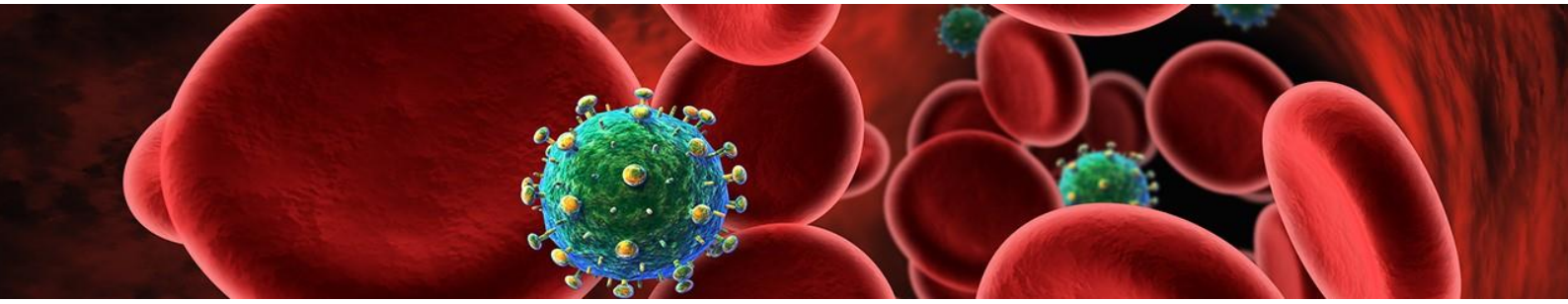
MINISTRY OF HEALTH

National AIDS and STI Control Programme



Costing the Implementation of the 2016 HIV Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya

April 2017

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Acknowledgments

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Abbreviations and Acronyms

AIDS	acquired immunodeficiency syndrome
ANC	antenatal clinic
ART	antiretroviral therapy
ARV(s)	antiretroviral(s)
CPT	Cotrimoxazole Preventive Therapy
GBV	gender-based violence
HIV	human immunodeficiency virus
IPT	Isoniazid Preventive Therapy
KASF	Kenya AIDS Strategic Framework
MOH	Ministry of Health
NASCOP	National AIDS/STI Control Programme
NCD	non-communicable disease
PEP	post-exposure prophylaxis
PHDP	Positive Health Dignity and Prevention
PMTCT	prevention of mother-to-child transmission
PrEP	pre-exposure prophylaxis
STI	sexually transmitted infection
TB	tuberculosis
WHO	World Health Organization

Executive Summary

In 2016, the Ministry of Health (MOH) updated Kenya's national HIV guidelines to provide guidance on the use of antiretrovirals (ARVs) to treat and prevent HIV infection. To inform implementation and resource mobilisation, the MOH needed to understand the costing implications of implementing the new guidelines. This created the need for a study to estimate the costs of implementing the new guidelines, based on the country targets and covering all known people living with HIV in Kenya. This study adopted a micro-costing approach using population data from 2015 HIV revised estimates. The study considered two costing scenarios—the "NASCOP scenario," based on NASCOP (National AIDS/STI Control Programme) targets to achieve the UNAIDS 90-90-90 targets; and the "Standard scenario," based on full adoption of the new guidelines.

The results show that the average annual unit cost of an adult on ARVs is Ksh 12,032.36 (US$115.7). The unit cost varies by regimen type, with the unit cost of an adults first-line regimen being Ksh 9,501.44 (US$91.4) per year, compared to Ksh 26,499.20 (US$254.8) for second-line. The annual unit cost of pediatric ARVs was estimated at Ksh 17,800.64 (US$171.2) per patient.

As shown in Table E1, implementation of the new antiretroviral therapy (ART) guidelines under the Standard scenario will cost about 20 percent more than under the NASCOP scenario. The estimated cost of implementing the new guidelines under the NASCOP and Standard scenarios in the next four years (FY2016/17–2019/20) is Ksh 197.8 billion (US$1.9 billion) and Ksh 239.2 billion (US$2.3 billion), respectively. The higher costs under the Standard scenario can explained by the higher number of people living with HIV expected to be initiated on treatment. In both scenarios, key commodities (ARVs, laboratory management, and test kits) are the main cost drivers, accounting for 61 percent of the total cost (see Table E1).

Table E1: Costs of Implementing the New Guidelines (2016/17–2019/20), US$ millions

NASCOP Scenario			Standard Scenario		
Programme Area	Cost	Percent of Total Cost	Programme Area	Costs	Percent of Total Cost
ARVs	852	45%	ARVs	1032	46%
Laboratory management	240.9	13%	Laboratory management	283	12%
Testing kits	74.8	4%	Testing kits	75.9	3%
NCD screening	89.7	5%	NCD screening	108.8	5%
Non-biomedical	644.6	34%	Non-biomedical	768.2	34%
Total	**1,902.0**	**100%**	**Total**	**2,267.9**	**100%**

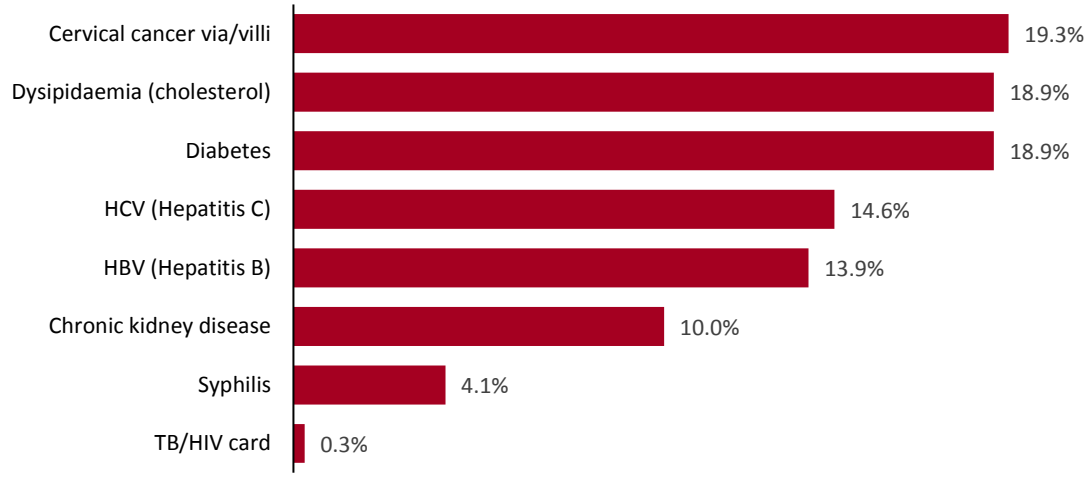
The new guidelines propose a shift from the use of CD4 towards viral load tests for patient monitoring. The viral load monitoring test will thus be a major cost driver for laboratory management, accounting for approximately 60 percent of costs for laboratory reagents (see Table E2).

Table E2: Test Costs as a Proportion of Total Lab Management Costs (FY 2016/17–2019/20)

Type of Test	NASCOP	Standard
CD4 tests	3.3%	1.7%
VL tests	60.0%	60.3%
Hematology	4.6%	4.9%
Chemistry	6.4%	7.0%
Crags test	2.2%	2.3%
DRT test	23.5%	23.8%

An important aspect of the new guidelines is the introduction of non-communicable disease (NCD) screening as part of ART treatment. The findings show that NCD screening will cost Ksh 9.1 billion (US$87.7 million) and Ksh 11.3 billion (US$108.8 million) in the next four years (FY2016/17–2019/20) under the NASCOP and Standard scenarios, respectively. Figure E1 shows the distribution of resource need for NCD screening for the HIV-positive population, by disease type. Cervical cancer, dyslipidemia, and diabetes account for over 57 percent of the resources needed for NCD screening for the entire period.

Figure E1: Relative Costs for NCD Screening, by Disease (FY2016/17–2019/20)



These results demonstrate that implementation of the new 2016 ART guidelines has financial implications that merit consideration. As more people living with HIV are enrolled in treatment programmes, the costs will increase under the NASCOP and Standard scenarios. Commodities remain the largest cost drivers, accounting for one-third of resources needed for guideline implementation. Therefore, Kenya must mobilise additional resources for HIV treatment to fully implement new ART guidelines.

1. Introduction

1.1 Context

HIV and AIDS remain a major public health problem in Kenya. Therefore, there is continued need for guidance from the Ministry of Health (MOH) and other key stakeholders on how to manage current and new infections. According to the *Kenya HIV Estimates Report 2015* (MOH, 2015), over 1.5 million people are estimated to be living with HIV in Kenya, of which 98,170 (or 7%) are children below age 15. The HIV incidence rate is 0.4 percent, translating to about 77,600 new infections annually. Major gains have been made over the last two decades in managing the HIV epidemic, most notably the increased access to HIV care and treatment. This has resulted in the reduction of AIDS-related morbidity and mortality and has improved the quality of life for people living with HIV. Kenya's long-term development blueprint, *Vision 2030*, envisages a Kenya free of new HIV infections, stigma, and AIDS-related deaths (GoK, 2007). In line with this aspiration, the MOH is collaborating with other stakeholders on strategies to achieve these goals. The MOH is also committed to achieving global commitments to ending AIDS, as articulated by the UNAIDS 90-90-90 Strategy (MOH, 2015).

The *Kenya AIDS Strategic Framework* (KASF) (2014/15–2018/19) provides guidance for leadership in the HIV response. It emphasizes an equitable HIV response that ensures no one is left behind, and sets clear goals and targets to achieve significant milestones in HIV epidemic control. The key goal of the KASF is to guide interventions that will reduce new HIV infections by 75 percent and AIDS-related mortality by 25 percent by 2019. The use of antiretroviral medicines (ARVs) for prevention and treatment of HIV infection is central to the achievement of these goals.

In recent years, strong evidence has shown the benefits of early initiation of antiretroviral therapy (ART) over delaying treatment among people living with HIV. Early HIV treatment, initiated upon an HIV-positive diagnosis, is associated with better outcomes for the patient, including reduced mortality and morbidity.

Treatment options have become safer and more effective, and increasingly available and affordable. HIV prevention studies have demonstrated the efficacy of pre-exposure prophylaxis (PrEP) among various HIV-free populations, setting the agenda for expanded use of ARVs for HIV prevention. Furthermore, achieving universal access appears more feasible if targeted approaches are used to identify people living with HIV, reduce levels of stigma, and increase domestic investments in HIV control.

The MOH provides policy guidance regarding the use of ARVs in Kenya. These guidelines outline eligibility for ARVs, regimen selection, and monitoring the effectiveness of use. Guidelines are developed and reviewed in line with available local and international evidence, but also consider the local context when adapting guidance provided by the World Health Organization (WHO). The updated 2014 MOH guidelines provided for earlier initiation of ART, based on eligibility criteria that included the following:

- All HIV-positive children less than 10 years of age, regardless of CD4 count, CD4 ≤ 500 copies/ ml
- All pregnant women
- Instances of tuberculosis (TB) and HIV co-infections
- Patients with advanced WHO clinical stages (3 and 4)
- All HIV-positive persons in sero-discordant relationships

However, the 2014 guidelines did not include the use of ARVs for prevention in HIV-negative populations beyond PrEP. In July 2016, the MOH made a significant shift in the management

of HIV infection in Kenya and launched revised guidelines[1] on the use of ARVs for treating and preventing HIV infection. The key highlights in the revised guidelines include test-and-start, differentiated care, and PrEP for HIV-negative persons.

The revised guidelines are an important tool for healthcare providers in HIV programming. Kenya intends to mobilize adequate resources to operationalize the revised guidelines to meet the 90-90-90 targets. To this end, the MOH conducted a study to establish the comprehensive cost of implementing the 2016 guidelines. Findings from the study will provide information to policymakers and programme planners and guide their advocacy for more resources for HIV care and treatment in Kenya.

1.2 Study Objectives

The costing exercise addresses two questions:

a) What is the cost of implementing the 2016 ART guidelines based on the country targets?

b) What is the total cost of implementing the 2016 ART guidelines to cover 100 percent of known people living with HIV?

[1] *Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya, 2016 Edition*

2. Summary of the 2016 HIV Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya

This section summarises key programme areas covered in the 2016 HIV guidelines. (For a detailed description, see MOH and NASCOP, 2016).

1. **HIV testing services will include:**
    - Annual testing for the general population and key populations (testing and retesting)
    - Confirmatory testing for HIV-positive status: Retesting of all newly diagnosed persons at comprehensive care centers/maternal and child health centres
    - Testing pregnant women at ANCs, third trimester or labour and delivery, post-natal
    - Testing breastfeeding women at six weeks and six months
    - Testing HIV-exposed infants at six weeks, six months, and 12 months
2. **Initial evaluation and follow-up for people living with HIV will involve:**
    - Initial clinical evaluation of people living with HIV, including complete medical history and a thorough physical investigation
    - Initial laboratory evaluation of people living with HIV, although comprehensive laboratory evaluation is not a prerequisite for ART initiation once a person has tested HIV-positive
    - Differentiated care for patients who present with advanced HIV disease and those who present well; this differentiation is important because patients who present with advanced disease may require a different level of care than those who are still clinically well
    - Follow-up for people living with HIV during the first year of ART to assess response to treatment, including adverse drug events, and to address barriers to adherence; recommended follow-up should be two weeks and four weeks after ART initiation, and then monthly until viral suppression is confirmed
    - Follow-up for people living with HIV beyond the first year of ART, to differentiate between stable and unstable patients; unstable patients require closer follow-up to address whatever issues lead them to be categorised as unstable, while stable patients require less-frequent facility follow-up, with up to six months between clinical appointments
3. **Standard package for care for people living with HIV will include:**
    - Provision of ART once a person is confirmed HIV-positive, regardless of CD4 counts; ART should be initiated within the shortest time possible, preferably within two weeks, once patient readiness has been determined
    - Positive Health Dignity and Prevention (PHDP), screening for gender-based violence (GBV), and health education/counselling: PHDP is aimed at emphasising the health and rights of people living with HIV, including reducing the risk of onward transmission of HIV; in addition, females ages 15–49 and emancipated minors accessing HIV care services should be screened for GBV, while all persons living with HIV and caregivers should receive focused education about HIV and its treatment

- Screening and prevention of specific opportunistic infections: all people living with HIV should receive lifelong Cotrimoxazole Preventive Therapy (CPT) unless they are allergic to sulfate or develop toxicity from CPT
- Reproductive health services, to involve screening for cervical cancer and sexually-transmitted infections (STIs); pregnancy status and intention should be established
- Screening and management of non-communicable diseases (NCDs), to include screening for high blood pressure, assessment of cholesterol levels, screening for diabetes, and assessment of mental health
- Nutritional services: all people living with HIV should receive nutritional assessment counselling and support tailored to the individual needs of patients
- Providing medicines to prevent opportunistic diseases

4. **Adherence preparation, monitoring, and support will involve:**
    - ART adherence preparation
    - Adherence monitoring, counselling, and support during the first six months of ART
    - Adherence monitoring, counselling, and support for patients with viral load <1,000 copies/ml
    - Enhanced adherence assessment and interventions for patients with suspected or confirmed treatment failure
    - Treatment preparation for second-line or third-line ART
    - Identifying, tracing, and supporting patients who default from care

5. **Antiretroviral therapy for infants, children, adolescents, and adults will involve:**
    - Eligibility for ART regardless of CD4 counts
    - Timing of ART initiation
    - Offering regimen according to whether first-line, second-line, or third-line; for example, first-line for infants, children, adolescents, and adults (including pregnant and breastfeeding women)
    - Initiating pediatric ARV regimens, depending on pediatric weight, before any other consideration
    - Monitoring and changing ART

6. **Prevention of mother-to-child transmission (PMTCT) of HIV will involve:**
    - ART for HIV-positive pregnant women and infant prophylaxis
    - Infant and young child nutrition in the context of HIV

7. **TB/HIV co-infection prevention and management will involve:**
    - TB screening for people living with HIV: intensified case finding
    - Isoniazid preventive therapy (IPT)
    - Provision of ART for TB/HIV co-infection

8. **Hepatitis B virus/Hepatitis C virus/HIV co-infection prevention and management will involve:**

- Screening for Hepatitis B/HIV co-infection
- Screening for Hepatitis C/HIV co-infection

9. ART for post-exposure prophylaxis will involve:

- Offering post-exposure prophylaxis (PEP) once the exposure has been found to be negative and has occurred within 72 hours
- Key populations of interest include health workers handling HIV patients, GBV patients, female sex workers, men who have sex with men, people who inject drugs, truck drivers, and sero-discordant couples
- Follow-up HIV testing at three and six months after exposure
- All PEP patients to be treated with regimen TDF + 3TC + ATV/r
- All PEP patients to receive one creatinine test due to use of TDF-based regimen

10. Oral pre-exposure prophylaxis will involve:

- Recommended ARVs for PrEP
- Indications and criteria for PrEP
- Risky behaviour assessment
- Minimum required laboratory evaluation for PrEP
- Criteria for discounting PrEP
- Who should provide PrEP, and where it should be provided

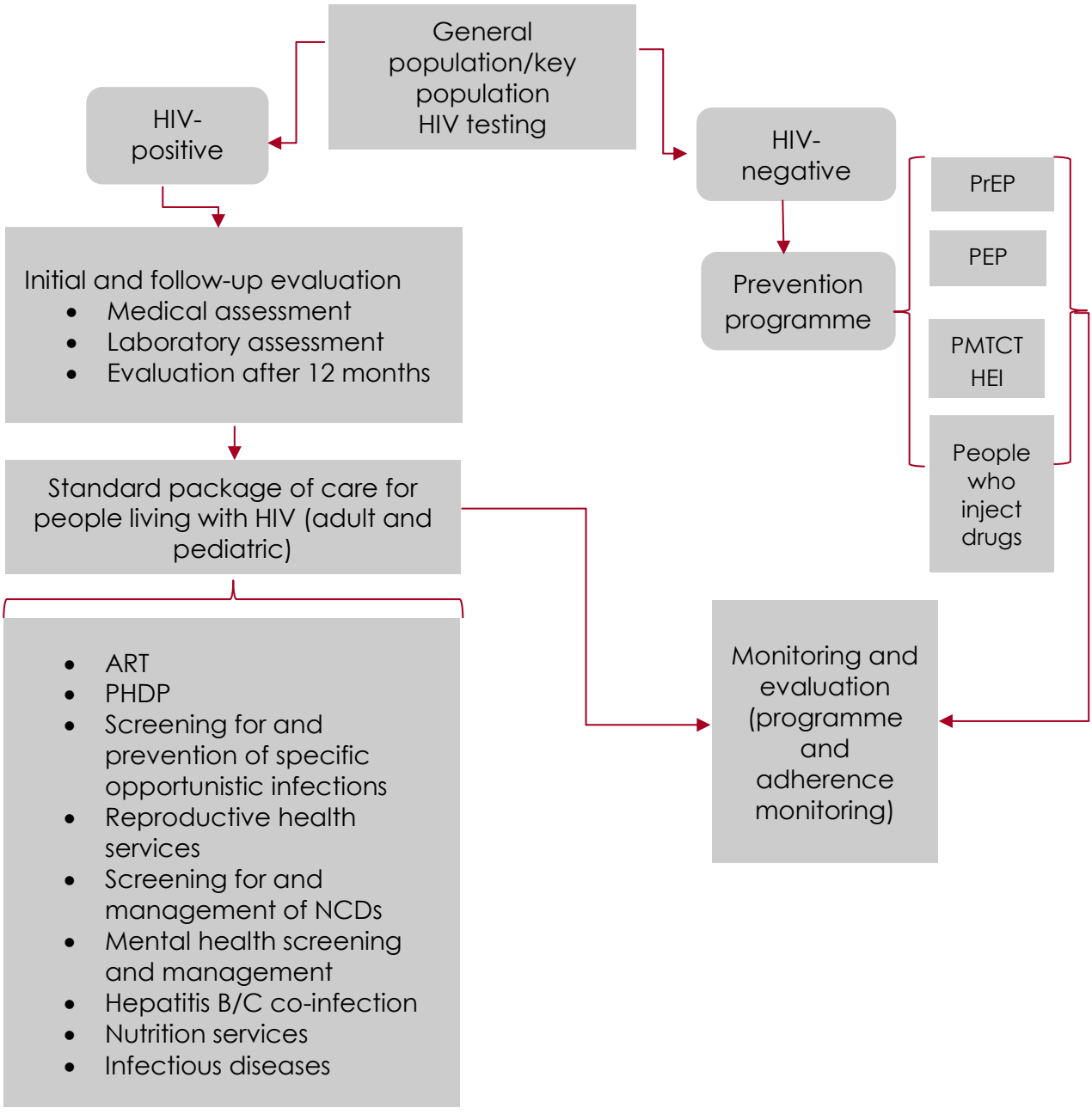
11. People who inject drugs will receive:

- Recommendation of right regimen or ARVs for people who inject drugs
- Linking people who inject drugs to needle and syringe programmes and medication-assisted treatment or opioid substitution therapy
- Screening for Hepatitis C virus among people living with HIV who inject drugs
- HIV testing every three months for HIV-negative persons
- Adherence, monitoring, and counselling for both HIV-positive and HIV-negative people who inject drugs

3. Costing Framework for 2016 ART Guidelines

Figure 1 provides a summary of how key programme areas are interlinked as outlined in the 2016 ART guidelines on care and treatment. The costing framework is comprised of the programme areas and activities as contained in the 2016 guidelines (MOH and NASCOP, 2016).

Figure 1: Linkages between Key Programmatic Areas and Costing Framework for 2016 HIV Guidelines



4. Methodology

The programme areas and activities costed are highlighted in Section Two, and in more detail in the *Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya, 2016 Edition* (see MOH, 2016).

This exercise adopted a micro-costing approach that used activity-based costing. The exception to this approach was around nonmedical costing, which used a proportional allocation method based on existing literature for HIV programme costs. The population data used in this exercise is based on 2015 HIV revised estimates. These data are used to estimate the two costing scenarios.

1. **NASCOP scenario**: The first scenario was based on NASCOP (National AIDS/STI Control Programme) targets—also referred to as the 'NASCOP scenario' in this document—which are in line with targets set by the national HIV programme. The NASCOP scenario considered scale-up targets set by the national programme in line with achievement of the UNAIDS 90-90-90 targets.
2. **Standard scenario**: The second scenario, known as 'Standard scenario,' was based on full adoption of the new guidelines with a 100 percent implementation target of the guidelines from the first period. This scenario makes some realistic assumptions on HIV incidence rate, mortalities, and population growth guided by available literature (see MOH, 2015; U.S. Centers for Diseases Control and Kenya Ministry of Health, 2013; and Republic of Kenya, 2013) and in line with the future HIV epidemiological environment.

Assumptions for this costing exercise were derived from consultative meetings and similar, relevant prior studies. Non-biomedical assumptions were based on a previous study (U.S. Centers for Diseases Control and Kenya Ministry of Health, 2013), an in-depth micro-costing of HIV and AIDS biomedical and non-biomedical interventions in Kenya. The proportion of identified non-biomedical interventions to total cost was adopted in this study. The price data for biomedical interventions were generated from various sources through a review of available unit costs for the programmes/interventions in the guidelines. A price mapping exercise was conducted on input prices and later discussed in a consensus-building meeting held with key HIV programming stakeholders. Detailed costing assumptions used are provided (see Annex 1).

5. Costing Results

This section presents the estimated cost of HIV treatment and prevention, based on the revised 2016 guidelines. The data shows the aggregated cost estimated for the NASCOP and Standard scenarios. This is followed by a disaggregation of these costs by programme area, and compared across two scenarios to provide some insight on what the guideline implementation would cost in the next four years.

5.1 Estimated HIV programme costs between NASCOP and Standard scenarios

The results presented in Table 1 show that the average unit cost of putting a patient on ARVs per year is Ksh 12,032.4 (US$115.7). The unit cost varies by regimen type, with the unit cost of an adult first-line ARV regimen at Ksh 9,501.44 (US$91.4) and second-line at Ksh 26,499.20 (US$254.8) per year. On the other hand, the annual unit cost of pediatric ARVs is 17,800.64 (US$171.2) per patient.

Table 1: Cost Estimates for Standard Scenario in US$, millions

Description	Annual Unit Cost
Unit cost adults, first-line	$91.4
Unit cost adults, second-line	$254.8
Average unit cost for adult ARV treatment	$115.7
Unit cost of pediatric ARV treatment	$171.2

Under the NASCOP scenario, the estimated cost of implementing the new guidelines in FY 2016/17 was Ksh 47.2 billion (US$454 million), increasing to Ksh 53.4 billion (US$513 million) in FY 2019/20 (Table 2). Under this scenario, coverage of people living with HIV is assumed to grow from 80 percent in 2016/17 to 95 percent in 2019/20, with a projected 5 percent increment in each consecutive year.

As shown in Table 2, the key cost drivers in this scenario were ART drugs[2] and non-biomedical costs. Laboratory management was a key biomedical intervention with a significant cost.

[2] ART drug costs include routine pediatric and adult ARVs, PMTCT ARVs, PEP regimens, PrEP regimens, and medicines for opportunistic diseases (CPT and IPT).

Table 2: Cost Estimates for NASCOP Scenario in US$, millions

Programme Area	2016/ 2017	2017/2018	2018/2019	2019/2020
ART drugs	196.9	201.7	218.5	234.9
Laboratory management	61.8	57.1	59.4	62.6
HIV testing services	20.7	21.1	15.7	17.3
NCD screening	20.5	21.7	23.1	24.4
Non-biomedical	154.1	154.6	162.1	173.8
Total	**454.0**	**456.2**	**478.8**	**513.0**

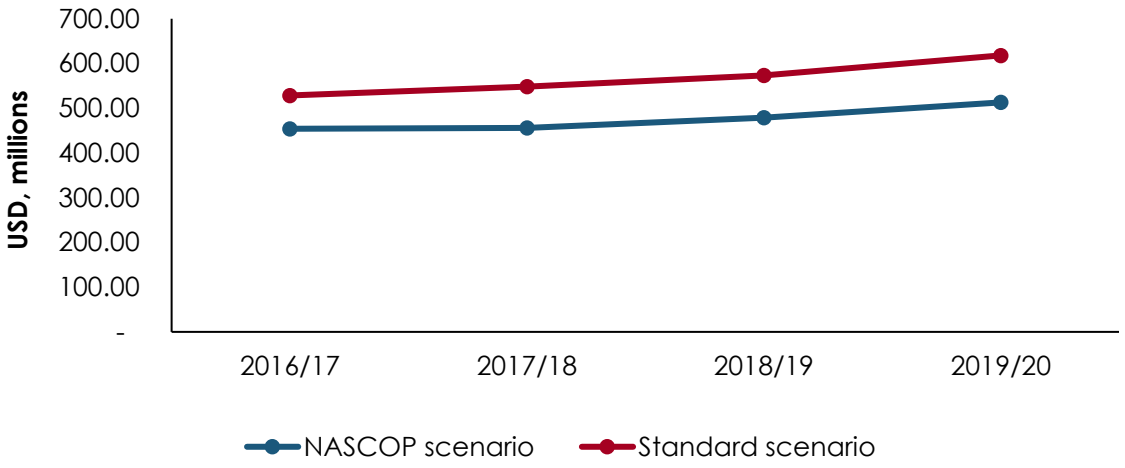
Table 3 provides cost estimates for the Standard scenario. The estimated cost for implementing this scenario was Ksh 55 billion (US$528.6 million) in 2016/2017, expected to rise to Ksh 64.3 billion (US$618 million) by 2019/20. As in the NASCOP scenario, ARVs and non-biomedical costs were the primary cost drivers. However, unlike the NASCOP scenario, total cost increased almost linearly throughout the period. This is explained by annual population growth, incidence rate, and attrition due to mortality. Additionally, the differences between the NASCOP and Standard scenario projections is explained by the assumption that the HIV programme interventions are effective, thus lowering mortality rates across years. This means fewer people living with HIV will be lost to follow-up as the programme approaches saturation and as the incidence rate approaches zero by 2030 (MOH, 2015).

Table 3: Cost Estimates of Standard Scenario in US$, millions

Programmes	2016/2017	2017/2018	2018/2019	2019/2020
ART drugs	230.2	247.5	266.2	288.1
Laboratory management	73.2	67.3	69.2	73.3
HIV testing services	20.6	21.3	16.1	17.9
NCD screening	25.6	26.4	27.6	29.2
Non-biomedical	179.0	185.6.0	194.1	209.5
Total	**528.6**	**548.1**	**573.2**	**618.0**

Figure 2 compares the NASCOP and Standard scenarios over a four-year period. The scenarios differ due to the population assumptions previously presented—the NASCOP scenario is based on scale-up targets while the Standard scenario is based on adjustments of incidence, mortality, and population growth rates. Figure 2 shows that the aggregated cost trend of implementing the new guidelines over a four-year period is expected to increase under both scenarios, with the Standard scenario being more costly than the NASCOP scenario.

Figure 2: Trend in the Costs of HIV 2016 Guideline Implementation



5.2 Cost of providing routine ARVs

Figure 3 presents the cost of providing routine ARVs to both adults and children[3] under the NASCOP scenario. In 2016/17, the cost of providing ARVs to adults was estimated at Ksh 15.1 billion (US$145 million) and is projected to reach Ksh 18.2 billion (US$175 million) by 2019/20. The cost of providing ARVs to children was around Ksh 1.56 billion (US$15 million) in 2016/17 and will remain similar until 2019/20. The effectiveness of PMTCT programmes and the transitioning of children to the adult age group explains why costs for pediatric ARVs remain low and almost constant over the periods.

Figure 3: Costs of Routine Adult and Pediatric ARVs under NASCOP Scenario

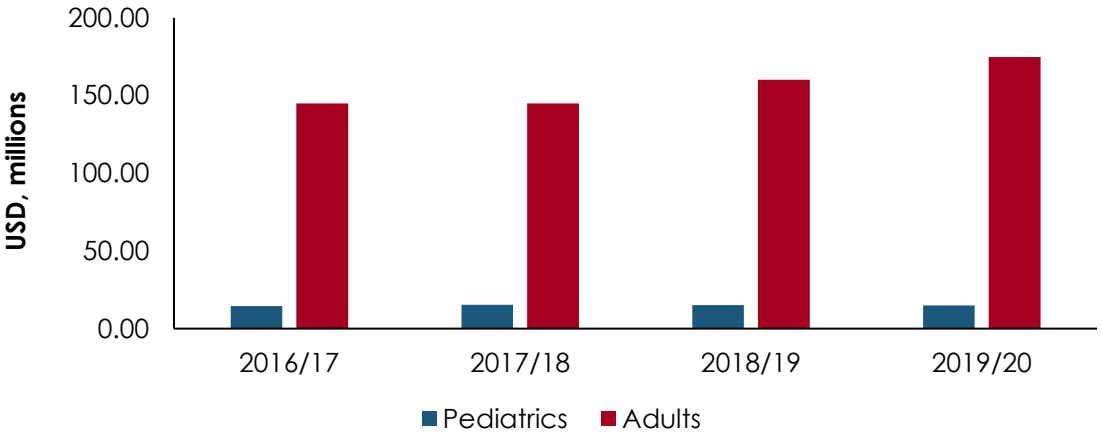
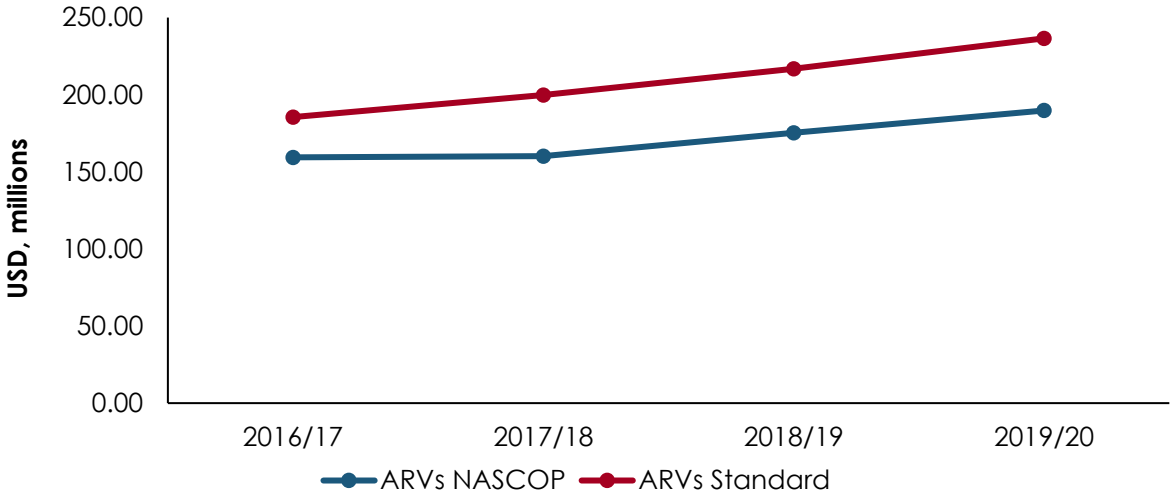


Figure 4 compares the costs of providing routine ARVs under the two scenarios. Costs increase over time in both, but at a faster rate for the Standard scenario because the population growth rate is higher compared to programme scale-up targets in the NASCOP scenario. Costs for 2016/17–2019/20 range from Ksh 19.24–24.7 billion (US$185–237 million) for the Standard scenario, and from Ksh 16.5–19.8 billion (US$159–190 million) for the NASCOP scenario.

[3] Pediatric HIV services cover children up to the age of 14. Fifteen-year olds and older are categorized as adults.

Figure 4: Trend in Costs of Providing ARVs for Care and Treatment



5.3 Laboratory management

Figure 5 shows that the cost of laboratory management is driven by adult tests in the NASCOP scenario.

Figure 5: Laboratory Management: Adults versus Pediatrics, NASCOP Scenario

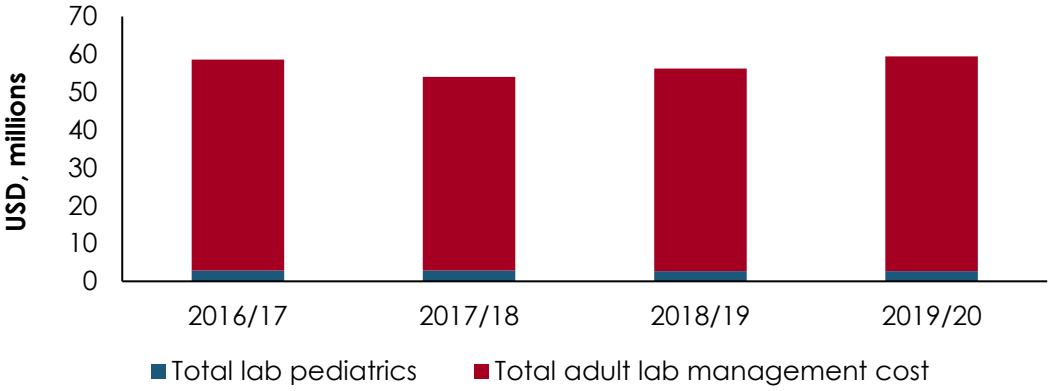
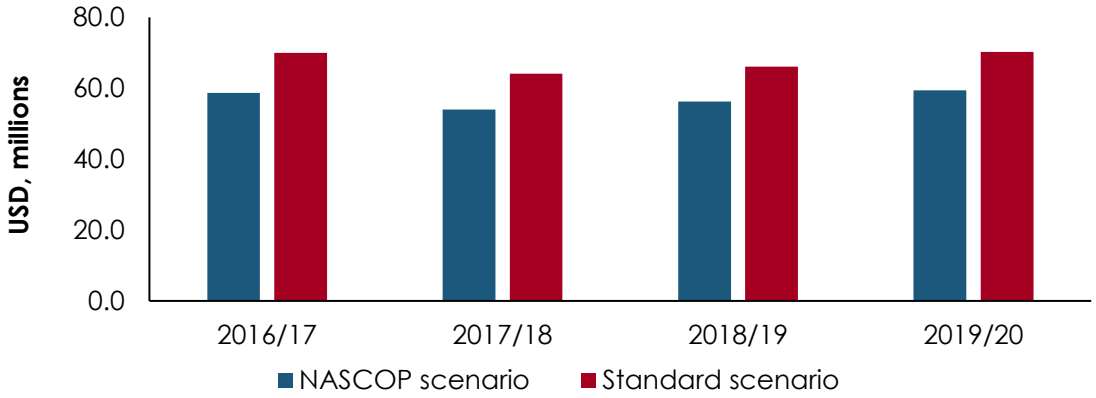


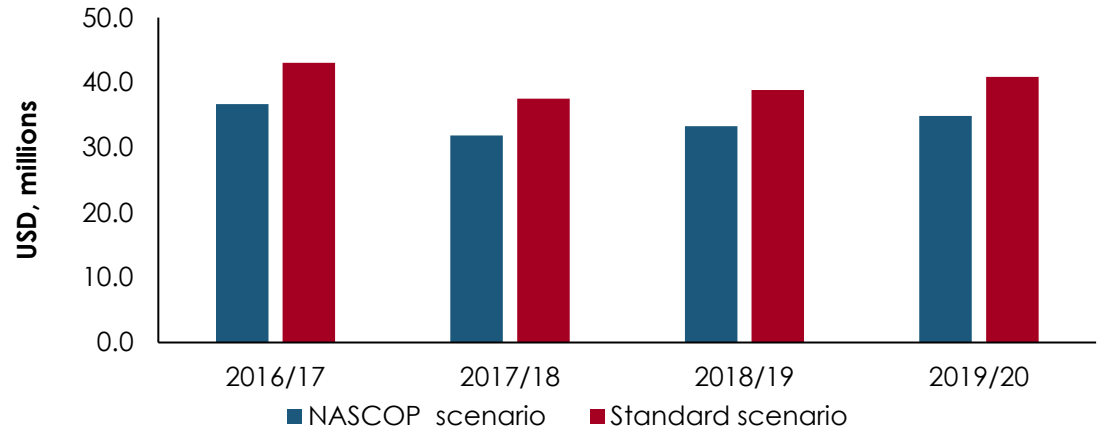
Figure 6 compares laboratory management costs between the NASCOP and Standard scenarios. Costs are higher for the Standard scenario in all years because laboratory monitoring tests are higher than under the NASCOP scenario, which has fewer people living with HIV on care and treatment.

Figure 6: Costs of Laboratory Management between NASCOP and Standard Scenarios



The new guidelines propose the adoption of viral load assessments in patient monitoring. Figure 7 shows that more viral load tests would be performed in both scenarios in the first period of implementing the guidelines. It is expected that there will be fewer new patients requiring viral load testing during the following period than in the base year (2016/17), as the programme reaches saturation. The costs associated with viral load testing were key drivers for laboratory management costs. These costs follow the trend for viral load costs in both scenarios (see Figure 6 and 7), signifying viral load cost as the main driver of aggregate laboratory management costs.

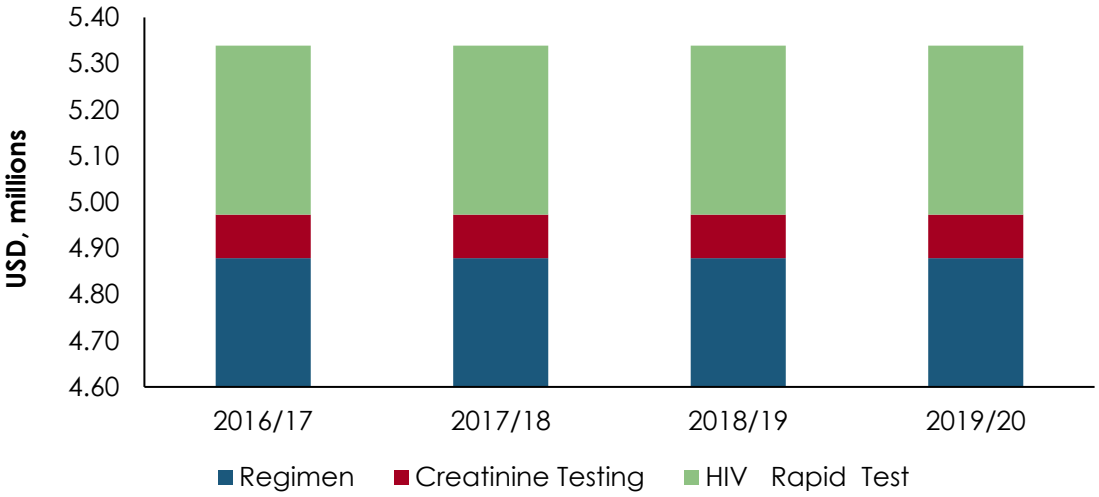
Figure 7: Costs of Viral Load Test



5.4 Cost of post-exposure prophylaxis

The costs of providing PEP under the NASCOP and Standard scenarios were equal at Ksh 555.7 million (US$5.3 million), structured as shown in Figure 8. The lack of variation between the two scenarios is explained by an assumption that an equal population will require PEP in both cases, because PEP population estimates were based on programme data and are the same in both scenarios. It is also assumed that ARVs for PEP are included under general adult ARV cost estimates. Therefore, the main cost elements were identified as additional HIV testing and kidney tests needed for the PEP programme due to use of a TDF regimen.

Figure 8: Cost for PEP, NASCOP and Standard Scenarios



5.5 Prevention of mother-to-child transmission

Figure 9 shows the estimated cost of PMTCT using the NASCOP scenario. The PMTCT costs incorporate three estimated cost components: rapid HIV testing for pregnant mothers, early infant diagnosis (or infant PCR test), and prophylaxis (the primary cost driver). HIV rapid testing for pregnant mothers, which includes blood collection bags and testing kits, is the second-greatest cost driver. The proportion of pregnant and breastfeeding women living with HIV remains constant over the four-year period, in line with the targets set by the national HIV programme.

Figure 9: PMTCT, NASCOP Scenario

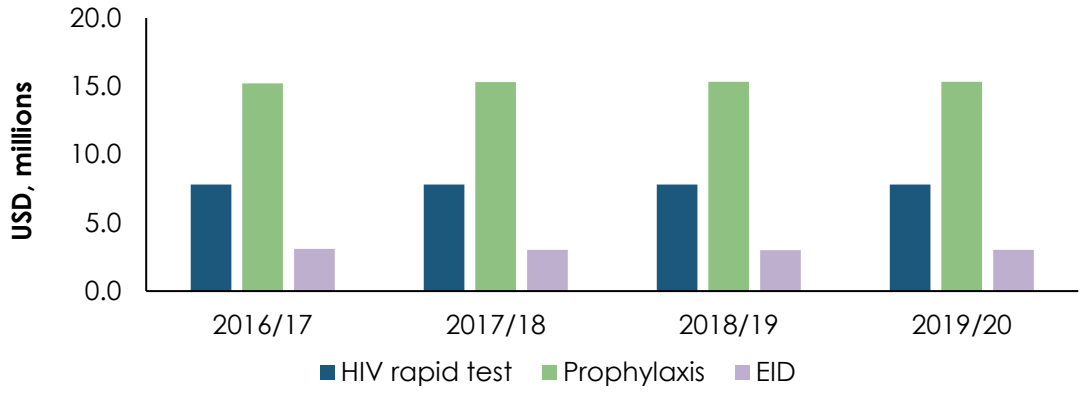
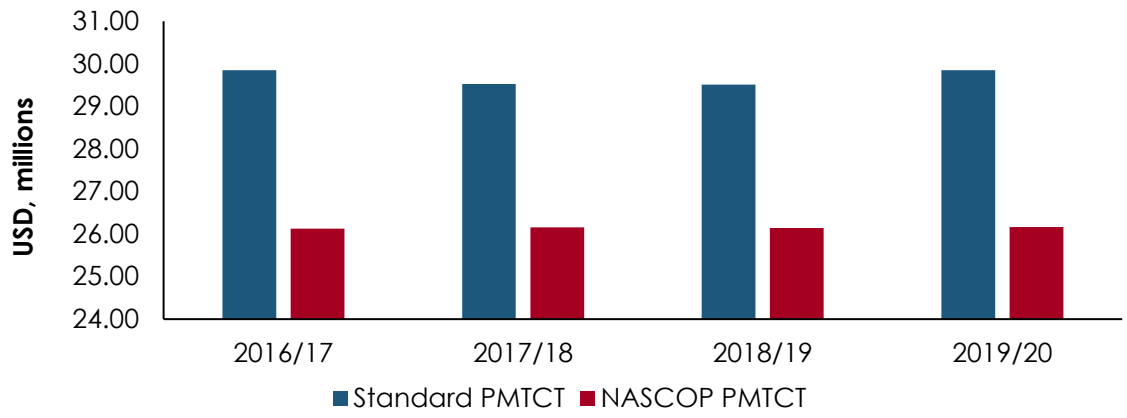


Figure 10 shows pronounced differences between the cost estimates for PMTCT between the two scenarios. The Standard scenario has higher cost estimates because it estimated a higher number of people in need of PMTCT interventions, consistent with the population's proportion of pregnant mothers—adjusted for population growth—while the number was held constant in the NASCOP scenario as per programme targets for the period.

Figure 10: PMTCT Costs, NASCOP versus Standard Scenarios



5.6 Pre-exposure prophylaxis

Figure 11 shows the cost of providing PrEP under the NASCOP scenario. This cost will increase to more than double current levels in the next four years as a result of increases in HIV-negative key populations under this prevention programme. The key cost driver under this programme is the regimen cost (the cost of ARVs), which increases over the entire period. However, the cost of HIV testing is also significant due to the numerous tests expected under this prevention programme.

Figure 11: PrEP, NASCOP Scenario

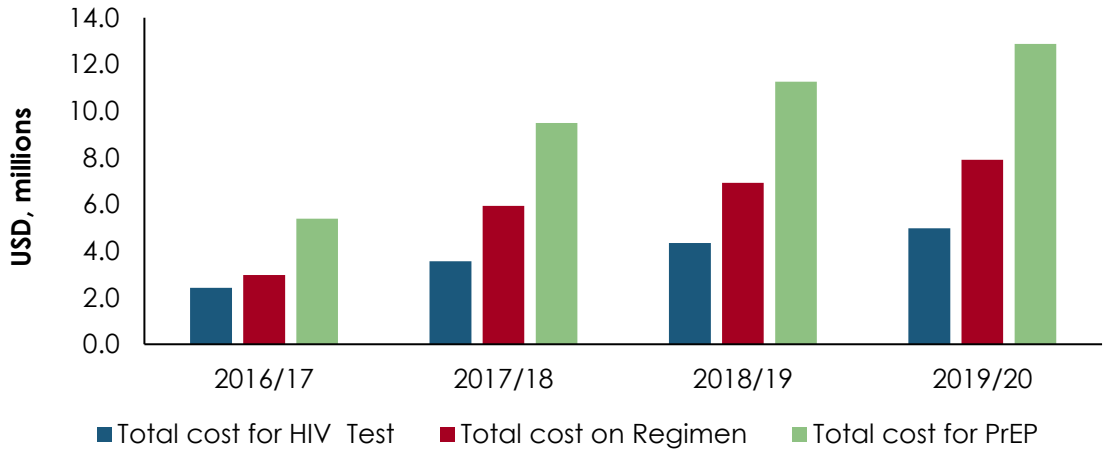
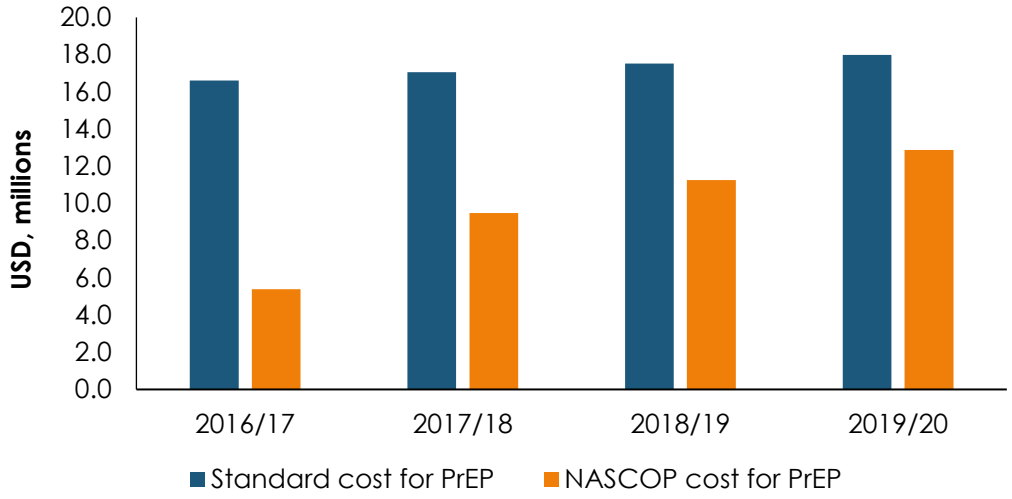


Figure 12 shows comparative cost estimates for PrEP under the NASCOP and Standard scenarios. The cost estimates for both scenarios increase over the period. PrEP population estimates are based on programme data and have been held constant for both scenarios. In the NASCOP scenario, costs increase under the assumption that the percentage of key populations with PrEP coverage will be more than the preceding period. On the other hand, the assumption for the Standard scenario is based on the fact that all HIV-negative key populations are put on PrEP, and that the growth of these populations will be in tandem with overall population growth. These assumptions explain the significant gaps in Figure 12 between the NASCOP and Standard scenarios over the entire projected period.

Figure 12: PrEP, NASCOP versus Standard Scenarios



5.7 HIV testing services for the general population

Under the NASCOP scenario, HIV testing services cost approximately Ksh 1 billion (US$10 million) in 2016/17 (see Figure 13). The total cost drops over the two subsequent periods and then increases slightly in the last period. Key cost drivers for HIV testing services are the HIV rapid kits, at a cost of approximately Ksh 936 million (US$9 million), and blood collection bags. The reason for the low estimated costs for confirmatory tests is that the test is only administered to people who have tested positive from the HIV rapid kits—this is expected to be a small proportion of the total population under testing.

Figure 13: HIV Testing Services Cost Estimates, NASCOP Scenario

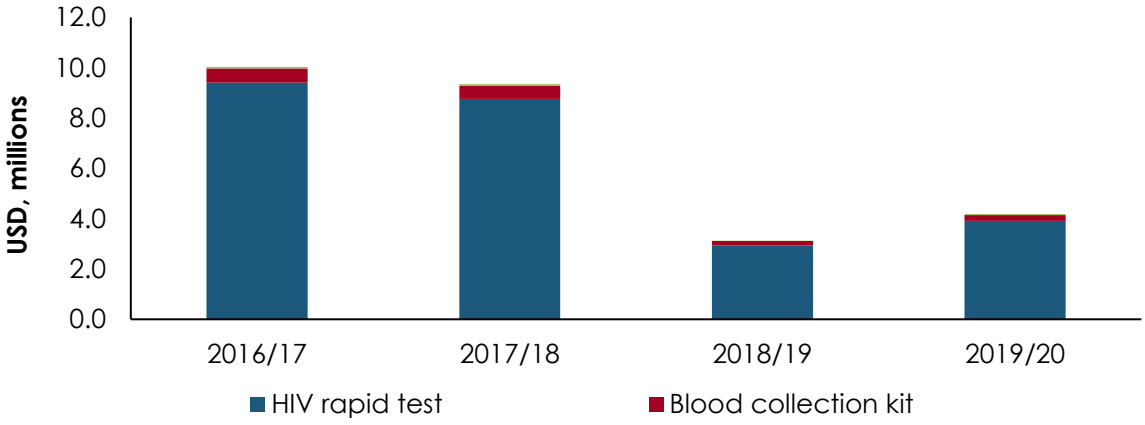
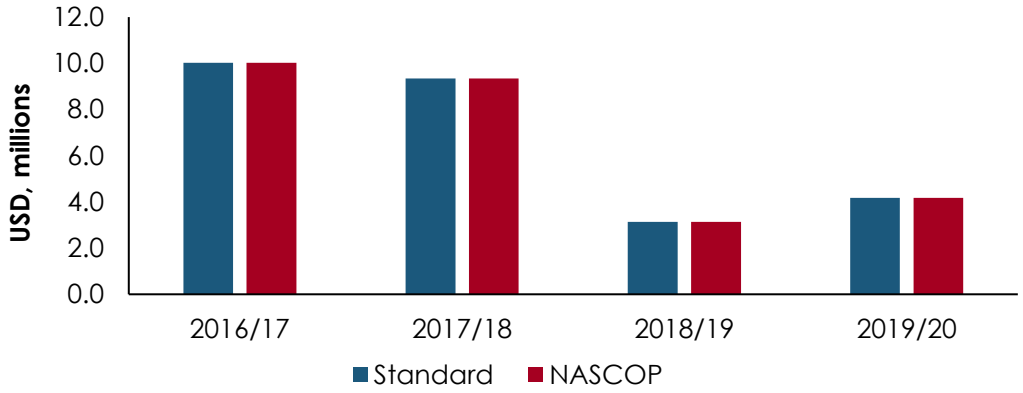


Figure 14 demonstrates that there were no HIV testing services cost differences between the NASCOP and Standard scenarios, as the whole population was targeted in both scenarios.

Figure 14: HIV Testing Services Cost Estimates, NASCOP versus Standard Scenarios



5.8 NCDs and other co-morbidity

The 2016 ART guidelines recommend screening among people living with HIV for key NCDs and co-morbidities, including cancer, high blood pressure, hepatitis B and C, diabetes, and liver functions. Figure 15 shows the estimated cost of screening for these NCDs and co-morbidities under the NASCOP scenario. Screening for cervical cancer, diabetes, and cholesterol are the main cost drivers for this new programme area. The estimates show rising costs in line with an increased incidence rate of NCDs and co-morbidities over the time periods, given that the NASCOP scenario expects to put more people living with HIV on treatment in the future and that the incidence rate is positive over the entire period.

Figure 15: Screening NCD and Co-morbidities, NASCOP Scenario

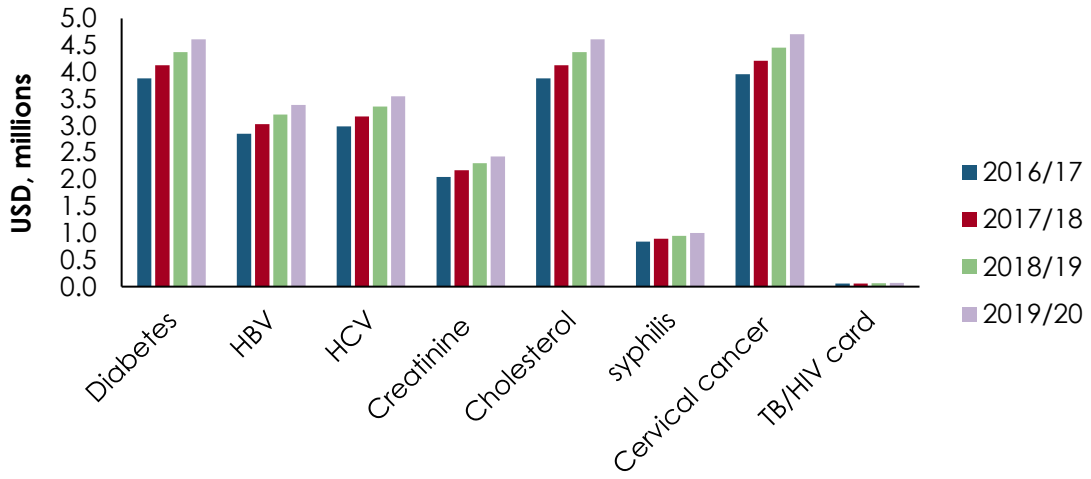
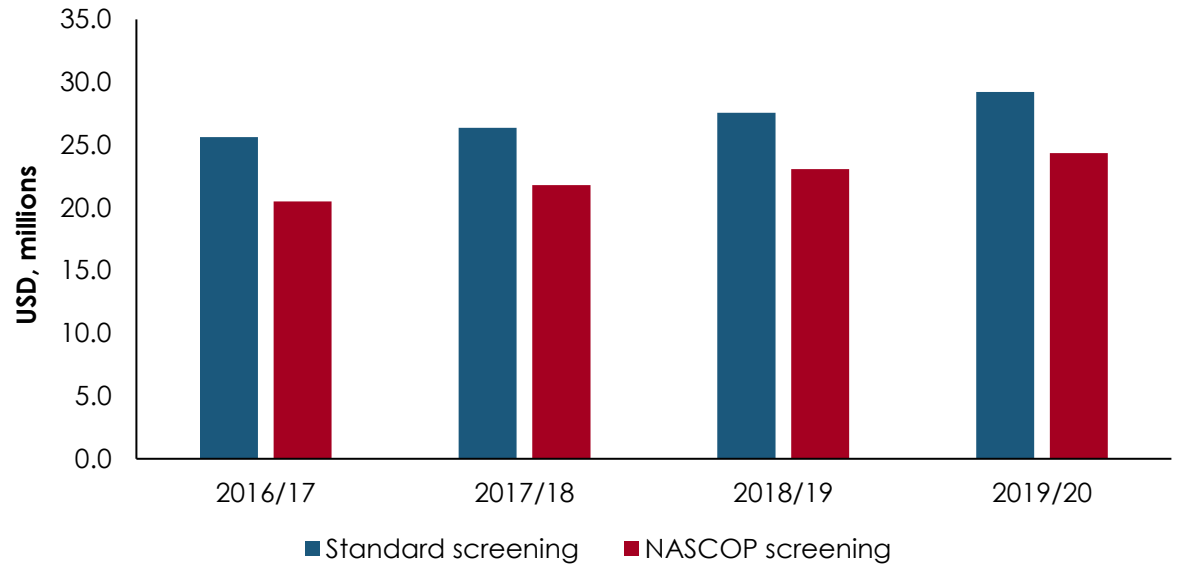


Figure 16 shows the costs for screening people living with HIV for NCDs and other co-morbidities, for both the NASCOP and Standard scenarios. Due to data limitations, the prevalence of NCDs is based on the general population (both HIV-positive and HIV-negative), rather than strictly on people living with HIV. The cost under the Standard scenario is higher than for the NASCOP scenario, which is expected due to population growth assumptions. The cost trends are also consistent with the assumption of providing HIV care to more people living with HIV in both scenarios.

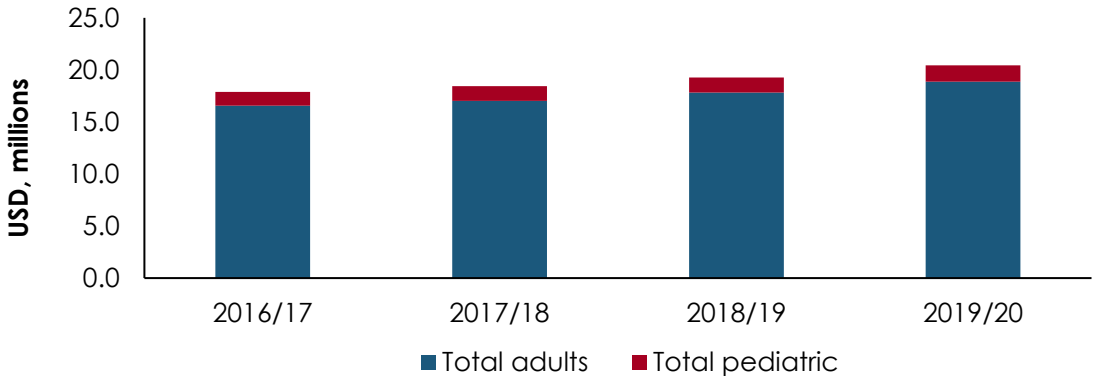
Figure 16: Screening for NCDs and Co-morbidities, NASCOP versus Standard Scenarios



5.9 Medicines for opportunistic diseases

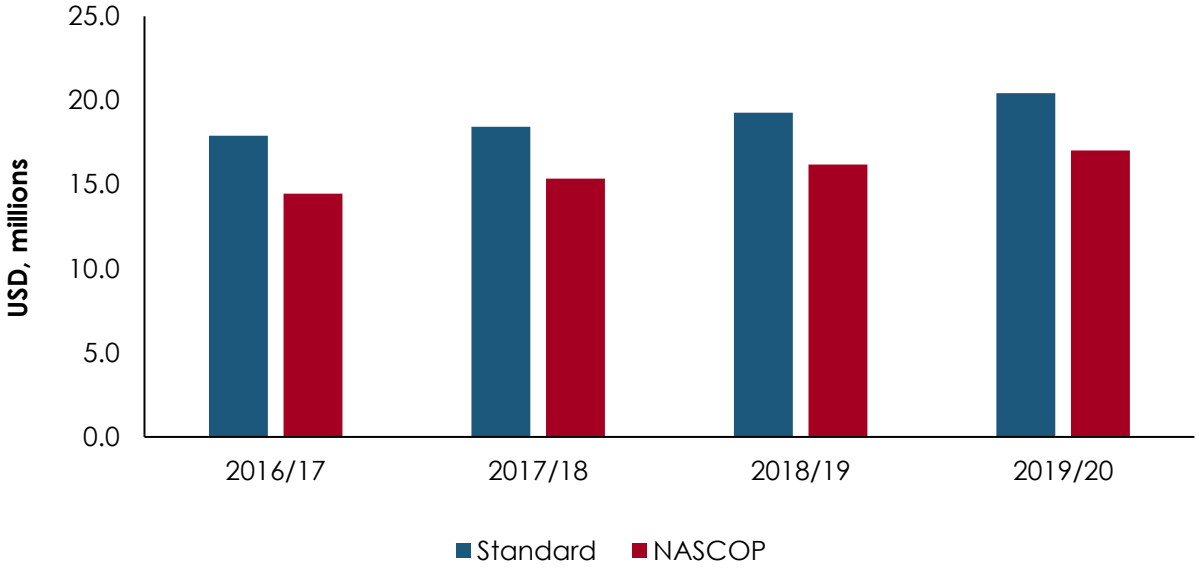
Figure 17 shows that the estimated cost of medicines for opportunistic diseases is projected to increase over time. This is consistent with the target of getting more people living with HIV into care over the projected period, as Kenya moves towards achieving the 90-90-90 targets under the test-and-treat policy. The new guidelines emphasise the need to put people living with HIV on medicines for opportunistic diseases to reduce their mortality rate. A lower mortality rate is expected to bring additional costs as demand for medicines for opportunistic diseases increases. The key driver of this programme cost is the cost for adults, which is not surprising as adults account for the bulk of people living with HIV.

Figure 17: Medicines for Opportunistic Diseases, NASCOP Scenario



The comparative cost estimates between the NASCOP and Standard scenarios are reported in Figure 18. As with the other cost estimates, the Standard scenario costs are higher than the NASCOP scenario due to the difference in the estimated population in need for each scenario. The assumption of placing more people living with HIV in HIV care means that they will benefit from acquiring medicines for opportunistic diseases. In the case of the Standard scenario, the assumption of a decrease in HIV mortality means that more people living with HIV will continue to require medicines for opportunistic diseases moving forward.

Figure 18: Medicines for Opportunistic Diseases, NASCOP versus Standard Scenarios



6. Conclusions

The costing of HIV interventions in this study is based on 2016 HIV guidelines and considers two scenarios: NASCOP and Standard. The NASCOP scenario was based on national HIV programme targets towards achievement of 90-90-90, and the Standard scenario was based on the assumption that the guidelines would be fully implemented as spelt out in the 2016 ART guidelines. In the NASCOP scenario, the population base is assumed to be constant for the four-year costing projections, while the Standard scenario adjusts its population in need to consider incidence, mortality, and population growth rates. However, both scenarios considered two key assumptions: the gains obtained from the reduction in HIV mortality and the reduction in HIV incidence rates.

Findings have shown that the average annual cost of putting a patient on ARVs is Ksh 12,032.36 (US$115.7). The Standard scenario costs more than the NASCOP scenario, although differences vary across programme areas. The key biomedical cost drivers in both scenarios were ARTs and laboratory management. Although non-biomedical interventions seemed to be a cost driver, these cost estimates were derived as a proportion of the total cost based on the report of a cost study of HIV treatment conducted in 2013 (U.S. Centers for Diseases Control and Kenya Ministry of Health, (2013), which had an in-depth micro-costing of both medical and non-medical HIV programme interventions.

In conclusion, there is an expected escalation in future costs with the implementation of the new 2016 ART guidelines. This is due to inclusion of more people living with HIV in care and treatment programmes, and further enhanced by a reduction in HIV-related mortality. The inclusion of PrEP and PEP as prevention measures might have a significant impact on reducing the HIV incidence rate. This will, however, come with a considerable increase in the resources needed to fund interventions.

Therefore, the key policy interventions introduced in the new guidelines center on prevention and acceleration of treatment aimed at reducing HIV incidence rates and related mortalities. This calls for resources to cover an increased number of people targeted for care and treatment programmes. A lowered mortality rate achieved through an ART programme implies increased HIV costs, as the number of people living with HIV who require HIV care will also increase.

Kenya must explore channels for financing its increased need for HIV care and treatment. These could include coverage of HIV services in health insurance benefits packages (social or private health insurance), increased domestic resource mobilisation (including allocations from national and county governments), and engaging the private sector to play a bigger role in HIV financing.

7. Study Limitations

1. The only data available on mortality rates for people living with HIV comes from the mortuary survey. This study is not representative of the current nationwide attrition rate, as it is based on Nairobi County data. A mortuary survey should be administered nationwide to create a countrywide database for attrition rate.
2. The costing model has not incorporated a six-month buffer stock, as this was not in the scope of the study. The model, however, can be customised to capture the buffer stock when used for commodity quantification for processes such as the Global Fund application.
3. The estimates for non-medical costs were based on the *Cost of Comprehensive HIV Treatment in Kenya* study, conducted in 2013 using 2011 data. The Government of Kenya needs to conduct a new study to generate more current costing data, which should account for changes in the HIV and AIDS epidemiological environment, guidelines, and macroeconomic variables.
4. Population estimates for PrEP and PEP were based on programme data and have been held constant for both scenarios. Because there is a lack of data on the two interventions, there is a need for modelling to estimate the population in need for both.
5. The prevalence of data on NCDs is based on the general population, both those who are HIV-positive and those who are negative. A study must be conducted to exclusively gather data on NCD prevalence rate amongst people living with HIV so that a more accurate population baseline is used for any future costing exercises.

8. References

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Republic of Kenya. 2013. *Annual Vital Statistics Report*. Nairobi, Kenya: Republic of Kenya.

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Annex 1: Detailed Assumptions Sheet for HIV 2016 Guidelines

Demographics

- Estimated PLHIV [people living with HIV] population is held constant at 1,517,707 for the four years as per the NASCOP scenario
- Coverage of PLHIV population under care is assumed to grow from 80% (2016/2017) of the estimated population to 95% for the fourth target year (2019/2020)
- PLHIV women are assumed to be 57% of the total estimated PLHIV adults
- To create a standard scenario that considered 100% implementation with some realistic assumption that adjusted PLHIV numbers by incidence rate, mortalities, and population growth rate, NASCOP estimates were used
- PLHIV pregnant and breastfeeding women are assumed to remain constant over the four period as per NASCOP estimates
- PLHIV prevalence rate is 5.9% for 2015 and NASCOP scenario to reach 3% by 2020; hence an assumption of linear reduction was done to arrive at 3% by 2019/2020 in the standard scenario
- The PLHIV incidence rate is 0.35% for 2015
- Population growth rate was 2.7%
- Proportion of pregnant mothers was established from the population projections given by UN Population

ART and Linkage to Care

- All individuals with confirmed HIV infection are eligible for ART, irrespective of CD4
- Assumed that 5% of all PLHIV on treatment are on/will be in need of 2nd-line ART
- ART should be initiated in all pregnant and breastfeeding women living with HIV, regardless of gestational age
- PLHIV who inject drugs > 15 years should use TDF + 3TC + ATV/r
- All regimen splits were as provided by NASCOP
- The pediatric regimen splits were provided in terms of weights
- All pediatrics were assumed to be unstable as per the guidelines for the purpose of receiving differentiated ART care
- All PLHIV should be linked to HIV care

Laboratory Management

- All patients newly initiated on ART will receive viral load test at 6 months and at 12 months
- All patients (new and old) on ART will need an annual viral load test
- Repeat viral load test should be done when load > 1,000 copies/ml
- All patients failing 2nd-line treatment will receive drug resistance testing to determine 3nd-line regimen; 20% PLHIV assumed to fail
- Baseline CD4 recommended for all new patients
- All adult PLHIV with a baseline CD4 count of 100 cells/ml should be screened for Cryptococci meningitis (CM) using the serum Crags test
- Assumed that 45% of PLHIV have CD4 count <100 cells/ml
- All new PLHIV to receive one ALT Test

- Percentage of patients on NVP regimen was estimated at 80% for the first year and 79% for the following years
- All PLHIV patients on NVP-regimen were to get one ALT Test
- All newly PLHIV to get one Creatinine test
- All PLHIV with treatment failure to receive one Creatinine test
- Number of patients failing 2nd-line ART was at 0.02 percent of the PLHIV
- All patient failing in the 2nd-line were to receive Crag Test
- Full blood count (FBC) to be done once for all new HIV patients
- FBC test to be done once for all patients with treatment failure
- One test on HB for patients on AZT regimens

Post-exposure Prophylaxis (PEP)

- The number of PEP patients were held constant at 48,000 for the three periods
- PEP to be offered once the exposure has been found negative and has occurred within 72 hours
- Offer PEP as soon as high-risk exposure is established and exposed individual tests HIV-negative at baseline
- Follow-up HIV testing at 3 and 6 months after exposure
- All PEP patients were to be treated with regimen TDF + 3TC + ATV/r
- All PEP patients to receive one Creatinine test due to use of TDF

Pre-exposure Prophylaxis (PrEP)

- All PrEP users to be confirmed HIV-negative
- High-risk groups included MSM [men who have sex with men], FSW [female sex workers], discordant couples, PWID [people who inject drugs], health workers, sero-discordant couples, and those experiencing GBV
- The high-risk population was assumed to grow with population growth assumption
- All sero-discordant couples to receive HIV testing twice in a year
- MSM HIV testing every three months (4 times)
- FSW HIV testing every three months (4 times)
- PWID HIV testing every three months (4 times)
- The recommended regimen for PrEP is TDF + 3TC - fixed dose has 30 tablets

HIV Testing Services

- Target general population - adults
- Target general population - pediatrics
- Target PMTCT - (antenatal, labour and delivery, postnatal)
- Target MSM
- Target FSW
- Target PWIDs
- Target TB patients
- Target discordant couples
- For all HIV tests that turn positive, a confirmatory test is to be done
- PMTCT
- Pregnant and breastfeeding women newly initiated on ART, obtain VL 6 months after initiation

- All HIV-negative pregnant mothers to get 3 tests for HIV
- All HIV-exposed infants to receive one regular HIV test (antibody test) after 18 months
- All exposed infants to receive 12 weeks of prophylaxis
- All infants to receive PCR at first contact
- All HIV-exposed infants to receive HIV testing at 6 weeks, 6 months, and 12 months

NCD and Other Comorbidity Screening

- All PLHIV should be screened for STIs at every clinic visit
- All HIV-positive women between the ages of 18 and 65 should be screened for cervical cancer
- All HIV-infected patients who are co-infected with hepatitis B should be started on ART irrespective of CD4 cell count
- All PLHIV to be tested for cholesterol
- All HIV-positive persons should be screened for HBV infection
- All PLHIV to be tested for kidney infections
- All PLHIV to be tested for high blood pressure
- All PLHIV to be tested for diabetes

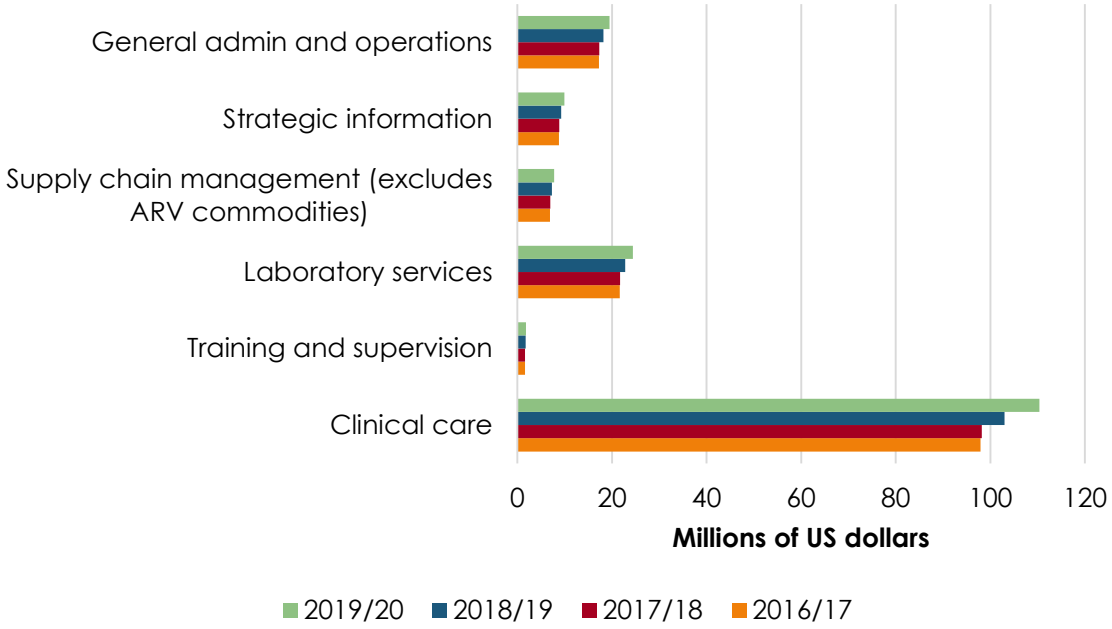
Medicine for Opportunistic Diseases

- All PLHIV should receive lifelong cotrimoxazole prophylactic therapy (CPT)
- Isoniazid preventive therapy (IPT) should be provided to those patients in whom TB is excluded
- All PLHIV children/infants should receive lifelong CPT based on weights for dosage
- IPT should be provided to children/infants based on weights for dosage

Non-biomedical Interventions (Others)

- The costing assumption for non-commodities was based on an earlier detailed costing that had linkage to care and other necessary attributes identified in the detailed cost study, The Cost of Comprehensive HIV Treatment in Kenya 2013
- Assumed that linkage to care includes all the clinical care that are non-commodities; clinical care non-commodities to include adherence assessment, counselling, monitoring support, frequency of follow-up, clinical evaluation, and treatment time; the proportion of clinical care to total cost of comprehensive care was calculated at 34%
- Laboratory services included all human resource time used in all laboratory tests; the proportion of laboratory services to total comprehensive cost was calculated at 8%
- Training and supervision cost was also assumed due to capacity building in the guideline implementation; the proportion of training and supervision to the comprehensive cost was calculated at 1%
- Supply chain management was considered to take care of logistics involved in non-commodity procurement; its cost to total comprehensive cost was calculated at 8%
- Strategic information included campaigns/advocacy and information gathering relating to the implementation of the guidelines; its proportion to total comprehensive cost was calculated at 3%
- General administration included any form of coordination, organisation, and management of the programme initiatives; the proportion of cost to total comprehensive cost was calculated at 6%

Annex 2: Non-medical Interventions, NASCOP Scenario



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