine
M&E	Monitoring and Evaluation

MEMS	Medication Event Monitoring System
MOF	Ministry of Finance
MOH	Ministry of Health
MSH	Management Sciences for Health
MSM	Men Who Have Sex with Men
OPTIONS	Optimizing Prevention Technology Introduction on Schedule (Consortium)
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PPP	Purchasing Power Parity
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
RC	Reference Case for Estimating the Costs of Global Health Services and Interventions
RSTT	Rapid Syphilis Test Toolkit
SMS	Short Message Service
STI	Sexually Transmitted Infection
TB	Tuberculosis
TDF	Tenofovir Disoproxil Fumarate (Brand Name Viread)
TDF/FTC	Tenofovir Disoproxil Fumarate/Emtricitabine (Brand Name Truvada)
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	U.S. Agency for International Development
WHO	World Health Organization
WHO-CHOICE	World Health Organization-Choosing Interventions that Are Cost-Effective

SECTION A: INTRODUCTION

GUIDELINES BACKGROUND

These guidelines provide a framework for estimating the cost of providing pre-exposure prophylaxis (PrEP), which is the use of antiretroviral (ARV) drugs for preventing the acquisition of HIV infection. These guidelines have been prepared by the Optimizing Prevention Technology Introduction on Schedule (OPTIONS) Consortium—an initiative to accelerate and sustain access to ARV-based HIV prevention products in Africa (with a particular focus on women)—and funded by the U.S. Agency for International Development (USAID) in partnership with the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR). The OPTIONS Consortium sought to produce a PrEP-specific resource for costing that could be accessible to individuals tasked with collecting, evaluating, and utilizing cost data, and who may have differing levels of familiarity with economics.¹ These PrEP Costing Guidelines are intended to build on a *Reference Case for Estimating the Costs of Global Health Services and Interventions* (RC), which was funded by the Bill & Melinda Gates Foundation and authored by the Global Health Cost Consortium (GHCC) in partnership with the World Health Organization (WHO); the Joint United Nations Programme on HIV/AIDS (UNAIDS); the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM); and PEPFAR.

Aims

The PrEP Costing Guidelines have three principal aims:

- 1. Support the estimation of the full and incremental total cost and unit cost of adding PrEP to existing HIV or other health services.**
- 2. Address some of the challenges faced by costing experts who are specifically assessing the costs of PrEP.**
- 3. Improve the quality, interpretation, and use of PrEP cost estimates through improved consistency and transparency of methods, assumptions, and reporting.**

¹ Additional overall guidance on cost estimation: Rapid Syphilis Test Toolkit (LSHTM 2013, available at <http://idc-dx.org/resources/the-rapid-syphilis-test-toolkit>; Guidelines for Cost and Cost-Effectiveness Analysis of Tuberculosis Control (WHO 2002, available at <http://apps.who.int/iris/handle/10665/67728>); and the Manual for Costing HIV Facilities and Services (Beck/UNAIDS 2011, available at <http://www.unaids.org/en/resources/presscentre/featurestories/2011/may/20110523manualcosting>).

INTRODUCTION TO COSTING

What is PrEP costing?

The term **costing**² is shorthand for the process of data collection and analysis that has a goal of estimating the cost of outputs, namely health services (e.g., tests, counseling visits) or health interventions (e.g., PrEP) that are provided in a specific context and in a specific manner.

What is a “unit cost,” particularly in reference to PrEP?

Estimation of the cost of outputs essentially builds from **inputs**, as illustrated in Figure 1, which provides examples of the components of the production process for PrEP. The **production process** is the process of combining different inputs (e.g., labor, commodities, equipment) to generate service-level outputs of the PrEP intervention (e.g., tests provided, counseling visits provided), which are then combined to generate intervention-level outputs for PrEP (e.g., clients provided with PrEP last year).

Inputs are the granular resources needed to produce some output necessary for improved health. Each input is assigned a **cost**, which is “the value of that input/resource” (GHCC 2017). The **quantity**³ of the input/resource used in production is then estimated. Although price and cost are not synonymous terms, they are often called the **Ps** and **Qs** of costing (orange boxes in Figure 1).

Inputs are multiplied by quantities and are then summed to produce service units (e.g., 1 X packaging material for a PrEP prescription + 30 X individual tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) pills = 1-month drug regimen of PrEP per person).

Service unit costs are then multiplied by the quantities of output units needed per client (e.g., 12-month regimen prescriptions per year), and are summed together to create an **intervention unit cost** (or a *quality-adjusted intervention unit cost*).

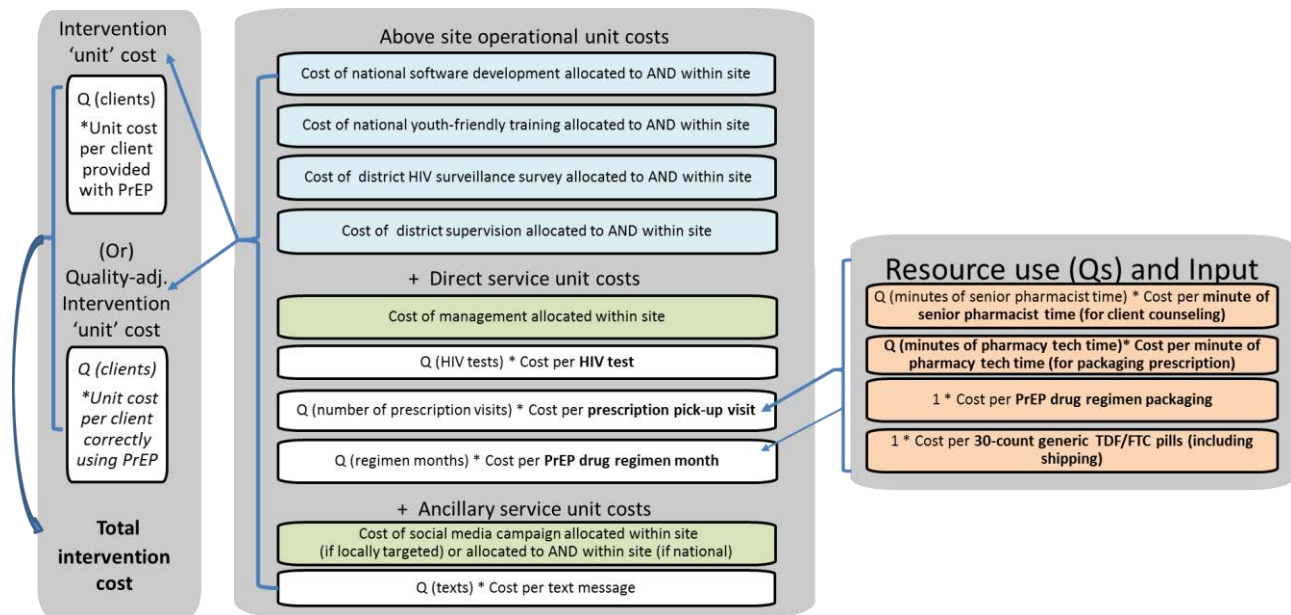
Output units can therefore be seen to be at the level of services (which are aligned with the activities that generate those service outputs), and at the level of interventions. **Unit costs** are representative of the **average** of all cost inputs needed to produce one unit of an activity/service (e.g., the cost of one client visit or test given to a client), or to produce the full intervention over a specified period (e.g., the cost for one client receiving PrEP last year).

The intervention unit cost (or the *quality-adjusted intervention unit cost*) can then be multiplied by the number of clients to create a **total intervention cost**.

Total cost is therefore equal to the summation of all cost inputs needed to produce *all units* of an activity, service, or intervention over a specified period (e.g., the cost to provide PrEP for every client participating in the PrEP program last year).

² Key costing concepts are highlighted in **gold** and can be additionally referenced in the glossary in Appendix 14. Where basic calculations are provided as examples, they are highlighted in **green** text.

³ For the purposes of these guidelines, we will be referring to quantities of inputs in numeric terms (i.e., 1,2,3) rather than “unit” terms. This is because in medical terminology, an input “unit” can have multiple meanings, such as some biological quantity (e.g., a unit of blood) or a unit of medical goods (e.g., a 100-count unit of gloves). Also, we want to keep the focus on output units for discussion of unit costs.

Figure 1: Mapping the construction of PrEP unit costs: the production process from inputs to outputs

Please note that the inputs in the orange boxes are examples, as space does not permit display of all inputs. The blue boxes give examples of above-site operational unit costs, and the green boxes give examples of operational costs at the site level. These operational costs are often calculated in a different way, because they are essentially “pieces” being broken down (i.e., allocated) from a larger shared lump sum cost, rather than being built up from inputs as a unit, like a drug regimen is. For more information, please see Principle 7 on “Measuring and allocating resource use.” Also, although costs such as utilities and capital items at the site level are not activities, their shared costs must also be broken down and apportioned to the site-level services. Again, the above-site operational unit costs, direct service unit costs, and ancillary unit costs shown in Figure 1 are just *examples*. Space does not permit showing, for example, laboratory costs under direct service costs and multiple activities around adherence support under ancillary service unit costs.

What is the Reference Case for Estimating the Costs of Global Health Services (RC)?

“The Reference Case is a guide that helps ensure that the process of cost estimation is clearly conveyed and reflects best practices, so that those using cost data can interpret the findings properly and assess their quality (accuracy, precision, generalizability, and consistency). The Reference Case provides a practical framework for analysts to ensure that they consider how methods may influence estimates and thereby improve the interpretation and use of cost data... The Reference Case structure adopts a ‘comply or justify’ approach, that allows the analyst to adapt to the specific requirements of the costing exercise, but introduces the condition that judgments about methods choices are made explicitly and transparently (GHCC 2017, page A-2).”

The PrEP Costing Guidelines are meant to **complement the RC by providing** a brief summary of the RC principles and method specifications, providing PrEP-relevant details to put the RC method specifications in readily understandable context and allow guideline users to tailor them to PrEP costing, and provide supplemental introductory costing materials (not available in the RC) for those new to

costing. This tool is not intended to go into the same advanced level of detail about costing that exists within the RC.

What is the process for costing, and for deriving total and unit costs, as outlined in the RC?

The RC is organized around a set of 17 **principles** (grouped into the four categories of **study design, resource use measurement, pricing and valuation, and analyzing and presenting results**). The order of the principles is intentional, charting in a step-wise manner the basic process for costing. This process can be summarized as follows:

- Study design
 - **Defining the purpose of the study (Principle 1a)**
 - Understanding how the intervention works and the expected outputs (Principles 1b, 4)
 - Articulating the scope for cost data collection (to inform study design) (Principles 2–5)
- Resource use measurement
 - Determining *which* inputs/services are used to implement the intervention; applying an appropriate method of resource use measurement to determine the *quantities* of each input and each output (e.g., visits per client-year of PrEP) (Principles 6, 7, 9)
 - Delineating how the study will be conducted (e.g., sampling) (Principles 8, 10)
- Pricing and valuation
 - Collecting the prices of inputs/services and adjusting the valuation as appropriate, to attach costs to each input/service (Principles 11–14)
- Analyzing and presenting results
 - Analyzing the data to show how output units and total intervention costs are derived from inputs; identifying cost drivers (Principles 15–16)
 - Reporting on the costing process and results (Principle 17)

*At each step of the process, it is necessary to **TRANSPARENTLY DOCUMENT** and **REPORT** not only the results that emerge but also the associated reasoning, methods, assumptions, sources, and limitations. For this purpose, it is often helpful to set aside specific sections within each record-keeping and analysis tool used in the costing exercise.

ORIENTATION THROUGH THE PREP COSTING GUIDELINES

Why are PrEP Costing Guidelines necessary?

Those advocating for PrEP can readily point to the demonstrated efficacy of PrEP. However, they may be at a loss when trying to respond to the inevitable follow-up question of “How much does it cost?” Understandably, government officials and donors are loath to invest large sums of money (which could be used to address other critical and underfunded areas) into the rollout of an intervention that is a financial black box. While a “back-of-the-envelope” guesstimate drawn from the costs of other interventions (e.g., staff time and salary for counseling on antiretroviral therapy [ART], some demand-generation activities for voluntary medical male circumcision) may suffice for the purpose of funding a pilot project or short-term budget, such an estimate would not be sufficient for a cost-effectiveness analysis (to use for comparison with other interventions) or a costed long-term strategic plan. A difference of even US\$0.10 in the unit cost of an intervention can be very significant when multiplied over millions of people and numerous years. To scale up and sustain PrEP implementation, rigorous and standardized cost data must be generated, and this is predicated on costing guidance that is rigorous, standardized, and cognizant of the cost-relevant aspects of how PrEP is specifically delivered.

For whom are the PrEP Costing Guidelines intended?

Like the RC, the PrEP Costing Guidelines are intended for multiple audiences involved in collecting, evaluating, and utilizing cost data at the international, national, and decentralized levels.



<https://ghcosting.org/pages/standards/introduction/background>
[https://ghcosting.org/pages/standards/introduction/guide through the reference case#one](https://ghcosting.org/pages/standards/introduction/guide%20through%20the%20reference%20case#one)
[https://ghcosting.org/pages/standards/introduction/guide through the reference case#two](https://ghcosting.org/pages/standards/introduction/guide%20through%20the%20reference%20case#two)
[https://ghcosting.org/pages/standards/introduction/guide through the reference case#two](https://ghcosting.org/pages/standards/introduction/guide%20through%20the%20reference%20case#two)

These audiences may include:

1. **Producers of cost data:**
 - Costing experts conducting cost studies or assisting in the preparation of national plans, budgets, and funding applications
 - Practitioners new to conducting cost studies or assisting in the preparation of national plans, budgets, and funding applications
 - Academic institutions
2. **Users of cost data:**
 - Country-level (government) program managers and decision makers (e.g., Ministry of Health [MOH], Ministry of Finance [MOF])
 - Country-based representatives of bilateral and multilateral organizations, including UNAIDS, WHO, PEPFAR, and GFATM
 - Economic analysts who utilize previously collected primary cost data for the cost piece of cost-effectiveness or benefit-cost estimates they are developing
 - Modelers
3. **Funders of cost data:**
 - UNAIDS, WHO, PEPFAR, GFATM, Bill & Melinda Gates Foundation, and bilateral or nongovernmental organizations (NGOs)
4. **Reviewers of cost data:**
 - Journal editors
 - Peer reviewers

- Dissertation committee members

The audiences are expected to have a range of familiarity with economics and costing methods. The PrEP Costing Guidelines aim to reach a point in this range that is slightly more basic than that reached by the RC. Some of the more advanced concepts in the RC may be intimidating for those newer to costing, and it is anticipated that more PrEP-specific and basic costing “how-to” information will be useful in these guidelines. As in the case of what makes for a “good” cost estimate, the manner of communication for the PrEP Costing Guidelines has been determined based on the balance of precision, accuracy, generalizability, and consistency best suited to the purposes for which diverse audiences will be conducting and utilizing cost estimation.

How do different audiences use the costing guidelines?

The PrEP Costing Guidelines are set up so that different audiences may use them in different ways and readily access the sections they want to utilize. Examples of potential use by three different audiences are provided below:

1. Costing expert conducting a cost study, for the purpose of long-term strategic planning:

A costing expert may want to refresh his or her memory of the RC principles and more advanced concepts related to method specifications. Therefore, links to relevant RC sections are posted at the beginning of each section in the PrEP Costing Guidelines. In addition, this user may not be an expert on PrEP so may want to go immediately to the detail sections of each principle to see how to adapt standardized costing methodology to the costing of PrEP interventions specifically. He or she could also go to the PrEP-specific pieces of the annex. For example, Appendix 1 includes links to currently available health-sector and national guidelines that describe how PrEP is to be implemented in a country, Appendix 4 outlines the potential activities in a PrEP program that would need to be costed, and Appendix 13 houses a PrEP-specific facility questionnaire to ascertain the types, quantities, and costs of inputs used by facilities to implement a PrEP intervention.

2. Practitioner new to costing, for the purpose of feeding into an analysis of cost-effectiveness:

A new costing practitioner may first wish to go to the “Introduction to Costing” section and the glossary in Appendix 14. After reading each principle and method specification, this user would then look further into the detail sections of the guidelines to better understand how to apply the principle and methods, and what to watch out for with respect to a given costing purpose that feeds into the evaluation. For example, obtaining costs for donated items/time/space is necessary for constructing accurate estimates of economic cost (see definition in Principle 3 and the glossary) that will be used to analyze cost-effectiveness. Many sections then refer to associated appendices that help newer costing practitioners. Appendix 6, for instance, gives potential sources to use when searching for the cost of specific inputs, and Appendix 10 instructs on how to adjust costs for inflation. Finally, the beginning user may want to look closely at the references for the guidelines, which include information ranging from PrEP efficacy and program implementation to details on costing concepts. Links to open access sources are given for each reference, where available. These references can be used not only for instructional purposes but also as reference material for proposals, plans, or other write-ups the user may be asked to complete for his or her PrEP analysis.

3. Country-level program manager or journal editor reviewing a cost estimate:

This audience member wants to understand if a received cost estimate is a valid one. He or she may want to simply visit the checklist in Principle 17 on transparency, and then review the summary

principles and method specifications if he or she is unfamiliar with what is being described in the checklist.

What is the scope of the PrEP Costing Guidelines?



https://ghcosting.org/pages/standards/introduction/guide_through_the_reference_case#four

There are many types of PrEP modalities⁴ (e.g., vaginal rings, injectables, implants). The principles and method recommendations presented here are meant to be relevant to costing any of them. For consistency's sake, oral PrEP is used as an example throughout the guidelines. However, the guidelines do highlight when it may be necessary to consider tailoring costing methods to another type of PrEP modality.

The scope of the cost data focuses on the costs of providing services, as determined through primary data collection. Although items paid for by clients (e.g., drugs, co-pays) are included within this scope as part of costing from the “provider” perspective (which makes up part of costing from the “health system” perspective, which additionally includes above-site costs),⁵ other aspects of client or household costs that are not directly paid to the provider are not yet included in the methodology. Such “client” perspective costs (which make up part of the “societal” perspective costs, which potentially include provider, above-site, and social and economic impact costs from the local to national levels) can include transportation to and from the point of care, child care, food while in transit or while at the point of care, and productivity losses for the clients for the time taken to access services.

These guidelines **do not describe how to do economic evaluation** through cost-effectiveness, cost-utility, or cost-benefit analyses (also known as benefit-cost analysis). However, these concepts will be introduced so that they can be later discussed in the principles where relevant, such as in defining the purpose of the costing, the denominator of the unit costs, and the sampling frame. As in the RC, the guidelines also do not provide standards and methods for **secondary analyses**, such as investment cases or global price tags, although the guidelines and RC do give a strong foundation for users of cost data to interpret whether the cost estimates they are utilizing are of good quality and fit for the purpose at hand.

⁴ Modalities are also known as “technologies” in the RC.

⁵ Please see Principle 2, “Defining the perspective,” and the glossary in Appendix 14 for definitions of the terms “costing perspective” and “above-site costs.”

PREP BACKGROUND INFORMATION

PrEP is the use of ARV drugs by HIV-negative individuals to prevent the acquisition of HIV infection. PrEP is not meant to substitute for condoms and other prevention measures, but it does offer an additional option in the arsenal of combination prevention that does not depend on shared decision making by both sexual partners. In theory, it can be utilized at the sole discretion of an individual and his or her health provider. For populations that can be at substantial risk of HIV infection, such as adolescent girls and young women (AGYW), in part due to lesser control and experience in negotiating sexual relationships, the option of PrEP may be particularly desired and useful (UNAIDS 2015a, UNAIDS 2015b). To meet the Fast Track target of reducing the number of people acquiring HIV by 75 percent by 2020 (UNAIDS 2015c), UNAIDS has recommended that oral PrEP be included in national planning and be prioritized for populations at substantial risk of acquiring and transmitting HIV. This prioritization may apply to population groups such as high-risk AGYW, men who have sex with men (MSM), people who are transgender, people who inject drugs (PWID), HIV-negative partners in serodiscordant relationships, migrants and refugees, or the general population, depending on the epidemiological context. With respect to those in serodiscordant relationships who wish to become pregnant, PrEP can protect the HIV-negative partner during sex without condoms. It can also prevent vertical transmission for the period between conception and cessation of breastfeeding, should the mother become HIV-positive and not know her status (UNAIDS 2015a, Centers for Disease Control and Prevention [CDC] 2014, WHO 2016).

Efficacy and safety

The effectiveness of oral PrEP has been documented in trials with MSM, heterosexual men, heterosexual women, transgender women, serodiscordant couples, and PWID (Fonner 2016, Spinner 2016, Molina 2015, McCormack 2015, Grant 2010, Anderson 2012, Van Damme 2012, Marazzo 2016, Baeten 2012, Donnell 2014). On the basis of these trials, researchers have estimated that it is possible to achieve 99 percent efficacy in MSM and 94 percent efficacy in women with perfect adherence to daily TDF/FTC (brand name Truvada) (Landovitz and Raphael 2015). However, caution should be taken, as some groups may be more socially vulnerable to poor adherence. **To achieve the promise of effectiveness over 90 percent for all populations at substantial risk of acquiring HIV, concerted attention to the factors underpinning poor adherence will be required.**

Oral PrEP is considered by the WHO and CDC to be safe and well tolerated, as studies have shown that experienced side effects (e.g., nausea, headache, fatigue) were generally mild and resolved within the first month or so after initiation (CDC 2014, WHO 2016, Grant 2010, Grant 2011, Arnold 2017, Baeten 2012, Thigpen 2012, Van Damme 2012, Landovitz 2015). Further, in statistical terms, there was no *significant* difference in the experience of side effects between intervention and placebo arms in most studies (Tetteh 2017). That said, it is important to note that there have been recent “word-of-mouth” reports from PrEP implementation in South Africa and Kenya of poor retention in care attributed to side effects. However, it is unclear if these were actual experiences of side effects or simply fear of anticipated or perceived side effects, as was the case in a recent study of oral PrEP for MSM in the Southern United States (Arnold 2017). Few healthy people are inclined to take a drug that could potentially make them even the slightest bit ill. Therefore, it may be important to remediate not only any experienced side effects attributed to the drugs, but also any related fear and anticipatory stress.

The WHO recommends testing for HIV, kidney function, hepatitis B virus (HBV), hepatitis C virus (HCV) (in certain populations), pregnancy, sexually transmitted infections (STIs), and signs of cirrhosis or substantial transaminase elevation (in certain populations) prior to initiation, and periodically during

continuation, on oral PrEP (WHO 2017a, Solomon 2016) (Appendix 4). These tests may differ by PrEP modality. Infection with hepatitis B is not listed as a contraindication for PrEP (WHO 2017a). Oral PrEP is considered safe during pregnancy and breastfeeding (CDC 2014, Heffron 2016), and fertility was not affected in HIV-negative men taking TDF/FTC in clinical trials (Were 2014). There has not been extensive research concerning risk compensation for people taking PrEP, although the majority of existing studies have shown no evidence of reduction in safe-sex behavior (Guest 2008, Marcus 2013, Calabrese 2017). The risk of ARV drug resistance in people who seroconvert while on oral PrEP continues to be studied.

Status of PrEP trials and program implementation

PrEP trials are currently being tracked by AVAC at <https://www.avac.org/pxrd>. For the current status of Truvada approval by national pharmaceutical regulatory boards for treatment and prevention, see <https://www.prepwatch.org/>. For those countries that do not have regulatory approval for Truvada for prevention, the PEPFAR recommendations on the use of PrEP for all populations suggest that countries could request 1) an expedited review on the grounds of public health (where registration is ongoing) or 2) establishment of local MOH memoranda of understanding for the off-label use of Truvada for prevention (where the registration process is not yet started) (PEPFAR 2015). Gilead (the maker of Truvada) has worked to grant voluntary licenses to partners in countries such as India and South Africa for the production of generic Truvada, pursuant to agreement that those holding voluntary licenses are obligated to buy the chemicals used in the production of Truvada from Gilead. Further reductions in price, to below the price of the generic drug in low- and middle-income countries, have therefore been restricted, although the Clinton Health Access Initiative (CHAI) has been working with manufacturers of the generic drug to further reduce costs through a streamlined manufacturing process.

Oral PrEP is being supported by the public sector in several countries, but it is mostly funded by donors such as PEPFAR, the Bill & Melinda Gates Foundation, and the GFATM. Links to national HIV prevention and treatment guidelines that reference oral PrEP program implementation (as of the date of publication of these costing guidelines) can be found in Appendix 1.

Because PrEP is a new intervention and the few low- and middle-income countries that offer it outside of trials do not yet have mature programs, there will be little cost information to draw upon from previous national or international costing studies. While numerous cost inputs can likely be derived or adapted from other interventions in a given country or from PrEP implementation in other countries, what works best in PrEP implementation is not yet well known. For example, it is not well known how much effort needs to be invested, and what modalities work best, in generating demand and supporting adherence for PrEP. This will require new cost analyses, as well as responsive adaptation in planning and budgeting, as new information becomes available.

SECTION B: METHODOLOGICAL PRINCIPLES

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METHODOLOGICAL PRINCIPLE 1A – DEFINING THE STUDY PURPOSE



https://ghcosting.org/pages/standards/principles/defining_the_purpose

https://ghcosting.org/pages/standards/principles/study_design

The principle:

The **purpose** of the PrEP cost estimation should be defined.

Summary recommendations:

The **purpose** of the PrEP cost estimation should be defined in alignment with how the data are going to be used. At a minimum, a broad description of the purpose should be stated. The purpose may include economic evaluation or priority setting, analysis of technical efficiency, short-term budgeting and price setting, or medium- and long-term financial planning and estimation of resource requirements.

Researchers are encouraged to further consider and report the specific purpose for the cost estimation, such as a medium-term HIV expenditure framework for medium-term health planning.

Detail:

Study purpose

This first principle is to define the purpose of estimating the cost of PrEP, because the first step of any costing exercise is to ask “How will the cost data be used?” Without a well-informed answer to this question, the PrEP cost data collected and the resulting estimates may not meet the needs of those who had requested or funded the research. In general, there are four main purposes for which PrEP cost data could be used:

1. Economic evaluation or priority setting

Local, national, or global bodies trying to decide whether to advocate for a new intervention such as oral PrEP, introduce it on a trial basis, or make it a standard part of an essential health services package covered by insurance will often seek to better understand how much oral PrEP costs in comparison to other HIV prevention interventions. However, because public health specialists do not solely consider cost or cost-effectiveness when determining whether to scale up interventions, cost data are only part of the equation.

To be specific, cost forms only the numerator in an **economic evaluation**, which can aid policymakers in the process of deciding on the most efficient and impactful use of resources (Brouwer 2012, Drummond 2015, Glick 2015, WHO 2002, Neuman 2017). In general, the primary forms of economic evaluation utilized in health are cost-minimization analysis, cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis (otherwise known as benefit-cost analysis). Please see Appendix 2 for more detail.

Please note, **cost-effectiveness ratios are not static**, and cost-effectiveness can improve if the cost forming the numerator goes down or if the benefit increases, as would be the case if HIV incidence were increasing in the population being studied. For example, the annual cost of TDF/FTC in South Africa has dropped in the past decade from US\$386 in 2008 to US\$51 in 2017, with a precipitous drop from US\$296 in 2012 down to US\$76 in 2013 when generic TDF/FTC was introduced (WHO Global Price Reporting Mechanism 2017). A 2016 unit-cost estimate for PrEP in South Africa put the cost at US\$219 per person per year, of which US\$55 (or 25 percent) was for TDF/FTC (Meyer-Rath 2017). Assuming that the cost for the remaining components of the PrEP intervention (i.e., US\$164) had not changed since

2012, and with a drug cost of US\$296, the cost of the PrEP intervention would have been US\$460, or more than double what it was estimated to be with the lower drug cost, in 2016. **Caution should also be taken that economic evaluation does not drive the decision-making process to the exclusion of other issues such as social and ethical impacts, equity, practicality/feasibility, and even politics.**

2. Technical (i.e., implementation) efficiency analysis

This purpose describes the use of costs to explore differences and drivers of implementation efficiency between providers or between modes of delivering health interventions or services. While economic evaluation seeks to understand the best “bang for the buck” and compares the cost and efficacy for different courses of action, analysis of technical efficiency seeks to understand “through what” service implementation modes these differences are caused (Hernández 2014, Jehu-Appiah 2014).⁶

3. Short-term budgeting and price setting

On the basis of economic evaluation or other information to support priority setting, decision makers may decide to initiate or refine PrEP programming for the immediate future, which requires cost data to predict expenditures by specific budget holders and sets prices for specific services. Examples of costing for short-term budgeting and price setting include annual program budgeting by managers for routine health services so that the addition or refinement of PrEP services can be paid for, price planning for specific goods (or services) such as the price for the specific regimen of oral PrEP, and re-allocation of unspent funds to activities (such as adherence support for PrEP) that may be more critical and costly than initially anticipated.

4. Estimation of medium- (3–5 years) and long-term financial planning and resource requirements

For PrEP to be sustainably available to clients, it is critical that it be considered and planned for over the longer term, during which both the modalities for PrEP and the HIV epidemic are expected to evolve. Medium- and long-term planning gives a “heads up” in regard to budgetary sustainability and the scope of resources required to meet need over a significant period. It also concretizes commitment by building PrEP into the expected expenditure for the whole government and for multi-sectoral frameworks that guide the HIV/AIDS-specific response. Examples of costing for medium- and long-term financial planning and resource requirements include global price tags, financial plans for investment cases, budgets for national strategic plans, and medium-term expenditure frameworks.

Macro context/policy purpose

Finally, it is very important that **the specific purpose for a particular costing study be understood within the larger health practice and policy decisions** (and the target audiences carrying out such practice and decisions) that the specific purpose is serving. For example, economic evaluation studies looking at comparative courses of action for PrEP will likely need to be combined with economic evaluation studies of voluntary medical male circumcision or prevention of maternal-to-child transmission to decide on the best mix to achieve overall reductions in HIV incidence. Therefore, knowledge of the planning cycles of national and global bodies (e.g., for the millennium/sustainable development goals) is quite helpful for understanding the big picture of how cost data may be utilized (Appendix 3).

⁶ These are two good online resources for technical efficiency analysis.

METHODOLOGICAL PRINCIPLE 1B – DEFINING THE INTERVENTION [CONTEXT AND IMPLEMENTATION]



https://ghcosting.org/pages/standards/principles/study_design#purpose

The principle:

The **context, the population, and the intervention or service/output of the PrEP cost estimation** should be defined.

Summary recommendations:

The context for the PrEP intervention, the population that will receive PrEP, and the delivery approach for the PrEP intervention should be clearly defined. This is important because costing analysts can't collect cost data for PrEP if they don't understand what PrEP is and how a PrEP intervention is being implemented. Potential key areas of study design that should be understood, and that should be clearly reported,⁷ are:

- Country
- Geography (e.g., urban, rural, peri-urban)
- Epidemiological context (e.g., incidence/prevalence in the county and in the studied area or population)
- Other contextual issues that analysts feel are relevant to service provision or uptake (e.g., economic turbulence, conflict, environmental changes, communication modality changes affecting social norms)
- Priority populations
- Delivery platform (e.g., at a fixed facility such as a health post, clinic, or hospital; outreach; community; population-wide)
- Ownership (public, private, nongovernmental [NGO])
- Modality (e.g., oral PrEP, vaginal ring, pharmaceutical composition of the modality)
- Main PrEP intervention activities, and clear description of the production process
- Treatment phase (e.g., initiation, continuation)
- Levels at which activities are carried out (e.g., site-level/provider level, above site level)
- Coverage level or project phase (e.g., pilot, implementation to scale, post scale-up)

Detail:

Starting a cost estimation without fully understanding the “who,” “where,” and “what” of a PrEP intervention is a setup for an erroneous end result. It would be like being asked to go to the store to find a price for bananas. The analyst would be wise to better acquaint himself or herself with bananas so that he or she can better discuss the request for banana cost data without having to go back to the store multiple times. This includes acquainting himself or herself with the priority population “who” is buying the bananas at the sample sites (e.g., people from a surrounding wealthy suburb and people without access to bananas anywhere else may support a higher price), the delivery platform “where” they are sold (e.g., supersize stores that buy and sell in bulk might be able to charge a lower price for individual bananas, street vendors that grow the bananas themselves can offer a lower price because there are no management or procurement costs), and “what” varieties (or “modalities” in health intervention terms)

⁷ Transparent reporting should also state what, such as specific intervention activities, have been **omitted** from the cost estimation and reporting.

are available for sale (e.g., roasting bananas, dessert bananas, and beer bananas likely have different prices). To continue this analogy, reporting out such specificity subsequent to the study also allows users of the cost estimates to make informed and fair comparisons with estimates from other cost studies. Users of the PrEP cost data can only understand if cost estimates are generalizable to their context/PrEP intervention design—and whether differing PrEP cost estimates are attributable to differences in the context, PrEP intervention production process, or study methodologies—if those factors are clearly reported.

Country and context

The countries of study (and specific areas within each country) will be determined by the purpose of the study, but are likely to be countries with generalized or concentrated epidemics where PrEP is most needed. Other contextual issues are important not only in terms of study feasibility but also in terms of understanding the scope of issues that may affect PrEP intervention costs (e.g., if religious leaders oppose delivering PrEP services to AGYW, then the potential costs and impacts of such barriers will need to be considered). For example, through discussions for initial work on costing PrEP in Kenya, analysts have learned that MSM (who are, once tested, initiated and retained in the program in higher proportions than other vulnerable groups such as sex workers) have developed uniquely cohesive beliefs and behaviors that are likely due to intensive exposure on intragroup social media and dating apps (i.e., personal communication). And, even if assessing the impact of social norms on demand generation for PrEP could not be included in the planned cost study, reporting of such contextual observations in the discussion or limitation sections of reports could assist in preparation for future lines of study. Priority populations will differ by country depending on which groups are at greatest risk of HIV and how the epidemic is being propagated through them.

Delivery platform

PrEP programs are expected to be implemented through health facilities—both facilities serving the general public and those focusing on specific populations (e.g., MSM, sex workers). Within the Kenya PrEP implementation framework, for example, as the program expands, delivery points for PrEP services may include prevention centers, pharmacies, stand-alone drop-in centers (DICs) for key populations, special clinics, maternal and child health/family planning/antenatal care service points, youth-friendly centers, comprehensive care centers, and outpatient departments (Kenya 2017). UNAIDS has proposed that some components of PrEP services could be delivered through community outreach (e.g., HIV testing, counseling, drug distribution) or be self-administered, such as through self-testing. Kenya has recently announced the Be Self Sure Campaign, which makes HIV self-test kits available at low cost in public health facilities, private health facilities, and pharmacies. In tandem, the program has established communication mechanisms associated with the test kits to draw those testing HIV-negative to the selected public health facilities where PrEP will be offered free of charge, and to private facilities where it will be offered for a fee (http://www.unaids.org/en/resources/presscentre/featurestories/2017/may/20170505_kenya).

Ownership

Although the majority of PrEP services are anticipated to be delivered primarily through the public sector, NGO and private providers are also expected to offer PrEP services. (In some countries, PrEP has been legal in private facilities prior to certification for public facilities). Several ongoing PrEP demonstration projects are studying implementation through faith-based or other private-sector platforms (Cowan 2016).

Modality

The currently available PrEP modality is oral PrEP. The current WHO recommendation is to use a regimen of one pill of TDF (300mg)/FTC (200mg) taken daily, until 28 days after cessation of exposure (Corneli 2015, Amico 2017, WHO 2017a). However, the choice of a [WHO-recommended] regimen containing TDF will depend on availability, cost, regulatory status, and current strategy in a specific country. For example, TDF/lamivudine (3TC) is listed as an alternate in the guidelines of several countries, and is already approved (for ART) and available in generic form at low cost in many countries.

The total length of time that PrEP will need to be taken remains unclear and may vary by focus population. For example, a young woman in a short-term relationship may have only a few months of exposure, while a brothel-based sex worker or a woman in a relationship with a man who is unfaithful may have years of exposure. Also, for individuals in contexts of sexual violence or coercive sex, it could be difficult to predict when exposure will occur, and therefore the timing whereby such populations may want to begin and end PrEP is difficult to judge. The standard for costing is to estimate one person-year of service, although [unpublished] estimates utilizing a time frame of six months of service have also been produced (Meyer-Rath 2017, Eakle 2017, Chen 2014a, Chen 2014b, Ying 2015). Therefore, individuals conducting cost studies will have to work closely with program planners to determine average duration of PrEP use for specific populations *within* a one-year (or other relevant) time frame necessary for the appropriate use of the cost estimate.

Activities and the production process

The specific activities/services and inputs making up the production process to deliver PrEP interventions have recently been formulated at a global level in the *WHO Implementation Tool for Pre-Exposure Prophylaxis of HIV Infection* (ITPrEP) (WHO 2017a), and a few of the national guidelines have some discussion of activities (Kenya 2016, Kenya 2017, Republic of South Africa 2016, Republic of South Africa 2017). In addition, South Africa has unpublished preparatory materials for expanding PrEP to all populations at substantial risk of acquiring HIV, and several unpublished studies estimate what it would cost to implement PrEP in Kenya (among sex workers and MSM) and in Zimbabwe (among all populations at substantial risk) (personal communication). From these sources, an outline of a “typical” PrEP intervention involving direct services (e.g., dispensing of PrEP drugs), ancillary services (e.g., demand generation), and operational activities (e.g., staff training) has been developed for these PrEP Costing Guidelines and can be found in Appendix 4. Thinking through the components of the studied intervention allows the analyst to start from a full picture, from which he or she can then decide which components to cost, at what level of detail, and with which methods.

METHODOLOGICAL PRINCIPLE 2 – DEFINING THE PERSPECTIVE



https://ghcosting.org/pages/standards/principles/study_design#three

The principle:

The **perspective** of the PrEP cost estimation should be defined.

Summary recommendations:

Due to heterogeneity in the conceptualizations of perspective across methodological sources and previous costing studies, it is recommended that:

- **The scope of the costs that are being included and being omitted in the perspective utilized by the analyst be clearly delineated.**
- **The “stopping rules” delineating what is in and out of the scope be justified.**

Detail:

The perspective of the cost estimation gives an idea of the scope of what is being paid for and by *whom*, and should be in line with the purpose and user of the PrEP cost data. The RC gives a good example of why the perspective is important:

“Some users, who make decisions on behalf of a population, may need to use a societal perspective that captures all costs incurred by an intervention, regardless of who pays the costs. For other analyses, a more limited perspective may be taken. For example, to set a budget, it may only be important to estimate the costs that fall on a specific payer.”

The most commonly used perspectives in the health costing literature are the **provider perspective** and the **societal perspective**. The provider perspective is often conceptualized as the costs by the service provider to produce the services at the point of care, while the societal perspective is commonly conceptualized as the provider perspective plus the client (or patient) perspective. However, these labels are not uniform. The provider perspective can be limited to specific **groups** involved in service provision (e.g., health personnel, social support/administrative personnel) or to specific **payers** (e.g., limiting the cost estimation to the government portion of costs, sometimes called the government perspective, for a PrEP intervention that is cooperatively funded or implemented by other entities such as national or international donors). Similarly, the societal perspective can broaden the “payers” from the client and his or her family, to economic or social impacts on the local community, the province or state, and the nation. An additional perspective that can be found in the health costing literature is for the “health system,” although there is not consensus on what this perspective entails.

Methodology for data collection and reporting regarding the client perspective is not yet available in this document or in the RC. One of the issues being grappled with in the development of guidance is the scope of the client perspective, as the interpretation and reporting of patient costs vary widely, extending from co-pays for visits, tests, and insurance; to costs for transportation, food, and childcare to be able to attend appointments; to opportunity costs for time spent during travel and at visits; and on to costs and their effects on households, communities, and even national economies. However, because the client perspective is very important, analysts should not discount it in the cost estimation for PrEP,

and can refer to other sources of guidance.⁸ It is expected that, due to the extensive consensus-building effort, the guidance newly available in *Tuberculosis Patient Cost Surveys: A Handbook* (WHO 2017b) may serve as a template for the development of client perspective guidance in other health areas.

PrEP drugs and counseling visits are expected to be provided free in most settings. However, in some settings, clients may have to pay for some laboratory tests (e.g., liver tests) that are in some contexts mandatory for initiation on PrEP. Also, the number of visits necessary for initiation and continuation phases is not yet well-determined in terms of counseling and drug pickup. And, given that each visit often involves travel and opportunity costs, the number of visits can be a determinant in uptake and retention on PrEP. Finally, PrEP is offered to individuals who are not testing HIV-positive or experiencing symptoms of HIV, and healthy individuals may be more reluctant to pay for preventative care/drugs than for symptomatic/curative care. For these reasons, demand for PrEP is likely to vary based on the price of the services (e.g., liver tests) and opportunity costs for visits associated with PrEP. Thus, the consideration of client costs in cost estimation is expected to be important, despite the offer of free drugs and counseling.

⁸ Please see WHO's *Tuberculosis Patient Cost Surveys: A Handbook*, which provides guidance on estimating catastrophic costs due to TB, at <http://apps.who.int/iris/bitstream/handle/10665/259701/9789241513524-eng.pdf?sequence=1&isAllowed=y>. See also the *Tool to Estimate Patients' Costs* at <http://www.tbcare1.org/publications/toolbox/costing/> and the WHO PowerPoint on "Measuring patient costs to monitor progress towards the target to eliminate catastrophic costs and help design social protection and UHC" at http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/meetings/tf6_p10_patient_cost_surveys.pdf.

METHODOLOGICAL PRINCIPLE 3 – DEFINING THE TYPE OF COST



https://ghcosting.org/pages/standards/principles/study_design#four

The principle:

The type of cost being estimated should be defined, in terms of **financial versus economic, real world versus guideline, incremental versus full cost**, and whether the cost is **net of future savings** or not. The type of cost should be directly linked to the purpose of the PrEP cost estimation. (For example, if the analysis is intended to assess the additional resources required to add PrEP to an existing key population program, then an incremental cost analysis should be pursued).

Summary recommendations:

Different types of costs are appropriate for different purposes, and these requisites then frame study design and measurement methods. The key issue in this principle is to transparently define the type of cost being studied.

It is recommended to:

- **Delineate if the cost is financial** (i.e., captures the resources that are “paid for”) **or economic** (i.e., **additionally** captures **opportunity costs**, which are the values of resources based on how they would otherwise be utilized, even if not paid for).
- Describe if the aim is to estimate the cost according to **normative best practice** (i.e., according to PrEP guidelines and where there may be additional cost to adhere to those guidelines) or to estimate the cost as a reflection of implementing PrEP in the **real world** (i.e., as actually delivered, where some components may not be included or might be added depending on the actual implementation of the program). In many cases, the cost estimate may include aspects of both, particularly if the sample seeks to include diverse implementation sites/modalities.
- Specify if the cost estimate is measuring a full cost or the incremental cost of adding PrEP to existing services. Please see Principle 6, “Scope of the costing,” for more information on incremental cost.
- Report if the cost is **net of future cost savings** for health providers or households.

Detail:

Economic and financial cost

Financial costs only include costs that are actually paid. Economic costs incorporate both financial costs and opportunity costs. To explain opportunity costs, the *Rapid Syphilis Test Toolkit* (RSTT) draws on Creese and Parker (1994) in stating that “the basic idea is that things have a value that might not be fully captured in their price. It is not difficult in many health programmes to identify resource inputs for which little or no money is paid.” Opportunity costs are included in the economic cost because those goods and labor have a value. That value can be equated to the cost of not using those goods or labor for a different opportunity. For example, drugs or facilities for a PrEP intervention could be used instead for ART, and volunteer leaders of adherence groups could use their time for paid employment. In common practice, the most important opportunity costs are (LSHTM et al. 2013):

- Donated goods, services, or labor. Please note that “donated” labor may include more than just the time people spend volunteering, such as community health workers providing PrEP

adherence support. It could also include the appropriation of time for health care staff whose time is already being budgeted elsewhere, or who could be completing tasks other than those specific to the intervention being costed (or even just taking some downtime). An example is an outreach coordinator for PrEP demand generation who has been seconded from an NGO to a group of public clinics, but who is paid by the original employer (i.e., the NGO).

- Donated indoor or outdoor physical space (or physical space utilized for PrEP that is part of the health system but is not specifically budgeted to PrEP) and “airtime” (e.g., for radio or television spots). In a financial analysis, a building would have value only if a rent or mortgage were being paid on it. However, in an economic analysis, the building would have value based on what would have been paid for a similar building, regardless of whether there is an actual payment occurring or not.
- Other inputs with prices that may be inaccurate or distorted (such as from subsidies on Truvada when it is initially introduced to a country). In this case, a financial analysis would include all items as they are paid. However, an economic analysis would attempt to reduce any distortions that might occur due to a range of factors, including taxes and subsidies.
- The way that capital costs are valued. **Capital costs** are one-time costs for resources/inputs that have a useful life of more than one year (e.g., buildings, vehicles, equipment, furniture, start-up training). For economic costing, the opportunity cost of not investing the same purchase (or resale) price, plus interest (or the expected rate of return on the alternate investment), for capital inputs needs to be considered. Capital costs can be compared with **recurrent costs**, which are the costs of resources or inputs with useful lives of less than one year (e.g., supplies, personnel). **Please see the PrEP-specific section on Principle 12, “Valuing capital inputs,”** for more information on how capital inputs are valued in financial and economic estimation.

Please note that both financial and economic cost estimation “smooth out” the one-time cost of a capital input by putting a “piece” of the cost across each of the years of use of that input (though they do the “smoothing” differently), while **expenditure** estimation “lumps” the cost of a capital item into the single year in which it was purchased. So, if an analyst completed a PrEP costing study at one site in Kenya and tried to validate the one-year estimate by looking at a one-year expenditure report from another site in Kenya, the analyst’s first estimate would likely be higher simply because it would include a “piece” of a capital cost, such as a building purchased five years ago. In contrast, the expenditure estimate the analyst was using for comparison would not include the capital cost for the building at all because it would not have been purchased in the year of the expenditure estimate.

Also note that capital costs are not synonymous with **fixed costs**, which are any costs that *remain constant* (at least in the short run)⁹ regardless of the quantity of services produced. Salaries, for example, may be classified as fixed costs, if they don’t directly vary with the number of clients seen. However, salaries are not classified as capital costs. In assigning the label of fixed costs or **variable** costs, which are costs that *do directly vary* with the quantity of services produced, we are moving into a different discussion of how a cost input “behaves” in relation to the scale of production (generally the

⁹ Short-run/long-run “fixity” is not a set time period, but rather the “run” of time before a fixed cost needs to change to keep accommodating the desired level of service provision. At a certain point, more buildings and more staff (or at least higher wages of current staff) may need to be added if the number of clients keeps increasing. In addition, structures such as buildings eventually need to be replaced. Therefore, all costs are variable at some point. This “fixity” point may depend on a number of factors, including the type of input (e.g., more staff numbers or higher staff wages may need to be added before more buildings), what the program is set up to accommodate, and how efficient the manager is.

number of people served in the case of PrEP) and other factors. Please see the RC introductory discussion on **cost functions**, which the RC states “describe how cost is determined by input cost, the amount of resources used, and other factors that may modify these such as the scale of production, or other characteristics such as quality,” for more advanced information on this topic.

The use of economic or financial costs depends on the purpose of the study. For example:

- For an **economic evaluation** comparing oral PrEP to vaginal ring PrEP, capturing **economic costs** is important for making a comprehensive assessment of the costs involved, including opportunity costs. If some quantity of oral PrEP had been donated by the manufacturer and that cost was not captured (e.g., all vaginal rings were purchased by the intervention to distribute), that would artificially lower the cost and the cost-effectiveness in comparison to the vaginal ring. Assessment of social, behavioral, or other spillovers of a PrEP intervention into other health sectors, or toward habit formation, would also require consideration of economic costs.
- For a **budget and for planning that is short-term**, **financial costs** should suffice. That is because payers are looking to plan for what they will pay for, and are not looking to include donated goods or volunteer labor.
- **For medium- and long-term planning**, it may depend on the assumptions in the plan or model. If it is assumed that existing programs will be replicated “as is” in terms of payment, then financial costs may be warranted. However, if it is expected that goods will cease to be donated or volunteer labor will need to be paid for to expand services, then it will be useful to have an understanding of the economic costs and to include them in the projections.

Normative best practice and real world

For PrEP, the distinction between “normative best practice” and “real world” can be challenging. This is in part because formal global guidelines in the form of the ITPrEP have only just been released, and these guidelines still have a lot of unknowns and room for interpretation/flexibility as to what a normative best practice is. Each country is generating its own draft guidelines (some of which were developed before the ITPrEP and were sources of information for it), anticipating that these guidelines might change rapidly as new information about PrEP implementation becomes available. Therefore, it is advisable that reporting of cost estimation state the source of the guidelines that are being utilized, the key normative best practice recommendations of those guidelines, and how well the studied program has been able to follow them.

“Normative best practice” may equate to “real world” implementation if the real world setting is well-equipped and well-functioning. For example, initial cost estimations for PrEP in Kenya focused on well-resourced urban clinics that already had years of experience serving FSWs, and that were anticipated to be able to meet normative best practice (Chen 2014a, Chen 2014b). For settings that are not well-equipped and well-functioning, there are several reasons why the normative best practice and real world costs may not be equal. For example, one of the Kenya PrEP study authors communicated that the cost estimation was not necessarily reflective of lesser-resourced or rural clinics, where the intervention cost might be lower because some tests (or test modalities) are not able to be offered and the number of visits might be lower due to poorer client access to the facilities.

However, it should not be assumed that, for example, lesser-resourced or rural clinics in the real world are less expensive than normative best practice ones. This is because service volume and the “cost of doing business” (e.g., transport) may be higher, and efficiency may be lower. This was the case for one

study of PrEP among sex workers in South Africa (Eakle 2017). In this study, at some sites, drugs were distributed by necessity at satellite locations (i.e., from truck containers positioned in remote locations), which involved considerable personnel cost in terms of the time for the pharmacist to package the drugs appropriately for transport and tracking. In addition, for those draft guidelines that have been proposed in countries like Kenya and South Africa, ancillary activities like demand generation and retention/adherence are not well-specified, and in the real world it may prove that these activities are critical and add significant cost.

Net of future cost savings

In regard to the RC statement on “net of future cost savings,” this essentially is the accounting used in economic evaluation to determine how cost estimates from collected cost data change if they include the expected future cost of providing the intervention plus/minus the costs/benefits that are:

- **Related** to the illness targeted (e.g., PrEP provision that may be more expensive but saves the medical/treatment costs from becoming HIV-positive, and potentially allows for greater productivity of the individual).
- **Unrelated** to the illness targeted (e.g., other illness that may occur when a person is spared HIV but lives a longer life), although this is less frequently done.¹⁰

¹⁰ As in the case of the general overview of economic evaluation provided in Principle 1, this information on “net of future cost savings” provides background on how collected cost data will be used. Although it is not expected that readers of these PrEP Costing Guidelines will conduct such advanced analysis, it is important to note that some audiences of reported PrEP cost estimates will be looking to the methodology description for clarification on whether or not the cost estimate is “net of future cost savings.” Therefore, this clarification should be reported, and if the analyst does decide to include analysis for future cost savings, the methodology utilized should also be clear. Further method specification can be found in Drummond 2015. Also, two open-source examples of cost estimates used for HIV planning that are net of cost savings are included in Meyer-Rather et al. 2017 at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393674/> and Haacker et al. 2016 at <https://www.ncbi.nlm.nih.gov/pubmed/27138961>.

METHODOLOGICAL PRINCIPLE 4 – CLEAR DEFINITION OF “UNITS”



https://ghcosting.org/pages/standards/principles/study_design#five

https://ghcosting.org/pages/standards/introduction/estimating_the_cost_of_health_interventions_an_introduction#four

The principle:

The [output] **units** in the unit costs for PrEP services and full interventions should be defined, relevant to the costing purpose, and generalizable.

Summary recommendations:

Clear definition of the [output] “units” in unit costs is critical for the comparison or synthesis of cost estimates, and for the creation of data sets that can be used to generalize to settings without cost data. For example, will the unit cost calculations be based on the cost per month of PrEP service delivery, per six months, or per 12 months?

It is recommended that analysts:

- **Report using standardized units that are clear, aligned with current national and international strategies, and respect the purpose of the study.**
- **Consider the use of “quality adjusted units,”** especially where the study of efficiency is of primary importance.

Detail:

From the production process outlined in the “Introduction to Costing” section, it can be seen that output units can be at the level of the services provided (as components of the PrEP intervention) or at the level of the PrEP intervention (as a whole).

Examples of output units at the activity/service level include:

- Cost per test (e.g., HIV test, HCB test)
- Cost per PrEP regimen per month
- Cost per PrEP pick-up visit
- Cost per text message (e.g., for adherence support)
- Cost per peer group session (e.g., for adherence support)

Standardized PrEP intervention units and standardized *quality-adjusted PrEP intervention units* suggested by these guidelines are, respectively:

- **Cost per client (month or year) provided with PrEP**
- **Cost per client (month or year) during which the client is correctly taking PrEP**

Quality-adjusted units are those that are adjusted by some measure of how well that [service or intervention] output achieved its purpose. Measures of quality are used to better understand if interventions with similar costs are actually comparable in terms of value for the provider and well-being for the client. For example, a mass media activity for PrEP may be less expensive than [interpersonal] peer-supported demand generation or adherence support, but it may be less effective at drawing in and retaining/supporting PrEP clients. Measures of quality may also be used to understand what additional investments are necessary to achieve specific targets for quality. For example, if a mass

media campaign had added radio call-in shows, web chats, or live streaming of peer or popular-opinion leaders, could it achieve similar quality as face-to-face interpersonal interactions?

It should be reiterated that the examples of activity/service-level output units listed above are not comprehensive or final. PrEP is a new intervention, and as is the case with all new interventions, the suggested units may not prove to be the most useful or regularly reported. Review of any published PrEP costing studies and discussion with colleagues involved in similar efforts will be useful for standardization. Further, as noted in the RC, some management information systems may not align with the standardized units proposed here (or those that may emerge as PrEP costing studies evolve). If possible, for generalizability of the PrEP cost data, we recommend collecting any additional cost detail that may be necessary to construct and report unit costs in a standardized manner.

The above examples of output units are more fully illustrated in Appendix 5 (see the columns in orange). Please note that Appendix 5 aligns with a “sister” appendix in the RC (https://ghcosting.org/pages/standards/appendices/standardized_TB_unit_costs). Appendix 5 not only provides the standardized PrEP intervention and service/activity output units. It also puts those units in the context of the key pieces of the guidelines that define the intervention, the activities/services and inputs that make up the intervention, and the alternate grouping of input costs into input-cost categories (as opposed to activity-based categories) required for some uses.

METHODOLOGICAL PRINCIPLE 5 – DETERMINING THE APPROPRIATE TIME FRAME OF COST DATA COLLECTION AND DISAGGREGATED PERIODS WITHIN THE TIME FRAME



https://ghcosting.org/pages/standards/principles/study_design#five

The principle:

The **time frame of PrEP cost data collection (i.e., start and end dates)** should be explicit and of **sufficient length** to capture costs relevant to the time horizon of the study purpose, and **consideration should be given to disaggregating costs into separate time periods** where they vary over the time frame.

Summary recommendations:

Different PrEP study purposes have different **time horizons**, or lengths of time during which the study data will be applied. For example, economic evaluations may require consideration of intervention costs and benefits far into the future, while short- and medium-term budgets and financial planning may require shorter time horizons of 1–3 years or 3–5 years. The time frame for cost data collection and specific time periods within that time frame must therefore be of sufficient length and variability to provide *a representative sample* that informs what the costs *would be* over the time horizon in which the cost data would be used.

It is recommended that:

- **The time horizon methodology specified in the International Decision Support Initiative (iDSI) reference case be utilized for economic evaluations (iDSI 2013¹¹), while length of time utilized for the planning cycle be used for budgets and financial planning.** For example, if the South Africa National Sex Worker HIV Plan is for the “cycle” of 2016–2019, costing of PrEP for the purpose of an aligned budget would need to take into account changes in costs over that three-year period.
- **Costs, at a minimum, be broken out into the program phases of “start-up” and “implementation.”** This is because intervention costs can change significantly between the initial start-up **program phase** (which occurs before service is provided to the first client and involves capital costs like investment in buildings and start-up training that can “front-load” investment) and more mature phases of the program. A good rule of thumb for the implementation phase is that **programs should be operating “normally” for at least six months in the implementation phase** for them to be considered as part of the sampling. This prevents costing interventions that have “growing pains” or are incurring unusual outputs or inputs.
- **One-year periods that are standard for reporting ART be disaggregated for PrEP into clinical service delivery phases (e.g., screening, initiation, continuation),** during which services (e.g., tests, visits) and costs may vary in accordance with the intensity of service use.
- **Seasonal variation** in costs be taken into consideration where relevant, **and study time frames of less than one year be justified.**

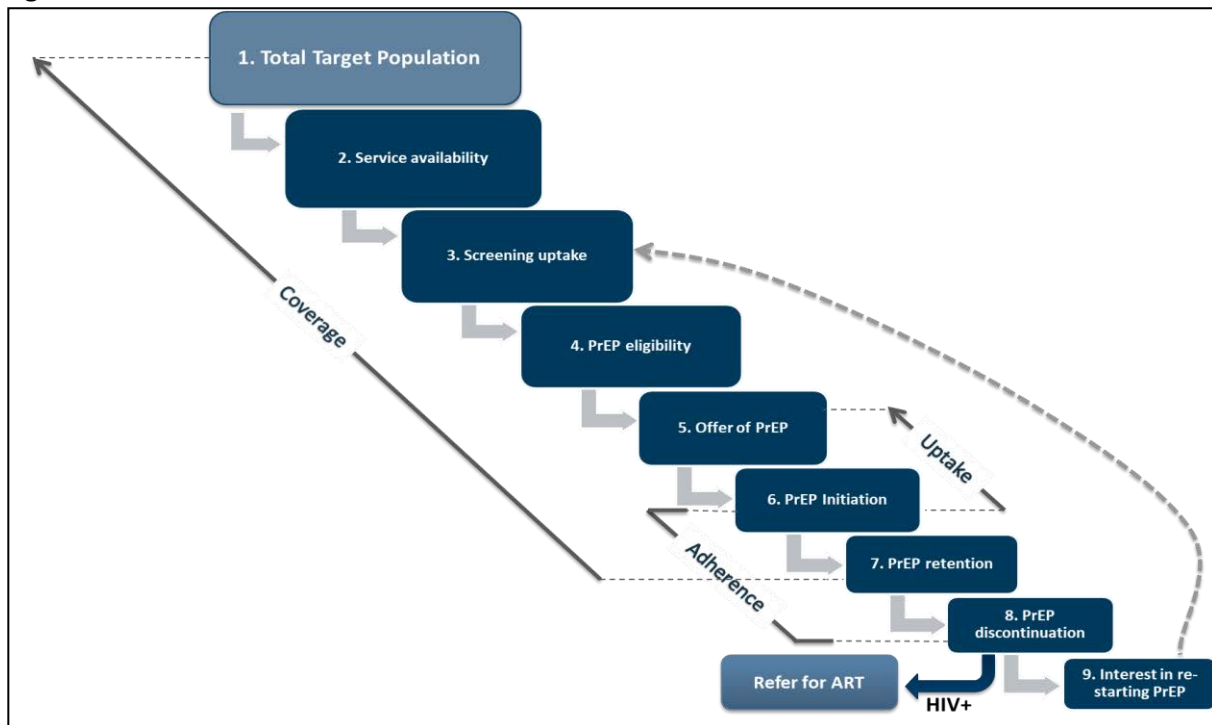
¹¹ Available at: <http://www.idsihealth.org/resource-items/idsi-reference-case-for-economic-evaluation/>.

Detail:*Program phase*

For the disaggregation of program phases for PrEP, there will be some **start-up costs** such as initial training, and potentially some infrastructure and equipment costs, which could vary depending on the platform for service delivery. Also, it is important to consider that an adaptation of an existing program can involve start-up costs for that adaptation. If, for example, an existing fixed facility-based PrEP program adds service through a new platform such as container trucks, a start-up investment will be required both in the containers and in the initial training, for those staff who package and distribute the drugs and for new counseling staff based in more decentralized locations.

Service delivery phase

PrEP is anticipated to also have service delivery phases that can be characterized as a care cascade, along the lines of the 90-90-90 targets of testing/diagnosis, initiation on treatment, and viral suppression that categorize the HIV care cascade. Figure 2 is a mock-up of a PrEP service delivery cascade that was adapted from materials prepared for a stakeholder consultation about dapivirine-ring modeling conducted by the OPTIONS project in November 2017.

Figure 2: PrEP care cascade

For most costing applications, it will be sufficient to **break PrEP into two phases (i.e., initiation and continuation)**, with the expectation that the initiation phase would group “service availability” through “PrEP uptake” and the continuation phase would be for “PrEP retention.” The cost calculation will need to take into account the proportion of those screened who are identified as eligible, the proportion of those offered PrEP who initiate it, and the proportions of clients retained at different points post-initiation. For quality-adjusted unit costs, the calculation will need to adjust for clients provided with the service who do not take the medication as directed, and also consider the deliberate cycling on and off

of PrEP based on longer-term changes in HIV risk (e.g., a PrEP client's only sexual partner is away on travel for several months). This deliberate cycling is referred to as "prevention effective adherence" (Haberer 2015, Haberer 2017).

Like other interventions, PrEP implementation may be affected by the season. Flooding in the rainy season or snow in the winter can make roads impassable. Greater cost can then be incurred in getting supplies to facilities, for mobile outreach services, or for clients trying to access care. Seasons can also affect the cost of utilities for heating and air conditioning/refrigeration, and the dry season can affect the accessibility of water necessary for maintaining hygiene in facilities. Service utilization may also fluctuate in different times of the year, affecting the cost-efficiency of service provision. For these reasons, it is important to collect cost data spanning a full year's time.

METHODOLOGICAL PRINCIPLE 6 – SCOPE OF THE COSTING



https://ghcosting.org/pages/standards/principles/resource_use_measurement

https://ghcosting.org/pages/standards/introduction/estimating_the_cost_of_health_interventions_an_introduction#six

The principle:

The scope of the **inputs** to include in the cost estimation should be defined, justified, and relevant to purpose. Where inputs are excluded for pragmatic reasons, this should be explicitly reported.

Summary recommendations:

Just as it is important to clearly describe the PrEP intervention and the services/activities that comprise it (i.e., the production process), to allow for comparison of cost estimates for nominally similar PrEP interventions, it is also essential to clearly describe the cost inputs that go into service provision. In this way, those interpreting the cost estimates can better decide if they are comparing the same intervention (e.g., mobile PrEP provision for vulnerable populations in Africa), and whether the same cost components have been included in the cost estimates.

There are several recommendations in relation to describing the scope of inputs:

- **Carefully consider the bounds of the scope for each cost type for the study, with respect to the purpose and perspective.**
 - **Where economic costs are estimated, it is essential that opportunity costs are considered.**
 - **Determine the scope of the incremental cost for including a PrEP intervention (i.e., specific activities) in a combination prevention package as compared to a combination prevention package without PrEP.** One of the primary concerns is the extent to which the PrEP intervention needs to add capacity (e.g., personnel hires, infrastructure, management) or can be absorbed within the existing system that the comparator combination prevention package is a part of. If costs are adjusted to account for “spare” capacity in the health system that will be absorbed/utilized by the new intervention, **any assumptions about existing capacity** need to be described when defining the scope of “incremental” cost.
 - **Above-site costs (also known as above-service costs) should be considered where possible and designated as above-site.**
- **Map the full range of resource use** (after the production process has been described).

Detail:

Purpose and type of cost

The types of costs used for the PrEP costing study are determined by the purpose and perspective. These “types” need to then be circumscribed in scope so that inputs can be mapped within that scope, in preparation for determining the cost of those inputs. Not all cost inputs necessarily need to be captured, if they are not within the determined scope. If economic costs are required for the purpose of the study, then it is important that all opportunity costs are captured. Thus, volunteer labor (and opportunity cost of labor drawn from other departments or from previous “downtime”) and donated goods would be within the scope of the costing, whereas in a financial costing they would not be.

Scope may also be narrowed when analysts are, for practical reasons, considering trade-offs in the time or difficulty needed to collect data on a more extensive list of inputs, and the supposition that some of the inputs “at the bottom of the list” would make up a small portion of the unit cost. For example, personnel, labs, and drugs can make up the majority of cost for PrEP (Chen 2014a, Gomez 2017). Therefore, it may be possible to focus attention on those inputs, and either leave off or utilize a general estimate for the cost of inputs such as office supplies and capital items that may contribute only a small fraction of the cost. **Note that any deviation from the ideal scope due to poor data availability or resource and logistic constraints should be reported, so that bias can be determined.**

However, caution should be taken, as this is only suitable for some purposes (e.g., as a rough estimate to advocate for inclusion of PrEP in the next year’s budget) *and* where previous costing evidence shows the proportional cost contribution of inputs for similar PrEP (or potentially ARV drug) interventions to the cost of the one that is being planned. It is also possible that a study may focus on a single cost category, such as service delivery personnel, if that aligns with the study purpose. For example, cost data may be needed to feed into a technical efficiency study of PrEP counseling when conducted by nurses, pharmacists, or peer counselors at prescription pickup.

Above-site costs

Although the RC advocates for the inclusion of above-site costs where feasible, there are unfortunately no clear standards on which inputs and activities to include in the scope, where the line is between above-site and site-level delivery, and how far up the “chain” to seek cost data (e.g., district level, regional/state level, national level, international level). A report entitled *Landscape Study of the Cost, Impact, and Efficiency of Above-Site Delivery Activities in HIV and Other Global Health Programs* was produced by Results for Development and gives some guidance and taxonomy (Clift 2016). More specific guidance is expected to be forthcoming from the GHCC in 2018–2019. In the Results for Development paper, procurement and supply chain, demand generation, laboratory system support, health information and record-keeping infrastructure, program management, monitoring and evaluation (M&E), supervision, surveillance, and training are listed as operational activity categories for above-site costs. These are all included in Figure A-4 of Appendix 5 on operational activities for PrEP and in Appendix 5 on standardized PrEP units. They often have a component that is at the site level and at the above-site level (e.g., procurement and supply chain). **The important point is, if above-site activities are costed, to be clear about the scope and delineation of the site-level service delivery and above-site costs that are included. If above-site activities can’t be accessed and feasibly measured, the analyst should clearly report which costs were omitted and why, and describe how this could bias the cost estimation.**

Incremental cost

Incremental cost is the term used to describe **the difference in cost between two or more courses of action**, such as interventions or programs (GHCC 2017, Drummond 2015, Neumann 2017). It is in contrast to the term **full cost**, which means that the cost estimate is covering all resources used within the standard of care for that intervention at current coverage. Full cost should not be confused with **marginal cost**, which is the cost to produce one extra unit of output.

The issue of deciding what is in an “incremental” cost versus a full cost is a difficult one for PrEP. As described above, *technically*, incremental cost is the difference between two comparators. Therefore, one would have to study both the [personnel, capital/infrastructure, and administrative] capacity in an existing HIV program before or without the addition of PrEP and the capacity in one that has already

added or will add PrEP, to be able to compare how well “spare” capacity is being utilized with the addition of PrEP. This would require conducting a cost estimation of the comparator and of the intervention with PrEP to obtain the average unit costs for each intervention (and the unit cost difference). This is particularly true for incremental *economic* costing, for which even if no new staff or new construction is expected, the portion of fixed input costs that are utilized by each comparator would need to be accounted for because that portion has an opportunity cost and could have been used for something else.

However, it can be more common that a study will simply observe that there are no new staff (e.g., service providers, administrators) hired or buildings built with the addition of the new intervention to existing services. The study will thus consider the incremental cost to be only those inputs that needed to be purchased (e.g., tests, drugs) for the new intervention. For example, where the DICs in Kenya were offering HIV prevention services to key populations, and PrEP was then added to this program, the incremental cost may be simply considered to be the additional cost of adding PrEP to the existing HIV prevention program for key populations. This may suffice if the purpose of the cost estimation is for budgeting, and incremental *financial* costs are needed. However, the opportunity cost of the “spare capacity” is not captured by that methodology. Some studies that have not had the resources to cost the original comparator intervention, or that have been conducted where the new intervention has not yet been implemented, have taken an approach to estimate the additional minutes used by personnel with the addition of PrEP, which will give some indicator of economic cost (and can be used to plan for whether addition staff may need to be hired). However, these studies generally have not attempted to estimate how the addition of PrEP may draw on existing infrastructure or administrative capacity.

Further complicating the scope of the term “incremental” is consideration for what services are “additional” with PrEP. Some services in combination prevention packages that include PrEP, such as HIV testing and STI screening, often already exist in programs serving key populations such as sex workers. These can be considered as *not* “incremental” to the existing program. However, an argument might be made that clients would not come in to initiate or maintain PrEP if such services were not offered, so therefore those services should be considered as integral to the PrEP intervention and costed as such.

Where cost estimation of a PrEP intervention and a comparator intervention without PrEP (that would show the incremental difference between the two) is not planned, and the study seeks to assess incremental cost by estimating the “add-ons” for PrEP, the reporting will have to be very clear. It will need to be clear about what are considered within the “add-ons” in terms of the services (and the proportion of those services) under the PrEP-specific intervention. For example, is the cost for an HIV test for every person who comes in for an HIV test considered part of PrEP demand generation? And is referral to ART for those testing positive considered to be a PrEP intervention-specific responsibility? Should only the cost of an HIV test for those people who initiate PrEP be used? And if so, should this cost be adjusted by the proportional increase in HIV testing once PrEP is offered (so as to exclude those who were likely getting tested under the comparator prevention program without PrEP)? For counseling for PrEP, are the staff minutes that are included for counseling assumed to be both for HIV prevention and for retention/adherence, or solely for the latter? Grappling with such questions will assist in reflecting on the purpose of the study, and in providing justification for why the cost estimation is considered “incremental” rather than full (or documenting both).

Mapping the full range of resources

Once the scope of the inputs in the cost estimation has been defined, and the production process has been described in terms of the activities included (see the “Introduction to Costing” section and

Appendices 4 and 5), the full range of resources can be mapped. One experienced cost analyst stated that it is often helpful to take a literal walk through service provision from the perspective of the client, to assist in mapping out who the client interacts with, where in the building (if applicable) services are obtained, what care is received (including the infrastructure and consumables in the medical/client service rooms, where necessary for the study purpose), and what inputs support that care (including back-office staffing, consumables, and infrastructure, where necessary for the study purpose). This will give a good idea of the inputs needed for each activity, and will fill in the “what” in the orange and green boxes in Figure 1 on mapping the components of standardized PrEP unit costs in the Introduction. Please note that a “map” of the intervention’s resource use may also exist from prior studies. This map could include recent cost data on some inputs, and thus could assist in targeting cost data collection efforts for the present study.

Categorizing inputs by input category

Including a full example that maps all of the inputs in a PrEP intervention to specific activities is not sensible for these guidelines, given that the scope, utilization, and specific brand/cadre/type of inputs will vary according to the context and implementation of the intervention. However, a general list of potential inputs may be useful for analysts to see the range of what *can* be looked at. The list in Appendix 6 has been gathered from previous costing guidelines, such as the RSTT and the WHO *Guidelines for Cost and Cost-Effectiveness Analysis of Tuberculosis Control* (LSHTM 2013, WHO 2002), published and unpublished PrEP studies, and review of the nearly 160 HIV intervention studies in the GHCC Unit Cost Study Repository.

Because **input costs can be summed not only by narrow** (e.g., HIV testing, PrEP-drug distribution; demand generation, adherence support; training, supervision) **and broad** (e.g., direct service, ancillary service, operational) **activity categories, but also by narrow** (e.g., direct service personnel, support personnel; capital buildings, capital vehicles; key drugs, intervention-specific supplies) **and broad** (e.g., personnel, capital, recurrent) **cost input categories**, the list of potential inputs to be costed is provided in Appendix 6 in cost category format. In this way, users of the PrEP Costing Guidelines can not only view the range of inputs but also conceptualize them in terms of the input cost categories that are often required for reporting. Please note, the GHCC uses an additional threshold (beyond the useful life of greater than/less than one year) in the extraction of cost data from the literature to differentiate between capital costs and recurrent costs. The additional threshold is >US \$100. That way, some of the time taken to determine life years for inputs that are of low value but could potentially be capital inputs is removed (e.g., a computer mouse pad, a USB drive, a bedsheet, a small bottle to carry PrEP drugs discreetly).

The >US\$100 threshold does not mean that inputs of less than US\$100 should not be accounted for, but simply that they would be categorized as recurrent costs. As aforementioned in the discussion of purpose and type of cost, there is some debate about whether all recurrent costs should be itemized (e.g., down to the level of pens and stapler, all capital costs), given the time it takes to do so. This speaks to the level of precision of the cost estimate, and depends on the purpose of the cost estimate. For budgeting, it may be important to have a precise estimate, because pens and pencils for the intervention may not be covered by some macro-level administrative budget, and the intervention may need a lot of pens and pencils, especially over time. However, for a planning purpose such as an estimate at the more conceptual/initial stage of planning, cost data users may be comfortable with

estimates of capital costs and some recurrent costs¹² (with the exception of drugs, medical supplies, and laboratory costs) that are educated “guesses” as to the percentage markup to add to the total cost of other inputs. These educated “guesses” take a top-down approach, utilizing records of total past program expenditure and assessing the proportion of that expenditure that was recorded for capital inputs or recurrent costs not directly attributable to a specific activity within the intervention.

It should be noted that Appendix 6 gives an example of standardized cost categorization that seeks to include all anticipated cost inputs in distinct categories as proposed by the GHCC (https://ghcosting.org/pages/standards/appendices/standardized_TB_unit_costs). The actual inputs and the cost category classification developed by the analyst will depend on the purpose for which the cost data are being collected and used, and whether the organization requesting the cost data is already using standard cost categories. If the GHCC cost categories are not used, four general rules for cost classification should be followed. Cost categories should:

- **Be relevant to the purpose of the costing, and be aligned with pre-existing cost categorization of the organization (if applicable)**
- **Cover all anticipated inputs**
- **Be mutually exclusive**
- **Have transparency as to what inputs are included in each category**

In terms of mutually exclusive categorization, it may be helpful to provide two examples. As a first example, an analyst may misassign cells in his or her tabulation, adding an estimate from the broad category of “personnel” to an estimate of the cost for nurse time to provide counseling (as both “personnel” and “nurses” were perhaps given some type of personnel label). However, the broad category of “personnel” includes the input cost for nurse time, and thus the analyst would have been double counting the cost of the nurse time. In another case, an analyst may list the cost of nursing time for a specific activity (e.g., initiation counseling) as the personnel cost for the entire intervention. Here, the analyst would be undercounting the personnel cost category estimate for the intervention, as the other activities (e.g., performing medical tests, screening) also require nurse time that would feed into the overall personnel cost estimate.

¹² Such recurrent costs can include building/space (e.g., rent, utilities, maintenance) and non-medical supplies, in some cases labeled together as “indirect costs.”

METHODOLOGICAL PRINCIPLE 7 – MEASURING AND ALLOCATING RESOURCE USE



https://ghcosting.org/pages/standards/principles/resource_use_measurement#three

The principle:

The methods for estimating the quantities of inputs should be described, including data sources, criteria for allocating shared costs, and exclusion of research costs.

Summary recommendations:

This principle is important for determining the quantity/level of inputs, as over- or underestimation will bias results.

Recommendations for measuring resource use and allocation are as follows:

- **Although micro-costing (described in the following “Detail” subsection) is sometimes viewed as a gold standard, it is not recommended here as a universal minimum standard.** A mixed-methods approach is common, and may also be the best option.
- **The methods/criteria and underlying data sources used to allocate each input should be clearly reported (including if these are “top-down” or “bottom-up”), reflective of the usage of each input, and of the least bias possible.**
- Cost inputs that are expected to have the greatest impact on cost (e.g., above-site, personnel costs) may merit more concerted focus on the accuracy of allocation method.
- If research cost data are collected, clearly describe them and disaggregate whether they are included in the cost estimate or considered separately.

Detail:

There are different approaches for estimating the quantities of inputs. For *overall costing*, there are two approaches: **gross costing** versus **micro-costing (also called “ingredients-based” costing)**. In gross costing, input use is estimated from total cost, usually total cost divided by number of services provided. In micro-costing, input use is estimated for each input individually, utilizing observational studies of services or records to determine how much of an input is used.

When *allocating joint costs*, there are also two approaches: **“top-down”** versus **“bottom-up.”** In the top-down approach, total cost for an input that is reported centrally (i.e., across interventions or services in either a facility or a program) is allocated to specific service units using predetermined criteria that capture the amount of usage for that unit (e.g., floor space, staff numbers/minutes, number of clients/tests). In the bottom-up approach, levels of input usage are observed.

In general, gross costing uses the top-down approach to allocate joint costs, while micro-costing uses either the top-down or bottom-up approach to allocate joint costs. For example, within micro-costing, individual commodities might be enumerated individually, while a top-down approach might be used to allocate capital costs.

Different methods can result in significantly different cost estimates (Cunnama 2016), and each method has advantages and disadvantages. Because bottom-up methods are often observational and the observations are conducted at specific points in time, they may not capture some inputs that are not

being used at the time of observation. Such inputs can be better captured by the “overview” across the time period that is established in the top-down approach.

Above-site costs are very difficult to piece together using a bottom-up approach, and therefore could be missed without the addition of a top-down approach. In the few PrEP cost estimation studies to date where site-level operational costs, ancillary service costs, and above-site operational costs have been included, a mixed-methods approach has been taken. Generally, these inputs were allocated using a top-down approach based on criteria utilizing a simple formula related to the proportion of PrEP clients among all clients served. To note, given that above-site activities could add costs of 45 percent or more on top of the site-level service delivery costs (Clift 2016), more sophisticated methods may be required in the future to allocate these costs more accurately. One such method is called step-down, and has been primarily used in hospitals, where total costs for inputs are progressively broken into smaller divisions—first assigned to departments, and then to services. Another method is through regression and matched comparisons (where total costs are available with and without the intervention) to estimate above-site costs for specific service units.

Although a bottom-up method is more expensive and time-consuming, it can have significant advantages. **A bottom-up approach can capture inputs missed in a top-down method that relies on [potentially incomplete] records or a manager’s understanding of how the program/service functions, and it details specific input usage.** While a top-down approach does capture wastage/downtime in the cost, and this is important in fully capturing the cost, it does not detail how efficiently the program is operating. That is, although the top-down approach captures wastage/downtime, *it does not say what the split is between actual service delivery and wastage/downtime for something like personnel cost or the capital cost of a building.* For example, although a PrEP service may occupy a certain amount of floor space, it may not be using the floor space in an efficient way (e.g., boxes of junk taking up space) or using the floor space continuously (e.g., sharing with other services). If done properly, a bottom-up method can capture this detail and be used to inform how to improve efficiency and predict how costs will change if efficiency is actually improved. The costing will determine whether a bottom-up, top-down, or mixed approach is the most appropriate.

As mentioned in Principle 6, **human resource costs** can make up the largest proportion of cost at the service delivery level. Therefore, the method used to estimate the quantity of resource use, whether it be for service delivery, administrative tasks, downtime, or other opportunity costs, also merits particular attention. Staff recall can be inaccurate, particularly if the activities being remembered are for small amounts of time or irregular intervals of time. Researcher or provider recording of staff time through “time and motion” or “work sampling” methods can be more accurate. Further detail on these terms may be helpful, and can be found in Appendix 7.

Time and motion studies are being conducted within PrEP costing studies to better measure human resource inputs. They are particularly critical for better understanding the economic cost of personnel time for PrEP and the absorptive capacity of existing human resources as PrEP is introduced and scaled up. Time and motion studies can also be complemented by other methods that can be applied to measuring resource use for a diversity of inputs (and outputs; see Principle 9, “Measuring of units of outputs”). Examples of these inputs include interviews or focus groups; surveys with providers, clients, or client families/companions; and review of client records, provider time sheets, and provider logbooks. Each method does have biases (which can differ whether inputs or outputs are being considered), and such biases should be considered and addressed. For example, in the use of medical records for input measurement, provider time may not be readily accounted for if not spent directly

with clients (e.g., on notes, meetings), or may be inaccurately accounted for if spent addressing multiple issues for a client but only coded for one issue (e.g., the most highly reimbursed, most readily remembered).

Finally, one further area for concern in estimating the quantities of inputs is the allocation of costs between **research settings** that adhere to “normative best practice” guidelines and **“real-world”** interventions. In PrEP studies to date, research costs have been excluded from the unit cost calculations. As described in Principle 3, “Defining the type of cost,” the line between research and real world depends on whether the research site/population/delivery platform/type of input can adhere to normative best practice guidelines or if it is assumed to mirror real world intervention implementation. Also, the “accuracy” of a research-setting estimate for a real-world setting depends on whether expected real-world prices (e.g., public-sector wages instead of research study wages) are used in the research cost estimation. Further, while it may be straightforward to isolate research costs such as survey preparation or activities to reduce loss to research follow-up, it is more difficult to determine quantitatively how to adjust the [research-inclusive] cost estimate by the effect that the choice of research site/study population may have had in comparison to the effect it would have in a real-world setting. In this case, at a minimum, such bias should be considered and the theoretical direction reported.

METHODOLOGICAL PRINCIPLE 8 – SAMPLING



https://ghcosting.org/pages/standards/principles/resource_use_measurement#four

The principle:

The **sampling** frame, method, and size should be determined by the precision demanded by the PrEP costing purpose and designed to minimize bias.

Summary recommendations:

The sampling frame is important because it determines the boundaries of “what” [national/regional/geographic] locations, priority populations, service delivery platforms, and other factors can be represented by the collected data (i.e., generalizability), while the method and size affect “how well” the collected data represent the true costs within those boundaries. Method and size affect the level/form of bias (i.e., accuracy) and how many data points are available to inform the precision of the cost estimate.

The published guidance on sampling for cost estimation is not extensive enough to specify one “gold standard” sampling strategy. However, several general recommendations, drawn from overall guidance on sampling, can be made:

- Sampling should **begin with a recent, accurate, and complete sampling frame** of the sites/programs from which the sample will be drawn, and for some purposes the individuals expected to receive services within those sites/programs. If master lists are not available, the analyst may need to conduct an inventory. Such a frame is necessary for probability sampling methods (e.g., simple random sampling, cluster sampling) and helpful for contemplating the presence and directionality of bias when other methods are used.
- Decide on the most **optimal sampling methods to meet the purpose** of the cost estimation, and which methods will likely provide the most representative data within any resource or logistical constraints (see below for an overview of methods). Although convenience sampling, which can involve significant bias, is “convenient” and may initially be felt to be the only option feasible, it should be avoided when possible. Other methods such as stratified sampling (e.g., by platform/ownership/location or funding) or cluster sampling, which both involve randomization at the first or second stage, should be considered to reduce bias. Other non-probability methods known to reduce bias could also be considered. These include maximum variation or snowball sampling, which are useful in exploring upper/lower bounds in representativeness, and which include a fuller sample (e.g., private/traditional providers; providers working with, or individuals from, stigmatized populations) than could otherwise be obtained.
- **There is no recommendation that can be offered yet on sample size**. However, it is recognized that because both service utilization and costs to the service provider/client can vary widely between sites/platforms/priority populations, a larger sample would yield greater precision.
- As repeated in other principles, **it is important to transparently report and justify the approach taken, in this case regarding the sampling frame, sampling method, and sample size**.

Detail:

The sampling frame, method, and size are determined by the purpose of the cost estimation. They are particularly important when taking a bottom-up costing approach, given the necessity in a bottom-up approach to look at costs at individual sites. For example, the sampling may need to encompass multiple

priority populations and multiple types of service delivery platforms to capture the breadth of costs needed to financially plan for comprehensive service delivery. However, it is also possible that only one priority population and one type of service delivery platform will need to be sampled. This could be the case if the purpose is for the economic evaluation of a difference between an intervention and comparator that is independent of the priority population and platform, or if there is some political purpose dictating that one specific priority population or service delivery platform will be budgeted for. The sampling strategy can also be affected by resource and logistical constraints, which can lead to sampling methods (e.g., convenience sampling) and sizes (e.g., number of sites/programs¹³ <10) that produce unrepresentative results. The sampling strategy can also be constrained by the novelty of the intervention. If the intervention only exists in trial, pilot, or early rollout stages, the number and diversity of sites/programs/clients may be very limited. Therefore, study analysts may need to look to developing multi-country studies.

In reference to the development of a sampling frame, several resources are available that can assist with inventory and creation of master lists (Turner 2001, Turner 2003, United Nations 2005, Bostoen 2007, WHO 2012, Escamilla 2014). In general, in addition to obtaining records held by national MOHs and demographic/statistical agencies, district and local public authorities can be contacted for records. Governmental providers outside of health care (e.g., military, prisons) and private, employment-based (e.g., mining hospitals), non-profit, and faith-based providers can also be contacted to supplement MOH records. Existing geographic information system/global positioning system studies and software may also be of use, in addition to mapping/networking drawn from dialogue with local populations.

While there is no gold standard for determining facility/program sample size, a limited number of documents provide guidance for formally determining sample size for cost estimation. The RC describes several examples. For facility/program sampling, these include using methods developed for economic evaluation to determine a threshold level of difference between the comparators, methods developed for efficiency analysis that seek to establish the significance of specific cost drivers, and literature on multi-country studies that demonstrates approaches that involve sampling more countries versus more sites in fewer countries (GHCC 2017). For individual sampling, one example is the methods developed by WHO for tuberculosis (TB) patient cost surveys that utilized an “acceptable” level of precision around the difference in catastrophic costs over time (WHO 2017b, GHCC 2017, Lloyd-Williams 2013). Annex 3 of *Tuberculosis Patient Cost Surveys: A Handbook* (https://www.who.int/tb/publications/patient_cost_surveys/en/) has step-by-step instructions for sample size calculations and an example sampling procedure for a cluster sample survey for patient [client] costs.

A basic primer on sampling can be found in Appendix 8.

¹³ Some interventions do not have specific sites, but are population-wide, such as mass media.

METHODOLOGICAL PRINCIPLE 9 – MEASURING “UNITS” OF OUTPUTS



https://ghcosting.org/pages/standards/principles/resource_use_measurement#five

The principle:

The **selection of the data sources and methods for estimating the “units” for PrEP unit costs** should be described, and potential biases should be reported in the study limitations.

Summary recommendations:

To estimate a unit cost from a total cost, the unit of output (or denominator) is necessary. In Principle 4, “Clear definition of units,” the challenge of *defining which units* are needed for measuring PrEP interventions was described. Here, we describe *how to measure those units* of output. This is particularly tricky when routine systems are utilized for data collection and records are missing/incomplete, or when the records are not helpful in tracking clients across multiple services and providers (including private providers).

It is recommended that:

- **No one “gold standard” approach be taken.** This is because of the differences in activities that comprise PrEP interventions. (For example, while the overall PrEP intervention may have an output unit of “per client-year of PrEP,” an activity such as a community awareness “fair” for PrEP may need to be directly measured by the number of events rather than by the number of people reached). Another reason is because of the differences in precision and accuracy of specific approaches for a given context and study population.
- **The source of data (for measuring the unit) and the approach used to sample or fill missing data be reported, and the reason for selecting the approach be justified.** Multiple methods may be used to cross-check results, but are subject to resource availability.

Detail:

Some units can be estimated using top-down methods with program accounting and service records from routine reporting systems. For example, to determine the cost per HIV test, total HIV testing costs for a year can be divided by the number of HIV tests provided in that year to program clients. This method allows for cost estimates for specific outputs at specific points (e.g., number of HIV tests required during one year of initiation and continuation on PrEP; number of PrEP clients initiating at months 1,2, etc.; number of PrEP clients who come in for a prescription refill at months 1,2, etc.). However, if routine data systems have incomplete records, the denominator (i.e., output) for the cost estimate will be incorrect. Further complexities arise because routine data systems may not capture which specific clients were served or follow clients through the cascade of care, particularly if their care was obtained through multiple locations, providers, or sectors (e.g., public, private). Because PrEP is an ongoing intervention with various stages, intervention units measured as “per person served” (e.g., cost per client-year of PrEP provision) can’t be obtained without data that track specific clients at each step of the care cascade—screening, initiation, and continuation. This is because the analyst needs to understand for “per person served” what the average person got “served” with. Data on the *number* of clients receiving HIV tests, initiating PrEP, or coming in for a PrEP refill in each month during the costing period does not tell you, for example, how many of those clients coming in for a refill in a given month had initiated in the prior month. To understand retention over time, individual cohorts of clients must be tracked.

Where practitioner logbooks are complete and available, these can be very good sources, although caution needs to be taken to understand client flows and what the care cascade for PrEP is, so that these records can be aligned to see which clients have received which services. This helps to avoid missing gaps in care or double counting when the same client shows up in multiple logbooks. This is particularly true for PrEP, because of the multiplicity of services that can be offered under the purview of a PrEP intervention, or that are potentially useful for PrEP clients but “pieced out” into different departments or delivery platforms. Those conducting the costing should remember that some of these delivery platforms for PrEP can be off-site.

For activities such as community outreach and health fairs, it may be difficult to immediately measure the output per PrEP client served. For example, for community health fairs to raise awareness of PrEP, it could be challenging to get an estimate of the crowd size or the extent to which those attending the fair took up and then acted on information about PrEP. Therefore, the measure of the output unit may simply be the cost per event (i.e., the health fair). This cost could then be divided by, for example, the number of clients initiating PrEP in the year of the health fairs, and added to the intervention unit cost for each client-year of PrEP provision.

METHODOLOGICAL PRINCIPLE 10 – TIMING OF DATA COLLECTION

https://ghcosting.org/pages/standards/principles/resource_use_measurement#timing

The principle:

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.

Please note that the detail for this principle in the RC describes methods that are less applicable to PrEP, such as retrospective versus prospective data collection, given that PrEP is just being introduced. Therefore, retrospective data collection will not likely be possible. In addition, because the audience for the PrEP guidelines may find it simpler to have information on “timing” centralized in one principle, the PrEP-relevant content for this principle was combined with that of Principle 5, “Determining the appropriate time frame of cost data collection and disaggregated periods within the time frame.” For those wishing more detail on Principle 10, as stated by the RC, please visit the RC link above.

METHODOLOGICAL PRINCIPLE 11 – SOURCES OF PRICE DATA



https://ghcosting.org/pages/standards/principles/pricing_and_valuation

https://ghcosting.org/pages/standards/principles/pricing_and_valuation

https://ghcosting.org/pages/standards/principles/pricing_and_valuation

The principle:

Sources of *price* data should reflect the purpose of the PrEP costing and be comprehensive enough for each input to allow¹⁴ for estimation of financial or economic input costs for a given setting and time period.

Summary recommendations:

Clarity on the prices used in a PrEP cost estimation is essential for utilizing/adapting the estimate, particularly in a context with differing prices and currency.

It is recommended that:

- **The source of price data be aligned with the purpose** of the costing. For example:
 - Because analyses of technical efficiency utilize the actual prices paid, expenditure records are most useful.
 - Financial planning can have a time horizon extending years into the future. Therefore, it may be necessary to contact sources of price data (e.g., human resource managers, drug manufacturers) to ascertain if there is an expectation that prices will change with higher service volumes or if subsidies/price ceilings will be removed.
 - ✓ **Additional sources may be needed to adjust** salary and wage prices if monetized benefits (e.g., bonuses) and non-salary forms of remuneration (e.g., housing, bus/train passes, phone airtime credits) were not included in the original price data source, or if the original data source estimated salaries and wages from a “net” rather than a “gross” approach (gross being the salary/wage before taxes and other forms of remuneration are taken out).
 - ✓ **Additional sources may be needed to adjust** drug/commodity prices if transportation costs were not included in the original price data source.
 - Economic evaluations involve accounting for opportunity cost. Therefore, sources for replacement prices are sought (see Principle 14, “Using shadow prices”).
- **Distinctions be made between local and international prices and between traded and non-traded inputs** (to facilitate comparability of costs across settings), and sourcing be reported.

Detail:

As mentioned above, the source of the price data should align with the purpose of the costing. If the collected data are to be used, for example, for a medium-term expenditure framework that includes PrEP, the prices will need to be as specific to the local context as possible.

If the purpose of the costing is to develop a rough estimate for an investment case or for short-term planning to introduce PrEP on a trial basis, and no PrEP intervention has yet been implemented in the country, then analysts could draw on [secondary] cost input data already generated in other countries.

¹⁴ In combination with proper valuation of capital inputs and proper use of discount, inflation, and currency conversion rates detailed in forthcoming principles.

They could then adapt the data to the local economic context, expectations for intervention design, and PrEP drug manufacturing/purchasing options. For example, if there are good data from PrEP implementation in Kenya, and Uganda wants to introduce a similar program, then the human resource components of the Kenya PrEP cost could be adjusted by the nurse salary ratio or the per capita gross national income ratio¹⁵ of the two countries. Or, where it may not be feasible to adapt cost data from another country because of wide variation in economic context or service delivery, it may be possible to adapt cost data for some inputs from a similar service that is being locally delivered, such as HIV testing and counseling (HTC) and ART. For example, the cost of [capital] buildings and of counseling time for nurses delivering HTC and ART services should be similar to that utilized for PrEP. If extrapolating price data from one country to another, it is particularly important to adjust for the local economic context or to obtain local prices from a similar program for **non-tradable inputs**. These are inputs that are difficult to move out of the country because of local “roots” (e.g., buildings, staff, electricity, water, hotel accommodation, goods/services that are culturally specific) or high transportation costs (e.g., gravel that is very heavy and would cost more to ship than to produce in another country). Because these inputs have only local prices, their cost estimates can vary widely between countries.

Non-tradable inputs are in juxtaposition to **tradable inputs**, which are inputs that can be readily transferred to another country (e.g., drugs, medical equipment). These inputs have local prices and an international price listed on a global website (e.g., the Management Sciences for Health [MSH]/WHO *Global Drug Price Indicator Guide*). If a less accurate price estimate is suitable to the costing purpose, an international price source could be utilized. However, caution should be taken that the obtained price is specific to the product being used in the studied location, as the local price for a specific [imported] product may vary from the international price depending on manufacturer/donor agreements with the country; transport costs; the size of orders; and local production, economic conditions, and political decisions about the brand/source of the products.

This is particularly true for PrEP drug prices. Some countries may be importing branded Truvada, while others are importing generic drugs. Some countries may choose to use TDF/3TC rather than TDF/FTC, even though TDF/3TC may appear in their guidelines as an alternate or secondary recommendation to TDF/FTC (because TDF/3TC is already available in the country for ART). In addition, some countries independently manufacture TDF/FTC or TDF/3TC, and in those cases, there will be local prices for the drugs. Further, while manufacturers sometimes provide subsidies or donations in the pilot phase of a PrEP intervention, they may not continue to do so once there is broader interest in and a bigger market for the drugs. Therefore, gathering input (if available from manufacturers or organizations like CHAI) on the continuation of subsidies or donations is advisable. Please note that the local prices of new PrEP technologies (e.g., gels, rings) may be more variable than those for oral PrEP because they are still in trial stages. Also, it is not clear how the introduction of new PrEP technologies might affect demand for oral PrEP and whether there may be price competition between the technologies in response to shifts in demand.

Caution is also merited for laboratory test prices, as tests can make up a significant proportion of the overall cost of tradable inputs, depending on the different tests that are provided under PrEP (i.e., HIV tests, HBV tests) and how many times each is given. Hypothetically, if one were to find an average price for the Determine rapid HIV test kit in sub-Saharan Africa of US\$1.00 from a global website, one could see how this may or may not reflect local prices. In a recent study on the costs of facility-based HIV testing in Malawi, Zambia, and Zimbabwe, the approximate cost per Determine test in Malawi and

¹⁵ Available at: <http://databank.worldbank.org/data/download/GNIPC.pdf>.

Zimbabwe was actually US\$1.00. However, the Determine test cost up to US\$1.20 in Zambia, and in Zimbabwe the First Response HIV rapid test was additionally available at US\$0.71 (Mwenge 2017). Ethiopia recently imported the Beijing Wanta test at about US\$0.50 per test. However, like other countries, Ethiopia is reconsidering its mix and sourcing for rapid HIV tests, after both the First Response and the Beijing Wanta tests have been below the standard for efficacy in algorithm tests by national MOHs (Endeshaw 2017). A difference in price of US\$0.50 per test over millions of tests per year and several years of testing can produce a differential in the tens of millions of dollars.

Potential sources for price information on PrEP inputs is provided in Appendix 6. Please see Principle 14 (“Using shadow prices”) for further sourcing in regard to economic cost, and Principles 12 (“Valuing capital inputs”) and 13 (“Discount, inflation, and conversion rates”) for further information on price adjustment to reflect economic and financial cost. **An example of a facility-based survey tool to ascertain prices and quantities of inputs that feed into outputs, and quantities of outputs, is included in Appendix 13.** The piloting of cost data collection instruments before full application is advised, to better understand the effort that will be involved, and to refine the targeting of data collection to best meet the purpose of the study within available resources.

METHODOLOGICAL PRINCIPLE 12 – VALUING CAPITAL INPUTS



https://ghcosting.org/pages/standards/principles/pricing_and_valuation#three

The principle:

Capital input prices should be appropriately annuitized or depreciated to reflect the opportunity cost of capital inputs over the time frame relevant to the costing purpose.

Summary recommendations:

The importance of properly valuing capital inputs relates to the ability to properly plan to replace them as their utility (i.e., “useful life”) depletes (i.e., “depreciates”), and to account for the opportunity cost of investment in those inputs if they could have been put to another purpose elsewhere. Even if a capital input is not new, if useful years remain in its life, the assumption is that it could potentially be resold. Therefore, this “lack of sale” for each year of remaining useful life is an opportunity cost.

It is recommended that analysts:

- Determine if the purpose of the cost estimation requires a financial or economic estimation.
- Use **straight-line depreciation for financial capital cost estimation, which =**
current value of the capital input/“useful life” (measured in number of years).
- Use **annualization (also called amortization) for economic capital cost estimation, which =**
current value of the capital input/an annualization (amortization) factor.
- Report the **method of capturing depreciation and opportunity cost, the discount rate, and the useful life (i.e., length and data sources) for each [narrow] capital input category (see GHCC input and cost category classification in Appendix 6) and for each specific input that involves a new modality.**

Detail:

The annualization factor can be looked up in a table (e.g., Appendix 9, replicated with permission from the RSTT), where the analyst finds the *row* corresponding to the years of useful life, and the *column* for the discount rate being utilized (which adjusts the useful life by the opportunity cost of not investing, and having gotten an expected rate of return, elsewhere). The cell that matches the appropriate row/column will be the annualization factor that is used in the denominator of the annualization calculation. It is recommended that 3 percent be used as the default discount rate, to allow for comparability with other studies and internationally. A calculation using local discount rates should also be conducted where relevant.

The determination of “useful life years” can be tricky. The workbook companion for the *Collection of Cost Information on HIV Facilities and Services* (Beck 2011¹⁶) gives rule-of-thumb guidance on years of useful life for capital inputs as follows:

- Buildings: 30 years
- Beds, tables, and other furniture: 10 years
- Vehicles: 5–10 years
- Computers: 3–5 years

The U.S. Federal Reserve System¹⁷ uses similar life-year estimates to those listed above, with the addition of:

- Software: 5 years

However, because of differences in the quality of manufacturing/construction, the purpose that a capital input was designed for (e.g., an airport terminal and a health clinic are both “buildings,” but the former may be expected to have a much longer life), *the environmental conditions that a capital input is exposed to, the availability of maintenance*, and the intensity of use, a capital input may wear out more quickly in one context than in another. This is particularly true for PrEP, as most PrEP interventions are being implemented in sub-Saharan Africa, where environmental conditions may be harsh and maintenance poor or infrequent. In addition, for capital inputs that involve innovative modality and are new to the market, their useful life may be less well-established. WHO, as part of WHO-Choosing Interventions that Are Cost-Effective (CHOICE), has listings for selected countries and for averages across countries of life years for equipment and vehicles.¹⁸ However, it is advisable to first consult the central bank or monetary authority of the country where the study is being conducted.¹⁹

¹⁶ Available at:

<http://www.unaids.org/en/resources/presscentre/featurestories/2011/may/20110523manualcosting>.

¹⁷ Available at: <https://www.federalreserve.gov/federal-reserve-banks/fam/chapter-3-property-and-equipment.htm#subsection-113-830f338d>.

¹⁸ Available at: http://www.who.int/choice/costs/useful_life/en/.

¹⁹ A list of central bank and monetary authority websites by country is available at: <https://www.bis.org/cbanks.htm>.

METHODOLOGICAL PRINCIPLE 13 – DISCOUNT, INFLATION, AND CONVERSION RATES



https://ghcosting.org/pages/standards/principles/pricing_and_valuation#four

The principle:

Where relevant, appropriate **discount, inflation, and conversion rates** should be used to adjust prices to estimate the cost for other settings and time periods.

Summary recommendations:

The discount, inflation, and currency conversion rates all have an impact on the cost estimate, and transparency in these rates allows for better interpretation of the estimate. The *Reference Case for Economic Evaluation* also states that the discount rate is important because “when projecting costs and effects into the future, those costs and effects need to be discounted to reflect their value at the time the decision [regarding course of action] is being made...[which] ensures that the time preferences of the population affected by the decision are taken into account” (iDSI 2013). The spreading of the cost over time and utilization of a discount rate accounts for the preference of the population to enjoy the benefits of their investment sooner and to pay later. It also accounts for the loss of opportunity to invest in something like a treasury bond that repays with interest.

It is recommended that:

- For comparison purposes, a minimum **3 percent discount rate, in addition to the local [national] currency discount rate²⁰ (typically the treasury bond rate), be used and clearly reported**. Other discount rates could additionally be used (and reported) if they are relevant to the purpose of the costing (e.g., a standardized rate used by the national health system administration for budgeting).
- Costs be **presented in both U.S. dollars and local currency, with the currency year and the exchange rate (including source)²¹ also clearly reported**. If costs are reported over time, the mean exchange rate over that time period should be used.²² To facilitate cross-country comparison, costs could also be presented in international dollars, using a purchasing power parity (PPP) conversion²³ (i.e., a ratio between the prices to purchase a standardized basket of goods and services in different currencies) to establish a cost estimate that is more representative of “economic value” relative to inflation and cost of living.²⁴

²⁰ A list of central bank and monetary authority websites by country is available at: <https://www.bis.org/cbanks.htm>.

²¹ Exchange rates can be found from the MOF or Ministry of Economic Planning; the World Bank Global Economic Monitor at [http://databank.worldbank.org/data/reports.aspx?source=global-economic-monitor-\(gem\)](http://databank.worldbank.org/data/reports.aspx?source=global-economic-monitor-(gem)); or online at <https://www.oanda.com/currency/converter/> or <http://www.xe.com/currencyconverter/>.

²² In practice, some analysts also use the exchange rate at the midpoint of the time period, such as July 1 of a fiscal year that runs from January 1 to December 31.

²³ Available at: <https://data.worldbank.org/indicator/PA.NUS.PPP>.

²⁴ A simplistic instruction on PPP is commonly presented using the example of hamburgers: “If the price of a Big Mac is \$4.00 in the U.S. as compared to 2.5 pounds sterling in Britain, we would expect that the exchange rate would be 1.60 ($4/2.5 = 1.60$). If the exchange rate of dollars to pounds is any greater, the Big Mac [PPP] Index would state that the pound was overvalued, any lower and it would be under-valued” (<http://www.investopedia.com/updates/purchasing-power-parity-ppp/>).

- **If prices need to be estimated across time, the gross domestic product (GDP)** (i.e., a measure of inflation based on locally produced goods) **or the consumer price index** (i.e., a measure of inflation based on the price to purchase a basket of goods and services at a specific point in time) **be used for local non-tradable inputs,²⁵ and the commodity-specific price changes be used for tradable inputs.** For non-tradable local goods, it is preferable to inflate local currency and then convert. Conversely, for tradable and often globally purchased and priced goods such as HIV test kits (where current prices are not available), it is preferable to inflate using the U.S. dollar GDP deflator and then convert into local currency (GHCC 2017). Clearly report the measures of inflation used and the time frame.

Detail:

The RSTT has a brief section on inflation that may be useful, and is repeated in Appendix 10 with permission.

²⁵ GDP deflators and consumer price indexes can be obtained from MOFs or central banks, or from the World Bank at <https://data.worldbank.org/indicator/NY.GDP.DEFL.ZS> and <https://data.worldbank.org/indicator/FP.CPI.TOTL.ZG>, respectively. If using the World Bank data, you will need to go to the country of interest, use the number under the date of the cost data collection as your numerator, and use whichever year the price estimate is from as your denominator to get the ratio to use for the inflation rate.

METHODOLOGICAL PRINCIPLE 14 – USING SHADOW PRICES



https://ghcosting.org/pages/standards/principles/pricing_and_valuation#five

The principle:

The use and source of **shadow prices** to value inputs without a market price and the opportunity cost of time should be reported.

Summary recommendations:

The use of **shadow prices**, or the assignment of [inferred] prices where the prices paid for inputs in the production services do not reflect the value of those inputs, is important for estimating economic cost. This is because shadow prices give approximate costs when the existing prices do not reflect the actual value of a good or service.

It is recommended that:

- [For economic costing] the **price of donated or subsidized goods be adjusted 1) by averaging multiple estimates of market prices, 2) by the purchase price paid by the donor, or 3) by another approach defined and justified by the analyst.**
- Where **no market price exists (e.g., volunteer time)**, these inputs be valued, at a minimum, according to hypothesized market values (e.g., local market prices, domestic wage rates) or other proxies defined and justified by the analyst. Once the method for valuing inputs such as volunteer time has been chosen, **a source such as domestic wage rates should be chosen.**

Detail:

Each step in the choice of method, price source, and normative adjustment can markedly affect the shadow price utilized. As aforementioned, PrEP drugs may be subsidized or donated in some countries (at least initially), and may be the most important consideration for shadow pricing. However, if PrEP implementation changes from a clinic-based model to a community-based model, valuation of volunteer time could also become prominent. If a source such as a domestic wage rate is chosen for the valuation of volunteer time, the price (i.e., wage) may be adjusted on the basis of **normative social valuation**, which is valuation that is based on social preferences or policy goals (e.g., equal pay between genders, a raise in the minimum wage, a discounted price to achieve some other social good) (Islam 2006), and then applied to the number of hours of productivity “lost.” **Any normative adjustment should be described and justified.**

METHODOLOGICAL PRINCIPLE 15 – EXPLORING COST FUNCTIONS AND HETEROGENEITY



https://ghcosting.org/pages/standards/principles/analysing_and_presenting_results#heterogeneity

The principle:

Variation in the cost of the intervention by site size/organization, subpopulations, or other drivers of heterogeneity should be explored and reported.

Please note, this principle is complex and beyond the scope of these PrEP Costing Guidelines. For those wishing more detail on Principle 15 as stated by the RC, please visit the RC link above.

METHODOLOGICAL PRINCIPLE 16 – DEALING WITH UNCERTAINTY



https://ghcosting.org/pages/standards/principles/analysing_and_presenting_results#three

The principle:

The **uncertainty** associated with cost estimates should be appropriately **characterized**.

Summary recommendations:

Uncertainty is likely in any cost estimate, and characterization of this uncertainty to the greatest extent possible will allow for better interpretation and use of the data.

For PrEP studies with more than one site, there should be measures of precision such as confidence intervals or percentages. Where there are observations in the cost data with multiple reference points, there should be an examination of the distribution of this data and, if the distribution is not normal, utilization of appropriate statistical techniques. **Sensitivity analysis** can also be used to assist in mediating uncertainty.

Bias in cost estimates can be characterized by addressing:

- Disproportionate sampling of higher/lower cost sites or populations
- Incompleteness in elements of costs (e.g., inputs, service use, providers)
- Under-/overreporting of elements such as service and time use (due to the data collection methods or program features)
- Distortions or incompleteness in input prices

It is recommended to:

- Address bias, even if it is not possible to do so quantitatively. The **expected direction of the bias should be considered and reported**.
- Report any other **recommendations in terms of generalizability**, for example highlighting if the observed population or context has unique characteristics that affect the cost estimation and would need to be considered for program replication elsewhere, or if the program implementation has unique characteristics (e.g., unexpectedly large start-up costs, gaps in funding or coverage, over-/underutilization of staff) that would require changes to planning for program replication or expansion.
- Conduct sensitivity analyses and clearly report the cost components that were tested, why those components were chosen for testing, how the testing was conducted, and the ranges of results based on upper and lower bounds for each scenario in the analysis.

Detail:

As PrEP is new, and programmatic experience with populations outside of sex workers and in diverse contexts is limited, discussion of sampling biases may be particularly important. In addition, given the interest in PrEP for AGYW, biases in sampling regarding age should be explored, as sexual activity and perception of risk can change rapidly in each year of adolescence and young adulthood. As discussed previously, time use is not yet well-documented. (Some PrEP cost studies were conducted before programs were actually implemented, provider time was estimated based on other services, or provider cost was allocated by the proportion of total clients expected to partake in PrEP services). There may be

unexpected time commitments from staff other than doctors/nurses, such as pharmacists (for packaging/distributing drugs) and support staff (for obtaining more extensive client contact information or sending reminder notices). Further, prices of PrEP products may be distorted if they are obtained by an importing country based on prices in a country that produces TDF/FTC locally, if subsidies and regulatory requirements are not accounted for, or if the products are new (e.g., injectable PrEP now in trial) and their prices not well-established.

Finally, although it is beyond the scope of this document to discuss examination of non-normal distributions through statistical techniques and the use of advanced uncertainty analysis techniques to mediate uncertainty, there are two areas where some basic additional information may be helpful. The first, in Appendix 11, is the calculation of a confidence interval and introduction to basic sensitivity analysis, which is drawn with permission from the RSTT (please note that items in brackets are additional to the RSTT language). The second, in Appendix 12, can assist in determining the direction of bias.

METHODOLOGICAL PRINCIPLE 17 – TRANSPARENCY



https://ghcosting.org/pages/standards/principles/analysing_and_presenting_results#four

The principle:

PrEP cost estimates, including the methods used, should be **communicated clearly and transparently** to enable decision makers to **interpret and use** the results.

Summary recommendations:

Throughout the methodological principles, one key recommendation has been transparency. No matter how strong the methodological rigor, without reporting that is clear and comprehensive, cost estimates can't be comfortably interpreted and utilized. Through experience conducting systematic reviews of HIV and TB cost studies, the authors of these guidelines have found that something as simple as reporting the year and the currency associated with the cost estimate can be overlooked by study authors, which then leaves the reader of the study at a loss as to what the cost estimate could be in his or her present setting.

Detail:

Check  that **the following key areas are described in reporting of cost study methodology and cost estimates:**

- Purpose
- Specification and justification of methodological choices to address the purpose
- Priority population, intervention, and context
- Unit of measurement (preferably a standardized unit of measurement)
- Number of units (Data on service use are particularly important if a total program cost is given and a unit cost has not been provided.)
- Where intervention unit costs per client are composed of unit costs for services (e.g., visit costs) multiplied by service use (e.g., number of visits), these costs and quantities of output use should be reported. If feasible, "Ps and Qs" should also be reported for inputs (e.g., wages, staff numbers).
- Disaggregation of cost by activity or input cost category, and description of those inputs that are "tallied" within the activity or the input cost category
- Where relevant, disaggregation of cost by site, service delivery platform, ownership, or "other" (e.g., subpopulation) as determined by the analyst
- Where relevant, measure of dispersion around the cost estimates and characterization of bias
- Limitations of specific methods and key issues that may affect generalizability
- Conflicts of interest

Also, please note that:

- Demand for data sets to be available, via repositories that safely house the collection of data on specific topics, is growing. Therefore, consideration for how data may be shared outside of the study team and original data owners is advised. This requires thinking about the implications of making data available and public from the outset, and then identifying the implications for the whole process, from accessing sources, to obtaining ethics approvals, data collection, data coding and management to remove personal identifiers, and analysis. For example, it may be prudent to have the issue of data ownership written into the study protocol and addressed in the institutional review board application. If there are any limitations to accessing the data or to the security of the data, these could be addressed with the relevant funder and institutional review board.
- The results of any study should be fed back to the sites and organizations that requested the data collection, to validate and propagate the results.

The first part of the RC Appendix provides a more detailed and very useful “Principles and methods reporting checklist,” including a step-by-step list of the areas for reporting within each principle, and suggested options for how each of these areas could be described. **It is strongly recommended that this checklist be visited and utilized.**



https://ghcosting.org/pages/standards/appendices/principles_and_methods_reporting_checklist

APPENDICES

APPENDIX 1 – CURRENT NATIONAL GUIDELINES FOR PrEP

At present, reference to oral PrEP program implementation is made in the HIV prevention and treatment guidelines of nine developing countries. The documents and associated links are listed below, to allow for easier reference.

Republic of Botswana:

- Republic of Botswana Ministry of Health. 2016. Handbook of the Botswana 2016 Integrated HIV Clinical Care Guidelines. Available at: https://aidsfree.usaid.gov/sites/default/files/botswana_art_2016.pdf

Kenya:

- Kenya Ministry of Health, National AIDS & STI Control Programme. 2016. Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya. Nairobi, Kenya, NASCOP. Available at: <http://www.prepwatch.org/wp-content/uploads/2016/08/Guidelines-on-ARV-for-Treating-Preventing-HIV-Infections-in-Kenya.pdf>
- Kenya Ministry of Health, National AIDS & STI Control Programme. 2017. Framework for the Implementation of Pre-Exposure Prophylaxis of HIV in Kenya. Nairobi, Kenya, NASCOP. Available at: http://www.prepwatch.org/wp-content/uploads/2017/05/Kenya_PrEP_Implementation_Framework.pdf

Republic of Namibia:

- Republic of Namibia Ministry of Health and Social Services. 2016. National Guidelines for Antiretroviral Therapy. Available at: https://www.prepwatch.org/wp-content/uploads/2017/09/namibia_national_guidelines_art.pdf

Nigeria:

- Nigeria Federal Ministry of Health. National Guidelines for HIV Prevention, Treatment, and Care. Abuja, Nigeria, Federal Ministry of Health. Available at: https://www.prepwatch.org/wp-content/uploads/2017/08/nigeria_national_guidelines_2016.pdf

Republic of South Africa:

- Bekker LG, Rebe K, Venter F, Moorhouse M, et al. 2016. Southern African Guidelines on the Safe Use of Pre-Exposure Prophylaxis in Persons at Risk of Acquiring HIV-1 Infection. *South African Journal of HIV Medicine*, ISSN 2078-6751. Available at: https://www.prepwatch.org/wp-content/uploads/2016/03/PrEP_Clinicians_Guidelines_SA_March2016.pdf
- Republic of South Africa Department of Health. 2016. Guidelines for Expanding Combination Prevention and Treatment Options: Oral Pre-Exposure Prophylaxis (PrEP) and Test and Treat (T&T). Available at: <https://www.prepwatch.org/prep-resources/national-policies-guidelines/>
- Republic of South Africa Department of Health and the OPTIONS Consortium (probably, as the authorship is unclear). 2017. PrEP Implementation Pack: South Africa 2016–2017. Available at: https://www.prepwatch.org/wp-content/uploads/2017/07/SA_ImplementationPack.pdf

Kingdom of Swaziland:

- Kingdom of Swaziland Ministry of Health. 2015. Swaziland Integrated HIV Guidelines. Available at: https://aidsfree.usaid.gov/sites/default/files/tx_swaziland_2015.pdf

Republic of Uganda:

- Republic of Uganda Federal Ministry of Health. 2016. Consolidated Guidelines for Prevention and Treatment of HIV in Uganda. Available at: https://www.prepwatch.org/wp-content/uploads/2017/08/consolidated_guidelines_hiv_prevention_uganda.pdf

Zambia:

- Republic of Zambia Ministry of Health. 2016. Zambia Consolidated Guidelines for Treatment and Prevention of HIV Infection. Available at: https://aidsfree.usaid.gov/sites/default/files/zambia_hiv_gl2016.pdf

Zimbabwe:

- Zimbabwe National Medicines and Therapeutics Policy Advisory Committee and the Ministry of Health and Child Care. 2016. Guidelines for Antiretroviral Therapy for the Prevention and Treatment of HIV in Zimbabwe. Harare, Zimbabwe, Ministry of Health and Child Care. Available at: https://aidsfree.usaid.gov/sites/default/files/zw_arv_therapy_prevention.pdf

APPENDIX 2 – BASICS OF ECONOMIC EVALUATION

Cost-minimization analysis divides the difference in cost between two comparators (C1, C0) by the difference in effectiveness between the comparators (E1, E0): $(C1-C0)/(E1-E0)$. However, because cost minimization *assumes* that the effectiveness of the alternatives is equal, the equation is reduced to only the difference in cost. Cost-minimization analysis is most often used in the case of pharmaceuticals, where there is reliable evidence that a generic drug is of equal therapeutic effect to a brand-name drug. Generic TDF/FTC has been demonstrated to be equally efficacious and safe in comparison to branded Truvada. Therefore, cost-minimization analysis could be used for the economic evaluation of generic vs. branded TDF/FTC.

Cost-effectiveness analysis uses the same cost data as cost-minimization analysis, but does not assume that effectiveness is the same. A measure of effectiveness must therefore be chosen, and cost-effectiveness analysis uses a one-dimensional measure such as HIV infections-averted. So, if for example PrEP costs \$200 per client-year (C1) and averts 10 HIV infections in a specified time period (E1), while a mass media intervention costs \$75 per client-year (C2) and averts 1 infection in the same time period (E0), the **incremental cost-effectiveness ratio** (ICER) would be $(200-75)/(10-1) = 13.9$. Note that although the ratio may be positive, a CE threshold for all interventions (typically a multiple of national per capita GDP) may be used to determine whether or not to fund PrEP (Bertram 2016).

Cost-utility analysis uses a measure of effectiveness in the denominator that is comparable for different diseases. This measure is typically either a **quality-adjusted life year**, which represents an estimate of an individual's years of life gained through exposure to the intervention that is then adjusted by a factor corresponding to quality of health over those life years, or a **disability-adjusted life year**, which represents an estimate of an individual's years of life gained through exposure to the intervention that is then adjusted by a factor corresponding to quality of "capacity" (i.e., disease burden or disability) over those life years. Technically, this calculation is called an incremental cost-utility ratio (Jackubiak-Lasocka 2014). However, in common practice, cost-utility analysis is subsumed under the cost-effectiveness analysis umbrella and utilizes the terminology of ICERs (Neumann 2017).

Cost-benefit analysis uses a monetary measure of gains achieved as the denominator, which is then combined with the cost estimate in the numerator. By monetizing the denominator (e.g., the economic value of health gains), it is possible to have both the numerator and the denominator in monetary terms. A measure of benefit providing either PrEP or a mass media intervention to adolescent girls *could be* the number of additional years remaining in school for those exposed to the intervention, each additional year of school having been calculated by UNICEF to be worth an additional 10% in income (UNICEF 2015). So if PrEP costs \$200 (C0) and increases retention in education by 2 years (10% of expected income without retention in school is \$1000, so the benefit is $(\$1000 \times 2)$ (E1), mass media intervention costs \$75 (C0) and increases retention by 1 year ($\$1000$)(E0), the calculation would be: $(200-75)/(2000-1000) = .125$. However, it should be noted that this ratio is most often inverted to a **benefit-cost ratio** $(2000-1000)/200-75 = 8$, to place benefits at the forefront of attention (i.e., "bang" for the "buck").²⁶

²⁶ Further information about economic evaluation can be found in the references cited in this section and in the *Reference Case for Economic Evaluation*, developed by the iDSI and funded by the Bill & Melinda Gates Foundation at http://www.idsihealth.org/knowledge_base/the-reference-case-for-economic-evaluation/ or from WHO CHOICE at <http://www.who.int/choice/cost-effectiveness/en/>. Guidelines for benefit-cost analysis are also under development, led by the Harvard T.H. Chan School of Public Health and funded by the Bill & Melinda Gates Foundation. Preliminary materials can be accessed at: <https://sites.sph.harvard.edu/bcguidelines/>.

APPENDIX 3 – EXAMPLE: NATIONAL STRATEGIC PLANNING CYCLE

A mock-up of a national strategic planning cycle²⁷ was completed by the GHCC to better understand how cost data fit into the national strategic planning process for HIV. It is presented in Figure A-1 to illustrate that 1) planning cycles can be lengthy and start several years before a plan is finalized, 2) macro-level planning like national strategic plans and medium-term expenditure frameworks can draw from cost data collected initially for a multitude of purposes, and 3) planning processes are cyclical and therefore cost information that was developed for one or more purposes in the past cycle/s could potentially be used or modified in the forthcoming cycle (i.e., that cost estimation is not always, or even usually, “starting from scratch”).

Figure A-1: [HIV] National strategic planning cycle



One caveat on Figure A-1 should be noted. Each country may be at a different stage within this cycle in a given year, and may utilize different types of costing in a particular cycle. For example, some countries may have completed investment cases for all of HIV and TB, or for specific interventions/activities in the previous cycle, while others may not have had the resources or the need to do so.

²⁷ This mock-up was based on documents circulated by the World Bank (available at: <http://siteresources.worldbank.org/INTHIVAIDS/Resources/375798-1151090631807/2693180-1151090665111/RoadMAPforNSFversion7.pdf>) and information about utilization of the resource needs and goals models developed by Avenir Health (Korenromp 2015).

APPENDIX 4 – EXAMPLE: PREP ACTIVITIES (THAT GENERATE SERVICES)

This outline is provided as an example to allow for a more concrete reference point when considering how the RC Principle 1b on “defining the intervention [context and implementation]” applies to the specific case of PrEP. The outline gives a possible PrEP intervention implementation description, in terms of *which* activities/services are offered and *how often* (i.e., the quantity) they may be offered for different priority populations using PrEP, which is a foundational step in conducting a costing study. Please note that PrEP interventions in different contexts may significantly deviate from this outline in the activities/services offered and the timing of those activities, and may evolve in the future. Therefore, users of these guidelines would want to create their own outline that is specific to the PrEP program that they are costing.

For the purpose of costing PrEP, it is useful to recognize three groupings of activities used in health intervention costing:

- **Direct service delivery:** These services are those that are provided at the point of care (site), and generally involve interaction between health/lab personnel and the clients/client samples.
- **Ancillary service delivery:** These are activities that support the utilization/effectiveness of direct service delivery.
- **Operational activities:** This grouping of activities supports the functioning of the program/facility (and therefore applies across services).

Direct service activities

The outline of an example PrEP intervention (for oral PrEP) begins with a representation of potential **direct service activities (Figure A-2)**. The categorization of treatment phases is not yet clear in terms of the cascade of care. In Principle 6 on “Scope of the costing,” it is hypothesized that there would be an initiation phase encompassing screening and initial uptake of PrEP treatment, and a subsequent continuation phase.

Ancillary activities

For PrEP, **ancillary activities** principally fall into two categories:

- **Demand generation** is focused marketing/engagement to deliver information on the safety and benefits of PrEP that encourages HIV testing and initiation of PrEP for those who qualify.
- **Adherence/retention support** involves information about the importance of adhering to the recommended regimen, reminders about taking PrEP, counseling to understand the client’s experience of side effects and social/practical factors that may be prohibiting full use of the PrEP, drugs to alleviate side effects, and peer/community engagement to reduce stigma and provide a supportive environment.

Demand generation and adherence support will likely be critical to the success of PrEP. However, it is unclear which specific ancillary activities will be included in PrEP interventions, as most guidance documents offer only suggestions for these activities, or limited description of what a line for “information, education, and communication” (IEC) entails. A mock-up of potential demand generation and adherence support activities is provided in Figure A-3, with those activities listed in italics representing activities that are less likely to be implemented in a combined prevention program inclusive of PrEP, according to presently available guidelines (Republic of South Africa 2016, Republic of South Africa 2017, Kenya 2016, Kenya 2017, Celum 2011, <http://www.prepwatch.org/early-insights-prep-demo/>). Cells with a diagonal line are considered in this mock-up not to be PrEP-specific. It should

be noted that the categories of demand generation and adherence support are not mutually exclusive. That is because activities set up for demand generation (such as text messaging or peer counselors) could also be utilized also for adherence support. Further, activities for adherence support (such as clinical adaptations) could affect demand generation, because better services draw clients in.

Operational activities

Operational activities can be performed at both the **site-level** (where services are provided, whether it be at a facility or through outreach or community modalities) **and the above-site level** (also known as above-service level). With the exceptions of PrEP-specific training, the activities listed in boxes with diagonal lines are not considered to be PrEP-specific (Figure A-4). Note that when costing is conducted for the purpose of economic evaluation, portions of non-PrEP-specific costs at the site level should be added to PrEP-specific costs, given that they are necessary for the PrEP intervention to be implemented (see Principle 7, “Measuring and allocating resource use”).

Again, the mock-ups presented here are only hypothetical examples. The activities included in a combined prevention program with PrEP, and the delineation of which activities are considered to be PrEP-specific, will depend on national program planning and the purpose of the costing study in relation to such planning and monitoring.

Figure A-2: Illustrative oral PrEP-specific direct service activities within a combination prevention program

	HIV test	HBV test	HCV test	Liver tests	Kidney tests	Counsel -ing	Drug Pick-up	<i>PrEP adher -ence test</i>	<i>Preg-nancy, cervical cancer tests</i>	<i>Condoms, family planning</i>	<i>Post-abortion care</i>	STI symptom screen	STI lab screen	TB screen	<i>Alcohol screen, GBV screen</i>
Screening	Green	Green	Yellow	Grey	Green	Intake screening			Pink	Green	Pink	Green	Purple	Green	Green
Initiation						Green	Green			Green	Pink				
Month 1						Blue	Blue			Green	Pink				
Month 2						Blue	Blue			Green	Pink				
Month 3	Green					Green	Green	Green		Green	Pink	Purple	Purple		
Month 4						Blue	Blue			Green	Pink				
Month 5						Blue	Blue			Green	Pink				
Month 6	Green				Green	Green	Green	Green		Green	Pink	Purple	Purple		
Month 9	Green					Green	Green			Green	Pink				
Month 12	Green		Yellow	Grey	Green	Green	Green	Green	Pink	Green	Pink	Purple	Purple	Green	Green
Month 15	Green					Green	Green			Green	Pink				
Month 18	Green				Green	Green	Green			Green	Pink	Purple	Purple		
Month 21	Green					Green	Green			Green	Pink				
Month 24	Green	Green	Yellow	Grey	Green	Green	Green	Green	Pink	Green	Pink	Purple	Purple	Green	Green

Key: Green= general population; Yellow= MSM and PWID; Grey= those with hepatitis; Pink= adolescent girls and women of childbearing age; Purple= FSWs, MSM, and those with multiple sexual partners; Blue= adolescents and young adults; HBV= hepatitis B; HCV= hepatitis C; STI= sexually transmitted infection; GBV=gender-based violence. Activities in italics are those considered here to be less likely to be consistently implemented in a combination prevention program that includes PrEP. Boxes without a diagonal line through them *are* considered here to be PrEP-specific, while those with a diagonal line are not considered here to be PrEP-specific.

Notes: Please see specific notes regarding each activity on the following page.

HIV tests: HIV testing should follow the nationally validated testing algorithm. The majority of the studied guidelines and demonstration projects utilized a rapid test (e.g., Unigold, Determine) for the initial test, a second rapid test if the first test was positive, and enzyme-linked immunosorbant assay (ELISA) if there was a discrepancy between the rapid tests. Some materials also suggested HIV testing again at initiation (if there was a gap between screening and initiation of two weeks or more). The ITPrEP states that HIV testing is necessary prior to initiation, and suggests having it done again every three months thereafter.

Hepatitis B surface antigen (HBsAg) testing is recommended by the ITPrEP prior to initiation. If the test is negative, vaccination should be considered (although the cost of vaccination has not typically been included in the cost of PrEP). The South Africa guidelines state that if the patient has a positive test for hepatitis B surface antibodies, a vaccine is not necessary. If the HBsAg surface antigen test is positive, the patient should be referred for follow-up to assess liver function and screen for cirrhosis before consideration of PrEP. Hepatitis B is not listed as a contraindication for PrEP in the ITPrEP, although liver tests will be important to monitor for flares.

Hepatitis C testing is recommended prior to initiation in the South Africa guidelines for PWID (unclear frequency) and in the ITPrEP for MSM (every 12 months). Physicians in the United States have been requesting routine monitoring for Hepatitis C in MSM due to evidence of sexual acquisition of Hepatitis C while on PrEP (<https://www.poz.com/article/sexual-acquisition-HCV-26831-4735>).

Liver tests can include alanine aminotransferase (ALT) (GPT) and aspartate aminotransferase (AST) (GOT). Some costing studies in preparation for PrEP implementation have envisioned conducting liver tests at screening, one month, and every three months thereafter (for the general population), while the South Africa guidelines suggest only at screening and at the conclusion of PrEP (for those with hepatitis).

The **kidney test** is for creatinine clearance. The ITPrEP recommends testing before initiation, and every six months thereafter, although higher frequency of testing may be necessary for clients with diabetes or uncontrolled hypertension. The toolkit also suggests that testing could be done less frequently than six months if age is less than 45, baseline estimate creatinine clearance is >90 ml/min, and weight is above 55 kg.

Counseling generally involves routine addressing of side effects or concerns about PrEP, and counseling on effective PrEP adherence. Non-PrEP-specific counseling may also include routine counseling on HIV prevention through condom and risk-reduction behavior, prevention of STIs and information on how to recognize symptoms, and the addressing of mental health, sexual violence, and/or substance abuse issues. The initiation visit should also discuss willingness to take PrEP, develop a plan for PrEP use and sexual/reproductive health, and possibly review vaccination status for hepatitis A (in MSM), human papilloma virus, tetanus, and meningitis (WHO 2017a). Early experience with PrEP demonstration projects and rollout have reported that improving retention and adherence may necessitate 1) more regular counseling in the first few months (perhaps up to about month 6) and 2) actions additional to facility-based counseling (<http://www.prepwatch.org/early-insights-prep-demo/>), which will be discussed with ancillary activities. The ITPrEP states that PrEP-specific counseling may need to be more frequent for populations such as adolescents and young adults; therefore, adolescents and young adults in this mock-up are theorized to come in for a counseling visit every month for the first six months. In the ITPrEP, it is estimated that the initial visit would take approximately 30 minutes, and continuation visits about 15 minutes.

It is unclear how often patients must return to **pick up the ARV drugs** for PrEP. In this mock-up, it is estimated that they must return to a health facility or pharmacy every three months after initiation, as that is the recommendation of the ITPrEP. However, the ITPrEP also states that because discontinuation is highest in the first four weeks, it may be necessary to have a more frequent pickup, such as at the first month after initiation, or monthly for the first six months or so. Here, it was assumed that more frequent pickup of drugs would be directed to adolescents and young adults. The number of pills given out at one pickup is also not clear yet. While the ITPrEP states a 90-day supply for a three-month interval in the “pocket card,” the toolkit also states that it may be advisable to give up to one month of extra supply in case the client is delayed in returning. Finally, it may be that programs evolve with differentiated care so that 1) refills could be given in sufficient quantities to last longer between pickups (known as multi-month scripting), potentially at 3- or even 6-month intervals (also dependent on PrEP modality); 2) not every drug pickup needs to also have a visit for counseling (known as fast-track drug refills), which is shown in the adolescent group for prescription pickup after the first three months; or 3) sufficient quantities of drugs could be given to one person to pick up for a group of people in a community PrEP adherence group (WHO 2017a)(Prust 2017).

It is not yet clear whether **PrEP adherence monitoring** will be conducted and how, or whether it will be included in the costing of direct service provision, with ancillary activities, or as a research cost separate from the program cost. For those materials that did include adherence testing in cost estimates, it was generally for testing of blood plasma. Other forms of electronic or biological PrEP adherence testing have also been proffered in the PrEP literature, as self-report and pill counts have been shown to be inaccurate (Baxi 2015). Electronic surveillance through the Medication Event Monitoring System (MEMS-cap) has been demonstrated to correspond to blood plasma levels for PrEP, although it is expensive, difficult to transport, and indiscreet, and studies with drugs given to children have shown the possibility for inaccuracy if a patient opens the bottles a greater/lesser number of times than the actual number of pills that are taken out (Baxi 2012, Ingerski 2016). PrEP adherence as measured through hair samples is also

comparable to measurement through blood plasma, and is inexpensive to collect and transport, although there may be some places where it is culturally inappropriate to take hair samples (Baxi 2012, Liu 2014). In general, timing of adherence testing varied in the materials that included it, and seemed to be aligned with the timing of overall program monitoring.

Contraceptives have not been included to date in PrEP-specific costing, although they are offered as part of combination HIV prevention.

For **STI screening and testing**, some programs call for an STI symptom screen, an exam if positive, and lab tests for syphilis only (a rapid test, and if positive, an RPR titer); other programs call only for STI lab tests, but for more conditions (syphilis, gonorrhea, chlamydia, and *B. vaginosis*). The ITPrEP gives examples of STIs to screen for (syphilis, gonorrhea, chlamydia).

TB screening and TB testing were recommended in some of the reviewed materials, but without specific direction for what type of screening and testing. Also, if TB activities were recommended, it seems that TB screening would be the focus. Again, TB screening has not been part of PrEP-specific costing.

Figure A-3: Potential oral PrEP-specific ancillary service activities, within a combination prevention program

	Social media	Texts/SMS	Peers	Community health volunteers	<i>Community groups/mobilization</i>	Community events	Small cash/items	Billboards/flyers	Radio or television ads/dramas	Clinic adaptations
Demand generation										
Adherence support										

Key: SMS= short message service. Activities in italics are those considered here to be less likely to be consistently implemented in a combination prevention program that includes PrEP. In this example, boxes without a diagonal line through them *are* considered to be PrEP-specific, while those with a diagonal line are not considered to be PrEP-specific in the particular program being costed.

Texts/SMS: These are generally used for appointment reminders.

Peers: Peer-educators/leaders are people who speak to individuals or groups of similar age, gender, sexual orientation, or other demographic characteristics. The peer-educators/leaders selected for adherence support are PrEP users. **Community health volunteers** have a similar role, but may be trained in health care and may share only those demographic characteristics common to the neighborhood. Peers may be paid a salary, or, like community volunteers, may receive either cash or small items for [in the case of demand generation] each client that goes for an HIV test and each client that initiates PrEP.

Community groups/mobilization: This activity usually centers on reducing stigma.

Small cash payments or small items: This can involve paying clients a small amount to cover food/travel, or giving incentives such as raffle tickets (e.g., for t-shirts, water bottles) for each follow-up visit.

Clinic adaptations: These can include youth-friendly services, extended clinic hours, couples counseling, and assistance with setting client cell phone alarms/reminders.

Figure A-4: Potential oral PrEP-specific operational activities, within a combination prevention program

	PrEP-specific training	Other training	Maintenance (vehicle, building)	Support services (driving, cleaning)	HMIS/Record-keeping	Surveil-lance	M&E	Management/supervision	Procurement/supply chain/waste management	Lab system strengthening
Site-level										
Above-site										

Key: HMIS= health management information systems; M&E= monitoring and evaluation. Activities in italics are those considered here to be less likely to be consistently implemented in a combination prevention program that includes PrEP. Boxes without a diagonal line through them *are* considered here to be PrEP-specific, while those with a diagonal line are not considered here to be PrEP-specific.

APPENDIX 5 – PULLING KEY GUIDELINE PIECES TOGETHER: DEFINING THE INTERVENTION, UNITS, AND INPUTS

Appendix 5 is meant to put PrEP units in the context of the key pieces of the guidelines that define the units:

- Defining the Intervention, including the activities/services that make up the intervention approach (from Principle 1: see the [blue columns](#))
- Defining the units that relate (as shown through arrows) to the intervention level and activity/service level outputs (Principle 4 defining units: orange columns)
- Delineating inputs into cost categories necessary for some budgeting and planning purposes (Principle 4 discussion of the production process, Principle 6 on scope of the costing, Principle 11 on sources on input price data, and Appendix 4: green column)

Appendix 5 pulls together not only principles from the guidelines, but also numerous appendices (4, 6, and 7). It is advisable to review this appendix in conjunction with appendices 4, 6, and 7, as it may be challenging to interpret solely on its own.

The table below should not be taken as the final word on units for PrEP, given the novelty and evolving nature of PrEP implementation. Quality-adjusted activity/service output units are also suggested, and are based on the work of the STRIVE consortium in respect to stigma (<http://strive.lshtm.ac.uk/>). Please be aware that the example units given here may not align with those in various management information systems, and therefore additional data may need to be collected to adjust the reporting and to understand/explain how this adjustment may bias the estimate. As previously mentioned in Principle 4, due to space constraints it is not possible to cover all potential activity/service output units in this appendix. Therefore, you will notice the word “examples” designating where this is the case.

Intervention class; Intervention	Unit cost per intervention (quality-adjusted unit cost)	Population demographic; Population clinical	Platform type	Platform ownership	Treatment phase	Direct service, ancillary service, and operational activities	(Modality)	Unit cost per output direct service	Unit cost per output ancillary service; Operational activity (quality adjusted unit cost)	Input category breakdown
HIV prevention; PrEP	<p>Cost per client-month of PrEP provision</p> <p>Cost per client-year of PrEP provision</p> <p><i>Cost per client correctly using PrEP</i></p>	<p>(Demographic examples):</p> <p>General Women</p> <p>Adolescent girls and young women</p> <p>Men</p> <p>Adolescent boys and young men</p> <p>Men who have sex with men</p> <p>Transgender</p> <p>Sex workers</p> <p>People who inject drugs</p> <p>Prisoners</p> <p>Migrants and mobile populations</p> <p>(Clinical):</p> <p>HIV-Sero-discordant</p>	<p>Fixed Health Facility</p> <p>[Facility to local]</p> <p>Mobile outreach</p> <p>Community-based</p> <p>Population-wide (e.g., mass media)</p> <p>Laboratory</p>	<p>Public</p> <p>Private</p> <p>International NGO</p> <p>In-country NGO</p>	<p>Initiation</p> <p>Continuation</p>	<p>(Direct service examples):</p> <p>HIV testing</p> <p>Hepatitis testing</p> <p>Liver testing</p> <p>Kidney testing</p> <p>Counselling</p> <p>PrEP drug distribution</p> <p>(Ancillary service)</p> <p>Demand generation</p> <p>Adherence support</p> <p>(Operational on-site and/or above site)</p> <p>Training</p> <p>Maintenance</p> <p>Support services</p> <p>HMIS/Records</p> <p>Surveillance</p> <p>M&E</p> <p>Management/Supervision</p> <p>Procurement/ Supply chain</p> <p>Waste management</p> <p>Lab system strengthening</p>	<p>(Direct service examples):</p> <p>Rapid HIV test(s)/ELISA</p> <p>HBsAg surface antigen</p> <p>HBcAb surface antibody</p> <p>GPT, GOT</p> <p>Creatinine clearance</p> <p>Oral PrEP : TDF (300mg)/ FTC (200mg)</p> <p>(Ancillary examples):</p> <p>Social media</p> <p>Peers</p> <p>Community volunteers</p> <p>Community events</p> <p>Text messages</p> <p>Cash/material incentives</p> <p>(Operational examples):</p> <p>Training on youth-friendly interactions</p> <p>Accreditation of labs</p>	<p>(Examples)</p> <p>Cost per test</p> <p>Cost per screening</p> <p>Cost per regimen per month</p> <p>Cost per counseling visit</p> <p>Cost per prescription pick-up visit</p>	<p>(Ancillary examples):</p> <p>*Cost per community event</p> <p>*Cost per social media campaign</p> <p>Cost per peer/community volunteer visit</p> <p><i>Cost per client initiating who reported being reached by one or more demand generation activities</i></p> <p><i>Cost per client reporting normative change in stigmatizing attitudes and behavior</i></p> <p>*Cost per peer group session</p> <p>Cost per text message</p> <p>Cost per cash/material incentive given</p> <p>adherence support</p> <p><i>Cost per client adhering to treatment at 6 months</i></p> <p>(Operational examples):</p> <p>*Cost of program management per region</p> <p>*Cost of national IT service support</p> <p>*Cost per training</p>	<p>(Personnel)</p> <p>Direct service personnel</p> <p>Support personnel</p> <p>(Capital)</p> <p>Lab equipment</p> <p>Medical/ intervention-specific equipment (excl. lab)</p> <p>Non-medical/intervention-specific equipment</p> <p>Vehicles</p> <p>Building/space</p> <p>Other capital</p> <p>(Recurrent)</p> <p>Key drugs</p> <p>Medical/ intervention-specific supplies (excl. key drugs)</p> <p>Non-medical/ intervention-specific supplies</p> <p>Capital maintenance</p> <p>Utilities</p> <p>Fuel and other transport fees</p> <p>Food and supplements</p> <p>Other recurrent</p>

Notes: Units in italics are suggested quality-adjusted units. Arrows show how the output units relate to the activity/service or the intervention levels. Items with a * are joint costs that must be broken down (allocated) into the appropriate share for the intervention unit or specific direct/ancillary service output unit.

Platform type: Fixed facility examples are health outposts, health centers (1-2 beds), clinics (non-disease-specific) at hospitals, clinics (disease-specific) at hospitals, primary (district) hospitals, secondary (regional) hospitals, and tertiary (teaching) hospitals. Mobile outreach examples include: facility-based workers in outfitted mobile trucks/vans, or facility-based workers setting up temporary sites in a community building or camps, or facility-based workers visiting at-risk settings (brothels, bars, prisons) or households. Community-based examples are where community-based workers/volunteers set up services in community centers, schools, workplaces, or visit households. Population-wide examples are mass media, human rights advocacy, etc. Laboratory examples include clinic-based labs, and stand-alone labs.

APPENDIX 6 – GHCC INPUT AND COST CATEGORY CLASSIFICATION, WITH SOURCES

Cost categories		Description of inputs in cost categories	Sources for input price information
Personnel	Service delivery personnel	Doctors, nurses, counselors; Pharmacists; Lab/diagnostic personnel; Outreach workers, peer supporters; Community volunteers or home visitors	Program/facility payroll records; Interviews with health staff and administrative officials; MOH salary scales; ILO STAT database and Global Wage Report (http://www.ilo.org/ilostat/GWR); Wageindicator.org (https://wageindicator.org/main/salary/minimum-wage) for minimum wage shadow pricing and days worked/holidays by country; Program/facility purchase and expenditure records and local rental values (for benefits)
	Support personnel	Administrators, supervisors; Procurement officers, supply clerks, accountants; Legal staff; Receptionists; Social media coordinators, community strategy/mobilization supervisors; Data and IT staff; Drivers; Gardeners; Security guards; Kitchen staff; Custodians or cleaning staff	
Capital	Lab/diagnostic equipment	Centrifuges, incubators, microscopes, water baths, orbital shakers, hemoglobin meters, urine analyzers, liver/renal biochemistry analyzers	Program/facility purchasing and shipping order forms, invoices, and expenditure records; MOH and Ministry of Public Works (equipment costs; estimates of the cost per square foot/meter for buildings and/or the cost to replace a specific facility type; typical training expenses); Market prices (obtained from catalogs, price lists, or by visiting local vendors such as auto dealerships, electronic equipment retailers, farm supply retailers, and furniture or office supply stores); Local laboratory managers; Local surveying firms or architects; Local vendors such as event facilities, hotels, and caterers for training expenses
	Equipment (medical/intervention, excluding lab)	Refrigerators, freezers; Incinerators and autoclaves; MEMS caps, monitoring equipment; Tents	
	Equipment (non-medical/intervention)	Furniture: beds, benches/couches, chairs, desks, tables, lamps/fixtures, filing/drug cabinets, bookcases; Computers, monitors, liquid crystal display (LCD) projectors, printers; Software; Power outlets, paper shredders.	
	Vehicles, capital	Bicycles; Motorcycles; Cars, vans or SUVs; Trucks; Boats; Airplanes	
	Building/space, capital	Construction/purchased floor space in a health facility or training school; Truck containers; Storage facilities; Administrative offices; Wells; Latrines.	
	Other capital	Start-up training and materials; Licenses/copyrights	

Recurrent	Supplies (key drugs)	PrEP; Hepatitis/STI/opportunistic infection medication; Post-exposure prophylactics; Antibiotics; Contraceptives	Purchasing and shipping order forms, invoices, and expenditure records; Central medical stores; Market prices (catalogs, price lists, local pharmacies or other lab managers); Donors and pharmaceutical manufacturers; WHO global price reporting mechanism (http://www.who.int/hiv/amds/gprm/en/); Stop TB partnership global drug facility (http://www.stoptb.org/gdf/drugsupply/pc2.asp); MSH International Medical Products Guide (http://mshpriceguide.org/en/home/); CHAI ARV Market Report (https://clintonhealthaccess.org/2017-arv-market-report/); Médecins Sans Frontières Access Campaign (https://www.msfacecess.org/content/untangling-web-antiretroviral-price-reductions)
	Supplies (medical/intervention, excluding key drugs)	Vaccines; Syringes, test kits, sputum bottles, speculum, cotton swabs, microscope slides reagents; Gloves, gowns, masks, bandages; Small medical equipment; Small containers to hold drugs	
	Supplies (non-medical/non-intervention)	Pens, pencils, dry-erase markers, highlighters; Printer paper, Post-it notes, notebooks, calendars; Paper clips, binder clips; File folders; Envelopes, stamps; Tape, glue; Scissors, staplers, hole punchers, calculators; Memory sticks; Batteries; Lanyards	Program/facility purchasing and shipping order forms, invoices, and expenditure records; MOH and Ministry of Public Works (equipment costs and estimates of the cost per square foot/meter for buildings and/or the cost to replace a specific facility type; Central motor pool staff interviews and vehicle logbooks; Building and vehicle service/utility records; Market prices (catalogs, price lists, or by visiting local vendors such as auto dealerships/repair services, electronic equipment retailers, farm supply retailers, and furniture or office supply stores); Local laboratory managers; Local surveying
	Capital rental/maintenance	<u>Rent</u> for capital inputs; Maintenance: Painting, roof, heating/plumbing, windows; Tires, spare parts, oil/lubricants, tune-ups; Computer repair	
	Utilities	Lighting, heating, water; Telephone, internet	
	Fuel and transport fees	Gasoline, fuel; Tolls; Contracted transportation services	

			firms or architects; WHO-CHOICE* (http://www.who.int/choice/cost-effectiveness/inputs/price_non-traded/en/ and http://www.who.int/choice/cost-effectiveness/inputs/assumptions/en/)
	Food and supplements	Food (at facilities/meetings, for nutritional support to improve health or lessen side effects of drugs); Vitamins; Contracted meal services	Ministry of Agriculture food price lists; Market prices from price lists, catalogs, or visiting local vendors; Food and Agriculture Organization Food Price Monitoring and Analysis Tool (http://www.fao.org/giews/food-prices/tool/public/#/home)
	Other recurrent	Recurrent training; Medical malpractice insurance; Insurance for capital building, vehicles, or equipment; Registration fees for capital items, for memberships in professional organizations, or for use of copyrighted materials for communication purposes (e.g., icons, photos); Contracted services such as laboratory, storage, waste removal (even if just burning and/or burying), security, information technology if outsourced; Courier/UPS service; Other recurrent costs	Local vendors such as event facilities, hotels, and caterers for training expenses; Program/facility purchasing forms, invoices, and expenditure records; Local laboratory managers; Market prices (obtained from price lists, or by visiting local vendors of contracted services such as security); WHO-CHOICE (http://www.who.int/choice/cost-effectiveness/inputs/price_non-traded/en/)

Notes: Personnel includes benefits such as paid leave/holidays, health and life insurance, pension, relocation allowance, and housing. Capital includes inputs with a unit cost >\$100 and an expected life >1 year. Recurrent includes inputs with unit cost <\$100 and/or an expected life <1 year. *The WHO-CHOICE website states that it has prices for local non-traded goods, but the link provided is to the methodology for collecting those prices. However, there is a link to email WHO to obtain the prices.

APPENDIX 7 – DETAIL ON MEASURING HUMAN RESOURCE COSTS

Time and motion: A data collection method used for determining how to allocate staff time, which involves the researchers continuously following the practitioners for [preferably] a full day, continued for some number of days.

Work-sampling: A data collection method used for determining how to allocate staff time, which involves researchers recording or practitioners self-recording time spent on activities, at specific points in the day, continued for some number of days. This is done through interviews, or time sheets/logs that are either paper- or electronic-based (such as through mobile apps). Both time-motion and work-sampling can also involve sampling in terms of the interval for recurrence of study (e.g., once a month or every six months).

Practitioner time is generally measured in minutes. The annual salary of the practitioner (plus benefits) and the average number of days and hours worked by that practitioner are then needed to calculate salary per minute, and that rate is then multiplied by the number of minutes observed/recorded having been spent on a specific direct PrEP service to obtain the practitioner cost for that activity.

Alternatively, the number of minutes in a day spent on PrEP direct service obtained from observation can be divided by the total number of minutes worked in a year, and that proportion multiplied by the annual salary. For example, if a nurse spends 15 minutes of an 8-hour day, each of 240 working days a year (which excludes weekends, holidays, and 3 weeks of vacation), on direct client care for a PrEP adherence counseling visit, and makes \$50,000, then the calculation for the direct service *unit cost* would be:

1. $15/(8 \times 60) = 0.03125$, or the proportion of the workday spent on direct service for PrEP adherence counseling
2. $\$50,000/240 = \208.33 salary per working day
3. $0.03125 * \$208.33 = \6.51 per PrEP adherence counseling visit

Please note that in the above example, only the time for direct patient care is included. In the time and motion study, it may be found that 200 minutes of the practitioner's day is taken up with administrative duties. The daily rate for this time could be ascertained, and then multiplied by the proportion of time spent on direct care for the specific service unit (as a proxy for knowing exactly how many of those 200 minutes are for administration related to a PrEP adherence counseling visit). Also note that these calculations are only for one activity/service, and would need to be applied to each PrEP service/activity:

1. $200/(8 \times 60) = .41666$, or the proportion of the workday spent on administrative duties
2. $\$50,000/240 = \208.33 salary per working day
3. $0.41666 * \$208.33 = \86.80 for administrative duties each day (for all activities)
4. $0.03125 * \$86.80 = \2.71 for administrative duties per PrEP adherence counseling visit, assuming the proxy is valid

However, that may not be the case, as perhaps PrEP clients coming in for adherence visits require a disproportional burden of provider administrative time (e.g., arranging for further tests, referral to other services or social/peer support). If the time and motion study tracks what administrative provider time is specifically used for, then the specific minutes (of 200) could be used in a repetition of Step 1. If 20 minutes were spent, for example, on administration specifically for each PrEP counseling visit, then the cost for that administration would be \$8.68 rather than \$2.71, because the proportion of administrative service time for PrEP adherence counseling (0.10) was actually more than triple the proportion of direct service time for PrEP adherence counseling (0.03125).

APPENDIX 8 – BASICS OF SAMPLING

The main difference between probability and non-probability sampling is that probability sampling relies on chance to select the sample, while non-probability sampling relies on the judgment of the researcher. With probability sampling, each site/individual in the sampling frame has a known non-zero probability of selection into the sample. Non-probability designs are used when it is not feasible or practical to construct a sampling frame from which to select a sample, and may be more appropriate for exploratory research, to generate hypotheses or to test potential specific research questions. It is not possible to calculate the probability of each member of the priority population being selected into the sample. These methods also do not necessarily produce samples that are representative of the priority population, and the sample may be biased (Turner 2001, GFATM 2016, UNAIDS 2015d, Rubin and Babbie 2009, Mantell 2013, WHO 2001).

Probability sampling designs

A **simple random sample** employs a list of all of the units in the area/population that could be sampled (i.e., a sampling frame), with a unique identification number assigned to each unit. The sample is randomly drawn from this sampling frame using a lottery procedure, random number tables, or a freely available random-number-generating computer program;²⁸ individual numbers are selected until the desired sample size is reached. A simple random sample has known statistical characteristics, has a small standard error (which can be further reduced by increasing the sample size), and produces a sample considered representative of the priority population/priority group of sites. However, there are some drawbacks. These include possible misrepresentation of groups/types of sites that are rare, and inefficiency in data collection if the sampling area is very large and it is difficult to collect data from the randomly chosen units because they are widely dispersed across the area.

A **systematic random sample** is similar to a simple random sample except that the selection of elements into the sample is done systematically rather than randomly. This serves to ensure the sites/respondents are spread throughout the entire sample frame. To conduct a systematic sample, the full sampling frame is divided by the intended sample size (say a 5,000-element sampling frame divided by a 100-element sample size) to get a sampling interval (in this case 50). Then the researcher would start at a random starting point within the sampling interval (say 20), and then every 50th element would be selected.

Cluster sampling involves multiple stages, and serves to disperse the sample throughout the priority population while minimizing costs when the sampling frame is spread over a large geographic area. First, the priority population is divided into mutually exclusive groups (or clusters), such as states, districts, or villages, from which a sample of clusters is drawn. Then, within each selected cluster, either all the elements in the cluster, or a sub-sample of elements in the cluster, is selected. If the elements in the cluster are clinics, and it is necessary to sample staff or patients (to assess for example staff time spent on PrEP clients or time spent by PrEP clients to access care), then the site selection may be followed by a final selection of individuals in/attending each selected clinic. Although more efficient in large geographic areas than a simple random sample, cluster sampling is less accurate through increased sampling error because there tends to be more diversity between clusters than within clusters, as

²⁸ Examples of free online number generator programs include:
<http://www.softpedia.com/get/Others/Miscellaneous/2xDSoft-Random-Number-Generator.shtml> and
<https://www.mediafireware.com/free-number-generator.html>

sampled elements tend to be more similar to those around them than those far away. Sampling error may be reduced by increasing the sample size and increasing the homogeneity of the elements sampled. This could be achieved by increasing the number of clusters selected initially (clusters are likely to be more diverse from each other) and reduce the number of individuals selected in each cluster (likely to be more homogenous within clusters).

Stratified sampling is typically used when the research question calls for ensuring that certain sub-elements are included or the analysis requires oversampling of some sub-elements (such as public/private/NGO clinics or priority groups for PrEP like adolescents, sex workers, and MSM). For stratification, the sampling frame is divided into strata aligned with the research question. The elements are then enumerated for each stratum and the sample is selected from the strata using simple random or systematic random sampling. The sampling may be proportionate, with the same proportion of elements from each stratum, or disproportionate, with varied proportions across strata. The decisions about the proportions would be determined based on the research question, standard error, and cost estimates. It should be noted that variance may be lower than in a non-stratified sample because there is likely to be more homogeneity within strata.

Non-probability sampling designs

Purposive sampling is when the researchers select elements that meet predefined criteria relevant to the research question. This may be necessary due to cost or time constraints, or because an intervention or technology (such as PrEP) is new and there are few sites providing care or few clients receiving care. In-depth knowledge of the services being provided and the populations prioritized for services is helpful for making the best judgment call about which elements to select. However, purposive sampling remains subject to numerous forms of bias because the selection is done to meet the predilections and efficiency needs of the researchers rather than to meet statistical rigor, and should be used with caution.

Quota sampling is a form of purposive sampling that selects elements that fit particular sets of characteristics (e.g., sites that are publicly owned, female adolescents 15–18 years old). The sampling frame is often divided into relatively homogeneous strata, and each stratum is then sampled proportional to its size in the overall sampling frame to increase representativeness. A matrix that represents all the characteristics of interest for a given element (such as platform, ownership, urbanicity for sites) be constructed. Once the cells are populated, they will be sampled proportional to the size of the cell in the total sampling frame.

Chunk sampling seeks to get a sample of elements (usually individual people) that fit specific characteristics and are “gathered” together by proximity of location or by some other feature, such as the time of day they are most commonly present/open/operational.

Snowball sampling is generally used when the elements in the sampling frame are people, and particularly people who are part of a priority population that is hard to reach (e.g., PWID, out-of-school children), although it can also be used to find service providers who are “under the radar” (e.g., traditional healers, providers of services that are not socially or politically popular). It begins with the selection of a few individuals who are members of the population of interest, and then these individuals are asked to provide contact information for additional respondents in their social network, and those additional respondents are then asked to provide information on their contacts in the priority population, and so forth until the target sample size is achieved. The sample may be biased because more interested/healthy/cooperative people could first come forward and then recommend people like

themselves, or respondents may be loath to provide contact information for friends they feel may get in trouble (e.g., sex workers, PWID). Although a larger sample may reduce some bias, a larger sample takes longer, and those who are selected later may have different exposure (van Rooyen 2015, Thompson 2002).

Respondent-driven sampling is a method developed to address common biases in snowball sampling. To sample sex workers in a particular city, for example, the researcher first uses pre-existing contacts to purposively select six to ten (preferably diverse) sex workers from the priority population who serve as the initial study respondents (seeds). The researcher provides the seeds with a reward for completing the interview and then offers an additional incentive if they recruit their peers to participate in the study. The seeds are given a set of recruitment coupons to use to recruit their peers, which does not require giving the researcher contact information for the peers or other sensitive information that may hinder recruitment or participation. When a new peer turns in the coupon and completes the interview, both he or she and the referring seed receive a reward, and the new peer becomes a seed and is given recruitment coupons. This recruitment process continues through multiple waves until the sample is considered unbiased, which is when in-group affiliation, or the degree to which individuals are quite similar to their peers, is equal across groups initiated by the seeds (Salganik 2004, Heckathorn 2002).

Capture-recapture is a method also used to sample hard-to-reach people such as sex workers or homeless adolescents. It requires that two samples are taken, and then the number of captures from the first sample are divided by the proportion of those captures that are re-captured in the second sample. The samples may be drawn from lists of clients served for a program, from registries, or by sampling from geographic areas. In practice, it is more of a non-probability method because it can be difficult to randomly “capture” members of the priority population. To make a capture-recapture more generalizable, the researcher may first want to interview members of the priority population or persons working with them to better understand and define the characteristics of the priority population, and could potentially enlist the support of those persons to do the “capturing.” Using a larger sampling area, using multiple sampling areas of diverse geographic representation, or drawing the sample from different times of day may help with obtaining a more diverse sample that can be generalizable. The researcher may also wish to validate with another method (Stark 2017, Vulsteke 2010, Ruiz 2016).

APPENDIX 9 – ANNUALIZATION FACTORS

N = Number of remaining years of useful life.

Column headings with % labels are the discount rates.

<i>N</i>	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%	11%	12%	13%	14%	15%	16%	17%	18%	19%	20%
1	0.99	0.98	0.971	0.962	0.952	0.943	0.935	0.926	0.917	0.909	0.901	0.893	0.885	0.877	0.87	0.862	0.855	0.847	0.84	0.833
2	1.97	1.942	1.913	1.886	1.859	1.833	1.808	1.783	1.759	1.736	1.713	1.69	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	2.21	2.174	2.14	2.106
4	3.902	3.808	3.717	3.63	3.546	3.465	3.387	3.312	3.24	3.17	3.102	3.037	2.974	2.914	2.855	2.798	2.743	2.69	2.639	2.589
5	4.853	4.713	4.58	4.452	4.329	4.212	4.1	3.993	3.89	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	3.41	3.326
7	6.728	6.472	6.23	6.002	5.786	5.582	5.389	5.206	5.033	4.868	4.712	4.564	4.423	4.288	4.16	4.039	3.922	3.812	3.706	3.605
8	7.652	7.325	7.02	6.733	6.463	6.21	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	8.53	8.111	7.722	7.36	7.024	6.71	6.418	6.145	5.889	5.65	5.426	5.216	5.019	4.833	4.659	4.494	4.339	4.192
11	10.368	9.787	9.253	8.76	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	5.66	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	6.75	6.424	6.122	5.842	5.583	5.342	5.118	4.91	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	10.38	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	4.73
17	15.562	14.292	13.166	12.166	11.274	10.477	9.763	9.122	8.544	8.022	7.549	7.12	6.729	6.373	6.047	5.749	5.475	5.222	4.99	4.775
18	16.398	14.992	13.754	12.659	11.69	10.828	10.059	9.372	8.756	8.201	7.702	7.25	6.84	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	8.95	8.365	7.839	7.366	6.938	6.55	6.198	5.877	5.584	5.316	5.07	4.843
20	18.046	16.351	14.877	13.59	12.462	11.47	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	4.87
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	19.66	17.658	15.937	14.451	13.163	12.042	11.061	10.201	9.442	8.772	8.176	7.645	7.17	6.743	6.359	6.011	5.696	5.41	5.149	4.909
23	20.456	18.292	16.444	14.957	13.489	12.303	11.272	10.371	9.58	8.883	8.266	7.718	7.23	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	12.55	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	7.33	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	10.81	9.929	9.161	8.488	7.896	7.372	6.906	6.491	6.118	5.783	5.48	5.206	4.956
27	23.56	20.707	18.327	16.33	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	13.406	12.137	11.051	10.116	9.307	8.602	7.984	7.441	6.961	6.534	6.152	5.81	5.502	5.223	4.97
29	25.066	21.844	19.188	16.984	15.141	13.591	12.278	11.158	10.198	9.37	8.65	8.022	7.47	6.983	6.551	6.166	5.82	5.51	5.229	4.975
30	25.8	22.396	19.6	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

APPENDIX 10 – ADJUSTING FOR INFLATION

Inflation is the process whereby the general price level is rising and money is losing its value (i.e., a dollar in 1900 is not the same as a dollar in 2018). As expenditures may not all occur in the same year, it is often necessary to adjust for inflation. This allows one to make calculations with costs from multiple years (e.g., to estimate total costs for a project spanning multiple years, to compare costs from different years, to understand if differences in costs are due to differences in real resource use or just differences in price levels, to help predict future costs).

To adjust for inflation, the cost must be multiplied or divided, depending on whether the adjustment is to the future or the past, respectively, by $(1 + \text{inflation rate})$ for each year of adjustment. When using an average inflation rate over several years, you can use a shortcut and have the years as the exponent of $(1 + \text{inflation})$. For example, adjust US\$10 in 2009 with the average inflation rate between 2005 and 2010 being 5%:

From 2009 to 2010: $\$10 * (1 + \text{inflation rate})^{\text{years of adjustment}} = \$10 * 1.05^1 = \$10.50$

From 2009 to 2005: $\$10 / (1 + \text{inflation rate})^{\text{years of adjustment}} = \$10 / 1.05^4 = \$7.83$.

APPENDIX 11 – CALCULATION OF A CONFIDENCE INTERVAL AND BASIC SENSITIVITY ANALYSIS

Calculating a confidence interval is a straightforward job. The data needed are:

- The average value (cost) of the parameter to be evaluated
- The standard deviation
- The number of items in the sample (or the population)

In Excel, an **average cost** can be calculated as:

=AVERAGE(select the range of the sample observations or estimates)

For example, in the Excel spreadsheet it would look like: =AVERAGE(A1:A12).

Do not forget to put the equal sign in front of the formula.

The **standard deviation** is calculated as:

=STDEV(select the range)

This is the same range over which the average was calculated, so from the example above, the standard deviation is calculated using =STDEV(A1:A12).

And finally, the confidence interval is calculated as:

=CONFIDENCE(alpha, s, n)

alpha: is the significance level. It equals 1 minus the confidence level (expressed as a decimal).

So, for 95% confidence interval (CI), alpha will be $1 - 0.95 = 0.05$.

For 90% CI, alpha will be $1 - 0.90 = 0.10$.

For 99% CI, alpha will be $1 - 0.99 = 0.01$.

Greater confidence would require more data to generate intervals of usable lengths. This can vary, but common practice is to use a value of 0.05 to start off the analysis.

s: standard deviation

n: the number of items in the sample ("population"). For the example above, this would be 12.

In a basic sensitivity analysis, the cost for specific cost categories, activities, or inputs that are anticipated to have a significant impact on total/average cost can be manipulated up/down by specific percentages. The percentages used should be in line with informed assumptions about potential magnitudes of change for those inputs. [For example, sensitivity analysis could explore if artificial ceilings on wage rates were lifted and wages rose by 10%, 20%, or 50%, or if there may be task shifting down to lower cadres that would have lower wage rates. The example below explores how variations of -50%, -20%, -10%, +10%, +20%, and +50% would affect an average cost estimate for personnel (say \$448). In this case, we would have:

- -50% of \$448 would be \$224
- -20% of \$448 would be \$358
- -10% of \$448 would be \$403
- +10% of \$448 would be \$493
- +20% of \$448 would be \$538
- +50% of \$448 would be \$672]

APPENDIX 12 – DETERMINING DIRECTION OF BIAS

Here is a simplistic version of assessment of direction of bias. Here we have effect, and a threat (something that will bias the estimate). Each has a positive or negative sign, and it is a matrix table.

	Threat >0	Threat <0
<i>Effect >0</i>	+	-
<i>Effect <0</i>	-	+

For example, if the effect you are looking at is that personnel costs increase total/average cost, then you have a positive sign for effect of personnel cost. If facilities that had higher cadres of personnel implementing the intervention were oversampled, the threat would have a positive sign. The direction of the bias (positive effect*positive threat) would then be a positive sign, and the cost estimate is likely to be an overestimate.

However, if the threat is that some inputs were not included in the data collection and they have an impact on personnel cost (such as some cadres of staff), the threat has a negative sign because those costs are essentially subtractions from what should have been the full input list for personnel. Therefore, the direction of the bias (positive effect*negative threat) is a negative sign, and the cost estimate is likely an underestimate.

APPENDIX 13 – FACILITY-BASED SURVEY TOOL***Introduction to the study and costing: consent form***

Good morning/afternoon. My name is _____. I am working on behalf of _____, on a project that aims to provide PrEP services to various populations. In this project, we want to learn the costs of providing PrEP services.

Invitation to participate: We are asking you to participate in a research study.

What is involved in the study: You will be participating in a 90–120 minute structured interview.

Risks: There are no risks associated with participation. Confidentiality will be maintained, and no names will be mentioned in the report.

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are entitled, and you may discontinue participation at any time without penalty or loss of benefits to you. However, although all efforts will be made to keep personal information confidential, absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the research ethics committee.

If results are published, this may lead to individual/cohort identification.

If you would like to know more about this study, please contact _____.

Your help with this survey is greatly appreciated!

Section I: Identification Information

Questions 1–8 should be answered by the research assistant. Section II onwards **should be asked of the facility in-charge/facility manager.**

	Name			Notes
1. Name of facility				
2. County				
3. Sub-county				
4. Cluster/region				
5. Location: 1 = Urban 2 = Rural 3 = Peri-urban				
6. Survey administrator information				
6.1: Name of interviewer: _____		6.5: Person interviewed: _____		
6.2: Signature of interviewer: _____		6.6: Title of person interviewed: _____		
6.3: Name of supervisor: _____		6.7: Phone number of person interviewed: _____		
6.4: Signature of supervising officer: _____		6.8: Email of person interviewed: _____		
7. Interviewer visits				
	1	2	3	Final visit
Visit date				Day: _____ Month: _____ Year: _____ Results*: _____
Interviewer name				
Results:				
Next visit: Date	_____	_____	_____	Total number of visits
Next visit: Time	_____	_____	_____	_____
Time started	Hour □ □ Minutes □ □		Time ended	Hour □ □ Minutes □ □

*** RESULTS CODES:**

- | | |
|--|--|
| 1. Completed | 8. Completed |
| 2. No facility in-charge/other respondent during the interview | 9. No facility in-charge/other respondent during the interview |
| 3. No personnel available during the time | 10. No personnel available during the time |
| 4. Postponed | 11. Postponed |
| 5. Refused | 12. Refused |
| 6. Partly completed | 13. Partly completed |
| 7. Others (specify) | 14. Others (specify) |

Section II: Questionnaire**1. Key population: (Check all that apply)**

- 1=MSM 2 = FSW 3 = AGYW 4 = General
 5 = Discordant couple 6 = IDUs 7 = Other (specify)

2. Facility category: (Check all that apply)

- 1=Hosp. 2 = HC 3 =Dispensary 4 = Youth friendly centre 5 = DICES/DICs
 6 = Private for-profit clinic 7 = Private not-for-profit clinics 8 = Outreaches
 9 = Other (specify)

3. Facility ownership: (Check all that apply)

- 1 = GoK 2 = CSO 3 = Private for profit 4 = Private not for profit
 5 = other (specify)

4. Provider of PrEP: (Check all that apply)

- 1= CSO 2 = MOH 3 = Private for profit 4 = Private not for profit

5. Mode of service: (Check all that apply)

- 1=YFC 2 =Integrated public facility 3 = DICES/DICs 4 = Private for-profit clinics
 5 = Private not-for-profit facilities/clinics

6. Total number of inpatient health clients at this facility (April–September, 2017)

7. Total number of inpatient health clients at this facility (April–September, 2017)

8. How many people were tested for HIV to determine their eligibility for PrEP (April–September, 2017)?

9. How many people declined to be tested for HIV?

10. How many were eligible after testing to participate (April–September, 2017)?
11. How many were accepted to pursue PrEP (April–September, 2017)?
12. How many actually enrolled in PrEP (April–September, 2017)?
13. What is the total number of MSM PrEP clients who have been enrolled for PrEP at this facility (April-September, 2017)?
14. What is the total number of FSW who have been enrolled for PrEP services at this facility (April-September, 2017)?
15. What is the total number of AYGW who have been enrolled for PrEP services at this facility (April-September, 2017)?
16. How many PrEP clients could your facility attend to in a month with your current staff and facilities?
17. Does your facility charge for any PrEP services? Yes No
18. If **YES**, for which specific PrEP services do you charge? And amount of fee? (Check each service and amount paid.)

Service	Check services charged	Charge (Kshs)
1. Consultation		
2. HIV testing and counseling		
3. PrEP drugs		
4. Kidney function test		
5. Liver function test		
6. Urinalysis		
7. Serum creatinine and creatinine clearance		
8. Hepatitis B surface antigen		
9. Hepatitis C antibody		
10. Rapid plasma reagent		
11. Pregnancy testing		
12. Other (specify)		

19. How much does your facility or do your partners typically spend on mobilization for PrEP services in a month?

20. What is the source of the money for mobilization?

Facility fund (revenue from facility)	
Partner fund (direct support by partners)	
Other 1(Specify)	
Other 2 (Specify)	
Other 3 (Specify)	

21. For how many months has your facility been providing PrEP services to key populations?

Number of PrEP visits per month	Enrollment visit	Follow-up visit 1	Follow-up visit 2
April			
May			
June			
July			
August			
September			

22. Please enter number of patients and visits by month according to the table breakdown below.

Client summary	Apr	May	Jun	Jul	Aug	Sep	Total
All clients for any service (in-patient and out-patient) including PrEP and non-PrEP)							
Patients for treatment services							
Clients for prevention services including PrEP							
PrEP clients (FSW)							
PrEP clients (MSM)							
PrEP clients (AYGW)							
Number of continuing PrEP clients (FSW)							
Number of continuing PrEP clients (MSM)							
Number of continuing PrEP clients (AYGW)							
Clients discontinued PrEP services (FSW)							
Clients discontinued PrEP services (MSM)							
Clients discontinued PrEP services (AYGW)							

23. Hours of operation for PrEP services

Day of the week	Hours of operation
Monday	
Tuesday	
Wednesday	
Thursday	
Friday	
Saturday	
Sunday	
Public holidays	

Notes:

Section III: Staffing, Equipment, and Maintenance

Please complete the table for all permanent personnel involved in the delivery of PrEP services at the facility.

For the annual salary, please include bonus, overtime, and other benefits. If preferred, feel free to share a personnel list; we do not necessarily need the information transcribed into the personnel table below.

III.1 Clinical Staff

24. Number of permanent clinical employees involved in the delivery of PrEP services (attach staff establishment)

Staff category	Number of employees	Annual salary (including benefits)	Hours employed per typical week	Weeks employed per typical year	% of salary to be allocated to PrEP	Notes: Note if any of the salaries are not reported in Kenyan Shillings. Also note if the employee receives any type of "top up" for delivering PrEP.
Clinical officer						
Counselor						
ERCN						
KRCHN						
Lab technician						
Lab technologist						
Medical officer						
Pharmacist						
Pharm Tech						
Other (specify)						

Notes:

25. Number of contracted/external clinical employees involved in the delivery of PrEP services

Please complete the table for all on contract involved in the delivery of PrEP services at the facility. For the salary, also include benefits (e.g., bonus, overtime). If volunteer cadres support PrEP delivery services, please include these personnel in the table as well, even if they do not receive monetary compensation. Then provide figures and detailed notes on allocation to PrEP. If preferred, feel free to share a personnel list; we do not necessarily need the information transcribed into the personnel tables below.

Staff category	Number of employees	Annual salary (including benefits)	Hours employed per typical week	Weeks employed per typical year	% of salary to be allocated to PrEP	Notes: Note if any of the salaries are not reported in Kenyan Shillings. Also note if the employee receives any type of "top up" for delivering PrEP.
Clinical officer						
Counselor						
ERCN						
KRCHN						
Lab technician						
Lab technologist						
Medical officer						
Nurse						
Pharmacist						
Other (specify)						

Notes:

III.2 Non-Medical Staff

26. Number of permanent support staff (*entire facility*, not only for PrEP)

Staff category	Number of full-time employees	Annual salary (including benefits)	Hours employed per typical week	Weeks employed per typical year	% of time allocated to PrEP (if applicable)	Notes: Note if any of the salaries are not reported in Kenyan Shillings.
Accountant						
Accounts clerk						
Administrator						
Assistant accountant						
Assistant HR officer						
Cook						
Community Mobilization officer						
Community strategy coordinator						
Coordinator 1 – HTC						
Driver						
Director, operations						
Data officer						
Executive director						
Finance manager						
Gardener						
Guard/watchman						
HR officer						
Hospital assistant						
Housekeeping staff						
Head of prevention						
HTC coordinator, national						
HIV C&T site coordinator						
HTC counselor						
IT officer 1						
Legal assistant						
Maintenance						

Management officer						
Mobile HTC coordinator						
M&E manager						
Office assistant						
Procurement & logistics officer						
Program officer, Prevention						
Program assistant, MSM						
Program assistant, youth						
Pharmacy technician						
Records officer						
Research assistant						
Receptionist						
Radiographic assistant						
Research manager						
Senior accountant						
Senior health assistant						
Supply clerk						
Technical officer						
Technical communications officer						
Training manager						
Youth program coordinator						
Ward attendant						

Notes:

27. Number of contracted support staff (entire facility), not only for PrEP

	Number of full-time employees	Annual salary (including benefits)	Hours employed per typical week	Weeks employed per typical year	% of time allocated to PrEP (if applicable)	Notes: Note if any of the salaries are not reported in Kenyan Shillings.
Accountant						
Accounts clerk						
Administrator						
Assistant accountant						
Assistant HR officer						
Cook						
Community mobilization officer						
Community Strategy Coordinator						
Coordinator 1 - HTC						
Driver						
Director, operations						
Data Officer						
Executive Director						
Finance manager						
Gardener						
Guard/Watchman						
HR officer						
Hospital assistant						
Housekeeping staff						
Head of Prevention						
HTC Coordinator, National						
HIV C&T Site Coordinator						
HTC Counsellor						
IT Officer 1						
Legal Assistant						
Maintenance						
Mgmt Officer						
Mobile HTC						

	Number of full-time employees	Annual salary (including benefits)	Hours employed per typical week	Weeks employed per typical year	% of time allocated to PrEP (if applicable)	Notes: Note if any of the salaries are not reported in Kenyan Shillings.
Coordinator						
M&E manager						
Office assistant						
Procurement & logistics officer						
Program officer, prevention						
Program assistant, MSM						
Program assistant, youth						
Pharmacy technician						
Records officer						
Research assistant						
Receptionist						
Radiographic assistant						
Research manager						
Senior accountant						
Senior health assistant						
Senior pharmacy technician supply clerk						
Technical officer						
Technical communications officer						
Training manager						
Youth program coordinator						
Ward attendant						
Accountant						

Notes:

III.3: Equipment

28. Provide information on the equipment used in each of the areas indicated.

Type of equipment/asset	Number of items at facility	Estimated replacement cost	% of equipment allocated to PrEP	Notes
Reception				
Benches for waiting area				
Computer UPS				
Desktop computer				
Desk				
Filing cabinet				
Filing shelves				
Laptop				
Laminator, paper cutter				
LCD				
Office chairs				
Plastic chairs & tables				
Photocopier				
Printer				
Receptionist desk				
Receptionist chair				
Telephone				
Water dispenser				
Other (specify) 1				
Other (specify) 2				
Other (specify) 3				

Type of equipment/asset	Number of items at facility	Estimated replacement cost	% of equipment allocated to PrEP	Notes
Other (specify) 4				
Other (specify) 5				
Triage				
BP machine				
Medical & examination couches				
Office chairs				
Office furniture				
Thermometer				
Weighing scale with height measure				
Weighing scales				
Other (specify) 1				
Other (specify) 2				
Other (specify) 3				
Health Education				
Benches for waiting area				
Bookshelves				
Camera & voice recorders				
Chairs				
Desktop computer				
Filing cabinet				
LCD projector				

Type of equipment/asset	Number of items at facility	Estimated replacement cost	% of equipment allocated to PrEP	Notes
Laptop				
Office furniture				
Penus model				
Vagina model				
TV screens				
Other (specify) 1				
Other (specify) 2				
Other (specify) 3				
Counseling Area				
Bin				
Desks				
Table				
Computer				
Filing cabinet				
LCD projector				
Penile model				
Registers/diary				
Office chairs				
Office tables				
Office furniture				
Other (specify) 1				
Other (specify) 2				

Type of equipment/asset	Number of items at facility	Estimated replacement cost	% of equipment allocated to PrEP	Notes
Other (specify) 3				
Lab Testing				
Benches for working area				
Black dustbin				
Computer (hardware and software)				
Chairs				
Cabinet				
Cooling box				
Desktop tables				
Red dustbin				
UPS backup				
Waiting couches				
Equipment				
Centrifuge				
ESR machine				
Fridges				
FBC analyzer				
GeneXpert				
Hemoglobin meter				
Incubator				
LFT/UEC/lipids (liver and kidney function test machine)				

Type of equipment/asset	Number of items at facility	Estimated replacement cost	% of equipment allocated to PrEP	Notes
Microscope				
Orbital shaker				
Water bath				
Equipment 2				
Abbott Real Time m2000rt (Abbott Molecular)				
Artus HI Virus-1 QS-RGQ Kit (QIAGEN)				
Artus HI Virus-1 RG RT-PCR (QIAGEN)				
COBAS TaqMan (Roche Molecular System)				
Centrifuge				
Generic HIV Viral Load (Biocentric)				
FACS Calibur CD4 Counter				
FACS Count CD4 Counter				
FACS Presto CD4 Counter				
Freezers				
Fridges				
GeneXpert				
Guava CD4 Counter				
LFT/UEC/lipids (liver and kidney fn test machine)				
Microscope				
NUCLISENS EasyQ (bioMerieux)				
Urine analyzer				
PARTEC Cyflow CD4 Counter				

Type of equipment/asset	Number of items at facility	Estimated replacement cost	% of equipment allocated to PrEP	Notes
PIMA CD4 Counter				
Other (HIV PCR equipment 1)				
Other (HIV PCR equipment 2)				
Other (CD4 counter equipment 1)				
Other (CD4 counter equipment 2)				
Other (specify) 1				
Other (specify) 2				
Other (specify) 3				
Pharmacy				
Analog card				
Computer tables				
Chairs				
Drawer				
Desktop computer				
Drawer filing cabinet				
Drug cabinet				
Desks				
Filing cabinet				
Files				
Filing shelves				
Laptop				
Metallic cabinets				

Type of equipment/asset	Number of items at facility	Estimated replacement cost	% of equipment allocated to PrEP	Notes
Office table				
Printer				
Pens				
Pallets				
Paper punch				
Paper trays				
Registers/diary				
Rechargeable lamp				
Refrigerator				
Shelves and drawers				
Scissors				
Spotlight for pelvic exam				
Stapler				
Tablet counters				
UPS				
Other (specify) 1				
Other (specify) 2				
Other (specify) 3				
Other (specify) 4				

III.4: Utilities and Construction Costs

29. Size of entire facility: _____
(square meters)

30. Size of space used for PrEP: _____
(square meters)

31. Percentage of time PrEP space is used for PrEP: _____ (%)

(Note: If the PrEP space is used exclusively for PrEP services, indicate 100%. However, if the PrEP space is also used for other services, indicate the percentage of time for which the space is used for PrEP services.)

32. Utility costs for entire facility (obtain expenditure for the whole facility)

	Annual cost	Notes
Building maintenance		
Electricity		
Telephone		
Other utilities cost		
Vehicle maintenance		
Water		
Other (specify)		

33. Rental or construction value of *entire facility*

Note: Provide either 1) the rental value of this facility or a similarly sized facility OR 2) the construction value of a similarly sized facility.

	Annual cost	Notes: If rental value of the facility is not available, indicate the construction cost and annualize.
Rental value of entire facility		
Construction value of entire facility		
Other (specify)		

34. Travel/transport cost of *entire facility*

Indicate the replacement value of the items below.

Vehicles:

Type		Type/ model	Year of manufacture	Purchase price per unit (KShs)	% allocation to PrEP	Annual operating costs
Ambulance	1					
	2					
	3					
	4					
	5					
Van	1					
	2					
	3					
	4					
	5					
Bus	1					
	2					
	3					
	4					
	5					

Type		Type/ model	Year of manufacture	Purchase price per unit (KShs)	% allocation to PrEP	Annual operating costs
Truck	1					
	2					
	3					
	4					
	5					
Car	1					
	2					
	3					
	4					
	5					
Other vehicle	1					
	2					
	3					
	4					
	5					
	6					
	7					
	8					
	9					
	10					

Section IV: Required Pharmaceutical and Non-Pharmaceutical Supplies for PrEP
(Match the stages for equipment and supplies.)

IV.1: Drugs, Supplies, and Consumables Provided at the Initiation to PrEP

35. What supplies are used during **PrEP provision**? Are there any other drugs/supplies they receive? (Write in.)

Consumables and medications	Number	Unit cost	Quantity in pack (packaging)	Notes
Stage 1: Reception				
Biros				
IEC materials				
Marker pens				
Notebook				
Printing paper				
Registers				
Staples				
Other (specify) 1				
Other (specify) 2				
Other (specify) 3				
Other (specify) 4				
Stage II: Triage				
Clean gloves (packs of 50 pairs)				
Face masks (3-ply) (packs of 50)				
Gloves 7.5" (packs of 50 pairs)				
Gloves 8" (packs of 50 pairs)				
Other (specify) 1				
Other (specify) 2				
Other (specify) 3				
Stage III: Health education				
Educational charts/materials				
Female condom				
Hand-washing soap				
Hand disinfectant				

Consumables and medications	Number	Unit cost	Quantity in pack (packaging)	Notes
Hand rub				
HIV test kits				
Lancets				
Latex gloves				
Male condom				
Vaginal speculum				
Contraceptives (if available)				
Family planning visual aids				
Individual cards or records for clients				
Intrauterine device				
Injectable				
Implants				
Pill				
Written family planning guidelines				
Stage IV: HIV testing and counseling				
Alcohol prep pads (box of 200)				
Bleach (JIK)				
Biogel				
Biro pens				
Brown tapes				
Cooling box				
Cotton swabs				
Cotton wool (400 g)				
Client suspension files				
Client cards (TCA)				
Cartridge 49A				
Counter book 1 quire				
Cotton gauze				
Dettol soap/liquid				
Distilled water (20l drums)				

Consumables and medications	Number	Unit cost	Quantity in pack (packaging)	Notes
Ethanol (GPR)				
Envelope A5				
Envelope A4				
EDTA tubes				
Frosted microscope slides				
HIV test kits				
Hand towels				
Hand rub				
Hand sanitizer				
Lancets				
Lab register KB 310				
Lotion				
Liquid soap (500 ml)				
Marker pens (Sharpie)				
Omo (1 kg)				
Methylated spirit				
Mark pens (fine tips)				
MOH cards (hard paper)				
Non-sterile gloves (box of 100)				
Powder-free gloves (medium & small)				
Pipettes lubricants				
Pipette (1000ul and 200ul)				
Purple tops (4 ml)				
Pritt (glue stick)				
Printing papers A4				
Paper clips				
Red tops				
Ring binder files				
Serviettes				
Sputum bottles				
Scrubbing brushes				
Scissors				

Consumables and medications	Number	Unit cost	Quantity in pack (packaging)	Notes
Staple pins (small)				
Staples pins (big)				
Tray – inlay & outlay				
Super adhesive labels yellow/red				
Utility gloves				
Wite-Out				
Waste bags				
Yellow stickers				
5-ml transfer pipettes				
15-ml conical tubes				
50-ml conical tubes				
Other (specify) 1				
Other (specify) 2				
Other (specify) 3				
Stage V: PrEP introduction and prescription				
Biros				
IEC materials				
Marker pens				
Notebook				
Staples				
Other (specify) 1				
Other (specify) 2				
Other (specify) 3				
Stage VI: Dispensing				
ARV drugs				
TDF 300 mg/FTC 200 mg once daily as FDC				
TDF 300 mg once daily				
TDF 300/FTC 300 mg once daily as FDC				

IV.2: Lab tests done during each visit

Note that if lab tests are performed elsewhere in the facility, these costs should be included as a direct cost of PrEP.

36. Indicate number of tests per patient done during each of the following visits.

	Rapid plasma reagin	CBC (complete blood count)	HIV test	HBV antigen	Hepatitis C antibody	Serum creatinine	Drug level	Pregnancy	Kidney/ liver	STI screening tests (chlamydia, VDRL, gonorrhoea)	Pregnancy test	Other (specify)
Initial visit/first contact												
30-day review												
3-month review												
Total tests all visits												

IV.3: Direct staff time – first visit/initiation

Stage 1: Reception/ enrollment	No. of minutes spent with each PrEP client
Receptionist	
Cashier	
Records officer	
Other (specify)	
Stage 3: Health education	
Counselor/nurse	
Clinical officer	
Medical officer	
Nutritionist	
Other (specify)	
Stage 5: PrEP introduction and prescription	
Nurse	
Clinical officer	
Medical officer	
Nurse	
Other (specify)	

Stage 2: Triage	No. of minutes spent with each PrEP client
Nurse	
Clinical officer	
Other (specify)	
Stage 4: HIV testing and counseling	
Lab technologist	
Lab assistant	
Counselor	
Other (specify)	
Stage 6: Dispensing	
Pharmacist	
Pharmacy technologist	
Clinical officer	
Nurse	
Other (specify)	

37. How much time does each of the following staff members spend with the client during first visit/initiation in the following service delivery stages?

38. Would that time be different for a revisit? YES NO

39. If YES, what is the range for a revisit?

Range of time spent with a client: From _____ to _____

Section V: Review Visits

40. What percentage of clients due for their 30-day visit actually show up?

	% of clients coming for review
FSW	
MSM	
AGYW	
Discordant couple	
IDUs	

Section VI: Recurrent Expenditure

41. What is the total recurrent expenditure for April–September 2017?

(Obtain expenditure record) _____

APPENDIX 14 – GLOSSARY



<https://ghcosting.org/pages/standards/glossary>

Please note: Unless otherwise indicated through italics, definitions below are from the RC.

Above-site/above-service costs: *costs incurred above the point-of-care/service delivery site, such as central management or administrative services, centralized training or education, centralized laboratory services, procurement/collection/distribution/storage of drugs, record keeping, and surveillance. Please note, above-site implies more centralized processes. There can also be management, procurement, etc. at the site-level, which are conducted by the site/program.*

Amortization/annualization: *estimates the annual opportunity cost of not investing the same purchase (or resale) price, plus interest (or the expected [discount] rate of return on the alternate investment). Both financial and economic cost estimation “smooth out” the one-time cost of a capital input by putting a “piece” of the cost across each of the years of use of that input (useful life years). Economic cost estimation uses the method of annualization.*

Benefit-cost analysis: *a form of economic evaluation in which the measures in both the numerator (difference in cost) and the denominator (difference in effect) are expressed as monetary values, so that the resulting benefit-cost ratio expresses value for investment in exclusively monetary terms (i.e., “x” dollars in for “x” dollars back).*

Capital costs: *one-time costs for resources/inputs that have a useful life of over one year (such as buildings, vehicles or medical equipment) and cost more than \$100.*

Client perspective: *the costs by the client to access/complete the activity, service, or intervention at the point of care. This can include co-pays, fees, purchase of medical supplies or drugs, travel expense, and childcare. It can also include opportunity costs such as lost wages due to the time spent traveling to/from a visit, waiting for a visit, and during a visit. To note, it can also extend to the costs borne by the household and even community to allow for the client to access/complete the activity, service, or intervention. This can include paying for drugs, medical supplies, food, and lost wages/productivity for the time spent caring for/accompanying the client.*

Cost-effectiveness analysis: *a form of economic evaluation that essentially divides the difference in cost between the alternatives [numerator](e.g., less/more comprehensive interventions, different ways of delivering an intervention, or different technologies such as drugs or tests) by the difference in a unidimensional measure of effect [denominator](e.g., HIV infections-averted, years of life gained) to calculate an ICER.*

Cost functions: *show the relationship between costs and components of cost (e.g., personnel, capital) or cost and the determinants/drivers of costs (e.g., scale, coverage, type of provider, time). Cost functions describe how cost is determined by input cost, the amount of resources used, and other factors that may modify these, such as the scale of production, or other characteristics such as quality.*

Cost-minimization analysis: *a form of economic evaluation that assumes that the effectiveness [denominator] between the alternatives is equal and therefore only the costs [numerator] are compared.*

It is often used in the case of pharmaceuticals, where there is reliable evidence that a generic drug has equal therapeutic effect to a brand-name drug in the same dose.

Cost-utility analysis: *a form of economic evaluation that translates the denominator of the ICER into a bi-dimensional measure of effect relative to 1) an individual's years of life gained AND adjusted by the quality of health (quality-adjusted life year) or 2) an individual's years of life "diminished" and adjusted by quality of "capacity" (i.e., disease burden or disability)(disability-adjusted life year). Technically, this result is called an incremental cost-utility ratio.*

Discount rate: *is the rate at which future costs are discounted to account for time preference. It can also be seen as the expected rate of return on an investment alternative to the purchase that had indeed been made.*

Economic costs: *costs that reflect the full value of all resources utilized in producing a good or service, inclusive of both financial costs and opportunity costs.*

Economic evaluation: *the process of systematic identification, measurement, and valuation of the inputs and outcomes of two alternative activities, and the subsequent comparative analysis of these (Wikipedia at: https://en.wikipedia.org/wiki/Economic_evaluation_from_Drummond_2005).*

Economies of scale: *economies due to scale occur when long-run average cost decreases as output increases.*

Expenditures: *a type of cost that reflects only the financial outlay that an agent (e.g., government, donor, individual) spends during a specific period of time for goods and services. Expenditures can refer to the entire sum required by specified health services, or it may pertain only to those outlays incurred by a subset of the organizations involved in delivering the service. Note that expenditure data are usually reported using the cash basis method of accounting (i.e., no amortization to capital goods is applied; all capital goods expenditures are recorded in full as they are incurred).*

Financial costs: *costs that reflect financial outlays for goods and services needed to carry out a public health or medical intervention (in the context of global health), and as such are similar to expenditures. However, in contrast to expenditure data, financial costs depreciate capital expenditures over time.*

Fixed costs: *those costs that do not vary with scale (changes in the level of output). These costs would be incurred even if the output were zero. Common examples are items such as buildings and equipment, but it should be noted that "fixity" depends on context and there are fixity "tipping" points in which existing numbers of resources such as personnel or buildings are no longer sufficient at a certain scale.*

Full cost: *a cost estimate that covers all resources used within the standard of care for that intervention at a specific level of coverage. This is in comparison to incremental cost, in which one is looking at the difference in cost between two interventions and there may only be one difference in the care provided. For example, a full cost for PrEP might include HIV counseling and testing and STI management, if these are considered a necessary part of PrEP service delivery, while an incremental cost would look only at the difference between the cost of a program already providing these services for the population and one that also includes PrEP for some members of the population.*

Gross costing approach: *a costing approach in which input use is estimated from total cost.*

Incremental cost: This is **technically** the positive difference in cost between comparison interventions or different amounts of an intervention (e.g., an HIV prevention program without PrEP and one that is offering PrEP). **However, in practice**, this is often calculated from observation of a single intervention, as the cost of “new” intervention activities or components that are additional to the standard of care—for example, the [incremental] cost only of PrEP drugs and adherence counseling, when integrating PrEP into an existing HIV prevention program that includes HTC, STI screening and treatment, and reproductive health care.

Incremental cost-effectiveness ratio: *a measure of the cost-effectiveness of an intervention that uses a unidimensional measure of effect in the denominator (see description of “cost-effectiveness analysis” above for the calculation). For the purpose of PrEP, effectiveness is typically measured in terms of HIV infections averted.*

Incremental cost-utility ratio: *a measure of the cost-effectiveness of an intervention that uses multidimensional measure of effect (disease burden or quality of life) in the denominator (see description of “cost-effectiveness analysis” above for the calculation).*

Inputs: *the basic granular resources needed to produce some output necessary for improved health.*

Marginal costs: the costs of producing one or more units of a service/output.

Micro-costing approach: a costing approach in which the cost and quantity of every input consumed in providing a service is estimated (see <http://dcp-3.org/sites/default/files/resources/Levin%20CFAR%20CE%20research%20methods%20workshop%20Session%203%20.pdf>).

Net of future cost savings: *an accounting of how costs (expressed in present values) change if there is consideration for including the expected future cost of providing the intervention +/- the costs/benefits from either the illness in question (related cost/benefits) or other future life happenings (unrelated costs/benefits).*

Non-traded inputs: services and commodities that can’t be traded on the international market.

Normative best practice: *an activity, service, or intervention provided according to guidelines. It should be noted that there may be additional cost to adhere to those guidelines.*

Opportunity costs: the value of the forgone opportunity to devote [usually “unpaid”] resources (such as volunteer time and donated goods) to another purpose. However, it should be noted that a resource could have been paid for, but the price may not have been reflective of the full value. A drug, for example, could have been undervalued only because of something like a subsidy; therefore, the opportunity cost is for the subsidy that could have gone to another opportunity. Or the opportunity cost could be the interest the provider could have gotten if the money for a purchased car or piece of medical equipment had instead been put into an interest-bearing bank account.

Production process: the process of combining different inputs (such as labor, commodities, and equipment) to generate outputs (such as health services). For example, combining a specific quantity of PrEP pills, a specific quantity of PrEP pill packaging, a specific quantity of time for the pharmacist to put the pills into the packaging, and a specific quantity of pharmacist time to give the packaged pills, to “produce” the service of PrEP drug distribution.

Provider perspective: *the costs by the service provider to produce the activity, service, or intervention at the point of care.*

Recurrent costs: the value of resources/inputs with useful lives of less than one year (such as supplies and personnel).

Real world practice: *an activity, service, or intervention in which some elements may not be included or implemented as guidelines suggest (due to local context, practice, or resource constraints).*

Societal perspective: *the provider perspective plus the client perspective, including all costs incurred by an activity, service, or intervention regardless of who pays for it.*

Straight-line depreciation: *divides the one-time cost by the years of useful life to obtain an “annual” cost. both financial and economic cost estimation “smooth out” the one-time cost of a capital input by putting a “piece” of the cost across each of the years of use of that input (useful life years). Financial cost estimation uses the method of straight-line depreciation.*

Shadow price: the estimated price of a good or service for which no market price exists.

Start-up costs: the one-time commitment of resources required to establish a program to the point where service delivery can begin. Some of these resources may be donated or subsidized; thus, the financial costs may be less than the full economic costs. Start-up costs typically include some capital costs, but also include activities related to planning, staff training, materials development, infrastructure expansion, legal fees, and personnel recruitment. Some start-up costs should be amortized; for example, if staff training needs to be repeated every five years, training costs would be spread over five years.

Total costs: *the summation of all cost inputs needed to produce all units of an activity, service, or program over a specified period of time.*

Unit costs: *the average cost of the inputs needed to produce one unit of activity, service, or intervention during a specified period of time. The unit can be a person served, or a specific service unit such as a test or a visit.* An example of a unit cost drawn from a total cost is if a PrEP prevention program costs \$1 million annually to provide 1,000 person-years of PrEP, the unit cost would be \$1,000 per client-year.

Variable costs: costs that vary with scale (changes in the level of output). *For example, the total cost of PrEP drugs required in a PrEP program depends on the number of person-years of PrEP provided by the program.*

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https://ghcosting.org/pages/standards/sources/rc_references

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