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QUANTIFICATION AND SUPPLY PLANNING FOR COMMODITIES NEEDED TO DELIVER THE WHO- RECOMMENDED ADVANCED HIV DISEASE PACKAGE OF CARE

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Introduction

To address the leading causes of morbidity and mortality caused by advanced HIV disease (AHD), the World Health Organization (WHO) recommends providing a package of interventions to all populations and age groups of people living with HIV (PLHIV) and presenting with AHD. The package of care includes screening for AHD through CD4 testing and/or WHO clinical staging; prevention, diagnosis, treatment, and/or prophylaxis for major opportunistic infections; rapid initiation of antiretroviral therapy (ART); and intensified treatment adherence support.¹ Successful delivery of the AHD package of care requires stable access to a range of diagnostic and therapeutic products. However, many national programs struggle to quantify, procure, and deliver critical AHD commodities to the health care services and clients who need them.

With funding from the CDC Foundation, EGPAF began working in 2020 with the governments of Malawi, Tanzania, and Zimbabwe to strengthen AHD services for PLHIV, with a focus on improving access to and use of key AHD commodities. Through these efforts, important challenges were identified in quantifying and planning for AHD diagnostics and therapeutics as well as ancillary supplies, such as sample transport tubes. Challenges included short shelf life for some diagnostic tests of 6 to 18 months after delivery in country; difficulties in quantifying the need for new commodities due to limited demographic, epidemiologic, and/or historical consumption data; the ability to diagnose but not treat opportunistic infections due to shortages of some medicines; challenges in ensuring access to all AHD clients of low-volume products that require highly skilled administration, such as amphotericin B; and the need to coordinate quantification and procurement among several different donors and ministry of health (MOH) programs, such as HIV, TB, and immunization programs.

Target audience and objectives

This guidance is intended for use by national program managers, technical and clinical advisors, procurement entities, funding agencies, implementing partners, and civil society organizations involved in advocacy, quantification, budgeting, procurement, distribution, and scale-up of commodities needed to deliver the WHO-recommended AHD package of care. It aims to ensure that these stakeholders are well informed to advocate for and support sustainable access to AHD diagnostics and therapeutics, with a focus on minimizing overstocks, shortages, stock outs, and expiries and on maximizing cost efficiencies and the rational use of scarce resources.

Recommendations for quantification and supply planning

Quantification of AHD commodities should support the delivery of the most recent WHO HIV prevention, testing, and treatment guidelines.¹ Appendix 1 of this document provides an overview of key AHD commodities at the time of its publication. Most products needed to identify, test, and treat patients with AHD are used across multiple health programs. For example, TB LAM tests and pneumococcal vaccines are used within different national health programs, and frequently, their procurement is supported by different quantification and supply planning processes and by different funding streams. It is not recommended to develop parallel forecasting or supply chain processes for AHD products. Rather, it is suggested to coordinate across MOH programs and units to integrate the commodities needed to deliver the AHD package of care into existing national quantification processes and supply chains.

However, during the introductory phase of a new diagnostic or therapeutic product, or when an existing product is used in a new way (e.g., TB LAM testing and pneumococcal vaccines provided with HIV services), an initial parallel forecasting system may be needed until accurate service delivery and commodity consumption data can be obtained. A mix of forecasting approaches may be needed not only to support new product introduction but also to improve overall forecasting efforts that consider missing data or data quality issues and to gradually adjust the quantities needed to account for scale-up plans.

For example, the initial forecasting approach for AHD commodities can use national demographic and epidemiological data as well as service-level data to estimate:

¹ World Health Organization. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. <https://www.who.int/publications/i/item/9789240031593>. July 16, 2021 (accessed 17 June 2022).

- the number of PLHIV who should be screened for AHD, preferably using CD4 testing but also through WHO staging when CD4 testing is not available;
- the proportion of those screened who have AHD (i.e., CD4 count <200 or WHO stage 3 or 4) and, therefore, require additional testing for TB and cryptococcal infection;
- the proportion of PLHIV with AHD who test positive for opportunistic infections and require treatment; and
- the proportion of PLHIV with AHD at risk of opportunistic infections and, therefore, require presumptive or prophylaxis treatment (e.g., TB preventive treatment, preemptive treatment for cryptococcus).

The initial approach must be managed carefully to avoid excess quantification. At the same time, it is recommended to include at least a three-month buffer in forecasts to avoid stock outs while also taking into consideration the shelf life of products to avoid wastage due to expiries. Once a new product has been introduced and scaled up, service-level data, consumption data, and morbidity data can be used to complete the national quantification process in a more accurate and integrated way. Box 1 lists additional factors that should be considered in the quantification and planning of AHD commodities.

Several software programs are available to support quantification and supply planning, but there is no single tool that does it all. For example, the Quantification Analytics Tool (QAT), developed by the USAID Global Health Supply Chain Program (GHSC-PSM), is a supply planning tool that enables program managers to optimize commodity procurement, delivery schedules and monitor the stock status of products (<https://www.ghsupplychain.org/quantificationanalyticstool>). The AHD Commodity Calculator, developed by CHAI (<https://www.newhivdrugs.org/post/advanced-hiv-disease-commodity-calculator>), can be used for the annual quantification of key commodities for the diagnosis and treatment of patients with AHD and related comorbidities. It is important to note, however, that some key commodities needed to deliver the WHO-recommended AHD package of care for adults, adolescents and children, such as the pneumococcal vaccine for children, are not included in the CHAI AHD Commodity Calculator.²

The supply plan for AHD commodities should be flexible and reviewed at least every three months, especially when new products are being introduced. To mitigate against overstocks, stock outs and expiries, the supply plan should take into consideration:

- the current availability of commodities and their expiry dates;
- the current orders in the procurement pipeline and their expected delivery dates;
- the shelf life of diagnostics and therapeutics when defining inventory control parameters for commodities. For example, if a product has a shelf life of 12 months from date of manufacture, and the procurement and custom clearance lead times are estimated at three months, a residual shelf life of no more than nine months can be expected at delivery;
- the option of quarterly orders and/or staggered deliveries to allow product lots with different expiry dates to be delivered at different times, even if part of the same procurement order;
- supply availability and lead time requirements from manufacturers for each product as well as a realistic time required for country-specific importation processes;
- the need for a running buffer of two to three months of stock; and
- coordinated procurement and deliveries of the full AHD package between various procurement entities and donors. For example, procurement and delivery of diagnostic tests should be well coordinated with procurement and delivery of therapeutics to ensure patients are put on treatment as soon as a diagnosis is made.

2 World Health Organization. Package of care for children and adolescents with advanced HIV disease: stop AIDS. <https://www.who.int/publications/i/item/9789240008045>. Published July 1, 2020 (accessed 17 June 2022).

Box 1: Key Factors to Consider When Quantifying and Planning for AHD Commodities

The following should be taken into consideration when developing quantification and supply plans for the AHD package of care for children, adolescents and adults:

- Three population groups should be systematically screened for AHD, preferably using CD4 testing. They are: (1) all newly diagnosed patients; (2) all patients who have defaulted ART and are returning to care; and (3) all patients on ART who have suspected or confirmed treatment failure. Up to 50% of patients with a CD4 cell count <200 may be asymptomatic and thus missed if WHO clinical stage 3 or 4 is used as the sole criteria for diagnosing AHD.
- Some national guidelines may recommend tests, such as CrAg LFA, for high-risk populations (e.g., hospitalized or severely ill), regardless of ART status and without need for a CD4 result.
- The AHD package of care for children and adolescents (e.g., STOP AIDS²) is slightly different from the package for adults. For example, the package of care for children includes pneumococcal, HPV, measles, and BCG vaccines and does not recommend cryptococcal antigen (CrAg) screening for children under 10 years of age.
- All children <5 years old with HIV are automatically considered as having AHD, except for children >2 years who have been receiving ART for more than one year and are clinically stable.
- Clients are less likely to travel to referral-level facilities for diagnostic testing. Decentralized point-of-care (POC) tests, such as VISITECT CD4, TB LAM, and CrAg LFA, are recommended at primary level facilities. If POC testing is not possible, then transport of samples from lower- to higher-level facilities for testing is recommended.
- Procurement and delivery of diagnostic tests should be well-coordinated with procurement and delivery of therapeutics to ensure patients can be put on treatment as soon as a diagnosis is made.
- PLHIV with AHD require close follow-up and support to overcome adherence challenges caused by the need to take several different medicines together (e.g., ART together with drugs for treatment or prophylaxis of opportunistic infections) with complicated dosing and usually more than once per day.
- Some treatments, such as for cryptococcal meningitis (CM), might be started at a higher-level health facility and completed at a lower-level facility. Therefore, a system of referral and counter-referral is needed with medicines available at both levels of facilities.
- Some therapeutics in the package are costly, but their prices are expected to decrease over time. For example, one vial of amphotericin B liposomal, injectable, lyophilized, 50 mg powder for injection costs around USD 18.00.
- Some products are available in different pack sizes (e.g., amphotericin B liposomal, injectable, lyophilized, 50 mg powder for injection is available in pack sizes of 1 vial and 10 vials).
- Dosages must be adjusted based on patient weight (e.g., adjustment of amphotericin B during induction phase, adjustment of fluconazole during consolidation and/or maintenance phases).

Proposed solutions for overcoming AHD commodity access challenges

As noted above, national programs face a number of challenges in ensuring stable and sustainable access to key AHD commodities. Table 1 below lists proposed solutions to overcome some common challenges.

Table 1. Solutions for Overcoming Common AHD Commodity Challenges	
Quantification and Supply Planning Challenges	Proposed Solutions
Initial quantification of new commodities and/or of commodities being used in a new way.	<ul style="list-style-type: none"> • Use a mix of available data and forecasting approaches until reliable service delivery and commodity consumption data can be obtained and the product can be integrated into national quantification processes.
Coordination between different MOH programs and units to quantify products for use in both AHD and other programs (e.g., TB LAM testing, TB treatment, pneumococcal vaccine).	<ul style="list-style-type: none"> • Coordinate across MOH programs and units to integrate AHD commodities into existing national quantification processes and supply chains. • Estimate the proportion of AHD patients and adjust quantification across different MOH programs to ensure sufficient quantities and distribution systems to deliver the AHD package of care.
Shortages, stock outs, overstocks and expiries of AHD commodities at health facilities.	<ul style="list-style-type: none"> • Train health care workers on stock management, consumption monitoring, ordering of AHD commodities from central medical stores, and reporting. • Switch as quickly as possible from a push to a pull logistics system after facilities gain initial experience with a new diagnostic or therapeutic. • Monitor stock levels of AHD commodities, including expiration dates, monthly. • Apply the “first expired, first out” (FEFO) principle to ensure products due to expire first are distributed and used first.
Short shelf life of some products.	<ul style="list-style-type: none"> • Plan for quarterly orders and/or staggered deliveries of products with a short shelf life. • Establish inventory control parameters for short-shelf-life commodities to be held at any given time. For example, if a product has a shelf life of 12 months from date of manufacture, and the procurement and custom clearance lead times are estimated at three months, a residual shelf life of no more than nine months can be expected at delivery. Consequently, the supply plan should be designed for the program to avoid deliveries of more than nine months of stock (including the buffer) at any one time.

Quantification and Supply Planning Challenges	Proposed Solutions
Ensuring access to low-volume, highly technical products, such as 5-flucytosine and liposomal amphotericin B for the treatment of CM, while avoiding overstocks at some facilities, understocks at other facilities, and wastage due to expiration before use.	<ul style="list-style-type: none"> • During initial forecasting, where historical consumption data is not available, CrAg positivity rate and percentage of patients who are CSF CrAg positive³ can be used for quantification assumptions. • Deliberately plan for small-volume products by placing orders early (at least six months in advance) and in quarterly order cycles to avoid expiration prior to use. • Develop approaches for rapid “on demand” distribution of products from warehouses or higher-level facilities to lower-level facilities to ensure access to low-volume products on an “as needed” basis.
Matching supply plans to the production and delivery capacity of manufacturers.	<ul style="list-style-type: none"> • Improve manufacturers’ capacity and commitment. • Conduct frequent reviews (e.g., quarterly) of the in-country stock situation, including a review of quantities of stock on hand at both warehouse and facility levels, monthly consumption rates, expiration dates, and orders in the procurement pipeline.
Aligning procurement and deliveries with different funding and procurement cycles of national governments and donors.	<ul style="list-style-type: none"> • Coordinate procurement and deliveries of key AHD commodities between various procurement entities and donors.

Information systems needed to capture data to accurately quantify AHD commodities

Readily available, high-quality data are critical to an accurate and robust quantification process. Different types of data and information are required at each step in the process. However, obtaining historical rates of consumption, service, morbidity, and demographic data is a major challenge in quantification and supply planning of AHD commodities. When data is available, it is often of inferior quality. In addition, there is a dearth of tools (both electronic and paper) at the health-facility level to capture the data required. Sometimes, the available tools are not being used, or, when used, the data is incomplete and of poor quality. Many health care workers are unclear about how to use the tools, analyze the data regularly, and utilize the analyses for decision making when it comes to quantification and supply planning for AHD commodities. In other instances, the tools available are not properly integrated into existing logistics management information systems (LMIS) and program (e.g., HIV) data systems. Table 2 below summarizes proposed solutions to overcome some common data challenges.

³ CrAg positivity rate is more useful when comprehensive screening programs are in place. In countries or settings procuring LFA for the first time, historical incidence of CM may underestimate the true incidence that will be detected when CrAg screening programs are in place.

Table 2. Data Challenges and Proposed Solutions

Data Challenges	Proposed Solutions
<p>Lack of high-quality data.</p> <ul style="list-style-type: none"> • Historical rates of consumption, service, morbidity, and demographic data are generally lacking or of poor quality. 	<ul style="list-style-type: none"> • Introduction and systematic use of data collection and reporting tools to facilitate rigorous, continuous, and reliable data capture and inform quantification and supply planning activities.
<p>Overwhelming number of tools (electronic and paper-based) for capturing data.</p> <ul style="list-style-type: none"> • Disjointed data capture systems, unclear procedures for use, and too many different systems lead to inaccurate or incomplete data being recorded. 	<ul style="list-style-type: none"> • Introduction of clear procedures and streamlined data capture tools, along with integration into the logistics management information system (LMIS) and program systems to ensure AHD commodities data is collected and integrated into the national systems.
<p>Lack of training on the data capture tools across multiple levels of staff.</p> <ul style="list-style-type: none"> • Health care workers and other key staff are not fully trained on how to use the various tools, how to analyze the available data, or how to maximize the data for programmatic benefits and cost savings. 	<ul style="list-style-type: none"> • Training programs must be provided for staff at all levels, with annual refreshers and updated training as systems evolve. • Specific training may be required for AHD commodities to ensure integration across different health departments and foster collaborative approaches to supply management.
<p>Incomplete indicators for patient monitoring.</p> <ul style="list-style-type: none"> • Weak indicators associated with patient monitoring compounds the inaccuracy of the available data and prevents accurate forecasting and national reporting. 	<ul style="list-style-type: none"> • Development and adoption of clear indicators to facilitate data collection and integration into national reporting and forecasting.

There is a need to update indicators and data systems at both health facility and central warehouse levels to ensure the integration of AHD commodities into existing data systems. Standardized data collection and monitoring tools should be developed or updated, and made available to capture the complete utilization of AHD commodities. In addition, clinic registers and reporting systems must be updated to include metrics and indicators that collect and monitor patient-level AHD data. Integration of AHD commodity consumption and patient-level data into national reporting systems will help ensure that the national quantification of AHD commodities is more accurate and, therefore, reduce wastage and inefficiencies while contributing to better health outcomes among PLHIV with AHD.

Estimating total commodity costs

When quantifying for AHD commodities, national programs should consider the full cost of diagnosis and treatment in the budgeting process. Commodity-related costs include procurement of diagnostics, any accessories required for testing, sample collection kits, and procurement and supply chain costs, such as shipping, insurance, clearance, storage, and distribution. Appendix 1 lists the key diagnostics, therapeutics, vaccines, and sample collection materials that must be included in the AHD package of care, including their packaging and current cost details.

Conclusions and recommendations

To ensure stable access to commodities needed to deliver the WHO-recommended AHD package of care for children, adolescents, and adults, it is recommended that all stakeholders involved in quantification and supply planning do the following:

- Involve a range of stakeholders across HIV, TB, vaccination, and other relevant MOH programs and units, including pharmacists, laboratory technicians, clinicians, supply chain and procurement personnel, and donors. Include them in the quantification and supply planning process to ensure a coordinated approach to securing the full package of AHD diagnostics and therapeutics.
- Fully integrate AHD commodity quantification and supply planning into national health commodities quantification, budgeting, procurement, and supply planning processes and discourage parallel, siloed approaches.
- Develop country-specific forecasting assumptions when quantifying new commodities that recognize the limitations created by lack of (or poor quality of) consumption, service, morbidity, and demographic data.
- Improve data systems at both facility and central warehouse levels, integrate AHD data into existing national and program systems, and train relevant staff in the use of these systems.
- Monitor supply plans regularly to track consumption and stocks on hand and on order; adjust forecasts, if needed.
- Quickly move from a push logistics system to a pull system as soon as reliable service delivery and commodity consumption data are available.
- Include in quantification, budgeting and procurement processes the ancillary commodities required for sample collection as well as those needed for patients being treated with 5-FC and L-AmB, such as magnesium and potassium oral supplementation.
- For low-volume, highly technical products, develop approaches for rapid “on demand” distribution from warehouses or higher-level health care facilities to lower-level facilities to ensure access on an “as-needed” basis and avoid overstocks and/or expiries at health facilities.
- Carefully coordinate procurement and delivery of diagnostic tests with therapeutics to ensure patients are put on treatment as soon as a diagnosis is made.
- For short-shelf-life commodities, plan for staggered deliveries together with inventory control parameters.
- Establish a system of referral and counter-referral between higher- and lower-level health care facilities and ensure medicines and diagnostics are available at both levels of facilities to maintain continuity of care and reduce loss to follow up.

APPENDIX 1

KEY DIAGNOSTICS, THERAPEUTICS, VACCINES, AND ANCILLARY SUPPLIES NEEDED TO DELIVER WHO-RECOMMENDED AHD PACKAGE OF CARE

NOTE: items listed in the tables below are not exhaustive, and all information should be confirmed for accuracy.

Diagnostics

Diagnostic	Packaging	Global Fund PPM Reference Price (EXW, USD) ⁴	Global Drug Facility Catalog Price (EXW, USD) ⁵
CrAg Lateral Flow Assay Tests		2.34	
TB LAM Tests	25 Tests	92.50	92.50
VISITECT CD4 Advanced Disease	Kit of 25 Tests	99.50	
Xpert MTB/RIF	Kit of 50 Tests		499.00
Xpert MTB/RIF Ultra	Kit of 50 Tests		499.00

Therapeutics

Medicines	Packaging	GHSC-PSM e-Catalog Estimated Price ⁶ (EXW, USD)	Global Drug Facility Catalog Price (EXW, USD) ⁷
Amphotericin B LIPOSOMAL (AmBisome), Injectable, Lyophilized, 50 mg Powder for Injection	1 Vial	17.00	
Amphotericin B LIPOSOMAL (AmBisome), Injectable, Lyophilized, 50 mg Powder for Injection	10 Vials	180.00	
Amphotericin B as Sodium Deoxycholate (CONVENTIONAL), Injectable, Lyophilized, 50 mg Powder for Injection	1 Vial	9.33	
Cotrimoxazole 120 mg Dispersible Tablet	100 x 10 Blister Pack	6.25	

⁴ The Global Fund. Pooled procurement mechanism reference pricing: RDTs. https://www.theglobalfund.org/media/7564/psm_hivrdtreferencepricing_table_en.pdf. Published February 15, 2022 (accessed 8 March 2022)

⁵ Global Drug Facility. Diagnostics, medical devices & other health products catalog. https://pro.stoptb.org/sites/default/files/gdfdiagnosticsmedicaldevotherhealthproductscatalog_0.pdf. Updated February 2022 (accessed 8 March 2022).

⁶ Chemonics International Inc. USAID global health supply chain program: procurement and supply management. <https://www.ghsupplychain.org/sites/default/files/2022-05/eCatalog%20April%2020220.pdf> (accessed 16 June 2022).

⁷ The Global Fund. Pooled procurement mechanism reference pricing: strategic medicines used in HIV programs. https://www.theglobalfund.org/media/7500/ppm_strategicmedicineshivreferencepricing_table_en.pdf. Published February 22, 2022 (accessed 16 June 2022).

Medicines	Packaging	GHSC-PSM e-Catalog Estimated Price (EXW, USD) ⁶	Global Drug Facility Catalog Price (EXW, USD) ⁷
Cotrimoxazole 120 mg Tablet	1000 Tablets	5.22	
Cotrimoxazole 240 mg/5 mL Suspension	100 mL	0.53	
Cotrimoxazole 480 mg Tablet	1000 Tablets	13.04	
Cotrimoxazole 960 mg Tablet	10 x 10 Blister Pack Tablets	2.71	
Cotrimoxazole 960 mg Tablet	1000 Tablets	24.99	
Cotrimoxazole 960 mg Tablet	500 Tablets	13.75	
Fluconazole 200 mg Capsule	10 x 10 Blister Pack Capsules	9.96	
Fluconazole 200 mg Tablet	1 x 10 Blister Pack Tablet	1.38	
Fluconazole 200 mg/100 mL Infusion Bag	100 mL	1.16	
Fluconazole 200 mg Infusion Bag	10 x 100 mL Bags	43.20	
Fluconazole 50 mg Capsule	1 x 7 Blister Pack Capsule	0.65	
Fluconazole 50 mg/5 mL Powder for Suspension	35 mL	32.19	
Flucytosine 250 mg Tablet	100 Tablets	52.49	
Flucytosine 500 mg Tablet	100 Tablets	65.00	65.00
Flucytosine Injection 10 mg/mL	5 Bottles x 250ml		200.00
Isoniazid 100 mg Tablet	10 x 10 Blister Pack Tablets	1.59	1.33
Isoniazid 50 mg Dispersible Tablet	10 x 10 Blister Pack Tablets	6.43	
Isoniazid 300 mg Tablet	24 x 28 Blister Pack Tablets	16.25	13.52
Isoniazid/Cotrimoxazole/VitaminB6 (INH/CTX/B6) 300/960/25 mg Tablet	30 Tablets	2.34	1.99
Isoniazid 100 mg Dispersible Tablet	10 x 10 blister	11.34	9.94
Rifapentine 300 mg/Isoniazid 300 mg Film-Coated Tablet	3 x 12 Blister Pack Tablets	29.47	15.00
Rifapentine 150 mg Film-Coated Tablet	8 x 3 Blister Pack Tablets	6.00	6.00

Vaccines

Vaccine	Packaging	UNICEF SD Catalog Indicative Price (EXW, USD) ⁸
Pneumococcal Conjugate Vaccine, 10-Valent	5 doses Vial	35.00
Human Papillomavirus Vaccine, 4-Valent	1 dose Vial	4.50
Measles Vaccine	10 doses Vial	3.85
BCG Vaccine	20 doses Vial	3.74

Ancillary products for sample collection

Item	Packaging	UNICEF SD Catalog Indicative Price (EXW, USD) ⁹
Tube, Capillary, Heparin	Box of 1000	15.40
Tube, Capillary, EDTA	Box of 1000	20.09
Tube, Vacuum, EDTA, 4 mL	Box of 100	5.02
Tube, Vacuum, Serum Gel, 4 mL	Box of 100	8.36
Tube, Vacuum, Plain/Dry, 4 mL	Box of 100	4.70
Needle, Vacuum Tube, 20 g	Box of 100	5.49
Lancet, 2.0 mm, Disposable	Box of 100	11.22
Envelope Packing, 27 x 36 cm	Box of 100	19.64

⁸ UNICEF. *Supply Catalogue*. (<https://supply.unicef.org/all-materials.html>) (accessed 8 March 2022).

⁹ UNICEF. *Supply Catalogue*. (<https://supply.unicef.org/all-materials.html>) (accessed 12 April 2022).

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