

*HIV Programme Review in Albania:
Antiretroviral therapy and procurement
and supply management*

March 2015

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Abstract

This WHO country mission, conducted in March 2015, aimed to review the antiretroviral therapy and procurement and supply management components of the HIV/AIDS programme in Albania in order to address current deficiencies and inform the development of a Concept Note for the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Albania has a low HIV prevalence overall with 699 individuals diagnosed with HIV in the country at the end of 2013. It is a concentrated epidemic and data on mode of transmission is incomplete. While most of the reported cases are heterosexual transmission there may be a number of unreported or undiagnosed cases among men who have sex with men, people who inject drugs, and sex workers.

As of February 2015, 21 children and 339 adult patients with HIV (total of 360) were receiving antiretroviral therapy (ART) in Albania. The number of HIV tests in the country is very low and thus the number of HIV-related deaths in the country is likely to be underestimated. The majority of people living with HIV in Albania are unaware of their infection and thus likely to be actively transmitting the virus.

This report provides main and specific recommendations for optimizing HIV testing, ART and developing efficient procurement and supply chain management for HIV in Albania.

Keywords

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Abbreviations

ART	Antiretroviral therapy
ARV	Antiretroviral
EFV	efavirenz
EML	Essential Medicines List
FDC	Fixed-dose combination
Global Fund	The Global Fund To Fight AIDS, Tuberculosis and Malaria
GMP	Good manufacturing practices
GP	General Practitioner
HMIS	Health Management Information System
HR	Human resources
ID	Infectious diseases
IGRA	Interferon gamma release assay
IPH	Institute of Public Health
LMIS	Logistic Management Information System
MSM	Men who have sex with men
MTCT	Mother-to-child transmission
NDRA	National Drug Regulatory Authority
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NVP	Nevirapine
OI	Opportunistic infection
PA	Procurement agent
PLHIV	People living with HIV
PQR	Price and quality reporting
PR	Principal Recipient
PSM	Procurement and supply management
QA	Quality assurance
QAP	Quality assurance plan
QC	Quality control
SCM	Supply chain management
SoP	Standard operating procedure
SRA	Stringent regulatory authority
STG	Standard treatment guideline
UNICEF	United Nations Children's Fund
WHO	World Health Organization
ZDV	Zidovudine (formerly AZT)

Executive Summary

This WHO country mission, conducted in March 2015, aimed to review the antiretroviral therapy (ART) and procurement and supply management (PSM) components of the HIV/AIDS programme in Albania in order to address current deficiencies and inform the development of a Concept Note for the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Albania has a low HIV prevalence overall with 699 individuals diagnosed with HIV in the country at the end of 2013. It is a concentrated epidemic and data on mode of transmission are incomplete. While most of the reported cases are heterosexual transmission there may be a number of unreported or undiagnosed cases among men who have sex with men, people who inject drugs, and sex workers.

As of February 2015, 360 people were receiving ART in Albania (21 children and 339 adults). The number of HIV tests in the country is very low and thus the low number of reported HIV-related deaths in the country is likely to be underestimated. The majority of people living with HIV (PLHIV) in Albania are unaware of their infection and thus likely to be actively transmitting the virus and presenting late for treatment and care.

This WHO mission report, developed six months after an earlier WHO mission, provides main and specific recommendations for optimizing ART in the country and developing efficient procurement and supply chain management for HIV in Albania.

Main recommendations

Priority Area 1. *Increase HIV testing*

- Expand testing for HIV. Better targeting of HIV testing towards most-at-risk groups through community-based rapid testing and linkage to care is highly recommended.
- Increase awareness for indicator diseases among general practitioners (GPs) and improve accessibility to provider-initiated HIV testing, including universal access to antenatal screening, and screening at TB and STI clinics, prisons and for patients with hepatitis clinical or lab markers.

Priority Area 2. *Optimize the provision of antiretroviral therapy*

- Plan for an increase in availability of viral load and CD4 count monitoring, with a capacity for over 1000 tests per year starting in 2015.
- Phase in the 2013 WHO Consolidated Guidelines recommendations over the next two years, aiming for first-line treatment in all newly diagnosed cases, preferably using single pill fixed-dose combinations for better adherence.
- Adapt draft ART treatment protocol for adults and children, developed by the mission for Albania.

- Consolidate and simplify management of HIV in the country. Consider having 2 paediatric ID specialists and 2-3 adult ID specialists at the University Hospital taking care of all HIV patients (4-5 in total, down from the current 17 doctors).
- As a general rule, stable patients should be given ARV drugs for three months if they are compliant with their regimens and clinically stable. This decreases visits to the clinic and reduces the burden of travel on patients, especially those living outside the capital.
- Expand coverage of ART, aiming for treatment initiations for all patients with a CD4 cell count of <500, as well as initiation of ART regardless of CD4 count for HIV-positive pregnant women, children, TB/HIV co-infected patients, hepatitis B/HIV co-infected patients, and the HIV-positive partner in discordant couples, in accordance with the WHO 2013 Consolidated Guidelines. However, priority should be given to earlier diagnosis to start those still undiagnosed and urgently in need of treatment (<350), and those lost to care.
- Peer consultants can help with accepting the HIV diagnosis, linkage to care, improving adherence and retention in care.

Priority Area 3. *An efficient Procurement and Supply Chain Management of ART in Albania*

- Create a Product Selection and Forecasting Committee by July 2015 to identify which of the current ART lines are or are not consistent with the WHO Consolidated Guidelines (2013) in order to optimize ART as per priority 1 above and to conduct accurate product selection and forecasting exercises. Members of the committee should come from various categories of health professionals associated with HIV as well as relevant programme staff (logistic, procurement, finance etc.) such as the Chief of Supply and Transport at the University Hospital and the UNICEF representatives, as they can provide technical information on the essential medical list (EML), the availability of medicines on the international market, lead time, procurement processes, product prices, etc., while the financial expert should be able to share information regarding the budgets available, saving funds, etc. It should ensure a comprehensive and accurate technical specification list.
- In order to mitigate the risks in terms of delays or stock-out during the procurement process, quarterly stock review meetings should be organized between the University Hospital Chief of Supply and Transport, UNICEF and the Product Selection and Forecasting Committee or those in charge of such PSM activity.
- The Mother Theresa University Hospital pharmacy should be urgently moved to a proper location with sufficient space, for example to the ID clinic. The pharmacy manager should follow the International Good Storage of Essential Medicines. It should be noted that with the current number of patients a room of 15m² should be sufficient enough to store ARVs drugs and other health products
- The managers responsible for monitoring patient data and those responsible for monitoring the supply of ARVs drugs should work together to strengthen the health management information system (HMIS) by identifying common data elements and developing methods in which data can be recorded and shared.

- To reduce the risk of expiration, procurement contracts for ARV drugs should specify a required minimum remaining shelf-life on the drugs at the time of arrival at the port of arrival in Albania with a minimum of 75% of total shelf-life. It is prudent to not accept drugs with less than the required shelf-life unless there is an emergency stock situation. Such a rule applies especially to HIV test kits and reagents when the shelf-life is around 4 months. This should be put into practice already in 2015.
- To ensure procurement of ARV drugs and HIV tests (CD4 and viral load), reagents and other health-products such as gloves, masks, slides, etc., at least twice a year, based on adjusted number of patients who need ART and lab monitoring.
- To have a National HIV Programme Manager appointed by the Ministry of Health to oversee PSM as well as all be responsible for overall HIV national programme. Such a programme manager should be in place by the time of the start of the next round of Global Fund support.

1. Introduction

Albania is a country with historically low incidence of HIV. However the annual number of new diagnoses has more than doubled in the past 4-5 years. Cumulatively, at the end of 2013, 699 individuals had been diagnosed with HIV in the country (1). There is no universal antenatal screening but six mother-to-child transmissions (MTCT) were recorded in 2013 and five in 2014 (1). There are no national estimates for MTCT cases.

The ratio of male:female diagnoses indicates that the HIV epidemic in men who have sex with men (MSM) is likely to be greatly underestimated in the country. Overall, 75% of HIV diagnoses in Albania are made at a late stage of infection (CD4 cell count <350 cells/mm³), and more than half of newly diagnosed patients have a CD4 cell count below 200 cells/mm³, which is indicative of severe immunosuppression and late stage disease. The number of HIV tests in the country is very low (1.1/1000 population) and thus the number of HIV-related deaths in the country is likely to be underestimated. Taken together, these facts suggest that the majority of people living with HIV (PLHIV) in Albania are unaware of their infection and thus likely to be actively transmitting the virus and presenting late for treatment and care.

HIV patients are treated at the university hospital in Tirana in two departments: at the Department of Paediatrics (for children, i.e. individuals with HIV below the age of 14), and the Department of Infectious Diseases (individuals above 14 years of age, who are considered adults). Clinical data is registered on paper charts. Excluding those who are reported to be deceased, as of the end of 2013, 58% of those ever diagnosed with HIV in the country receive HIV treatment and care (1). However, over a third of persons diagnosed are not accounted for in monitoring systems and patients who do not attend HIV care following their diagnosis are not actively followed up. This incurs an additional risk for ongoing transmission, as well as increased morbidity and mortality. As of February 2015, 21 children and 339 adult patients with HIV were receiving ART in Albania; these treatments have been interrupted on a regular basis for up to three months due to ARV drug stock-outs. Medical services for these 360 patients are provided by 17 physicians, many of whom are only taking care of a handful of patients. Data are not available to perform a treatment/continuum of care cascade analysis for HIV in the country, and measurements of HIV RNA (viral load testing) are largely unavailable due to a lack of reagents (1). As a result, it is impossible to estimate the percentage of patients who achieve suppression of viral load and no data is available regarding prevalence of antiviral resistance.

2. Purpose, objectives and methods

Albania is eligible for a Global Fund grant to support its national programme on HIV/AIDS. The country requested the WHO Regional Office for Europe to provide technical assistance to conduct an HIV programme review and a first review of its draft Global Fund Concept Note. The review included two key components:

1. *Clinical practice on HIV treatment and care*

- Review current clinical practice on HIV treatment and care, focusing on ART regimens in adults, children and laboratory monitoring of the response, and provide recommendations on switching ART regimens and aligning HIV treatment and care with the WHO Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (2013).
- Review current national protocol(s) on ART for adults and children and update it (them) in accordance with the WHO 2012 protocol and the WHO 2013 Consolidated Guidelines recommendations and in discussion with national stakeholders and WHO.

2. *Procurement and supply management (PSM)*

- Based on revised ART regimens and estimated number of PLHIV who will need ART, provide assistance to the national partners in planning ARV drug procurement in order to avoid ARV stock outs.
- Based on the new Guidelines assist with developing a laboratory monitoring schedule, compiling the list of tests and reagents required and with planning, procurement and monitoring of stock of lab reagents and consumables in Albania.
- Provide guidance on sound inventory management procedures, including the use of tools, the implementation of minimum and maximum stock levels, and the inclusion and management of buffer stock.

Methods

The evaluation builds on a national programme report as well as an epidemiological report from September 2014. It took place in 23–27 March 2015. During the country mission, the three WHO experts undertook interviews and visited sites in the capital, Tirana. In addition to field visits and data collection, the review included key informant interviews, focus group discussions including with service providers at the Mother Theresa University Hospital, field observations and qualitative analysis.

With regards to PSM, the consultant adopted a system approach to analyse the challenges and their causes. The PSM cycle (see Annex 1) was assessed stage by stage. Each stage is then related to other stages of the cycle. For each stage of the PSM cycle, this report presents a short definition,¹ strengths and weaknesses, improvement strategies and recommendations.

¹ The following definitions are based on the UNDP Operations Manual for Projects Financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria (June 2011) and are adjusted for an audience unfamiliar with procurement and supply chain management issues.

3. Findings

Priority Area 1. Increase HIV testing

It is of paramount importance to expand HIV testing in the country. As noted above, data are not available to perform a continuum of care cascade analysis for HIV in the country. Increased testing for HIV is essential to better understand the HIV and AIDS epidemics in Albania, identify more PLHIV and increase the number of people in treatment and care.

Main recommendations:

- Expand testing for HIV. Better targeting of HIV testing towards most-at-risk groups through community-based rapid testing and linkage to care is highly recommended.
- Increase awareness for indicator diseases among GPs and improve accessibility to provider-initiated HIV testing, including universal access to antenatal screening, and screening at TB and STI clinics, prisons and for patients with hepatitis clinical or lab markers.

Priority Area 2: Optimize the provision of antiretroviral therapy

Strengths

- There is one clinic in the country, at the University Hospital, Tirana, which is responsible for the management of all adult PLHIV (approximately 339 people on ART).
- One clinic in the country, at University Hospital Centre, Tirana, is responsible for management of all paediatric cases of HIV (approx. 21 cases).
- As of March 2015, 72% of all adult patients on ART were on a first-line therapy recommended in the 2013 Consolidated WHO Guidelines (2).
- There is one pharmacy in the country, at the University Hospital, which stocks all antiretroviral (ARV) drugs.
- Medical care is free of charge in the country.

Weaknesses

Organization and structure of clinical services

A high number of clinicians take care of patients with HIV (currently, 6 paediatric ID specialists and 11 adult ID specialists).

In general, patients need to come to the clinic every month or every other month to get their prescriptions filled, most of which remain unchanged due to the nature of the problem. This creates an increased workload for the clinical staff.

In general, patients who are not receiving ART do not receive reminders or reinforcement to visit the clinic and they frequently miss appointments.

There is no common forum for paediatric ID specialists, adult ID specialists, pharmacists and PSM staff to discuss cases, challenges, medication supply issues and transfer from paediatric to adult services.

A high proportion (75%) of newly diagnosed patients present late (CD4 cell count <350) (1), often with late-stage AIDS and/or opportunistic infections (OIs). No screening for HIV is performed among pregnant women.

PLHIV who present with OIs are frequently managed in the hospital during the acute phase of their illness, but subsequently discharged to home where they are advised to complete their treatment course, which need to be prescribed by their GP in order for the medications to be covered by the national health insurance. Experience shows that this frequently does not happen, possibly due to stigmatization and concerns about confidentiality and the patients may end up with additional hospitalizations due to relapses resulting from not getting treated for their OI.

Antiretroviral therapy – selection of agents and indications for treatment

Currently, the selection of ART regimens is marked by complexity and variability. According to an overview of ART combinations prescribed by physicians in the ID clinic (February 2015) there are currently 19 different combinations being used (see Annex 2). According to the 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV, four different regimens should be used as first-line therapy with the most preferable scheme being: TDF/FTC or 3TC/EFV – one pill a day. At present, 257/339 active patients on ART (72.2%) receive first-line therapy. The remaining 27.8% of the adult patients (82/339) are currently on other regimens.

As of March 2015, 207/339 adult patients on ART were receiving ZDV as a first-line NRTI component to their therapy (61%). Only 4 adult patients are receiving ABC as a first line NRTI component of their ART.

At present, few patients with CD4 cell counts of 350-500 are started on ART and only 2-3 patients are receiving ART due to serodiscordance with their partners.

Information systems, data availability, laboratory support:

There are no electronic medical records or a comprehensive database where information on patients managed at the clinics is registered. As a result, it is very difficult to retrieve information about the patients and their management with little available data as a result. This situation has serious implications for treatment decision-making.

There is a lack of information on CD4 cell counts and viral loads in patients on ART. Only 150 patients on ART reportedly have had their VL measured, which is carried out at the Institute of Public Health (IPH), where the equipment is, over the past year, but the results have not been presented. This is concerning given the fact that detection of treatment failures will be substantially delayed to the detriment of the patient. In addition the development and spread of resistance to ARV drugs will be facilitated, which subsequently incurs more complex and costly ART regimens. Optimally, all patients should have their viral loads checked periodically following the initiation of ART and every 6-12 months thereafter, as per WHO Guidelines (3).

Lack of data regarding antiviral resistance of HIV in Albania. Periodic stock-outs, lasting up to 3 months, have left the patients on partial or no antiretroviral therapy for long periods of time. This generates and promotes the development of drug resistance – a situation compounded in Albania due to the lack of resistance monitoring.

Recommendations

Main recommendation:

It is vital to improve clinical information systems and facilitate the availability of critical clinical data. By accomplishing this, treatment-related decisions will be improved, translating into better patient- and public-health outcomes. Laboratory support needs to be strengthened, both with respect to CD4 cell count and viral load monitoring. The organization and structure of clinical services to PLHIV need to be redesigned. Guidelines for ART need to be revised and indications for treatment expanded.

Specific recommendations:

- Establish an electronic medical record for PLHIV in Albania.
- Plan for an increase in the availability of VL and CD4 count monitoring (>1000 tests per year starting in 2015, average number of tests for a stable patient, 1-2, average number of annual tests for a newly diagnosed patient, 3-4. It should be stressed however that less frequent monitoring may be required for CD4 cell counts than for VL measurements).
- Ensure a buffer on ARV drug procurement to avoid stock-outs.
- Generate data on resistance from a sample of newly diagnosed patients. This can be done prospectively (ID clinic).
- Generate data on resistance among patients already on ART by analysing blood samples which are stored at the Institute of Public Health (sentinel survey).
- Given the lack of genotyping facilities and the lack of expertise for generating such data, and considering the urgency of the matter, as well as the relatively low number of patients with HIV in Albania, it may be cost-effective to outsource resistance testing to a core laboratory outside the country.
- Consolidate and simplify ART when possible. It is very hard to keep up to date with HIV management with only a couple of patients. Consider having two paediatric ID specialists and 3-4 adult ID specialists taking care of all HIV patients. (5-6 in total, down from 17).
- As a general rule, stable patients should be given three months' worth of ARV drugs if they are compliant with their regimens and clinically stable. This decreases patient traffic in the clinic and reduces the burden of travel on patients, especially the ones living outside the capital, Tirana.
- Make a log of patients who are not currently receiving ART and establish a system of reminders (e.g. phone calls/SMS by the department social worker, clinic nurse etc.).
- Establish a formal, regular professional forum for major stakeholders dedicated to HIV management, for the exchange of information, advice and consensus building (further developed under Priority 2, below).
- As a part of a comprehensive plan, increase awareness for indicator condition guided testing among GPs and improve accessibility to rapid HIV testing, including antenatal screening – which should be universal. Better targeting of HIV testing towards most-at-risk groups is also highly recommended.

- Improve laboratory services to diagnose OIs and TB (e.g. pneumocystis jirovecii pneumonia and interferon-gamma releases assay (IGRA) tests).
- In the case of PLHIV, make an exception to the general principle that all prescriptions for non-hospitalized patients need to be written by GPs in order for the patients to have their medications free of charge and to complete treatments which have been prescribed by their ID physicians at the university hospital.
- Develop and adopt an updated ART treatment protocol for adults and children in Albania based on the 2012 WHO Guidelines and the 2013 Consolidated Guidelines.
- Phase in the 2013 WHO Consolidated Guidelines recommendations over the next two years, aiming for first-line treatment in all newly diagnosed cases, preferably using single pill fixed-dose combinations for better retention in care and adherence (2).
- Review the treatments of the 82 patients on second-line treatment and assess their indications with a view to switch to first-line therapy, if this is deemed medically appropriate. It is recommended that two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) and efavirenz (EFV) (a non-nucleoside reverse transcriptase inhibitor [NNRTI]) be combined in the first-line ART regimen, preferably using a single fixed-dose combination. If EFV cannot be used, a ritonavir-boosted lopinavir or atazanavir treatment or nevirapine (NVP) are alternatives. Second-line ART is the next regimen used in sequence immediately after first-line ART has failed. The PI class is preferentially reserved for second-line use in settings using a public health approach. Ideally, ritonavir-boosted PIs are recommended, supported by two NRTIs.
- Given the safety and long-term tolerability issues associated with ZDV, the high utilization of this drug is concerning and should be reduced.
- Given the lack of human leukocyte antigen typing facilities, ABC use should be discouraged and this agent is not listed among first-line NRTIs.
- Expand the coverage of ART, aiming for treatment initiations in all patients with CD4 cell counts <500, as well as treatment for discordant couples, in accordance with the 2013 WHO Consolidated Guidelines (2).
- Plan and prepare for an increased patient load in the ID Department's HIV clinic (not simple linear increase), both with respect to the utilization of laboratory resources, expansion of indications for ART and the time commitment of staff.

Priority area 3. An efficient Procurement and Supply Chain Management of ART in Albania

Procurement and supply chain management (PSM) of essential health commodities, including high-value medicines like ARV drugs, involves a series of activities to guarantee the continuous flow of products from the point of manufacture to the end-user points or patient. The supply chain, or its functions, operates within a management system that provides managers with data to help determine what types of products are needed, where and when they are needed, and in what quantities. Supply chain managers can increase a sustainable quality of supply by better ensuring the availability of the products they manage and using available resources efficiently to reduce wastage and to enhance accountability. Insufficient funding for health programmes often results in insufficient financial, human, and technical resources for implementing and strengthening PSM. As a result, supply interruptions and shortages of critical health commodities are common in many countries around the world, and Albania is one of them.

Supply chain management consists of a series of functions that must be routinely performed in a synchronized way. This is often represented as a circle because of its repetitive process throughout the life of the programme. The cycle refers to the sequence of technical stages following each other in the PSM process.

The PSM system seeks to ensure that the “Six Rights” (4) are met:

1. Right source (supplier)
2. Right product (selection)
3. Right quantity
4. Right quality
5. Right time
6. Right place (Central warehouse or lower level)

3.1 Product Selection: Quantification and Forecasting

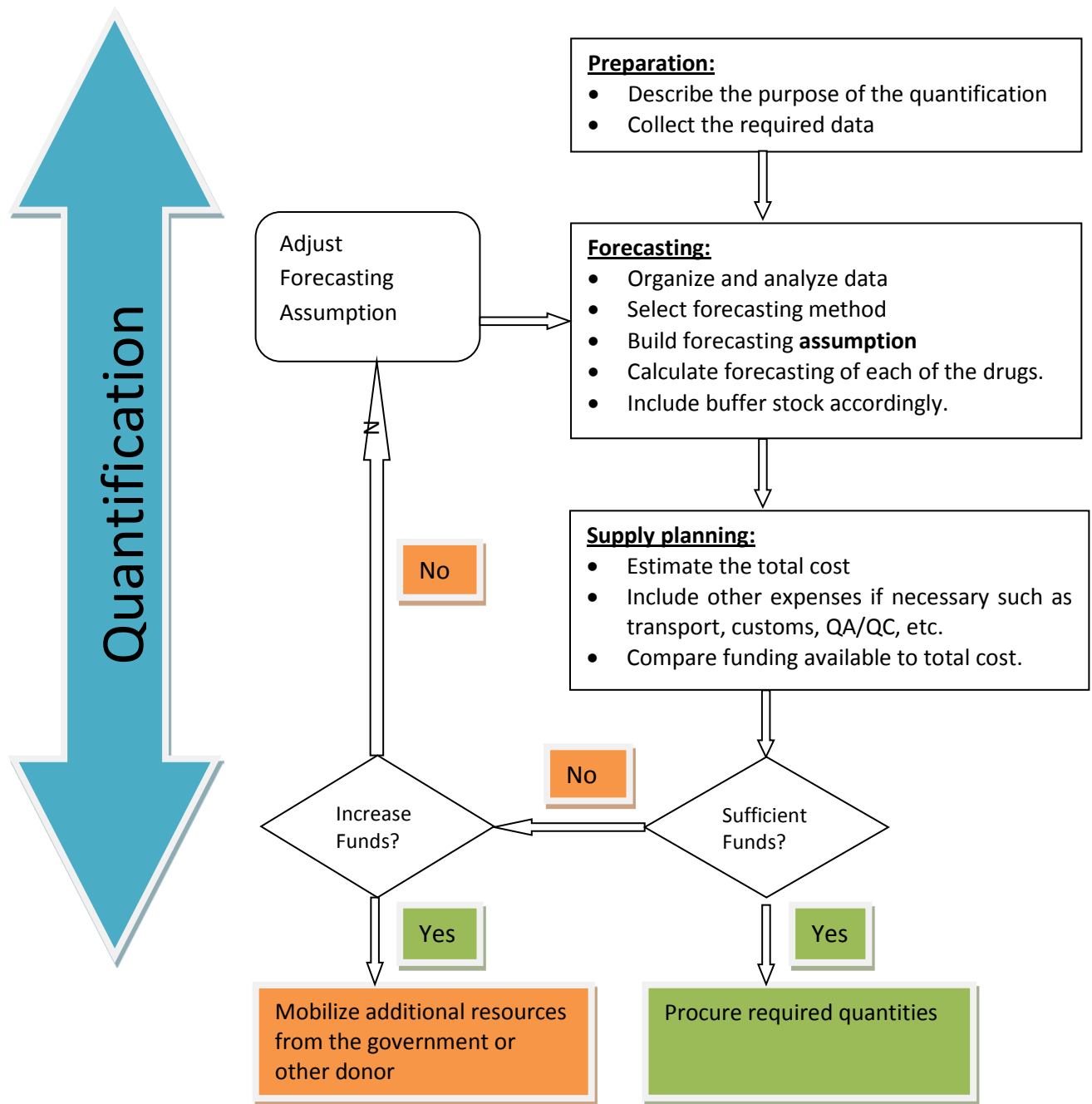
Production Selection. The selection process identifies which medicines are required to provide the intended health care interventions, such as antiretroviral therapy. Mistakes in selection may not be easy to rectify when the procurement process is launched and along the supply chain process, especially when the lead time is long, like in Albania.

The person responsible for procurement can only procure the products that have been selected. And the Hospital University in Tirana can only distribute the products that have been procured.

Mistakes can have serious consequences for patients, such as during the 2014 ARV drug stock-out in Albania. In addition, when there is a change or correction in selection, it may take many months before providers and patients have access to the new medicine.

A **good** selection process facilitates access to treatments and ensures the efficient use of funding. A **wrong** specification list may result in receiving a product which meets all the stated requirements but which is wrong for the intended application. It may put at risk the entire programme implementation.

Figure 1: Steps in Quantification/Forecasting²



² Based on the ARV Quantification Guide: http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/ARVQuantGuide.pdf.

Quantification. After having identified what medicines are needed, the next step is to determine in what quantities the selected products are needed. This process is called quantification. It follows the selection of products stage in the PSM cycle. Quantification is used not only for pharmaceutical products, but also for HIV test kits, reagents, and other health products (masks, gloves, syringes, etc.), services and other inputs that are needed by the programme to provide the intended health services. If sufficient quantities of medicines are not available, the intended health services cannot be provided. This may have serious consequences for patients. On the other hand, having too much of a product in stock may be costly as they may expire, and therefore must be discarded.

Forecasting is the estimation of quantities of products that must be procured to ensure continuous availability of supplies during a given period. Forecasting involves planning demand on the basis of allocated funds and actual needs. For example, to forecast the actual number of packs of each medicine required at each level of the supply chain, one must take into account the results of the quantification exercise, stocks on hand, buffer stocks required, anticipated losses and pack sizes. Forecasting also takes into account delivery lead time and the time needed to clear and test the products before becoming available for distribution.

Strengths

- A large pool of clinicians (adults and paediatrics care) is able to participate in the product selection and quantification/forecasting exercises.
- The product selection and forecasting exercises are led by a professional and dedicated clinician.
- There is potential support from partners if required (UNICEF, WHO, UNDP, etc.).

Weaknesses

- In spite of having a national HIV focal point, there is no proper HIV/AIDS team, with a clinician, nurse, focal point, PSM expert, financial expert, psychologist or social worker.
- There is no PSM professional involved in the quantification and forecasting.
- There is no financial expert involved in the quantification and forecasting.
- There is no product selection and forecasting coordination between the clinicians for adults and paediatric care.
- Too many clinicians for adults care (around 17) are dealing with HIV patients, which may complicate the product selection and forecasting process.
- There are no national treatment guidelines endorsed by the Government, which may complicate the product selection among the line/regimen recommended in the 2013 WHO Consolidated Guidelines.
- It is unclear if a health management information system (HMIS) is in place; HMIS helps to provide data regarding patients on ART.
- The main purpose of the WHO Essential Medicines List (EML) principle is not well known.
- It is not clear what the laboratory needs are in term of equipment, rehabilitation (if necessary) and HIV test kits and reagent quantities.
- There is no proper forecasting for HIV test kits, reagents or other health-products (masks, gloves, etc.), which makes the needs and the required budget unclear.

Recommendations - Product Selection: Quantification and Forecasting

Main recommendation:

Create a Product Selection and Forecasting Committee by July 2015 to identify if the current ART lines are consistent with the WHO Consolidated Guidelines (2013) in order to optimize ART as per priority 1 above and to conduct accurate product selection and forecasting exercises. Members of the committee should come from various categories of health professionals associated with HIV as well as relevant programme staff (logistic, procurement, finance etc.) such as the Chief of Supply and Transport at the University Hospital and the UNICEF representatives, as they can provide technical information on the EML, the availability of medicines on the international market, lead time, procurement processes, product prices, etc., while the financial expert should be able to share information regarding the budgets available, saving funds, etc. It should ensure a comprehensive and accurate technical specification list.

Specific recommendations:

- A realistic quantification/forecasting exercise should be conducted for ARV drugs as well as for the HIV test kits, reagents, other health-products (gloves, masks, etc.) and other services.
- To facilitate accountability, the roles and responsibilities of all committee members should be clearly defined.
- The newly created Product Selection and Forecasting Committee should avoid any conflict of interest—particularly commercial such as pharmaceutical industry interests—and come to a consensus.
- The committee should conduct the quantification/forecasting exercise through the collection, analysis, sharing and validation of data, and by developing a strong data collection process through an HMIS.
- The Committee should:
 - develop and validate assumptions used for quantification.
 - disseminate information and make decisions about the introduction of new products.
 - determine the implications of guideline updates on quantification.
 - monitor stock and commodity needs throughout the year.
 - coordinate funding and prevents overlapping procurement.
 - determine the timing of procurement and coordinate with partners.
- In addition, on the basis of the selection for HIV and AIDS needs, the EML should be understood and used to avoid poor procurement or wrong product selection (5).
- The committee should regularly meet in order to update a product phase-out or treatment change to be able to react adequately along the supply chain management.
- Quantification is not an ad-hoc process. Quantification should be reviewed on a regular basis, preferably quarterly, to reflect changes in consumption and the kind of products used.
- For the quantification exercise, in general, it is advisable to combine consumption method (the estimated need is based on past use) and morbidity data to strengthen the estimates.

- The forecasting should take into account:
 - the result of quantification
 - stock in hand at the time of the order
 - stock in hand at the delivery time
 - the needs (difference between the 2 points above)
 - pack size
 - buffer stocks (minimum of 25% and may vary according to the available budget, the procurement flexibility and the uncertainty of the forecasting)
- The total cost should be calculated using:
 - products unit price. These prices are available either using the last procurement price list with UNICEF or on several websites (6).
 - total price according to the quantities
 - international transport cost
 - customs clearance cost
 - in-country transport cost
 - other expenses should be added if necessary.
- The following should be taken into account to avoid stock-out or overstock:
 - the time between the final order to the procurement agent (currently UNICEF in Tirana) and the transfer of funds
 - the procurement lead time (time between the order confirmation and the arrival of goods)
 - the time needed to clear the products before becoming available for distribution.
- Regarding the laboratories, a complete assessment should be conducted of the existing laboratories in order to identify the following:
 - existing infrastructure
 - existing equipment
 - the need for new equipment
 - test kits
 - reagents
 - Human Resources (HR) rehabilitation
- A set of SoPs should be written to understand what to do during the product selection and quantification and forecasting exercises.

3.2 Procurement

Procurement follows the selection and quantification of products. After it has been determined what products are going to be used and how much is needed of each product, the next step is to purchase the products. The procurement of pharmaceutical products is a crucial stage in the supply process, ensuring the supply of quality products at the best value for money for programmes.

Procurement in Albania should be based on the WHO Essential Medicines List (7) and the Global Fund Quality Assurance Policy Requirements. The Global Fund list includes:

- Products that are WHO pre-qualified:
WHO has, since 2001, in collaboration with other United Nations agencies, carried out a process of prequalification of specific ARV drugs (8). For the Global Fund, for example, it has become a requirement to use medicines that are WHO prequalified.
- Products that have Stringent Regulatory Authority (SRA) approval:
Here, the assessment of the suppliers is carried out by strong national regulatory agencies. SRA authorization means either approved or subject to a positive opinion under the “Canada S.C. 2004, c.23 (Bill C-9) procedure, or Article. 58 of European Union regulation (EC) No. 726/2004 or United States FDA tentative approval”.

List of countries considered as SRA from 1 July 2009 (9)

The national drug regulatory authorities which are member, observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (10) are considered as SRA as per the Global Fund Quality Assurance Policy for Pharmaceutical Products from 1 July 2009.

The members are:

- **European Union Member States** (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, and United Kingdom)
- **Others:** Japan and the United States of America

Strengths

- UNICEF is the Procurement Agent (PA).
- As PA, UNICEF understands very well the procurement process, the EML, the QA/QC constraints and other procurement matters.

Weaknesses

- According to the clinician in charge of ARV drug procurement, Albanian law only allows for procurement to be conducted once a year and there is no possibility to revise the quantity or the product list during the year.
- Some procurement mistakes from UNICEF and from the Mother Theresa University Hospital have led to the stock-out of medicines.
- The Chief of Supply and Transport and UNICEF are not involved in the quantification/forecasting process, which may create gaps and misunderstanding during the procurement and the lead-time.
- No procurement plan is available.
- No procurement report at the Mother Theresa University Hospital is available.

Recommendations – Procurement

Main recommendation:

In order to mitigate the risks in terms of delays or stock-out during the procurement process, regular meetings should be organized between the Chief of Supply and Transport, UNICEF and the Product Selection and Forecasting Committee or those in charge of such PSM activity.

Specific recommendations:

- Revise as needed the quantities to be procured, responding to uncertainties, fluctuations, product phase-out, unexpected quantities increase or decrease or treatment changes.
- Conduct several procurements per year, especially when it is related to HIV test kits and reagents (due to the very short shelf-life of these products).
- In order to mitigate the risks of patients not receiving ART, the procurement process (cost-estimate confirmation to UNICEF or any procurement agent) should start 6 months before expecting product delivery to the University Hospital pharmacy.
- An annual procurement plan should be prepared in coordination with all partners, including UNICEF (see Annex 3).
- To track all supplies in the pipeline and to monitor procurement efficiency, the Mother Theresa University Hospital and those in charge of the procurement should create a procurement follow-up form (See Annex 4 – Example of procurement follow-up) and a procurement evaluation report (See Annex 5 – Example of procurement evaluation report).
- Once the procurement is completed, the procurement documents should be filed for further requests. Such documentation should be maintained and available to the Global Fund and/or auditors to demonstrate efficiency in this activity.
- The purchaser should update price and quality reporting (PQR) on the Global Fund website: <http://www.theglobalfund.org/en/procurement/pqr/>.
- A set of SoPs related to procurement with UNICEF or any other procurement agent should be produced.

3.3. Inventory Management and Distribution

After the products have been selected, quantified and procured, they will arrive in the country. At this point they must be properly received, inventoried, stored and later distributed to the University Hospital pharmacy and dispensed to patients.

The purpose of inventory and distribution management is to ensure that quality is maintained and that products are readily accessible to programmes and service providers when and where the products are needed.

Mistakes in selection, quantification and procurement cannot be rectified at the inventory and distribution management stage: the Mother Theresa University Hospital can only pick up the products available and can only dispense the products they have in stock.

Inventory management is an essential part of ensuring that the "Six Rights" are addressed. Inventory and distribution management affect the quality, and is critical in ensuring that products are available in the right quantity, in the right place and at the right time. Inventory management refers to the processes involved in ensuring that adequate stocks of products are kept, the quality maintained and that programmes and service delivery points have the needed products available when they need them. Inventory management is at the heart of the drug supply chain, from placing the order to the receipt of pharmaceutical products for use. Inventory management is essential to monitor stock levels and to ensure product availability.

Although inventory and distribution management mostly involves simple routine day-to-day tasks, it is of strategic importance to service providers and programmes in providing the intended health care services, and to generate the desired health care outcomes (11). For patients, it may be a matter of life and death.

Strengths

- There are personnel dedicated to the Mother Theresa University Hospital pharmacy.
- There is an existing computerized logistics management information system (LMIS), but not at the Mother Theresa University Hospital.
- The clinicians for adults use software to order ARV drugs. After one or two hours they receive the drugs and dispense to the patients.
- Albania and the World Bank signed a contract to strengthen the health care facilities, including the University Hospital.

Weaknesses

- The Mother Theresa University Hospital pharmacy is located in an old building in poor condition.
- The Mother Theresa University Hospital pharmacy is not well managed in accordance with good storage practices, i.e. storage facilities that meet international standards are safe, secure and reliable.
- There is no existence of adequate inventory management. There is no temperature control and recording. There are no monitoring systems to assure the efficacy of drugs received by end users/final beneficiaries. An on-site inspection by the mission team revealed that ARVs drugs are stored either below 15°C in the winter or above 25°C during summertime, when it should be "not below 15° and not above 25°.
- The inspection also found some OI drugs about to expire in April 2015.
- There are no stock cards, i.e. no proper label identifying products and expiring date. It is difficult to find ARV drugs as they are mixed with other drugs, such as those for OIs. Some drugs are stored on the floor. The store does not appear to follow a commodities arrangement method.
- The store management seems to be poor.
- The clinicians for adults and paediatric care did not visit the pharmacy and are not aware of product quality assurance issues.
- The ARV drugs pharmacy is not located in the ambulatory or paediatric clinic and cannot be dispensed immediately to the patients.
- The Albania-World Bank contract is for five years and it is unclear which health care facilities will be renovated.

Recommendations - Inventory Management and Distribution

Main recommendation:

The Mother Theresa University Hospital pharmacy should be urgently moved to a proper location with sufficient space, for example to the ID clinic. The pharmacy manager should follow the International Good Storage of Essential Medicines. It should be noted that with the current number of patient a room of 15m² should be sufficient enough to store ARVs drugs and other health products.

Specific recommendations:

- Careful forecasting, strict monitoring of inventory levels and secure transportation to storage facilities should play a key role in streamlining the supply.
- A regular inventory stock alert should be put in place in order to avoid stock-outs.
- A quarterly inventory management report should be sent to those in charge of stock level monitoring (clinicians for adults and paediatric care) or the future Products Selection and Forecasting Committee.
- Training on international good storage of essential medicines and other health commodities should be immediately conducted in order to ensure product quality along the supply chain management.
- An inventory and distribution management tools system should be set-up. This is often referred to as a logistics management information system (LMIS). The system should greatly facilitate the analysis of statistics, stock monitoring, order calculations and so forth. Once the paper system is working properly, a computerized system should be set up. However, to function properly, computerized systems require resources, including well-trained staff using and managing the system, reliable power and back-up of data, and IT support to resolve hardware and software issues.
- A set of SoPs should be written for every step of the inventory and distribution management.

3.4 Health Management Information System (HMIS)

The **HMIS** is at the centre of PSM. It is used to collect data and provide statistics on the public health sector essential for many of the processes in PSM. It is a system of record-keeping, reporting, processing, analysis, interpretation, use and feedback of relevant information and on timely manner at different levels of beneficiaries. HMIS is used to formulate policy and to plan, implement, monitor, supervise and evaluate health-related activities.

Strength

- There is an existing HMIS in place.

Weakness

- The HMIS seems not to be standardized throughout the country.

Recommendations - Health Management Information System

Main recommendation:

The managers responsible for monitoring patient data and those responsible for monitoring the supply of ARVs drugs should work together to strengthen the HMIS by identifying common data elements and developing methods in which data can be recorded and shared.

Specific recommendations:

- When designing a national HMIS, programme managers should consider the costs and benefits of manual and partly computerized approaches to data collection and management. For example, at the central level, it would be useful to crosscheck data from an LMIS with that from an HMIS for strategic and policy-related decisions and actions.
- The managers should use the existing system and strengthen it rather than building a parallel system.
- An HMIS should always include a guideline on how to implement it, which includes standard case definitions, data collection methods and SoPs.

3.5 Quality Assurance and Quality Control

The Right Quality is one of the “Six Rights”, and a critical component of ensuring that patients receive the treatment they need. Not only is the quality of medicines critical to getting the intended treatment result; it may have serious adverse effects in terms of resistance and delay in proper treatment if poor quality medicines are inadvertently being used. Quality assurance is at the centre of the PSM cycle and part of every step of it. QA starts at manufacturing and is part of all processes up to end-users taking their medicines. QA processes are used for products and for services needed for the programme to provide the intended health services.

Quality Assurance and Quality Control play a crucial role in pharmaceutical manufacturing and throughout the procurement and supply chain.

Quality Assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of arrangements made to ensure that pharmaceutical products are of the quality required for their intended use. QA is essential for pharmaceuticals as the efficacy of the medicines is the basic conditions for efficient treatment of patients. All relevant QA standards and a reference document for pharmaceuticals can be found on the Global Fund or WHO websites.

Quality Control (QC) comprises the practical activities involved in sampling and testing of products, checking documentation against specifications, and acceptance and rejection procedures. The purpose of QC is to check products and consignments before they are released for distribution and use at the different levels of the supply chain. QC also takes place in the pre- and post-shipment stages of the procurement process. QC is carried out in a WHO pre-qualified Laboratory or an ISO 17025 certified one, which undertakes testing to confirm that the delivered product meets internationally pre-defined quality standards. QC sampling is random, and certifies the quality of a product at a given time. It checks the quality of specific pharmaceuticals and/or consignments.

Strengths

- There is an NDRA (National Drug Regulatory Authority) in Albania, named the National Agency for Medicines and Medical Devices. It appears to be active in the area of QA/QC.
- The Agency follows a national protocol during QA and sampling procedures at various levels of the supply chain management.
- Regarding the QA process for ARV drugs, the Agency only checks documents and products at the port of arrival.
- During the procurement process, the QA is ensured by a constant follow-up by UNICEF.
- UNICEF products procured have sufficient shelf-life at the port of destination in Albania.

Weaknesses

- No QC is conducted by the National Agency for Medicines and Medical Devices when receiving products.
- No QC is conducted when storing products at the Mother Theresa University Hospital pharmacy.
- There is no WHO pre-qualified or ISO 17025 laboratory in the country.

Recommendations - Quality Assurance and Quality Control

Main recommendation:

To reduce the risk of expiration, procurement contracts for ARV drugs should specify a required minimum remaining shelf-life of the drugs at the time arrival at the port of arrival with a minimum of 75% of total shelf-life. It is prudent to not accept drugs with less than the required shelf-lives unless there is an emergency stock situation. Such a rule applies especially with HIV test kits and reagents when the shelf-life is around 4 months.

Specific recommendations:

- A QC system should be set-up up in Albania, especially when storing products in the main pharmacy such as the one in the Mother Theresa University Hospital.
- As a QA/QC general rule and the UNDP Operations Manual for Projects Financed by the Global Fund, a specific budget should be allocated to QA/QC activities which should be between 2–10% of the total procurement and according to other needs such as, but not limited to, training and PSM activity strengthening.

4. Recommendations

The following main recommendations and specific recommendations should be carefully considered.

Priority Area 1. Increase HIV testing

Main recommendations:

- Expand testing for HIV. Better targeting of HIV testing towards most-at-risk groups through community-based rapid testing and linkage to care is highly recommended.
- Increase awareness for indicator diseases among GPs and improve accessibility to provider-initiated HIV testing, including universal access to antenatal screening, and screening at TB and STI clinics, prisons and for patients with hepatitis clinical or lab markers.

Priority Area 2. Optimize the provision of antiretroviral therapy

Main recommendations:

- Plan for an increase in availability of viral load and CD4 count monitoring, with a capacity for at least 1000 tests per year starting in 2015.
- Phase in the 2013 WHO Consolidated Guidelines recommendations over the next three years, aiming for first-line treatment in all newly diagnosed cases, preferably using single pill fixed-dose combinations for better retention in care and adherence.
- Develop and adopt an updated ART treatment protocol for adults and children in Albania based on the 2012 WHO Guidelines and the 2013 Consolidated Guidelines.
- Consolidate and simplify management of HIV in the country. Consider having 2 paediatric ID specialists and 2-3 adult ID specialists taking care of all HIV patients (4-5 in total, down from the current 17 doctors).
- As a general rule, stable patients should be given ARV drugs for three months if they are compliant with their regimens and clinically stable. This decreases visits to the clinic and reduces the burden of travel on patients, especially those living outside the capital.
- Expand coverage of ART, aiming for treatment initiations for all patients with a CD4 cell count of <500, as well as treatment for discordant couples, in accordance with the WHO 2013 Consolidated Guidelines. However, priority should be given to earlier diagnosis to start those still undiagnosed and urgently in need of treatment (<350), and those lost to care.
- Peer consultants can help with accepting the HIV diagnosis, linkage to care, improving adherence and retention in care.

Specific recommendations:

- Establish an electronic medical record for PLHIV in Albania.
- Plan for an increase in the availability of VL and CD4 count monitoring (>1000 tests per year starting in 2015, average number of tests for a stable patient, 1-2, average number of annual tests for a newly diagnosed patient, 3-4. It should be stressed however that less frequent monitoring may be required for CD4 cell counts than for VL measurements).
- Ensure a buffer on ARV drug procurement to avoid stock-outs.

- Generate data on resistance from a sample of newly diagnosed patients. This can be done prospectively (ID clinic).
- Generate data on resistance among patients already on ART by analysing blood samples which are stored at the Institute of Public Health (sentinel survey).
- Given the lack of genotyping facilities and the lack of expertise for generating such data, and considering the urgency of the matter, as well as the relatively low number of patients with HIV in Albania, it may be cost-effective to outsource resistance testing to a core laboratory outside the country.
- Consolidate and simplify ART when possible. It is very hard to keep up to date with HIV management with only a couple of patients. Consider having two paediatric ID specialists and 3-4 adult ID specialists taking care of all HIV patients. (5-6 in total, down from 17).
- As a general rule, stable patients should be given three months' worth of ARV drugs if they are compliant with their regimens and clinically stable. This decreases patient traffic in the clinic and reduces the burden of travel on patients, especially the ones living outside the capital, Tirana.
- Make a log of patients who are not currently receiving ART and establish a system of reminders (e.g. phone calls/SMS by the department social worker, clinic nurse etc.).
- Establish a formal, regular professional forum for major stakeholders dedicated to HIV management, for the exchange of information, advice and consensus building (further developed under Priority 2, below).
- As a part of a comprehensive plan, increase awareness for indicator condition guided testing among GPs and improve accessibility to rapid HIV testing, including antenatal screening – which should be universal. Better targeting of HIV testing towards most-at-risk groups is also highly recommended.
- Improve laboratory services to diagnose OIs and TB (e.g. pneumocystis jirovecii pneumonia and interferon-gamma releases assay (IGRA) tests).
- In the case of PLHIV, make an exception to the general principle that all prescriptions for non-hospitalized patients need to be written by GPs in order for the patients to have their medications free of charge and to complete treatments which have been prescribed by their ID physicians at the university hospital.
- Develop and adopt an updated ART treatment protocol for adults and children in Albania based on the 2012 WHO Guidelines and the 2013 Consolidated Guidelines.
- Phase in the 2013 WHO Consolidated Guidelines recommendations over the next two years, aiming for first-line treatment in all newly diagnosed cases, preferably using single pill fixed-dose combinations for better retention in care and adherence (2).
- Review the treatments of the 82 patients on second-line treatment and assess their indications with a view to switch to first-line therapy, if this is deemed medically appropriate. It is recommended that two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) and efavirenz (EFV) (a non-nucleoside reverse transcriptase inhibitor [NNRTI]) be combined in the first-line ART regimen, preferably using a single fixed-dose combination. If EFV cannot be used, a ritonavir-boosted lopinavir or atazanavir treatment or nevirapine (NVP) are alternatives. Second-line ART is the next regimen used in sequence immediately after first-line ART has failed. The PI class is preferentially reserved for second-line use in settings using a public health approach. Ideally, ritonavir-boosted PIs are recommended, supported by two NRTIs.

- Given the safety and long-term tolerability issues associated with ZDV, the high utilization of this drug is concerning and should be reduced.
- Given the lack of human leukocyte antigen typing facilities, ABC use should be discouraged and this agent is not listed among first-line NRTIs.
- Expand the coverage of ART, aiming for treatment initiations in all patients with CD4 cell counts <500, as well as treatment for discordant couples, in accordance with the 2013 WHO Consolidated Guidelines (2).
- Plan and prepare for an increased patient load in the ID Department's HIV clinic (not simple linear increase), both with respect to the utilization of laboratory resources, expansion of indications for ART and the time commitment of staff.

Priority Area 3. *An efficient Procurement and Supply Chain Management of ART in Albania*

Main recommendations:

- Create a Product Selection and Forecasting Committee by July 2015 to identify if the current ART lines are consistent with the WHO Consolidated Guidelines (2013) in order to optimize ART as per priority 1 above and to conduct accurate product selection and forecasting exercises. Members of the committee should come from various categories of health professionals associated with HIV as well as relevant programme staff (logistic, procurement, finance etc.) such as the Chief of Supply and Transport at the University Hospital and the UNICEF representatives, as they can provide technical information on the EML, the availability of medicines on the international market, lead time, procurement processes, product prices, etc., while the financial expert should be able to share information regarding the budgets available, saving funds, etc. It should ensure a comprehensive and accurate technical specification list.
- In order to mitigate the risks in terms of delays or stock-out during the procurement process, regular meetings should be organized between the University Hospital Chief of Supply and Transport, UNICEF and the Product Selection and Forecasting Committee or those in charge of such PSM activity.
- The Mother Theresa University Hospital pharmacy should be urgently moved to a proper location with sufficient space, for example to the ID clinic. The pharmacy manager should follow the International Good Storage of Essential Medicines. It should be noted that with the current number of patients a room of 15m² should be sufficient enough to store ARVs drugs and other health products
- The managers responsible for monitoring patient data and those responsible for monitoring the supply of ARVs drugs should work together to strengthen the HMIS by identifying common data elements and developing methods in which data can be recorded and shared.
- To reduce the risk of expiration, procurement contracts for ARV drugs should specify a required minimum remaining shelf-life on the drugs at the time of arrival at the port of arrival in Albania with a minimum of 75% of total shelf-life. It is prudent to not accept drugs with less than the required shelf-life unless there is an emergency stock situation. Such a rule applies especially to HIV test kits and reagents when the shelf-life is around 4 months. This should be put into practice already in 2015.

- To have a National HIV Programme Manager appointed by the Ministry of Health to oversee PSM as well as all HIV-related issues. Such a programme manager should be in place by the time of the start of the next round of Global Fund support.

Specific recommendations (Product Selection: Quantification and Forecasting):

- A realistic quantification/forecasting exercise should be conducted for ARV drugs as well as for the HIV test kits, reagents, other health-products (gloves, masks, etc.) and other services.
- To facilitate accountability, the roles and responsibilities of all committee members should be clearly defined.
- The newly created Product Selection and Forecasting Committee should avoid any conflict of interest—particularly commercial such as pharmaceutical industry interests—and come to a consensus.
- The committee should conduct the quantification/forecasting exercise through the collection, analysis, sharing and validation of data, and by developing a strong data collection process through an HMIS.
- The Committee should:
 - develop and validate assumptions used for quantification.
 - disseminate information and make decisions about the introduction of new products.
 - determine the implications of guideline updates on quantification.
 - monitor stock and commodity needs throughout the year.
 - coordinate funding and prevent overlapping procurement.
 - determine the timing of procurement and coordinate with partners.
- In addition, on the basis of the selection for HIV and AIDS needs, the EML should be understood and used to avoid poor procurement or wrong product selection (5).
- The committee should regularly meet in order to update a product phase-out or treatment change to be able to react adequately along the supply chain management.
- Quantification is not an ad-hoc process. Quantification should be reviewed on a regular basis, preferably quarterly, to reflect changes in consumption and the kind of products used.
- For the quantification exercise, in general, it is advisable to combine consumption method (the estimated need is based on past use) and morbidity data to strengthen the estimates.
- The forecasting should take into account:
 - the result of quantification
 - stock in hand at the time of the order
 - stock in hand at the delivery time
 - the needs (difference between the 2 points above)
 - pack size
 - buffer stocks (minimum of 25% and may vary according to the available budget, the procurement flexibility and the uncertainty of the forecasting)
- The total cost should be calculated using:
 - products unit price. These prices are available either using the last procurement price list with UNICEF or on several websites (6)
 - total price according to the quantities

- international transport cost
- customs clearance cost
- in-country transport cost
- other expenses should be added if necessary.
- The following should be taken into account to avoid stock-out or overstock:
 - the time between the final order to the procurement agent (currently UNICEF in Tirana) and the transfer of funds
 - the procurement lead time (time between the order confirmation order and the arrival of the goods)
 - the time needed to clear the products before becoming available for distribution.
- Regarding the laboratories, a complete assessment should be conducted of the existing laboratories in order to identify the following:
 - existing infrastructure
 - existing equipment
 - the need for new equipment
 - test kits
 - reagents
 - human Resources (HR) rehabilitation
- A set of SoPs should be written to understand what to do during the product selection and quantification and forecasting exercises.

Specific recommendations (Procurement):

- Revise as needed the quantities to be procured, responding to uncertainties, fluctuations, product phase-out, unexpected quantities increase or decrease or treatment changes.
- Conduct several procurements per year, especially when it is related to HIV test kits and reagents (due to the very short shelf-life of these products).
- In order to mitigate the risks of patients not receiving ART, the procurement process (cost-estimate confirmation to UNICEF or any procurement agent) should start 6 months before expecting products delivery to the University Hospital pharmacy.
- An annual procurement plan should be prepared in coordination with all partners, including UNICEF (see Annex 3).
- To track all supplies in the pipeline and to monitor procurement efficiency, the Mother Theresa University Hospital and those in charge of the procurement should create a procurement follow-up form (See Annex 4 – Example of procurement follow-up) and a procurement evaluation report (See Annex 5 – Example of procurement evaluation report).
- Once the procurement is completed, the procurement documents should be filed for further requests. Such documentation should be maintained and available to the Global Fund and/or auditors to demonstrate efficiency in this activity.
- The purchaser should update price and quality reporting (PQR) on the Global Fund website: <http://www.theglobalfund.org/en/procurement/pqr/>

A set of SoPs related to procurement with UNICEF or any other procurement agent should be produced.

Specific recommendations (Inventory Management and Distribution):

- Careful forecasting, strict monitoring of inventory levels and secure transportation to storage facilities should play a key role in streamlining the supply.
- A regular inventory stock alert should be put in place in order to avoid stock-outs.
- A quarterly inventory management report should be sent to those in charge of stock level monitoring (clinicians for adults and paediatric care) or the future Products Selection and Forecasting Committee.
- Training on international good storage of essential medicines and other health commodities should be immediately conducted in order to ensure product quality along the supply chain management.
- An inventory and distribution management tools system should be set-up. This is often referred to as a logistics management information system (LMIS). The system should greatly facilitate the analysis of statistics, stock monitoring, order calculations and so forth. Once the paper system is working properly, a computerized system should be set up. However, to function properly, computerized systems require resources, including well-trained staff using and managing the system, reliable power and back-up of data, and IT support to resolve hardware and software issues.

A set of SoPs should be written for every step of the inventory and distribution management.

Specific recommendations (Health Management Information System):

- When designing a national HMIS, programme managers should consider the costs and benefits of manual and partly computerized approaches to data collection and management. For example, at the central level, it would be useful to crosscheck data from an LMIS with that from an HMIS for strategic and policy-related decisions and actions.
- The managers should use the existing system and strengthen it rather than build a parallel system.
- An HMIS should always include a guideline on how to implement it, which includes standard case definitions, data collection methods and SoPs.

Specific recommendations (Quality Assurance and Quality Control):

- A QC system should be set-up up in Albania, especially when storing products in the main pharmacy such as the one in the Mother Theresa University Hospital.
- As a QA/QC general rule and the UNDP Operations Manual for Projects Financed by the Global Fund, a specific budget should be allocated to QA/QC activities which should be between 2–10% of the total procurement and according to other the needs such as, but not limited to, training and PSM activity strengthening.

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Annex 1. Albanian PSM Cycle

Management, information and quality assurance (at the centre of the cycle) are a part of all stages.



Annex 2. ART regimens used in Albania (adult patients), February 2014 and February 2015

	Regimen	Feb 2014 (n, patients)	Feb 2015 (n, patients)
1	ZDV/3TC/EFV	153	171
2	TDF/FTC/EFV	66	85
3	ZDV/3TC/LPV/r	38	35
4	TDF/FTC/LPV/r	30	27
5	TDF/ddI/LPV/r	5	3
6	TDF/3TC/EFV	8	4
7	ABC/3TC/EFV	3	
8	TDF/LPV/r	1	1
9	ABC/TDF/LPV/r	1	1
10	3TC/ddI/LPV/r	1	
11	ABC/TDF/EFV	1	1
12	3TC/ddI/EFV	1	
13	TDF/3TC/LPV/r	2	2
14	ddI/EFV/LPV/r	1	
15	TDF/FTC/ATV/r	3	5
16	ABC/3TC/LPV/r	1	1
17	ZDV/3TC/ABC	1	1
18	ABC/ddI/LPV/r		1
19	3TC/ddI/ATV/r		1
		316	339

Abbreviations:

ZDV, zidovudine; 3TC, lamivudine; EFV, efavirenz; TDF, tenofovir, FTC, emtricitabine; LPV, lopinavir; r, low-dose ritonavir (for boosting); ddI, didanosine; ABC, abacavir; ATV, atazanavir.

Annex 3. Example of a procurement plan

	Procurement period	Year 3				Year 4				Year 5				Observations
		Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	
ARV s drugs	Procurement Order	Yellow												
	Lead time (consumption of the		Green											During first procurement current stock would be used
	Delivery of products (indicate also partial			Blue										
	Consumption time			Brown	Brown	Brown	Brown							
	Procurement Order			Yellow										Second procurement, current stock would be used
	Delivery of products (indicate also partial				Blue	Blue								Partial delivery (deliveries during Q4 Year 3 and Q1 year
	Consumption time						Brown	Brown	Brown	Brown	Brown	Brown	Brown	
	Buffer 6 month	Red	Red											

Quarterly, monthly or weekly period may be used according to the product procured.

When buffer stock is used to cover some unexpected events, it should be mentioned.

Buffer stock should be used before its expiration date and replaced by new products.

Annex 4. Example of procurement follow-up

Request No	Supplier	Category	Short Description	Procurement information		Original Plan		Completion		Remarks
				Request date	Product Estimate date of Arrival (EDA)	Procurement Plan Amount	Request estimated Amount	Progress date	Progress to date	
Request No XXX	UNICEF	ARVs	GFATM Grant R6 - paediatrics	10-04-2014	25-11-2014	\$1.200.000	\$300.000	10-04-2014	0%	Meeting with UNICEF - National Programme provides the request form. UNICEF mentioned that the procurement will take 6 months
								10-05-2014	25%	Meeting with UNICEF - The order was sent to UNICEF Copenhagen. Manufacturer is producing the drugs.

Annex 5. Example of procurement evaluation report

Procurement Evaluation Report (PER)

Procurement of ARVs with UNICEF

November 2014

Requisition From #: **NAP/GF/ARV/005/PER01**

Name of Project: **Global Fund R6 Year 1**

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- A- Procurement Process**
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Documents attached:

- Annex 1 – SOPs (procurement process with UNICEF)**
- Annex 2 – Requisition Form**



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