

Drug management cycle

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Objectives

- ▶ At the end of the session you will be able to
- ▶ List DSM cycles
- ▶ Define selection
- ▶ List purpose of selection
- ▶ Know selection process

Why Do We Manage Drugs?

- Drugs Save Lives and Improve Health
- Drugs promote trust and participation in the health services
- Drugs are costly
- Drugs are different from other consumer products
- Substantive improvements in the supply and use of drugs are possible; like:
 - Savings in drug costs (Competitive procurement)
 - Improved drug availability (better quantification)
 - More reliable delivery (redesigning of distribution systems)

Importance of managing drugs

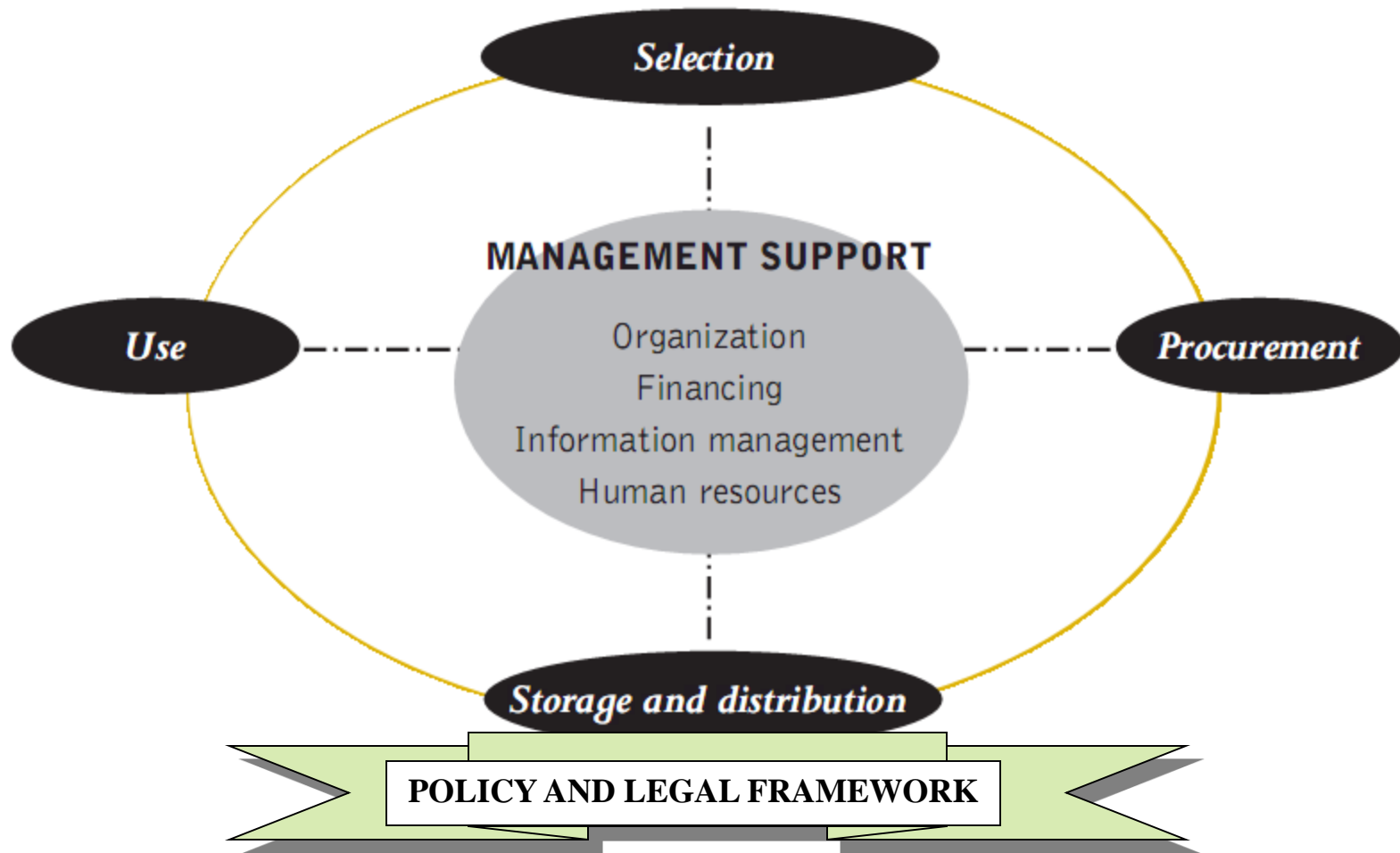
- All of the above reasons contribute to
 - Appropriate financial expenditure
 - Avoid wastage
 - Increase access and
 - Ensure proper use of drugs

- Most leading causes of death and disability in developing countries can be prevented, treated, or at least alleviated with cost effective essential drugs/medicines.
- But hundreds of millions of people do not have regular access to essential drugs
- Many of those who do have access are given wrong treatment, receive too little medicine for their illness or do not use drugs correctly
- Drug Supply Management(DSM) helps to ensure that high quality drugs are available, affordable, and used rationally.

Introduction...

- ▶ DSM is the management of drugs, medical supplies, equipment's and reagents to be used rationally.
- ▶ Four basic functions of drug management cycles:
 - Selection,
 - Quantification and procurement,
 - Distribution and
 - Use.

Components of Drug Supply Management



Drug selection

- ***Drug selection***: is a process of deciding the type of needed drug products for the prevalent diseases
- Drug selection involves
 - Reviewing the prevalent health problems
 - Identifying treatments of choice
 - Choosing individual drugs and dosages forms and
 - Deciding which drugs will be available at each level of health care

Drug selection...

Rationale:

- Determine the type of drug products relevant for the prevalent diseases
- Leads to
 - Better supply
 - More rational use and
 - Lower costs

Why do we need to select drugs?

- About 70% of the pharmaceuticals on the world market are duplicative or non essential
- Some drugs show high toxicity relative to their therapeutic benefit
- Some drugs are newly released with insufficient information on the efficacy or toxicity
- Many new products for therapeutic indications are not relevant to the basic needs of the population, which are more expensive than existing drugs

Why do we need to select...

- With so many drugs available, it is ***impossible for Prescribers to up to date and to compare alternatives***
- Variety of available products may also contribute to ***inconsistent prescribing*** within the same health care system or health facility
- ***Funds are limited***: essential drugs are usually available from multiple suppliers - making possible the *negotiation of favorable prices*
- ***Purchasing power is significantly lessened*** by the large number of duplicate and non essential drug products.

Criteria for drug selection

- Relevance to the pattern of prevalent diseases
- Treatment facilities
- Training and experience of available personnel
- Financial resource
- Genetic, demographic and environmental factors
- Drug products with adequate scientific data on efficacy, safety, quality, bioavailability and stability be selected
- Possibilities of easy and prompt procurement, local manufacture
- Drug products with widest possible coverage for the prevailing health problems (broad spectrum)

Criteria for drug selection...

- Physical facilities for proper distribution and storage could be assured
- Drug products with affordable cost by considering total cost of treatment not only the unit cost of drug(s)
- Single ingredient drug products
 - Combination drug products (fixed ratio) are acceptable, If
 - Better therapeutic effect and safety
 - The cost of the combination product is less than the sum of individual products
 - Better patient compliance

Criteria for drug selection...

- When two or more drugs seem similar in the above respect, select
 - The most thoroughly investigated drug
 - Drug(s) which offers better patient compliance
 - Drug product(s) which is locally available
 - Relatively safe, effective, quality, low price and available

Basic steps in drug selection

A. Establish Drug Selection Committee

- Also called Drug and Therapeutic Committee (DTC)
- Composed of prescriber, pharmacy personnel and other concerned health personnel
- Determine the prevalent health problems and patient characteristics:
 - *Morbidity Registration Book or*
 - *Patient Prescription Registration Book*

Basic steps in drug selection...

B. Decide which health problems may be treated at the level of drug selection

- Determine the level of health care unit by determining the
 - Level of training of prescriber
 - Level of training of dispenser, etc. and
 - Available diagnostic facilities

C. Choose the drugs to be used for the health problems (1st , 2nd or 3rd choices)

Basic steps in drug selection...

D. Structure the list of drug products: it could be

- Pharmaco-therapeutically and /or alphabetically; e.g. the National list of drugs
- By level of health care; e.g. the list of Essential drugs for Ethiopia.
- By level of importance (VEN system):
- All the drugs included in the list may not be equally important
 - They should be categorized by level of importance into three categories

Basic steps in drug selection...

I. (V) Vital

- Drugs which are potentially life saving (very essential)
e.g. Antimalarials, ORS, Vaccines, etc.

II. (E) Essential

- Drugs which are effective against less life threatening, but significant health problems; e.g. Antibiotics

III. (N) Normal usage or Less-essential

- Drugs used for minor or self limiting health problems or
- Drugs which have a high cost for small extra effectiveness; e.g. Cough Syrups, Antacid tablet or Suspension.

Basic steps in drug selection...

- E. Introducing the list of drugs to health professionals of institution and other concerned bodies

- F. Updating the list of drugs

Advantages of drug selection

- **Supply**
 - Easier to procure, store and distribution
 - Lower stocks
 - Better quality assurance
 - Easier dispensing

Advantages of drug selection...

- **Prescribing**
 - Training more focused and therefore easier
 - More experience with fewer drugs
 - No irrational treatment alternative available
 - Focused drug information
 - Better recognition of adverse drug reactions

Advantages of drug selection...

- **Cost**
 - Lower prices, more competition.
- **Patient use**
 - Focused education efforts
 - Reduced confusion and increased adherence to treatments
 - Improved drug availability
 - Cost effective treatments are provided.

Treatment Guidelines and Formularies

- Essential drugs lists, formularies, and treatment guidelines are interdependent
- Developed based on
 - Needs of the patients and
 - Job descriptions of health workers
- The supply of drugs (based on the national list of essential drugs) be consistent with the treatment guidelines in public sector facilities and training institutions

Standard Treatment Guidelines

- STG is disease oriented
- Reflects a consensus on the treatment of first choice for a range of medical conditions, together with basic information needed by the prescriber
- Include any appropriate non-drug treatments
- Exist in different levels of health care
- Promote the rational use of drugs
- STG benefits health officials, supply management staff, health care providers, and patients

STG...

- **Information in treatment guidelines:**
 - Diagnostic criteria
 - Treatment of first choice
 - Cost of treatment
 - Important contraindications, side effects, warnings, and precautions
 - Referral criteria

Potential benefits of STG

- **For health officials**
 - Identification of cost effective treatments for common health problems
 - Basis to assess and compare quality of care

Potential benefits of STG...

- **For supply management staff**
 - Identification of which drugs should be available for the most commonly treated problems
 - Facilitation of prepackaging of course of therapy quantities of commonly prescribed items
 - Drug demand more predictable, so forecasting more reliable

Potential benefits of STG...

- **For health care providers**
 - Expert consensus on most effective, economical treatment for a specific setting
 - Opportunity for providers to concentrate on correct diagnosis
 - Quality of care standard
 - Basis for monitoring and evaluation

Potential benefits of STG...

- **For patients**
 - Encouragement of adherence to treatment through consistency among prescribers
 - Most cost effective treatments are provided
 - Improvement in availability of drugs
 - Better treatment

Formulary

Formulary manual

- A drug oriented manual
- Contains summary of drug information on a selected number of drugs, combined with practical prescribing and dispensing information
- It includes
 - Generic name of the drug
 - Indications for use
 - Dosage schedules
 - Contraindications
 - Side effects and
 - Other important information that should be given to the patient;
- **Used as source of drug information**

Formulary ...

Formulary list:

- A list of drug products approved for use in a specific health care setting
- It may be a national formulary list or a hospital list
- In developing countries it is synonymous with essential drugs list
- **Used as a selection tool**

Formulary...

Formulary system:

- Encompass the whole system for developing, updating and promoting the formulary list.
- A fully developed formulary system usually includes, in addition to the formulary manual and formulary list
 - Regular newsletters or bulletins,
 - Guidelines for the use of non-formulary drugs and
 - Methods for evaluating the need for changes in the formulary list or manual
- **Used for drug management process**

Economic evaluation in formulary decisions

Economic evaluation

- A set of analytical tools that can help identify which of several alternatives offers the greatest benefit compared with its cost
- Pharmacoeconomic analysis can help to address questions
 - What drugs should be included on the formulary?
 - What are the patient outcomes of various treatment modalities?
 - How to compare two options for providing pharmacy services?

Steps for conducting a cost effectiveness evaluation

Step one:

- Define the objective, for example, in terms of program out put:
 - Which drug regimen should be the therapy of choice for the treatment of disease X?
 - What is the best approach to transport essential drugs to health facilities?

Steps for conducting a cost effectiveness...

Step two:

- Enumerate the different ways to achieve the objective, e.g.
- Short course chemotherapy with more expensive drugs (option 1), **versus**
 - Traditional long course chemotherapy with cheaper drugs (option 2);
- Purchase of program vehicles for delivery of drugs to health facilities (option 1), **versus**
 - A contract with a private transport firm for delivery of drugs (option 2)

Steps for conducting a cost effectiveness...

Step three:

- Identify and measure the ***cost of each option***:
- All the inputs required for each option should be identified and the costs be determined.

Step four:

- Identify and measure ***benefits of each option***:
- Benefits could be measured in quality adjusted life year (QALY, which is measure of health out come).

Steps for conducting a cost effectiveness...

Step five:

- Calculate and interpret the cost effectiveness of each option:
- The total cost of treatment must be considered

Step six:

- Perform sensitivity analysis on the conclusions:
- It measures how different assumptions made in the courser of estimating costs and outputs affect the conclusions.

Essential Medical Supplies and Equipment

- Selection and management of medical supplies and equipment are similar to drugs
- Essential in providing effective and efficient medical services
- They consume up to 40% of the amount spent on drugs
- Three main issues associated with supplies and equipment are lack of:
 - Policies
 - Standardization and
 - Quality assurance

Criteria for selection

- Local possibilities for servicing and spare parts
- Local availability of essential supplies such as chemicals and filters
- Local possibilities for training staff in its use and maintenance
- Defining the minimum specifications before procuring
- These specifications are needed for the procurement department for claims in case of faulty products

Monitoring and evaluation of drug selection

- Drug selection should be monitored and evaluated against its objectives using indicators

Sample indicators:

- Availability of drugs which are not relevant
- Availability of drugs above the level of a given health institution
- Unavailability of relevant drug(s)

Advantages of an Essential Drugs List

- The advantages of adopting an Essential Medicines List are mainly **four-fold**.
- The advantages are:
 - 👉 medical,
 - 👉 social,
 - 👉 economic and
 - 👉 administrative

Use of INN (Generic name)

- Each drug on the market has three different names:
 - i. Chemical name
 - ii. INN (generic name) name
 - iii. Brand/trade names.

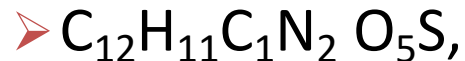
i. CHEMICAL NAME

Example:

$C_{12}H_{11}C_1N_2 O_5S$ (frusemide)

- Its chemical name(IUPAC names), 4-chloro-N-furfuryl-S-sulphamoylanthranilic acid,
 - however these are less suited to common usage, being typically very long and unwieldy.
- Its INN is furosemide,
- A brand (or proprietary trade) name is Lasix.

ii. INN (generic name) name



- 4-chloro-N-furfuryl-S-sulphamoylanthranilic acid,
- Its INN is furosemide,
- An International Nonproprietary Name (INN) is the official nonproprietary or generic name given to a pharmaceutical substance, as designated by the World Health Organization.
- The generic name is the drug's official name, regardless of who manufactures or markets it.

INN (generic name) name.....

- INNs facilitate communication by providing a standard name for each substance.
 - INN are assigned through WHO following a well-established procedure.
 - A generic drug can enter the market when the patents on the brand name drug (or other marketing exclusivities) have expired or been waived.
- ☞ It will ensure clarity by giving information about the class of drug and thus avoid confusion arising out of many dissimilar brand names of one drug.
- ☞ Quality drugs are cheaper when purchased under their generic names rather than their brand names.

INN (generic name) name.....

- ☞ Use of generic names is a valuable aid to memory as it is easier to remember only selected names than of numerous brand names.
- ☞ Use of generic names will make the selection of essential drugs and formulations for a national formulary easier.
- ☞ Use of generic names will curtail the heavy promotion of brands and their high cost.
- ☞ Use of generic names demystifies medicine for consumers and health personnel.

Generic Competition

- **helps keep drug costs down**
- **encourages research**
- **helps keep insurance premiums down**
- **saves consumers \$8 to \$10 billion yearly(USA)**

Myths about Generic Drugs

There are many misconceptions or myths about generic drugs

Compared to brand drugs:

- **Generics...are not as safe**
- **Generics...are not as potent**
- **Generics...take longer to act in the body**
- **Generics...are made in sub-standard facilities**

Myths and Facts.....

MYTH 1: Generics are not as safe as brand-name drugs.

FACT: Generics use the same ingredients, and

- work the same in the body have the same risk-benefit

MYTH 2: Generics are not as potent as brand-name drugs.

FACT 2: Generic drugs have the same quality, strength, purity and stability.

Myths and Facts.....

MYTH 3: Generics take longer to act in the body.

FACT 3: The generic drug delivers the same amount of active ingredient in the same time as the original drug.

MYTH 4: Brand-name drugs are made in modern manufacturing facilities, and generics are often made in sub-standard facilities.

FACT 4: Sub-standard facilities are not permitted by the FDA.

iii. Brand Name

- A proprietary/commercial/trade/brand/product name is chosen by the manufacturer to facilitate recognition of the product with a particular firm for marketing purposes.
- The plethora of named proprietary preparations containing a given substance can lead to confusion about the identity of the active ingredient.
- Use of brand name is an important issue for the profit-oriented drug companies.

Brand Name.....

- For most common drugs there are several branded products that all contain **the same active ingredient** and therefore **share the same generic name**.

➤ The same with different names

☞ Metronidazole(generic),

☞ Amivan, Flagyl, Aristogyl (brand names).....

Brand Name.....

Brand-name drug

- supplied by one drug company, the pharmaceutical manufacturer
- sold under drug company's trademarked name
- a pioneer drug/an innovator drug/the referenced drug/reference-listed drug

Generic drug

- may be supplied by more than one company
- most often sold under by the chemical name of the active ingredient(s) name(s)

Opponents and proponents

- **Opponents** argue that the quality of generic drugs is inferior to that of brand-named products.
- **Proponents** of generic drug purchasing and prescribing point out that:
 - Generic names are **more informative** than brand names and facilitate purchasing of products from multiple suppliers.

Brand Name.....

- Generic drug products are often cheaper than products sold by brand name.
- Generic prescribing facilitates product substitution and avoid confusion on health professionals.
- Generic products are **equivalent** to brand products in **quality, safety and efficacy**.

FDA Requirements for Brand-Name and Generic Drugs(i.e USA)

	Brand Name Drug	Generic Drug
For reformulations of a brand-name drug or generic versions of a drug, FDA reviews data showing the drug is bioequivalent to the one used in the original safety and efficacy testing.	✓	✓
FDA evaluates the manufacturer's adherence to good manufacturing practices before the drug is marketed.	✓	✓
FDA reviews the active and inactive ingredients used in the formulation before the drug is marketed.	✓	✓
FDA reviews the actual drug product.	✓	✓
FDA reviews the drug's labeling.	✓	✓
Manufacturer must seek FDA approval before making major manufacturing changes or reformulating the drug.	✓	✓
Manufacturer must report adverse reactions and serious adverse health effects to the FDA.	✓	✓
FDA periodically inspects manufacturing plants.	✓	✓
FDA monitors drug quality after approval.	✓	✓

THANK YOU!