

INTRODUCTION TO RATIONAL DRUG USE AND ROLE OF PHARMACIST IN RATIONAL USE OF DRUGS

By: Dr. Madhuri Pandole

Assistant Professor

Saraswati Institute of Pharmaceutical Sciences

Gandhinagar, Gujrat.

ESSENTIAL DRUGS

“Essential drugs are those that satisfy the health care needs of the majority of population”

Should be : Available at all time, in adequate amount, appropriate dosage forms.

use of essential drugs:

Development of treatment guidelines.

Development of national drug formularies.

Drug financing.

Drug donations.

Research priorities.

Drug needed for specific diseases.

Guidelines for establishing a national program for essential drugs

- A national drug regulatory authority should be established. This authority should interact with other parties like drug procurement agencies, both in public and private sector.
- A national, drug and therapeutic authority should be established (NDTC). This committee should include competent people from medical, clinical, pharmacology, pharmacy, public health fields as well as from other appropriate, health care fields. It remains the part of national programme for essential drugs and should continuously advise on matters of technical importance.
- Generic names should be used for all drugs. Prescribers should be provided with a cross index of generic names and brand names.
- A concise, accurate and comprehensive drug information booklet should be prepared to serve as a pocket guide for all essential drug list.

- The quality of all products including stability and bioavailability should be assured through a product registration process. Additional laboratory tests, if reacquired should be done for imported products.
- Competent health authorities should decide level of expertise needed to prescribe drugs.
- Efficient administration of supply storage and distribution in the essential drug list is indeed reacquired for the success of ED program, government interventions may be needed to ensure availability of certain drugs .,special arrangement may be needed for drugs that have short half life and those which required refrigeration's.
- There should be well documented procurement policy based on records of turn over of drugs . This will ensure management of stocks and eliminate waste. (due to poor inventory control) and ensure continuity of supply.
- Research , both clinical and pharmaceutical is sometimes needed to settle the choice of a particular drug under local conditions.

SELECTION OF PHARMACEUTICAL DOSAGE FORM

Guidelines:

- General utility and wide availability of the dosage form.
Tablets have wide acceptability and are also cost-effective.
- Stability of dosage forms in different climate conditions.
- Established local preference.
- Considerations of bioavailability and pharmacokinetics of the dosage form.
- Convenient dosage form for convenient population.
- Sustained release or controlled release tablets have short half-lives, (*Example : Theophylline, Carbamezipine*) Which require special expertise for production and good level of understandings. Their inclusion and exclusion should be justified with adequate documentations.

QUALITY ASSURANCE

After selection of essential drugs and their appropriate dosage forms the next step is quality assurance of the drugs.

Quality assurance = product development+ GMP+subsequent monitoring of quality throughout its distribution chain

1.WHO certification scheme:

2.Bioavailability:

international pharmacopoeia

3.Nomenclature:

International Nonproprietary names(INN)

EG: Paracetamol = *N*-acetyl-*p*-aminophenol

Aspirin = 2-acetoxybenzoic-acid

MODEL LIST OF ESSENTIAL DRUGS

- Therapeutic class usually prefer , not necessarily in pharmacological class.
- Under each class , sub class eg:
 - Anaesthetics
 - local anaesthetics , general anaesthetics
- Most commonly used drugs and readily available drugs are only listed.
- formulations and doses are listed along with drugs.
- Many drugs in the list are preceded by a square symbol , to indicate they represent example of a therapeutic drug group.
- There are number in the parentheses following drug name, which indicate example

TASK AFTER THE FORMATION OF ESSENTIAL DRUG LIST(EDL)

1. Updating the ED list:
2. Essential drugs list for primary health care centers:
 - i. National health infrastructure
 - ii. The pattern of endemic diseases
 - iii. Supplies
3. Specialist control of drug use:

eg: Antibiotics, Drugs for TB and Leprosy, Antineoplastic and Immunosuppressive drugs

4. Research and development

- Pharmaceutical aspect:

Quality assurance, Procurement procedures, Processing and Packing Distribution system.

- Clinical and epidemiological aspects:

1. To assess safety and efficacy.
2. To assess benefit and safety of traditional and medicinal plants in that region.
3. To assess the effect of genetic and ethnic factors.

- Educational aspects:

1. Development training program in policy formation, quality control, information system.
2. Development of educational and training programmes for prescribers and other health cares.
3. Development of appropriate public education programmes, information programme on diagnosis early recognition of symptoms and use of correct self-medication.
4. Development of information booklets and leaflets for consumer education.

5. Drug information and educational activities:

1. make effective use of several WHO publications on “model prescribing information”
2. develop model formulary to complement model list of EDs
3. develop drug information sheets in EDL , to guide the prescriber to safe and effective use of drugs
4. educational activities such as drug information through universities and all

6. Making list of reserve antimicrobials:

“reserve antimicrobials”

(example from who reserve antimicrobials)

The Committee considered the following drugs and formulations essential for the treatment of multidrug-resistant tuberculosis, as de-fined above:

- amikacin: powder for injection, 1000mg in vial
- p-aminosalicylic acid: tablet, 500 mg; granules, 4 g in sachet
- capreomycin: powder for injection, 1000mg in vial
- ciprofloxacin: tablet, 250 mg, 500 mg
- cycloserine: capsule or tablet, 250 mg
- ethionamide: tablet, 125 mg, 250 mg
- kanamycin: powder for injection, 1000mg in vial
- levofloxacin: tablet, 250 mg, 500 mg
- ofloxacin: tablet, 200 mg, 400 mg.

- Examples:

Amoxicillin +clavulanic acid = beta-lactamase-inhibitor producing bacteria

Ceftriaxone = meningitis due to *staphylococcus pneumoniae*

Artemisin and its derivatives=malaria

7.Post registration drug studies:

Drugs used in practice will fail to produce benefit that was expected out of it

WHY???

- Clinical Trials do not include groups like children's, pregnant women, old people
- Variation in genetic and environmental factors
- Data on overdose and long term use are usually not available
- Poor manufacturing practices in some countries

RATIONAL USE OF DRUGS

“The appropriate timely use of drugs for an ailment which is properly diagnosed by physician and prescribed by a physician in right dosage of a right regimen and right duration of treatment”

Factors:

Self medications,

Medicines will take for small ailment.

Easily access to medications

Information's from peers and friends and compelling desire to avoid going to doctor.

Misuse and irrational use of drugs:

Self medication is undertaken because

- Easy accessibility to prescription drugs
- East access to OTC drugs
- “prescription only” drugs are easily available with out doctors prescription
- Advice by the friends, relatives, and person on medication
- Not filling the whole prescription
- Self decision regarding how and when to take the drugs

- Promotion or advertisements in newspaper, TV, radio by drug manufacturers
- Pharmaceutical marketing to prescribers
- False and misleading claims

Most frequently misused drugs:

- Self medications with out doctors prescription
- Potent drugs for small ailments or high dose of a potent drugs
- Drugs which are used for something , for which they are not meant
- Drugs which are not used according to the regimen

Examples:

ANTIBIOTICS

1. Pencillins- PENTID or PENTID-SULFA

2. ampicillin- for children's

3. amoxicillin- MOX, (sulphamethoxazole+cotrimoxazole)

4. ciprofloxacin- even doctors will prescribe with out proper indication

1. Aspirin- safe drug , taking in overdose may leads to ulceration and bleeding

2. Ibuprofen-commonly misused drug for pain.

3. Diclofenac –misuse for small ailment.

4. Nimeslide –after ibuprofen and Diclofenac most commonly misusing drug

CENTRAL NERVOUS SYSEM

- Diazepam- sedative drug.
- Lorazepam-most potent drug , often used when diazepam does not work
- Fluoxetine- top selling drug in over the counter in USA
- Domperidone-continue in prescription even after symptoms fade

ALIMENTARY DRUGS

- Antacids-over use of antacids constitute their irrational use, people often fail to understand what is acidity and confuse indigestion for it
- Antidiarrheal- Metronidazole single drug therapy is enough, but cipro+ metronidazole is prescribing.

RESPIRATORY SYSTEM DRUGS:

- Salbutamol-potent drug for asthma, but prescribed for common cold and bronchitis
- Codeine, dextromethorphan-narcotic analgesics, continues use may leads to addictive effects

OTHER MISCELLANEOUS DRUGS:

Anti- diabetic drugs:

Anti- hyperlipidemic drugs:

STEPS TO IMPROVE RATIONAL DRUG USE

PRESCRIBING RECOMMENDATIONS OF WHO FOR RATIONAL USE OF DRUGS

WHO recommends 12 key interventions in order to promote the rational use of drugs.

- Establishment of a multidisciplinary national body to coordinate policies on medicine use.
- Use of clinical guidelines.
- Development and use of National Essential Medicines List.
- Establishment of drug and therapeutics committees in districts and hospitals.
- Inclusion of problem-based pharmacotherapy training in undergraduate curricula.
- Continuing in-service medical education as a licensure requirement
Supervision, audit and feedback.

- Supervision, audit and feedback.
- Use of independent information on medicines.
- Public education about medicines.
- Avoidance of perverse financial incentives.
- Use of appropriate and enforced regulation.
- Sufficient government expenditure to ensure availability of medicines and staff.

WHO Drug use Indicators

I. Prescribing indicators

- * Average number of drugs per encounter
- * Percentage of drugs prescribed by generic name
- * Percentage of Encounters with an antibiotic prescribed
- * Percentage of encounters with an injection prescribed
- * Percentage of drugs prescribed from essential drug list or formulary.

II. Patient care Indicators

- * Average consultation time
- * Average dispensing time
- * Percentage of drugs actually dispensed
- * Percentage of drugs adequately labelled
- * Patients knowledge of correct dosage

III. Facility Indicators

- * Availability of essential drug list or formulary
- * Availability of key drugs.

IV. Complementary drug use indicators :

- * Percentage of patients treated without drugs.
- * Average drug cost per encounter.
- * Percentage of drug costs spent on Antibiotics.
- * Percentage of drug costs spent on Injections.
- * Prescriptions in accordance with treatment guidelines.
- * Percentage of patients satisfied with the care they received.
- * Percentage of health facilities with access to impartial drug information.

Guidelines for Rational Prescribing

- ❖ Define patient problem and establish therapeutic goal.
- ❖ Use drug only when indicated and when potential benefits outweigh the risk.
- ❖ Choose a drug of proven efficacy and safety and must be suitable for individual patient.
- ❖ Avoid using more than one drug of the same chemical class at the same time.
- ❖ Inform the patient.
- ❖ Monitor the effects of treatment.
- ❖ Decide whether the drug should be continued at the present dose or stopped.
- ❖ If treatment has not been effective, identify the reason.

Misuse of Antibiotics

- Common cold.
- Upper respiratory infection.
- Starting antibiotics without diagnosis.
- Frequently changing antibiotics.
- Giving suboptimal dose.
- Not completing the course of treatment.

Rational Use of Antibiotics

- Use antibiotics only when indicated.
- Before commencing antibiotic therapy, specimen for gram stain, culture, sensitivity testing should be obtained
- Choice should be based on suspected causative organism, safety, previous clinical response, cost, ease of use, potential for resistant organism.
- Adequate dose and duration of treatment.
- History of allergy or ADR.
- Prophylactic use of antibiotics restricted.
- Oral therapy preferred more than parenteral therapy.
- Antimicrobial combination should only be used where indicated
- More effective and least toxic.
- Topical antibiotics restricted to few proven indication.

Rational use of Injections

- Oral administration is not tolerated.
- Absorption problem.
- Drug of choice formulated as parenterals.
- High tissue concentration are needed.
- Urgent treatment required.
- Not comply with oral therapy.

Rational use of OTC drugs

- Patient desire for treatment
- Pharmacist desire
- Contraindication
- Drug interaction

Role of pharmacist contribute towards promoting the Rational use of Drugs

1. Member of Drug and Therapeutic Committee.
2. Drug procurement.
3. Drug storage.
4. Dispensing.
5. Patient education.
6. Drug information service.
7. Pharmaceutical care.

ROLE OF PHARMACIST IN PROMOTING RATIONAL USE OF DRUGS IN DISPENSING SETUP

- The Pharmacist shall keep all controlled drugs in a locked cabinet under his/her own direct supervision and control.
- The Pharmacist must check validity of the prescription and identity of the patient before dispensing
- The Pharmacist shall consult the prescribing doctor if there is any doubt about the prescription.
- The Pharmacist shall only dispense controlled drugs if the prescription provided by the physician is complete and valid.
- The Pharmacist shall properly label and mark containers to avoid undue intermixing that may cause harm to the patient.
- The Pharmacist shall provide complete information to the patient about the prescribed drug he /she is dispensing including cautions, warnings and clear direction for use.
- Under the current regulation, the pharmacist is not permitted either to refill or substitute a generically equivalent controlled drug unless instructed by the physician

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DEDICATING TO ALL PHARM.D. 2ND YEAR STUDENTS