



pharmacOLOGIC

The logic behind using drugs.....



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DEPARTMENT OF PHARMACOLOGY

NEWS LETTER

From the Editor's Desk

Greetings from the Pharmacology Department. This issue is dedicated to the aspect of Essential Drugs List (EDL). Our hospital has come out with an EDL of its own. This was the effort from the Pharmacy and Therapeutic Committee. We have an interesting article on Transgenic Animals. We had organized a state level CME on "Pharmacovigilance-Medication Safety" on December 3rd 2015. The CME was attended by delegates from all over the state. Finally we have the list of publications from our department. Happy reading...



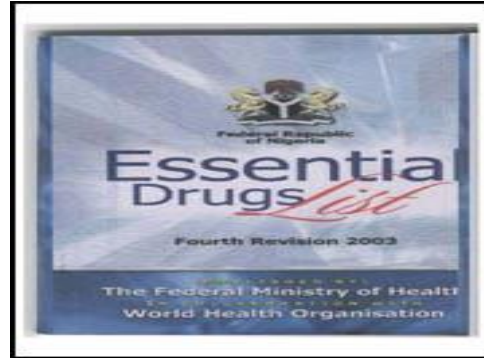
ESSENTIAL DRUGS LIST (EDL)

DR CHANDRAKANTHA T, POSTGRADUATE

INTRODUCTION: ‘WHO’ definition - “Essential medicines are those that satisfy the priority health care needs of the population”

Essential medicines are intended to be available within the context of functioning health systems,

- At all times
- In adequate amounts
- In appropriate dosage forms
- With assured quality
- At affordable prices



HISTORY

- ❖ WHO published the first model list of essential drugs in 1977 and includes 208 individual drugs as essential medicines, it was a major breakthrough in the history of public health care.
- ❖ The WHO model list of Essential Medicines has been updated every TWO years since 1977.
- ❖ In 2007, thirty years after introduction of this concept, a model list for children was also introduced.
- ❖ Since the medicines listed in the EDL are limited, it should not be viewed that those drugs that do not find a mention are not useful.
- ❖ Essential medicines are one of the most **cost-effective** elements in the modern health care.
- ❖ Provides **safe and effective** treatment for majority of communicable and non-communicable diseases.

RATIONALE BEHIND THE ESTABLISHMENT OF EDL

- ⊙ To avoid the use of drugs that were indiscriminately marketed without considering the health needs of the local population.
- ⊙ Another important and major concern is that population belonging to the rural areas could not access to the essential drugs.
- ⊙ Safe, efficient, inexpensive essential drugs can be life saving.

GLOBAL CONCEPT

- ⊙ The concept of essential medicines is forward looking
 - To reflect new therapeutic options and changing therapeutic needs
 - Medicines to meet changing resistance patterns
- ⊙ Many international organizations, including UNICEF, UNHCR, UNFPA as well as non-governmental organizations and international non-profit supply agencies have adopted the concept of essential medicines.

CRITERIA FOR SELECTION OF ESSENTIAL MEDICINES

- Adequate data on its efficacy and safety should be available from clinical studies.
- The quality, including bioavailability and stability on storage should meet the standards.
- In case of two or more similar medicines, choice should be made on their relative efficacy, safety, price and availability.
- In case where two drugs bear close resemblance with respect to efficacy, stability, bioavailability etc. then,
 - the drug which has thoroughly investigated should be selected
 - which has more appealing pharmacokinetic parameters should be selected
- The COST ; BENEFIT ratio is an important consideration rather than unit cost of the drug, total cost of the treatment should be taken into consideration.
- Most essential medicines should be single compounds rather than fixed combinations unless proven advantage in therapeutic effect and safety parameters.
- Selection of essential drugs should be a continuous process considering the,
 - changing trends in public health
 - epidemiological conditions
 - progress in pharmacological knowledge

SEVEN STEPS TO GET A NEW MEDICINE ON THE 'WHO' – EDL

- ❖ Identification of public health need for a drug
- ❖ Development of drug through different phases of clinical trial
- ❖ Regulatory approval in number of countries
- ❖ Post-marketing surveillance
- ❖ Price indication for public sector use
- ❖ Review by WHO disease programme
- ❖ Submission to WHO expert committee on essential drugs

CURRENT LIST

- ⊙ The 19th is the current model list of essential medicines prepared by the WHO expert committee in April 2015.

- ⊙ The current versions are the 19th WHO Essential medicines list and 5th WHO essential medicines list for children updated in April 2015.

‘WHO’ MODEL LIST OF ESSENTIAL DRUGS – DESCRIPTION

- ⊙ The classification of drugs has been done based on the therapeutic indication.
- ⊙ The recent model list comprises 30 classes of drugs.
- ⊙ The generic names of the drugs have been used with respective doses and available dosage forms.

NATIONAL LIST OF ESSENTIAL MEDICINES (NLEM)

- ⊙ About 156 countries have a national list of essential drugs
- ⊙ India released its first NLEM in the year 1996
- ⊙ Recently revised in the year 2011 and includes 348 medicines
Which are considered to be adequate to meet the priority healthcare needs of the Country.
- ⊙ For essentiality of requirements, medicines have been categorized as, P, S and T based on their requirement at Primary, secondary and Tertiary levels.
- ⊙ Out of 348 medicines,
 - 181 drugs under category P, S and T
 - 106 drugs under S and T
 - 61 drugs under T

ADVANTAGES OF EDL

- ⊙ Promoting better procurement policy and practice from using a restricted list.
- ⊙ Reducing cost of procurement.
- ⊙ Effective monitoring and evaluation of pharmaceutical use.
- ⊙ Enforcing rational prescription, by focusing on limited list of pharmaceuticals.
- ⊙ Effective control of medicines in public circulation.

As the ‘WHO’ has not made it compulsory to only prescribe drugs under the model, this is beneficial in two aspects,

1. It allows the countries, states or even hospitals to compile their own EDL according to their respective needs (provided that the WHO model list serves as a guide).
2. This list being flexible can be regularly updated to keep up with the rapid advancements in the field of medicine.

TRANSGENIC ANIMALS

DR NEHA K, POSTGRADUATE



INTRODUCTION: Transgenic animals are animals that have had a foreign gene deliberately inserted into their genome. Transgenesis is the process of introducing an exogenous gene called transgene into a living organism so that the organism will exhibit a new property and transmit that property to its offspring. The foreign gene is constructed using recombinant DNA technology. Such animals are most commonly created by the micro-injection of DNA into the pronuclei of a fertilized egg which is subsequently implanted into the oviduct of a pseudo pregnant surrogate mother. The majority of transgenic animals produced so far are mice, the animal that pioneered the technology. The first successful transgenic animal was a mouse. A few years later, it was followed by rabbits, pigs, sheep, and cattle.

METHODS TO PRODUCE TRANSGENIC ANIMALS: To date, there are three basic methods of producing transgenic animals:

- **DNA microinjection**
- **Retrovirus-mediated gene transfer**
- **Embryonic stem cell-mediated gene transfer**

Gene transfer by microinjection is the predominant method used to produce transgenic farm animals. Since the insertion of DNA results in a random process, transgenic animals are mated to ensure that their offspring acquire the desired transgene. However, the success rate of producing transgenic animals individually by these methods is very low and it may be more efficient to use cloning techniques to increase their numbers.

BENEFITS OF TRANSGENIC ANIMALS: The benefits of these animals to human welfare can be grouped into areas of agriculture, medicine & industry.

1. **Agricultural applications** are usually for breeding to allow larger herds with specific traits. It is possible to develop traits in animals in a shorter time and with more precision. It is an easy way to increase yields. It improves the size of livestock genetically.
2. **Medical applications** are for xenotransplantation which is still under research and nutritional supplements and pharmaceuticals. Milk-producing transgenic animals are especially useful for medicines. Advances in transgenic technology provide the opportunity either to change the composition of milk or to produce entirely novel proteins in milk. Products such as insulin, growth hormone, and blood anti-clotting factors may soon be or have already been obtained from the milk of transgenic cows, sheep, or goats. Transgenic animals are also used for human gene therapy.
3. **Uses in industry** include material fabrication and safety tests of chemicals. In 2001, two scientists at Nexia Biotechnologies in Canada spliced spider genes into the cells of lactating goats. The goats began to manufacture silk along with their milk and secrete tiny silk strands from their body by the bucketful. By extracting polymer strands from the milk and weaving them into thread, the scientists can create a light, tough, flexible material that could be used in such applications as military uniforms, medical micro sutures and tennis racket strings.

THE PITFALLS AND RISKS OF TRANSGENIC ANIMALS:

- Unregulated expression of genes resulting in over- or underproduction of gene products
- Too high a copy number resulting in over expression of products
- Possible side effects, e.g., GH transgenic swine had arthritis, altered skeletal growth, cardiomegaly, dermatitis, gastric ulcers, and renal disease
- Insertional mutations (inserting a fragment of DNA into an important gene) that result in some essential biological processes being altered
- Mosaicism (only a portion of the cells incorporate the gene being transferred) in the founders, which results in transmission of the transgene to only some of the offspring
- Transgene integration on the 'Y' chromosome, which results in only males carrying the transgene.

GLIMPSE OF DEPARTMENTAL CME ON “PHARMACOVIGILANCE – MEDICATION SAFETY” CONDUCTED ON DECEMBER 3RD 2015.



LIST OF PUBLICATIONS:

ORIGINAL RESEARCH ARTICLE

1. **Ravi Shankar M**, Anurag Srivastava. Estimation of body mass index and risk evaluation of diabetes and cardiovascular diseases in undergraduate students. *Int J Res Med Sci.* 2015 Sep; 3(9): 2410-418.
2. **Manu G, Madhav K Savkar, Deepika G, Suparna Podder.** Polypharmacy in clinical practise: Nurse's opinion, a cross sectional questionnaire study in a tertiary care centre. *American Journal of Advanced Nursing Research* 2015; 2(2):73-76.
3. **Gangadhar M, Guruppanavar D.** Assessment of knowledge, attitude and perception of Pharmacovigilance among nurses in a tertiary care centre. *Int J Basic Clin Pharmacol* 2015; 4: 1009-12.
4. **Padmanabha T S, Bhaskara K, Manu G, Chandrakantha T.** Post operative utilization pattern of analgesics in orthopaedic department of an Indian tertiary care teaching hospital. *International Journal of Current Pharmaceutical & Clinical Research* 2016; 6(1): 27-31.
5. **Shwetha Shivamurthy, Ghorpade Voomojirao Anand Prakash, Vinay Hosagavi Ramalingaiah.** *Int J Res Med Sci.* 2015 Dec; 3(12): 3651-3654.
6. **Shivamurthy S, Manchukonda R, Ramadas D.** Evaluation of learning and memory enhancing activities of protein extract of *Withania somnifera* (Ashwagandha) in Wistar albino rats. *Int J Basic Clin Pharmacol* 2016;5(2):453-7.

CASE REPORTS

1. **Ravi Shankar M, Rakshith N.** Disulfiram induced hemoptysis: a case report. *Int J Basic Clin Pharmacol* 2016; 5(1):220-2.
2. **Shivamurthy S, Manchukonda R.** Carbamazepine induced anticonvulsant hypersensitivity syndrome. *Int J Basic Clin Pharmacol* 2015; 4(5):1037-9.