Chapter

1

Pharmacotherapeutics

Q 1. Define pharmacotherapeutics? Give the scope and objectives of pharmacotherapeutics.

Pharmacotherapeutics

Pharmacotherapeutics is a branch of pharmacology that deals with the therapeutic uses and effects of drugs.

Scope of Pharmacotherapeutics

1. To increase the knowledge and upgrade the skills which are necessary for the safe use and medicine distribution by the pharmacists and nurses in hospital to the patients.
2. The study of pharmacotherapeutics improves the understanding of the concept of pharmacist working in retail shop for disease eradication and prescribed medicines.
3. It helps to understand the pathophysiology of common diseases and their management.
4. It helps to clear the basic concepts of person working in different diagnostic and pathology laboratories.
5. The knowledge of pharmacotherapeutics helps patients to gain their functional capacity and reduces the costs to both patients and society.

Objectives of Pharmacotherapeutics

1. To define the patient's problem for which treatment is indicated.
2. To prepare an appropriate therapeutic plans based on diagnosis.
3. To ensure patient's compliance.
4. To verify suitability of the choosen treatment.
5. To avoid medical errors.
6. To maximize the effects and minimize the side effects.

7. To summarize the possible therapeutic approach in disease management.
8. To understand the positive benefits of the drug therapy.
9. To discuss the preparation of individualized plans based on diagnosis.
10. To carry on ongoing assessment and continue or stop the treatment.

Q 2. Define 'rational use of medicines'. What are different ways of irrational use of medicines. Give the causes/reasons for irrational use of medicines.

Rational Use of Medicines

WHO defines rational use of medicines as "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community".

- It simply means, "prescribing right drug in adequate dose for a sufficient period of time and appropriate to the clinical needs of the patient at the lowest cost.
- Rational use of medicines is the process of safe, effective and rational dispensing and rational patient use.

Rational Use of Medicines

It includes:

- Right medicine
- Right indication
- Right dose
- Right route of administration
- Right duration
- Rightly dispensed
- Right patient counselling
- Right patient adherence

Irrational Use of Medicines

It includes:

- Unnecessary uses of antibiotics
- Unnecessary combination
- Incorrect dosing
- Incorrect route of administration
- Unnecessary use of supplementary drugs
- Selection of wrong drug
- Unnecessary use of expensive medicines

- Unsafe use of corticosteroids
- Polypharmacy
- Inappropriate self medication

Causes/Reasons for Irrational Use of Medicines

- Lack of information about the medicines
- Getting hurry and cure of the disease
- Role models of seniors
- Lack of diagnostic facilities
- Demand from the patients
- OTC drugs/self-medication
- Promotional activities of pharmaceutical industries
- Defective drug supply systems
- Poor regulation control on the supply of drugs

Q 3. What are the various strategies to promote rational use of medicines? Mention different steps/processes of rational use of medicines.

Strategies to Promote More Rational Use of Medicines

World Health Organization (WHO) advocates 12-key interventions to promote more rational use:

- 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.
- 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.

Steps of Rational Use of Medicines

Step 1: Identify the patient's problem based on symptoms and recognize the need for action.

Step 2: Diagnosis of the disease.

Step 3: List possible intervention or treatment (drug or no drug).
Step 4: Start the treatment by writing an accurate and complete prescription, e.g. name of drug with dosage forms, dosage schedule and total duration of the treatment.
Step 5: Give proper information, instruction and warning regarding the treatment given, e.g. side effects (ADR), dosage schedule and risk of stopping the therapy suddenly.
Step 6: Monitor the treatment to check, if the particular treatment has solved the patient's problem. There are two types of monitoring.

1. **Passive monitoring:** It is done by the patient himself. Explain him what to do if the treatment is not effective or if too many side-effects occur.
2. **Active monitoring:** It is done by physician and he make an appointment to check the response of treatment.

Q 4. What do you mean by 'evidence-based medicine'? Give objectives/significance/importance and five essential steps involved in evidence-based medicine.

Evidence-based Medicine (EBM)

"Evidence-based medicine is a systematic approach to medicine in which doctor and other health professionals use the current, best scientific evidence from clinical research to make decision about the care of individual patients".

Objectives of Evidence-based Medicine

1. To utilize current knowledge and connect it with patient preferences and clinical expertise to standardize and improve care process, and ultimately, patient outcomes.
2. To recognize an information needed while caring for a patient.
3. To identify the best existing evidence to help resolve the problems.
4. To integrate the evidence into a medical plan.

Importance/Significance of Evidence-based Medicine

1. The use of evidence-based medicine is crucial in maintaining quality medical care and ensuring good clinical outcomes.
2. It provides cost-effective medical care.
3. It promotes consistency of treatment and optimal outcomes.
4. It helps to establish national standards of patient care.
5. It keeps doctors and other healthcare professionals updated.
6. It identifies and promotes practices that work and eliminates those that are ineffective or harmful.

Steps Involved in Practice of Evidence-based Medicine

1. Framing answerable clinical questions.
2. Finding the evidence.
3. Appraising the evidence.
4. Applying the evidence.
5. Evaluating performance.

Q 5. Write a note on 'essential medicine list'.

Essential Medicines

Essential medicines are defined as the medicines that satisfy the priority healthcare needs of the population.

- The essential medicines should be available at all the times in adequate quantity and in appropriate dosage forms.
- The list of essential medicines needs to be updated periodically.
- Each country can prepare its own list of essential medicines based on disease burden, priority health concern of that country.

History of the Essential Medicine List

- In 1970, Tanzania became the first country to prepare essential medicine list (EML).
- The first WHO model list of essential medicines was published in the year 1977 which contained 186 medicines.
- The latest WHO model list of essential medicines is 22nd list published in 2021.
- The WHO model lists of essential medicines are updated every two years by the Expert Committee on Selection and Use of Essential Medicines.

Factors Considered for Selection of Essential Medicines

The following factors are considered for selection of essential medicines:

1. Incidence and prevalence of disease (public health relevance).
2. Efficacy, safety, and comparative cost-effectiveness of available medicines (price of total treatment is considered and not the unit price of a medicine).
3. The medicine should be aligned with the current treatment guidelines for the disease.
4. Level of healthcare facility available.
5. Treatment facilities available.
6. Training and experience of the available personnel.

7. Local availability of individual drugs.
8. Available financial resource.
9. Environmental factor/stability of the product.

Advantages of Essential Medicines Lists

1. An essential medicines list (EML) results in better quality of medical care, better management of medicines and cost-effective use of healthcare resources.
2. The essential medicines list has a positive impact on the availability and rational use of medicines.
3. The essential medicines list can be used as guidelines for the procurement and supply of medicines in public sector, schemes for reimbursement of drug costs and local drug production.
4. In hospitals, it improves the quality of prescribing and reduces the cost of patient care.

Q 6. Write a note on 'national list of essential medicines (NLEM)'.

National List of Essential Medicines (NLEM)

- The Ministry of Health and Family Welfare, Government of India prepared and released the first National List of Essential Medicines (NLEM) of India in 1996 consisting of 279 medicines.
- ICMR under Ministry of Health and Family Welfare, Government of India revises and publishes NLEM in India.
- NLEM 2021, is the latest list of essential medicines available in India contains 399 essential medicines.
- Union Health Minister Mansukh Mandaviya released NLEM 2021 on 2nd September, 2021.

Objectives/Purpose of the National List of Essential Medicines

1. Guide safe and effective treatment of priority disease conditions of a population.
2. Promote the rational use of medicines.
3. Optimize the available health resources.

It is also a guiding document for:

a. State governments to prepare their list of essential medicines.
b. Procurement and supply of medicines in the public sector.
c. Reimbursement of cost of medicines by organizations to its employees.

d. Reimbursement by insurance companies.
e. Identifying the '**must know**' domain for the teaching and training of healthcare professionals.

Criteria for Inclusion of Medicines in Essential List of Medicines

The criteria are as follows:

- The medicine should be approved/licensed in India.
- The medicine should be useful in disease which is a public health problem in India.
- The medicine should have proven efficacy and safety profile based on valid scientific evidence.
- The medicine should be aligned with the current treatment guidelines for the disease.
- The medicine should be stable under the storage conditions in India.
- When more than one medicine are available from the same therapeutic class, preferably one prototype/medically best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, cost-effectiveness.
- Price of total treatment to be considered and not the unit price of a medicine.
- Fixed dose combinations (FDCs) are generally not included unless the combination has unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.
- The listing of medicine in NLEM is based according to the level of health care, i.e. primary (P), secondary (S) and tertiary (T) because the treatment facilities, training, experience and availability of health care personnel differ at these levels.

Criteria for Deletion of Medicines in Essential List of Medicines

- The medicine has been banned in India.
- There are reports of concerns on the safety profile of a medicine.
- A medicine with better efficacy or favourable safety profiles and better cost-effectiveness is now available.
- The disease burden for which a medicine is indicated, is no longer a national health concern in India.
- In case of antimicrobials, if the resistance pattern has rendered a medicine ineffective in Indian context.

Q 7. What do you mean by 'standard treatment guidelines'? Give its advantages and disadvantages.

Standard Treatment Guidelines (STGs)

Standard treatent guideline (STG) is a systematically developed statement designed to assist practitioners and patients in making decision about appropriate healthcare for specific clinical circumstances.

- These are also known as standard treatment protocols (STPs), standard treatment schedules, therapeutic guidelines, prescribing policies.
- These guidelines are beneficial to healthcare providers, supply managers and health policy makers.

Benefits/Advantages of Standard Treatment Guidelines (STGs)

1. Provide standardized guideline to practitioners.
2. Provide the most effective therapy in terms of quality.
3. Encourage practitioners for high quality care.
4. The healthcare system needs to provide only the medicines as per formularly or list of essential medicines.
5. Provide valuable assistance to all practitioners, especially to those with lower-level skills.
6. Enable healthcare providers to concentrate on making the correct diagnosis because treatment options are available for them in the form of STG.
7. Provide a basis for evaluating quailtiy of care provided by the health care professionals.
8. Provide a system for cost controlling.
9. Can be a vehicle for integrating special programs (e.g. diarrhoea disease control, tuberculosis control, malaria, etc.) at the primary healthcare facilities using a single set of guidelines.
10. Help to manage drug supply system.

Disadvantages of Standard Treatment Guidelines

1. Inaccurate or incomplete guidelines will provide the wrong information for providers may be harmful.
2. Establishing, developing and implementing of STGs are very difficult, and time-consuming processes.
3. Updation of STGs is essential from time to time.
4. The extent of information to be pounded in each medical condition is often a difficult decision.
5. STG manual should be concise and small enough to carry it easily.

Q 8. What are the good characteristics/features of a successful STG manual?

Characteristics/Features of a Successful STG Manual

1. **Simplicity:** The number of health problems is limited to commonly observed conditions. Each clinical condition lists a few salient features with clear and concise information on pharmacological and nonpharmacological treatment.
2. **Credibility:** Guidelines developed by the most respected, experienced clinicians in the country and revision is based on actual experience.
3. **Treatment standards for all levels of health care facility:** Health care providers use the same standard treatment; however, the referral criterion differs. While the first-choice treatment for a patient depends upon the patient's diagnosis and condition and not on the prescriber.
4. **Medicine supply based on standards:** The supply of medicines must match with the standard treatment and list of essential medicines.
5. **Regular updating:** Any change in the therapeutic options, bacterial resistance pattern should be incorporated in the revised version to reflect current recommendations.
6. **User friendly:** The STGs should be published as small, durable pocket manual which make it convenient to carry and use.

SHORT ANSWER TYPE QUESTIONS 3 Marks

1. Define pharmacotherapeutics. Give the objectives of pharmacotherapeutics.
2. Define 'rational use of medicines'. Mention various reasons for irrational use of medicines.
3. What are evidence based medicines? Give the objectives and importance of EBM.
4. Define essential medicines. Which factors are to be considered while selection of essential medicines?
5. What is NLEM? Give the objectives/purpose of NLEM.
6. What are standard treatment guidelines (STGs)? Give the benefits of standard treatment guidelines.

OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS

1. The branch of pharmacology that deals with therapeutic uses and effects of drugs is known as **pharmacotherapeutics**.
2. EBM stands for **evidence-based medicine**.

3. **Essential medicines** are the medicines that satisfy the priority healthcare needs of the population.
4. In 1970, **Tanzania** became the first country to prepare essential medicine list (EML).
5. The first WHO model list of essential medicines was published in the year **1977** which contained **186** medicines.
6. The latest WHO model list of essential medicines is 22nd list published in **2021**.
7. The WHO model lists of essential medicines are updated every **two years**.
8. EML stands for **essential medicine list**.
9. NLEM stands for **national list of essential medicines**.
10. The first NLEM of India was released in **1996** consisting of **279** medicines.
11. **ICMR** revises and publishes NLEM in India.
12. Union Health Minister Mansukh Mandaviya released NLEM 2021 on **2nd September, 2021**.
13. FDCs stands for **fixed dose combinations**.
14. STGs stands for **standard treatment guidelines**.
15. Drugs that satisfy the priority health care needs of majority of the population, are called **essential medicines**.
16. The study of **pharmacotherapeutics** imports knowledge and skills necessary for contribution to quality use medicine.
17. The use of at least five drugs daily by an individual is **polypharmacy**.
18. The aim of **clinical pharmacology** is to generate data for optimum use of drugs and the practice of evidence-based medicines.
19. Standard treatment guidelines are also known as **standard treatment protocols**.
20. NGOs stands for **nongovernmental organizations.**