CHAPTER-I

Concept of essential drugs

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Definition

“Essential drugs are those that satisfy the health care needs of majority of population”
- Should available at all times
- In adequate amounts
- In the adequate dosage forms
History of the WHO Model List of Essential Drugs

- 1977 First Model list published, ± 200 active substances
- List is revised every two years by WHO Expert Committee
- Last essential drug list established in the year 2010
Great importance for developing countries

- Development of treatment guidelines and national formularies
- Comprehensive national drug formulary
- Strategies to drug procurement and supply
- Drug financing and Drug donations
- Research priorities for drug use
- Drugs needed for specific disease
Guidelines for establishing a national programme for essential drugs

- National drug regulatory authority should be established
- National drug and therapeutic committee (NDTC) should be established
- Committee includes people from
  - Medical
  - Clinical Pharmacology
  - Pharmacy
  - Public health fields
  - Also from other appropriate health care fields
• Generic names should be used for all drugs
• Concise, accurate and comprehensive drug information should be prepared
• Stability and bioavailability should be assured
• Efficient administration of supply, storage and distribution of drugs
• Management of stocks and eliminate waste
Criteria for the selection of essential drugs

- Pattern of prevalent disease and treatment facilities
- Level of training and experience of the personnel
- Financial resources available in the country
- Genetic, demographic and environmental factors
- Evidence based and not suituation based
- Selected drugs should have adequate data on their efficacy and safety
- Performance of drugs in general has been proved in a variety of medical setting
- Available in adequate quantities and in the dosage forms that is recommended by NDTC
- Assured quality, stability and bioavailability
- Two or more drugs having same quality, stability and bioavailability, choice on the basis of efficacy, safety, quality, price and availability
- **Cost**, an issue; unit cost of drug alone should not be considered. Cost of total treatment, cost/benefit ratio should also be considered.

- Comparative pharmacokinetic properties of drugs in the same therapeutic category.

- Local facilities to manufacture and storage also be considered.

- Should contain only single drug, combination advantage over single drug in therapeutic effect, safety and patient compliance.
Selection of Pharmaceutical dosage forms

- General utility and wide availability of the dosage forms
- Tablets have wide acceptability and also cost effective
- Stability of dosage form under ambient climate conditions
- Established local preference
- Bioavailability and pharmacokinetics of dosage forms
- Selection of convenient dosage forms for selected population

Eg: Paediatric dosages, SR/CR dosage inclusion require adequate documentation

- Selection of specified salt form for a particular drug

Example: Chloramphenicol Palmitate, Amlodipine Besylate, Erythromycin estolate
Quality Assurance and WHO certification scheme

- Should confirm with required standards of good Manufacturing practice (GMP) and quality control
- Bioavailability of drugs
- Should confine International Pharmacopoeia and its standards
Nomenclature

- Each pharmaceutical substance by a globally acceptable generic name is importance

- International nonproprietary (INN) names becomes an important arm of essential drug list and is almost globally accepted

- INN periodically published by WHO for new addition of pharmaceutical products

- Brought uniformity in the names of medicine

- Stop confusion and to ensure, safety of drugs for patients
Tasks after the formation of Essential drug list

- Updating the essential drug list
- Essential drug list for primary health care centres
- Specialist control of drug use
- Research and development
- Drug information and education activities
- Making a list of reserve microbials
- Post registration drug studies
Updating the essential drug list-Continuous process

WHO guiding principles

- Must accommodate local situations to meet health needs of majority of population
- Extent to which country establish EDL
- Guiding essential drug list by WHO is a contribution to solve problems
- Need to include additional drugs for rare disease. Eg: TB drugs in India
- Exclusion does not mean rejection
- Public health issue, epidemiological changes, new drugs availability, progress in pharmacological and pharmaceutical knowledge
Essential drug list for primary health care centres

- Existing system of medicine
- National health infrastructure
- Pattern of endemic diseases
- Supplies
Specialist control of drug use

- Adequate specialist skills and complementary resources needed before the introduction of new drugs. Examples of situations requiring specialist control of drug use
  - Use of reserve antibiotics for multiresistant bacteria
  - Adequate regimen for TB and leprosy
  - Use of antineoplastic, immunosuppressive agent, antiretroviral agent
Research and development

- Pharmaceutical aspects
  - Development of drug procurement, drug quality, processing, packaging and distribution
- Clinical and epidemiological aspect
  - To assess efficacy, safety, genetic and ethnic difference
- Educational aspects
  - Development of training programme
Drug information and education activities

- Develop formulary and drug information sheet on all drugs in EDL
- Continual education programme on all aspects of medical care, disease pattern, selection of antimicrobials, diagnostic and other therapeutic guidelines
Making a list of reserve microbials

- Amoxicillin plus clavulanic acid
- Ceftriaxone
- Ceftazidime
- Vancomycin etc...
Post registration drug studies

- Some drugs fail to produce benefit. Reasons are
  - Clinical trial does not include groups like children, pregnant women, old people
  - Genetic and environment factors differs from population to population
  - Unexpected use of drugs, data on overdose not available
  - Poor manufacturing practice

- Post registration drug studies help to estimate future demands, quantify drug inventory, evaluate drug use
Thank you