Objectives of the Presentation

• Discuss some key issues associated with the use of medicines
• Highlight the concept of essential medicines (EMs)
• Describe World Health Organization’s work on EMs
• Familiarize with the latest WHO Model list of EMs
• Discuss application of EM concept at country level
• Brainstorm the Do’s and Don’ts in developing and implementing EM lists
• List selected indicators relating to EMs
• Review and discuss the “Delhi program on rational use of drugs” as a case study
Issues and Complexities with the Use of Medicines (1)

- Numerous medicinal products are available in the world
- Several therapeutic groups and medicines are available to treat many diseases
- Both new medicinal products and new information about existing drugs are emerging
Issues and Complexities with the Use of Medicines (2)

• Developing countries spend up to 40% of their health care budgets on medicines

• An estimated 70% of medicines are considered duplicative or non-essential

• Lack of access to medicines is a major and chronic issue in resource-constrained settings

• Lack of availability of medicines erodes public confidence in the public health care system

• In low- and middle-income countries, most people pay for medicines out-of-pocket

Issues and Complexities with the Use of Medicines (3)

Globally, more than 50% of medicines are prescribed, dispensed, or sold inappropriately*

Consequences of irrational medicine use:

- Increased morbidity
- Increased mortality
- Increased adverse drug events
- Increased drug resistance
- Increased cost and wasted resources
- Financial hardships

Essential Medicines Concept

• Careful selection and implementation of a limited list of essential medicines contribute to both access and rational use.

• Global and national policy makers and health program managers support the concept of essential medicines.

• The essential medicines concept is a key element of national medicines policies.

• WHO has promoted this concept for 35 years and regularly publishes its model list of essential medicines.

WHO = World Health Organization
Benefits of Essential Medicines Concept

- **Supply**
  - Easier procurement
  - Lower stock quantities
  - Improved quality assurance
  - Easier dispensing

- **Patient use**
  - Focused education efforts
  - Improved availability

- **Prescribing**
  - More experience with fewer medicines
  - Irrational alternatives not available
  - Focused medicine information
  - Adverse drug reactions easier to manage

- **Cost**
  - Lower prices, more competition
Full Description of Essential Medicines

**Definition:** Essential medicines are those that satisfy the priority health care needs of the population

**Selection criteria:** Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness

**Purpose:** Essential medicines 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 at a price the individual and the community can afford.

**Implementation:** The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.

WHO’s Model Essential Medicine List (EML)

- WHO published its first model list in 1977
  - Had 216 molecules including duplicates and 204 molecules excluding duplicates
- The list is revised every two years
- The latest version was published in 2011
  - Includes 445 molecules including duplicates and 358 molecules excluding duplicates
  - Uses Anatomic Therapeutic and Chemical (ATC) classification system and International Nonproprietary Names (INN) or generic names
  - Includes “core” and “complementary” lists
  - URL for the list: http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf

The first list was a major breakthrough in the history of medicine, pharmacy, and public health
— Médecins Sans Frontières, 2000

WHO’s EML for Children

• The 3rd list came out in 2011
  • As a separate document and also integrated in the EML for adults
  • Intended for children up to 12 years of age
  • Has “core” and “complementary” lists

• URL for the children’s list:
WHO Model List of Essential Medicines: Model Product and Process

- More than a mere list; it is a model product and a public health tool
- It follows a model process:
  - Independent committee membership
  - Consideration of conflict of interest
  - Transparent process (standard application, web review)
  - Link to evidence-based clinical guidelines
  - Systematic review of comparative efficacy, safety, cost-effectiveness, and public health relevance
  - Rapid dissemination, electronic access
  - Regular review

The Process of Selecting and Using an EML

Development of a National Essential Medicines List

1. Disease burden

2. Evidence-based standard treatment guidelines (STGs) by level

3. Essential Medicines List (EML)

   - Rational drug use:
     - Training
     - Supervision
     - Monitoring

   - Drug information:
     - National Pharmacopoeia
     - Formulary

   - Drug supply:
     - Procurement
     - Donation
     - Production

The Essential Medicines Target
Application of the EDL Concept at Country Level

• WHO survey of 156 countries in 2007
  • 86% (134 of the 155 responding countries) had EMLs
  • The median number of medicines in the EML was 397 (n = 94)
  • 89% (116/130) had a committee for EML medicines selection
  • 69% (107/155) had updated the EML in the previous 5 years
  • 94% (125/133) were using EML for public sector procurement
  • 44% (47/108) were using for public insurance reimbursement
  • 13% (12/92) were using for private insurance reimbursement

http://apps.who.int/medicinedocs/documents/s16874e/s16874e.pdf
Other Applications of EML

- UNICEF, UNHCR, UNFPA, as well as NGOs and international non-profit supply agencies base their medicine supply system on the WHO Model List

- The WHO Model List has been used to develop
  - Interagency Emergency Health Kit (2006)

- The WHO Model Formulary follows the structure and sections used in the WHO Model List

Source: Medicines: essential medicines. WHO Fact sheet N°325, Revised June 2010
Developing and Implementing an EML

Recipes for Success

• Multidisciplinary EML committee
• Participatory/transparent process
• Link to STGs and formularies
• Clarity on the purpose of EML (legal and administrative authority)
• Official product launch
• Initial and reinforcement orientation/trainings
• Regular updates
• Monitoring of use

Recipes for Failure

• Poor participation in developing and updating
• Outdated
• Lack of purpose and lack of medicine policy framework
• Not obtaining support from professional organizations
• Not widely disseminated

Illustrative Indicators to Monitor Application of Essential Medicines Concept (1)

- Is there a national EML/formulary using INN officially adopted and distributed countrywide?
- Is there an official drug committee whose duties include updating the national EML?
- Has the national EML/formulary been updated and distributed countrywide in the past five years?
- Do drug donations comply with the national EML?
- Value of drugs from the national EML procured in the public sector, out of total value of drugs procured in the same sector
- Number of drugs from the national EML prescribed, out of total number of drugs prescribed
- Number of locally manufactured drugs sold in the country from the national EML, out of total number of drugs from the national EML
- Number of drugs from the national EML among the 50 best selling drugs

Source: Indicators for monitoring national drug policies: A practical manual
http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf
Illustrative Indicators to Monitor Application of Essential Medicines Concept (2)

- What is the total number of pharmaceuticals (in dosage forms and strengths) on the National EML?
- Is there consistency between the drugs included in the EML and STG?
- Is there a National Medicines Policy statement to encourage use of essential medicines?
- Are EML and STG used for pre-service and in-service training of health care personnel?
- What % of public-sector health facilities has a copy of EML and STG?
- What % of prescriptions complies with STG?

Sources: Health
(2) Pharmaceutical Management for Technical Assistance: An Introductory Course. Management Sciences for Health (MSH), CPM, 2004
Quality medicines for the poor: experience of the Delhi programme on rational use of drugs

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Prior to 1994, most Delhi hospitals and dispensaries experienced constant shortages of essential medicines. There was erratic prescribing of expensive branded products, frequent complaints about poor drug quality and low patient satisfaction. Delhi took the lead in developing a comprehensive Drug Policy in 1994 and was the only Indian state to have such a comprehensive policy. The policy’s main objective is to improve the availability and accessibility of quality essential drugs for all those in need.

The Delhi Society for the Promotion of Rational Use of Drugs (DSPRUD), a non-governmental organization, worked in close collaboration with the Delhi Government and with universities to implement various components of the policy. The first Essential Drugs List (EDL) was developed, a centralized pooled procurement system was set up and activities promoting rational use of drugs were initiated. In 1997, the Delhi Programme was designated the INDIA-WHO Essential Drugs Programme by the World Health Organization.

The EDL was developed by a committee consisting of a multidisciplinary group of experts using balanced criteria of efficacy, safety, suitability and cost. The first list contained 250 drugs for hospitals and 100 drugs for dispensaries; the list is revised every 2 years. The pooled procurement system, including the rigorous selection of suppliers with a minimum annual threshold turnover and the introduction of Good Manufacturing Practice inspections, resulted in the supply of good quality drugs and in holding down the procurement costs of many drugs. Bulk purchasing of carefully selected essential drugs was estimated to save nearly 30% of the annual drugs bill for the Government of Delhi, savings which were mobilized for procuring more drugs, which in turn improved availability of drugs (more than 80%) at health facilities. Further, training programmes for prescribers led to a positive change in prescribing behaviour, with more than 80% of prescriptions being from the EDL and patients receiving 70–95% of the drugs prescribed. These changes were achieved by changing managerial systems with minimal additional expenditure. The ‘Delhi Model’ has clearly demonstrated that such a programme can be introduced and implemented and can lead to a better use and availability of medicines.
Summary

- Essential Medicines Concept has become an established approach in international public health and is supported by most governments of the world.

- Carefully developed and implemented EMLs can contribute to access and rational use.

- EML is only a starting point—for success, it needs to be linked with procurement/supply, STGs, and training of health care providers.