



Ministry of Medical Services
and
Ministry of Public Health & Sanitation

Basic Concepts of Inventory Management,
Appropriate Medicine Use and
Pharmacovigilance

January 2012



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MSH/Health Commodities and Services Management

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About MSH/HCSM

The MSH/HCSM Program strives to build capacity within Kenya to effectively manage all aspects of health commodity management systems, pharmaceutical and laboratory services. MSH/HCSM focuses on improving governance in the pharmaceutical and laboratory sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines and related supplies.

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ACRONYMS AND ABBREVIATIONS

GOK	Government of Kenya
HCSM	Health Commodities Services Management Program
KEMSA	Kenya Medical Supplies Agency
MOH	Ministry of Health
MSH	Management Sciences for Health
USAID	United States Agency for International Development
WHO	World Health Organization

1. INTRODUCTION

Health commodities play a vital role in saving lives and improving health. Availability, quality, safety and appropriate use of health commodities are key aspects in providing quality and effective care to patients/clients

Several assessments on health commodity management, appropriate use of medicines and pharmacovigilance have been conducted in Kenya. These have revealed gaps in the health system that impact on the availability, quality, safety and appropriate use of health commodities and ultimately health care. Some of the gaps include poor inventory management and prescribing practices and lack of adherence to treatment guidelines. To address some of these gaps, health facility staff need to be equipped with the required technical skills and knowledge necessary for improving inventory management and appropriate use of health commodities,

2. PURPOSE OF THE COURSE

The goal of this course is to equip health facility staff with the necessary knowledge, skills and attitudes to enable them to manage health commodities effectively.

3. TARGET GROUP

The course is designed for all persons involved in the management of health commodities. These include doctors, clinical officers, nurses, pharmacists, pharmaceutical technologists, laboratory staff, nutritionists and procurement/ supplies officers.

4. COURSE DURATION

The course is designed to take two days and will focus on the theory and practice of inventory management, appropriate medicines use and pharmacovigilance.

5. COURSE ORGANIZATION

This course is organized into 11 sessions which are closely related.

Session 1: Background, Course Overview and Objectives

Session 2: Overview of Inventory Management

Session 3: Quantification

Session 4: Receiving

Session 5: Storage

Session 6: Issuing

Session 7: Dispensing

Session 8: LMIS

Session 9: AMU

Session 10:PV

Session 11:MTP

6. TRAINING/FACILITATION

This course will involve various teaching methods and will emphasize methods appropriate for adult learners. These methods will include overview and illustrated lectures, small group discussions, class exercises and demonstrations.

8. PERFORMANCE ASSESSMENT

Facilitators will continuously assess participants through question and answer sessions. Pre- test and post-test questions will be administered at the beginning and at the end of the course. Assignments will be given and the learners will be expected to make decisions based on the information provided in the assigned case studies. This will form an important part of the assessment.

9. CURRICULUM IMPLEMENTATION

The trainers/facilitators for the course will be drawn from among qualified healthcare professionals who have expertise and experience in inventory management, appropriate medicines use and pharmacovigilance. These include trained members of the DHMT who will be involved in follow up of facility staff post training to ensure implementation of action plans. Time schedule for the course will be between 8 am to 5 pm with tea breaks and a lunch break in between. The course will last approximately 2days providing 8 hours of didactic and practical sessions as outlined in this curriculum.

10. CURRICULUM REVIEW AND CHANGE

There will be a course evaluation by participants and implementers at the end of each course and appropriate changes should be made where necessary. After the second course there will be a review of the curriculum by all stakeholders. The stakeholders will evaluate the course objectives, course content and all the resources for the course. Subsequent periodic reviews will be as determined by stakeholders.

11. REFERENCES AND RECOMMENDED READINGS

- *Managing Drug Supply*. 2nd edition. West Hartford, Connecticut. Kumarian Press, Inc. Management Sciences for Health and World Health Organization.1997

Session 1: Background, Course Overview and Objectives

Background, Course Overview and Objectives



About the Course

Why the course:

- ◆ Health commodities play a vital role in saving lives and improving health
- ◆ Availability, quality, safety and appropriate use of health commodities are key aspects in providing quality and effective care to patients/clients
- ◆ Several assessments have revealed gaps in the health system that impact on the above aspects



Brainstorming: Gaps in Health Commodity Management

- Has the district undertaken any previous assessments in Commodity management? What were the key issues / challenges observed?
- What are key gaps in Commodity management in your district /Facilities has noted?
- What interventions can be applied to address these issues in your district?



HCSM Baseline Assessment : Facility specific findings (1)

- High stock-out levels: 25% of the sampled facilities reported a stock-out lasting more than 7 days for AL (all sizes); 26% for DMPA and 22.9% for TB patient packs.
- Inappropriate use of stock control and reporting tools despite their availability
- 1/3 of the facilities still operating under the “push” system
- About 45% of the sampled facilities had Medicines & Therapeutics committees (MTCs); however, they were not functional in most places.



HCSM Baseline Assessment : Facility specific findings (2)

- Limited availability of National Clinical Management guidelines (2009):- only 37% of the sampled facilities had the guidelines
- Low adherence to treatment guidelines when managing tracer conditions with only 20% of the sampled cases having undergone a laboratory test and AL issued only where the lab results were positive



HCSM Baseline Assessment : Facility specific findings (3)

- Poor coordination of laboratory commodities and service delivery at the peripheral levels
- Poor record-keeping, as evidenced by the relatively high proportion of facilities reporting disagreement between physical stock counts and record counts



Course Objectives

- To identify and discuss gaps in health commodity management
- To provide an overview of inventory management for health commodities
- To discuss concepts of appropriate medicines use and pharmacovigilance
- To outline action planning and problem solving using the MTP approach in improving health commodity management



Target Audience

- Health care providers who are involved in management of health commodities in all levels of care.
- The primary target for includes doctors, dentists, clinical officers, pharmacists, pharmaceutical and laboratory technologists, nurses and supply chain officers.



Course Structure & Methodology

Course Structure:

- 2 day Residential training of didactic and practical sessions

Course Methodology:

- Pre and Post test
- Adult learning Training Methods Applied:
 - Lectures, Discussions, Buzz sessions, Class exercises/practice sessions, Case Studies & presentations
- Overall Course Evaluation



Course Outline...(1)

This course is comprised of 10 Sessions

1. Overview of Inventory Management
2. How to determine quantities to order
3. How to receive health commodities
4. Storage of Health Commodities
5. How to Issue Health Commodities



Course Outline...(2)

6. How to Dispense Health Commodities
7. LMIS Reporting, Commodity and Information Flow
8. Appropriate Medicines Use
9. Pharmacovigilance
10. MTP: A quality Improvement Approach



Course Materials

Participant Material

- Pen
- Writing Pad
- Name Tag
- Participants' manuals





Session 2: Overview of Inventory Management

Overview of Inventory Management



Objectives

- On completion of this session one will be able to:
 - Define key terms used in inventory management
 - Describe the components of inventory management
 - Give reasons for the importance of good inventory management
 - List the tools/ records required during the inventory management processes



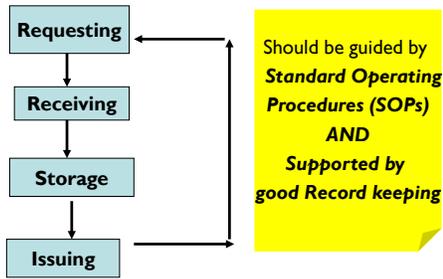
Definition

Inventory means the stock of all items in the medical store

Inventory management
The process of ordering, receiving, storing, issuing, and dispensing of health commodities.



Inventory Management for Commodities



4

Aims of Inventory Management (IM)

To ensure:

- continuous supply (reduce stock-outs)
- minimize expiry, damage and other losses
- identification, marking & correct disposal of expired stock
- transparency and accountability through record keeping and reporting



5

Inventory Control Records

- To achieve these aims we need inventory records which must always be:
 - legible
 - complete
 - accurate
 - up-to-date
- Inventory records include: bin/ stock control cards, charts to track expiry dates, SI I, Temperature monitoring log, etc



6

Demonstration

- Good record keeping practices job aid



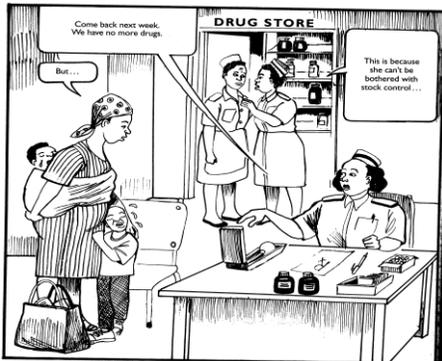
Consequences of Poor Inventory Management

Poor Inventory Management leads to:

- stock-outs
- accumulation of unwanted excess stocks with associated problems of space utilisation/stores congestion, disposal, theft
- deterioration and expiry of items
- serious financial losses due to all the above
- poor pharmaceutical, laboratory and clinical services



What Happens When Inventory Is Not Managed Well in your Facility?



Demonstration

- Overview of Inventory Management job aid



Questions?

Discussion



Job Aid 1: Good Inventory Management Practices for Health Commodities

GOOD INVENTORY MANAGEMENT PRACTICES FOR HEALTH COMMODITIES

1

1. Ordering

- a) ensure you know to order
- b) ensure you know to order adjust for
 - stock on hand.
 - will need manual or electronic tools to
- c) ensure you know to order



2

2. Receiving

Only authorized persons should receive health commodities

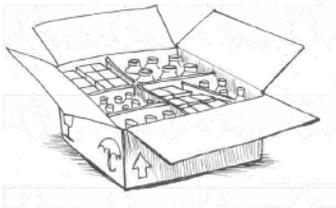
- inspect goods for quantity and quality
- sign delivery notes
- enter received items in Stock ledger and Bin card



4

4. Issuing

- confirm the order
- pick and package items ordered
- indicate quantities issued and countersign the order
- update Bin cards/ Stock cards



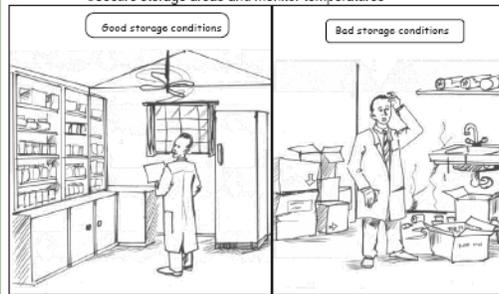
Fill voids in cartons with package material

Good Inventory Management Practices are guided by Standard Operating Procedures

3

3. Storing

- ensure appropriate storage
- maintain updated Bin cards and track expiry dates
- secure storage areas and monitor temperatures



Session 3: How to Determine Quantities to Order

How to Determine Quantities to Order



1

Objectives

At the end of this unit, the participants will be able to:

- Define Quantification and related terms
- Quantify the commodity needs for a facility using the Consumption method



2

What is Quantification?

- Quantification is the process of estimating the quantities of required health commodities
- Quantification is an important step in **procurement** and in **ordering** supplies



3

What is the purpose of Quantification?

- To avoid surpluses that may lead to over-stocking, expiries and/or wastage of commodities
- To avoid shortages/stock-outs
- To make informed adjustments to procurement when faced with budgetary constraints



4





Terms used in Quantification (1)

Total Consumption

- Refers to the total quantities of a health commodity used over a specified period

Average monthly consumption (AMC)

- A measure of quantities used on average per month

Stock on Hand (SoH) / Closing stock (CS)

- The quantity in stock at the time of the order (based on a physical count)



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Terms used in Quantification (2)

Lead time

- The period between when an order is placed and when the items ordered are available for use by clients/patients

Safety/Buffer stock

- This is the quantity that should be kept in stock to cushion against any changes in demand and supply



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Terms used in Quantification (3)

Months of Stock (MoS) on hand

- Calculated by dividing the Stock on Hand by Average Monthly Consumption

Scaling-up

- Refers to incremental increase in number of patients being treated over a period of time



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How do you quantify?

Quantification Methods

Two main methods

- Consumption-based
- Morbidity-based



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Consumption-based method

- It estimates the commodity needs based on records of past consumption
- Works well where:
 - all records are available, up-to-date and the information is reliable
 - There are minimal stock out periods
 - Consumption patterns are stable
- Adjustments are made for stock-outs, wastage and losses.



11

Morbidity-based Method

- Estimates needs based on the frequency of health problems and their standard management
- Is used to:
 - estimate needs for a new program or in disaster situations or where consumption data is not available/ reliable
 - developing and justifying budgets



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Consumption-based method: Steps

Step 1:

Select the Consumption period (CP)

A one year consumption period would be ideal as it provides more information and captures seasonal variations.



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Consumption-based method: Steps

Step 2:

Calculate the consumption (C) over the selected consumption period

Option 1: Mostly applied for program commodities

Add all the quantities issued/ dispensed as indicated in the issuing/ dispensing register (e.g. Daily Activity Register).

Option 2: Mostly applied for EMMS

Add all the quantities issued in the bin / stock control card



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Calculating Consumption Using Bin Card / Stock Control Card Data

Item Description (in full)		Code no.	Order Unit	
Lignocaine injection 2%, 30mL vial		PHA0145	1	
Expiry Dates		Max Stock	Issue Unit	
08/2005 03/2006		3,000	1	
Date	Reference	Receipt	Issue	Balance
1-Jan-04	Balance b/f			20
5-Jan-04	from KEMSA (inv no. 272)	60		80
18-Jan-04	to dispensary		20	60
10-Apr-04	to dispensary		10	50
6-Jun-04	to dispensary		10	40
8-Jun-04	from KEMSA (inv no. 487)	70		110
15-Jul-04	to dispensary		20	90
20-Aug-04	to dispensary		20	70
10-Sep-04	to dispensary		10	60
25-Oct-04	to dispensary		10	50
10-Nov-04	to dispensary		10	40
20-Nov-04	to dispensary		10	30
31-Dec-04	Balance c/f			30



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Consumption-Based method: Steps

Step 3:

Adjust for any avoidable wastage, losses or adjustments

Consumption adjusted for avoidable adjustments/ losses (C1) = Consumption – Adjustments or Losses

* This step only applies when quantifying using bin/ stock control data



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Adjusting for wastages and losses when using Bin or Stock Control Card Data

Item Description (in full)			Code no.	Order Unit
Benzylpenicillin injection 600mg (1MU) vial			PHA0025	1
Expiry Dates		Max Stock	Issue Unit	
05/2006 04/2007		3,000	1	
Date	Reference	Receipt	Issue	Balance
1-Jan-04	Balance brought forward			1,800
14-Jan-04	to dispensary		600	1,200
5-Feb-04	from KEMSA (inv no. 1104)	1,500		2,700
10-Mar-04	to dispensary		600	2,100
15-May-04	to dispensary		600	1,500
10-Jun-04	from KEMSA (inv no. 1567)	1,500		3,000
12-Jul-04	to dispensary		600	2,400
14-Aug-04	expired (July 2004)		800	1,600
30-Sep-04	to dispensary		600	1,000
1-Oct-04	crushed in store		300	700
18-Nov-04	to dispensary		600	100
30-Nov-04	from KEMSA (inv no. 1778)	1,500		1,600
15-Dec-04	to dispensary		600	1,000
31-Dec-04	physical stock check			500
31-Dec-04	unaccounted for (?)			500
31-Dec-04	Balance carried forward			500



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Consumption-based method: Steps

Step 4

Adjust for stock-outs if necessary

Consumption adjusted for stock-outs (C2) =
 Consumption adjusted for losses/adjustments x
 [Consumption period (in days) / Period in
 stock (in days)]



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Adjusting Consumption for Stock-outs

Item Description (in full)		Code no.	Order Unit	
Paracetamol tablets 500mg		PHA0178	1,000	
Expiry Dates		Max Stock	Issue Unit	
06/2006 09/2007		50	1,000	
Date	Reference	Receipt	Issue	Balance
1-Jan-04	Balance brought forward			10
20-Jan-04	to dispensary		10	0
1-Feb-04	from KEMSA (inv. no. 1125)	30		30
25-Feb-04	to dispensary		10	20
20-Apr-04	to dispensary		10	10
1-Jun-04	to dispensary		10	0
31-Jul-04	from KEMSA (inv. no. 1598)	30		50
1-Aug-04	to dispensary		10	40
7-Sep-04	to dispensary		10	30
20-Oct-04	to dispensary		10	20
10-Dec-04	to dispensary		10	10
31-Dec-04	Balance carried forward			10



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Consumption-based method: Steps

Step 5

Calculate the Average monthly consumption (AMC)

$$\text{AMC} = \frac{\text{Adjusted consumption (C2)}}{\text{Consumption period (in months)}}$$



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Consumption-based method: Steps

Step 6

Calculate the Maximum stock level

$$\text{Maximum Stock level} = \text{AMC} \times \text{Maximum Months of Stock}$$



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Consumption-based method: Steps

Step 7

Calculate the quantity to order

Quantity to order = Maximum Stock level – Closing Stock



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Records that provide Information for Quantification

1. For Consumption
 - Daily Activity Register/ Dispensing Register
 - Issues Register (issues to clients/patients)
 - Consumption report & request forms
 - Service data (e.g. number of clients/patients)
 - Bin cards
2. For Morbidity
 - District Health records
 - Hospital Health records



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Demonstration

Quantification Job Aids for Laboratory Commodities and Medicines



Job Aid 1: Quantification of Laboratory Commodities



QUANTIFICATION OF LABORATORY COMMODITIES

Quantification is the process of estimating how much of an item is needed to last for a particular period

Preparation

1. Collect the necessary materials i.e. pen, paper, calculator, stock cards, DAR for Laboratory commodities (MoH 642), laboratory registers
2. Prepare a quantification worksheet similar to the one overleaf
3. Write a list of laboratory commodities to be ordered
4. For each commodity, carry out the steps listed below.

PROCEDURE A:- SITUATIONS WHERE THERE ARE NO STOCK OUTS

Step 1

Determine the **Consumption Period [CP] (in months)**- this is the period over which consumption is being reviewed e.g. 3 months.

Step 2

Determine **Consumption [C]**

This is the quantity of stock used during the Consumption Period [CP].

Step 3

Determine the **Average Monthly Consumption [AMC]**. The AMC is calculated from the Consumption [C] divided by the Consumption Period [CP].

$$AMC = C / CP$$

Step 4

Determine **Maximum Months of Stock [Max MOS]** - This is the period being ordered for plus buffer.

For example, if the period for which stock is being ordered for is 3 months and buffer stock for one month is required, then the Max MOS will be 4 months.

Step 5

Determine **Maximum Stock Level [MSL]** - This is the stock that a facility should not exceed at one given time.

Maximum Stock Level [MSL] = Average Monthly Consumption [AMC] x Maximum Months of Stock [Max MOS]

Step 6

Carry out a physical stock count for each item listed to get the **Stock on hand [SOH]**

Step 7

Determine the **Quantity to Order [QO]**

Quantity to Order [QO] = Maximum Stock Level [MSL] - Stock on hand [SOH].

PROCEDURE B:- WHERE STOCK-OUTS HAVE BEEN EXPERIENCED

Step 1

Determine the **Consumption Period [CP]** and **Consumption [C]** as above.

Step 2

Determine the **Adjusted Consumption for Stock out [C2]**

$$C2 = \frac{C \times CP \text{ (in days)}}{\text{Period in stock (days)}}$$

(the period in days when stock was available during the CP eg if CP is 90 days and may be the item had stocked out for 10 days. The period in stock is 90-10 = 80 days)

Step 3

Calculate the Average Monthly Consumption [AMC]

$$\text{AMC (Units/month)} = \frac{C2}{\text{CP (months)}}$$

Step 5

Calculate the **Maximum Stock Level [MSL]**

Maximum Stock Level [MSL] = Average Monthly Consumption [AMC] x Maximum Months of Stock [Max MOS]

Step 6

Carry out a physical stock count for each item listed to get the **Stock on hand [SOH]**

Step 7

Determine the **Quantity to Order [QO]** as in procedure A above

Worked Example

Opening Stock	100 Units
Receipts	600 Units
Issues	400 Units
Wastage and losses	10 Units
Stock on hand [SOH]	300 Units
Consumption Period [CP]	3 months or 90 days
Period in stock	2 months or 60 days
Maximum Months of Stock [Max MOS]	4 months

Laboratory Commodities Quantification Worksheet

Worked Example:-

Commodity	Consumption (C)	Adjusted Consumption for stock-out (C2)	Average Monthly Consumption (AMC)	Maximum Stock Level (MSL)	Stock on Hand (SOH)	Quantity to Order (QO)
Formula	Issues	$\frac{C \times CP \text{ (days)}}{\text{Period in stock (days)}}$	$\frac{C2 \text{ (Units)}}{CP \text{ (Months)}}$	AMC x Max MOS	Closing stock in units	MSL – SOH
e.g. for a Rapid HIV Test	400	$\frac{400 \times 90}{60}$ =600	$\frac{600}{3}$ =200	200 x 4 =800	300	800 – 300 = 500

NB. Maintain the same unit of measure throughout the calculations e.g. tests or kits/packs



Job Aid 2: Quantification of Medicine Needs

HOW TO QUANTIFY YOUR FACILITY MEDICINE NEEDS



What is quantification?

Quantification is the process of estimating the quantities of needed drugs and supplies

SIMPLE STEPS TO QUANTIFICATION

Step 1:

Carry out physical stock taking for each drug to determine closing stock (CS)

Step 2:

Define your facility parameters for

Consumption Period = _____ Months
Maximum Months of Stock = _____ Months

Step 3:

Calculate Consumption by adding all the quantities dispensed in the DAR for each drug

Step 4:

Adjust for any losses/ avoidable waste reflected in the DAR as dispensed

Total quantities dispensed – losses/ avoidable waste = C1

Step 5:

Adjust for stock outs if necessary

C1 X $\frac{\text{Consumption period (in days)}}{\text{Period in stock (days)}} = C2$

Step 6:

Calculate Average Monthly Consumption

$\frac{C2}{\text{Consumption Period in Months}}$

Step 7:

Calculate the Maximum Stock level

AMC X Maximum Months of Stock

Step 8:

Determine Actual Quantity to Order

Maximum Stock Level - Closing Stock



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Session 4: How to Receive Health Commodities

How to Receive Health Commodities



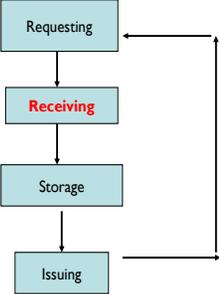
Objectives

At the end of this session, the participants will be able to:

- Describe the appropriate procedures and records used to receive medical commodities



Inventory Management for Commodities



```
graph TD; Requesting[Requesting] --> Receiving[Receiving]; Receiving --> Storage[Storage]; Storage --> Issuing[Issuing]; Issuing --> Requesting;
```

3

How Commodities should be Received

- They should always be received by an authorized person at the health facility
- There should be clear written guidelines on the Procedures for Receiving commodities
- The commodities received should be Inspected
- Any discrepancies should be documented immediately and communicated to the supplier of the commodities



Checklist for Receiving commodities

- | |
|---|
| 1. Is the Delivery Note / Invoice for your facility? |
| 2. Are the goods delivered the same as the ones that were ordered? |
| 3. Are the quantities delivered the same as those in the Delivery note or Invoice? |
| 4. Is the condition of the boxes at the time of delivery acceptable? |
| 5. Are the goods delivered in good condition? (check liquids for leakages; check also for broken containers, unsealed, unusual odors) |
| 6. Is the Expiry date of the commodities acceptable to your facility? |
| 7. Document any discrepancies and follow up with supplier. |

5

Check Before You Receive



Document used for Receipts

Delivery documents include:

- MoH forms
 - KEMSA Delivery note
 - S12 (Issue & Receipt voucher)
 - Packing Lists
 - Transporters delivery note
- Other
 - Supplier Delivery note
 - Supplier Invoice



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Documents used for Receipts

- MoH forms
 - Bin Cards (MoH S5)
 - Stock cards
- Other
 - Counter Receipt Voucher (S13)
 - Shipment Discrepancy form
 - Checklist for Receiving health commodities



8

Exercise: Receiving commodities

Instructions:

Use the available Delivery Note from KEMSA to record the delivered quantities of commodities in the MoH Bin card



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Thank you



Exercise 1: Receiving Health Commodities

 KEMSA	Kenya Medical Supplies Agency	DATE	02/04/20X0		
	P O Box 47715 - 00100	DELIVERY NOTE NO.	K2101		
	Nairobi, Kenya.	CUSTOMER ORDER NUMBER	Q02/20XX		
	Tel: (254-20) 537670 /1/2/3	VEHICLE REG. NUMBER	KZA 122VX		
	Fax: (254-20) 558100 / 554359	WAREHOUSE	NAIROBI		
Email: info@kemsa.co.ke					
CUSTOMER NAME		CUSTOMER ADDRESS			
TAHIDI S.D.H.		P.O. BOX 21,			
CENTRAL DISTRICT		TAHIDI			
DELIVERY NOTE					
Item Code	Description	Unit of Issue	Batch No.	Expiry Date	Qty per Batch
1	LEVONORGESTREL TAB 0.03mg	3 x 35	XY015	09/20X2	10
2	POVIDONE IODINE SOLN. 10%	5L	210AB	--	1
3	DEPOT MEDROXYPROGESTERONE ACETATE 150MG INJ. (1 X 100 VIALS)	1	ABC124	11/20X1	1
4	AMITRYPTYLINE TAB 25mg	1000's	N001B	11/20X2	1
Special Notes					
Security		Storekeeper Signature		Warehouse Manager Signature	
NM		AZ		XN	
Driver's Name		Transporter		Received By	
HENRY NAMBA		HARAKA COURIERS		KALI MWENDA	
Driver's ID. No.		Date		Date	
1051XX		06/04/20X0		10/04/20X0	
Driver's sign		Vehicle No.		Sign	
HN		KZA 122V		KM	
Distribution		Designation		ID. No.	
White: Customer, Blue: Logistics, Yellow: Warehouse/Store, Pink: Finance		STOREMAN		P/No. 0214	
				Tel No.	
				2754 TAHIDI	

Job Aid 1: Checklist for Receiving Health Commodities

RECEIVING CHECKLIST

1. Is the Delivery Note / Invoice for your facility?
2. Are the goods delivered the same as the ones that were ordered?
3. Are the quantities delivered the same as those in the Delivery note or Invoice?
4. Is the condition of the boxes at the time of delivery acceptable?
5. Are the goods delivered in good condition? (check liquids for leakages; check also for broken containers, unsealed, unusual odors)
6. Is the Expiry date of the commodities acceptable to your facility?
7. Any discrepancies? Document and follow up with the supplier

Session 5: Storage of Health Commodities

Storage of Health Commodities



1

Objectives

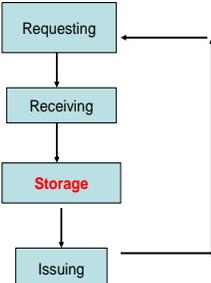
At the end of this session, the participants will be able to:

- Describe the appropriate procedures and records used to store commodities
- Be able to store commodities appropriately in a facility
- Identify storage problems in their facilities and suggest adequate solutions



2

Inventory Management for Commodities



```
graph TD; Requesting[Requesting] --> Receiving[Receiving]; Receiving --> Storage[Storage]; Storage --> Issuing[Issuing]; Issuing --> Requesting;
```

3

A Store?



Key factors to consider during storage

- Security
- Organization
- Storage conditions
 - Temperature
 - Ventilation and Humidity
 - Lighting
 - Cleanliness
- Records



5

Security: Restricted Access



Basic storage systems

Direct storage of cartons on the warehouse floor should be avoided.

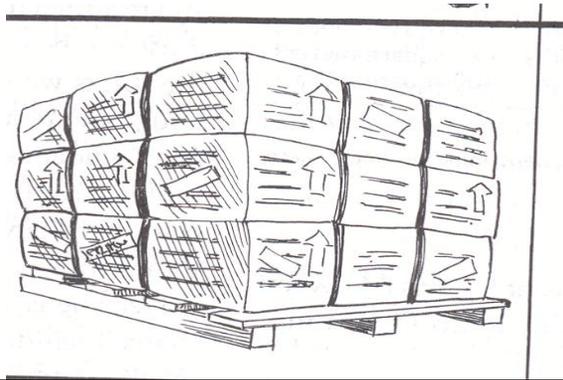
Instead use:

- Shelves
- Floor pallets
- Racks



7

Organization: Keep drugs off the floor, in cartons facing up to avoid spillage of syrups. This also allows easy cleaning.

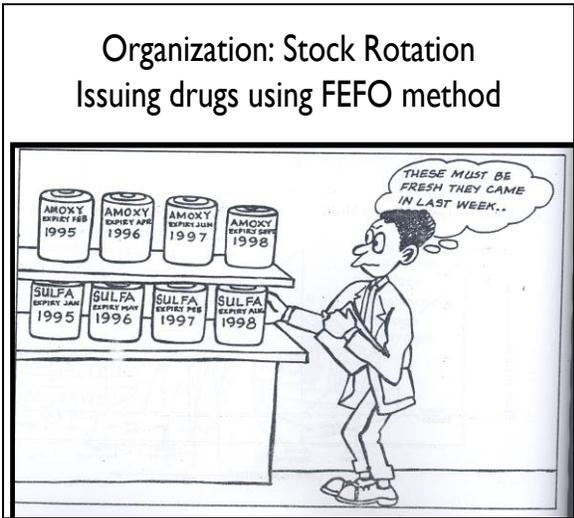


Organization: Separate dosage forms and label them clearly









Storage conditions: Temperature

- The recommended temperature for refrigerated items is between 2-8° C
- Recommended room temp: 18-25° C
- Have Air conditioner if possible
- Should have the Max-Min thermometers



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Storage conditions: Humidity, Ventilation and Lighting

- Sufficient windows
- Note: Fans only circulate air and do not regulate temperature
- Keep drugs off the floor to avoid contact with moisture
- Have curtains on windows to control direct light or paint the windows



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Storage conditions: Cleanliness

- Post a schedule and instructions for cleaning
- Clean the floor and the shelves regularly
- Dispose garbage regularly
- Keep area outside the store clean
- Schedule regular inspection (senior staff)



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Storage conditions: Fire precautions

- Dispose flammable trash
- Prohibit smoking
- Provide fire extinguishers and/or smoke detectors, and inspect them regularly
- Make sure the emergency exit is accessible
- Keep buckets of sand if no fire extinguishers available



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Records

Records to track stock levels and transactions:

- **Bin Card (S5)**
- **Stock Control Card**

Other records:

- **Chart to track Expiry dates:** Lab commodities and Medicines
- **Temperature Log:** To monitor temperature
- **Checklists:** for storage



18

Disposal of Expired or Damaged commodities

- Keep a schedule to regularly check on and removing expired or damaged drugs from shelves
- Set aside a designated space for damaged, expired or unusable stock.
- Should fill in F.O. 58 available from the district procurement officers.



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GOOD STORAGE PRACTICES FOR ART COMMODITIES

- 1. Ensure security**
 - Store in secure storage facility
- 2. Use orderly arrangement**
 - Store in neat, orderly manner
 - Use appropriate shelving
- 3. Use pallets for bulk products**
 - Use pallets for bulk products
 - Use appropriate pallets
- 4. Use Bin cards**
 - Use bin cards for inventory control
 - Use bin cards for inventory control
- 5. Use FIFO for stock rotation**
 - Use FIFO for stock rotation
 - Use FIFO for stock rotation
- 6. Maintain appropriate temperature**
 - Maintain appropriate temperature
 - Maintain appropriate temperature
- 7. Control lighting and ventilation**
 - Control lighting and ventilation
 - Control lighting and ventilation
- 8. Remove unusable products from stock**
 - Remove unusable products from stock
 - Remove unusable products from stock
- 9. Adhere to safety precautions**
 - Adhere to safety precautions
 - Adhere to safety precautions

Orientation to Store Records

- Storage Checklists
- Temperature Control log
- Bin cards
- Chart to Track Expiry dates
- Storage guidelines Job Aid



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Exercise

Use the summary information provided to complete the chart to track the expiry dates of drugs

Drug Name	Batch No	Expiry Date
Lamivudine 150mg tablets	AB1000	01/2013
Chlorphenamine 4mg tabs	13D455	03/2013
Amoxicillin Suspension 125mg/5ml	BBI4569	10/2012
Erythromycin 250mg Tablets	AB2345	12/2012
Inj. Gentamicin 10mg/ml	AB23467	10/2012

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Thank you



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Job Aid 1: Good Storage Practices for Health Commodities

GOOD STORAGE PRACTICES FOR HEALTH COMMODITIES

1. Ensure Security

- control access to storage areas
- use lockable cupboards/ cabinets



2. Adhere to safety Precautions

- keep functional fire extinguishers within easy reach
- maintain an easily accessible emergency exit
- prohibit smoking in the storage areas
- maintain a first aid kit within easy reach



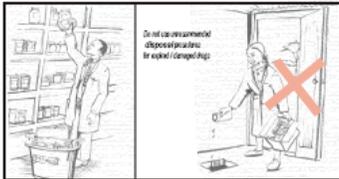
2. Use Orderly Arrangement

- provide sufficient shelving
- use a system for arranging e.g. dosage form, alphabetically or by generic name.



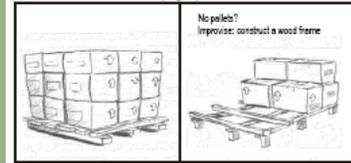
3. Remove expired or damaged drugs

- do not keep expired / damaged drugs with non-expired stock
- develop a procedure for isolating and disposing unusable stock



3. Place Bulky off the floor

- place bulky goods on pallets or shelves
- do not over stack items to avoid crushing
- stack boxes in upright position



4. Control lighting and Ventilation

- minimize direct light exposure on stock
- allow air circulation between stock
- consider use of ventilation equipment e.g. fans



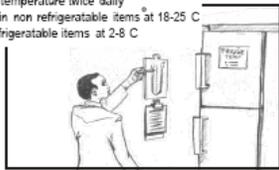
4. Use Bin Cards/ Stock Cards

- maintain an updated Bin card for every commodity
- place Bin card next to the item



5. Maintain appropriate

- use minimum / maximum thermometer
- maintain a temperature log
- record temperature twice daily
- maintain non refrigeratable items at 18-25 C and refrigeratable items at 2-8 C



5. Use FEFO for Stock rotation

- place medicines on the shelf according to "First Expiry First Out"



Job Aid 2: Guidelines for Proper Storage of Health Commodities



GUIDELINES FOR PROPER STORAGE OF HEALTH COMMODITIES

1. Clean and disinfect the Storeroom regularly, and take precautions to discourage harmful insects and rodents from entering the storage area.
2. Store the Health commodities in a dry, well-ventilated Storeroom and out of direct sunlight.
3. Protect the Storeroom from water penetration.
4. Keep fire safety equipment available, accessible and functional; and train the health facility staff on how to use it.
5. Store latex products away from electric motors and fluorescent lights.
6. Maintain cold storage, including a cold chain, for health commodities that require it.
7. Limit storage area access to authorized personnel and lock up controlled substances
8. Stack cartons at least 10cm off the floor, 30cm away from the walls and not more than 2.5 meters high.
9. Arrange cartons with arrows pointing up (↑), and with identification labels, expiry dates and manufacturing dates clearly visible.
10. Store the Health commodities to facilitate ease of “First-to-Expire, First-Out” (FEFO) and stock management procedures.
11. Store the Health commodities separately and away from insecticides, chemicals, flammable products, hazardous materials, old files, office supplies and equipment.
12. Keep narcotics and other controlled substances in a locked place.
13. Separate damaged and expired Health commodities from usable commodities, remove them from inventory immediately and dispose them of using established procedures.



Explanatory Notes on Guidelines for Storage of Health Commodities

The following are general guidelines for storage of health commodities:

Task:	Storage of Health Commodities at Rural Health Facilities
Responsible Person:	Facility In-Charge/ Pharmacy In-Charge and Facility Committee Representative.
Objective:	To maintain quality and package integrity of health commodities
Storage Guidelines	Notes
1. Clean and disinfect storeroom regularly. Take precautions to prevent harmful insects and rodents from entering the storage area.	Rodents and some insects (for example, termites and roaches) like to eat certain health commodities. They also eat shipping cartons and inner packaging. Pest-proof your store to stop the pests from getting in. If your store becomes infested with pests, use appropriate pesticides; and use cats, which are effective against termites, rodents, roaches, etc. After you clear pests from the store, keep it clean. A clean store keeps pests away. Food and drinks in the warehouse increases the risk of pests.
2. Store health commodities in a dry, well lit, well-ventilated storeroom—out of direct sunlight.	A hot store may cause some of the commodity supplies to spoil, which will <i>decrease shelf life</i> . For example, the shelf life of Uni-Gold rapid HIV test is 9 months. However, the shelf life will probably be much shorter if the temperature inside the warehouse rises above 27°C. Although air conditioning is ideal, it is expensive. Alternatives are ceiling fans and/or forced ventilation. Direct exposure to sunlight can also reduce the shelf life of commodities. Use roofing and windows that shade the interior of the store from sunlight. Store supplies in their shipping cartons.
3. Protect storeroom from water penetration.	Water can destroy commodity supplies or their packaging. If packaging is damaged, the product is unacceptable to the client even if the commodity is undamaged. Repair the warehouse so water cannot enter. Other measures include stacking commodity supplies off the floor on pallets (at least 10 cm off the floor and 30 cm away from walls), because moisture can seep through walls and floors and into the commodity supplies.
4. Keep fire safety equipment available, accessible, and functional. Train employees to use it.	Stopping a fire before it spreads can save thousands of shillings in stored commodities and save the storage space. Keep fire extinguishers accessible and in working order. Keep one extinguisher near the door and others throughout the inside of larger warehouses. Ensure that the right equipment is available—water works on wood and paper fires but should not be used on an electrical or chemical fire. If a fire extinguisher is not available, keep sand or soil in a bucket nearby.
5. Store latex products away from electric motors and fluorescent lights.	Latex products, including gloves, can be damaged if they are directly exposed to fluorescent lamps. The lamps and electric motors create chemical called ozone, which can rapidly deteriorate gloves. Move glove boxes away from these sources. Leave gloves in paper boxes and cartons.

<p>6. Maintain cold storage, including a cold chain, as required.</p>	<p>Cold storage, including the cold chain, is essential for maintaining the shelf life of certain products. After these items are removed from cold storage and not used immediately, they become irrevocably damaged. If electricity is unreliable, it may be necessary to use bottled gas or kerosene-powered refrigeration. Cold boxes or insulated coolers may be sufficient for rapid transport. Ensure that all cold storage has a thermometer to monitor temperatures.</p>
<p>7. Limit storage area access to authorised personnel. Lock up controlled substances.</p>	<p>To ensure that all stock movement is authorised, lock the storeroom; limit access to persons other than authorised staff; and verify that both incoming and outgoing stock matches documentation. Periodically perform a systematic physical inventory to verify inventory records.</p> <p>More than one key to the storeroom should be available to ensure that the storeroom can always be accessed. However, the second key should not be available for everyone. Keep the key in a centrally located lock box, under the control of the In-Charge.</p>
<p>8. Stack cartons at least 10 cm off the floor, 30 cm away from the walls and other stacks, and no more than 2.5m high.</p> <p>Note: This may not be possible in all facilities.</p>	<p>Use pallets to keep products off floors to make them less susceptible to pest, water, and dirt damage. Stack pallets away from walls and far enough apart so an employee can walk completely around each pallet. This promotes air circulation and facilitates movement of stock, cleaning, and inspection.</p> <p>Pallets are usually more efficient than shelving, particularly for bulk items because they—</p> <ul style="list-style-type: none"> • Reduce the amount of unpacking for storage and repacking for delivery. • Facilitate shipment in lot sizes. • Are cheaper to construct. • Hold more stock for the space they occupy. <p>Most facilities are more likely to have shelving than pallets.</p> <p>Correct stacking of supplies will <i>avoid crushing cartons</i> at the bottom of a stack. Stack cartons no more than 2.5 meters high. This will also reduce potential injury to warehouse personnel.</p> <p>Keep commodities <i>away from walls to promote air circulation</i> and prevent cartons from moisture damage, which may occur if water condenses or penetrates walls.</p>
<p>9. Arrange cartons with arrows pointing up (↑), with identification labels, expiry dates, and manufacturing dates clearly visible.</p>	<p>Arrows indicate that the commodity should be stored with the arrows pointing up. Identification labels make it easier to <i>follow FEFO</i>, and make it easier to select the right product.</p> <p>If shipping cartons do not show either a date of manufacture or an expiration date, the date of receipt of supplies at the receiving warehouse should be clearly marked on the cartons and bin cards. Write large, easy-to-read numbers with a marking crayon. If the original markings are small or difficult to read, rewrite the manufacturing or expiration dates in large numbers.</p>
<p>10. Store health commodities to facilitate FEFO procedures and stock management.</p>	<p>Ensure FEFO is followed. Recently received commodity supplies may sometimes be <i>older</i> than the store's existing stock. On receipt of new stock, always review existing stock expiry dates to ensure FEFO.</p>

<p>11. Store health commodities away from insecticides, chemicals, flammable products, hazardous materials, old files, office supplies, and equipment; always take appropriate safety precautions.</p>	<p>Insecticides and other chemicals may affect the shelf life of many products. To make health commodities easy to access, keep other supplies away from health commodities. Some health commodities have a relatively short shelf life overall, and they must be moved quickly to the end user.</p> <p>Storing old junk may slow down access to products and take up needed storage space. Some medical procedures require the use of flammable products. Bottled gas or kerosene is used to power refrigerators, alcohol is used in sterilisation, and mineral spirits is used to power Bunsen burners. These products should be stored away from other products, near a fire extinguisher.</p>
<p>12. Separate damaged and expired health commodities from usable commodities, remove them from inventory immediately, and dispose of them using established procedures.</p>	<p>By separating these products, FEFO is more easily implemented. By destroying damaged products immediately, more space will be available.</p>
<p>This task is complete after—</p> <ul style="list-style-type: none"> • All health commodities are stored according to these guidelines. 	

Records/ Forms for Storage of Health Commodities



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Temperature Control Log: Bulk Store/ Outpatient pharmacy store

Month/Year:/201

Acceptable Range: +18–25°C

Date	A.M. Time	Recorded Temp (°C)	Acceptable Yes(✓)/No	Initials	P.M. Time	Recorded Temp (°C)	Acceptable Yes(✓)/No	Initials
1								
2								
3								
4								
5								
6								
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31								





Republic of Kenya

Temperature Control Log: Bulk Store /Pharmacy Refrigerator

Month/Year:201__

Acceptable Range: 2–8°C

Date	Time	Recorded Temp (°C)	Within Acceptable Range Yes(✓)/No	Initials
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
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31				



Storage Checklist



Republic of Kenya
STORAGE CHECKLIST

Checklist for Evaluating the Bulk Store

Instructions: Use the following guide to assess the bulk store area. You are advised to use a combination of techniques including making observations, key informant interviews and record reviews. After making your assessment, please tick (✓) the appropriate box (either YES or NO). For any additional comments depending on the feedback or observations, please make brief comments under the “Remarks” section.

Bulk Store	Yes	No	Remarks
GENERAL ORGANIZATION & APPEARANCE OF THE BULK STORE			
Is the room clean?			
Is their trash inside or near storage areas?			
Is there evidence of pests?			
Are products arranged for easy access with labels for each drug?			
Is there room for easy movement about storage area?			
Is the space sufficient?			
Are the ceilings, windows and doors in good condition?			
Is the bulk store secure?			
Are there lockable cabinets in the Bulk Store?			
Are all products and containers off the floor?			
Are containers stacked so they will not fall?			
Are different types of products/drugs stored separately, especially: Liquids, tablets, creams			
Are there stock/bin cards for each item?			





Republic of Kenya

Bulk Store	Yes	No	Remarks
Are the stock/bin cards next to the products/drugs?			
Are products with shorter expiration dates stored in front of others (FEFO)?			
Are products without expiry dates stored using the FIFO principle?			
Does the Store have electricity/power?			
Does the Store have a Functional fire extinguisher?			
Is the temperature in the Bulk Store adequately controlled?			
Is the bulk store equipped with cold room and/or refrigeration?			
Are the temperature monitoring charts/logs for the bulk store updated?			
Are the temperature monitoring charts/logs for the cold room and the refrigerator updated?			
PROCEDURES, SYSTEMS AND DOCUMENTATION			
Have there been stock-outs of any medicine in the storeroom in the last 6 months?			
Are there damaged, expired or excess levels of stock?			
Are Bin Cards Up to Date?			
How often are physical stock counts conducted?			
Is there documentation for physical stock counts?			
Is there a stock discrepancy report For commodities?			
Do you have written standard operating procedures for maintaining the bulk store in good condition?			
Do you have a written standard operating procedure for ordering?			





Republic of Kenya

Bulk Store	Yes	No	Remarks
Do you have a written standard operating procedure for Receiving?			
Do you have a written standard operating procedure for storing?			
Do you have a written standard operating procedure for stock control?			
Do you have a written standard operating procedure for stock rotation?			
Is there a way of tracking expiry dates of commodities?			
Is there a system of dealing with short-dated commodities?			
Is there clear instruction and procedure on disposal of expired commodities?			
Are there requisition forms?			
Are all orders prepared based on inventory levels /Consumption Report?			



Session 6: Issuing Health Commodities

Issuing Health commodities



1

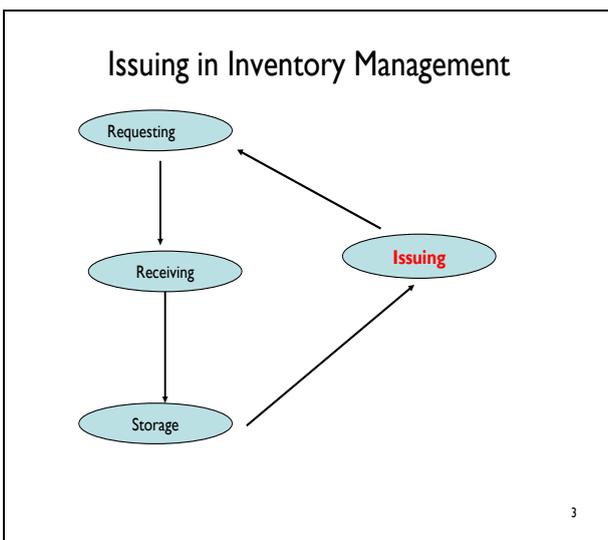
Objectives

At the end of this session, the participants will be able to:

- Describe the appropriate procedures used to issue commodities
- Describe the appropriate forms and records used to issue commodities
- Be able to issue commodities at a facility



2



How are Commodities Issued?

What is Issuing?

The process of moving commodities from one place to another.

- **Inter-facility issuing**
 - the movement of commodities *between* health facilities
- **Intra-facility issuing**
 - the movement of commodities *within* a facility, e.g. from the main hospital store to the lab



4

Tools used for Issuing of commodities

Forms used for issuing:

- S11 (Counter Requisition and Issue voucher) – for Intra-facility issuing
- S12 (Issue and Receipt voucher) – for Inter-facility issuing

Records used for reference when issuing:

- S5 (Bin card)



Procedure for Issuing

- 1) At the facility, fill in the following in the S11 clearly:-
 - Indicate point to which the issue is being made and the point of use
 - Include description of commodities, unit of issue and quantities to be issued
 - Depending on available quantities, determine the quantities to be issued compared to the quantities requested
 - Sign, date and stamp the form
- 2) Forward the appropriate copies to the relevant officers once the transaction is complete.



Guidelines for Issuing Commodities (I)

During the issuing process, ensure the following:

- Correctly fill the referenced information
- Correctly determine the issue quantity
- Fill in the issue form correctly and completely



Guidelines for Issuing Commodities

- Develop SOPs for Issuing Commodities
- Ensure that the points of use or sites you are issuing to are authorized by the facility and/or your SOPs
- Ensure proper forms are used and maintained, e.g. S11
- File all forms



Exercise: Let's practice - Issuing

Using the information below, please fill out the S11 form

Commodity	Code	Unit of issue	Quantity requested	Quantity Issued
Depot Medroxy progesterone (DMPA)	D001	100 vials	10	5
Combined Oral Contraceptive pills (COCs)	C001	1 cycle x 21's	100	100
Progesterone-only pills (POPs)	P001	1 cycle x 35's	50	48
IUCD (Copper T)	I001	1 set	13	11
Male condoms	M005	1 piece	1000	500

Assume:-

- Value of each commodity (per Unit of Issue) is 100/- for DMPA and 1/- for all others
- Issue point is Afya District store
- Point of Use is Tahidi health centre

9

Form S11 Counter Requisition and Issue Voucher

FORM S11						Serial No.....
REPUBLIC OF KENYA						
COUNTER REQUISITION AND ISSUE VOUCHER						
Ministry		Dept/Branch.....			Unit.....	
To (Issue point).....						
Please issue the stores listed below to (Point of use).....						
Code No.	Item Description	Unit of Issue	Quantity Required	Quantity Issued	Value	Remarks/Purpose
Account No:		Designation:			Date:	
Requisitioning Officer:					Sign:	
Issued by:					Date:	
Received by:					Sign:	

Completed S11

FORM S11						Serial No... XXXX
REPUBLIC OF KENYA						
COUNTER REQUISITION AND ISSUE VOUCHER						
Ministry HEALTH		Dept/Branch..... MEDICAL		Unit..... AFYA DISTRICT STORE		
To (Issue point)... AFYA DISTRICT STORE						
Please issue the stores listed below to (Point of use)..... TAHIDI HEALTH CENTRE						
Code No.	Item Description	Unit of Issue	Quantity Required	Quantity Issued	Value	Remarks/Purpose
1	<i>Depot Medroxy progesterone (DMPA)</i>	<i>100 Vials</i>	10	5	100	<i>RE-SUPPLY</i>
2	<i>Combined Oral Contraceptive pills (COCs)</i>	<i>1 cycle x 21's</i>	100	100	1	--
3	<i>Progesterone-only pills (POPs)</i>	<i>1 cycle x 35's</i>	50	48	1	--
4	<i>IUCD (Copper T)</i>	<i>1 set</i>	13	11	1	--
5	<i>Male condoms</i>	<i>1 Piece</i>	1,000	500	1	--
Account No:		Requisitioning Officer: A N OTHER ...		Issued by: ANNE NJAMA		Received by: A M WAMBA
		Designation: KRHCN		Designation: SO		Designation: KRHCN
		Date: ... 02/04/20X0		Sign: AN		Date: 03/04/20X0
		Date: 03/04/20X0		Sign: AW		

Session 7: Dispensing

**How to Dispense
Health Commodities**



Objectives

At the end of this session, the participants will be able to:

- Describe the appropriate procedures and records used to dispense medical commodities
- Be able to dispense for a facility



What is Dispensing?

Dispensing:
Is preparation and issuing of medicines to a patient on the basis of a prescription



Good Dispensing Practices

These ensure that:

- an effective form of the medicine is delivered to the right patient in the recommended dosage and quantity
- with clear instructions and in a package that maintains the potency of the medicine



The Dispensing process (1)

1. Receive Prescriptions

- Check information on patient, e.g. age, height, weight, Body Surface Area (BSA), pregnancy status
- Check validity of prescription
- Communicate with prescriber if prescription is unclear or incorrect



The Dispensing process (2)

2. Interpret Prescription

- Check the names of the medicines
- Check availability of medicine
- Check dosage, frequency, duration
- Check for medicine interactions



Prescription characteristics

A good prescription should have:

- Date
- Name of Patient
- Patient File number
- Age of patient
- Weight of patient
- Medicine dose
- Frequency and duration of treatment
- Prescriber's name and signature
- Address (name and telephone no.) of the facility



The Dispensing process (3)

3. Retrieve Medication from storage

- Select the appropriate medication
- Check storage condition
- Check Expiry date
- Use older stock (FEFO)
- Double-check medicine identity, strength, dosage form



The Dispensing process (4)

4. Prepare and Process

- Count or Reconstitute the medicines
- Put in appropriate container
- Label with dosage regimen, warnings/cautions



Sample Medicine Label

Name of Medicine..... Quantity.....
Batch No.....

Take _____ Caps/Tabs/mls _____ times daily
at _____ AM and _____ PM

Name _____ Date _____

Special Instructions: -----

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The Dispensing process (5)

- Communicate with Patient or caregiver on correct way to take medicines
- Ensure patient's / guardian's understanding of instructions on use of the medicines (demonstration may be needed)



The Dispensing process (6)

- Monitor Compliance by patient
- Monitor Adherence by patient

Note:

- Compliance to treatment: Regularity in taking treatment
- Adherence: Long-term continuity



The Dispensing process (7)

Keep Records

- Enter detail of encounter on electronic or manual patient profile cards
- Enter/record in prescription register
- Complete inventory records immediately (and/or dispensing records, e.g. DAR)



Factors that Promote Good Dispensing

- Availability of reference materials (National Guidelines, Manuals and BNF)
- Availability of Dispensing Aids, Dispensing envelopes, Counting trays
- Appropriate dispensing environment: Cleanliness, orderliness, storage shelves and cabinets
- Continuous and reliable supply of commodities







Exercise: Dispensing

4438109 M.O.H. 501 (Rev 1989)

N
 REPUBLIC OF KENYA
 MINISTRY OF HEALTH
 Name.....**NEWTON MUSEE**
 Department...**OP**
 No...**10473**
 Date...**23/04/2011**
 Rx
 Paracetamol 500mg tabs TDS x 3/7
 Erythromycin 500mg tabs TDS x 1/52
Dr Murigi, MBChB

For the prescription to the left:

- What are the gaps in this prescription?
- Discuss

17

Demonstration: Tools to aid in Dispensing

Medication Counseling checklist

Good Dispensing practices job aid



18

Thank you



Job Aid 1: Good Dispensing Practices



Good Dispensing Practices

1. Receive prescriptions

- Check accuracy of information on patient
- Check validity of prescription
- Verify any discrepancy with prescriber or patient
- Request for remaining pills and do a pill count



6. Keep records

- Update patient appointment card
- Complete all dispensing records at the time of dispensing



2. Interpret Prescription

- Review patient medication history to verify current regimen
- Check if medicine and dosage is appropriate
- Check for medicines interactions communicate
- Any discrepancies to prescriber



5. Counsel the patient

- communicate correct use of medicines to the patient
- ensure patient understands all instructions
- discuss side effects and important interactions



3. Retrieve medication from storage

- Select the appropriate medication
- Check the general condition of the medication
- Use "First Expire First Out" principle



4. Prepare and process

- Count medicines using dispensing tray or counter
- Put medicines in moisture-proof, light protective, child protective containers
- Label medication as per sample label
- Counter check medicines prepared against prescription



Job Aid 2: Medication Use Counseling



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Medication Use Counseling Checklist

1. Introduce yourself
2. Identify who is being counselled
3. Check what the client / patient or his/her representative already knows about the medicines
4. Make sure the client / patient or his/her representative understands how these medications work
5. Ask for the client / patient's questions and concerns
6. Give the name of medicine and describe appearance
7. Name the route of administration
8. Give directions/instructions
9. Give information on the possible drug interactions (herbs, other medicines)
10. Give information on the side effects of the medicines
11. Give instructions on how the medication should be stored
12. Check the understanding of the client / patient or his/her representative by asking them to repeat back to you key information. Remind them of information they left out.
13. Final check for questions and concerns



Session 8: LMIS

LMIS Reporting, Commodity & Information flow



Unit-specific Objectives

At the end of this unit the participants will be able to:

- Discuss the importance of logistics management information systems (LMIS) for health commodities
- Discuss the importance of the **flow of commodities and information** for management for health commodities
- Describe how data is collected and summarized into reports
- Identify the key data elements and records required to complete health commodity reports



Definition

Logistics Management Information System (LMIS)

- An organized system for **collecting, processing, and reporting** on the use of commodities to inform decision-making.
- The LMIS improves quality of commodity management decisions since it provides a means of tracking commodities as they enter and leave the supply system



Importance of LMIS

It indicates

- When to place an order for re-supply
- Higher or lower than expected consumption, necessitating adjustments to procurement and supply
- Helps prevent over- and under-stocking, stock-outs
- Stocks that may need re-distribution
- Provides information early on about
 - About expiring or short expiry stock
 - Sites with problems – needing supportive supervision



Information collection: what is important?

• How is information collected for LMIS?

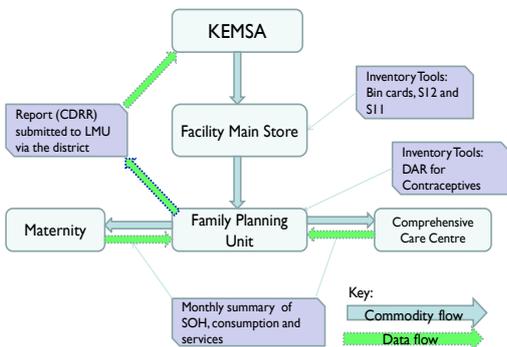
- Information is collected using
- Record-keeping documents, e.g. Bin card
 - Reporting forms, e.g. CDRR
 - Feedback reports

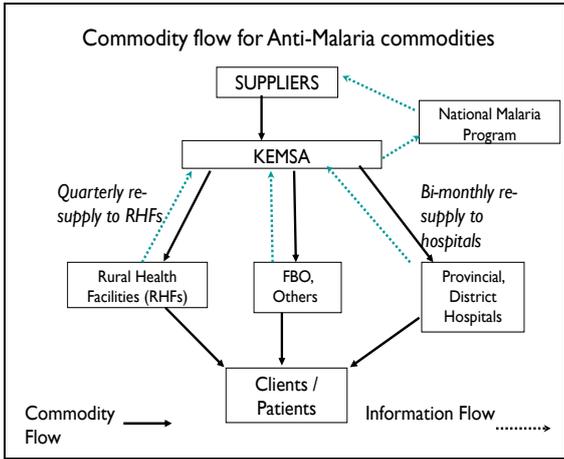
• What is the most important data?

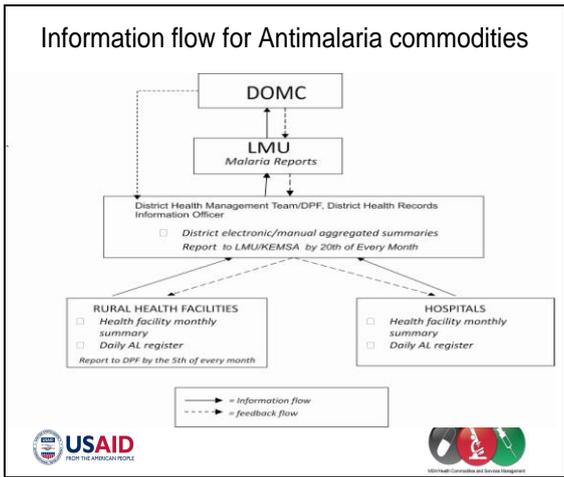
- **Stock on hand (SoH)** [or Physical count]
- **Consumption (Quantity Dispensed to the user)**
- **Losses & Adjustments (L&A)**



FP Program: Intra-Facility Commodity Flow







Importance of Reports

Definition:
 Reports are forms for collection of essential data from a specific Facility and specific time period

Reports:

- Make the collected data available to commodity managers in a useful form
- Summarize data covering activity over a period of time
- and / or Aggregate data covering a number of sites

Design of a reporting system

Key aspects of the design are:-

- How often to report?
- By When to report?
- Who is responsible for reporting?
- To whom are the reports sent?
- How are the reports transmitted?
 - Courier, email, hand delivery, etc



Challenges in Reporting

Why?

- No Reports!
- Late reports
- Inaccurate reports:
 - data collection errors; incorrect filling of the report; incorrect calculations
- Incomplete data collection- not all data elements are collected
 - Missing data; Missing facility details
- Old reporting formats / tools



Data Collection Tools

- ART:
 - DAR for ART patients
 - DAR for patients in care (OIs)
- FP
 - DAR for Contraceptives
- TB
 - DAR for TB & Leprosy drugs
- Malaria
 - AL Dispenser's Register
- Lab
 - DAR for Lab reagents & consumables



Data Reporting Tools

- EMMS
 - Standard Order & Report form
- ART:
 - Facility CDRR (Satellite sites, Standalone sites)
- FP
 - SDP CDRR
- TB
 - Facility TB & Leprosy commodities CDRR
- Malaria
 - Health Facility Monthly Summary report for Anti-Malaria medicines
- Lab
 - Facility CDRR for Lab Commodities
 - Facility CDRR for ART Lab Monitoring Reagents



Questions?

Discussion



Group Exercise

Using the sample data on the records and registers availed

- complete the register with the transactions
- complete the summary report provided



Exercises on FP commodity logistics reporting tools

Exercise 1: Filling in the Daily Activity Register (DAR) for Contraceptives

Materials needed:

For this exercise you will need:

- blank copies of the DAR for Contraceptives (MoH 512) – *provided below*
- a copy of the job aid for the completion of the DAR
- Pen and paper for rough-work or a calculator.

Assignment:

You are Nurse Jane Njema working at the MCH/FP clinic in Tahidi SDH. Your clinic provides a full range of FP services and also HIV counselling and testing. You keep some stocks of FP commodities at the clinic but the bulk of the stocks is kept in the hospital store.

At the end of the month May 20X0, you conducted a physical count and found the following stock balances at the MCH/FP clinic:

Stock count at the beginning of June 20X0:

Item	Levonorgestrel/ Ethinylestradiol tabs 0.15/0.03mg (1 x 21's) (Combined Oral contraceptive pills)	Levonorgestrel 0.03mg tabs (1 x 35's) (Progestin only pills)	Depot Medroxy- Progesterone acetate 150mg injection (Injectables)	Etonorgestrel implant 68mg (Implants (1- Rod))	Levonorgestrel tabs 750mcg (2 tabs) (Emergency contraceptive pills)	IUCDs "Copper T" (IUCDs)	Male condoms	Female condoms
	Cycles	Cycles	Vial	Set	Dose	Set	Pieces	Pieces
Stock Balance (as at 31 st May 20X0)								
At the MCH/FP clinic	30	50	30	50	50	20	0	30

Your clinic does not keep Cycle beads or Implants (2-Rod).

Based on your requests during the month, the hospital store supplied you with the following on S11s:

- Progestin only pills - 20 cycles (1 x 35's) on 1st June
- Male condoms – 300 pieces on 1st June
- Copper T IUCD - 10 sets on 28th June

The clients you served during the month of June are as follows:

2nd June:

- Anita, a revisit client aged 38, was given 3 cycles of Microgynon (Combined Oral contraceptive pills)

5th June:

- Wanja, a new client aged 21, was given 1 dose of Postinor II (Emergency contraceptive pills) and referred for HIV testing.
- Kanja, a new male client, 19 years old with multiple partners, requested information on STIs and male condoms. You counselled him on STIs and HIV&AIDS, and tested him. He was found to be HIV-positive and you gave him 30 condoms.

8th June:

- Mona, aged 28 and a revisit client, was given 20 pieces of female condoms.

10th June:

- Nora, a revisit client aged 33, who has been using the pill for 2 years, requested for an IUCD. She was not on her menses. Pregnancy was ruled out through use of FP checklists and the IUCD was inserted.

15th June:

- Jenny aged 28, a revisit, was given an injection of Depo provera (Injectables).

21st June:

- Joy, a new client aged 36, was referred for Implanon (Implants (1-Rod)) insertion by a CHEW. You assessed her, found her eligible for the method and inserted the implant.

25th June:

- Lucy, a 27-year old revisit client who is breast-feeding a 6-week old baby, requested for oral contraceptives and you gave her 3 cycles of Microlut (Progestin only pills).
- Jane, a 24 year old revisit client previously on Lo-Femenal (Combined Oral contraceptive pills), was changed to Depo Provera (Injectables) on request.

30th June:

- Liza, 27 years old and a revisit, who is going out of the country, was given 6 cycles of Microgynon (Combined Oral contraceptive pills).

On 29th June, you noticed that 10 of the Postinor II (Emergency contraceptive pills) after doses in the clinic were expiring on 30th June so you returned them to the hospital store.

Instructions:

You are required to complete the DAR for Contraceptives using the above transactions made in June.

Exercise 2: Filling in the SDP Consumption Data Report and Request Form (CDRR)

Materials needed:

For this exercise you will need:

- blank form of the SDP CDRR – *provided below*
- a copy of the job aid for the completion of the SDP CDRR
- Pen and paper for rough-work or a calculator.

Assignment:

You are Nurse Jane Njema working at the MCH/FP clinic in Tahidi SDH, which is located in Central district of Northern province. The hospital store is managed by Kweli Mawe, the store man, while the Medical Superintendent in-charge of your facility is Felix Anza.

On 1st July 20X0, you and the store man, Kweli Mawe, sat down together to compile the monthly report for the month of June 20X0.

You and the store man counted the following closing stock balances at the hospital store and the FP clinic:

Stock count at the beginning and end of the month of June 20X0:

Item	Levonorgestrel/ Ethinylestradiol tabs 0.15/0.03mg (1 x 21's) (Combined Oral contraceptive pills)	Levonorgestrel 0.03mg tabs (1 x 35's) (Progestin only pills)	Depot Medroxy- Progesterone acetate 150mg injection (Injectables)	Etonorgestrel implant 68mg (Implants (1- Rod))	Levonorgestrel tabs 750mcg (2 tabs) (Emergency contraceptive pills)	IUCDs "Copper T" (IUCDs)	Male condoms	Female condoms
	Cycles	Cycles	Vial	Set	Dose	Set	Pieces	Pieces
Stock Balance (as at 31 st May 20X0)								
At the hospital store	0	30	0	0	10	30	660	0
Stock Balance (as at 30 th June 20X0)								
At the hospital store	0	10	0	0	20*	20	160	0

*Includes 10 doses that expired on June 30th.

During the month, there were no stock receipts from KEMSA, however the storeman transferred 200 pieces of male condoms to Afya Health centre.

Instructions:

Using the data provided above, you are required to complete the monthly commodity consumption report for the Service Delivery Point (SDP) Tahidi SDH for the month ending June 20X0.

The instructions / job aids for the completion of the DAR and the SDP CDRR are provided.

Note:

To complete the column **Quantity Requested**:

To calculate the Quantity to order for each contraceptive, multiply the number in the **Dispensed** column by 4, and then subtract the **Ending Balance**.

This gives you the quantity requested to top up to a 4-month Maximum stock level.

For example: If the number of male condoms dispensed in the month is 3,000 pieces and the Ending balance from your physical count is 2,000, what is the Quantity Requested?

Answer:

$$(3,000 \times 4) - 2,000 = 12,000 - 2,000 = 10,000$$

If the calculated quantity to order is negative, fill a zero (0) in the column.

MINISTRY OF HEALTH
SDP CONTRACEPTIVES CONSUMPTION
DATA REPORT AND REQUEST FORM

Province/County:	District:
Full SDP Name:	MFL No.:
Facility Type:	<input type="checkbox"/> Dispensary <input type="checkbox"/> H/C <input type="checkbox"/> SDH <input type="checkbox"/> DH <input type="checkbox"/> PGH <input type="checkbox"/> Referral Hospital
Agency:	<input type="checkbox"/> GoK <input type="checkbox"/> FBO <input type="checkbox"/> NGO <input type="checkbox"/> Private
Reporting Month:	Beginning <input type="text" value="20"/> Ending <input type="text" value="20"/>

Contraceptive	Beginning Balance	Received This Month	Dispensed	Losses	Adjustments	Ending Balance	Quantity Requested
Combined Oral contraceptive pills							
Progestin only pills							
Injectables							
Implants (1-Rod)							
Implants (2-Rod)							
Emergency contraceptive pills							
IUCDs							
Male Condoms							
Female Condoms							
Cycle Beads							

SERVICE STATISTICS (Indicate only the number of Clients issued with Contraceptives)

	New Clients	Revisits	Change of method		New Clients	Revisits	Natural FP Counseling	Natural FP Referrals
			From	To				
Combined oral contraceptive pills								
Progestin only pills								
Injectables								
Implants (1-Rod)								
Implants (2-Rod)								
IUCDs								
Male Condoms								
Female Condoms								
Standard Days Method (SDM)								
Others								

HIV COUNSELING & TESTING			
Counseled & Tested	Referred for Counseling & Testing	Known HIV status	
		1	2

Comments: (Logistics and Clinical)

Submitted by:	Name	Signature
Designation:		Date:

Exercises on Laboratory Commodity Logistics Reporting Tools

Exercise 1: Filling in the Daily Activity Register (DAR)

Materials needed:

For this exercise you will need:

- blank copies of the DAR for Laboratory Reagents and Consumables (MoH 642) – provided below
- a copy of the job aid for the completion of the DAR
- Pen and paper for rough-work or a calculator.

Assignment

Use the following to fill in the DAR:-

You are John Mali, working on the Serology and Haematology bench at Serowe District Hospital (DH). You are working on the day shift for the entire month of March 20XX, and there is no night shift.

You started the month with quantities indicated in the table below. On 1st March, using the Lab Top-up form, you requested and received the following commodities from the Lab store:-

Commodity name	Batch No.	Expiry date	Beginning balance	Quantity received
Rapid Test kit – HIV screening	0060	Dec 20XX	200	500 tests
Carbol Fuschin solution	0020	Sept 20XX	0	500ml
Malaria Rapid diagnostic test (RDT)	A0254	Dec 20XX	0	40 tests
FACS Count CD4CD3 reagent (Adult)	00125	June 20XX	0	50 tests

During the month, you conducted the following transactions:

March 2nd

- 20 tests for HIV

March 5th

- 30 tests for HIV
- 15 TB AFB microscopy smears (Note: each smear uses 3ml of Carbol fuschin solution)

March 18th

- 50 tests for HIV
- 15 malaria tests using the RDT, including 1 repeat test. Of these, 10 were for patients < 5years and 4 of these turned positive, while 4 were for patients aged 5 years and above, and all were negative.
- 15 TB AFB microscopy smears (note: each smear uses 3ml of Carbol fuschin solution)

March 29th

- 30 CD4 tests plus 2 controls
- 100 tests for HIV

During the month, you also made the following adjustments:

- On 30th March, you noticed 100 Rapid HIV tests had been damaged by rain water
- On 29th March, you gave 30 Rapid HIV tests to the MCH clinic for HIV testing under PMTCT
- Assume you had no stock-out days

Instructions

Please complete the DAR pages provided below using the information provided above.

Blank page of DAR 1:

MOH 642																
Bench / Section:							Name of Commodity:									
Date	Shift	Unit of Issue	Beginning balance at the Bench / section	Quantity Received during the Shift	Origin of the received stock	Batch Number	Expiry Date	Quantity used during the Shift	Number of Tests done during the Shift	Losses during the Shift	Adjustments during the Shift [Indicate if (+) or (-)]		Ending Balance at the end of the Shift	Remarks (including explanation for Losses or Adjustments)	Name of officer	Signature
											Positive	Negative				
Page Totals																
Date:			Balance carried forward:							Days out of stock:						
			<i>(use the Ending Balance quantity from last row on the page)</i>													

Blank page of DAR 2:

MOH 642																
Bench / Section:							Name of Commodity:									
Date	Shift	Unit of Issue	Beginning balance at the Bench / section	Quantity Received during the Shift	Origin of the received stock	Batch Number	Expiry Date	Quantity used during the Shift	Number of Tests done during the Shift	Losses during the Shift	Adjustments during the Shift [Indicate if (+) or (-)]		Ending Balance at the end of the Shift	Remarks (including explanation for Losses or Adjustments)	Name of officer	Signature
											Positive	Negativ				
Page Totals																
Date:				Balance carried forward:				Days out of stock:								
				<i>(use the Ending Balance quantity from last row on the page)</i>												

Blank page of DAR 4:

MOH 642																
Bench / Section:							Name of Commodity:									
Date	Shift	Unit of Issue	Beginning balance at the Bench / section	Quantity Received during the Shift	Origin of the received stock	Batch Number	Expiry Date	Quantity used during the Shift	Number of Tests done during the Shift	Losses during the Shift	Adjustments during the Shift [Indicate if (+) or (-)]		Ending Balance at the end of the Shift	Remarks (including explanation for Losses or Adjustments)	Name of officer	Signature
											Positive	Negative				
Page Totals																
Date:				Balance carried forward:				Days out of stock:								
<i>(use the Ending Balance quantity from last row on the page)</i>																

Exercise 2: Filling in the Facility Consumption Data Report and Request Form (FCDRR)

For this exercise you will need:

- blank copy of the F-CDRR for ART Laboratory monitoring reagents
- blank copy of the F-CDRR for Laboratory commodities (MoH 643)
- filled DAR for Laboratory Reagents and Consumables (MoH 642) – from Exercise 1 above
- a copy of the job aids for the completion of the F-CDRRs
- Pen and paper for rough-work or a calculator.

On 1st April, the Lab Tech in/charge, Felix Mambo, and the hospital store person sat down together to compile the monthly report for the month of March 20XX for Serowe DH, which is located in Central district of Northern province.

They conducted a physical count and found the following closing stock balances at the District hospital store, and then compared with the Laboratory stock cards for the various commodities. They then compiled the following information:

Stock count at the beginning and end of the month of March 20XX:

Item	Rapid Test kit – HIV screening	Carbol Fuschin solution	Malaria Rapid diagnostic test (RDT) kit	FACS Count CD4CD3 reagent (Adult)
	Tests	mls	Tests	Tests
Stock Balance (as at 29 th February)				
At the hospital store	150	0	120	50
Received during the month Date of receipt: 1 st March 20XX	600 Batch/Lot No. 0065	1000 ml Batch/Lot No. 0020	0	50 Batch/Lot No. 00126
Expired during the month	0	0	10	0
Stock Balance (as at 31 st March)				
At the hospital store	250	300	70	100

The stock receipts from KEMSA and the District store during the month are noted in the table above.

Adjustments: During the month, the Lab Tech in/charge issued to Kutus Health centre 200ml of Carbol Fuschin solution. In the same month, the DH received 50 tests of FACS Count CD4CD3 reagent (Adult) from Faidha PGH.

The PMTCT clinic, being the other user point in the DH, provided the following report for the month:-

Name of commodity	Beginning balance	Adjustments	Quantity used	Number of Tests done	Balance carried forward	Days out of stock
Rapid Test kit – HIV screening (tests)	10	+30 (from Serology bench)	10	10	30	0

The PMTCT clinic had no losses and adjustments.

The Lab Tech in-charge also noted that the F-CDRR for ART Laboratory monitoring reagents was nearly finished so another copy of the tool should be ordered.

Using the data provided above and the completed DAR from No. 1, you are required to complete the following reports on behalf of Felix Mambo

F-CDRR for ART Laboratory monitoring reagents, and

F-CDRR for Laboratory commodities (MoH 643)

for Serowe DH for the month ending 31st March 20XX.

Blank page of F-CDRR for Laboratory commodities (MoH 643):

MOH 643

MINISTRY OF HEALTH

FACILITY CONSUMPTION DATA REPORT AND REQUEST (F-CDRR) FOR LABORATORY COMMODITIES

Name of Facility:		Facility Code:		Type of service	No. of Tests done
District:		Province / County:		Applicable to HIV Test Kits only	
				VCT	
				PITC	
Affiliation:		Ministry of Health	Local Authority	FBO	
		NGO	Private		
				PMCT	
				Blood screening	
				Other (please specify)	
Report for Period:		Beginning:		Ending:	
		dd/mm/yyyy		dd/mm/yyyy	
				Applicable to Malaria testing only	
				Test	Category
					No. of Tests performed
					No. Positive
				RDT	Patients under 5 years of age
					Patients aged 5 years and over
				Microscopy	Patients under 5 years of age
					Patients aged 5 years and over

Commodity Name	Unit of Issue (e.g. Test)	Beginning Balance	Quantity Received	Quantity Used	Number of Tests done	Losses	Adjustments [Indicate if (+) or (-)]		End of Month Physical count	Quantity expiring in less than 6 months	Days out of stock	Quantity Requested for Re supply
							Positive	Negative				
MALARIA-RELATED LABORATORY												
Malaria Rapid Diagnostic Test (RDT) kit												
Field Stain A												
Field Stain B												
Giemsa Stain												
TB-RELATED LABORATORY COMMODITIES												
Auramine-O (*for District hospital labs)												
Carbol Fuschin (solution)												
Falcon tubes												
Hydrochloric acid (HCL)												
Lens Tissue												
Methylene Blue												
Microscope slides												
Potassium Permanganate (*for District hospital labs)												
Sputum mugs (AFB Polypots with lids)												
Sulphuric acid												
HIV-RELATED LABORATORY COMMODITIES												
Rapid HIV 1+2 Test 1 - Screening												
Rapid HIV 1+2 Test 2 - Confirmatory												
Rapid HIV 1+2 Test 3 - Tiebreaker												
Hepatitis B (ELISA) Test (Hepanostika)												
Hepatitis C (ELISA) Test (Murex HCV)												
ELISA HIV & AIDS 1+2 Test (Vironostika)												
ELISA HIV & AIDS 1+2 Test (Murex HIV)												
Rapid Syphilis Test (RPR)												

Explain Losses & Adjustments:

--

Order for extra LMIS tools:-

To be requested only when your Data collection or reporting Tools are nearly full. Indicate quantity required for each tool type.

(1) Daily Activity Register for Laboratory Regents and Consumables (MOH 642):

(2) F-CDRR for Laboratory Commodities (MOH 643):

Completed by:	Tel:	Designation:	Sign:	Date:
Approved by:	Tel:	Designation:	Sign:	Date:

Exercises on the Anti-Malaria medicines commodity logistics reporting tools

Exercise 1: Filling in the Daily AL Register

Materials needed:

For this exercise you will need:

- blank copies of the Daily AL Dispenser's Register (provided on following page)
- a copy of the job aid for the completion of the Daily AL register
- Pen and Paper for rough-work or calculator.

Assignment:

Hodari health centre in Kisumu district received a delivery of AL on 30th August 2011 on the KEMSA delivery note number D 456.

The following AL quantities were received in packs of 30's:-

- 6's – 2 packs
- 12's – 0 packs
- 18's – 5 packs
- 24's – 1 pack

Previously the health facility had been stocked out of AL.

On the same day, the pharmaceutical technologist then issued to the following quantities (in packs of 30's) from the store to the out-patient clinic using S11 No. 99:-

- 6's – 2 packs
- 12's – 0 packs
- 18's – 2 packs
- 24's – 1 pack

The following patients were seen on the dates shown:-

1. 30th August 2011
 - a. OP 23456 – Weight 20 kg - the nurse dispensed 2 of the 6's to the patient as the 12's pack was stocked out
 - b. OP 23457 - Weight 12 kg
 - c. OP 23458 - Weight 60 kg
 - d. OP 23459 - Weight 66 kg
 - e. OP 23460 - Weight 15 kg – similarly 2 of the 6's were dispensed to the patient
2. 31st August 2011
 - a. OP 23461 - Weight 45 kg
 - b. OP 23462 - Weight 15 kg – half of the 24's was dispensed
 - c. OP 23463 - Weight 22 kg – half of the 24's was dispensed.

Please fill the Daily AL Dispenser's register using the information provided.

Exercise 2: Filling in the Health Facility Monthly Summary report for Anti-Malaria medicines

Materials needed:

For this exercise you will need:

- blank form of the Health Facility Monthly Summary report
- a copy of the job aid for the completion of the Health Facility Monthly Summary report
- Pen and Paper for rough-work or calculator.

Assignment:

You are Nurse Jane Njema working at Hodari health centre in Kisumu district.

On 1st Sept 2011, you and the pharmaceutical technologist, Felix Dawa, sat down together to compile the monthly report for the month of August 2011.

You both counted the following closing stock balances at the health centre store and the Out-patient clinic:

Stock count at the beginning and end of the month of August:

Item	AL 6's	AL 12's	AL 18's	AL 24's
	Packs (30's)	Packs (30's)	Packs (30's)	Packs (30's)
Stock Balance (as at 31 st July)				
At the health centre store	0	0	0	0
Stock Balance (as at 31 st August)				
At the health centre store	1	0	1	0

During the physical count, for AL 6's, 1 pack was found to have expired while the rest of the stock had good expiry dates greater than 6 months.

The stock receipts from KEMSA during the month are noted in Exercise 1 above.

There were no other types of losses for the period. During the month, Hodari transferred to Gari dispensary 2 packs of AL 18's.

Assume the facility did not have stocks of any other Anti-malarial commodities.

Using the data provided above, you are required to complete the Health Facility Monthly Summary report for Anti-Malaria medicines for Hodari health centre for the month ending 31st August 2011.

Blank page of Health Facility monthly summary report

MINISTRY OF HEALTH HEALTH FACILITY MONTHLY SUMMARY REPORT FOR MALARIA MEDICINES												
Province:				District:								
Facility Name:												
Facility Type: <input type="radio"/> Level 2			<input type="radio"/> Level 3			<input type="radio"/> Level 4			<input type="radio"/> Level 5			<input type="radio"/> Level 6
Period of Reporting: Beginning:				Ending:								
(Day/Month/Year)				(Day/Month/Year)								
Drug name	Basic Units	Beginning Balance	Quantity Received this period	Total Quantity dispensed	Losses (Excluding Expiries)	Postive Adjustments	Negative Adjustments	Physical Count	Quantity of Expired Drugs	Medicines with 6 months to Expiry	Days out of stock	Adjusted Consumption (to be filled by DPF)
		A	B	C	D	E	F	G	H	I	J	C x (Period covered (days) / Days in Stock)
Antimalaria Drugs												
Artemether-Lumefantrine 20/120 Tabs	6s											
Artemether-Lumefantrine 20/120 Tabs	12s											
Artemether-Lumefantrine 20/120 Tabs	18s											
Artemether-Lumefantrine 20/120 Tabs	24s											
Quinine Tabs (200mg)	Tabs											
Quinine Tabs (300mg)	Tabs											
Quinine inj (600mg/2ml)	Amps											
Sulphadoxine Pyrimethamine	Tabs											
Rapid Diagnostic Tests	Tests											

Patients on AL by Weight Band Summary:-																																					
5 -14 kgs <input style="width: 50px;" type="text"/>			15 -24 kgs <input style="width: 50px;" type="text"/>			25 -34 kgs <input style="width: 50px;" type="text"/>			35+ kgs <input style="width: 50px;" type="text"/>																												
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td colspan="5" style="text-align: center;">RDT TEST RESULTS</td> </tr> <tr> <td style="width: 15%;">Age (Years)</td> <td style="width: 15%; text-align: center;">< 5</td> <td style="width: 15%; text-align: center;">5-14</td> <td style="width: 15%; text-align: center;">>14</td> <td style="width: 15%; text-align: center;">TOTAL</td> </tr> <tr> <td>Positive</td> <td></td> <td></td> <td></td> <td style="text-align: center;">0</td> </tr> <tr> <td>Negative</td> <td></td> <td></td> <td></td> <td style="text-align: center;">0</td> </tr> <tr> <td>Invalid</td> <td></td> <td></td> <td></td> <td></td> </tr> </table>													RDT TEST RESULTS					Age (Years)	< 5	5-14	>14	TOTAL	Positive				0	Negative				0	Invalid				
RDT TEST RESULTS																																					
Age (Years)	< 5	5-14	>14	TOTAL																																	
Positive				0																																	
Negative				0																																	
Invalid																																					
Number of days facility did NOT have ANY of the AL packs <input style="width: 50px;" type="text"/>																																					
Number of Pregnant women receiving IPTp <input style="width: 50px;" type="text"/>																																					
Comments (including explanations of losses and adjustments):																																					
Report Prepared by:				Name of Reporting officer				Signature				Designation																									
Contact Telephone:				Date:																																	
Report reviewed by:				District Pharmaceutical Facilitator				Signature				Designation																									
Contact Telephone:				Date:																																	

To be Submitted to the District Pharmaceutical facilitator by the 5th Day of Every Month)

Session 9: Appropriate Medicines Use

Overview: AMU Framework,
Clinical Guidelines & the
Essential Medicines List



Objectives

- Define appropriate medicine use
- List factors contributing to inappropriate medicine use
- Describe the AMU Framework
- Describe the background and organization of the clinical guidelines and the essential medicines list
- Discuss the process of revising the clinical guidelines & essential medicines list



What Is Rational Use of Medicines?

The rational use of drugs requires that patients receive medicines 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 the community
(WHO 1985)

- > Appropriate indication
- > Appropriate drug
- > Appropriate administration, dosage, and duration
- > Appropriate patient
- > Appropriate patient information
- > Appropriate evaluation



Aspects of Irrational Medication Use (1)

- **Diagnosis**
 - Inadequate examination of client / patient
 - Incomplete communication between patient and doctor
 - Lack of documented medical history
 - Inadequate follow-up/support of clients / patients
- **Prescribing**
 - Extravagant prescribing
 - Over-prescribing
 - Incorrect prescribing
 - Under-prescribing
 - Multiple prescribing



Aspects of Irrational Medication Use (2)

- **Dispensing**
 - Incorrect interpretation of the prescription
 - Retrieval of wrong medications or ingredients
 - Inaccurate counting or preparation
 - Inadequate labeling and instructions (both verbal and written)
 - Unsanitary procedures (e.g. dirty environment, hands)
 - Packaging
 - Poor-quality packaging materials
 - Odd package size, which may require re-packaging
 - Unappealing package e.g. for condoms



Aspects of Irrational Medication Use (3)

- **Patient adherence**

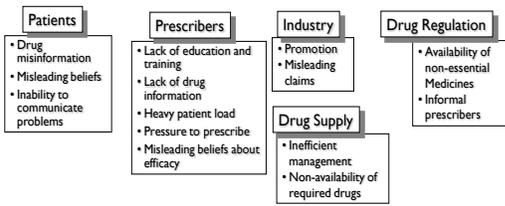
e.g. Missing of doses, taking drugs without regard to food, drug-drug interactions, etc,

due to:

 - Therapy and dosage instructions that do not consider the patient's beliefs, environment or culture (e.g. *use of contraceptives in Catholics*)
 - Patient's literacy level
 - Socio-economic status (family burden, transportation)
 - Other conditions (poor eyesight, poor hearing, etc)
 - Other illnesses (e.g. psychiatric problems, diabetes)

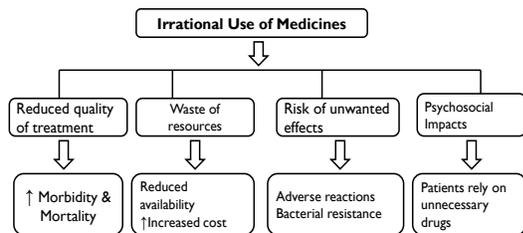


Factors Underlying Irrational Use of medicines

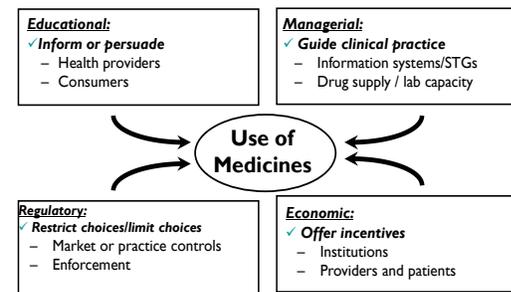


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Results of Inappropriate medicine use

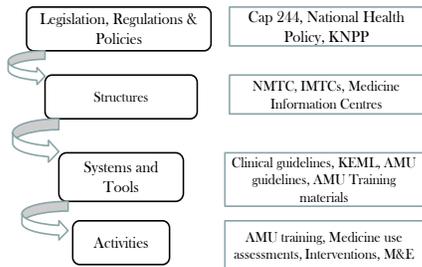


Approaches to improving medicine use



9

Framework for Supporting AMU in Kenya

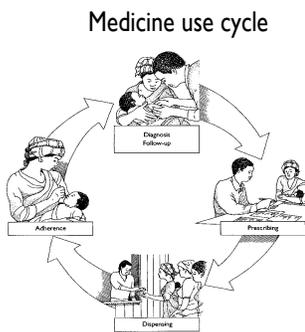


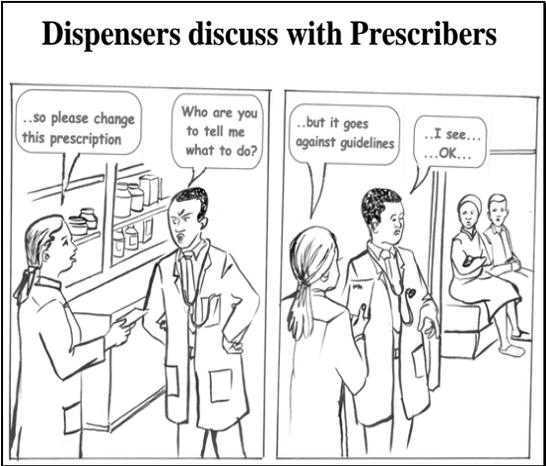
AMU Activities at institutional level

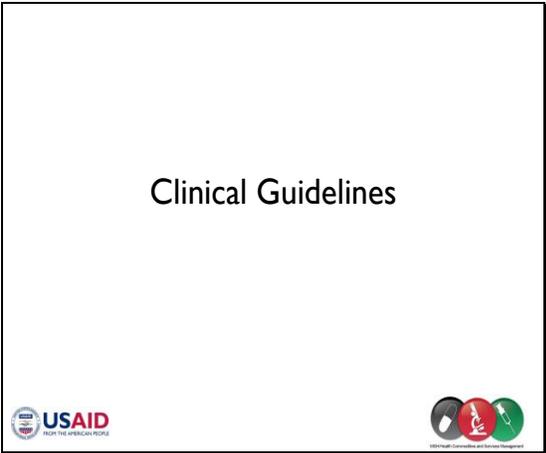
- Institutional MTCs lead & provide oversight for AMU activities including
 - Evaluating and selecting medicines- based on the KEML, SCGs and morbidity patterns
 - Developing medicine policies and procedures e.g. institutional AB policies, medicine procurement guidelines
 - Identifying medicine use problems
 - Promoting effective interventions to improve use of medicines
 - CME and AMU trainings



AMU Activities at the individual HCW level : Discussion







Clinical guidelines- Definition

- **Definition-** Document(s) designed to assist healthcare providers in making **appropriate** decisions when diagnosing, treating or managing diseases or conditions

Clinical guidelines- Purpose

- To provide guidelines for standardized management of patients
 - Define management approaches for key conditions
 - Define care protocols by level of service delivery
- To provide clearly articulated guidelines for referral
 - Provide linkages needed across different levels of the health system
 - Rationalize the delivery of services within the health system



Rationale for revision

Last edition of clinical guidelines produced in 2002

- New management protocols in health
- New / emerging disease conditions
- Re-defined comprehensive approach to community services
- 2002 guidelines not aligned to current priorities
- Revised sector Service Delivery Approach
 - Defined services at different levels
 - Referral care being prioritised

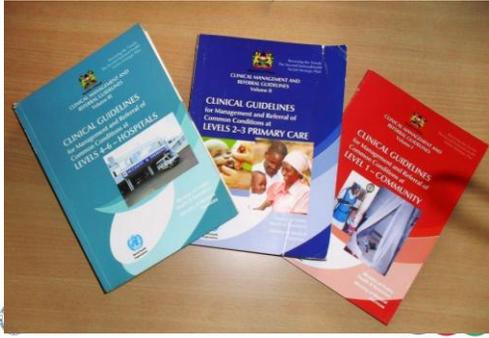


Organization

- For ease of reference and use, the guidelines are presented in 3 volumes
 - Volume I- Community level [KEPH level 1]
 - Volume II- PHC level [KEPH level 2 &3]
 - Volume III- Hospital level [KEPH level 4-6]



Clinical Guidelines



Kenya Essential Medicines List



Introduction

- KEML derived from the national clinical guidelines
 - Lists medicines classified as essential for the country's health system
- Based on the concept of essential medicines, defined by WHO as:
 - those that meet priority health care needs of the population



Layout of KEML

Cover Page



Content Areas

Background Information

- Essential medicines concept
- Revision process & Use

List of Medicines

- Listed by therapeutic categories
- Alphabetical Index

22

Item coding in the KEML

- There are three codes which characterize each item on the KEML- examples

Drug	Dose/form	Size/strength	LOU	VEN	AB
Digoxin	Tablet	250 mcg	4	V	A
Ampicillin	PFI	500mg	4	E	B

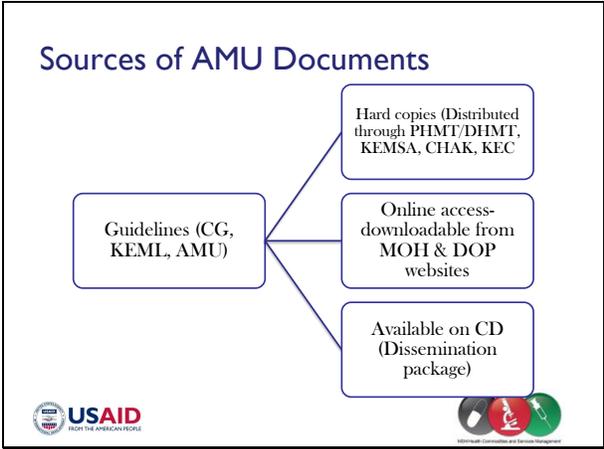
Item Codes



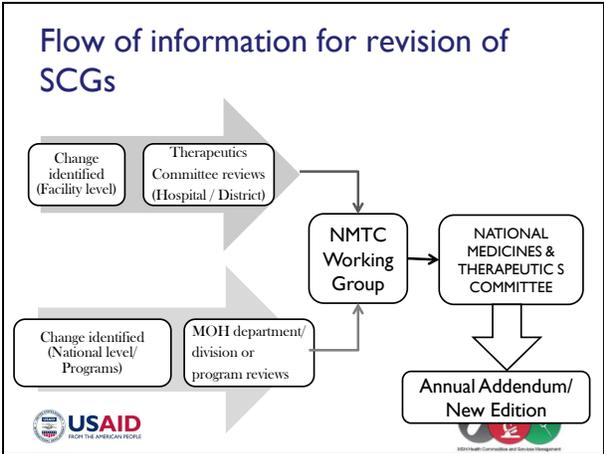
Main uses of the KEML

- Procurement, supply and distribution
- Healthcare financing and medicines supply budgeting
- Healthcare workforce development
 - Key references for training of health workers
 - Providing the correct orientation on evidence-based management of health conditions
- Appropriate medicine use
 - Basis for designing strategies and initiatives to improve medicine use
- Antimicrobial resistance and antibiotic use policies
- Medicine policy monitoring and operational research
- Pharmaceutical manufacturing
 - Basis for local manufacturing decisions focusing on priority health items and formulations





- ### Roles of provincial/ district teams in Use of SCGs and KEML
- Train health workers at lower levels
 - Support supervision of health workers
 - M&E of the utilization process
 - Support implementation of IMTC for uptake of guidelines
- Logos: USAID, Ministry of Health and Family Welfare



CLINICAL MANAGEMENT GUIDELINES AMENDMENT PROPOSAL FORM

Mail or drop at: Ministry of Medical Services, Department of Pharmacy, Attention NMTC Secretariat, P.O Box 30016-00100, Nairobi. Room 502, 5th Floor Alfa House, Cathedral Way, Nairobi.

SECTION A: TO BE COMPLETED BY THE APPLICANT

Applicant's Contact Details **Date of Application:** _____
Name: _____ **Designation:** _____
Institution: _____ **Telephone:** _____ **Email:** _____

Type of Amendment Proposed (Please tick)
A. Erratum/Corrigendum B. Changes to management protocols
C. Changes to medicine D. Inclusion of new disease management
E. Other reasons (State) _____

Location of the proposes change in guidelines: Volume _ Chapter _ Page Number(s) _____

Description of desired changes (Attach additional page if needed) _____

Supporting evidence (Attach documentation e.g. list of publications, references) _____

SECTION B: TO BE COMPLETED BY THE NMTC SECRETARIAT

Date application received: _____ Received by: _____ Date submitted to NMTC: _____

NMTC Decision: _____

Date decision communicated to applicant: _____

Thank you



Session 10: Pharmacovigilance

PHARMACOVIGILANCE

**ENSURING SAFE USE OF
MEDICINES**



Objectives

By the end of this session participants will be able to

- Define pharmacovigilance, adverse drug reactions, and side effects
- Explain the rationale for Pharmacovigilance
- Discuss the roles and responsibilities of health care workers in pharmacovigilance
- Discuss the Guideline for the National Pharmacovigilance System in Kenya
- Discuss the tools for reporting in pharmacovigilance



What do you see here? When did this happen first?



Definition of Pharmacovigilance

“Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines, with the view to:

- Identifying new information about hazards, and
- Preventing harm to patients.”

From:

- Greek *pharmakon* - drug
- Latin *vigilare* - to keep awake or alert, to keep watch



What is an adverse drug reactions?

- A response to a medicine which is **noxious** and **unintended**, and which occurs at **doses normally used** in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function¹.

¹ WHO Technical Report No 498 (1972)



What is a side effect?

- Any **unintended effect** of a pharmaceutical product occurring at **doses normally used** in humans, which is **related to the pharmacological properties of the medicine**



Why Pharmacovigilance?



Why Pharmacovigilance?

- To minimize harm
 - 'Drugs are double-edged weapons'
 - do good
 - do harm
- To control economic impact
 -Adverse reactions are a cost of modern medical therapy.....
 - Goodman and Gilman, 1995



New Areas in Pharmacovigilance

These include:

- Product development
- Substandard and counterfeit medicines
- Medication error reporting
- Efficacy monitoring
- Off-label use of medicines
- Case reports of acute and chronic poisoning
- Assessment of drug-related mortality
- Abuse and misuse of medicines reports
- Adverse interactions of medicines with chemicals, other medicines, and food reports



Healthcare Providers supporting Pharmacovigilance

- Pharmacists
- Pharmaceutical technologists
- Clinicians (Consultants, Medical Officers and Clinical Officers)
- Nursing Officers
- Laboratory technologists
- Records officers



Role of the Prescriber

Every medicine prescribed has risk : benefit relationship

The prescriber should:

- consider risk : benefit relationship of each medicine
- prescribe the safest medicine among those of similar efficacy
- explain to the patient the nature, purpose and risks associated with the treatment
- ensure that the patient consent is based on an adequate understanding of the likely risks and benefits
- Report all suspected ADRs



Role of the Nurse

- Collect important ADR related information that a patient may not reveal to a doctor
- Inform clinicians of concerns in a patient's vital signs and laboratory reports



Role of the Pharmacist

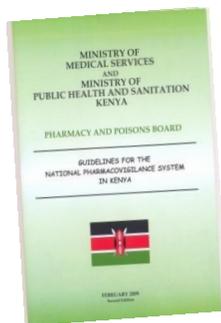
- Ensuring that medicines are used safely
- Prevention and early detection of suspected ADRs through involvement in patient care
- Review of treatment charts and medication counseling to alert patients of potential ADRs
- Collecting data on ADRs
- Educating other healthcare professionals about the prevention, detection and reporting of suspected ADRs.



National Pharmacovigilance Guidelines and Tools



Guidelines for the National Pharmacovigilance System in Kenya



Guideline contents

- Introduction to ADRs and PV
- The proposed PV system in Kenya
- Reporting
- Flow of information
- Tools in PV
- ADR monitoring
- Roles and responsibilities
- Roll out and training
- Principles of efficient reporting
- Annexes and references



Tools

- Yellow form (PV 1) – Form for reporting suspected adverse drug reactions
- White card (PV 4)-Alert card
- Pink form (PV 6)- Form for reporting poor quality medicinal products



IN CONFIDENCE

MINISTRY OF HEALTH
THE NATIONAL PHARMACEUTICAL BOARD
IN THE REPUBLIC OF KENYA
SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Name of patient: [Red circle] Sex: [Red circle] Age: [Red circle]

Reaction: [Red circle]

Drug: [Red circle]

Reporter: [Red circle]

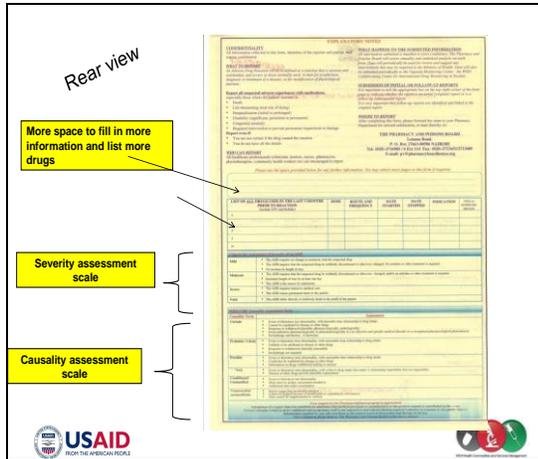
Identifiable patient

Identifiable reaction

Identifiable drug

Identifiable reporter





Elements

- **Patient:** The patient may be identified through name, initials or registration number.
- **Event:** The event should contain information on signs, symptoms, disease, diagnosis, labs values, order of events, description of the event in patients own words, etc. Information on baseline characteristics including medical history, co-morbid conditions, etc., if available should also be reported.
- **Product:** Information on the product should include the generic name, brand name, strength, dosage, and batch number.
- **Reporter:** The reporter should provide their name, address, contact information, and relationship to the patient

USAID
FROM THE AMERICAN PEOPLE

Alert card

(front side)

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
LENANA ROAD, NAIROBI P.O. BOX 27663 - 00506
TEL: (020) 2716905/6 Ext 114 Fax: (020)-2713431 / 2713409
ADVERSE DRUG REACTION ALERT CARD

PV 4

PATIENT NAME:

AGE: GENDER:

DATE ISSUED: ADDRESS:

SUSPECTED DRUG(S):

DESCRIPTION OF REACTION:

Other comments (if any):

Tafadhali hakikisha umebeba haki kila wakati. Kumbaka kumwonyesha mhudumu wa afya haki hii unapo pata matibabu

Please carry this card with you at all times and remember to produce it to your health care professional at each time of consultation.

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FROM THE AMERICAN PEOPLE

Alert card

(back side)

CRITERIA FOR ISSUE OF A PATIENT ALERT CARD

The criteria for issue of the Patient Alert Card is as follows:

The alert card is given to:

- ◆ Patients who are hypersensitive / allergic / intolerant to a particular drug
- ◆ Patients who develop a 'near-fatal' reaction to any particular drug
- ◆ Patients who had a drug- induced morbidity to any drug
- ◆ Patients who had hospital admission due to an ADR to any drug
- ◆ Patients who developed an ADR which caused increase in the health care expenditure



PV 6 (PINK FORM)

FORM FOR
REPORTING POOR
QUALITY
MEDICINAL
PRODUCTS



Pharmacovigilance in Kenya: Flow of Information

What to report

- Suspected ADR
- Poor quality medicinal product

Who should report

- Patient
- Relatives
- Healthcare worker

When to report

- Fill the form - as soon as possible on suspicion
- Send the form - as soon as possible on completion

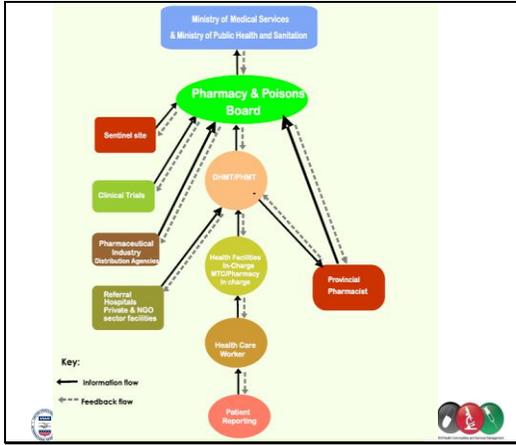
Where to send

- District pharmacist
- Designated official/organization
- PPB-department of pharmacovigilance

How to send

- Appointed courier
- Direct post
- Fax/Telephone/Email
- MoH system in existence





Sources of Reporting tools

- PPB
- PPB website
- All health facilities

Case study I

ANM is a 32 year old male who comes to your facility complaining of dysphagia, cough, oral candidiasis and considerable weight loss. After several tests the patient is found to be eligible for ART and the clinical team decides to initiate him on d4T + 3TC + NVP and CTX for prophylaxis. 2 weeks later, patient presents with SJS, diarrhea and excessive dehydration.

- Identify the problem in the above case
- Use the relevant tool (s) to enter and report the information

Case study 2

- A consignment of Xmol (Paracetamol 120mg/5ml) is received at PPB dispensary in Koinange district on 10 June 2010 from KEMSA. The manufacturing date is 10 June 2009 and expiry date is June 2012. The batch number is X100 and the manufacturer is Koinange Pharma box 100 Koinange Kenya. 2 days after receiving it, you notice that the syrup appears to have glass like particles at the bottom and on comparing with the previous stock, the colour appears to be yellowish instead of pink. On examination, the product conforms with the labeling requirements



Case Study 2 (cont'd)

- Identify the problem in the above case
- Use the relevant tool (s) to enter and report the information



THANK YOU

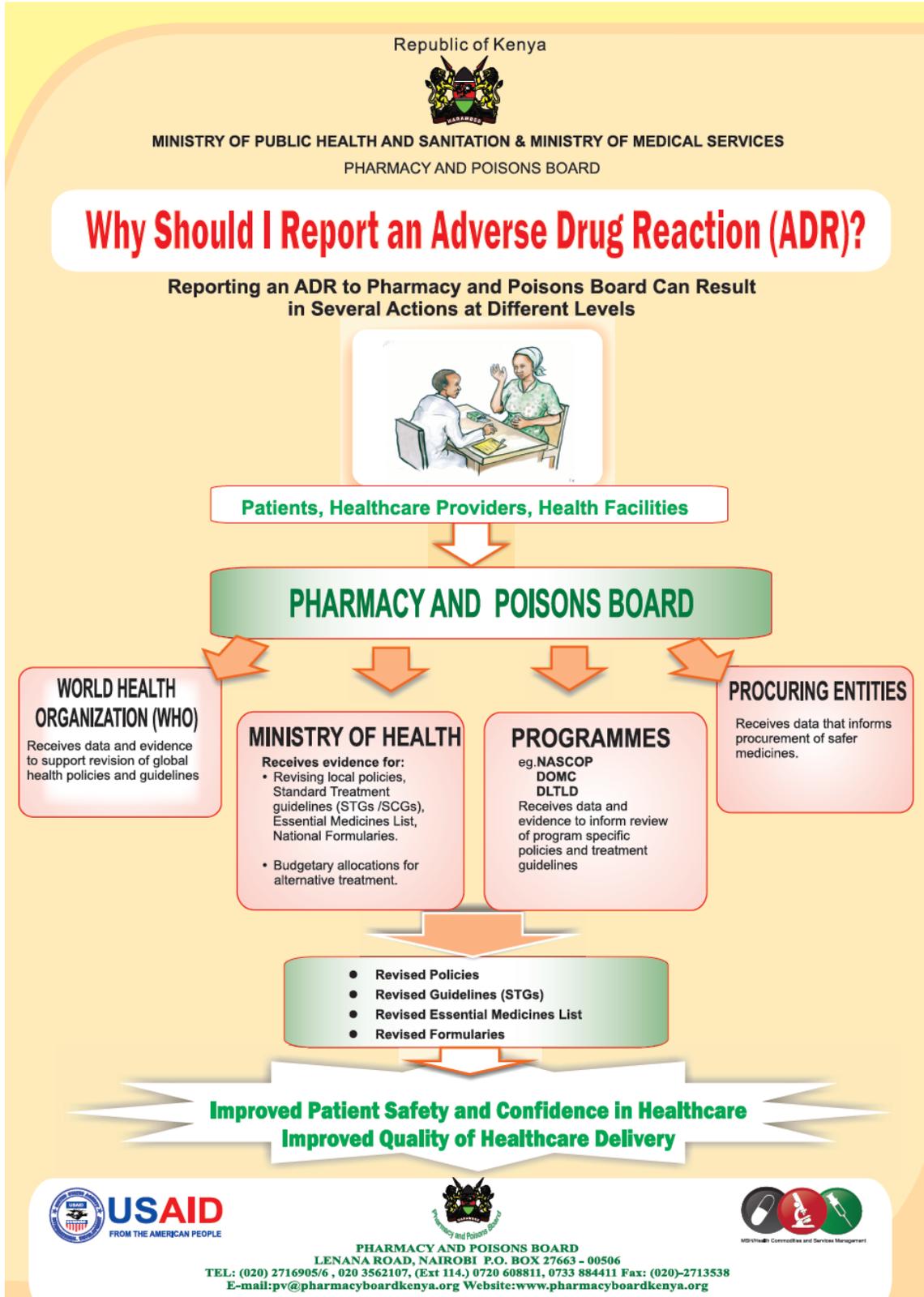


"You need not be certain...
Just be suspicious"

Report all **SUSPECTED**
adverse drug reactions



Job Aid 1-6



Republic of Kenya



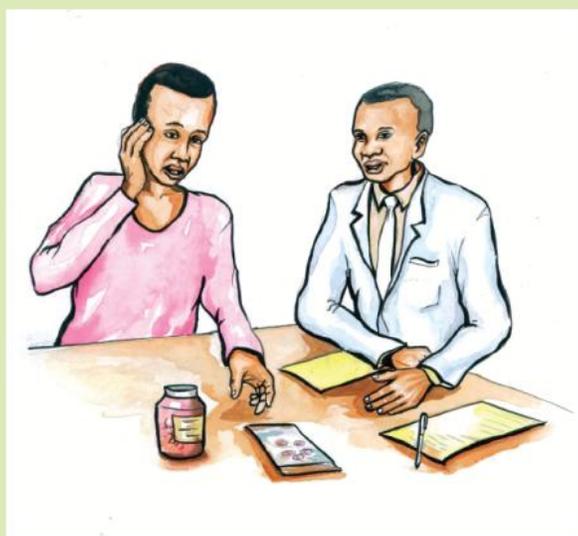
MINISTRY OF PUBLIC HEALTH AND SANITATION & MINISTRY OF MEDICAL SERVICES
PHARMACY AND POISONS BOARD

When Should I Suspect an Adverse Drug Reaction?

An Adverse Drug Reaction is an unpleasant unintended reaction to medicines that occurs at the normal recommended doses.

Suspect an Adverse Drug Reaction if:

- **One develops symptoms soon after beginning medications**
- **One develops a new problem while on medications**
- **A Child is born with birth defects**



YOU NEED NOT BE CERTAIN...JUST BE SUSPICIOUS



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LENANA ROAD, NAIROBI P.O. BOX 27663 - 00506
TEL: (020) 2716905/6, 020 3562107, (Ext 114.) 0720 608811, 0733 884411 Fax: (020)-2713538
E-mail:pv@pharmacyboardkenya.org Website:www.pharmacyboardkenya.org



Republic of Kenya



MINISTRY OF PUBLIC HEALTH AND SANITATION & MINISTRY OF MEDICAL SERVICES
PHARMACY AND POISONS BOARD

Pharmacovigilance Tools

Form for Reporting Suspected Adverse Drug Reactions

Front Side

Back Side

Adverse Drug Reaction Alert Card

Alert card is given to

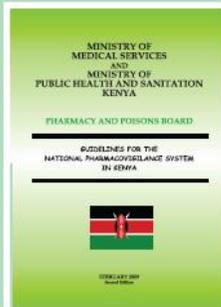
- » Patients who are hypersensitive / allergic / intolerant to a particular drug.
- » Patients who develop a 'near fatal' reaction to any particular drug.
- » Patients who had a drug-induced morbidity to any drug
- » Patients who had hospital admission due to an ADR to any drug.
- » Patients who develop an ADR which caused increase in the health care expenditure.

Front Side

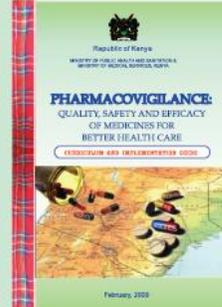
Back Side

Form for Reporting Poor Quality Medicinal Products

Guidelines for the National Pharmacovigilance System in Kenya



Curriculum and Implementation Guide



Ensure your report is timely, accurate and complete.

TODAY'S REPORTING PREVENTS TOMORROW'S ADVERSE DRUG REACTION.

All reports are handled in confidence.



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E-mail:pv@pharmacyboardkenya.org Website:www.pharmacyboardkenya.org



How to Report a Suspected Adverse Drug Reaction

- Document the facility's details
- Document the patient's information (for females, indicate the pregnancy status)
- Write the diagnosis
- Describe the adverse drug reaction
- List all medicines used within the last 3 months
- Grade the severity of the reaction
- Indicate the action taken
- Indicate the outcome of any intervention
- Document the probable cause of the reaction
- Write your name, contact and date of reporting

Key elements of a suspected ADR Report:

- Patient information
- ADR description
- Medication history
- Name contact of reporter
- Date of reporting

Remember.....

- Report all cases of Adverse Drug Reaction as soon as they occur regardless of:
 - Uncertainty of the drug that caused the reaction
 - Unavailability of all details



Where to report

- Forward the completed form to your pharmacy department for onward submission, mail or E-mail directly to the Department of Pharmacovigilance, Pharmacy & Poisons Board



Reporting is the responsibility of all healthcare workers

DEPARTMENT OF PHARMACOVIGILANCE,
PHARMACY AND POISONS BOARD
LENANA ROAD, NAIROBI P.O. BOX 27663 - 00506
TEL: (020) 2716905/6 , 020 3562107, (Ext 114.) 0720 608811, 0733 884411 Fax: (020)-2713538
E-mail:pv@pharmacyboardkenya.org Website:www.pharmacyboardkenya.org



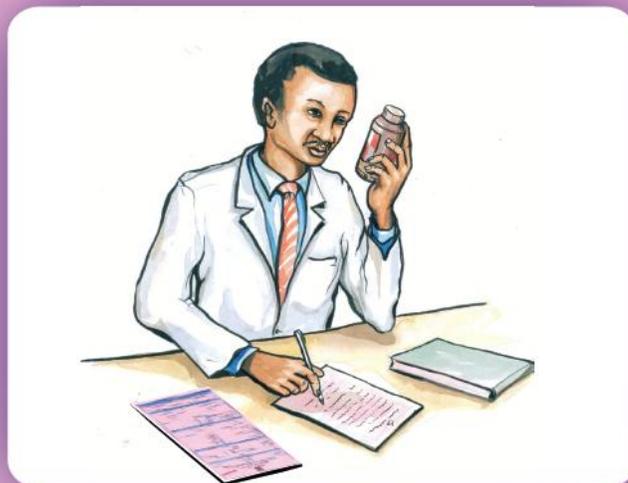
Republic of Kenya



MINISTRY OF PUBLIC HEALTH AND SANITATION & MINISTRY OF MEDICAL SERVICES
PHARMACY AND POISONS BOARD

How to Report on Poor Quality Medicinal Products

- Document the facility's details
- Document product details :brand name, generic name, batch number, date of manufacture & expiry, name of manufacturer, name of supplier, product formulation
- Describe the complaint (e.g. broken, discoloration, moulding, crumbling, incomplete pack etc)
- Describe the storage conditions of the product
- State whether the product was dispensed and returned by a patient
- Write your name, contact and date of reporting



- Send the report and appropriate quantity of sample to:
Department of Pharmacovigilance at the Pharmacy and Poisons Board for evaluation.



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E-mail:pv@pharmacyboardkenya.org Website:www.pharmacyboardkenya.org



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Flow of Information on Adverse Drug Reactions and Poor Quality Medicines



Key:
← Information flow
← - - - Feedback flow



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E-mail:pv@pharmacyboardkenya.org Website:www.pharmacyboardkenya.org

Form for Reporting Suspected ADRs



MINISTRY OF HEALTH
THE PHARMACY AND POISONS BOARD
P.O. Box: 2766300506 NAIROBI
 Tel: (020)-2716905 / 6 Ext 224 Fax: (020)-2713431/2713409

IN CONFIDENCE

Report Title:

Name of Institution:

Address: Contact:

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

PATIENT NAME / INITIALS: IP/OP. NO.: D.O.B:

PATIENT ADDRESS: WARD /CLINIC: GENDER: Male Female
(NAME / NUMBER)

ANY KNOWN ALLERGY: No Yes (specify)..... PREGNANCY STATUS: Not Applicable Not Pregnant 1st Trimester 2nd Trimester 3rd Trimester
 WEIGHT:Kg
 HEIGHT:cm

DIAGNOSIS: (what was the patient treated for)

BRIEF DESCRIPTION OF REACTION:

LIST OF ALL DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION <small>(include OTC and herbals) {use rear side of this form for additional drugs}</small>	BRAND NAME	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	TICK (?) SUSPECTED DRUG(S)
1.							
2.							
3.							
4.							
5.							

SEVERITY OF THE REACTION	ACTION TAKEN:	OUTCOME:	CAUSALITY OF REACTION
<input type="checkbox"/> Mild	<input type="checkbox"/> Drug withdrawn	<input type="checkbox"/> Recovering / resolving	<input type="checkbox"/> Certain
<input type="checkbox"/> Moderate	<input type="checkbox"/> Dose increased	<input type="checkbox"/> Recovered / resolved	<input type="checkbox"/> Probable / Likely
<input type="checkbox"/> Severe	<input type="checkbox"/> Dose reduced	<input type="checkbox"/> Requires or prolongs hospitalization	<input type="checkbox"/> Possible
<input type="checkbox"/> Fatal	<input type="checkbox"/> Dose not changed	<input type="checkbox"/> Causes a congenital anomaly	<input type="checkbox"/> Unlikely
<input type="checkbox"/> Unknown	<input type="checkbox"/> Unknown	<input type="checkbox"/> Requires intervention to prevent permanent damage	<input type="checkbox"/> Conditional / Unclassified
		<input type="checkbox"/> Unknown	<input type="checkbox"/> Unassessable / Unclassifiable

ANY OTHER COMMENTS:

NAME OF PERSON REPORTING: **DATE:**

E-MAIL ADDRESS: **PHONE NUMBER:**

DESIGNATION: **SIGNATURE:**



You need not be certain... just be suspicious!

Your support in this Pharmacovigilance program is appreciated.
 Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event. Patient's identity is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya.
 Once completed please send to: The Pharmacy and Poisons Board on the above address

EXPLANATORY NOTES

CONFIDENTIALITY

All information collected in this form, identities of the reporter and patient, will remain confidential

WHAT TO REPORT

An Adverse Drug Reaction (ADR) is defined as a reaction that is noxious and unintended, and occurs at doses normally used in man for prophylaxis, diagnosis or treatment of a disease, or for modification of physiological function.

Report all suspected adverse experiences with medications, especially those where the patient outcome is:

- Death
- Life-threatening (real risk of dying)
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You are not certain if the drug caused the reaction
- You do not have all the details

WHO CAN REPORT

All healthcare professionals (clinicians, dentists, nurses, pharmacists, physiotherapists, community health workers etc) are encouraged to report.

WHAT HAPPENS TO THE SUBMITTED INFORMATION

All information submitted is handled in strict confidence. The Pharmacy and Poisons Board will assess causality and statistical analysis on each form. Data will periodically be used for reviews and suggest any interventions that may be required to the Ministry of Health. Data will also be submitted periodically to the Uppsala Monitoring Centre the WHO Collaborating Centre for International Drug Monitoring in Sweden.

SUBMISSION OF FOLLOWUP REPORTS

Any follow-up information for an ADR that has already been reported can be sent to us on another form or paper. **Please indicate that it is a "FOLLOW-UP REPORT" on the top right corner of the report submitted.** It is very important that followup reports are identified and linked to the original report.

WHERE TO REPORT

After completing this form, please forward the same to your Pharmacy Department for onward submission, or mail directly, to:

THE PHARMACY AND POISONS BOARD

Lenana Road
P.O. Box: 2766300506 NAIROBI

Tel: (020)-2716905 / 6 Ext 224 Fax: (020)-2713431/2713409

E-mail: pv@pharmacyboardkenya.org

Please use the space provided below for any further information. You may attach more pages to this if required.

.....

.....

.....

.....

.....

LIST OF ALL DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION (include OTC and herbals)	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	TICK (v) SUSPECTED DRUG(S)
6.						
7.						
8.						
9.						
10.						

WHO-UMC Causality Assessment Scale

Causality Term	Assessment
Certain	<ul style="list-style-type: none"> • Event of laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically, i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon • Re-challenge satisfactory, if necessary
Probable / Likely	<ul style="list-style-type: none"> • Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Re-challenge not required
Possible	<ul style="list-style-type: none"> • Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal lacking or unclear
Unlikely	<ul style="list-style-type: none"> • Event or laboratory test abnormality with a time to drug that makes a relationship improbable (but not impossible) • Diseases or other drugs provide plausible explanations
Conditional/ Unclassified	<ul style="list-style-type: none"> • Event or laboratory test abnormality • More data for proper assessment needed or • additional data under examination
Unassessable/ unclassifiable	<ul style="list-style-type: none"> • Report suggesting an adverse reaction • Cannot be judged because of insufficient or contradictory information • Data cannot be supplemented or verified

Your support in this Pharmacovigilance program is appreciated.

Submission of a report does not constitute an admission that medical personnel or manufacturer of the product caused or contributed to the event. Patient's identity is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya.

Once completed please send to: The Pharmacy and Poisons Board on the above address

Form for Reporting Poor Quality Medicinal Products

		PV 6
MINISTRY OF HEALTH PHARMACY AND POISONS BOARD DEPARTMENT OF PHARMACOVIGILANCE		IN CONFIDENCE
FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS		
Name of Facility		District Name
Province Name		
Facility Address		Facility Telephone
PRODUCT IDENTITY		
Brand Name	Generic Name	
Batch/Lot Number	Date of Manufacture	Date of Expiry
Name of Manufacturer	Country of Origin	
Name of Distributor/Supplier	Distributor/Supplier's Address	
PRODUCT FORMULATION (Tick appropriate box)		COMPLAINT (Tick appropriate box/boxes)
<input type="checkbox"/> Oral tablets / capsules <input type="checkbox"/> Oral suspension / syrup <input type="checkbox"/> Injection <input type="checkbox"/> Diluent <input type="checkbox"/> Powder for reconstitution of suspension <input type="checkbox"/> Powder for reconstitution of injection <input type="checkbox"/> Eye drops <input type="checkbox"/> Ear drops <input type="checkbox"/> Nebuliser solution <input type="checkbox"/> Cream / Ointment / Liniment / Paste <input type="checkbox"/> Other		<input type="checkbox"/> Colour change <input type="checkbox"/> Separating <input type="checkbox"/> Powdering / crumbling <input type="checkbox"/> Caking <input type="checkbox"/> Moulding <input type="checkbox"/> Change of odour <input type="checkbox"/> Mislabeling <input type="checkbox"/> Incomplete pack <input type="checkbox"/> Other
Describe complaint in detail:		
Storage Conditions		
Does the product require refrigeration?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Was product available at facility?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Was product dispensed and returned by client?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Was product stored according to manufacturer/MoH recommendations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Other details (if necessary):</i>		
Comments (if any)		
Name of Reporter		Contact number
Cadre / Job Title		Signature
		Date
Once completed one copy of this form should be e-mailed or posted to:		
Pharmacy and Poisons Board	Department of Pharmacovigilance	P. O. Box 27663-00506 NRB
		Fax: 2713431
		E-mail: pv@pharmacyboardkenya.org
Your support in this Pharmacovigilance program is appreciated. Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to an event. All information is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to: The Pharmacy and Poisons Board on the above address.		

Adverse Drug Reaction Alert Card (Front)

 MINISTRY OF HEALTH PHARMACY AND POISONS BOARD LENANA ROAD, NAIROBI P.O. BOX: 27663- 00506 TEL: (020) 2716905/6 Ext 114 Fax: (020)-2713431 / 2713409	
<u>ADVERSE DRUG REACTION ALERT CARD</u>	
PATIENT NAME:	
DATE OF BIRTH:.....GENDER.....	
DATE ISSUED:	ADDRESS:
SUSPECTED DRUG(S):	
DESCRIPTION OF REACTION:	
.....	
Other comments (if any):	
<i>Tafadhali hakikisha umebeba kadi hii kila wakati. Kumbuka kumwonyesha mhudumu wa afya kadi hii unapo pata matibabu</i>	<i>Please carry this card with you at all times and remember to produce it to your health care professional at each time of consultation.</i>

(Back)

CRITERIA FOR ISSUE OF A PATIENT ALERT CARD

The criteria for issue of the Patient Alert Card is as follows:

The alert card is given to:

- Patients who are hypersensitive / allergic / intolerant to a particular drug
- Patients who developed a 'near-fatal' reaction to any particular drug
- Patients who had a drug-induced morbidity to any drug
- Patients who had hospital admission due to an **ADR to any drug**
- Patients who developed an ADR which caused increase in the health care expenditure

Pharmacovigilance SOPs

Republic of Kenya



Ministry of Medical Services and Ministry of Public Health and Sanitation

Pharmacy and Poisons Board

SOP TITLE: PHARMACOVIGILANCE: REPORTING ADVERSE DRUG REACTIONS	
Date Approved: October 2011 Valid up to: September 2013	Approved by Name: Signature Date:

1. Objective

To describe the procedure for reporting suspected Adverse Drug Reactions (ADRs) of medicines.

2. Responsible persons

- ALL healthcare providers
- Medicine and Therapeutics Committees (MTC)
- Facility Pharmacist/Staff member in charge or MTC secretary or Clinical Pharmacist where available: to collect and forward ADR reports to National Pharmacovigilance Centre

3. Definitions:

Adverse Drug Reaction (ADR): A response to a medicine that is noxious and unintended, and occurs at doses normally used in man for the prophylaxis, diagnosis, therapy of disease, or modification of physiological function.

Serious Adverse Effect (SAE): any reaction that is fatal, life-threatening, permanently/significantly disabling, requires or prolongs hospitalization, causes a

congenital anomaly, or requires intervention to prevent permanent impairment or damage.

Pharmacovigilance (PV): is the science of collection, monitoring researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines with the view to:

- Identify new information about hazards
- Preventing harm to patients

Grading of severity of ADRs (Ref: *Guidelines for the National Pharmacovigilance System in Kenya, February 2009, Pg 33*)

- **Grade 1: Mild**
Transient or mild discomfort, no limitation in activity; any medical intervention / therapy required
- **Grade 2: Moderate**
Mild to moderate limitation in activity; some assistance may be needed; no or minimal medical intervention/therapy required
- **Grade 3: Severe**
Marked limitation in activity, some assistance usually required; medical/intervention/ therapy required, hospitalization possible
- **Grade 4: Life-Threatening**
Extreme limitation in activity, significant assistance required; significant medical intervention/therapy required, hospitalization or hospice care probable

4. Tools Needed

- 4.1. *Guidelines for National Pharmacovigilance System in Kenya, February 2009*
- 4.2. *Suspected Adverse Drug Reaction (ADR) Reporting Form.*
- 4.3. *Adverse Drug Reaction (ADR) Alert Card*
- 4.4. *Patient's clinic record*
- 4.5. *Pharmacovigilance job aids*
- 4.6. *Current Kenya National Treatment Guidelines e.g. Standard Clinical Guidelines 2010*
- 4.7. *Other reference materials e.g. British National Formulary (BNF), Martindale: The Complete Drug Reference, Lexi's Drug Information Handbook, www.medicinescomplete.com etc.*
- 4.8. *Medication use counseling checklist.*
- 4.9. *Stationary: pens, carbon paper etc*

5. Procedure:

Healthcare personnel shall:

5.1 Interview the patient on presentation of suspected ADR and/or review the patient's clinic record.

5.2 Counsel the patient, where applicable, on use of medication (using the Medication Use Counseling Checklist and appropriate reference materials). Consult with a clinician on management of the suspected ADR and issuance of ADR alert card, if appropriate.

5.3 Complete the suspected ADR Reporting Form as described below:

The healthcare personnel shall:

5.3.1 Indicate the title of the report Tick to indicate whether it is an initial or follow-up report

Fill in the:

5.3.2 Institution name/code number if applicable

5.3.3 Patient Identifier e.g. Initials, reference number etc

5.3.4 Patient' gender– indicate whether male or female

5.3.5 Patient's Inpatient / Outpatient (IP/OP) Number

5.3.6 Patients' Date of Birth (DOB)

5.3.7 Patient's address

5.3.8 Patient's Source (Ward/Clinic)

5.3.9 Patient's Weight (in Kg)

5.3.10 Patient's known allergies

5.3.11 Patient's Pregnancy Status (Indicate trimester)

5.3.12 Diagnosis of what patient was being treated for

5.3.13 Summary of the suspected ADR according to details given by patient or healthcare (including yourself if you are the first reporter)

5.4 Document all relevant medications the patient was taking at least three months prior to the onset date of the suspected ADR and:

- List all drugs, dose, the start and stop dates and indication.
- Tick the relevant box for any drug suspected to have caused the ADR (use appropriate reference materials to obtain required information)

5.5 Select the severity of the reaction from the following list by placing a tick (v) on the appropriate box:

- Mild,
- Moderate,
- Severe,
- Fatal,
- Unknown

5.6 Select and document action taken from the following list by placing a tick (v) on the appropriate box:

- Drug withdrawal
- Dose increased
- Dose reduced
- Dose not changed

- Unknown

5.7 Select the outcome from the following list by placing a tick (✓) on the appropriate box:

- Recovering/resolving
- Recovered/resolved
- Requires or prolongs hospitalization
- Causes a congenital anomaly
- Requires interventions to prevent permanent damage
- Unknown

5.8 Select the causality of ADR from the following list by placing a tick (✓) on the appropriate box:

- Certain
- Probable/Likely
- Possible
- Unlikely
- Conditional/unclassified
- Unassessable /unclassifiable

Note: The minimum required fields for reporting any suspected ADR are:

- 1. Title of the report**
- 2. Identifiable Patient i.e. who is the patient?**
- 3. The age of the patient**
- 4. Identifiable Medicine i.e. name, formulation, dose, route, frequency and dates taken**
- 5. Identifiable suspected ADR i.e. what is the adverse drug reaction?**
- 6. Identifiable reporter i.e. name and contact details of reporter**
- 7. The date of onset of the ADR**
- 8. The type of reaction**
- 9. The suspected medication**

5.9 Document any other comments: Include any relevant laboratory and diagnostics reports. Add additional pages if needed. (A typed summary is acceptable and should be signed, dated and submitted with the Suspected ADR forms).

5.10 Fill his/her details i.e. Name, Date, E-mail, Telephone number, Designation and Signature as the person reporting the ADR or completing the Suspected ADR forms.

5.11 Send the completed Suspected ADR reporting form to the Facility Pharmacist for submission to PPB and a copy made for the Hospital Medicine and Therapeutic Committee for assessment of trends.

6. Distribution and Storage of Tools

6.1 The completed Suspected ADR reporting form shall be submitted to the Facility Pharmacist who will distribute the copies as follows:

6.1.1 The original is forwarded to the MTC'S secretary or pharmacy in-charge or responsible clinical pharmacist for onward submission to PPB

6.1.2 The 2nd copy is retained at the facility in the patient's file.

6.1.3 The 3rd copy is maintained by the MTC's secretary or pharmacy in-charge or responsible clinical pharmacist

6.2. All suspected ADR reports shall be kept chronologically and confidentially in file named "Pharmacovigilance ADR File".

6.3. Upon receipt at the PPB, The PV Department will acknowledge receipt, provide and adequately document feedback to the facility (MTC, facility-in-charge, pharmacy-in-charge). Upon evaluation, the feedback will be used/ shared in forthcoming communications such as Newsletter, Reports, Presentations and others.

7.0. Ordering for Reporting Tools

When stock of reporting tools are running low, inform PPB in writing immediately for purposes of re-stocking.

Republic of Kenya



Ministry Of Medical Services and Ministry Of Public Health and Sanitation

Pharmacy and Poisons Board

SOP TITLE: REPORTING POOR QUALITY MEDICINAL PRODUCTS	
Date Approved: October 2011	Approved by Name: Signature Date:
Valid up to: September 2013	

1. Objective

To describe the procedure for reporting poor quality medicinal products

2. Responsible persons

- Qualified health personnel
- Overall facility, pharmacist or staff member in charge

3. Tools Needed

- 3.1. *Guidelines for National Pharmacovigilance System in Kenya February 2009*
- 3.2 *Form for Reporting Poor Quality Medicinal Product*
- 3.3 *Pharmacovigilance job aids*
- 3.4 *Bin cards*
- 3.5 *Temperature logs*
- 3.6 *Other reference materials e.g. British National Formulary (BNF), Martindale: The Complete Drug Reference, British Pharmacopoeia, Micromedex, www.medicinescomplete.com etc.*
- 3.7 *S11 Counter Issue and Receipt Voucher or any other appropriate ordering/issuing records*

4. Definitions

Qualified health personnel -Pharmacist or other health personnel trained on identifying and reporting product quality problems

5. Procedure:

The health personnel shall:

5.1 Quarantine the suspected poor quality medicinal product and notify the qualified health personnel immediately.

The Pharmacist/Designee shall:

5.2. Assess the product quality and withdraw all unused quantities of the suspected poor quality medicinal product from the dispensing points at the facility. Appropriate records e.g. S11 should be completed when withdrawing unused quantities.

5.3 Quarantine the withdrawn quantities in a designated area until a written order from the Chief Pharmacist is received authorizing use or disposal.

5.4 Assess whether the quality problem could be as a result of poor storage practices at the facility.

5.5 Fill in the following details in the Poor Quality Medicinal Product Form;

5.4.1 Institution details (Name, Location, Facility address and contact information).

5.4.2 Product identification information (Brand name, Generic name, Batch number, Manufacturer details, Date of manufacture, Expiry date, Country of origin, Local distributor/supplier and date received in the facility.)

5.4.3 The product formulation and check/tick the relevant box under the product formulation. If 'other', the pharmacist/designee shall specify the details.

5.6 Document the product complaint by checking the appropriate space/box provided. If 'other', the pharmacist/designee shall specify the details.

5.7 Provide a detailed summary of the complaint stating the extent and health implications, where necessary state steps taken within the facility. Add a separate typed and signed report with the form.

5.8 Fill in the storage conditions of the product as stated by the product monograph. Check the boxes as appropriate.

5.9 Attach copies of temperature logs indicating the facility storage conditions under which the product had been stored.

5.10 Add any additional comments to the section on any other comments; if none, the pharmacist/designee shall write 'NONE'. (A typed report shall be acceptable and should be signed, dated and submitted with the Poor Quality Medicinal Product Report

5.11 Fill his/her details i.e. Name, E-mail, Telephone number, Designation, Signature as the person reporting the poor quality medicinal product and Date of reporting

5.12 Write any other useful additional information at the back of the form or on a separate sheet of paper that should be attached to the form.

Note: Where possible, samples of the poor quality medicinal products should be submitted with the report.

6. Distribution and Storage of Tools:

6.1. The qualified health personnel shall submit the completed Poor Medicinal Quality form to the pharmacy in-charge or designee who shall distribute the copies as follows:

6.1.1 The original copy shall be forwarded to Pharmacy and Poisons Board (PPB)

6.1.2 The 2nd copy shall be maintained by the pharmacy in-charge or the MTC secretary

6.1.3 A 3rd copy shall be sent to the provincial pharmacist through the DMOH

6.1.4 Where medicines were supplied by KEMSA, a 4th copy shall be forwarded to the Regional Liaison Officer

6.2. All Poor Quality Medicinal Products reports shall be kept in a confidential file

6.3 PPB & KEMSA shall acknowledge receipt, provide and adequately document feedback to the facility/ pharmacy-in-charge or MTC secretary on action taken

7. Ordering for Reporting Tools

When stock of reporting tools are low, inform PPB in writing immediately for purposes of re-stocking.

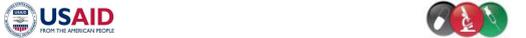
Session 11: MTP- A Quality Improvement Approach

Action planning, Problem solving and Quality Improvement: The Monitoring Training and Planning (MTP) approach



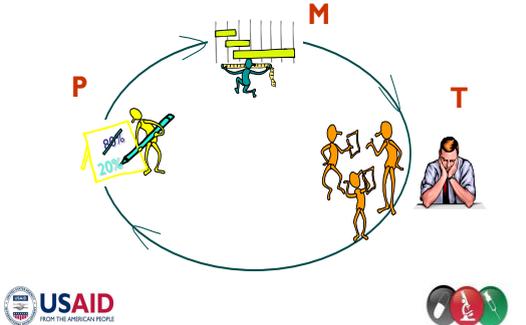
Objectives

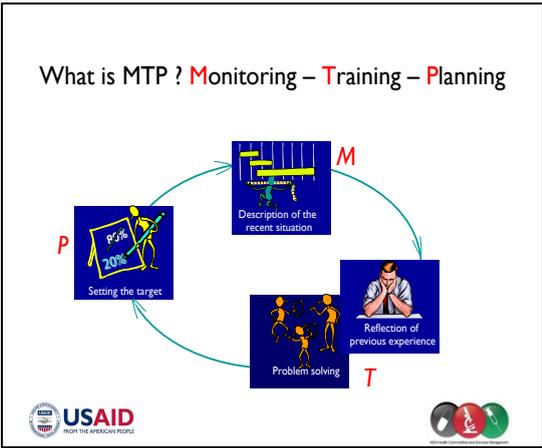
- What is MTP?
- Describe the importance of MTP in **continuous quality improvement**
- Describe the importance of MTP in **institutional and human capacity strengthening**
- Development of **action plans**



What is MTP?

Monitoring – Training – Planning





Monitoring:

First Visit

- Discuss the gaps identified during the visit.
- Identify specific problems.
- Measure the extent of the problem
- Prioritize problems

Subsequent visits

- Follow up on commitments from the previous visit
- Evaluate the result of the intervention.
- Document and communicate outcomes.

Problem Prioritization: Example

Criteria

- **Priority A** - Those which if **not** corrected would cause a program or service to collapse. (**Immediate action required**) e.g. Stock-out of medicines
- **Priority B** - Those which if corrected would improve service delivery. (**Action required in the short term**) e.g. increased staffing levels
- **Priority C** - Those which if **not** corrected would hinder improvement of service delivery (**Action required in the long term**) e.g. infrastructural improvements

Logos for USAID and other partners are at the bottom.

•Training/ Problem Solving

Discuss the problem—

1. Why is it happening? What are the underlying factors? -Root Cause Analysis
2. Decide how to solve the problem. Find a solution- Intervention

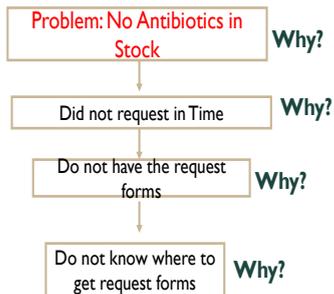


Root cause analysis

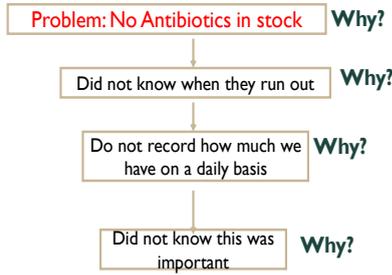
- It is important to differentiate between the cause of a problem and the symptoms of a problem
- Treating the symptoms only leads to short term solutions
- Asking the question *Why?* several times helps to identify the “real” reason or cause of a problem
- A single problem can have more than one root cause



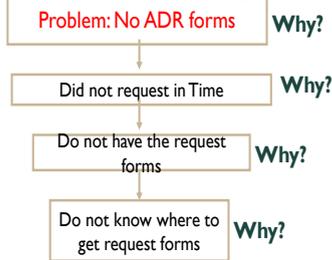
Root cause analysis (Example 1)



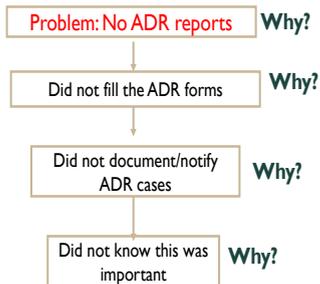
Root cause analysis: Example (2)



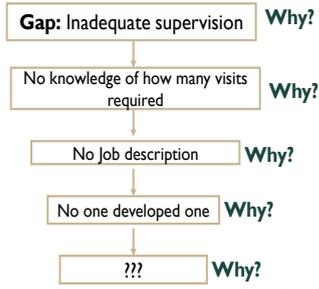
Root cause analysis (Example 3)



Root cause analysis: Example (4)

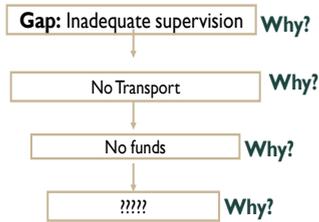


Root cause analysis (Example 5)



Example: Ghana, 2000

Root cause analysis (Example 6)



Example:
Ghana, 2000

Finding Solutions

- The solution should address the root cause
- Find local solutions:- think of
 - "What can I do to solve the problem"
 - Discourage staff from going to outside authorities, stake holders, government for assistance as their first option
- Be creative
- If there are no local solutions then the mentor becomes the liaison to outside authorities.
 - Prepare information on the extent of the problem and the difficulties in solving the problem locally
 - Take the problem to regional/national authorities
 - Assist the staff to write a letter/proposal/follow up



Planning:

- Set a target for improvement
- Set measures to achieve the target
- Assign someone the responsibility for execution of the plan
- Set the date for the next supervisory visit



Action Plans (I)

- Once the solution is agreed on, then a plan to implement the solution is needed
- **An Action Plan answers**
 - What will be done
 - Who will do what
 - When will they do it
 - Where will they do it
 - How will they do it
- Action Plans should also include Targets and means of monitoring progress towards targets



Action Plans: Class Discussion

*Review the action plan below and think about what might be problematic about it

Problem	Solution	By Whom	By When
Frequent Stock outs	Order from medical stores	In Charge	Immediately
Inadequate space for storage	Request for Donor Funding	In Charge	Two weeks
Inadequate staff	Hire More Staff	Government	ASAP

Applying the MTP concept for Quality Improvement

- Train staff on the **quality improvement approach** using the MTP
- Assist staff in identifying **root causes**
- Assist staff in identifying **creative solutions**
- Assist staff in developing **practical action plans**
- Assist staff in **reviewing progress** towards targets
- Provide **follow up support**



ACTION PLANS

Objectives	Activities	Responsible person	Resources	Time By when	Indicators



MTP Action Planning Template

Objectives	Activities	Responsible person	Resources	Time By when	Indicators
1.					
2.					
3.					
4.					
5.					

MTP Action Planning Template

Objectives	Activities	Responsible person	Resources	Time By when	Indicators
1.					
2.					
3.					
4.					
5.					

APPENDICES

Appendix 1: Timetable



Ministry of Medical Services and Ministry of Public Health and Sanitation

BASIC CONCEPTS OF INVENTORY MANAGEMENT, APPROPRIATE MEDICINES USE AND PHARMACOVIGILANCE

Date: _____

Venue: _____

TIME	SESSION	FACILITATOR
8:00 – 8.15am	Arrival & Registration	
8:15- 8:45am	Introductions and Climate Setting	
8.45 - 9.00 am	Welcoming remarks & Opening Address	DMOH
9.00-9:15 am	Brief on the Health Commodities and Services Management Program	
9.15 – 9:40am	Background, Course Overview & Objectives	
9.40 – 10:00 am	Overview of Inventory management	
10:00 – 11.00 am	How to Determine Quantities to Order – Part I	
11.00 - 11.15 am	TEA BREAK	
11.15 - 12.15 pm	How to Determine Quantities to Order – Part II	
12.15 – 1.00 pm	Receiving Health Commodities	
1.00 - 2.00 pm	LUNCH BREAK	
2.00 – 3.00 pm	Storage of Health Commodities	
3.00 – 4.00 pm	Issuing Health Commodities	
4.00 – 5.00 pm	Dispensing of Health Commodities	
5.30 pm	TEA & DEPARTURE	





Ministry of Medical Services and Ministry of Public Health and Sanitation

TIME	SESSION	FACILITATOR
8.00 - 8.15 am	Recap	
8.15 – 10.15am	LMIS Reporting, Commodity and Information Flow	
10.15 – 10.30am	TEA BREAK	
10.30 – 11.30 am	Appropriate medicines use	
11.30 – 1.15 pm	Overview of Pharmacovigilance	
1.15 - 2.00 pm	LUNCH BREAK	
2.00 - 2.45 pm	MTP: A quality Improvement Approach	
2.45 – 3.30 pm	Action planning	
3.30 - 4.00pm	Way forward and Closing Remarks	
4.00 pm	TEA & DEPARTURE	



Appendix 2: Instructions for completing Laboratory Commodity Management Forms/Cards/Charts



REPUBLIC OF KENYA
MINISTRY OF HEALTH

INSTRUCTIONS FOR LABORATORY COMMODITY MANAGEMENT FORMS / CARDS / CHARTS

1. LABORATORY STOCK CARD

2. LABORATORY TOP -UP FORM

**3. EXPIRY TRACKING CHART FOR LABORATORY REAGENTS
AND CONSUMABLES**

4. 2-8 °C TEMPERATURE MONITORING CHART



INSTRUCTIONS FOR COMPLETING THE LABORATORY STOCK CARD

1. Title:

Laboratory Stock Card

2. Objective of Instructions:

To describe how to fill and use the laboratory stock card correctly

3. Description of the stock card

- Is a serially numbered, single-copy, two-sided card
- Must exist for each laboratory stock preparation
- Is used for inventory control of laboratory commodities (including reagents, consumables, chemicals, etc) in the facility or district laboratory store
- Is used for checking physical stock against records in the laboratory store
- A supply of Laboratory Stock cards is to be kept as a stock item by each laboratory in-charge of a PGH as well as the DMLT.

4. Other forms or resources needed to complete the stock card:

- *Invoice or Delivery note number accompanying the commodity from KEMSA or other supplier*
- *Counter Requisition and Issue Voucher (S11) serial number accompanying goods from the general stores of the hospital/ facility or district*

5. Location

Must be located next to each item if space is available, or in a file or box in close proximity to the commodities - preferably within the laboratory store.

6. Who fills the card

The Laboratory in-charge / laboratory manager (or his/her designated proxy) is responsible for documentation and recording of all laboratory commodity receipts and issues from the laboratory stores (including storage refrigerators, cool rooms etc).

7. When is the card filled

Every new receipt and issue must be entered **at the time** that stock is received or removed, without exception, for purposes of tracking movement of laboratory stock in storage.

8. Steps for completing the stock card:

8.1 Open /complete a separate stock record card for differing strengths/concentrations and units of issue

8.2. When opening a New Stock card, record the following:

- District: laboratory in charge enters the name for the district where facility is located followed by name of facility
- Commodity name and description: enters the generic name (trade name in brackets) and strength/ concentration of the item as appropriate
- Unit of Issue: enters pack size (e.g. number of tests per kit, or number of pieces per box, etc)
- Item code: enters the code number allocated by the supplier/ requisitioning office and normally reflected against the item name on the delivery note from KEMSA / supplier; or S11, S12, S13 or S3
- Add storage requirements: Enter special storage conditions (e.g. refrigeration at +2 to 8 °C)
- Average monthly consumption: enters a figure which he/she has calculated from previous months' consumption

(Note:- Since these values change over time, the calculations are best done using the electronic lab commodity inventory tracking tool)

- Minimum level of stock for that commodity - as calculated by the lab manager or per national program recommendations
- Maximum level of stock - as calculated by the lab manager or per national program recommendations

8.3 Receipts: In the Receipts column, the Lab in-charge will enter information as follows:-

- **Date:** enter the date the transaction occurred in the format dd/mm/yyyy
- **Received from:** enter the supply source of the stock item, e.g. KEMSA or name of other supplier, DLTLTD, the Hospital stores, NPHLS, etc
- **Doc. No. :** Write the **Document Number** of the invoice or delivery note accompanying the commodity, or the serial number of the S11 or S12 that prompted the order being received.
- **Quant.:** enters the **Quantity** / amount received (e.g. 1000 tests, 500 pairs of gloves)
- **Batch No.:** indicate the **Batch Number(s)** as is written on the packaging
- **Expiry:** indicate the Date of expiry as written on the item container / packaging
- **Loc.:** indicate the **Location** / where goods are received and stored e.g. Cold room, Lab store, or refrigerator
- **Name:** enters name of the officer receiving the commodity

8.4 Disbursements / Issues: In the disbursements/ issues column, the Laboratory in-charge will enter information as follows:-

- **Doc. No. :** Write the **Document Number**, i.e. the serial number of S11 or Top- Up Form, or any other order / request form accompanying the goods that are disbursed / issued
- **Quant.:** enters the **Quantity** / the amount of stock disbursed (e.g. 10 liters of ethanol, 2 boxes of slides)
- **Dest.:** specifies the **Destination**, i.e. the unit or bench or ward to which the goods are being issued. For the district and PGH Laboratory store, the destination could be a lower level/satellite facility such as a health centre or sub-district hospital, or police clinic
- **Name:** enters the name of person who physically receives and takes the commodities away

8.5 Stock: In the Stock column, the Laboratory in-charge will enter the following information:-

- **Balance:** insert the quantity of commodity in stock after each transaction i.e. after each receipt or issue
- **Unit value:** enters value in Kenya shillings for each unit of issue, if known
- **Total value:** calculate and indicate the total value of commodity left in stock. This is calculated as Balance multiplied by Unit Value.

8.6 Balance C/F, to Card No.: At the bottom of each page, once the card is full, indicate the Balance carried forward and to which card number the balance is moved.

INSTRUCTIONS FOR COMPLETING THE LABORATORY TOP -UP FORM

1. Title:

Laboratory Top-Up Form

2. Objective of instructions:

To describe the correct use of the supply Top -Up Form

3. Description and location of the form

- a. Is a serialized two-sided card used to order supplies for use on the bench or section from the laboratory store / laboratory in-charge.
- b. It allows for documentation of all issues from the lab store made to the bench or section in order to replenish or top-up lab supplies
- c. It helps the lab in-charge to see at a glance the usage of a particular commodity on the bench or section.

4. Location:

The card under current use is kept in a file within the section or next to the bench.

5. Who fills the Top-Up Form?

- a. Both the staff who is requesting /ordering items for the bench or section and the one issuing from Laboratory store(s) will fill the form
- b. The staff of the bench/ section/unit will fill in this card every time he/she is requesting initial or additional commodities from the laboratory store(s).
- c. The laboratory in-charge /or the designated laboratory staff will fill relevant columns of this card to the bench or section.

6. Steps for filling the top up form

6.1 The staff or section head who initiates the order fills in the following information:

- **Name of Facility:** enter name of the laboratory, e.g. “Coast PGH” or 'Hola D/H’
- **Department/Section:** indicate the bench or section, e.g. serology, parasitology, etc or the unit/area ordering this item, e.g. “VCT” or “MCH”, etc
- **Date:** write down the date of the transaction
- **Commodity:** indicate the name of the commodity as it appears on the laboratory stock card in the store(s)
- **Unit of issue:** enter as it appears on the laboratory stock card
- **Current balance:** enter the amount/quantity of units that are remaining for use on the bench/section
- **Tests done:** enter the number of tests done between your last order from the store and this order
- **Order quantity:** indicate the number of units you are ordering through this request

Present the top-up form with this order to the laboratory in-charge or the staff member designated to man the laboratory store(s).

6.2 The laboratory in-charge or his/her designated proxy fills the relevant column as follows:

- **Issue quantity:** enter the number of units the laboratory in-charge is issuing to the bench
- **Issued by:** enter name of the issuing officer who also appends his/ her signature
- **Received by:** enter name of the staff officer collecting/receiving the issued stock for the bench/section
- **Remarks:** enter any relevant remarks.

INSTRUCTIONS FOR COMPLETING THE EXPIRY TRACKING CHART FOR LABORATORY REAGENTS AND CONSUMABLES

1. Title :

Expiry tracking chart for laboratory reagents and consumables

2. Objective of these instructions:

To describe how to complete the expiry tracking chart for reagents and consumables

3. Description of the chart:

- Is a laminated, re-usable chart that accommodates information covering three consecutive years
- It is used to track expiry dates of reagents and other supplies
- It also serves to alert the laboratory in-charge when stocks should be removed for exchange, re-distribution or destruction
- Provides ready information on remaining stock levels, thus helping staff to know if all stock can be used on time.

4. Location of the chart

Displayed at a spot on the wall readily seen by the laboratory in-charge within the laboratory store or office of the laboratory in-charge

5. Who fills the chart

The Laboratory in-charge / manager or any laboratory staff designated to receive new stock or maintain the facility inventory

6. When to fill the chart

The chart should be filled or updated as follows:

- Upon receiving new issues of commodities
- Every time a batch expires or is used up
- At the beginning of every calendar year

7. Commodities whose expiry date should be closely tracked using this chart

It is not possible or necessary to track all reagents and consumables, therefore the laboratory manager with his/her staff should select a few key commodities for close tracking.

Selection criteria includes:

- Commodities with short expiry dates, e.g. HIV Test kits
- Commodities of very high value / expensive items, e.g. CD4 reagents
- Commodities with very long expiry dates or not used up quickly
- Commodities with a tendency of expiring from time to time

8. Resources needed for filling the chart include:

- Marker pen whose writing can be wiped off with spirit if necessary (Erasable Marker Pens in red and blue colours). Use Red for actual month of expiry, and Green for warning / alert at 3 months to expiry

OR

- Coloured Stickers - Red for actual month of expiry, and Green for warning / alert at 3 months to expiry
- The blank laminated chart for tracking expiry of lab reagents and consumables

9. Steps for filling the form

Upon receiving an item appearing on the list for expiry tracking, the laboratory in charge or an officer assigned the duty:

9.1 Completes a blank chart by first inserting the current year in the first column on the space provided, i.e. against “Year”

9.2 He/she completes column no. 2 with the next year, and column 3 with the third year.

He/she fills the rest of the chart as follows:-

9.3 **Commodity:** Enter the name of the commodity or item as it appears in the Laboratory stock card

9.4 **Batch number:** enter as it appears on the item or its proper packaging

9.5 **Expiry date:** enter as indicated on the commodity itself or packaging, in the format dd/mm/yyyy.

9.6 Places the **Red** Expiry sticker on the actual month of expiry in the appropriate year column.

9.7 Places the **Green** Warning sticker on the month that is three (3) months prior to the expiry date.

9.8 **Monthly tracking:** For three (3) consecutive months before the Green Warning sticker, **enter** the current stock levels of that item in the relevant grid, to guide decision for the action to take to prevent loss of the item.

INSTRUCTIONS FOR COMPLETING FOR THE +2 TO +8 °C TEMPERATURE MONITORING CHART

1. Title:

+2 to +8 °C Temperature Monitoring chart

2. Objective of SOP:

To describe the procedure for using the +2 to +8 oC temperature chart correctly

3. Description:

A loose-leaf form for regular charting of the temperature of the refrigerator storing reagents/ media/samples/blood units for the purpose of monitoring the maintenance of the cold chain.

4. Location of the chart:

The temperature chart should be physically located or pinned on the door of each 4 °C fridge in the laboratory or section.

When using a non-digital thermometer, ensure that it is placed in an easy-to-reach rack inside the Refrigerator; however a digital thermometer is preferred to avoid unnecessarily opening the Refrigerator.

5. Who fills the chart?

The technical officer on duty for the week in the particular section.

6. When to fill the chart

TWICE a day at 9.00 AM and 4.00 PM

Steps for completing the Temperature Monitoring Chart:

At the beginning of each new month, enter the following details in the order in which they appear on the chart:

6.1 The District where facility is located

6.2 The name of the facility

6.3 Name and type of the refrigerator (e.g. LG + 2 to +8°C)

6.4 Tick the appropriate box to indicate the source of power for the refrigerator

6.5 Fill in the month and the year to which the chart applies.

6.6 Read and note the temperature on the thermometer or the digital thermometer screen

6.7 For the particular day of the month, in the AM or PM column, place a clear dot (●) in the center of the appropriate AM or PM space to represent the temperature you have read on the thermometer.

6.8 Ensure that each day has two dots, one dot at the center in the space of AM and the other at the center in the space of PM

6.9 Link or join the two dots every day with those of the previous day using a straight line

6.10 Enter the initials of the person filling in the chart and his/her signature (the person on duty for the week).

7. Faults and problems:-

7.1 If a fault is noted, for instance, if the temperature is outside the acceptable range, then enter the date the problem was noted and the exact fault as observed.

7.2 When corrective action is taken, then record the exact action and the date are indicated.

8. Completed temperature charts

The section head should keep completed temperature charts on file in the section as a quality control record.