

A REVIEW ON ESSENTIAL MEDICINES AND RATIONAL USAGE OF DRUGS

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ABSTRACT

Establishing a list of essential medicines was aimed to improve the availability of affordable medicines for the world's poor. Access to essential medicines is a major determinant of health outcomes but access to essential medicines in developing countries like India is not adequate. So, in this review we have tried to present the Indian scenario in respect to availability and accessibility of essential medicines over last one decade. To enhance the credibility of Indian healthcare system, procurement and delivery systems of essential medicines have to be strengthened through government commitment, careful selection, adequate public sector financing, efficient distribution systems, control on taxes and duties, and inculcating a

culture of rational use of medicines in current and future prescribers. The selection of essential medicines is only the first step to improve the quality of health care. It should be followed by the appropriate use of the selected medicines so rational use of drugs concept was introduced. Irrational use of Medicines is a global phenomenon, Rational use of drugs may be defined as patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and the lowest cost to them and their community. Overuse, poly pharmacy and incorrect use of drugs are the most common problems of drug use today. Irrational use of drugs may result due to various reasons at various levels including the prescribing errors and over the counter drugs. Irrational use of medicines may lead to serious negative health and economic consequences. Many irrational drug combinations are available in Indian market. Proper implementation of rational use of drugs will improve the quality of life and result in better community healthcare.

KEYWORDS: Essential medicines, Rational use.

ESSENTIAL MEDICINES

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

INTRODUCTION

1975 World Health Assembly (WHA) meeting, report by WHO Director-General regarding problems facing countries in area of medicines, first mention of essential medicines. 1977 first Expert Committee on essential medicines issues technical report and compilation of essential medicines. The Alma-Ata declaration during the International Conference on Primary Health Care in 1978 reaffirms that health is a fundamental human right and the attainment of the highest possible level of health is a most important worldwide social goal. The Alma Ata declaration has outlined the eight essential components of primary health care and provision of essential medicines is one of them. Alma-Ata Declarations on primary care issued hand book on essential drugs. 1978 Resolution WHA 31.32 passed urging members to establish national essential medicine lists.^[1, 2]

CONCEPT

Original definition (1977): Essential medicines of utmost importance, basic, indispensable, and necessary for the healthcare needs of the population.

World Health Organization (WHO) introduced the concept of essential medicines in 1977. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

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 adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations. It incorporates the need to regularly update medicines selections to reflect new therapeutic options and changing therapeutic needs; the need to ensure drug quality; and the need for continued development of better medicines, medicines for emerging diseases, and medicines to meet changing resistance patterns.^[1, 2]

NEED FOR ESSENTIAL MEDICINES

Normal people are not affordable to buy the medicines, that leads to cause death of people. Hence most leading causes of death and disability can be prevented or treated with cost-effective essential drugs. So government and other organizations introduced the essential drugs list by expert committee's advices.^[3]

DEVELOPMENT

In 1975, before representatives of WHO Member States at the World Health Assembly, Dr Halfdan Mahler insisted on the need to develop national pharmaceutical policies based on the affordability, quality, and availability of drugs. The States responded to the report by the Director-General by adopting a resolution in support of national pharmaceutical policies that meet actual health needs and urged the Secretariat of WHO to help States to formulate them.^(4,5) Rapidly, the concepts of "essential drugs" and of "National Drug Policy" entered the vocabulary of global public health.^[3]

INDIAN SCENARIO

In India first National Essential Medicine List (NEML) was prepared in 1996. The first and second revision was published in 2003 and 2011, respectively. NEML 2011 was revised based on the Indian Pharmacopeia 2010 and the National Formulary of India, 4th Edition, 2010. The Central Government's share of medicines in its total health budget is around 12%. In all, roughly 10% of the health budget goes into procuring medicines in India. Even then, availability of medicines often is a big issue. The non-availability of required medicines jeopardizes the credibility of the public health system. Access to essential medicines is closely linked to health system performance and its utilization.^[4]

SELECTION CRITERIA

Essential medicines are selected with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness. When adequate scientific evidence is not available on current treatment of a priority disease, the Expert Committee may either defer the issue until more evidence becomes available, or choose to make recommendations based on expert opinion and experience. The 20th Expert Committee meeting took place at WHO Headquarters, Geneva, 20-24 April 2015 in order to revise and update the WHO Model List of Essential Medicines (EML) for both adults and children. Medicine will be deleted from NLEM 2011 in the following conditions.^[5]

1. The medicine has been banned in India.
2. If there are reports of concerns on the safety profile of a medicine.
3. If medicine with better efficacy or favorable safety profile and better cost-effectiveness is now available National List of Essential Medicines (NLEM) 2015.
4. The disease burden for which a medicine is indicated is no longer a national health concern.
5. In case of antimicrobials, if the resistance pattern has rendered a medicine ineffective.

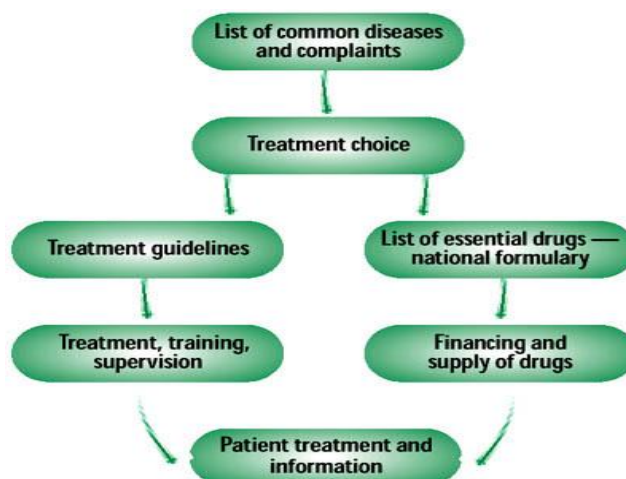
❖ Information supporting the public health relevance.^[6]

The application should include information on the public health need for the medicine, including:

- Epidemiological information on disease burden.
- Assessment of current use.
- Target population(s).
- Likely impact of treatment on the disease.
- ❖ Review of benefits: summary of comparative effectiveness in a variety of clinical settings.^[7]
 - Identification of clinical evidence (search strategy, systematic reviews identified, reasons for selection/exclusion of particular data).
 - Summary of available data (appraisal of quality, outcome measures, summary of results).
 - Summary of available estimates of comparative effectiveness
- ❖ Review of harms and toxicity: summary of evidence on safety.^[7]
 - Estimate of total patient exposure to date.
 - Description of the adverse effects/reactions and estimates of their frequency.
 - Summary of available data (appraisal of quality, summary of results).
 - Summary of comparative safety against comparators.
 - Identification of variation in safety that may relate to health systems and patient factors

❖ CRITERIA FOR INCLUSION^[8]

- Be approved/licensed by DCGI
- Be useful in disease which is a health problem in India
- Proven efficacy and safety profile based on valid scientific evidence
- Be comparatively cost effective
- Aligned with the current treatment guidelines for the disease
- Stable under the storage conditions in India



UPDATED AND REMOVED LIST

Updated every 2 years by expert committee. New medicines or updates are submitted via application. Expert committee reviews applications and available data and recommend medicines to add.

The core list presents a lot of minimum medicines need for the basic health care system, listing the most efficacious, safe and cost effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance and potential for safe and cost effective treatment.

The complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed. In case of doubt medicines may also be listed as complementary on the basis of consistent higher costs or less attractive cost effectiveness a variety of settings.^[9]

The number of medicines deleted and added to National List of Essential Medicines (NLEM) 2015 is given below:

TABLE 1: Medicines Added to NLEM 2015:^[10]

CATEGORY	MEDICINES
Anesthetic agents	Glycopyrrolate
Analgesics, antipyretics, non steroidal anti inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders	Mefenamic acid
Antiallergics and medicines used in anaphylaxis	NIL

Antidotes and other substances used in poisonings	Neostigmine
Anticonvulsants / Antiepileptics	Clobazam, Levetiracetam
Anti-helminthics	Mebendazole
Anti-bacterial medicines	Benzyl penicillin, Cefadroxi, Cefazolin Piperacillin + Tazobactam, Clarithromycin
Antileprosy medicines	NIL
Antituberculosis medicines	Capreomycin, Cycloserine, Ethionamide Kanamycin, Levofloxacin, Moxifloxacin Linezolid, Para amino salicylic acid, Rifabutin
Anti-fungal medicines	NIL
Antiviral medicines	Ganciclovir, Abacavir, Abacavir + Lamivudine Tenofovir + Lamivudine, Lopinavir + Ritonavir Tenofovir + Lamivudine + Efavirenz, Ribavirin Raltegravir, Atazanavir + Ritonavir, Darunavir Entecavir, Pegylated interferon alfa 2a and 2b Sofosbuvir, Tenofovir
Anti-Protozoal medicines	Miltefosine, Paromomycin, Artesunate Artemether + Lumefantrine
Antimigraine medicines	Sumatriptan, Flunarizine
Antineoplastic, immunosuppressives and medicines used in palliative care	All trans retinoic acid, Arsenic Trioxide Bortezomib, Capecitabine, Docetaxel, Gefitinib Rituximab, Temozolomide, Thalidomide Trastuzumab, Bicalutamide, Dexamethasone Letrozole, Mycophenolate mofetil, Diazepam Tacrolimus, Amitriptyline, Fluoxetine Haloperidol, Lactulose, Loperamide, Tramadol, Metoclopramide, Midazolam, Zoledronic acid
Antiparkinsonism medicines	NIL
Medicines affecting the blood	Erythropoietin, Ferrous salt + Folic acid Hydroxocobalamin, Hydroxyurea, Iron sucrose Tranexamic acid
Blood products and plasma substitutes	Red blood cells, Whole blood
Cardiovascular medicines	Labetalol, Ramipril, Telmisartan, Alteplase Noradrenaline
Medicines used in dementia	Donepezil
Dermatological medicines	Clotrimazole, Benzoyl peroxide, Fusidic acid Podophyllin resin, White Petrolatum
Diagnostic agents	Gadobenat, Iohexol
Dialysis solution	Haemodialysis fluid
Disinfectants and antiseptics	NIL

Diuretics	NIL
Ear, nose and throat medicines	Budesonide, Ciprofloxacin, Clotrimazole Xylometazoline
Gastrointestinal medicines	Sucralfate, Somatostatin, Lactulose
Hormones, other endocrine medicines and contraceptives	Human Chorionic Gonadotropin, Levonorgestrel Glimepiride
Immunologicals	Hepatitis B immunoglobulin, Human Normal Immunoglobulin, DPT + Hib + Hep B vaccine Japanese encephalitis vaccine
Muscle relaxants and cholinesterase inhibitors	Baclofen
Medicines for neonatal care	Alprostadil, Caffeine, Surfactant
Ophthalmological Medicines	Acyclovir, Erythromycin, Carboxymethylcellulose Proparacaine, Natamycin, Tropicamide,
Oxytocics and Antioxytocics	Dinoprostone
Psychotherapeutics	Clozapine, Fluphenazine, Risperidone, Zolpidem Escitalopram, Clonazepam, Clomipramine
Medicines acting on the respiratory tract	Budesonide, Budesonide + Formoterol Tiotropium
Solutions correcting water, electrolyte disturbances and acidbase disturbances	NIL
Vitamins and minerals	Cholecalciferol

TABLE 2: Medicines Deleted from NLEM 2015.^[10]

CATEGORY	MEDICINES
Anesthetic agents	Ether, Diazepam, Promethazine
Analgesics, antipyretics, non steroidal anti inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders	NIL
Antiallergics and medicines used in anaphylaxis	Dexchlorpheniramine, Promethazine
Antidotes and other substances used in poisoning	Flumazenil
Anticonvulsants / Antiepileptics	NIL
Anti-helminthics	Piperazine
Anti-bacterial medicines	Cephalexin, Amikacin, Sulfadiazine Erythromycin
Antileprosy medicines	NIL
Antituberculosis medicines	Ofloxacin
Anti-fungal medicines	NIL
Antiviral medicines	Didanosine, Lamivudine, Stavudine, Indinavir Nelfinavir, Saquinavir
Anti-Protozoal medicines	Pentamidine, Sodium Stibogluconate Pyrimethamine, Sulfadoxine +

	Pyrimethamine
Antimigraine medicines	Dihydroergotamine
Antineoplastic, immunosuppressives and medicines used in palliative care	Alpha interferon, Busulfan, Mitomycin-C Danazol, Flutamide, Raloxifene
Antiparkinsonism medicines	Bromocriptine Mesylate
Medicines affecting the blood	Cyanocobalamin, Iron dextran, Pyridoxine
Blood products and plasma substitutes	Dextran 70, Hydroxyethyl starch (Hetastarch) Polygeline, Albumin
Cardiovascular medicines	Diltiazem, Procainamide, Losartan potassium Nifedipine, Urokinase
Medicines used in dementia	NIL
Dermatological medicines	Miconazole, Acyclovir, Neomycin + Bacitracin Zinc Oxide, Dithranol, Benzyl benzoate
Diagnostic agents	Calcium Iodate, Iopanoic Acid, Propyl iodone Meglumine Iothalamate, Meglumine Iotroxate Sodium Iothalamate
Dialysis solution	NIL
Disinfectants and antiseptics	Acriflavin + Glycerin, Benzoin compound Formaldehyde
Diuretics	NIL
Ear, nose and throat medicines	NIL
Gastrointestinal medicines	Promethazine, Aluminium Hydroxide + Magnesium Hydroxide, 3 Famotidine
Hormones, other endocrine medicines and contraceptives	Testosterone, Glibenclamide, Glucagon, and Iodine
Immunologicals	NIL
Muscle relaxants and cholinesterase inhibitors	Pyridostigmine
Medicines for neonatal care	NIL
Ophthalmological Medicines	Chloramphenicol, Miconazole Sulphacetamide sodium, Tetracaine hydrochloride, Betaxolol hydrochlorid
Oxytotics and antioxytotics	Terbutaline
Psychotherapeutics	Chlorpromazine, Olanzapine, Imipramine Alprazolam, Diazepam
Medicines acting on the respiratory tract	Beclomethasone Dipropionate, Codeine Phosphate, Dextromethorpha
Solutions correcting water, electrolyte disturbances and acidbase disturbances	NIL
Vitamins and minerals	Multivitamins, Vitamin D (Ergocalciferol)

Total number of medicines may differ due to duplication of medicines within and across therapeutic categories/ difference in terms used in NLEM 2011 and NLEM 2015.

RATIONAL USAGE OF DRUGS

The selection of essential medicines is only the first step to improve the quality of health care. It should be followed by the appropriate use of the selected medicines so rational use of drugs concept was introduced.^[11, 12]

INTRODUCTION

In 1985, the World Health Organization defined the rational use of medicines as requiring that “patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community.”^[13, 14]

In simplest words rational use means “prescribing right drug, in adequate dose for the sufficient duration & appropriate to the clinical needs of the patient at lowest cost. The concept of rational drug use is age old, as evident by the statement made by the Alexandrian physician Herophilus 300 B.C that is “Medicines are nothing in themselves but are the very hands of god if employed with reason & prudence.”^[15]

Rational use of drugs was introduced to prevent irrational use of drugs. Irrational medicine use occurs in all countries and in all health care settings, from hospitals to homes. It involves cases in which no medicine is needed but is prescribed; cases in which the wrong medicines, or ineffective or unsafe medicines, are prescribed or dispensed; cases in which effective and available medicines are not used; and those in which medicines are used incorrectly by patients. These actions negatively affect the quality of medicine treatment, raise health care costs, and may cause adverse reactions or the development of antimicrobial resistance. Strategies for rational use of drugs includes: A multidisciplinary national body to coordinate medicine use policies, Clinical guidelines, Essential medicines list for different therapeutic domains, Drugs and therapeutics committees in hospitals, Problem-based pharmacotherapy training in undergraduate curriculum. Continuing medical education as a licensure requirements, Supervision, audit, and feedback. Independent information on medicines, Public education and awareness about medicines, Avoidance of perverse financial incentives, Appropriate and enforced regulation, Sufficient government expenditure to ensure availability of medicines and staff.^[16]

FACTORS THAT HAVE LED SUDDEN REALIZATION FOR RATIONAL DRUG USE ARE:^[17, 18]

- Drug explosion:- Increase in the number of drugs available has incredibly complicated the choice of appropriate drug for particular indication.
- Efforts to prevent the development of resistance – Irrational use of drugs may lead to the premature demise of highly efficacious & life saving new antimicrobial drug due to development of resistance.
- Growing awareness:- Today, the information about drug development, it's uses & adverse other end with amazing speed through various media.
- Increased cost of the treatment:- Increase in cost of the drug increases economic burden on the public as well as on the government. This can be reduced by rational drug use.
- Consumer protection Act. (CPA):- Extension of CPA in medical profession may restrict the irrational use of drugs.

REASONS FOR IRRATIONAL USE OF DRUGS:^[19]

- Lack of information
- Faulty and inadequate training and education of medical graduates
- Poor communication between health professionals and patients
- Lack of diagnostic facilities/uncertainty of diagnosis
- Demand from the patients
- Defective drug supply system and ineffective drug regulations
- Promotional activities of pharmaceutical industries

HAZARDS OF IRRATIONAL USE OF DRUGS:^[20, 21]

Irrational use of drugs may lead to:

1. Ineffective & unsafe treatment
2. Exacerbation or prolongation of illness
3. Distress & harm to patient
4. Increase the cost of treatment

MEASURES TO PROMOTE RATIONAL DRUG USE:^[22]

Medicines (drugs) cannot be used rationally unless every one involved in the pharmaceutical supply chain has access to objective information about the drug they buy and use. Knowledge & ideas about drugs are constantly changing & a clinician is expected to know about the new development in drug therapy. The pre-requisites of rational drug use are: -

Critical assessment & evaluation of benefits & risk of drug used.

Compare the advantages, disadvantages, safety & cost of the drug with existing drug for some indication.

OBSTACLES EXIST IN RATIONAL DRUG USE.^[23, 24]

Various obstacles in rational drug use are:-

- ✓ Lack of objective information & of continuing education & training in pharmacology.
- ✓ Lack of well organized drug regulatory authority & supply of drugs.
- ✓ Presence of large number of drugs in the market & the lucrative methods of promotion of drugs employed by pharmaceutical industries.
- ✓ The prevalent belief that “every ill has a pill.”

STEPS TO IMPROVE RATIONAL DRUG PRESCRIBING:^[16]

Step:- I Identify the patient's problem based on symptoms & recognize the need for action.

Step:-II Diagnosis of the disease. Identify underlying cause & motivating factors. This may be specific as in infectious disease or non specific.

Step:-III List possible intervention or treatment. This may be non drug treatment or drug treatment. Drug must be chosen from different alternatives based on efficacy, convenience & safety of drugs including, drug inter-actions & high risk group of patients.

Step:-IV Start the treatment by writing an accurate & complete prescription e.g. name of drugs with dosage forms, dosage schedule & total duration of the treatment.

Step:-V Given proper information instruction & warning regarding the treatment given e.g. side effects(ADR), dosage schedule & dangers/risk of stopping the therapy suddenly.

Step:-VI Monitor the treatment to check, if the particular treatment has solved the patient's problem. It may be:

(a) Passive monitoring – done by the patient himself. Explain him what to do if the treatment is not effective or if too many side effect occurs.

(b) Active monitoring done by physician and he make an appointment to check the response of the treatment.

CONCLUSION

World Health Organization (WHO) pointed out that approximately 67% of the population lives without an access to essential medicines. India is reckoned among the global leaders in the manufacturing of generic medicines. However, it is also held that the largest number of populace in India is living without having an access to basic medicines. For meeting the

requirements of medicines at reasonable prices as also for strengthening of the indigenous manufacturing capacity and capability, the Government has, over the years, formulated policies and issued drug price control orders from time to time. Currently, National Pharmaceuticals Policy, 2005 has been drafted with key objectives of price regulation of the essential medicines, availability of good quality medicine, higher investment for increased production, emphasis on drug research and development and promoting good manufacturing practice in domestic pharmaceutical companies. Availability of essential & life saving drugs and unbiased drug information with generic name. Adequate quality control & drug control. Withdrawal of hazardous & irrational drugs. Drug legislation reform.

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