SREE DATTHA INSTITUTE OF PHARMACY

(Approved by AICTE & PCI, New Delhi, Affiliated to JNTU, Hyderabad)
Sagar Road, Sheriguda, Ibrahimpatnam, R.R.Dist.-501510
Ph.:08414-202206, 320919, 9393808082
www.sreedattha.org, E-mail: principalsdip@sreedattha.ac.in

COURSE FILE

NAME OF THE SUBJECT: Clinical Pharmacy SUBJECT CODE: PROGRAMME: Pharmacy	
BRANCH: Pharm D YEAR: IV SEMESTER:	
PREPARED BY: 1) NAME : Dr Amatul Ali Sameera 2) SIGN: Sameera 3) DESIGN: Assistant Professor 4) DATE:	
VERIFIED BY: 1) NAME : Dr. U. Sambasivarao 2) SIGN: 3) DESIGN: Professor 4) DATE: 01/08/25	FOR QC ONLY: 1) NAME : Dr. J. Arun Kumar 2) SIGN: 3) DESIGN: Professor 4) DATE: 9/9/25
APPROVED BY: PRINCIPAL : Dr. Bonagiri Chandrashekar SIGN: DATE: 10/9/25	

SREE DATTHA INSTITUTE OF PHARMACY * Sheriguda *

SREE DATTHA INSTITUTE OF PHARMACY

(Approved by AICTE & PCI, New Delhi, Affiliated to JNTU, Hyderabad)
Sagar Road, Sheriguda, Ibrahimpatnam, R.R.Dist.-501510
Ph.:08414-202206, 320919, 9393808082
www.sreedattha.org, E-mail: principalsdip@sreedattha.ac.in

INDEX

Vision and Mission of Sree Dattha Institute of Pharmacy

Vision:

To be a globally recognized pharmacy education and research centre producing budding pharmacists into perfect pharmacists who can integrate science and technology to advance pharmaceutical drug discovery and formulate patient friendly dosage forms, supporting health care.

Mission:

M1: Nurture students into knowledgeable, skillful and ethical professionals

M2: Nurture the faculty to expose all to world-class research and pharmaceutical infrastructure

M3: Sustain high performance by excellence in teaching, research and innovations

M4: Extensive partnerships and collaborations with industries/foreign universities for technology up gradation

M5: Develop skilled pharmacist to support healthcare locally, nationally and globally

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR 2023-24

Pharm D. (Regular) IV Year

Pharm. D. (Regular) IV Year

S. No	Description	Duration	
		From	To
1	Commencement of classwork	24.07.2023	
2	1st Spell of Instructions	24.07.2023	13.10.2023 (12 Weeks)
3	First Mid Term Examinations	16.10.2023	21.10.2023 (1 Week)
	Dussehra Recess	23.10.2023	28.10.2023 (1 Week)
4	2nd Spell of Instructions	30.10.2023	25.01.2024 (12 Weeks)
5	Submission of First Mid Term Exam Marks to the University on or before	04.11.2023	
6	**Supplementary Examinations**	06.11.2023	13.11.2023
7	Second Mid Term Examinations	27.01.2024	02.02.2024 (1 Week)
8	3rd Spell of Instructions	03.02.2024	04.05.2024 (13 Weeks)
9	Submission of Second Mid Term Exam Marks to the University on or before	09.02.2024	
10	Third Mid Term Examinations	06.05.2024	11.05.2024 (1 Week)
11	**Summer Vacation**	13.05.2024	25.05.2024(2 Weeks)
12	Submission of Third Mid Term Exam Marks to the University on or before	27.05.2024	
13	Preparation Holidays and Practical Examinations	27.05.2024	01.06.2024 (1 Week)
14	End / Supplementary Examinations	03.06.2024	15.06.2024 (2 Weeks)

06/7/23

REGISTRAR

4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

a. monitor drug therapy of patient through medication chart review and clinical review;
b. obtain medication history interview and counsel the patients;
c. identify and resolve drug related problems;
d. detect, assess and monitor adverse drug reaction;
e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
   a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
   b. Ward round participation
   c. Adverse drug reaction management
   d. Drug information and poisons information
   e. Medication history
   f. Patient counseling
   g. Drug utilisation evaluation (DUE) and review (DUR)
   h. Quality assurance of clinical pharmacy services

3. **Patient data analysis**
   The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
   a. Haematological, Liver function, Renal function, thyroid function tests
   b. Tests associated with cardiac disorders
   c. Fluid and electrolyte balance
   d. Microbiological culture sensitivity tests
   e. Pulmonary Function Tests
5. **Drug & Poison information**
   a. Introduction to drug information resources available
   b. Systematic approach in answering DI queries
   c. Critical evaluation of drug information and literature
   d. Preparation of written and verbal reports
   e. Establishing a Drug Information Centre
   f. Poisons information- organization & information resources
6. **Pharmacovigilance**
   a. Scope, definition and aims of pharmacovigilance
   b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   c. Reporting, evaluation, monitoring, preventing & management of ADRs
   d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

CLINICAL PHARMACY

COURSE OUTCOME:

Student shall be able to:

CO.1	Define Clinical Pharmacy and explain in its scope, history and development
CO.2	Monitor drug therapy of patient through medication chart review, clinical review, history interview and discuss about the daily activities of a clinical pharmacist
CO.3	Summarize the patient's case history by evaluating drug therapy and interpreting laboratory test results.
CO.4	Explain the establishment and organization of Drug information and poison information center.
CO.5	Explain about pharmacovigilance.Detect, assess, and monitor ADRs. Explain the importance of ADRs reporting and the role of pharmacist.
CO.6	Learn to provide counseling to the patients in a systematic way and explain the concept of pharmaceutical care.
CO.7	Identify medication errors and evaluate biomedical literature.

SREE DATTHA INSTITUTE OF PHARMACY

(Approved by AICTE & PCI, New Delhi, Affiliated to JNTU, Hyderabad)
Sagar Road, Sheriguda, Ibrahimpatnam, R.R.Dist.-501510
Ph.:08414-202206, 320919, 9393808082
www.sreedattha.org, E-mail: principalsdip@sreedattha.ac.in

PROGRAMME OUTCOMES

Based on the B. Pharmacy program's educational objectives, students will achieve the following specific program outcomes. The programme outcomes are given by the NBA as given below.

1. Pharmacy Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.

2. Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

3. Problem analysis: Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.

4. Modern tool usage: Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.

5. Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.

6. Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).

7. Pharmaceutical Ethics: Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

8. Communication: Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

9. The Pharmacist and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

10. Environment and sustainability: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

11. Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assement and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

SREE DATTHA INSTITUTE OF PHARMACY

(Approved by AICTE & PCI, New Delhi, Affiliated to JNTU, Hyderabad)
Sagar Road, Sheriguda, Ibrahimpatnam, R.R.Dist.-501510
Ph.:08414-202206, 320919, 9393808082
www.sreedattha.org, E-mail: principalsdip@sreedattha.ac.in

College code: SDIP

LESSON PLAN

Department: Pharmacy **Session:** Pharm D IV Year **Semester:**

Subject: Clinical Pharmacy **Faculty Name:** Dr. Amatul Ali Sameera

Text Book 1: A textbook of Clinical Pharmacy Practice Essential concepts and skills (Dr.G.Parthasarathi) **Reference Book 1:** Hospital and Clinical Pharmacy (S.Balasubramanian, N.Narayana)

Text Book 2: **Reference Book 2:**Clinical Pharmacy (Dr.Amrita Bajaj and Dr.Tipnis)

S.No	Starting date	Completion date	Unit	Topic	LOL	HOL	Text Book & Page No.	Reference book & Page No	Method of Teaching
1.	01-08-23	07-08-23	I	Definitions, development and scope of clinical pharmacy	Student will be able to define clinical pharmacy	Student will be able to explain the scope and development of clinical pharmacy	TB 1 34-46		PPT
2.	14-08-23	18-08-23	II	Introduction to daily activities of a clinical pharmacist	Student will be able to list the daily activities of clinical pharmacist	Student will be able to describe the daily activities carried out by a clinical pharmacist		RB 2 10-26	Chalk and Talk
3.	21-08-23	29-08-23	II	Drug therapy monitoring	Student will be able to define drug therapy monitoring, medication review and clinical review	Student will be able to discuss about drug therapy monitoring, medication review and clinical review		RB 1 264-268	
4.	01-09-23	05-09-23	II	Ward round participation	Student will be able to define ward round	Student will be able to elaborate the steps of	TB 1 211 - 220	RB 1 214-219	PPT

					participation	ward round participation			
5.	08-09-22	15-09-23	II	Adverse drug reaction management	Student will be able to define and classify ADRs	Students will be able to identify the role of pharmacist in the management of ADRs	TB 1 219 - 220	RB 1 318-327	Chalk and Talk
6.	18-09-22	29-09-23	II	Drug information and poisons information	Student will be able to define drug and poison information	Student will be able to explain about the organization of drug and poison information centre	TB 1 325-343	RB 1 353-374	PPT
7.	03-10-23	06-10-23	II	Medication history	Student will be able to define medication history and list its goals	Student will be able to explain the components of medication history	TB 1 190-202	RB 1 195-201	PPT
8.	09-10-23	13-10-23	II	Patient counseling	Student will be able to define patient counseling	Student will be able to explicate the steps involved in patient counseling	TB 1 124-135	RB 1 346-351	PPT
9.	17-11-23	28-11-23	II	Drug utilization evaluation (DUE) and review (DUR)	Student will be able to define DUE and DUR	Student will be able to explain the steps involved in DUE and DUR	TB 1 447-460	RB 1 304-309	PPT
10.	01-12-23	05-12-23	II	Quality assurance of clinical pharmacy services	Students will be able to define Quality assurance of clinical pharmacy services	Students will be able to elaborate different types of clinical pharmacy services.		Internet: https://www.slideshare.net/VELSPHARMD/clinical-pharmacy-services Internet:	Chalk and Talk

								https://en.wikipedia.org/wiki/Clinical_audit .	
11.	11-12-23	15-12-23	III	Patient data analysis	Students will be able to outline the components of patient's case history	Students will be able to discuss the structure and use of patient's case history in evaluation of drug therapy		RB 1 276-278	PPT
12.	18-12-23	19-12-23	IV	Introduction to Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results	Students will be able to list different lab tests	Students will be able to explicate the clinical lab tests used in the identification of diseases and also interpret the test results		RB 1 279	
13.	22-12-23	19-01-24	IV	Haematological, Liver function, Renal function, thyroid function tests	Students will be able to identify the normal values in the lab tests	Students will be able to describe the about the abnormalities in the tests and interpret the results	TB 1 256-277		
14.	22-01-24	02-02-24	IV	Tests associated with cardiac disorders	Students will be able to list the tests carried out in cardiac conditions	Students will be able to discuss about the invasive and non-invasive tests		RB 1 291	

15.	05-02-24	09-02-24	IV	Fluid and electrolyte balance	Students will be able to list the electrolytes	Students will be able to explain about fluid and electrolyte balance and its abnormalities		RB 1 276-280	
16.	12-02-24	13-02-24	IV	Microbiological culture sensitivity tests	Students will be able to define microbiological culture sensitivity test	Students will be able to elaborate the microbiological culture and procedure and testing its sensitivity		RB 1 294-301	
17.	16-02-24	19-02-24	IV	Pulmonary Function Tests	Students will be able to list different pulmonary tests	Students will be able to evaluate the pulmonary tests and interpret diseases		RB 1 286-287	
18.	23-02-24	23-02-24	V	Introduction to drug information resources available	Students will be able to define drug information and list its resources	Students will be able to describe different types of drug information resources	TB 1 325-332	RB 1 355	Talk and Chalk
19.	26-02-24	27-02-24	V	Systematic approach in answering DI queries	Students will be able to summarize the approaches in answering DI queries	Students will be able to explain systematic approach in answering drug information questions or queries by the patients of any other enquirer	TB 1 360-362	RB 1 332-337	PPT

20.	01-03-24	01-03-24	V	Critical evaluation of drug information and literature	Students will be able to illustrate critical evaluation of drug information and literature	Students will be able to explicate about critical evaluation of drug information and literature		RB 1 358-359	PPT
21.	04-03-24	04-03-24	V	Preparation of written and verbal reports	Students will be able to enumerate the preparation of written and verbal reports	Students will be able to discuss about preparation of written and verbal reports		RB 1 362-363	PPT
22.	05-03-22	05-03-24	V	Establishing a Drug Information Centre	Students will be able to outline about the establishment of DIC	Students will be able to explain about establishment of DIC		RB 1 362-363	PPT
23.	11-03-24	11-03-24	V	Poisons information-organization	Students will be able to define poison information	Students will be able to explain about the organization of poison information center	TB 1 346-47		PPT
24.	12-03-24	15-03-24	V	Poisons information-information resources	Students will be able to categorize the resources of poison information	Students will be able to explique the resources of poison information	TB 1 348-350		PPT

25.	19-03-24	19-03-24	VI	Scope, definition and aims of pharmacovigilance	Students will be able to define pharmacovigilance	Students will be able to discuss the scope and aims of Pharmacovigilance		RB 1 336-338	Chalk and Talk
26.	22-03-24	22-103-24	VI	Adverse drug reactions - Classification, mechanism	Students will be able to define Adverse drug reactions	Students will be able to classify ADRs and describe its mechanism	TB 1 105-107		Chalk and Talk
27.	26-03-24	23-03-24	VI	Adverse drug reactions- predisposing factors, causality assessment [different scales used]	Students will be able to summarize the predisposing factors of ADRs	Students will be able to describe causality assessment scales	TB 1 107-116		PPT
28.	26-03-24	26-03-24	VI	ADRs: Reporting and evaluation	Student will be able to enumerate about the evaluation of ADRs	Students will be able to explain about the reporting of ADRs.	TB 1 116-117		PPT
29.	01-04-24	01-04-24	VI	Monitoring, preventing & management of ADRs	Students will be able to summarize preventive measures of ADRs	Students will be able to explain illustrate Management of ADRs		RB 1 322-324	PPT

30.	02-04-24	02-04-24	VI	Role of pharmacist in management of ADR	Student will be able to identify the role of pharmacist in ADRs	Students will be able to elucidate the role of pharmacist in ADRs	TB 1 119		PPT
31.	08-04-24	12-04-24	VII	Communication skills, including patient counseling techniques	Student will be able to define patient counseling	Student will be able to explicate the steps involved in patient counseling and about the communication skills for counseling of patients	TB 1 88-135		Chalk and talk
32.	15-04-24	16-04-24	VII	Medication history interview	Student will be able to define medication history and list its goals	Student will be able to explain the components of medication history	TB 1 190-202	RB 1 195-201	PPT
33.	19-04-24	19-04-23	VII	Presentation of cases	Student will be able to summarize about the case presentation	Student will be able to explain the guidelines of case presentation.		RB 1 381-383	PPT
34.	22-04-24	22-04-24	VIII	Pharmaceutical care concepts	Student will be able to define pharmaceutical care concept	Students will be able to explicate the functions of Pharmaceutical care.		RB 1 341-334	PPT

35.	23-04-24	23-04-24	VIII	Pharmaceutical care concepts	Students will be able to list the basic elements of pharmaceutical care	Students will be able to discuss about the types of pharmaceutical care		RB 2 534-548	PPT
36.	26-04-24	29-04-24	IX	Critical Evaluation of Biomedical Literature	Student will be able to define Critical Evaluation of Biomedical Literature	Students will be able to explicate the Procedure of Evaluation of Biomedical Literature		RB 1 385-388	PPT
37.	30-04-24	30-04-24	X	Medication errors	Students will be able to define medication errors	Students will be able to discuss different types of medication errors	TB 1 486-500	RB 1 389-392	PPT

SLIP TESTS

S.No	SLIP TEST	DATE OF CONDUCTION
1.	SLIP TEST I	14/08/23
2.	SLIP TEST II	06/10/23
3.	SLIP TEST III	
4.	SLIP TEST IV	
5.	SLIP TEST V	
6.	SLIP TEST VI	

CLINICALPHARMACY

Learning Objectives

Upon completion of the subject student shall be able to (Know, do, appreciate) –

a. monitor drug therapy of patient through medication chart review and clinical review.

b. obtain medication history interview and counsel the patients.

c. identify and resolve drug related problems.

d. detect, assess and monitor adverse drug reaction.

e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states.

f. retrieve, analyse, interpret and formulate drug or medicine information.

CLINICAL PHARMACY

QUESTION BANK

UNIT-I

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
1.	1	L1	Define Clinical pharmacy.	2
2.	1	L6	Explain the need of clinical pharmacy in India.	3
3.	1	L6	Elaborate about the development of clinical pharmacy in India.	3
4.	1	L6	Explain about the scope of clinical pharmacy practice in India.	3
5.	1	L3	Summarize the history of clinical pharmacy.	3

UNIT-II

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
6.	2	L1	Define drug therapy monitoring.	2
7.	2	L1	List the aims or goals of drug therapy monitoring.	2
8.	2	L1	Define patient's records.	2
9.	2	L1	Mention different types of patient's records.	2
10.	2	L6	Explain about patient's records.	5
11.	2	L6	Describe the process of drug therapy monitoring.	5
12.	2	L1	List the steps involved in monitoring of drug therapy.	2
13.	2	L1	Define medication review.	2
14.	2	L3	Illustrate medication review goals and significance.	3
15.	2	L6	Explain about the components of medication review.	5
16.	2	L1	Define medication order review.	2
17.	2	L1	Mention the aims and objective of medication order review.	2
18.	2	L6	Explain about the steps involved in medication order review.	5

19.	2	L5	Discuss about the role of pharmacist in medication order review.	5
20.	2	L1	Define clinical review.	2
21.	2	L3	Summarize the importance of clinical review.	3
22.	2	L1	Mention the goals of clinical review.	2
23.	2	L5	Discuss the procedure involved in clinical review.	5
24.	2	L1	Define pharmacist interventions.	2
25.	2	L1	Enumerate the importance of pharmacist interventions.	3
26.	2	L6	Explain the steps involved in pharmacist interventions.	3
27.	2	L6	Explain about the responsibilities pharmacist in interventions.	5
28.	2	L1	Define ward round.	2
29.	2	L5	Discuss about the goals and objectives of clinical pharmacist on ward rounds.	2
30.	2	L6	Explain about pre-ward round participation.	3
31.	2	L1	Mention the guidelines of ward round participation.	3
32.	2	L6	Explain about the interventions at the time of ward round.	3
33.	2	L6	Explain about the communication skills at the time of ward round.	5
34.	2	L6	Describe about the ward round follow up.	3
35.	2	L1	Define ADRs.	2
36.	2	L6	Explain the management of ADRs.	5
37.	2	L1	Define drug information.	2
38.	2	L6	Explain about the methods how drug information is obtained.	5
39.	2	L1	Define poison information.	2
40.	2	L1	List the different sources of poison information.	2
41.	2	L1	Define medication history interview.	2
42.	2	L1	List out the aims or goals of medication history interview (BL-1)	2

43.	2	L6	Explain about different components involved in obtaining a medication history.	5
44.	2	L1	Mention the components of health history.	2
45.	2	L1	List the parts of medication history.	2
46.	2	L1	Mention the essential skills involved for obtaining medication history.	2
47.	2	L1	Define patient counseling.	2
48.	2	L1	List the aims of patient counseling	2
49.	2	L2	Outline different types of communication skills.	2
50.	2	L6	Explain about verbal communication.	3
51.	2	L6	Explain non-verbal communication.	3
52.	2	L6	Explicate the steps in patient counseling.	5
53.	2	L3	Summarize preparing for the session.	2
54.	2	L6	Explain about opening the session.	2
55.	2	L6	Describe about the counseling content.	3
56.	2	L1	Define closing the session.	2
57.	2	L1	List the counseling aids used in patient counseling.	2
58.	2	L1	Mention the barriers in patient counseling.	2
59.	2	L6	Explain the strategies to overcome the barriers during patient counseling.	3
60.	2	L3	Illustrate the role of pharmacist in patient counseling.	5
61.	2	L1	Define drug utilization evaluation.	2
62.	2	L1	Define drug utilization review.	2
63.	2	L1	Mention the aims of DUE.	2
64.	2	L1	List the types of DUE.	2
65.	2	L2	Outline the composition of DUE.	2
66.	2	L6	Describe the role of pharmacist in DUE.	3
67.	2	L1	Mention the function of DUE committee.	2
68.	2	L1	List the activities performed in DUE cycle.	2
69.	2	L6	Explain the steps involved in DUE cycle (BL	5

70.	2	L1	Define prospective review.	2
71.	2	L1	Define retrospective review.	2
72.	2	L1	Define concurrent review.	2
73.	2	L6	Explain the detailed classification of DUR.	3
74.	2	L1	Mention the aims of DUR.	2
75.	2	L6	Explain about quality assurance in clinical pharmacy services.	5
76.	2	L1	Define audit.	2
77.	2	L6	Explain the steps involved in audit cycle.	5

UNIT-III

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
78.	3	L1	Define patient case history.	2
79.	3	L2	Outline of the structure of patient case history.	2
80.	3	L6	Explain the evaluation of drug therapy.	5
81.	3	L1	List medical abbreviations used in clinical practices.	2
82.	3	L1	Mention the medical terms used in clinical practice.	2
83.	3	L6	Explain the importance of patient case history.	3

UNIT-IV

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
84.	3	L1	Define hematological tests.	2
85.	3	L6	Explain the process of formation of RBCs.	3
86.	3	L1	Define : MCV,PCV,MCH, MCHC	4
87.	3	L3	Summarize about reticulocytes.	3
88.	3	L1	Define : microcytic anemia, normocytic anemia and macrocytic anemia	3
89.	3	L6	Explain about different types of WBCs.	3
90.	3	L1	Define leucopenia and leukocytosis.	2

91.	3	L1	Define ESR.	2
92.	3	L1	Define C-reactive protein.	2
93.	3	L1	List different types of liver function tests.	2
94.	3	L6	Explain about different types of liver enzymes (BL	2
95.	3	L6	Explain about role of serum bilirubin in diagnosis.	3
96.	3	L1	Mention different types of serum proteins and add a note on each of them.	2
97.	3	L6	Explain about the following a. creatinine clearance b. serum creatinine	4
98.	3	L6	Describe about serum urea and BUN.	3
99.	3	L6	Explain about different types of renal function tests.	5
100.	3	L6	Explain about different types of thyroid tests.	5
101.	3	L6	Explain the physiology of formation of thyroid hormones.	3
102.	3	L6	Explain the causes, clinical features and investigations of hypothyroidism.	3
103.	3	L6	Explain in detail about autoimmune hypothyroidism.	3
104.	3	L6	Explain the etiology, clinical features and investigations of hyperthyroidism.	5
105.	3	L5	Discuss about autoimmune hyperthyroidism.	5
106.	3	L6	Explain about different types of tests in cardiac disorders	5
107.	3	L6	Explicate about the non-invasive tests in cardiac disorders.	5
108.	3	L6	Describe about invasive tests performed in cardiac disorders.	5
109.	3	L6	Explain in detail about fluid and electrolyte imbalance.	5
110.	3	L6	Explain about different types of cardiac enzymes and biomarkers.	5
111.	3	L6	Explain about the abnormalities caused due to imbalance in sodium levels.	3

112.	3	L3	Illustrate the abnormal clinical effects caused by the fluctuations in the levels Potassium.	3
113.	3	L3	Illustrate the effect of chloride ions.	3
114.	3	L3	Summarize about the imbalance in calcium ions on the body.	3
115.	3	L6	Describe about microbiological culture sensitivity tests.	5
116.	3	L1	Define microbiological culture sensitivity tests.	2
117.	3	L1	Mention the basis of microbiological culture sensitivity tests.	2
118.	3	L1	Enumerate the purpose of microbiological culture sensitivity tests.	3
119.	3	L6	Explain the test procedures in microbiological culture.	5
120.	3	L6	Explain about the different stages in the preparation of culture.	5
121.	3	L6	Explain in detail about inoculation technique.	3
122.	3	L3	Summarize about lawn technique.	3
123.	3	L6	Explain about streak plate technique.	3
124.	3	L3	Illustrate about pour plate technique.	3
125.	3	L6	Explain about incubation, isolation and identification of culture techniques.	5
126.	3	L6	Explain about the procedure involved in sensitivity tests.	5
127.	3	L1	Define pulmonary function tests.	2
128.	3	L1	Mention the purpose of pulmonary function tests.	2
129.	3	L1	Define Spirometry.	2
130.	3	L6	Explain about different volumes and capacities.	3

UNIT-V

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
131.	4	L1	Define drug information.	2

132.	4	L6	Explique about different types of drug information resources.	3
133.	4	L6	Explicate about systematic approach in answering drug information questions.	3
134.	4	L6	Explain about critical evaluation of drug information and literature.	5
135.	4	L5	Discuss about preparation of verbal and written reports.	3
136.	4	L5	Discuss the establishment of drug information center.	3
137.	4	L6	Explain the role of pharmacist in providing drug information.	3
138.	4	L1	Define poison information.	2
139.	4	L1	Enumerate different types of poison information resources.	2
140.	4	L6	Explain about the organization of poison information center.	5
141.	4	L6	Explain the role of pharmacist in providing poison information.	5

UNIT-VI

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
142.	5	L1	Define pharmacovigilance.	2
143.	5	L1	Illustrate the scope of pharmacovigilance.	2
144.	5	L1	Mention the aims of pharmacovigilance.	2
145.	5	L1	Define adverse drug reactions.	2
146.	5	L2	Classify ADRs.	2
147.	5	L1	Define Type A reactions.	2
148.	5	L1	Define Type B reactions.	2
149.	5	L1	Define Type C reactions.	2
150.	5	L	Define Type D and E reactions.	2
151.	5	L3	Illustrate the mechanisms involved in Type A reactions.	3

152.	5	L6	Describe the mechanisms involved in Type B reactions.	3
153.	5	L5	Discuss the predisposing factors in ADRs.	5
154.	5	L6	Explicate causality assessment of ADRs.	5
155.	5	L6	Explain about the different scales used in the assessment of ADRs.	5
156.	5	L6	Explain about WHO assessment scale.	5
157.	5	L1	Define dose related reactions.	2
158.	5	L	Define time related reactions.	2
159.	5	L1	List the example of type A and type B reactions.	2
160.	5	L3	Summarize the management of type A and type B reactions.	3
161.	5	L1	Define withdrawal reactions.	2
162.	5	L1	Mention how withdrawal reactions are managed.	2
163.	5	L6	Explain about the unexpected failure of drug therapy and management of these reactions.	5
164.	5	L4	Distinguish between type A and type B reactions.	3
165.	5	L1	List the features of type A reactions.	2
166.	5	L1	Mention the features of type B reactions.	2
167.	5	L1	State the effects of type C reactions.	2
168.	5	L1	List the examples of dose related ADRs.	2
169.	5	L1	List the examples of augmented and bizarre reactions.	2
170.	5	L6	Explain the management of delayed and end of use reactions.	5
171.	5	L6	Explain about Naranjo scale.	5
172.	5	L6	Explain about the detection of ADRs.	5
173.	5	L6	Explain about the monitoring of ARDs.	5
174.	5	L5	Discuss about reporting of ADRs.	3
175.	5	L6	Describe about the prevention of ADRs.	3
176.	5	L6	Explain about the management of ADRs.	3

177.	5	L1	Mention the role of pharmacist in management and detection of ADRs (BL	2
178.	5	L6	Explain the role of pharmacist in the reporting and monitoring of ADRs (BL	5

UNIT-VII

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
179.	6	L1	Define medication history interview.	2
180.	6	L1	Mention the aims or goals of medication history interview.	2
181.	6	L6	Explain about different components involved in obtaining a medication history.	5
182.	6	L2	Outline the components of health history.	3
183.	6	L1	List the parts of medication history.	2
184.	6	L3	Illustrate the essential skills involved for obtaining medication history.	3
185.	6	L1	Define patient counseling.	2
186.	6	L1	Mention the aims of patient counseling.	2
187.	6	L1	List different types of communication skills.	2
188.	6	L6	Explain about verbal communication.	3
189.	6	L6	Elaborate about non-verbal communication.	3
190	6	L6	Explain the steps in patient counseling.	5
191.	6	L3	Summarize about preparing for the session.	3
192.	6	L6	Explain about opening the session.	3
193.	6	L6	Describe about the counseling content.	3
194.	6	L1	Define closing the session.	2
195.	6	L1	Mention the counseling aids used in patient counseling.	2
196.	6	L1	Enumerate the barriers in patient counseling.	3
197.	6	L1	Mention the strategies to overcome the barriers during patient counseling.	2

198.	6	L6	Explain the role of pharmacist in patient counseling.	5

UNIT-VIII

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
199.	6	L1	Define pharmaceutical care concept.	2
200.	6	L6	Explain the steps in pharmaceutical care concept.	5

UNIT-IX

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
201	7	L6	Explain the concept of critical evaluation of biomedical literature	5

UNIT-X

S.No	CO	BLOOMS LEVEL	QUESTIONS	MARKS
202.	7	L1	Define medication errors.	2
203.	7	L5	Discuss about medication errors.	5

CLINICAL PHARMACY

ASSIGNMENT QUESTIONS

CO	BLOOMS LEVEL	QUESTIONS	MARKS
		ASSIGNMENT I	
1	5	Explain about Thalidomide Tragedy and Phenytoin Toxicity.	5
		ASSIGNMENT II	
2	5	Explain about the daily activities of a clinical pharmacist.	5
		ASSIGNMENT III	
4	6	Discuss about any one drug information query enquired to you on your ward rounds.	5
		ASSIGNMENT IV	
5	1&5	Define ADR and explain about the ADRs that occur due to reaction with drugs.	5
		ASSIGNMENT V	
6	6	Elaborate any one case study and write it in SOAP format.	5
		ASSIGNMENT VI	
7	5	Explain about the study that has been carried out by collecting an one article	5

CLINICAL PHARMACY

SLIP TEST QUESTIONS

CO	BLOOMS LEVEL	QUESTIONS	MARKS
		SLIP TEST I	
1	1&6	Define clinical pharmacy and explain about its history and development.	10
		SLIP TEST II	
2	1&5	Define Patient Data Analysis and explain about it	10
		SLIP TEST III	
3	5	Explain about Pulmonary Function Test	10
		SLIP TEST IV	
5	1&6	Define adverse drug reaction and describe the role of pharmacist in management of ADRs	10
		SLIP TEST V	
6	1&5	Define Patient Counselling and explain its steps	10
		SLIP TEST VI	
7	1&5	Define medication errors and explain its classification	10

Code No: PD303

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
Pharm.D IV Year Regular/Supplementary Examinations, July/August - 2021
CLINICAL PHARMACY

Time: 3 hours **Max.Marks:70**

Answer any five questions
All questions carry equal marks

1.a) Describe the methodology of patient data collection and its use in evaluation of drug therapy.
b) Discuss the importance of good communication skills for a clinical pharmacist. [8+6]

2. Discuss the role of a clinical pharmacist in patient care. [14]

3. Write in detail about the clinical lab tests used in the evaluation of disease and interpretation of results of:
a) Pulmonary function tests
b) Thyroid function tests. [8+6]

4. Describe the various types of adverse drug reactions and how their causality assessment is carried out. [14]

5. Write a short note on:
a) Establishment of drug information centre
b) Systematic approach in answering of drug information queries. [8+6]

6. Describe in detail about medication errors with suitable examples. [14]

7. Write a short note on:
a) Cardiac function tests and interpretation of their results
b) Poison information. [8+6]

8. Write a short note on:
a) Scope and aims of pharmacovigilance
b) Common medical terminologies used in clinical practices. [6+8]

—ooOoo—

Code No: PD403

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
Pharm.D IV Year Regular/Supply Examinations, October - 2020
CLINICAL PHARMACY

Time: 2 hours **Max.Marks:70**

Answer any five questions
All questions carry equal marks

1. What is clinical pharmacy? Enlist the daily activities of a clinical Pharmacist? Discuss in detail about role of clinical pharmacist in patient counseling and drug utilization evaluation. [14]

2. What is patient's case history? Write its use in evaluation of drug Therapy. Enlist any four medical terminologies used in clinical practices? [14]

3. Discuss about the following clinical laboratory tests and write their significance.
   a) Liver and renal function tests
   b) Pulmonary function tests. [7+7]

4. What are the resources of poisons information? Describe the systematic approach in queries related to drug information. [14]

5. Discuss in detail about scope and aims of Pharmacovigilance. What is the role of Pharmacist in the management of ADR? [14]

6. Discuss about different patient counselling techniques. Briefly outline various concepts of Pharmaceutical care. [14]

7. Describe in brief about:
   a) Evaluation of biomedical literature and
   b) Medication errors. [7+7]

8.a) Explain the role of clinical pharmacists in drug Therapy monitoring.
b) Write about Haematological and Thyroid function tests. [7+7]

---oOOoo---

Code No. 4.3

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
Pharm.D IV Year Regular Examinations, April/May - 2019
CLINICAL PHARMACY

Time: 3hours Max.Marks:70

Answer any five questions
All questions carry equal marks

---

1. Define and write the scope of Clinical Pharmacy. [14]

2.a) Explain the role of pharmacist in management of adverse Drug Reaction.
b) Write a note on pharmaceutical care concepts. [7+7]

3. What are Liver and Renal function tests? How are there used in evaluation of disease and how are the results interpreted? [14]

4. What are the different drug information resources? Enlighten them briefly. [14]

5. Write about scope, definition and aim of pharmacovigilance. [14]

6. What are the various patient counseling techniques in relation to Antibiotics and Antihypertensives? [14]

7. Write different medication errors. How can you prevent and overcome them? [14]

8. Write about patient case history, its structure and use in evaluation of drug therapy. [14]

—ooOoo—

Established

Code No. 4.3

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
Pharm.D IV Year Regular Examinations, March/April - 2018
CLINICAL PHARMACY

Time: 3hours **Max.Marks:70**

Answer any five questions
All questions carry equal marks

1.a) Discuss the management of Adverse Drug Reactions. [7+7]
b) Write any two methods of Drug Therapy Monitoring.

2.a) Explain the role of patient's case history in the evaluation of drug therapy. [7+7]
b) Describe various types of audit for clinical pharmacy services.

3.a) Discuss the significance of Renal and Pulmonary Function Tests.
b) Write microbiological culture sensitivity tests in the evaluation of health and disease. [8+6]

4.a) Describe the requirements for establishing Drug Information Centre. [7+7]
b) Explain Drug Information Services.

5.a) Discuss causality assessment of adverse drug reactions. [7+7]
b) Write the role of pharmacist in the management of ADRs.

6.a) Explain biomedical literature evaluation. [7+7]
b) Discuss the concepts of pharmaceutical care.

7. Write notes on:
a) Drug Utilization Evaluation
b) Medication Errors
c) Patient Counseling Techniques. [4+5+5]

8.a) Explain the preparation of written and verbal reports. [6+8]
b) Describe medication history interview.

---ooOoo---

Code No. 43

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
Pharm D IV Year Regular Examinations, April/May - 2017
CLINICAL PHARMACY

Time: 3hours **Max.Marks:70**

Answer any five questions
All questions carry equal marks

1. Define Clinical Pharmacy. Discuss in detail the role of clinical Pharmacist in drug information and drug Therapy monitoring. [14]

2. Write the structure of Patient's case history. How is it useful in evaluation of drug Therapy? [14]

3. Write about following clinical laboratory tests along with the interpretation of test results.
   a) Tests associated with cardiac disorders
   b) Microbiological culture sensitivity tests. [7+7]

4. What are the resources for drug information? Discuss about the establishment of drug information centre.. [14]

5. What is Pharmacovigilance? Write its status in India. Classify various types of ADR's? How are they prevented? [14]

6. Discuss various methods of counselling of patients. Add a note on presentation of cases. [14]

7. Discuss about the following:
   a) Bio-medical Literature
   b) Medication errors. [7+7]

8.a) Explain the role of clinical Pharmacist in DUE and DUR.
b) Discuss the significance and importance of pulmonary function tests and Thyroid function tests. [7+7]

ooOoo

21/6/13 afternoon

Code No. 4.3

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
Pharm D Fourth Year End Examinations, June-2013
Clinical Pharmacy

Time: 3hours Max.Marks:70

Answer any five questions
All questions carry equal marks

---

1. Write a detailed note on development and scope of clinical pharmacy in India. [14]

2.a) What is ward round participation? Describe the types, procedure and significance of ward round participation.
b) Discuss various test performed to evaluate Liver function. [10+4]

3.a) Discuss the protocol and importance of Drug Utilisation Evaluation (DUE) and Reviesw(DUR) Programme in hospital.
b) Short note on Pharmaceutical care concepts. [10+4]

4.a) Discuss the importance of communication skills in patient counseling.
b) Importance of Patient Medication history review. [7+7]

5. Short notes on:
a) Role of pharmacist in management of ADR.
b) Scope and aims of pharmacovigilance. [7+7]

6.a) Define Medication error, Explain the various categories of medication errors with examples.
b) Systematic approach in answering DI queries. [10+4]

7. Discuss in detail about importance of:
a) Drug information services
b) Fluid and electrolyte balance. [7+7]

8.a) Write a brief notes on drug and poison information.
b) Discuss the indicators used to evaluate renal function. [7+7]

****

1

DEFINITION, DEVELOPMENT AND SCOPE OF CLINICAL PHARMACY

DEFINITION:

Clinical pharmacy is the branch of Pharmacy where pharmacists provide patient care that optimizes the use of medication and promotes health, wellness, and disease prevention. The practice of clinical pharmacy embraces the philosophy of pharmaceutical care, blending a caring orientation with specialized therapeutic knowledge, experience, and judgment to ensure optimal patient outcomes. Clinical pharmacy is a key area of the pharmacy profession.

CLINICAL PHARMACIST:

Clinical pharmacist is the expert in therapeutic use of medication therapy, evaluation and recommendation of drugs to the patient and other health care professionals. The term clinical pharmacy is being used to describe the new growth of pharmacists. It comprises of functions necessary to discharge a particular set of social responsibilities related to therapeutic drug use in the following major categories.

1. Prescribing drugs
2. Dispensing and administering drugs
3. Documenting professional services
4. Direct patient involvement
5. Reviewing drug use
6. Education
7. Consolation

AIM OF CLINICAL PHARMACY:

The aim of clinical pharmacy is to ensure the patient's maximum well-being and to play a meaningful role in the safe and rational use of drugs.

The main roles of clinical pharmacy are:

1. To assist the physician in doing a better job of prescribing and monitoring drug therapy for the patient.
2. To assist medical and paramedical staff and documenting medication indications correctly.
3. To maximize the patients' compliance in drug use process.

QUALITIES OF CLINICAL PHARMACISTS:

The clinical pharmacist should have the following qualities.

1. Good communication skills
2. Clinical skills
3. Professional relationship
4. Empathy
5. Monitoring drug therapy

ROLE OF CLINCIAL PHARMACIST IN HEALTHCARE TEAM:

The Clinical Pharmacist has the following roles.

1. Taking medication history of the patient
2. Drug interactions
3. Selection of drug therapy
4. Drug monitoring
5. Adverse drug reactions
6. Management of drug policies
7. Research and development programme
8. Drug information

DUTIES OF CLINICAL PHARMACIST:

The daily routine duties of Clinical Pharmacist are,

1. Assisting pharmacokinetic consultations with necessary follow up.
2. Monitoring drug therapy schedule.
3. Taking rounds with health care team
4. Teaching pharmacy students
5. Patient counseling
6. Review of hospital forbid art
7. Preparation of drug monograph to be reviewed by pharmacy and the therapeutic community of hospital.

In this manner, clinical pharmacy is totally patient oriented and deals with rationale of drug therapy.

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.

DEVELOPMENT OF CLINCIAL PHARMACY:

- India's first degree in pharmacy at Banaras Hindu University was established seventy years ago under the able leadership of Professor Mahadev Lal Schroff.
- The pharmacy Act was drafted after Independence in 1948 under the aegis of the Pharmacy Council of India, the body established to control the standards of the pharmacy profession.
- During the 1980s and 1990s the consequences of drug use, such as poor health outcomes from drug treatment, antibiotic resistance, adverse drug reactions and economic loss to patient and the wider healthcare system were acknowledged not just by the pharmacy profession but also by the medical profession, consumer and patient organizations and the government.
- The early development of pharmacy practice and clinical pharmacy was hampered by a lack of teaching personnel with this problem, academic leaders of the profession examined options including the possibility of support from overseas.

- As a result the first Master's in Pharmacy Practice programs were offered by the JSS College of Pharmacy at Mysore and Ooty in 1996 and 1997.
- In Tamil Nadu, a program was initiated at Sri Ramakrishan Institute of Paramedical Sciences, Coimbatore and its attached hospital in 1998.
- KLE College of Pharmacy,Belgaum began its clinical pharmacy practice and education program in 1999 using KLE hospital as a teaching base.
- The National Institute of Pharmaceutical Education and Research (NIPER) in Mohali, Punjab also established a new department of Pharmacy Practice.
- The result of this expansion is that the pharmacy profession in India is in transition.
- It is moving from being a technical, industry oriented profession to one that also has a significant role in the healthcare system.
- Clinical pharmacy has been evolving now for some 40 years. One of the most exciting recent development is the introduction of clinical pharmacy education and practice in countries such as India, where these services have previously been limited.

SCOPE OF CLINICAL PHARMACY:

There is a tremendous scope of clinical pharmacy practice at various levels of the pharmacy profession.

1. Preparation of patient medication histories:

- 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 over dosages, 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.

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 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.

7. 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 patient's responses to drug therapy and help him in the selection and use of OTC drugs.

8. 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.

9. Clinical research and continuing education program:

- The clinical pharmacist can participate in an evaluation program on investigational drugs. θHe 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.

10. 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.

DRUG THERAPY MONITORING

- Drug therapy monitoring is also called as monitoring drug therapy. It is process which encompasses all those functions necessary to ensure appropriate, safe, efficacious and economical drug therapy to the patient.
- They include;
  - Reviewing the prescriber's choice of a drug for the diagnosed condition
  - Reviewing drug administration
  - Assuring correct dosing (which includes amount, frequency, route and dosage form)
  - Recognizing the pressure or lack of adequate therapeutic response
  - Assessing the potential for and occurrence of adverse effects.
  - Recommending changes or alternatives in therapy as the particular situation dictates
- The goal of monitoring drug therapy can be phrased as "maximizing the benefits of drug therapy and minimizing the risks.
- Patient's records especially medical records play an important role in the process of monitoring drug therapy. There are two types of medical records

1. The source oriented records

- In this type of record the clinical information written or placed in the medical record has been recorded in a narrative chronological sequence in major subsections of the chart. This is termed the source oriented record (SOR)

2. The problem oriented records

- This system of record keeping of clinical information is more in an orderly format and provides a more organized approach to clinical data than SOR and allows for easy interpretation of patient's status.
- It is divided into
  1. Data base section: This section contains pertinent history, physical and laboratory information.
  2. Problem list: This section contains proven diagnosis, syndrome, operation, symptoms, abnormal laboratory test values, allergies and or social or psychological problems.
  3. Progress reports: This section consists of chronological notes on the problems listed for the patient. Each problem is approached in a specific format called SOAP.
  4. Discharge summary: This section contains a problem-by-problem discharge summary utilizing the SOAP format.

PROCESS OF DRUG THERAPY MONITORING:

1. Take patient data and orient the data into a problem format:

- The pharmacist should review patient's medical record
- Patient's problem list should be reviewed and patient profile should be prepared which should be simple.
- The profile should consist of patient's name, age, sex, reason for admission, provisional diagnosis.

- Once this patient profile is documented each problem should be listed by number and under each problem the pharmacist should develop SOAP format. This allows for the goal of therapy for that problem.
- The pharmacist should review and re-evaluate the plan daily for any changes that may have occurred and update the same.

2. **Relate drug therapy to the specific problem or disease states in order to determine the appropriateness of the specific therapy:**

- Rationality of drug use is determined by experience, judgment and reference to appropriate resources.
- This requires evaluation of the specific drug used for a given disease or problem, correctness of dose, dosage form and dosing interval.
- Frequency of administration and dosage form should be reviewed regularly for appropriateness.
- If dosing problems are noted at any point, the pharmacist should determine an alternative.

3. **Develop specific therapeutic goals:**

- The goal of therapy for a disease or problem will be to cure it.
- The physician will set certain goals for treatment for individual patient
- These goals are included in the plan section of the SOAP format
- For example, the goal for most infectious diseases is to cure the disease, whereas for diseases like diabetes or heart failure, the goal is to halt the progress of the disease.

4. **Develop monitoring parameter for each drug used:**

- Specific parameters to be utilized in the process of monitoring drug therapy should be prepared by the pharmacist
- These parameters will be helpful to determine the therapeutic effectiveness and the occurrence of adverse effects
- The pharmacist should review daily and routinely, the nursing and physician progress notes, lab test reports and assess any changes in drug therapy.

5. **Identify problems and/or the potential for ADR:**

- Problems such as contraindications to drug use, dosing inappropriateness, drug toxicity, administration error, inappropriate therapy etc. may arise during the monitoring process.
- The pharmacist should identify such problems and take corrective measures.
- The pharmacist first must determine if this problem is drug related and then confirm.

6. **Develop alternatives or solution to problems:**

- Alternatives or solutions must be formulated to the problems identified
- After confirming the alternative solution the pharmacist should recommend it to the physician
- These recommendations can be either oral/written and should include the identification and confirmation of the problem.

7. **Communicate any findings and recommendations for solutions or alternatives:**

- Before the pharmacist communicates his recommendations for corrective action, he should identify exactly the person who should be communicated and in whose area of operations the problem lies.
- The pharmacist should develop his clinical skills so that he can meet the demands and responsibilities of monitoring drug therapy successfully.

MEDICATION REVIEW

DEFINITION:

Medication review involves the review of a patients medication regimen to ensure that therapy is appropriate, safe, efficacious and cost effective. This can be achieved by pharmacists attending ward rounds on a day to day basis and applying their knowledge of therapeutics in the management of specific diseases or conditions.

GOALS:

- The goal of medication review is to optimize drug therapy and patient health outcome by identifying and solving drug related problems and ensuring that all therapeutic objectives are being achieved.

SINIFICANCE:

- Daily review of patients drug therapy enables the pharmacist to:

1. Assess whether desired therapeutic are being achieved.
2. Monitor for drug related problems/ toxicity.
3. Ensure rational and quality use of medicines
4. Assess patient compliance (medication adherence)
5. Assess the completeness of medication charts.

COMPONENTS:

1. Medication order review/ Treatment chart review
2. Clinical review/ Daily progress review.
3. Detection and management of adverse drug reactions

MEDICATION ORDER REVIEW (MOR):

- Medication order review is one of the fundamental responsibilities of clinical pharmacy practice.
- MOR is a systematic review of a patient's drug therapy to ensure that the prescribed medication is appropriate for the patient.
- It involves the assessment of all current and recent medication orders, including routine medication and over the counter (OTC) drugs and the use of other systems of medicine (unani, Ayurveda, siddha).

GOALS OF MOR:

- The steps involved in MOR include:

1. Collection and interpretation of patient-specific information including medication history interview.
2. Assessment of therapeutic goals
3. Identification of drug related problems
4. Individualizing medication regimens
5. Monitoring of treatment outcomes
6. Medication chart endorsement
7. Documentation

1. Collection and interpretation of patient-specific information including medication history interview:

- Collection of patient-specific information is he first step in setting the therapeutic goal for a

patient.
- Pharmacists need to collect information that will assist them to determine the appropriateness of drug therapy. This includes the patient's demographic details such as age, gender, body weight, social history, present compliant, past medical history, allergy and sensitivity status, current and recent medication and results of relevant laboratory tests and other investigations.
- This enables the pharmacist to understand patient's disease condition, the reason why certain drugs are being administered and patient's daily clinical progress.
- When a patient is admitted to hospital, medical staff document relevant information regarding the admission in patient's case notes.
-By speaking personally to patient's about their medication, pharmacist can obtain further information which may be of importance to patient. This process is sometimes referred to as medication history interview (MHI).
- The goal of MHI is to obtain a complete and accurate summary of the medications that a patient has been using, together with other information which may usefully contribute to pharmaceutical care.
- The MHI enables the pharmacist to:
1. Establish a rapport with the patient.
2. Explain their role in patient management
3. Conduct preliminary medication counselling
4. Plan ongoing patient management/ pharmaceutical care
- The pharmacist should assess the patient's understanding and attitude towards their medications and health condition.

2. Assessment of therapeutic goals:

- In order to determine appropriateness of drug therapy it is essential to understand the therapeutic goals for the individual patient. These may include one or more of the following:
1. Cure of the disease
2. Reduction / elimination of signs and symptoms
3. Arresting or slowing disease progression
4. Preventing disease/symptoms
- These goals should be tailored to the patient's individual circumstances and may differ from patient to patient based on their age, co-morbidities and the nature and severity of their illness.

3. Identification of drug related problems:

- While reviewing patient's drug therapy, one of the main objectives is to identify and resolve any drug related problems.
- A drug related problem is any event or circumstance involving drug treatment that interferes or potentially interferes with the patient achieving an optimum outcome of medical care.
- Drug related problems include:
1. Untreated indication
2. Improper drug selection
3. Sub therapeutic dose
4. Over dosage
5. Adverse drug reactions
6. Failure to receive drugs

7. Drug interactions
8. Drug use without indication

1. Untreated indication:

- Does the patient have an untreated medical condition or indication which may benefit from drug therapy? When reviewing the indication for drug therapy, it is important to consider whether the indication may be an unrecognized ADR

2. Improper drug selection:

- Does the patient have a medical condition for which the wrong drug is taken? It is important to ensure that the most appropriate drug has been chosen to treat the patients' medical condition.

3. Sub therapeutic dose:

- Does the patient have a medical condition for which too little of the correct drug us being taken? The dose and dosing regimen should be individualized based on the patients' medical condition.
- For some drugs with a narrow therapeutic index and where there is an established relationship between serum concentration and therapeutic effect, therapeutic drug monitoring can be useful aid.

4. Over dosage:

- Does the patient have a medical problem for which too much of the correct drug is being taken? Once again, TDM may be useful for some drugs. Over dosage may also occur if a patient takes a drug for a longer period than necessary.
- Over dosage can also occur if the same generic drug has been prescribed twice under different brand names. Both individual doses and the total daily dose should be assessed.

5. Adverse drug reactions:

- Does the patient have a medical condition which is the result of an ADR?
- The detection of an ADR is crucial in the management of any patient since failure to recognize an ADR may result in continuing patient morbidity.
- As a first step the pharmacist should check that the patient is not allergic to the prescribed drug, or has had an adverse reaction to the drug in the past.
- Secondly it is important to assess the patient for the presence of any new symptoms, increased severity of baseline symptoms, abrupt cessation of medication or addition of anti-allergic medicines and or steroids.
- All patients especially those who are most susceptible to develop an ADR should be monitored on a daily basis for any possible ADR.

6. Failure to receive drugs:

- Does the patient have a medical condition that is the result of him or her not receiving a drug?
- This may be due to many factors including non-adherence, poor administration techniques, missed doses due to medication errors, sub-standard drugs, non-availability of the prescribed drug or the patient's inability to pay for the medication.

7. Drug interactions:

- Does the patient have a medical condition that is the result of a drug -drug or drug food interaction?
- Does interactions vary in their clinical significance and the pharmacist needs to make a professional judgement whether a change in drug therapy is necessary?

- The pharmacist should identify and resolve drug-drug interactions of clinical significance to avoid adverse consequences.

8. Drug use without indication:

- Is the patient taking a drug for which there is no valid indication?
- Pharmacists should prioritize any drug related problems that are identified according to their severity and possible consequences, using their knowledge and clinical experience, pharmacists must make a professional judgement about which problems are of greatest importance to the patient's welfare.
- After the drug related problems have been assessed for severity and acuity, potential corrective action needs to be considered before deciding on the most appropriate action to resolve the problem.
-If a change in therapy appears necessary the pharmacist must outline the problem to medical staff caring for the patient, and discuss the options for resolving the problem.

4. Individualizing medication regimens:

- Once drug related problems relating to individual drugs on the medication chart have been resolved, the next step is to consider the patients overall medication regimen. This is particularly important for patients with chronic diseases who are on many drugs on a long term basis.
- In individualizing the medication regimen, the pharmacist should consider patient data including past medical history, co-morbid conditions, allergic history and concurrent disease.
- The aim should be to simplify the regimen as much as possible and to adjust the regimen maximize long term medication adherence. This may involve switching to slow release formulation of the same drug, using a different route of administration, changing the time at which doses are taken or switching to a cheaper but effective and safe medication.
- Sometimes a combination formulation can be used to replace two drugs which are being taken at similar doses as in the combination product. This should only be done after the doses for the individual drugs have been stabilized.

5. Monitoring of treatment outcomes:

- Monitoring of treatment outcomes is the key to assessing whether the therapeutic goals of drug treatment have been achieved.
- It is an ongoing process and involves a review of the patient's clinical status, laboratory data and other markers of drug therapy response.
- In hospitals monitoring of treatment outcomes is usually carried out on a daily basis by the attending doctors as part of their overall clinical review of the patient's progress and clinical status.

6. Medication chart endorsement:

- Chart endorsement is one of the primary responsibilities of the pharmacist in ensuring that medication orders are unambiguous, legible and complete.
- It is now routine practice for pharmacists to document on the medication chart the relevant aspects of medication administration.
- It is essential to avoid medication errors, including those that might occur at the level of prescribing and/or administration due to incompleteness of the order, lack of adequate instructions and illegibility.
- Medication charts should be reviewed on a daily basis so that new drug orders can be annotated

in a timely manner

7. Documentation:

- The pharmaceutical care provided to a patient should be an integral part of the patients' medical record.
- The documentation of pharmaceutical care provided can be made either in the medication chart or in case notes with a clear title, with the pharmacist's signature.
- Documentation of services in the patients' medical record is then accessible to all other healthcare professionals.
- Computerization of relevant information relating to pharmaceutical problems may be useful in hospitals where patient's data is accessible to healthcare providers through a networking system

CLINICAL REVIEW

DEFINITION:

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 patient's progress for the purpose of assessing the therapeutic outcome.

GOALS:

- The primary aims of the clinical review are to:

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

PROCEDURE:

- Clinical review should be done routinely for all patient's.
- It is usually carried out every day by the attending doctor's, while evaluating their patient's to monitor the patient outcome to drug therapy.
- In evaluating a patient's response to drug therapy the pharmacist may need to review biochemical, hematological, microbiological and other investigations as appropriate.
- Other essential information required may be obtained from other healthcare professionals and patient's
- Collection of all clinically relevant data involves the use of the following sources:

1. Case notes
2. Observation charts (fluid balance, blood/urine sugar, temperature and pulse)
3. Medication history interview record.
4. Discussion with the patient and other healthcare professionals.

- The data should be interpreted to assess whether or not progress is being made towards the targeted objectives.
- These objectives should be specific to the patient's condition and could be cure of the disease, reduction in the patient's signs and symptoms, arresting/slowing the disease process, prevention of disease and improving the quality of life.
- The information obtained must be interpreted and evaluated with reference to:

1. The clinical features of the disease being treated.
2. The need for an investigation
3. Aspects related to drug effects (onset and duration)
4. Medication history of the patient.
5. The desired therapeutic outcomes

- If the therapeutic objectives are not being achieved, the clinical pharmacist should re-evaluate the appropriateness of treatment and discuss any relevant issues with the clinicians.
- The intervention could be of any type (change of drug, dose adjustment, cessation of drug etc.), but the recommendations should be specific and directed towards achieving the therapeutic goals for the problem identified.

WARD ROUND PARTICIPATION

MEDICAL WARD ROUND:

1. A medical ward round is a visit made by a medical practitioner, alone or with a team of health care professionals and medical students, to hospital in-patients at their bedside to review and follow up progress in their health.
2. At least one ward round is conducted every day to review the progress of each inpatient, although more than one is not uncommon.

GOALS AND OBJECTIVES OF CLINICAL PHARMACISTS ON WARD ROUNDS:

The goals of a clinical pharmacists participation in ward rounds are to:

1. Gain an improved understanding of the patients clinical status and progress, current planned investigations and therapeutic goals.
2. Providing relevant information on various aspects of the patient's drug therapy such as pharmacology, pharmacokinetics, drug availability, cost, drug interactions and adverse reactions.
3. Optimize therapeutic management by influencing drug therapy selection, implementation, monitoring and follow up.
4. Investigate unusual drug orders or doses.
5. Assimilate (collect) additional information about the patient such as co-morbidities, medication compliance or complementary and alternative medicine (eg. herbal remedies).
6. Detect adverse drug reactions and drug interactions.
7. Participate in patient discharge planning.
8. Ward round participation also provides many learning opportunities for pharmacists.
9. It allows them to see first-hand how medicines are used and prescribes and to see the effects of these medicines on patients.
10. For those involved in academia and research, ward rounds allows identification of cases for clinical teaching and publication.
11. Finally ward round participation strengthens the inter-professional relationship among various health professionals, leading to better healthcare practice and research.

PRE-WARD ROUND PREPARATION:

1. Pharmacists need to prepare adequately before participating in ward rounds.
2. Accurate and up to date information on the patient's health status, disease management and medical and medication history is essential for active participation in clinical decision making.
3. To achieve this, a review of the medication chart and case record should be completed before to the ward round.
4. Pre ward round participation gives an overview of the medication and condition related issues that may be brought up during a ward round and allows the pharmacists to be proactive during the round.
5. Many clinical pharmacists maintain individual patient profile which summaries relevant information about patient's drug therapy. This includes allergies or hypersensitivities, the reason

for admission, provisional or final diagnosis, post medical history, laboratory data, other relevant investigations and reports, and also information such as medication compliance and medication administration skills.

6. These details are collected by reviewing the patient's care record and treatment charts as well as by interviewing the patient.
7. Information may be recorded on specific forms designed by pharmacists.
8. During pre-ward round preparation issues may arise that need to be clarified by referring appropriate information resources.
9. It may also be useful to make a note of the interventions or recommendations to be made during the ward rounds listed in order to priority.
10. For all newly admitted patients it is appropriate to collect a detailed medication history from the patient or their attenders, which needs to be cross-checked with information collected by other health care professionals.
11. Any relevant new information obtained during the medication history interview which may change patient management (eg. history of allergy to a medicine) should be brought to the attention of the appropriate healthcare professionals and used to update existing patient profile.

Thus pre-ward round preparations allows the pharmacists to be well-informed and organized before discussing patient management and contributing to the decision making process.

GUIDELINES/PRACTICAL TIPS FOR WARD ROUND PARTICIPATION:

1. Pharmacists should complete their pre ward round preparation well ahead of commencement of the round.
2. In hospitals with a formulary or drug list, the pharmacists should ensure that all prescriptions are in accordance with the hospital formulary.
3. Clinical pharmacists may wish to carry appropriate references while working in wards like British National Formulary (BNF), Drug Information Handbook and Australian Medicines Handbook are some commonly used references.
4. When identifying potential problems such as drug interactions, adverse reactions and medication errors, pharmacists should be prepared to suggest alternatives to resolve the problem. For eg: If the medical team accepts the pharmacists suggestion that the amlodipine may be contributing to a patient's peripheral edema, the pharmacists should be prepared to answer the obvious question which may follow, which alternative anti-hypertensive would you recommend for this patient.
5. Pharmacists should avoid the temptation to enter discussions concerning diagnosis.
6. Thorough pre-ward round familiarity with the patient's medical history will allow the pharmacists to discuss the appropriate options.

INTERVENTIONS DURING WARD ROUNDS:

During ward rounds the physician first interviews the patient or care taker about the patient's symptoms, complaints and progress. This is usually followed by physical examination, then a review of laboratory data and other diagnostic tests.

PHARMACY INTERVENTIONS:

A pharmacy intervention is defined as any action by a pharmacist that directly results in changes in patient's management or therapy.

Opportunities for interventions arise during various clinical pharmacy activities including medication history interview, medication chart review, therapeutic drug monitoring providing drug information and ward round participation.

The main drug-related queries that may arise during ward rounds relate to:

1. Dose and frequency
2. Choice of medication
3. Adverse effects
4. Drug interactions
5. Formulations
6. Duration of therapy
7. Actions and uses/pharmacology
8. Drug availability/ supply
9. Identification of patient's medication's on admission
10. Legal and administrative issues
11. Miscellaneous such as storage conditions

Interventions are more likely to be successful when pharmacists recommend solutions/alternatives for the drug therapy which has been identified. They should have good contact with the physicians, nurses and other healthcare professionals, medical and research staff. The experience and communication skills of the pharmacists and their relationship with medical staff are critical factors determining the success of pharmacist intervention.

COMMUNICATION DURING WARD ROUNDS:

1. Clinical pharmacists must work closely with other healthcare professionals to meet the healthcare needs of patients.
2. Effective communication skills and clinical knowledge are important for effective participation in ward rounds and clinical meetings.
3. Pharmacists need to take an active role in patient care by conveying their views on patient management to other healthcare professionals.
4. Good inter-professional relationships are key for success.
5. On most occasions the clinicians will speak to their patients in the regional language.
6. Knowledge of the regional language helps the pharmacists to follow the conversation between clinicians and patients.
7. It also helps the pharmacists to interact effectively with patients.
8. Pharmacists should be cautious while discussing drug-related issues on the ward round in the presence of patients on their care takers.
9. Interventions or recommendations should be made in a way which does not challenge the prescriber's integrity or affect the patient's faith in the prescriber.
10. Whenever pharmacists are uncertain about an answer, they should not try to bluff or guess,

but rather acknowledge this to prescriber.
11. Health professionals and patients may underestimate the skills of the pharmacists and may question their potential role in patient care. There should be good relationship between the pharmacists, healthcare professionals and patients.
12. Pharmacists should not expect a pat on the back from physicians even for recommendations that result in significant improvement in patient outcome.
13. In countries where clinical pharmacy is well established, pharmacists and physicians share responsibility for the management of the patient's drug therapy.
14. Pharmacists should always avoid open or implied criticism of other healthcare professionals.
15. Inter-professional respect and teamwork are key factors for success.

WARD ROUND FOLLOW-UP:

Some of the issues that may arise during a ward round includes:
1. Responding to enquiries:
All unwanted queries raised during ward-rounds should be recorded and followed up at the earliest.

2. Communicating information:
In some instances, the clinical pharmacists may need to communicate changes in drug therapy during ward rounds to relevant healthcare personnel such as medical , nursing, pharmacy, technical or dietetics staff.

3. Completing documentation:
In some situations, recommendations or interventions made by the pharmacists during a ward round may need to be documented appropriately. ADRS identified during the round may need to be documented on an alert sheet.

4. Alerting the patient's care plan:
The pharmacist may need to make alterations to the patient's care plan as a result of changes in patient management. Eg: monitoring of drug levels or other laboratory investigations.

5. Discussions with patient's:
If appropriate, the pharmacist should discuss drug therapy issues with patient's. Eg: Reasons for alteration in therapy, drug administration etc.

ADVERSE DRUG REACTION

DEFINITION:
WHO defines ADRs as any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases.

CLASSIFICATION:
1. Type A (Augmented)
2. Type B (Bizarre)
3. Type C (Continuous)
4. Type D (Delayed)
5. Type E and F

TYPE A:
- These are dose dependent
- Eg: insulin induced hypoglycemia
- These reactions are predictable due to known pharmacology of a drug and are thus preventable
- Less morbidity and mortality

TYPE B:
- These are hypersensitivity reactions and are not dose dependent
- Eg: Penicillin induced hypersensitivity reaction
- These reaction are not predictable and preventable
- High morbidity and mortality

TYPE C:
- Type C reactions are diseases that occur at a higher frequency among exposed patients than those unexposed.
- Eg: Higher frequency of cardiovascular events among patients exposed to COX-2 inhibitors rofecoxibe compared with an unexpected control group.

TYPE D:
- These are time dependent

TYPE E:
- Withdrawal reaction
- Eg: Opiate reaction

TYPE F:
- Unexpected failure of therapy
- Failure of use of oral contraceptives along with enzyme inducers often caused by drug interaction.

Type of Reaction (Mnemonic)	Features	Examples	Management
A: Dose related (Augmented)	Common Related to the pharmacologic action of the drug – exaggerated pharmacologic response Predictable Low mortality	Dry mouth with tricyclic antidepressants, respiratory depression with opiods, bleeding with warfarin, serotonin syndrome with SSRIs, digoxin toxicity	Reduce dose or withhold drug Consider effects of concomitant therapy
B: Non–dose related (Bizarre)	Uncommon Not related to the pharmacologic action of the drug Unpredictable High mortality	Immunologic reactions: anaphylaxis to penicillin Idiosyncratic reactions: malignant hyperthermia with general anesthetics	Withhold and avoid in future
C: Dose related and time related (Chronic)	Uncommon Related to the cumulative dose	Hypothalamic-pituitary-adrenal axis suppression by corticosteroids, osteonecrosis of the jaw with bisphosphonates	Reduce dose or withhold; withdrawal may have to be prolonged
D: Time related (Delayed)	Uncommon Usually dose related Occurs or becomes apparent sometime after use of the drug	Carcinogenesis Tardive dyskinesia Teratogenesis Leucopenia with lomustine	Often intractable
E: Withdrawal (End of use)	Uncommon Occurs soon after withdrawal of the drug	Withdrawal syndrome with opiates or benzodiazepines (e.g., insomnia, anxiety)	Reintroduce drug and withdraw slowly
F: Unexpected failure of therapy (Failure)	Common Dose related Often caused by drug interactions	Inadequate dosage of an oral contraceptive when used with an enzyme inducer Resistance to antimicrobial agents	Increase dosage Consider effects of concomitant therapy

PREDISPOSING FACTORS:

Polypharmacy:

- Patients on multiple drug therapy are more prone to develop an ADR either due to alteration of drug effect through an interaction mechanism or by synergistic effect.
- Amount of risk which is associated with multiple drug therapy increases with an increase in the number of drugs administered

Multiple and intercurrent diseases:

- Patient with multiple diseases are at increased risk of developing an ADR due to multiple drug use for their diseases.
- Patients with hepatic or renal status are also at high risk of developing an ADR to drugs which are eliminated by these organs.
- Eg: Patient with decreased renal function treated with aminoglycosides is at an increased risk of developing nephrotoxicity unless appropriate dose adjustments are made.

Age:

- Elderly and pediatrics are more vulnerable to ADRs

* Elderly patients are more susceptible to ADRs due to physiological changes which accompany ageing and also due to the intake of drugs for chronic and multiple diseases.

* Nitrates or ACE-I induced postural hypotension is an eg where reaction may be exacerbated by

age related impaired baroreceptor response to a change in posture

* Pediatric patient may develop serious ADRs to some drugs since all children especially neonates differ in their drug handling capacity compared to adults.

- Eg of such a serious reaction is the grey baby syndrome with chloramphenicol.

 # Drug Characteristics:

- Some drugs are highly toxic in nature and patients treated with these agents are at an increased risk of ADRs

- Eg: Nausea and vomiting is a common ADR seen in patients treated with cytotoxic anti-cancer drugs.

 # Gender:

- Women are more susceptible to ADR than men due to the following reasons:

1. Physiological
2. Pharmacodynamic
3. Pharmacokinetics
4. Hormonal

- Chloramphenicol induced aplastic anemia and phenylbutazone induced agranulocytosis are twice and thrice as common in women as in men.

 # Race and genetic factors:

- ADRs are common in genetically predisposed individuals.

- Eg: Patients with glucose-6-phosphate dehydrogenase deficiency are at higher risk of developing hemolysis due to primaquine than those who are not.

MECHANISMS:

- MECHANISMS OF TYPE A ADRs:

 # Pharmaceutical Causes:

- Pharmaceutical causes include changes in the drug quantity present in a particular product and changes in drug release properties.

- Eg:

1. Two brands of poorly soluble antifungal agent griseofulvin having widely different particle size in the final dosage form.
2. Another eg for risk of ADR is doxycycline
3. Brands containing hydrogen chloride salt-associated with high frequency of esophageal strictures and ulcers in patients lying down or who do not take the medicine with an adequate amount of water.

 # Pharmacokinetic causes:

- Changes in drug effect due to alteration in pharmacokinetic parameters may be experienced as therapeutic failure or toxicity.

*** Absorption:**

- Alteration in rate and extent of drug absorption may result in adverse drug effects.

- The plasma concentration of drug is partly determined by the rate at which the drug is absorbed after ingestion or injection.

- The plasma concentration of an orally administered drug in urn depends on gastric emptying rate.

- Factors influencing the extent of drug absorption includes drug formulation, gastrointestinal

motility, first pass metabolism, concomitant administration of other drugs and the absorptive capacity of gastrointestinal mucosa.

*** Distribution:**

- Factors determining the extent of distribution of drug includes: regional blood flow, membrane permeability and protein/tissue binding.

*** Metabolism:**

- Increased risk of ADRs in an individual with reduced metabolic rate due to higher accumulation of drug in the body.
- Therapeutic failure may occur in an individual who has an enhanced metabolic rate.
- CYP3A4 is responsible for metabolism of medicines like nifedipine, erythromycin and cyclosporine which shows a genetically determined ten-fold difference in activity between individuals.
- This enzyme is irreversibly inhibited by grape fruit juice.

***Elimination:**

- Main routes of excretion for many drugs are the kidney (excretion through urine) and liver (yields metabolites which are then excreted by kidneys).
- Most important cause of type A ADR is a change in the drug elimination rate.

 # Pharmacodynamic causes:

- Increased sensitivity of target tissues or organs may predispose a person to ADRs.

*** Drug receptors:**

- Drugs combine with receptors and elicit response.
- Receptors are either protein molecules or enzymes.
- Amount and sensitivity of receptors differ from one individual to another.
- Some individuals have fewer specific drug receptors while others may have a higher number of less active receptors.
- This intervariability between different individuals can affect the drug when the drug acts through specific receptors.

*** Homeostatic mechanisms:**

- Many physiological factors determine the extent of a drug's effect in an individual as drug effect occur within the environment of body's physiological mechanisms.
- Eg: Atropine (I.V)- causes variable increase in heart rate some individuals develop tachycardia of 160 beats per minute at a dose which is almost ineffective in others.
- Magnitude of the observed effect is dependent on the balance between para and sympathetic cardiac tone which appears to be under genetic control.

*** Disease:**

- Eg: Asthmatic patients who develops bronchoconstriction taking non-selective beta blockers such as propranolol.

- MECHANISMS OF TYPE B ADRs:

 # Pharmaceutical Causes:

- Pharmaceutical causes of type B reactions include decomposition of the active ingredients, effects of the non- drug excipients and synthetic byproducts of active constituents.
- Some decomposed drug products may result in therapeutic failure.
- Death reported due to decomposition of paraldehyde to aldehyde and its subsequent oxidation

to acetic acid.
- Additives including propylene glycol and carboxymethylcellulose may cause hypersensitivity reactions.
- Patients are at risk of acquiring hypersentivity reactions if they switch from one product to another.
- Patients prescribed with a particular brand of a biological product should be kept on the same brand throughout their treatment.

 # Pharmacokinetic causes:

- Changes in pharmacokinetic parameters may lead to a type B reactions.
- Metabolism of a drug to unusual reactive metabolites may rise to type B reactions either by a direct or by an immune-mediated mechanism.
- Eg: Phenacetin induced methaemoglobinaemia and carbamazepine induced hypersensitivity reactions.
- Reasons for occurrence of type B reactions in an individual are not clear.

 # Pharmacodynamic causes:

- Factors including age, sex, body weight, medical condition and drug therapy influence end response of a patient to an administered drug.

 # Genetic causes for abnormal responses:

- It was thought that type B reaction were due to qualitative abnormality in patients and were known as an idiosyncrasy.
- But not it is clear that these reactions may have a genetic basis.
- Eg: Glucose 6 phosphate deficiency results in hemolysis, accompanied by a fall in hemoglobin level, fever and formation of dark urine. G6PD deficiency results in a corresponding deficiency in reduced glutathione and under such conditions oxidizing agent denature the intracellular proteins including the globin part of hemoglobin.
- Drugs having oxidizing property are known to cause hemolysis in those patients with G6PD.
- Eg: Examples of the drugs having oxidizing property include primaquine, sulphones, sulphonamides, chloramphenicol, quinine and quinidine.
- Other genetically determined ADRs include methahemoglobinemia (nitrates), porphyria (sulphonamides and barbiturates), malignant hyperthermia (halothane and suxamethonium), osteogenesis imperfect (halothane) and familial dysautonomia (general anaesthetics and parasympathomimetics).

 # Immunological reasons for abnormal response:

- Cause of the most important group of qualitatively abnormal responses to drugs is immunological.
- If the drug is immunogenic then the reaction is type A effect.
- Most allergic drug reactions are response to immunologically mediated mechanisms
- These reactions may vary from rash and serum sickness of life threatening reactions such as anaphylaxis.
- Patients with atopic or allergic disorders are at high risk of developing allergic drug reactions
- Important features of allergic drug reactions are

1. Symptoms are not correlated with known pharmacological effects of the drug.

- Delay between first exposure to the drug and development of a subsequent reaction.

- If an allergy is established even small doses may elicit, the reaction.
- Reaction disappears on stoppage of therapy and reappears after re-exposure to even small dose.
- Illness is recognizable and may include a rash, angioedema, serum sickness or anaphylaxis.
- Occur in very few patients receiving the drug.
- There is a possibility of desensitization.

 # Teratological and neoplastic reasons for abnormal response:

- Drugs can cause neoplastic or teratological changes.
- Important to consider the possibility of occurrence of qualitatively abnormal response to a drug in the presence of some neoplastic and teratological tissues in the body.
- Administration of estrogen or an androgen may transform the pre-neoplastic condition into neoplastic state.

CAUSALITY ASSESSMENT:

- Assessing casuality: Casuality assessment is the method by which the extent of the relationship between a drug and a suspected reaction is estimated.
- If an ADR is suspected, the assessment starts with collection of all the relevant data pertaining to patient.
- Using all the collected data, correlation of a suspected drug with an ADR can be established and categorized by using one or more available casuality assessment scales.
- Algorithms- These are in the form of questionnaries which helps to gather information while seeing the relation between the medication and the reaction.
- Eg of algorithms: Naranjo's scale, Kramer's and the French implication method.
- When assessing casuality many factors need to be considered, which includes:

● Time relationship between the administration of the suspected drug and the reaction.
● Dose and duration of drug treatment
● Possible alternative causes other than the drug for the occurrence of an ADR.
● Outcome of the reaction upon stoppage of drug (dechallenge)
● Outcome of the reaction upon re-introduction of drug (rechallenge)

- The assessment and establishment of casuality relationship between suspected drugs and reactions has certain applications:

1. Patient treatment
2. Signal generation
3. Drug regulation
4. Scientific publication
5. Data exchange

- Every suspected ADR should be assessed for its causality and documented in the patient's medical record.
- Documentation of reported ADR is essential to avoid re-exposure of the patient to the same drug or drug class.
- Documentation should be made in the patient's medical and pharmacy records where appropriate.
- Method for causality assessment of ADRs are classified as:

1. Opinion of experts, clinical judgment or global introspection methods.
2. Algorithms (with/without scoring) or standardized assessment methods.

3. Probabilistic or Bayesian approaches.

- Different Scales:

* WHO causality assessment scale: categories the causality relationship into certain, probable, possible, unlikely, assessable/unclassifiable and conditional, unclassified
* Narinjo's scale: categorises reaction as definite, probable, possible or unlikely

- WHO CAUSALITY ASSESSMENT SCALE:

1. Certain:

- Event of laboratory test abnormality with plausible time relationship to drug intake.
- Cannot be explained by disease or other drugs.
- Response to withdrawal plausible (pharmacologically, pathologically)
- Event definite pharmacologically or phenomenological (an objective and specific medical disorder or a recognized pharmacological phenomenon).
- Rechallenge (if necessary).

2. Probable:

- Event or lab test abnormally with reasonable time relationship during intake.
- Unlikely to be attributed to disease or other drugs.
- Response to withdrawal clinically reasonable.
- Rechallange not necessary.

3. Possible:

- Event or lab test abnormality with reasonable time relationship to drug intake.
- Could also be explained by disease or other drugs.
- Information on drug withdrawal lacking or unclear.

4. Unassessable/Unclassifiable:

- A report suggesting an adverse reaction.
- Cannot be judged because of insufficient or contradictory information.
- Report cannot be supplemented or verified.

5. Unlikely:

- Event or laboratory test abnormality with improbable time relationship to drug intake.
- Plausible explanations by disease or other drugs.

6. Conditional/unclassified:

- Event or lab test abnormality
- More data for proper assessment needed.
- Additional data under examination.

- **NARANJO ADR PROBABILITY SCALE:**

Question	Yes	No	Do Not Know	Score
1. Are there previous conclusive reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	
4. Did the adverse event appear when the drug was readministered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that, on their own, could have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	

Total Score	ADR Probability Classification
9	Highly Probable
5–8	Probable
1-4	Possible
0	Doubtful

DETECTION AND MONITORING OF ADRs:

PRE-MARKETING STUDIES:

- When new medicines are developed their safety is tested in animal models.
- Information can be obtained from such tests such as the level of acute toxicity, which organs will be affected in case of toxicity and the dose dependency of such tissue injuries.
- Specific animal tests for carcinogenicity, teratogenicity and mutagenicity are also available.
- Animals can only serve as approximate model for humans.
- Clinical trials are carried out in three different phases.
- Clinical trials normally have the power to identify adverse reactions of a frequency greater than 0.5-1.0%
- Clinical trial programmes are designed to maximize the chance of demonstrating a therapeutic effect in relation to a control group.
- Children and elders are excluded from the studies.
- Once the drug is used in clinical practice it is used to treat children, elders and patients with complicated disease and multiple drug exposure.

POST- MARKETING SURVEILLANCE:

- Most sensitive, powerful and cost effective system for the identification of unknown drug-related risks is spontaneous adverse reaction reporting.
- Every health care professional should think it as his/her responsibility to monitor and detect ADRs.
- Pharmacovigilance helps in reporting of ADRs
- Epidemiological methods:

1. Cohort studies
2. Case control studies

1. Cohort studies: Patients exposed to a particular drug are followed up actively and systematically and adverse reaction frequencies are compared to an unexposed control population.
2. Case control studies: Individuals affected by the adverse event being studied are identified.

Detection of ADRs:

1. Health care professionals should be ready for detecting of ADRs.
2. ADRs should be detected during ward rounds with the medical team or during review of patients chart.
3. Patient counselling, medication history interview and communicating with other health care professionals provides additional clues in detection of ADRs.
4. Detection of an ADR is important to the management of any patient, since failure to recognize an ADR may result in continuing patient morbidity.
5. To assist the detection of ADRs, healthcare professional should closely monitor patients who are at high risk, which includes:
- Patients with renal and hepatic impairment
- Patients taking drugs which have the potential to cause ADRs, eg narrow therapeutic range drugs.
- Patients who had previous allergic reactions.
- Patients taking multiple drugs
- Pregnant and breastfeeding women.
6. First step in detection of ADRs is collection of data.
7. Collection of data includes the patient's demographic information, present complaints, past medication history, drug therapy details including OTC and current medication and medication on admission, lab data such as hematological, liver and renal function tests.
8. Details of suspected ADR such as time of onset, duration of reaction, nature and severity of reactions.
9. Details on the suspected drug including dose, frequency, time of administration, duration of treatment, plasma concentration of the drug, previous report on reaction, data on any other cause including risk factors and predisposing factors are useful.

MANAGEMENT:

- Management and prevention of ADRs is an important aspect in patient care activities.
- Rapid action is sometimes important because of the serious nature of a suspected ADR for eg anaphylactic shock.
- Emergency treatment and withdrawal of all medicines may be essential.
- If several medicines may be causative the non-essential medicines should be withdrawn first, probably one at a time depending on the severity of the reaction.
- If the reaction is likely to be dose-related, dose reduction should be considered rather than with holding the drug.
- If the patient cannot manage without a medicine that has caused an adverse reaction, symptomatic relief may be given while continuing the essential treatment.

DOCUMENTATION AND PREVENTION OF ADRs:

- Documentation of reported ADRs is essential to avoid re-exposure of the patient to the same drug or drug class.
- In the event of a suspected ADR, the attending pharmacist should complete appropriate documentation in the patient medical record, including attachment of alert card stickers and/or placing an alert sheet in the front of the patients case notes.
- It is essential that medical staff, including the original prescriber are notified of suspected ADRs.
- Pharmacist should ensure completion of in-house documentation for future reference.

REPORTING:

- One of the major difficulties of spontaneous reporting programmes is the failure of health professional to identify and report drug related injuries.
- Under reporting varies with a number of factors

1. Reporting is higher for new drugs than for old.
2. Serious reactions are reported to a higher degree
3. Type B reactions are reported more commonly
4. Reporting is affected by promotional claims of the drug sponsor.
5. Publicity of a specific drug related problem triggers further reporting, not necessarily related to the real frequency.
6. Reporting is affected by general publicity around the adverse reaction reporting scheme.

- Reasons given most often by health professionals for not reporting are:

1. Lack of time
2. Lack of knowledge on what, how and where to report
3. The reaction is already well known
4. The drug reaction association is uncertain
5. Guilt or fear of litigation
6. Belief that all registered medicines are safe
7. Non-availability of reporting forms

- Activities that may increase the reporting rate include:

1. Ease of reporting for eg by improving the design of reporting forms or by the use of online reporting acknowledging the receipt of ADR reports by personal letter or phone call.
2. Providing feedback to clinicians in the form of articles, in journals, ADR bulletins or newsletters.
3. Participation in pre and post graduate educational and scientific meetings.
4. Collaboration with local drug and therapeutic committees.
5. Collaboration with professional associations
6. Integrating pharmacovigilance in public health care programmes.
7. The involvement of not only physicians but also pharmacists, dentists, nurses and patient's in the reporting of suspected ADR.

- Pharmacists in all hospitals have responsibilities in the detection and reporting of ADRs.
- A drug reaction and medication error should be reported immediately to the patient's physician.
- Any entry of medications given and /or the drug reactions should be properly recorded in the patient's medical record.

- Hospitals are encouraged to report any unsuspected or significant ADRs to the FDA or medical associations.
- Retrospective and active surveillance.

ROLE OF PHARMACISTS:

- Monitoring patients who are at greater risk of developing ADRs.
- Monitoring patients who are prescribed with drugs highly likely to cause ADRs
- Assessing and documenting the patient's previous allergic status.
- Assessing patient's drug interactions in multiple therapies.
- Assessing the patient's drug therapy for appropriateness
- Assisting healthcare professionals in the detection and assessment of ADRs.
- Educating healthcare professionals about the importance of reporting an ADR.
- Creating awareness about ADRs amongst healthcare professionals, patient's and the public.
- Conducting workshops/conferences/seminars on ADRs for health care professionals.
- Educating patient's
- Encouraging healthcare professionals in reporting an ADR
- Obtaining feedback about the reported reaction
- Follow up of patients to assess the outcome of the reaction and management.
- Detection of common symptoms:

* A pharmacist may reduce the likelihood of allergic and hypersensitivity reactions by asking the patient whether or not he has ever experienced an allergic reaction to a drug.
* Inquiring about the type of reaction and the drug which has caused the reaction.
* Eg: skin rash or anaphylactic shock caused by penicillins.

- Overdosage:

* Another type of ADR that can be prevented is that caused by overdosage, which can be a result of physician error or the patient's voluntary administration.
* Dosage error can be detected by seeing the physician's prescription.
* Sedative and hypnotics are the major concern in the patient's overdoses.
* The two ways of limiting such products when dispensed are:

1. To request the physician to limit prescription quantities.
2. Ask permission from the prescriber to lower the quantity dispensed and increase the number of refills if possible.

- Patient monitoring/counselling:

* Careful monitoring of signs and symptoms of ADRs.
* Eg: Patients on daily diuretics therapy may experience weakness and fatigue that could be the result of hypokalemia due to the medication.
* The pharmacists should suggest supplemental potassium therapy for the patient.
* Patient should be advised on the potential ADRs and measures to be taken if they occur.

- Drug profile records:

* Patient profile can help in controlling and preventing ADRs.
* This will result in increase in quality of patient care
* It provides information for prediction of potential ADRs and drug interactions
* By monitoring the wealth record and the medications used by the patient, it's possible to detect a potential reaction.

- Other prophylactic measures:
* Providing basic references
* Services related to detection, prevention and reporting of ADR

1. Patient review
2. Daily visits to the nursing units to discuss possible and reported adverse effects.
3. Review of patient chart
4. Recognize the potential ADRs
5. Identify the cause of an ADR
6. Recognize abuse of prescription or OTC drugs

SIDE EFFECT: It is an unintended effect of a drug related to its pharmacological properties and can include unexpected benefits of treatment.

ADVERSE DRUG EVENT: It is an adverse outcome that occurs after the use of a drug but which may or may not be linked to use of the drug. All ADRs are ADEs but all AEDs are not ADRs.

DRUG INFORMATION

INTRODUCTION:

- Drug information: It means providing clinically relevant information on any aspect of drug use relating to individual patient's or genera; information on how best to use drugs for population.
- Providing drug information is a fundamental responsibility of all pharmacists.
- Pharmacists have knowledge and skills which are required for drug information practice.
- These include knowledge of pharmaceutics, pharmacology, pharmacokinetics and pharmacotherapy.
- Providing information to patient's during counselling is an important aspect of pharmaceutical care.
- Pharmacist also provide basic drug information to other health professionals in the course of their clinical activities
- Drug information service: Applied to any activity where information about drug use is transferred and includes patient related aspects of pharmaceutical care.
- Drug information center: It is an area where pharmacists specialize in providing information to health professionals or the public.
- Medicines information: It is used to avoid confusion with services which are limited to problems relating to drugs of abuse.

DRUG INFORMATION RESOURCES:

- Information about drugs is available in a wide range of formats, media types and levels of quality.

1. Primary resources
2. Secondary resources
3. Tertiary resources
4. Journals
5. Bibliographic data bases
6. Miscellaneous/other sources

1. Primary Resources:

- Primary reports include the results of research at all levels and also clinical experience in the form of individual responses to drugs and small case series.
- Primary resources are the peer reviewed journals which contain latest information or therapeutic conclusions and scientific research.
- Primary literature is published in scientific journals in the form of research results, concise reports and letters to the editor.
- Eg: Adverse drug reaction reports.
- Eg of primary resources: American druggist, drug information journal, American journal of cardiology.
- Advantages:

1. Provide the most recent information
2. Gives the opinion of other health care providers
3. Information regarding recent developments will be available on application of drugs in various

clinical situations.
- Disadvantages:
1. No guarantee of accuracy
2. Inadequacy of articles are common.

2. Secondary Resources:

- Secondary sources consist of reviews of primary reports.
- Secondary sources are indexing and abstracting services which comes in CDs rom and consists of abstract and information published in primary literature and newsletters.
- Eg: Medline, internet, Micromedex, pharmaceutical abstracts.
- These contain condensed and referred view of primary data and are used in drug information practice.
- Advantages:
1. Provide sufficient information to serve as reference foe answering drug information questions.
2. Valuable tool for quick and selective screening of the primary literature for specific information, data, citation and articles.
- Disadvantages:
1. Abstracts are generally interpretations
2. Usually describes only articles of clinical studies,
3. Reviews a limited number of journals.

3. Tertiary Resources:

- Tertiary resources are summaries of the primary and secondary published literature.
- Eg: Printed textbooks
- These usually include textbooks and compendia
- In drug information practice, a tertiary text is usually consulted first as a quick reference and if necessary secondary and primary sources are the checked.
- Eg: AHFs drug information, drug information handbook, clinical pharmacology
- Advantages:
1. Background information on drugs and diseases is available.
2. Provides easy and convenient access to a broad spectrum of related topics
- Disadvantages:
1. Omission of pertinent data
2. Misinterpretation of literature possible
3. Gap between developments and actual publication of books.

4. Journals:

- Important research and clinical experiences is published in scientific journals.
- Most journals have to depend on subscription or advertising to support the cost of accurately transmitting information to readers.

5. Bibliographic databases:

- These services are sometimes called indexing and abstracting services because they provide a copy of the published abstracts of primary and secondary reports together with an indexed database to help locate relevant reports.
- Eg: Iowa drug information services (IDIS), medline.
- Databases can directly link to the full text of journal articles but only some full text articles will

be available free of charge.

6. Other sources:

*** Internet:**

- Internet has enhanced our access to information from reputable organization.
- Many clinical guidelines and drug assessments are not indexed in bibliographical databases but can located on recognized sites or using search engines which focus on reputable sources of information.
- Eg: National institute for health and clinical excellence, UK (www.nice.org.uk), national prescribing center, UK (www.npc.org.acc)
- Tools for clinical guidelines include:

* National guideline clearing house, USA (www.guidelines.gov)

* National library for health, UK (www.library.hhs.uk)

- Limitation:

1. Essential to evaluate any facts critically
2. Lack of control over internet content
3. Relatively slow speed of retrieval

*** Electronic bulletin boards (EBBs):**

- EBBs are local bulletin boards which are posted via a server and can be accused using a computer and a modem
- Eg: clinvet, pharmanet, PDA, pharmline
- Advantages:

1. Prevents duplication of drug information searches
2. Expands the ability to monitor therapies recently published.

- Disadvantages:

1. Not as reliable as other sources
2. Peer view of articles usually not available.

SYSTEMATIC APPROACH IN ANSWERING DRUG INFORMATION QUESTIONS:

1. Requester's details:

- Identify the enquirer and obtain sufficient contact details.
- For regular clients, these details should be recorded in a database to facilitate future enquiries.
- Experienced clinicians are likely to prefer concise factual information whereas junior staff may also seek guidance on clinical management.
- A deadline for a response should always be established.
- If a specific deadline is not offered then an expected response time should be provided.
- This can be extended later to adequately address the issue.

2. Background information:

- This should focus on the question at hand and not attempt to cover all the clinical details.
- This is a difficult step and clinical pharmacy experience is needed to maximize the outcome of this initial exchange of information.
- It may be necessary to obtain additional information such as age, other medical conditions, renal and liver function, other relevant drugs (including traditional medicines), history of allergic reactions and stage of pregnancy.

3. Refine and categorize the question:

- It may be necessary to understand some aspects of the question before seeking an answer.
- For pharmacists, this applies particularly to medical technology and aspects of disease and pathology.
- This information may help to refine the question and to estimate the time required to achieve an acceptable response.
- Almost all drug information requests can be categorized by their nature and this will dictate the most efficient and rewarding strategy.
- Selecting the resources most likely to contain the required information can save time and also increase the accuracy of the response.

4. Develop a strategy and conduct a search:

- Consider all the available information resources and prioritise them based on the probability of locating the required information.
- Beginning the search with tertiary sources (textbooks) and then progressing to secondary literature will provide an adequate answer and there will be no need to attempt a literature search.
- Record the sources used and a summary of the information derived. However, only the most relevant references need to be documented in the actual reply.

5. Interpret data:

- The information retrieved must be critically evaluated within the context of the enquiry.
- It is important to consider consistency of information between various references and whether clinical research is relevant to your population or a specific patient.
- Where possible the full text of published reports should be consulted as it is often the details, such as how the patients were selected for a trail, how the drug was given, and limitations of the study, which will help with interpretation for specific enquiries.

6. Formulate and provide a response:

- Answers should be derived only after critically analyzing the available information obtained from a comprehensive search.
- It is also important to provide a formulated response to the enquirer in a timely manner.
- All responses should be documented with the minimum detail necessary to justify the response.
- Even rapid verbal responses should include the resources used as well as the question and response.
- Clinicians prefer direct and concise replies but this does not mean that all the necessary details should not be recorded and referenced within the drug information service.
- I a written response is provided, state the answer first and then justify it with the details.
- All written responses should be based on a template which includes the contact details of your service as well as the question.
- If responding by telephone, document the main points you need to state before making the call.

7. Follow-up and document the outcome:

- Try to determine the consequences of your advice and any patient outcomes.
- This may only be possible in a hospital or clinic but it is critical to developing skills in drug information.
- Advice provided should be recorded in at least one mode of documentation (log book, paper

worksheet, computer programme).
- Practicing clinical parameters have the advantage that they receive continuous education based on the response of their patients to interventions.
- Feedback can also be sought by email, written requests or by the telephone.

8. Quality assurance:

- Establishing a process for quality assurance in drug information is difficult because the service may be considered as the highest authority to those seeking guidance.
- The quality assurance programme is an integral part of a drug information service as it provides opportunities to improve and to provide guidelines for future development.
- Quality assurance can be assessed in terms of resources and operating procedures. It is necessary to maintain up-to-date references and search strategies. This is best done by regular comparison to similar services and accepted standards.
- General assessment of the service can also be sought from users through periodic circulation of feedback questionnaires.

CRITICAL EVALUATION OF DRUG INFORMATION AND LITERATURE:

-For successful running if a DIC, pharmacist in charge has to add latest information to his collections.
- This information is mainly coming from drug manufacturers through their representatives about new formulations introduced in the market by them.
- These drugs bring with them lot of literature claiming that they are superior and the best among the existing drugs.
- Pharmacists have to go through the full text of these references and arrive at a conclusion about it worthfulness and reliability.
- The pharmacist must be vigilant while including a literature to his DIC and if necessary he should consult senior clinicians or research scientists for the purpose.
- Pharmacist should critically evaluate all drug information and literature coming to his notice.
- Critical evaluation is the ability to judge the scientific value of literature or drug information sent to him.
- This he must do before adding them to DIC and dissipating to information seekers.
- In order to perform that function successfully he must ask the following questions and get satisfactory answer for them:

1. Whether the drug claimed in the literature has new molecule?
2. If so is it approved in the country of origin and in other countries?
3. Whether it is approved by government agencies and listed in pharmacopoeia or drug index or purchase list of those governments?
4. Whether scientific references quoted in support of the drug is by reputed authors and published in reputed journals.
5. Is those references are readily available fully for verification? Is it worth including after verification?
6. Is there any conditional approval for the product? If yes what are those conditions?
7. Whether any important information is partial, hidden or left out?
8. Is there any ADR reported anywhere in the world because of the drug?

9. Is the particular drug still sold in the country of origin? If stopped the reason for it.
10. Whether the drug is exorbitantly priced?

PREPARATION OF VERBAL AND WRITTEN REPORTS:

- The pharmacist has to provide information either verbally or by written report.
- To prepare good report pharmacist should have good communication skill
- With basic understanding and knowledge of the subject, pharmacist can easily prepare written reports.
- A good written report should have a basic format.
- It should start with the question asked, followed by its purpose as told by the enquirer.
- This information helps to evaluate whether the answer given is appropriate or not.
- Then the answer may be given in a clear language with the interpretation of technical terms.
- Where ever necessary, the source of information or reference can be given, so that, the receiver can cross check it or search for more information.
- The report can be concluded with the name and signature of pharmacist answering the query.
- Verbal reports are given either directly to the patient or his care takers.
- Verbal reports should be in clear tone and inn simple language.
- At the end of verbal report pharmacist should ask few questions, to know whether the information given has been understood.
- The information seeker can be encouraged to seek clarification of his doubt about the verbal report. This is important because verbal report cannot be verified later, if it is not recorded.
- In order to avoid future complications pharmacist must develop good verbal and written communication skills.

ESTABLISHMENT OF DRUG INFORMATION CENTER:

- **DIC:** It is an area where pharmacists or other healthcare professionals specialize in providing information to health professionals or the public.

A. Personnel:

- The number of personnel required depends on the activities and the hours of services.
- Should provide direct service.
- A center specializing in drug information requires coordination, monitoring and promotion.
- The managers responsibility includes:

1. Staff recruitment and coordination
2. Training
3. Promoting the service
4. Identifying and maintaining appropriate resources
5. Data management and reporting
6. Quality assurance and improvement
7. Good contact with colleagues, professionals, and government agencies etc
8. Strategic development

B. Facilities:

a. Equipment's
b. Information resources

C. Finance:

- DIC should have an independent source if income and status
- Services should be provided free of charge
- Separate charges may be made for specific reports which do not directly relate to patient care
- Sufficient expenditure to maintain up to date resources is essential
- Staff: salaries and wages
* principal pharmacist
* Basic grade pharmacist
* Trainees
* Administrative staff
- Other expenditures
* Technical literature
* Printing and stationary
* Office equipment's
*computer services
* Travel expenses
* Equipment maintenance cost
* Training expenses
* Telephone costs

D. Training of staff
- Specific training is required for drug information practice
- Drug information practitioners require:
* Communication skills to receive and comprehend enquiries.
* Knowledge of all available resources
* Literature searching skills
* Capacity for critical analysis
* Writing skills
* Ability to summarize complex data

POISON INFORMATION

DEFINITION:

* Poison information is a specialized area of drug information which includes information about the toxic effects of chemicals and pesticides, hazardous material spills, household products, over dose of therapeutic medicines, plants including mushrooms, animal toxins from bites of snakes, spiders and other venomous creatures and stings.
* A poison information service deals with the risk assessment, diagnosis, management and prevention of exposure to any poison in patients of any age irrespective of type and route of exposure.

GOAL:

1. The goal of PI services is to reduce the morbidity and mortality caused by poisoning and improve patient's health related quality of life. PI services are provided by a specialized center known as poison information center, which provides immediate information on poisoning management through well trained poison information specialists.
2. Providing information on poisoning prevention and management to general public and health care professionals by providing assess to poisoning information.
3. Conducting educational programs for healthcare professionals so as to update them with the relevant information about poisoning management.

FUNCTIONS:

1. Patient management
2. Toxicological analytical services
3. Toxicovigilance
4. Education and training of healthcare professionals and public
5. Prevention of poisoning
6. Research in poisoning
7. Development of therapeutic guidelines/protocols for poison management.

ORGANISATION:

- PICs cab operate effectively with various types of organizational structures
- The organization pattern of a PIC should be based on the anticipated ideal human exposure call volume (average number of queries that the PIC receives regarding the management of poisoning cases in humans).

1. Personnel:

- Staff is necessary for effective functioning of center
- Staff includes:

1. Physicians
2. Pharmacists
3. Administrator
4. Clinical toxicologist
5. Poison information specialist with the required secretarial assistance

- Personnel working in the PICs should be qualified

- The responsibility of medical and technical directors is to promote research, raise funds, ensure quality service and undertake further development of the information services.
- Medical functions of the center must be the responsibility of a clinical toxicologist
- The responsibilities of the PI specialist include:

1. Provide poison information
2. Prepare standard protocols
3. Maintain an accurate record of all queries
4. Participate in continuing education
5. Update and maintain information resources
6. Carry out research

2. Facilities:

a. Location:

- Located within a hospital or an area closely associated with a hospital providing emergency and intensive care services.
- It should be co-located with a hospital clinical toxicology service which is concerned with the identification, treatment and prevention of the harmful effects of chemicals including natural substances on humans.
- This type of set up will provide ready access to a network of medical disciplines that will support and enhance the work of the center.
- Other locations include a medical library, medical university, pharmacy department and medical or pharmacy college.

b. Space:

- It should be placed in a spacious facility to accommodate the services, staff and need.
- A work area of 200 sq feet/work station is recommended with a separate office for the medical director and manager/supervisor.
- Working area should have adequate lightening and ventilation.

c. Equipment:

- PIC should be well equipped with the necessary basic facilities.
- Communication equipment is important for the center.
- As most communication with the enquirer is over on the phone, at least 2 telephone with sufficient incoming lines with toll free numbers should be reserved to receive the queries.
- It is also important to be equipped with computers, printers, photocopying machines, UPS.
- Book shelves and filing cabinets for storage of case records and documentation files are also essential.
- Lockable cabinet should also be available to store confidential data.

d. Information resources:

- Information regarding the management of poisoning cases is available from a wide range of information sources including primary, secondary and tertiary resources and the internet.
- It is important to have all types of information resources to provide poison information.

a. Primary resources:

- Primary resources include journals of medicines and toxicology
- These are essential for updated and recent advances in a particular area.
- Eg: Clinical toxicology- Published by informa healthcare

Indian journal of toxicology

b. Secondary resources:

- Eg of secondary resources include POISINDEX, MEDLINE, Intox etc
- These must be present for quick retrieval of updated information

c. Tertiary resources:

- Among tertiary resources, the standard textbooks of medicines, chemistry, pharmacology, analytical toxicology and animal and plant toxins of the region and standard medical dictionaries are essential
- Eg: Oxford medical dictionary, Indian pharmacopoeia

d. Internet:

- It provides a vast amount of information.
- It is important to develop treatment protocols for the management of the most common types of poisoning.
- Developing education material such as posters on the safe use of pesticides and chemicals, and booklets and leaflets on the safe storage of medicines and household products at home are of great importance in educating the public and in the prevention of poisoning.

3. Legal and ethical prerequisites:

- PIC should be recognized either by government authorities or the WHO.
- For effective functioning the center should have independent status, stability and neutrality.
- The center should have a governing body which should have experts to provide policy guidance.
- The center is required to provide the information free of cost to enquiries.

4. Policies and procedures:

- For the effective functioning of the center, it should have well defined policies and procedures.
- The PIC should develop policies for personnel, method of operation, documentation of services and quality assurance programs, staff training, ethical and legal aspects.
- Detailed policies and procedures are to be established with respect to a quality assurance program and quality improvement strategies.
- Guidelines for staff training are essential.

5. Training of staff:

- Adequate training to the personnel is essential for new and inexperienced staff.
- PIC should provide internal and external training to the staff in various areas of poison information.
- PIC should develop and implement a need based staff training manual.
- Training in updating knowledge in clinical toxicology, communication skills, handling of databases, analytical skills and handling of equipment's such as computers, telephones and other instruments.

Comparison of DIC and PIC

Parameter	DIC	PIC
Clientile of service	Mainly health care professionals	Mainly general public
Expected call volume	Minimal	Maximum
Call complexity	Minimal	Low
Reply time	More	Low
Information resources required	Less	More
Working hours	Regular working hours or week days	Round the clock and round the year
Staff requirement	Fewer number	Greater number
Operation cost	Less expensive	More expensive
Financial support	Sponsoring instution	Govt/non-govt organization and public.

MEDICATION HISTORY INTERVIEW

DEFINITION:

- 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 newly initiated institutionalized or ambulatory care.
- It provides valuable insights into patients' allergic tendencies, adherence to pharmacological and non-pharmacological treatments, social drug use and probable self-medication with complementary and alternative medicines.
- Interviewing a patient in collecting the data medical history is called medication history interview.

GOALS:

The goal of medication history interview is to obtain information on aspects of drug use that may assist in overall care of patient.

The information gathered can be utilized to:

Compare medication profiles with the medication administration record and investigate the discrepancies.

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

Document allergies and adverse reactions.

Screen for drug interactions.

Assess patient medication compliance.

Assess the rationale for drug prescribed.

Assess the evidence of drug abuse.

Appraise the drug administration techniques.

Examine the needs for medication aids.

Document patient initiated medication administration.

COMPONENTS:

Components of Health History:

 # Chief Complaint:

- The chief complaint is the issue or issues that the patient is presenting with and the primary reason for the visit.

 # History of Present Illness:

- The history of present illness is the story of the illness. The goal of the history of present illness is to ascertain a complete, accurate and chronological account of the illness from the patient.

 # Past History:

- Past history includes the past medical history, surgical history, history of childhood illnesses, and obstetric/gynecologic history.

 # Past Medical History:

- The Past Medical History includes chronic as well as past acute medical conditions including diabetes, hypertension, hepatitis etc.

 # Surgical History:

- The surgical history should include the type of operation, when it occurred and the indication for the operation.

 # Childhood illness:

- Childhood illnesses include measles, mumps, whooping cough, chickenpox, rheumatic fever, polio etc.

 # Obstetric/Gynecologic History:

- The obstetric history include the number of pregnancies including deliveries, miscarriages and terminations etc.

 # Health Maintenance/Immunizations:

- It includes the immunizations the patient has received such as influenza, tetanus, hepatitis B etc.

 # Family History:

- It includes information about the parents, grandparents, siblings, children and grandchildren etc.

 # Personal and Social History:

It has information about patient's life including health behavior and personal choices. Which include about tobacco, alcohol and illicit substance use.

Components of Medication History:

- To effectively and efficiently conduct a medication history, appropriate training, education and practice is necessary.

*** Introduction:**

- The interview should be started with polite introduction. Clinical pharmacist should open the interview with self-introduction after verification of patient's identification. This is followed by defining the role as interviewer, the purpose, probable time required for the interview etc.

*** Medication History:**

- After the introduction, the next step is to obtain information on all of the prescription and OTC medications as well as any herbal medication products the patient is currently taking.
- The information regarding the medication name, strength and dose, frequency, timing, indication, adverse reactions, past medication use, medication adherence, and allergies should be obtained from the patient at the time of interview.
- All these information will not be coming out straight away, hence the pharmacist has to put clever questions, some may be open questions and some may be closed questions.
- Open questions are the one, for which patient can give lengthy, descriptive answers and the closed questions are required to be answered with yes or no.

-Careful questioning will not lead to any unpleasant end. Hence the pharmacist must be attuned to the types of questions asked, the manner in which questions are asked and avoid repetitions.

- Possible technical terms should be avoided, if absolutely necessary its meaning should be explained.

*** Essential Skills for Medication History Interview:**

- Skills which are needed for conducting a good medication history interview include:

1. Formal form of addressing the patient
2. Rapport with patient
3. Active listening, empathetic responding

4. Open ended questions
5. Closed ended questions
6. Transition from one subject to another
7. Verbal involvement/repeating patient's own words
8. Avoidance of leading questions
9. Avoidance of why questions
10. Timing
11. Clarifying conflicting information
12. Silence
13. Answering questions by the patient
14. Mentioning previous answer and questions

- If a clinical pharmacist develop these skills, a useful medication interview can be obtained.

*** Closing an Interview:**

- To close the interview pharmacist must highlight a part or entire interview to the patient.
- Closing the medication interview includes assessing the patient's understanding, providing an opportunity for the patient to ask questions and discussing any follow-up plans.

CONCLUSION:

- If the interview is conducted properly and all the relevant information is obtained from the patient, it helps the medical fraternity.
- Some of the advantages include:

* It helps speedy and correct diagnosis
* It avoids unnecessary repetition of earlier infective treatment
* It saves the patient from unpleasant exposure to drug allergies
* Prevents patient's from ADR and drug interactions.
* Gives information about patient's habits, weakness and dependence or requirement.

- Hence clinical pharmacist can effectively monitor the drug therapy later or modify the drug therapy to suit the need or condition of the patient. Without prior medication history of the patient on hand, these things are not possible and it may be too late to have such data at later stages.

PATIENT COUNSELLING

DEFINITION:

- Patient counselling refers to the process of providing information, advice and assistance to help patients use their medications appropriately.
- The information and advice is given by the pharmacist directly to the patient or the patient's representatives and also information about the patient's illness or recommended lifestyle changes.
- During counselling the pharmacist should assess the patients understanding about his or her illness and the treatment and provide individualized advice and information which will assist the patient take their medications in the most safe and effective manner.
- To provide accurate advice and information, the pharmacist should be familiar with the pathophysiology and therapeutics of the patient's disease.
- Good communications skills are required to gain the patient's confidence and to motivate the patient to adhere to the recommended regimen.

AIMS:

- Better patient understanding of their illness and the role of medication in its treatment.
- Improved medication adherence.
- More effective drug treatment.
- Improved quality of life of the patient.
- Better copying strategies for medication related adverse effects.
- Reduce incidence of medication errors, adverse effects and necessary healthcare costs.
- Improved professional rapport between the patient and pharmacist.

COMMUNICATION SKILLS AND EFFECTIVE COUNSELLING:

- The counselling process uses verbal and non-verbal communication skills.

 # VERBAL COMMUNICATION:

- Verbal communication skills include language, tone, volume, pitch and rate of speech.

1. Language:

- Use simple language when speaking to patients.
- Avoid unnecessary medical terms.
- Speak in patients own language.

2. Tone:

- The tone of voice has a great impact on patient understanding.
- When counselling. the tone of the voice should be caring and reassuring.

3. Volume:

- Counselling should be conducted in a quiet, private setting where it is unnecessary to raise one's voice.
- Many people speak with wide variation in volume depending on the situation and where and to whom they are speaking.

4. Speed:

- For good verbal communication, the pharmacist should present clear, relevant messages in a logical sequence and at a speed which gives the patient time to think about what is being said.
- The clarity of communication depends on the rate of speech.

- Patient may feel reluctant to interact with a pharmacist who speaks quickly because they may feel the pharmacist is too busy.
- If the pharmacist speaks too slowly, it may lead to the loss of interest of the listener.

 # NON-VERBAL COMMUNICATION:

- Language such as the movement and position of the head, limbs, body and other aspects.
- Aspects of non-verbal communication include head movement, gestures with hands and arms and body parts.

1. Proximity:

- This refers to the distance that people maintain between themselves during counselling.
- Space (4 zones):

Intimate: 45cm or less
Personal: 45 cm- 1.2 m
Social: 1.2 m – 3.6 m
Public: > 3.6 m

2. Eye contact:

- The amount that people look at one another during conversation varies depending on whether they are speaking or listening.
- For cultural or personal reasons such as timidity, sadness or depression some people may avoid looking into the counsellors eyes.

3. Facial expression:

- These can be used during counselling to demonstrate empathy towards the patients.
- Head movements such as nodding, hand gesture and body posture also can be advantageous.

STEPS OF PATIENT COUNSELLING:

- Counselling is a two way communication process and interaction between the patient and the pharmacist is essential for counselling to be effective.

1. **Preparing for the session:**

- Success of counselling depends on the knowledge and skill of the counsellor.
- The pharmacist should know as much as possible about the patient and his/ her treatment details.
- In hospital setting this may be accomplished by referring to the patient's case notes.
- In community pharmacy setting, source of information include the patient and their prescription and in some case, a record of previous dispensing for the patient.
- Another issue is patient's mental and physical status.

2. Opening the session:

- The pharmacist should introduce him or herself to the patient and greet them by name.
- Should identify the purpose of the session.
- As patients who visit community pharmacies are in a hurry to go home with their medication, this type of introduction prepares them to spend some time with the pharmacist.
- The pharmacist gathers information from the patient about their understanding of the disease they are suffering from, drug treatment and use of alternative medications.
- Other information which may be helpful include previous drug allergies, past medical history and personal habits such as chewing pan masala, smoking and consuming alcohol.
- Using open ended questions is useful technique for gaining the confidence of the patient and

the answers allow the pharmacist to assess the patients information needed.
- For eg what did your doctor tell you about your illness?, what do you know about your disease?, can you tell me about the symptoms you have been experiencing?
- In case of the patients who are disturbed and distressed due to their illness, which may reduce their ability to receive and understand information from the doctor and the pharmacists, min such situation few kind words will help assist the counselling processes.
- During counselling the pharmacist should avoid asking questions in a direct or embarrassing way, discuss patient's personal problems, pass moral judgments, interrupt when the patient is speaking, make mature interpretations or argue with the patient.

3. Counselling content:

- Pharmacist should explain to the patient about his or her medications and treatment regimen.
Name and strength of the medication
The reason why it has been prescribed, how it works.
How to take the medication.
Expected duration of treatment
Expected benefits of treatment.
Possible adverse effects
Possible medication or dietary interactions
Advice on correct storage
Minimum duration required to show therapeutic benefit.
What to do if the dose is missed.
Special monitoring requirements eg blood tests
Arrangement of obtaining further supplies
It is important that the pharmacist uses language that the patient understands
Simple medical term usage terms should be avoided.
Instead of saying this medication is for HTN, it is better to say this medication is for high BP.
If the patients family visits the pharmacy to collect the medication, they should be provided with suitable advice after gathering information, such as their relationship with the patient and their awareness of the patient disease and medication history.

4. Closing session:

- Before closing the session, it is essential to check that patients understanding.
- This can be assessed by feed back questions such as can you remember what this medication is for? or for how long should you take this medication.
- Before final closure and if the time permits, summarise the main points in logical order.
- If appropriate the pharmacist can supply their telephone number to encourage the patient to make contact if they need further advice or information.

COUNSELLING AIDS:

- When information is provided to the patient verbally, there is a chance that the patient may forget the information over a period of time.
- A variety of teaching and educational aids have been developed to assist patient counselling.
- If information is provided in a printed format, the patient can go through the information at leisure as and when the information is required.
- Medication cards can be useful aid for patients on many medications on a long term basis.

- A medication card is a written summary of a patients medication presented in a way which is easy for the patient to understand.
- Cards may be written by hand or generated by computer.
- Once a card is given to the patient it can be used to assist the patient to organize their medication routines at home.
- It is important that the card is updated when changes to the medication regimen are made.
- Patient information leaflets produced by the drug manufacturers for their products are called as consumer product information (CPI) or consumer medicine information (CMI).
- PILs are written information leaflets in simple language about the patient's illness and its treatment including medications and relevant lifestyle changes.
- Written information should be considered as a supplement to verbal counselling and is useful for literate patients.
- Development of useful PILs using knowledge of therapeutics and local language for review to ensure accurate and high quality content.
- While preparing PILs, reading case, layout, and design are important.

BARRIERS TO PATIENT COUNSELLING:

- Patient counselling may not take place in community pharmacies due to various reasons known as barriers.

1. Patient based barriers:

- Many patients are unaware that pharmacist may provide counselling and generally ask their prescriber about medication use.
- Gender and language differences may also inhibit patients from asking the pharmacists about medication use information.

2. Provider-based barrier:

- Many pharmacists lack the confidence to counsel patients due to lack of knowledge and counselling skills.
- Heavy patient load for prescription filling is another barrier.

3. System based barriers:

- In India counselling is not a mandatory legal requirements and officially pharmacists are not entitled to charge for dispensing or for the information provided to patients.
- Lack of privacy in many busy community and hospital pharmacies can also be a problem.

STRATEGIES TO OVERCOME BARRIERS:

- Provider based barriers are easy to modify.
- Pharmacists can start by updating their knowledge and counselling skills.
- Confidence can be developed by initially focusing on one particular disease or group of drugs.
- A good approach is to ask patients have you used this medication before?, when they collect their prescription.
- Encouraging individual patients to ask questions about their medications or media campaigns will also improve counselling opportunities.

DRUG UTILIZATION EVALUATION

DEFINITION:

Drug utilization evaluation is an ongoing, authorized and systematic quality improvement process, which is designed to

- Review drug use and / or prescribing patterns.
- Provide feedback of results to clinicians and other relevant groups
- Develop criteria and standards which describe optimal drug use.
- Promote appropriate drug use through education and other interventions.

AIMS:

- Reducing drug and health related treatment costs.
- Improving health related quality of life
- Improving quality of medical treatment.
- Improving coordinated healthcare
- Decreasing the number of medication- related problems and medication errors.
- Decreasing the number of hospital admissions
- Improving prescriber awareness and practice towards appropriate prescribing.

TYPES:

1. Drug- focused: Use of single drug (eg amikacin) or a class of drugs (3rd generation cephalosporins) is examined.

2. Indication-focused: Use of drug or drugs (eg IV omeprazole for bleeding peptic ulcers) for a specific indication is examined.

3. Quantitative: It involves the collection, organization and display of estimates or measurements of drug use. This type of data is often used for making purchasing decisions or other financial activities such as preparing drug budget.

4. Qualitative: It involves collection, organization, analysis and reporting information on actual drug use.

- It is possible to combine both quantitative and qualitative DUE studies into a single study, which gives information about the patterns and amount as well as quality of drug use.

DUE COMMITTEE:

- The DUE Committee should be composed of physicians, pharmacists and other relevant healthcare professionals.
- The committee must include professionals with an interest in improving drug therapy in the hospital and have ready access to experts in medicine, surgery and major hospital specialties.
- Pharmacists generally play a major role in the delivery of DUE and it is usual for the committee to include pharmacy department representation.

ROLE OF PHARMACIST IN DUE:

- Planning, organizing and implementing a DUE programme.
- Programme development, supervision and coordination.
- Education of hospital staff about DUE in conceptual and practical terms.
- Promotion of the goals and objectives of DUE.
- Development / review of audit criteria, guidelines, study protocols and educational materials.
- Development of data collection, analysis and report writing.

- Documentation of programme outcome, effectiveness and cost benefits.
- Participation on hospital committees concerned with quality assurance in general and drug usage.
- Presentation of DUE results at meeting and conferences.
- Publication of results in peer-viewed journals.

FUNCTIONS OF DUE COMMITTEE:

- The committee should draft and approve the policies and procedures.
- Establish and maintain adequate means of communication with hospitals administration and other relevant hospital committee.
- Medical and other hospital staff should understand that the DUE programme is a continuous quality improvement activity designed to ensure safe and effective drug use.
- The committee should prepare a schedule including a yearly meetings and meetings for selecting and approving criteria, evaluating data, designing interventions and reviewing the programme.
- The committee should develop or review standards and criteria of DUE studies based on their knowledge, experience and literature findings.
- Reviewing the data generated from study.
- Initially, monthly meetings may be necessary to discuss start up problem and make corrections in the programme.
- Later quarterly meetings may be sufficient.
- The committee should ensure compliance with good clinical research guidelines such as maintaining the confidentially of all patient data.

THE DUE CYCLE:

- It is important to keep in mind that DUE operates in a repeating cycle.
- The DUE cycle should include the following seven major activities or phases.

1. Planning (step 1-4)
2. Data collection (step 5)
3. Evaluation (step 6)
4. Feedback of results (step 7)
5. Interventions (step 8)
6. Re-evaluation (step 9-10)
7. Feedback of results (step 11)

STEPS INVOLVED IN CONDUCTING A DUE CYCLE:

1. Step 1: Identify drugs or therapeutic areas of practice for possible inclusion in the programme:

- The DUE committee must identify priority drugs or areas of practice where improvement in use will result in the greatest clinical impact.
- These areas can be identified through various sources of information such as medication error reports, ADR reports, feedback from prescribers or clinical pharmacists, local microbiological data and the medical and pharmaceutical literatures.
- ABC/VEN analysis is another important tool used to identify high priority or target drugs. ABC analysis divides the drugs into three classes based on their annual usage:

* Class A drugs constitute 75-80% of the total value of drugs consumed or purchased and are the

highest cost or highest volume items.
* Class B items constitutes 15-20% of expenditure.
* Class C includes low cost or low volume items, which form 5-10% of expenditure.
- ABC analysis is generally done to assist the selection of drugs to be included in the hospital formulary.
- In VEN analysis the drugs are generally classified as vital (V), essential (E) and non-essential (N).
- Common targets for DUE include:
* Commonly prescribed drugs such as antibiotics and PPIs.
* Expensive drugs such as low molecular weight heparin, broad spectrum cephalosporin's, anti-HIV medication.
* New drugs.
* Drugs with a narrow therapeutic index such as digoxin, phenytoin, cyclosporine, theophylline etc.
* Drugs used in the management of common conditions such as chronic pain, respiratory tract infections or urinary tract infection.

2. Step 2: Design of study:

- Research Methods:
1. Observational research method: most commonly used
2. Experimental methods: eg. randomised controlled trials.
3. Cross sectional studies: Drug use is examined at a single point in time, are useful for problem identification.
- Based on design of study, DUE studies may also be categorized as prospective, concurrent, retrospective depending on the timing of data collection.

1. Prospective review:
- It involves evaluating a patient's planned drug therapy before a medication is administered.
- Depending on the study design, interventions may be provided if necessary before the patients receive the prescribed drug.
- Identification of drug-drug interactions is one issue commonly addressed by a prospective DUE.
- For example, a patient who is on warfarin for atrial fibrillation may be prescribed an NSAID by another physician. This increases the risk of gastrointestinal bleeding in the patient. Thus a DUE of concurrent use of warfarin and NSAIDs should be designed in a way that allows the pharmacist to advise the treating doctor of the risks with this drug combination.

2. Concurrent review:
- It is performed during the course of treatment and involves the ongoing monitoring of drug therapy. This may involve consideration of laboratory test results and other monitoring data when appropriate and usually does not offer immediate benefit to the patient. It differs from prospective review in that data collection does not have to occur prior to the administration of a first dose.
- This method of data collection is convenient when pharmacists perform a daily review of medication charts as part of routine clinical care, for example: in the setting of a DUE evaluating aminoglycoside dosing, a patient with reduced renal function may be prescribed a high dose of

gentamicin which may be inappropriate for the patient based on the patients estimated creatinine clearance.

- The clinical pharmacist identifies the dose as inappropriate during their regular treatment chart review and alerts the prescriber about the problem.

3. Retrospective review:

- Drug therapy is reviewed after he patient has completed a course of therapy.
- The patients medication sheets (including discharge, prescription, daily progress notes, nursing observations, pathology/biochemistry results and therapeutic monitoring results are screened to determine whether drug therapy met predetermined criteria.
- The main advantage of this method is that prescribers and others are unaware of data collection and results may therefore be less biased.
- Another advantage is ease of data collection as records are accessed at the data collector's conveniences.
- A disadvantage is that some information may be unclear or missing and that reviewed patients do not gain immediate benefit, as interventions are delayed until the intervention phase.

3. Step 3: Define criteria and standards:

- After the DUE target has been selected it is important to conduct a comprehensive literature review.
- The extent of work involved in this step depends on what has been done previously, or what is already available for example local, reliable and authoritative guidelines or previous DUE criteria. The step involved in literature review are:

* Perform an exhaustive literature search for the chosen drug or therapeutic area using multiple search mechanisms such as medical (medline, Micromedex, drugdex, Cochrane library, embase) and pharmacy-based systems (IOWA, drug information service, international pharmaceutical abstracts)
* Assemble full copies (not just the abstracts) of all the relevant original research papers.
* Critically evaluate the studies directly relevant to the chosen drug or therapeutic area. This includes identifying strengths and weakness in the study design and deciding whether appropriate conclusions have been made from the data presented.
* Briefly summarize the literature review, identifying the key papers in the chosen area and the drug use criteria that can be derived from the evidence based literature.

4. Step 4: Design the data collection form:

- As it is impossible to monitor and evaluate all the drugs used in a hospital, it is also impossible to address all aspects of use for each drug.
- It is important to limit data collection to only the most important and relevant aspects of drug use and to factors which may influence these.
- Some aspects of drug use which are commonly surveyed during DUE's are:

1. Patient demographics 2. Prescriber details 3. Disease severity 4. Co-morbidities 5. Indication for drug use 6. Drug-disease contraindications 7. Side / adverse effects 8. Dosing information 9. Duration of drug treatment 10. Drug or drug class duplication 11. Therapeutic duplication 12. Preparation and administration 13. Drug-drug and drug food interactions 14.Monitoring of drug therapy 15. Patient education/ instructions 16. Cost of therapy 17. Over/under utilization of drugs.

5. Step 5: Data collection:

- Data collectors should be chosen carefully, and should be familiar with how information is arranged in the patients case notes.
- Knowledge of drug names, strength and the way orders are written is also important
-Depending on their availability, physicians, pharmacists and nurses make ideal data collectors

6. Step 6: Evaluate results:

- Data evaluation is one of the most critical steps in a DUE.
- The data obtained should be collected using available resources such as spread sheeting, data basing and word processing.
- The next step is to summaries the main categories of results and to identify where exactly the data shows deviation should be evaluated.
- If there is a true reason for deviation, it may be necessary to redefine the criteria. The reasons may not be evident from the DUE data and may require further investigations, survey or interviews.
- Reasons for deviation may include:

1. Drug being used for new indications
2. Outdated procedures
3. Inadequate resources
4. Gaps in knowledge or misinformation/misunderstanding

7. Step 7: Provide feedback of results:

- The success of any DUE strategy depends on feedback of the results to prescribes, other hospital staff involved in the study and to administrative heads.
- The presentation of any report is also very important.
- The report should be well presented and well-reasoned document with no grammatical or typographical errors.
- It is important to prepare a scientific interpretation of the results rather than a value judgment.
- The results can also be circulated to hospital staff through newsletters, DUE meetings or the hospitals academic meetings.

8. Step 8: Develop and implement interventions:

- If a drug use problem was identified , the next step is to consider how the problem can be addressed.
- Interventions to improve drug use can be educational meetings, academic detailing, circulation of protocols, feedback of study results, letters to individual physicians, newsletters and other informational materials such as posters and guidelines.
- Operational interventions include the development/ modification of drug order forms manual or computerized reminders, prescribing restrictions, formulary additions/deletions, automatic stop orders or re-allocation of staff.
- Some interventions may be both educational and operational in nature, such as improving the availability of information and resources to support clinical decision making.
- The choice and development of interventions require careful planning.

9. Step 9: Re-evaluate to determine if drug use has improved:

- Drug use and prescribing patterns need to be monitored to determine the success of interventions.

- Re-evaluation is done 3-12 months after the introduction of the intervention, and should involve collecting the same data as in the original DUE evaluation.
- If a complete evaluation with several criteria uncovered only a few problems, the focus may be narrowed to problematic criteria.

10. Step 10: Re-assess and revise the DUE programme:

- At the collection of a DUE evaluation cycle an evaluation of the DUE programme is necessary.
- The questions addressed should include the following:

1. Did the programme address important aspects of care?
2. Were the criteria developed appropriate?
3. Were the drug use problem was identified?
4. Were the interventions made appropriate?
5. Did the interventions have any unexpected or adverse effects?
6. Were drug use problems solved?
7. Did the DUE have an impact on the incidence of adverse drug reactions, drug-drug interactions or medication errors?
8. The DUE process involved cooperation and coordination between various hospital staff.

11. Step 11: Feedback results:

- It is important to circulate the results of the DUE to clinicians and other involved hospital staff.
- This is also a suitable time to obtain their opinions about the success or otherwise of the interventions and how these can be improved.

DRUG UTILIZATION REVIEW

INRODUCTION:

- Drug Utilization Reviews (DUR), also referred to as Drug Utilization Evaluations (DUE) or Medication Utilization Evaluations (MUE), are defined as an authorized, structured, ongoing review of healthcare provider prescribing, pharmacist dispensing, and patient use of medication.
- DURs involve a comprehensive review of patient's prescription and medication data before, during, and after dispensing to ensure appropriate medication decision making and positive patient outcomes.
- DURs are classified into three categories:
• Prospective - evaluation of a patient's therapy before medication is dispensed
• Concurrent - ongoing monitoring of drug therapy during the course of treatment
• Retrospective - review of therapy after the patient has received the medication

IMPORTANCE:

- DUR programs play a key role in helping managed health care systems understand, interpret, and improve the prescribing, administration, and use of medications.
- Pharmacists play a key role in this process because of their expertise in the area of pharmaceutical care.
- DURs afford the managed care pharmacist the opportunity to identify trends in prescribing within groups of patients such as those with asthma, diabetes, or high blood pressure.
- Pharmacists can then, in collaboration with other members of the health care team, initiate action to improve drug therapy for both individual patients and covered populations.
- DURs serve as a means of improving the quality of patient care, enhancing therapeutic outcomes, and reducing inappropriate pharmaceutical expenditures, thus reducing overall health care costs.

CLASSFICATION:

Prospective DUR:

- A Prospective DUR involves evaluating a patient's planned drug therapy before a medication is dispensed.
- This process allows the pharmacist to identify and resolve issues before the patient actually receives the medication.
- Pharmacists routinely perform prospective reviews in their daily practice by assessing a prescription medication's dosage and directions and reviewing patient information for possible drug interactions or duplicate therapy.

-Issues Commonly Addressed by Prospective DUR:

• Drug-disease contraindications
• Therapeutic interchange
• Generic substitution
• Incorrect drug dosage
• Inappropriate duration of drug treatment
• Drug-allergy interactions

- Clinical abuse/misuse Example of a Prospective DUR: A patient being treated with warfarin to prevent blood clots may be prescribed a new drug by another specialist to treat arthritis. If taken

together, the patient could experience internal bleeding. Upon reviewing the patient's prescriptions, the pharmacist notes the potential drug interaction and contacts the prescriber to alert him/her to the problem.

Concurrent DUR:

- A Concurrent DUR is performed during the course of treatment and involves the ongoing monitoring of drug therapy to ensure positive patient outcomes.
- Some refer to this as case management or health management.
- It presents pharmacists with the opportunity to alert prescribers to potential problems and to intervene in areas such as drug-drug interactions, duplicate therapy, over or underutilization, and excessive or insufficient dosing.
- This type of review allows therapy for a patient to be altered if necessary.
- Concurrent DURs often occurs in institutional settings.
- Issues Commonly Addressed by Concurrent DUR:

• Drug-drug interactions
• Excessive doses
• High or low dosages
• Duplicate therapy
• Drug-disease interactions
• Over and underutilization
• Drug-age precautions
• Drug-gender precautions

- Drug-pregnancy precautions Example of a Concurrent DUR: Patients in institutional settings often receive multiple medications. Periodic review of patient records can detect actual or potential drug-drug interactions or duplicate therapy. This type of review can also alert the pharmacist to the need for changes in medications such as antibiotics or the need for dosage adjustments based on laboratory test results. The key physician(s) must then be alerted to the situation so that corrective action can be taken.

Retrospective DUR:

- A retrospective DUR is the simplest to perform since drug therapy is reviewed after the patient has received the medication.
- A retrospective review may detect patterns in prescribing, dispensing, or administering drugs to prevent recurrence of inappropriate use or abuse and serves as a means for developing prospective standards and target interventions.
- In retrospective DUR, patient medical charts or computerized records are screened to determine whether the drug therapy met approved criteria and aids prescribers in improving care for their patients, individually and within groups of patients, such as those with diabetes, asthma, or high blood pressure.
- Issues Commonly Addressed by Retrospective DUR:

• Therapeutic appropriateness
• Over and underutilization
• Appropriate generic use
• Therapeutic duplication
• Drug-disease contraindications

• Drug-drug interactions
• Incorrect drug dosage
• Inappropriate duration of treatment
- Clinical abuse/misuse Example of a Retrospective DUR: An analysis of member prescription utilization may identify of a group of patients whose therapy does not meet approved guidelines. Upon retrospective review the pharmacist may identify a group of patients with asthma who, according to their medical and pharmacy history, should be using orally inhaled steroids. Using this information, the pharmacist can then encourage physicians to prescribe the indicated drugs.

QUALITY ASSURANCE OF CLINICAL PHARMACY SERVICES

DEFINITION:
Quality assurance is a management technique used to ensure the quality of practice and its assurance.

QUALITY ASSURANCE SERVICES:

Patient counselling	Drug interactions
ADR reporting	Pharmacoeconomics
Drug information services	Hospital pharmacy
Patient interview	Newsletters
Case note review	Dosage adjustment calculations
Poison management	TDM
Medication chart review	Therapeutic guideline preparation
Therapeutic consultation	

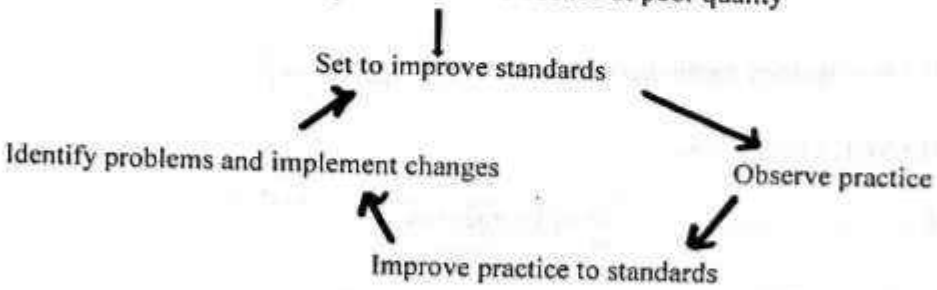
Assuring the quality through customers who may be
- patients
- care takers
- clients
- other health care professionals

AUDIT:
Clinical audit:
- It is multidisciplinary in nature.
- It involves receiving the services and discover deficiencies.

Types of audit:
- Self audit- eg community pharmacist
- Peer or group audit- eg pharmacist from one hospital look at the services provided from other hospital
- External audit

WHAT IS MEASURED IN AUDIT?
- Three aspects are audited
1. Structures or resources involved
eg: staff, their experiences and knowledge, books, training courses, drug stock etc.
2. The processes used:
eg: prescribing policies, disease management protocols
3. The outcome of the activity:
eg: Change in health status, attitude or behavior of the patient, also change in BP, serum biochemistry etc.

AUDIT CYCLE:
- It is a continuous process.
- It involves a cycle of measurement, evaluation and improvement.



QUALITY ASSURANCE (DRUG INFORMATION):

1. The quality assurance programme is an integral part of drug information services as it provides opportunities to improve and to provide guidelines for future development.
2. Quality assurance can be assessed in terms of resources and operating procedures.
3. It is necessary to maintain up to date references and search strategies.
4. This can be done by regular comparison to similar services and accepted standards.
5. Output is best assessed within the services and by external peer view.
6. There will be time for checking many responses by a colleague before making the final response. It may be possible to have a sample of enquiries considered by drug information pharmacists or clinical pharmacists from another site etc.
7. General assessment of the services can also be done through periodic circulation of feedback questionnaires.

QUALITY ASSURANCE (POISON INFORMATION):

1. Quality assurance activities should be an integral part of the poison information services.
2. A formalized quality assurance programme must be developed and implemented in the PIC for the services provided.
3. The aim is to improve the quality of services provided and improve patient health outcomes.
4. The quality assurance can be applied to different areas of practice which may be divided into the levels: input level, process level, output level
5. The input level in poison information service refers to the area of staff, resources, facilities and organization.
6. The process level includes the areas of receiving queries, search strategies, data collection, literature evaluation, formulation of reply, documentation and storage.
7. The output level refers to the areas of user satisfaction and patient outcome.
8. All these help in resolving identified problems to improve patient care.
9. Clinical governance of the PIC should include meetings at regular intervals to discuss quality improvement strategies.
10. As part of the quality improvement the PIC staff should receive feedback from the consultant clinical toxicologist regarding all cases that have been referred to them.

PATIENT CASE HISTORY

INTRODUCTION:

1. Name 2. Age 3. Gender 4. Religion 5. Address

CASE HISTORY:

1. Presenting complaints
2. History of present illness
3. History of previous illness
4. The menstrual history
5. Obstetric history
6. Treatment history
7. Family history
8. Social history
9. Occupational history

INTRODUCTION:

1. Name:
   - Gives a clue of the country, state and religion to which the patient may belong.
2. Age:
   - Problems that occur in childhood are congenital in origin.
   - Degenerative, neoplastic and vascular disorders are more common in the middle aged or elderly groups.
   - In women beyond the menopausal age group, the incidence of problem like ischemic heart disease, osteoarthritis etc increases in equal proportions as that in males.
3. Gender:
   - Males are prone to inherit certain conditions like hemophilia.
   - They are more prone to develop conditions like ischemic heart disease, bronchogenic carcinoma, decompensated liver disease and they are habituated to smoking, alcohol in larger number than females.
   - Females are more prone to develop autoimmune disorders like SLE, thyroid disorders etc.
4. Religion:
   - Muslims and Jews practice circumcise soon after birth and so development of carcinoma of penis is rare in them.
   - Muslims do not consume alcohol and so less prone to develop problems related to its consumption like alcoholic liver diseases.
5. Address:
   - People from the urban religion are prone to develop problems related to urbanization like exposure to constant stress and atmospheric pollution, increased risk of ischemic heart disease, COPD, interstitial lung disease etc.
   - Inhabitants of mountains, hilly regions may develop pulmonary hypertension.
   - The particular place from which the patient comes may be endemic for certain diseases eg: fluorosis.

CASE HISTORY:

1. Presenting complaints:
   - Allow the patient's to tell his complaints in his own words, current complaints and its duration should be noted in order.
2. History of present illness:
   - Allow the patient to elaborate the story of his illness from its onset to its present state.
   - Take care so as not to put any leading questions to the patient which may detest the patient history.
3. History of previous illness:
   - This should include all important previous illness, operations and injuries that the patient might have suffered from birth onwards.
   - It is always wise to be cautious while accepting readymade diagnosis from the patient like typhoid fever, malaria etc unless the patient has records of the mentioned illness.
   - Tactful enquiry about STD and its treatment etc.
4. The menstrual history:
   - Age of menarche
   - Duration of each cycle
   - Regular or irregular cycles
   - Appropriate volume of blood loss in each menstrual cycle
   - Age of attainment of menopause.
5. Obstetric history:
   - No of times patient conceived
   - No of abortions (spontaneous or therapeutic)
   - No of living children, their ages and age of the last child delivered.
   - Time interval between successive pregnancies
   - Mode of delivery (vaginal, forceps assisted or caesarean etc)
6. Treatment history:
   - This should include all previous medical and surgical treatment and also any medication that the patient may be continuing to take to the present date.
   - Details of the drugs taken including analgesics, oral contraceptives and psychotropic drugs.
   - It is important to find out if the patient had been allergic or had experienced any reaction to any medications that he may have consumed previously, so that the same medication can be avoided.
7. Family history:
   - Enquire about the presence of any disease state the patient parents, brother, sister and close relatives (presence of disease like hypertension, diabetes, ischemic heart disease) which may make the patient more prone to develop a similar problem.
   - Marital status, no of children that the patient has, should also be enquired for (infertility in patient may give a clue to the presence of immotile cilia syndrome, cystic fibrosis or young's syndrome).
8. Social history:
   - Enquire about patients lifestyle

- Daily habits
- Diet
- About the nature of patient's work (hard work or sedentary)
- About the possibility of overcrowding at home/ overcrowding aids in the spread of communicable diseases.
- Sanitation in and around the house.
- About the presence of pets in the house.
- About the use of alcohol (no of days in a week and also the quantity consumed each day)
- Tobacco (whether chewed or smoked)
- Betel nut
- An alcoholic consumer, consumes alcohol every day and develops withdrawn symptoms in abstaining from alcohol.
- Smoking:
- Enquire about the no of cigarettes/ beedies smoked per day and the duration of smoking. This may be present as:

Pack year: Duration of smoking inn years X no of packets of cigarettes smoked / day
eg. Two packs of cigarettes smoked/day for 20 years constitutes 40 packs year (risk for development of bronchogenic carcinoma increases when pack years exceeds 40).
Smoking index: It is the no of cigarettes or beedies smoked/ day and its duration.
eg. the smoking index of a person smoking 20 cigarettes or beedies/ day for 20 years is 400

- smoking index greater than 300 constitutes a risk factor for bronchogenic carcinoma.
- Chewing betel nut or tobacco is a habit common with people living in rural areas, this increases the risk of developing oral malignancies.
- Enquire about history of travel abroad or other places within the country as it may give clue to the impact of a disease by the patient.

HAEMATOLOGICAL TESTS

RBC COUNT:

- Normal range: 4.3-5.9 million/mm^3X10^{12}L (men)
  3.5- 5.0 million/mm^3X10^{12}L (women)
- RBC's are produced in the bone marrow by the process called as erythropoiesis.
- Immature erythroblasts develop into mature erythrocytes which are released into the circulation.
- Erythroblasts → normoblasts (nucleated) → reticulocytes (non-nucleated) →erythrocytes
- The life span of matured RBC is 120 days, if it is shortened in hemolysis, the circulating no of RBC's is reduced and with it the supply of oxygen to tissues is decreased.
- A high RBC (erythrocytosis or polycythemia) indicates increased production by the bone marrow and may occur as physiological response to hypoxia, as in chronic airway disease or as a malignant condition of RBC's such as in polycythemia rubra vera.

1. Reticulocytes:

- Non-nucleated red cells.
- Represent between 0.5% and 1.0% of the total RBC.
- Increased production of reticulocytes is called reticulocytosis.
- Reticulocytosis can be detected in time of rapid red cell regeneration as occurs in response to hemorrhage or hemolysis. In such conditions the reticulocyte count may reach 40% of the RBC.
-Reticulocyte count: It is useful in assessing the response of the marrow in iron, folate or vitamin B_{12} therapy.
- The reticulocytes count peaks at about 7-10 days after starting such therapy and then subsides.

2. Mean cell volume (MCV):

- MCV is the average volume of a single RBC.
- Measured in femtoliters (10^{-5}L)
- Microcytic-Low MCV
- Macrocytic- High MCV
- Useful in the identification of various types of anemia's such as caused by iron deficiency (microcytic) or vitamin B_{12} or folic acid deficiency (macrocytic).
- Normal range: 90 +/- 10 fl
  87- 110 fl

3. Packed cell volume (PCV):

- Normal range: 42% - 52% (men) / 0.42 – 0.52 L (men)
  37% - 47% (women) / 0.37 – 0.47 L (women)
- PCV or hematocrit is the ratio of the volume occupied by RBC's to the total volume of blood.
- Measured by centrifugation of a capillary tube of blood.
- Reported as a fraction of unity or as a percentage.
- PCV decreased in any sort of anemia.
- PCV increased in polycythemia
- PCV is a product of MCV and RBC.

4. Mean cell hemoglobin (MCH):

- Normal range: 30 +/- pg.

- MCH is the average weight of hemoglobin contained in a red cell.
- Measured in pictograms (10^{-12}).
- Calculated from MCH= Hb/ RBC.
- MCH depends on the size of RBC as well as the concentration of hemoglobin in the cells.
- MCH: Low in iron deficiency anemia- microcytosis and less Hb in each cell.
- MCH- raised in macrocytic anemia.

5. Mean cell hemoglobin concentration (MCHC):

- Normal range: 34+/- g/dL.
- MCHC is a measure of the average concentration of Hb in 100ml of red cells.
- Expressed as grams per liter.
- Low MCHC: reduced Hb synthesis- iron deficiency anemia.
- Normal or slightly reduced- macrocytic anemia because the large RBC's may contain more Hb.
- Raised MCHC- severe prolonged dehydration.
- Low MCHC- condition is called hypochromic.
- Normal MCHC- normochromic.

6. Hemoglobin:

- Normal range: 12-16 gm/dL (women)
  14-18 gm/dL (men)
- Measured to detect anemia.
- The Hb content of blood determines its oxygen carrying capacity.
- In rare genetic disease, alternation in the structure of the Hb molecule can be detected by electrophoresis.
- Abnormal Hb which can be detected include Hbs (sickle Hb in sickle cell disease) and HbA_2 in β-thalassemia carriers.

7. Microcytic anemia:

- Low Hb, MCV, MCHC.
- Microcytic hypochromic anemia-associated with iron deficiency.
- Iron deficiency- due to malnutrition or a vegetarian diet, malabsorption of iron.
- Iron deficiency and microcytic anemia- large and / sustained blood loss.
- Chronic blood loss eg; peptic ulcer, occult malignancy in lower GIT, hemoptysis (seen in TB).
- Drugs which causes iron deficiency anemia- warfarin, aspirin and NSAID's.

8. Normocytic anemia:

- When MCV and MCHC are within normal ranges.
- Sometimes called as anemia of chronic disease, this condition may be associated with chronic infection, R.A, hypothyroidism and some forms of malignancy.
- Another important cause of normocytic anemia is acute blood loss (may occur after trauma or major surgery or can be secondary to major acute internal bleeding such as that associated with bleeding peptic ulcer).

9. Macrocytic anemia:

- Hb is low and MCV is high.
- Occurs in some forms of liver disease.

- Most common cause- malabsorption of either folic acid or vitamin B_{12}.
- Drugs associated with folate deficiency- methotrexate and phenytoin.

WBC COUNT:

- Normal range: 4000 – 11000 WBC/cumm^3.
- WBC count used to describe the number of leucocytes circulating in peripheral blood.
- WBC's are of two types

1. Granulocytes (Neutrophils, basophils, eosinophil's)
2. Agranulocytes (Lymphocytes and monocytes)

- Leucopenia:

* WBC count is lower than the reference range.
* Drugs causing leucopenia-cytotoxic and immunosuppressant drugs, antibiotics, anti-convulsants, DMARD's and some psychotropic agents such as clozapine.

- Leucocytosis:

* WBC count is increased than the reference range.
* This occurs in UTI, bacterial pneumonia, TB, cholangitis, meningitis or cellulitis.

- Neutrophils:

* Also called as polymorphonucleocytes.
* Function: Phagocytosis.
* Constitute 40% - 70% of circulating WBC's in normal blood.
* Formed in bone marrow from the stem cells which form myoblasts and these develop through a number of stages into the neutrophils with a multiple segmented nucleus.
* Increase in neutrophils- in infection, tissue damage (eg infarction) and inflammation (eg. R.A, acute gout).
* Neutropenia: associated with malignancy and drug toxicity, viral infections such as influenza, infectious mono nucleosis and hepatitis.

- Basophils:

* Constitutes 0- 1% of total WBCs
* Basophilia occurs in malignant and premalignanat disorders such as leukemia and myelofibrosis.

- Eosinophils:

* Contributes less than 6% of WBCs.
* Function: inactivation of mediators released from mast cells.
* Eosinophilia: apparent in allergic conditions such as asthma, hay fever, drug sensitivity reactions and some malignant diseases.
* Common causes of eosinophilia include parasitic infections.

- Lymphocytes:

* Found in spleen and other lymphatic tissue.
* Formed in bone marrow.
* Increase in lymphocytes in – viral infections such as rubella, mumps, infectious hepatitis, infectious mononucleosis.

- Monocytes:

* Monocytes are macrophages.
* Number increases in – infections such as typhoid, sub-acute bacterial endocarditis, infectious

mononucleosis and TB.

PLATELET (THROMBOCYTES) COUNT:

- Normal range: 150,000 – 3,00,000.
- Formed in bone marrow.
- Thrombocytopenia- depressed synthesis in the marrow or destruction of formed platelets.
- Life span- 8 to 12 days.
- Small fall in platelet count- seen in pregnancy and viral infection.
- Severe thrombocytopenia- result in spontaneous bleeding.
- Reduced platelet count- found in disseminated intravascular coagulation, manifests as sever hemorrhages in skin and results in rapid consumption of clotting factors and platelets.
- **Thrombocytosis:**

* Occurs in malignancy, inflammatory disease and in response to blood loss.

OTHER BLOOD TESTS:

ERYTHROCYTE SEDIMENTATION RATE:

- ESR is a measure of the setting rate of red cells in a sample of anticoagulated blood, over a period of 1 hour in a cylindrical tube.
- Normal range: 0 – 20 mm/hr (males)
  0 – 30 mm/hr (females)
- ESR raised in the active phase of R.A, IBD, malignant disease and infection.
- ESR is nonspecific and is of little diagnostic value.
- In youth the normal value is less than 10 mm/hr, but normal values do rise with age.

C-REACTIVE PROTEIN (CRP):

- This nonspecific acute phase response occurs in response to tissue damage, infection, inflammation and malignancy.
- Produced in hepatocytes under the control of cytokines (IL-6).
- Serum concentration rise by about 6 hrs, peaking around 48 hrs.
- Serum half-life is about 19 hrs.
- In most diseases CRP reflects ongoing inflammation or tissue damage more accurately than do other acute phase parameters such as ESR.
- Sensitive marker of inflammation.

LIVER FUNCTION TESTS

A. Liver Enzymes:

1. Levels of certain enzymes e.g. LDH, ALP, AST, ALT increase with liver dysfunction.
2. These enzyme tests indicate only that the liver has been damaged. They do not assess the liver's ability to function.

a. Alkaline phosphate (ALP):

- Normal range: 30-120 μ/L
- ALP is produced primarily in the liver and bone.
- Serum ALP levels are particularly sensitive to partial or mild biliary obstruction-either extrahepatic (e.g. caused by a stone in the bile duct) or intrahepatic, both of which cause levels to increase.
- Increased osteoblastic activity, as occurs in Paget disease, hyperparathyroidism, osteomalacia and others also increase serum ALP levels.

b. Aspartate aminotransferase (AST):

- Normal range: < 30 μ/L
- AST- formerly known as serum glutamic-oxaloacetic transaminase (SGOT)- is found in a number of organs, primarily in heart and liver tissues and to a lesser extent in skeletal muscles, kidney tissue and pancreatic tissue.
- Damage to the heart (e.g. from myocardial infarction) results in increased AST levels about 8 hours after injury.
  1. Levels are increased markedly with acute hepatitis, they are increased mildly with cirrhosis and a fatty liver
  2. Levels are also increased with passive congestion of the liver, such as occurs in congestive heart failure.

c. Alanine aminotransferase (ALT):

- Normal range: < 30 μ/L
- Alanine aminotransferase- formerly known as serum glutamic-pyruvic transaminase (SGPT)- is found in the liver with lesser amounts in the heart, skeletal muscles and kidney.
- Although ALT values are relatively specific for liver cell damage, ALT is less sensitive than AST and extensive or severe liver damage is necessary before abnormally increased levels are produced.
- ALT also increases less consistently and less markedly than AST after acute myocardial infarction.

B. Serum Bilirubin:

- Bilirubin, a breakdown product of Hb.
- It is pigment of bile.
- Bilirubin conjugation and excretion depends on hepatobiliary function and on the rate of RBC turn over
- Serum bilirubin levels are reported as total bilirubin (conjugated and unconjugated) and as direct bilirubin (conjugated only)

1. Bilirubin is released by Hb breakdown and is bound to albumin as water-insoluble indirect bilirubin (unconjugated bilirubin), which is not filtered by the glomerulus.
2. Unconjugated bilirubin travels to the liver, where it is separated from albumin, conjugated with diglucouronide and then actively secreted into the bile as conjugated bilirubin (direct bilirubin) which is filtered by the glomerulus.

- Normal values of total serum bilirubin are 0.1-1.0 mg/dL of direct bilirubin –0.0-0.2 mg/dL
- An increase in serum bilirubin results in jaundice
- Jaundice is a yellowish tint in the body tissues including yellowness in the skin and deep tissues
- It is caused due to the large quantity of bilirubin in the extracellular fluids either from free or conjugated bilirubin.
- Categories of jaundice include
  1. Pre hepatic-due to excessive production of bilirubin
  2. Hepatic- congenital liver disease, liver cirrhosis, hepatitis
  3. Extra hepatic- due to blockage of bile drainage due to gall stone, cancer of bowel or pancreas.
- There are three major causes of increased serum bilirubin

1. Hemolysis:

- Increase total bilirubin, direct bilirubin (conjugated) is usually normal or slightly increased. Urine color is normal and no bilirubin is found in the urine.
- In hemolytic jaundice the excretory function of the liver is not impaired but red blood cells are hemolyzed so rapidly that the hepatic cells simply cannot excrete the bilirubin as quickly as it is formed. Therefore the plasma concentration of free bilirubin rises to above normal levels.

2. Biliary obstruction:

- Which may be intrahepatic (as with chlorpromazine reaction) or extra hepatic (as with biliary stone), increase total bilirubin and direct bilirubin intrahepatic cholestasis (e.g. from chlorpromazine) may increase direct bilirubin as well. Urine color is dark and bilirubin is present in the urine.
- In obstructive jaundice caused either by obstruction of the bile ducts (which most often occurs when a gall stone or cancer blocks the common bile duct or by damage to the hepatic cells.

3. Liver cell necrosis as occur in viral hepatitis, may cause an increase in both direct bilirubin (because inflammation causes some bile sinusoid blockage) and indirect bilirubin (because the liver's ability to conjugate is altered). Urine color is dark and bilirubin is present in the urine.

C. Serum Proteins:

1. Primary serum proteins

a. Primary serum proteins measured are albumin and globulin
b. Normal value for total serum proteins: 6.0- 8.0g/dL

1. Albumin:

- Normal value: 4.0-6.0 g/dL
- Albumin is the most abundant serum protein
- It is synthesized in the liver and accounts for up to 65% of total protein
- Albumin has three major functions:

- Controlling oncotic pressure in the plasma
- Transporting amino acids synthesized in the liver to other tissues
- Transporting poorly soluble organic and inorganic ligands

- Malnutrition, malignancy, severe trauma or burns causes a net catabolic state decreasing serum albumin and oncotic pressure.
- In hepatic cirrhosis there is decreased synthesis of albumin and increased portal capillary pressure resulting in ascites.
- In severe sepsis, toxin mediated increase in capillary permeability allow intravascular albumin to escape into the interstitial tissue accounting for increase in interstitial oncotic pressure.
- Nephrotic syndrome and protein-losing enteropathies cause increased losess of serum albumin resulting in anasarca.
- Congestive failure alters pulmonary capillary hydrostatic pressure, resulting in pulmonary odema.
- Malnutrition decreases protein synthesis and increases its catabolism. In malignancy and burns also there is increased protein catabolism besides skin capillary permeability gets altered in burns.
- Medication that are highly insoluble in serum bind more than 90% to albumin including phenytoin, salicylates, phenylbutazone, first generation sulfonylureas, valproic acid, warfarin and sulfonamides.

2. Globulin:

- The globulin fraction makes up one-third of total protein and has four major components α(α_1, α_2), β, γ.
- Normal value: 23-35 g/L

1. α:

α_1:

- α_1 antitrypsin which is a scavenger enzyme for lysosomal protease, and α_1 acid glycoprotein (AAG).
- AAG is an acute phase reactant that acts as a carrier protein for certain poorly soluble medications.
- AAG is elevated transiently in a variety of clinical conditions including rheumatoid arthritis, morbid obesity, MI, malignancy, surgery and trauma.
- Medication binding to AAG include amitriptyline, chlorpromazine, dipyridamole, disopyramide, erythromycin, imipramine, lidocaine, methadone, propranolol and quinidine.

α_2:

- This portion consists primarily of
  1. Macroglobulin: a protease inhibitor
  2. Haptoglobulin: a carrier protein for hemoglobin
  3. Ceruloplasmin: a copper binding protein

2. β:

- This portion is composed of low density lipoprotein, transferrin C_3 and fibrinogen.
- LDL is the major transport protein for cholesterol to tissues.
- Transferrin transports ferric iron stores to bone marrow for erythropoiesis.
- C_3 is a major component of the complement system and fibrinogen is a coagulation precursor for fibrin.

3. γ:
   - This portion is composed of antibody immunoglobulins IgA, IgE, IgG and IgM.
   - IgA is responsible for surface immunity
   - IgE bind to mast cell and is responsible for hypersensitivity reaction
   - IgM is responsible for initial humoral immunity
   - IgG is responsible for sustained humoral immunity
   - The primary disorder associated with hypergamaglobulinemia is a multiple myeloma

RENAL FUNCTION TESTS

- Renal function tests are used to evaluate kidney and its functions
- GFR is tested by a creatinine clearance, serum creatinine and serum urea.
- Renal plasma flow is tested by para amino hipparate (PAH)
- Tubular transport is tested by serum phosphate urate, urinary amino acids, maximum loading osmolarity and acid bicarbonate loading.

1. **Creatinine clearance:**
   - GFR is estimated using creatinine clearance
   - Normal value for men is 140-240L/day
   - Normal value for women is 120-180L/day
2. **Serum creatinine:**
   - Normal range: 0.6-1.5 mg/dL
   - Creatinine is a metabolic byproduct of muscle metabolism
   - It is formed by the degradation of creatine
   - If GFR increases, serum clearance is a useful index of GFR
   - It is increased only when there is kidney damage/presence of impaired renal function
   - Drugs that may cause an elevated serum level by interfering with tubular secretion of creatinine are cephalosporin's, cimetidine, salicylates, trimethoprim, amilorde, probenecid, triamterene.
   - Creatinine levels will also rise in conditions such as rhabdomyolysis/crush injury.
   - The relationship between the extent of elevation of serum creatinine concentration and the relative decline in renal function is estimated using Cockcroft Gault equation

     Estimated GFR= $\frac{(140\text{-age}) \times \text{weight (kg)}}{\text{Serum creatinine (mmol/L)} \times 0.84}$

     For female: multiply by 0.85
3. **Serum Urea and Blood Urea Nitrogen (BUN):**
   - Serum urea- 3.0-8.0 mmol/L
   - BUN- 3.0-6.5 mmol/L
   - Serum urea and BUN are the secondary indicators of renal function
   - When there is a large increase of non-protein compounds such as urea in the blood it is called as azotemia.
   - Extreme form of azotemia is known as uremia
   - Types of azotemia include
     - **Pre renal:**
     - Inadequate perfusion of kidneys with otherwise normal renal function
     - Dehydration, shock, heart failure, decrease blood volume
     - **Renal:**
     - Decreased GRF
     - Glomerulonephritis, interstitial nephritis, tubular necrosis
     - **Post renal:**

- Urinary tract obstruction
- Renal calculi

- Increase in BUN is by drugs such as chloral hydrate, chloramphenicol, ammonium salts, acetohexamide and sulfonylureas
- Decrease in BUN is due to poor nutrition, high fluid intake, severe liver disease where urea synthesis is decreased, chloramphenicol and streptomycin.

4. Uric acid:

- Normal range: 2.0-7.0 mg/dL
- Uric acid is the end product of purine metabolism
- Hyperuricemia: It is condition in which uric acid levels are increased
  1. Renal failure
  2. Gout
  3. Increased breakdown of nucleoprotein (burns. crush injuries, very severe hemolytic anemia, plasma cell myeloma, myeloproliferative disorders)
  4. High protein diet
  5. Lead poisoning
  6. Methotrexate, busulfan , vincristine, prednisone, azathioprine, tacrolimus, cyclosporine
  7. Thiazide and loop diuretics, pyrazinamide, ethambutol
- Drugs that decrease uric acid levels-allopurinol, probenecid, salicylates, phenylbutazone.

5. Other renal function tests:

1. N-acetyl-beta-D-glucosaminidase (NAG):

- It is a lysosomal enzyme found in serum and urine
- It is a marker for tubular disease especially sublet industrial poisoning, acute pyelonephritis, early acute tubular necrosis and early transplant rejection.

2. Adenosine Deaminase binding protein:

- It is an enzyme from the brush borders of the proximal tubule.
- Like NAG its presence in urine indicates tubular disease.

3. Serum Beta-2-m:

- It is a measure of glomerular filtration rate similar to creatinine, but is not used for patients with tissue necrosis, lymphomas etc.

THYROID FUNCTION TEST

THYROID PHYSIOLOGY:

- The thyroid gland consists of two lobes and is situated in the lower neck.
- The gland synthesizes, stores and releases two major metabolically active hormones
a. Tetra-iodothyronine (Thyroxine T4)
b. Tri-iodothyronine (T3)
- Regulation of hormone synthesis is by TSH secreted by anterior pituitary.
- In turn TSH is regulated by hypothalamic secretions of the tripeptide thyrotrophin releasing hormone.
- Low circulating levels of thyroid hormones initiate the release of TSH and also TRH.
- Rising levels of TSH promote increased iodide trapping by the glands and a subsequent increase in thyroid hormone synthesis.
- Increase in circulating hormone levels feedback on the pituitary and hypothalamus, shutting off TRH,TSH and further hormone synthesis.
- Both T4 and T3 are produced within the follicular cells in the thyroid.
- Ratio of T4:T3 secreted by the thyroid gland is approximately 10:1.
- The thyroid gland secretes approximately 80-100µcg of T4 and 10µcg of T3 per day.
- However only 10% of circulating T3 is derived from direct thyroidal secretion, the remaining 90% being produced by peripheral conversion from T4.
- T4 is converted to either T3 or to the biologically inactive reverse T3 in peripheral tissue (kidney, liver and brain).
- In the circulation the hormones exists in both the active free and inactive protein bound forms.
- T4 is 99.98% bound with only 0.02% circulating free.
- T3 is slightly less protein bound, with only 0.02% circulating free fraction.
- Half-life of T4 in plasma is about 6-7 days and that of T3 is 24-36 hours in euthyroid adults.
- Apparent volume of distribution for T4 is about 10L and for T3 is about 40L.

- **HYPOTHYROIDISM:**
- In primary disease, the levels of T4 and T3 are low and the TSH levels rises markedly.
- Secondary and tertiary hypothyroidism- decrease level of free T4 and TSH and TRH levels respectively.

-Etiology:

- Hypothyroidism is usually due to a failure of the thyroid gland itself as a result if autoimmune destruction or the effects of treatment of thyrotoxicosis
- It may be drug induced eg amiodarone and Lithium
- Secondary disease is due to failure of hypothalamus.
- Peripheral hypothyroidism is due to tissue insensitivity to the action of thyroid hormones.

-Clinical Manifestations:

- Myotonic (slow-relaxing) tendon reflexes
- Bradycardia
- Hair loss
- Effusion in pericardial, pleural, peritoneal or joint
- Mild anemia of macrocytic type
- Myxoedema coma
- Dry Skin

- ***Investigations:***
- In primary disease the levels of free T4 and T3 are low and the TSH levels rises markedly
- Some labs offers only TSH as a Ist line test of thyroid function this can result in delayed diagnosis of 2° and 3° hypothyroidism, which should be suspected on the basis of a low free T4 along with low TSH levels.
- Elevation of the TSH level occurs early in the course of thyroid.
- A chest radiography may detect the presence of effuxins and ECG is useful especially in patients with angina or secondary heart disease.

AUTOIMMUNE HYPOTHYROIDISM:

- Autoimmune hypothyroidism may be associated with goiter (Hashimoto's or goitrous thyroiditis) or at the later stages of the disease, minimal residual thyroid tissue (atrophic thyroiditis).
- In hashimoto's disease presence of Tg (thyroglobulin) and TPO antibiodies are useful markers in autoimmune hypothyroidism.
- In autoimmune disease once clinical and subclinical hypothyroidism is confirmed the etiology is usually established by demonstrating the presence of TPO antibodies which are present in 90-95% of patients with autoimmune hypothyroidism.
- Because the autoimmune process gradually reduces thyroid function, there is a phase of compensation when normal thyroid hormone levels are maintained by a rise in TSH.
- Though some patients may have minor symptoms, this state is called subclinical hypothyroidism.
- Later unbound T4 levels fall and TSH levels rise further symptoms become more readily apparent at this stage, which is referred to as clinical hypothyroidism.

- ***Differential Diagnosis:***

- An asymmetric goiter in Hashimoto's thyroiditis may be confused with a multinodular goiter or thyroid carcinoma in which thyroid antibodies may be present.
- Ultrasound can be used to show the presence of a solitary lesions or a multinodular goiter rather than the heterogenous thyroid enlargement typical of Hashimoto's thyroiditis.
- FNA biopsy is useful in the investigation of focal nodules
- In addition to detecting thyroid nodules, ultrasound is useful for monitoring nodule size for guiding FNA biopsies.

-Other causes of Hypothyroidism:

- Iatrogenic hypothyroidism is a common cause of hypothyroid mans can often be detected by screening before symptoms develop.
- In the first 3-4 months after radioiodine treatment, transient hypothyroidism may occur due to reversible radiation damage.
- Iodine deficiency is responsible for endemic goiter and cretinism but is an uncommon cause of adult hypothyroidism unless the idine intake is very low or there are complicating factors, such as the consumption of thiocynaates in carsawa or selenium deficiency.

- HYPERTHYROIDISM:

- It is defines as the production by the thyroid gland of excessive amounts of thyroid hormones.
- Thyrotoxicosis refers to the clinical syndrome associated with prolonged exposure to elevated

thyroid hormone.
- Thyrotoxicosis is characterized by increases in metabolic rate and actively of many systems due to excessive circulating quantities of thyroid hormones
- ***Clinical Manifestations:***

Skin and appendages	Warm, moist skin, thinning or loss of hair, increased sweating, heat intolerance
Nervous system	Insomnia, irritability, nervousness, lid retraction, symptoms of an anxiety state, psychosis
Musculo skeletal	Fine motor tremor, proximal muscle weakness, rapid deep tendon reflexes, osteoporosis
Gastro intestinal	Weight loss despite increased appetite, thirst, diarrhea
Cardiovascular	Palpitations, tachycardia, shortness of breath on exertion, atrial fibrillation, CHF, worsening angina.

-Investigations:
- Patients suspected with thyrotoxicosis- diagnosis with two sets of thyroid function tests
- Plasma free T4 and or T3 levels are elevated
- TSH levels are suppressed to subnormal levels in all causes of thyrotoxicosis, except the exceptionally rare cases of TSH secreting pituitary adenomas
- Radioactive iodine uptake scans will differentiate those patients with thyroiditis.
- Measurement of TRABs will identify Grave's disease patients.
- **AUTOIMMUNE HYPERTHYROIDISM (GRAVE'S DISEASE):**
- Hyperthyroidism of Grave's disease is caused by TSI that are synthesized in the thyroid gland, bone marrow and lymph nodes.
- Such antibodies can be detected by bioassays or using more widely available TBII assays.
- The presence of TBII in a patient with thyrotoxicosis is strong indirect evidence for the presence of TSI and these assays are useful in monitoring pregnant grave's patient in whom high levels of TSI can cross the placenta and cause neonatal thyrotoxicosis.
- The term hyperthyroidism means the disorder resulting from the over production of T3 and T4 by thyroid itself.
- Thyrotoxicosis results from ingestion of excessive quantities of thyroid hormones (eg: while treating hypothyroidism) rather than from over activity of thyroid gland.
- In Grave's disease patient produces TSH receptors stimulating antibodies also called as thyroid stimulating immunoglobulins.
- These antibodies mimic the action of TSH on the thyroid gland but not regulated by the normal feedback control through over production of T3 and T4.
- As a result the thyroid gland is continually bombarded with TSI to produce T3 and T4.
- In these patients the serum of T3 and T4 and TSI are elevated while TSH levels are low.

-Diagnosis:

- Diagnosis of grave's disease is straight forward in a patient with thyrotoxicosis, diffuse goiter on palpitation, opthalmopathy, positive TPO or TSH-R antibodies and often a personal or family history of autoimmune disorders.
- Patients with thyrotoxicosis who lack these features the most reliable diagnostic method is a radio nucleotide (^{99M}TC, ^{123}I or ^{131}I) scan of the thyroid, which will distinguish the diffuse, high uptake of grave's disease from nodular thyroid disease, destructive thyroiditis, ectopic thyroid tissue and factitious thyrotoxicosis.
- In 2° hyperthyroidism due to TSH-secreting pituitary tumor, there is also a diffuse goiter.
- The presence of a non- suppressed TSH level and finding of a pituitary tumor on CT or MRI scan can readily identify such patients.
- Diagnosis of thyrotoxicosis can be easily excluded if the TSH and unbound T3 and T4 levels are normal.
- A normal TSH also excludes grave's disease as a cause of diffuse goiter.

-Etiology:

1.Nodular disease
2. Grave's disease
3. Thyroiditis

TESTS ASSOCIATED WITH CARDIAC DISORDERS

Patients may be affected by various cardiac disorders. The frequently encountered disorders are angina pectoris, myocardial infarction, congestive heart failure and atherosclerosis etc.

TYPES OF TESTS:

- The tests are classified into

1. Non-Invasive tests
2. Invasive tests

1. Non-Invasive Tests:

a. Auscultation:

- This is nothing but testing the patient's heart beat with stethoscope which helps to hear the normal and abnormal sounds of heart beat.
- Changes in heart beat associated with breathing and murmurs also heard with stethoscope.

b. Blood Tests:

- The first test ordered after physical examination of the patient with stethoscope is blood test.
- Blood tests include total cholesterol, LDL, HDL, TGs, fibrinogen, lipoprotein (a).
- When damage to the heart is suspected cardiac biomarkers are useful for the evaluation, diagnosis and monitoring of patients in clinical practice.
- These markers which include some enzymes are often released into the blood when the heart becomes damaged.
- The cardiac biomarkers include creatine kinase, troponin, myoglobin, homocystine, lactate dehydrogenase, brain natriuretic peptide and C - reactive protein.

 # Creatine kinase:

- Reference range: <150 units/L
- Also known as creatine phosphokinase.
- Catalyzes the transfer of high energy phosphate groups in tissues that consume large amounts of energy (eg. Skeletal muscle, myocardium, brain)
- The serum concentration can be increased by strenuous exercise, intramuscular injections of drugs that are irritating to tissues (eg.diazepam, phenytoin), acute psychotic episodes, crush injuries or myocardial damage.
- CK is composed of M and B subunits.
- Isoenzymes include MM, BB MB.
- CK MM found in skeletal muscles
- CK BB found in brain
- CK MB found in myocardium
- Myocardial CK activity consists of 80%-85% CK MM, 15-20% CK MB.
- Non cardiac tissues that contain large amount of CK have either CK MM or CK BB.
- CK MB is rare in tissues other than the myocardium
- CK-MB begins to increase 3-6 hours after an acute MI and peaks at 12-24 hours.
- Myocardial damage correlated with the amount of CK MB released into the serum ie the higher the amount of the CK MB the more extensive the myocardial damage.
- CK serum concentration usually do not rise above normal values until 4-8 hours after myocardial injury and usually peak in about 12-24 hours.

- Values remain elevated for about 2-3 days.
- When CK-MB is greater than 6% of total CK, an MI has probably occurred even if the total CK is not elevated.

 # Troponin:

- Reference range: <1.5 mcg/L
- Troponins are proteins that regulate calcium mediated interaction of actin and myosin within muscles.
- Cardiac specific troponins include cardiac troponin I and T.
- Troponin T is found in cardiac and skeletal muscle cells
- Troponin I is found in cardiac muscle only.
- When compared to CK-MB the presence of troponin I is more specific and sensitive indicator of myocardial damage.
- Concentration of Troponin I increases within 2-4 hours of an acute MI.
- They remain elevated for about 10 days.
- Troponin I levels greater than 2.0mcg/ml-suggests acute myocardial tissue injury.

 # Lactate Dehydrogenase:

- Reference range: <200 units/L
- Present in heart, kidney, liver and skeletal muscle
- Abundantly present in erythrocytes and lung tissue.
- Iso-enzymes of LDH include LDH_1, LDH_2 (present in heart), LDH_3 (present in lungs) LDH_4, LDH_5 (present in skeletal muscle).

 # Myoglobin:

- Reference range: 0-90 mcg/L
- Provide oxygen to working muscles
- When muscle is damaged, myoglobin is released into blood stream.
- It concentration in serum rises within 3 hours after insult to the myocardial tissue, peak in about 8-12 hours and return to normal in about a day.
- Myoglobin serum concentrations however tends to be less specific for myocardial tissue compared with CK MB
- Trauma or ischemic injury to non-cardiac tissue can increase serum myoglobin.
- As troponin serum concentration in serum also increases rapidly after myocardial damage troponin is often preferred over myoglobin as a biomarker of cardiac damage.

 # Homocystine:

- Reference range: 4.6-11.9 µmol/L
- Patients with deficiencies in folate, vitamin B6, vitamin B12 tend to have elevated serum levels of homocystine.
- Homocystine is believed to have a destructive effect on vascular epithelium.
- With time patients with elevated homocystine levels (> 12µ mol/L) are believed to be at increased risk for cardiac diseases.

 # Brain Natriuretic Peptide:

- Reference range: < 100 µg/mL
- Released from the heart when increased demands are placed on the myocardial tissue
- Elevation in BNP are indicative of patients with CHF.

- To reduce work load on heart the BNP counteracts the RAAS all geared at reducing blood volume.
- BNP levels greater than 500 µg/L- Left ventricular dysfunction
- BNP is also been used as a tool for patients presenting to emergency department with severe dyspnea.

c. Chest-X ray:

- A chest-x ray gives the picture of internal organs like heart, lungs and chest wall.
- It can reveal the signs of heart failure, enlarged heart and edema.

d. Electrocardiogram:

- It records the electrical activity and rhythm of the heart. The electrical signals of each heart beat are recorded by the ECG machine.

e. Echocardiography:

- It produces a moving picture of heart using sound waves that provides information about the structure and pumping function of the heart.
- It also reveals the movement of heart valves and heart muscle thickness.
- The images produced can show the damages to heart muscle due to poor blood supply and non-functional area of heart.
- Echo tests are carried out by more than one method. M.mode echo cardiography, Two-dimensional echo, Doppler echo and contrast echo are often used methods to diagnose cardiac disorders.

f. MRI Scan:

- MRI produces detailed pictures of heart.
- Patients are scanned using magnetic and radio waves when lying inside the tunnel like scanner

g. Radio nucleotide test:

- Here small amount of radioactive substance is injected into the blood of the patient. A camera is held near the chest which picks up the radiation released by the isotope as it passes through the heart, indicating the areas where there is poor blood supply.

h. Stress test:

- These test are carried out using a tread mill and/or exercise bike.
- The following signs and symptoms can be detected

a. Breathing difficulty b. Chest pain

c. Abnormal heart rate or BP

d. Abnormal changes in heart rhythm and electrical activity which are measured using ECG and other equipment's.

2. Invasive Tests:

a. Cardiac catheterization or Coronary Angiography:

- It is a technique in which a thin, flexible catheter is passed along vein or artery into the heart and connected vessels either for diagnosis or treatment of cardiac disorders.

FLUID AND ELECTROLYTE BALANCE

 # Serum Sodium:

- Major cation in the ECF.
- Normal range: 135-145 mmol/L
- Mild abnormalities in serum sodium concentration are common, particularly in patients with multiple medical conditions or significant polypharmacy etc.
- Serum sodium concentration is function of available sodium and water it is dissolved in.
- Overall amount of sodium in the body is maintained within a relatively narrow range by the kidneys, the sodium concentration is most affected by the fluid volume status of the patient.

*** Hyponatremia:**

- When sodium is present in a relatively excessive amount of water (eg in edematous conditions), the sodium concentration is often reduced to low below the reference range this is called hyponatremia.

- Causes:

♠ may be due to decreased intake of sodium
♠ increased sodium loss through vomiting, diarrhoea
♠ syndrome of inappropriate ADH (either production of excessive ADH or kidney become abnormally responsive to ADH levels)
♠ aldosterone deficiency
♠ taking certain diuretics
♠ excessive water intake
♠ drugs that cause SIADH: carbamazepine, SSRIs, antidepressants, narcotics and some antineoplastic drugs.

- Signs and symptoms:

♠ muscle weakness, dizziness, headache, hypotension, tachycardia and shock, mental confusion, stupor and coma.

- Rarely assumes clinical significance until the sodium concentration is below 125 mmol/L, but urgent attention is needed if level is below 120 mmol/L.
- It can be acute or chronic.
- Acute hyponatremia develops within 48 hours and require rapid treatment.
- If left untreated may cause complications such as cerebral edema, brainstem and death may also occur.

*** Hypernatremia:**

- If there is excessive fluid loss and the available sodium is dissolved in a smaller volume of water than normal, the sodium concentration is increased above the reference range and this is called hypernatremia.

- Causes:

♠ may occur with dehydration, vomiting (because large volumes of fluids are lost and oral intake may be insufficient to compensate for this)
♠ water depletion/loss of water
♠ excessive sodium in diet or I.V fluids
♠ hypertonicity of ECF which pulls water out of the body cells into the ECF causing cellular

dehydration.
♠ Diabetes insipidus (kidney produces inappropriately large amount of dilute urine).
- Signs and symptoms:
♠ intense thirst, hypertension, edema, agitation and convulsions.

 # Serum Potassium:
- Major cation in ICF.
- Normal range: 3.5-5.0 mmol/L

*** Hypokalaemia:**
- It is a situation where serum potassium concentration is below the lower limit of the reference range.

- Causes:
♠ excessive loss due to vomiting or diarrhea, gastric suction
♠ decreased potassium intake
♠ hyperaldestronism
♠ kidney disease
♠ with some diuretics (thiazide and loop diuretics)
♠ over use of laxative agents

- Signs and symptoms:
♠ muscle fatigue, flaccid paralysis, mental confusion, increased urine output, shallow respiration and changes in ECG including flattening of T wave.
- If hypkalaemia is severe or persistent or if the patient is treated with digoxin, some form of potassium replacement may be required.
- I.V potassium should always be diluted in a large volume of fluid and infused slowly as the delivery of KCl as a rapid I.V push is likely to cause serious and dangerous cardiac arrhythmias.
- Conventional approach is to dilute 20-30 mmol of KCl in 1000ml of infusion fluid and infuse over 6-8 hours.

*** Hyperkalaemia:**
- It is a situation where serum potassium concentration is above the limit of the reference range.

- Causes:
♠ may be due to excessive potassium intake
♠ renal failure
♠ aldosterone deficiency
♠ injuries to body tissues
♠ transfusion of hemolysed blood
♠ may be drug related (combined use of potassium supplements, potassium sparing diuretics, ACE-I,ARBs and NSAIDs is implicated)

- Signs and symptoms:
♠ irritability, nausea, vomiting, diarrhea, muscle weakness can cause death by inducing ventricular fibrillation.
- It is a very dangerous electrolyte abnormality that may require urgent intervention

 # Serum Calcium:
- It is an ECF cation.
- Normal range: 2.20-2.55 mmol/L or 8.8-10.2 mg/dL
- As it is present in larger amounts in bone it is the most abundant mineral in the body.
- Important requlator of the calcium concentration in blood plasma is parathyroid hormone.

*** Hypocalcemia:**
- Hypocalcemia is a condition in which there are lower-than-average levels of calcium.

- Causes:
♠ increased calcium loss
♠ vitamin deficiency (poor nutrition, inadequate exposure to sunlight or treatment with some anti-convulsants or anti-tubercular drugs)
♠ reduced calcium intake
♠ hypoparathyroidism
♠ elevated levels of phosphate
♠ chronic renal failure

- Signs and symptoms:
♠ numbness and tingling of the fingers, muscle cramps, tetany and convulsions, bone fractures, spasms of laryngeal muscles that can cause death by asphyxiation, hyperactive reflexes

*** Hypercalcemia:**
- Hypercalcemia is a condition in which the calcium level in your blood is above normal.

- Causes:
♠ hyperparathyroidism
♠ excessive intake of vitamin D
♠ paget's disease of bone
- drug related- thiazide treatment

- Signs and symptoms:
♠ lethargy, weakness, anorexia, nausea, vomiting, polyuria, itching, bone pain, depression, confusion, paresthesia, stupor and coma.

 # Serum Chloride:
- Major anion in ECF
- Can help balance the level of anions in different fluid compartments
- Example Chloride shift that occurs between RBCs and blood plasma as the blood level of carbondioxide either increases or decreases.
- ADH helps regulate chloride balance in body fluids because it governs the extent of water loss in urine.
- It is important in maintenance of acid base balance.

*** Hypochloremia:**
- It is an electrolyte disturbance in which there is an abnormally low level of the chloride ion in the blood.

- Causes:
♠ due to vomiting, diarrhea
♠ over hydration
♠ aldosterone deficiency

♠ CHF
♠ therapy with certain diuretics (furosemide)
♠ renal disorders
♠ fasting
♠ adrenal insufficiency

- Signs and symptoms:

♠ muscle spasms, metabolic alkalosis, shallow respiration, hypotension and tetany.

*** Hyperchloremia:**

- It is an electrolyte disturbance in which there is an elevated level of the chloride ions in the blood.

- Causes:

♠ dehydration due to water loss or water depletion
♠ excessive chloride intake
♠ acute renal failure
♠ hyperaldosteronism
♠ certain type of acidosis
♠ drugs

- Signs and symptoms:

♠ lethargy, weakness, metabolic acidosis and rapid or deep breathing.

MICROBIOLOGICAL CULTURE SENSITIVITY TESTS

INTRODUCTION:

A microbiological culture sensitivity test is a laboratory procedure to identify the microorganisms present in the patient's body fluids or other samples and to determine which antibiotic kills or prevents their growth.

BASICS OF CULTURE AND SENSITIVITY TEST:

* These tests are performed in two stages.
* In the first stage the microorganism present in the sample are grown suitably and identified.
* In the second stage they are tested against the range and dose of antibiotics to determine their susceptibility to the particular antibiotics.

PURPOSE AND USE OF CULTURE AND SENSITIVITY TEST:

1. Identifying the microorganisms
2. Testing against sensitivity to antibiotics
3. It helps the clinicians to test the dose of antibiotics.
4. If the sensitivity profile of microorganisms reveals any change in its resistance, doctor has to change or control his antibiotic prescribing pattern.
5. Above all the culture and sensitivity tests are useful to study the value of new antibiotic before the clinical trials.

- Thus culture and sensitivity tests play an important role in usual treatment, change in treatment and discovering new treatment with antibiotics.

TEST PROCEDURE:

- Culture and sensitivity tests have two stages, microbiological culture and testing its sensitivity to antibiotics.

- **Microbiological culture:** It is a method of growing and multiplying microorganisms by reproducing them in predetermined culture medium under controlled lab conditions. It is one of the primary diagnostic methods to find out the causes of infection. There are two ways by which microbial culture can be carried out.

1. In petriplates with solid medium
2. In culture tubes and flasks with liquid medium (broth)

Requirements:

- The first requirement is a suitable medium followed by a proper procedure. It starts with preparation of medium (if not a ready-made medium is used) and preparation of plates.

Stages:

- Stages of microbial culture are four I's: Inoculation, incubation, isolation and identification of microorganisms.
- Medium: For bacterial culture though many media are available, soya bean-casein digest medium to be incubated at 20° to 25° and fluid thioglycollate medium incubated at 30° to 35° are much used.

Preparation of Agar Plates:

- The culture medium should be prepared as per the composition and method given in standard books like pharmacopoeia. The media used must be sterile.

Stages:

1. Inoculation:

- The sample collected from the patient may be any of the body fluid or solid or semi-solid like sputum. They are suitably prepared for inoculation by serial dilution or by growing in liquid broth medium.

a. Streak plate dilution technique:

- In this method series of streaks are made on the surface of the medium using sterile loop dipped in the inoculums. The loop is sterilized by passing through the flame after each streak, so that the amount of material in each set of streak is reduced. It helps in the formation of well isolated colonies of microorganisms in the final set of streaks, there by bacteria are separated. Then they grow to form colonies and thus various species of bacteria are isolated from the sample if available.

b. Lawn technique:

- Aliquot of liquid sample is applied on the surface of medium to produce continuous growth of bacteria as grass grows in a lawn. Actually the lawn is nothing but growth of numerous colonies very close to each other. Among all the methods this is the most suitable method of inoculation to study sensitivity to antibiotics.

c. Pour plate technique:

- This is a technique in which liquid sample prepared from the patient's body fluid is mixed with molten agar and then poured into the petri dish. Obviously the microorganisms present in the sample is uniformly dispersed throughout the diameter and depth of medium.

2. Incubation:

- After inoculation, the pertiplate's are incubated in an incubator at around 35° for 2-7 days or more depending on the requirement. Some media may require less temperature.

3. Isolation:

- After incubation, the plate may show mixture of microbes.
- Before identifying microbes they are separated so that their identity can be easily established without doubt.
- Isolation of pure culture is done by pour plate or dilution method.
- This method has the advantage of colonies forming throughout the plate unlike the streak method where they are formed only on the surface.
- Thus the pour plate method offers easy isolation of microbes due to its good distribution.

4. Identification:

- Microorganisms are identified by two methods, by microscopical identification after staining and culturing.
- When bacteria grow by binary fission they form colonies of genetically identical bacyeria and hence genetically pure in nature.
- Their shape, consistency, color , margin etc are verified from which some identification is possible.
- This can be confirmed by using chemicals (stains), PH, nutrients, temperature, salinity and

other conditions of incubation.
- Once the organism is identified treatment can be started immediately.
- However different strains of some species of microorganisms have different resistance. Hence undertaking sensitivity tests on the isolated and partially identified microorganisms is necessary.

Sensitivity Test:

- This is usually carried out by disc diffusion method.
- In the direct (primary) tests antibiotics of varying concentration are placed directly on the agar plates that have been inoculated with samples like pus or urine.
- The results of sensitivity of microorganisms to the particular antibiotic can be obtained after over nigh culture of those pertiplates.
- The indirect (secondary) test results of pure culture are usually available after 48 hours of receiving of sample collected from the patient.
- While performing sensitivity tests the inoculums, the medium and the antibiotic discs are carefully selected so as to give a uniform growth and inhibition.

INTRODUCTION TO PULMONARY FUNCTION TESTS

Pulmonary function tests (PFTs) are a group of tests that measure how well ~~your~~ lungs work.
PFTs can help diagnose:

- Asthma
- Allergies
- Chronic bronchitis
- Respiratory infections
- Lung fibrosis
- Bronchiectasis, a condition in which the airways in the lungs stretch and widen
- COPD, which used to be called emphysema
- Asbestosis, a condition caused by exposure to asbestos
- Sarcoidosis, an inflammation of ~~your~~ lungs, liver, lymph nodes, eyes, skin, or other tissues
- Scleroderma, a disease that affects ~~your~~ connective tissue.
- Pulmonary tumor
- Lung cancer
- Weaknesses of the chest wall muscles

TESTS:

1. Spirometry:

The apparatus commonly used to measure the volume of air exchanged during breathing and the respiratory rate is a **spirometer or respirometer.**

The record is called a **spirogram.**

Inhalation is recorded as an upward deflection, and exhalation is recorded as a downward deflection.

1. Tidal volume (TV): This is the amount of air that can be inhaled into the lungs during quiet breathing (500 ml).

2. Inspiratory reserve volume (IRV): This is the extra volume of air that can be inhaled into the lungs during maximal inspiration (3100 ml).

3. Expiratory reserve volume (ERV): This is the largest volume of air which can be expelled from the lungs during maximal expiration. (1200ml).

4. Residual volume (RV): This cannot be directly measured but this is the volume of air remaining in the lungs after forced expiration. (1200 ml)

5. Inspiratory capacity (IC): This is the amount of air that can be inspired with maximum effort ((3600 ml) TV + IRV
It consists of tidal volume + inspiratory reserve volume.

6. Functional residual capacity (FRC): This is the amount of air remaining in the air passage and alveoli at the end of quiet expiration. Tidal air mixes with this air, causing relatively small changes in the composition of alveolar air. RV + ERV

7. Vital capacity (VC): This is the maximum volume of air which can be ~~moved into~~ forcefully expelled ~~and out of the~~ lungs. from the lungs following maximal inspiration

VC= TV+IRV+ERV

8. Total lung capacity (TLC): Total volume of air that lungs can hold.
TLC = VC + RV

8. Alveolar ventilation: This is the volume of air that moves into and out of the alveoli per minute. It is equal to the tidal volume minus the anatomical dead space, multiplied by the respiratory rate.
Alveolar ventilation = Tidal volume − anatomical dead space × Respiratory rate

9. Forced expiratory volume (FEV1): The volume of air that can be exhaled from the lungs in 1 second with maximal effort following a maximal inhalation.

10. Forced vital capacity (FVC) :- It is the maximum amount of air which can be exhaled or inhaled during forced breathing maneuver

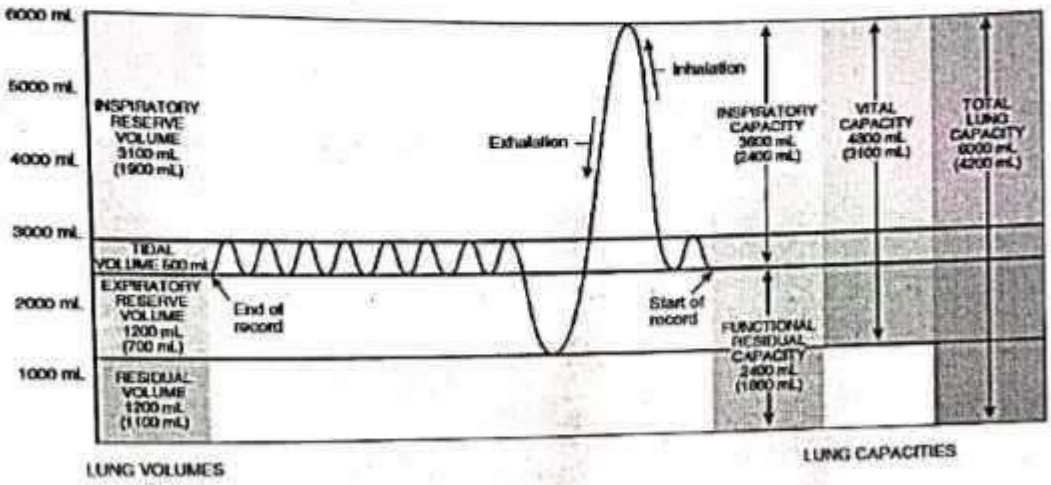
Lung capacities are combinations of specific lung volumes.

Inspiratory capacity is the sum of tidal volume and inspiratory reserve volume (500 mL+3100 mL =3600 mL in males and 500 mL+1900 mL=2400 mL in females).

Functional residual capacity is the sum of residual volume and expiratory reserve volume (1200 mL+1200 mL =2400 mL in males and 1100 mL +700 mL =1800 mL in females).

Vital capacity is the sum of inspiratory reserve volume, tidal volume, and expiratory reserve volume (4800 mL in males and 3100 mL in females).

Finally, total lung capacity is the sum of vital capacity and residual volume (4800 mL +1200 mL =6000 mL in males and 3100 mL +1100 mL =4200 mL in females).



2. Plethysmography test:

A plethysmography test measures the volume of gas in ~~your~~ lungs, known as lung volume.

3. **Diffusion capacity test:**

This test evaluates how well the small air sacks inside the lungs, called alveoli, work.

Anatomical dead space
It is the volume of lung that does not exchange gas. This includes the nose, pharynx, trachea and bronchi (conducting airways to terminal bronchioles)

PHARMACOVIGILANCE

DEFINITION:

-Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug.

- WHO established its program for International Drug Monitoring in response to the thalidomide disaster detected in 1961.

AIMS:

1. Early detection of unknown adverse reactions and interactions.
2. To improve patient care
3. To enhance public health.
4. Detection of increase in frequency of known adverse reactions.
5. Identification of risk factors and possible mechanism underlying ADRs.
6. To improve public health and safety in relation to the use of medicines
7. To encourage monitoring, understanding and training in pharmacovigilance program.
8. To evaluate drug's benefit, risks and effectiveness and thereby to promote safe and rational use of drugs.

SCOPE:

- It is an important and integral part of clinical research.

1. Pharmacovigilance and Clinical Pharmacy Practice:

- Therapeutic Drug Monitoring and Drug Therapy Review are the important tools in pharmacovigilance.
- The information gathered during this program has to be conveyed to all healthcare providers, other PV centers and health policy developers.
- Thus an effective patient care can be ensured.

2. Pharmacovigilance and medicine policy:

- In order to frame a national drug policy, pharmacovigilance program is of much use to the authorities, as it provides needed information about which drugs are not suitable in community setting.

3. Pharmacovigilance and drugs control:

- Pharmacovigilance program is more helpful to Drugs control department than others as it make their work easier.
- Drugs control organization is gathering information about spurious drugs, sub-standard drugs etc, by its own vigilance and intelligence wings.
- Pharmacovigilance program also emphasize monitoring of clinical trials, medicines of alternative systems and vaccines.

4. Pharmacovigilance and public health program:

- Pharmacovigilance program stress the need to monitor these public health programs as many of them are overlapping and can cause ADR, drug interaction etc on the unsuspecting, illiterate and innocent rural masses.

COMMUNICATION SKILLS

Communication is the most basis of sending and receiving of messages.

1. Empathy:

- It is the ability to see and feel the way another person does.
- Eg. A pharmacist may need to discuss paracetamol dosing with a mother who is anxious about her child's illness.
- When feelings are not shared and empathy has not developed communication can be impaired.
- The significance of empathy is that it enables rapport (a sympathetic relationship based on understanding) to develop and this is an important first step in establishing successful and interactive communication.

2. Non-verbal communication:

- Non-verbal messages being to be received and interpreted as soon as something catches our attention.
- Non-verbal communication includes messages conveyed through body postures such as the movement and position of the head, limbs, body and other aspects.
- Aspects of non-verbal communication include proximity, touch, eye contact, facial expression, head movement, gesture with hands and arms and body postures.

 # Proximity:

- This refers to the distance that people maintain between themselves during counselling
- Space (4 zones)

1. Intimate: 45 cm or less
2. Personal: 45 cm-1.2 m
3. Social: 1.2-3.6 m
4. Public: >3.6 m

 # Eye contact:

- The amount that people look at one another during conversation varies depending on whether they are speaking or listening.
- For cultural or personal reasons such as timidity, sadness or depression some people may avoid looking into the counsellors eyes.

 # Facial expression:

- It is an important indicator of emotional state.
- These can be used during counselling to demonstrate empathy towards the patients.
- People observe the face to gain information which is not provided verbally.
- For e.g: Does the person look angry, happy, worried, friendly, and relaxed and so on.

 # Diagrams:

- Diagrams are another form of non-verbal messages used to convey information.
- Pictograms have recently been developed to communicate medical and medication information to people who are illiterate.
- To show how to administer a dosage form such as eye drops.
- It is important that pharmacists are aware of the non-verbal messages they are transmitting to others especially if these are likely to inhibit communication.

3. Verbal communication:

- Verbal communication occurs through meaning of words which may be spoken or written.
- Verbal communication skills include language, tone, volume, pitch and rate of speech, listening skills, interactive communication.

 # Language:

- Use simple language when speaking to patient's
- Avoid unnecessary medical technology.
- Choosing appropriate terms is important to both communicate effectively and to convey suitable verbal messages.

 # Tone:

- Tone of the voice has a great impact on patient understanding.
- When counselling, the tone of the voice should be caring and reassuring.

 # Volume:

- Counselling should be conducted in a quiet private setting where it is necessary to raise one's voice.
- Many people speak with wide variations in volume depending on the situation and where and to whom they are speaking.

 # Speed:

- For good verbal communication the pharmacist should present clear, relevant messages in a logical sequence and at a speed which gives the patient time to think about what is being said.
- The clarity of communication depends on rate of the speech.
- Patient may feel reluctant to interact with a pharmacist who speaks quickly because they may feel the pharmacist is too busy.
- If the pharmacist speaks too slowly, it may lead to the loss of interest of the listener.

 # Listening skills:

- Developing good listening skills is important to promote clear interactive communication and to obtain reliable information.
- When giving key information it is an important practice to check for correct understanding by asking the listener to identify the main points of the message.

 # Written communication:

- There are different writing styles which are appropriate for different purposes.
- All forms of professional writing requires clarity and precisions.
- Short sentences and paragraphs, unambiguous words or statements and precise structure are important qualities.
- Words should be chosen carefully with correct spelling and grammar and should be presented in an easy to read handwriting or font.
- Written messages require a logical structure.

COMMUNICATION IN PROFESSIONAL PRACTICE:

- Communication with medical and health professionals:

 # Spoken messages:

- Spoken messages can occur with person or over the telephone.
- Commonly used to obtain information about a patient or their treatment to provide medicine information to a practitioner or to clarify or recommend modifications in the patient's therapy.

- Telephone skills are an important aspect of professional life.
- Telephone conversations differ from face to face contact as these are fewer non-verbal eves which can represent a distraction.

 # Case note annotation:

- Comments in a patients case notes convey important information to those caring for the patient and provide a record of the patients hospital management.
- Alerting the appropriate staff member verbally is important.
- This provides an opportunity for discussion and clarification of a complex message and reduce the possibility of misunderstanding.
- Case note entries can be of legal importance when prescribing could harm the patient.
- Entries should be dated and have a short informative heading.
-The authors name, position and contact telephone, cellphone number should be included.
- In many hospitals, pharmacists use a colored pen or an identification mark o distinguish their entries.

- Communication with patient's:

 # Medication history interview:

- To review current medical treatment and identify suitable additional treatments, medical professionals will require complete and reliable medication history.
- The following information is commonly recorded:

! Currently or recently prescribed medicines
! Medicines purchased without prescription (OTC)
! Vaccinations
! Alternatives or traditional remedies
! Description of reactions and allergies to medicines
! Medicines found to be ineffective
! Adherence to past treatment courses and the use of adherence aids.

 # Labelling medicines:

- Labelling of medicines aid the effective and safe use of medicines.
- All the containers of the medicines should be clearly labelled to identify

1. The medicine
2. Dosage form, number of dosage units supplied, strength
3. Number of dose units to be taken at a time and its frequency
4. Date of dispensing
5. Batch numbers and expiry dates for non-prescription medicines and medicines not likely to be used immediately.

- Patient Information Leaflets (PIL's):

- PIL's are used to outline key information to assist patients and their care givers in the effective and safe use of a medicine.
- The following information is commonly included:

1. Trade and generic names
2. Indications for which the medicine is being taken
3. Precautions or contraindications
4. Administration advice

- Telephone skills are an important aspect of professional life.
- Telephone conversations differ from face to face contact as these are fewer non-verbal eves which can represent a distraction.

 # Case note annotation:

- Comments in a patients case notes convey important information to those caring for the patient and provide a record of the patients hospital management.
- Alerting the appropriate staff member verbally is important.
- This provides an opportunity for discussion and clarification of a complex message and reduce the possibility of misunderstanding.
- Case note entries can be of legal importance when prescribing could harm the patient.
- Entries should be dated and have a short informative heading.
-The authors name, position and contact telephone, cellphone number should be included.
- In many hospitals, pharmacists use a colored pen or an identification mark o distinguish their entries.

- Communication with patient's:

 # Medication history interview:

- To review current medical treatment and identify suitable additional treatments, medical professionals will require complete and reliable medication history.
- The following information is commonly recorded:

! Currently or recently prescribed medicines
! Medicines purchased without prescription (OTC)
! Vaccinations
! Alternatives or traditional remedies
! Description of reactions and allergies to medicines
! Medicines found to be ineffective
! Adherence to past treatment courses and the use of adherence aids.

 # Labelling medicines:

- Labelling of medicines aid the effective and safe use of medicines.
- All the containers of the medicines should be clearly labelled to identify

1. The medicine
2. Dosage form, number of dosage units supplied, strength
3. Number of dose units to be taken at a time and its frequency
4. Date of dispensing
5. Batch numbers and expiry dates for non-prescription medicines and medicines not likely to be used immediately.

- Patient Information Leaflets (PIL's):

- PIL's are used to outline key information to assist patients and their care givers in the effective and safe use of a medicine.
- The following information is commonly included:

1. Trade and generic names
2. Indications for which the medicine is being taken
3. Precautions or contraindications
4. Administration advice

PRESENTATION OF CASES

INTRODUCTION:

- A case presentation in a clinical settings is a formal communication between healthcare professionals like doctors, pharmacists, nurses, physiotherapists and lab technologists regarding a patient's clinical condition while under treatment or after discharge.
- It is the language that health care team use to communicate with each other in their day to day practice.

NEED FOR CLINICAL CASE PRESENTATION:

- As the treatment for patients is a team work, effective communication between the team members is essential.
- A clinical pharmacy student is expected to express what he learned in wards in the form of case presentation to his teacher or to members of health care team or to classmates.
- It is required even after he is fully qualified and appointed as clinical pharmacist. There may be occasions when a clinical pharmacist has to hand over the case to other clinical pharmacist or has to send the patient to other specialty or has to get opinion from experts to proceed with the patient care or explain the case to higher authorities. On all these circumstances he is expected to present the case fully, without confusion and in the manner his listeners understand even the finer points.
- Case presentation give the students some opportunities to access patient information, detect drug related problems, method of solving them and ultimately to take decisions and recommendations which he should able to defend or justify.
- If a case presentation is effective it stimulates the listeners to facilitate patient care and help to identify the learning needs of individual as well as the team.
- Case presentation is a tool to access the clinical competence of a clinical pharmacy student.

GUIDELINES FOR CASE PRESENTATION:

* Student must have worked or involved in the case before presenting it. Obviously then only he can present the case with first knowledge and point out his role or contribution in the treatment.
* All the team members as well as the students of the class must be present for case presentation. A brief summary or background information about the case can be given to the participants before presentation, so that an effective discussion can be held.
- Most of the time an oral presentation is sufficient. If the presenter so desires and if it is necessary audio-visual equipment's can be used.
- Presentation must be short and to the point, so that it can be of 10 to 15 minutes duration. Another 15-20 minutes can be allotted for questions and discussions on drug related topics.
- A well-organized format should be followed for case presentation, a model of which is given below.

Case Presentation Format:

1. Patient information (name, age, gender, race etc.)
2. Reason for admission (present complaints)
3. History of present illness (circumstances that lead to present illness)
4. Past medical history (diseases treated, medicines taken in past)
5. Past surgical history (any surgery done, its result, complications etc.)

6. Present medical conditions and medications
7. Relevant history about family, social, allergy and compliance
8. Result of physical examination (pulse, heart rate, temp, BP etc.)
9. Results of lab tests (including biopsy, imaging etc.)
10. Description of hospital events and its management after admission in chronological order with dates.
11. Identification of drug related problems and patient care plan
12. Present condition of drug related problem and therapeutic outcome.
13. Alternative therapeutic plans (after studying cost, contraindications, efficacy, side effects etc.)
14. Suggestions of one patient specific therapeutic plan from the above with justification and implementation method)
15. Monitoring above plan (parameters, person, duration etc.)
16. Causes of success or failure of the treatment so far

- Case presentation enriches the knowledge of not only the participants, but also of the presenter himself, if a sincere attempt is made to present a useful presentation.

PHARMACEUTICAL CARE CONCEPT

DEFINITION:

- The pharmaceutical care is defined as "The responsible provision of drug therapy for the purpose of achieving definite therapeutic outcomes that improve the patients quality of life".
- These outcomes are:

☐ Cure of the disease
☐ Elimination or reduction of patient`s symptomology
☐ Arresting or slowing of a disease process
☐ Preventing a disease or symptoms.

BASIC ELEMENTS OF PHARMACEUTICAL CARE:

☐ Patient oriented
☐ Both acute and chronic problems addressed
☐ Stress on prevention of drug related problems
☐ Documented system on patients record need and care
☐ Offering continuous care in systematic way
☐ Taking help of other health care providers in integrating the care provided
☐ Highly accountable and responsible
☐ Emphasis on optimizing patients health quality of life
☐ Emphasis on patient`s health education and health promotion.

- 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 patients.
- Three major functions:

1-Identifying potential and actual drug related problems.
2-Resolving actual drug-related problems
3-Preventing potential drug-related problems.

FUNCTIONS OF PHARMACISTS:

- The pharmacist ,who is the central figure of pharmaceutical care, then has the following functions to perform:

1-Collection of patient data
2-Identification of problems
3-Establishing outcome goals through a good therapeutic plan
4-Evaluating treatment alternatives, by monitoring and modifying therapeutic plan
5-Individualising drug regimens
6-Monitoring outcomes.

1-Collection of patient data:

- Pharmacist must collect and/ or generate subjective and objective information regarding health and activity status, past medical history, medication history, social history, diet, exercise, history of present illness, and economic situation.
- Sources of information may include: medication charts, and reports, health/physical assessment, patient's family or care taker, insurers and from healthcare providers.

- The latter forms the basis of decisions regarding the development and subsequent modifications of drug therapy plan. It must be readily retrieval and updated from time to time.
- Elements of patient information data:
Demographics: Age, gender, race, height, weight
Current problems: Signs and symptoms
Past medical history
Current medication
Allergies and intolerance
Pregnancy and lactation status
Habits: tobacco, alcohol consumption
Economic conditions
Relevant laboratory data

2-Identification of problems:

- Identify the problems from the data collected, which may be actual or potential drug related problems.
- Problems might be related to the current drug therapy, drug administration, drug compliance, drug toxicity, adverse drug reactions, failure to achieve desired outcomes by the treatment.
- Some of the drug related causes are:
Actual: The patient has a medical condition that requires the initiation of a new or additional drug:
i. For which a wrong drug is administered.
ii.For which too little of the right drug is given (sub therapeutic dose)
iii.For which too much of the right drug is given (high dose) which may provoke ADR or drug toxicity.
iv.Resulting from not taking drug appropriately (before food, after food, two hours after food or on empty stomach)
v. ADR from the drug that the patient is currently taking.
vi. Resulting from drug-drug or drug food interaction
vii. Non-compliance for no valid reason
vii.Self medication for no medically valid reason
Potential: By which the patient may be at risk to develop a new medical problem, created due to:
i. Additional drug therapy being indicated
ii.Taking unnecessary medication
iii.Wrong drug being prescribed
iv.Too much or too little of the correct drug
v. Occurrence of ADR
vi. Non-compliance of the prescribed medicines.

3. Establishing outcome goals:

- Drug therapy can produce a range of positive clinical outcomes such as:
Cure of disease
Elimination or reduction of patient's symptoms
Arresting or slowing of a disease process

Prevention of a disease or its symptoms for future.
- It is also important to take into account patient's expectations of the treatment, the patient's suitability for the treatment and above all his resources to meet the cost of the treatment.

4. Evaluating treatment alternatives by monitoring and modifying therapeutic plan:

- When evaluating treatment alternatives or therapeutic options, the following factors have to be considered such as efficacy and safety, availability and cost of treatment and suitability of treatment to the patient.
- Efficacy and safety must be considered when evaluating the risk benefit ratio of a particular treatment.
- Risk-benefit ratio will depend upon many factors. Some of the factors are:

Seriousness of the disease/ condition
Consequences of not treating the disease
Efficacy of the drug
ADRs associated with the drug therapy
Efficacy of alternative drug or non-drug therapy
Side effect profile of alternative drugs.

- As therapeutic options include both drug and non-drug treatments, both must be used in evaluation.
- Whenever possible, the choice should be determined by evidence based guidelines or standard treatment guidelines (STG).

5. Individualizing drug regimens:

- When more than one therapeutic alternatives exist, the patient's therapy is tailored based on multiple factors:

Patient Factors	**Drug Factors**
Diagnosis	Efficacy
Treatment goals	Adverse effects
Physiological and pathological factors	Prevalence, ability to minimize
Past medical history, past medicines received	Ability to monitor for efficacy and avoid ADR
Contraindications	Drug-drug interactions
Allergies and adverse effects	Pharmacokinetics and pharmacodynamics
Patient compliance	Dosage form
Patient's cooperation and convenience	Route and method of administration
Special considerations	Cost to the patient
	Government or insurance company payments, presentation of bills in their formats.

6. Monitoring Outcomes:

- The goals of any therapeutic treatments are obviously, the following:

Cure of disease
Elimination or reduction of patient's symptoms
Arresting or slowing of a disease process

Prevention of a disease or its symptoms for future.

- It is important to review each patient at the beginning of the therapy and ensure that the desired outcomes are achieved. This will involve monitoring four S's: these are signs, symptoms, side effects and sequelae (consequences).

TYPES OF PHARMACEUTICAL CARE:

SOAP Analysis

CORE Pharmacotherapy plan (C= Condition/ patient need, O=Outcome, desired for the condition or need, R=Regimen to achieve desired outcome, E= Evaluation parameter to assess outcome achievement)

FARM Analysis.(F= Findings, A=Assessment, R=Resolution (prevention), M= Monitoring and follow up

SOAP ANALYSIS:

- SOAP is an abbreviation of subjective, objective, assessment and plan. These four components can be broken down as follows:

1. Subjective:

- These are non-quantifiable data, on how the patient feels (symptoms) and any subjective observations that pharmacist may have made on the patient, that cannot be confirmed by diagnostic or testing procedures.

2. Objective:

- These notes are facts that are verifiable. These include measurements made by testing and other items such as medications, diet and other factual notes provided by other health care providers.

3. Assessment:

- This is the interpretation of subjective and objective findings and the method by which the pharmacist derives the recommendations of forms a plan.

4. Plan:

- The plan is the action, intervention or recommendation made by the pharmacist. This would also include any follow up measures if at all they are needed.

SOAP is thus a simple format that can be followed easily.

CRITICAL EVALUATION OF BIOMEDICAL LITERATURE

INTRODUCTION:

* Critical evaluation is the ability to judge the scientific value of a literature.
* This has to be done in a systematic manner, so that all the information in the biomedical literature is verified without oversight or bias.
* A clinical pharmacist has to evaluate biomedical literature about clinical trials or review papers or papers describing invention or therapeutic guidelines developed by hospital and other institutions.

SELECTION AND EVALUATION:

* Lakhs of biomedical literatures are published every year which makes it impossible to verify each of them. Hence literatures should be carefully selected for full evaluation.
* By careful preliminary evaluation biomedical literatures are selected, fully evaluated and then interpreted.
* Information obtained from it is applied for patient care problems.
* Dividing the biomedical literature into various components help to select and evaluate them correctly.

1. Evaluation of Tertiary Literatures:

- Tertiary literatures are the collection of information from secondary and primary sources. Hence there is always possibility of error, bias and insufficiency of information.
- With proper evaluation of these sources, a DIC pharmacist can decide, how far they can be relied upon for giving to DIC queries.
- The following are the questions to be asked to select a tertiary literature for evaluation.

a. Who are the authors or editors if the literature?
b. What are their credentials?
c. How much recent are those literatures?
d. Does the literature have single or multiple authors?
e. Is it supported by references?
f. Are the references easily available for verification?
g. Is the cost worth of material?

- Positive answers to these questions determine selection of such literatures for evaluation and subsequent addition to the collection of DIC.

2. Evaluation of Secondary Literatures:

- Secondary literatures are those in which information is indexed or abstracts are presented. As it represents huge volume of resources, they are now a days published as soft copy in CD's, rather than printed form.
- Soft copy format made it easy to go for full text of the biomedical literature which are also included along with index and abstract by enterprising publishers of these secondary literatures.
- However to select these literatures too some basic questions needs to be asked for evaluation of its worth.

a. How many journals are covered for indexing or abstracting?
b. How much time has gone between date of original publication and indexing?

c. Whether this secondary literature covers only drugs or secondary literature also?
d. What is the cost?

3. Evaluation of Primary Literature:

- Primary literature has to be evaluated part by part or component after component, only then, the pharmacist can determine its applicability in practice setting.
- The components of the primary literature are:

a. Introduction: Reasons and objective of the study.
b. Materials and methods: Subjects (patients), study design and test methods.
c. Results: Data and its statistical analysis.
d. Discussion: Conclusions drawn.

- The evaluation of these components is discussed below:

a. Introduction:

In this part of biomedical literature, the author usually describes the reason or rational for conducting the study and then the aims and objectives, he proposes to achieve through this research.
A careful analysis of this part gives the reader some confidence that the authors have defined a valuable course of investigation.
The rational for study also indicates that the investigators have taken up a task of solving some problem which does not have answer at present.
Also the aim mentioned in the introduction gives an opportunity to the evaluator to verify whether it is achieved at the end or not.

b. Materials and methods:

It is the most important part of the literature in that it describes how the research was carried out.
While evaluating this part the critical points to be noted are the sample, study design and the test method.
In biomedical studies the samples included are patient's. Next number of patient's selected for the study and how far they are representative of the population the study proposes to apply, criteria for their inclusion are to be thoroughly evaluated.
Inclusion of patients require many factors to be considered like their age, sex, severity of disease, physical fitness etc. How far these factors have been accommodated should be verified.
Next component to be evaluated in materials and method section is study design.
Once study design is evaluated, then the test method are evaluated.
The tests conducted on the subjects should be uniform and reproducible.
Here usually many biochemical lab tests are carried out, apart from physical examination, x-ray, microbiological and pathological investigations. All these tests should be sensitive enough to detect the activities of test and standard drugs.

c. Results:

In this section all the data collected during the study is summarized. They are the statistically analyzed.
Before verifying statistically analyzed data, it should be checked for completeness, correctness and relevance to the study design. It should be first verified whether results of all patient's enrolled in the project are given, if not, reason for drop out or omission.

If graphs are included how far they are integrated with the data and how well they are prepared should be evaluated.
Next whether all the data given in the test table and graph agree with each other and subjected to statistical analysis has to be verified.
Finally the entire process of statistical analysis and the result interpreted from it has to be fully investigated.

d. Discussion:

The last section of biomedical literature is the discussion section in which conclusions are drawn.
The conclusions have to be checked, as to whether they are in conformity with the aim/objectives mentioned in the introduction section.
If not the study design has to be once again evaluated whether it gives needed data to come to this different conclusion.
Conclusions should be fully supported by data obtained and there should not be any extrapolation.

ROLE OF EDITORIAL BOARD OF BIOMEDICAL LITERATURE:

- In order to critically evaluate biomedical literature guidelines are developed and published in biomedical journals by their editorial boards.
- Detail evaluation methods are sent to outside reviewers or evaluators of these journals or their own editorial board members for evaluating the articles received by these journals for publication.
- The committees frame and update guidelines as and when required.
- Those guidelines are published in these journals itself and students are advised to go through them.

MEDICATION ERRORS

DEFINITION:

The administration of wrong medicine or dose of medicine, diagnostic agent or chemical or treatment requiring use of such agents to the wrong patient or at the wrong time in the wrong manner is known as medication error.

CLASSIFICATION OF MEDICATION ERROR:

1. Errors in Drug Administration:

A. Wrong dosage form:

- In this type of error, for instance, tablet might have been given instead of injection and vice versa.
- Depends upon the patient's condition oral dosage may produce, nausea, vomiting or stomach irritation, apart from delaying onset of action by the drug. On the other hand, needless injection raises the cost of treatment.

B. Unordered drug given:

- Drug not repeated in the prescription is not noted and previous day prescription is routinely followed and there by unordered drug may be administered to the patient.
- Not only patients looses the benefit of drug written in the prescription but also their agony is prolonged.
- Similar to starting of drugs at right time, stopping of it at appropriate time is also important.
- Without noticing such decision, administering previous day's drug may complicate the treatment.

C. Wrong time:

- If any drug is given half an hour before or after the time specified it is considered as administration of drug at wrong time.
- It may seem to be a simple error but in some critical cases it may lead to drug-drug interaction, if the required dosing interval is not followed between drugs.

D. Wrong administration:

- If a drug is given through different route than the one mentioned in the prescription it is known as wrong drug administration of drug.
- One has to be careful while reading the label. Some injections have to be given only through IM not by IV.
- Many health care professionals think all injections can be administered via IM or IV depends on emergency.
- It is a wrong conception as the excipients of injections differ depends on many factors, hence wrong route may cause local irritation, swelling and dispersal problems at the site of injection.

2. Errors in Dose of Drugs:

A. Omission of any dose:

- If a drug is administered by the time the next dose is due, it is called a omission of dose,
- Nurses may fail to administer a drug, forgetfully or due to other emergencies in the ward, till the time of next dose.
- If not for all drugs, for few drugs like Digoxin and antibiotics this may lead to complicaions.

B. Wrong Dosage:

- Correct quantity of the dose written in the prescription should be administered to the patient.
- Any dose above or below 5% of correct dose is considered as wrong dose, hence a careful measuring, counting and double reading of prescription is a must to avoid complaints of wrong dose.

C. Extra dose:

- Sometimes patient may be given an extra dose of the prescribed medicine without checking whether the drug has been already given or not.
- This usually happen when it is not recorded in the medication charts immediately or during change in duty staff at the end of working hours.

REASONS FOR MEDICATION ERROR:

1. Engaging non-professionals:

- Medication error occurs when the members of health care team is not able to find out while the error is being committed.
- Usually it happens when non-professionals are involved in professional works where professional judgment is required. For example if a non-pharmacist dispenses drugs, he is not able to find out incompatible drugs prescribed or how to instruct the patient about the use of those drugs without interaction.

2. Inadequate labeling:

- Insufficient information on the label leads to medication error.
- All the necessary information like dose, route of administration, expiry date, storage etc should be mentioned in the label, otherwise patients tend to assume things and consume the drugs as they presume.
- Important points like 'poison' 'caution' or 'warning' has to be highlighted in labels.
- They are printed in red or different colors to attract the attention of the patients or auxiliary labels has to be affixed on the container. Sometimes, pictograms are fixed on the containers to help the illiterate patients.

3. Non-reporting of medication error:

- Many people think it is unnecessary to report such errors, even it occurs due to some other reason than their fault. Thus prevention, treatment, correction and subsequent benefits are denied to the patient for that inadequate hospital policies have to be blamed.
- If an incident is not reported it goes uninvestigated and thereby the chance for detecting its real reason is diminished.
- Thus without knowing the root cause, the team looses foresight if it occurs at another time for the same patient or other patient. Hence this time and every time they fail in preventing similar medical error. Thus absence of proper education and policies by hospital administration, inculcated to health care team, is one of the reason for medical error.

MINIMIZING MEDICATION ERROR:

- Medication error can be prevented to a maximum extend, but it is difficult to eliminate altogether.
- Engaging only pharmacists for handling drugs, good dispensing practices by way of adequate labeling and faithful reporting of errors etc help the hospital administration to minimize medication errors.

- Pharmacists and nurses can help to avoid medication error by their co-ordinate works.
- Pharmacist if appointed in wards can prepare patient medication profile card for each in-patient in which he can record list of drugs given, allergy, possible drug-drug interaction, precautions to be followed etc, which can be viewed by nurses before administering drugs.
- Similarly nurses while preparing to administer drugs to the patient should

a. Verify whether the medicine was already given.

b. Collect the drug from the cupboard read the label 2 to 3 times and check the content for physical stability.

c. Discard any balance left over medicine.

d. Check whether the previous medicine or dose is incompatible with the present one.

- During the administration of medicine nurses should once again verify all the information. The medicine should be prepared just few minutes before administration. Patient should be properly identified and she should wait until the administration of medicine is completed. Then she should write 'given' on the medication card against the name and time of the drug and put her initials.
- If the above regulations are followed sincerely medication errors can be reduced to very minimum and the patient who is already suffering from his disease can be saved from unnecessary trouble and problems.