Scoping Visit to Zambia - Summary of Findings[1]

[1]Questions can be sent to Anna Konstantinova, Senior Manager, Maternal Syphilis Program, at Evidence Action (anna.konstantinova@evidenceaction.org). All of the findings laid out in this report represent the best summary of information shared by the Zambian government and local stakeholders during an in-country visit in October 2021. It is possible that some of the information provided was misinterpreted, and so further engagement with stakeholders should occur before critical program decisions are made based on the content of this report.

Executive Summary and Recommendations

Based on conversations and feedback shared by key officials within the Zambian Ministry of Health, local NGOs, and major development partners, there are several areas where a partner's support in Zambia could lead to meaningful increases in syphilis screening and treatment. As of now, between one-third and half of all pregnant women are screened for HIV but not syphilis, and gaps in syphilis treatment have emerged in the past several years; both syphilis screening and treatment are suffering from inconsistent availability of commodities nationally and at health facilities. Many stakeholders believe the country's high and rising incidence of stillbirth and neonatal death are due in part to unaddressed maternal syphilis and the absence of coordinated partner support to address the issue. The government (namely, the Prevention of Mother-to-Child Transmission Coordinator), with the support of a core team of largely laboratory stakeholders, has taken initial steps to combat this issue and introduce a dual HIV/syphilis rapid test into antenatal care settings. Further partner support would aid in taking this program to national scale and eliminate mother-to-child transmission of syphilis once and for all in Zambia.

In this report, Evidence Action details: (1) estimates of syphilis prevalence in Zambia; (2) the current state of the Zambian healthcare system; (3) the dual testing policy environment; and (4) the stakeholders which may be involved in potential maternal syphilis efforts.

Syphilis Prevalence

Evidence Action had identified two estimates of syphilis prevalence prior to the scoping visit:

- Via Spectrum-STI modeling, the prevalence of active syphilis was estimated at 2.53% in 2016. The Spectrum-STI modelers used country-reported data from the Global AIDS Monitoring System (GAMS) and applied a smoothing curve to take into account realistic changes in prevalence year-on-year. The modelers also validated outlying point estimates with country focal persons and down-weighted estimates they believed were biased (most often accounting for situations where a small subset of the population was tested).[2]
- Via the WHO's Global Health Observatory (GHO), the country has been reporting that the percentage of ANC attendees who tested positive for syphilis ranged from 3.5% to 5.3% between 2008 and 2018, with the most recent data reporting a prevalence of 5% in 2018.

During the scoping visit, Evidence Action identified two other sources of data on syphilis prevalence. The first is the Zambia Population-Based HIV Impact Assessment (ZAMPHIA), a nationally representative, cross-sectional, population-based survey which was conducted between March and August 2016 to measure the status of Zambia's national HIV response. The target populations of the survey were children aged 0-14 years (target sample of 8,974) and adults aged 15-59 years (target sample of 19,168), excluding institutionalized children and adults.

[2] Based on a conversation with Eline Korenromp who developed the Spectrum-STI model.

According to the report, "testing for syphilis infection was conducted in each household among participants aged 15-59 years using the DPP Syphilis Screen and Confirm Assay for the simultaneous detection of antibodies against non-Treponemal and Treponemal pallidum antigens. Confirmatory testing was done using the SD BIOLINE Syphilis 3.0."

Among 789 currently pregnant women tested across the sampled households, the ZAMPHIA study found an active[3] syphilis prevalence of 3.0%. Among 10,021 non-pregnant women, the ZAMPHIA study found an active syphilis prevalence of 3.4%.

The Republic of Zambia's Ministry of Health also published the Annual Health Statistical Report covering 2017 through 2020 based on data reported by health facilities through routine DHIS2 reporting. Of note, the DHIS2 reporting forms include indicators on syphilis-related outcomes (number of cases of total stillbirths, premature birth, congenital syphilis, syphilis among females by age category), the number of women screened for syphilis and the number reactive, as well as the number of women given a confirmatory test for syphilis and the number positive. According to the Annual Health Statistical Report, there was a syphilis RPR positivity rate of 4.3% amongst the 507,060 women screened in 2019.[4]

Overall, Evidence Action recommends relying on the active syphilis prevalence measured via the ZAMPHIA study as the survey was nationally representative and a sequence of tests was used to directly measure active syphilis. Thus, the prevalence of active syphilis is 3.0% nationally.

Description of the Healthcare System

Physical and Human Infrastructure

Administratively, Zambia is divided into 10 provinces overseeing approximately 116 districts.[5] Activities below the national Ministry of Health are coordinated by the Provincial and District Health Offices (PHO and DHO, respectively). The national MoH is responsible for formulation of policy and standards, quality assurance, and resource mobilization. The PHOs serve as a link between the national MoH and the districts, providing supervision, technical support, logistics support, and capacity development to the DHOs. The DHOs are responsible for managing all healthcare facilities and providers under their jurisdiction.

As of 2017, there were 2,931 health facilities in the country.[6] These are divided amongst hospitals, clinics, health centers, and health posts as follows:

- 141 hospitals (including first-level, or district-level, secondary-level, and third-level)

[3] The testing scheme used for syphilis distinguishes among the stages of syphilis infection and allowed the researchers to directly measure and report active syphilis, rather than a combination of active and latent syphilis.
[4] See Table 4-12 in the Zambian Ministry of Health's Annual Health Statistical Report covering 2017 through 2020.
[5] There were 105 districts prior to a reorganization in 2018.
[6] See Table A.4 in the World Bank's report on health expenditures in Zambia. The last known national census of health facilities was conducted in 2017. It is likely the number of facilities has increased in the years since but more accurate data is not available at this time.

- 17 clinics[7]
- 1,820 health centers (659 in urban areas and 1,161 in rural areas)
- 953 health posts

All facility levels in Zambia are capable of providing comprehensive ANC services, including HIV and syphilis screening. Health posts, the lowest level of health facility, are staffed by community-based volunteers (CBVs) with occasional support from nurses and midwives. CBVs - non-professional medical staff - conduct the majority of HIV rapid testing at the point-of-care across all facility levels. Trained lab aids, nurses, and midwives are also able to administer rapid tests, but only nurses and midwives are able to administer injectables -- as a result, syphilis screening can be done effectively at the lowest level health facility while treatment may sometimes require referral from health posts to other facilities.[8]

Antenatal Care

According to the 2018 DHS, 97% of women aged 15-49 who had a live birth in the five years leading up to the survey had received at least one ANC from a skilled provider, such as doctors, nurses/midwives, and clinical officers. In 93% of instances, this care was provided by a nurse/midwife. Most antenatal care visits took place in the public sector[9]:

- 73% at government health centers
- 13% at government health posts
- 10% at government hospitals
- 1% at mobile clinics
- 4% at private or mission-based hospitals and clinics[10]

The 2018 DHS survey reaffirms the results found in the 2016 ZAMPHIA study which found that 99% of women aged 15-49 years who delivered in the three years preceding the survey attended at least one ANC visit.

Looking at the MoH's 2017-2020 Annual Health Statistical Report, over 90% of pregnant women attended at least one ANC visit each year. In this case, the attendance rate is based on the number of pregnant women who attended one visit via facility reports in DHIS2 and the estimated population of women aged 15-49 who are expected to be pregnant.[11] In 2020, there were an estimated 786,691 pregnant women across the country and 762,409 first ANC visits reported via DHIS2 (96.9% attendance rate).

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[7] Based on the report, it's not clear how clinics compare to other facility types in terms of health services available.
[8] According to the 2018 DHS survey, 13% of pregnant women sought antenatal care from a government health post.
[9] Based on Evidence Action's analysis of the DHS 2018 raw data.
[10] In 2018, Zambia created the National Health Insurance scheme (NHIS) under the Management of the National Health Insurance Management Authority (NHIMA). Mandatory to all citizens and established residents in Zambia, the scheme covers maternal, newborn and pediatric services, which are free of charge at public facilities. Syphilis screening at private facilities will still require out-of-pocket payments by the patient.
[11] It was noted in discussions with the MoH that the country was due for a census in 2020 that was disrupted by the COVID pandemic.

Overall, across the various sources, Evidence Action can conclude that the ANC1 attendance is at or near 100% and most pregnant women can be screened for syphilis by focusing on ANC settings.

Coverage & Barriers to HIV and Syphilis Screening and Treatment in Pregnancy

Both HIV and syphilis screening are part of the essential package of services for a first ANC visit. Per discussions with midwives at the two health facilities visited, the other core components of a first ANC visit include a physical examination, a hemoglobin test, a malaria test, iron and folic acid supplementation, IPT, deworming, provision of bednets, education on nutrition and scheduling of future visits.

According to numerous sources, HIV screening among first time ANC attendees generally exceeds 80%. According to the 2018 DHS report, 81.7% of women aged 15-49 who gave birth in the 2 years before the survey received counseling, were tested for HIV, and received their test results during ANC.[12] Similarly, the 2017-2020 Annual Health Statistical Report reports that the testing rate for HIV in ANC was 81.6% in 2020 (see Figure 1 below for monthly testing coverage between 2018 and 2020). Finally, UNICEF's data warehouse reports that 91.1% of pregnant women presenting at ANC in 2018 were either tested for HIV or were already known HIV positive. In addition, there is relatively high enrollment and adherence to antiretroviral therapy (ART) in Zambia -- 96.5% of HIV+ women were on ARVs and 88% had achieved viral suppression.

Syphilis screening lags far behind HIV screening among ANC attendees. According to the 2017-2020 Annual Health Statistical Report, the syphilis screening rate in ANC was 56.3% in 2018, 54.1% in 2019, and 47.6% in 2020.[13] Based on this data, between one-third and half of all pregnant women in the country are getting tested for HIV but not syphilis during antenatal care. See Figure 1. Anecdotally, from the facilities Evidence Action visited, syphilis screening was acknowledged to be a mandatory component of a first ANC visit but was not being done consistently. For example, in one facility, there were lab tests available but midwives in the ANC rarely referred pregnant women to the lab because of long wait times and only tested women at the ANC itself when syphilis rapid tests were available, which was very sporadic.

[12] The DHS survey asks women who are pregnant or were previously pregnant three separate questions related to HIV testing: if they were counseled for HIV, if they were tested, and if they received their results from a health provider. Looking at Table 13.8, 89.3% of pregnant women were tested and received their HIV test result at ANC (excluding pre-test counseling). 93.1% of pregnant women were tested for HIV if one includes tests which took place during labor.

[13] Prior to the scoping visit, Evidence Action noted that the syphilis screening rate reported on the WHO Global Health Observatory database was 65% in 2019, 56.4% in 2018, and 56% in 2017.

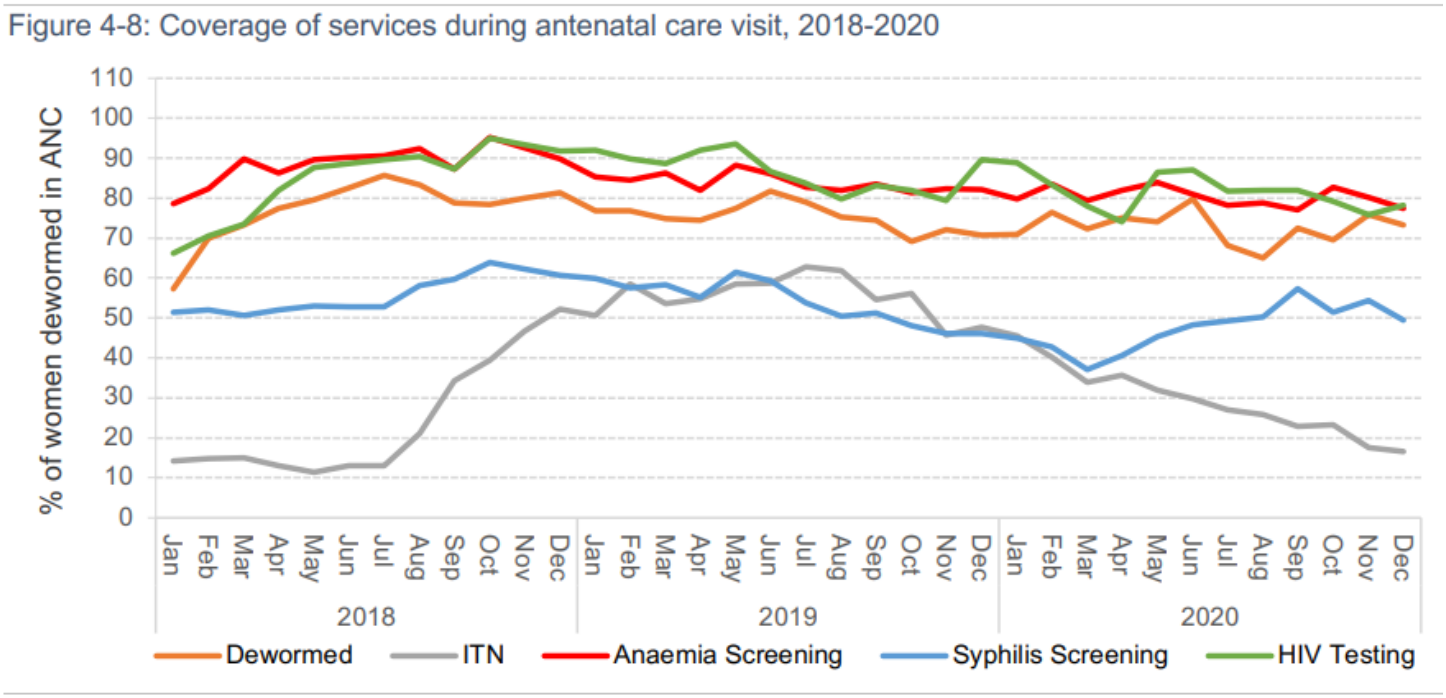

Figure 1. Coverage of HIV testing, syphilis testing, anemia testing, deworming, and provision of insecticide treated bednets among antenatal care attendees between 2018 and 2020. Copied from the MoH 2017-2020 Annual Health Statistical Report.

Based on discussions with stakeholders and observations while visiting health facilities, the key reason for the low rate of syphilis screening is challenges with consistent availability of test supplies across facilities where women seek antenatal care. The lack of availability is due to (1) limited government funding allocated to procure the commodities, since procurement of syphilis tests is often not directly supported by partners, and (2) challenges in supply chain distribution at the last mile for the commodities. For example:

- According to the EpiC program, among their 20 focal facilities and 5 district health offices, in a recent survey, only 5 had sufficient stock status of syphilis testing supplies (either RPR or rapid tests). 4 reported low stock of syphilis testing supplies and 16 (or 64%) were stocked out.
- One of the facilities visited in Lusaka noted that syphilis rapid tests were provided by the central government sporadically and in small volumes since Oct 2020. As a result, they are rarely able to do point-of-care testing in the ANC which means many pregnant women are not being screened for syphilis at all.
- In Eastern province, the stockouts of syphilis commodities led the Provincial Health Office there to request and receive CDC funding to buy some of its own commodities (2-3 month supply) from a local pharmaceutical distributor.

Shifting to treatment coverage, on the WHO's Global Health Observatory database, syphilis treatment was reported to be 87.3% in 2019 and 100% in the years prior. Based on a presentation shared by Dr. Priscilla Mulenga, syphilis treatment was 100% in 2017 but fell to 73% in 2020. Dr. Mulenga also shared that, "data for Q1 2021 showed that 30-40% of pregnant

women who were positive for syphilis received treatment." There is no reporting on syphilis treatment in the 2017-2020 Annual Health Statistical Report.

Based on observations during the scoping visit, there were several potential gaps identified in syphilis treatment, especially in same day treatment. First, it was noted by stakeholders that availability of benzathine penicillin may be intermittent as it is a commodity procured solely by the MoH. Within the same survey by EpiC, 15 facilities/district health offices (60%) were stocked out of benzathine penicillin while 7 had low stock and only 3 had adequate or excess stock. Second, many facilities rely on lab-based testing for syphilis which often means results are not available until a later date thereby preventing same day treatment. Finally, there are a few key misconceptions that exist related to syphilis treatment which may delay access by pregnant women -- it is believed by some midwives benzathine penicillin cannot be given on an empty stomach (so women are asked to return another day after having eaten) and it is believed treatment is ineffective if the partner is not treated too (so women are only treated when they present with a partner or after much effort is made to bring the partner in).

Procurement, Distribution, and Supply Chain Management

How the Supply Chain Functions

Zambia Medicines and Medical Supplies Agency (ZAMMSA), formerly known as the Medical Stores Limited, is the main entity which oversees the supply chain in the country. ZAMMSA is responsible for procurement[14], storage, and distribution of all medical commodities. In addition, the Zambia Medicines Regulatory Authority (ZAMRA) is the regulatory body that regulates and approves all medical products imported and used in the country.

Each year, the country does a national forecasting and quantification exercise led by the national quantification committee, which is made up of a mix of partners, MoH program staff, and MoH M&E staff. In the HIV sector, once the committee has estimated the number of commodities needed for the next year, those projections are shared with PEPFAR and the Global Fund so those partners can determine which portion they will cover; the remainder is procured directly by the national government through ZAMMSA.

Once commodities are procured and enter the country, they are stored and distributed from the ZAMMSA central warehouse. The MoH, with support from GHSC-PSM, is in the midst of decentralizing distribution to regional and provincial hubs to reduce the burden on the central warehouse.[15] Some regional and provincial hubs are already operational while others are being constructed.

When it comes to last mile distribution, the intention is for facilities to "pull" commodities rather than for the MoH to "push" them. Primary health facilities request commodities via paper-based report and requisition forms. These are consolidated and entered into the

[14] The scope of ZAMMSA was recently expanded to include procurement, and so the upcoming tendering process will be the first implemented solely by ZAMMSA.
[15] See the MoH's 2019-2021 Health Sector Supply Chain Strategy and Implementation Plan

electronic Logistics Management Information System (eLMIS) at the district level. Typically, secondary and tertiary health facilities have the means to enter requisitions directly into the eLMIS. The eLMIS does not include all commodities in the country; it only lists the commodities which appear on each program's 'essential list'.[16] The provincial hub is responsible for approving requisitions from all facilities that are supplied by the hub with the exclusion of third-level hospitals. Pooled provincial requisitions and those from third-level hospitals are approved at ZAMMSA and then commodities are dispatched to the hub/hospital.

The Role of CHAZ

Churches Health Association of Zambia (CHAZ), a Principal Recipient of the Global Fund, maintains an independent and parallel supply chain for *HIV* commodities[17] for their 151 member health institutions. CHAZ participates together with the MoH in the national forecasting and quantification exercise for HIV commodities. From there, CHAZ does an independent tendering process, stores commodities at their own warehouse at the CHAZ compound in Lusaka, and does distribution through their own fleet of vehicles. There is some sharing of HIV commodities between the MoH and CHAZ on an as-needed basis. CHAZ does its bulk procurement at the start of each three year Global Fund funding cycle, though additional procurement can be done during the cycle if there is a change in policy which requires procurement of different products or there is an anticipated shortage.

Gaps in the System

In general, the intention is for the supply chain to be integrated, ie. commodities from different program verticals are supposed to be distributed together. However, in practice, commodities are often distributed according to these verticals. This may result in some difficulty as benzathine penicillin and syphilis-only rapid tests are considered part of the STI program rather than the HIV program.

In-country logistics and distribution were noted to be especially challenging at the district and facility levels. Zambia is vast and last-mile delivery can be especially difficult in rural areas. There is also a reliance on paper-based systems at the primary care level, including some paper-based inventory management at district supply hubs, which makes real-time monitoring of stock status challenging. Finally, some facilities may not have a pharmacist, who would normally be in charge of ordering commodities, and instead rely on midwives or other health practitioners who are not trained for the task.

Data Reporting

There is a very elaborate and extensive data system in Zambia, especially for the HIV program. At the health facility itself, there is a mix of paper and digital tools. The key resources are:

- ANC register: The MoH-developed ANC register is longitudinal, which means data from each ANC visit for a single pregnant woman is recorded in the same section (with space

[16] Evidence Action has not seen the list of commodities included in eLMIS and are not sure whether HIV/syphilis dual tests and benzathine penicillin are included.
[17] Non-HIV products are distributed to the 151 member facilities directly from the MoH.

for reporting up to 8 visits). Pregnant women are given unique identifiers called Safe Motherhood Numbers. The register includes indicators for all essential components of an ANC visit, and specifically includes a variety of HIV and syphilis indicators that would allow robust program monitoring. There is a column to designate whether a syphilis test was performed, with reporting options of "N=Negative", "P=Positive", "ND=Test was not done", "NA=Not applicable". There is an additional column for syphilis treatment, which allows someone to mark the number of benzathine penicillin injections received or specify that another drug was given for treatment. Finally, there is a column to designate the partner's syphilis test result. These are in addition to the HIV testing results columns present in the register.

- HIV testing services (HTS) register: The MoH-developed HTS register is intended to capture information on HIV testing for every person at the health facility who is screened for HIV. This register is not specific for ANC, though it does capture pregnant clients, and does not include any data related to syphilis.
- Ad-hoc notebooks capturing testing and treatment information for ANC clients: Among the two facilities visited, each used regular notebooks to track additional information related to testing and treatment. Each facility had a notebook where they listed all ANC clients by the Safe Motherhood Number with additional columns for HIV, hemoglobin, and syphilis test results. Each facility also maintained a notebook to track benzathine penicillin injections.
- Daily Activity Register (DAR) for HIV Tests: The MoH Laboratory Team requires facilities to use the DAR forms when using HIV rapid tests. The intention is to capture every individual who is tested for HIV at the health facility and report the test results for screening and confirmatory testing, including the final determination of HIV status. The DAR also includes a page for reporting and requisitioning HIV test kits. In the long run, the intention of the Laboratory Team is to modify the DAR so that it captures when a dual HIV/syphilis test is used and which results are obtained for HIV and syphilis rather than solely focusing on HIV.
- DHIS2 reporting form: DHIS2 is an open source, web-based health management information system. Facilities submit monthly paper reports on the incidence of disease and the number of people reached via different health services. These are entered into the database at the district level and reviewed for quality control centrally. As mentioned above, DHIS2 includes indicators on syphilis-related outcomes (number of cases of total stillbirths, premature birth, congenital syphilis, syphilis among females by age category), the number of women screened for syphilis and the number reactive, and the number of women given a confirmatory test for syphilis and the number positive. Evidence Action did not observe an indicator for syphilis treatment on the DHIS2 reporting form that was examined at one of the health facilities visited.
- SmartCare: SmartCare is an electronic health record system for storing patient-level medical records. The system originated to monitor HIV+ clients who were enrolled in ART but has since been adapted to include other services beyond HIV. For ANC care, the SmartCare system directly mirrors the content in the ANC register. All facilities implement paper-based data collection and reporting in addition to SmartCare.

Ultimately, SmartCare is desktop-based and not yet networked across facilities so data is centralized through the physical transport of flash drives which include records identified by a National Unique Patient Identification Number (NUPIN). In 2022, the Ministry of Health is planning to expand their rollout of the web-based SmartCare+, which will allow for the integration of data between facilities and real-time access to data. A pilot of SmartCare+ started in approximately 100 of the 1600 facilities in the country.

Dual Testing Policy Environment

The Government of Zambia, led by the efforts of the National PMTCT Coordinator, Dr. Priscilla Mulenga, is committed to expanding syphilis screening and treatment for all pregnant women in the country. This work is motivated by a desire to achieve the WHO target of dual elimination of mother-to-child transmission (EMTCT) of HIV and syphilis and in response to the high incidence of macerated stillbirths and neonatal deaths which many believe are due to unidentified and untreated syphilis infections in the mothers.[18]

There are several policy documents which are being used as the backbone for dual test adoption. The first is the National ANC Guidelines, which, according to the MoH's Chief Safe Motherhood Officer, list syphilis screening and treatment as essential components of the ANC package. The second is the EMTCT of HIV and Syphilis National Operational Plan 2019-2021, which lists the adoption of HIV/syphilis dual testing as one of the strategic interventions that will enable greater syphilis screening among pregnant women. Finally, the Zambia Consolidated Guidelines for Treatment and Prevention of HIV Infection list syphilis screening as an essential service to be provided for pregnant women alongside HIV screening.

While Zambia has made substantial progress and established a good foundation for supporting the work, there are still further efforts needed on the policy side. Namely, the dual test is not wholly recognized as part of official MoH policy as the Consolidated HIV guidelines published in 2020 do not mention the dual test nor do they establish separate testing algorithms for the general population and for pregnant women. Having recognized this gap, efforts are underway now to include the dual test in the upcoming revision to the Consolidated HIV guidelines.

Funding Landscape

The majority of HIV funding in Zambia is provided by PEPFAR, with secondary funding via the Global Fund.[19] PEPFAR directs its support via the CDC in four[20] provinces and via USAID in the other six[21] provinces. CDC and USAID themselves award contracts to implementing partners to take on particular activities within their focal areas. The recent allotment of HIV/syphilis dual

[18] Dr. Kennedy Malama, the former Permanent Secretary of Technical Services, noted that he believes the high incidence of macerated stillbirths in Zambia "causing catastrophic impacts on families" is largely attributable to syphilis.
[19] Gates Foundation, AHF Zambia, and some HBCUs also provide funding for HIV work but the amount is very small in comparison to PEPFAR and the Global Fund.
[20] Lusaka, Eastern, Southern, and Western
[21] Central, Copperbelt, Luapula, Muchinga, North-Western, and Northern

tests - 422,500 - was procured via the Global Fund.[22] There is no money set aside for HIV/syphilis dual tests in PEPFAR's Country Operational Plan 2021 (COP21), though there remains an opportunity to include funding for dual test procurement in the Country Operationational Plan 2022 (COP22).

In general, funding for syphilis commodities - both benzathine penicillin and syphilis testing supplies - largely comes from essential medicines procurement by the Government of Zambia. This has led to shortages in test kits and treatment which has reduced the coverage of syphilis screening and treatment services for pregnant women.

[22] There are an additional 422,500 HIV/syphilis dual tests expected via the Global Fund sometime in 2022.