

# Clinical Pharmacy



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# Clinical Pharmacy

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 the patient care.

# STATUS OF CLINICAL PHARMACY IN INDIA

- ❑ 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 a large 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, shaving supplies, 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 to pharmaceutical production, exports, imports etc.
- ❑ There is still a need to develop the concept of clinical pharmacy.



# Why Clinical Pharmacist ?

- ❑ 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 **their potential hazards of side effects** are on rise.

- ❑ **First**, there is **little time for doctor-patient dialogue** as the doctor usually has too little time to spend with each patient.
- ❑ many a times doctors to patients by excessive and wrongful use of drugs. More and more people fall in what is called **iatrogenesis** (drug induced diseases) and misuse of drugs.
- ❑ has been increase in "**self-medication**" by the patients.
- ❑ These have led to the development of "Clinical Pharmacy" as a new subject.

# HISTORY OF CLINICAL PHARMACY

- ❑ The term clinical pharmacy was first used in 1953.
- ❑ The concept of clinical pharmacology started in 1960s with two incidences.
- ❑ First, in 1962 "***The Thalidomide Tragedy***", wherein it was found that consumption of popular sedative thalidomide resulted in birth of babies with sealed limbs.
- ❑ Second, in 1968 ***phenytoin toxicity*** was reported in Australia which was because of change in formulation i.e. switching over from calcium sulfate to lactose as an inert excipient in the tablets.



# Activities of Clinical Pharmacist

- ❑ to investigate bioavailability, pharmacokinetics and toxicity of different formulations.
- ❑ Obviously, this job was mainly given to pharmacology and clinical pharmacology developed as a subject in medical institutions. (Clinical Pharmacist)



# SCOPE OF CLINICAL PHARMACY



## 1. Preparation of patient medication history

- any hypersensitivity's or allergies to specific drugs observed in the past, any particular drug or food habits, drug dependence or intoxication with chemicals due to occupational hazards, all of which are likely to interfere with the therapy.
  
- This will help in saving physicians time and efforts and thus will result in faster and more accurate selection of drug therapy.

## **2. Rational prescription :**

- The clinical pharmacist can suggest the physician and help him in selecting the right drug. Some of the examples of irrational combinations identified by pharmacist are :
- Haloperidol + Diazepam + Amitriptyline
- Reserpine + Sintamil

## **3. Bioequivalence and generic equivalence of pharmaceutical formulations :**

- Number of factors influence the bioavailability of drugs from the dosage forms.
- selection of proper drug therapy based on bioequivalence studies on different dosage forms of the same drug moiety.

## 4. Patient monitoring :

- ❑ observes the signs and symptoms that indicate the need for or reaction to drugs.
- ❑ Clinical pharmacist who knows correct route of administration, the signs and symptoms of overdoses, contraindications, desired effects, undesired effects and side effects can help in monitoring the drug therapy for safety and efficiency, a necessity with the increasing applications of potent and toxic chemicals and drugs.
- ❑ drugs with **narrow therapeutic index**, or when drugs administered in patients who are critically ill or are suffering from chronic diseases.

Table 1.1

| Disease condition | Class of drug used | Parameter measured     |
|-------------------|--------------------|------------------------|
| Hypertension      | Diuretics          | Blood pressure changes |
| Diabetes          | Insulin therapy    | Urine glucose levels   |

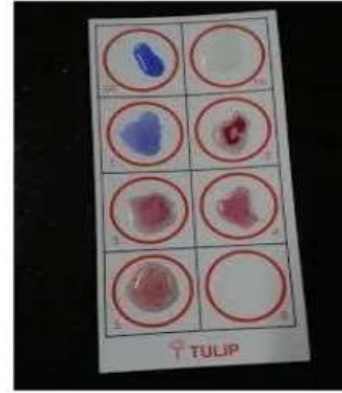
## **5. Adverse drug reactions and drug interactions :**

### ***The clinical pharmacist:***

- Can compile and process data using computers and make it available to the medical staff.
- May suggest an alternate therapy if applicable
- Identify drug effect modifications due to interactions with several foods, alcohol, smoking, environmental chemicals, as well as due to pregnancy.



## 6. Drug diagnostic test inferences :



## 7. Intravenous admixtures :



## 8. Drug Information Specialist :

- ❑ A clinical pharmacist being an expert on drugs may operate a drug information service.
- ❑ Through effective utilization and retrieval of clinical drug literature, the pharmacist can actively communicate drug information.
- ❑ He can help during medical emergencies, by providing immediate information on antidotes in case of poisoning or overdosing.



## **9. Retail pharmacy stores :**

- ❑ Many OTC drugs have the potential to interact with prescription drugs.
- ❑ A clinical pharmacist at retail drug stores can maintain patient drug profiles, family drug profiles and family records based upon which the pharmacist can counsel the patient each time while filling the prescription.
- ❑ He can determine the patients responses to drug therapy and help him in the selection and use of OTC drugs.



## 10. Discharge counseling and patient compliance :

- ❑ The compliance to drug therapy can be improved several times, by educating and counselling the patient at the time of discharge from hospital or while dispensing the prescription at the retail counter.
- ❑ The patient may be made aware of the purpose of medication, proper mode of administration, dosage schedule and storage conditions.
- ❑ He may be told of any potential adverse or side effects to expect and any food or activities to be avoided during therapy.



*Pharmacists from an outpatient retail pharmacy deliver prescribed medications to patients' bedsides at DeKalb Medical.*



## ***11. Clinical research and continuing education program :***

- The clinical pharmacist can participate in an evaluation program on investigational drugs.
- He can help in conducting clinical trials based on sound principles of biostatistical methods of evaluation.
- He can also develop training programs for pharmacists, nurses and interns.

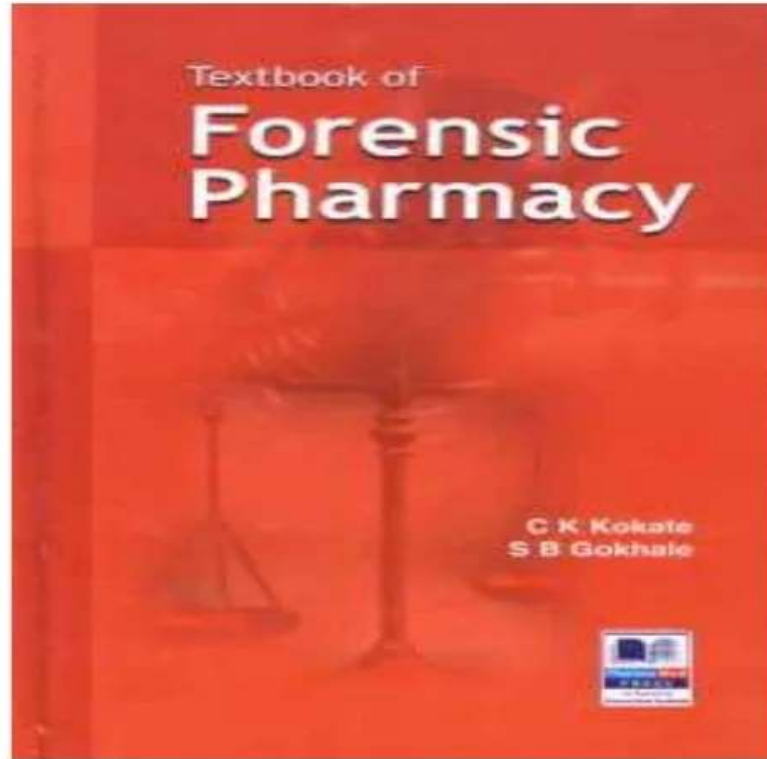


## **12. Medical Audit :**

- ❑ Medical audit is a logical and necessary procedure within organized teamwork. The clinical pharmacist is either the initiator or a very active member of a functioning committee. Following are the activities, concerning medical audit:
  - i. Legislation.
  - ii. Contractual obligation.
  - iii. Regulation and registration of pharmacotherapy orders and administration.
  - iv. Regulation of clinical experiments with drugs
  - v. Information per subject and per patient
  - vi. Pharmacotherapy-committee policy
  - vii. Regulation of information from the pharmaceutical industry
  - viii. Local or regional microsymbosia per patient
  - ix. Formulary policy
  - x. Retrospective study of drug use patterns
  - xi. Medical audit committee work.



**(i) Legislation :** The pharmacist is responsible for the quality of the medicines he dispenses.



**(ii) Contractual obligation :** The authorized pharmacist should be charged with the supervision over the maintenance of the organization included involving the storage, the distribution and the registration of drugs, regardless they are in the pharmacy or elsewhere in the institution.

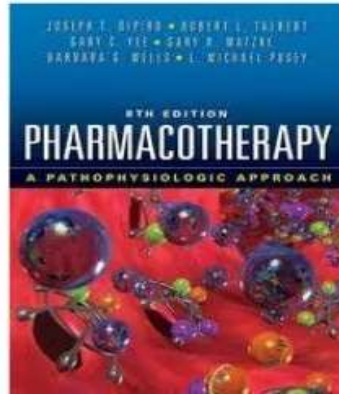


***(iii) Regulation and registration of pharmacotherapy orders and administration :***

Clinical pharmacy must provide the means for pharmacotherapy.

The follow-up should be reviewed by pharmacist with head nurses and the medical director.

Specific problems should be discussed with the concerned members of the health care team and regulated.



(iv) **Regulation of clinical experiments with drugs :**  
Regulation of clinical trials is necessary –

- a. To ensure that there are no ethical problems that may harm patients
- b. To control trials
- c. To control pharmacotherapy through :
  - Registration and processing of requests for the use of unregistered drugs
  - Purchasing
  - Control of stock and turnover
  - Quality control
  - Supply
  - Compounding
  - Control of code and key of "blind" experiments
  - Reporting of deviation of standard operating and registration procedures to the directorate.

**(v) *Information per subject and per patient:***

Information per subject and per patient may be provided by clinical pharmacy. Information is a service and should be given unasked for when deemed necessary.

**(vi) Pharmacotherapy-committee:** In this information specific subject policy is prepared within a multidisciplinary team and produced as advice. Clinical pharmacists can recommend, motivate and must ensure the continuity of pharmacotherapy-committee work.



***(vii) Regulation of information from the pharmaceutical industry :***

Promotional activities of the pharmaceutical industry are primarily physician oriented. Part of their information may be essential.

Clinical pharmacists and physicians have different requirements for additional information.

Thus, it is possible to select information and representatives from industry for the discussion of specific subjects with clinical pharmacists and physicians.

# Goal

to promote the correct and appropriate use of medicinal products and devices.

These activities aim at:

- maximising the clinical effect of medicines
- minimising the risk of treatment-induced adverse events
- minimising the expenditures for pharmacological treatments.



# Clinical Pharmacy Requirements



# Level of Action of Clinical Pharmacists

Clinical pharmacy activities may influence the correct use of medicines at three different levels: before, during and after the prescription is written.

Mainly 3 Levels are there



# 1. Before the prescription

- Clinical trials
- Formularies
- Drug information
- drug-related policies





## 2. During the prescription

- ❑ Counselling activity
- ❑ Clinical pharmacists can influence the attitudes and priorities of prescribers in their choice of correct treatments.
- ❑ The clinical pharmacist monitors, detects and prevents **Medication related problems**
- ❑ The clinical pharmacist pays special attention to the dosage of drug which need therapeutic monitoring.
- ❑ Community pharmacists can also make prescription decisions directly, when over the counter drugs are counselled.



# Medication-related Problems

- Untreated indications.*
- Improper drug selection.*
- Subtherapeutic dosage.*
- Medication Failure to receive*
- Medication Overdosage.*
- Adverse drug reactions.*
- Drug interactions.*
- Medication use without indication.*

### 3. After the prescription

- Counselling
- Preparation of personalised formulation
- Drug use evaluation
- Outcome research
- Pharmacoeconomic studies







# Activities of Clinical Pharmacists

The principle activities of a clinical pharmacist include:

## **Consulting**

Analysing therapies, advising health care practitioners on the correctness of drug therapy and providing pharmaceutical care to patients both at hospital and at community level.

## **Selection of drugs**

Defining "drug formularies" or "limited lists of drugs" in collaboration with hospital doctors, general practitioners and decision makers.

## **Drug information**

Seeking information and critically evaluating scientific literature; organising information services for both the health care practitioners and the patients.



# Activities of Clinical Pharmacists

## **Medication Review**

Review medication chart, Review medication history

## **Attending Rounds**

## **Drug use studies and research**

Drug use studies/ pharmacoepidemiology/ outcome research/ pharmacovigilance and vigilance in medicinal devices: collecting data on drug therapies, their costs and patient outcome through structured and scientific methods.

## **Pharmacokinetics/ therapeutic drug monitoring**

Studying the kinetics of drugs and optimising the dosage.

## **Clinical Trials**

Planning, evaluating and participating in clinical trials



# Activities of Clinical Pharmacists

## **Pharmacoeconomy**

Using the results of clinical trials and outcome studies to determine cost- effectiveness evaluations.

## **Teaching & Training**

Pre- and post-graduate teaching and activities to provide training and education programmes for pharmacists and other health care practitioners

# Information Source

- Medical record
- Patient
- Family
- Health care team



# Medical Record

- 
- 
- Admission Information
  - Initial history
  - physical examination
  - Progress notes
  - Consultations
  - Nursing notes
  - Laboratory data
  - Diagnostic Procedures
  - Radiology
  - Surgery
  - Orders
  - Medication  
administration orders
  - Consent forms

# Medical Team





# Clinical Pharmacy Practice areas

- Ambulatory care
- Critical care
- Drug Information
- Geriatrics and long –term care
- Internal medicine and subspecialties
- Cardiology
- Endocrinology
- Gastroenterology
- Infectious disease
- Neurology
- Nephrology
- Obstetrics and gynecology
- Pulmonary disease
- Psychiatry
- Rheumatology
- Nuclear pharmacy
- Nutrition
- Pediatrics
- Pharmacokinetics
- Surgery

# Practice Guidelines for Pharmacotherapy Specialists

- The pharmacotherapy specialist designs, implements, monitors, evaluates, and modifies patient pharmacotherapy to ensure effective, safe and economical patient care.



# Practice Guidelines for Pharmacotherapy Specialists

- The pharmacotherapy specialist retrieves , analyzes, evaluates, and interprets the scientific literature as a means of providing patient- and population-specific drug information to health professionals and patients





# Practice Guidelines for Pharmacotherapy Specialists

- The pharmacotherapy specialist participates in the generation of new knowledge relevant to the practice of pharmacotherapy, clinical pharmacy and medicine
- The pharmacotherapy specialist educate health care professionals and students, patients, and the public regarding rational drug therapy
- The pharmacotherapy specialist continually develops his/her knowledge and skills in applicable practice areas and demonstrates a commitment to continued professional growth by engaging in a lifelong process.

# Evaluation Of a Clinical Pharmacist

Evaluation Form



# How to Pursue a Profession in Clinical Pharmacy in Saudi Arabia

- Pharm.D
- Master Degree in clinical pharmacy
- Residency with 3 years of training





# Clinical pharmacokinetics

Clinical pharmacokinetics is the process of applying pharmacokinetic principles to determine the **dosage regimens** of specific drug products for **specific patients** to maximize **pharmacotherapeutic effects** and minimize **toxic effects**.

TDM stands for therapeutic drug monitoring



## Clinical pharmacokinetics

- Application of these principles requires an understanding of the absorption, distribution, metabolism, and excretion characteristics of specific drug products in specific diseases and patient populations

# Drugs that can be monitored

- when the range between minimal effectiveness and toxicity is narrow
- the results of the drug assay provide significant information for clinical decision-making.



# Why request TDM?

- Noncompliance
- Inappropriate dosage
- Poor bioavailability
- Drug interaction
- Kidney and liver disease
- Altered protein binding
- Fever
- Cytokines
- Genetically determined fast or slow metabolizers







# Responsibilities

- Designing patient-specific drug dosage regimens
- Recommending or scheduling measurements of drug concentrations in biological fluids
- Monitoring and adjusting dosage regimens
- Evaluating unusual patient responses to drug therapy for possible pharmacokinetic and pharmacologic explanations.



# Responsibilities

- ❑ Communicating patient-specific drug therapy information to physicians, nurses, and other clinical practitioners and to patients orally and in writing, and including documentation of this in the patient's health record.

# Responsibilities

- Educating pharmacists, physicians, nurses, and other clinical practitioners about pharmacokinetic principles and appropriate indications for clinical pharmacokinetic monitoring, including the cost-effective use of drug concentration measurements.



# Responsibilities

- ❑ Developing quality assurance programs for documenting improved patient outcomes and economic benefits
- ❑ Promoting collaborative relationships with other individuals and departments involved in drug therapy





# Responsibilities

Pharmacists with specialized education, training, or experience may have the opportunity to assume the following additional responsibilities:

1. Designing and conducting research
2. Developing and applying computer programs and point-of-care information systems to enhance the accuracy and sophistication of pharmacokinetic modeling and applications to pharmaceutical care.



# Responsibilities

- 3.** Serving as an expert consultant to pharmacists with a general background in clinical pharmacokinetic monitoring.

**THANK YOU**