



SUPPLY CHAIN MANUAL



Foreword

The AIDSRelief health supply chain management manual was written in response to field requests for support in building and maintaining sustainable health supply chain management systems in resource-limited settings in Africa, Latin America and the Caribbean. One of the major challenges building capacity in health supply chain management throughout the developing world is a chronic undersupply of skilled staff coupled with a consistently high rate of staff turnover.

A successful antiretroviral therapy, care and treatment program requires a host of inputs and resources including drugs, reagents, equipment and other consumables and supplies. The overall management of these resources includes ensuring supplies are in the right place at the right time, in the right quantities, at the lowest possible cost, with minimal or no waste. This is a daunting but critical management task.

AIDSRelief supply chain management mechanisms are designed to create a balance of responsibility and authority between the facility, the distributor and AIDSRelief management. This builds capacity with local institutions in order to ensure long-term sustainability. One of AIDSRelief's goals is to avoid the set-up of parallel systems.

This manual is both a guide and a training tool for staff at AIDSRelief local partner treatment facilities in nine countries. All pharmacy staff should have a copy of this manual. New staff should receive a copy and training as part of their orientation.

In each of the nine countries, AIDSRelief Health Supply Chain Specialists are responsible for creating a supportive environment where pharmacy staff can effectively use the manual in the course of their daily work. With these resources and ongoing support from the AIDSRelief health supply chain team, we expect continued improvement at each level in our health supply chain management.

Beyond the AIDSRelief program, this manual is intended to be handed over to the local partners or organizations, to be used as a resource in maintaining supply chain management standards and in continuous improvement of pharmaceutical systems at health facilities to ensure end-user satisfaction.

Acknowledgements

This manual was revised in April 2011 for use in combination with the Site Capacity Assessment tool developed by AIDSRelief during its transition and sustainability phase.

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The contributions of the AIDSRelief local partner treatment facilities are greatly appreciated. The staff of these facilities have worked tirelessly to participate in the supply chain management of drugs and other medical supplies.

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Acronyms

ADR	Adverse Drug Reaction
ART	Antiretroviral Therapy
ARV	Antiretroviral Drugs
CHAN	Christian Health Association of Nigeria
HAZ	Christian Health Association of Zambia
CMMB	Catholic Medical Mission Board
CRS	Catholic Relief Services
CTCT	Country Technical Coordinating Team
EHML	Essential Hospital Medicines List
FEFO	First Expiry First Out
FIFO	First In First Out
HIV	Human Immunodeficiency Virus
IHV	University of Maryland School of Medicine Institute of Human Virology
IMA	IMA World Health
JMS	Joint Medical Store
LMIS	Logistics Management Information System
LPTF	Local Partner Treatment Facility
MEDS	Mission for Essential Drugs
MTC	Medicines and Therapeutic Committee
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NtRTI	Nucleotide Reverse Transcriptase Inhibitors
OI	Opportunistic Infection
PEPFAR	President's Emergency Plan For AIDS Relief
PI	Protease Inhibitor
SCM	Supply Chain Management
SOP	Standard Operating Procedure
STG	Standard Treatment Guidelines
TOR	Terms of Reference

Drug Abbreviations

3TC	Lamivudine
ABC	Abacavir
AZT	Zidovudine
CBV	Lamivudine + Zidovudine
D4T	Stavudine
EFV	Efavirenz
FTC	Emtricitabine
KAL or Lop/r	Lopinavir + Ritonavir
NVP	Nevirapine
TDF	Tenofovir
TVD	Truvada

Background of AIDSRelief Supply Chain Management

AIDSRelief is a five-member consortium funded through the U.S. President's Emergency Plan for AIDSRelief (PEPFAR.) Since 2004, the project has supported rapid scale up of antiretroviral therapy (ART) to poor and under-served populations in ten countries. The consortium brings together international experience in HIV care and treatment: Catholic Relief Services (CRS) as prime grantee; the University of Maryland School of Medicine Institute of Human Virology (IHV) as clinical lead for medical care and treatment; Futures Group International (Futures) as lead agency for strategic information; and Catholic Medical Mission Board (CMMB) and IMA World Health as implementing partners on the ground. AIDSRelief currently operates in nine countries: Ethiopia, Guyana, Haiti, Kenya, Nigeria, Rwanda, Tanzania, Uganda, and Zambia. The tenth country program, South Africa, transitioned to local partners in 2010.

The AIDSRelief-supported ART program is managed through an interlinked global network that includes clinicians, pharmacists and nurses as well as program support, strategic information, finance and supply chain specialists. Service delivery and treatment takes place in hospitals and clinics owned and managed by faith-based organizations, private organizations, national and local governments.

Well-managed ART programs require a range of inputs and resources including (but not limited to) drugs, reagents, equipment, and other consumables and supplies. Managing these inputs and ensuring that they are available where they are needed – **in the right quantities, at the right time, at an optimal cost, with minimal or no waste** – is a daunting but critical task.

Without these critical commodities and equipment there would not be a treatment program. Supply chain management teams work to ensure a secure, reliable and efficient supply system for antiretroviral drugs (ARVs) and other related commodities to support treatment objectives of all nine AIDSRelief country programs.

AIDSRelief supply chain management mechanisms balance responsibility and authority and are guided by the need to enhance capacity of local institutions in order to ensure long term sustainability. Care has been taken to avoid set-up of parallel systems and, where such systems exist, efforts have been made to integrate the ART program into existing hospital systems.

The AIDSRelief supply chain team works to ensure a supply system that is reliable, efficient, sustainable, cost-effective, well-coordinated, and relevant to each country context. The system is built on the premise of balanced relationships between different partners and levels: global and country programs; country programs and treatment sites; treatment sites, patients and communities; program and national systems, including other stakeholder systems.

The key functions involved in managing health supplies include the following:

- Product selection
- Forecasting
- Procurement
- Warehousing and distribution
- Use, monitoring and evaluation
- Drug financing and expenditure
- Systems strengthening
- Other management support functions

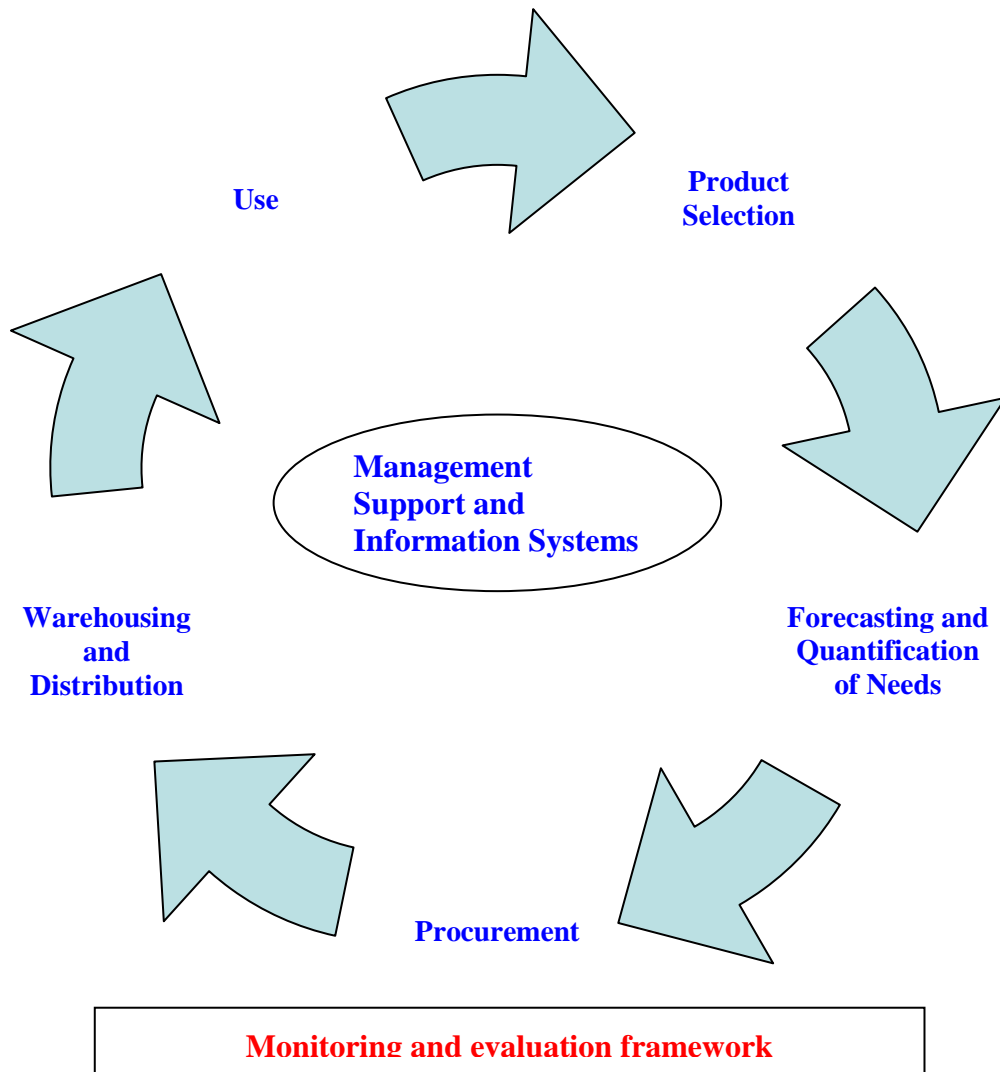
Within these specific areas, the focus is on the following:

- Building capacity for needs determination, forecasting and quantification
- Improving drug transaction reporting mechanisms at country and treatment site levels
- Supporting development of standard operating procedures (SOP) for ARV and opportunistic infection (OI) drug management at all treatment sites
- Equipping all involved personnel with key knowledge and skills essential for optimal commodity resource management. This focuses on forecasting, procurement/requisition planning, inventory management, monitoring and evaluation of supply systems
- Supporting development of infrastructure necessary for ARV and non-ARV drug management
- Establishing a system for continuous and timely delivery of ARVs to each treatment site
- Working towards integration of ARV and essential drug supply systems at a treatment site level

Key strategic issues continuously emerge. These include, but are not limited to, the following:

- Unpredictable world-wide drug supply dynamics that could upset treatment plans and disrupt the supply chain
- Lead time versus changing treatment patterns that could lead to a mismatch between what is needed in the future and what is purchased at present
- A multiplicity of actors in the supply chain sector with minimal coordination and harmonization. Coupled with this is the move in some countries to common commodities funding and supply basket before coordination and harmonization issues are resolved, a situation that could lead to confusion and a dysfunctional overall system.

The AIDSRelief supply chain follows the traditional cycle for managing drug supply:



Product selection, forecasting and quantification are undertaken by a multi-disciplinary team of professionals that includes clinicians, pharmacists, and supply chain, programming and finance specialists guided by national treatment guidelines, science and best practices. Structurally, the program has instituted medicines and therapeutic committees (MTC) which work at various levels of the program and are now being rolled out at all treatment sites in collaboration with individual hospital management and medical teams. Where hospital formulary committees exist, they are supported to address commodities used in HIV care and treatment. Where they do not exist MTCs will be formed. These committees, when fully functional, will be a structural best practice that will improve management of ARVs and related commodities within the institution. They will continue to receive support from AIDSRelief to strengthen their product selection, forecasting and quantification systems through use of innovative technological solutions.

Procurement planning is the next step and involves navigating international supply dynamics while recognizing the individual country context and the availability and timing of

programming funding. Issues of lead times, safety and buffer stock requirements inform the process of procurement planning and management. ARV procurement presents unique challenges due to the fact that patients require lifetime treatment. Uninterrupted supply and pipeline integrity are non-negotiable. This requirement presents the challenge of ensuring continuous product availability in a rapidly changing treatment environment that might include regimen changes due to toxicity, treatment failure and drug resistance. Through a combination of operations management solutions and continuous interface with manufacturers and treatment sites, these uncertainties have been reduced to manageable limits and to date the process has worked smoothly. It is important to note that even in the face of these challenges AIDSRelief's procurement and overall supply chain costs continue to decline and the program's supply chain management team has remained small.

In-country product receipt, warehousing and distribution are all stages in the supply chain cycle that are very relevant to country operations that this manual is aimed primarily at. Ensuring product quality integrity throughout the distribution chain remains the number one priority in whatever is done to get the products from a central warehouse to treatment sites and ultimately to the end users. AIDSRelief executes these important functions in collaboration with local organizations with proven competency. The decision to team up with these organizations (CHAZ in Zambia, JMS in Uganda, CHAN MEDI-Pharm in Nigeria, MEDS in Kenya and PROMESS in Haiti) was intentional and in recognition of the fact these organizations will ensure sustainability of supply chain systems needed to support HIV care and treatment programs now and in the future, long after programs like AIDSRelief are gone.

The ultimate goal of any supply chain system is to ensure that end users receive quality products, when they need them, where they need them, in the right quantities, and at the right cost. The penultimate step in this process is dispensing the product to patients. AIDSRelief has invested in improving the process of dispensing and using products. Training of pharmacy staff, improvement of records management, and computerization of dispensing using novel technology solutions are just some of the steps taken to improve pharmacy management systems. Emphasis is placed on tracking of all inventory transactions throughout the pipeline.

Dispensing ARVs calls for extra pharmaceutical care as staff navigate regimen choice, counseling for potential adverse effects, dosing instructions and, most importantly, scheduling for future pharmacy refills given the chronic and long term nature of the treatment. It is hoped that ART programs can improved communication and interaction among health care delivery teams, which can translate into broader improvement of health care teams' interactions.

Finally, all steps in the supply chain cycle are constantly improving through continuous monitoring and evaluation. If these initiatives and efforts are not well-monitored and evaluated, supply chain systems may be interrupted. The entire chain is monitored for performance on a regular basis and evaluations are undertaken every six months to measure progress and re-affirm or change future action steps. Benchmarking against best practices in the industry, within the sector, and from other sectors is an essential part of this work.

The long term sustainability of supply chain systems for ART and other health commodities will largely depend on strong institutional systems for managing these commodities at user institutions – hospitals, clinics and other health care facilities. Often this downstream part of the supply chain is not given enough attention; many actors focus on the upstream functions such as international and national procurement, a situation that has perpetuated chronic stock-outs and expiries. AIDSRelief and local partners have, therefore, invested more effort and resources in downstream efforts in the hope that experiences and lessons learned from

managing ART-related commodities will have a ripple effect across the entire spectrum of health commodities management.

1.0 Goals, Objectives and Key Concepts

1.1 Target Audience

This manual was written to assist all those involved in the handling of ARVs and related supplies at the facility level. The manual borrows from contemporary pharmacy practice with emphasis on management of ARVs but the issues addressed apply to any other drugs and commodities used in care delivery. It is therefore hoped that lessons learned from the management of ARVs can be applied to other health commodities.

While this manual is designed to provide comprehensive advice, it is not possible to anticipate all issues that may arise in the course of daily work. In such cases, the pharmacy team and hospital management should work collaboratively to reach a decision or solution, using this manual as a guide

The objectives of this manual include the following:

- Supporting AIDSRelief's hospital partners in improving inventory management practices, with focus on ARV drugs and related supplies
- Supporting institutionalization of standard operating procedures (SOPs) in the management of health commodities, especially ARVs
- Improving management of records and reporting related to drug inventory transactions used within an ART program and generally in care delivery
- Improving accountability and promoting institutional memory through documentation of all drug management activities that routinely take place at a care facility level
- Improving accountability systems related to drug procurement and reporting on financial resources

1.2 Key Concepts

1.2.1 Philosophy of Good Pharmacy Practice¹

The mission of pharmacy practice is to provide medications and other health care products and services and to help people and society to make the best use of them. Comprehensive pharmacy service involves activities to secure good health and to avoid ill health in the population. When ill health is treated, it is necessary to assure quality in order to achieve maximum therapeutic benefit and avoid side effects.

This presupposes the acceptance by pharmacy professionals of shared responsibility with other professionals and with patients for better therapeutic benefits/outcomes.

In recent years the term "pharmaceutical care" has become established as a philosophy of practice, with the patient and the community as the primary beneficiaries of the pharmacist's actions. The concept is particularly relevant to special groups such as the elderly, mothers and children, and chronically ill patients, as well as to the community as a whole in terms of,

¹ International Pharmaceutical Federation. (1997). *Standards for Quality of Pharmacy Services*. Retrieved from. http://www.fip.org/www/uploads/database_file.php?id=261&table_id=

for example, cost containment. While the basic concepts of pharmaceutical care and good pharmacy practice are largely identical, it can be said that good pharmacy practice is the way to implement pharmaceutical care.

1.2.2 The Requirements of Good Pharmacy Practice

- Good pharmacy practice requires that a pharmacist's first concern in all settings is the welfare of patients.
- Good pharmacy practice requires that the core of pharmacy activity is the supply of medication and other health care products of assured quality, appropriate information and advice for the patient, and monitoring of the effects of use.
- Good pharmacy practice requires that an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and appropriate use of medicines.
- Good pharmacy practice requires that the objective of each element of pharmacy service is relevant to the patient, is clearly defined and is effectively communicated to all those involved.
- Good pharmacy practice, specifically related to ART, includes the counseling of patients as part of treatment preparation, as well as throughout the treatment process, to ensure adherence.

In satisfying these requirements, the following conditions are necessary:

- Professionalism should be the main philosophy underlying practice, although it is accepted that economic factors are also important.
- Pharmacists should have input into decisions about the use of medicines. A system should exist that enables pharmacists to report adverse events, medication errors, defects in product quality or detection of counterfeit products. This reporting may include information about drug use supplied by patients or health professionals, either directly or through pharmacists.
- The ongoing relationship with other health professionals, particularly physicians, should be seen as a therapeutic partnership that involves mutual trust and confidence in all matters relating to pharmacotherapeutics.
- The relationship between pharmacists should be as colleagues seeking to improve pharmacy service, rather than as competitors.
- The pharmacist should be aware of essential medical and pharmaceutical information about each patient. Obtaining such information is made easier if the patient chooses to use only one pharmacy or if the patient's medication profile is available.
- The pharmacist needs independent, comprehensive, objective and current information about therapeutics and medicines in use.
- Pharmacists in each practice setting should accept personal responsibility for maintaining and assessing their own competence throughout their professional lives.
- National standards of good pharmacy practice should be specified and should be adhered to by practitioners.

Although the above philosophies seem directed at pharmacists, pharmacies in hospitals are not necessarily populated by pharmacists. Other categories of staff work in the pharmacy and carry out different functions, some of which are traditionally reserved for the pharmacist. Irrespective of the category of staff working in the pharmacy, the standards outlined above are ideals to which all staff should aspire.

1.2.3 Supply Chain Management (SCM)

Supply chain management (SCM) is the process of planning, implementing, managing and controlling all activities involved in sourcing, procurement, conversion, and logistics management, with the aim of satisfying the end users as efficiently as possible. Importantly, it also includes coordination and collaboration with middle-level partners who serve as a link to the end users. These middle-level partners can be suppliers and intermediaries who have a stake in the supply chain process. Organizations planning for effective growth concentrate on their core competences, which may be managerial, while outsourcing logistics to other organizations or partners. Supply chain management therefore seeks to improve collaboration among partners. In order to ensure that commodities are available when and where they are needed, a robust and responsive supply chain must be in place.

HIV treatment requires an effective supply chain to ensure that ARVs are available at all times so as not to cause treatment interruptions. Therefore, ARV supply chain management must take the following issues into consideration:

- Special distribution requirements for ARVs and diagnostics
- Constant stock availability (shortages can interrupt treatment and lead to drug resistance)
- ARVs are high-value, high-demand products which require extra security

The components of the supply chain include procurement, distribution, resources, information and management. The supply chain is as strong as each of its components, therefore security and assurance of commodities depends on the interplay among all these components.

- Procurement involves planning, selection, pre-qualification, quantification, reception and quality control, threats.
- Distribution involves supply chain planning, stores management, distribution planning, threats
- Resources involves financing, budgets, human resources
- Information involves communication systems, reporting systems, information sources
- Management involves program management, monitoring and evaluation, financial management, human resources management

The AIDSRelief SCM process takes all these components into consideration. The procurement of ARVs is now fully country-led and flexible enough to adapt to the different local realities. Distribution is outsourced to organizations that specialize in warehousing and distribution while AIDSRelief has maintained a managerial role over the process, which will currently be transitioned to local partners. The robust information and management systems which comprise central and local LMIS (logistical management information systems) have resulted in efficient management of the ARV pipeline. Resources and management are cross-cutting issues that affect the entire AIDSRelief program.

1.2.4 Logistics

Some schools of thought contend that supply chain management and logistics are one and the same, while others believe they are distinct. For the purpose of this manual, supply chain management deals with processes while logistics refers to the specific functions or activities

that must be undertaken. Therefore, logistics includes product selection, forecasting, ordering, warehousing, inventory management, distribution and managing data. For health programs, an excellent logistics system will deliver the product to the right person.

1.2.5 Pipeline

The pipeline is the entire chain of storage facilities and transportation links through which supplies move from the manufacturer to the consumer, including the port facilities, central warehouse, regional warehouses, district warehouses, all service delivery points and transport vehicles. The list of commodities needed for an effective ART program includes more than simply ARVs. A full range of commodities support prevention, treatment and care objectives. In order to sustain and expand successful interventions, the supply chain must become more robust, agile and flexible through better management. There is a need for increased capacity building at the local partner treatment facility (LPTF) to achieve optimization.

2.0 Know Your Drugs

2.1 Classes of Antiretroviral Drugs

There are about six classes of ARVs available on the market at this time. Of these, the drugs used within the AIDSRelief fall into four classes as follows:

- Nucleoside reverse transcriptase inhibitors (NRTI), also known as “nukes”
- Nucleotide reverse transcriptase inhibitors (NtRTI), also known as “nukes”
- Non-nucleoside reverse transcriptase inhibitors (NNRTI), also known as “non-nukes”
- Protease inhibitors (PI)

Some of the drugs used in the AIDSRelief program are shown in the table below.

NRTI	NtRTI	NNRTI	PI
Lamivudine	Tenofovir	Nevirapine	Lopinavir
Stavudine		Efavirenz	Ritonavir
Zidovudine			
Didanosine			
Emtricitabine			

2.2 Individual Drug Information

S/N	Generic Name	Strength	Brand Name ²	Usual Dose
1	Lamivudine (3TC)	150 mg	Epivir [®]	one tablet twice a day
2	Nevirapine (NVP)	200 mg	Viramune [®]	one tablet once a day for the first two weeks of therapy, then one tablet twice a day
3	Efavirenz (EFV)	600 mg	Stocrin [®] Sustiva [®]	one capsule at night
4	Zidovudine (AZT)	300 mg	Retrovir [®]	one tablet twice a day
5	Tenofovir (TDF)	300 mg	Viread [®]	one tablet daily
6	Abacavir	300 mg	Ziagen [®]	one tablet twice a day
7	Lopinavir + Ritonavir (Lop/r)	200 mg + 50 mg	Aluvia [®]	two tablets twice a day
8	Emtricitabine (FTC) + Tenofovir (TDF) (TVD)	200 mg + 300 mg	Truvada [®]	one tablet daily
9	Lamivudine + Zidovudine (CBV)	150 mg + 300 mg	Combivir [®]	one tablet twice a day

² Where applicable, AIDSRelief is now substituting branded drugs with the recently FDA- approved bioequivalent generic ARVs

2.3 Paediatric Antiretroviral Drugs (as adapted from BIPAI paediatric ARV dosing chart November 2006)

S/N	Generic Name	Strength	Usual Dose
1	Lamivudine oral solution (3TC)	10 mg/ml	4 mg/kg/dose twice daily
2	Stavudine dry powder (D4T)	1 mg/ml	<ul style="list-style-type: none"> Patients <30 kg, 1 mg/kg/dose The above dose is given twice daily
3	Nevirapine oral suspension (NVP)	10 mg/ml	Induction dose is 160-200 mg/m ² /dose once daily for 14 days. Thereafter, the maintenance dose is 160-200 mg/m ² /dose twice daily
4	Efavirenz capsules (EFV)	200 mg	<ul style="list-style-type: none"> 200 mg for patients 10 kg – 14 kg 250 mg for patients >14 kg but <20 kg 300 mg for patients >20 kg but <25 kg 350 mg for patients >25 kg but <30 kg 400 mg for patients >30 kg but <40 kg The above doses are given once daily
	Efavirenz capsules (EFV)	50 mg	
	Efavirenz syrup (EFV)	30 mg/ml	
5	Zidovudine syrup (AZT)	10 mg/ml	180-240 mg/m ² /dose twice daily
	Zidovudine tablets (AZT)	100 mg	
6	Didanosine tablets (DDI)	50 mg	<ul style="list-style-type: none"> 120 mg/m² for children The above dose is given twice daily
	Didanosine tablets (DDI)	100 mg	
7	Lopinavir/Ritonavir syrup (KAL or Lop/r)	80 mg Lop/20 mg ritonavir per ml	10-16 mg/kg/dose The dose of Kaletra is usually based on the Lopinavir content. The above doses are given twice daily
8	Abacavir syrup (ABC)	20 mg/ml	8 mg/kg/dose twice daily

There are adult and paediatric fixed dose combinations available.

Other classes of ARVs available include fusion inhibitors and integrase inhibitors.

- Fusion inhibitors interfere with the process of viral attachment, fusion and entry into host cells and prevent HIV from infecting the CD4 cell. Enfuvirtide (T-20) is a fusion inhibitor available and in use.
- Integrase inhibitors interfere with the ability of the HIV DNA to insert itself into the host DNA and thereby copying itself. Integrase inhibitors are still under development.

2.4 Storage and Administration Requirements

Drug	Storage	When to Administer Drug
Lamivudine <ul style="list-style-type: none"> • 150 mg tablets • 10 mg/ml OS 	<ul style="list-style-type: none"> • Tablets and oral solution are stable at room temperature • Discard oral solution one month after opening 	Drug may be taken with food
Stavudine <ul style="list-style-type: none"> • 20 mg capsules • 15 mg capsules • 1 mg/ml OS 	<ul style="list-style-type: none"> • Capsules are stable at room temperature • Oral suspension comes as powder for reconstitution. It is stable at room temperature for only 24 hours or in the refrigerator for 30 days after constitution • Keep oral solution refrigerated and discard one month after constitution 	Drug may be taken with food
Nevirapine <ul style="list-style-type: none"> • 200 mg tablets • 10 mg/ml OS 	<ul style="list-style-type: none"> • Tablets and oral solution are stable at room temperature 	Drug may be taken with food
Efavirenz <ul style="list-style-type: none"> • 600 mg tablets • 200 mg tablets • 50 mg tablets • 30 mg/ml OS 	<ul style="list-style-type: none"> • Tablets and oral solution are stable at room temperature 	Drug may be taken with or without food
Zidovudine <ul style="list-style-type: none"> • 300 mg tablets • 100 mg tablets • 10 mg/ml OS 	<ul style="list-style-type: none"> • Tablets and oral solution are stable at room temperature 	Drug may be taken with food
Didanosine <ul style="list-style-type: none"> • 100 mg tablets • 25 mg tablets 	<ul style="list-style-type: none"> • Oral suspension is stable at room temperature for only 24 hours or in the refrigerator for 30 days • For dispersion in water, it should be used within one hour 	Drug should be taken on an empty stomach 30 minutes before or two hours after eating Tablets may be chewed or dispersed in water
Kaletra <ul style="list-style-type: none"> • 167 mg capsules • 100 mg/ml OS 	Should be refrigerated at facility level. When dispensed, capsules and oral solution are stable at room temperature for one month	Drug should be taken with food and should be swallowed whole
Aluvia <ul style="list-style-type: none"> • 250 mg tablets 	Tablets are stable at room temperature	Drug may be taken with or without food

- It is important to note that room temperature refers to 25°C. Since room temperature some countries is generally above 25°C, it is important to let the patient know that the drugs should be kept in the coolest part of the house.

Questions

- Mention the classes of ARVs available in the AIDSRelief program.
- Give examples of ARVs in each class.
- Fill in the table below

Abbreviation	Generic Name	Strength	Usual Dose
3TC			
NVP			
EFV			
AZT			
KAL or Lop/r			
FTC			
TDF			

3.0 ART Regimens in Use in the Hospital

3.1 Principles of Antiretroviral Therapy and Regimens in Use

With extensive and improving experience in ART, combination therapy with drugs from at least three classes has become the accepted trend in the management of HIV. Monotherapy is no longer acceptable as it is associated with a high level of drug resistance. Drugs to be used should come from different classes so that different stages in the replication of the virus are targeted simultaneously. The AIDSRelief program also subscribes to the use of combination therapy in line with these international standards. The only exceptions to the use of combination therapy involving three drugs from different classes is in the areas of post-exposure prophylaxis (PEP) and prevention of mother-to-child transmission (PMTCT).

The regimens used by all ART programs in a specific country must follow the guidelines set by the national committee responsible for enacting policies that control HIV treatment in that country. Therefore, different treatment guidelines exist in each country. AIDSRelief conforms to local regulations in each country context.

The most common first-line combination in use is two NRTIs combined with one NNRTI. This has remained standard practice and has been reaffirmed in the most recent WHO guidance for managing HIV in resource-limited settings.

The regimens used by AIDSRelief fall into two broad classes – first line regimens and alternative regimens:

- *Examples of First Line Regimens*

- 3TC/AZT/NVP - Lamivudine/Zidovudine/Nevirapine
- 3TC/AZT/EFV - Lamivudine/Zidovudine/Efavirenz
- 3TC/TDF/NVP - Lamivudine/Tenofovir/Nevirapine
- 3TC/TDF/EFV - Lamivudine/Tenofovir/Efavirenz
- TVD/NVP - Truvada/Nevirapine
- TVD/EFV - Truvada/Efavirenz

- *Examples of Alternative Regimens (Usually contain a PI)*

- 3TC/AZT/Lop/r - Lamivudine/Zidovudine/Aluvia
- 3TC/TDF/Lop/r - Lamivudine/Tenofovir/Aluvia
- TVD/Lop/r - Truvada/Aluvia
- CBV/Lop/r - Combivir/Aluvia

Watch out for a regimen that contains **AZT/D4T**. The AZT/D4T combination is antagonistic.

3.2 Forecasting and Quantification Principles

For AIDSRelief to adequately forecast and quantify drug needs for the LPTFs, a sound knowledge of regimens, the percentage projections for use of the regimens and the scale-up and/or maintenance plans for the LPTF is necessary. The forecasting percentages for various drugs differ and this is a reflection of the differences in the kinds of drugs used in different countries. The basic framework is outlined as follows:

- Determine the percentage of patients that will be placed on each of the drugs used within the program. This is best determined by studying the historical consumption pattern to which a number of assumptions have been added (for example, uninterrupted supply has been maintained all through that period, there has been a steady increase of patients initiated onto ART).
- Consider the scale up plan for each country and LPTF
- A sound knowledge of the interplay of the above factors is crucial to accurate forecasting and quantification.

The distribution plan which provides a complete mix of drugs will include 100% first line regimen and 10-20% alternative regimen in accordance with the number of patients to be maintained for the month plus new patients to be added. This should be projected for three months of use. In due course, deliveries will be set at a particular time to be mutually agreed between the warehouse and distribution agents and the Health Supply Chain Specialist.

When all these have been worked out, the drugs are procured and received in the countries at the level of the warehouse. Distribution to the facilities then occurs in line with the distribution plans set forth by the Health Supply Chain Specialist. The LPTF pharmacies should be prepared to receive drugs from the warehousing and distribution agent. Drugs will be supplied initially on the basis of the projected percentage of drug use but thereafter will be in line with the order of drugs placed by the LPTFs.

Questions

- What is the current accepted trend in the management of HIV?
- Why is monotherapy no longer acceptable?
- What are the exceptions to the rule of using three drugs from different classes?
- What is the most common first-line combination in use for managing HIV?
- What are the major requirements for a proper quantification activity?

4.0 Ordering of ARVs for the Hospital

4.1 Responsibility

It is the responsibility of the **Pharmacist in charge** of the LPTF or his/her designated proxy to order ARV drugs for use in the hospital.

4.2 Resources

The main resource required for ordering ARVs for the hospital is the **LPTF Requisition Form or the Consolidated Report Form**. Country programs may also have different reports, especially if they are harmonized with the national reporting formats. One of these forms should be saved in the pharmacy computer to be printed when required.

4.3 Process

- Requests for new ARVs for use in the hospital are usually placed at the end of the month using the **LPTF Requisition Form or the Consolidated Report Form**. The pharmacist should open a file to keep a copy of all requisitions from the hospital each month.
- In preparing a request for a particular month, staff should consider the existing balance of drugs sat the LPTF (i.e., a stock taking exercise should have been done), the number of patients to be maintained on therapy for the month and the number of new patients to be added to the program for the month.
- The AIDSRelief supply chain policy states that LPTFs should have a buffer stock of two months and the emergency order point is one month. Therefore, at the time of delivery the LPTF should have three months stock (one month for dispensing + two months for buffer.)
- Therefore, the quantity of drugs ordered for the three-month period is derived from **subtracting the stock balance from the total projected quantities needed for the next three months**.
- For the purposes of planning, ART patient uptake for all LPTFs is set at a given number of patients per month and this figure is usually agreed with the LPTFs at the beginning of every year (The figure usually varies in line with the realities on ground)
- The Pharmacist in charge of the hospital makes the requisition, which is then reviewed and approved by the hospital management (e.g. the AIDSRelief coordinator.)
- All requisitions carry a requisition number which can take any suitable form.
- A proper requisition can only be made **if a proper report of the month's activities has been prepared**. Therefore, all requisitions for ARVs for the hospital must be accompanied by a report of the immediate past month's activities. However, if the consolidated report form is used for ordering purposes, then the report of the month's activities will already be part of the report process.
- The requisition is sent to **the Health Supply Chain Specialist** for approval.

- If the Health Supply Chain Specialist agrees with the report of activities of the previous month, he or she approves the requisition and sends it to the warehousing and distribution agent to request delivery.
- Any requisition not approved by the Health Supply Chain Specialist will not be honored by the warehousing and distribution agent. In addition, the Health Supply Chain Specialist reserves the right to alter the quantities of drugs ordered by the LPTF if such an action is necessary to protect the integrity of the national supply chain.
- In reality, sending a physical requisition to the Health Supply Chain Specialist every month may be a cumbersome exercise; therefore the hard copy of the request, which has been signed by the requesting officer and management, should be prepared and kept in the hospital.
- It may be more realistic to send a soft copy of the requisition by e-mail to the Health Supply Chain Specialist who, after review and approval, will forward a consolidated distribution plan consisting of all LPTF drug requests to the warehousing and distribution agent.
- The Health Supply Chain Specialist will pick up the hard copy of the requisition when s/he visits the site.
- The requisition should be made before the **fifth day of a new month**. Ideally, it should be made at the end of the month or within the first two days of the new month.

Requirements for a Proper Order

- Information on balance quantities at the end of the month.
- Information on number of patients using each of the drugs
- Information on regimen in use
- Information on the projected number of patients to be treated in each month
- Report for the previous month

Managing satellite pharmacies

The LPTFs may operate satellite pharmacies outside the parent hospital. The ARVs for the satellites should be supplied directly from the drug store. The stock supplied to satellite units should be accounted for as part of the entire stock supplied to the LPTF. If the satellite is a mobile one where staff take the drugs in the morning and return with the drugs in the evening, that stock should be taken from the pharmacy. Movement of drugs from the main store or pharmacy to satellite pharmacies should be properly documented using the designated issues transfer forms, complete with all the necessary approvals.

Questions

- Whose responsibility is it to order ARVs for the LPTF?
- What are the possible resources/tools used to order ARVs for the LPTF?
- What is AIDSRelief's stocking policy for ARVs?

- To whom should a requisition be sent to and how should the requisition be sent?
- When should the report of the month's activity and the requisition for the new month be sent?

Case Study 1

AIDSRelief Foundation Hospital started its ART program on December 1, 2004 and by the end of October 2006, 500 patients had been enrolled on ART. Assume that the information listed below are facts.

- The stock of Lamivudine 150 mg tablets (3TC), Stavudine 30 mg capsules (D4T-30), Stavudine 40 mg capsules (D4T-40), Nevirapine 200 mg tablets (NVP), Zidovudine 300 mg tablets (AZT) and Efavirenz 600 mg (EFV) remaining in the hospital at the beginning of this month are as shown in the table below.

	3TC	D4T-30	D4T-40	NVP	AZT	EFV	CBV	KAL
Pack Size	60	60	60	60	60	30	60	180
Opening Stock	1000	460	580	700	300	400	270	200
Qty. received during the month	0	0	0	0	0	0	0	0
Qty. dispensed during the month	600	390	520	580	270	240	85	87

- The regimens in use in the hospital and the number of patients on each regimen at the end of October 2006 are as shown in the table below.

Regimen	No. of Patients
3TC/D4T-30/NVP	87
3TC/D4T-30/EFV	68
CBV/KAL	90
3TC/D4T-40/NVP	68
3TC/D4T-40/EFV	74
3TC/AZT/NVP	26
3TC/AZT/EFV	48
Total	461

- The hospital is supposed to bring on 150 new patients on ART every month for the next three months.

Use the data provided above to answer the questions below:

- It has been said that the number of patients on ART as of October 2006 is 500, but only 461 patients have been accounted for in the regimen table. What could be the reason for the discrepancy?
- Calculate the number of patients on each of the drugs using the regimen list above.
- In percentage terms, what proportion of patients is on each of the drugs used in the hospital?
- Calculate the quantity of each of the drugs left at the end of October 2006.
- Keeping in mind the number of new patients to be placed on ART every month, calculate the quantities of the various drugs that will be required monthly and the total

amount of drugs that will be required in the next three months to meet the needs of the patients.

- Calculate the quantity of each drug that should be ordered from the central warehouse to be used in the hospital for the period November 2006 – Jan 2007.

Solution Structure

Use the table below to calculate the answers.

Regimen	No. of Pts	3TC	D4T-30	D4T-40	NVP	AZT	EFV	CBV	KAL
3TC/D4T-30/NVP									
3TC/D4T-30/EFV									
CBV/KAL									
3TC/D4T-40/NVP									
3TC/D4T-40/EFV									
3TC/AZT/NVP									
3TC/AZT/EFV									
Total	a	b	c	d	e	f	g	h	i
% Drug Usage		(b/a) X 100	(c/a) X 100	(d/a) X 100	(e/a) X 100	(f/a) X 100	(g/a) X 100	(h/a) X 100	(i/a) X 100
Opening Stock		B	C	D	E	F	G	H	I
Quantity Received		K	L	M	N	O	P	Q	R
Quantity Dispensed		T	U	V	W	X	Y	Z	AA
Balance Stock		B+K-T	C+L-U	D+M-V	E+N-W	F+O-X	G+P-Y	H+Q-Z	I+R-AA

Maintenance Patients	A	3TC	D4T-30	D4T-40	NVP	AZT	EFV	CBV	KAL
Month 1	P = A+150	(b/a) x P	(c/a) x P	(d/a) x P	(e/a) x P	(f/a) x P	(g/a) x P	(h/a) x P	(i/a) x P
Month 2	Q = P+150	(b/a) x Q	(c/a) x Q	(d/a) x Q	(e/a) x Q	(f/a) x Q	(g/a) x Q	(h/a) x Q	(i/a) x Q
Month 3	R = Q+150	(b/a) x R	(c/a) x R	(d/a) x R	(e/a) x R	(f/a) x R	(g/a) x R	(h/a) x R	(i/a) x R
Total Requirement	P+Q+ R	Sum	Sum	Sum	Sum	Sum	Sum	Sum	Sum
Qty. to Order		Sum - Balance	Sum - Balance	Sum - Balance	Sum - Balance	Sum - Balance	Sum - Balance	Sum - Balance	Sum - Balance

Case Study 2

AIDSRelief Foundation Hospital started its ART program on December 1, 2004. Assume that the information listed below are facts.

- The stock of ARVs in the hospital was managed as presented in the table below.

	3TC	D4T-30	D4T-40	NVP	AZT	EFV	CBV	KAL	TVD
Pack Size	60	60	60	60	60	30	60	180	30
Opening Stock	1000	460	580	700	300	400	270	200	0
Qty. received during the month	450	300	250	150	80	510	160	280	300
Qty. dispensed during the month	600	200	200	295	90	330	200	150	135

- The regimens in use in the hospital and the number of patients on each regimen at the end of October 2006 is as shown in the table below.

Regimen	No. of Patients
3TC/D4T-30/NVP	87
3TC/D4T-30/EFV	68
CBV/KAL	90
CBV/NVP	45
CBV/EFV	59
TVD/NVP	34
TVD/EFV	70
TVD/KAL	21
3TC/AZT/KAL	13
3TC/D4T-30/KAL	20
3TC/D4T-40/KAL	12
3TC/D4T-40/NVP	68
3TC/D4T-40/EFV	74
3TC/AZT/NVP	26
3TC/AZT/EFV	48
Total	735

- The hospital is supposed to bring on 150 new patients on ART every month for the next three months.

Use the data provided above to answer the questions below:

- Calculate the number of patients on each of the drugs using the regimen list above.

2. In percentage terms, what proportion of the patients is on each of the drugs used in the hospital?
3. Calculate the quantity of each of the drugs left at the end of October 2006.
4. Keeping in mind the number of new patients to be placed on ART every month, calculate the quantities of the various drugs that will be required monthly and the total amount of drugs that will be required in the next three months to meet the needs of the patients.
5. Calculate the quantity of each drug that should be ordered from the warehousing and distribution agent to be used in the hospital for the period November 2006 – Jan 2007.

Resources/Tools Used

LPTF Requisition Form

CRS/AIDS Relief Programme

LPTF Requisition Form

Requisition Number: Date:

Name of Facility:

Product Code	Adult ARVs	Form	Strength	Pk. Size	Qty. needed for 3 Months (a)	Qty. in Stock (b)	Qty. Requested (a)-(b)
NVP-200	Nevirapine/ Viramune	tablets	200 mg	60			0
EFV-600	Efavirenz/ Stocrin/Sustiva	tablets	600 mg	30			0
TVD-500	Emtricitabine+Tenofovir/ Truvada	tablets	200 mg + 300 mg	30			0
CBV-450	Zidovudine+Lamivudine/ Combivir	tablets	300 mg + 150 mg	60			0
KAL-167	Lopinavir+Ritonavir/ Alluvia	tablets	200 mg + 50 mg	120			0
3TC-150	Lamivudine/ Epivir	tablets	150 mg	60			0
D4T-30	Stavudine/ Zerit	capsules	30 mg	60			0
D4T-40	Stavudine/ Zerit	capsules	40 mg	60			0
AZT-300	Zidovudine/ Retrovir	tablets	300 mg	60			0
Product Code	Pediatric ARVs	Form	Strength	Pk. Size	Qty. needed for 3 Months (a)	Qty. in Stock (b)	Qty. Requested (a)-(b)
AZT-10	Zidovudine/ Retrovir	syrup	10 mg/ml	200 mls			0
AZT-100	Zidovudine/ Retrovir	capsules	100 mg	100			0
DDI-10	Didanosine/ Videx	solution	10 mg/ml				0
DDI-25	Didanosine/ Videx	tablets	25 mg	60			0
DDI-100	Didanosine/ Videx	tablets	100 mg	60			0
3TC-10	Lamivudine/ Epivir	solution	10 mg/ml	240 mls			0
D4T-1	Stavudine/ Zerit	suspension	1 mg/ml	200 mls			0
D4T-15	Stavudine/ Zerit	capsules	15 mg	60			0
D4T-20	Stavudine/ Zerit	capsules	20 mg	60			0
NVP-10	Nevirapine/ Viramune	syrup	10 mg/ml	240 mls			0
EFV-30	Efavirenz/ Stocrin/Sustiva	syrup	30 mg/ml	180 mls			0
EFV-50	Efavirenz/ Stocrin/Sustiva	capsules	50 mg	30			0
EFV-200	Efavirenz/ Stocrin/Sustiva	capsules	200 mg	90			0
KAL-100	Lopinavir+Ritonavir/ Kaletra	syrup	80 mg + 20 mg	5 x 60 mls			0
ABC-20	Abacavir/ Ziagen	solution	20 mg/ml	240 mls			0

Requisitioning Officer

Name:	<input type="text"/>
Title:	<input type="text"/>
Sign:	<input type="text"/>
Date:	<input type="text"/>

Approved by Pharmaceutical Management Specialist/Health Supply Chain Specialist

Name:	<input type="text"/>
Title:	<input type="text"/>
Sign:	<input type="text"/>
Date:	<input type="text"/>

Consolidated Report Form

ADULT ARV DRUG UTILISATION AND SCALE-UP REPORT

Name of LPTF
Aug-06

REGIMENS	Cum. No. of Pts. on this Regimen	3TC-150	D4T-30	D4T-40	AZT-300	NVP-200	EFV-600	TVD-500	KAL-167	CBV-450	EFV-200
D4T30 + 3TC + NVP		0	0			0					
D4T40 + 3TC + NVP		0		0							
D4T30 + 3TC + EFV-600		0	0				0				
D4T30 + 3TC + EFV-600 + EFV-200		0	0				0				0
D4T40 + 3TC + EFV-600		0		0			0				
D4T40 + 3TC + EFV-600 + EFV-200		0		0			0				0
D4T30 + 3TC + KAL		0	0						0		
D4T40 + 3TC + KAL		0		0					0		
CBV + NVP						0				0	
CBV + EFV-600							0				0
CBV + EFV-600 + EFV-200							0				0
CBV + KAL									0	0	
TVD + NVP						0		0			
TVD + EFV-600							0	0			
TVD + EFV-600 + EFV-200							0	0			0
TVD + KAL								0	0		
AZT + 3TC + KAL		0			0				0		
AZT + 3TC + NVP		0				0					
AZT + 3TC + EFV-600		0			0		0				
AZT + 3TC + EFV-600 + EFV-200		0			0		0				0
No. of patients on Drugs	-	-	-	-	-	-	-	-	-	-	-
ACTUAL CONSUMPTION											
OPENING STOCK											
QUANTITY RECEIVED THIS MONTH											
CALCULATED BALANCE		-	-	-	-	-	-	-	-	-	-
ACTUAL BALANCE											
% USAGE OF DRUGS		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
MONTHLY SCALE-UP PLAN											
PROJECTIONS FOR MONTH-1	-	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
PROJECTIONS FOR MONTH-2	-	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
PROJECTIONS FOR MONTH-3	-	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
TOTAL PROJECTIONS	-	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
QUANTITY TO ORDER		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
ADJUSTED ORDER QUANTITY		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

5.0 Preparing the Drug Store

5.1 General

Medicines and related supplies are expensive and valuable, especially medicines and diagnostics for HIV and AIDS. If not cared for properly they may deteriorate, in which case they may lose their potency, cause the wrong effects on patients or, in the case of test kits, produce incorrect results.

Therefore, items in stock should always be stored in a proper storage place. The store should be secure, in good condition and well-organised. It should be separate from the dispensary. All supplies should be kept in the store and requisitions made for what is required in the dispensary. If the facility does not have a room to use as a drug store, improvise with a lockable cupboard with shelves to serve as the "store". However, this solution can be used only for a short time as the program in the hospital will expand in due course.

5.2 Keeping Your Store in Good Condition

In principle, extreme temperatures, light or humidity may affect medicines and cause supplies to deteriorate. Humidity can spoil tablets and capsules as they easily absorb water from the air making them sticky.

- Repair any damage to the roof, walls, door, windows and floor.
- Check that there is a ceiling in the store.
- Allow warm air to escape. Open the door and windows while someone is in the store. Put air vents in the walls or ceiling.
- Secure all openings with grills or bars to prevent theft.
- If you have a fan/air conditioner, use it. Keep it in good working condition.
- If light enters the store through windows, block the direct light. Paint the windows white or hang curtains.
- Check that there is good drainage. There should be drainage channels around your store.
- Containers of tablets and capsules may be packed with a sachet of desiccant (non-edible drying crystals). The desiccant keeps the inside of the container dry. Do NOT open the sachet. Keep the sachet in the container. Keep the container closed except when dispensing the medicines.
- Control pests such as rats, cockroaches, ants and wasps. Spilled items may attract pests. Clean spills and remove broken containers immediately. Use screens to keep insects out.

5.3 Keeping Your Store Clean and Organised

In a clean and organised store, it is easy to find supplies. The supplies are likely to be in good condition and ready to be used.

- Mop the floor, dust the shelves and wipe down the walls regularly. Dust contaminates supplies and makes labels difficult to read. Spills and breakages collect dirt.
- Shelves are an easy way to organise supplies.
- Do NOT put boxes or boards directly on the floor. The floor may be wet and moisture may spoil the carton. Use pallets for heavy or bulky products.

- Air should circulate around the boxes and they should be stored with sufficient space from the wall and from the floor.
- Use the refrigerator to store heat-sensitive medicines. Opening and closing the door may increase the temperature and cause medicines or test kits to deteriorate. Do NOT keep staff food in the refrigerator.
- Record the temperature of the refrigerator at least twice daily. Check that there is enough space around the refrigerator so air can move freely.



Questions

- What are the ideal conditions for a good store?
- Why should the store be separate from the dispensary?
- What are three elements that must be controlled in the store to avoid deterioration of supplies?
- Why are desiccants packed in drug containers along with the drug?
- In organizing your store, where should lightweight products be kept? Where should bulky products be kept?
- Should boxes be placed directly on the floor? If not, where should they be placed?
- How often should the temperature of the refrigerator be checked?

6.0 Organising Your Supplies

The organisation of medicines and related supplies in the pharmacy store should enable anyone who works in the store to access and find supplies easily. Similar supplies should be shelved together, arranged in alphabetical order, by therapeutic class, or by classified groups in accordance with generic name. Items with a shorter shelf life (short expiry dates or older stock) should be placed in front of similar items with a longer shelf life (later expiry dates or newer stock).

To organise medicines and other supplies, follow the procedures below in both the regular storage area and in the secure area:

6.1. *Store Similar Items Together on the Shelves.*

In the case of ARVs, store them separately from other medicines, e.g. in a lockable cupboard or cabinet. Arrange them by therapeutic class (e.g. nukes, non-nukes, protease inhibitors, etc.) or by their inclusion in first-line or second-line ART regimens.

6.2. *Arrange and Label the Supplies on the Shelves.*

- Within each group, arrange the supplies in alphabetical order by generic name. Allow enough space for each item.
- Group identical items in amounts that are easy to count, such as in pairs or groups of five or ten.
- Print the generic name of each item on a label. Attach the label to the front of the shelf.

When supplies are organised in this way, it is easy to see what and how much stock is in the store. Staff will be less likely to confuse items that are similar in appearance or name.

6.3 *Store Medicines Using FEFO (First Expiry First Out) Principles*

- As a general rule, do NOT use expired products.
- At regular intervals, check all stock for expiry dates. Place items with shorter expiry dates in front of those with longer expiry dates.
- This method is referred to as **first expiry first out** (FEFO). FEFO procedures reduce waste caused by product expiry.
- If two containers have the same expiry date, put the newly-received one behind the one already on the shelves. Use the **first in first out** (FIFO) principle to dispense.

It is important to note that the order in which products are received is not necessarily the order in which they will expire. Products received most recently may expire sooner than products received earlier. It is extremely important to check the expiration dates and to make sure the dates are visible while the products are in storage. There should be an expiry tracking chart in the store.

6.4. Remove Expired and Poor Quality Items from the Store

- Poor quality or damaged medicines and related supplies are as risky as expired ones.
- Identify all expired and other poor quality medicines and related supplies and remove them from the store.
- Keep a record of all expired and damaged products removed from the store.
- Identify overstocked items and any items that are no longer used at the facility. Report to management and the Health Supply Chain Specialist for a decision about what to do with such items.

Questions

- How can drugs be arranged in the store?
- Why should drugs be properly arranged in the store?
- What do the terms FEFO and FIFO mean?
- Under what conditions can FEFO and FIFO be implemented?
- If overstocking occurs, what should be done?

7.0 Keeping Records

It is important to keep good records of all the medicines and related supplies in stock. This helps everyone to understand the flow of supplies into and out of the facility, including information such as:

- What items are in stock
- How much there is of each item in stock
- How much stock is used on a regular basis
- When an item should be reordered.



7.1 Why Keep Records?

- Keeping records saves time.
- Keeping records protects you. In the case of theft or misuse of supplies, records that document the movement of supplies can show who, if anyone, is responsible for the problem.

There are different methods of recordkeeping. The procedures recommended in this chapter are based on using a stock card. Each facility may have its own stock card. Stock cards can be made or modified to fit any type of record-keeping system.

7.2 The Stock Card

There should be a stock card for each item in the store. Keep the stock card with the item on the shelf. Use the stock card to track the movement of the item. Record when and how the item is used. This should include all movements, such as when a new shipment of an item arrives at the store or when an item is moved out of the storeroom to the dispensary.

See the example of a stock card below. The top of the stock card lists:

- **ITEM:** name of product including its form and strength
- **CODE NUMBER:** a number that identifies the item (if there is one)
- **UNIT and SIZE OR TYPE of container:** bottle, blister package, etc., and the amount in the container
- **REORDER LEVEL:** number of units needed in stock (as buffer or minimum stock), below which an order should be placed to bring supply up to the minimum level.

EXAMPLE:

STOCK CARD

CODE; ITEM DESCRIPTION _____ STRENGTH _____:							
UNIT: _____ MINIMUM (REORDER) LEVEL _____:							
DATE	REF NO.	RECEIVED FROM/ISSUED TO	QUANTITY RECEIVED	QUANTITY ISSUED	BALANCE IN STOCK	REMARKS	SIGNATURE

There may be items in the store with different forms, strengths or unit sizes. Examples include:

- **Forms:** a medicine can be produced in tablet, liquid or capsule form
- **Strengths:** Stavudine, for example, comes in 15 mg capsules or 20 mg capsules
- **Unit sizes:** a bottle of tablets can contain 30, 60, or more tablets

If the store includes items with more than one form, strength or unit size, use a separate stock card for each item. **Do NOT use the same card for different forms, strengths or unit sizes of an item.**

The stock card also includes columns for information about movement of the item:

- **DATE:** when the item is received into the store or issued out of the store
- **REFERENCE NUMBER**
- **RECEIVED FROM:** name of supplier
- **ISSUED TO:** name of dispensing area where item will be dispensed to patients
- **QUANTITY RECEIVED:** number of units received at the store
- **QUANTITY ISSUED:** number of units issued out of the store
- **BALANCE IN STOCK:** number of units remaining in the store
- **REMARKS:** important information about the movement of the item, batch numbers, expiry dates, etc.
- **SIGNATURE:** person who records the movement of the item

When you record information on a stock card:

- **Use a pen** to record item, code number, unit and size and all information about the movement of the item. This information does not change.
- **Use a pencil** for the reorder level. This information may change (see Chapter 4, “Ordering of Supplies.”)
- **Use a different coloured pen** (e.g. red) only for inventory control and when conducting a physical stock count.
- On the first line, record the words “balance brought forward” for a replacement stock card or “new stock” for a new item in the store.
- For new or reordered stock, record the order requisition number, expiry date and price, if necessary.
- For expired, poor quality or excess stock, record information about the removal of the items.
- Record any other information that is important to the management of medicines and related supplies at the facility.

Record every time items are issued or received. Record only one movement (i.e., one receipt or one issue) per line. Record at the time of movement. See the notations on the stock card.

7.3 To Keep Accurate Stock Records

Follow the procedures below to record the movement of items in and out of the store.

7.3.1 Make a stock card for each item in the store

Remember that there may be more than one card needed for the same item. Donors may require that you keep their items separate from the stock received by central stores or other suppliers. This will require a separate stock card.

7.3.2 Keep the stock card with the item on the shelf

Attach the card to the front of the shelf near the label of the item or place the card with the containers on the shelf.

7.3.3 Record on the stock card every time items are issued or received

Use a pen as this information does not change. Record at the time of movement. Do NOT wait until the end of the clinic session, the day, the week, or the month.

- A. Record all items when they are received.

When an item is received, put it in its place on the shelves. Record its movement on its stock card.

1. Record the DATE of receipt.
2. Record where the item was RECEIVED FROM.
3. Record the QUANTITY RECEIVED in units.
4. Add the quantity received to the previous BALANCE IN STOCK (count the stock every time you receive stock.)
5. Record the NEW BALANCE IN STOCK.

6. Record the requisition number of the order and the item's expiry date in the "remarks" column.

B. Record items issued out of the store.

Only whole units should be issued out of the store. Do NOT issue partial units from the store.

1. Record the DATE of issue.
2. Record where the item was ISSUED TO.
3. Record the QUANTITY ISSUED in units.
4. Subtract the QUANTITY ISSUED from the previous BALANCE IN STOCK.
5. Record the new BALANCE IN STOCK.
6. Record any significant information about the movement of the item in the REMARKS column.

Tell a supervisor if a particular item is being issued more often or in greater quantity than usual. This may indicate that the facility must prepare for a new supply of drugs.

7.3.4. Always keep an accurate running tally of the number of units in the "balance in stock" column

- There may be partial units remaining at the end of the clinic session. If so, do NOT put them back into the store. Lock them in the pharmacy until the next clinic session.
- Make sure that the "balance in stock" number on the stock card is the same as the number of containers of the item in the store.

7.3.5 Count stock at regular intervals, such as once a month

Count the number of containers of each item in the store regularly. This is called a "physical count" or "physical inventory." A physical count checks that the amount actually in the store is equal to the "balance in stock" on the stock card. When checking inventory, make sure that each item has the same generic name, form, strength and unit size.

7.4 Physical Stock Counts

Physical counts are particularly important for ARVs and should be done at least once a month.

7.4.1. Review the information on the top of the stock card

Check that the information is current and correct.

7.4.2 Make a physical count

Use a red pen for this exercise and make the following entries on the card:

- On a fresh row in the tally card, record the DATE of the count. Write the words "physical count" across the columns.
- Count the actual number of units (e.g. bottles) of the item. The number of units is the physical count.
- Record the physical count number in the BALANCE IN STOCK column. If the physical count and the previous balance are not the same, write "discrepancy" and note how many are missing in the REMARKS column.

If the physical count and the previous balance are not the same, INVESTIGATE.

- There may be more items or fewer items on the shelf than noted on the stock card. Reasons for such a discrepancy may include:
 - Someone may have forgotten to record a movement on the stock card.
 - Calculations of running balances may not have been correct.
 - Physical count may be wrong. Redo the count to confirm the figure.
 - Theft

Therefore, cross check all entries made between the last count and the current count. Check who was on duty and who had access to keys. Watch for any unusual or suspicious activity over the next few days.

If a stock card is missing, INVESTIGATE.

- Again, as mentioned above, check who was on duty and who has access to keys. Confirm that the missing card has not been confused with the other stock cards or been moved to another drug by mistake. Watch for any unusual or suspicious activity over the next few days.
- In the interim, make a new stock card. Note that it is a replacement card in the “remarks” column. If you find the old stock card, copy the information from the replacement card to the old one. Then, destroy the replacement card.

**KEEPING ACCURATE RECORDS
HELPS YOU KNOW WHEN TO REORDER!**

8.0 Receiving Supplies

When supplies are received, the person who receives them should check the delivery (that is, the goods from the supplier). The delivery should contain what was ordered. The receiver should check that no supplies have been lost or stolen, and that the delivered items are of assured quality and not expired or nearly expired.

Discrepancies in orders are common and may include missing items, quantities lower than those ordered, expired or nearly-expired items, or damaged or poor quality goods. Discrepancies are very costly and should not be ignored.

8.1 Receiving Supplies in the LPTF

8.1.1. Receive the supplies in person

All delivered supplies should be received by at least one staff member at the time of delivery. Sometimes there will be an additional person designated to receive specific items, for example ARV medications. If this is the case, both staff members must be present to undertake the initial supply and quantity check.

8.1.2. Check the outside of the boxes for theft

Check for opened and/or torn boxes.

8.1.3. Keep a record of deliveries

Delivery trucks often carry orders for several facilities on a delivery route. Supplies intended for one facility may be delivered to another. Or supplies may disappear. Keeping records of deliveries helps find and correct problems.

A. Record delivery information each time supplies are received.

The delivery note issued by the supplier should be checked and signed off by the driver and the person in charge. Keep the delivery information organized.

Record the following information:

- DATE of delivery
- REQUISITION (ORDER)/DELIVERY NUMBER: a number that identifies the order
DELIVERY PERSON'S NAME + SIGNATURE
- VEHICLE REGISTRATION NUMBER (or license number of the vehicle)
- NUMBER OF BOXES in the order
- STAFF MEMBER SIGNATURE: of the health worker who receives the supplies
- DESIGNATED OR SECOND STAFF PERSON SIGNATURE, if required for receiving antiretroviral medicines and test kits.
- Use a pen. This information does not change.

Always keep delivery information in a safe place. Make sure there is a copy of the information for the driver/delivery person.

B. Ask the delivery person to sign the form before he leaves the facility.

Do NOT sign on behalf of the delivery person. His/her signature is proof that he/she delivered the supplies to the facility.

8.1.4. Check the supplies received against the items on the delivery note and the requisition form

Remove the supplies from the box, read the requisition form, and review the items and quantities received in the box. Check that what was ordered is the same as what was received.

If items are missing, notify the Health Supply Chain Specialist. If fewer supplies were received than were ordered, keep and use them, but plan on reordering these items soon. Notify your Health Supply Chain Specialist.

If you receive items that were not ordered or that are not listed on the delivery note or requisition form, do not accept them and inform the Health Supply Chain Specialist.

8.1.5. Check the expiry dates of all items

Do NOT accept expired items. Expired items may harm a patient or have no effect on the patient at all.

8.1.6. Miscellaneous Checks

1. Check refrigerated items

All refrigerated items should be stored first, and therefore should be checked first.

If refrigerated items, such as Lopinavir/ritonavir (brand name Kaletra) or the soft-gel capsules Saquinavir, are not packed in cold packs, they may have spoiled. Do NOT accept them.

2. Check for broken containers. Check for leaks

Carefully remove broken containers. If there is a leak, remove and dispose of any supplies damaged from the leak according to your facility's policies (these policies should be adapted from the national and/or donor guidelines on disposal of damaged and expired drugs).

3. Check for unsealed or unlabelled items

Someone may have tampered with unsealed items. It is dangerous to use unlabelled items. Do NOT accept them.

4. Check tablets and capsules

Open sealed containers only if you suspect deterioration. Once opened, check the quality. Pour a small amount onto a clean surface, such as a counting tray or table cover with a piece of paper, and observe.

Store the good quality supplies in their proper place in the store immediately after checking them. This keeps the store tidy at all times.

Put any damaged or poor quality items in a box to return to the supplier. Dispose of or return expired and poor quality supplies at the earliest opportunity.

8.1.7. Document all discrepancies

If any medicines or related supplies are missing or over-issued, expired, damaged or of poor quality, inform the Health Supply Chain Specialist and record it in writing.

- **If the discrepancy is noticed at the time of delivery**, ask the driver or delivery person about this and make a note of it on the delivery note. Both parties should sign against the discrepancy.
- **If the discrepancy is found after the delivery**, contact the Health Supply Chain Specialist and report the discrepancy. Documenting discrepancies provides protection against any liability resulting from the discrepancy.

**CHECK THE EXPIRY DATES AND QUALITY OF SUPPLIES
BEFORE ITEMS ARE PLACED IN THE STORE!**

Resources/Tools (may or may not be used depending on the country program)

Delivery Note

CRS-AIDSR relief Program

Delivery Note

Distributor: _____ Country: _____

LPTF: _____ Ref. No. _____ Date: _____

Drug Code	Drug	Unit Pack	Quantity	Batch No.	Mfg. Date	Exp. Date

Delivered By:		Received By:	
Name:		Name:	
Designation:		Designation:	
Signature:		Signature:	
Date:		Date:	

Stores Ledger

CRS-AIDSRelief Program

Stores Ledger

Drug Unit of Issue

Date	Delivery Note Ref. No. or Requisition Ref. No.	Supplier or Requisitioning Unit	Receipts	Issues	Balance

Confirmation of Receipt of Drugs

CRS-AIDSRelief Program

LPTF Confirmation of Receipt of Drugs and Other Medical Supplies

LPTF

Date Received

To: The Health Supply Chain Specialist
CRS-AIDSRelief Program

Product Code	Product Description	Form	Strength	Pk. Size	Amount Requested	Amount Received	Batch No.	Mfg. Date	Exp. Date

Prepared By:

Name:	
Title:	
Sign:	
Date:	

Discrepancy Form

CRS/AIDSRelief Programme

LPTF Discrepancy Form

Country:

LPTF:

Date:

Description of Discrepancy

S/N	Drug Item	Unit of Issue	Recorded Qty	Physical Count	Difference	Explanation of Discrepancy
1						
2						
3						
4						
5						
Prepared By:				Witnessed By:		
Name				Name		
Designation				Designation		
Signature				Signature		
Date				Date		

9.0 Dispensing Medicines

When a medicine is given to a patient, it is important that the patient receives:

- the correct medicine
- the correct quantity of the medicine
- the correct information on how to take the medicine
- the correct information on how to store the medicine

Dispensing to a patient consists of checking the prescription; collecting, counting and packaging the medicine; dispensing the medication; and counselling the patient.

In some health facilities, a health worker other than a trained pharmacy professional may be the dispenser. In any case, the dispenser should carefully and clearly explain to the patient how to take the medicine. This is very important. Medicines are effective only if taken correctly. The dispenser should check that the patient understands how to take the medicine. The patient should be able to repeat to the dispenser how he or she will take the medicine.

Dispense medicines from a dispensing area (or dispensary). Keep this area separate from the store. **Do NOT dispense to patients directly from the store!**

9.1 *How to Prepare Medicines and Related Supplies*

- 1. Go into the store. Determine the supplies needed. Place the items on a tray. Take them to the dispensing area.**

Estimate the number of units of each item that will be needed for the day or the clinic session. Base the amount on past use.

Use the appropriate stock card to record the movement of each item issued out of the store.

Once items are issued to a dispensing area, do NOT return them to the store. Keep them in the dispensing area.

- 2. Keep supplies in the dispensing area safe and organized.**

Make sure that security in the dispensary is the same as in the drug store. Staff should always be present in the dispensing area. Do NOT leave any area unattended and unlocked.

9.2 How to Dispense Medicine (or other items) to Patients

1. Check that the prescription is appropriate for the patient

Review the prescription. Find its generic name. If you cannot read it or if you have any questions about it, ask the person who wrote the prescription to explain it to you.

Check that the prescription is appropriate for the age, weight and sex of the patient. Also check that the medicine prescribed is appropriate in form, strength and dosage.

2. Collect a container of the item, and check its expiry date

Some medicines look the same and may easily be confused. Read the generic name on the label of the container. Check that it is the correct medicine. Check that it is the correct form, strength and unit size. Check that the item has not expired.

3. Label the package to be given to the patient

4. Count the quantity needed in a clean, safe manner

Count tablets or capsules using a counting tray. Count the tablets or capsules with a clean spatula. Do NOT use your hands, which may contaminate both the medicine and your hands.

Do NOT use the same tray to count new medicines without cleaning the tray. If you use a sheet of paper to count, use a new sheet each time. If you reuse the same tray or paper, you may contaminate both the medicines and yourself.

5. Put the correct amount of the medicine into the package for the patient to take home

Put the medicine into its own labelled package using the tray and spatula. Do NOT mix prescriptions or medicines.

6. Put any extra tablets or capsules back into the appropriate container immediately

If more than one medicine has been prescribed, close one container before opening another container. Prepare all of the prescribed items before dispensing them to the patient.

7. Give the package to the patient and teach the patient how to take the medicine

If the patient is a child, review the following steps with the mother or caretaker.

Explain to the patient how to take the medicine. If the patient has more than one prescription, dispense one item at a time.

- a. *Tell the patient the name of the medicine, its form (tablet, syrup, etc.), what it is for, and the dosage.*

The dosage includes:

- When to take the medicine (for example, in the morning)
- How much of the medicine to take (for example, one tablet)
- For how long to take the medicine (for example, 2 days)
- How to take the medicine (for example, with food)

Some facilities display the dosage instructions about how to take the most common medicines in the dispensary. This helps health workers to give consistent (and correct!) instructions to patients.

b. Show the patient how to prepare the dose. Allow the patient to practice.

If a dose is less than a whole tablet, show the patient how to divide the tablet. If it should be mixed with food, show how to crush the tablet and mix it with food.

For oral solutions or syrups, show the patient how to measure the correct amount. Use the dispensing syringe contained in the syrup packet or the measuring cap of the oral solution or syrup bottle to show the patient how to measure and administer the drug.

Ask the patient to practice measuring the dose. Use the medicine that has already been packaged for the patient to take home. When you are confident that the patient understands how to prepare the dose, you may ask the patient to take the first dose if that is convenient for the patient.

c. Tell the patient to take all of the prescribed medicines.

d. Ask the patient to tell you how he/she will take the medicine.

Each time you dispense a medicine, check the patient's understanding. If the patient answers correctly, compliment him or her. If not, explain the dosage to him or her again. Explain until he or she can answer correctly.

8. Keep accurate patient records

Resources/Tools Used

Daily Drug Dispensing Book

CRS-AIDSR relief Program

Daily Drug Dispensing Book

Date	S/N	Name of Patient	Hospital No.	Enrolment No.		3TC-150	D4T-30	D4T-40	AZT-300	NVP-200	EFV-600	TVD-500	KAL-167	CBV-450

Dispensary Ledger

CRS-AIDSR relief Program

Dispensary Ledger

Drug Unit of Issue

Date	Requisition Ref. No.	Details	Receipts	Issues	Balance

10.0 Medicines and Therapeutics Committee (MTC)³

Availability of, and accessibility to safe, quality and cost-effective medicines are fundamental to providing an effective health service. Many developing countries spend up to 40% of health budgets on drugs, however, inefficient and inappropriate use of medicines is a widespread problem at all levels of health care. This leads to public health systems being unable to sustain the supply of sufficient medicines to meet patient demand.

At hospitals and health facilities, there have been many factors contributing to inappropriate and inefficient use of medicines:

- Lack of procedures for drug selection and procurement, storage and distribution.
- Lack of appropriately trained staff.
- Lack of continuing education and updates on correct medicine management and utilization.
- Lack of sharing of drug issues and information amongst departments.

These, in turn, lead to:

- Poor selection, quantification and procurement of medicines, without consideration for relative efficacy or cost-effectiveness. This results in shortages/stock outs, overstocking with waste or procurement of unnecessarily expensive medicines.
- Prescribing that does not follow standard clinical/treatment guidelines.
- Poor dispensing practices, leading to medication errors.
- Patients' lack of knowledge about correct use and storage of medicines, leading to poor adherence to treatment (a major issue in HIV treatment)

At the AIDSRelief country level, MTCs have been an effective way for the supply chain, clinical, and strategic information teams and program managers to come together on a regular basis to review drug use, address issues, set patient targets and plan central drug procurements. Likewise, the AIDSRelief program and supply chain team advocates for set-up of MTCs at the LPTF level because they can provide a forum to bring together all the hospital stakeholders involved in decisions about drug use, including ART-related issues. The AIDSRelief supply chain team is therefore actively involved in providing all the technical support necessary to form and strengthen MTCs at the site level as a way to improve overall hospital pharmaceutical management.

10.1 Goals and objectives of MTC

An MTC is a tool for increasing efficiency and promoting rational use of medication by providing a forum for all the relevant stakeholders to meet and collectively decide on the various processes of the pharmaceutical commodity management cycle (selection, procurement, distribution and storage). Therefore, each hospital should have an MTC that works as an integral part of the facility.

MTCs aim to ensure that “patients receive the best possible cost-effective quality of care through deciding what medicines will be available, at what cost, and how they will be used”⁴ This is especially important in HIV programs where patients are prescribed life-long treatment which requires diligent adherence and full support to ensure successful viral suppression and improved quality of life.

³Drawn from Drugs and Therapeutics Committee, a practical guide. WHO, 2003

⁴ ibid

The main objectives of MTC are:

- To develop and implement essential hospital formularies that will help ensure that only efficacious, safe, cost-effective and good quality medicines are used
- To ensure the implementation of recommended standard clinical/treatment guidelines
- To maximise drug safety through monitoring and evaluation, thereby preventing, as far as possible, adverse drug reaction and medication errors.
- To develop and implement rational use of medication by all health care workers.

10.2 Functions of MTC

MTCs generally promote rational use of medication, which requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at the lowest cost to them and their community.

To achieve these goals, the MTC undertakes many functions, and the committee must decide what to prioritize depending on local capacity, structure and needs. Certain functions may require liaison with existing hospital committees or teams in the health facility (e.g., the procurement team.) It is important to remember that the MTC is a hospital-wide committee and not solely a function of the HIV clinic.

The most important MTC functions are as follows:

1. Advisory committee

The MTC should consider and provide practical advice to medical staff (i.e., clinicians, nurses, pharmacy) and other hospital departments as well as hospital administration on all matters concerning pharmaceutical management practices. The committee will do this by advising and sharing information on best practices and lessons learnt during drug selection, procurement, distribution, and use of medication.

The MTC should also provide advice and expertise on emergent issues such as disease outbreaks. Usually the MTC will provide advice and hospital management will carry out implementation.

2. Drug Policies and Procedures

The MTC should be the body to develop drug policies within a hospital and/or health facility. All healthcare facilities should have specific policies concerning:

- Drug selection, procurement, storage and distribution of medicines
- Recommended standard clinical/treatment guidelines and other interventions which should be the basis of the Essential Hospital Medicines List (EHML)
- Use of medication not on the EHML (e.g. restricting their use to specified prescribers)
- Generic substitution and therapeutic interchange
- Drug promotion (from medical sales representatives and promotional literature)
- Interventions to promote more rational use of medication
- Adoption of structured order forms
- Expensive or dangerous medicines such as oncological drugs which are restricted to certain prescribers, departments or patients.
- Drug safety concerns

3. Determination of drugs for the hospital formulary

Drugs on the essential medicines list and hospital formulary should be selected based on standard clinical/treatment guidelines (STGs) that have been developed/adapted for use in the hospital or health facility.

Medicines should be selected based on efficacy, effectiveness, safety, quality and cost. The criteria used should be evidence based, transparent and address local context. Periodic reviews should be carried out to include changes in international and national trends e.g. changes in costs and indications, new information on safety, and the emergence of new medicines.

Health facilities will often adapt their EHML and STGs from those prepared by the Ministry of Health.

4. Implementing rational use of medicines

MTCs should identify medicine use problems and make appropriate recommendations. Such interventions may include:

- Monitoring adherence to standard treatment guidelines
- Managing adverse drug reactions. The MTC is responsible for ensuring that patients are treated as safely as possible. This is usually part of pharmacovigilance activities which are initiated at country level. ADR forms are completed at sites and analysis is done at higher levels.
- Managing medication errors. Medication errors may be caused by lack of knowledge of policies and procedures, outdated treatment guidelines and dosage forms. Human error due to work overload, tiredness of staff and careless work attitudes also contribute. MTCs should have plans to monitor, assess, report and correct any problems. The most important goal, however, is to prevent future errors. Strategies include:
 - Educational programmes through hospital newsletters and continuous medical education sessions
 - Provision of unbiased drug information
 - Regular prescription analysis
 - Prescribing restrictions

10.3 Structure, organization and institutionalization of MTCs

AIDSRelief advocates for creating MTCs at all LPTFs as a way of sustaining and integrating HIV activities into the main hospital functions. An MTC should be an integral hospital committee with a multidisciplinary, transparent approach, technical competence and an official mandate.

Administrative support is very important in enabling the MTC to implement its decisions through ensuring cooperation of senior medical staff and well as providing funds needed to undertake many of the activities.

Steps in setting up and managing the MTC

1. Selection of members

The committee should have sufficient members to represent all hospital departments and stakeholders. Members should be selected with reference to their positions and

responsibilities and not based on individual personalities. Members should have defined terms of reference.

Membership should include:

- Medical superintendent or senior medical doctor as the committee chairperson
- Chief pharmacist as the secretary
- A representative clinician from each major specialty department
- A nursing officer in charge
- An administrator, representing the hospital administration and finance department
- A member of the lab technical staff
- A member of the hospital records department

The members should be consistent in attending meetings and should avoid delegating their attendance to others.

2. Determine MTC objectives and functions

The MTC cannot do everything, so clear terms of reference (TOR) should be defined from the beginning. The TOR will specify the MTC's place in the hospital's organizational structure, its goals, objectives, scope of authority, functions and responsibilities (a sample TOR is included at the end of this chapter.)

3. Determine MTC operations

Guiding principles:

- Establish a regular schedule of meetings: MTCs should meet at least quarterly but preferably monthly. The length of the meetings should be limited and known in advance as members may not attend if the meetings are too long. The meeting venue should remain the same, as much as is possible, for consistency.
- Regular attendance: The meeting time should be chosen carefully to encourage regular attendance.
- There should be sufficient advance notice of the meeting and the secretary should circulate the agenda and minutes to members before the meeting.
- Documents (e.g. minutes, action steps, recommendations, and policies) should be kept as a permanent record and circulated to heads of all clinical departments as well as to other concerned parties and authorities within the hospital.
- Operations should be harmonized with other hospital committees.

4. Institutionalizing the MTC

A mandate should be sought from the most senior authority in the hospital (in most cases, the hospital management committee.) The MTC TOR should specify:

- its goals and objectives
- its functions and responsibilities
- its place in the organizational structure
- its membership and scope of authority

5. Identify resources

The hospital or facility should provide resources for MTC activities. Usually the budget requirement is not substantial and can be justified to hospital administration on the basis of drug cost savings which can be realized through MTC activities.

The MTC should, therefore, prepare an action plan with corresponding budgetary requirements.

6. Formation of sub-committees

Sub-committees may be necessary depending on the size of the facility and should be specifically for areas requiring extra work and expertise. These can be formed when the need arises as issues are presented at the meetings. Sub-committees are particularly useful when time is limited and feedback is required urgently.

7. Assessment of performance

Self-assessment and evaluation of the MTC, based on benchmarks and set targets, is important for continuous improvement in performance. Performance assessment is useful for feedback to administration to justify continued support. Performance assessment also encourages facility-wide participation and interest in MTC-related activities.

10.4 Reviving non-functional and/or dormant MTCs

Despite efforts to initiate MTCs at LPTFs, in some instances committees do not function or are dormant. Some of the reasons include:

- Lack of agenda items
- Lack of quorum for meetings and persistent non-attendance
- Lack of awareness of drug use problems
- Lack of awareness of MTC's role to resolve problems
- Lack of time or incentive for members to undertake activities
- Lack of mandate from authorities
- Conflicting priorities among authorities

The AIDSRelief supply chain team usually conducts training or orientation courses for prospective hospital MTC members at the initial start-up of the committees. This training equips members with knowledge of the goals, objectives and functions of MTCs. This has helped to demystify the role of MTCs and help members understand its importance in promoting rational drug use.

It has also proved beneficial to have the MTC members prepare their Terms of Reference (TOR) and develop action plans at the end of the training. Members then return to their facilities fully prepared to roll out MTC activities. The action plans set the initial agenda for MTC meetings. Seeking mandate from hospital administration is usually the first action item.

In many cases, committees have existed but have fallen dormant. The action plans usually deal predominantly with revival of the committee by identifying the probable reasons for dormancy (such as those listed above) and possible solutions. It is important to first quantify the problem and understand the underlying causes, and then resolve any outstanding issues one by one. It is easier to resolve the simpler problems (e.g. in case of non-attendance due to lack of knowledge about the meetings; the solution would be to circulate notice of the next meeting in advance and ensure confirmation from members) before tackling the more complex issues (e.g. lack of awareness of drug use problems which would require research to be carried out.)

Resources: Example of a TOR

XYZ HOSPITAL

MEDICINES AND THERAPEUTICS COMMITTEE

TERMS OF REFERENCE

Purpose

The Medicines and Therapeutics Committee is an advisory, enforcement and educational committee of the Medical Advisory Committee.

The purpose of the committee is to promote safe, rational and cost-effective supply and use of pharmaceuticals and non-pharmaceuticals in the hospital.

Functions

1. To serve in an advisory capacity to the Medical Advisory Committee (MAC) on all matters relating to drug use in the hospital.
2. To develop a formulary for drugs accepted for use in the hospital and provide its revision.
3. To establish programs and procedures that ensure cost-effective drug therapy.
4. To establish or plan suitable programs on matters relating to drug use for all cadres of technical/professional staff.
5. To participate in quality assurance activities related to procurement, storage and distribution, administration and use of medicines.
6. To document and review adverse drug reactions from all clinical areas in the hospital.
7. To initiate and direct drug use review programs in the hospital and document, review and provide feedback on the results.
8. To advise the pharmacy on the implementation of effective drug distribution and control procedures.
9. To make recommendations on drugs to be stocked in patient care areas.

11.0 Standard Operating Procedures

Following are sample standard operating procedures (SOP) which can serve as a guide for facility-based SOPs. The SOPs should be adopted to suit individual facility conditions, taking into consideration standard acceptable procedures.

AIDSRelief Hospital	
STANDARD OPERATING PROCEDURE FOR [NAME]	
Number of Pages: 1	Serial number PH04/01
Prepared by: Title: Sign: Date:	Approved by: Title: Sign: Date:

1. Start with the title of the SOP, which should be unambiguous.
2. Provide a number for it; the suggested numbering system is a code for the department from which the SOP originates followed by a number for the SOP, followed by a stroke and number of issue, followed by a dot and the revision status of the SOP. For example, an SOP for the pharmacy department may be numbered as PH 01/1.0 when it is issued for the first time.
3. Indicate the date of issue, the number and date of the SOP it supersedes, the number of every page (as the number of the total number of pages of the document).
4. Make provision for the signature and designations of the persons preparing, checking and authorizing the document.
5. State the nature and purpose of the document and the name/s of the person/s responsible for implementing the procedure in the document.
6. Lay out the document in an orderly fashion with the contents in clearly defined parts to facilitate revision of any part without having to rewrite the whole document.
7. The way the document is to be used, and by whom, should be clearly apparent from the document itself.
8. Where SOPs bear instructions, write them in the imperative, as numbered steps. Make them clear, precise, unambiguous and in language that the user can understand.
9. Where the SOP refers to other documents, list the number/s of such document/s.
10. List annexes such as forms, tables, or charts referred to in the SOP. All annexes should bear distinguishing numbers consisting of a suffix (such as L for a label, T for a table, and so on) added to the number of the document, e.g. PH 01/L (if more than one label is in the annexure the suffixes may be numbered L1, L2 and so on).

AIDSRelief Hospital	
Standard Operating Procedures For RECORD KEEPING	
Number of Pages:	Serial number PH01/01
Prepared by: Title: Sign: Date	Approved by: Title: Sign: Date

Objective:

To describe procedures for maintaining records for all activities that concern AIDSRelief ARV stock in the store.

Responsibility:

Documentation and recording of all ARV drug receipts and issues from the store is the responsibility of the pharmacist in charge or his/her designated proxy.

Resources:

Forms used for record keeping of AIDSRelief ARVs
Stores and ledger stock cards and store bin cards

Procedures:

1. When ARVs are received in the store, receipts are to be entered in red ink and issues in blue or black ink.
2. Complete a separate stock card for differing strengths/concentrations and units of issue (i.e. for each different pack size.)
3. The card should have an item code, name, strength, dosage, form of the drug, and unit of issue.
4. Cards must be used until all entries are completed on both sides of the card. Balances from the completed card must be transferred to a new card.
5. The designated pharmacy staff should check the physical count of each ARV preparation in stock any time there is a receipt or issue in the store to ensure that the physical stock balance corresponds with that shown on the store bin card.
6. When receiving stock, record the date of receipt, voucher number, supplier, quantity, and new balance in stock
7. When issuing stock, record the date of issue, voucher number, requisitioning department, quantity, and balance left in stock.
8. If there is a loss or adjustment for an item, provide a brief explanation.
9. At the end of each month, calculate the monthly usage and record. Do not count expired stock removed. At the end of each month, perform a physical inventory and record it in red ink, skip a line and begin recording the next month's transaction on the next line.

Distribution

The ledger cards are kept in a serialized booklet and are stored in the ARV store under custody of the designated pharmacist in charge.

The bin cards are kept with the goods in the ARV store. Each bin card is kept on top of the stock of the corresponding item.

AIDSRelief Hospital	
Standard Operating Procedure For RECEIVING ARVs	
Number of Pages;	Serial number PH01/01
Prepared by: Title: Sign: Date	Approved by: Title: Sign: Date:

Objective:

To describe procedures for receiving ARVs from the distributor.

Responsibility:

Pharmacy staff in charge of ARV bulk store or his/her designated proxy
Pharmacist or proxy in charge of the ART Program
Stores officer

Resources:

Drug order form
Distributor goods delivery note
Discrepancy report form
Invoice or picking list

Procedures:

1. Receive drugs from the deliverer or supplier (distributor).
2. Check the quantities of ARVs supplied against the distributor delivery note/packing list before signing it.
Inspect for the following:
 - a. Broken, cracked, or leaking bottles or bottles with broken seals
 - b. Broken or crushed tablets
 - c. Expired drugs
 - d. Items without labels
 - e. Inappropriate storage procedures during transportation of refrigerated items (e.g. items that have arrived at room temperature or are warm)
 - f. Items requested for but not received
 - g. Items listed on the Distributor delivery note/packing list that are missing from the consignment
 - h. Items received that were not ordered.
3. Inspect the ARV packs for instability of formulation (e.g. foul smell, discoloration and disintegration).
4. Enter the quantities received and any remarks, and then sign the delivery note.
5. Record all discrepancies, if any, on the Discrepancy report form and inform the Health Supply Chain Specialist.
6. Enter the items into the stock record books and let the pharmacist in charge verify.

Distribution

The store bin cards are kept with the goods in the ARV store. Each bin card is kept on top of the stock of the corresponding item.

Send signed copy of the delivery note back to the Distributor and keep a copy on file.

AIDSRelief Hospital	
Standard Operating Procedure For DISCREPANCY REPORTING	
Number of Pages;	Serial number PH01/01
Prepared by: Title: Sign: Date	Approved by: Title: Sign: Date:

Objective:

To describe procedures for documenting any discrepancies with the supplied consignment of ARVs.

Responsibility:

The pharmacist in charge or his/her designated proxy and a witnessing pharmacy staff member.

Resources:

Discrepancy report form to record consignment discrepancies

Forms needed to complete the discrepancy report:

- stock control card
- supply voucher
- goods delivery note

Procedures:

1. Record discrepancies in consignment on the discrepancy report form.
2. Discrepancies may include the following:
 - a. Damaged products, including broken, cracked, or leaking bottles, broken or foul smelling tablets, expired drugs, items without labels, refrigerated items that arrive at room temperature
 - b. Ordered items that have not been sent
 - c. Items listed on the invoice that are missing from the consignment
 - d. Items received that were not ordered or were not listed on the invoice
3. Complete the discrepancy report form as follows:
 - a. Enter delivery note number, number of boxes/tins/bottles actually received, number of items missing, number of boxes/tins/bottles received with broken seals
 - b. Enter the following for items with discrepancies
 - i. Generic drug name, Strength, dosage form, Unit of issue, quantity issued, quantity received, quantity not opened by the pharmacist or proxy in charge for inspection
 - ii. Number of units of damaged items
 - iii. Remarks describing nature of discrepancy.
4. Record the name of the person who delivered and the vehicle registration number.
5. Have the deliverer sign the report.
6. Enter your name and sign the report.
7. Have the report witnessed by a pharmacy staff member.

Distribution

Send original copy back to the Distributor and a copy to the Health Supply Chain Specialist.

AIDSRelief Hospital	
Standard Operating Procedure For RECORD KEEPING IN DISPENSING	
Number of Pages; 1	Serial number PH002/001
Prepared by: Title Date Sign	Approved by: Title: Sign: Date:

Objective:

To describe the procedure for maintaining records of issues and receipts of ARV drugs at the outpatient pharmacy

Responsibility:

Documentation and recording of all ARVs receipts and issues from the bulk store to the outpatient pharmacy is the responsibility of the designated pharmacist in charge or his/her designated proxy.

Resources:

Forms used for record keeping of ARVs in the outpatient pharmacy:

- pharmacy bin card: a single copy, loose-leaf form
- ART patient dispensing record: contains a summary reference page listing all patients and their ART regimens, with separate forms for adults and children. It is used to check for discrepancies in repeat ART prescriptions and to check whether patients are using more or less medicine than is expected.
- ARV dispensing tool: an Access database used to check for discrepancies in repeat ART prescription and to check whether patients are using more or less medicine than is expected

Procedure:

1. All receipts of stock from the ARV bulk store must be documented on the pharmacy bin card and the ARV dispensing tool.
2. All issues of stock, both to outpatients and inpatients, must be documented on the pharmacy bin card and the ARV dispensing tool.
3. All issues must be recorded on the ART patient dispensing record.
4. All entries must be completed at time of receipt or issue.
5. Receipts on pharmacy bin card are to be made in red ink and issues in blue or black ink.
6. Each pharmacy bin card must be used until all entries are completed on both sides of the card. Balance from the completed card must be transferred to a new card.
7. Any time there is a receipt or issue at the outpatient pharmacy, the designated pharmacy staff should check the physical count of each ARV preparation in stock to ensure that the physical stock balance corresponds with that shown on the pharmacy bin card and on the ARV dispensing tool. If a difference is found, a stock count discrepancy report is completed.

AIDSRelief Hospital	
Standard Operating Procedure For CLEANING THE PHARMACY	
Number of Pages;	Serial number: PH03/01
Prepared by: Title: Sign: Date:	Approved by: Title: Sign: Date:

Objective:

To ensure that the pharmacy premises are kept in a clean state at all times. The major aim is to constantly ensure that the pharmacy maintains an appearance that reflects its role as a health care outlet.

Application: cleaning of the pharmacy.

Definition: Cleaning means freeing something from substances that are unpleasant, harmful or not wanted.

Materials:

1. All surfaces (i.e. tables, counters and shelves) shall be freed from all dirt and other unwanted substances using a clean cloth.
2. All medicine and non-medicine containers should be cleaned of dirt or any other unwanted substances using a clean cloth.
3. The floor shall be swept using a broom and mopped using water and detergents and/or disinfectants using a rug or any other appropriate cleaning equipment.
4. All surfaces should be thoroughly dried using a clean dry cloth or rug.

Responsibility:

1. The cleaner

It shall be the responsibility of the pharmacist in-charge to ensure that the pharmacy is kept clean at all times.

Distribution:

All staff in the pharmacy

AIDSRelief Hospital	
Standard Operating Procedures For MONTHLY REPORTING, QUANTIFYING AND ORDERING FOR ARVS	
Number of pages:1	Procedure number: PH01/01
Prepared By: Title: Sign: Date:	Approved By: Title: Sign: Date:

Objective:

To describe the correct procedure for preparing and submitting monthly reports for ARVs in order to avoid stock outs

Responsibility:

Preparing and submitting the monthly ARV report is the responsibility of the pharmacist in charge or his/her designated proxy.

Resources:

- Bin card/stock cards/ARV dispensing tool/patient register
- Daily activity register/ARV drug daily issues record
- Packing list/goods received note, AIDSRelief LPTF monthly order form

Procedure:

1. The person filling the form should only fill in areas highlighted in yellow, as the unshaded areas are protected.
2. At the end of every month the pharmacist in charge will use the bin card/stock card to fill in the opening stock for the month for every drug.
3. The packing list/goods received note will be used to update the “quantity received” column and indicate the amount of the particular drug that was received that month in full packs.
4. Using the daily activity register/ARV dispensing tool, the pharmacist in charge will update the consumption record for each drug per regimen.
5. Using the dispensing tool, the pharmacist in charge will fill in the number of patients per regimen at the beginning of the month and the new patients per regimen during the month, for both adults and children.
6. The total amount consumed in the month for pediatric drugs is then filled in the column for “total consumption” (highlighted in blue).
7. The physical balance should be verified by a physical count of the stocks and entered on the order form (sheet 2).
The maximum stock for each drug is three months, i.e. two months buffer stock and one month distribution stock.
The “order quantity” for each drug, therefore, is (3 x total/average monthly consumption + new patient needs – balance)
8. He/she will also fill in the name of the facility, name of the person filling the form, month for which the report is prepared, authorizing person, sign and date the report.
9. Please do not fill in the other areas of the form.

Distribution:

- Health Supply Chain Specialist to get a copy before 5th of the month.
- A copy is filed at the LPTF.

AIDSRelief Hospital	
Standard Operating Procedures For MEDICATION USE AND COUNSELING FOR ART	
Number of pages:1	Procedure number: PH01/01
Prepared By: Title: Sign: Date:	Approved By: Title: Sign: Date:

Objective:

To describe the correct procedure for counseling patients on ART

Responsibility:

Counseling patients on ART is the responsibility of the pharmacy staff dispensing medicines to patients.

Resources:

Pharmacy form
Reference books
Dispensing data base

Procedure:

1. Introduce yourself and identify who is being counseled.
2. Check what the patient or his/her representative already knows about the medicines. What did the doctor/nurse say the medication was for? How did the doctor/nurse instruct the patient to take the medication? What else did the doctor/nurse say about taking this medication?
3. Make sure the patient or his/her representative understands how these medications work (not a cure, only suppresses the virus, can still infect others, can still get sick from other illnesses, etc.)
4. Ask the patient about his/her concerns.
5. Give the name of the medicine and describe its appearance. Show the patient the identifier code on solid dosage forms and show the label, if possible open the package and show the tablets.
6. Name the route of administration.
7. Give directions/instructions/pharmacokinetics/adherence:
 - Explain to the patient or his/her representative the directions for taking the medication (number of pills, amount of fluid, when to take, not to share/miss doses, not take more or less, missed doses to be taken soonest or skip and go to regular dosing schedule, no double dosing, continue taking even when feeling better, otherwise medicines may not work and are limited. Do not stop taking drugs without doctor's knowledge.)
8. Give information on the possible drug interaction (e.g. with herbs, other medicines).
9. Give information on the side effects of the medicines.
10. Give information on storage of the medicines.
11. Check the patient's/representative's understanding. Ask them to repeat back key information. Remind them of information they left out.
12. Final check for questions and concerns.
13. Remind them of the return date.

Distribution:

A copy should be displayed at all dispensing areas
A copy goes to the file.

AIDSRelief Hospital	
Standard Operating Procedures For TEMPERATURE CONTROL	
Number of pages:1	Procedure number: PH01/01
Prepared By: Title: Sign: Date:	Approved By: Title: Sign: Date:

Objective:

To describe the correct procedure to ensure that antiretroviral drugs are stored at the appropriate temperature to maintain the quality of the products

Responsibility:

Designated hospital staff in charge of the ARV drug store

Designated pharmacy staff in charge of dispensing for the pharmacy ARV dispensing room

Resources:

Temperature control log: ARV drug store

Temperature control Log: ARV drug store and pharmacy refrigerator

Temperature control: ARV pharmacy/dispensing room

Maximum-minimum thermometers

Procedure:

1. Record the maximum and minimum temperatures from the thermometers in the ARV drug store and the ARV pharmacy/dispensing room twice daily. Record the temperatures of the ARV drug store and pharmacy refrigerator once daily.
2. Complete the temperature control logs: ARV drug store, ARV drug store and pharmacy refrigerator and ARV pharmacy/dispensing room as described below.
3. Endorse with your initials.
4. Acceptable limits for the ARV storage areas are:
 - ARV drug store and ARV pharmacy/dispensing room temperatures: 15-25 C
 - ARV drug store and pharmacy refrigerator: 2-8 C
5. Report temperatures not within the temperature range to the ART pharmacist or his/her proxy immediately.
6. Check regularly to ensure that the ARV drug store air-conditioning is working effectively (where it is present) and report any faults immediately.
7. Hang the temperature logs on the wall or refrigerator door.
8. Keep the completed logs on the file in the ARV drug store.

Distribution:

Completed logs are filed

Logs in use are displayed in the store and on the refrigerator door

AIDSRelief Hospital	
Standard Operating Procedures For TRACKING EXPIRY DATES OF ANTIRETROVIRAL DRUGS	
Number of pages:1	Procedure number: PH01/01
Prepared By: Title: Sign: Date:	Approved By: Title: Sign: Date:

Objective:

To describe the correct procedure for using a chart to track the expiry dates of antiretroviral drugs and alert the supply chain specialist or unit manager when ARVs should be removed from stock for exchange or destruction

Responsibility:

Expiry date tracking is the responsibility of the pharmacy staff in charge of the ARV bulk store and pharmacy store

Resources:

Chart to track the expiry dates of drugs

Procedure:

- Design a chart similar to the one below or ask the Health Supply Chain Specialist to provide one.
- The chart has three columns for three years. Use the first column for the current year.
- If there are more than three batches/lots, record the batches/lots of the ARV that expire first.
- Use a yellow dot to mark the expiry warning date, and a red dot to mark the month when the drug expires.
- Contact the Health Supply Chain Specialist (HSCS) to find out the minimum expiry date that is acceptable for exchange. Consider adding one month to this minimum date to allow for transport back to the distributor. Place the yellow dots on the month in which action must be taken.
- For the three months before the yellow warning dot, enter the current stock level of that batch/lot in the relevant grid. The stock levels also show the rate of use and determine how much, if any, stock to return.
- Remove the red dot only after the expired stock has been disposed of or removed from the stock.
- When a batch/lot expires or is used up, erase the entry and replace it with the next batch to expire. When drugs are received, enter the new batch/lot number and expiry date on the chart.
- If a drug expires after the three years covered in the chart, record the drug in the chart, but do not include the stickers. When updating the chart at the beginning of the new year, if the drug is still in stock and expires within three years, add the stickers accordingly.
- To reduce the number of entries, make separate charts for syrups and tablets/capsules.
- Hang the chart on a wall for easy reference.

Distribution:

A copy should be displayed at all dispensing areas

A copy goes to the file

Drug Name	Batch	Year												Year												Year														
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D			