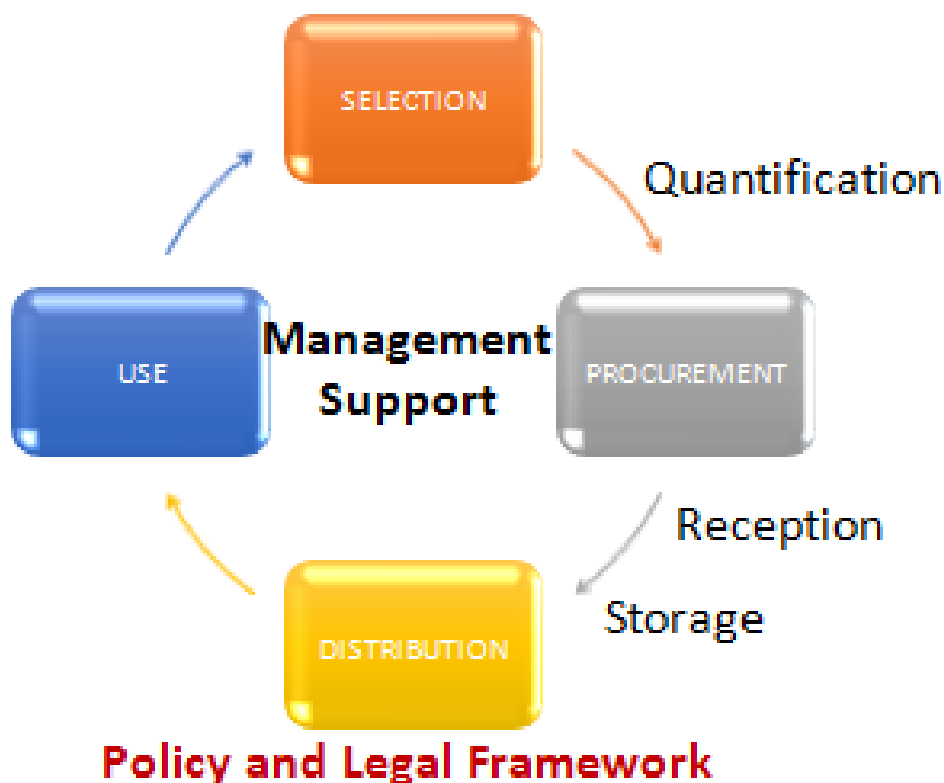




Principles of Drug Management

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. This will provide a very good background on Drug Management (a photocopy of the chapter is found in the separate booklet of references).

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

SESSION OBJECTIVES

1

1. Discuss the importance of managing medicines
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

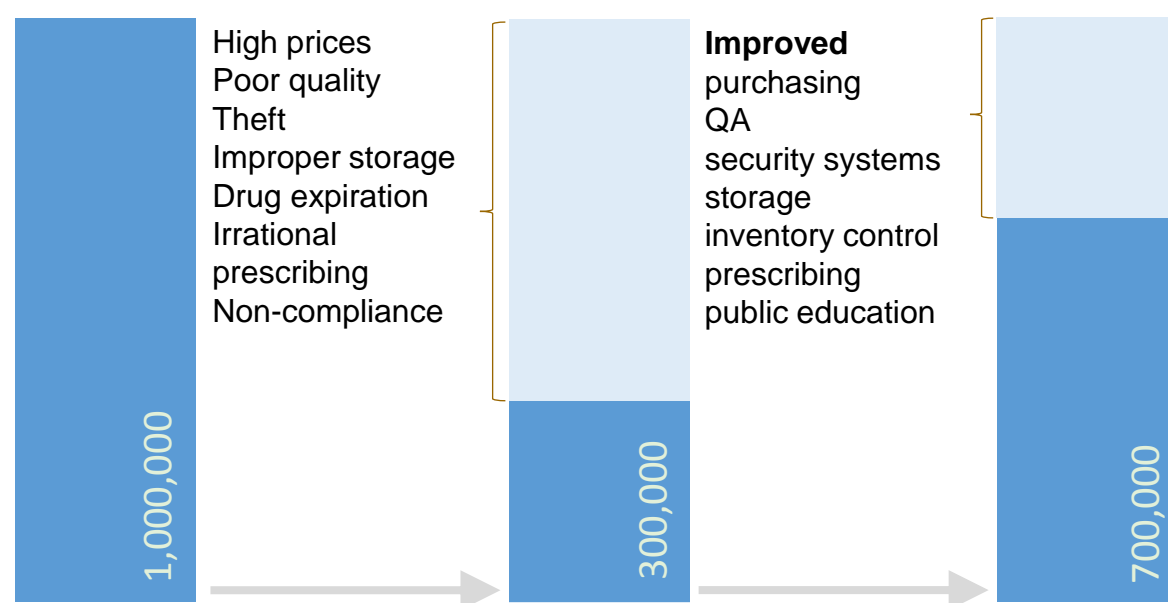
Slide 1.3

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



Source: Managing Access to Medicines and Health Technologies, 2012

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.

WHY MANAGE DRUGS?

1

- Medicines are part of the link between the patient and health services.
- Poor drug management is a critical issue, but major improvements are possible that can save money and improve access.
- Medicines are no longer the sole responsibility of health professionals.

Slide 1.5

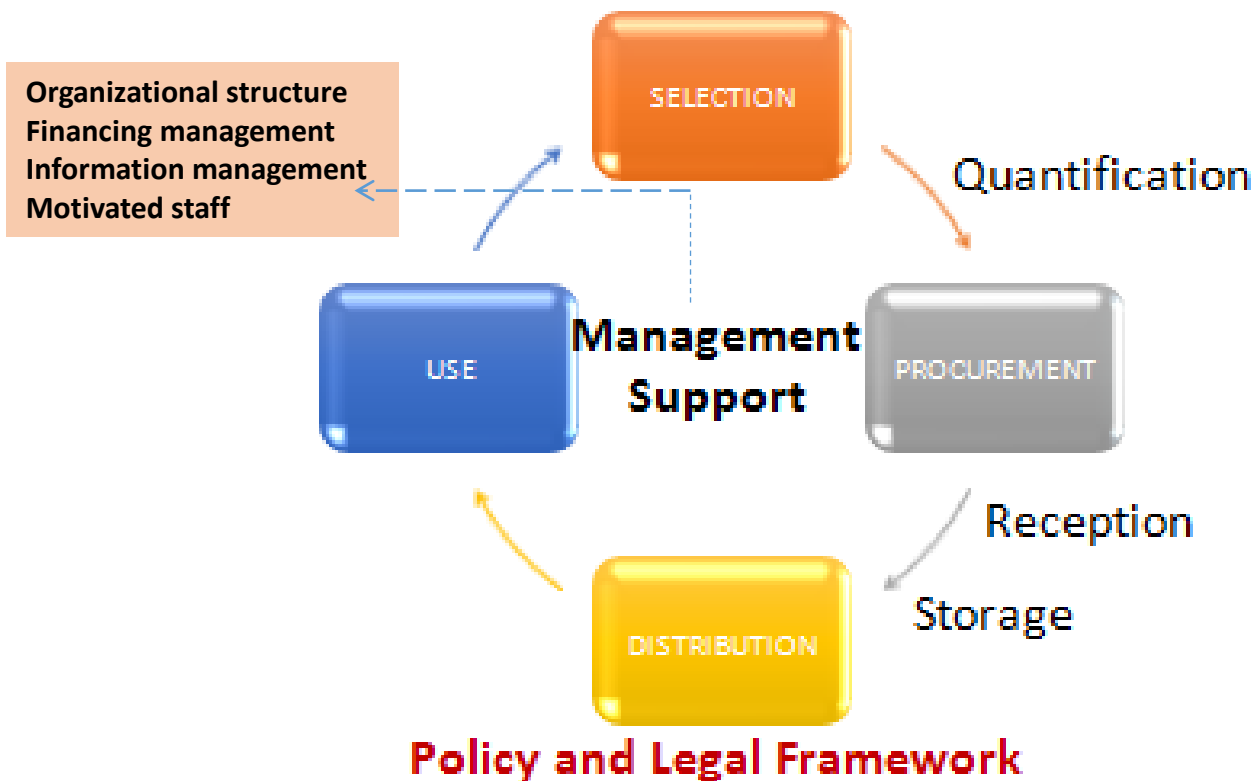
WHY MANAGE DRUGS?

Slide 1.5

Three reasons can be given to explain why medicines need to be managed properly. Firstly, medicines are part of the link between the patient and health services. Consequently, their availability or absence will contribute to the positive or negative impact on health. Secondly, poor drug management, specifically in the public sector of developing countries such as the Philippines, is a critical issue, but major improvements are possible that can save money and improve access. Finally, medicines are no longer the responsibility of health professionals only. Political, economic, financial and traditional considerations have become so crucial in healthcare that it has become imperative to look at medicines and healthcare from these perspectives. All of these factors contribute to appropriate financial expenditure, prevention of wastage, increased access and proper use of medicines.

DRUG MANAGEMENT CYCLE

1



Slide 1.6

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 1.6

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.

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

1. Give the (4) phases of the drug management cycle.
2. Give the meaning of GMP.

Slide 1.7

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

1. Selection, procurement, distribution, use
2. Good Manufacturing Practice

REVIEW QUESTIONS

For numbers 3 to 5, write T if the statement is true and F if the statement is false.

3. Quality of medicines is the sole responsibility of the manufacturer.
4. Poor management of medicines leads to poor quality of health care.
5. Medicine promotes trust and participation in health services.

Slide 1.8

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

3. False or F
4. True or T
5. True of T

REFERENCES

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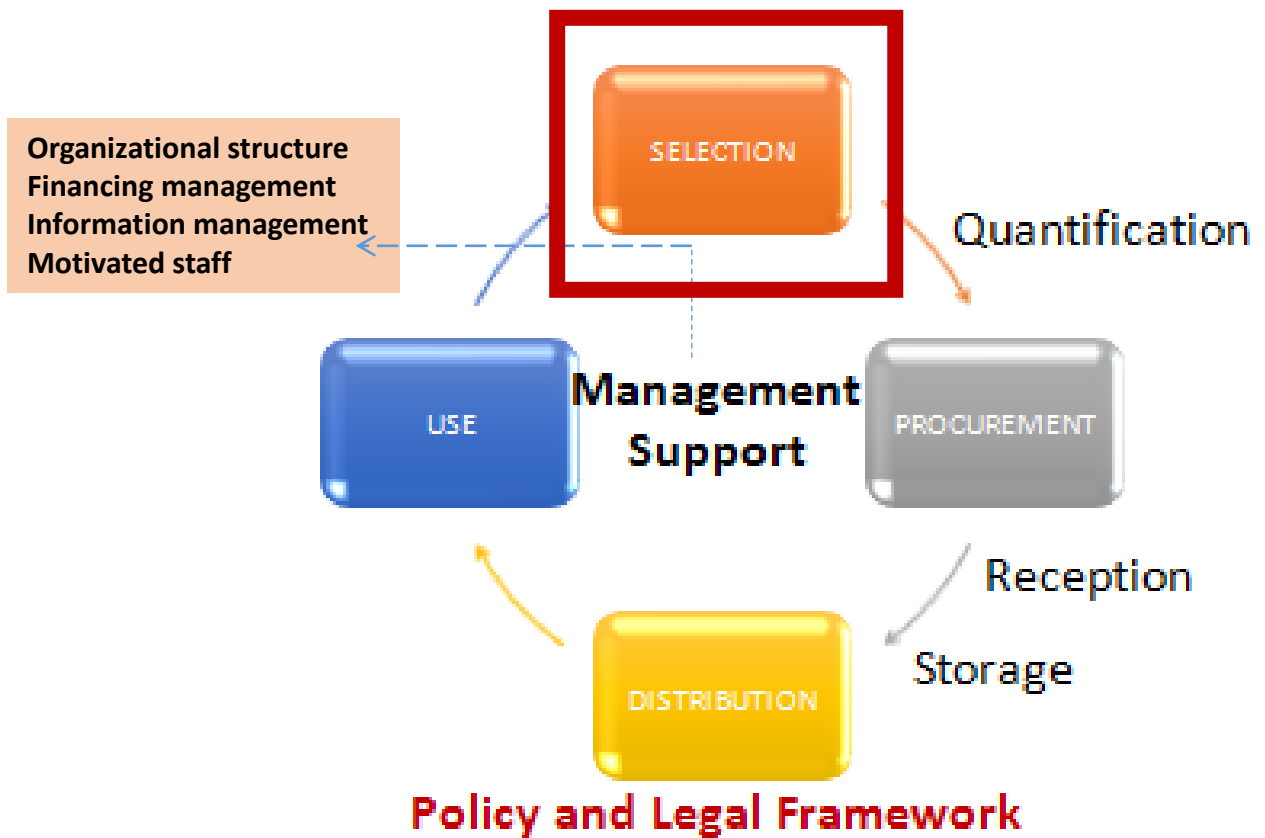
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Selection of Medicines



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 increased drastically. However, given that financial resources are finite and the costs of medicines are still high, selection must be managed efficiently.

Slide 2.2



SESSION OBJECTIVES

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

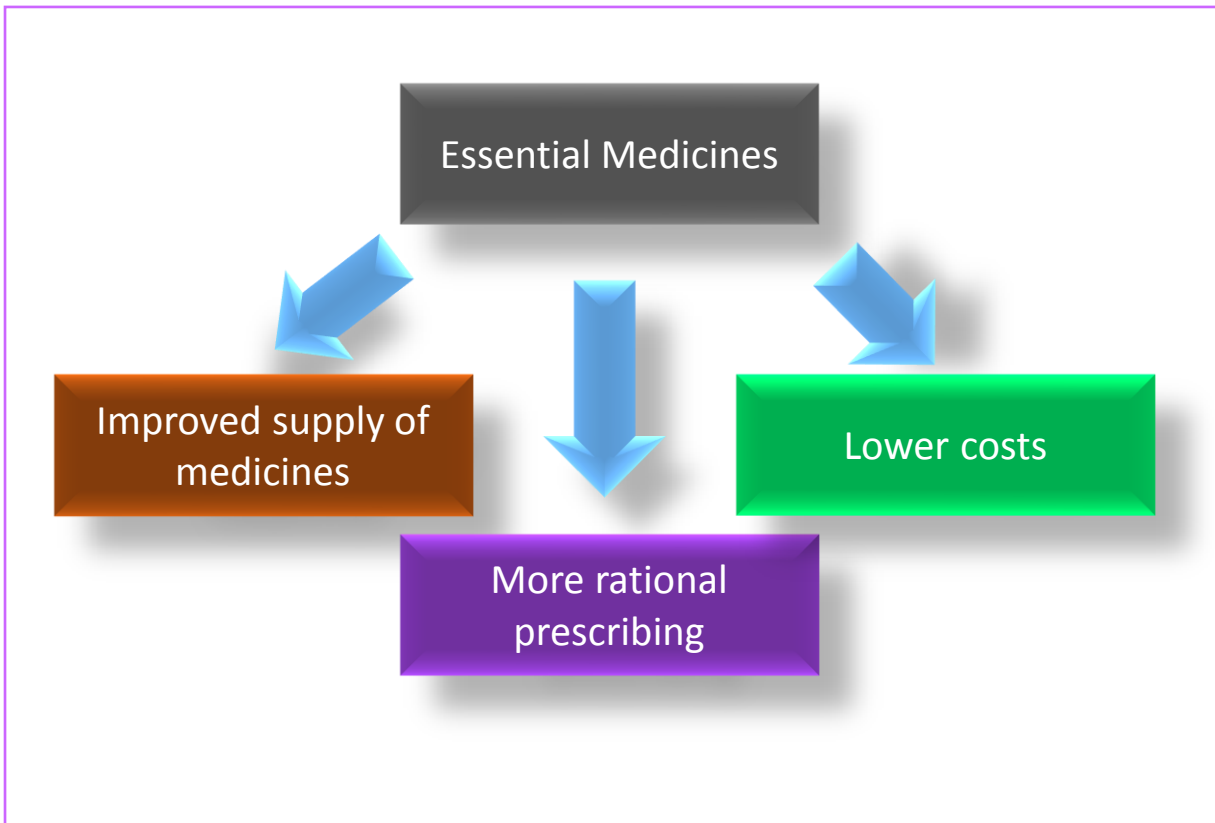
Slide 2.3

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 drugs**. 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.

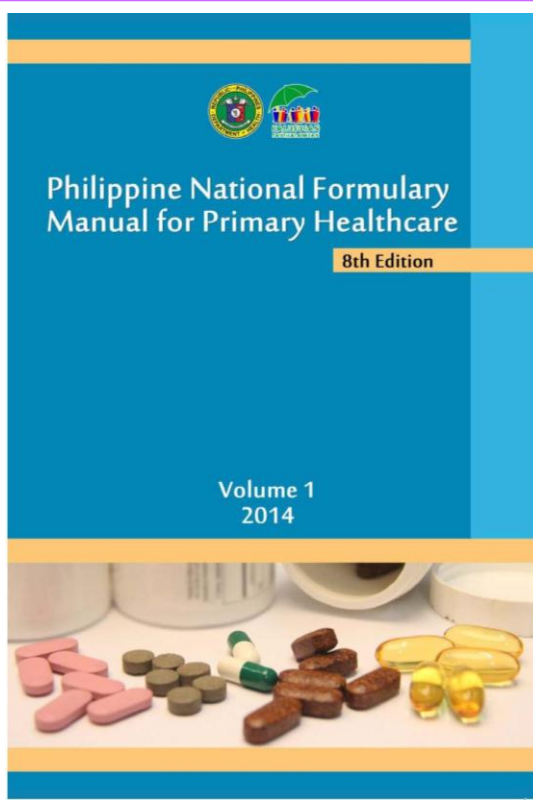
- Essential medicines list
- Describes the appropriate use of these essential medicines
- Basis for selection of medicines at the hospital

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

PHILIPPINE NATIONAL FORMULARY



Slide 2.7

The PNF serves as basis for selection of medicines in a government health facility such as the hospital. However, the hospitals may also create their own hospital formulary.

fections).

^a 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 2.8

These are the criteria for inclusion into the formulary.

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; and
- **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. 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.

INTERNATIONAL NON-PROPRIETARY NAME

| 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.

PHARMACY AND THERAPEUTICS COMMITTEE (PTC)

2

- Drug selection committee in the hospitals
- Often the same as the formulary committee

Slide 2.12

The Pharmacy and Therapeutics Committee (PTC) is the drug selection committee in the hospitals. It is often the same as the Formulary Committee.

PTC MEMBERS

- Doctors
- Pharmacists
- Nurses
- Hospital administrators
- Quality assurance staff
- Others as appropriate

Slide 2.13

Usually, a doctor chairs the committee, and a pharmacist serves as secretary.

The PTC may occasionally invite a specialist to make a presentation or provide advice on a particular issue.

- Developing relevant policies and procedures for:
 - Drug selection
 - Procurement
 - Distribution
 - Use

Slide 2.14

The PTC is responsible for developing relevant policies and procedures for drug selection, procurement, distribution, and use to promote rational drug use. Its functions include:

- ✓ Management of the approved hospital formulary;
- ✓ Ongoing drug use review;
- ✓ Adverse drug event reporting; and
- ✓ Implementation of safe drug practices.

RESPONSIBILITIES OF PTC

- Developing, managing, updating, and administering a formulary system

Formulary system: encompasses the whole system for developing, updating, and promoting the formulary list

Slide 2.15

A formulary system is part of the drug selection process.

- Formulary list
- Formulary manual
- Regular newsletter or bulletins
- Guidelines for the use of non-formulary medicines
- Methods for evaluating the need for changes in the formulary list or manual

Slide 2.16

A fully developed formulary system usually includes the following:

- ✓ Formulary list;
- ✓ Formulary manual;
- ✓ Regular newsletter or bulletins;
- ✓ Guidelines for the use of non-formulary medicines; and
- ✓ Methods for evaluating the need for changes in the formulary list or manual.

REVIEW QUESTIONS

For numbers 1 to 3, write T if the statement is true and F if the statement is false.

1. The use of the PNF as basis for the selection of medicines in government hospitals 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 2.17

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

2

For numbers 4 to 5, write the letter of the best answer.

4. The following are justifiable reasons for selection of medicines outside the PNF except:
 - a. The drug is needed for prevention of a condition not but not yet listed in the PNF.
 - b. The drug is more effective than the one listed in the formulary.
 - c. The drug is a novel drug/ product which has recently been launched in the market.
 - d. None of the above

Slide 2.18

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

4. c

REVIEW QUESTIONS

5. The following are criteria for inclusion of a drug/ medicine into the PNF except:
 - a. Local health problems
 - b. Quality
 - c. Safety
 - d. None of the above

Slide 2.19

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

5. d

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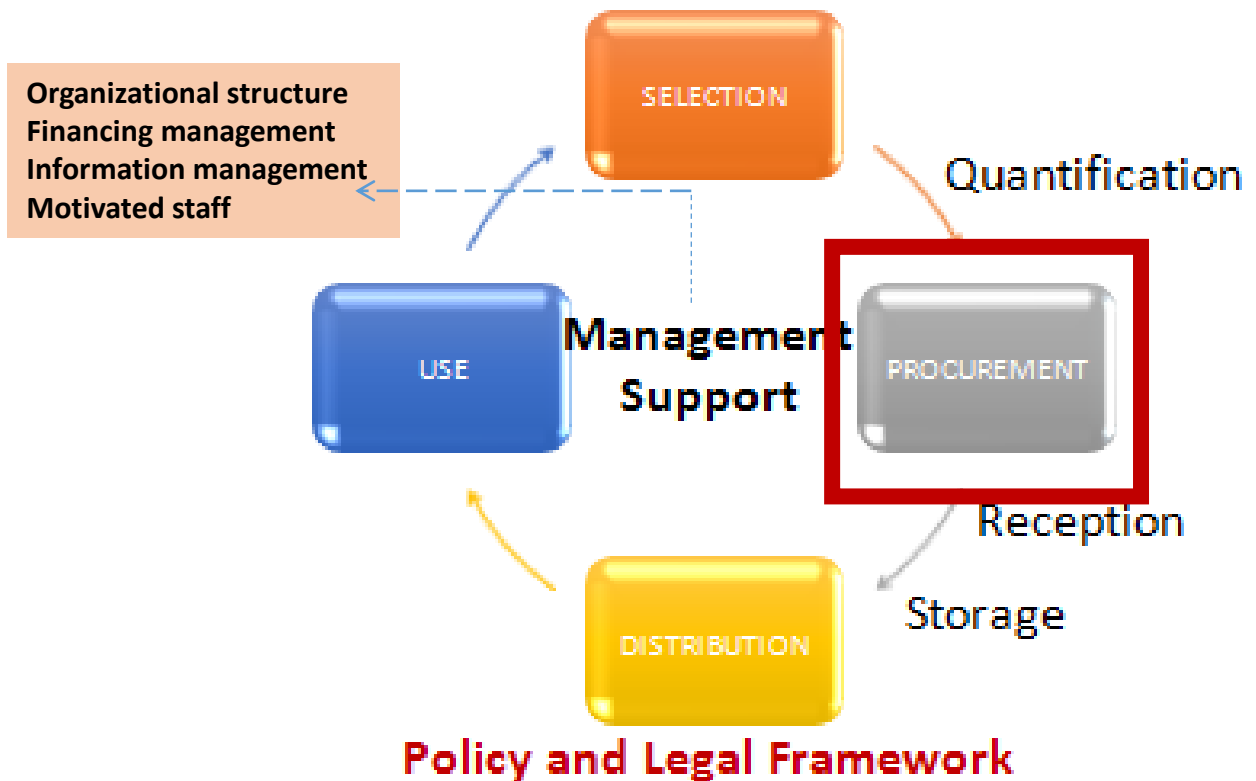
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H

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 IN HOSPITALS

3



Slide 3.2

After selecting medicines appropriate for the hospital, the procurement process commences.

Procurement of Medicines

SESSION OBJECTIVES

- Discuss the medicine procurement process
- Calculate order quantities and request indicator for procurement
- Identify components of medicine requisition form and delivery form
- Describe procedure of receipt of medicines in the hospital and detection of discrepancies in supplies/ orders

Slide 3.3

Present the learning objectives for the session.

- Procurement in government entities (including hospital) 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

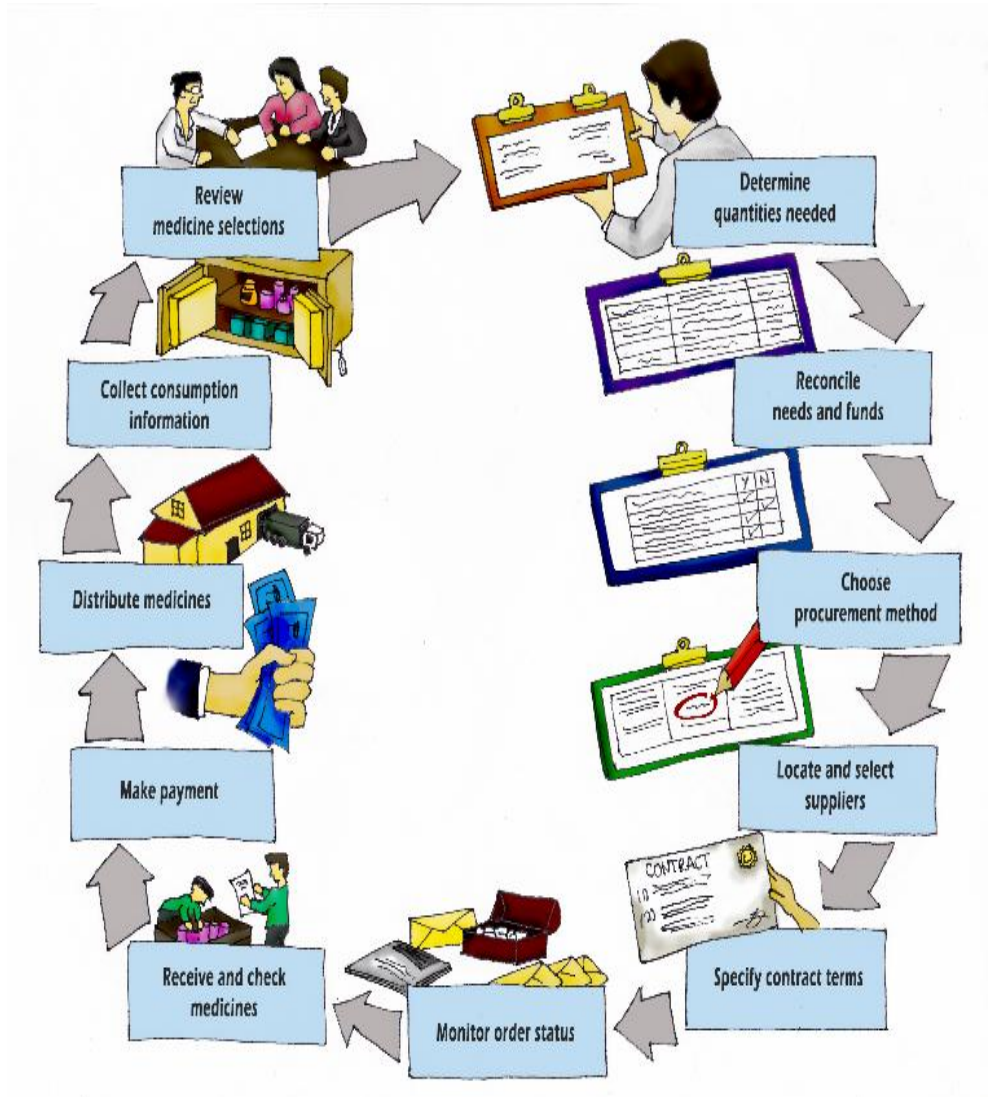


Slide 3.5

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 REQUIREMENTS

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.

OBJECTIVES OF QUANTIFICATION

3

- 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 and
- Calculate emergency needs for disaster relief and/ or epidemics

Slide 3.8

The objectives of quantification are:

- ✓ 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; and
- ✓ 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

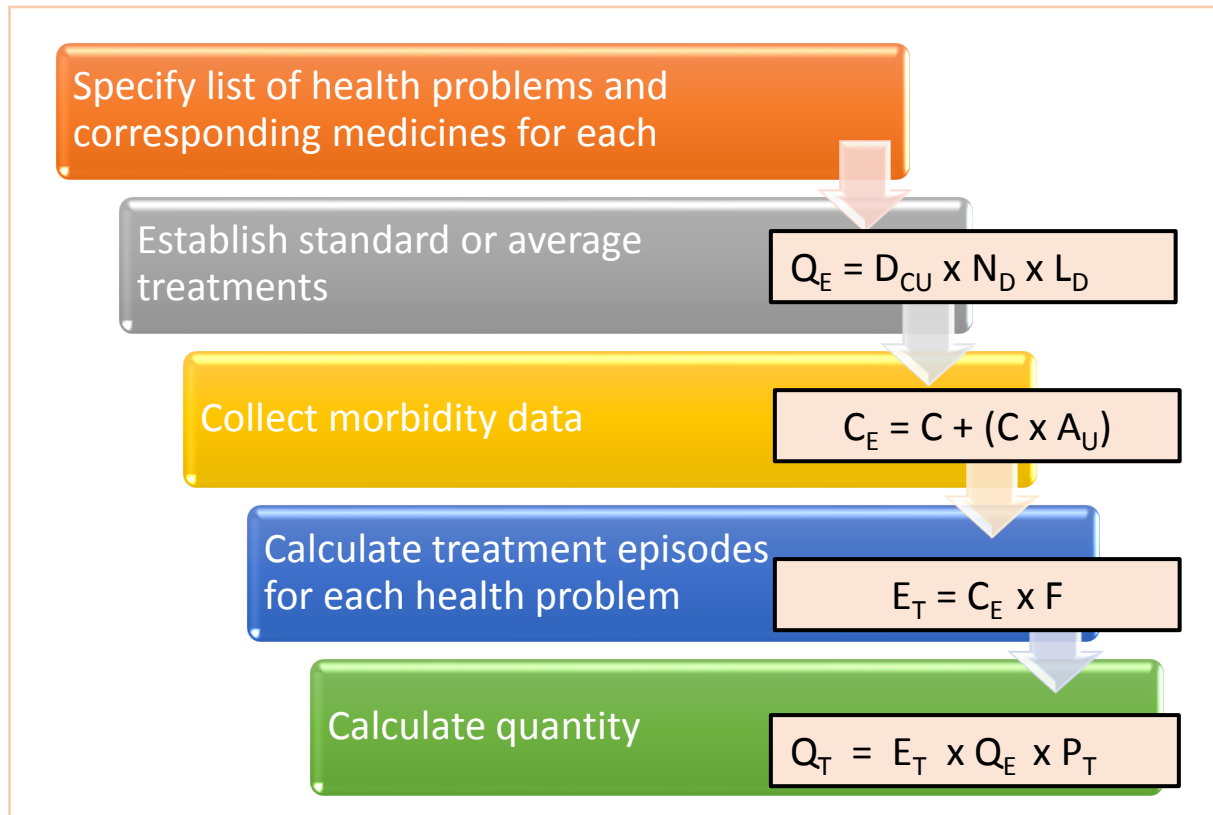
Consumption method

- 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

MORBIDITY METHOD

3

| Example: | | | | | | | | | | | | | |
|----------------------|-----------|----------------|-----------------------------------|-------------------------|--------------|---------------------------|-------------------------|------------|------------------|------------|-----------|----------------------|----------------|
| | age group | episodes /1000 | past year estimated # of episodes | projected # of episodes | # of regimen | %cases treated w/ regimen | drug product | basic unit | basic Unit /dose | doses /day | # of days | basic units /episode | Q _T |
| gastritis, heartburn | <5 | 11 | 34,537 | 36,955 | 1 | 100% | antacid susp | mL | 5 | 4 | 5 | 100 | 3,695,459 |
| | >5 | 77 | 240,502 | 257,337 | 1 | 70% | antacid susp | mL | 10 | 4 | 5 | 200 | 36,027,200 |
| | | | | | 2 | 30% | cimetidine 300mg tablet | 1 | 1 | 4 | 5 | 20 | 1,544,023 |

Slide 3.11

This is an example of quantification of drug requirements using Morbidity Method.

Procurement of Medicines

CONSUMPTION METHOD

Prepare list of medicines to be quantified.

Determine data on the following: past consumption for each product, no. of days of stockout, losses and inventory

Calculate average monthly consumption

$$\text{AMC} = \text{consumption} / \text{months}$$

Calculate the quantity of each medicine required in the next procurement period

$$Q_o = \text{number of months to cover} \times \text{AMC} - \text{remaining stock}$$

Slide 3.12

This illustrates quantifying medicine requirements using consumption method. Data that need to be determined include past consumption data, number of days of stockout, losses and inventory.

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

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

Slide 3.13

This is an example of quantification of drug requirements using Consumption Method.

DATA SOURCES OF CONSUMPTION

May be collated with data obtained from:

- Stock (bin) cards
- Daily use record
- Daily cash record
- Drug register

Slide 3.14

Monthly consumption may be collated with data obtained from:

- Stock (bin) cards
- Daily use records
- Daily cash records
- Drug register

Competitive or public bidding

Limited source bidding

Direct contracting

Repeat order

Shopping

Negotiated procurement

Slide 3.15

These methods of procurement are explained in the next page.

PROCUREMENT METHODS

Slide 3.15

The primary method of procurement in 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. Limited bidding involves a prequalification process where a supplier's technical capacity, financial capability and reputation are evaluated before the invitation to bid is released. Only pre-qualified suppliers receive a request for bids.

Slide 3.16

REQUEST INDICATOR (RI)

- 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 3.17

The 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.

REQUISITION/ DELIVERY FORM

3

- Name of drug and dosage form
- Unit of issue and quantity requested
- Requisition number (it is preferable to begin with a new number each year)
- Name of the dispensary and the date the requisition was made
- Where the stores requisition/ delivery form is designed to contain all the items listed, fill in only the quantities of those items needed

Slide 3.18

REQUISITION/ DELIVERY FORM

- Approximate unit price of each requested item and the approximate total cost of each item
- Name and signature of the health worker making the requisition
- Name and signature of the head of health facility
- Name and signature of a member of health committee

Slide 3.19

It is advisable to make a request on a standard stores requisition/ delivery (issue) form. Ensure that the following items are filled in correctly:

- ✓ Name of drug and dosage form;
- ✓ Unit of issue and quantity requested;
- ✓ Requisition number (it is preferable to begin with a new number each year);
- ✓ Name of the dispensary and the date the requisition was made;
- ✓ Where the stores requisition/ delivery form is designed to contain all the items listed, fill in only the quantities of those items needed;
- ✓ Approximate unit price of each requested item and the approximate total cost of each item;
- ✓ Name and signature of the health worker making the requisition;
- ✓ Name and signature of the head of health facility; and
- ✓ Name and signature of a member of health committee.

RECEIPT OF MEDICINES AT THE HOSPITAL



Quantity

Packaging

Labels

Expiry dates

Dosage form

Strength

Physical condition

Slide 3.20

Upon delivery of supplies to the hospital, 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, etc. are within 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 3.21

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 the statement is false.

1. Procurement in a government health facility such as a public hospital 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 3.22

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. Write the letter of the best answer. 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 3.23

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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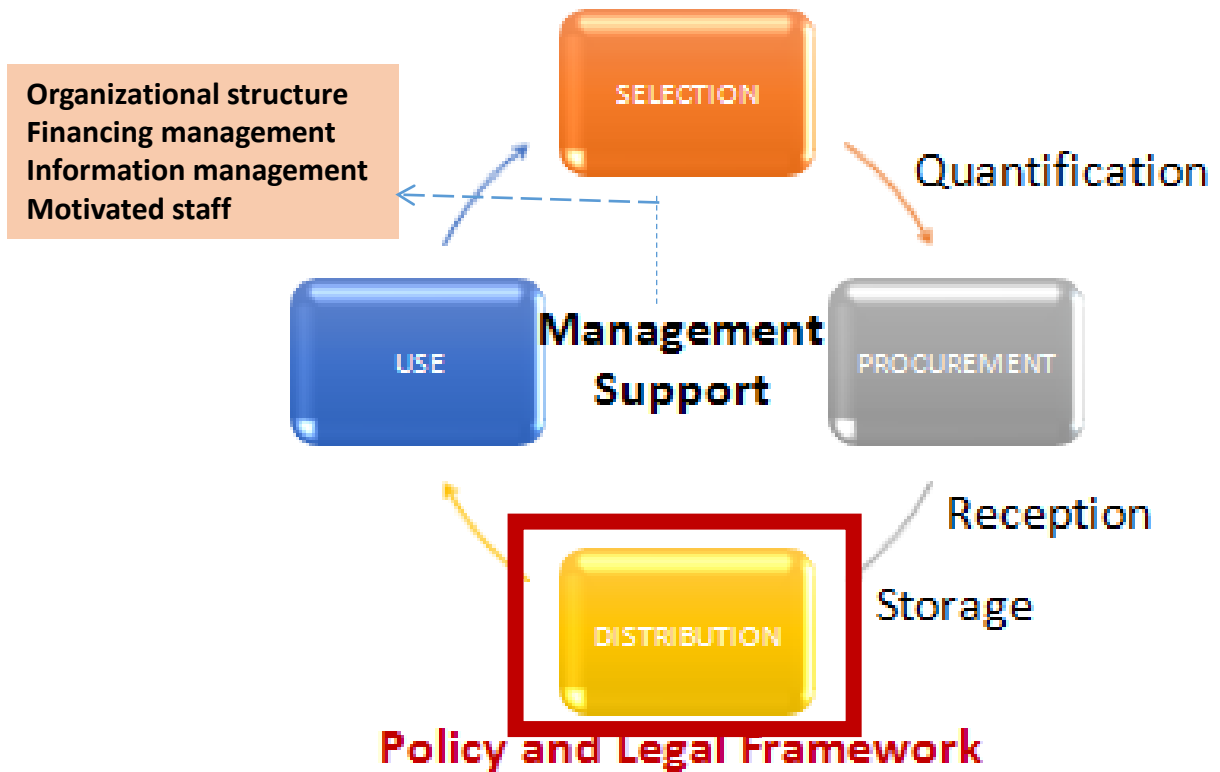
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Storage and Distribution of Medicines



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. Differentiate the drug distribution systems in the hospital
4. Identify common problems encountered in storage and distribution of medicines

Slide 4.3

Present the learning objectives for the session.

- Among the hospital pharmacist's most important responsibilities
- Drug distribution
- Drug storage

Slide 4.4

Slide 4.4

Drug control is among the hospital pharmacist's most important responsibilities.

An important part of drug control is drug distribution. Safe distribution of all drugs and related supplies to both inpatients and outpatients should be provided.

Storage is also an important aspect of the total drug control system. Proper environmental control (i.e., proper temperature, light, humidity, conditions of sanitation, ventilation, and segregation) must be maintained wherever drugs and supplies are stored in the hospital.

- 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 4.5

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 4.6

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 4.7

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

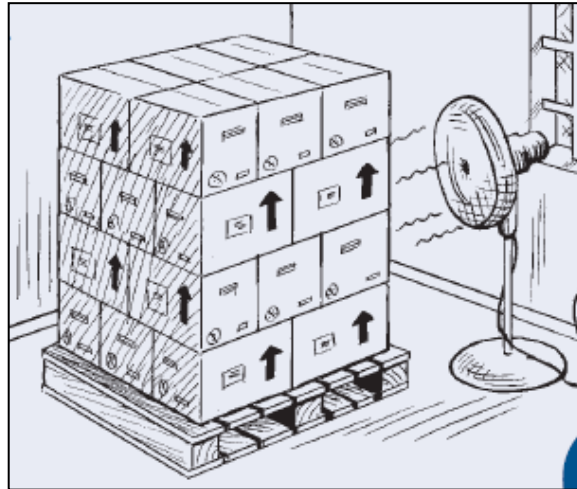


Source: Managing Access to Medicines and Health Technologies, 2012

Slide 4.8

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 4.9

When product labels say “protect from moisture,” store the product in a space with no more than 65% relative humidity. To reduce the effects of humidity consider the following:

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.

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

Slide 4.10

Protect products from sunlight as it may cause damage especially if they are 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.

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

Slide 4.11

Orderly Arrangement

Provide sufficient shelving

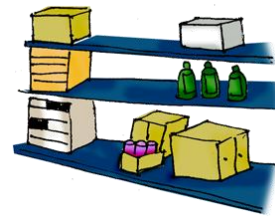
Use a system for arrangement: by order code/
drug category or alphabetic by generic name

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 4.12

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 4.13

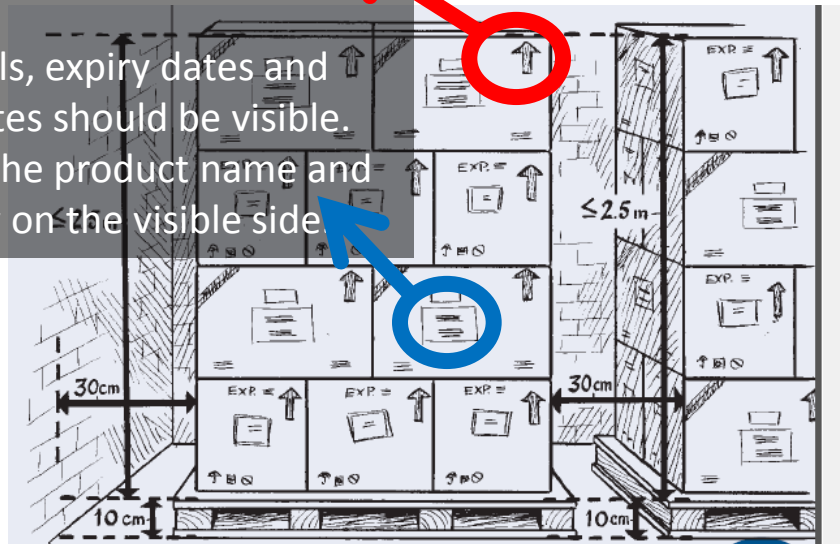
The distance mentioned in the first two bullets, will facilitate ease in cleaning the areas.

GOOD STORAGE PRACTICES

4

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 4.14

Arrange medicines in shelves and label accordingly.



Slide 4.15

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 4.16

Slide 4.16

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 4.17

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

Stock (bin) cards

- must be maintained for each drug stored in the storeroom
- should be made of cardboard and placed near the drug products that they refer to on the shelves

| <i>Ampicillin – capsule 250 mg (Totapen®)</i> | | | | | |
|---|-----------------------|----------|----------|---------|--------------------|
| N° Rack _____ Mini 100.000 Maxi _____ | | | | | |
| EXADOMPTA Ref. S 3 | | | | | |
| DATES | ORIGIN OR DESTINATION | INCOMING | OUTGOING | STOCK | ORDERED OR REMARKS |
| 12.12.91 | M.S.F. | | | | 130.000 |
| 04.01.92 | M.S.F. | 130.000 | | 130.000 | |
| 05.01.92 | Béboro | | 30.000 | 100.000 | |
| 05.01.92 | Koumra | | 5.000 | 95.000 | |
| 06.01.92 | Motssala | | 25.000 | 70.000 | |
| 30.01.92 | Inventory | | | 70.000 | |
| 01.02.92 | UNICEF | | | | 150.000 |
| 01.02.92 | Béboro | | 20.000 | 50.000 | |
| 05.02.92 | Goundi | | 40.000 | 10.000 | |
| 04.03.92 | UNICEF | 150.000 | | 160.000 | |

Slide 4.18

Record-keeping is part of good storage practice.

Stock (bin) cards must be maintained for each drug stored in the storeroom. This document is important for good accountability of stock movements. The cards should be made of cardboard and placed near the drug products that they refer to on the shelves.

- Enter quantity of seed stock under the “in” and “balance” columns with date, price and supplier.
- Enter quantity of any new stock under the “in” column with date, price, supplier and delivery number.
- Enter balance of stock brought forward under the “balance” column with date.

Slide 4.19

- Entries of receipt and issue of drugs are made after the event.
- Always have a balance of stock entered under the “balance” column with date.
- Always issue out full containers of drugs from the store and enter the quantity of drug issued under the “out” column.

Slide 4.20

- Physically check the actual balance of stock against current balance in stock card from time to time to detect any discrepancy.
- Keep spoons and measuring cups within reach for dispensing.

Slide 4.21

Slide 4.19-21

The following procedures are recommended:

- ✓ Enter quantity of seed stock under the “in” and “balance” columns with date, price and supplier.
- ✓ Enter quantity of any new stock under the “in” column with date, price, supplier and delivery number.
- ✓ Enter balance of stock brought forward under “balance” column with date.
- ✓ Entries of receipt and issue of drugs are made after the event.
- ✓ Always have a balance of stock entered under the “balance” column with date.
- ✓ Always issue out full containers of drugs from the store and enter the quantity of drug issued under the “out” column.
- ✓ Physically check the actual balance of stock against current balance in stock card from time to time to detect any discrepancy.
- ✓ Keep spoons and measuring cups within reach for dispensing.

- Inspect medicines for quality and quantity before distribution.
- Maintain proper storage conditions during transport.
- Verify and document delivery orders.
- Check the integrity of packaging when medicines arrive.

Slide 4.22

- Clearly label containers.
- Maintain delivery records.
- Provide easy access to delivery records.

Slide 4.23

Good distribution practices include the following:

- ✓ Inspect medicines for quality and quantity before distribution.
- ✓ Maintain proper storage conditions during transport.
- ✓ Verify and document delivery orders.
- ✓ Check the integrity of packaging when medicines arrive.
- ✓ Clearly label containers.
- ✓ Maintain delivery records.
- ✓ Provide easy access to delivery records.

- Bulk ward stock replenishment
- Individual medication order system
- Unit-dose system

Slide 4.24

These are the basic types of drug distribution systems that exist in the hospitals. Variations of each system exist, and all systems may be used in the same facility, depending on the strategy developed.

- Pharmacy functions as a warehouse and dispenses bulk containers on requisition without reviewing individual patient drug orders for appropriateness
- Advantage: shorter turnaround time between prescribing and administering the medication

Slide 4.25

In a ward stock system, the pharmacy functions as a warehouse and dispenses bulk containers on requisition without reviewing individual patient drug orders for appropriateness.

The main advantage is shorter turnaround time between prescribing and administering the medication.

- Course of therapy is dispensed according to a written prescription for an individual patient
- Advantages:
 - Pharmacist can review the appropriateness of therapy
 - Patient-specific medication profile can be maintained
 - Pharmacy charges to patients are facilitated
 - Closer control of inventory is possible

Slide 4.26

The individual medication order system closely resembles dispensing to outpatients: a course of therapy is dispensed according to a written prescription for an individual patient.

Compared with bulk ward stock, the advantages are that the pharmacist can review the appropriateness of therapy, a patient-specific medication profile can be maintained, pharmacy charges to patients are facilitated, and closer control of inventory is possible.

- Preferred system from a patient care perspective
- Medications are dispensed in unit-dose packages in separate bins or drawers for each patient
- Efficient but requires a large initial capital outlay

Slide 4.27

A preferred system from a patient care perspective is the unit-dose system, which has a lower possibility for error. Medications are dispensed in unit-dose packages (i.e. each dose is separately packaged) in separate bins or drawers for each patient. Commonly, a 24-hour supply is provided. Drugs returned to the pharmacy can be put back in stock without concern for identity or contamination. This system is efficient but requires a large initial capital outlay for the purchase of repackaging machines and medication cabinets with individual patient drawers. The cost per delivered dose is higher than with bulk packaging, but this increased expense may be offset by reduced wastage and easier detection of leakage. Hospitals in some countries have found innovative ways of adapting local technologies to construct their own fixtures and equipment.

| Factor | Bulk Ward Stock Replenishment | Individual Medication Order System | Unit-dose System |
|---------------------------|-------------------------------|------------------------------------|------------------|
| Material and supply costs | Low | Medium-low | High |
| Pharmacy labor costs | Low | Medium | High |
| Nursing labor costs | Medium-low | Low | Low |
| Pilferage risk | High | Medium | Low |
| Medication error risk | High | Medium-low | Low |

Source: Managing Access to Medicines and Health Technologies, 2012

Slide 4.28

This table compares the different drug distribution systems in the hospitals.

1. Give the meaning of FEFO and FIFO.

For numbers 2 to 4, write T if the statement is true and F if the statement is false.

2. Humidity in the storage area must not be greater than 56% RH.
3. The stock cards should be placed near the drugs that they refer to on the shelves.

Slide 4.29

Ask participants to answer the review questions. Discuss answers.

1. First expiry/ first out; first in/ first out
2. False or F
3. True or T

4. Drug distribution is an important part of drug control.
5. It is the preferred drug distribution system from a patient care perspective.
 - a. Bulk ward stock replenishment
 - b. Individual medication order system
 - c. Unit-dose system

Slide 4.30

Ask participants to answer the review questions. Discuss answers.

4. True or T
5. c

Storage and Distribution of Medicines

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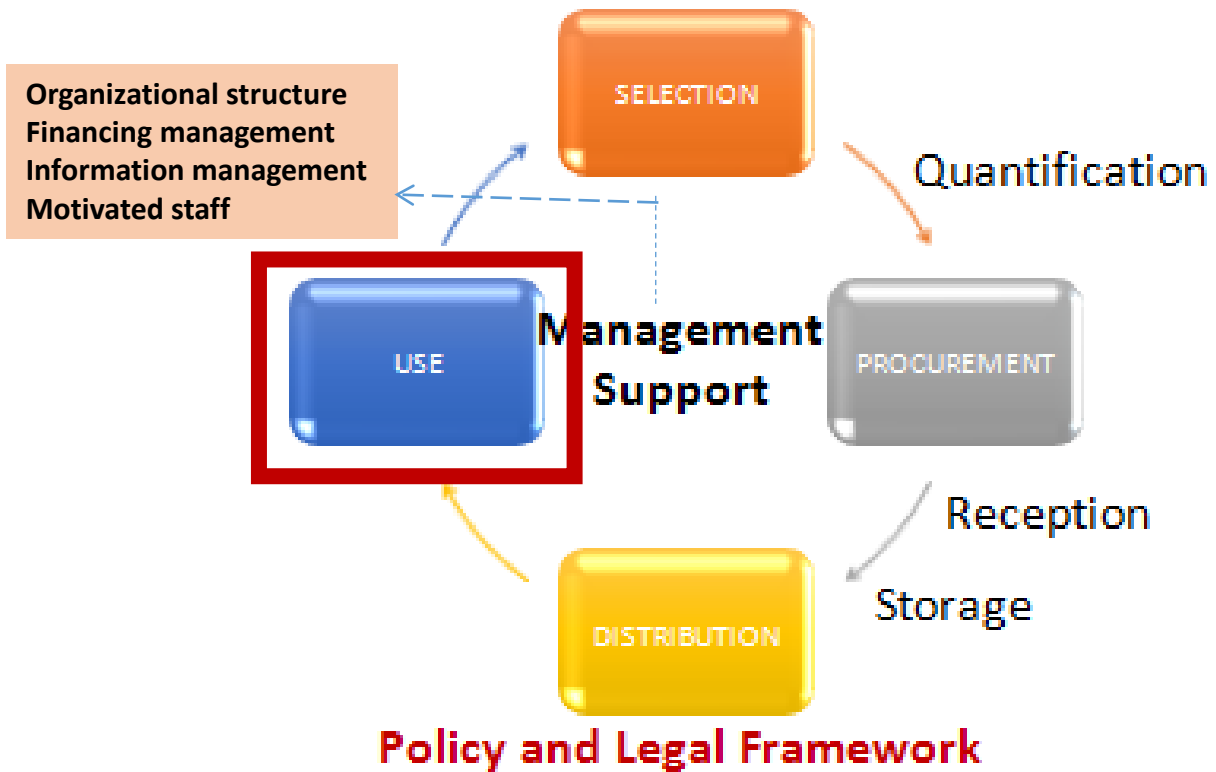
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H

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.



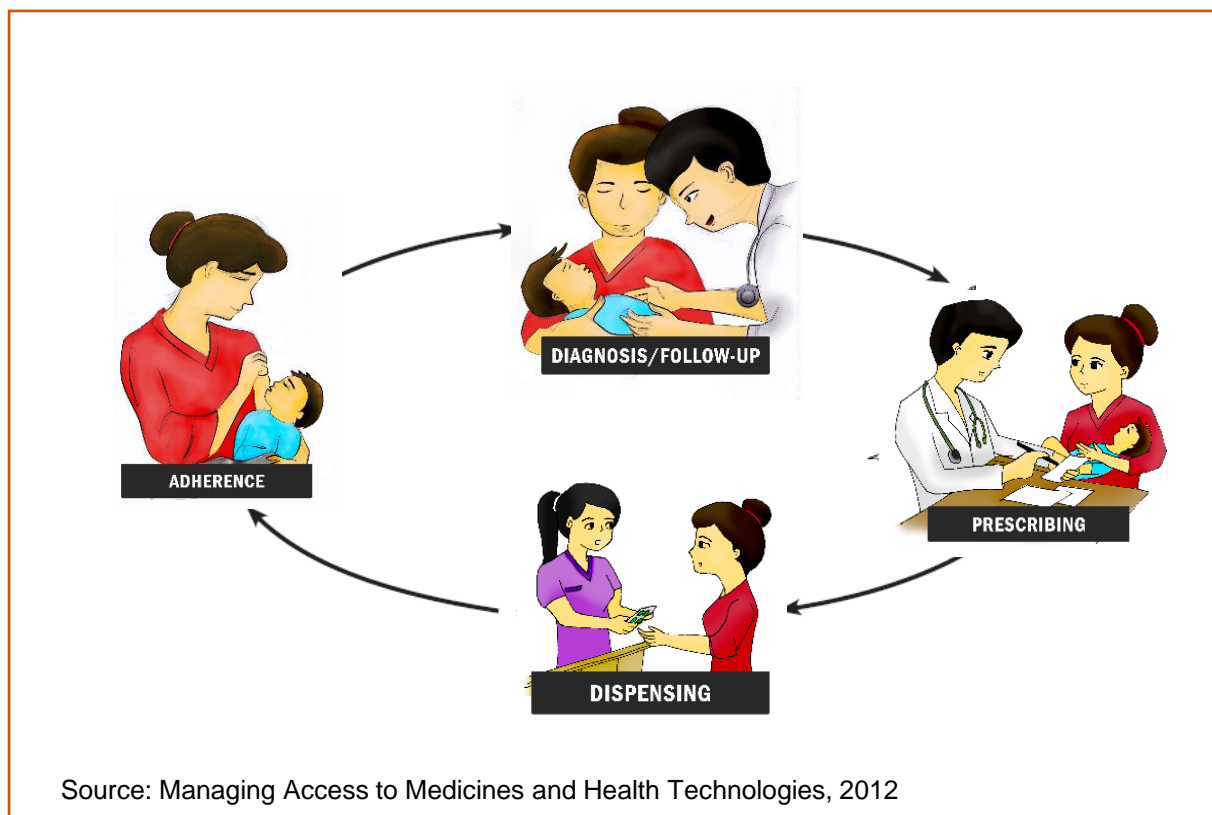
Slide 5.2

SESSION OBJECTIVES

- Define rational use of medicine
- Explain the medication use process
- Identify parts of the prescription
- Interpret a prescription
- Prepare and dispense the required medication
- Record consumption of medicines
- Determine the actions to be taken in the case of adverse drug reactions and medication errors

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.”

Appropriate indication

Appropriate drug

Appropriate patient

Appropriate patient information

Appropriate 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 799 days</p> |
| | <p>Date prescription is written</p> |
| | <p>Inscription (medication prescription)</p> |
| | <p>Signa (directions for patient)</p> |
| | <p>Physician's Sig. <u>J. Dela Cruz</u> Lic. No. <u>12345</u> PTR No. <u>1234567</u> S2 No. _____</p> |

Slide 5.7

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

TYPES OF INCORRECT PRESCRIPTIONS

Erroneous Prescription:

- The brand name precedes the generic name.
- The generic name is the one in parenthesis.
- The brand name is not in parenthesis.
- More than one drug product is prescribed on one prescription form.

Slide 5.8

What to do with erroneous prescriptions:

- ✓ Erroneous prescriptions shall be filled. Such prescriptions shall be kept and reported by the pharmacist of the drug outlet or any other interested party to the nearest DOH Office for appropriate action.

Violative Prescription:

- The generic name is not written.
- The generic name is not legible and a brand name which is legible is written.
- The brand name is indicated and instructions added, such as the phrase “No substitution” which tend to obstruct, hinder, or prevent generic dispensing.

Slide 5.9

What to do with violative prescriptions:

- ✓ Violative prescriptions shall not be filled. They shall be kept and reported by the pharmacist of the drug outlet or any other interested party to the nearest DOH office for appropriate action. The pharmacist shall advise the prescriber of the problem and/or instruct the customer to get the proper prescription.

TYPES OF INCORRECT PRESCRIPTIONS

Impossible Prescription:

- Only the generic name is written but is not legible.
- The generic name does not correspond to the brand name.
- Both the generic name & the brand name are not legible.
- The drug product prescribed is not registered with FDA.

Slide 5.10

What to do with impossible prescriptions:

- ✓ Impossible prescriptions shall not be filled. They shall be kept and reported by the pharmacist of the drug outlet or any other interested party to the nearest DOH office for appropriate action. The pharmacist shall advise the prescriber of the problem and/or instruct the customer to get the proper prescription.

- The process of preparing and giving medicine to a patient on the basis of a prescription
- Involves the correct interpretation of orders of the prescriber and the accurate preparation and labelling of medicine for use by the patient

Slide 5.11

Dispensing refers to the process of preparing and giving medicine to a patient on the basis of a prescription. It involves the correct interpretation of the orders of the prescriber and the accurate preparation and labelling of medicine for use by the patient.

DISPENSING ENVIRONMENT

- Staff
- Physical surroundings
- Shelving and storage areas
- Surfaces used during work
- Equipment and packaging materials

Dispensing environment must be clean and organized.

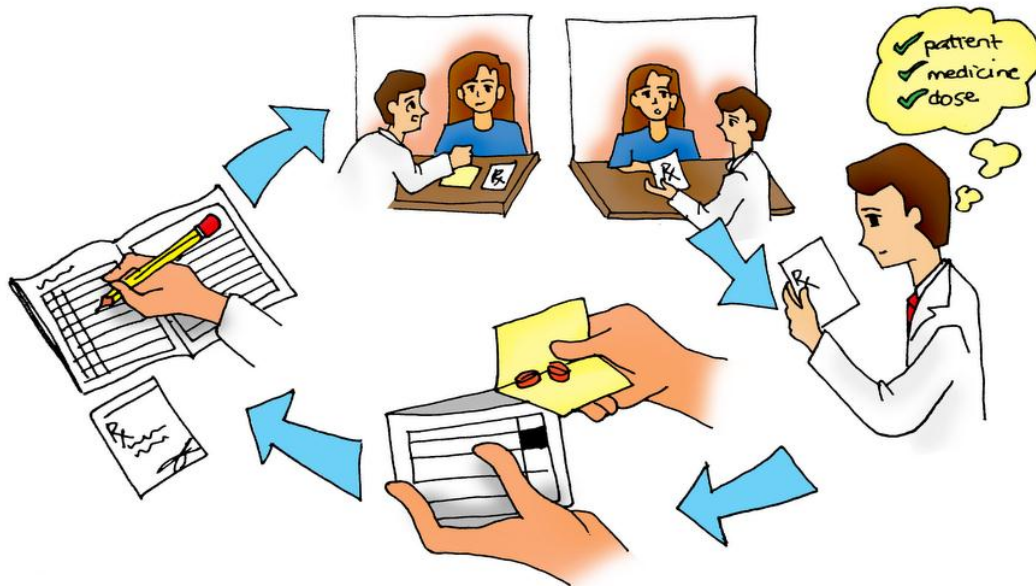
Slide 5.12

Dispensing environments must be clean, because most drug products are for internal use, making it important that they be hygienic and uncontaminated. The environment must also be organized so that dispensing can be performed accurately and efficiently. The dispensing environment includes:

- ✓ Staff;
- ✓ Physical surroundings;
- ✓ Shelving and storage areas;
- ✓ Surfaces used during work; and
- ✓ Equipment and packaging materials.

THE DISPENSING PROCESS

5



Source: Managing Access to Medicines and Health Technologies, 2012

Slide 5.13

It covers all activities involved, from receiving the prescription to issuing the prescribed medicine to the patient. It involves six major steps:

- ✓ Receive and validate the prescription;
- ✓ Understand and interpret the prescription;
- ✓ Prepare and label items for issue;
- ✓ Make a final check;
- ✓ Record the action taken; and
- ✓ Issue medicine to the patient with clear instructions and advice.

1. RECEIVE AND VALIDATE THE PRESCRIPTION

- Upon receiving a prescription, the staff member responsible should confirm the name of the patient.

Slide 5.14

Cross-checking the name and identity of the patient must also be done when issuing the medicines.

2. UNDERSTAND AND INTERPRET THE PRESCRIPTION

5

- Interpreting a prescription must be done by a staff member who can:
 - Read the prescription;
 - Correctly interpret any abbreviations used by the prescriber;
 - Confirm that the doses prescribed are in the normal range for the patient (in consideration of sex and age);
 - Correctly perform any calculations of dose and issue quantity; and
 - Identify any common drug-drug interactions.

Slide 5.15

Interpreting a prescription must be done by a staff member who can:

- Read the prescription;
- Correctly interpret any abbreviations used by the prescriber;
- Confirm that the doses prescribed are in the normal range for the patient (in consideration of sex and age);
- Correctly perform any calculations of dose and issue quantity; and
- Identify any common drug-drug interactions.

3. PREPARE AND LABEL ITEMS FOR ISSUE

Select stock container or prepack

- A good dispenser selects the item by reading the label and cross-matching the product name and strength against the prescription.
- The dispenser should check the stock to make sure that it has not expired and choose the oldest stock (FIFO) or first expiry (FEFO).

Slide 5.16

Select stock container or prepack

- A good dispenser selects the item by reading the label and cross-matching the product name and strength against the prescription. The dispenser should check the stock to make sure that it has not expired and choose the oldest stock (FIFO) or first expiry (FEFO). Most well-trained staff members deliberately read the container label at least twice during the dispensing process.

3. PREPARE AND LABEL ITEMS FOR ISSUE

5

Measure or count quantity from stock containers

- Liquids must be measured in a clean vessel and should be poured from the stock bottle with the label kept upward.
- Tablets and capsules can be counted with or without the assistance of a counting device.

Slide5.17

Measure or count quantity from stock containers

- Liquids must be measured in a clean vessel and should be poured from the stock bottle with the label kept upward. Tablets and capsules can be counted with or without the assistance of a counting device. The most important rule to follow is that the dispenser's hands must not be in direct contact with the medicine.

3. PREPARE AND LABEL ITEMS FOR ISSUE

Measure or count quantity from stock containers

Counting should be done using one of the following:

- Clean piece of paper and clean knife or spatula;
- Clean tablet-counting device;
- Lid of the stock container in use; or
- Any other clean, dust-free surface.

Slide 5.18

Immediately after measuring or counting, the stock container lid should be replaced and the stock container label should be rechecked for drug name and strength.

3. PREPARE AND LABEL ITEMS FOR ISSUE

5

Pack and label medicine

- Tablets or capsules should be packed into a clean, dry container, such as a bottle, plastic envelope, cardboard box, or paper envelope.

Slide 5.19

Pack and label medicine

Tablets or capsules should be packed into a clean, dry container, such as a bottle, plastic envelope, cardboard box, or paper envelope.

PACKAGING CATEGORIES FOR MEDICINE DISPENSING

Packaging Materials for Medicine Dispensing (continued)

| Category of Packaging | Package Characteristics | Examples |
|--------------------------|---|---|
| Tablets/ capsules | | |
| Desirable | Clean, dry, plastic or glass container with tight-fitting cap or seal | Blister packages, plastic sachets, tightly sealing plastic or glass containers with screw or snap cap |
| Acceptable | Clean, dry container that provides protection from dirt and moisture | Zipper-lock plastic bags, glycine paper, tin with tight-fitting lid |
| Undesirable | Unclean absorbent paper, cotton, cardboard containers with no provision for closure | Unsealed plastic bags, paper bags, newspaper or other printed paper |

Slide 5.20

This table covers packaging categories and materials for dispensing tablets and capsules.

PACKAGING CATEGORIES FOR MEDICINE DISPENSING

5

Packaging Materials for Medicine Dispensing (continued)

| Category of Packaging | Package Characteristics | Examples |
|-----------------------------------|--|---|
| Liquids (oral and topical) | | |
| Desirable | Clean, dry, light-resistant glass container with tight-fitting cap | Amber or opaque bottle with screw cap |
| Acceptable | Clean, dry plastic or glass container with tight-fitting cap | Glass or plastic bottle with tight-fitting cap |
| Undesirable | Unclean paper, cardboard, metal, or plastic (not formed) container with no provision for closure | Previously used liquid-containing cartons, plastic-lined paper bags, plastic bags |

Slide 5.21

This table covers packaging categories and materials for dispensing liquids (oral and topical preparations).

PACKAGING CATEGORIES FOR MEDICINE DISPENSING

Packaging Materials for Medicine Dispensing (continued)

| Category of Packaging | Package Characteristics | Examples |
|--------------------------------------|---|--|
| Liquids (otic and ophthalmic) | | |
| Desirable | Clean (preferably sterile), light-resistant glass or plastic container with a dropper incorporated into a tight-fitting cap or a top fitted with a dropper with a protective sleeve | Amber dropper bottle, opaque plastic dropper bottle |
| Acceptable | Clean, dry plastic or glass container with tight-fitting cap and a clean plastic/ glass dropper (separate) | Glass or plastic bottle with tight-fitting cap, glass or plastic dropper with protective container (cardboard, zipper-lock, plastic, or paper) |
| Undesirable | Anything other than above | Anything else |

Slide 5.22

This table covers packaging categories and materials for dispensing liquids (otic and ophthalmic preparations).

PACKAGING CATEGORIES FOR MEDICINE DISPENSING

5

Packaging Materials for Medicine Dispensing (continued)

| Category of Packaging | Package Characteristics | Examples |
|-----------------------|---|--|
| Creams/ ointments | | |
| Desirable | Clean glass or porcelain wide-mouth jar with tight-fitting lid or collapsible plastic or metal tube | Wide-mouth jar with tight-fitting lid, cream or ointment tube with cap |
| Acceptable | Clean glass or porcelain jar with lid | Glass or porcelain jar |
| Undesirable | Anything other than above | Anything else |

Source: Managing Access to Medicines and Health Technologies, 2012

Slide 5.23

This table covers packaging categories and materials for dispensing creams and ointments.

4. MAKE A FINAL CHECK

The final check should include:

- Reading and interpreting the prescription before looking at the dispensed medicines;
- Checking the appropriateness of doses prescribed and checking for drug interactions;
- Checking the identity of the medicine dispensed;
- Checking the labels; and
- Countersigning the prescription.

Slide 5.24

At this point, the dispensed preparation should be checked against the prescription and against the stock containers used. Although this step can be done as a self-check, it is valuable to have the final check done by another staff member. The final check should include:

- ✓ Reading and interpreting the prescription before looking at the dispensed medicines;
- ✓ Checking the appropriateness of doses prescribed and checking for drug interactions;
- ✓ Checking the identity of the medicine dispensed;
- ✓ Checking the labels; and
- ✓ Countersigning the prescription.

5. RECORD ACTION TAKEN

5

- When the prescription is retained, the dispenser should initial and annotate the prescription with strength and quantities dispensed and either file it or enter the details into a record book as soon as time is available.

Slide 5.25

The three different methods that can be used to keep a record of medicines dispensed are the following:

- When the prescription is retained, the dispenser should initial and annotate the prescription with strength and quantities dispensed and either file it or enter the details into a record book as soon as time is available.
- When the prescription is returned to the patient, details of the medicines dispensed must be entered into a record book before the items are issued to the patient. The date, the patient's name and age, the medicine name and strength, the amount issued, and the dispenser's name should be entered into the register.
- When dispensers use computers to record the dispensing details, the computer program should retain the information, which can then be recalled to generate summary reports.

5. RECORD ACTION TAKEN

- When the prescription is returned to the patient, details of the medicines dispensed must be entered into a record book before the items are issued to the patient. The date, the patient's name and age, the medicine name and strength, the amount issued, and the dispenser's name should be entered into the register.

Slide 5.26

5. RECORD ACTION TAKEN

5

- When dispensers use computers to record the dispensing details, the computer program should retain the information, which can then be recalled to generate summary reports.

Slide 5.27

6. ISSUE MEDICINE TO THE PATIENT OR THE PATIENT'S REPRESENTATIVE WITH CLEAR INSTRUCTIONS AND ADVICE

- Apart from information on the dose, frequency, length of treatment, and route of administration, priority should be given to providing information that will maximize the effect of the treatment.
- Advice should therefore concentrate on:
 - When to take the medicine
 - How to take the medicine
 - How to store the medicine

Slide 5.28

Apart from information on the dose, frequency, length of treatment, and route of administration, priority should be given to providing information that will maximize the effect of the treatment. Advice should therefore concentrate on:

- ✓ When to take the medicine (particularly in relation to food and other medicines);
- ✓ How to take the medicine (chewed, swallowed whole, taken with plenty of water, etc.); and
- ✓ How to store the medicine.

6. ISSUE MEDICINE TO THE PATIENT OR THE PATIENT'S REPRESENTATIVE WITH CLEAR INSTRUCTIONS AND ADVICE

5

- Warnings about possible side effects should be given cautiously.
- Every effort must be made to confirm that the patient understands the instructions and advice.
- Every patient must be treated with respect.

Slide 5.29

6. ISSUE MEDICINE TO THE PATIENT OR THE PATIENT'S REPRESENTATIVE WITH CLEAR INSTRUCTIONS AND ADVICE

Slide 5.29

Warnings about possible side effects should be given cautiously. Common but harmless side effects should be mentioned to prevent a frightened patient from stopping the treatment. More serious side effects should be mentioned only with the agreement of the prescriber, who needs to take those risks into account when prescribing the medicine.

Every effort must be made to confirm that the patient understands the instructions and advice. Whenever possible, the staff member dispensing the medications should have the recipient repeat back the instructions.

Every patient must be treated with respect. The need for confidentiality and privacy when explaining the use of some types of medicine must be recognized, and efforts should be made to structure medicine collection so that advice to patients can be as individualized as possible.

- The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem

Slide 5.30

WHO defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.”

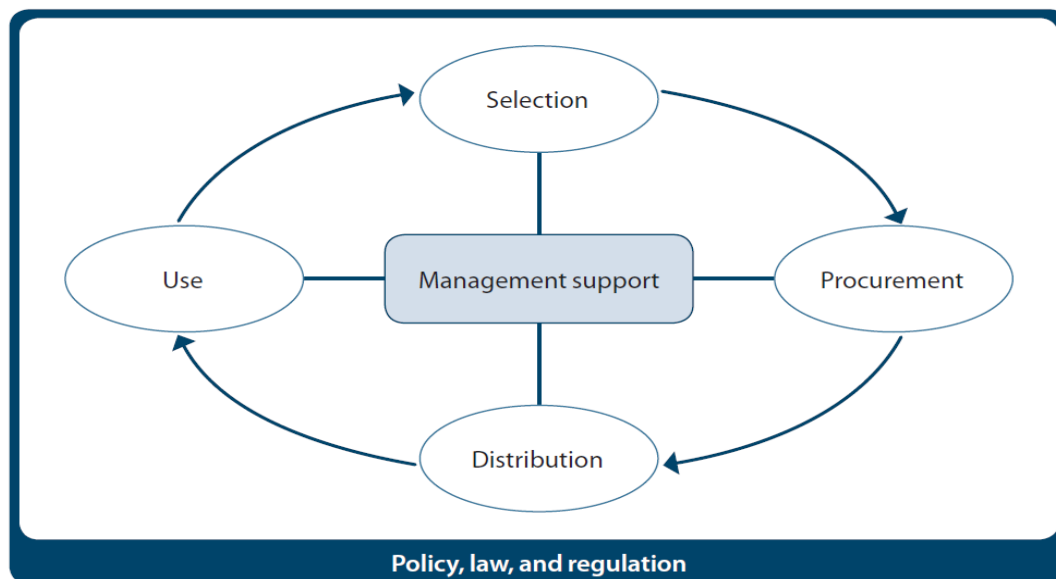


Fig. 5.1. Pharmacovigilance and Drug Management Framework

Source: Managing Access to Medicines and Health Technologies, 2012

Slide 5.31

Health professionals may still think of pharmacovigilance strictly in terms of identifying and reporting previously unknown and serious ADEs related to new products; however, pharmacovigilance activities are related to every sector of the drug management cycle. **Slide 5.31** shows the relationship between pharmacovigilance and drug management.

PHARMACOVIGILANCE ACTIVITY

5

| Pharmacovigilance Activity | Detection Within the Pharmaceutical Management Framework | Prevention |
|----------------------------|--|--|
| Product quality assurance | <ul style="list-style-type: none"> Most product quality issues are detected in the distribution portion of the pharmaceutical management cycle. Physician inspection is done at the time of receiving the product from the supplier and at other points of distribution to the patient. Complaints about efficacy occur during use. | <ul style="list-style-type: none"> Prequalify suppliers during procurement. Establish a pharmaceutical quality assurance program. Establish a policy and legal framework that addresses pharmaceutical quality. Enforce laws and regulations related to product quality. |

Use of Medicines

Slide 5.32

| Pharmacovigilance Activity | Detection Within the Pharmaceutical Management Framework | Prevention |
|----------------------------|---|--|
| ADR detection | <ul style="list-style-type: none"> Management support functions, such as surveillance and monitoring systems, during use are the primary methods for detecting ADRs. | <ul style="list-style-type: none"> Consider ADR information during the selection process to make formulary decisions and establish standard treatment guidelines. Report ADRs to the appropriate parties at the facility, national, and international levels. Train health professionals about ADRs. Communicate with patients about ADRs. |

Slide 5.33

| Pharmacovigilance Activity | Detection Within the Pharmaceutical Management Framework | Prevention |
|---|---|--|
| Medication error prevention and detection | <ul style="list-style-type: none"> Errors can be detected in all phases of the drug management cycle: ordering, storing, labelling, compounding, dispensing, transcribing, prescribing, administering, and monitoring. | <p>Prevention strategies should focus on all processes:</p> <ul style="list-style-type: none"> Promote a culture of safety through a nonpunitive environment for reporting events. Improve availability of drug information. Train and educate staff. Consider past and potential errors when selecting products or a formulary. Issue prescribing guidelines. Establish monitoring guidelines. Improve written and oral communication. Involve patient and family in care plan. |

Source: Managing Access to Medicines and Health Technologies, 2012

Slide 5.34

Areas:

- product quality
- adverse drug reactions
- medication errors

Slide 5.35

These are the three different areas of pharmacovigilance.

- Purpose of quality assurance in drug supply systems: to help ensure that each medicine reaching a patient is safe, effective, and of appropriate quality
- Ensured by the technical and managerial activities of the quality system

Slide 5.36

The quality of drug products is ensured by the technical and managerial activities of the quality system, which includes evaluating drug product documentation, performing or reviewing quality-control laboratory tests, and monitoring product performance.

- Selecting reliable suppliers
- Preparing contract terms
- Monitoring supplier performance
- Performing inspection procedures throughout the distribution network

Slide 5.37

Managerial activities include selecting reliable suppliers, preparing contract terms, monitoring supplier performance, and performing inspection procedures throughout the distribution network.

ADVERSE DRUG REACTION (ADR)

5

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

Slide 5.38

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.

Any reaction:

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

Slide 5.39

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.

- 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.

Slide 5.40

- The completed case report form is then sent to the regional or national ADR center or to the manufacturer of the product.

- The form contains the following:
 - Patient's particulars
 - Details of the ADR
 - Management of ADR
 - Reporter's particulars

Slide 5.42

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.

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)

***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

Can the adverse reaction be due to:

- Product quality defect ☐ No ☐ Yes, Specify, encircle: color change; caking; powdering; counterfeit; odor change; defective container; contaminants; separation of components; undissolved suspension/powder
- 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


Sequela/e: (any permanent complications or injuries as a result of the ADR) Re-challenge? ☐ Yes Result _____
☐ Yes (Please specify) _____ ☐ No ☐ Unknown ☐ No

***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 _____

FDA
 Food and Drug Administration
 PHILIPPINES

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

 National Center for Pharmacovigilance
 Food and Drug Administration

Slide 5.43

This slide shows an example of an ADR monitoring form.

ADVERSE DRUG ONLINE REPORTING SYSTEM (ADORS)

5

- Was developed by the Department of Health (DOH) to strengthen the reporting of ADR as required by the Pharmacovigilance Unit of FDA
- Allows online reporting of medical practitioners, hospitals or the public

Slide 5.44

The Department of Health has developed the Adverse Drug Online Reporting System (ADORS) to strengthen the reporting of ADR as required by the Pharmacovigilance Unit of the FDA. The system allows online reporting of medical practitioners, hospitals or the public.

ADVERSE DRUG ONLINE REPORTING SYSTEM (ADORS)

- Establishes a central database of ADR cases and promotes efficiency in data collection, processing, validation, analysis and dissemination of data
- Provides quality data and/or information that is accurate, reliable, timely and meaningful; and it is also a mechanism to inform the Pharmacovigilance Unit on suspected drug reactions and complications.

Slide 5.45

The system establishes a central database of ADR cases and promotes efficiency in data collection, processing, validation, analysis and dissemination of data. It provides quality data and/or information that is accurate, reliable, timely and meaningful. It is also a mechanism to inform the Pharmacovigilance Unit of the FDA on suspected drug reactions and complications

- Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer
- Caused by faulty systems, processes, and conditions that lead people to make mistakes

Slide 5.46

Slide 5.46

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) in the United States defines medication error as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer”. Errors can either be harmless or detrimental to the patient.

Medication errors are caused by faulty systems, processes, and conditions that lead people to make mistakes. For example, stocking wards in hospitals with certain concentrated solutions, even though they are toxic unless diluted, has resulted in deadly errors. Other problems can result from illegible handwriting, use of dangerous abbreviations (see **Participant’s Handbook**), overlooked interactions with other medicines, verbal miscommunications, and sound-alike or look-alike drugs (SALADs).

ADVERSE DRUG EVENT (ADE)

5

- Harmful response that is caused by a drug or the inappropriate use of a drug
- Preventable when they are the result of a medication error or nonpreventable, as would be the result of an unknown allergy

An ADR is always an ADE.

Slide 5.47

Adverse Drug Event (ADE) is a harmful response that is caused by a drug or the inappropriate use of a drug. While ADR is a harmful response that is caused by the use of drugs at normal doses. Therefore, an ADR is always an ADE, but an ADE might include the result of an overdose because of a dispensing error or some other error occurring during the medication-use process.

INCIDENCES OF ADEs

- Medication-usage patterns
- Self-medication
- Lack of regulatory control over the sale of medicines
- Irrational prescribing

Slide 5.48

Medication-usage patterns strongly influence the incidence of ADEs. In addition, self-medication, lack of regulatory control over the sale of medicines, and irrational prescribing all contribute to the incidence of ADEs.

After the ADR data have been collected, they should be analyzed to determine:

- Severity
- Probable causality
- Preventability

Slide 5.49

After the ADR data have been collected, they should be analyzed to determine severity, probable causality, and preventability. Specific algorithms and classification systems have been developed for these analyses.

NCCMERP Index for Categorizing Medication Errors

| Category | Description |
|----------|--|
| A | Circumstances or events that have the capacity to cause error |
| B | An error occurred but the error did not reach the patient |
| C | An error occurred that reached the patient but did not cause patient harm |
| D | An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient or required intervention to preclude them |
| E | An event occurred that may have contributed to or resulted in temporary harm to the patient and required intervention |
| F | An event occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization |
| G | An event occurred that may have contributed to or resulted in permanent patient harm |
| H | An event occurred that required intervention necessary to sustain life |
| I | An event occurred that may have contributed to or resulted in the patient's death |

Source: Managing Access to Medicines and Health Technologies, 2012

Slide 5.50

Severity (impact on the patient's health): **Slide 5.50** shows a classification for determining the severity of ADRs. It addresses both ADEs associated with medication error and those not associated with error, so it can be applied to all medication events.

Determining ADR Probability Using Indicators

| Probability Scale: Indicators | Yes | No | Don't know |
|--|-----|----|------------|
| 1. Are there previous conclusive reports on this ADR? | +1 | 0 | 0 |
| 2. Did the ADR appear after the suspected drug was administered? | +2 | -1 | 0 |
| 3. Did the ADR improve when the drug was discontinued or a specific antidote was administered? | +1 | 0 | 0 |
| 4. Did the ADR reappear when the drug was readministered? | +2 | -1 | 0 |
| 5. Could alternative causes (other than the drug) have caused the ADR on their own? | -1 | +2 | 0 |
| 6. Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? | +1 | 0 | 0 |
| 7. Was the ADR more severe when the dose was increased or less severe when the dose was decreased? | +1 | 0 | 0 |
| 8. Did the patient have a similar ADR to the same or similar drugs in any previous exposure? | +1 | 0 | 0 |
| 9. Did any objective evidence confirm the ADR? | +1 | 0 | 0 |
| Total score = _____ Possible = 0-4 Probable = 5-8 Definite = >9 | | | |

Source: Managing Access to Medicines and Health Technologies, 2012

Slide 5.51

Probable causality (likelihood that the medicine's use or lack of use contributed to the ADR): **Slide 5.51** illustrates how to calculate the Naranjo Probability Score, a common method for determining whether a particular medicine was actually related to the ADR.

PREVENTABILITY

Determining whether a Medication Error Occurred

- ☐ Was the drug involved appropriate for the patient's clinical condition? (NO=Preventable)
- ☐ Was the dose, route, or frequency of administration appropriate for the patient's age, weight, or disease state? (NO=Preventable)
- ☐ Was required therapeutic pharmaceutical monitoring or other necessary laboratory tests performed? (NO=Preventable)
- ☐ Was there a history of allergy or previous events to the drug? (YES=Preventable)
- ☐ Was an interaction (medicine-medicine; medicine-food; medicine-herbal) involved in the ADR? (YES=Preventable)
- ☐ Was a toxic serum drug concentration (or laboratory monitoring test) documented? (YES=Preventable)
- ☐ Was poor compliance involved in the ADR? (YES=Preventable)
- ☐ Was the error considered preventable because of deviations in procedures or standards of practice? (YES=Preventable)

Source: Managing Access to Medicines and Health Technologies, 2012

Slide 5.52

Preventability (Was an error associated with the event?): **Slide 5.52** is a checklist used to help determine if the ADE was caused by a medication prescribing error, and therefore, preventable.

REVIEW QUESTIONS

5

Write T if the statement is true and F if the statement is false.

1. Rational use of medicines includes rational prescribing, good dispensing procedures and patient adherence.
2. Bottles and plastics are recommended for repacking tablets and capsules.
3. Written information is provided to the patient to replace actual provision of information by the dispenser.

Slide 5.53

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

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

REVIEW QUESTIONS

4. Adverse drug events are not preventable when they are the result of a medication error.
5. The Pharmacovigilance Unit of the Food and Drug Administration is responsible for ADR monitoring and reporting.

Slide 5.54

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

4. False or F
5. True or T

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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

Slide 6.2

Present the learning objectives for the session.

SESSION OBJECTIVES

3. Identify criteria for accepting donations
4. Identify current weakness of the existing policy/ process in accepting donations at the hospital
5. Recommend improvements to the current system

Slide 6.3

Present the learning objectives for the session.

PROBLEMS WITH DONATIONS

6

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 6.4

Pharmaceutical Donations

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 and difficult to identify;
- Labelled with brand names or other language not readily understood;

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

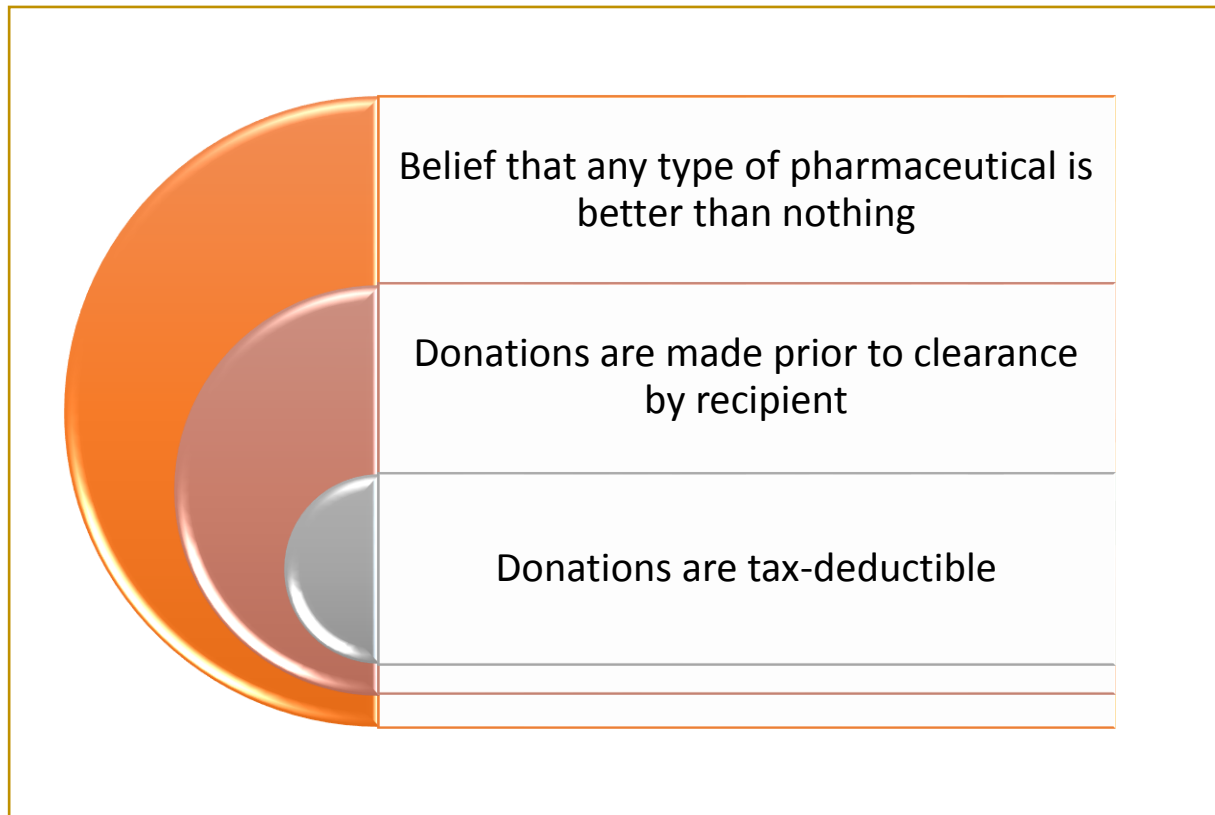
Donated in wrong quantities

Slide 6.5

- 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 that have been returned to the pharmacy or free samples given to health professionals) or they may be unwanted by the donor because they are close to expiration or the product is being discontinued (donating such products is also known as drug dumping). Donations may spoil or become damaged, which may be impossible to detect in the recipient country;
- 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.

CAUSES OF PROBLEMS

6



Slide 6.6

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; and
- 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.

IMPLICATIONS OF INAPPROPRIATE PHARMACEUTICAL DONATIONS



Slide 6.7

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.

THE PHILIPPINE EXPERIENCE

6



Slide 6.8

The same problems were experienced especially during the typhoon Yolanda.

Pharmaceutical Donations

NEED FOR GUIDELINES

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 country and by situation

Medicines are different from donated items

Slide 6.9

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 need to be destroyed in a particular way.

WHO CORE PRINCIPLES

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 6.10

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;
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 6.11

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

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 6.12

CRITERIA FOR ACCEPTING DONATIONS

6

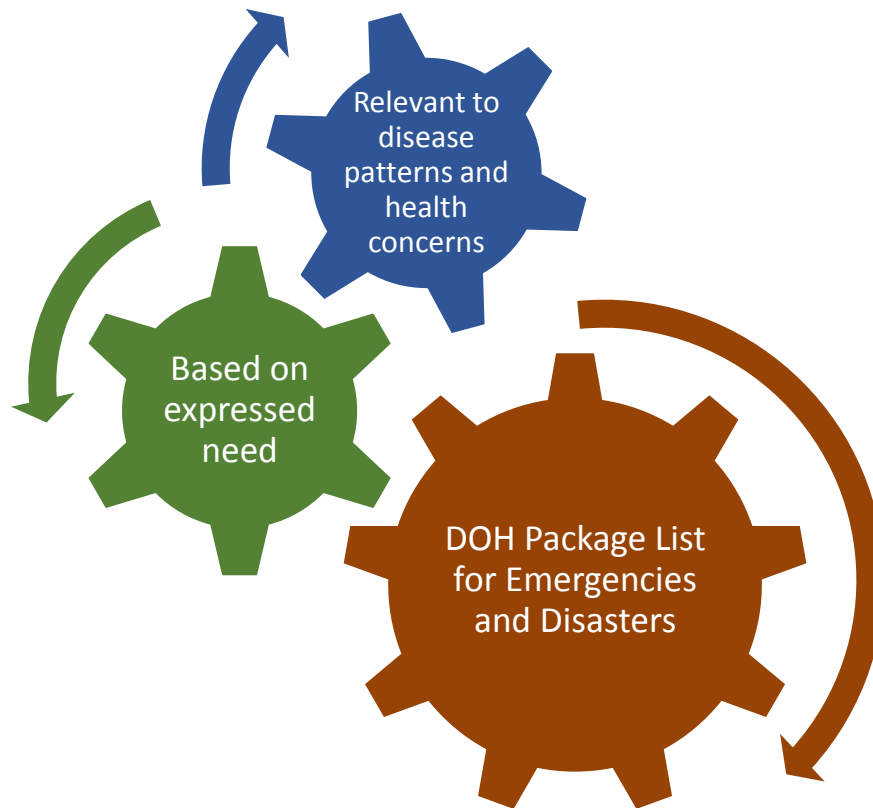
Weight per carton should not exceed 50 kg

Exclusive packaging with regard other supplies

Documentary proof of compliance to applicable quality standards

Documentary proof that items are obtained from reliable sources

Slide 6.13



Slide 6.14

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.

ACCEPTING DONATIONS IN THE HOSPITAL

6

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

Slide 6.15

The hospitals 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 the hospital. The absence of clear administrative procedures may result to problems discussed earlier. This indicates the great need for clear guidelines for pharmaceutical donations.

IMPORTANT ISSUES TO ADDRESS

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 6.16

IMPORTANT ISSUES TO ADDRESS

6

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 6.17

Slide 6.16-17

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?
- 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 hospitals create specific and clear guidelines regarding acceptance of donations taking into consideration the current policy of the DOH.

REVIEW QUESTIONS

6

For numbers 1 to 3, write T if the statement is true and F if the statement is false.

1. Medicine donation with short expiration dates may be accepted as long as it can be utilized prior to expiration.
2. Donations must be accepted only if there is an expressed need for the said medicine/ supply.
3. The hospitals may accept donations but are expected to follow the existing criteria set forth by the DOH.

Slide 6.18

Ask participants to answer review questions. Discuss answers.

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

REVIEW QUESTIONS

4. Write the letter of the best answer. It states that donations related to health and medicine fall under the jurisdiction of the DOH. Write the letter of the best answer.
 - a. AO 2007 – 0015
 - b. AO 2007 – 0016
 - c. AO 2007 – 0017
 - d. AO 2007 – 0018
5. Give 2 implications of inappropriate donations.

Slide 6.19

Ask participants to answer review questions. Discuss answers.

4. c
5. Logistical problems, environmental threat, expensive

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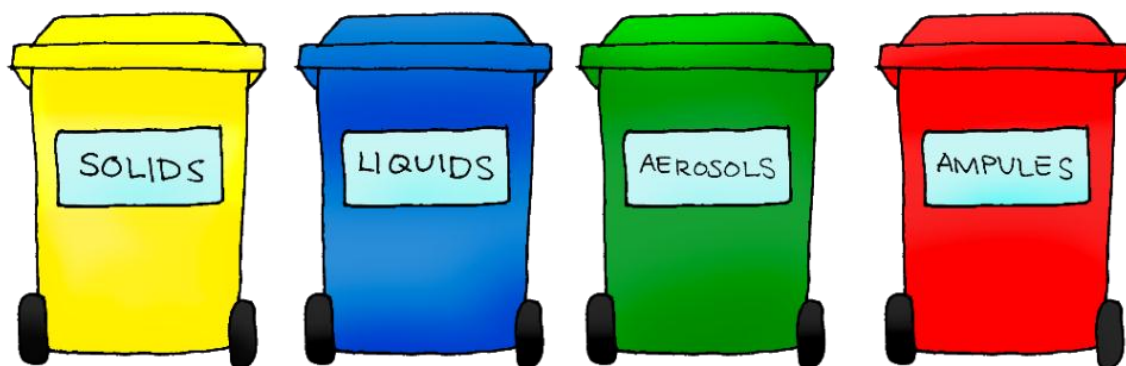
H

Disposal of Pharmaceuticals

Slide 7.1

Before the training, read the **WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals** and the **Safe Management of Wastes from Health-care Activities**. A photocopy of these 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 hospital 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

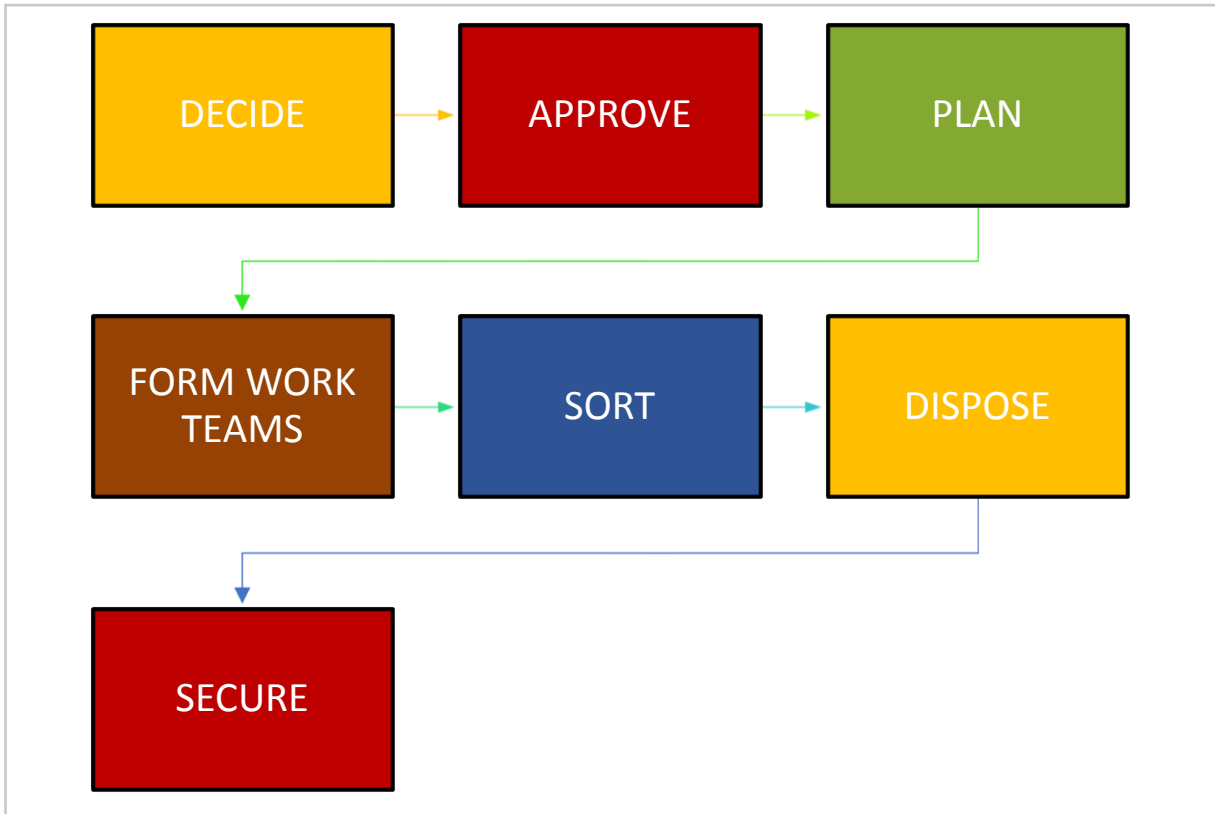
Diversion for resale of expired drugs to the general public

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; and
- 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

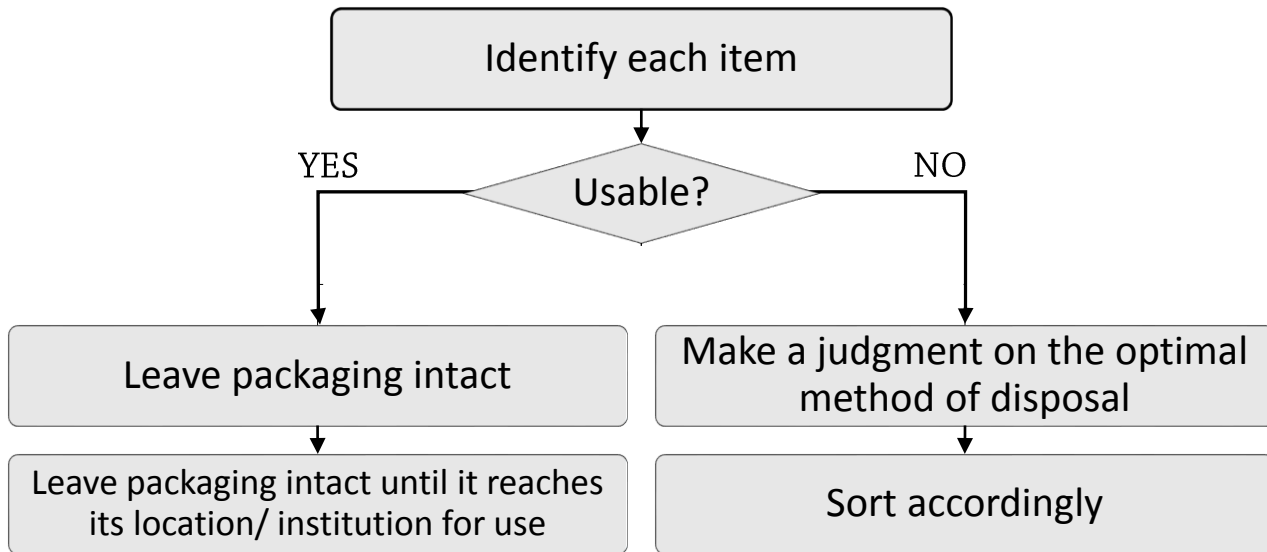


Slide 7.5

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

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
- 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.

- Pharmaceutical waste
 - Disposal of small quantities of drug waste
 - Disposal of large quantities of drug waste
- Cytotoxic waste

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.

DISPOSAL OF SMALL QUANTITIES OF DRUG WASTE

Landfill disposal

Encapsulation

Safe burial on
hospital premises

Discharge to a
sewer

Incineration

Slide 7.8

These are the disposal options for small quantities of drug waste.

DISPOSAL OF SMALL QUANTITIES OF DRUG WASTE

7

Landfill disposal

- Small quantities of drug waste produced on a daily basis may be landfilled provided that they are dispersed in large quantities of general waste.
- Cytotoxic and narcotic drugs should never be landfilled, even in small quantities.

Slide 7.9

Landfill disposal:

- Small quantities of drug waste produced on a daily basis may be landfilled provided that they are dispersed in large quantities of general waste.
- Cytotoxic and narcotic drugs should never be landfilled, even in small quantities.

DISPOSAL OF SMALL QUANTITIES OF DRUG WASTE

Encapsulation

- Small quantities of drug waste may be encapsulated, together with sharps if appropriate.

Slide 7.10

Encapsulation:

- Small quantities of drug waste may be encapsulated, together with sharps if appropriate.

DISPOSAL OF SMALL QUANTITIES OF DRUG WASTE

7

Safe burial on hospital premises

- Safe burial of small quantities of drug waste prevents scavenging and may be an appropriate disposal method for establishments applying minimal programs.

Slide 7.11

Safe burial on hospital premises:

- Safe burial of small quantities of drug waste prevents scavenging and may be an appropriate disposal method for establishments applying minimal programs.

DISPOSAL OF SMALL QUANTITIES OF DRUG WASTE

Discharge to a sewer

- Moderate quantities of relatively mild liquid or semi-liquid drugs may be diluted in a large flow of water and discharged into municipal sewers.
- It is not acceptable to discharge even small quantities of drug waste into slow-moving or stagnant water bodies.

Slide 7.12

Moderate quantities of relatively mild liquid or semi-liquid drugs, such as solutions containing vitamins, cough syrups, intravenous solutions, eye drops, etc. (but not antibiotics or cytotoxic drugs), may be diluted in a large flow of water and discharged into municipal sewers.

DISPOSAL OF SMALL QUANTITIES OF DRUG WASTE

7

Incineration

- Small quantities of drug waste may be incinerated together with infectious or general waste, provided that they do not form more than 1% of the total waste.

Slide 7.13

Small quantities of drug waste may be incinerated together with infectious or general waste, provided that they do not form more than 1% of the total waste in order to limit potentially toxic emissions to the air.

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 an acceptable method for disposing medicines in the Philippines.

DISPOSAL OF LARGE QUANTITIES OF DRUG WASTE

Incineration

Encapsulation

Slide 7.14

These are the disposal options for large quantities of drug waste.

DISPOSAL OF LARGE QUANTITIES OF DRUG WASTE

7

Incineration

- It is the best way to dispose of drug waste.
- The wastes should be mixed with their cardboard packaging, and possibly with other combustible material and infectious waste, to ensure optimal combustion conditions.

Slide 7.15

Cement kilns are also particularly suited to the treatment of drugs; in many countries, cement producers accept drug waste as an alternative fuel, thus reducing fuel costs. As a “rule of thumb”, however, it is suggested that no more than 5% of the fuel fed into the furnace at any time is pharmaceutical material.

Again, it should be noted that RA 8749 specifically bans the method of incineration for the disposal of waste, including medical and pharmaceutical wastes.

DISPOSAL OF LARGE QUANTITIES OF DRUG WASTE

Incineration

- Large amounts of drugs should be treated in incinerators designed for industrial waste (including rotary kilns), which can operate at high temperatures ($>1200^{\circ}\text{C}$).

Slide 7.16

Incineration:

- Large amounts of drugs should be treated in incinerators designed for industrial waste (including rotary kilns), which can operate at high temperatures ($>1200^{\circ}\text{C}$).

DISPOSAL OF LARGE QUANTITIES OF DRUG WASTE

7

Encapsulation

- Solid, liquid, and semi-liquid waste can be encapsulated in metal drums.

Slide 7.17

Encapsulation:

- Solid, liquid, and semi-liquid waste can be encapsulated in metal drums.

SPECIAL CASES

- Intravenous fluids can be disposed of to a landfill or discharged into a sewer
- Glass ampoules should be crushed on a hard, impermeable surface. The glass should then be swept up, collected, and disposed of with sharps.

Slide 7.18

Intravenous fluids (salts, amino acids, lipids, glucose, etc.) which are relatively harmless, can be disposed of to a landfill or discharged into a sewer.

Ampoules should be crushed on a hard, impermeable surface; workers should wear protective clothing, eye protection, gloves, etc. The glass should then be swept up, collected, and disposed of with sharps. Ampoules should not be incinerated as they may explode, damaging the incinerator or injuring workers.

Return to original
supplier

Incineration at high
temperatures

Chemical degradation

Slide 7.19

These are the disposal options for cytotoxic waste.

CYTOTOXIC WASTE

Return to
original supplier

- Safely packaged but outdated drugs and drugs that are no longer needed should be returned to the supplier.
- This is currently the preferred option for countries that lack the facilities for incineration.
- Cross-frontier transfer of pharmaceutical waste

Slide 7.20

Drugs that have been unpacked should be repackaged in a manner as similar as possible to the original packaging and marked “outdated” or “not for use”.

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.

Incineration at high temperatures

- Full destruction of all cytotoxic substances may require temperatures up to 1200°C.
- Modern double-chamber pyrolytic incinerators are suitable, provided that a temperature of 1200°C with a minimum gas residence time of 5 seconds can be achieved in the second chamber.

Slide 7.21

While incineration is considered internationally as a good way of disposing cytotoxic wastes, RA 8749 prohibits this disposal method in the Philippines.

CYTOTOXIC WASTE

Incineration at
high
temperatures

- Incineration is also possible in rotary kilns designed for thermal decomposition of chemical wastes, in foundries, or in cement kilns, which usually have furnaces operating well in excess of 850°C.

Slide 7.22

Incineration at high temperatures:

- Incineration is also possible in rotary kilns designed for thermal decomposition or chemical wastes, in foundries, or in cement kilns, which usually have furnaces operating well in excess of 850°C.

Chemical degradation

- Chemical degradation methods can be used not only for drug residues but also for cleaning of contaminated urinals, spillages, and protective clothing.

Slide 7.23

Chemical degradation methods, which convert cytotoxic compounds into non-toxic/non-genotoxic compounds, can be used not only for drug residues but also for cleaning of contaminated urinals, spillages, and protective clothing.

SUMMARY OF DISPOSAL METHODS

| Technology or Method | Pharmaceutical Waste | Cytotoxic Waste |
|----------------------------------|----------------------------------|----------------------------------|
| Rotary kiln | Yes | Yes |
| Pyrolytic incinerator | Small quantities | No |
| Encapsulation | Yes | Small quantities |
| Safe burial on hospital premises | Small quantities | No |
| Sanitary landfill | Small quantities | No |
| Discharge to sewer | Small quantities | No |
| Inertization | Yes | Yes |
| Other methods | Return expired drugs to supplier | Return expired drugs to supplier |

Source: Safe Management of Wastes from Health-care Activities, 1999

Slide 7.24

This table summarizes the disposal methods.

REVIEW QUESTIONS

7

Write T if the statement is true and F if the statement is false.

1. Improper disposal of expired pharmaceuticals may pose a threat to public health of 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 7.25

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

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

REVIEW QUESTIONS

4. Cytotoxic and narcotic drugs should never be landfilled, even in small quantities.
5. Chemical degradation methods convert cytotoxic compounds into less toxic compounds.

Slide 7.26

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

4. True or T
5. False or F

REFERENCES

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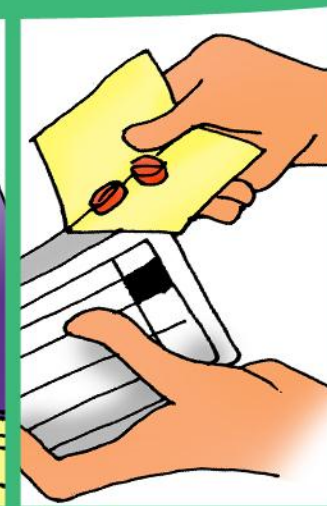
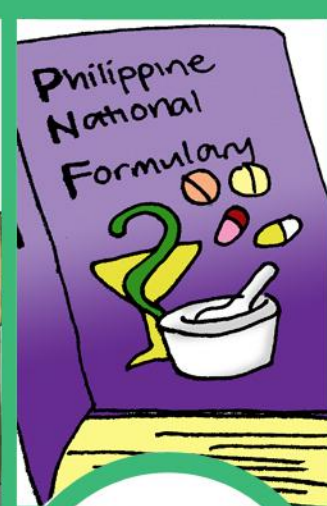
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Training Manual on Pharmaceutical Supply Chain Management

TRAINER'S MANUAL
for Government Hospitals



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Training Manual on Pharmaceutical Supply Chain Management

TRAINER'S MANUAL
for Government Hospitals



This “Training Manual on Pharmaceutical Supply Chain Management for Government Hospitals” 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 |