Session 4:
The Drug Management Cycle: Selection

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Unit Objectives

1. Be able to apply evidence-based criteria for pharmaceutical product selection

2. Describe approaches to developing Essential Medicines Lists, Formularies, and Standard Treatment Guidelines

3. Recognize the challenges in implementing treatment guidelines and formulary systems and ways to overcome them
Session Outline

1. Introduction (case)
2. Key Definitions
3. Approaches to Implementation
4. Implementation Issues
5. Summary of Session
Why Be Selective With Drugs?

• Drugs represent a large part of the public health budget
• Funds are limited
• Large numbers of drugs are available
• Impossible to keep up-to-date with all the drugs on the market
Reasons to Support Rational Selection

- Promotes improved drug availability
- Regular drug supply can improve health outcomes
- Prescribers can become familiar with a smaller number of drugs
- Improved drug therapy can lower health care costs
- Procurement, storage, and distribution are simplified
- Buying larger quantities of fewer drugs can lower procurement costs
- Facilitates drug information and education efforts
Selection Options

- Formulary list = Essential medicines list
- Formulary manual
- Formulary system
Definition of Essential Medicines

• Are those that satisfy the priority health care needs of the population

• Are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness

• Are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information and at a cost that individuals and the community can afford
Definition of a Medicines Formulary

• **Formulary List** – Medicines approved for use in the health care system by authorized prescribers

• **Formulary Manual** – The document that describes medicines that are available for use in the hospital and clinics (provides information and indications, dosage, length of treatment, interactions, contraindications, etc.)

Standard Treatment Guideline

• A systematically developed statement designed to assist practitioners and patients in making decisions about appropriate treatment for specific clinical circumstances

The Essential Medicines Target

All medicines worldwide

Registered medicines

National EML

Different levels of use of the EML

Supplementary specialist medicines

CHW/Dispensary

Health center

Hospital

Referral hospital

Private sector

Source: MSH: Management Sciences for Health. Used with permission.
There are 156 countries with an official selective list for training, supply, reimbursement, or related health objectives. Some countries have selective state/provincial lists instead of or in addition to national lists.
Approaches to Implementation

• Build list based on most common health problems
• Start with existing list of drugs
• Tips:
  selection by committee
  coordinate selection and procurement activities
List of common diseases and complaints

Treatment choice

Standard treatment guidelines

Training and supervision

Essential medicines formulary

Essential medicines list

Financing and supply of drugs

Prevention and care

Source: MSH: Management Sciences for Health. Used with permission.
Drug Selection Criteria

- *Need* based on prevalent disease patterns
- *Personnel* capable of using the drugs
- *Financial resources* available
- *Safety and efficacy* demonstrated and documented
- *Quality*, bioavailability, and stability
Drug Selection Criteria, cont.

- *Therapeutic equivalence* of drugs based on efficacy, safety, quality, price, and availability
- *Total cost of treatment*, not only the unit cost of the drug
- *Proven advantage of combination products* over single compounds being used separately
Use of International Nonproprietary (Generic) Names

• Advantages of generic products:
  – names are more informative
  – often less expensive
  – generic prescribing facilitates substitution

• Arguments against generic products:
  – inferior and have bioequivalence problems
  – names are hard to remember
Therapeutic Classification Schemes

- Provide a framework for drafting list
- The formulary manual is organized according to the scheme chosen
- It is reasonable to use or adapt an existing scheme
Use of Information

• Sources of current information are often limited
• Some references commonly used by formulary committees include:

  *Martindale: The Extra Pharmacopoeia*

  *The AMA Drug Evaluations Annual*

  *The British National Formulary*

  *Medical Letter on Drugs and Therapeutics*
Role of Drug and Therapeutics Committees

- Develop or adapt STGs
- Assess adherence to STGs
- Develop and implement appropriate strategies to ensure adherence
Number of Medicines on National Essential Medicines Lists

Source: MSH: Management Sciences for Health. Used with permission.
Availability of EMLs in Health Facilities

Source: MSH: Management Sciences for Health. Used with permission.
Percentage of Medicines Prescribed from EML, by Sector

Source: MSH: Management Sciences for Health. Used with permission.
Percentage of Prescribed Medicines That Were Actually Dispensed

Source: MSH: Management Sciences for Health. Used with permission.
Average Cost of Medicines Prescribed as a Percentage of Cost if IMCI Treatment Guidelines Were Followed

Source: MSH: Management Sciences for Health. Used with permission.
Examples of Standard Treatment Guidelines
HIV/AIDS-Related Pharmaceuticals

- Antiretrovirals (ARVs):
  - Postexposure prophylaxis
  - Prevention of mother-to-child transmission
  - Clinical AIDS
- Anti-infectives (antibacterials, antifungals, and antivirals) for prevention and treatment of opportunistic infections
- Treatment of sexually transmitted infections (STIs)
- Tuberculosis treatment
- Analgesics and palliative care pharmaceuticals
- Anticancer pharmaceuticals
- Pharmaceuticals for noninfectious and other complications:
  - Cardiac
  - Renal
  - Hepatic
  - Neuropathic
  - Dermatologic
  - Hematologic
  - Pulmonary
  - Gastrointestinal/diarrhea
  - Oral and esophageal
  - Psychiatric
Adult ART Regimens Included in STGs

Source: MSH: Management Sciences for Health. Used with permission.
Changes in No. of Adult ART Regimen in STGs

Source: MSH: Management Sciences for Health. Used with permission.
Country Consistency with WHO 2003 Recommendations for Adult ART Guidelines

Source: MSH: Management Sciences for Health. Used with permission.
ART Guidelines Available – Rwanda and Namibia

Source: MSH: Management Sciences for Health. Used with permission.
ART Guidelines in Health Facilities - Rwanda

Source: MSH: Management Sciences for Health. Used with permission.
Complexities in Establishing and Implementing STGs for HIV/AIDS (1)

- Multiple single agents and fixed-dose combinations
- Multiple regimens approved
- Differing laboratory monitoring capacities
- Differing and often weak pharmaceutical management capacities
- Different recommendations for special groups (e.g. pregnant women, children)
- Rapid change in recommendations due to treatment failure, drug resistance patterns, and/or new treatments becoming available
- Cost and logistics involved in changing from one regimen to another
- Need to mobilize both public and private sectors
- Non-pharmaceutical management and counseling issues
Why Are EMLs and STGs Not Followed?

- Do not reach the right people
- Pharmaceutical products available in facilities not on EML or STGs
- Lack of appropriate training in the use of STGs
- Lack of transparency during development process, which leads to the lack of credibility and acceptance
- Lack of involvement from respected members of the professional community
- Not based on adequate evidence
- Not current
- Not realistic – finances not available to purchase
Avoiding Failure

• Involve a wide group of experts
• Have a purpose and goals
• Gain official status
• Be open
• Have mechanisms for additions, revisions, and use of non-formulary drugs
• Obtain the support of professional organizations
• Use medical and pharmacy schools
• Have a launching campaign
Implementing STGs

• Disseminate printed reference materials
  – STGs manual, posters, training materials

• Official launch—Ministry of Health officials and opinion leaders

• Initial training
  – Vital to implementing STGs
  – Prior to actual start date

• Reinforcement training

• Monitoring adherence to STGs

• Supervision
Summary

• Essential medicines lists, formularies and standard treatment guidelines can have considerable impact if developed and used properly

• STGs can also be an expensive waste of effort

• With STGs, the processes of production and use are as important as the product