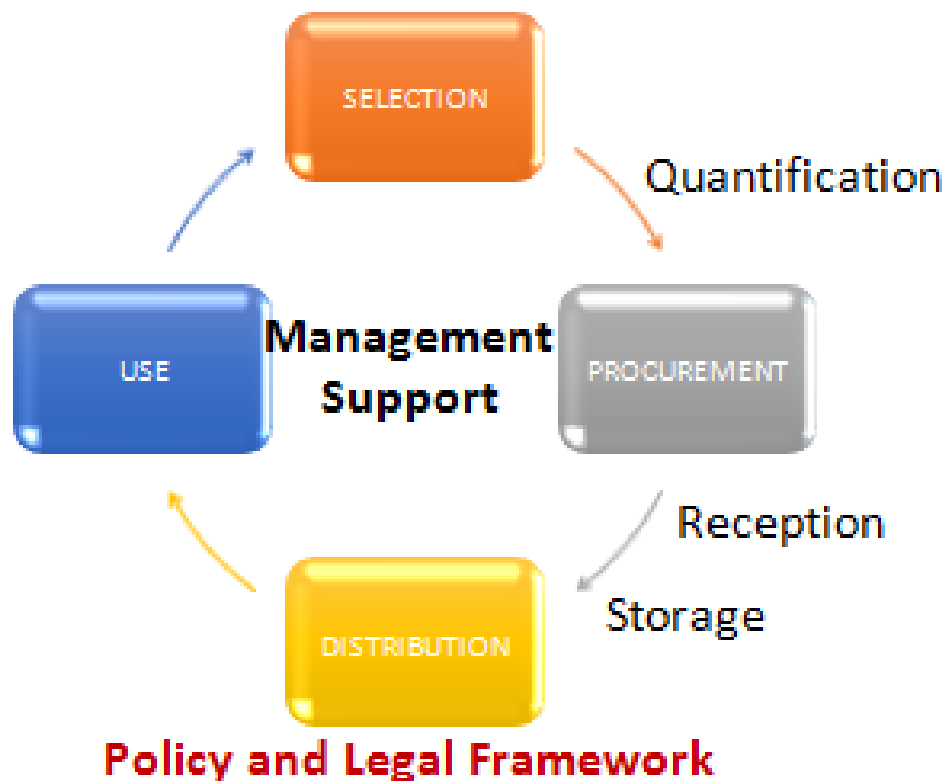




Principles of Drug Management

1 PRINCIPLES OF DRUG MANAGEMENT

Principles of Drug Management



Source: Managing Access to Medicines and Health Technologies, 2012

Slide 1.1

Read Chapter 1: Toward sustainable access to medicines of “**Access to Medicines and Health Technologies**” prior to lecture (a photocopy of the chapter is found in the separate booklet of references). This will provide a very good background on Drug Management.

For the purpose of this manual, the terms “drugs” and “medicines” are used interchangeably.

SESSION OBJECTIVES

1

1. Discuss the importance of managing drugs
2. Identify main elements of the drug management cycle

Slide 1.2

Present the learning objectives for the session.

IMPORTANCE OF MEDICINES

Save lives & improve health

Promote trust and participation in health services

Costly

Different from other consumer products

Substantive improvements in the supply and use of medicines are possible

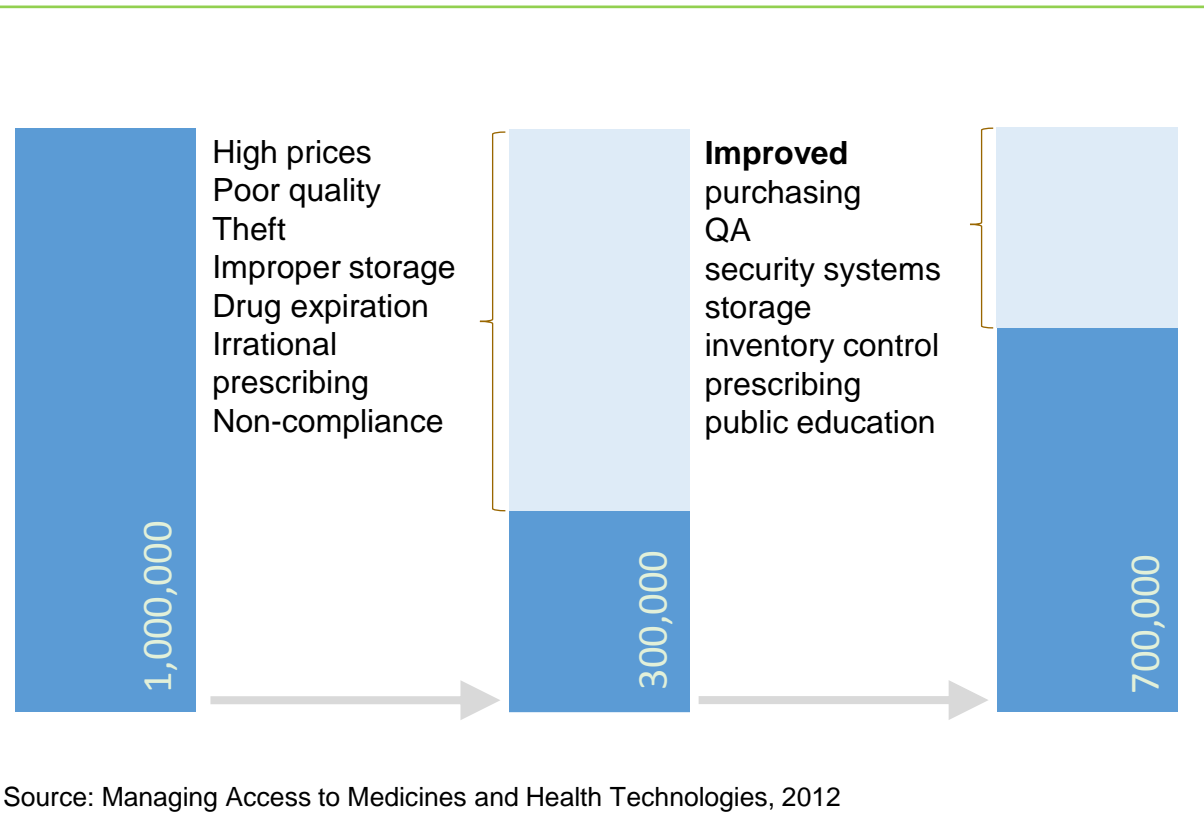
Slide 1.3

Medicine is a special health resource:

1. It saves lives and improves health – most leading causes of discomfort, disability and premature death can be prevented, treated or at least alleviated with cost-effective essential medicines.

2. Promote trust and participation in health services – the credibility of health workers depends on their ability to save lives using medicines as a tool to alleviate symptoms and suffering. The provision of essential medicines is one element of primary health care that families take an interest in and that brings them to health facilities.
3. Costly – medicines can be costly for an individual, a household, government health system or of the country. At the individual and household level, medicines represent a major out-of-pocket health expenditure. At the government and national level, medicines are likewise a major expenditure - 20 to 40% of the total health expenditure.
4. Different from other consumer products – medicines are different from other consumer products because of the following reasons:
 - a. The consumer often does not choose the medicine but usually prescribed by a doctor or recommended by pharmacy staff;
 - b. Even when consumer chooses the medicine, he is not trained to judge its appropriateness, safety, quality or value for money;
 - c. Neither the average medical practitioner nor the average pharmacist is equipped to independently assess quality, safety or efficacy of each new medicine;
 - d. Fear of illness can lead patients to demand or buy costly medicines even when cheaper or no medicines can achieve the same result; and
 - e. The consumer often cannot judge the consequences of not obtaining a needed medicine.
5. Substantive improvements in the supply and use of medicines are possible.

IMPORTANCE OF MEDICINES



Slide 1.4

Lack of careful selection, incorrect quantification, high prices, poor quality, theft, improper storage, expiration of medicines, irrational prescribing, corruption and incorrect medicine use by patients cause losses of as much as 70% of the original expenditure.

With substantial efforts on properly managing medicines – improving purchasing, security systems, better storage, managing inventory effectively, improved prescribing and public education – and additional funding, potential cost reductions and therapeutic improvements are dramatic.

Medicines are accessible:

- Right time
- Right place
- Sufficient quantity
- Reasonable price
- Acceptable quality

Slide 1.5

A well-functioning and efficient supply chain management system (or drug management system) means that medicines are accessible when and where it is needed, in sufficient quantities at reasonable prices and with acceptable quality.

POOR MEDICINE MANAGEMENT

1. Stockouts and treatment interruptions
2. Overstock and economical losses due to expiry
3. Negative impact on the quality of health care

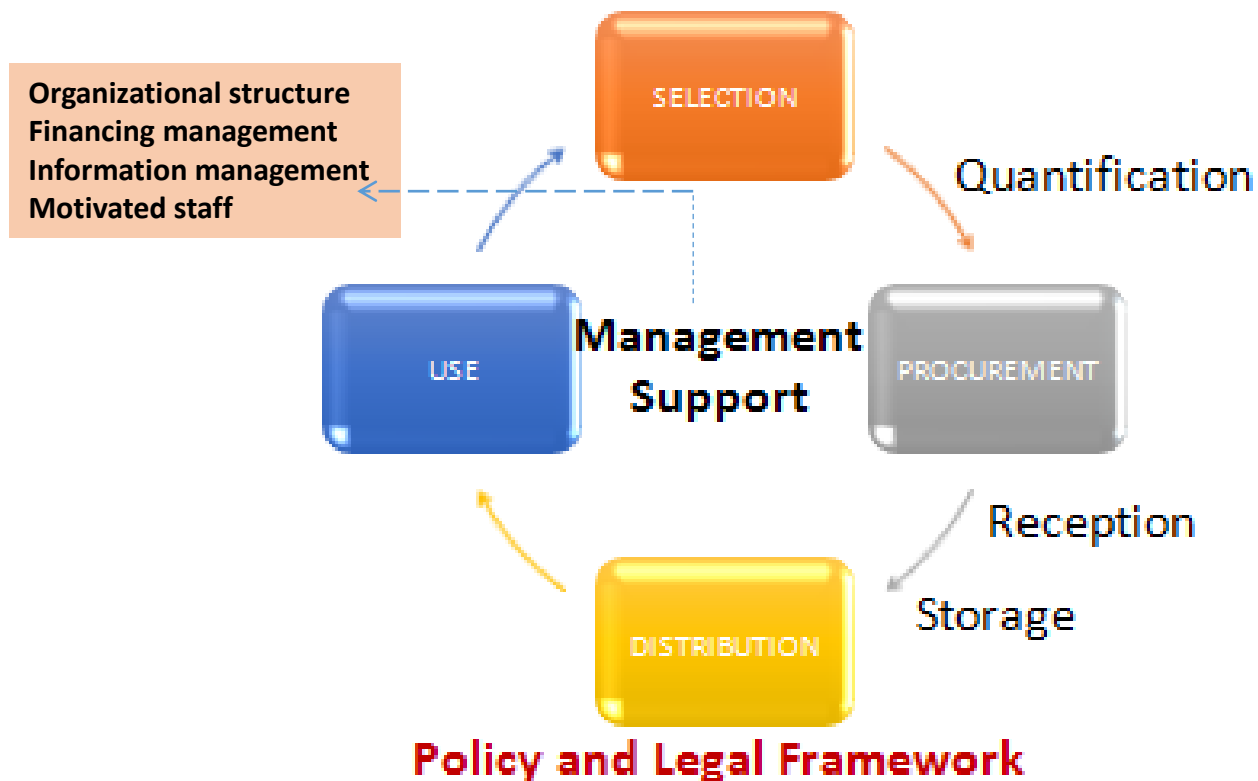
Slide 1.6

The consequences of a poorly managed supply chain management system are the following:

1. Stockouts and treatment interruptions;
2. Overstock and economical losses due to expiry; and
3. Negative impact on the quality of health care.

DRUG MANAGEMENT CYCLE

1



Slide 1.7

Medicines are selected based on pre-determined criteria. After determination of the quantities required, the selected medicines go through a procurement process. Medicines are then delivered to the procuring entity and distributed to the different health facilities. Finally the use of medicines requires prescribing, packaging, dispensing and counseling. These tasks require qualified health personnel with adequate knowledge, appropriate skills and the right attitude. Management support tools are important for the acquisition of relevant skills in drug management within a given legal and policy framework.

DRUG MANAGEMENT CYCLE

Slide 1.7

Emphasize the importance of quality in the management cycle:

Quality is built into a medicine during its design, development and manufacture. This is the primary responsibility of the manufacturers by following Good Manufacturing Practices (GMP).

Quality of medicines must be maintained when it leaves the manufacturer's premises. In each phase of the medicine management cycle, the quality of the product must be ensured through proper storage, transport, distribution, dispensing and use by the people responsible in each phase such as distributors, procurement agencies, dispensers and users.

REVIEW QUESTIONS

1

Answer the following, for numbers 2 to 4, write T if the statement is true and F if it is false:

1. Give the (4) phases of the drug/ management cycle.
2. Quality of medicine is the sole responsibility of the manufacturer.
3. Poor management of medicines leads to poor quality of health care.
4. Poor management of medicines entails additional costs to the health system.
5. Medicines promote trust and participation in health services.

Slide 1.8

Ask them to answer review questions found on their handbook. Discuss the answers:

1. Selection, procurement, distribution, use
2. False or F
3. True or T
4. True or T
5. True of T

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CANN, JM. 2014. *Drug Management Cycle: Overview and Introductory Concepts*. [Powerpoint slides]. Presented at a lecture at Smallville 21 Hotel, Iloilo City.

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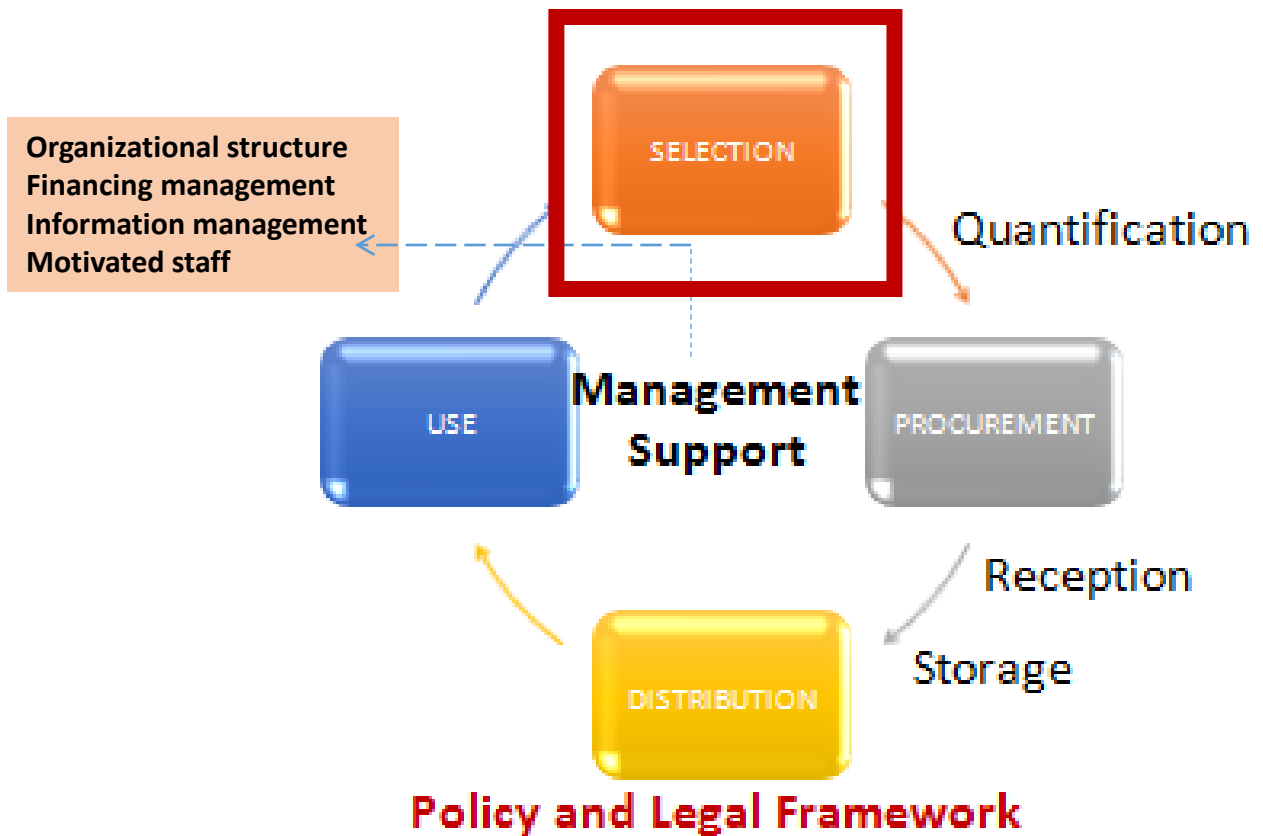
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Selection of Medicines



Slide 2.1

Introduce the drug management cycle once again. Mention that for this session, the focus will be on medicine **selection**.

SELECTION OF MEDICINES

2

Read the **Participant's handbook** prior to the lecture.

Medicines comprise as much as 40% of the health care budget in developing countries like the Philippines. It is also a noted fact that at present, the country's budget for medicines has doubled.

With limited financial resources and rising costs of medicines, its selection must be managed efficiently.

Slide 2.2



SESSION OBJECTIVES

1. Explain the medicine selection process
2. Discuss criteria used in medicine selection

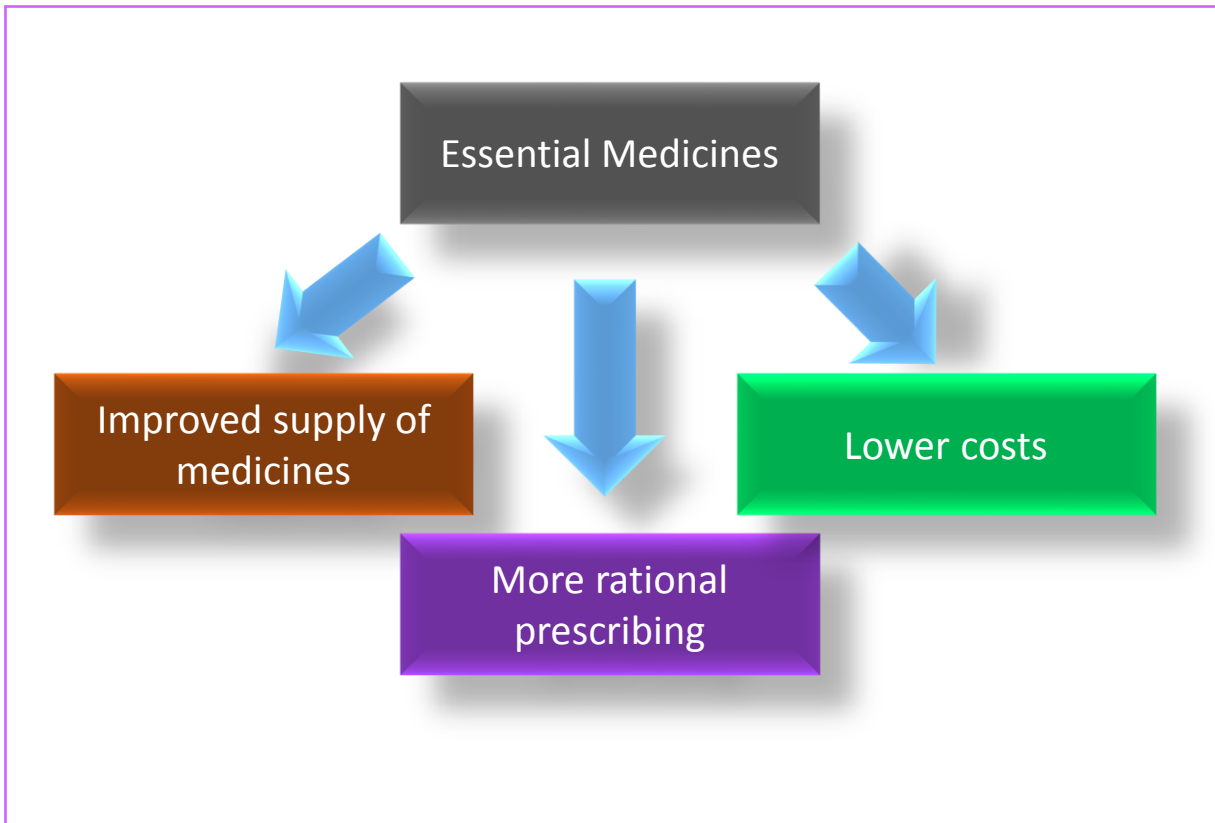
Slide 2.3

Present the learning objectives for the session.

Those that satisfy the needs of the majority of the population and therefore should be available at all times.

Slide 2.4

Introduce the concept of **essential medicines**. The definition provided is that of WHO.



Slide 2.5

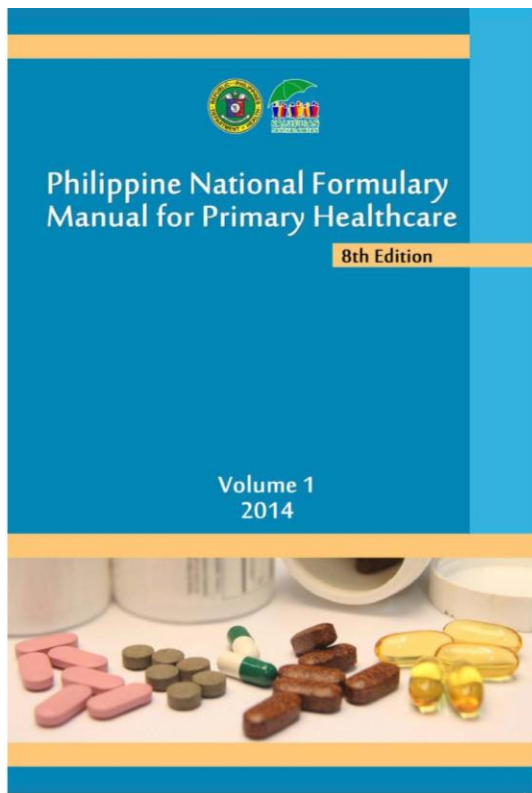
The use of essential medicines in a locality or area has several advantages. The selection and use of essential medicines lead to an improved supply of medicines, more rational prescribing and lower costs.

- Essential medicines list
- Describes the appropriate use of these essential medicines
- Basis for selection of medicines at the local health facility

Slide 2.6

The **Philippine National Formulary** (PNF) or what was used to be called the Philippine National Drug Formulary (PNDF), lists the essential medicines in the country. It also describes the appropriate use of essential medicines.

The Department of Health (DOH) through the Formulary Executive Council (FEC) determines the types of medicines and dosage forms included in the formulary.



fections).

* The Philippine Clinical Practice Guidelines in the Diagnosis, Treatment and Prevention of Leptospirosis in Adults, 2010, PSMID, Quezon City.

Dose Adjustment:

Renal Impairment:

Patients with impaired renal function do not generally require dose reduction unless impairment is severe, in which case, the patient should be referred to a specialist.

Precautions:

History of allergy to penicillins; renal impairment (risk of crystalluria with high doses); high incidence of erythematous rash in glandular fever, acute lymphoblastic leukemia, infectious mononucleosis, chronic lymphocytic leukemia, CMV infection, HIV infection; risk of crystalluria (maintain adequate hydration with high doses); superinfection (prolonged use may result in fungal or bacterial superinfection).

Pregnancy (not known to be harmful); breastfeeding (monitor infant; trace amounts found in milk, but appropriate to use).

Adverse Drug Reactions:

Common: Diarrhea, headache, nausea.

Less Common: Abdominal pain, antibiotic-associated colitis, vomiting.

Rare: Allergic reactions including anaphylaxis, angioneurotic edema, CNS disorders, including convulsions (associated with high doses, or impaired renal function); coagulation disorders, hemolytic anemia, interstitial nephritis, mucocutaneous candidiasis, neutropenia, pustular drug eruption, rash, serum sickness-like reactions, thrombocytopenia, urticaria.

NOTE: A widespread, erythematous maculopapular rash (pseudoallergic) is common; often occurs after >7 days treatment and resolves 1-7 days after treatment is stopped, or after 6-14 days if it continues (although not immune-mediated, consider skin testing to check for hypersensitivity before using penicillin again).

AMPICILLIN

Inj.: 125 mg, 250 mg, 500 mg and 1 g vial (IM, IV) (as sodium salt)

An extended-spectrum aminopenicillin useful for treating serious conditions not amenable to oral therapy, or infections caused by penicillin-susceptible bacteria, such as anaerobes, enterococci, and beta lactamase-negative strains of gram-negative cocci and bacilli. This is given parenterally because only less than half of the oral dose is absorbed (absorption is further decreased by food).

Indications: Sepsis neonatorum (with gentamicin); enteric fever.

Antimicrobial Resistance ALERT!

Due to high resistance of *Haemophilus pneumoniae* to ampicillin, this antibiotic is not recommended as empiric therapy for infections caused by this pathogen.

Contraindications: Known hypersensitivity to penicillins or any component of the formulation; patients with glandular fever or acute lymphatic leukemia.

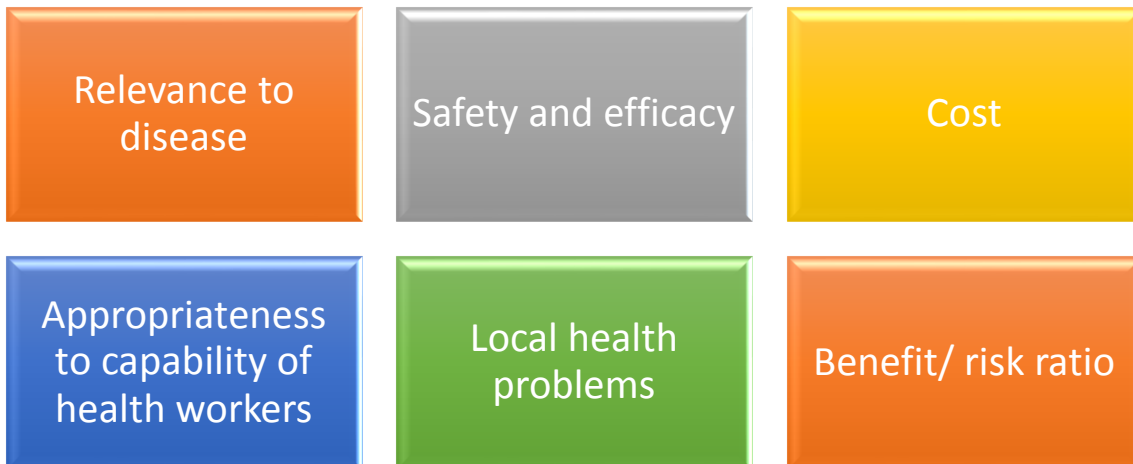
Dose:

Enteric fever (typhoid fever), by IV push over 3-5 minutes or IV infusion over 15-30 minutes; **ADULT**, 50-100 mg/kg/day divided every 6 hours for 1-2 weeks; **CHILD**, 100 mg/kg/day divided every 6 hours for 1-2 weeks. Once with clinical improvement and oral medication is tolerated, the antibiotic may be shifted to oral amoxicillin (See under Amoxicillin).

Sepsis neonatorum (with gentamicin), by IV push over 3-5 minutes or IV infusion over 15-30 minutes; **NEONATE** <7 days, ≤2 kg weight: 25-50 mg/kg/dose every 12 hours; >2 kg weight: 25-50 mg/kg/dose every 8 hours; **NEONATE**

Slide 2.7

The list of medicines that may be found in local public health facilities like Rural Health Units (RHUs) used to be listed under Category A or B of the PNDF. In 2014 however a separate PNF Manual for Primary Healthcare was released. This PNF does not simply list down the medicines but provides basic information about the medicine such as dose, administration, Adverse Drug Reactions (ADRs) and antimicrobial alerts for anti-infectives.



Slide 2.8

Slide 2.8

The criteria for inclusion of medicines into the formulary include the following (among others):

- **Relevance to disease** or indicated in the treatment of prevalent diseases;
- **Safety and efficacy** based on objective results from adequate pharmacologic studies including at least expanded Phase II and/or additional Phase III among Filipinos;
- **Quality** must have met adequate quality control standards including stability and when necessary bioavailability;
- **Cost** of treatment regimen not just unit cost;
- **Appropriateness to the capability of health workers at different levels of health care** or consideration of the level of expertise required to prescribe, administer and monitor the safety and adverse effects of single drugs or group of drugs in a therapeutic category;
- **Local health problems** or concomitant, locally prevalent diseases or conditions on pharmacokinetic and pharmacodynamics parameters modifying therapeutic response;
- **Benefit/risk ratio** looking at one with the most favorable ratio.



INN or Generic Name

Slide 2.9

The **international non-proprietary name** (INN) or the generic name is the medicine's official name, regardless of what company or organization manufacturers or markets it.

A **proprietary, commercial, trade** or **brand name** is chosen by the manufacturer to facilitate recognition and association of the product with a particular firm for marketing purposes.

In the Philippines, **RA 6675 (Generics Act)** requires the use of generic names in all transactions related to purchasing, prescribing, dispensing and administration of medicines. In prescriptions, if the product comes with a brand name, the brand name shall in all cases be preceded by the generic name and enclosed in parenthesis or brackets.

GENERIC NAMES	BRAND NAMES
AMLODIPINE	AMVASC® NORVASC® VASALAT®
AMOXICILLIN	AMOXIL® HIMOX® MOXILIN®
CIPROFLOXACIN	CIPRO® CIPROBAY®
COTRIMOXAZOLE	BACTRIM®
DIPHENHYDRAMINE	BENADRYL®
SALBUTAMOL	ASMALIN® VENTOLIN®

Slide 2.10

This table shows some examples of generic names and brand names.

- Generic names are more informative and facilitate purchase of products from multiple suppliers.
- There is easy recognition of the type of medicine.
- Generic prescribing facilitates product substitution whenever appropriate.
- The confusion associated with the use of brand names can be avoided.

Slide 2.11

The use of generic names in medicine selection and eventually procurement and prescribing offers these advantages. The generic name helps identify the class of medicines. The common stem of the INN usually indicates a “family” of medicines (i.e. names of benzodiazepines end with –zepam) which facilitates easy recognition.

Slide 2.11

With regard to price, the patents on many common medicines have expired, allowing various manufacturers to produce and market equivalent products by the medicines' generic names. These generic products are usually sold at a lower price than that of branded equivalents. Therefore the use of the generic name introduces elements of price competition. If a prescription is written using the generic name of the medicine, the pharmacist may dispense an equivalent product with a price that is more acceptable to the consumer but that also meets quality standards.

Generic substitution may also be facilitated. The pharmacist may substitute a generic equivalent unless the prescriber specifically indicates that this should not be done. This measure may lead to large savings in pharmaceutical costs.

REVIEW QUESTIONS

2

For numbers 1 to 4, write T if the statement is true and F if it is false; for number 5, choose the letter of the correct answer.

1. The use of PNF as basis for the selection of medicines in public health facility is voluntary.
2. Cost should be the primary criterion considered in the inclusion of medicines in any health facility.
3. The use of generic names facilitates purchase from multiple sources thus leading to a more competitive price.

Slide 2.12

Ask the participants to answer the review questions found in their handbooks. The answers are as follows:

1. False or F
2. False or F
3. True or T

REVIEW QUESTIONS

4. The public health facility may request medicine outside the PNF.
5. The following are criteria for inclusion of a drug/ medicine into the PNF except:
 - a. Local health problems
 - b. Quality
 - c. Safety
 - d. Appropriateness to the capability of health workers at different levels of health care
 - e. None of the above

Slide 2.13

Ask the participants to answer the review questions found in their handbooks. The answers are as follows:

4. False or F
5. e

REFERENCES

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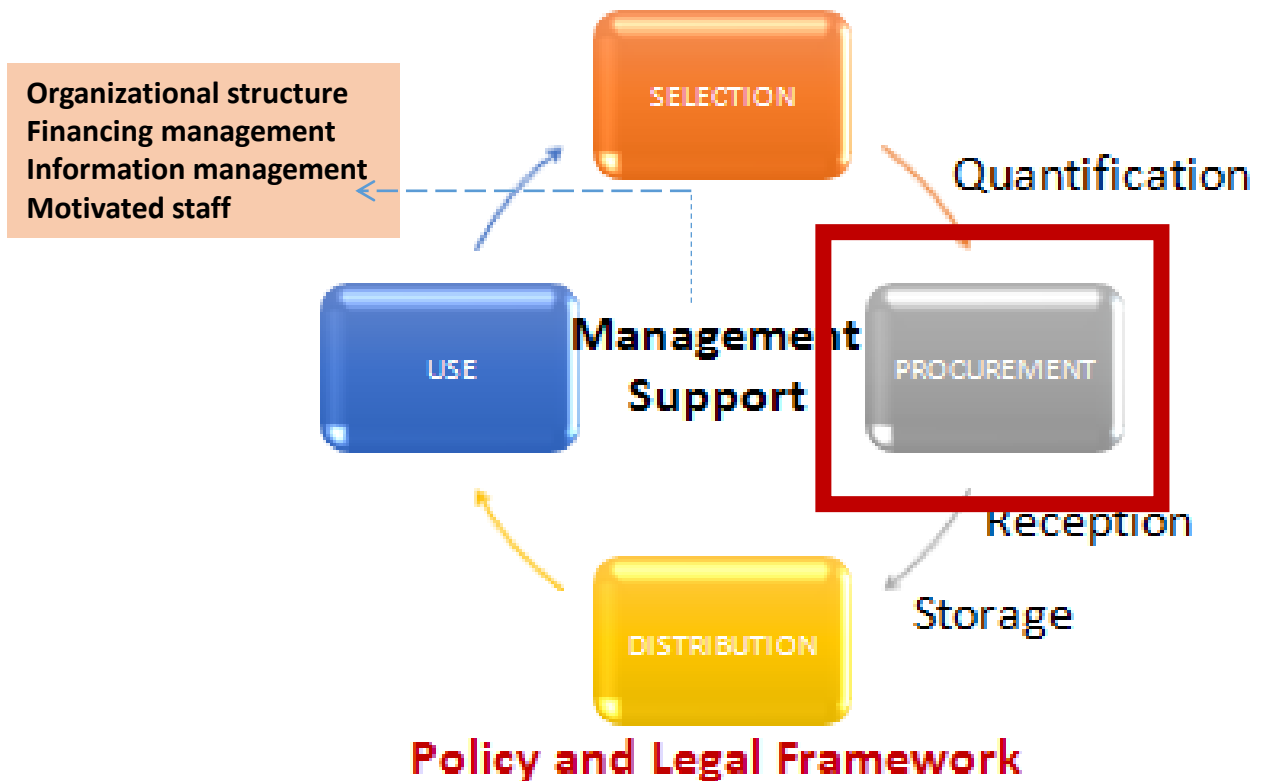
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Procurement of Medicines

DRUG MANAGEMENT CYCLE



Slide 3.1

Present the drug management cycle once again but emphasize that this session will be on **quantification** and **procurement**.

PROCUREMENT OF MEDICINES AT THE LOCAL HEALTH FACILITIES

3



Slide 3.2

After selecting medicines appropriate for the local health facility, the procurement process commences.

SESSION OBJECTIVES

1. Discuss the medicine procurement process
2. Calculate order quantities and request indicator for procurement
3. Identify components of a medicine requisition and delivery forms
4. Describe procedure of receipt of medicines at the local health facility and detection of discrepancies in supplies/orders

Slide 3.3

Present the learning objectives for the session.

- Procurement in government entities is governed by Republic Act 9184 “Government Procurement Reform Act”
 - Acquisition of goods, consulting services and the contracting for infrastructure projects by the procuring entity

Slide 3.4

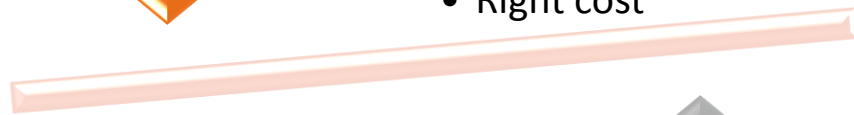
RA 9184 or “**Government Procurement Reform Act**” governs the procurement process in all government entities in the country.

Procurement is defined by RA 9184 as the acquisition of goods, consulting services and the contracting for infrastructure projects by the procuring entity.

PROCUREMENT SYSTEM



- Right medicine
- Right quality
- Right time
- Right quantity
- Right cost



Effective and
efficient

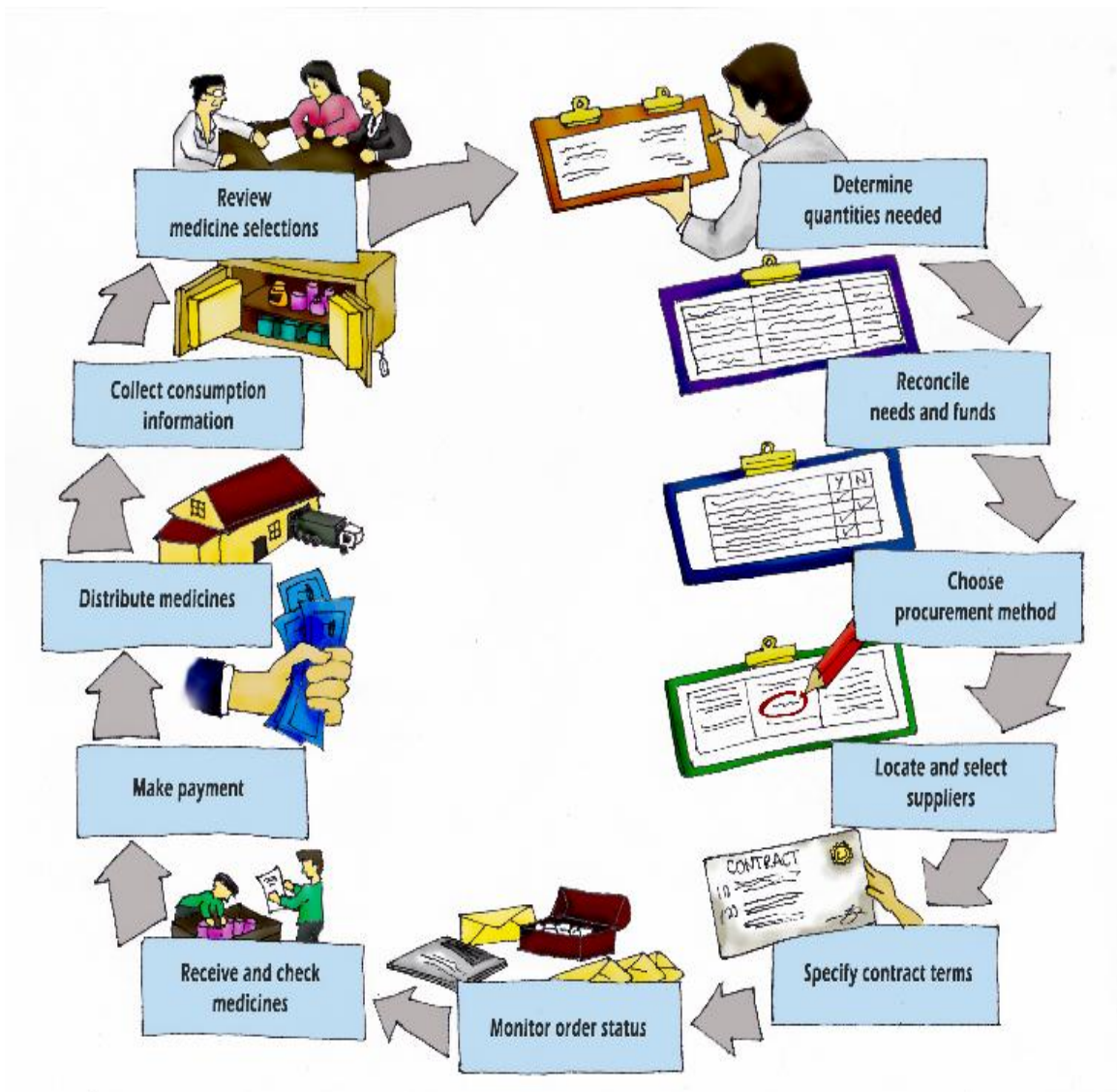


Slide 3.5

An effective and efficient procurement system ensures that the right medicine, of the right quality are obtained at the right time in the right quantity and the right cost.

PROCUREMENT PROCESS

3



Source: Managing Access to Medicines and Health Technologies, 2012

Slide 3.6

This diagram shows the procurement process.

QUANTIFICATION

Quantification

- Process of determining the estimated quantity of a needed product for a specific period of time based on a set of assumptions
- Also includes the estimation of the financial means required for purchasing the item

Slide 3.7

After medicines are selected, the next step is to quantify the requirements needed.

- Determine rational quantities of products to be procured
- Avoid stockout and ensure continuous availability
- Avoid overstock and wastage due to expiry
- Make the best use of resources and budgets
- Provide data on specific products use
- Calculate emergency needs for disaster relief and/ or epidemics

Slide 3.8

The objectives of quantification are the following:

- ✓ Determine rationale quantities of products to be procured
- ✓ Avoid stockout and ensure continuous availability
- ✓ Avoid overstock and wastage due to expiry
- ✓ Make the best use of resources and budgets
- ✓ Provide data on specific products use
- ✓ Calculate emergency needs for disaster relief and/ or epidemics

METHODS FOR QUANTIFICATION

Morbidity method

- Forecasts the anticipated quantity of medicines needed to treat an expected number of cases for specific diseases based on incidence data

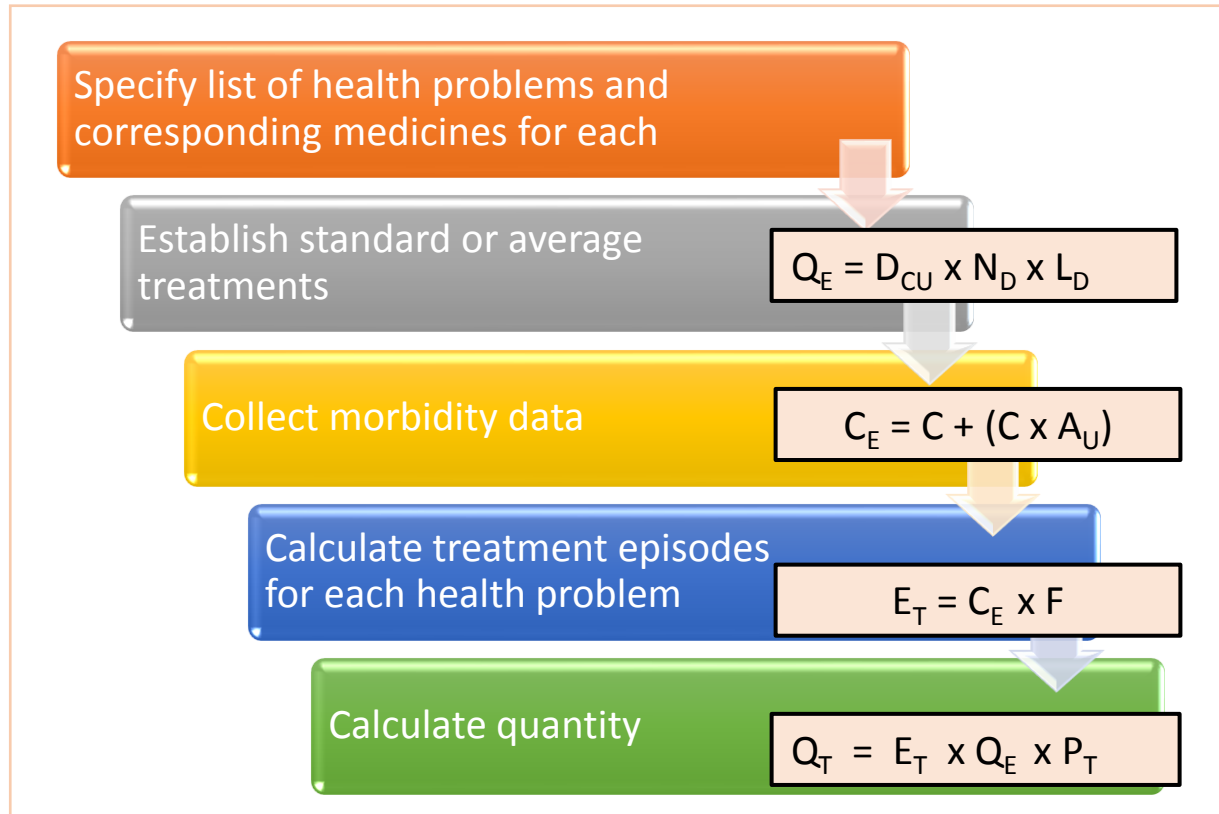
Consumption method

- Based on past consumptions of every item
- Involves analysis of historical consumption trends and assumptions about factors that may influence the demand in the future

Slide 3.9

The two most common methods of quantification are:

1. **Morbidity** method – which forecasts the anticipated quantity of medicines needed to treat an expected number of cases for specific diseases based on incidence data.
2. **Consumption** method – which is based on past consumption of the item. It involves analysis of historical consumption trends and assumptions about factors that may influence the demand in the future.



Slide 3.10

This illustrates quantifying medicine requirements using morbidity method. The steps are explained in the next page.

MORBIDITY METHOD

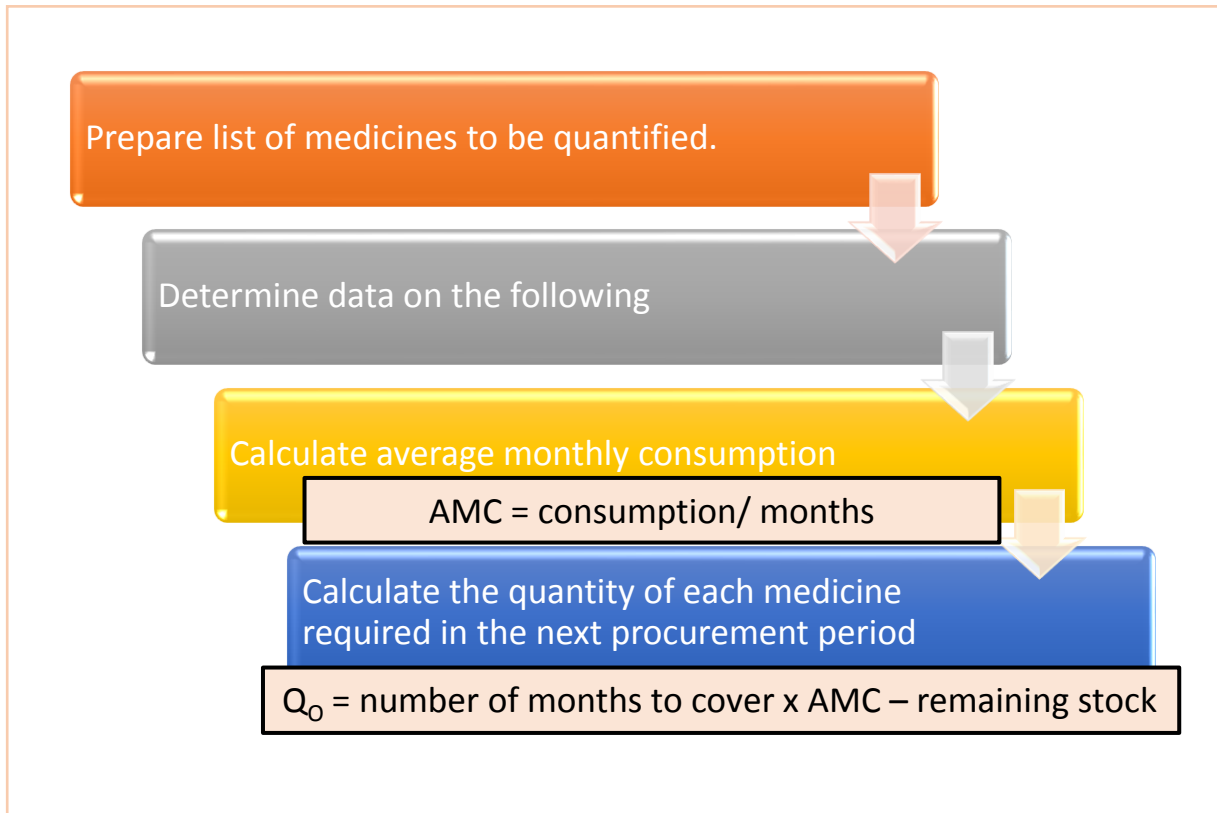
Slide 3.10

1. Specify list of prevalent health problems in your area. For each health problem, identify the medicine indicated for that condition.
2. Establish standard or average treatments. To forecast medicine needs, standard or average treatment regimens (per patient) for each health condition must be computed $Q_E = D_{CU} \times N_D \times L_D$
 - where D_{CU} = Basic units per dose;
 - N_D = Number of Doses per day;
 - L_D = Length of treatment in days
3. Collect morbidity data – This step estimates the expected number of treatment episodes for each health problem. $C_E = C + (C \times A_U)$
 - where C_E = Expected total number of contacts;
 - C = Past total number of contacts;
 - A_U = Utilization adjustment
4. Calculate treatment episodes for each health problem $E_T = C_E \times F$
 - Where C_E = Expected total number of contacts;
 - F = Frequency of health problem (per thousand)
5. Calculate quantity of medicines to be procured, $Q_T = E_T \times Q_E \times P_T$
 - Q_T = Total quantity required;
 - E_T = Expected treatment episodes;
 - P_T = Percentage of cases expected to be treated

Slide 3.11

Procurement of Medicines

CONSUMPTION METHOD



Slide 3.12

These are the steps in consumption method. Data that need to be determined include past consumption data, number of days stockout, losses and inventory.

CONSUMPTION METHOD

3

Example Consumption Method

Data of monthly consumption of paracetamol 500-mg tablets over a six-month period.

April 2014	2,000 tablets
May 2014	3,100 tablets
June 2014	2,300 tablets
July 2014	2,100 tablets
August 2014	3,100 tablets
September 2014	3,200 tablets
Total	15,800 tablets

Average monthly consumption of tablet:

$$\frac{15,800}{6} = 2633.3 \text{ tablets}$$

If number of months to cover is also 6 months and remaining inventory is 4,000 tablets

$$Q_0 = (2,633.3 \times 6) - 4,000 \\ = 11,799.8 \text{ tablets}$$

Slide 3.13

This is an example of quantifying medicine requirements using consumption method.

REQUEST INDICATOR

- The level of drugs in stock
- Indicates when new orders should be made
- The quantity that is calculated to last between the period of placing the order and the delivery of the new consignment

Each stock card must have an RI that is updated from time to time as consumption varies.

Slide 3.14

The request indicator (RI) is marked with pencil in the space “RI” on the top right-hand corner of the stock card. It should be updated at least twice a year because consumption may vary due to seasonal changes or epidemics.

This will ensure that no stockout occurs before the next consignment is expected. The stock should not be allowed to fall below this level before a new order is placed. Each stock card must have an RI that is updated from time to time as consumption varies.

The stock should never reach “0 level” before a request is made, as there will be a stockout for some time. It is easy to calculate the RI once the monthly consumption is obtained.

If the delivery time is three months and the monthly total consumption is 2633.3. RI is:

$$2633.3 \text{ tablets} \times 3 \text{ months} = 7,900 \text{ tablets}$$

Since the unit of issue is tins of 1,000 tablets, the above figure must be brought to the nearest tin, which is:

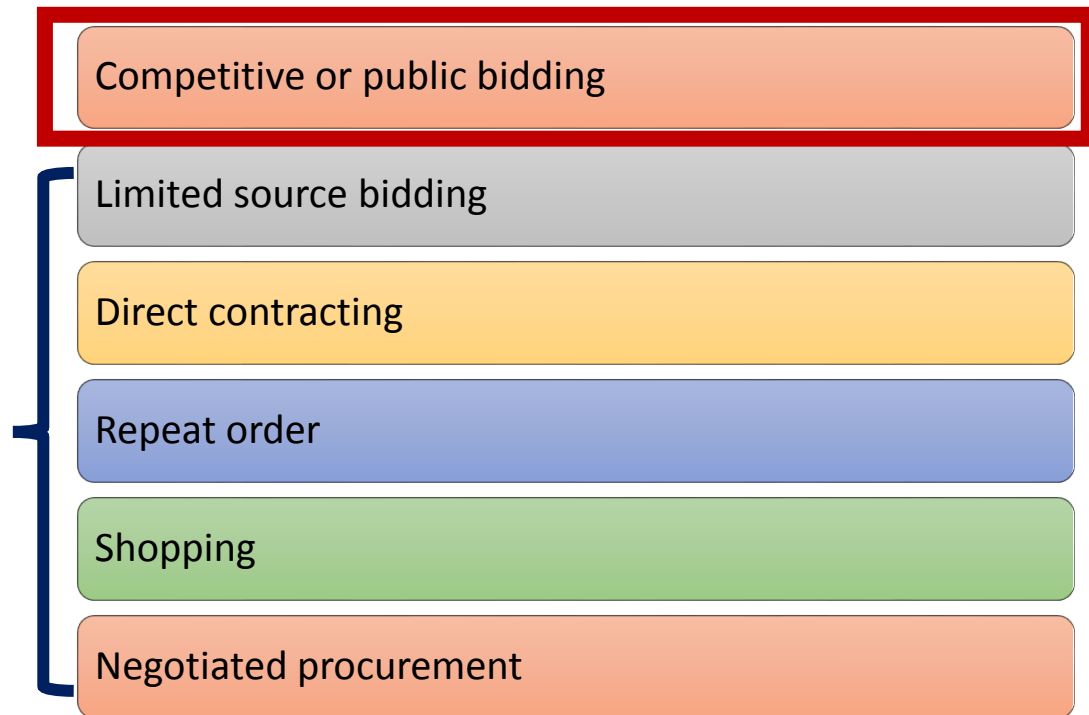
$$\begin{array}{r} 7,900 \\ \text{-----} \\ 1000 \end{array} = 7.90 \text{ or } 8 \text{ tins}$$

This means that when the stock of paracetamol is reduced to 8 tins, a new request must be made.

Slide 3.15

This is an example of computing for RI of a particular medicine.

PROCUREMENT METHODS



Slide 3.16

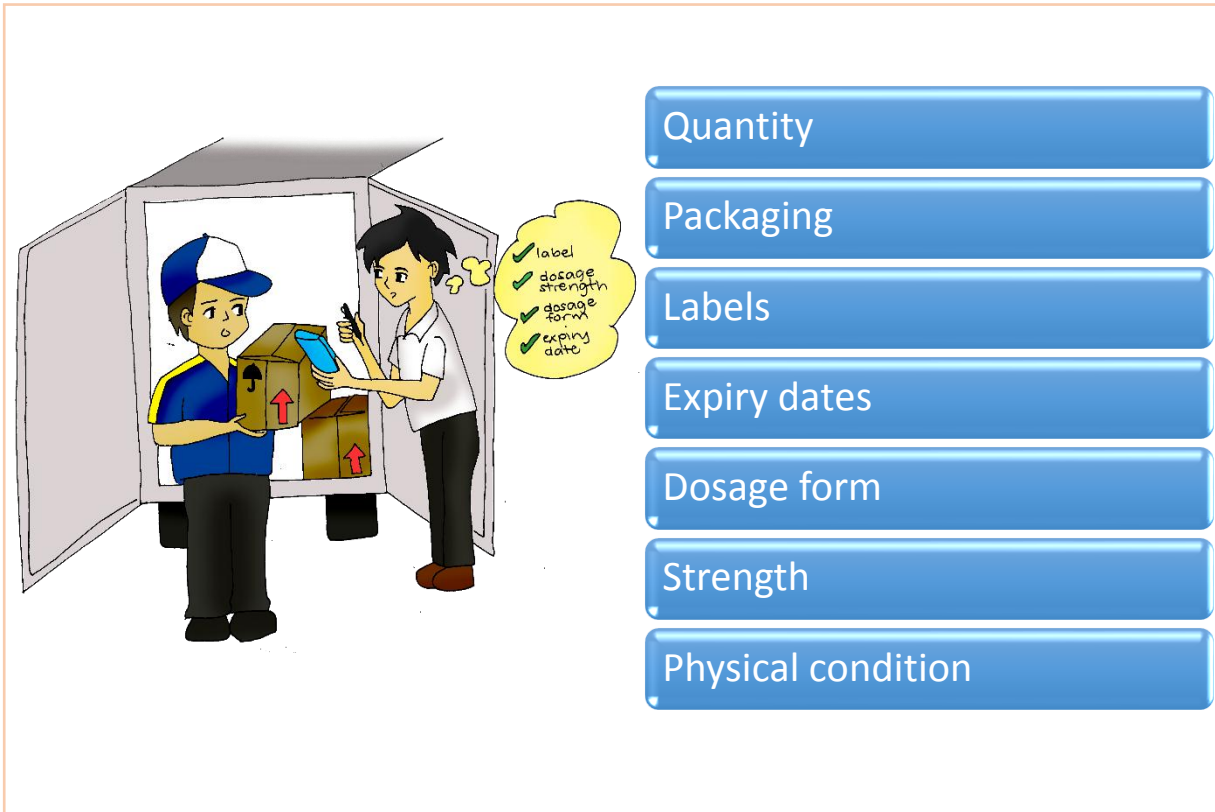
These methods of procurement are explained in the next page.

The primary method of procurement in a government facility is competitive or public bidding. There are however other methods of procurement that can be used. RA 9184 outlines conditions when the alternative methods of procurement may be employed.

1. Competitive bidding is open to participation by any interested party.
2. Limited source bidding, also known as selective bidding is a method of procurement that involves direct invitation to bid from a list of pre-selected suppliers with known experience and proven capability on the requirements of the contract. This method is recommended for procurement of medicines.
3. Direct contracting does not require elaborate bidding documents but rather asks for price quotations with the conditions of sale from suppliers.
4. Repeat order refers to procurement of goods from previous winning bidder.
5. Shopping is the method where procuring entity simply requests for the submission of price quotations from suppliers of known qualifications.
6. Negotiated procurement is the method where the procuring entity directly negotiates a contract with the supplier.

The United States Pharmacopeia (USP) however suggests that the preferred method for procuring medicines is Limited Source Bidding.

RECEIPT OF MEDICINES AT THE HEALTH FACILITY



Slide 3.17

Upon delivery of supplies to the local health facility, these should be inspected and checked against the specifications listed in the Purchase Order:

- Quantity actually corresponds to the quantity indicated on the requisition/ delivery form;
- Original boxes, tins or bottles are unopened and in good condition;
- Labels, expiry dates, dosage form, strength indicated are consistent with the specifications;
- Physical conditions such as appearance, color, volume, clarity, etc. are written specifications.

If there are discrepancies in the deliveries and specifications, these should be properly documented and deliveries should not be accepted.

- Lead (delivery) time
- Compliance with pricing terms
- Compliance with remaining shelf life requirements
- Compliance with packaging and labelling instructions
- Compliance with technical specifications
- Compliance with contract terms
- Summary of outcomes of performed inspections

Slide 3.18

In order to enhance safety and ensure quality of products, performance of suppliers must be monitored. A reporting system must be in place and shared to the Bids and Awards Committee (BAC) for use in evaluating suppliers in the future. Data regarding supplier performance that may be tracked include the aforementioned.

The performance of the supplier may be used to determine whether the supplier will still be allowed to join future bidding projects. Other consequences for performance problems should likewise be determined.

REVIEW QUESTIONS

For numbers 1 to 4, write T if the statement is true and F if it is false; for number 5, choose the letter of the correct answer

1. Procurement in a government health facility such as the RHU is governed by RA 6675.
2. An efficient procurement system avoids stockouts and ensures continuous availability of medicines.
3. Monitoring supplier performance should be an integral part of the procurement process.

Slide 3.19

Ask the participants to answer the review questions found in their handbooks. The answers are as follows:

1. False or F
2. True or T
3. True or T

REVIEW QUESTIONS

3

4. Limited bidding is USP's recommended procurement method because of the pre-qualification process for suppliers.
5. The following factors are considered in quantifying medicine requirements using consumption method except:
 - a. Lead time
 - b. Stockouts
 - c. Prevalence data
 - d. Procurement period

Slide 3.20

Ask the participants to answer the review questions found in their handbooks. The answers are as follows:

4. True or T
5. c

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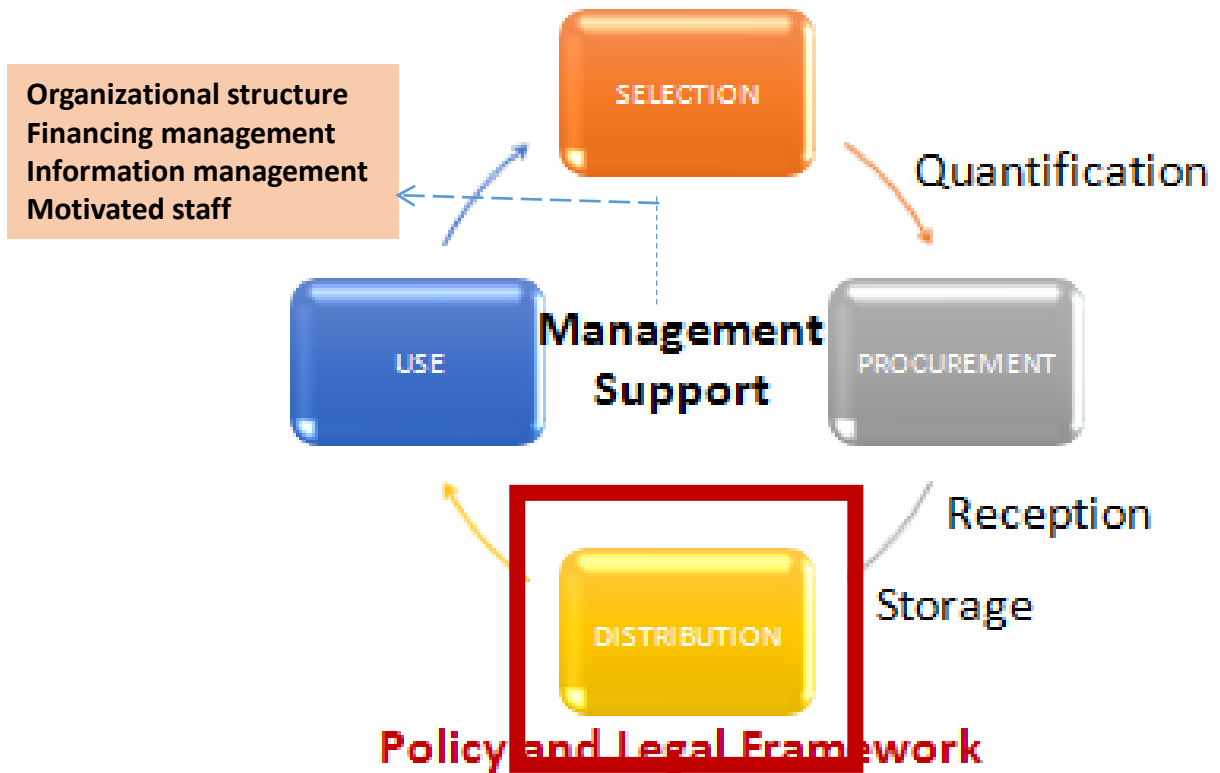
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Storage and Distribution of Medicines



Slide 4.1

Show the drug management cycle figure and emphasize that this session is devoted to **storage** and **distribution**.



Slide 4.2

Good medicine quality depends in large part on proper storage and distribution practices.

Clear policies must be in place and good practices must be observed in order to protect the quality and stability of the product throughout the distribution chain.

1. Explain importance of good storage and distribution practices
2. Describe good storage and distribution practices
3. Identify common problems encountered in storage and distribution of medicines

Slide 4.3

Present the learning objectives for the session.

Primary Goal of Distribution System

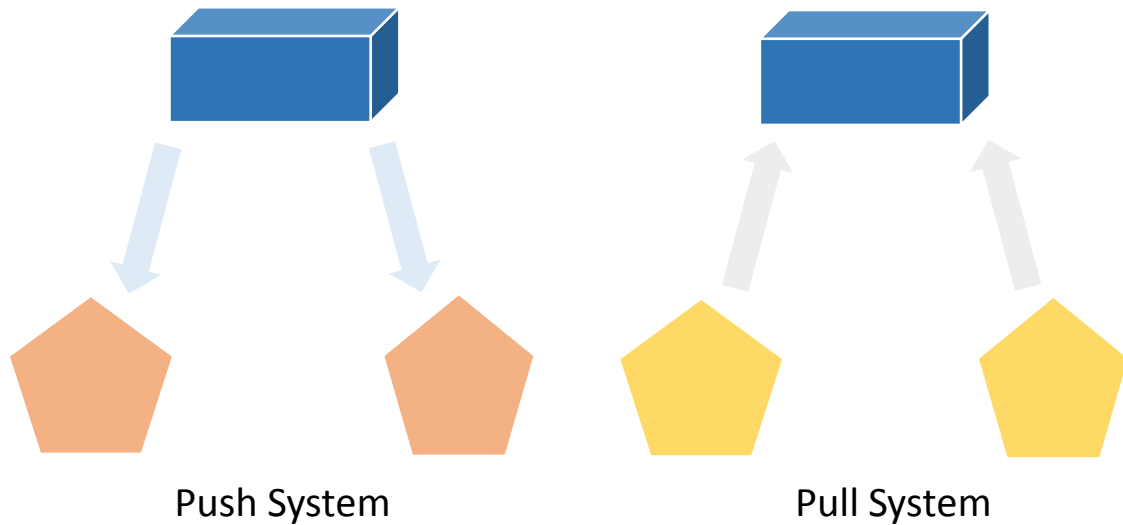
Maintain a steady supply of pharmaceuticals and supplies to facilities where they are needed

- ✓ Constant supply;
- ✓ Maintenance of quality of medicines;
- ✓ Minimal loss or pilferage;
- ✓ Accurate and timely inventory and transaction information;
- ✓ Proper storage;
- ✓ Efficient transport and delivery; and
- ✓ Adequate geographic coverage.

Slide 4.4

The next phase of the drug management cycle is distribution. The primary distribution management goal is to maintain a steady supply of pharmaceuticals and supplies to facilities where they are needed, while ensuring that resources are being used in the most effective way.

Activities pertaining to distribution include storage, inventory control, delivery, and the return of overstocked and nearly expired medicines.



Slide 4.5

There are two systems of distribution – push and pull system.

The **push system** is also known as allocation system. In this system, quantities of drugs sent to the facility are determined by the upper level in the supply chain. This is normally used if sufficient data is not available to conduct quantification. It is also useful after disasters.

The **pull system** is when quantities requested by the facility is actually provided after the quantification exercise has been performed. This is the recommended system of distribution.

- Ensure stability of the products
- Avoid contamination and deterioration of the products
- Avoid deterioration of the packaging/ labelling
- Prevent or reduce pilferage, thefts and losses
- Prevent infestation of pests or vermin

Slide 4.6

Medicines are usually stored in health facilities prior to distribution.

Proper storage conditions are critical to maintain the quality of medicines. Good storage practices should be implemented in order to achieve the aforementioned.

- Identified area
- Sufficient space
- Sufficient lighting
- Clean conditions
- With temperature and humidity controls
- Cold chain facilities (if needed)
- Shelves and pallets

Slide 4.7

In setting up a store room or space for storing medicines, the following should be considered:

- **Identified area** – a specific area must be identified which is specifically for the purpose of storage of medicines.
- **Sufficient space** – storage areas should be of sufficient capacity to allow orderly storage of medicines present. The size therefore will vary depending on the size of the facility, the population it serves and more importantly the stocks that it usually carry.
- **Sufficient lighting** – the store room must have adequate lighting to enable all operations to be carried out accurately and safely.
- **Clean conditions** – storage areas should be clean and free from accumulated waste and vermin. A written sanitation program should be available indicating the frequency of cleaning and methods to be used to clean the premises.
- **With temperature and humidity controls** – the room should be designed or adapted to ensure good storage conditions. It should be equipped with temperature and humidity monitoring equipment to facilitate monitoring.
- **Cold chain facilities (if needed)** – if there are medicines with special requirements, a specially designed refrigerator must be available.
- **Shelves and pallets** – shelves are important to store medicines in retail or in smaller boxes. This will facilitate ease in arrangement. Pallets are especially useful for storing medicines in bulk or those in large boxes so that these will be stored off the floor and permit cleaning and inspection. Both shelves and pallets should be kept in a good state of cleanliness and repair.

Limit access to storage areas to authorized personnel.

- Limit access to only designated staff
- Secure locks and doors (limited number of keys)

Ensure proper storage conditions (temperature, humidity, lighting)

Slide 4.8

Good storage practices however involve more than maintaining adequate facilities. It is also equally important to develop procedures for receiving, labelling, inventory and security.

The key points of good storage practices include the following:

- Limit access to storage areas to authorized personnel – only authorized personnel should have access to locked storage areas. Storage areas must be equipped with locks and there should be limited number of duplicate keys available. It should also be clear who can have access to the duplicate keys.
- Ensure proper storage conditions – storage conditions for medicines and other pharmaceuticals must be in compliance with the labelling, which is based on the results of stability testing.

Security

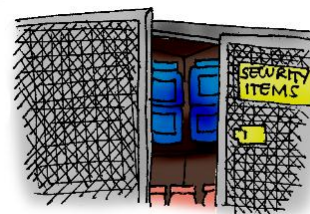
Secure the storeroom

- double doors/double locks on entrance
- burglar bars on windows

Use extra precaution for "attractive items"



No lockable cupboards?
Then improvise: secure using
wire mesh, latch, and padlock

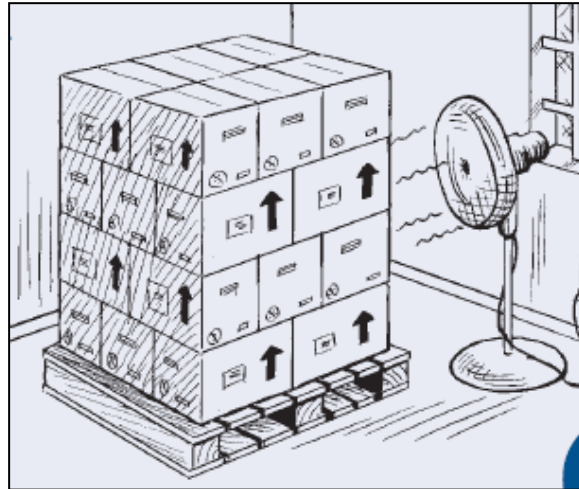


Source: Managing Access to Medicines and Health Technologies, 2012

Slide 4.9

Humidity must not be more than 65% RH

- Packaging
- Circulation
- Air conditioners



Source: Guidelines for the Storage of Essential Medicines and Other Health Commodities, 2003

Slide 4.10

Medicines must be protected from moisture. Humidity must not be more than 65% RH. In order to reduce effects of humidity, the following practices are encouraged:

1. Packaging – Secure all lids. Do not open a new container unless necessary.
2. Circulation – Use a fan to circulate fresh air. Standing fans are more useful in smaller store rooms but requires electricity and some maintenance.
3. Use of air conditioners is encouraged. A dehumidifier may also be used.

- Protect from sunlight
- Keep room dry, well-ventilated and with temperature not more than 25°C
 - Monitor temperature and RH twice a day
- For products which require low temperature, a commercially available refrigerator especially designed for medicine products is recommended

Slide 4.11

Protect products from sunlight as it may cause damage especially if it is photosensitive. To protect products from sunlight:

- Shade the windows or use curtains, if they are in direct sunlight;
- Keep products in cartons;
- Do not store or pack products in sunlight;
- Use opaque plastic or dark glass bottles for products that require them; and
- Maintain trees on the premises around the facility to help provide shade, but check them regularly to ensure that there aren't any branches that can damage the facilities.

Keep room dry, well-ventilated and with temperature not more than 25°C. Air conditioning units or fans may be used. Thermometers and RH monitors must be available so monitoring can be facilitated.

For products which require low temperature, a commercially available refrigerator especially designed for medicine products is recommended.

- Organize and clearly label storage areas
 - Arrange by pharmaceutical form then by alphabetical order of generic names then by expiry dates
- Label clearly an expiry date on all containers.

Slide 4.12

Orderly Arrangement

Provide sufficient shelving

Use a system for arrangement: by order code/
drug category or alphabetic by generic name

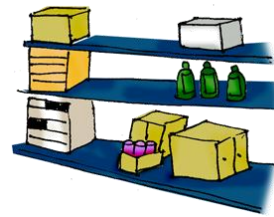
Guard against spoilage: lightweight items
higher up; heavy fluids, fragile items lower

Arrange neatly and label shelf for each item



No shelves?

Then improvise: support planks with
bricks or crates; use strong cartons
and other empty containers



Source: Managing Access to Medicines and Health Technologies, 2012

Slide 4.13

Arrange by pharmaceutical form then by alphabetical order of generic names then by expiry dates.

If using pallets, stack cartons on pallets:

- ❑ at least 10 cm (4 in) off the floor
- ❑ at least 30 cm (1 foot) away from the walls and other stacks
- ❑ no more than 2.5 m (8 ft) high (general rule)



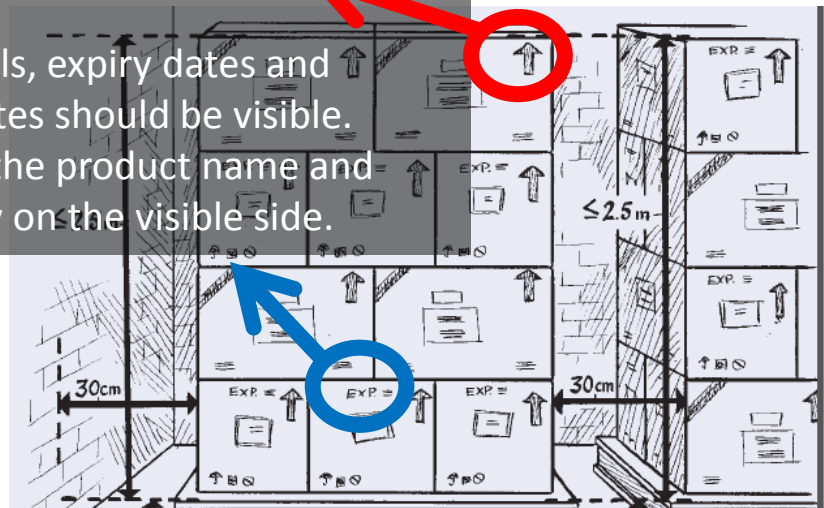
Source: Guidelines for the Storage of Essential Medicines and Other Health Commodities, 2003

Slide 4.14

The distances mentioned in the first two bullets, will facilitate ease in cleaning the areas.

Follow the manufacturer's or shipper's directions when stacking and follow labels for storage conditions.

Identification labels, expiry dates and manufacturing dates should be visible. Otherwise, write the product name and expiry date clearly on the visible side.



Source: Guidelines for the Storage of Essential Medicines and Other Health Commodities, 2003

Slide 4.15

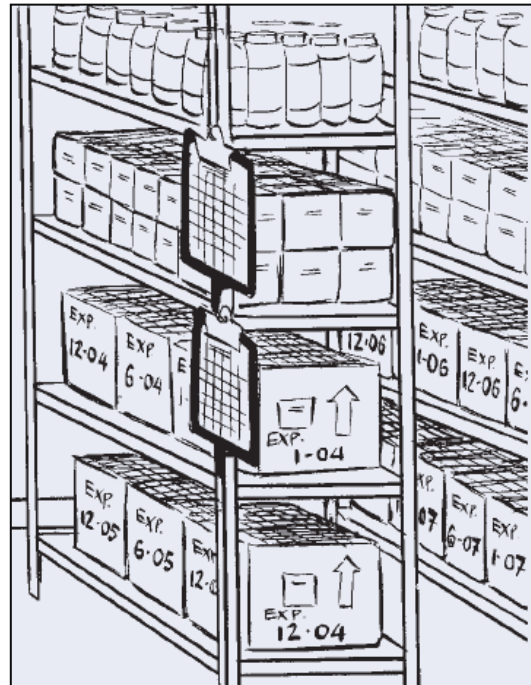
Arrange medicines in shelves and label accordingly.



Slide 4.16

Arrange medicines (in small boxes) on the shelves rather than placing them on pallets or on the floor. Shelves must be labelled accordingly. Expiry dates of products must likewise be visible. Since expiry dates on small boxes are usually in very small fonts, it is a good practice to write down these expiry dates and posted near the area where the products are stored.

Arrange products following First Expiry/First Out (FEFO) and First In/First Out (FIFO) principles.



Source: Guidelines for the Storage of Essential Medicines and Other Health Commodities, 2003

Slide 4.17

Slide 4.17

Arrange products following First Expiry/First Out (FEFO) and First In/First Out (FIFO) principles. Following FEFO minimizes wastage from product expiry.

- When issuing products FEFO policy must be followed. Products that will expire first should be issued first, ensuring that they are not too close to or past their expiration date. The shelf life remaining must be sufficient for the product to be used before the expiry date.
- To facilitate FEFO, products that will expire first must be placed in front of products with a later expiry date.

On the other hand, FIFO is used for items without indicated expiry date. This method generally minimizes the chance of drug expiration.

- Perform regular inventories of pharmaceutical materials and products.
- Maintain records of all materials in storage and update regularly.

Slide 4.18

A list of stock items in the store room must be maintained and regularly updated by performing regular inventories of the products.

Accountability

Restrict access and check stock frequently

Maintain a stock card for each item if possible

- keep stock card next to item
- fasten stock card to shelf



No stock cards?
Then improvise: make your own
or use a book



Source: Managing Access to Medicines and Health Technologies, 2012

Slide 4.20

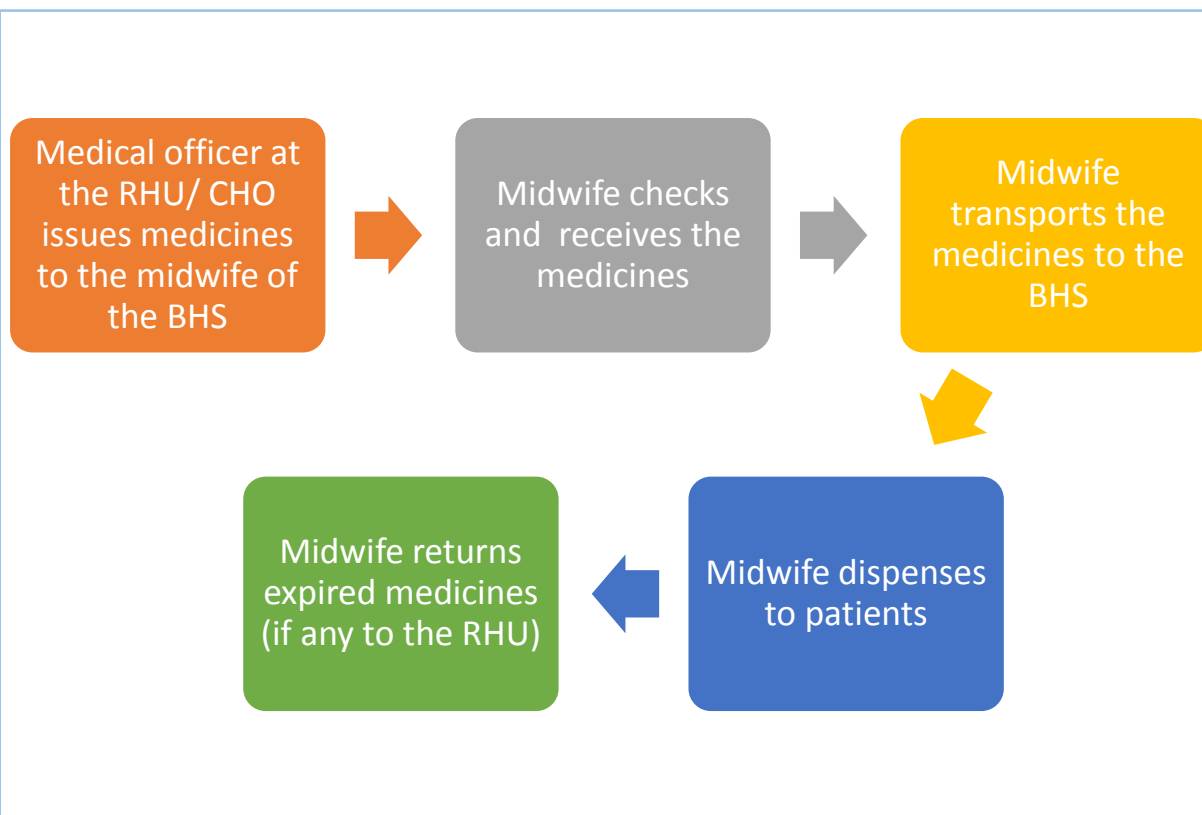
- Periodic stock reconciliation
- Check for expired, rejected and recalled products

Slide 4.21

Damaged containers should not be issued unless the quality of the product has been shown to be unaffected. All damaged containers must be replaced by new containers.

All stocks should be checked regularly for expired products. Expired products should be identified and disposed of following the protocol set

.
For recalled items, these should be handled by approved procedures according to regional or national regulations. These should be stored separately from other materials and products while awaiting destruction or return to the supplier.



Slide 4.22

Slide 4.22

Dispatch and delivery of medicines to the BHS are scheduled once these are available at the local health facility such as the RHU/ CHO. The midwife, who primarily manages the BHS, receives the requested or allocated medicines at the RHU/ CHO. Dispatch records should include the date of dispatch; the name of midwife; BHS served and product description which includes name, dosage form and strength, batch number, quantity and expiry date. The midwife should verify and check the products against the dispatch records. He/she should also keep a list of medicines received.

Medicines should be transported in a way that maintains their quality and meet their storage requirements. The outside container should offer adequate protection from all external influences and should be indelibly and clearly labelled.

Expired medicines in the BHS should be returned to the RHU/ CHO for proper disposal. This should be accompanied by proper documentation.

Name	Dosage form	Strength
Batch number	Quantity	Expiry date

Slide 4.23

Midwife should check for these details upon receipt/ delivery of medicines to the BHS.

For each of the following statements, write T if the statement is true and F if it is false:

1. Access to storage room for medicines must be secured with locks and limited to authorized personnel.
2. Storage rooms must be equipped with a temperature monitoring device.
3. Expired medicines may still be dispensed to patients as long as it can be consumed within a month after its expiry date.

Slide 4.24

Ask participants to answer the review questions. Discuss answers.

1. True or T
2. True or T
3. False or F

REVIEW QUESTIONS

4

4. All medicines must be placed in an insulated container equipped with ice packs when transported from one facility to another.
5. First Expiry First Out is a good practice to observe in storing medicines.

Slide 4.25

Ask participants to answer the review questions. Discuss answers.

4. False or F
5. True or T

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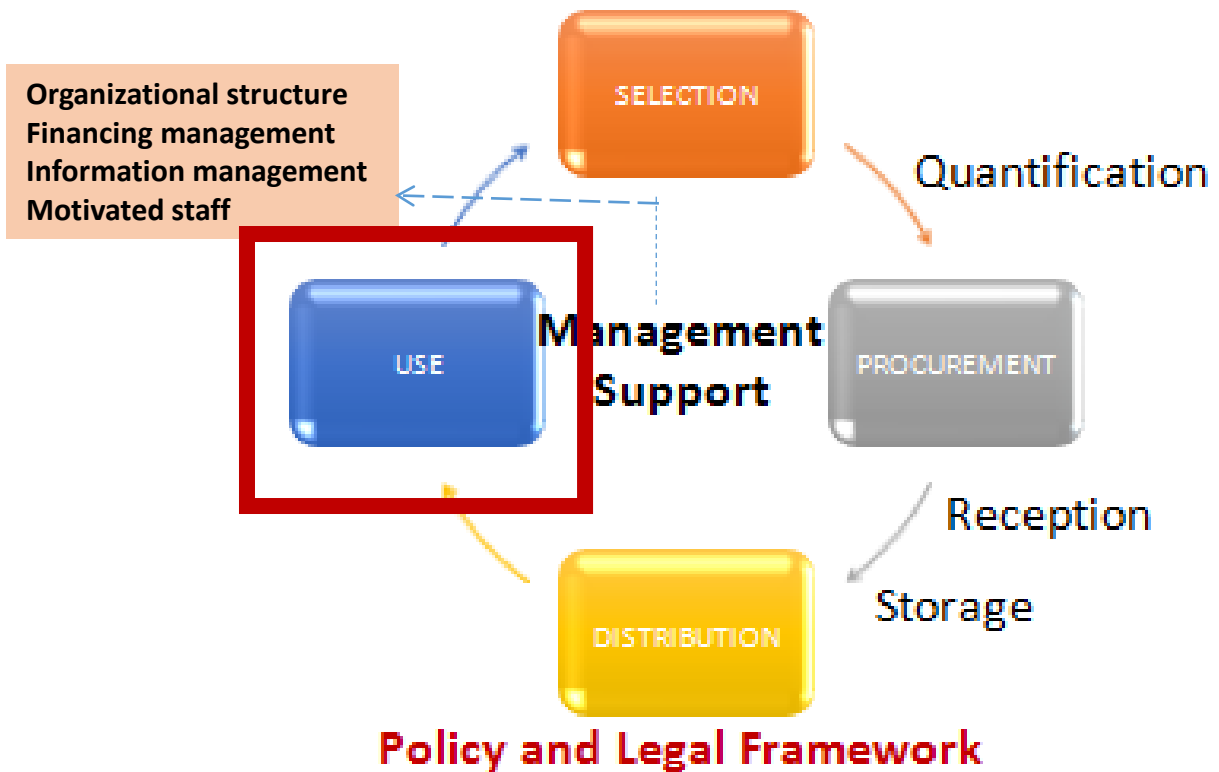
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Use of Medicines



Slide 5.1

Present the drug management cycle once again but emphasize that this session will be on **use** of medicines.

The last step in the drug management system is the use of medicines or provision of medicines to the patients. This requires rational prescribing practices, good dispensing procedures and patient adherence.



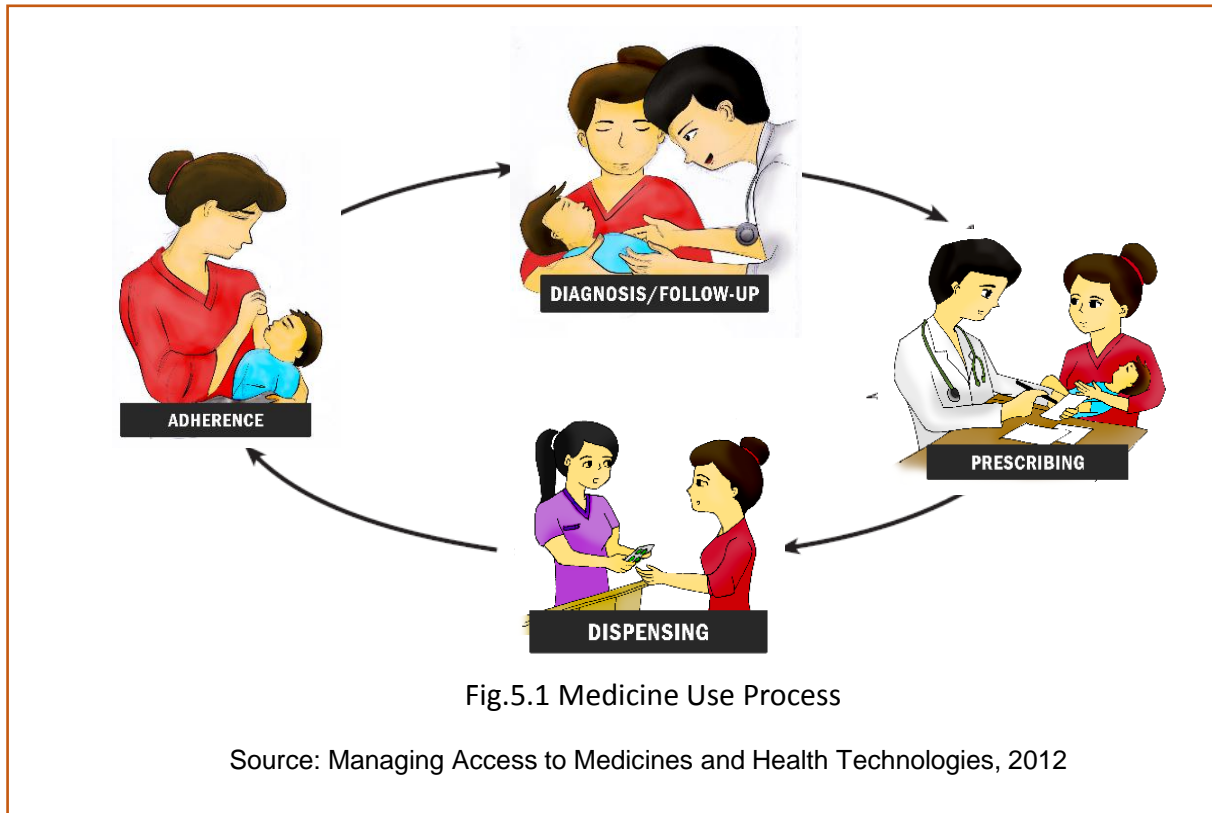
Slide 5.2

SESSION OBJECTIVES

1. Define rational use of medicine
2. Explain the medication use process
3. Identify parts of the prescription
4. Explain processes involved in preparing, proper labelling and dispensing the required medication
5. Explain process of recording consumption of medicines

Slide 5.3

Present the learning objectives for the session.



Slide 5.4

Rational use of medicines requires that the patient is prescribed with the appropriate medicine after proper diagnosis. It also requires that the patient receives the medicine accordingly.

The conference of experts convened by the WHO in 1985 in Nairobi defined rational use of medicines as “when patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time and at the lowest cost to them and their community.”

- A**ppropriate indication
- A**ppropriate drug
- A**ppropriate patient
- A**ppropriate patient information
- A**ppropriate evaluation



Slide 5.5

Rational or responsible use of medicines in a biomedical context include the following criteria:

- Appropriate indication: reason to prescribe is based on sound medical considerations;
- Appropriate drug: considering efficacy, safety and suitability for the patient and cost;
- Appropriate patient: no contraindication exist and likelihood of ADR is minimal;
- Appropriate patient information: correct dispensing including provision of the right information With the hope that the patient will be adherent to the treatment; and
- Appropriate evaluation: the anticipated and unexpected effects of medications are appropriately monitored and interpreted.

A set of instructions written by a doctor to the dispenser for supply of medicines

Slide 5.6

Prescriber information	<p>Juan Dela Cruz, MD Tower A Bldg., Boni Ave, Mandaluyong City Tel No.: 531-4534</p> <p>Clinic Schedule: Monday: 1:00PM – 5:00PM Friday: 9:00AM – 12:00PM Tue – Thur: 10:00AM – 3:00PM Saturday: 12:00PM – 3:00PM</p>
Patient information	<p>Name: <u>Sarah Gonzales</u></p> <p>Address: <u>Boni Avenue, Mandaluyong City</u></p> <p>Age: <u>8</u> Sex: <u>F</u> Date: <u>6/21/2012</u></p>
Superscription (meaning recipe)	<p>R_x</p>
Subscription (instructions to pharmacist)	<p>Amoxicillin 250mg/5ml Susp.</p> <p># 2 lots</p> <p>Reconstitute with water to make 60 mL suspension</p>
	<p>Sig. Take 1 tablespoon TID for 7/7 days</p>
	<p>Physician's Sig. <u>J. Dela Cruz</u></p> <p>Lic. No. <u>12345</u></p> <p>PTR No. <u>1234567</u></p> <p>S2 No. _____</p>

Date prescription is written

Inscription (medication prescription)

Signa (directions for patient)

Slide 5.7

These are the parts of the prescription which should be evaluated for completeness by the dispenser.

THE DISPENSARY

Area for dispensing work

- Keep it clean and organized
- Retain a daily drug use record
- Do not overcrowd dispensing table
- Arrange documents in an orderly manner on the table
- Arranging drugs on the table in alphabetical order
- Always close drug containers from which drugs are not being dispensed



Slide 5.8

Just as there is proper area for storing medicines, there should also be a proper area for dispensing work. The following practices are encouraged:

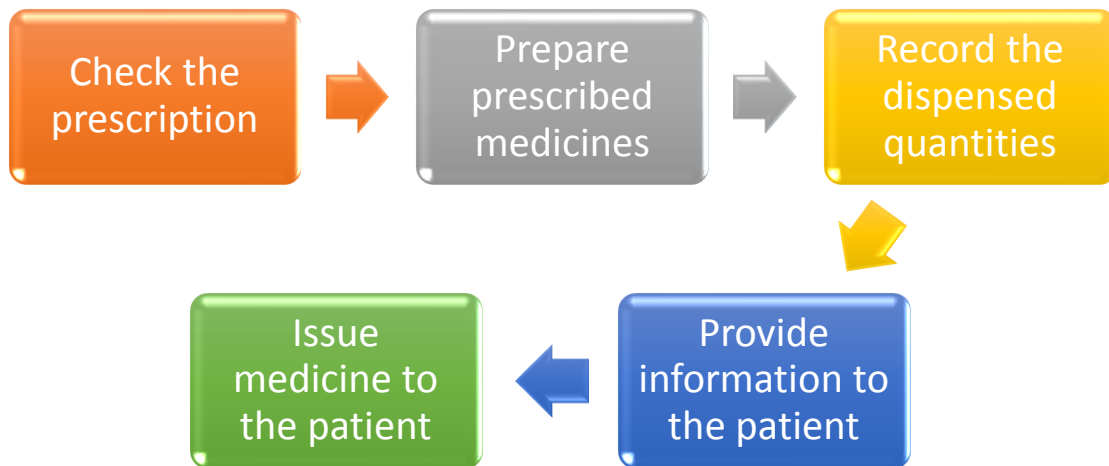
- Retain a daily drug use record in the dispensary;
- Provide a table for dispensing drugs;
- To facilitate work, do not overcrowd the dispensing table;
- Arrange documents in an orderly manner on the table, away from the dispensing area;
- Clean after each use tablet counters and place within easy reach on the table;
- Avoid dispensing wrong drugs by arranging drugs on the table in alphabetical order so that the drug being dispensed is not confused with another; and
- Always close drug containers from which drugs are not being dispensed to prevent spillage or dispensing the wrong drug.

- Issue the correct medicine in the form and dose prescribed and the quantity corresponding to the duration stated in the prescription
- Detect an error at the time of prescription
- Record all medicine movements

Slide 5.9

The dispenser has to issue the correct medicine in the form and dose prescribed and in quantity corresponding to the duration stated on the prescription. Ideally, he should be able to detect an error done at the time of prescription or a misunderstanding from the patient about his illness and his treatment. The dispenser should also be rigorous in recording all medicine movements.

DISPENSING AT THE LOCAL HEALTH FACILITY



Slide 5.10

These are the steps in dispensing at the local health facility such as CHO and RHU.

DISPENSING AT THE LOCAL HEALTH FACILITY

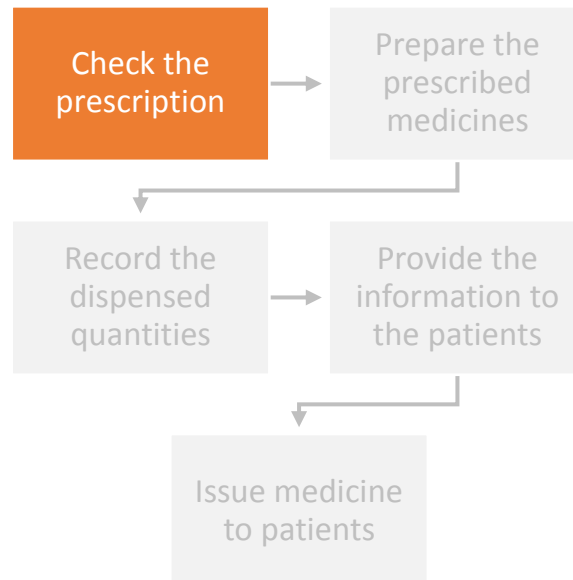
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Name and signature of the prescriber and the stamp (or other identifiers) of the RHU/ CHO

Date, name and age of patient

Endorsement of the prescriber of the center if prescription did not come from the RHU/ CHO

In case of doubt or error, report to the prescriber



Slide 5.11

The following information on the prescription must be checked:

- Name and signature of the prescriber and the stamp (or other identifiers) of the RHU/ CHO;
- Date, name and age of patient; and
- Endorsement of the prescriber of the center if prescription did not come from the RHU/ CHO.

In case of doubt or error, report to the prescriber.

DISPENSING AT THE LOCAL HEALTH FACILITY

Check name of prescribed drug
with container

Check expiration date on the
container

Prepare the correct quantities

Repack if needed

Prepare labels

Double check

Check the
prescription

Prepare the
prescribed
medicines

Record the
dispensed
quantities

Provide the
information to
the patients

Issue medicine
to patients

Slide 5.12

DISPENSING AT THE LOCAL HEALTH FACILITY

5

Slide 5.12

Prepare the prescribed medicines by doing the following:

- Check name of prescribed drug with container – the container label should be read and the medicine name and dosage strength cross-checked against the prescription.
- Check expiration date on the container.
- Prepare the correct quantities – counting products to confirm quantity should always be done on a clean, dust-free surface. Tablet counters, a sheet of paper and knife or pan weighing scales may be used for counting. Reseal the storage container after obtaining the needed quantity. After closing the container, the label should be re-checked for the medicine's name and strength.
- Repack if needed – use a suitable container to preserve the quality of the product. Bottles and plastic envelopes may be used for tablets and capsules.
- Prepare labels – prepare labels as prescribed by the Generics Act.
- Double check.

DISPENSING AT THE LOCAL HEALTH FACILITY



Slide 5.13

Labelling of dispensed medicines

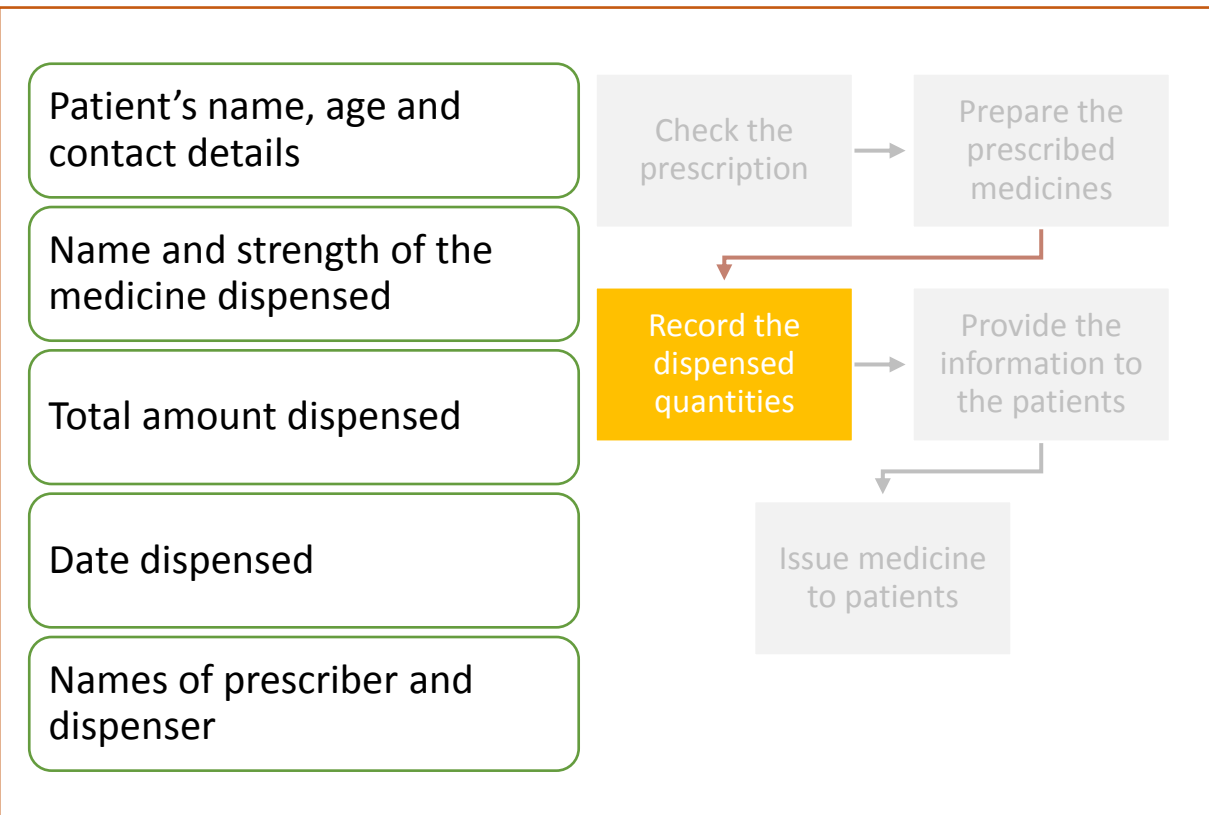
Name of patient	Name of RHU	Generic name of medicine
Strength	Quantity	Clear instructions
Date of dispensing	Expiration date	Cautionary label

Slide 5.14

In dispensing medicines to the buyer, medicines in unit dose or those which are not in their original containers but transferred to small bottles, tin cans, boxes, plastic and/ or paper envelopes and the like, the following information must be written legibly on the label:

- Name of patient;
- Name of RHU;
- Generic name of medicine;
- Strength;
- Quantity;
- Clear instructions;
- Date of dispensing;
- Expiration date; and
- Cautionary label.

DISPENSING AT THE LOCAL HEALTH FACILITY



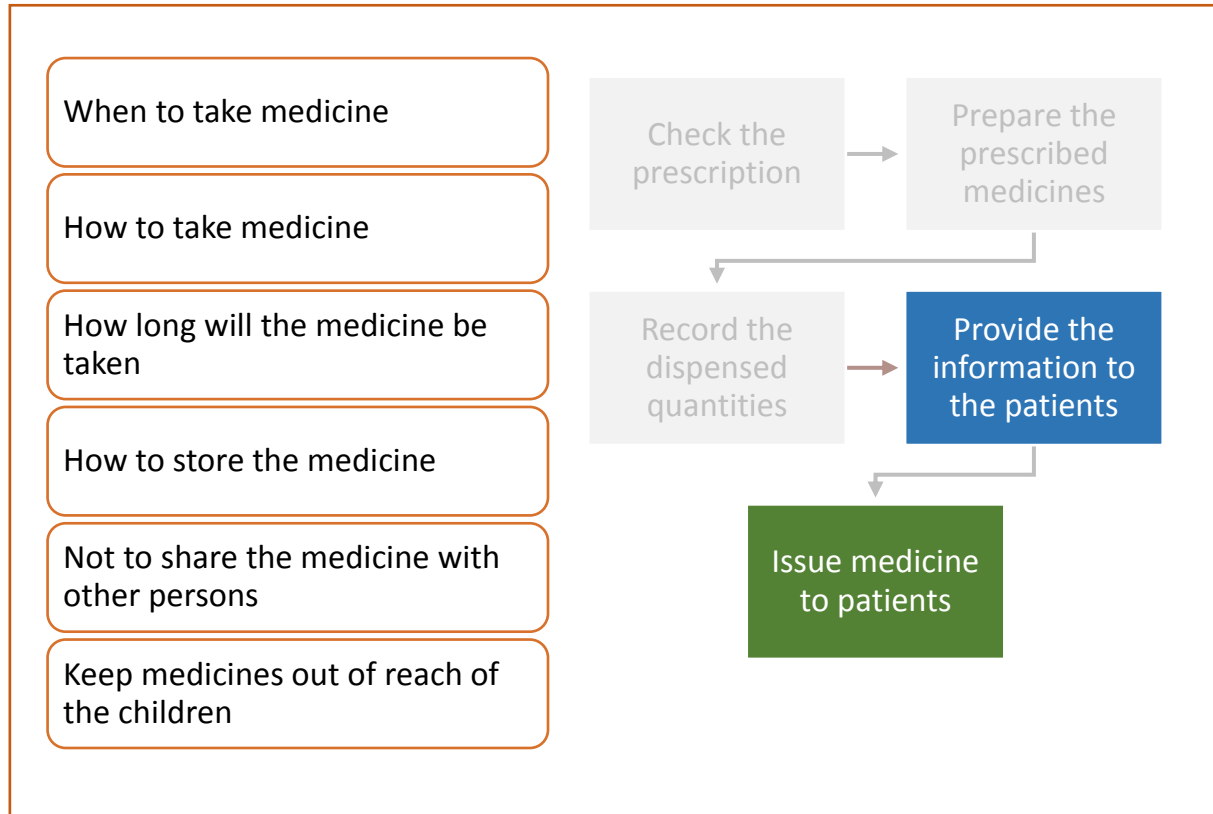
Slide 5.15

In order to track inventory, records must be maintained of all products dispensed. This will also allow contact with a patient should a problem with the medication arise. Key information to record includes:

- Patient's name, age and contact details;
- Name and strength of the medicine dispensed;
- Total amount dispensed;
- Date dispensed; and
- Names of prescriber and dispenser.

DISPENSING AT THE LOCAL HEALTH FACILITY

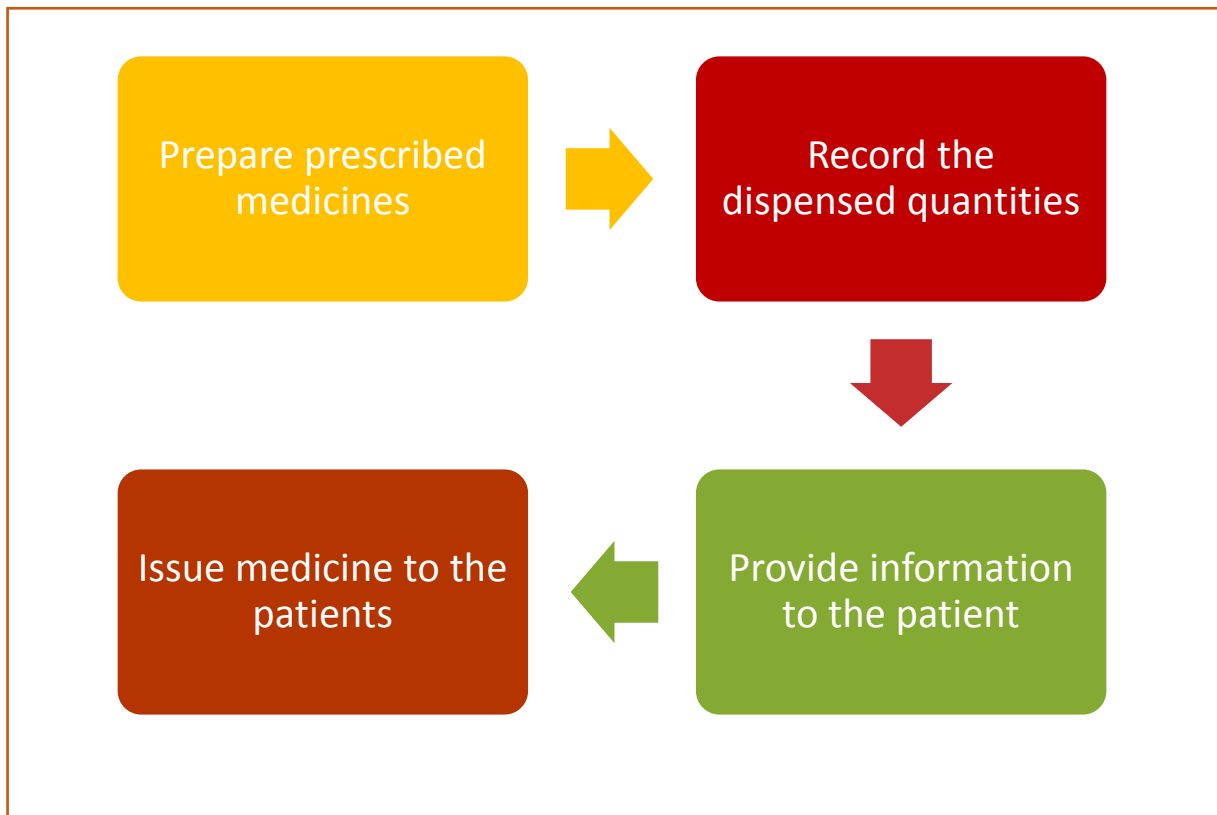
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Slide 5.16

To enable patients to comply with the instructions on the prescription, these should be adequately explained. Written information will also be helpful. Among the information that should be provided to the patient are:

- When to take medicine;
- How to take medicine;
- How long will the medicine be taken;
- How to store the medicine;
- Not to share the medicine with other persons; and
- Keep medicines out of reach of the children.



Slide 5.17

At the BHS, only the midwife may dispense medicines. Since most of these medicines are over-the-counter (OTC), a prescription is not necessary. The midwife makes an initial assessment of the patient's condition and recommends the OTC preparation for minor ailments.

If however the symptoms presented by the patient were not relieved by the OTC preparation or if the midwife believes that the patient requires a physician's attention, the patient is referred to the RHU/ CHO for proper diagnosis. Ideally, the dispensing process in the BHS is similar to what is done at the RHU/ CHO.

- A harmful response in the patient caused by the drug itself given in the recommended manner

Slide 5.18

An ADR is a harmful response in the patient caused by the drug itself given in the recommended manner (dose, frequency, route, administration technique). Examples include allergic reactions, effects from withdrawal, or reactions caused by interactions with other drugs.

SERIOUS ADR

Any reaction

- Fatal, life-threatening, or permanently or significantly disabling
- Requires or prolongs hospitalization
- Relates to misuse or dependence

Slide 5.19

WHO defines a serious ADR as any reaction that is fatal, life-threatening, or permanently or significantly disabling; requires or prolongs hospitalization; or relates to misuse or dependence. For example, Bromfenac (Duract) was a non-steroidal anti-inflammatory agent (NSAID) that was removed from the market in 1998, less than 1 year after it was introduced. Bromfenac caused serious hepatotoxicity in only 1 in 20,000 patients taking the drug for longer than 10 days.

- Pharmacovigilance Unit of the Food and Drug Administration is responsible for ADR monitoring and reporting
- Case report forms
- All healthcare providers should report ADRs as part of their professional responsibility

Slide 5.20

The Pharmacovigilance Unit of the Food and Drug Administration is responsible for ADR monitoring and reporting.

To facilitate information gathering, the Pharmacovigilance Unit provides case report forms to health providers on ADRs.

All healthcare providers, including doctors, pharmacists, nurses, dentists, and others, should report ADRs as part of their professional responsibility.

ADR MONITORING

- The completed case report form is then sent to the regional or national ADR center or to the manufacturer of the product.
- For the BHS, it should sent to the RHU or the CHO.

Slide 5.21

The form contains the following:

- Patient's particulars
- Details of the ADR
- Management of ADR
- Reporter's particulars

Slide 5.22

The ADR Monitoring Form consists of the following information:

- Patient's particulars which include name, contact details, medical history, any known allergy, etc.;
- Details of the ADR including date of onset, description of reaction, possible causes (i.e. medication error, product quality defect, therapeutic failure);
- Management of ADR; and
- Reporter's particulars which include name, contact details, and date reported, etc.

ADR MONITORING FORM

SUSPECTED ADVERSE REACTIONS FORM v 5 (4/2012)

"Saving Lives Through Vigilant Reporting"

*FIELDS MUST BE COMPLETED.

For FDA use only

All reports are confidential.

AER No. 2012-0001

Date received: _____

PATIENT'S PARTICULARS

*Patient's Name or Initials: _____ * Sex: ☐ Male ☐ Female Weight: _____ Kg
 Address or Contact Number: _____ *Age: _____ Date of Birth (mm/dd/yr): _____
 Medical History/Admitting Diagnosis: _____ Ethnic group: ☐ Filipino ☐ Chinese ☐ Caucasian
 Any Known Allergy: ☐ No ☐ Yes, Specify: _____ Pregnancy Status: ☐ No
 Hospital/facility, if admitted: _____ Yes (1st, 2nd, 3rd trimester)

Patient's
Particulars

*DETAILS OF THE ADVERSE REACTION

Date of onset: _____: _____ am, _____ pm Do you consider the reaction to be serious? ☐ Yes, if yes indicate why: ☐ No

Describe the reaction, including pertinent laboratory data:

- ☐ Patient died due to reaction
☐ Involved or prolonged in-patient hospitalization
☐ Life threatening
☐ Involved persistent or significant disability
☐ Congenital anomaly in the newborn
☐ Other outcome, please give details:

Can this be due to Medication Error? ☐ No
☐ Yes, if yes, which type:

- ____ Prescribing
 ____ Transcription
 ____ Dispensing
 ____ Administration

Details of the
ADR

Can the adverse reaction be due to:

1. Product quality defect ☐ No ☐ Yes, Specify, encircle: color change; caking; powdering; counterfeit; odor change; defective container; contaminants; separation of components; undissolved suspension/powder
2. Therapeutic failure: ☐ No ☐ Yes, Specify, encircle: antimicrobial resistance, drug interaction, poor compliance, counterfeit, expired; improper storage; under-dosing; inappropriate medication; inappropriate route of administration; excipients/preservatives

*Suspected drug product(s) Indicate brand name	Daily Dose	Route	Date started	Date stopped	Reason (s) for using the product (Indication)	Manufacturer and Batch/Lot #

List all other drug/s taken at the same time and/ or 3 months before. If none, check box. ☐ No Other drug/s taken

Brand name of the drug	Daily Dose	Route	Date started	Date stopped	Reason/s for using the drug	Manufacturer and Batch & Lot No.

*MANAGEMENT OF ADVERSE REACTION

Was treatment given? ☐ No ☐ Yes (if yes, please specify): _____
 Outcome:
☐ Recovered (Date of recovery): _____ ☐ Unrecovered Other diseases: _____ liver _____ renal _____
☐ Fatal (Date of death): _____ ☐ Unknown _____ Diabetes _____ CVS _____ Endocrine _____ Cancer
 Sequela/e: (any permanent complications or injuries as a result of the ADR) Re-challenge? ☐ Yes Result: _____
☐ Yes (Please specify) _____ ☐ No ☐ Unknown ☐ No

Management
of ADR

*REPORTER'S PARTICULARS

*Printed Name of Reporter: _____ *Contact no: _____
 Signature of reporter: _____ Email address: _____
 Date reported (mm/dd/yr): _____ *Profession: _____ MD _____ RPh _____ RN _____ Patient _____ Dentist _____
 *Facility: _____ Clinic _____ Trial site _____ Other _____

Reporter's
Particulars



National Pharmacovigilance Center
 "Saving Lives Through Vigilant Reporting"
 Send completed form to: ADR Unit, FDA, Civic Drive, Filinvest Estate, Alabang, Muntinlupa, 1781.
 Or fax to: (02) 8070751 or 807-85-11, c/o The ADR Unit. Send sample, if any, of suspect drug for analysis.
 Website: www.fda.gov.ph



Slide 5.23

REVIEW QUESTIONS

5

For each of the following statements, write T if the statement is true and F if it is false.

1. Rational use of medicines includes rational prescribing, good dispensing procedures and patient adherence.
2. All health care providers are encouraged to report ADRs as part of their professional responsibility.
3. Bottles and plastics are recommended for repacking tablets and capsules.

Slide 5.24

Ask the participants to answer review questions and discuss answers

1. True or T
2. True or T
3. True or T

4. Written information is provided to the patient to replace actual provision of information by the dispenser.
5. An ADR is a life-threatening, disabling response caused by medicines.

Slide 5.25

Ask the participants to answer review questions and discuss answers

4. False or F
5. False or F

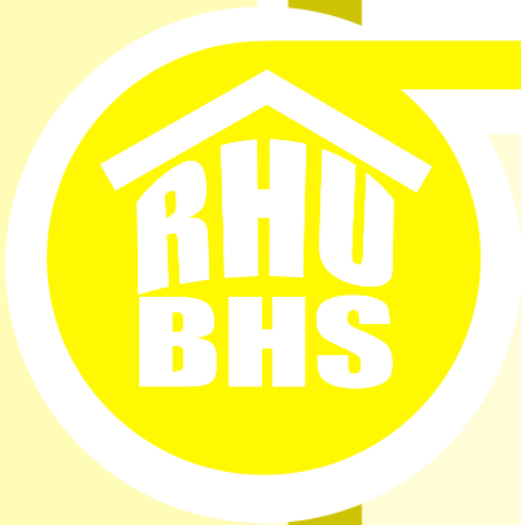
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Pharmaceutical Donations



Slide 6.1

The Philippines has consistently suffered from health problems and disruption of health services arising from various forms of disasters. In times of disasters, large quantities of pharmaceuticals from local and international sources are donated thereby partially addressing the medical needs of its recipients.

SESSION OBJECTIVES

6

1. Explain the need for guidelines on the acceptance of foreign and local donations especially during emergency and disaster situations
2. Discuss the national policy governing foreign and local donations
3. Identify criteria for accepting donations
4. Identify problems encountered on pharmaceutical donations at the local public health facility

Slide 6.2

Present the learning objectives for the session.

Not relevant for the emergency situation

Unfamiliarity of the health workers with donated pharmaceuticals

Not registered for use in the country

Unsorted

Labelled with brand names or other language not readily understood

Slide 6.3

In times of disasters, large quantities of pharmaceuticals from local and international sources are donated thereby partially addressing the medical needs of its recipients. Often however, these donations also cause problems:

- Not relevant for the emergency situation – donations are often not relevant for the disease patterns or for the level of care that is available;
- Health workers are not always familiar with the donated pharmaceuticals;
- Not registered for use in the country – and sometimes may not comply with the local treatment guidelines;
- Unsorted – unsorted and difficult to identify;
- Labelled with brand names or other language not readily understood;

PROBLEMS WITH DONATIONS

6

Quality not compliant with standards of donor country

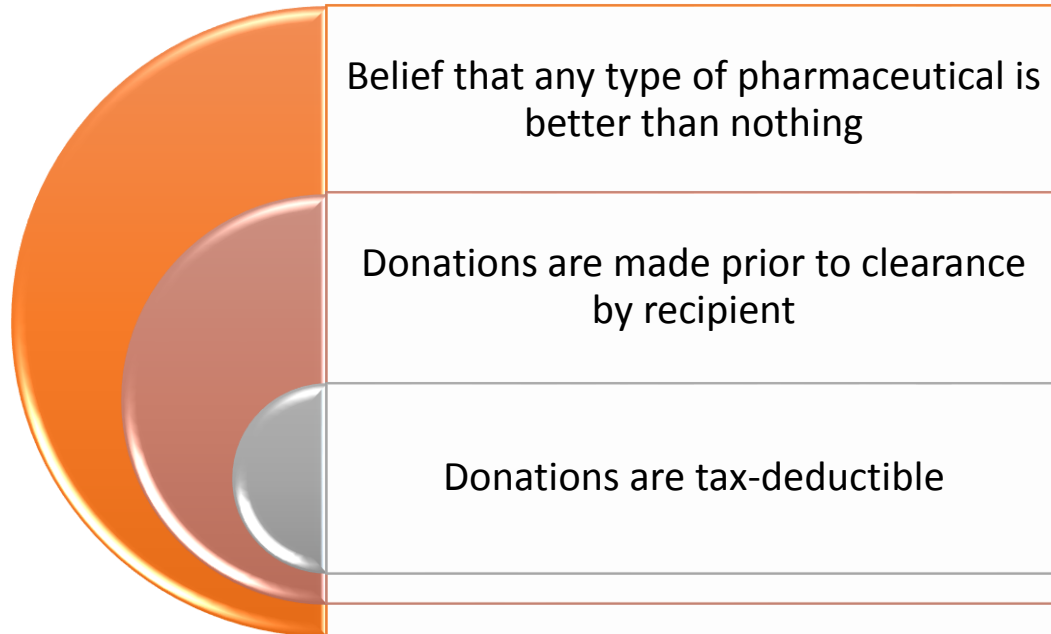
Distribution plan ignores normal administrative procedures

High declared value reflective of market value in donor country rather than world market price

Donated in wrong quantities

Slide 6.4

- Quality not compliant with standards of donor country – donated pharmaceuticals may have expired or may expire before they reach the patient; they may be returned pharmaceuticals (half-finished packages) or may be unwanted by the donor because they are close to expiration or the product is no longer marketed (drug dumping);
- Distribution may bypass central government stores or conflict with the plan of national authorities;
- High declared value reflective of market value in donor country rather than world market price – this valuation may result in high import taxes and overheads for storage and distribution in the recipient country and the inflated value may be deducted from the recipient government's pharmaceutical budget; and
- Donated in wrong quantities – too many rendering them unusable hence disposal becomes a concern which also entails resources.



Slide 6.5

There are several underlying causes for these problems:

- Belief that any type of pharmaceutical is better than nothing at all or similarly that expired pharmaceuticals are good enough for people in need.
- Donations are made prior to clearance by recipient.
- Donations are tax-deductible at full market price. This is why so many donations arrive close or past their expiry dates and why such products are typically not high-use, high-volume items. Those initiated by pharmaceutical manufacturers in exchange for tax breaks consists of medicines and supplies that are not commonly viewed as essential.



Slide 6.6

Inappropriate pharmaceutical donations create logistical problems because donated products must be sorted, stored and distributed, sometimes using precious resources and transport volume in disaster area or war zones. They may also pose an environmental threat if they have to be destroyed. Often the total transport costs are higher than the value of pharmaceuticals. Stockpiling of unused pharmaceuticals can encourage pilfering and black market sales.

Even donations that are appropriate in every way can cause problems when they far surpass the quantities that are needed.



Slide 6.7

The same problems were experienced especially during the typhoon Yolanda.

NEED FOR GUIDELINES

6

Donor and recipient do not communicate on equal terms

Donors mean well but do not realize the difficulties at the receiving end

Pharmaceutical needs vary by county and by situation

Medicines are different from donated items

Slide 6.8

Pharmaceutical Donations

Slide 6.8

These problems necessitate the need for clear policies to guide both donors and recipients and hence maximize the potential benefit of drug donations. Guidelines are needed because:

- Donor and recipient do not communicate on equal terms. The recipients therefore need assistance in specifying how they want to be helped.
- Donors mean well but do not realize the difficulties at the receiving end, and therefore need guidance.
- Pharmaceutical needs vary by county and by situation. Donations should be based on analysis of actual needs and selection and distribution must fit within pharmaceutical policies and administrative systems. Inappropriate donations frustrate the implementation of national policies and programs to promote rational drug use.
- Medicines are different from donated items. Medicines can be harmful. They require labels and written information. They need special storage conditions and adequately trained personnel to be used effectively. They may expire and needs to be destroyed in a particular way.

Maximum benefit to the recipient

Respect for wishes and authority of the recipient

No double standards in quality

Effective communication between donor and recipient

Slide 6.9

WHO identified four core principles for a useful pharmaceutical donation:

1. A donation benefits the recipient to the maximum extent possible;
2. Donation should be given with full respect for the wishes and authority of the recipient;
3. Items that are not acceptable in the donor country for quality-related reasons are also not acceptable as donations; and
4. Effective communication between donor and recipient is necessary before any donation.

- Guidelines on the Acceptance and Processing of Foreign and Local Donations during Emergency and Disaster Situations
 - Provides a rational and systematic procedure for the acceptance, processing and distribution of foreign and local donations that are exclusively for unforeseen, impending, occurring and experienced emergency and disaster situations

Slide 6.10

AO 2007-0017 known as Guidelines on the Acceptance and Processing of Foreign and Local Donations during Emergency and Disaster Situations, provides a rational and systematic procedure for the acceptance, processing and distribution of foreign and local donations that are exclusively for unforeseen, impending, occurring and experienced emergency and disaster situations. It specifies the criteria for accepting donations as well as responsibilities of the different government institutions within the DOH.

CRITERIA FOR ACCEPTING DONATIONS

6

Shelf life of at least 12 months from the time of arrival to the Philippines

Labelling with English translation or in a language understood by health professionals

Packaging that complies to international shipping regulations accompanied by a detailed packing list

Slide 6.11

Pharmaceutical Donations

CRITERIA FOR ACCEPTING DONATIONS

Weight per carton should not exceed 50 kg

Exclusive packaging with regard other supplies

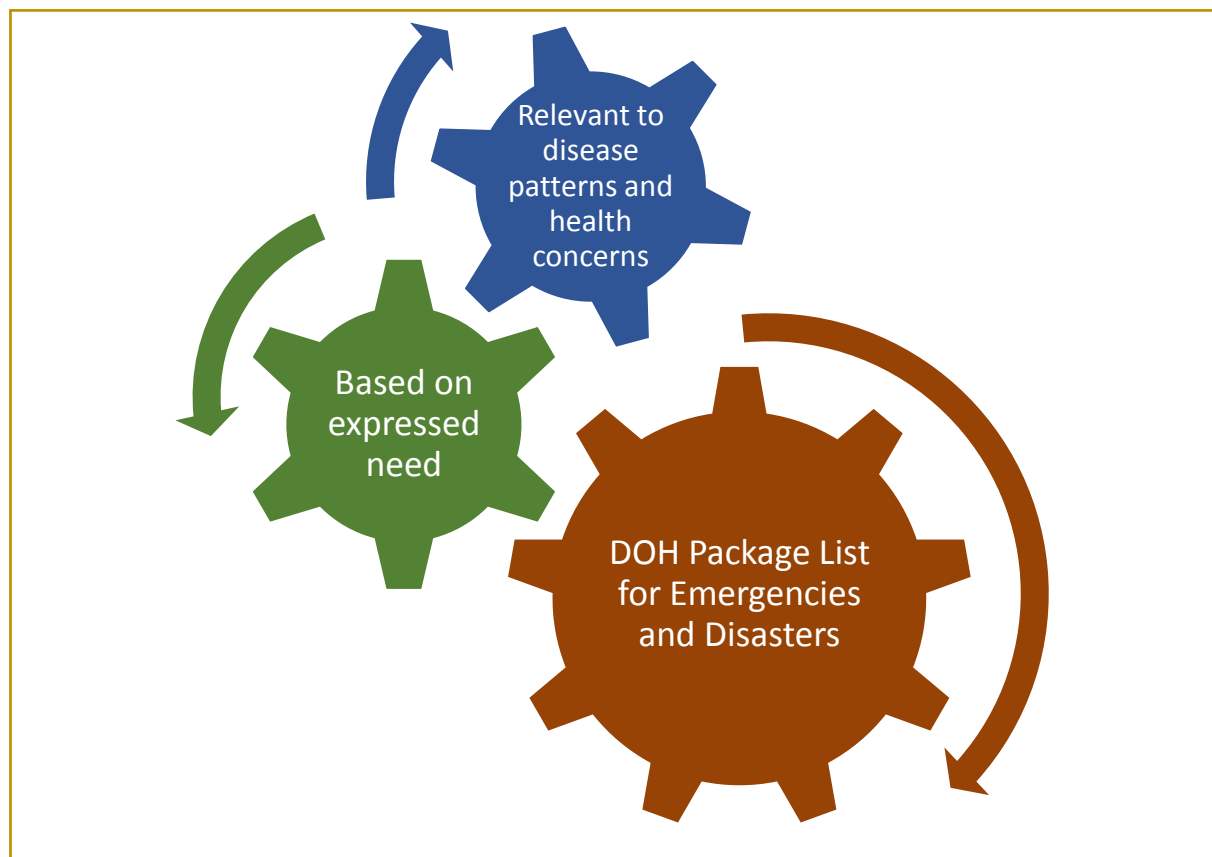
Documentary proof of compliance to applicable quality standards

Documentary proof that items are obtained from reliable sources

Slide 6.12

CRITERIA FOR ACCEPTING DONATIONS

6



Slide 6.13

This policy also states that acceptance of donations shall be based on the expressed need of the beneficiaries and relevant to the diseases pattern and health concerns that are prevailing in the affected area. The DOH Package List for Emergencies and Disasters shall be the basis for determining the acceptability of items for emergencies and disaster situations.

- Expect to follow existing criteria for accepting donations
- Existing national policy does not define administrative procedures for receipt of donations at the RHU/ CHO level

Slide 6.14

At the LGU level, the primary health care facilities in the locality, may accept donations but are likewise expected to follow the existing criteria set forth by the DOH. The policy however does not define administrative procedures for receipt of donations at their level. The absence of clear administrative procedures may result to problems discussed earlier.

IMPORTANT ISSUES TO ADDRESS

6

Decide who is responsible for defining the needs, and who will prioritize them.

Decide who coordinates all drug donations.

Which documents are needed when a donation is planned; who should receive them?

Which procedure is used when donations do not follow the guidelines?

Slide 6.15

The absence of clear administrative procedures may result to problems discussed earlier. The WHO Guidelines on Drug Donations listed important issues that should be addressed and defined:

- Decide who is responsible for defining the needs, and who will prioritize them.
- Decide who coordinates all drug donations.
- Which documents are needed when a donation is planned; who should receive them?
- Which procedure is used when donations do not follow the guidelines?

IMPORTANT ISSUES TO ADDRESS

What are the criteria for accepting/ rejecting a donation, and who makes the final decision?

Decide who coordinates reception, storage and distribution of the donated drugs.

How are donations valued and entered into the budget/ expenditure records?

How will inappropriate donations be disposed of?

Slide 6.16

- What are the criteria for accepting/rejecting a donation, and who makes the final decision?
- Decide who coordinates reception, storage and distribution of the donated drugs.
- How are donations valued and entered into the budget/expenditure records?
- How will inappropriate donations be disposed of?

It is important that RHUs/ CHOs create specific and clear guidelines regarding acceptance of donations taking into consideration the current policy of the DOH.

REVIEW QUESTIONS

6

Answer the following, for numbers 2 to 5 write T if the statement is true and F if it is false.

1. Give 2 implications of inappropriate donations.
2. Medicine donation with short expiration dates may be accepted as long as it can be utilized prior to expiration.
3. Donations must be accepted only if there is an expressed need for the said medicine/ supply.

Slide 6.17

Ask participants to answer review questions. Discuss answers.

1. Logistical problems, environmental threat, expensive
2. False or F
3. True or T

REVIEW QUESTIONS

4. RHUs should never accept donations but rather course it to the PHO or CHD.
5. Medicine donation will always be beneficial to the recipient.

Slide 6.18

Ask participants to answer review questions. Discuss answers.

4. False or F
5. False or F

Pharmaceutical Donations

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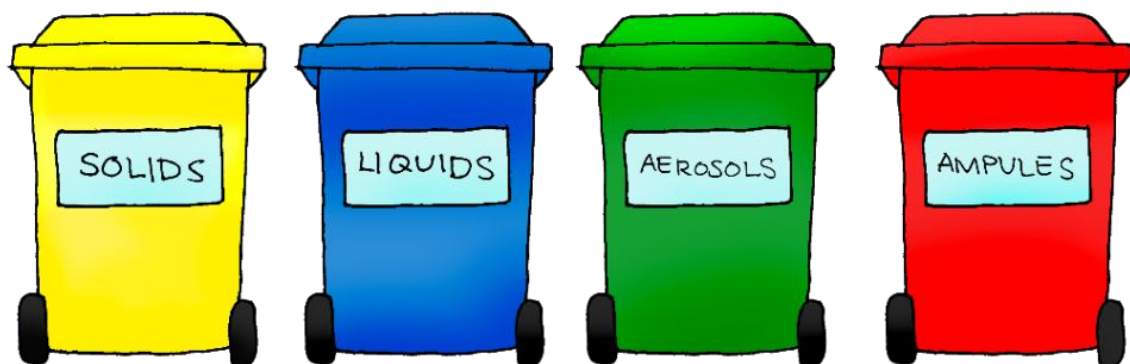


Disposal of Pharmaceuticals

Slide 7.1

Before the training, read the **WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals**. A photocopy of the Guidelines is provided in the booklet of references.

In times of disasters, calamities and other emergencies, large quantities of pharmaceuticals are often donated as part of assistance. And while many of these save lives by addressing the medical needs of the affected areas, a significant number of these pharmaceuticals may also cause problems. Some pharmaceuticals may arrive past or near expiry, in extremely large or unwanted quantities, labelled in a foreign language or simply unwanted or not needed in the particular area. These problems result to additional concerns of inadequate storage rooms and disposal. Safe disposal of these expired or unwanted pharmaceuticals is often a major problem for the RHU especially that it also entails additional resources.



1. Discuss the importance of safe disposal for unwanted pharmaceuticals
2. Explain the importance of sorting pharmaceuticals into categories that require different disposal methods
3. Differentiate the various methods for disposing unwanted pharmaceuticals
4. Identify the appropriate disposal method for a sorting category

Slide 7.2

Present the learning objectives for the session.

IMPORTANCE OF SAFE DISPOSAL

Contamination of water supplies

Reduction or destruction of bacteria necessary for treatment of sewage

Release of toxic pollutants into the air

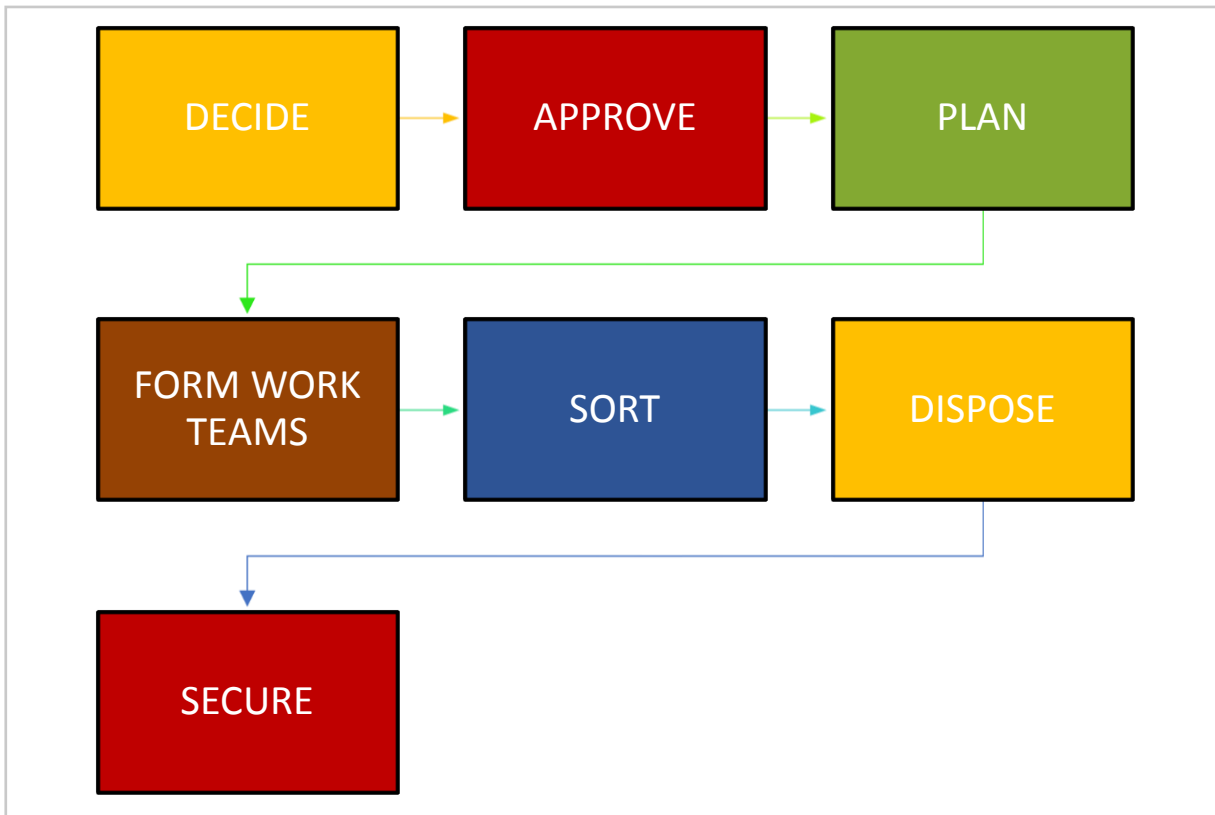
Diversion for resale of expired drugs to the general public

Slide 7.3

Safe disposal of unwanted pharmaceuticals is a necessary task because of the possible threat to public health and the environment if improperly disposed of. The WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies list these threats as:

- Contamination of water supplies or local sources used by nearby communities or wildlife.
- Reduction or destruction of bacteria necessary for treatment of sewage when non-biodegradable antibiotics, antineoplastics and disinfectants when thrown into the sewage. Antineoplastics flushed into watercourses may damage aquatic life or contaminate drinking water.
- Release of toxic pollutants into the air when burning pharmaceuticals at low temperatures or in open containers.
- Diversion for resale of expired drugs to the general public due to inefficient and insecure sorting and disposal. Most pharmaceuticals past their expiry date become less efficacious and some may develop a different adverse drug reaction profile.

STEPS IN DISPOSAL



Slide 7.4

Disposal of unwanted pharmaceuticals may require a series of steps to be taken:

1. **DECIDE** (Decide when action needs to be taken)
2. **APPROVE** (Seek approval of disposal from the appropriate authority)
3. **PLAN** (Plan in terms of funding, necessary expertise, human resources, professional time, space, equipment, material and available disposal option)
4. **FORM WORK TEAMS** (Organize team that will be responsible for the task)
5. **SORT** (Separate the pharmaceuticals into separate categories for which different disposal methods are required)
6. **DISPOSE** (Dispose the unwanted pharmaceutical using the appropriate method)
7. **SECURE** (Ensure security of disposed pharmaceuticals)

Work teams should consist of supervising pharmacists and general medical workers, who are preferably pharmaceutical technicians or experienced pharmaceutical warehouse personnel. Health and safety of work teams must likewise be ensured by wearing appropriate protective equipment including overalls, boots, gloves, masks and caps when appropriate.

SORTING

- Separate pharmaceuticals into categories that require disposal methods
- Dosage form as primary consideration for disposal

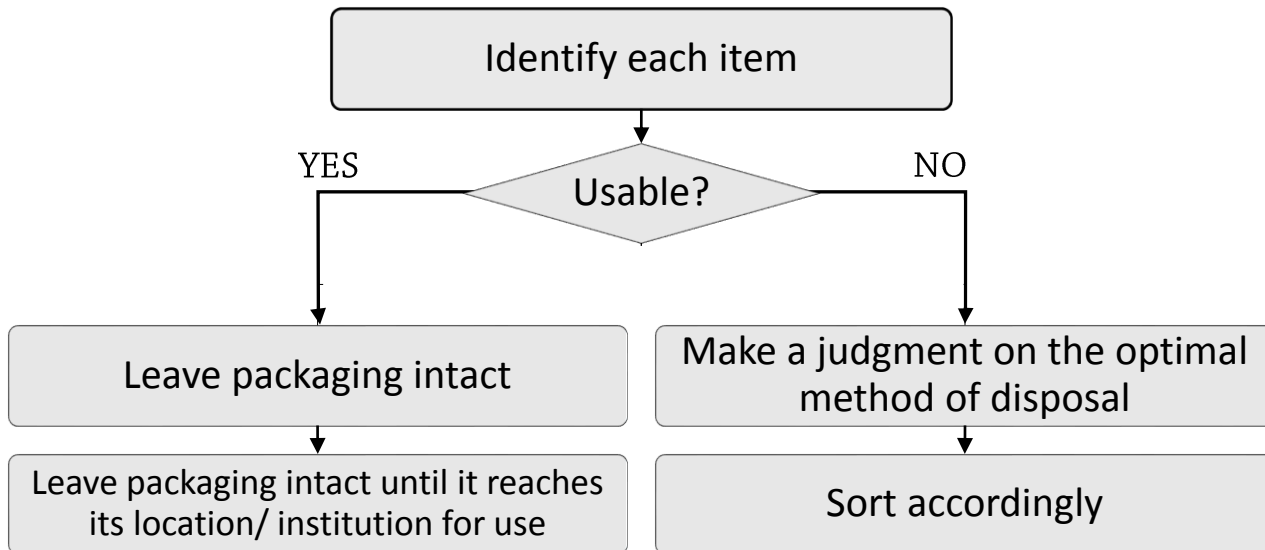


Slide 7.5

Sorting is to separate pharmaceuticals into categories that require disposal methods. The dosage form of the drug is a primary consideration in determining the appropriate safe disposal method.

THE SORTING PROCESS

7



Slide 7.6

Disposal of Pharmaceuticals

THE SORTING PROCESS

Slide 7.6

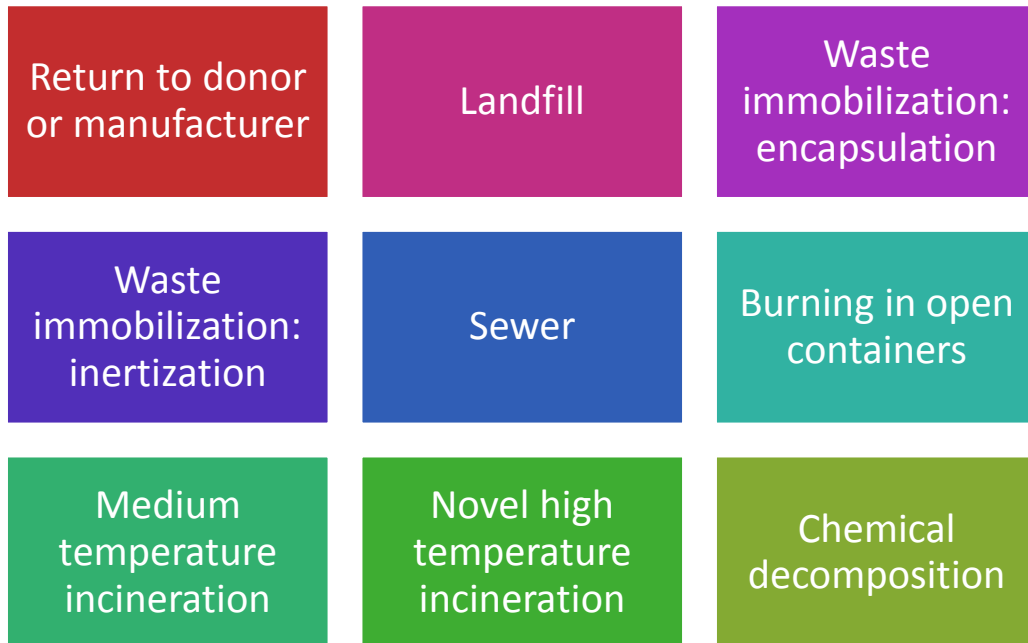
Segregated temporary storage areas must be provided for each sorted category. The sorting process includes:

- Identify each item;
- Make a decision on whether it is usable;
- If usable, leave packaging intact;
- Leave packaging intact until it reaches its location/ institution for use;
- If not usable, make a judgment on the optimal method of disposal; and
- Sort accordingly.

Sorting must be conducted in a well-ventilated, covered area. The staff performing the sorting process must be supplied with protective gear, have undergone proper training on the sorting criteria and health and safety risks associated with handling the materials, and should work under the direct supervision of a pharmacist. Once sorting is completed, the pharmaceuticals must be carefully packed into steel drums or into sturdy containers, labelled properly and stored in a dry, secure and preferably separate room (from other pharmaceuticals) until disposal is carried out.

METHODS OF DISPOSAL

7



Slide 7.7

There are several methods that can be employed to dispose unwanted pharmaceuticals. These methods have its advantages and disadvantages and may be appropriate for specific types of pharmaceuticals only.

METHODS OF DISPOSAL

Return to donor
or manufacturer

- For medicines which present disposal problems (i.e. antineoplastics)
- Unwanted, unrequested donations
- Cross-frontier transfer of pharmaceutical waste
 - Expired or spoiled pharmaceuticals

Slide 7.8

Wherever practical the possibility of returning unusable drugs for safe disposal by the manufacturer should be explored; particularly drugs which present disposal problems, such as antineoplastics. For unwanted, unrequested donations, especially those that arrive past or unreasonably near their expiry date it may be possible to return them to the donor for disposal.

Cross-frontier transfer of pharmaceutical waste:

- Pharmaceutical wastes are considered as hazardous wastes and as such if transferred across borders, become regulated and subject to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal. The Basel Convention regulates transboundary movements of hazardous wastes to ensure that such wastes are managed and disposed of in an environmentally sound manner. This involves prescribed procedures to obtain permission to cross international borders along the transit route prior to actual transport. These procedures can take several months to complete.

METHODS OF DISPOSAL

Landfill

- To place waste directly into a land disposal site without prior treatment or preparation
- Oldest and the most widely practiced method of disposing of solid waste

Slide 7.9

To landfill means to place waste directly into a land disposal site without prior treatment or preparation. It is the oldest and the most widely practiced method of disposing of solid waste.

Landfill

Open uncontrolled non-engineered dump

- Most common land disposal method
- Not applicable for untreated waste because of possible contamination

Engineered landfill

- With features to protect from loss of chemicals into the aquifer

Highly engineered sanitary landfill

- Safe disposal route
- Consists of an evacuated pit isolated from watercourses and above the water table

Slide 7.10

There are three types of landfill:

- Open controlled non-engineered type – this is the most common land disposal method in developing countries. Discarding of untreated waste pharmaceuticals into such a site is not recommended because of possible contamination.
- Engineered landfill – this type of landfill has some features to protect from loss of chemicals into the aquifer.
- Highly engineered sanitary landfill – this landfill offers a relatively safe disposal route for municipal solid wastes, including pharmaceuticals because it is able to protect the aquifer.

METHODS OF DISPOSAL

Waste immobilization: encapsulation

- Involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum
- Sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste

Slide 7.11

Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. Drums should be cleaned prior to use and should not have contained explosive or hazardous materials previously.

Waste immobilization: inertization

- Variant of encapsulation and involves removing the packaging materials from the pharmaceuticals
- Pharmaceuticals are then ground and a mix of water, cement and lime added to form a homogenous paste
- Paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste

Slide 7.12

Inertization is a variant of encapsulation and involves removing the packaging materials, paper, cardboard and plastic from the pharmaceuticals. This process is relatively inexpensive and may be carried out using unsophisticated equipment.

METHODS OF DISPOSAL

Sewer

- Flushing into the sewers in small quantities over a period of time
- Fast flowing watercourses - flush small quantities of well-diluted liquid pharmaceuticals or antiseptics

Slide 7.13

Some liquid pharmaceuticals such as syrups and intravenous fluids can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental effect. Fast flowing watercourses may also be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics.

Burning in open containers

- Not advocated as a method of disposal
- Only for very small quantities of pharmaceutical waste
- Not used for PVC plastic
- May release toxic pollutants into the air

Slide 7.14

Burning in open containers of pharmaceuticals is not advocated as a disposal method because toxic pollutants may be released into the air. If this method will be used, it is strongly recommended that only very small quantities of waste pharmaceuticals be disposed in this manner. Paper and cardboard packaging, if they are not to be recycled, may be burnt. Polyvinyl Chloride (PVC) plastic however must not be burnt.

METHODS OF DISPOSAL

Medium temperature incineration

- Encouraged as an interim measure, rather than less safe options, such as inadequate discharge to a landfill
- Not designed to incinerate halogenated compounds safely

Slide 7.15

The use of medium temperature incinerators is encouraged as an interim measure, rather than the less safe options such as inadequate discharge to landfill. These incinerators are not designed to incinerate halogenated compounds safely.

If medium temperature incinerators will be used, it is recommended that the pharmaceutical waste is diluted with large quantities of municipal waste (1:1000)

Novel high temperature incineration

- High-temperature dry oxidation process that reduces organic and combustible waste to inorganic, incombustible matter and results in a very significant reduction of waste volume and weight

Slide 7.16

Incineration is a high-temperature dry oxidation process that reduces organic and combustible waste to inorganic, incombustible matter and results in a very significant reduction of waste volume and weight. Examples of disposal facilities that use high temperature technology are cement kilns and coal fired thermal power stations or foundries.

It should be noted, however, that the Philippine Clean Air Act (RA 8749) of 1999 which sets the standard for environmental protection while pursuing national development specifically bans the method of incineration for the disposal of waste, including medical and pharmaceutical wastes. This is in view of the amount of chemical pollutants that may be released into the atmosphere that could adversely affect humans, animals and vegetation. Because of this restriction of the law, the use of incineration, while accepted globally as a method of waste disposal, may not be considered as an acceptable method for disposing medicines in the Philippines.

METHODS OF DISPOSAL

Chemical decomposition

- Used in accordance with the manufacturer's recommendations, followed by landfill
- Not recommended unless chemical expertise is readily available
- Tedious and time consuming

Slide 7.17

The option of chemical decomposition can be used in accordance with the manufacturer's recommendations followed by landfill. This method is tedious and time consuming and is not recommended unless chemical expertise is readily available.

Solids, semi-solids and powders (tablets, capsules, granules, powders for injection, mixtures, creams, lotions, suppositories etc.)

Liquids (solutions, suspensions, syrups etc.)

Aerosol containers (including propellant-driven sprays and inhalers)

Slide 7.18

In sorting, the top priority is to separate out the pharmaceuticals that are categorized as controlled substances, antineoplastics and any other non-pharmaceutical products that may have been mixed among the pharmaceuticals. These should be stored in separate, secure areas prior to safe disposal. The remaining unwanted pharmaceuticals should be sorted into different categories by dosage form:

- Solids, semi-solids and powders (tablets, capsules, granules, powders for injection, mixtures, creams, lotions, suppositories etc.)
- Liquids (solutions, suspensions, syrups etc.)
- Aerosol containers (including propellant-driven sprays and inhalers)

SOLIDS, SEMI-SOLIDS, AND POWDERS

Anti-infective drugs, controlled drugs & antineoplastics

- Return to manufacturer
- Encapsulation or inertization before discharge to landfill

Other drugs

- If quantity is not more than 1% of the total daily waste, landfill may be used

Slide 7.19

For solids, semi-solids and powders the following are the recommended disposal methods:

- Anti-infective drugs, controlled drugs & antineoplastic
 - ✓ Return to manufacturer
 - ✓ Encapsulation or inertization
- Other drugs
 - ✓ If the quantities of solid and semi-solid pharmaceuticals is not more than 1% of the total daily waste, landfill may be used

Pharmaceuticals with no or low toxicity

- Sewer
- Dilute with large volume of water then poured into large watercourses
- Cement encapsulation procedure
- Never in slow moving or stagnant surface waters

Slide 7.20

For liquid preparations the following are the recommended disposal methods:

- Pharmaceuticals with no or low toxicity
 - ✓ Sewer
- Other liquid pharmaceuticals (except controlled drugs, antineoplastics or anti-infectives)
 - ✓ Sewer
 - ✓ Dilute with large volumes of water then poured into large watercourses
 - ✓ Cement encapsulation procedure
 - ✓ Never in slow moving or stagnant surface waters

AMPOULES

- Crushed on a hard impermeable surface
- Not burnt or incinerated as they will explode, possibly causing injury to operators and damage to the furnace or incinerator
- Volatile liquids in small quantities can be allowed to evaporate in the open air

Slide 7.21

Ampoules of antineoplastics or anti-infective drugs must not be crushed and the liquid discharged to sewers. They should be treated using the encapsulation or inertization disposal methods described above.

- Drugs should not be discarded in an untreated form
- Encapsulation or inertization
- May be diluted in water, left for two weeks and disposed to the sewer

Slide 7.22

Anti-infective medicines should not be discarded in an untreated form. Generally they are unstable and are best incinerated, and if that is not possible encapsulated or inertized. Liquid anti-infective medicines may be diluted in water, left for two weeks and disposed to the sewer.

CONTROLLED SUBSTANCES

- Destroyed under supervision of a pharmacist or the police depending on national regulations
- Rendered unusable, by encapsulation, or inertization, and then dispersed among the municipal solid waste in a landfill

Slide 7.23

Controlled substances must be destroyed under the supervision of a pharmacist or the police depending on national regulations. Such substances must not be allowed into the public domain as they may be abused. These should either be rendered unusable by encapsulation or inertization and then dispersed among the municipal solid waste in a landfill or incinerated.

- Returned to the supplier for disposal
- Waste encapsulation
- Do not use:
 - Low and medium temperature incineration
 - Disposal to sewers and water courses
 - Directly to landfill

Slide 7.24

Antineoplastic medicines have the ability to kill or stop growth of living cells. These are used in the chemotherapy of cancer which is usually performed in specialized treatment centers. Antineoplastics should never be discharged into the environment because of serious environmental threats.

Antineoplastics should be segregated from other pharmaceuticals and kept separately in clearly marked containers with rigid walls. Ideally, these should be safely packaged and returned to the supplier for disposal. Other options are high temperature incineration and waste encapsulation.

DISINFECTANTS

- Store and gradually use
- Large quantities of disinfectants must not be flushed into the sewer
- To sewer or fast-flowing watercourse: small quantities of diluted disinfectants (max. 50 L/day under supervision)

Slide 7.25

In general disinfectants do not have an expiry date. As such these can be stored and gradually used over time. Large quantities of disinfectants must not be flushed into the sewer, as they may kill the bacteria in a sewage works and so stop the biological treatment of the sewage. Similarly large quantities should not be put into watercourses since the disinfectants will damage aquatic life. Small quantities of diluted disinfectant may be disposed of by discharge to a sewer providing the operation is supervised by a pharmacist and the quantities are strictly controlled to set limits.

- Do not burn or incinerate
- Disposed of in a landfill, dispersed among municipal solid wastes

Slide 7.26

Disposable aerosol canisters and inhalers should not be burnt or incinerated, as high temperatures may cause them to explode, possibly causing injury to operators and/or damage to the furnace or incinerator. Provided they do not contain poisonous substances they should be disposed of in a landfill, dispersed among municipal solid wastes.

REVIEW QUESTIONS

For each of the following statements, write T if the statement is true and F if it is false:

1. Improper disposal of expired pharmaceuticals may pose a threat to public health and the environment.
2. All liquid pharmaceutical preparations maybe disposed into the sewer but require dilution prior to disposal.
3. The dosage form of the drug is a primary consideration in determining the appropriate disposal method.

Slide 7.27

Ask the participants to answer the review questions. Discuss answers:

1. True or T
2. False or F
3. False or F

REVIEW QUESTIONS

7

4. Disposal of unwanted medicines is the sole responsibility of the pharmacist- or personnel-in-charge of managing medicines in the local public health facility.
5. Returning to donor or manufacturer is the easiest and most practical way of disposing unwanted medicines.

Slide 7.28

Ask the participants to answer the review questions. Discuss answers:

4. False or F
5. False or F

REFERENCES

BASEL CONVENTION ON THE CONTROL OF TRANSBOUNDARY MOVEMENTS OF HAZARDOUS WASTES AND THEIR DISPOSAL. 1999. *Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and their Disposal, Texts and Annexes* [online]. [Accessed 12 November 2014]. Available from:

<<http://www.basel.int/Portals/4/Basel%20Convention/docs/text/BaselConventionText-e.pdf>>

WORLD HEALTH ORGANIZATION. 1999. *Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies*. [online]. [Accessed 12 November 2014]. Available from: <http://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf>



Training Manual on Pharmaceutical Supply Chain Management

TRAINER'S MANUAL

for Local Government Health Facilities
(City Health Offices, Municipal Health Offices,
Rural Health Units and Barangay
Health Stations)



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Training Manual on Pharmaceutical Supply Chain Management

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Health Stations)**



This “Training Manual on Pharmaceutical Supply Chain Management for Local Government Health Facilities (City Health Offices, Municipal Health Offices, Rural Health Units and Barangay Health Stations)” is meant to guide facilitators in the conduct of the training. The PowerPoint presentations for each of the steps in the drug or medicine management cycle are found in this Manual. More importantly it includes explanation for each slide to guide lecturers/ facilitators in the discussion. Important readings referred to in this Manual are found in a separate booklet (Appendix). At the end of each step of the cycle, review questions and answer to these questions are found. The Training Manual is color coded. Different colors are used for each step and topic in the drug management cycle – Green (Principles of Drug Management), Violet (Selection of Medicines), Orange (Procurement of Medicines), Blue (Storage and Distribution of Medicines), Red (Use of Medicines), Yellow (Pharmaceutical Donations) and Gray (Disposal of Pharmaceuticals).

The instructional design for the entire training is found at the end of the manual.

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Glossary of Abbreviations

ADE	Adverse Drug Event
ADORS	Adverse Drug Online Reporting System
ADR	Adverse Drug Reaction
AO	Administrative Order
BAC	Bids and Awards Committee
BHS	Barangay Health Stations
CHO	City Health Officer
DOH	Department of Health
FDA	Food and Drug Administration
FEC	Formulary Executive Council
FEFO	First Expiry, First Out
FIFO	First In, First Out
GMP	Good Manufacturing Practice
INN	International Non-proprietary Name
LGU	Local Government Unit
MHO	Municipal Health Office
NCPAM	National Center for Pharmaceutical Access and Management
NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention
OTC	Over-the-Counter
SALADs	Sound-alike look-alike drugs
PNDF	Philippine National Drug Formulary
PNF	Philippine National Formulary
PTC	Pharmacy and Therapeutics Committee
PVC	Polyvinyl Chloride
RA	Republic Act
RH	Relative Humidity
RHU	Rural Health Unit
RI	Request Indicator
USP	United States Pharmacopeia
WHO	World Health Organization