Program	**:**	B. Pharmacy
Name of Unit	**:**	Budget Preparation, Clinical Pharmacy, OTC sales
Subject /Course name	**:**	Pharmacy Practice
Subject/Course ID	**:**	BP 703T
Class: B.Pharm. Semester	**:**	VII
Module	**:**	IV
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Learning Outcome of Unit

LO	Learning Outcome (LO)	Course Outcome Code
LO1	Students will learn about Expenditure Of budget and Implementation of budget.	BP703.5
LO2	Students able to understand Therapeutic drug monitoring and pharmacist responsibilities	BP703.3
LO3	Students will learn about Pharmaceutical care plan and its functions	BP703.1
LO4	Students able to understand Rational Use and Safety Of OTC Pharmaceuticals.	BP703.6

Module Content Table

No.	Topic
1	Budget preparation and implementation:- Budget preparation and implementation
2	Clinical Pharmacy:- Introduction to clinical pharmacy, Concept of clinical pharmacy, Functions and responsibilities, Drug therapy monitoring- medication chart review, clinical review, pharmacist intervention, ward round participation, medication history and pharmaceutical care, Dosing pattern and drug therapy based on pharmacokinetic and disease pattern.
3	Over the counter (OTC) sales:- Introduction and sale of over the counter and rational use of common over the counter medications.

a) BUDGET PREPARATION AND IMPLEMENTATION

Budget preparation and its implementation are one of the important tasks of the pharmacy department of any hospital. It requires several factors into consideration like planning & strategy for maintenance and development etc. The word budget means the financial plan of a hospital for the period of a year. Budget is a quantity of plan of action and aid to the coordination and implementation of plan.

DEFINITION:- Budget is described as an instrument through which hospital administration, management at the department levels and the governing bodies can review the hospital services in relationship to the prepared plan in a comprehensive and integrated form expressed in financial terms.

OBJECTIVES:

a) Development of standards
b) Comparison of actual results with standards
c) Identification of deviation or fluctuation
d) Analysis of deviation
e) The responsible person will use the budget
f) Details to determine whether the proposal is economically feasible and realistic.
g) To monitor the hospital financial activities.
h) Estimate the cost of completing objectives identified in the proposal.

ADVANTAGES OF PLANNING THE BUDGET:

a) Develop better financial planning.
b) Gives a better focus on decision making to the management.
c) Effectively manage the financial aspects of the hospital
d) Exposes the reasons of over expenditure
e) Helps to focus on hospital priorities
f) Enhance efficiency of staffs and others

TYPES OF BUDGET PREPARATION:

Based on the duration of budget, it can be divided in to:

Short term budget (2 years)
Long term budget (5 - 10 years)

DIVISION OF BUDGETS:

1. Income accounts or revenue accounts

2. Expenditure accounts
3. Asking for capital investments

Income accounts or revenue accounts

1. Total income must be calculated for the implementation of the budget.
2. Pharmacy department or accounts department maintains daily, weekly, monthly & annualcost of the pharmaceuticals issued to the patient services.
3. The other statistic includes:

No of prescriptions
No of prescriptions dispensed by each pharmacist Hours of work put in Prescription volume per hour of service Medication cost per patient day Average drug cost per clinic visit Average salary cost per prescription Average supply cost per requisition

Expenditure accounts:

1. Administrative and general expenses.
2. Professional care of the patients.
3. Out-patients and emergency expenses.
4. Miscellaneous expenses.

The **expenditure accounts** include the following categories

1. Salaries and wages
2. Supplies and materials
3. Drugs and pharmaceutical expenses
4. Purchase expense
5. Equipment and construction budget
6. Miscellaneous supplies and expenses.

1. Salaries and wages

Salaries and wages include complete break-up of all salaries and wages paid to permanent and temporary staff (Full-time and Part-time).

The chart should be prepared in tabular form so as to give an overall view at a glance.

The Chief Pharmacist/Administrator should sub-divide the staff into three important categories like administration, professional and non-professional staff. The total of all three expenses constitutes the anticipated salary and wages, expenditure for next year.

2. **Expenses of supplies & materials**:

1. Chief pharmacist or the responsible person should prepare the financial statement

regarding the requirement of amount in rupees for supplies and materials with the help of the latest financial budget.
2. Necessary to show the actual cost of the materials.
3. If the budgeted figure and the previous figure was the same then the previouslyprepared budget was well prepared.

3. Drugs and pharmaceuticals:
Preparations are categorized as those dispensed by hospital pharmacy or those used in the OPD, emergency and other departments.

4. Purchase expense:
It includes the cost of prescriptions purchased from an outside pharmacy.

5. Equipment and construction budget:
In hospital always a separate budget is prepared for equipments and for construction because it requires major monetary funds. While preparing budget for machinery, equipments both professional and administration take depreciation values into consideration. Therefore, budgetfor immediate arrangements of a new model equipment and budget for remodeling and replacement of equipment are considered.

6. Miscellaneous supplies and expenses.
Miscellaneous supplies and expenses include glasswares, labels, stationary, uniform, repair and maintenance etc. In practice, there should be a close liaison between the Chief Pharmacist and accounts department for maintenance of statistical data.

IMPLEMENTATION OF BUDGET

It includes the following parameters

1. Requirement of different departments
2. Actual fund position
3. Utility of particular item
4. Cost of products
5. Quantity of product

FACTORS AFFECTING BUDGET:

- Local conditions and compulsion
- Management policy
- Confidence of higher authorities
- Ability of higher authorities

b) CLINICAL PHARMACY

Introduction to Clinical Pharmacy

Definition: Clinical pharmacy is defined as the branch of pharmaceutical science dealing with utilization of pharmacist knowledge, skills and judgments related to biomedical and pharmaceutical sciences, to prove the safety, the cost and the precision of the drug usage in thepatient care.

Development of Clinical Pharmacy:
In developed countries like United States of America. Canada etc.
□ Clinical Pharmacy has already taken good shape. In India, it is in the infancy stage.

□ The role of the retail pharmacist is viewed by many people as simply transferring pills from alarge bottle to a small one - counting tablets, typing labels and calculating the price.

□ Much of his time is seen as devoted to routine merchandising of cosmetics, skin, hair, dentalproducts, stationery and other commodities which have little or no relation to health care.

□ India stands among top fifteen in the world in pharmaceutical market with respect topharmaceutical production, exports, imports etc.

□ There is still a need to develop the concept of clinical pharmacy.

□ Today there is 'drug-explosion' and 'information explosion' in relation to the drugs.

□ On one hand there is development of newer and more-effective drugs and on other hand theirpotential hazards of side effects are on rise.

SCOPE OF CLINICAL PHARMACY:

Clinical pharmacy has emerged as one of the latest branches of pharmacy in 21st Century. It is where pharmacists deal with various aspects of patient care, dispensing of drugs and advising patients on the safe and rational use of drugs. It can also be explained as a part of pharmacy in which the clinical pharmacist provides patient care that optimizes the use of medication and promotes health, wellness, and disease prevention. To elaborate the story we can say that clinical pharmacy is to use drug control and the effective application of the knowledge. Professional skills and ethics assure the optimal safety in the distribution and use of medicine. The purpose of the Professional Education in Clinical Pharmacy and Public Health is to qualify each pharmaconomist (expert in pharmaceuticals) to practice

clinical pharmacy at a higher and more professional level. Hence, ensures the patient's maximum well-being during the drug therapy.

Clinical pharmacy describes the new role of the 21st Century's pharmacists. It doesn't restrict the role of a pharmacist merely to good manufacture practices, easy procurement, proper preparation, distribution and control of drug products. In addition, it also comprises functions necessary to discharge a particular set of social responsibilities related to proper therapeutic use of drugs in the aspects like prescribing, dispensing and administrating drugs, documenting professional services, direct patient involvement, reviewing drug use, education, consultation and counseling. The aim of clinical pharmacy practice is to ensure the patient's maximum well-being and to play a meaningful role in the safe and rational use of the drugs. These goals are to enable the physician do a better job of prescribing and monitor the drug therapy for patient. Further, to help the medical and para-medical staff to enable effective drug therapy. Clinical pharmacy practice also deals with proper maintenance of the documentation regarding the medication incidents effectively to maximize the patient's compliance in drug use process.

Qualities of clinical pharmacist Clinical pharmacists care for patients in all health care settings but the clinical pharmacy movement initially began inside hospitals and clinics. Often collaborate with physicians and other healthcare professionals. Pharmacists should be well- versed with the common language used by the people in order to communicate with the patient and co-professionals easily and effectively. Pharmacists are also expected to have thorough knowledge of the etiology of the disease, its signs, symptoms, pathophysiology, diagnostic tests, pharmacokinetics, etc. Proper clinical training should be given to the clinical pharmacist to provide information regarding rational drug use, drug therapy and drug doses.

Condition for a clinical pharmacy -A clinical pharmacy professional should appreciate the role of medical and para-medical staff. There should be enough bondage between the physician and the pharmacist to visit the patients together. All of the medical staff should develop an inter- professional relationship to enhance the quality of patient care. Further, there should be a deep sense of responsibility in the clinical pharmacist with respect to medical care. It helps in maintaining proper patient history and gaining confidence. As drug therapy is an ongoing process it needs to be checked by the clinical pharmacist timely. It may be changed according to the patient's condition and requirement.

Health care team and a clinical pharmacist There are certain laid roles and responsibilities of a clinical pharmacist in a health care team that consists of several medical and para-medical professionals. These responsibilities should be executed by the clinical pharmacist with immense care. The clinical pharmacist should interact with the patients and maintain their complete and exhaustible medical history. The clinical pharmacist should also do proper documentation of the hypersensitivities or allergy to certain drugs, food habits, drug dependence or intoxications to certain chemical substances, side effects of some drugs, incorrect drug administration, etc about the patient. The prescribed drugs may interact with certain OTC drugs; therefore, after receiving the prescription the clinical pharmacist should

check the patient's medical history for drug related interactions and patient's habits. This helps in effective and accurate medical therapy.

In the selection of a proper drug product/generic formulation (depending on the bio-availability and equivalence of such products) the clinical pharmacist can help the physician. Clinical pharmacist can help in monitoring of drug therapy to ensure safety and efficacy. Monitoring of the drug therapy is very important particularly for those drugs that have narrow therapeutic index or administered chronically. Various pharmacokinetic parameters can also be checked by the clinical pharmacist based on: plasma concentration of drug, enzymes and measurement of glucose quantity in blood, etc.

Patients with kidney impairment or hepatic disorders are more prone to adverse drug reactions. Clinical pharmacist can help in detection, prevention and reporting of adverse drug reactions. He may advice the physician for alternate drug therapy for the concerned patients. Clinical pharmacists may play a major role in designing health and drug policies, and assist as a source of information for the health care professionals and to the public. The drug management greatly relies on the clinical pharmacist to check the selection, requirement, procurement, distribution and use of the drugs. Also, research and development in the field of biological availability of active ingredients requires active participation by the clinical pharmacists. The clinical pharmacist can help in executing clinical trials and based on standard principles and bio- statistical evaluation. A clinical pharmacist is an expert to provide detailed information to the health professionals and the general public. Effective selection, utilization and retrieval of drug literature by the clinical pharmacist can enable in the proper understanding of the facts by the medical team. He can also abstract information from periodic bulletins, newsletters or other pharmacy literature.

Scope of clinical pharmacy in India In hospitals the services regarding clinical pharmacy are of considerable value because the concerned clinical pharmacist serves as a guide to the physician for safe and rational use of drugs. He also assists to achieve economy in the hospital by planning safe drug policies, suggestive means of reduction of waste, by preventing misuse or pilferage of drugs. In addition to it the preparation of preventing forecasting future drug requirements of the hospital, based upon their drug utilization patterns. Therefore, scope of clinical pharmacy covers areas to foster innovation, improve public health and provide a knowledge exchange. Clinical pharmacist enables rational drug use by providing correct drug information including the proper utilization of the drugs utilized as drug therapy, along with all the precautions to be taken as indicated or asked by the pharmacist or the physician. It discourages any irrational or reckless use of drugs and also, concerns with the procurement of the drugs into the market from the industry and their channelization to the patient for use. Clinical pharmacy also deals with ensuring safety and efficacy of the drugs after marketing. Safety can be evaluated by means of non-experimental research, whereas evaluation of efficacy in a variety of settings representing normal medical practice generally requires experiments, randomized and blinded. National or International markets are flooded with tens of drug combinations, low therapeutic value products

or duplicate brand names. Thus, under this study it is clarified how to choose the correct drug for administration or treatment.

Functions and responsibilities of clinical pharmacist

- Collection of patient data
- Identification of problems
- Establishing outcome goals through a good therapeutic plan
- Evaluating treatment alternatives by monitoring and modifying therapeutic plan
- Individualizing drug regimens
- Monitoring outcomes

COLLECTION OF PATIENT DATA:

- □ Demographics
- □ Current problems
- □ Past medical history
- □ Current medication
- □ Social habits
- □ Relevant laboratory data
- □ Subsequent modifications of therapy plan

IDENTIFICATION OF PROBLEMS:

- □ The data collected can be used to identify actual or potential drug related problems.
  - □ ACTUAL: A condition that requires the initiation of a new or additional drug.
  - □ POTENTIAL: The patient may be at risk to develop a new medical problem.
- □ These problems may be related to the patient's current drug therapy, drug administration, drug compliance, drug toxicity, ADR's and a failure to achieve desired outcomes by thetreatment.

ESTABLISHING OUTCOME GOALS:

- □ Drug therapy can produce positive outcome:
  - □ Cure of the disease
  - □ Elimination or reduction of patient's symptomology
  - □ Arresting or slowing of a disease process
  - □ Preventing a disease or symptoms
  - □ It may also produce negative result, i.e. resulting in disease morbidity and sometimesmortality.

EVALUATING TREATMENT ALTERNATIVES BY MONITORING AND MODIFYING THERAPEUTIC PLAN:

- Efficacy, safety, availability and cost of treatment and suitability of the treatment to thepatient should be considered while evaluating.
- The risk-benefit ratio factors should also be considered: seriousness of the disease,complications if untreated, efficacy of drug, ADR's.

INDIVIDUALISING DRUG REGIMENS:

- When more than one therapeutic alternatives exist, the following factors to be considered:
  - Patient factors:- diagnosis, treatment goals, past medical and medication history,contraindication, allergies, compliance
  - Drug factors:- efficacy, adverse effects, dosage form, cost, drug-drug interactions

MONITORING OUTCOMES:

- The goals are: Cure of the disease, elimination or reduction of patient's symptomology,arresting or slowing of a disease process, preventing a disease or symptoms.
- But often leads to suboptimal outcomes due to:- inappropriate or unnecessary prescribing ordrug regimen, dispensing error, non-compliance, inappropriate monitoring.
- To ensure good monitoring outcomes;
  - Regularly should review whether satisfactory progression is made or not according tothe therapeutic plan.
  - To determine whether original plan should continue or any treatment modifications tobe made or not.
  - Reviews ongoing progress and provides report to patient's other healthcare providers. Should regularly update patient's medical/pharmacy records with information concerningpatient's progress.

PHARMACEUTICAL CARE IN HOSPITALS:

- Prescription monitoring
- Prescribing advice to medical and nursing staff
- Medication errors and adverse reaction monitoring
- Medication history interview
- Patient education and counselling
- Pharmacokinetics and therapeutic drug monitoring Hospital formulary

PHARMACEUTICAL CARE FOR THE COMMUNITY:

- Participate in health screening
- Participate in health promotion and education
- Serve as a source of drug and poison information
- Collaborate with other health care professionals to develop treatment guidelines
- Design and monitor procurement and drug distribution system including storage anddisposal.

BARRIERS TO PHARMACEUTICAL CARE:

- □ Pharmacist barrier
- □ Practice setting constraints
- □ System impediments
- □ Intra professional barrier

DRUG THERAPY MONITORING

□ Drug therapy monitoring, also known as Therapeutic Drug Monitoring (TDM), is a means ofmonitoring drug levels in the blood.

□ Therapeutic drug monitoring (TDM) refers to the measurement and interpretation of principally blood or plasma drug concentration measurements with the purpose of optimising apatients drug therapy and clinical outcome while minimising the risk of druginduced toxicity.

□ TDM involves tailoring a dose regimen to an individual patient by maintaining the plasma orblood concentration within a particular range.

To achieve optimal drug therapy 3 objectives should be met:

- To attain desired pharmacological effect of the drug.
- To reach the maximal effect in shortest possible time.
- To decrease the risk of toxicity.

TDM is useful in drugs:

- With a narrow therapeutic index.
- Which are highly protein bound.
- Which are liable to interact.
- In which the metabolite might be toxic.

Drug therapy monitoring is an ongoing process in which pharmacists actively review patients' records, identify and resolve drug therapy problems such as adverse drug events (ADEs), and communicate with prescribers when problems occur. Pharmacists educate patients and their caregivers about potential adverse effects and work with patients to ensure adherence to therapyand attainment of therapeutic goals.

MEDICATION CHART REVIEW

f It is a fundamental responsibility of a pharmacist to ensure the appropriateness of medication orders.

*It serves as starting point for other clinical pharmacy activities (medication counselling, TDM,DI, and ADR).
*Organizing information according to medical problems (example disease) helps breakdown a complex situation into its individual parts.

GOALS:
1. To optimize the patients drug therapy.
2. To prevent or minimize drug related problems/medication errors.

PROCEDURE:
The patient's medical record should be reviewed in conjugation with the medication administration record.
Recent consultations, treatment plans and daily progress should be taken into account when determining the appropriateness of current medication orders and planning each patient's care.
All current and recent medication orders should be reviewed.

COMPONENTS OF MEDICATION ORDER REVIEW include:
1. Checking that medication order is written in accordance with legal and local requirements.
2. Ensuring that the medication order is comprehensible and unambiguous, that appropriateterminology is used and that drug name are not abbreviated. Annotate the chart to provide clarification as required.
3. Detecting orders for medication to which the patient may be hypersensitive/intolerant.
4. Ensuring that medication order is appropriate with respect to:
    a) The patient's previous medication order.
    b) Patient's specific considerations e.g disease state, pregnancy.
    c) Drug dose and dosage schedule, especially with respect to age, renal function,liver function.
    d) Route, dosage form and method of administration.
5. Checking complete drug profile for medication duplication, interactions or incompatibilities.
6. Ensuring that administration times are appropriate e.g. with respect to food , otherdrugs and procedures.
7. Checking the medication administration record to ensure that all ordered have beenadministered.
8. Ensuring that the drug administration order clearly indicates the time at which drugadministration is to commence.
9. special considerations should be given especially in short course therapy as inantibiotics and analgesics.
10. Ensuring that the order is cancelled in all sections of medication administrationrecord when the drug therapy is intended to cease.

11. If appropriate follow up of any non-formulary drug orders, recommending a formularyequivalent if required.
12. Ensuring appropriate therapy monitoring is implemented.
13. Ensuring that all necessary medication is ordered. E.g. premedication, prophylaxis.
14. Reviewing medication for cost effectiveness.
15. Identification of drug related problems.
    - Untreated indication.
    - Inappropriate drug selection.
    - Sub therapeutic dose.
    - Adverse drug reaction.
    - Failure to receive drug.
    - Drug interactions.
    - Drug use without indication.
    - Overdosage.

MEDICATION CHART ENDORSEMENT

Another important goal of treatment char review is to minimise the risk of medication errorsthat might occur at the level of prescribing and / or drug administration.

A medication error is any preventable error that may lead to inappropriate medication useor patient harm.

To prevent potential morbidity and mortality associated with these errors, pharmacists should systematically review the medication chart and write annotations on the chart where the medication orders are unclear.

CLINICAL REVIEW:

Clinical review is one of the integral components of medication review and should preferably be performed on a daily basis. It is the review of the patients' progress for the purpose of assessing the therapeutic outcome.

The therapeutic goal for the specific disease should be clearly identified before the review.

GOALS:

The primary aims of the clinical review are to:

- Assess the response to drug treatment.
- Evaluate the safety of the treatment regimen.
- Assess the progress of the disease and the need for any change in therapy.
- Assess the need for monitoring, if any.
- Assess the convenience of therapy(to improve compliance).

PHARMACIST INTERVENTION

ROLE OF PHARMACIST

A reliable and responsive TDM service depends on team work between nurses, doctors, pharmacist, scientist and technical staff. The clinical pharmacist should provide advice to medical staff on the appropriate use and timing of TDM and assist with the interpretationof results.

In addition the pharmacist maybe involved in :

• Initial selection of drug regimen: this may involve decisions about drug choice, dose, dosing interval, route of administration and dosage form of the drug, taking into account factors such assex, age, body weight, race, metabolism status, renal function, plasma albumin concentration, use of other drugs and laboratory results.

Adjustment of the dosage regimen based on TDM results and the patients clinical response.

□ Assessment of possible causes for unexpected results, such as non- compliance, bioavailabilityproblems, medication errors, drug interactions or pharmacogenetic variability.

□ Dose adjustment for patients on haemodialysis or peritoneal dialysis.

□ Provision of poisons information.

WARD ROUND PARTICIPATION

A ward round is a visit made by a medical practitioner, alone or with a team of health professionals and medical students, to hospital inpatients at their bedside to review and follow up the progress in their health. Usually at least one ward round is conducted every dayto review the progress of each inpatient, though more than one is not uncommon. In certain practice settings such as psychiatry, the "ward round" may be conducted away from the patient's bedside in a non-traditional fashion, where the team meets elsewhere to review eachcase.

Goals and objectives for clinical pharmacists on ward rounds:

As an important member of the healthcare team, pharmacists should attend ward rounds and clinical meetings whenever possible. This enables pharmacists to contribute prospectively to patient care through the provision of drug therapy. The goals of a clinical pharmacists participation in ward rounds are to:

- Gain an improved understanding of patient's clinical status and progress, currentplannedinvestigations and therapeutic goals.
- Provide relevant information on various aspects of the patient's drug therapy such as pharmacology, pharmacokinetics, drug availability, cost, drug interactions and adversereactions.
- Optimize therapeutic management by influencing drug therapy selection, implementation,monitoring and follow-up.

- Investigate unusual drug orders or doses.
- Assimilate additional information about the patient such as co-morbidities, medicationcompliance or alternative medicine use that might be relevant to their management.
- Detect adverse drug reactions and drug interactions.
- Participate in patient discharge planning.

Ward round participation also provides many learning opportunities for pharmacists. It allows pharmacists to see firsthand how drugs are used and prescribed and to see the effects of these drugs on patients. With time, pharmacists develop an appreciation of how the patient's own wishes and their social, cultural and economic circumstances may influence therapeutic choices. Even for experienced clinical pharmacists in teaching hospitals, it is very rare to finish a ward round without gaining new perspectives on some aspect of therapeutics or patient care. For those involved in academia and research, ward rounds allow identification of cases for clinical teaching and publication. Not the least, ward round participation strengthens the inter-professional relationship among various health professionals, leading to better healthcare practice and research.

MEDICATION HISTORY

A medication history is a detailed , accurate and complete account of all prescribed and non-prescribed medications that a patient had taken or is currently taking prior to a initially institutionalized or ambulatory care .

It provides valuable insights in to patient's allergic tendencies , adherence to pharmacological and non-pharmacological treatments and self medication with complementary and alternative medicines .

Interviewing a patient in collecting the data medical history is called medication history interview.

Importance of accurate drug history

1. Preventing prescription errors and consequent risk to patients.
2. Useful in detecting drug –related pathology or changes in clinical signs that may be the resultof drug therapy.
3. It should encompass all currently and recently prescribed drugs, previous adverse drug reactions including herbal or alternative medicines and adherence to therapy for better care plan.

Goals

The goal of medication history interview is to obtain information on aspects of drug use thatmay assist in over all care of patient . The information collected can be utilized to :

1.Compare medication profile with the medication administration record and investigate the discrepancies .

2.Verify medication history taken by other staffs and provide additional information where appropriate.

The following information is commonly recorded:
1.Currently or recently prescribed medicines
2.OTC medication
3.Vaccinations
4.Alternative or traditional remedies
5.Description of reactions and allergies to
medicine6.Medicines found to be ineffective
7.Adherence to past treatment and the use of adherence aids

Information sources
1.Patient
2.Family or caregiver
3.Medication vials / bubble
packs4.Medication list
5. Community pharmacy
6.DPIN (Drug programs information network)

Question to Ask
•Which community pharmacy do you use?
•Any allergies to medications and what was the reaction ?
•Which medications are you currently taking:
•The name of the medication
•The dosage form
•The amount (specifically the dose)
•How are the taking it(by which route)
•How many times a day
•For what reason
•What prescription medications are you taking on a regular basis or as needed basis?
•What over the counter medications are you taking on a regular or as needed basis?
•What herbal or natural medicines are you taking on a regular or as needed basis?
•What vitamins or other supplement are you taking?
•Have you recently started any new medicines?
•Did a doctor change the dose or stop any of your medications recently?
•Did you change the dose or stopped any of your medications recently?
•Are any of the medications causing side effects
•Have you change the dose or stopped any medications because of unwanted effects ?
•Do you sometimes stop taking your medicine whenever you feel better?
•Do you stop taking your medicine if it makes you feel worse?

Pharmaceutical Care

Pharmaceutical Care is a patient-centered, outcomes oriented pharmacy practice that requires thepharmacist to work in concert with the patient and the patient's other healthcare providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective.

The goal of Pharmaceutical Care:

The goal of Pharmaceutical Care is to optimize the patient's health-related quality of life, and achieve positive clinical outcomes.
A structured approach to achieve these goals:

1) It requires an established patient-to pharmacist relationship.
2) It requires records of medication to be kept and, with the patient's informed consent, additional patient specific information to be collected, organized, recorded, monitoredand maintained.
3) It requires patient-specific medical information to be evaluated and, in the case of prescribed medicines, a therapy plan to be developed involving the patient and the prescriber.
4) It requires the pharmacist to ensure that the patient has all supplies, information, andknowledge, necessary to carry out the drug therapy plan.
5) It requires the pharmacist to review, monitor, and modify the therapeutic plan in concertwith the patient and healthcare team.

Elements to provide quality pharmaceutical care are:

(1) Knowledge and skills of personnel,
(2) Systems for data collection, documentation, and transfer of information,
(3) Efficient workflow processes,
(4) References, resources and equipment,
(5) Communication skills,
(6) Commitment to quality improvement and assessment procedures.

1) Knowledge and skills of personnel

The implementation of pharmaceutical care is supported by knowledge and skills in thearea of patient assessment, clinical information, communication, adult teaching and learning principles and psychosocial aspects of care.

To use these skills, responsibilities must be reassessed, and assigned to appropriate personnel, including pharmacists, technicians, automation, and technology. A mechanism of certifying and credentialing will support the implementation of pharmaceutical care.

2) Systems for data collection and documentation

The implementation of pharmaceutical care is supported by data collection and documentation systems that accommodate patient care communications (e.g. patient contact notes, medical and medication history), inter-professional communications (e.g. physician communication, pharmacist-to-pharmacist communication), quality assurance(e.g. patient outcomes assessment, patient care protocols), and research (e.g. data for pharmacoepidemiology, etc.). Documentation systems are vital for reimbursement considerations.

3) Efficient workflow processes

The implementation of pharmaceutical care is supported by incorporating patient careinto the activities of the pharmacist and other personnel.

4) References, resources, and equipment

The implementation of pharmaceutical care is supported by tools, which facilitate patient care, including equipment to assess medication therapy adherence and effectiveness, clinical resource materials, and patient education materials.

Tools may include computer software support, drug utilization evaluation (DUE) programs, disease management protocols, etc.

5) Communication Skills

The implementation of pharmaceutical care is supported by patient-centered communication. Within this communication, the patient plays a key role in the overall management of the therapy plan.

6) Quality Assessment/ Improvement Programs

The implementation and practice of pharmaceutical care is supported and improved by measuring, assessing, and improving pharmaceutical care activities utilizing the conceptual framework of continuous quality improvement.

PRACTICE PRINCIPLES OF PHARMACEUTICAL CARE

Pharmaceutical care involves the process through which a pharmacist cooperates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

Dosing pattern or Drug dose frequency is called dosage regimen. Designing the correct dosage regimen is important for achieving the desired therapeutic efficacy and avoiding undesired effects. Because of significant homogeneity among humans, the dosage regimen is calculated on a population basis. Despite the same dose of drug, it produces variations in pharmacological response, which is generally attributed to intersubject variability . This intersubject variability leads to pharmacokinetic or pharmacodynamic variations for the same drug administered in the same frequency in different individuals**.**

Various factors like metabolizing enzymes, interactions (drug–drug, herb–drug, food–drug), multiple treatments, and dosage regimen affect the drug disposition. Enzymes regulate metabolism, interactions alter pharmacokinetic or pharmacodynamic parameters, genetic factors may produce individual variation, etc., hence resulting in drug disposition, and also transporters are involved in the disposition process. Proteins are the transporters in drug disposition.

DIFFERENT TYPES OF DOSES

Effective dose: It is the amount of drug which will produce specific intensity of effect i.e.; eitherto treat the disease or prevent the disease successfully.

Median effective dose (ED50): It is the amount of a drug which produces the desired therapeutic effect in 50% of experimental animals

OR

□ It is the dose of a drug required to produce a specific intensity of effect in 50% of individuals

□ It is measure of effectiveness of a drug.

Lethal dose: It is the amount of a drug which will kill certain percentage of experimental animalsto whom the drug is administered

Fatal dose: When lethal dose reaches 100%

orLD_{100} is known as fatal dose

Median lethal dose (LD50): It is the amount of a drug which is fatal to 50% of the experimentalanimals

□ [i.e.; which kills 50% of the experimental animals]

□ It is the measure of acute toxicity of drugs

Initial loading dose: In some conditions certain drugs are given in large doses in the beginning toobtain an effective blood level rapidly, this is known as initial loading dose.

Maintenance dose: After achieving a desired blood level by initial loading dose, smaller quantity of drug is then required to maintain the blood level, this is known as maintenance dose.

□ Loading Dose: Dose = $Cp_{(Target)}$ x V_dMaintenance Dose = CL x $CpSS_{av}$

□ $CpSS_{av}$ is the target average steady state drug concentration

□ The units of CL are in L/hr or L/hr/kg

□ Maintenance dose will be in mg/hr so for total daily dose will need multiplying by 24.

DOSAGE ADJUSTMENT IN RENAL AND HEPATIC DISEASE

Adjustment of Dosage in Renal Impairment:

□ In patient with renal failure, the half life of the drug is increase and its clearance drasticallydecreases if it is predominantly eliminated by way of excretion.

□ Hence , dosage adjustment should take into account the renal function of the patient and thefraction of unchanged drug excreted in urine.

□ There are two additional method for dose adjustment in renal insuffiency if the Vd change isassumed to be negligible.

General Approach:

□ No change in the desired or target plasma concentration.

□ Diminished renal clearance but unchanged non-renal clearance.

□ Unaltered drug protein binding & volume of distribution in the renally impaired patient.

□ Unchanged drug absorption from the GIT.

Three Major Approaches are:

□ Dose adjustment based on Total body clearance.

□ Dose adjustment based on Elimination rate constant or half life.

□ Dose adjustment in renal failure.

Dose adjustment based on Total body clearance:

The average drug conc. at steady-state css,av is a function of maintenance dose X0 , the fractionof dose absorbed F, the dosing interval & ꞇclearance Cl T of the drug.

$$Css,av = Fxo / ClT ꞇ$$

Dose adjustment based on Elimination rate constant or Half life:

The average drug conc. at steady-state css,av is a function of maintenance dose X0 , the fraction of dose absorbed F, the dosing interval & ↑ volume of distribution vd & t1/2 of the drug.

Css, av =1.44 FXo t ½ Vd ↑

□ Diseases are the major source of variation in drug response.

□ Both pharmacokinetic and Pharmacodynamic of many drugs are altered by disease other than the one which is being treated.

Disease state:

□ Renal dysfunction - It greatly impair the elimination of drug especially those that are primarily excreted by the kidney. Causes of renal failure are hypertension, diabetes mellitus.

□ Uremia - It is characterized by impaired glomerular filtration and accumulation of fluid and protein metabolism. In both the cases the half life of the drug are increased as a consequencesdrug accumulation and toxicity increases.

Adjustment of Dosage in Hepatic Impairment:

□ The influence of Hepatic disorder on the drug bioavailability & disposition is unpredictable because of the multiple effects that liver produces.

□ The altered response to drugs in liver disease could be due to decreased metabolizing capacityof the hepatocytes, impaired biliary elimination, due to biliary obstruction.

□Impaired Hepatic blood flow leading to an increase in bioavailability caused by a reduction in first pass metabolism (e.g Bioavailabilities of Morphine and Labetalol have been reported to double in patients with Cirrhosis)

□ Decreased protein binding and increased toxicity of drugs highly bound to plasma protein (e.g. Phenytoin, Warfarin) due to impaired albumin production, altered volume of distribution of drugs due to increased extracellular fluid (e.g. Rifampicin accumulates in obstruction jaundice).

□ Oedema in liver disease may be increased by drugs that cause fluid retention (e.g. Acetylsalicylic acid, Ibuprofen, Prednisolone, Dexamethasone).

□ Generally , drug doses should be reduced in patients with hepatic dysfunction since clearance is reduced & bioavailability is increased in such a situation.

c) OVER THE COUNTER (OTC) SALES

OTC drugs are those drugs which are safe and effective for use by the general public without adoctor's prescription.

- It is also called prescription de controlled drugs.
- These drugs are the non prescription or over-the-counter drugs.
- These have little significant pharmacological activity and therefore the physician neednot to be very much concerned about their use by the patients themselves.
- It is used primarily for symptomatic relief and not as substitutes for prescription drugs.

SIGNIFICANCE

- Comparatively cheaper
- Chemist himself may prescribe OTC
- Consumers are able to
  - Self diagnose
  - Self treat
  - Self manage
- OTC considered as time saving medications. Some patients do not want to spend muchtime at physicians clinic.
- Lesser number of side effect compared to prescription medications.

Drugs Used by Indians

Over-the-counter drug products account for 55 percent of drugs used by Indians, whereas Prescription Drugs account for 45 percent

TYPES OF OTC MEDICATIONS

- ANALGESICS
- ANTIBIOTICS
- COUGH SUPPRESSENTS
- ANTI ACNE DRUGS
- NSAIDS
- ANTISEPTICS
- DECONGESTANTS
- ANTACIDS

- ANTIFUNGALS
- ANTI HISTAMINES
- SMOKING CESSATION DRUGS

RULES FOR THE PROPER USE OF OTC DRUGS

- Always know what you are taking.
- Know the effects.
- Read and heed the warnings and cautions.
- Don't use anything for more than 1 to 2 wks.
- Be particularly cautious if also taking prescription drugs.
- If you have questions, ask a pharmacist.
- If you don't need it, don't use it!

SPECIAL PATIENT GROUPS

Many patient groups may be particularly susceptible to adverse events that are caused by OTCproducts.

They include:

- Children
- Women who are pregnant or breast feeding
- Geriatric patients
- People taking prescription drugs & people having health problems

OTC MEDICATIONS ARE SAFE BUT NOT RISK-FREE

As with all medications, there can be risks with use.

The risks of OTC use include:

- Delay in seeking medical advice for a serious illness.
- Risk of drug-drug/herbal/dietary supplement interactions.
- Risk of adverse events.
- Potential for dependence, misuse and abuse.

MISUSE AND ABUSE OF OTC DRUGS

- Physical dependence
- Psychological dependence
- Nonprescription products that can be severely habit-forming: decongestants, laxatives,antihistamines, sleep aids, antacids and ephedrine.
- Only 16% reads the entire product label.
- If they read them they do not follow the directions on the label.

Abuse is most common in adolescents aged 10-17 years. Adolescents are 18% times more likelyto die from an OTC overdose than from a illicit drug dose overdose.

RATIONAL USE OF OTC DRUGS

Rational use of medicines refers to the correct, proper and appropriate use of medicines. Rational use requires that patients receive the appropriate medicine, in the proper dose, for an adequate period of time and at the lowest cost.

ANALGESICS

Pain relief medicines (also known as "analgesics" and "painkillers") are regulated by the Food and Drug Administration (FDA).Some analgesics, including opioid analgesics, act on the body's peripheral and central nervous systems to block or decrease sensitivity to pain. Others act by inhibiting the formation of certain chemicals in the body.These relieve the minor aches and pains associated with conditions such as headaches, fever, colds, flu, arthritis, toothaches, and menstrual cramps.

There are basically two types of OTC pain relievers:

- acetaminophen
- non-steroidal anti-inflammatory drugs (NSAIDs).

Acetaminophen is an active ingredient found in more than 600OTC and prescription medicines, including pain relievers, cough suppressants, and cold medications.

NSAIDs are common medications used to relieve fever and minor aches and pains. They include aspirin, naproxen, and ibuprofen, as well as many medicines taken for colds, sinus pressure, and allergies. They act by inhibiting an enzyme that helps make a specific chemicals.

Use as Directed

Pain medications are safe and effective when used as directed. However, misuse of theseproducts can be extremely harmful and even deadly.

- Consumers who take pain relief medications must follow their health care professional'sinstructions carefully. If a measuring tool is provided with your medicine, use it as directed.
- Do not change the dose of your pain relief medication without talking to your doctorfirst.
- Also, pain medications should never be shared with anyone else. Only your health careprofessional can decide if a prescription pain medication is safe for someone.

SPECIAL PATIENT GROUPS

Talk with your doctor before taking any NSAID if you:

- Are over age 60
- Are pregnant or nursing
- Have three or more drinks of alcohol every day
- Have bleeding problems

• Have liver or kidney disease
• Have heart disease
• Take a medicine to thin the blood, such as warfarin (Coumadin)
• Take a medicine for high blood pressure
• Children and teenagers who are recovering from a viral infection such as the flu or chickenpox should not take aspirin. It has been linked to Reye's syndrome, a serious butrare condition that can result in brain, kidney, and liver damage.
• Naproxen sodium is not recommended for children under 2.
• Ibuprofen is considered safe for children 6 months and older in the right dose.

OTC COUNSELING QUESTIONS

Counseling patients about self-care and nonprescription drugs is not the same and cannot follow the same procedure as for prescription drugs. That is why OTC counseling requires much more exploratory open or close- ended questions on the part of the pharmacist which areespecially useful to clarify information gathered about the patient's condition. It allows gathering the most abundant amount of information.

These questions usually start with who, what, how, why or where. For example:

□ "Which of the prescription medications do you take on regular basis?"
□ "Which of the nonprescription and herbal medications do you use?"
□ "What types of conditions do you routinely see your doctor for?"Some other questions are also possible:
□ "Have you ever experienced any side effects after taking the OTC medication?"
□ "Have you taken this OTC medication before?"

PATIENT COUNSELING

Step l

Every pharmacist should begin the OTC counseling session by introducing himself/herself byname which identifies him/her as the pharmacist. He/she should try to relax the patient by beginning the session with a friendly smile and a handshake. The pharmacist should also explain that he/she can provide assistance with OTC product selection and explain how to usesuch medication.

Step 2

In order to elicit key information the pharmacist should first and foremost try to obtain relevant information about patient's demographic (e.g. sex, age, pregnant, nursing, weight, allergies, social history etc), disease (e.g. history of present illness, current symptoms, course of illness, past history, other underlying medical conditions) and drug (e.g. current medication, medicationtaking history, OTC history etc.) Moreover, by using suitable verbal and written communication

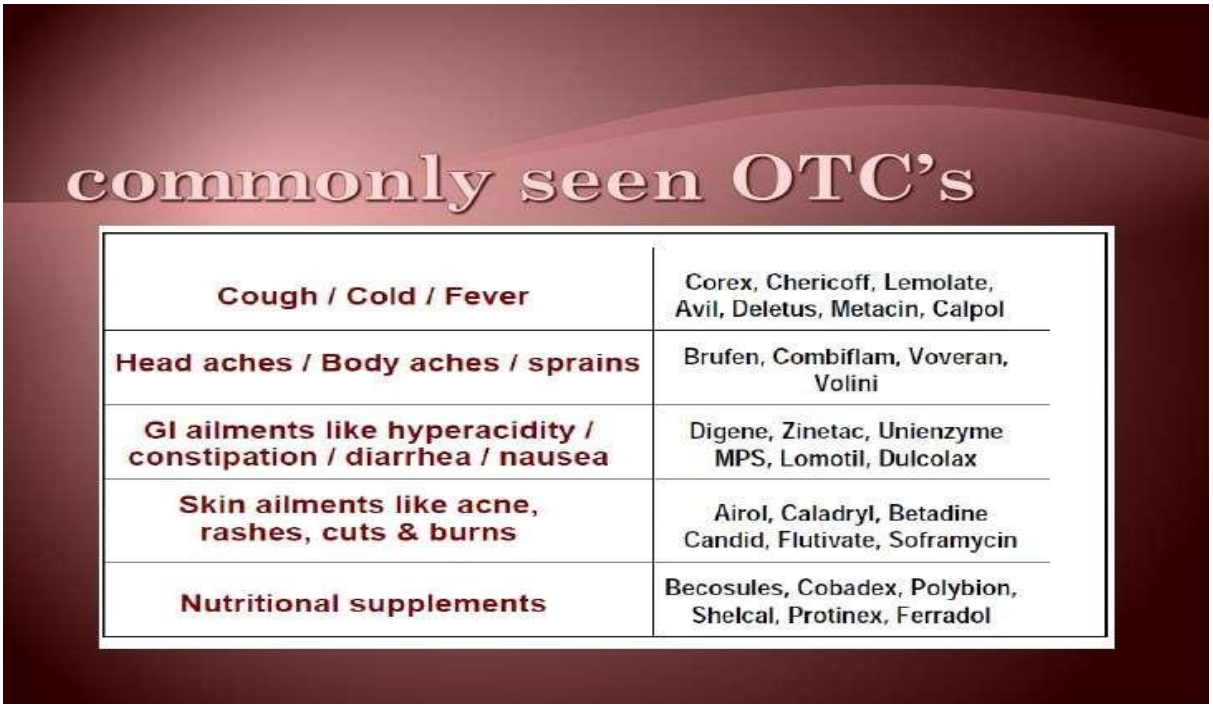
techniques, the pharmacist should inform, educate, and counsel patients about the following:

□ Drug name (generic and/or brand name)
□ Route, dosage form, dosage and administration schedule;
□ Special directions for preparation and administration as well as precautions to betaken during the process;
□ Techniques for self-monitoring of drug therapy;
□ Storage;
□ Potential drug-drug or drug-food interactions or other therapeuticcontraindications ; and
□ Accordingly other Information "peculiar to the specific patient or drug etc.

In addition, it is of vital importance to demonstrate to patient's- how to use medications in various forms such as inhalers, patches, drops, ointments, lozenges, gargles etc.

And

Ask them to demonstrate making sure that patients understand which route of administration should be used thus ensuring that patients have all the necessary instructions in writing and thatthey understand how to schedule their medications in accordance with meals and other medications.



QUSETION BANK

A. 2 MARKS QUESTIONS

1. Define budget.

2. Give characteristics of budget.

3. Enlist types of budget according to time.

4. Enlist techniques of budget.

5. What is PBBS?

6. What is "The Thalidomide tragedy" in clinical pharmacy?

7. Write goal of medication chart review.

8. Enlist types of pharmaceutical care.

9. What are OTC drugs?

10. Give advantages of OTC drugs.

11. What are the risks associated with use of OTC Drugs.

B. 5 MARKS QUESTIONS

1. Write a short note on rational use of OTC drugs.

2. What is the role of pharmacist in ward round participation.

3. Explain concept and scope of clinical pharmacy.

4.Explain clinical review in clinical pharmacy?

5. Differentiate between fixed budget and flexible budget.

6. Define budget? Give its objective and purpose.

C. 10 MARKS QUESTIONS

1. Write a short note on budget preparation and implementation of budget.

2. Write short note on techniques of budget and give its advantages and disadvantages.

3. What is clinical pharmacy? Describe history & status of clinical pharmacy in India.

4. Explain medication chart review in clinical pharmacy.

5. Explain misuse and abuse of OTC drugs & give risks associated with OTC use.

6. Write a short note on OTC Drugs.