PHARMACY PRACTICE

B.Pharma, Semester-VII

According to the syllabus based on 'Pharmacy Council of India'

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"Dedicated

To

***my family** & **Students**"*

- Dr. Sachin Tyagi

"Dedicated

to

*my **Wife,** my lovely Daughter **Suhani***

&

*my **Parents**"*

- Dr. Vinay Chhanalal Darji

"Dedicated

To

***my family members**"*

- Dr. K. Krishnaveni

Preface

It gives us immense pleasure to place before the **B.Pharma Seventh Semester** pharmacy students the book on **"Pharmacy Practice"**.

This book has been written strictly in accordance with the current syllabus prescribed by Pharmacy Council of India, for B.Pha rma students. Keeping in view the requirements of students and teachers, this book has been written to cover all the topics in an easy -to-comprehend manner within desired limits of the prescribed syllabus, and it provides the students fundamentals of hospi tal and clinical pharmacy which are required by them during their pharmaceutical career.

All efforts have been made to keep the text error -free and to present the subject in a student friendly and easy to understand. However, any suggestions and construc tive comments would be highly appreciated and incorporated in the future edition.

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Acknowledgement

Firstly, I express my sincere gratitude to the **'Almighty'**, for giving me an opportunity and strength to write this book, without whose blessings and grace this challenging task could not have been accomplished.

I must unreservedly acknowledge my deep sense of gratitude that I owe to numerous **authors** whose great & master work I have consulted during the entire course of this work. I express my sincere gratitude to my **Parents**, for their realizing the need of writing this book and encouraging me to write it.

I am thankful to **Thakur Publication Pvt. Ltd.** , especially **Ms. Tuhina Bane rjee** (Editor in Pharmacy Department) and **Mr. Anoop Kumar** (Marketing Coordinator), for providing necessary facilities and support for speedy completion of this book.

- Dr. Sachin Tyagi

This is a golden moment for me as I am successfully completing my book with the gracefulness of god and all my supporters to whom I want to thank individually. It would not have been possible without the helping hands of others. I would like to thank all those hands that have contributed directly or indirectly to the successful completion of this work.

I am very thankful to my Wife **Dr. Aditi Bariya**, **HOD** & **Associate Professor**, **Arihant School of Pharmacy & BRI** , **Gandhinagar** who deserves to be complimented for her constant and unconditional support and motivation to complete this book.

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I express my sincere thanks to all my **Gurus/Mentors/Guides** for giving their invaluable guidance and support.

My special thanks to our management of **Sharda School of Pharmacy** for their great encouragement to write this book.

I am highly indebted and express special thanks to my **parents** for their encouragement, inspiration and moral support all the time.

I want to extend my gratitude towards my colleagues for encouraging me to write a book.

Finally I wish to express my sincere thanks to all those who helped me directly or indirectly.

- Dr. Vinay Chhanalal Darji

I acknowledge with thanks the encouragement showered on me by many person. I thank Professor **Dr. R. Sambath Kumar** , **Principal**, **J.K.K. Nattraja College of Pharmacy** for his valuable suggestions and encouragement. I also thank Professor, **Dr. R. Shanmugasundaram**, **Vice Principal, J.K.K. Nattraja College of Pharmacy** for his unfailing guidance. I need to thank especially **Dr. S. Bhama**, who offered me unflagging support and wise advice.

- Dr. K. Krishnaveni

Syllabus

Module 01 **10 Hours**

Hospital and Its Organization

- Definition, Classification of hospital.
- Primary, Secondary and Tertiary hospitals.
- Classification based on clinical and non- clinical basis.
- Organization Structure of a Hospital, and Medical staff s involved in the hospital and their functions.

Hospital Pharmacy and Its Organization

- Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

Adverse Drug Reaction

- Classifications –Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, and toxicity following sudden withdrawal of drugs.

Drug Interaction

- Beneficial interactions, adverse interactions, and pharmacokinetic drug interactions.
- Methods for detecting drug interactions.
- Spontaneous case reports and record linkage studies.
- Adverse drug reaction reporting and management.

Community Pharmacy

- Organization and structure of retail and wholesale drug store, types and design.
- Legal requirements for establishment and maintenance of a drug store.
- Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Module 02 **10Hours**

Drug Distribution System in A Hospital

- Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labeling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

Hospital formulary

- Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

Therapeutic Drug Monitoring

- Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

Medication Adherence

- Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

Patient Medication History Interview

- Need for the patient medication history interview, medication interview forms.

Community Pharmacy Management

- Financial, materials, staff, and infrastructure requirements.

Module 03 **10 Hours**

Pharmacy and therapeutic committee

- Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

Drug information services

- Drug and Poison informa tion centre, Sources of drug information, Computerised services, and storage and retrieval of information.

Patient Counselling

- Definition of patient counselling; steps involved in patient counselling, and Special cases that require the pharmacist.

Education and Training Program in the Hospital

- Role of pharmacist in the education and training program.
- Internal and external training program.
- Services to the nursing homes/clinics.
- Code of ethics for community pharmacy.
- Role of pharmacist in the interdepartme ntal communication and community health education.

Prescribed Medication Order and Communication Skills

- Prescribed medication order- interpretation and legal requirements.
- Communication skills- communication with prescribers and patients.

Module 04 **08 Hours**

Budget Preparation and Implementation

- Budget preparation and implementation

Clinical Pharmacy

- Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.
- Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

Over The Counter (OTC) Sales

- Introduction and sale of over the counter.
- Rational use of common over the counter medications.

Module 05 **07 Hours**

Drug Store Management and Inventory Control

- Organisation of drug store, types of materials stocked and storage conditions.
- Purchase and inventory control: princip les, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level.
- Methods used for the analysis of the drug expenditure.

Investigational Use of Drugs

- Description, principles involved, classification, contr ol, identification, role of hospital pharmacist, advisory committee.

Interpretation of Clinical Laboratory Tests

- Blood chemistry, hematology, and urinalysis.

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Chapter 12: Pharmacy and Therapeutic Committee

Chapter 13: Drug Information Services (DIS)

Chapter 14: Patient Counselling

Chapter 15: Education and Training Program in the Hospital

Chapter 16: Prescribed Medication Order

Chapter 20: Drug Store Management

Chapter 21: Investigational Use of Drugs

Chapter 22: Interpretation of Clinical Laboratory Tests

CHAPTER 1

Hospital and Its Organisation

1.1. HOSPITAL

1.1.1. Definition of Hospital

Hospital is a **complex organisation**. It is an institute of providing health to individuals with the help of complex and special scientific equipments in the presence of trained staff who are well-educated in the problems of modern medical science. For achieving the goal of maintaining a good health of individuals suffering from diseases and relieving them from pain, all the staff members of hospitals coordinate together. Hence, hospital is a specialised organisation in which patient care is the main focus.

In modern hospitals, there is ample of space and well-qualified and skilled personnel who provide curative, restorative, and preventive services of extreme quality to all the patients irrespective of their race, colour, creed, or financial status.

As per WHO, "Hospitals are reservoirs of critical resources and knowledge. They can be classified according to the interventions they provide, the roles they play in the health system and the health and educational services they offer to the communities in and around them."

1.1.2. Classification of Hospital

All the hospitals have different features as they vary in their structure, functions, performance, and the community it he lps. Hospitals are classified into different types based on different standards. The classification of modern hospitals has been done based on the criteria shown in the **figure 1.1**:

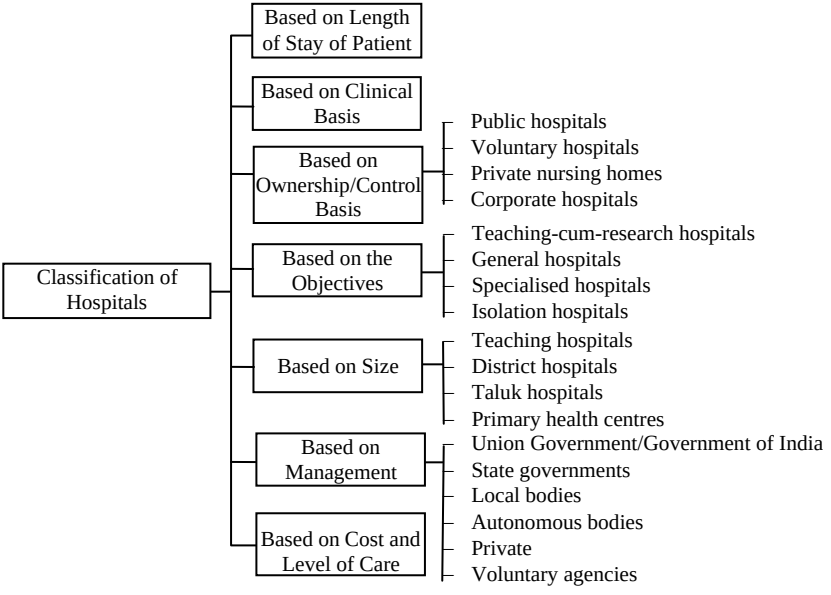


Figure 1.1: Classification of Hospitals

1.1.2.1. Classification Based on Length of Stay of Patient

In a hospital, a patient stays for a short term for the treatment of acute diseases (**e.g.,** pneumonia, peptic ulcer, gastroenteritis, etc.); while for the treatment of chronic diseases (**e.g.,** tuberculosis, leprosy, cancer, psychosis, etc.) a patient stays in the hospital for a long term. Thus on this basis of short term and long term, the hospitals are categorised into **acute care hospitals** and **chronic care hospitals**, respectively.

1.1.2.2. Classification Based on Clinical Basis

Hospitals categorised based on this crite ria are general hospitals which cure all types of diseases. However, they are mainly focused on curing heart disease, cancer, ophthalmic, maternity, etc. conditions. Hospitals are classified as follows **based on their anatomical-physiological specialisation**:

1) ENT (Ear, Nose and Throat) hospitals,
2) Eye hospitals,
3) Orthopaedic hospitals, and
4) Kidney hospitals.

Hospitals are classified as follows **based on the client group they serve**:

1) Paediatric hospitals for children,
2) Gynaecological hospitals for women, and
3) Maternity hospitals for mothers.

Hospitals are classified as follow**based on thesystem of medicine adopted for treatment**:

1) Allopathic hospitals,
2) Ayurvedic hospitals,
3) Homeopathic hospitals,
4) Unani hospitals, and
5) Hospitals of other systems of medicine.

1.1.2.3. Classification Based on Non-Clinical Basis

Hospitals on non-clinical basis are classified as follows:

1) **Classification Based on Ownership/Control Basis:** Hospitals categorised based on this criteria are of the following types:
   i) **Public Hospitals:** These hospitals are under the control of Central or State Governments or local bodies on non -commercial lines. They can be general hospitals or specialised hospitals or both.
   ii) **Voluntary Hospitals:** These hospitals are recognised and combined under the Societies Registration Act 1860 or Public Trust Act 1882 or any other act of Central or State Governments. They are supported by the public or private funds on a non-commercial basis.
   iii) **Private Nursing Homes:** These are regulated by an individual doctor or a group of doctors on a comm ercial basis. Patients suffering from infirmity, advanced age, illness, injury, chronic disease, disability, etc. are admitted here. However, patients having communicable diseases, alcoholism, drug addiction, or mental illness are not treated.
   iv) **Corporate Hospitals:** These hospitals are public limited companies running on commercial lines and formed under the Companies Act. They can be general or specialised or both.

2) **Classification Based on the Objectives:** Hospitals based on this criteria can be sub - divided as follows:
   i) **Teaching-cum-Research Hospitals:** These are the hospitals having a college for education of medical, nursing, dental, or pharmacy. Teaching is the major aim of these hospitals and the provision of healthcare is secondary. AIIMS (New Delhi), PGIMER (Chandigarh), JIPMER, (Pondicherry), KR Hospital (Mysore), Victoria Hospital (Bangalore), etc. are some **examples** of teaching-cum-research hospitals.
   ii) **General Hospitals:** These hospitals help for curing the common diseases. They have at least two or more doctors, who can offer in -patient accommodation and provide medical and nursing care for more than one category of medical discipline, such as general medicine, general surgery, obstetrics, gynaecology, paediatrics, etc. Their primary aim is to provide med ical support to the people, and teaching and research are secondary. **Examples** of these hospitals are all districts and Taluk or PHC or rural hospitals.
   iii) **Specialised Hospitals:** These hospitals provide medical and nursing care for one discipline or a disease or a condition of one system. They concentrate on a particular aspect or body organ and give medical and nursing care in the particular field, **e.g.,** tuberculosis, ENT, ophthalmology, leprosy, orthopaedics, paediatrics, cardiology, mental health/psychiatric, oncology, STDs, maternal, etc.
   iv) **Isolation Hospitals:** These hospitals treat patients who are suffering from infections and communicable diseases and need to be isolated. Epidemic diseases hospital (Bangalore) is an **example** of isolation hospital.

3) **Classification Based on Size (Bed Strength):** According to the **Health Committee Report**, the following pattern of development of hospitals should be accepted on the basis of size:
   i) **Teaching Hospitals:** These hospitals have 500 beds and can be increased depending on the number of students.
   ii) **District Hospitals:** These hospitals have 200 beds and can be increased up to 300 depending on the population.
   iii) **Taluk Hospitals:** These hospitals have 50 beds and can be increased depending on the population.
   iv) **Primary Health Centres:** These hospitals have 6 beds and can be increased up to 10 depending on the needs.

4) **Classification Based on Management:** Hospitals based on this criteria can be sub - divided as follows:
   i) **Union Government/Government of India:** These hospitals are controlled by the Government of India. Hospitals run by the railways, military/defence, mining or public sector activities of Central Government are the **examples** of such hospitals.
   ii) **State Governments:** These hospitals are controlled by the state or union territory. Government authorities and public sector activities running through the state or union territories comprising the police, prison, irrigation department, etc. are the **examples** of such hospitals.
   iii) **Local Bodies:** These hospitals are managed by the local bodies, such as municipal corporation, municipality, Zila Parishad, Panchayat, **e.g.,** corporation maternity homes.
   iv) **Autonomous Bodies:** These hospitals are formed under a special act of parliament or state legislation. They are financially supported by the Central/State Governme nt/Union territory. AIIMS (New Delhi), PGIMER (Chandigarh), NIMHANS (Bangalore), KMIO (Bangalore), etc. are some **examples** of such hospitals.

v) **Private:** These hospitals are run by an individual or by private organisation. MAHE (Manipal), Manipal Hospital (Ba ngalore), Hinduja Hospital (Mumbai), etc. are some **examples** of such hospitals.

vi) **Voluntary Agencies:** These hospitals are run by a voluntary body, a trust, or a charitable society registered under a suitable authority under Central/State Government laws. They include hospitals run by missionary bodies and cooperatives. CMC hospital (Vellore) is an **example** of such hospital.

5) **Classification Based on Cost:** Hospitals based on this criteria can be sub -divided as follows:

i) **Elite Hospitals:** These hospitals are a symbol of high -tech medical development. The per day room rates vary between 300-1200. The deluxe rooms have fridge, television, and telephone. Excluding the medical care, they are similar to five -star hotels, thus, are also called **five-star hospitals**. These institutions reserve a particular percentage of their capacity for poorer sections and also support a particular percentage of their accommodation cost. **For example**, Jaslok has reserved 25% for the poorer sections and 30% at half the rates. In Mumbai hospital, 315 beds out of 680 are free and 112 beds are funded.

ii) **Budget Hospitals:** These hospitals are for moderate budget and low budget users, **e.g.,** civil hospitals, corporation hospitals, etc.

6) **Classification Based on the Level of Care:** Hospitals based on th is criteria can be sub-divided as follows:

i) **Primary Hospitals:** These hospitals denote the first level of contact between the individuals (including their families) and the health system. According to **Alma Ata Declaration** of **1978**, primary health care indicat es serving the community it served; including mother and child care, which comprised of family planning, immunisation, prevention of locally endemic diseases, treatment of common diseases or injuries, delivery of essential facilities, health education, pro vision of food and nutrition, and adequate supply of safe drinking water.

Primary healthcare in India involves a network of **sub-centres** and **primary health centres** in rural and urban areas, which are provided through health posts and family welfare centre s. A sub -centre has one **auxiliary nurse midwife** and **multipurpose health worker**. It provides services to around 5000 users in plain areas and 3000 in hilly and tribal areas. The **Primary Health Centre** (PHC) having a **medical officer** and **other paramedical staf f** serves 30,000 users in plain areas and 20,000 in hilly, tribal and backward areas. Each PHC supervises 6 sub-centres.

ii) **Secondary Hospitals:** These hospitals are provided by such medical specialists, who do not have direct contact with the patients, like ur ologists, dermatologists, cardiologists, etc. According to **National Health System Policy** , a patient proceeds further for secondary care after being referred by a primary care professional. A patient cannot directly move to secondary care as sometimes health systems impose a restriction of referral on a patient in terms of payment; however, this varies from countries to countries. The following **two systems** come under this category:

a) **District Health System:** This system provides child health and maternity care. It serves around 25,000 -50,000 users and includes various healthcare centres and district hospitals. These healthcare centres receive referrals from various primary health cares and remain open for 24 ×7. District hospitals include emergency services, neon atal care, comprehensive emergency obstetrics, etc.

b) **County Health System:** This system includes hospitals that receive referrals from district and community health systems. County hospitals provide gynaecologic services, general medicine, obstetrics, general surgery, etc. and remain open for 24×7.

iii) **Tertiary Hospitals:** These hospitals are a third level of health system. They provide a specialised consultative care to a patient referred from primary and secondary medical care. Specialised intensive care units, advanced diagnostic support services, and specialised medical personnel are the key features of tertiary health care. Tertiary care service in India is provided by medical colleges and advanced medical research institutes.

1.1.3. Organisation Structure of a Hospital

The organisation of modern day hospitals is a complex network of com mittees, departments, personnel, and services. The hospitals are not only car ing, people-oriented institutions, but also many -faceted, high -tech business. They operate like other large businesses constantly concerned about their bottom line, and have a hierarchy of personnel and channels of authority. However, the number of administrative personnel depends on the hospital size.

The organisation of hospitals includes the following:
1) Administrative staff,
2) Medical staff,
3) Associated medical services, and
4) Supportive paramedical services and staff.

Organisational chart of a hospital is represented in **figure 1.2**:

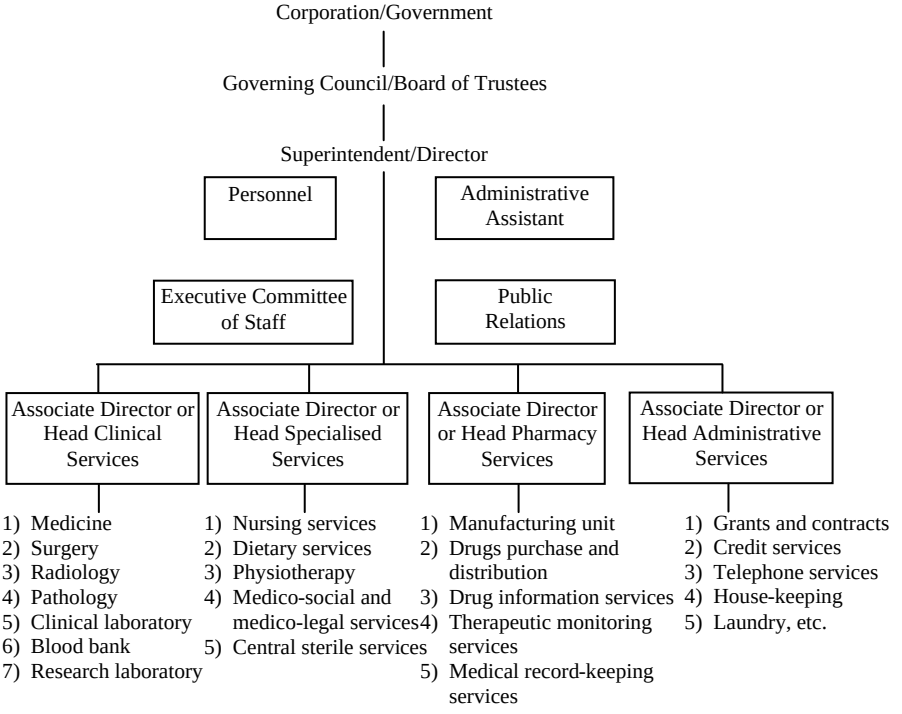


Figure 1.2: Organisation of a Hospital

1.1.3.1. Administrative Staff

The administrative services of a hospital are controlled by a **chief executive officer** or **president**. They have day-to-day responsibility for handling all the hospital businesses. He or she is the highest ranking administrative officer who manages all the administrative departments associated with financial operations, public relations, and personnel. In many large hospitals, a **chief operating officer** manages the activities of certain departments, and a **chief financial officer** guides the financial activities of the hospital. These key administrative officers are **corporate vice presidents** of the hospital.

The huge number of employees and the extensive collection of individual skills needed to staff a hospital calls for a **personnel or human resources department** with specialised labour expertise. This department is also headed by a vice president for human resources. Nursing is a great component of the hospital's service operations, thus larger facilities also have a **chief nursing executive** at the vice president level.

1.1.3.2. Medical Staffs Involved in the Hospital and Their Functions

Each hospital should have a medical staff with the aim to provide medical care to the patients as per the ethical conduct and professional practices of their membership. The structure of medical staff is different in every hospital.

Following are the divisions of medical staff in large hospitals:

1) **Residential Medical Staff:** These staff members remain available for 24 hours to attend the patients. They are also responsible for the organisational and administrative duties.
2) **Associate Medical Staff:** These staff members include the physicians allotted to different services similar to the members of the active medical staff. These can be progressive as the residential medical staff.
3) **Consulting Medical Staff:** These staff members include medical physicians of known professional ability.
4) **Honorary Medical Staff:** These staff members are like part-time consulting medical staff. These members are retired physicians or physicians possessing a clinic and providing nominal facilities to the hospital.

1.1.3.3. Associated Medical Services

Associated medical services include the following:

1) **Medicine Division:** Following are the departments of the medical division:
   - i) Internal medicine,
   - ii) Cardiology,
   - iii) Gastroenterology,
   - iv) Nephrology,
   - v) Pulmonary diseases,
   - vi) Psychiatry and neurology,
   - vii) Infectious diseases,
   - viii) Allergy,
   - ix) Skin and venereal diseases,
   - x) Endocrinology,
   - xi) Geriatrics,
   - xii) Immunology, and
   - xiii) Paediatrics.
2) **Surgery Division:** Following are the departments of surgery division:
   - i) General surgery,
   - ii) Obstetrics and gynaecology,
   - iii) Orthopaedic surgery,
   - iv) Ophthalmology,
   - v) Otolaryngology,
   - vi) Dental and oral surgery,
   - vii) Nephrology,
   - viii) Neurological surgery,
   - ix) Cardiothoracic surgery,
   - x) Plastic surgery, and
   - xi) Anaesthetics.

3) **Radiology:** It is the branch of medicine that deals with the diagnostic and therapeutic application of radiant energy in the form of roentgen X -rays and radium. The radiology department is headed by a M.D., who provides services on receiving a written order by a member of medical staff.

   Radium or sealed radioactive sources can be therapeutically used by those physicians who have been given permission in consultation with the radiologist and/or radiation safety committee. Radioactive substances should be handled by appropriately trained and experienced personnel. This department includes physicians trained as radiologists, physicists, technicians, radiotherapists, isotope -pharmacists, nurses, assistants, and secretarial persons.

   Modern radiology departments also have facilities of sonography, Computer-aided Tomography (CT) scanning, MRI (Magnetic Resonance Image), etc.

4) **Pathology and Clinical Biochemistry Services:** These services provide the facility of collecting samples of blood, urine, sputum, faeces, etc., in order to detect the presence of pathogenic infection or abnormality in biochemical parameters such as sugar, urea, etc. The related processes are done as per the instructions of the physician, surgeon, etc. A medical person qualified in the branch of pathology or medicine is appointed as the head of these services.

5) **Blood Bank:** This service provides facility of collecting, processing, and supplying blood and its products (blood plasma, etc.). A blood bank is a store or a bank of blood and its components collected (from blood donations), stored, and preserved to be used later in blood transfusion.

1.1.3.4. Supportive Paramedical Services and Staff

Supportive paramedical services and staff comprises of the following:

1) **Nursing Services:** The nursing team comprises of workers with variable degrees of skill in nursing and are directed by a professional nurse. This team replaces the single nurse who has done everything for the patient.

   Following are the main assumptions about the nursing care which helps for the better healthcare. These were started by National League of Nursing in the U.S.A. in 1964:
   i) Nursing care includes health promotion, care and prevention of disease, rehabilitation, teaching and counselling, emotional support, and treatment of disease.
   ii) It is an essential part of the healthcare system and is performed in combination with related medical, educational, and welfare facilities.
   iii) The nursing team should respect individuality, dignity, and rights of every person irrespective of race, colour, breed, origin, and social and economic status.

2) **Dietary Services:** Food service plays an important role in hospitals. This is also a therapeutic measure directly related to scientifically-prepared nutritious diet meant for certain diseases. These services impose on the clinical care of the patient.

   Following are the functions:
   i) Plans menu for general or special diet for patients and employees,
   ii) Selects and purchases food,
   iii) Maintains relationship with food vendors,
   iv) Receives and stores food,
   v) Prepares and distributes food,
   vi) Maintains cleanliness and safety in the department,
   vii) Trains and supervises the staff,
   viii) Educates nations on dietary habits along with the medical or nursing staff, and
   ix) Conducts research programs in teaching hospitals.

3) **Medical-Social Service Department:** This department serves as a link between the hospital and the patient and his/her relatives. The qualified social worker is a discipline who focuses on the social aspects of the patient and his/her family. The worker gives information regarding the medical and social study of suitable patients, and their home environmental particulars.

4) **Central Sterile Services:** The main function of the Central Sterile Services Department (CSSD) is to give sterile items, linens, and equipment to wards and OT's. The department sterilises the reusable equipment and linens received from various wards. The department exchanges items as per the need. The linens are sent for washing to the laundry either directly or via CSSD, and the washed linens are then sent to CSSD for sterilisation. These sterilised items are then issued to the wards and OT's whenever they demand for.

5) **Medical or Patient Treatment Records:** These are the systematic documentation of a patient's medical history and care. Medical record is a physical folder for each individual patient as well as an information body that contains the complete history of patient's health.

6) **Drug Information Services or Centre:** The aim of these services or centre is to document drugs by extracting information about them. Drug information is the information on physical, chemical, biological and health care sciences collected either in written forms (i.e., books, journals, periodicals, etc.) or conveyed by oral communication or by electronic devices.

7) **Drug Distribution System:** Every hospital use drugs and therapeutic substances in in-patient and out-patient departments. Bigger the institution, bigger is the problem of procurement and distribution of drugs.

   The following **two types** of drug distribution system exist in hospitals:
   i) Drugs are distributed to indoor patients, operation theatres, X-ray, and other specified departments.
   ii) Drugs are distributed to outdoor patients (i.e., who are not admitted).

   Two more drug distribution types are:
   i) Dispensing of narcotics and other controlled substances, and
   ii) Distribution and dispensing of ancillary substances and articles.

1.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) Hospital is an institute of providing health to individuals with the help of complex and special scientific equipments in the presence of trained staff who are well-educated in the problems of modern medical science.

2) On this basis of short term and long term, the hospitals are categorised into **acute care hospitals** and **chronic care hospitals**, respectively.

3) **Public hospitals** are under the control of Central or State Governments or local bodies on non-commercial lines.

4) **Voluntary hospitals** are recognised and combined under the Societies Registration Act 1860 or Public Trust Act 1882 or any other act of Central or State Governments.

5) **Private nursing homes** are regulated by an individual doctor or a group of doctors on a commercial basis.

6) **Corporate hospitals** are public limited companies running on commercial lines and formed under the Companies Act.
7) **Teaching-cum-research hospitals** are the hospitals having a college for education of medical, nursing, dental, or pharmacy.
8) **General hospitals** help for curing the common diseases.
9) **Specialised h ospitals** provide medical and nursing care for one discipline or a disease or a condition of one system.
10) **Isolation hospitals** treat patients who are suffering from infections and communicable diseases and need to be isolated.
11) **Teaching hospitals** have 500 beds and can be increased depending on the number of students.
12) **District h ospitals** have 200 beds and can be increased u p to 300 depending on the population.
13) **Taluk hospitals** have 50 beds and can be increased depending on the population.
14) **Primaryhealth centres** have 6 beds and can be increased up to 10 depending on the needs.
15) **Union government hospitals** are controlled by the Government of India.
16) **State government hospitals** are controlled by the state or union territory.
17) **Local b ody hospitals** are managed by the local bodies, such as municipal corporation, municipality, Zila Parishad, and Panchayat.
18) **Autonomous body hospitals** are formed under a special act of parliament or state legislation.
19) **Private hospitals** are run by an individual or by private organisation.
20) **Voluntary hospitals** are run by a voluntary body, a trust, or a charitable society registered under a suitable authority under Central/State Government laws.
21) **Elite hospitals** are a symbol of high-tech medical development.
22) **Budget hospitals** are for moderate budget and low budget users, **e.g.,** civil hospitals, corporation hospitals, etc.
23) **Primary h ospitals** denote the first leve l of contact between the individuals (including their families) and the health system.
24) **Secondary h ospitals** are provided by such medical specialists, who do not have direct contact with the patients, like urologists, dermatologists, cardiologists, etc.
25) **District health system** provides child health and maternity care.
26) **County health system** includes hospitals that receive referrals from district and community health systems.
27) **Tertiary h ospitals** provide a specialised consultative care to a patient referred fro m primary and secondary medical care.
28) The administrative services of a hospital are controlled by a **chief executive officer** or **president**.
29) In many large hospitals, a **chief operating officer** manages the activities of certain departments, and a **chief financ ial officer** guides the financial activities of the hospital.
30) **Residentialmedical staff** members remain available for 24 hours to attend the patients.
31) **Associate medical s taff** members include the physicians allotted to different services similar to the members of the active medical staff.

32) **Consulting medical staff** members include medical physicians of known professional ability.

33) **Honorary medical staff** members are like part-time consulting medical staff.

34) **Radiology** is the branch of medicine that deals with the diagnostic and therapeutic application of radiant energy in the form of roentgen X-rays and radium.

35) **Medical-social service department** serves as a link between the hospital and the patient and his/her relatives.

36) The main function of the **central sterile services department** is to give sterile items, linens, and equipment to wards and OT's.

37) **Medical or patient treatment records** are the systematic documentation of a patient's medical history and care.

1.3. EXERCISE

1.3.1. True or False

1) Corporate Voluntary hospitals are recognised under the Societies Registration Act 1860 or Public Trust Act 1882 or any other act of Central or State Governments.

2) Private nursing homes are regulated by an individual doctor or a group of doctors on a commercial basis.

3) Voluntary Corporate hospitals are public limited companies running on commercial lines and formed under the Companies Act.

4) Teaching hospitals have 1000 beds and can be increased depending on the number of students.

5) Taluk hospitals have 200 beds and can be increased up to 300 depending on the population.

6) Elite hospitals are a symbol of high-tech medical development.

7) Tertiary hospitals are provided by such medical specialists, who do not have direct contact with the patients, like urologists, dermatologists, cardiologists, etc.

8) District health system provides child health and maternity care.

1.3.2. Fill in the Blanks

9) _____ hospitals help for curing the common diseases.

10) _____ hospitals treat patients who are suffering from infections and communicable diseases and need to be isolated.

11) Taluk hospitals have _____ and can be increased depending on the population.

12) _____ department serves as a link between the hospital and the patient and his/her relatives.

13) _____ include medical physicians of known professional ability.

14) _____ are formed under a special act of parliament or state legislation.

15) _____ remain available for 24 hours to attend the patients.

16) _____ serves as a link between the hospital and the patient and his/her relatives.

Answers

1) False 2) True 3) False 4) False 5) False
6) True 7) False 8) True 9) General 10) Isolation
11) 50 beds 12) Medical-social service 13) Consulting medical staff
14) Autonomous hospitals 15) Residential medical staff
16) Medical-social service department

1.3.3. Very Short Answer Type Questions

1) Define hospital.
2) Classify hospital.
3) What medical staffs are involved in the hospital and their functions?
4) Draw the organisation chart of hospital.

1.3.4. Short Answer Type Questions

1) Write a note on the classification of hospital based on ownership and objectives.
2) Discuss about the classification of hospital based on level of care.
3) Discuss about the supportive paramedical services and staff of hospital.

1.3.5. Long Answer Type Questions

1) Discuss about the organisation of hospital.
2) Write an illustrative note on the classification of hospital based on non-clinical basis.

CHAPTER 2

Hospital Pharmacy and its Organisation

2.1. HOSPITAL PHARMACY & ORGANISATION

2.1.1. Definition of Hospital Pharmacy

Hospital pharmacy functions for receiving, storing and dispensing drugs and medicines to patients. The hospital pharmacy may also manufacture pharmaceuticals and parenteral products. The department provides a range of pharmacy services for the hospitalised and ambulatory patients, including purchase, manufacture, compounding, storage, dispensing, distribution, and maintaining record for the same.

Hospital pharmacy is the health care service, which comprises the art, practice, and profession of choosing, preparing, storing, compounding, and dispensing medicines and medical devices, advising healthcare professionals and patients on their safe, effective and efficient use.

2.1.2. Functions of Hospital Pharmacy

The various functions performed by a hospital pharmacy are:

1) It attains supply of drugs, chemicals, biological and pharmaceutical formulations only from licensed vendors and manufacturers.
2) It inspects the received items and maintains an inventory for the same.
3) It dispenses drugs, chemicals, and pharmaceutical preparations to the patients. The pharmacists repack the medicament in appropriate containers and label them.
4) It keeps a record of all the narcotic drugs and alcohol received and issued.
5) It predicts the demand for drugs, chemicals, antibiotics, biologicals, radio pharmaceuticals, etc. and takes suitable steps to fulfil the demand.
6) It keeps a record of each supply dispensed.
7) It manufactures large volume parenterals and other drug preparations in case of unavailability, high cost, or lack of authentic vendors or cautious.
8) It implements strict control on the quality of the supplies received, manufactured, and dispensed.
9) It discusses about the drug related information with the medical staff, resident nurses, health care team, and the patients.
10) It participates in minimising the incidence of illness, and improves the general health of the population.
11) It provides patient counselling.
12) It implements the recommendations of pharmacy and therapeutic committee.

2.1.3. Organisation Structure

The hospital pharmacy has various divisions, like compounding and dispensing, manufacturing or production, quality control, central sterile supply, research, education and training, administration, and library.

The **Chief Hospital Pharmacist** is the **head of pharmacy** who reports to the Administrator. The number of **Assistant Chief Pharmacist**, who assists the Chief in administration, depends on the work, nature and scope of operations, staff strength, etc. Assistant Chief Pharmacist supervises and controls the various functions of the pharmacy.

The Chief has a secretary and other office clerks to assist him. Staff pharmacists, technicians, pharmacy helpers, and other workers of hospital pharmacy are involved in compounding, dispensing, manufacturing, drug supply, central sterile supply, and library duties.

The complete organisation of the hospital pharmacy is shown in **figure 2.1**:

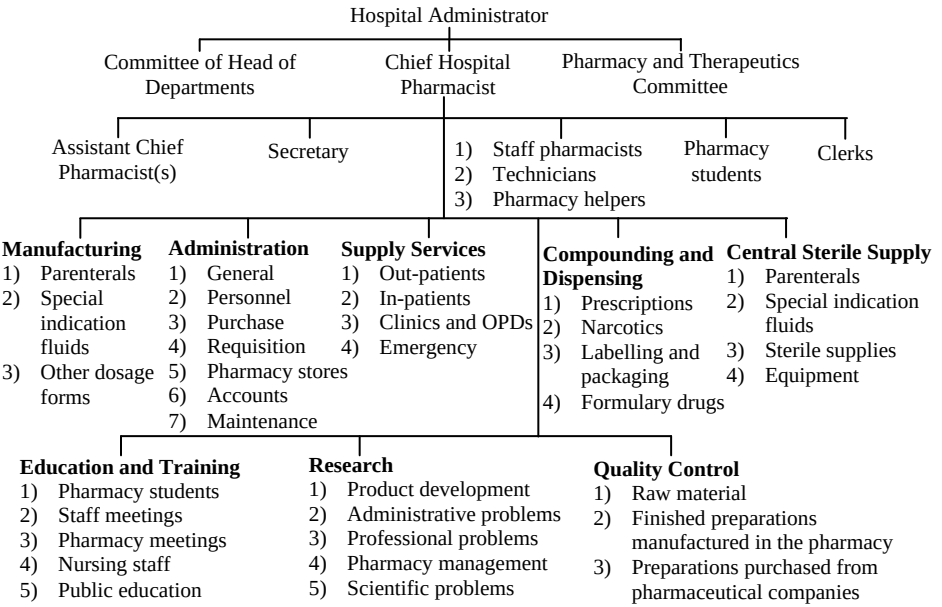


Figure 2.1: Organisation of the Hospital Pharmacy

2.1.4. Location

The pharmacy should be situated at the ground floor or the first floor to ease its accessibility and to provide adequate service to various departments and nursing st ations. If the hospital has an out-patient department, the pharmacy or its branch should be near it. In a multi -storey hospital, each floor should have a pharmacy. The layout of floor pharmacies should be such that continuous flow of men and materials is maintained.

A complete unit of the hospital pharmacy includes the following **areas**:

1) Office of the chief,
2) Out-patient dispensing unit,
3) Bulk compounding area,
4) Manufacturing unit for sterile and non - sterile preparations,
5) Packaging and labelling area,
6) Alcohol and volatile liquid area,
7) Narcotic vaults,
8) Radioisotope storage & dispensing area,
9) Central sterile supply area,
10) Cold storage area,
11) Research wing,
12) Pharmacy store room,
13) Library, and
14) Waiting room.

An out -patient pharmacy should look pleasant, and have enough space and seating arrangement for patients waiting for the medicine to avoid overcrowding. The waiting room in out-patient pharmacy should have a professional look, bear educative posters on health and hygiene, and hold light literature for reading to engage the visitors. This puts a positive impact of the pharmacy on the visitors. To manufacture bulk preparations (like stock solutions, bulk powders and ointments, etc.) routinely, a suitable space adjacent to the pharmacy or in the basement directly below the pharmacy should be provided. The medical stores of pharmacy should lie adjacent to the pharmacy or beneath the pharmacy.

2.1.5. Layout

The general design and construction of a hospital pharmacy should consider its functionality. The location and size should accommodate anticipated personnel and inventory movement, work processes, and activities. Built-in storage and fixed equipment should be provided for storing documents, bulk supplies, dangerous drugs, psychotropic substances, portable medical gas cylinders, and refrigerated and cold -chain items. Drainage and sewerage system should be present outside the premises.

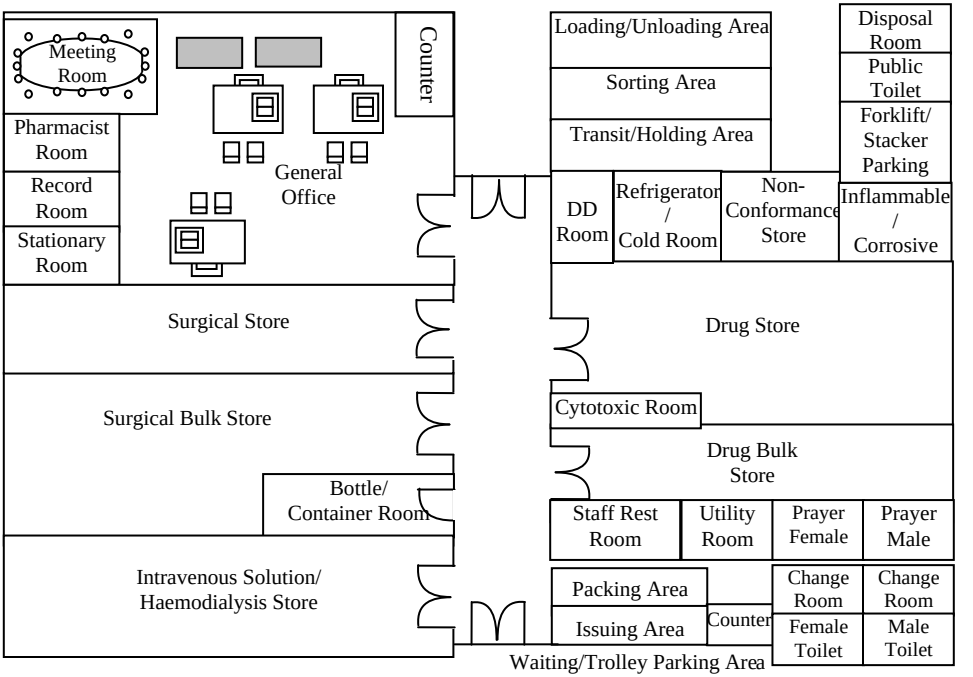


Figure 2.2: Layout of Hospital Pharmacy

2.1.5.1. Structural Design

1) **Wall:** The walls should be of non -porous material and plaste red on both sides. The indoor wall finishing should be of washable antifungal paint and the outdoor finishing should be of weather -proof paint. The walls for cold room should be of a special building material and design to prevent condensation.

2) **Floor:** The floor should be of concrete and smoothly plastered. The floor finishing should be of a non-slippery heavy duty material to withstand heavy loads and traffic. The floor should be non-porous, damp-proof, and resistant to detergent. The floor-to-ceiling heigh t should range from 15 -30 feet according to the functional area and handling equipments used.

3) **Ceiling:** The ceiling should be of fire -retardant, asbestos -free, and non -shedding materials or mineral fibres.

4) **Roof:** The roof should be pitched or sloped to prevent heavy rain damage.

5) **Door:** The doors should be of fire -retardant material. The doors should have two leaves, and should be sufficiently wide to allow free and easy movement of supplies and handling equipment (such as forklifts and stackers). The exit door s should be purposefully located and fitted with luminous emergency exit signage.

6) **Window:** The windows should be available at workstation, office and staff areas, but not in storage areas.

2.1.5.2. Receiving Area

1) **Loading and Unloading Area:** This area should be adequately spaced and properly sheltered by taking care of the vehicle height.
2) **Receiving Counter:** It should have adequate waiting space and should be equipped with suitable office furniture and equipment.
3) **Sorting and Unpacking Area:** This area should be adequately spaced to enable sorting and checking of goods. The space should be sufficient for the utilisation of forklift.
4) **Transit/Holding Area:** The transit/holding area should be adequately spaced for storing:
   i) Items requiring further clarification/investigation before receiving,
   ii) Transit items not requiring special storage conditions, and
   iii) Pallets.
5) **Disposal Room:** This room should store discarded items (like , used boxes, wrappers and plastic covers).

2.1.5.3. Storage Area

1) **General Storage Requirement:** The storage area should be provided with air-conditioning facilities for 24 hours. Its temperature should be effectively controlled between 160-250°C. The electrical supply to refrigerators, freezers, cold room and air conditioning facilities should be linked to the hospital emergency power supply.

   A computerised alarm system should be connected to the main electrical control system of the hospital for detecting electrical failure of cold chain equipment. Adequate space should be provided for forklifts, stackers, and trolleys, and for accommodating IT facilities. The area should have sufficient numbers of pallets, shelves, and racks.
2) **Drug Store:** It should have adjustable, modular, heavy duty open racks for storing packages of different sizes. It should have a sufficient storage area for bulk items. It should be equipped with heavy duty plastic pallets for storing bulk items and larger cartons off the floor. These pallets should be designed to be used with forklifts to move around groups of larger items. The drug store should have designated area with cautionary signage and chemo-spill kit for cytotoxic drugs.
3) **Dangerous Drugs/Psychotropic Substances Store:** This area is meant for storing dangerous drugs/psychotropic substances, thus should be kept under lock and key in a special room/cabinet with alarm system.
4) **Cold Room/Pharmaceutical Refrigerator/Freezer Area:** This area should be provided based on the functionality of hospital. It should be present within the drug store for storing drugs that require low storage temperature (like vaccines, antisera, and other biological products). Every cold room/pharmaceutical refrigerator/freezer should be equipped with a computerised temperature recorder system.
5) **Intravenous (IV) Fluid Store:** This area should be adequately spaced to accommodate haemodialysis and peritoneal dialysis solution, and intravenous solutions. The space should also be sufficient for using forklift.
6) **Surgical Store:** This area is designed for storing bulk surgical/consumable/disposable items/X-ray films. It should have adjustable, modular, and heavy duty open racks. It should be provided with adequate space to accommodate bulk items.
7) **Non-Drug Bulk Store:** This area is designed for storing dispensing bottles, containers, labels, and envelopes. It should have adjustable, modular, and heavy duty open racks. It should be provided with adequate space to allow easy movements.

2.1.5.4. Store with Special Requirement

1) **Inflammable Store:** This area should be located at minimum 10 feet distance away from other adjacent buildings. It should be designed for storing inflammable items (ethanol, methanol, acetone, etc.) and should be equipped with fire fighting equipments, smoke detectors, and exhaust fans for proper ventilation. The location and design of inflammable store should provide maximum air circulation so that accumulation of fumes or gases can be avoided. Spark-proof switches should be present outside the room.
2) **Corrosive Items Store:** This area should be designed for the storage of corrosive items (such as phenols and hypochlorites). It should be equipped with special plumbing and drainage system, and eye wash station.
3) **Medical Gas Store:** This area should be designed for the storage of portable medical gas cylinders. The floor should be reinforced to bear the weight of heavy gas cylinders. Loading and unloading area should be made present and sheltered well. The bay should be constructed to enable direct loading and unloading of goods. All electrical facilities should fulfil the requirements of the Fire Fighting and Rescue Departments and Department of Environment. Proper ventilation should be maintained.
4) **Quarantined Item Store:** A designated area or cabinet should be provided and clearly labelled.
5) **Non-Conformance/Condemned Item Store:** Designated store/cabinet for expired, obsolete or damaged items should be provided prior to disposal.

2.1.5.5. Issuing Area

1) **Temporary Holding Area:** Supply to various departments is carried out in this area. Indents from various departments should be processed and prepared for supply and kept here till collected. Designated secure area should be provided close to the issuing area.
2) **Issuing Counter:** It should have an adequate waiting space, and should be equipped with appropriate office furniture and equipment. It should provide a sufficient space for material handling equipment.

2.1.5.6. Administrative Area

1) **Pharmacist In-Charge Office:** This area is provided for the pharmacist in-charge to perform the administrative work. It should be located to allow supervision.
2) **Pharmacist Work Station:** This area is provided for the pharmacist. It should be half-glass panelled to allow supervision. Workstations and computer terminals should also be present here.
3) **General Office:** This area is provided for the assistant administrative officers and administrative assistants. Work-stations with computer terminals should be present here.
4) **Meeting/Discussion Room:** This area should have sufficient space for discussion and routine administrative meetings.
5) **Document Room:** This area should have sufficient space for storing files and records.
6) **Reception Counter and Customer Waiting Area:** This area should be equipped with appropriate office furniture and equipments. The customer waiting area should have audio-visual facilities, water dispenser and settee.

2.1.5.7. Ancillary Area

1) **Personnel/Staff Rest Room:** This room should be provided for staff rest, and should be equipped with staff lockers and domestic appliances such as refrigerator, electric kettle, water dispenser, microwave oven, table, chairs, and sofa.

2) **Wash Room:** Separate wash rooms for male and female with separate changing rooms, toilets and shower facilities should be provided. A dedicated toilet for visitor should be made available.
3) **Housekeeping/Utility Room:** This room should have sufficient space for storing cleaning materials and equipment. It should have good ventilation for washing and drying of equipment.
4) **Security Guard Post:** This area should be located at the main entrance of the store. The room should be equipped with necessary equipments for the convenience of the security guard.

2.1.6. Floor Space Requirements

Hospital pharmacy floor area depends on the range of its operations, number of divisions, medicaments manufactured, number of patients served (out-patient pharmacy), number of indoor patients, strength of the pharmacy staff, etc. The floor space should be in accordance to the norms laid down by the Drugs and Cosmetics Act (under Schedule M). The floor area should be minimum 250m^2. The area requirements increase at 10m^2 per bed for 100 beds, 6m^2 per bed for 200 beds, and at least 5m^2 per bed for larger hospitals. Teaching institutes demand a greater area.

2.1.7. Staff Requirements

The hospital pharmacy comprises of many departments as per the set-up of the hospital. In small set-up, it has a dispensing department and a medical store; while in big set-up, it has manufacturing, quality control, and clinical pharmacy departments also.

The number of pharmacy staff members relies on the following factors:
1) Number of beds,
2) Service-out-patients and in-patients,
3) Whether the pharmacy is involved in manufacturing drugs or formulations, and
4) Whether the pharmacy is involved in stocking and dispensing of surgical and laboratory supplies.

A hospital pharmacy should appoint the following **staff personnel**:
1) One member as the Chief pharmacist or Director.
2) Atleast 4 registered pharmacists in smaller hospitals so that one pharmacist handles 60 patients. Total patients involve (both in-patients and out-patients).
3) Sufficient number of assistants, attendants, and sweepers.
4) Pharmacist-cum-clerk or clerks depending on the hospital size.
5) A hospital pharmacy manufacturing drugs and formulations should have manufacturing chemists and analytical chemists supported by additional assistant pharmacists.
6) For 50 bedded, 100 bedded, 200 bedded, 300 bedded, and 500 bedded hospitals, 3, 5, 8, 10, and 15, respectively pharmacists are needed. In big hospitals, one pharmacist is recommended for 133 patients.

Qualification

The Chief Pharmacist or Director should be a post graduate degree holder in pharmacy (preferably in pharmacology or hospital pharmacy). The manufacturing chemist is required to have graduated in pharmacy and hold experience in manufacturing drugs and formulations for at least 18 months. The analytical chemist should be a post graduate in pharmaceutical chemistry or analytical chemistry. Registered pharmacist and pharmacist-cum-clerk require diploma in pharmacy and registration in state pharmacy council.

2.1.8. Responsibilities and Functions of Hospital Pharmacists

Hospital pharmacists are engaged in hospital pharmacy services in public sector. They are skilled in practice of medicines and dispense prescriptions, purchase, manufact ures, and performs quality test of all medicines used in a hospital. Being the members of healthcare team, they coordinate with medical and nursing staff for better treatment of patient. They help and refer knowledge to patients on their medicines. The re sponsibilities of a pharmacist vary with the departments and this has been discussed below.

2.1.8.1. In-Patient Pharmacist Responsibilities

The areas of in-patient pharmacy department are:

1) **Dispensing Area:** The responsibilities of the pharmacist in dispensing area are:
   i) **Policies:** He/she ensures that the framed hospital policies and procedures are being obeyed.
   ii) **Accuracy:** He/she maintains proper control on the accuracy of dosages prepared (particularly for intravenous administration).
   iii) **Maintenance of Records:** He/she maintains records of drugs supplied, returned bills of investigational drugs and intravenous admixtures, etc.
   iv) **Storage:** He/she have adequate control over the stocked drugs.
   v) **Working:** He/she ensures the compliance of all the laws and rules, and that compounding is done by adequate techniques.
   vi) **Coordination:** He/she manages all the conducts of dispensing area.
   vii) **Drug Information:** He/she remains updated about the drugs in the hospital in terms of their side effects, therapeutic efficacy, stability, etc.

2) **Patient Care Area:** This area indicates any site of a hospital where patients are examined. Parts of the patient care area where pharmacists are involved are:
   i) **Coordination:** He/she coordinates all the pharmacy services in the nursing unit.
   ii) **Communication:** He/she consults nurses and medical staff for medicine administration problems.
   iii) **Technical:** He/she shares technical sections giving instructions to the technicians for new procedures and dealing with difficult patients. Pharmacist connects the technician, nursing, and medi cal staff, thereby ensuring that proper techniques are followed by the technician for drug administration.
   iv) **Supervisory:** He/she supervises and re -checks all the prescriptions for their correct entry in the unit dose system. The pharmacist periodically inspe cts individual patient's drug administration form for all doses being administered and charted correctly. He/she periodically ensures whether the administered doses are mentioned on patient's chart and the drug charges are correctly calculated. He/she re-examines the missed doses, re-schedules them, and signs all "Drugs not given" notices. He/she timely checks the medication areas for maintenance of adequate level of floor stock drugs and supplies.

3) **Direct Patient Care:** This relates to any facet of health ca re of a patient , like treatments, counselling, self -care, patient education, and drug administration. Parts of the direct patient care area involving pharmacists are:
   i) **Patient's Medication History:** He/she takes down the patient's medication history and forwards it to the physician.
   ii) **Identification of Drugs:** He/she identifies the drugs brought in the hospital by patient.
   iii) **Patient Monitoring:** He/she monitors the overall patient's drug therapy for its effectiveness, side effects, toxicities, and allergic reactions.

iv) **Patient Counselling:** He/she counsels the patient for self -administered drugs and discharge drugs.

v) **Selection of Drug:** He/she supports the physician while selecting the drugs, dose regimens, and schedule the time for drug administration.

vi) **Cardiopulmonary Emergencies:** He/she gets involved in emergencies , like cardiopulmonary cases.

4) **General Responsibilities:** He/she provides education and drug information to other health professionals.

2.1.8.2. Out-Patient Pharmacist Responsibilities

These responsibilities are categorised into three categories:

1) **Central Dispensing Area:** The pharmacists perform the following tasks:
   i) He/she ensures the use of correct compounding techniques.
   ii) He/she maintains adequate record and billing for patient's medication particulars, records of tentative drugs, records of out-patient's bills (charging of services and material), and maintaining and preparing all reports.
   iii) He/she keep up with the prescription files.
   iv) He/she maintains the tidiness of outdoor pharmacy.

2) **Patient Care Area:** The pharmacists perform the following tasks:
   i) He/she regularly visits an d checks the medication areas in the nursing unit. He/she ensures adequate supply of required drugs and other articles.
   ii) He/she identifies the drugs brought in the clinic by the patients.
   iii) He/she pharmacist records the patient's medication history and delivers it to the physician's knowledge.
   iv) He/she assists the physicianin selecting the drug regimen.
   v) He/she also helps in selecting right drug products and their entities.
   vi) He/she involves in patient counse lling for use of medication and preparation for intravenous administration.

3) **General Responsibilities**
   i) He/she understands and coordinates complete pharmaceutical needs of the outdoor service area.
   ii) He/she makes sure that all drugs are properly managed.
   iii) He/she takes part in cardiopulmonary emergencies.
   iv) He/she offers in -service education and training to pharmacists, pharmacy students taking practical training for their diploma or degree courses, and nurses.

2.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) **Hospital pharmacy** functions for receiving, storing and dispensing drugs and medicines to patients.
2) The **Chief Hospital Pharmacist** is the **head of pharmacy** who reports to the Administrator.
3) The number of **Assistant Chief Pharmacist**, who assists the Chief in administration, depends on the work, nature and scope of operations, staff strength, etc.
4) The pharmacy should be situated at the ground floor or the first floor to ease its accessibility
5) The **walls** should be of non-porous material and plastered on both sides.
6) The **floor** should be of concrete and smoothly plastered.

7) The **roof** should be pitched or sloped to prevent heavy rain damage.
8) The **doors** should be of fire-retardant material.
9) The **loading and unloading area** should be adequately spaced and properly sheltered by taking care of the vehicle height.
10) The **receiving counter** should have adequate waiting space and should be equipped with suitable office furniture and equipment.
11) The **sorting and unpacking area** should be adequately spaced to enable sorting and checking of goods.
12) The **disposal room** should store discarded items (like used boxes, wrappers and plastic covers).
13) The **storage area** should be provided with air-conditioning facilities for 24 hours. Its temperature should be effectively controlled between 160-250°C.
14) **Cold room/pharmaceutical refrigerator/freezer area** should be provided based on the functionality of hospital.
15) **Surgical store** is designed for storing bulk surgical/consumable/disposable items/X-ray films.
16) **Intravenous fluid store** should be adequately spaced to accommodate haemodialysis and peritoneal dialysis solution, and intravenous solutions.
17) **Non-drug bulk store** area is designed for storing dispensing bottles, containers, labels and envelopes.
18) **Corrosive items store** should be designed for the storage of corrosive items.
19) **Inflammable store** should be located at minimum 10 feet distance away from other adjacent buildings.
20) **Medical gas store** should be designed for the storage of portable medical gas cylinders.
21) Supply to various departments is carried out in **temporary holding area**.
22) **Issuing counter** should have an adequate waiting space, and should be equipped with appropriate office furniture and equipment.
23) **Pharmacist in-charge office area** is provided for the pharmacist in-charge to perform the administrative work.
24) **Pharmacist work station** is provided for the pharmacist.
25) **General office** is provided for the assistant administrative officers and administrative assistants.
26) **Document room** should have sufficient space for storing files and records.
27) **Meeting/discussion room** should have sufficient space for discussion and routine administrative meetings.
28) **Reception counter and customer waiting area** should be equipped with appropriate office furniture and equipments.

2.3. EXERCISE

2.3.1. True or False

1) The loading and unloading area should be adequately spaced and properly sheltered by taking care of the vehicle height.
2) The transit area should be adequately spaced to enable sorting and checking of goods.
3) Bulk store area is designed for storing dispensing bottles, containers, labels and envelopes.
4) General office is provided for the assistant administrative officers and administrative assistants.
5) Reception counter should be equipped with appropriate office furniture and equipments.

2.3.2. Fill in the Blanks

6) The _____ is the head of pharmacy who reports to the Administrator.
7) The floor should be of _____ and smoothly plastered.
8) _____ is designed for storing bulk surgical/consumable/disposable items/X-ray films.
9) Supply to various departments is carried out in _____.
10) _____ should have sufficient space for storing files and records.

Answers

1) True 2) False 3) False 4) True 5) True
6) Chief Hospital Pharmacist 7) Concrete 8) Surgical store
9) Temporary holding area 10) Document room

2.3.3. Very Short Answer Type Questions

1) Define hospital pharmacy.
2) Draw the organisation chart of hospital pharmacy.
3) What are the floor space requirements in a hospital pharmacy?
4) What qualification should the staff of a hospital pharmacy possess?

2.3.4. Short Answer Type Questions

1) Write a note on hospital pharmacy and its functions.
2) Discuss the responsibilities and functions of hospital pharmacists.
3) Give the out-patient responsibilities of hospital pharmacists.

2.3.5. Long Answer Type Questions

1) Discuss about the organisation of hospital pharmacy.
2) Write an illustrative note on the layout of hospital pharmacy.

CHAPTER 3

Adverse Drug Reactions

3.1. ADVERSE DRUG REACTIONS

3.1.1. Introduction

Any appreciable harmful or unpleasant reaction result ing from an intervention related to the use of a medicinal product, which predicts hazard from future administra tion and warrants prevention or specific tr eatment, or alteration of the dosage regimen or withdrawal of the product is known as an **Adverse Drug Reaction** (**ADR**).

Both toxic effects and side effects differ from each other. **Toxic effects** result due to higher doses, are harmful, and occur via the same mechanism as the therapeutic effects. **Side effects** are not associated with dose, may or may not be harmful, and occur via separate mechanism.

The terms **adverse drug reaction** and **adverse drug effect** can be used interchangea bly as the only difference between them is that an adverse reaction is related to the change in patient, while an adverse effect is related to the drug effect. However, the term **adverse event** should be considered separate from the other terms, because it i s an adverse outcome that occurs when a patient is receiving a drug but for which causality has not been determined, and it may or may not be related to the drug being administered.

3.1.2. Classification

ADRs can be classified into different categories by the **alphabetical classification system** (**table 3.1**). An **augmented response** (A) is related to the dose and predictable pharmacological action of the drug. This type of ADR can be managed by reducing the dose. **Bizarre effects** (B) are not related to the drug dose an d the reactions are also unpredictable. This type of ADR can be managed by not using the drug even in the future. **Chronic effects** (C) are related to drug dose and its administration time. This type of ADR can be managed by reducing the drug dose or withdra wal of the drug. **Delayed effects** (D) are carcinogenic, such as secondary cancers that occur years after chemotherapy. **End-of-treatment effects** (E) arise due to sudden withdrawal of many drugs. This type of ADR can be managed by re -introducing and subsequen tly slowing down the drug withdrawal.

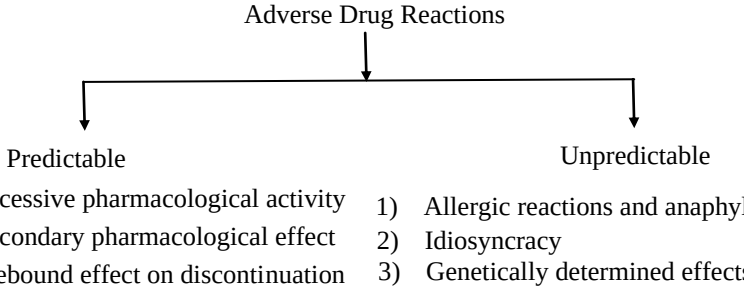
Table 3.1: Alphabetical Classification of Adverse Drug Reactions

Type	Type of Effects	Definition	Examples
A	Augmented Effects	Occur from the pharmacology of drug and are dose related.	Hypoglycaemia caused by insuli n injection; Bradycardia caused by β-adrenoceptor antagonists; Hypotension caused by calcium channel blockers; Haemorrhage caused by anticoagulants.
B	Bizarre Effects	Occur unpredictably and have a high rate of morbidity and mortality.	Anaphylaxis caused by penicillin; Acute hepatic necrosis caused by halothane; Tendon rupture with statin drugs and ciprofloxacin; Bone marrow suppression by chloramphenicol.

C	Chronic Effects	Occur only during prolonged treatment and not with single doses.	Iatrogenic Cushing's syndrome with prednisolone; Orofacial dyskinesia by phenothiazine tranquilisers; Colonic dysfunction by laxatives.
D	Delayed Effects	Occur either in children of any treated patients or in the patients themselves years after treatment.	Secondary cancers in patients treated with alkylating agents for Hodgkin's disease; Craniofacial malformations in infants whose mothers took isotretinoin; Clear-cell carcinoma of the vagina in daughters of women who took diethylstilbestrol during pregnancy.
E	End-of-Treatment Effects	Occur when a drug is suddenly stopped.	Unstable angina after β-adrenoceptor antagonists are suddenly stopped; Adrenocortical insufficiency after glucocorticosteroids (such as prednisolone) are stopped; Withdrawal seizures when anticonvulsants (such as phenobarbital or phenytoin) are stopped.

There is one more classification system of ADRs, which is comparatively simpler, i.e., **adverse drug events type A** including dose-related reactions, and **adverse drug events type B** including idiosyncratic or unpredictable reactions and adverse drug withdrawal events.

Adverse drug reactions are also classified as follows:



3.1.2.1. Excessive Pharmacological Effects

The excessive pharmacological effects a drug may produce lead to the most common adverse drug reactions. CNS depressants, hypoglycaemics, cardioactive agents, and hypotensive agents can give rise to such reactions.

These reactions develop in all patients when any drug is given in excessive dosage. However, these reactions may also occur at normal doses in neonates, geriatrics, in patients suffering from more than 70% kidney dysfunction, and in patients with lower albumin level due to liver or kidney damage.

Some **examples** of excessive pharmacological effects are:

1) Bradycardia in patients administering digoxin in excessive dosage.
2) Respiratory depression if patients having severe bronchitis are administered with morphine or benzodiazepine hypnotics.

3.1.2.2. Secondary Pharmacological Effects

Dose-related reactions include secondary pharmacological effects, iatrogenic effects, hyper-susceptibility, and overdose. Along with therapeutic effects, a drug also produces adverse or beneficial secondary effects. **For example,** morphine is an analgesic that can cause two adverse secondary effects, i.e., constipation and respiratory depression. Diphenhydramine is an antihistamine that produces sedation as a secondary effect, thus is used for inducing sleep.

There are many drugs that at average doses give rise to multiple pharmacological effects. Still, these drugs are prescribed for any one of these many actions. **For example,** antihistamines are prescribed either in allergic skin reactions or for their anti-nausea effects. In hospitalised patients, antihistamines cause drowsiness; but in travellers, they may produce secondary adverse pharmacological effects involving CNS depression that may be dangerous if the individuals are consuming hypnotics, tranquillisers, or OTC drugs.

Hence, excessive as well as secondary pharmacological effects give rise to a wide range of undesired drug effects in different patients.

3.1.2.3. Toxicity Following Sudden Withdrawal of Drugs

When an individual suddenly stops taking a drug that he/she has been taking for a long-term, a withdrawal or abstinence syndrome occurs. Acute withdrawal gives rise to variable symptoms, like sweating, tremors, anxiety, seizures, hallucinations, and delirium. Irritability and discomfort develops when the drug is stopped, and this stimulates many users to resume the intake of that drug. Such use of drugs acts as a self-medication to treat the unpleasant symptoms developed by not using those drugs. As a result, a vicious and escalating cycle is generated.

For CNS depressants (**e.g.,** alcohol, barbiturates, and benzodiazepines), a rebound effect of hyper-excitability may occur when their effects wear off after a drinking episode ends. This withdrawal reaction occurs markedly with higher use levels.

Withdrawal symptoms start occurring from 12-24 hours after stopping the drug and last for several days; however, this depends on the drug. The medical treatment for alcohol withdrawal involves sedating the hyper-excitability of the nervous system by using another drug of the same class of depressants, benzodiazepines, and vitamins. Barbiturates have also been used but they are associated with the risk of cross-tolerance (tolerance to one drug generalises to other drugs in the same category), thus are less preferred.

If alcoholic patients are given barbiturates to reduce withdrawal symptoms, they may quickly adapt due to cross-tolerance and fail to benefit. Thus, newer drugs such as clonidine and β-adrenergic blockers are used. With the reduction in withdrawal symptoms, the medical treatment is progressively decreased.

Naltrexone is an alcohol antagonist, which has been used for treating alcohol withdrawal symptoms. Naloxone is a heroin antagonist that competes with it to bind on the opiate receptors, therefore, has been used for treating heroin withdrawal symptoms.

3.1.2.4. Allergic Drug Reactions

Drug allergy (or hypersensitivity) is a type B adverse drug reaction. A drug allergy is often difficult to be diagnosed as there are no consistent laboratory tests for identifying the related drug (for which the allergic reaction has occurred). In some cases, the symptoms imitate that of the infectious disease. Diagnosis of an allergic reaction becomes easier if the administered drug is known to produce such a reaction (**e.g.,** penicillin); however the situation is difficult if the drug is hardly ever reported to produce any allergy.

Some drug can produce **pseudoallergic reactions** which resemble an allergic reaction but have no immunological basis. These reactions occur due to mast cell degranulation and consequent histamine release. These reactions also resemble type I hypersensitivity reaction. Histamine release on administration of opiates (**e.g.,** morphine), vancomycin, and radiocontrast media is an **example** of a pseudoallergic reaction.

Allergic reactions to drugs follow the type I -IV classification. In **table 3.2**, the types of reactions, main clinical manifestations, and examples of the concerned drugs are listed:

Table 3.2: Allergic Drug Reactions

Types/Reactions	Clinical Manifestations	Examples of Drugs
Immediate Hypersensitivity	Urticaria, anaphylaxis, angio-oedema, and bronchospasm.	Penicillins, streptomycin, local anaesthetics, neuromuscular blocking drugs, and radiological contrast media.
Antibody-Dependent Cytotoxic	Cytopenia, vasculitis, and haemolytic anaemia.	Quine, quinidine, rifampicin, and metronidazole.
Complex-mediated	Serum sickness, vasculitis, and interstitial nephritis.	Anticonvulsants, antibiotics, hydralazine, and diuretics.
Cell-mediated or Delayed Hypersensitivity	Contact sensitivity.	Local anaesthetic creams and antihistaminic creams.

3.1.2.5. Idiosyncrasy

Idiosyncratic adverse reactions are less common than pharmacological adverse reactions, but sometimes they may become serious and lead to many deaths. Drug metabolising system of the body is involved in the pathogene sis of several idiosyncratic reactions. Metabolism of drug (divided into phases I and II) serves as a defense mechanism as it triggers the excretion of parent drug and its metabolites, thereby preventing their accumulation in the body that might cause dose -dependent toxicity. Drug metabolism also inhibits the accumulation of some drugs within particular cells or cellular compartments to prevent toxicity. **For example**, perhexili ne (an anti -anginal agent) caused hepatotoxicity and peripheral neuropathy in indi viduals lacking CYP2D6 (debrisoquine hydroxylase) isoform of cytochrome P-450.

Enzymes involved in drug metabolism, mainly the phase I cytochrome P-450 enzymes, may form chemically reactive and toxic metabolites by **bioactivation** process. In many individuals, formation of such metabolites is counter-balanced by **bioinactivation** (a detoxification mechanism). However, the balance between bioactivation and bioinactivation in vulnerable individuals is disturbed by either genetic or host factors such as age, enzy me induction, and disease. These factors prevent the detoxification of toxic metabolites, thus allowing them to bind covalently to various cellular macromolecules and cause toxicity. With most of the drugs, the factors causing this imbalance are not known, and this is the reason such reactions continue to occur.

In some cases, chemically reactive metabolites are formed regardless of the dose. At therapeutic doses, the formed toxic metabolite is detoxified by cellular defense mechanisms. On the other hand, in case of overdoses, an imbalance occurs between bioactivation and bioinactivation. This leads to the formation of excessive chemically reactive metabolites that overcome the cellular detoxification capacity and cause cell damage.

Cancer of Organ	Causative Drugs
Vaginal adenocarcinoma	High doses of stilbestrol during pregnancy.
Kidney pelvis	Analgesic-induced nephropathy
Uterus	Oestrogens (long-term use)
Lymphoid tissue	Azathioprine and cyclophosphamide (long-term use)

The term **idiosyncrasy** is used for uncommon and unexpected drug effects. It also includes drug -induced foetal abnormalities, **for example** , phocomelia in progeny of mothers taking thalidomide. This drug is a potential teratogen, but its mechanism is unidentified. If mothers take this dru g in the initial period of gestation when the limb buds are forming, the new -born will have sealed limbs. One more idiosyncratic reaction is drug-induced cancer. A long induction period exists between the exposure to drug and

development of tumours, thus very less is known about the drug factors involved in cancer etiology.

3.1.2.6. Genetically Determined Toxicity

Patients with special genotype or genetic make-up have an increased risk of drug toxicity. Some **examples** of such reactions are:

1) Patients with hereditary deficiency of pseudocholinesterase cannot metabolise succinylcholine (muscle relaxant), thus its use results in prolonged paralysis and apnoea.
2) Glucose-6-phosphate dehydrogenase enzyme causes glucose degradation. Individuals who are deficient in this enzyme can develop haemolytic anaemia after taking primaquine, quinidine, aminoquinolines, sulphonamides, and nitrofurantoin.
3) Isoniazid, hydralazine, and procainamide are metabolised in the liver by N-acetyl transferase enzyme. Some individuals are slow and some are fast acetylators. The slow acetylators of isoniazid suffer from peripheral neuropathy; while the slow acetylators of hydralazine and procainamide suffer from drug-induced lupus syndrome.

Other **examples** of genetically determined drug toxicities are given below:

Table 3.3: Examples of Genetically Determined Drug Toxicities

Hereditary Conditions	Drugs Causing Toxicity
Porphyria	Barbiturates, sulphonamides, tolbutamide, and griseofulvin
Glaucoma	Corticosteroids
Methemoglobinemia	Phenacetin and salicylates

3.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) Any harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen or withdrawal of product is known as an **Adverse Drug Reaction** (**ADR**).
2) **Toxic effects** result due to higher doses, are harmful, and occur via the same mechanism as the therapeutic effects.
3) **Side effects** are not associated with dose, may or may not be harmful, and occur via separate mechanism.
4) **Adverse event** is an adverse outcome that occurs when a patient is receiving a drug but for which causality has not been determined, and it may or may not be related to the drug being administered.
5) An **augmented response** (A) is related to the dose and predictable pharmacological action of the drug.
6) **Bizarre effects** (B) are not related to the drug dose and the reactions are also unpredictable.
7) **Chronic effects** (C) are related to drug dose and its administration time.
8) **Delayed effects** (D) are carcinogenic, such as secondary cancers that occur years after chemotherapy.
9) **End-of-treatment effects** (E) arise due to sudden withdrawal of many drugs.
10) Drug allergy (or hypersensitivity) is a type B adverse drug reaction.
11) The term **idiosyncrasy** is used for uncommon and unexpected drug effects.

3.3. EXERCISE

3.3.1. True or False

1) Side effec ts result due to higher doses, and occur via the same mechanism as the therapeutic effects.
2) Adverse event is an adverse outcome that occurs when a patient is receiving a drug but for which causality has not been determined.
3) An augmented response is related to the dose and predictable pharmacological action of the drug.
4) Bizarre effects arise due to sudden withdrawal of many drugs.
5) Drug allergy or hypersensitivity is a type C adverse drug reaction.

3.3.2. Fill in the Blanks

6) The term _____ is used for uncommon and unexpected drug effects.
7) _____ effects are carcinogenic, such as secondary cancers that occur years after chemotherapy.
8) _____ effects are related to drug dose and its administration time.
9) _____ effects are not related to the drug do se and the reactions are also unpredictable.
10) _____ are not associated with dose, may or may not be harmful, and occur via separate mechanism.

Answers

1)	False	2)	True	3)	True	4)	False	5)	False
6)	Idiosyncrasy	7)	Delayed	8)	Chronic	9)	Bizarre	10)	Side effects

3.3.3. Very Short Answer Type Questions

1) Define adverse drug reaction.
2) Classify the types of allergic drug reactions.
3) Give two examples of excessive pharmacological effects.
4) Give examples of genetically determined toxicity.

3.3.4. Short Answer Type Questions

1) Write a short note on genetically determined toxicity.
2) Discuss idiosyncrasy.
3) Write about excessive and secondary pharmacological effects.

3.3.5. Long Answer Type Question

1) Write an illustrative note on the classification of adverse drug reactions.

CHAPTER 4

Drug Interactions

4.1. DRUG INTERACTIONS

4.1.1. Introduction

A situation in which a substance **affects the drug activity** (i.e., either increases or decreases the effects) or **produce a new effect** that does not produces on its own is termed as **drug interaction**. Interaction between drugs (i.e., drug-drug interaction) occurs most commonly. However, interactions also occur between drugs and foods (i.e., drug - food interactions), and drugs and herbs (i.e., drug-herb interactions).

Drug interactions should be avoided, or else they will give rise to poor or unanticipated consequences. However, sometimes **drug interactions are used deliberately**, such as co-administering probenecid and penicillin prior to mass production of penicillin. Manufacturing penicillin was difficult, so it was necessary to find a way by which the amount of penicillin required can be reduced. Probenecid delays penicillin excretion, thus penicillin persists longer within the body if taken with probenecid. As a result, patients take less penicillin during their therapy.

4.1.2. Beneficial Interactions

Some drug interacti ons are beneficial and intended when a combination of therapeutic agents shows improved therapy, produces greater therapeutic window or safety margin, gives a good onset or duration of action, and reduces toxicity or increases potency by minimising the side effects. These beneficial interactions are also termed as **intentional drug interactions**.

Table 4.1 enlists some common drug combinations that prove to be beneficial:

Table 4.1: Drug Combinations with Potential Advantages

Potential Advantages	Examples
Improved compliance	Anti-tubercular agents (rifampicin and isoniazid) + Ferrous sulphate + Folic acid.
Ease of administration	Triple vaccine (diphtheria, pertussis, and tetanus).
Synergistic effect	Trimethoprim + Sulphamethoxazole. Aspirin + Codeine Estrogen + Progesterone (oral contraceptives)
Decreased adverse effects	Levodopa + Carbidopa Aluminium salt + Magnesium salt (antacids).

4.1.3. Adverse Interactions

The drug-drug interactions which counteract or alter the therapeutic effects of prescribed medications negatively are termed **adverse interactions**. Such interactions result from the errors that occur during prescribing, dispensing or administering a combination of drugs that potentiate, inhibit or oppose the normal therapeutic or physiological effects inside the body. Generally by altering the dosage, an adverse drug interaction can be avoided or re duced up to an acceptable limit; but if any serious effect occurs, it is better to avoid the interacting combination completely.

Table 4.2: Adverse Drug Interactions

Analgesics		
Analgesics	**Interacting Drugs**	**Possible Effects**
Opioids	Phenoxybenzamine	Depressor effect of opioids is exaggerated.
Salicylates	Alkalinisers and antacids	Serum levels of salicylate decreases as the renal reabsorption of salicylate from alkaline urine reduces.
Salicylates	Indomethacin	Serum level of indomethacin decreases due to inhibition of gastrointestinal absorption.
Salicylates	Acidifiers, ascorbic acid, and ammonium chloride	Serum levels of salicylate increases due to enhancement in the renal absorption of salicylate from acidic urine.
Salicylates	Heparin and warfarin	Aspirin inhibits platelet aggregation, thus giving rise to additive effect which causes bleeding.
Salicylates	Probenecid	Uricosuric activity of probenecid decreases as both compete for the same binding site (albumin molecule) on plasma.
Phenylbutazone	Tolbutamide	Hypoglycaemic response increases as tolbutamide metabolism is inhibited.

Diuretics		
Diuretics	**Interacting Drugs**	**Possible Effects**
Furosemide, thiazides, and ethacrynic acid	Sulfonylureas	Effect of sulfonylureas antagonises due to depression of islets of Langerhans.
Thiazides	Methyldopa, guanethidine, and reserpine	Antihypertensive effects are increased by thiazides and this may cause hypotension.
Furosemide, thiazides, and ethacrynic acid	Digoxin	Cardiac effect and toxicity due t o potassium depletion enhances.
Furosemide	Phenytoin	Response of furosemide decreases due to increase in sodium absorption.
Acetazolamide	Quinidine	Serum level of quinidine increases.
Spironolactone	Potassium chloride	Hyperkalaemia occurs as spironolac tone is a potassium sparing diuretic.

Cardiovascular Drugs		
Cardiovascular Drugs	**Interacting Drugs**	**Possible Effects**
Digitalis glycosides	Magnesium, calcium, and aluminium salts containing antacid	Absorption of cardiac glycosides decreases in GIT.
Digitoxin	Barbiturates	Digitoxin effect decreases due to induction of hepatic microsomal enzymes (responsible for digitoxin metabolism).
Quinidine	Digitalis glycoside	Clearance of digitalis glycosides is decreased and also displaced from the binding site by qui nidine, thus cardiac effect and toxicity of cardiac glycoside increases.
β-blockers (propranolol and atenolol)	Anti-diabetic agents	Release of glucose from the liver glycogen is inhibited by β-blockers and this causes hypoglycaemia.
Guanethidine	Tricyclic antidepressant	Antihypertensive effect antagonises as guanethidine uptake is inhibited.

Gastrointestinal Drugs

Gastrointestinal Drugs	Interacting Drugs	Possible Effects
Antacids	Aspirin	Absorption of aspirin decreases.
Magnesium carbonate and magnesium trisilicate	Digitalis glycoside	Absorption of cardiac glycosides decreases.
Aluminium hydroxide gel	Isoniazid	Absorption of isoniazid decreases.
Metoclopramide (antiemetic)	Levodopa	Absorption rate of levodopa decreases due to decrease in GIT motility.
Kaolin-pectin mixture	Digoxin	Absorption of digoxin decreases.

Vitamins

Vitamins	Interacting Drugs	Possible Effects
Vitamin B_{12}	Chloramphenicol	Vitamin B_{12} effect decreases due to interference in erythrocyte maturation.
Vitamin A	Mineral oil	Mineral oil impairs v itamin A absorption.
Vitamin B_6	Levodopa	Pyridoxine increases levodopa metabolism, thus decreases its effectiveness.
Vitamin D	Phenytoin and phenobarbital	Vitamin D metabolism is stimulated which reduces calcium serum level.
Vitamins	Oral contraceptives	Oral contraceptives cause deficiency of vitamin $B_{12,}$ vitamin C, vitamin B_6, and folic acid by inhibiting enzyme required for their absorption.

Hypoglycaemic Agents

Hypoglycaemic Drugs	Interacting Drugs	Possible Effects
Hypoglycaemic drugs	Alcohol	Hypoglycaemic effect of alcohol causes hypoglycaemia.
Hypoglycaemic drugs	Oral contraceptives	Glucose tolerance impairs.
Insulin	Propranolol	Insulin activity increases.
Sulfonylureas	Anticoagulant	Hypoglycaemic activity increases.
Sulfonylureas	Rifampin	Hypoglycaemia occurs due to increase in metabolism.

4.1.4. Pharmacokinetic Drug Interactions

Pharmacokinetic drug interactions are those in which the absorption, distributio n, metabolism and/or excretion of object drug are altered by the precipitant. The resultant effect is altered plasma concen tration of the object drug. Some important pharmacokinetic drug interactions are enlisted in **table 4.3**:

Table 4.3: List of Important Pharmacokinetic (ADME) Interactions

Object Drug(s)	Precipitant Drug(s)	Influence on Object Drug(s)
Absorption Interactions		
1) **Complexation and Adsorption**		
Tetracycline and penicillamine	Antacids, food and mineral supplements containing Al, Mg, Fe, Zn, Bi and Ca ions	Formation of poorly soluble and unabsorbable complex with such heavy metal ions.
Ciprofloxacin and norfloxacin	Antacids containing Al, Mg and Ca and sucralfate	Reduced absorption due to complexation with metal ions.
Cephalexin, sulfamethoxazole, trimethoprim, w arfarin and thyroxine	Cholestyramine	Reduced absorption due to adsorption and binding.

2) **Alteration of GI pH**		
Sulphonamides and aspirin	Antacids	Enhanced dissolution and absorption rate.
Ferrous sulphate	Sodium bicarbonate and calcium carbonate	Decreased dissolution and absorption.
Ketoconazole, t etracycline, and atenolol	Antacids	Decreased dissolution and bioavailability.
3) **Alteration of Gut Motility**		
Aspirin, diazepam, levodopa, lithium carbonate , paracetamol, and mexiletine	Metoclopramide	Rapid gastric emptying and increased rate of absorption.
Levodopa, lithium carbonate, and mexiletine.	Anti-cholinergics (atropine and homatropine)	Delayed gastric emptying and decreased rate of absorption.
4) **Alteration of GI Microflora**		
Digoxin	Antibiotics (erythromycin and tetracycline)	Increased bioavailability due to destruction of bacterial flora that inactivates digoxin in lower intestine.
Oral contraceptives	Antibiotics (ampicillin)	Decreased reabsorption of drugs secre as conjugates via bile in the intestine.
5) **Malabsorption Syndrome**		
Vitamin A, B_{12}, and digoxin	Neomycin (colchicine)	Inhibition of absorption due to malabsorption/ steatorrhea caused by neomycin.

Distribution Interactions (Resulting from Altered P-D Binding)		
Competitive Displacement Interactions		
Displaced Drug(s)	**Displacer(s)**	**Influence on Displaced Drug(s)**
Anticoagulants (warfarin)	Phenylbutazone, c hloral hydrate, and salicylates	Increased clotting time and risk of haemorrhage.
Tolbutamide (long acting)	Sulphonamides	Increased hypoglycaemic effect.
Methotrexate	sulphonamides, and salicylic acid	Increased methotrexate toxicity.
Phenytoin	Valproic acid	Phenytoin toxicity.

Metabolism Interactions		
1) **Enzyme Induction**		
Corticosteroids, oral contraceptives, coumarins, phenytoin, tolbutamide, and tricyclics	Barbiturates	Decreased plasma levels and efficacy of displaced drugs.
Corticosteroids, oral contraceptives theophylline, and cyclosporine	Phenytoin	-do-
Oral c ontraceptives, oral hypoglycaemic, coumarins	Rifampicin	-do-
2) **Enzyme Inhibition**		
Tyramine rich food (cheese, liver, yeast products)	MAO inhibitors (phenelzine, pargyline, etc.)	Enhanced absorption of unmetabolised tyramine; increased pressure activity, potentially fatal risk of hypertensive crisis.
Folic acid	Phenytoin	Decreased absorption of folic acid due to inhibition of an enzym e responsible for its efficient absorption.
Tricyclic antidepressants	Chlorpromazine and haloperidol	Increased plasma half -life of tricyclics; increased risk of sudden death from cardiac disease in such patients.

Coumarins	Metronidazole and phenylbutazone	Increased anticoagulant activity; risk of haemorrhage.
Oral hypoglycaemics	Phenylbutazone, sulfaphenazole, and chloramphenicol	Hypoglycaemia may be precipitated.
Alcohol	Disulfiram, metronidazole, and tinidazole.	Disulfiram-like reactions due to increase in plasma acetaldehyde levels.
Azathioprine and mercaptopurine	Xanthine oxidase inhibitors (allopurinol)	Increased toxicity of anti - neoplastics.
Alcohol, benzodiazepines, warfarin, phenytoin, theophylline, and phenobarbital	Cimetidine	Increased blood levels of object drugs.

Excretion Interactions		
1) **Changes in Active Tubular Secretion**		
Penicillin, PAS, cephalosporin, methotrexate, nalidixic acid, and dapsone	Probenecid (acid).	Elevated plasma levels of acidic drugs; risk of toxic reactions.
Procainamide and ranitidine	Cimetidine (base)	Increased plasma levels of basic object drugs; risk of toxicity.
Acetohexamide	Phenylbutazone	Increased hypoglycaemic effect.
2) **Changes in Urine pH**		
Amphetamine, tetracycline, and quinidine	Antacids, thiazides, and acetazolamide	Increased passive reabsorption of basic drugs; increased toxicity.
3) **Changes in Renal Blood Flow**		
Lithium	NSAIDs (inhibitors of prostaglandin synthesis; the latter con trol renal blood flow partially by vasoconstriction)	Decreased renal clearance of lithium; risk of toxicity.

4.2. METHODS FOR DETECTING DRUG INTERACTIONS

4.2.1. Introduction

ADR is detected by the following two methods:

1) Pharmacovigilance, and
2) Epidemiological methods.

4.2.2. Pharmacovigilance (Spontaneous Case Reports and Record Linkage Studies)

Pharmacovigilance is a branch of clinical pharmacy in which drug -induced unknown adverse effects and their ris k factors are detected and studied to prevent iatrogenic disease and promote safe and rational use of drugs. The WHO defined pharmacovigilance as "**the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem**".

The newly marketed drugs should be studied so that their undesirable and unexpected effects can be determined. Clinical trials can produce limited data regarding the rare and unexpected adverse effects. The dru g-related knowledge increases with time, and this is essential for post -marketing investigation, i.e., safety evaluation of a drug that has been

approved for marketing in order to provide alert signals about the possible adverse effects the drug may cause.

Monitoring of Adverse Drug Reaction

The process of detecting an adverse drug effect consists of:

1) Hypothesis generation,
2) Hypothesis strengthening and preliminary assessment of the available data, and
3) Signal testing, evaluation, and explanation.

A **signal** is defined as a set of pharmacological, pathological or epidemiological data and arguments establishing a hypothesis which is significant for the rational and safe use of a drug in humans. These signals are derived by making observations in a patient or in populations or from experimental studies.

Spontaneous Case Reports

The spontaneous case reports include the **results obtained after post-marketing surveillance of drugs**. Such reporting has been started since 1960s in developed countries, where a spontaneous reporting system was developed for collecting the data of ADRs voluntarily. Generally, reports obtained from ADRs are available in national drug formularies or drug bulletins.

Spontaneous reporting systems provide information about serious and unpredicted drug reactions. They are relatively inexpensive 'early warning systems' that inform about any potential problems observed during the post-marketing phase of a drug. Once the clinical trial is completed, the drug is marketed and prescribed to a population that usually differ to a great extent from the population on which it was tested during the clinical trials (**e.g.,** elderly people, people with co-morbidity patterns that differ from the trial populations, pregnant women or children). Spontaneous reporting systems do not provide any information about the population consuming a certain drug and the duration of therapy. These systems do not calculate the frequency of ADRs and also do not compare ADRs between drugs; therefore, pharmacoepidemiological studies are performed.

There are a large number of under-reported cases with spontaneous reporting system. Almost 90% of prescribers never report a suspected ADR and also reporting rates are rarely stable over time. It has been observed that the pharmacists report more frequently, but are less aware of an ADR, because patients contact to physician or doctor and not to their pharmacist about the adverse effects. The reasons behind the under-reporting are named as **the seven deadly sins** by **Inman** in **1986**:

1) Satisfaction with the wrong belief that only safe drugs are allowed to be marketed and prescribed.
2) Fear of any legal action.
3) A feeling of guilt because the patient health has been harmed by the drugs prescribed by a doctor.
4) Ambition to collect and publish a personal series of cases.
5) Lack of desire for reporting.
6) Hesitancy on reporting measly doubts which might lead to mockery.
7) A person is not bothered to report the ADR.

Under-reporting of ADRs may lead to various problems that are characteristic for spontaneous reporting systems:

1) Frequency of ADRs remains unnoticed most of time.
2) Causing delayed detection of ADRs.
3) A significant under-reporting may not be random but a selective process.
   For example, reporting rates of a newly launched drug are generally more during the first year.

Many countries have tried to improve the reporting rates of ADRs and for this purpose, they have developed methods of feedback to reporters. This feedback includes a preliminary evaluation of a reported adverse case, therapy advice on how to deal with the adverse action, recording the report by a telephone call, a personal visit, occasional publication of a case series in scientific medical journals, or regular public ation of recently reported ADRs.

It is a common method of raising doubts about drug-induced diseases. If a physician doubts that an undesirable condition occurring in a patient is because of a particular prescribed drug, he/she reports about it either in a letter to the medical journals or to the drug manufacturer. This alerts the other physicians and they avoid prescribing that drug.

Spontaneous reporting agencies are set-up to collect and gather such case reports. Although the resulting information collected gives no idea of the frequency with which a given event is caused by a drug, it indicates that a number of prescribers feel that the event is possibly drug related.

Advantages of Spontaneous Reporting

1) This reporting process is relatively cheap.
2) A medicine can be monitored throughout its life.
3) Monitoring of over-the-counter medications and herbal therapies is also possible.

These methods are included under passive surveillance systems. The efficiency and accuracy of these systems depend on the ability of health professionals to identify potential ADRs and to differentiate them on the basis of symptoms related to underlying disease. Here it is essential to know that only a suspicion of a causal link between a drug and an adverse event is sufficient, and confirmation of the association is not required.

The main **drawback** of **spontaneous reporting systems** is their inability to quantify the risk. These systems only provide information on the number of cases of ADRs reported and not the incidence of reactions because the population exposed to the drug cannot be accurately determined. Along with this, only a few reactions of ADR are reported. However, spontaneous reports are important evidences that lead to drug withdrawals and are crucial for generating hypothesis.

Record Linkage Studies

Details regarding the cause of death (as recorded on death certificate) or of hospitalisation (as recorded on the discharge letter) are collected and analysed routinely. This provides an early warning of an epidemic of drug-related disease. Record linkage studies can be used to facilitate the research for drug-induced disease.

Medical record linkage uses computer and related software to study life and health events (birth, marriage, death, hospital admission) of the population along with prescription event monitoring and history of drug used. They are developed till resources are available.

4.2.3. Epidemiological Methods

The various epidemiological methods are:

1) **Case-Control Studies:** In these studies, a group of patients having a disease assumed to be caused by a drug (the 'cases') is compared with another group of patients not having the disease (the 'controls'). Drug histories of the cases and controls are compared. If the disease is caused by the suspected drug, the drugs have been extensively used in the cases that in the controls. Such case-control studies are performed at relatively low cost; however, they should be conducted properly and the obtained data should be appropriate.

During the case control studies, following **precautions** should be taken:

i) Selection of case should be performed carefully.
ii) A clear, precise and accurate description of the disease should be given. The disease under study should have a reasonable risk of being drug induced.
iii) The controls defined should be according to the population of cases but not according to the disease of interest. Controls are usually the hospitalised patients.
iv) The results should be determined accurately and precisely.

2) **Cohort Studies:** Cohort is a group of recipients of drug of interest and studies involve observing them for different time periods to check what happens to them. These studies are used for short-term clinical trials of new drug. Cohort studies are beneficial in detecting predictable adverse effects arising due to excessive pharmacological effects during or after short-term treatment.

4.3. ADVERSE DRUG REACTION REPORTING AND MANAGEMENT

4.3.1. Introduction

During reporting an ADR, the healthcare professional should keep in mind that these reports are only showing suspected associations of a drug with a particular adverse event. Reporting an ADR does not confirm a causal relationship between the drug and the adverse reaction. But, it is always better to report a case in a doubtful situation.

Any undesirable ADR suspected to be resulted due to the use of any drug, biological (including blood products), herbal agents, cosmetics or medical devices should be reported. Some of the **examples** are:

1) All suspected ADRs to be associated with a prescribed or non-prescribed medication.
2) The marketing companies should provide all suspected ADRs regardless of whether or not the product was used according to the information provided.
3) All the information related to the unexpected reaction should be reported regardless of their nature, severity, and frequency.
4) The frequency of a given reaction is observed to be increased.
5) Any serious reaction, whether expected or not should be reported.
6) All the adverse reactions that may occur due to drug-drug, drug-food or drug-food supplements interactions should be monitored.
7) Monitoring of ADRs in special cases, like drug abuse and drug use in pregnancy and during lactation, should be done properly.
8) ADRs due to overdose or medication error should also be reported.
9) Reporting of ADRs that result due to unusual lack of efficacy or when suspected pharmaceutical defects are observed.

4.3.2. ADR Case Report

The minimal standard information is required for proper assessment of the ADR reports and it covers the following information:

1) **Patient Information**
   i) **Patient Identity:** It includes initials or record number of the patient in hospital, medical institution, dispensary, clinic, or pharmacy.
   ii) **Birth Dates or Age:** It includes date, month and year.
   iii) **Sex:** Male or female.
   iv) **Weight:** It should be measured in kilograms.

2) **Adverse Reaction(s)**

i) **Brief Description of the ADR(s):** It giv es information about the adverse reaction(s) by marking X on the right box. It gives clear and brief information about the adverse reactions being reported along with the body site and severity.

ii) **Time/Date of Onset of the Adverse Reactions:** Clear informati on should be provided about the time of onset or the occurrence of the adverse reaction with respect to the drug administration. The date of onset should be given in the order of day, month and year. **For example,** adverse reactions appeared immediately after drug administration or there was a temporal or spatial correlation with administration.

iii) **Other Relevant Information:** It includes information about:

a) Patient's medical history or laboratory data along with the dates (if available), considered relevant to the case or the adverse reaction being reported should be entered.

b) Laboratory tests done to the patient and results should be mentioned to confirm the adverse reaction.

Such information should be concise and clear.

3) **Suspected Drug(s)**

i) **Name of the Suspect ed Drug (s):** The trade name of the drug should be mentioned clearly. But in case the trade name is not available, the generic name should be documented along with the strength of drug(s).

ii) Dosage, f requency and administration route of drug should be clearly mentioned. **For example,**

Examples

a) **Dosage:** The dosage form (tablet, capsules, syrup, injection, cream, eye drops, etc.) along with the total amount of drugs should be mentioned.

b) **Frequency:** The unit (i.e., mg, ml, mg/kg) and number of time s a drug is to be administered (**e.g.,** 4 times daily or q.i.d.) should be mentioned.

c) **Route of Administration:** The drug administration route should also be mentioned either in full form or abbreviated form according to the WHO codes:[1]

Routes	Codes	Routes	Codes
Buccal	BU	Intrathecal	IT
Conjunctival	CO	Intratracheal	TR
Dental	DE	Intrauterine	IU
Implant	MP	Intravenous	IV
Inhalation	IH	Intravesical	IB
Insufflation	IS	Per oral	PO
Intra-arterial	IA	Per rectal	PR
Intra-articular	IR	Subcutaneous	SC
Intra-cardiac	IC	Sublingual	SL
Intradermal	ID	Systemic (if route is not specified)	SY
Intramuscular	IM	Topical (external)	TO
Intranasal	IN	Transmammary transfer	TM
Intraperitoneal	IP	Urethral	UR
Intrapleural	IL	Vaginal	VA

iii) **Therapy Date:** The starting and ending date of drug administration should be given clearly in the following manner, i.e., date, month and year. In case exact dates are not available, the duration of treatment should be mentioned. If drug administration has been continued and not ended at th e time of reporting, it should be stated as 'Continuing'.

iv) **Batch Number and Expiry Date:** These should be provided if available.

v) **Reason for Use:** The condition or disease for which the drug(s) was being administered should be mentioned.

vi) **Particular of Concurrently Drugs (or Other Treatment):** Information about the other drug(s) administered by the patient along with the suspected drug should be given. Also, information on the drugs administered for atleast 1 month back along with the dosage, administration route, duration and indications should be mentioned. Information related to medical devices used should also be provided.

4) **Management of the Adverse Reaction**

i) **Confirmation of the ADRs:** It includes the procedures required to confirm the suspected adverse reactions. **For example,**

a) ADRs confirmed by disappearance on stopping the administration of the drug or reducing the doses.

b) Patient recovers on withdrawal of the suspected drug(s) if no other drug is withdrawn and no therapy is given.

c) Recovery includes withdrawal of drug causing ADR along with the treatment of ADRs.

ii) **Criteria:** The criteria for considering a drug reaction as ADR should be mentioned

iii) **Treatment:** Information about any treatment given to the patient after experiencing the ADRs should be mentioned.

iv) **Outcome:** The symptoms of adverse reaction should be mentioned by marking X in the appropriate box with dates in case of fatal outcome.

5) **Reporter Information:** The name, address of the health facility (hospital, institution, dispensary, clinic, company, pharmacy or maternity home), E-mail address (optional), signature, telephone number, and date of reporting the reaction (indicate date, month and year) should be mentioned.

4.3.3. Reporting Person

Submission of a report does not mean that a healthcare professional or the drug or the product caused or contributed to the ADR in any way because all reports are considered as suspected results. The reporters should keep in mind that any information related to them and the patient identities should remain confidential.

It is the professional responsibility of all healthcare professionals practicing in India including specialists, doctors, dentists, pharmacists, nurses, assistant medical officers, clinical officers, pharmaceutical technicians, pharmaceutical assistants, traditional medicine practitioners and other healthcare providers to provide reports of any case of suspected ADRs.

A system should be developed by the manufacturers or product registrants to follow-up ADR within their company and to analyse impact of notification of significant safety data on their products.

All government hospitals, private hospitals, health centres, dispensaries, private clinics, private pharmacies, and private nursing homes should report all ADR cases about which the patients have complained.

A local person should be appointed by the government and private hospitals, health centres, and dispensaries to coordinate the ADRs collection and report within the facility.

It is compulsory to report an ADR to CDSCO even if a precise relationship is not confirmed with the given medication or all the data and facts are not available. Reports from various healthcare providers in different parts of country should be collected to identify the associations between a particular drug and the ADR.

Therefore, it is necessary that all required information for submission of ADR reports should be obtained and reported through the reporting forms.

4.3.4. Time to Report

Reporting of any suspected ADR should be done immediately as any delay in reporting may lead to wrong and unreliable reporting. Reporting should possibly be done when the patient is still in the health facility as it gives a chance to the reporter to re-question or examine the patient to clear any doubt.

4.3.5. Way to Report

For making a better and efficient programme on ADRs monitoring, the reporter should send accurate information. Following are the ways which make an efficient and accurate reporting of ADRs:

1) Report should be prepared on a standardised form (specially designed for reporting ADRs). This reporting form is self-adhesive postage paid "red coloured form".
2) The ADRs reporting form (annexed) should be filled when a patient experiences ADR.
3) A different form should be used for different patients.
4) A duly filled ADR reporting form should be sealed and mailed within three days directly to CDSCO or through other reporting centres for onward transmission to the CDSCO.
5) Reports can also be submitted online by going to the CDSCO website or can be sent by e-mail.
6) In case of urgency, the ADR reports should be faxed to CDSCO or related agency.
7) Any additional information related to an ADR case that has been reported later can be sent on another ADR form, or communicated by telephone, fax or e-mail. The information in the follow-up reports should be matched with the original report and for this following information should be provided in the follow-up report:
   i) It is a follow-up information,
   ii) Date of the original report, and
   iii) Patient's identity.

4.3.6. Basic Principles of Efficient Reporting

An efficient reporting is based on the following basic principles:

1) The adverse reaction should be reported as early as possible after it occurred.
2) If possible, the report should be prepared when the patient is still with the reporter, so that the details can be filled in at once on the reporting form.
3) Any other factors which may explain the occurrence of adverse event such as any other prescribed drugs, self-medication, herbal products, food, and chemicals should be mentioned. The patient should be asked particularly about other medicines they are taking.
4) If any supplementary data is collected later in case the patient later develops some other symptoms or if something happens which increases suspicion or seem to exclude the reaction, a supplementary note should be immediately send using ADRs reporting form along with the patient identifiers.

5) All the ADR reports should have the following four basic points:
   i) An identifiable patient,
   ii) A suspected adverse effect,
   iii) A named suspected drug(s), and
   iv) An identifiable reporter.
6) The report should be written clearly in a readable format.

4.3.7. Source of ADR Reporting Form

The ADR reporting form can be obtained free of charge from the following agencies:
1) CDSCO offices,
2) The website of CDSCO, downloaded at http://www.cdsco.nic.in,
3) Zonal Drug Information Centres, and
4) Regional hospital, district hospitals , and ADRs l ocal persons in hospitals, health centres, clinics, and dispensaries.

4.4. SUMMARY

The details given in the chapter can be summarised as follows:
1) A situation in which a substance **affects the drug activity** (i.e., either increases or decreases the effects) or **produce a new effect** that does not produces on its own is termed as **drug interaction**.
2) Beneficial interactions are also termed as **intentional drug interactions**.
3) The drug-drug interactions which counteract or alter the therapeutic effects of prescribed medications negatively are termed **adverse interactions**.
4) **Pharmacokinetic drug interactions** are those in which the absorption, distribution, metabolism and/or excretion of object drug are altered by the precipitant.
5) **Pharmacovigilance** is a branch of clinical pharmacy in which drug -induced unknown adverse effects and their risk factors are detected and studied to prevent iatrogenic disease and promote safe and rational use of drugs.
6) The WHO defined **pharmacovigilance** as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem".
7) The **spontaneous case reports** include the results obt ained after post -marketing surveillance of drugs.
8) **Spontaneous reporting systems** provide information about serious and unpredicted drug reactions.
9) The main **drawback** of **spontaneous reporting systems** is their inability to quantify the risk.
10) **Record linkage studies** can be used to facilitate the research for druginduced disease.
11) In **case-control studies**, a group of patients having a disease assumed to be caused by a drug (the 'cases') is compared with another group of patients not having the disease (the „controls').
12) **Cohort** is a group of recipients of drug of interest and studies involve observing them for different time periods to check what happens to them.
13) **Cohort studies** are beneficial in detecting predictable adverse effects arising due to excessive pharmacological effects during or after short-term treatment.

4.5. EXERCISE

4.5.1. True or False

1) The drug -drug interactions which counteract or alter the therapeutic effects of prescribed medications negatively are termed adverse interactions.
2) The spontaneous case reports include the results obtained before post-marketing surveillance of drugs.
3) Record linkage studies can be used to facilitate the research for infection-induced disease.
4) Case-control studies are beneficial in detecting predictable adverse effects arising due to excessive pharmacological effects during or after short-term treatment.
5) Pharmacokinetic drug interactions are those in which the absorption, distribution, metabolism and/or excretion of object drug are altered by the precipitant.

4.5.2. Fill in the Blanks

6) _____ is a branch of clinical pharmacy in which drug -induced unknown adverse effects and their risk factors are detected.
7) Beneficial interactions are also termed as _____.
8) In _____ studies, a group of patients having a disease assumed to be caused by a drug is compared with another group of patients not having the disease.
9) _____ provide information about serious and unpredicted drug reactions.
10) _____ is a group of recipients of drug of interest and studies involve observing them for different time periods to check what happens to them.

Answers

1) True 2) False 3) False 4) False 5) True
6) Pharmacovigilance 7) Intentional drug interactions
8) Case-control 9) Spontaneous reporting systems 10) Cohort

4.5.3. Very Short Answer Type Questions

1) Define drug interaction.
2) Give examples of beneficial interaction.
3) What are pharmacokinetic drug interactions?
4) What is pharmacovigilance?
5) Give two examples of adverse interactions with cardiovascular drugs.

4.5.4. Short Answer Type Questions

1) Write a short note on adverse interactions.
2) Discuss idiosyncrasy.
3) Write about spontaneous case reports.
4) Give the basic principles of efficient reporting.

4.5.5. Long Answer Type Questions

1) Write an illustrative note on pharmacokinetic drug interactions.
2) Discuss the methods for detecting drug interactions.
3) Write about ADR case report.

CHAPTER 5

Community Pharmacy

5.1. COMMUNITY PHARMACY

5.1.1. Introduction

Community pharmacy deals with compounding, counselling, and dispensing of drugs to the patients. The above responsibilities are dealt with care, accuracy, and legality. Community pharmacy also involves proper procurement, storage, dispensing and documentation of medicines. The community pharmacist is a qualified and pertinent professional having good knowledge, skills and competence to deliver the service to the community.

A **community pharmacist** should:

1) Have a good understanding of pharmaceutical care, pharmacotherapy, and health promotion strategies,
2) Have good skills of communication with patients and healthcare providers,
3) Maintain high standards with respect to products, services, and communication, and
4) Document everything in order.

In order to define community pharmacy broadly, all the privately-owned establishments whose function is to serve the needs of societies for both drug product and pharmaceutical service should be included. Community pharmacy is a branch of pharmacy that **deals with varied areas of patient care, drug dispensing, and advising patient on safe and rational use of drug**.

5.1.2. Organisation and Structure of Retail and Wholesale Drug Store

The organisational structure of a retail store will vary with size and type of the business. Most tasks involved with operating a retail business will be the same. However, small or independent retail stores may combine many sectors together under one division, while larger stores create various divisions for each particular function along with many layers of management. **For example**, the small shop of any particular goods or products may have all of its employees under one category called **store operations**.

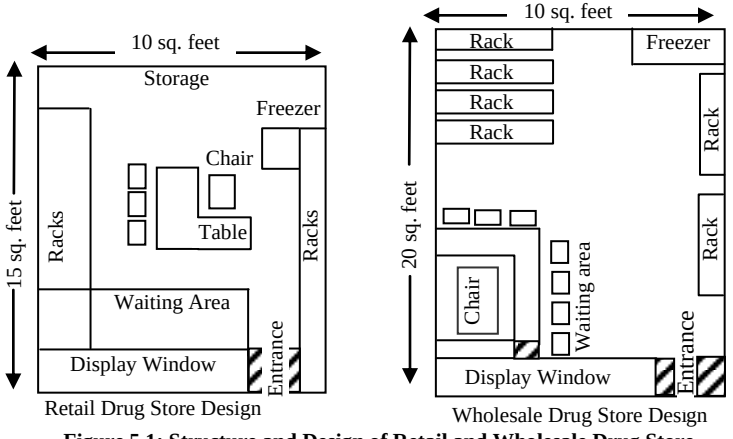


Figure 5.1: Structure and Design of Retail and Wholesale Drug Store

5.1.3. Types and Design of Drug Stores

A modern drug store complies with the requirements of schedule "N" of Drug and Cosmetics Rules . A drug store establishment needs a mi nimum of 150 sq. feet area , whereas a wholesale drug store requires a minimum of 200 sq. feet.

The types and designs of drug stores are:

1) **Pharmaceutical Centre:** This centre keeps the medicine mostly of prescription type along with convenience goods and orthopaedic and surgical applications. The store is well decorated with good atmosphere and uncluttered (not in use) floor space is the hallmark of the pharmaceutical centre. Separate room for orthopaedic and surgical appliances is provided.
2) **Prescription-Oriented Drug Store and Design:** Comfortable waiting area should be provided. Health related items, including drugs, home -healthcare appliances and supplies, and prescription accessories should be displayed near the vicinity. Separate room should be provided for orthopaedic and surgical appliances . Cosmetics should be displayed in other area of drug store.
3) **Traditional Drug Store and Design:** Major objective is to disperse customers and expose them to all areas of drug store. A drug store having pleasing appeara nce, professional atmosphere, and convenience for employees and customer provides opportunity for maximum sale at minimum expense. Surveillance for shoplifters should be considered as a major objective.
4) **Super Drug Store and Design:** The store should be 5,000 - 10,000 sq. ft. with a square design. Traffic control is a major objective rather than traffic dispersal design, which is in self -service style and all the items one can get in such drug store. Maximum sale at minimum cost is achieved.
5) **Personal Service Drug Stores:** In this type of design, the whole area is not exposed to the customer but the customer is required to interact with the drug store personnel at the service counter. During the purchasing process the customer demands an article and the personnel provides it.

   This service and design facilitates maximum interaction between the drug store employee and the customers. The success of such drug store depends upon the convenience and friendly service of the personnel at the service counter.

5.1.4. Legal Requirements for Establishment and Maintenance of Drug Store

If a community needs a pharmacy, the analysis should be done in terms of evaluating various alternatives that are available for satisfying it. Such alternatives provide the opportunity for improving services to the community while promoting the most efficient use of professional personnel and facilities.

5.1.4.1. Legal Requirements for Retail or Wholesale Drug Store

Following are some of the legal requirements to be fulfilled for opening a retail drug store or a wholesale drug store:

1) **Licenses:**
   i) **General Licenses:** These licenses are granted to an individual having premises for the business and who may employ or may himself be a qualified p erson to supervise the sale of a drug store. Form 20 deals with license for retail sale of drug store , other than th ose specified in schedule C, C1, and X. For drug specified in schedule C, C1 excluding those specified in Schedule X is governed

through for m 21 and for Schedule X in 20F. The c onditions applicable for general licenses are:

a) The owner should display the license in a prominent place within the premises allowing public to see.
b) The license should fulfill all the provisions of Drug and Cosmetics Act and Rules.
c) Any change in the staff should be brought in the knowledge of the Licensing Authority within a month.
d) Schedule C and C1 drugs should be stored as per the precautions prescribed by the Licensing Authority.
e) The owner should take permission fro m the License Authority for the sale of additional categories of drug listed in Schedule C and C1, excluding X.

ii) **Restricted Licenses:** These licenses are granted for the restricted sale of drugs other than those specified in Schedule C , C1, and X and those specified in Schedule C and C1, excluding X are governed by the form 20A and 21A , respectively. The conditions for restricted licenses are:

a) The drug should be sold in its original container.
b) The l icense should fulfill all the provision s of Drugs and Cosme tics Acts and Rules.
c) The drug should be purchased from a duly licensed dealer.
d) The licenser should bear premises equipped with required storage facilities for drug.

2) **Minimum Qualifications:** The minimum qualification for starting a wholesale drug store is matriculation with four years' experience in selling of drugs in a chemist shop on salary basis or Diploma in Pharmacy and alsoshould be Registered Pharmacist with the State Pharmacy Council. The minimum qualification to get registered with State Pharmacy Council is Diploma in Pharmacy from a recognised institution.

A person who has sufficient capital and is interested to start a drug store, can also do so by appointing a 'Registered Pharmacist' on whole time basis.

3) **Minimum Space:** Though, there is no mini mum prescribed area mentioned in the Drugs and Cosmetics Act and Rules, 1945, the minimum desirable area to open a new retail as well as wholesale drug store is 10 sq. metre s. However, the minimum desirable area to open a new combined wholesale and retail drug store is 15 sq. metres.

4) **Store Arrangements:** There should be a sufficient number of racks to store drugs and pharmaceutical preparations. For storage of antibiotics, vitamin products, vaccine, sera, and enzymatic preparations , which are required to be stored at a temperature between 2-8°C, a refrigerator is necessary.

If the analysis indicates that a new pharmacy should be established, the pharmacist should consider the following factors:

1) **Organisation:** The pharmacist may choose from three widely recog nised forms of legal organisation for the drug store enterprise.

2) **Unincorporated Sole Proprietorships:** The business enterprise owned and managed by an unincorporated sole proprietor is not considered in law as a separate legal entity; rather, the owner and the enterprise are considered one.

3) **Partnerships:** Partnership arrangements and incorporation are mechanisms that may be used to broaden the financial or talent base for an enterprise and also may serve to spread the risk. As to liability, a partnership may be described as an association of sole proprietors, because at law the partnership is not considered separate from those who compose it.

4) **Corporations:** Co-ownership also may be affected through a more formal organisation known as the corporation, which is a separate legal entity, created by the expressed authority of the state.
5) **Site Selection:** The factors such as population in the trading area, distribution of income among the population, type of industry, and the competitive climate have been cited as being important for site selection.
6) **Capital:** Planning and assembling the capital requirements for a new pharmacy are predicted on careful evaluation of projected sales volume, breadth and depth of inventory requirements, and estimated operating expenses. The amount of capital required for the operation of a successful pharmacy is a function of its productivity.

5.1.4.2. Documents Required to Open a Retail Drug Store

A licence is required to sell, stock, exhibit for sale, or distribute drugs. In order to open a retail drug store in any state, the following **documents** are needed for a new licence:

1) **Application** (in duplicate) on Form 19 of the Drugs and Cosmetics Rules, 1945. One copy is for biological drugs and the other is for non-biological drugs.
2) A **fee** of ₹1500 per licence (total ₹3000) to be deposited in State Bank of India/Government Treasury under specific head for grant of a retail sale licence.
3) The following documents should be carried with the qualified person while submission of the fee:
   i) An attested copy of Diploma in Pharmacy from any institution duly recognised by Pharmacy Council of India,
   ii) An attested copy of registration certificate issued by State Pharmacy Council,
   iii) An attested copy of matriculation certificate, and
   iv) Affidavit from the qualified person in case he/she is an employee of a drug store.
4) Affidavit on non-judicial stamp paper, duly attested by a first class magistrate by each partner in case of partnership concern or by the proprietor in case of proprietorship concern.
5) A **map** of the retail drug store duly signed by proprietor/partners of firm.
6) **Rent receipt** in case of rented premises or an affidavit to that effect if the person is the owner of the premises.
7) A **copy of the partnership** deed in case of partnership concern.
8) Refrigerator **purchase receipt**.

The licence is valid for a period of five years. It is required to be renewed for next five years before its expiry.

Pharmacy Council of India is planning to make it mandatory to wear a white coat bearing the name of the registered pharmacist who is running the retail pharmacy.

5.1.4.3. Maintenance of Drug Store

A drug store can be maintained as follows:

1) **Proper Drug Storage:** Drugs are stored in an especially designed secure area or space in a building so as to:
   i) Avoid contamination or deterioration,
   ii) Avoid disfiguration of labels,
   iii) Maintain integrity of packaging and guarantee quality and potency of drugs during shelf-life,
   iv) Prevent or reduce pilferage, theft or losses, and
   v) Prevent infestation of pests and vermin.

2) **Storage Environment:** It should possess:
   i) Adequate temperature,
   ii) Sufficient lighting,
   iii) Clean conditions,
   iv) Humidity control facilities,
   v) Cold storage facilities, and
   vi) Adequate shelving to ensure integrity of the stored drugs.

3) **Arrangement of Drugs on Shelves**
   i) Shelves should be made of steel or treated wood.
   ii) Shelves should be strong and robust.
   iii) Drugs should be arranged in alphabetical order of their generic names.
   iv) Each dosage form of drug should be arranged in separate and distinct areas.
   v) Sufficient empty space should demarcate one drug or dosage form from another.
   vi) Most recently received drugs should be placed behind old stock on the shelf except where new drugs have shorter expiration dates.
   vii) The environment should be kept clean.
   viii) Lids should be placed properly on tins at the time of closing the shop.
   ix) Drugs should be kept in a dry place protected from light and heat.
   x) Liquids should be stored in a pallet on the floor or on the lowest shelf.
   xi) The store should be cleaned daily and mopped atleast once a week.

4) **Storeroom**
   i) A well-arranged store enables easy identification of drugs and saves time when picking a drug from the shelves.
   ii) Drugs should be put on the shelves in alphabetical order corresponding to the essential drug list. This helps to remove drugs quickly and makes for easy inventory control.
   iii) The rule of **First In First Out** (FIFO) should be applied always. So, the drugs received first should be used first, except in cases when the new stock has shorter expiration date than the old one. In this regard, the principle of **First Expire First Out** (FEFO) should be applied.
   iv) To have access to drugs with shorter expiration dates first, they should be put in front of the shelves.
   v) Those with longer expiration dates should be placed behind those with shorter expiration dates.

5) **Dispensary**
   i) A daily drug use record should be maintained in the dispensary.
   ii) A table for dispensing drugs should be provided.
   iii) The dispensing table should not be overcrowded.
   iv) The documents should be arranged in an orderly manner on the table, away from the dispensing area.
   v) After use each tablet counter should be cleaned and placed within easy reach to the table.
   vi) Dispensing of wrong drugs should be avoided by arranging drugs on the table in alphabetical order so that the drug being dispensed is not confused with another.
   vii) The drug containers from which drugs are not being dispensed should always be closed to prevent spillage or dispensing the wrong drug.

It must be ensured that drugs stored in a drug store remain preserved during their storage. There should not be any damage due to high temperature or exposure to sunlight.

The drugs are to be stored as per the prescribed conditions of their storage. The drugs stored in a drug store should be arranged in such a way that they are easily traceable (whenever required). It can be done:

i) According to the manufacturers,
ii) According to the pharmacological action, and
iii) Alphabetically.

6) **Storage and Maintenance**

i) Drugs should be stored under condition that prevent contamination and as far as possible, deterioration.
ii) "Well closed container" precautions should be taken in relation to the effects of the atmosphere, moisture, heat and light.
iii) "Protected from moisture" means that the product should be "stored in air tight container".
iv) "Protected from light" means that the product should be stored either in a container made of material that absorbs light sufficiently to protect the contents from change induced by such light.
v) Temperature requirement will be:
   a) In a deep freeze (–15°C),
   b) In a refrigerator (–2°C to 8°C),
   c) Cold or cool (–8°C to 15°C), and
   d) Room temperature (–15°C to 25°C).

Look-alike and sound-alike drugs should be stored separately. Temperature should be maintained between 59-86°F for non-refrigerated medications. Where refrigeration is necessary, a "Medications Only" refrigerator should be used and temperature should be maintained between 36-46°F.

On daily basis check, the proper temperature should be verified and documented. All multiple-dose injectable medications should be initialled and have the date of first entry recorded on the label. Multiple dose vials remain potent until manufacturer's date on the vial. The medication stock should be monthly rotated employing a FIFO (First In/First Out) process.

5.1.5. Dispensing of Proprietary Products

Patent or proprietary medicine is a drug that behaves as a remedy or prescription dispensed in a form given through internal or external route in human beings or animals and presently excluded in the edition of the Indian Pharmacopoeia or any other Pharmacopoeia authorised by the Central Government after consultation with the Drugs Technical Advisory Board.

Availability of proprietary medicines is increasing day by day. Henceforth, traditional compounding of medicines is not practised more often except in hospitals where physicians prescribe compounded prescriptions in limited cases. So the pharmacists focus more in dispensing of proprietary medicines. The proprietary medicines available in the market expand to a wide range of therapeutic categories of drugs.

Mostly, the proprietary medicines have identical nomenclature that presents difficulty for pharmacists. The pharmacist should clearly understand the wishes of the prescriber, should not have any confusion, and should avoid errors during the dispensing of proprietary medicines. Computer programmes and softwares are used to resolve such problems.

Principles

To facilitate the compounders in spontaneous preparation of powders and capsules, the following principles are laid down:

1) **Packaging:** The packaging of powders and capsules is done on the basis of formulation:
   i) **Bulk Powders for External Use:** Packing of these powders should be done either as bulk oral powders or as powder-shaker with a sifter top.
   ii) **Bulk Oral Powders:** These powders need to be packaged in an air -tight glass or plastic jar. It is advised to avoid expos ure of bulk oral powders to moisture as this may form a thick mass of product favouring microbial growth.
   iii) **Individual Unit Dose Powders:** After preparation these powders are kept flap to flap and secured using a rubber band. The whole set of powders is put in a tough cardboard container and labelled before dispensing the preparation to the patient.

   Preparations with effervescent or deliquescent ingredients should be packed in an air tight container (**e.g.,** an ointment jar).
   iv) **Unit Dose Capsules:** For packing and dispensing of these capsules, glass or plastic tablet bottle having a child-resistant closure is preferred.

2) **Discard Dates:** Manufacturing of proprietary powders and capsules are done in special environments to provide a long shelf-life. In case of extempor aneous preparations, the compounder should consider several points while deciding the expiry for a product , **e.g.,** stability of the ingredients in the preparation and the vulnerability of the preparation to microbial attack. A general rule states an expiry of up to three months for any preparation, although every preparation should be dealt as an individual formulation.

   As the term **expiry** is misunderstood by the patients, hence shelf-life should be indicated on the label of extemporaneously compounded prepa ration and replace the expiry term with **discard after** followed by a definite date and/or time.

3) **Labelling:** Along with the standard requirements for the labelling of extemporaneous preparations, the points stated below should be considered:
   i) Bulk oral powders, individual unit dose powders, and bulk powders for external use are moisture-sensitive. Hence , a caution saying „ **Store in a dry place** ' is mandatory on their label.
   ii) Any preparation intended for external use (like bulk powders for external use) should bear an additional caution „**For external use only**' on their label.
   iii) Likewise, dusting powders also need a caution on their label, stating „**Not to be applied to open wounds or raw weeping surfaces**

5.1.6. Maintenance of Records of Retail and Wholesale Drug Store

For various legal, financial, and professional reasons, the maintenance of records in the drug store is becoming increasingly important. The **types of records required** may be classified as:

1) Records required by law regarding the acquisition and disposition of drugs,
2) Records regarding patient utilisation of drugs, and
3) Records regarding the past and present financial status of the pharmacy.

Management's role in this function is to identify the specific records required, develop systems for keeping them, and delegate the responsibility for day -to-day record keeping to capable personnel.

Types of Records

Types of records that should be maintained in a drug store are as follows:

1) **Legal Records:** According to Federal and State law, the pharmacy owner or manager is charged with maintaining accurate up -to-date records on specific classes of drugs and poisons. Under the provisions of the Federal Controlled Substances Act of 1970, the pharmacist is required t o maintain accurate records related to the acquisition and disposition of certain drugs that are deemed to be subject to possible misuse or abuse. Improperly maintained or incomplete records can bring legal action and penalties.

   Advantage: Abuse and misuse of drugs do not take place.

2) **Patient's Records:** In recent years, many pharmacists have broadened their record - keeping activities to include patient drug histories. Although the form of patient record varies with time, the basic idea is to establish a re cord (usually on a family-unit basis) that allows the pharmacist to monitor the drug usage of each member of the family, since there is a need of drug history for every individual and to reduce the problems associated with drug interactions and individual idiosyncrasies to drugs. In addition, these records also may serve economic purposes, as sources of information for insurance claims and for income tax deductions of the patient.

   Advantages

   i) Patient compliance.
   ii) In case of insurance claims and income tax de ductions to patient, it serves as an information source.
   iii) It provides information regarding the number of patients visiting the drug store. This facilitates to know the drug store business, and also the relationship between pharmacist and patient.

3) **Financial Records:** Properly collected and organised accounting data serves various important uses and are of value to the pharmacy owner in the following ways:

   i) Providing the basic tools for efficient management and measuring its effect.
   ii) Making sound decisions rega rding future cash needs, inventory requirements, personnel matters, and expansion of facilities.
   iii) Evaluating past operations, controlling current operations, and provid ing information for planning and forecasting.
   iv) Analysing revenues and expenses.
   v) Measuring return on investment.
   vi) Providing the required information to potential granters of credit and loans as well as to Federal, State, and Local governmental agencies regarding income and business taxes.
   vii) Helping to ensure a profitable operation.

   Advantages

   i) Efficient management of drug store,
   ii) Requirement of inventory,
   iii) Helps in making good decisions for future money requirements,
   iv) Investment returns,
   v) Analysis of financial statements,
   vi) Ensures profits to the drug store,
   vii) Checks out the past and current financial pos ition, i.e., revenues and expenses of drug store,
   viii) Less time-consuming process than the journals,
   ix) Accounts are proper and accurate,

x) Labour economy,
xi) Statistical records of sales, i.e., total sales information of various areas, and
xii) Some account books are not needed to maintain, i.e., cheque no., the payment date, etc., as these are recorded in the purchase book itself.

5.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) **Community pharmacy** is a branch of pharmacy that deals with varied areas of patient care, drug dispensing, and advising patient on safe and rational use of drug.
2) The organisational structure of a retail store will vary with size and type of the business.
3) A modern drug store complies with the requirements of schedule "N" of Drug and Cosmetics Rules.
4) A drug store establishment needs a minimum of 150 sq. feet area, whereas a wholesale drug store requires a minimum of 200 sq. feet.
5) **Pharmaceutical centre** keeps the medicine mostly of prescription type along with convenience goods and orthopaedic and surgical applications.
6) In **personal service drug stores**, the whole area is not exposed to the customer but the customer is required to interact with the drug store personnel at the service counter.
7) **General licenses** are granted to an individual having premises for the business and who may employ or may himself be a qualified person to supervise the sale of a drug store.
8) **Restricted licenses** are granted for the restricted sale of drugs other than those specified in Schedule C, C1, and X and those specified in Schedule C and C1, excluding X are governed by the form 20A and 21A, respectively.
9) The **minimum qualification** for starting a wholesale drug store is matriculation with four years' experience in selling of drugs in a chemist shop on salary basis or Diploma in Pharmacy and also should be Registered Pharmacist with the State Pharmacy Council.
10) The minimum desirable area to open a new retail as well as wholesale drug store is 10 sq. metres.
11) **Patent** or **proprietary medicine** is a drug that be haves as a remedy or prescription dispensed in a form given through internal or external route in human beings or animals and presently excluded in the edition of the Indian Pharmacopoeia or any other Pharmacopoeia authorised by the Central Government after consultation with the Drugs Technical Advisory Board.

5.3. EXERCISE

5.3.1. True or False

1) Patent medicine is a drug that behaves as a remedy or prescription dispensed in a form given through internal or external route in human beings or animals
2) The minimum desirable area to open a new retail as well as wholesale drug store is 20 sq. metres.
3) Restricted licenses are granted to an individual having premises for the business and who may employ or may himself be a qualified person to supervise the sale of a drug store.
4) Pharmaceutical centre keeps the medicine of prescription type along with convenience goods and orthopaedic and surgical applications.
5) The minimum qualification for starting a wholesale drug store is matriculation with two years' experience in selling of drugs in a chemist shop on salary basis.

5.3.2. Fill in the Blanks

6) _____ licenses are granted for the restricted sale of drugs other than those specified in Schedule C, C1, and X and those specified in Schedule C and C1, excluding X are governed by the form 20A and 21A, respectively.
7) In _____ drug stores, the whole area is not exposed to the customer but the customer is required to interact with the drug store personnel at the service counter.
8) A drug store establishment needs a minimum of _____ area, whereas a wholesale drug store requires a minimum of _____.
9) The organisational structure of a retail store will vary with _____ and type of the business.
10) A modern drug store complies with the requirements of _____ of Drug and Cosmetics Rules.

Answers

1) True 2) False 3) False 4) True 5) False
6) Restricted 7) Personal service 8) 150 sq. feet and 200 sq. feet 9) Size
10) Schedule N

5.3.3. Very Short Answer Type Questions

1) Define community pharmacy.
2) Give the roles of community pharmacist.
3) Draw a well-labelled diagram of the design of retail and wholesale drug store.
4) What is a proprietary medicine?
5) Give the advantages of patient's records.

5.3.4. Short Answer Type Questions

1) Write a short note on types and designs of drug stores.
2) Discuss financial records.
3) Write about the principles for dispensing proprietary products.
4) What documents are required to open a retail drug store?

5.3.5. Long Answer Type Questions

1) Write an illustrative note on legal requirements for establishment and maintenance of drug store.
2) Discuss about the maintenance of records of retail and wholesale drug store.

CHAPTER 6

Drug Distribution System in a Hospital

6.1. DRUG DISTRIBUTION SYSTEM IN A HOSPITAL

6.1.1. Introduction

Hospitals make use of drugs and therapeutic substances in in -patient and out -patient departments. They are of such a variety that the patients mostly fail to understand them. The problem of procurement and distribution is bigger in bigger institutions.

6.1.2. Types of Drug Distribution Systems

Hospitals have **two types** of drug distribution system:

1) Distribution of drugs to indoor patients or in-patients (patients in wards , operation theatres, X-ray, and other specified departments), and
2) Distribution of drugs to outdoor or ambulatory patients or out-patients (patients not admitted and not occupying bed).

There are **two more types** of drug distribution:

1) Dispensing of narcotics and other controlled substances, and
2) Distribution and dispensing of ancillary substances and articles.

6.1.3. Charging Policy

All the hospitals should have a uniform charging policy for drugs. An unbiased price for drugs should be charged to all the patients while considering the financial interests of the hospital.

The charging policies are categorised under the following heads:

1) **Per *Diem* Drug Charge or all Inclusive or no Special Rate:** In this system, charges for 250 patients are studied and their average daily charges for drugs and pharmaceutical services are calculated.

   On comparing the actual charge with the projected per *diem* rate, the same revenue will be obtained as the itemised charging method. This system provides superior pharmaceutical services and also reduces the administrative and accounting cost of hospitals.

2) **Part-Inclusive Rate:** In this system, charges are made for drugs not on the free or supplied list.

3) **Professional Fee Concept:** This is the exclusive professional fee for all the operating expenses (including overhead and compensation) but not the actual cost of drug and container. This concept is being employed as it recovers expenses of pharmacy and total hospital expense. This fee concept should not be combined with **mark-up** or **margin** as these terms indicate that a percentage of wholesale or selling price is used as a base for the recovery of direct and indirect expenses.

Calculation of Professional Fee

Professional Fee = Cost of Dispensing + Profit

$$\text{Cost of Dispensing} = \frac{\text{Total Operating Expenses} - \text{Drug Costs}}{\text{Number of Prescriptions Filled in}}$$

Professional fee can also be calculated from operating expenses:

$$\text{Professional Fee} = \text{Executive Salary} + \left(\frac{\text{Prescription Sales}}{\text{Total Sales}} \times \frac{\text{Operating Expenses Excluding Executive Salary}}{\text{Total Number of Prescriptions}} \right) + \text{Desired Net Income per Prescription}$$

Another formula for calculating professional fee is:

$$\text{Professional Fee} = \frac{\text{Desired Profit} + \text{Prescription Lab Expenses}}{\text{Number of Prescriptions Filled in}}$$

The prescription fee is realistic and made with the costing methods. Prescription fee can be either kept constant or can be varied depending on the time taken to compound the prescriptions.

Some hospitals, however, may follow a system of simple mark -up (set by a responsible costing committee) on the total costs of ingredients to price the prescriptions. **For example,** a mark-up of 10% on a prescription of ₹10/- (drug costs are ₹10) will be ₹10 + ₹1.00 = ₹11.00. It is assumed that ₹1.00 includes the cost of operating the pharmacy by taking into account the total volume of the business. Each priced prescription should be suitably coded with letters consisting of digits assigned to the alphabets.

Alphabets	Digits Assigned
P	1
H	2
A	3
R	4
M	5
O	6
C	7
I	8
S	9
T	10

Thus, a price of ₹6.50 will be denoted by O.M. Zero, and ₹6.55 will be d enoted by O.M.M.

4) **Break-Even Point Pricing:** It is a useful tool in overall analysis of cost volume relationship and is defined on the level at which there is neither profit nor loss. For this, pharmacist should ascertain the fixed and indirect expenses incl uding expenses of hospital administration, maintenance, housekeeping, depreciation of plant and equipment. Various costs , like housekeeping costs, and overhead costs (administration, light, water) , are calculated by dividing the actual cost of these services by the number of prescriptions filled.

5) **Cost-Plus Rate System:** In this system, pharmacist maintains a better control using the formula:

$$\frac{\text{Desired Income from Drugs}}{\text{Cost of Prescription Drugs}} \times 100 = \% \text{ Above Cost to be Charged for Prescription}$$

It helps in the adjustment of cost fluctuation, difference in currency value, and financial requirement. It offers fairness to the hospital and patients.

6) **Profit Aspect:**In this, profit is calculated into price to the patient by the following ways:
   i) A fixed fee per prescription, and
   ii) Addition of predetermined percentage of the break-even point figure.

7) **Computerised Pricing:** This system is quite fair and provides computerised on -line pharmacy pricing. The computer program will ask for the following information:
   i) Patient number,
   ii) Drug identification number,
   iii) Dose factor, and
   iv) Total number of doses dispensed.

6.1.4. Labelling

The stock drugs in the ward are not labelled with the directions for use because there may be a few patients who are receiving the same medication under different therapeutic regimen. If a direction for use is labelled on the container of such drugs, the patients may get confused and may end up taking wrong doses. Due to this reason, the stock drugs are only labelled with the ward number, name and strength of the preparation, and any other relevant information.

After a medicine is dispensed i n a container, it should be labelled to provide the required information regarding the use of medicine. The label of dispensed medicines should bear the following **characteristics**:

1) **Accurate:** After writ ing and before fixing it to the container, the label sh ould be checked properly.

2) **Legible:** The information on the label should be either type -written or printed to make it easily readable.

3) **Intelligible:** The information on the label should be unmistakable to avoid any confusion.

4) **Adequate and Relevant:** The infor mation on the label should be sufficiently relevant to avoid confusion. Limited but clear information should be provided on the label to make it noticeable.

The label should comply with the requirements mentioned in the Drugs and Cosmetics Act and Rules and with current professional opinions.

6.1.4.1. Preparation of Labels for Dispensed Medicines

The following information should be provided by the label on the dispensed medicines:

1) **Name and Address of the Patient:** The first name(s) or initial(s) and surname of the patient should be put on the label of each dispensed medicine to avoid confusion with other members of the patient's family who might be taking similar medicines.

2) **Name and Addr ess of the Supplier and Date of Supply:** The name and address of the pharmacy from where the drug is dispensed is pre -printed on the labels. The supply date is also mentioned on the label.

3) **Precise Details Regarding the Contents of Container when Dispensed:**
   i) **Name of the Medicine:** The name and strength of the dispensed medicine is mentioned on the label for safety purpose; however, sometimes it causes unnecessary anxiety and distress to the patients. The preparation name

written by the prescriber (whether prop rietary name, non -proprietary name, official drugs given in I.P., B.P., U.S.P., B.P.C., B.N.F., etc.) should be on the label.

If the prescriber uses a non-proprietary name for a preparation, that name should be present on the label, even if the medicine is available as a proprietary product. If the prescribed medication has several ingredients but no official or proprietary name, the medication is labelled by its pharmaceutical form, **e.g.,** the mixture, the ointment, the lotion, etc.

ii) **Strength of the Medic ine:** The medication strength should be on the label if preparations are available in different strength. If an official preparation has its strength mentioned in the monograph, the official publication can be referred on the label, **e.g.,** Calamine Lotion I. P., Sulphur Ointment I.P., Tannic Acid Glycerine I.P., etc.

However, if the strength of an official preparation is not stated in the monograph, then its strength should be included in the label, **e.g.,** Chloramphenicol Oral Suspension I.P., Chlorohexidine Cream I.P., and Aminophylline Suppositories.

iii) **Quantity in the Container:** The total quantity of the medication dispensed in the container should be given on the label. If more than one container with the same medicine is dispensed, the amount in each contain er should be mentioned on the label.

4) **Storage Conditions and Shelf -Life of the Product:** The pharmacists should provide the following **guidelines** on the label regarding the storage conditions:

i) **Temperature:** There are many products that need to be stored in a cool place below 15°C temperature. High temperature can damage pessaries and suppositories that are designed to melt at body temperature. Immunological products and insulin injections should be stored between 2 -8°C temperatures. Formaldehyde should be stored in a moderately warm place.

ii) **Humidity:** The solid unit dosage forms that need to be protected from moisture should be dispensed in air - and moisture-proof containers. The patients should be guided to replace the cap after every use. Powdered dosage forms should be stored in a dry place.

iii) **Light:** The light -sensitive products should be stored in amber -coloured containers, which should be further stored in cardboard boxes. Even the light - resistant containers should not be exposed to direct sunlight.

5) **Instructions to the Patient:** The following clear and com plete **instructions** should be provided on the label for the patients regarding the use of medication:

i) **Directions:** The prescriber writes in the prescription the directions for use including the dose, frequency, timing, and route of the drug administration.

ii) **Shaking of the Bottle:** Emulsions, suspensions, and aerosols for internal or external use should be shaken well before use to make the preparation homogeneous. Thus, this instruction should be provided on the la bel of such preparations to ensure dosage accuracy.

iii) **Take with Water:** Mixtures that can cause gastrointestinal irritation or mixtures for geriatrics having a dose of 10ml or more should be diluted with water before administration. Medicines for paediatrics having a dose of 5ml are not diluted; however, the preparations causing irritation need to be diluted.

6.1.4.2. Cautionary and Advisory Labels

To make the patients take their medicine in a safe and effective manner, they should be provided with essential information. The following **instructions** should be given on the label:

1) **For External Use Only:** This label should be applied on the containers of liquid preparations and all semi-solid and solid medicinal products, like gels, ointments, creams, pastes, and dusting powders, to be used externally.

2) **Not to be Taken:** This label should be applied on preparations not meant for oral intake or topical use. It is used for preparations meant for internal use, **e.g.,** medicines for rectal, vaginal or nasal application. The labels, 'For nasal use only', 'For rectal use only', or 'For vaginal use only', is preferred over 'For external use only'.

3) **Drowsiness Warning:** Some medicines can cause drowsiness, dizziness, blurred vision, or may impair the ability to drive or operate machinery safely. The patients should be warned about these indications while the medicines are being dispensed. The following **instructions** should be written on the label:

> **Warning:** May cause drowsiness. If affected, do not drive or operate machinery, avoid alcoholic drink.

4) **Potential Interactions with Food or Drink:** The following instructions should be written on the label:
   i) Absorption of some drugs is enhanced if taken before food.

   > **Warning:** To be taken an hour before food or on an empty stomach.

   ii) Some drugs cause gastrointestinal irritation and are better absorbed if taken with food.

   > **Warning:** To be taken with or after food.

   iii) Absorption of antibiotics is reduced by the presence of food and acid in the stomach.

   > **Warning:** To be taken an hour before food or on an empty stomach.

   iv) Drugs like metronidazole can cause flushing if taken with alcohol.

   > **Warning:** Avoid alcoholic drink.

5) **Potential Interactions with other Medicines:** The following instructions should be written on the label:
   i) Absorption of some drugs is delayed in the presence of calcium, magnesium, and iron as they undergo chelation.

   > **Warning:** Do not take milk or iron preparation with this medicine.

   ii) The activity of some drugs is reduced by aspirin.

   > **Warning:** Do not take aspirin while taking this medicine.

6) **Special Methods of Administration:** The following instructions should be written on the label if a drug is to be administered by a special method:
   i) Drugs which need to be dissolved in the mouth.

   > **Warning:** To be chewed.

ii) Drugs which need to be absorbed through sublingual mucosa.

Warning: To be dissolved under the tongue.

iii) Drugs which are water-soluble or powders or granules that need to be dispersed in water before administration.

Warning: Dissolve or mix with water before taking.

iv) Drugs which may cause gastrointestinal irritation and are need to be well-diluted.

Warning: To be taken with plenty of water.

v) Drugs which are enteric coated, sustained release or have unpleasant taste.

Warning: To be swallowed whole, not to be chewed.

7) **Cautions in Use:** The following instructions should be written on the label to warn a patient about the uncommon incidents that may occur on taking some medicines:

i) Drugs which may induce photosensitisation.

Warning: Avoid exposure of skin to direct sunlight.

ii) Drugs which may produce unusual effect.

Warning: The preparation may colour the urine or stool.

iii) Drugs which contain a high proportion of flammable solvent.

Warning: Keep away from naked flame.

6.1.5. Dispensing of Controlled Drugs

There are many natural substances of vegetable, animal and mineral origin. These substances are mostly beneficial but some are even harmful to the mankind if not used properly and are misused. Morphine and allied alkaloids of opium, cocaine and coca leaves, cannabinoids and other resins of *Cannabis indica*, ergot, etc. are **examples** of such drugs. These are added substances of synthetic organic chemistry origin, like heroin and pethidine that produce injurious effects. These drugs unnecessary depress or stimulate the human brain and also produce euphoria, personality destabilising effects, addiction, etc.

These drugs are termed **narcotics** and to put exercise control on their use, International level convention was held in **1919** at **Geneva**. After which, many other such conventions were organised. Before India got independence, the Dangerous Drugs Act was passed in 1930. Different states have framed their own rules for the implementation of this Act. As per the laws of this Act, the cultivation, possession, transport, dispensing, distribution and administration of opium, Indian hemp, and coca are regulated and controlled.

This law however did not cover synthetic and semi-synthetic products, like pethidine, L.S.D., etc., which were not yet identified at that time. These aspects of sale and possession by retailers, etc., are now covered by schedules H, L and X of the Drugs and Cosmetics Act, 1940. In the Rules 1945, drugs other than opium, coca and Indian hemp which are covered by Schedule H and cannot be sold except against a prescription of the registered medical practitioner are included. Drugs causing addiction, like opium, coca, etc., are included in schedule X.

Hospital Control Procedures

The procedure given below has been evolved by the American government authorities and is applicable to Indian hospitals:

1) **Responsibility for Controlled Substances in the Hospital:** The administrative head of the hospital properly safeguards and handles the controlled substances in the hospital. Medical Superintendent or Dean is the administrative head in Indian hospitals. The Chief Pharmacist (in U.S.A.) or the medical officer (in India) looks after the purchase, storage, accountability and proper dispensing of bulk controlled substances in the hospital. The Matron or Head Nurse looks after the proper storage and use of the controlled substances in the nursing unit.

2) **Ordering Ward Stock of Controlled Substances from the Pharmacy:** The procedure given below is followed while ordering controlled substances from the ward stock of pharmacy:

   i) By placing a checkmark (✓) in front of the name and desired strength of the controlled substance, the requisition forward stock controlled substances is completed. This form along with the empty containers and the nurses' inventory sheet is then forwarded to the pharmacy. A model of such a sheet is shown in **figure 62**.

ABC Hospital, Delhi

Ward_____ **Code**_____ **Date**_____

Each floor is entitled to contain each of the following tablets and units of injectables. Empty bottles, except tubes along with narcotics or barbiturate accounting, sheets must be returned. All other narcotics and barbiturates must be ordered for and charged to the patient. These special narcotics and barbiturates orders must be accompanied by a prescription.

No. of Tablets Capsules	Check Item Needed	Price
20	Codeine sulphate tabs. 15mg.	
25	Codeine sulphate tabs. 20mg.	
20	Morphine sulphate H.T.	
25	Morphine sulphate ampoules	
10	Pethidine hydrochloride injection.	
1	Pentobarbitone injection 50mg/ml. 20ml.	
20	Phenobarbitone tablets I.P.	
25	Secobarbitone capsules 50mg.	

Figure 6.2: Requisition Form for Ward Stock Controlled Substances

   ii) Before issuing any new controlled substances to a ward, the previous supply should be fully looked into. Therefore, the request for every new supply should be accompanied by the daily controlled substances (**figure 6.3**).

ABC Hospital, New Delhi

Daily Controlled Drugs Administration Form Part-1

Date _____ **Ward No.** _____ **Floor** _____

Patient's Name	Specific Description of Drug	No. of Tablets or Injections	Strength Used	Ordered by Doctor	Adm. by Nurse	Time Given

Signature of Nurse _____

ABC Hospital, New Delhi					
Part-2					
Daily Controlled Drugs Administration Form Summary of Daily Report					
Name of the Tablets or Injections	**Opening Day Record**	**Received**	**Total**	**Drugs Used**	**Balance**

Signature of Nurse _____

Figure 6.3: Request for New Controlled Substances

3) **Ordering Non-Ward Stock Controlled Drugs from Pharmacy:** Drugs not stocked on the nursing stations are ordered from the pharmacy through written prescriptions. Only the amount of drugs stated on the prescription by the physician's signature should be sent to the nursing unit. If additional amount is required, a new signed prescription should be obtained. Such a prescription should carry the following information:
   i) Patient's full name,
   ii) Patient's hospital number or address,
   iii) Date,
   iv) Name and strength of the prescribed drug,
   v) Quantity of the drug to be dispensed, and
   vi) Physician's registration number.

   The prescription should be written properly with no cuttings or alterations u sing ink or permanent pencil. A physician cannot write a prescription for controlled drugs for his own use.

4) **Prescribing Controlled Drugs in the Out -Patient Department:** The prescription for narcotic drugs under the Narcotics and Psychotropic Substances Act, 1985 and those covered by schedule X to be dispensed from the out -patient pharmacy should bear the following information:
   i) Patient's full name,
   ii) Patient's hospital number or address,
   iii) Date,
   iv) Name and strength of the prescribed drug,
   v) Quantity of the drug to be dispensed,
   vi) Frequency and route of administration, and
   vii) Physician's signature.

   The prescription should be written properly with no cuttings or alterations using ink or permanent pencil.

5) **Dispensing Controlled Drugs for Home Use when Pharmacy is Closed:** Sometimes, patients are discharged from the hospitals during hours when the hospital pharmacy is closed and are prescribed with controlled drugs for home use. In such cases, a prescription should be signed by a registered medical practitioner, who is also a uthorised to prescribe narcotics and other controlled drugs. A physician authorised to prescribe controlled drugs should write on prescription blank. If this is not available, he/she should mention the office address on the hospital prescription blank so t hat the patients or their relatives can purchase the

drugs from an outside pharmacy. This could be followed if a physician is unavailable or even the local pharmacies are closed; however, this should be done only in an emergency situation.

The attending physician will calculate the smallest amount of narcotic drug required for the patient at that moment until the pharmacy opens. He/she will write a prescription for this amount and the nurse dispenses the medication from her stock supply. The next day when the pharmacy opens, this prescription should be presented to the pharmacy for stock replacement.

6) **Procedure in Case of Waste, Destruction, Contamination, etc.**

i) **Aliquot Part of Narcotic Solution Unused:** The nurse should use proper number of tablets or ampoul es from the nursing stock. She should keep a record of number of tablets or ampoules used and the dose given in proper columns on daily Controlled Drugs Administration Form (**figure 6. 4**). On attaining the proper aliquot part, the portion of solution that is not used should be discarded into the sink by the nurse.

ii) **Prepared Dose Refused by Patient or Cancelled by Doctor:** When a dose has been prepared but is left unused in case the patient refuses to take in or the physician cancels the dose, the nurse should d iscard the solution into the sink and record the reason for drug not being administered. **For example,** "Discarded refused by patient or order cancelled by Doctor". This statement should be countersigned by the head nurse of the nursing unit.

iii) **Accidental Des truction or Contamination of Drugs:** If any solution, ampoules, tablets, etc., gets accidentally destroyed or contaminated in a nursing unit, the responsible person should indicate the loss.

ABC Hospital, Delhi
Request for Replacement of Narcotic Loss or Waste on Wards

Date _____

Name of Drug _____

Quantity _____ Tablets/ml _____

Container No. _____ Record Sheet No._____

Statement what happened:

_____
_____
_____
_____

_____
Signature of Reporting Nurse

_____
Head Nurse/Supervisor

_____
Receiving Pharmacist

Figure 6.4: Narcotic Loss or Waste Form

iv) **Control of Narcotics on the Ward by Nurses:** When the pharmacy has dispensed the narcotics for the ward, the nursing service assumes the responsibility for administration, control and auditing of the inventory. The auditing of narcotic inventory takes place with each charge of nursing shift. At this t ime, the nurse coming on duty as well as the nurse going off -duty physically counts the narcotics on the nursing station.

The audit record is signed by both of them if the tally is correct. And in case the tally is not correct, the medications ordered on that day by the physician is re-checked to immediately amend the recording error. If the error cannot be explained, the narcotic loss report should be forwarded to the pharmacy department.

ABC Hospital
Eight Hour Nurse Audit Record

Date	Time	Signature of On-Coming Nurse	Signature of Out-Going Nurse
	7.00 a.m.		
	3.00 p.m.		
	11.00 p.m.		
	7.00 a.m.		
	3.00 a.m.		
	11.00 p.m.		

Returned to pharmacy by
_____
Date _____

Figure 6.5: Nurse Audit Record

7) **Narcotics-Delivery to the Ward:** The narcotics from the pharmacy should be delivered to the ward and nursing station by a reliable individual working in the hospital. This responsibility is mainly given to a member of the messenger staff. Sufficient control records are maintained to detect illegal delivery of any narcotics and to take necessary steps for their recovery.

8) **Charges for Narcotic to Patients:** Charges for narcotics depend on the policy of each hospital. The general pattern of charging is as follows:
   i) Charges are made for each dose received.
   ii) A flat charge is made for all narcotics and hypnotics. Hospitals include narcotics alone with other floor stock drugs for which the patient is not specifically charged.
   iii) In hospitals having 'split' policy, the patient is not charged for narcotics used routinely but is charged for those obtained on special order.

6.1.6. Distribution and Dispensing of Ancillary Substances and Articles

Ancillary supplies are such that the laboratories, wards and special service areas can predict their rate of use and order them from the pharmacy either weekly or bi-weekly.

The following **two methods** are utilised to inform the wards, laboratories and special service areas about what is to be carried in inventory:

1) Pre-printed requisition form that contains the list of all the supplies should be used or a catalogue should be issued. Using a pre-printed requisition form is considered the most ideal and practical, if the total number of items stocked is less.

2) For informing about those who must requisition the supplies for their area, a published catalogue having the materials alphabetically arranged under a major heading is used. This catalogue should be cross-indexed to facilitate its use and should show the unit size of the package to be dispensed. This saves much time for the dispensing personnel and the pricing clerk.

In hospitals where a catalogue has been published, a special requisition form should be used. This form should be simpl e but capable of being used for any type of supply. A prototype of such a form is given in **figure 6.6**:

ABC Hospital		
Requisition for Laboratories Supplies		
Ward No_____		**Date** _____
Description of the item	**Quantity**	**Cost**
	Requested by _____ **Approved by** _____	
Received by _____		

Figure 6.6: Requisition Form for Laboratory Supplies

This requisition form is prepared in the ward/laboratory and sent to th e pharmacy, where the pharmacist checks each dispensed item, prices it, and sends the completed requisition form to the accounts department.

The department head prepares this requisition form in duplicate order so that the original copy is retained as a receiving slip to make sure that all the ordered supplies have been received. Some items at one time or another will go out of stock in the inventory, therefore, it is advised to use an 'out of stock' notice to inform the indentor. A sample of such a form is shown in **figure 6.7**:

ABC Hospital, Delhi **Pharmacy** **Date:** _____ **Department** _____ **Name on Original Requisition** _____ We are temporarily out of stock of the following.	
Quantity	**Items**
18 only	Hypodermic Needles 26 G. Charged/Not charged.
We have these items are available your order will be completed. PLEASE DO NOT ORDER AGAIN	

Figure 6.7: Out of Stock Notice

The pharmacy attending the requisition form initiates it in duplicate. The original copy is retained by the pharmacy and the duplicate is sent to the indentor.

6.2. DISPENSING OF DRUGS TO IN-PATIENTS

6.2.1. Introduction

At the present time, very few stock items are prepared on a spontaneous basis in hospitals. However, prepared or procured preparations are sent as floor stock medications, stored in the cabinets by the nursing staff, and administered to the patients

as ordered by the physician. Further responsibilities of storage, maintenance, and r ecords of administration are also fulfilled by the nursing staff. A modern hospital should take feedback from the nursing staff for the medical and pharmacy staff to make a drug information centre.

The nursing staff should spend considerable time to visit the pharmacy frequently to obtain the supplies. Many hospitals have a messenger service between these two. Generally, ward boys are employed to carry indent slips for regular and emergency supplies. If mechanisation for the conveyance of drugs is not pres ent, the best alternative is the floor stock system, which is selected by the clinical staff of the hospital.

6.2.2. Location, Layout, and Personnel

In-patient department should be located on the ground floor or first floor of the building. It should be central ly located and also near the OPD so that the staff can easily reach there. The pharmacist along with skilled and qualified staff should carry out in -patient dispensing. When the in -patients and out -patients receive services from a hospital, the hospital ph armacy should combine both the departments. In -patient service should be near to the medical departments (like maternity, orthopaedic, etc.) and should be located such that it does not disturb the in -patients. In -patient pharmacy is a multi -functional department, which stores, dispenses, and also manufactures (IV fluids, parenterals, etc.). Nowadays, satellite pharmacies are being operated either at the level of wards or on the basis of the number of doors. These pharmacies need to be operated by a professi onal pharmacist.

The manpower trained in pharmacy varies with the hospital size and its services. The number of pharmacists required for a hospital depends on the workload norm like the number of prescriptions received and dispensed or the number of beds available in hospital and their occupancy rate. Therefore, minimum 3 pharmacists should be present in a very small hospital; and 5 pharmacists should be present in a 100 -bed hospital.

The number of pharmacists increases with the number of beds. While ca lculating the number of pharmacists required in very large hospitals (with 1000 beds, 2000 beds, or 3000 beds), the service points available for dispensing to the in -patients and out - patients are considered. The out -patient attendance as compared to bed st rength in hospitals is in the ratio of 3:1. For larger hospitals, 133 patients are guided by one pharmacist.

Table 6.1: Pharmacist Requirement

Bed Strength	Number of Pharmacists Required
Upto 50 beds	3
Upto 100 beds	5
Upto 200 beds	8
Upto 300 beds	10
Upto 500 beds	15

6.2.3. Types of Services Provided to In-Patients

The following **four systems** of drug distribution to in -patients are used in different hospitals in India:

1) Individual prescription order system,
2) Floor ward stock system,
3) Combination of individual drug order and floor stock system, and
4) Unit dose dispensing system.

6.2.4. Individual Prescription Order System

Individual prescription order system, though old is still followed in small private hospitals. In this system, doctors write a prescription and ask the patient to get the medicines from licensed medical stores. Medications should be di spensed in properly labelled individual prescription containers. The amount of drug dispensed should be determined by the hospital policy.

Medication for administration should be labelled with:

1) Patient's name and location,
2) Drug's name and strength,
3) Drug dose,
4) Administration route,
5) Accessory and cautionary statements,
6) Dispensed date, and
7) Hospital's name.

Advantages

1) Less number of staff is required in the hospital.
2) Prescription is directly reviewed by the qualified pharmacist at the medical store.
3) Doctors, pharmacists, and the patients can interact well.

Disadvantages

1) The chances for medication errors increase due to lack of checks in the distribution of medication doses and al so due to the inefficiencies in scheduling, preparing, administering, controlling, and recording during drug distribution and administration.
2) Excessive nursing manpower is required while preparing medication doses and conducting other medication-related activities.
3) The potential for drug loss due to waste, obsolescence, and deterioration also increases.

6.2.5. Floor Ward Stock System

Floor ward stock system is seen in private hospitals. In th is system, the drugs are stored in the pharmacy stores, supplied to the wards when ordered, and are supervised by a registered nurse at the nursing station. There are **two types of drugs**:

1) **Charge Drugs:** These are costly drugs obtained from the pharmacy store when the pharmacist receives the prescription for patients. The cost of drugs is billed in the patient's account for charging.
2) **Non-Charge Drugs:** These are cheaper and commonly used drugs. Their cost is not directly entered in the patient 's account but included into the per day cost of hospital ward.

6.2.5.1. Methods Employed for Prescribing Complete Floor Stock Drugs

There are **three methods** of transmitting drug order information from the nursing stations to the pharmacist:

Method 1: In this method, the physician writes the prescription order on a separate blank paper (**table 6.2**).

Table 6.2: Physician's Order Form

Physician's Order		Name:	
		Regd. No. :	Bed No:
		Doctor's Name:	
Date	Date	Orders	

Ordered	Discontinued		
7 /7/2018		Digitoxin 0.1mg O.D. in morning	
8/7/2018		T. Diazepam 10mg one H.S	
9/7/2018	14/7/2018	Potassium chloride 1gm daily in morning.	

Some smaller hospitals still require separate prescription for all medications. This method also establishes a professional relationship.

Method 2: In this method, the physician writes the medicine order in duplicate, one copy of which is received by the pharmacist. The registered nurse or other person posted at the nursing station does not need any copy to obtain the prescribed medication initially ordered.

In this method, the medication errors are reduced as the hand written prescription order is directly reviewed by the pharmacist. The physician mixes all types of orders for the patients on one sheet to provide a total picture to the ph armacist of what is happening to the patient. The physicians should limit the writing of their drug order in a single medication order sheet. After the order is written, other responsible staff members should remove the copy portion and send it to the pharmacy to avoid delay in dispensing.

Method 3: In this method, the in -charge of nursing unit copies the physician's written order on another document (called a **drug regulation slip**) and sends it to a pharmacy in - charge for reviewing and dispensing. The pha rmacist with this copied order creates the patient's drug profile and initiates the medication charge. In case of non -charge drugs, the nurse makes an entry on her records and removes the drug from the ward stock container to administer to the patients when ordered.

6.2.5.2. Selection of Charge and Non-Charge Floor Stock Drugs

On the following basis, it is decided whether the drug is to be placed in charge or non - charge floor stock:

1) **Selection of Charge Floor Stock Drugs:** The Pharmacy and Therapeutics Committee (PT C) decides which drugs should be categorised as charge drugs. Physicians, surgeons, and other specialists (who are PTC members) have the complete knowledge of drugs or other items in a hospital. Representatives of nursing, pharmacy, and administration sect ions should be consulted for guidance. On the final confirmation of floor stock list, the hospital pharmacist implements the decision of PTC and makes the drugs available. The decision of PTC should be materialised based on priority. While preparing the f inal list of charge floor stock drugs, the PTC will make available the effective drugs required for diagnosis or symptomatic treatment. **Table 6 .3** provides a list of pharmaceuticals and related preparations considered to be charge floor stock drugs:

Table 6.3: Pharmaceuticals and Related Preparations

Categories	Preparations
Anti-allergics	Phenergan injection and Prednisolone tablet.
Antibiotics	Penicillin G-potassium injection and Procaine penicillin injection.
Anticoagulants	Heparin (10,000 units/1ml).
Anti-hypertensives	Reserpine HCl (0.5mg/2ml).
Cardiovascular agents	Digoxin injection.
Diuretics	Furosemide injection (B.P.) and tablets.
Tranquilisers	Chlordiazepoxide (100mg/2ml).
Miscellaneous	Potassium chloride (49m Eq/20ml), Dextrose (50%) , and Mannitol injection (25%).

2) **Selection of Non-Charge Floor Stock Drugs:** The non-charge floor stock drugs list is prepared based on the following criteria:
   i) The preparation cost,
   ii) The frequency of use,
   iii) The quantity used,
   iv) The hospital budget, and
   v) Recompense from third party payers.

Given below is the list of non -charge drugs which should be available in the cabinets of wards and nursing stations:

1) **Ampoules**

Adrenaline	(1ml)
Aminophylline	(10ml. 250mg)
Atropine sulphate	(25ml 0.4mg/ml)
Digoxin	(2ml-0.25mg)
Digitoxin	(1ml-0.2mg)
Lidocaine HCl	(50ml. 1%)
Lidocaine HCl (1%) with epinephrine	(1: 1000/50ml)
Phenol sulphonapthalein	(1ml-6mg/ml)
Saline for injection	(500ml)
Scopolamine HBr	(1ml-0.65mg)
Bromosulphophthalein sodium	(3ml-50mg/ml)
Water for injection	(30ml)

2) **Capsules and Tablets**

Aspirin	(0.3gm)
Aspirin buffered	
Paracetamol	(500mg)
Ammonium chloride	(enteric coated 0.5gm)
Amylobarbitone	(0.2gm)
Atropine sulphate tablets	(0.65mg)
Phenolphthalein chewable tablets	(10%)
Dulcolax	(5mg)
Dicoumarol	(25mg)
Chloralhydrate	(0.5gm)
Digitalis	(0.1gm)
Digitoxin	(0.1gm)
Digoxin	(0.25mg)
Ferrous gluconate	(300mg)
Ferrous sulphate	(0.3gm)
Nitroglycerine H.T.	(03mg hypodermic tablets)
Isosorbide dinitrate	
Pentobarbitone	(50mg)
Phenobarbitone	(15mg)
Placebo	
Multivitamins	
Potassium chloride	(enteric coated 1gm)
Quinidine sulphate	(0.2gm)
Secobarbital	(50mg)
Sodium bicarbonate	(0.5mg)

3) **Solutions (Internal)**

Ammonium chloride syrup mixture	240ml
Tincture belladonna	60ml

Tincture benzoin compound	120ml
Castor oil	240ml
Chloralhydrate (1gm/5ml)	240ml
Kaolin pectin mixture	240ml
Tincture opium camphorated	120ml
Spirit peppermint	50ml
Elixir potassium chloride or flavoured potassium chloride solution	204ml
Potassium iodide, saturated solution	6ml
Elixir terpin hydrate or equivalent formulation (flavoured)	120ml
Suitable flavouring agent (orange, lemon etc.)	120ml

4) **Powders**

Glucose (dextrose)	100gm
Sodium bicarbonate	400gm

Talcum (individual units)
(to be stored in utility room.)

5) **Miscellaneous**
Amylnitrite, spirit ammonia aromatic.

6) **In the Refrigerator**

i) **Suppositories**

Glycerine suppositories	
Aminophylline suppositories	500mg

ii) **Liquids**

Hydrogen peroxide	400ml
Milk of magnesia	800ml
Paraffin liquid	500ml
Contents of the utility room (General service in pharmaceutical etc.)	

iii) **Solutions (For External Use)**

Alcoholic sponge lotion	480ml
Mouth wash solution	480ml
Benzalkonium chloride 1litre of 1:750, 1:1000 and 1 litre of 1:20,000 each	
Tincture benzoin compound	120ml
Calamine lotion	240ml
Chlorinated soda (5%)	1 litre
Denatured alcohol (for spirit lamp)	240ml
Deodorising spray	500ml
Ether (non-anaesthetic)	240ml
Alcohol ether-mixture	240ml
Glycerine	240ml
Suitable detergent solution	1 litre
Iodine (aqueous 2%)	240ml
Tincture-iodine (2%)	240ml
Instrument sterilising solution	50ml
Thermometer germicide solution	1 litre

iv) **Ointments and Creams**

Lanolin	30gm
Petroleum jelly	30gm
Surgical instruments (single use only)	
Zinc oxide ointment	30gm

The list mentioned above is just a sample and hospitals should compile a list of non - charge floor stock drugs, as per the needs of their staff and patients.

6.2.5.3. Dispensing and Distribution of Non-Charge Floor Stock Drugs

1) **Drug Basket Method:** In this method, the nurse o n night duty checks the medicine closet, utility room, and drug refrigerator inventory of supplies with the master list provided by the pharmacy and the nursing service. The nurse tick marks the number required for each drug on the requisition for floor st ock supplies where there is an empty container, she places the drug basket.

   On the completion of this procedure, the drug basket containing the empty containers and requisition for floor stock supplies in them are sent to the pharmacy. In the morning, the pharmacy staff fills each container and dispense the ordered ampoules and vials. When the basket is completed, it is delivered to the floor via messenger service.

2) **Mobile Dispensing Unit:** Pharmacy uses an especially designed stainless steel mobile truck, having two mobile units operating such that when one unit is in use, the other is being serviced. The pharmacy and the nursing service together decide the delivery frequency and the hours during which the mobile unit will visit the pavilion. If this system is used, the nurse on night duty need not to check the pharmacy inventory or transport empty containers to the pharmacy.

   In its place, the pharmacist running the mobile unit will inventory the pavilion drug cabinets and check the items and remaining qua ntity of supplies. The carbon copy of the requisition for floor stock supplies is left on the pavilion as a record of delivery and the original is returned to the pharmacy:
   i) For restocking the mobile unit,
   ii) For determining the use or consumption rate, and
   iii) For serving as a charge document for the internal allocation of costs.

6.2.5.4. Advantages

Floor ward stock system has the following advantages:

1) The required drugs are delivered easily and quickly.
2) The drug returns are eliminated.
3) The pharmacy staff members required is reduced.
4) The number of drug order transcription for the pharmacy is also reduced.

6.2.5.5. Disadvantages

Floor ward stock system has the following disadvantages:

1) Drug interaction or adverse drug reactions can occur as the pharmacist does not review the prescription.
2) Drug inventory on the pavilions is increased.
3) In order to avoid drug deterioration, proper storage facilities are required in wards; and this increases the cost.
4) There are greater chances for pilferage.
5) There are greater load upon the nurse time.

6.2.6. Combination of Individual Drug Order and Floor Stock System

This medication distribution method is commonly used. The drugs in this method are mostly dispensed on an individual pre scription basis; while remaining drugs are obtained via limited floor stock. Included in the floor stock , are the frequently used drugs, i.e., analgesic controlled substances, non -prescription drugs (like Paracetamol), pre -operative anaesthetic agents, and those not suited for individual prescription orders. In this system, nursing personnel prepare individual doses, reconstitute injectable medications, and order floor stock. The system has a **disadvantage** that it lacks adequate checks of dosages prepared and accuracy of charting of medication administration is less than desirable.

This system is followed in government and private hospitals running based on no profit and no loss. Individual prescription or medication system is mainly followed. Requirement of drugs or surgical items are given to the patient who purchases and deposits these items in hospital wards under the supervision of registered nurse.

6.2.7. Unit Dose Dispensing System

Unit dose medications are ordered, packaged, administered, and charged in multiples of single dose units containing a pre -determined amount of drug or supply sufficient dose for one regular dose, application, or use. This con cept of unit dose dispensing is not new; single dose disposable syringes of medications and single unit foil or cellophane wrapped capsules and tablets are commercially available since many years. Unit dose dispensing is the pharmacist's job, but in hospitals it requires the cooperation of nursing, administrative, and medical staff. Hospital pharmacist educates the other staff members involved in unit dose dispensing about this system.

6.2.7.1. Types of Unit Dose Systems

Either of the following two types of unit dose dispensing system exists in the hospitals:

1) **Centralised Unit Dose Dispensing (CUDD):** In this system, the in -patient drugs are dispensed in unit doses; the drugs are stored in the main pharmacy, and dispensed when the dose is to be given to the patient. D rugs are transferred from the pharmacy to the indoor patient by medication cards and dumbwaiters. Suction tube system (called pneumatic tubes) is used to send a copy of the physician's original medication order to the pharmacy for direct interpretation and filling.

2) **Decentralised Unit Dose Dispensing (DUDD) or Satellite Pharmacy Services:** Satellite pharmacy (or small pharmacy) should be located on each floor of the hospital. The main pharmacy procures, stores, manufactures, packages, and supplies the drugs t o the satellite pharmacies on receiving the medication order. This system can be used for a hospital with separate building.

   The procedure followed in decentralised unit dose system is as follows:
   i) The patient is admitted to the hospital and is entered in this system. Diagnosis, allergies, and other data are recorded on the patient profile card.
   ii) The copy of medication order is sent to the hospital pharmacist.
   iii) The pharmacist enters the medication order on the patient profile card.
   iv) The pharmacist checks t he medication order for allergies, drug -interaction, and rationale of therapy.
   v) The pharmacist schedules the dosage by consulting the nursing station.
   vi) Medication cost is filled for particular schedule delivery after inspection.
   vii) The nursing staff administers the medication to the patient and makes entry on their medication record.
   viii) The medication card is returned to the pharmacy and re -checked.

6.2.7.2. Advantages

Unit dose dispensing system has the following advantages:

1) Patients receive a letter service and are charged for doses administered to them.
2) Nurses get more time for patient care as all medication doses are prepared in the pharmacy.
3) Pharmacists check the original copy of physician's order, thus the medication errors are minimised.
4) Paper work is reduced at nursing unit and at the pharmacy.
5) Better financial control can be provided.
6) Less pilferage occurs.
7) The loss of partially used medications is prevented.
8) Storage facilities at the nursing station are not required.
9) Communication of medication orders and delivery system are improved.
10) The hospital pharmacist gets better provisions to control the entire operation throughout the hospital from the time the physicians write the medication order till the time the patients receive the unit dose.

6.2.7.3. Disadvantages

Unit dose dispensing system has the following disadvantages:

1) **Increased Cost:** A unit dose system requires additional equipment and more expensive medications. Unit dose medications are more costly than the same medications available in bulk packaging.
2) **Time Consuming:** A pharmacist takes more time in handling each dose individually than in sending the bulk drug to a ward. Also, checking and transcribing orders, and identifying drug interactions and contraindications are time-taking processes.
3) **Increased Staffing:** Unit dose system is time-consuming and labour intensive, thus more pharmacy personnel are required.
4) **Frequent Ordering:** In the ward issue system, orders are frequently placed.

6.3. DISPENSING OF DRUGS TO OUT-PATIENTS (AMBULATORY PATIENTS)

6.3.1. Introduction

An out-patient or ambulatory patient is not admitted in hospital and is given general or emergency treatment which could be diagnostic, therapeutic, or preventive. An out-patient department keeps a check on patients who need not to be admitted and require only diagnostic and therapeutic services.

There are **three types** of out-patients:

1) **General Out-Patient:** Such a patient is given treatment for a general condition, i.e., other than emergency condition, and is not a referred case.
2) **Referred Out-Patient:** Such a patient is referred to out-patient department by the attending medical/dental practitioner for specific treatment, and the patient for further treatment returns to the practitioner.
3) **Emergency Out-Patient:** Such a patient is given emergency or accidental care for conditions (determined clinically or considered by the patient or his representative) demanding instant medical attention.

6.3.2. Location of Out-Patient Pharmacy

There is no such rule based on which an out -patient dispensing pharmacy should be established. In today's practice, it has been proved that **three suitable provisions** are made for this area:

1) A separate out-patient pharmacy,
2) A com bined in -patient and out -patient unit with service provided from the **same window**, and
3) A combined in -patient and out -patient unit with service provided from **separate windows**.

A **separate out -patient pharmacy** is established when the out -patient department an d the pharmacy are geographically separate. However, this arrangement of separate and distinct unit with a specialised function requires a separate staff and also consumes a great deal of time , on the part of other pharmacy department personnel, in transpo rting supplies and drugs to the area. These **drawbacks** are eliminated by combining the in - patient and out -patient facilities. Another **advantage** of this arrangement is that the director of the pharmacy service can control and supervise the work more effectiv ely.

In India, out -patient department and pharmacy are usually in the same building; while in some hospitals, they are present as separate units, and in such a condition, an autonomous independent out-patient pharmacy should be established.

6.3.3. Layout of Out-Patient Department (OPD)

Out-patient department should be well -organised for patient convenience as it involves maximum interaction between the public and hospital. The servic es provided by this department should be of utmost quality as it deals with most of the patients.

An important property of OPD is that the **waiting period for the patients should be minimum**. If it is not, it is reduced by keeping sufficient space in the de partment for receiving and filling-up prescription.

Waiting rooms should have sufficient furniture, reading materials, and informative posters. In case of a rush in the department, more staff members should be there; however, this increases the expenses.

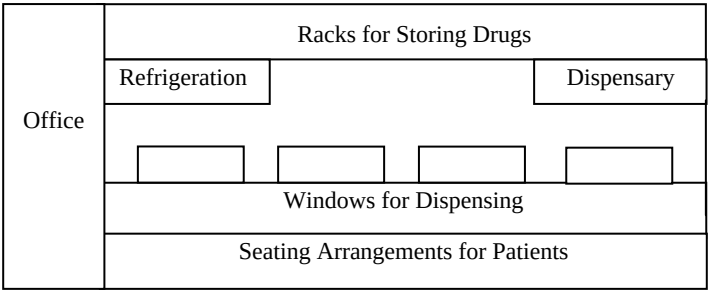


Figure 6.1: Typical Layout of an OPD

6.3.4. Method Adopted for Dispensing of Medications for Out-Patients

The steps involved in dispensing drugs to out -patients are as follows:

1) The patient on visiting the OPD goes to the reg istration counter to get registered. Thereafter, they are guided for medical department based on their clinical symptoms. On their second visit, they take the case file from the registration counter and go to the respective medical department.

2) They are diagnosed by the physician and are given a prescription, bearing their name, age, sex, registration number, disease, and medication schedule (i.e., time and manner).
3) The patients take the prescription from the physician and give it to the pharmacist in a pharmacy.
4) The pharmacist should carefully dispense the prescribed drugs without making any errors. He/she should not change facial expressions, and should receive the prescription without raising any doubt in the patients' mind.
5) In case of a waiting period, the pharmacist provides a token to the patients for their identification.
6) The prescription is recorded in the register. The pharmacist should check the token number of each patient to dispense correct drugs.
7) If the pharmacist has any doubt regarding the pr escription, he/she should contact the physician without letting the patients know about it.
8) The pharmacist checks the ingredients and collects the materials for compounding and dispensing the drugs. The ingredients are mostly liquid (to be poured) or tablets/capsules (to be counted).
9) The compounded drugs are filled in containers and labelled with the patients' name, age, sex, and registration number, and also the directions for use and storage of drugs.
10) The pharmacist should maintain a register for accounti ng, in which mixture, lotion, ointment, and powders are not recorded. But the costly drugs like injections, antibiotics, etc., are issued to poor patients only on special drug form.
11) The pharmacist gives back the prescription to the patients so they can pro duce it on their next visit.
12) The prescriptions related to schedule G, H, and X drugs should be written and dealt with the provision of the Drugs and Cosmetics Act.
13) The emergency cases of the hospitals should be immediately issued medicines.

6.4. SUMMARY

The details given in the chapter can be summarised as follows:

1) **In-patient department** should be located on the ground floor or first floor of the building.
2) Minimum 3 pharmacists should be present in a very small hospital; and 5 pharmacists should be present in a 100-bed hospital.
3) The number of pharmacists increases with the number of beds.
4) In **individual prescription order system** , doctors write a prescription and ask the patient to get the medicines from licensed medical stores.
5) In **floor ward stock system**, the drugs are stored in the pharmacy stores, supplied to the wards when ordered, and are supervised by a registered nurse at the nursing station.
6) **Charge drugs** are costly drugs obtained from the pharmacy store when the pharmacist receives the prescription for patients.
7) **Non-charge drugs** are cheaper and their cost is not directly entered in the patient's account but included into the per day cost of hospital ward.
8) In **drug basket method** , the nurse on night duty checks the medicine closet, utility room, and drug refrigerator inventory of supplies with the master list the pharmacy and the nursing service provides.
9) **Unit dose medications** are ordered, packaged, administered, and charged in multiples of single dose units containing a pre -determined amount of drug or supply sufficient dose for one regular dose, application, or use.

10) In **Centralised Unit Dose Dispensing (CUDD)** system, the in -patient drugs are dispensed in unit doses; the drugs are stored in the main pharmacy, and dispensed when the dose is to be given to the patient.
11) **Satellite pharmacy** (or small pharmacy) should be located on each floor of the hospital.
12) An **out-patient** or **ambulatory patient** is not admitted in hospital and is given general or emergency treatment which could be diagnostic, therapeutic, or preventive.
13) **General out -patient** is given treatment for a general condition, i.e., other than emergency condition, and is not a referred case.
14) **Referred out -patient** is referred to out -patient department by the attending medical/dental practitioner for speci fic treatment, and the patient for further treatment returns to the practitioner.
15) **Emergency out -patient** is given emergency or accidental care for conditions (determined clinically or considered by the patient or his representative) demanding instant medical attention.
16) A **separate out -patient pharmacy** is established when the out -patient department and the pharmacy are geographically separate.
17) In **per *diem* drug charge or all inclusive or no special rate** system, charges for 250 patients are studied and their av erage daily charges for drugs and pharmaceutical services are calculated.
18) In **part-inclusive rate** system, charges are made for drugs not on the free or supplied list.
19) **Professional fee concept** is the exclusive professional fee for all the operating expenses (including overhead and compensation) but not the actual cost of drug and container.
20) **Break-even point pricing** is a useful tool in overall analysis of cost volume relationship and is defined on the level at which there is neither profit nor loss.
21) **Ancillary supplies** are such that the laboratories, wards and special service areas can predict their rate of use and order them from the pharmacy either weekly or bi -weekly.

6.5. EXERCISE

6.5.1. True or False

1) Out-patient department should be located on the ground floor or f irst floor of the building.
2) Minimum 3 pharmacists should be present in a very small hospital; and 10 pharmacists should be present in a 100-bed hospital.
3) In individual prescription order system, doctors write a prescription and ask the patient to get the medicines from licensed medical stores.
4) Charge drugs are costly drugs obtained from the pharmacy store when the pharmacist receives the prescription for patients.
5) Satellite pharmacy should be located on the ground floor of the hospital.
6) General out -patient is given treatment for a condition other than emergency condition, and is not a referred case.
7) In cost plus rate system, charges are made for drugs not on the free or supplied list.

6.5.2. Fill in the Blanks

8) In _____ system, the drugs are stored in the pharmacy stores, supplied to the wards when ordered, and are supervised by a registered nurse at the nursing station.
9) _____ drugs are cheaper and their cost is not directly entered in the patient's account but included into the per day cost of hospital ward.
10) In _____ method, the nurse on night duty checks the medicine closet, utility room, and drug refrigerator inventory of supplies with the master list the pharmacy and the nursing service provides.
11) _____ are ordered, packaged, administered , and charged in multiples of single dose units containing a pre -determined amount of drug or supply sufficient dose for one regular dose, application, or use.
12) In _____ system, the in-patient drugs are dispensed in unit doses; the drugs are stored in the main pharmacy, and dispensed when the dose is to be given to the patient.
13) A _____ is established when the out -patient department and the pharmacy are geographically separate.
14) _____ is a useful tool in overall analysis of cost volume relati onship and is defined on the level at which there is neither profit nor loss.

Answers

1) False 2) False 3) True 4) True 5) False
6) True 7) False 8) Floor ward stock 9) Non-charge 10) Drug basket
11) Unit dose medications 12) Centralised unit dose dispensing
13) Separate out-patient pharmacy 14) Break-even point pricing

6.5.3. Very Short Answer Type Questions

1) Give the types of drug distribution system.
2) What types of services are provided to in-patients?
3) Mention the advantages and disadvantages of floor ward stock system.
4) What is a centralised unit dose dispensing system?
5) Give the types of out-patients.
6) Draw the layout of an OPD.
7) Give the formula for calculating professional fee.

6.5.4. Short Answer Type Questions

1) Write a short note on location of in-patient department.
2) Discuss individual prescription order system.
3) Write about the types of unit dose system.
4) What methods are adopted for dispensing of medications for out-patients?
5) Write a short note on charging policy.
6) Write about the dispensing of ancillary substances and articles.

6.5.5. Long Answer Type Questions

1) Write an illustrative note on dispensing of drugs to in-patients.
2) Discuss about dispensing of controlled drugs.
3) Write about labelling of drugs in hospitals.
4) Give a brief note on floor ward stock system.

CHAPTER 7

Hospital Formulary

7.1. HOSPITAL FORMULARY

7.1.1. Definition

The hospital formulary system is a method in which the medical staff of a hospital along with the pharmacy and therapeutic committee selects and evaluate medical agents and their dosage form which are not considered useful in the patient care. It is not easy for a hospital pharmacy to stock all the medications that doctors may want to prescribe to their hospitalised patients. Thus, the hospital pharmacist along with the medical staff of the hospital makes a hospital formulary, which includes a list of drugs that the hospital pharmacy stocks. The formulary also lists the information about each drug. The hospital staff along with the PTC meets regularly to make changes in the formulary and revise it periodically.

The hospital formulary is used by the physicians to check whether or not the medications required to treat a particular patient are available in the hospital. They also use the formulary to avoid prescribing medications that can undergo dangerous interactions with other medications. The physicians know about specific medications to be prescribed for specific conditions, but a hospital may substitute similar drugs for those medications. **For example**, a formulary may contain a less expensive generic version of a commonly used medication. Also, a hospitalised patient is treated by multiple physicians, and each physician prescribes different medications for the same patient.

7.1.2. Objectives

The hospital formulary aims to provide the hospital staff with the information given below:

1) **Information on Drug Products:** It provides information on PTC-approved drug products and their therapeutic use. This section includes descriptive entries for each item to facilitate its use like:
   i) **Entries in Formulary**
      a) Generic name of drug,
      b) Common names (brand names),
      c) Dosage forms, strength, and packaging,
      d) Formulation (name of the active ingredient and formulation of the product),
      e) Dose for adults and paediatrics,
      f) Administration route, and
      g) Cost.
   ii) **Indexes to the Drug Product Listing:** There are two ways of making the indexes included either at the beginning or at the end of the section to facilitate the use of formulary:
      a) **Generic Name/Brand Name:** Proper page number should be given for reference to a particular product.
      b) **Therapeutic or Pharmacological Index:** This index is based on the therapeutic category, **e.g.,** antihistaminic drugs, anti-infective drugs, etc.

2) **Information on Hospital Policies:** The formulary provides the following information regarding the hospital policies and procedures for drug usage:
   i) Various policies and procedures for drug usage and restrictions on drug usage.
   ii) PTC and its membership responsibilities.
   iii) Hospital regulations governing the prescribing, dispensing, administrat ion of drugs, generic names, drug orders, investigational drug policies, rules to be followed by medical representatives, emergency drug products, etc.
   iv) Operating procedures (such as hours of services, out -patient prescription policies, prescription labelli ng, packaging and practice, in -patient drug distribution procedure, patient education program, etc.).
   v) Information on the use of formulary, like the procedure for entry of a drug, the manner of arranging the entries, etc.

3) **Special Information:** The formulary provides information on the drug dosage schedule, hospital-approved abbreviation, and special information about drugs. The information provided in this section though varies from hospital -to-hospital, but should be useful to the hospital staff and should be readily available. It includes:
   i) Nutritional products list,
   ii) Equivalent dosage of similar drug,
   iii) List of hospital-approved abbreviations,
   iv) Guidelines for calculating paediatric dose,
   v) List of sugar-free drug products,
   vi) Number of items available for emergency boxes,
   vii) Metric conversions and tables,
   viii) Tables of drug interaction, and
   ix) Poison control distribution.

7.1.3. Limitations

The hospital formulary system has the following limitations:
1) It may prevent the physician's right to pre scribe and obtain the drug brand of his choice.
2) In many cases, the system allows the pharmacist to decide which drug brand is to be purchased and dispensed.
3) It does not provide any discount or scheme to reduce the drug cost to the patients which the hospital received while purchasing the drugs in bulk quantity.
4) In a hospital pharmacy with no staff pharmacist, the system may allow purchasing of inferior quality drug.

7.1.4. Contents of Hospital Formulary

The formulary is composed depending on those who are responsible for its publication. A section of prescription writing should be included in the formulary, as it will be useful for young physicians under training period. The following contents should be included in the hospital formulary:
1) The prescriptions should be written clearly in a correct manner, and every prescription should include:
   i) The patient's name and address,
   ii) The date,
   iii) The prescribed drug written in the terminology used in the formulary,
   iv) The strength of the drug prescribed in appropriate metric system.
2) The format.
3) Size, loose leaf or bound, printed, or mimeographed.
4) Index and assigning categories.

7.1.4.1. Prescription Writing

The prescriptions should be written clearly, appropriately, and should include:

1) The patient's name and address,
2) The date,
3) The prescribed drug written in the terminology used in the formulary,
4) The strength of the drug prescribed in the appropriate metric system,
5) The total amount to be dispensed,
6) The "Signa" with instructions for the patient should be mentioned clearly in simple terms so that the patient can understand it easily, and
7) If any drug is to be repeated, the physician should clearly mention the number of times the drug is to be taken. If this is not done, the pharmacist may not dispense the prescription again.

The prescriptions for narcotic drugs, apart from the above information should also have the patient's age. The prescribing physicians should sign the prescriptions, and should prepare three copies of the prescription; one copy of which is retained by him and the other two copies are given to the patient. Normal laboratory values, tables of weights and measures, tables for the calculations of percentages, milliequivalents and dosages, formulas of various diagnostic stains and reagents commonly used in the hospitals should be included in the formulary.

7.1.4.2. Format

The daily use and publishing cost of the formulary depends on its format. The hospital pharmacist collects the formularies of various hospitals and decides the format. After the formulary is published, two copies of it are sent to the American Society of Hospital Pharmacist.

The formulary depending on the local need of the hospital should be of a specific size to make it convenient to use for the physicians. Smaller size formularies are always preferred.

7.1.4.3. Size, Loose Leaf or Bound, Printed or Mimeographed

A formulary of sufficiently small size can be carried by the clinicians, nurses, etc., easily in the pockets of their uniform or laboratory coats. A small-sized formulary can also be carried by the physician in his/her bag along with the blank prescription forms. Many physicians use the formulary in their private clinics also. The hospitals generally determine the size of their formulary.

The hospital authorities along with the PTC decide whether the formulary should be in the form of a loose leaf volume or bound book. A **loose leaf type formulary** can be easily kept, and can be revised whenever required by printing, distributing, and inserting necessary pages. **Bound volumes** are prepared using paper and cardboard covers, or plastic or leather binding.

It is also decided whether the formulary will be printed or mimeographed (a modified version of cyclostyled volume). The appearance of printed formulary is more attractive, and is easier to read. However, a study of many formularies has shown that some better formularies are mimeographed.

Some formularies are developed by individuals with a goal of its publication or advertisement. They include drawings using coloured inks and coloured paper. This approach however should be avoided as formulary is a professional publication and should reflect the high ethical standard of the hospital and its staff. Therefore, a **white or slightly off-white paper** and use of **black ink** is recommended.

7.1.4.4. Indexing and Assigning Categories

While compiling a formulary, the authorities consider an approach which will aid the physician to locate an item in the formulary. A formulary contains all the required information, but sometimes data are not easily found due to imp roper indexing. Index thus is the key to formulary, and the pharmacist should spend efforts and time to make it useful so that the desired data can be easily located.

Formularies mostly have a general index at the end of the text. This index is arranged alphabetically by generic names of the drugs and cross -indexed with brand names in the text portion of the formulary. General index is an essential part in a formulary and cannot be missed.

For example, a physician has the knowledge of generic and brand n ames of a number of anticholinergic drugs; he/she will search the index to find a familiar anti -cholinergic drug. This approach is burdensome and time -taking, thus the general index should be supplemented with a pharmacological index which will be a matter of finding any particular data in a very short time. Therefore, key pharmacological classification with main headings is only suggested.

The pharmacists along with the PTC should classify all the drugs used in the hospital and mention about them in the formulary under each heading. This compiled index should then be placed either in the front or at the back of the formulary.

Apart from the general and the pharmacological indexes, the formulary is divided into specific sections, each separated by a divid er. The type of sub -division of sections can be achieved in the following pattern.

1) Ear,
2) Eye,
3) Nose,
4) Rectal,
5) Throat,
6) Vaginal,
7) Skin,
8) Nutritional aids,
9) Oral products, and
10) Injectables.

This sub -division enables the physician to readily refer to the specif ic agent used for either automatic entry or to the broad category of oral or parenteral drugs.

7.1.4.5. Selection of Text

This is a very important part of the formulary. Selection and scope of the text under each generic drug should be given appropriately. The amo unt of text published depends on the goals established by the PTC. It should be appreciated by all the readers as insufficient information will not enhance the use and acceptance of the formulary by the staff. On the other hand, the busy practitioner will also not use the formulary if it is a miniature text book on pharmacology.

7.1.5. Differentiation of Hospital Formulary and Drug List

A **drug formulary** is a manual containing clinically oriented summari es of pharmacological information about some of the selected drugs. It may also include administrative and regulatory information regarding the prescribing and dispensing of drugs. A **National Formulary** (NF) focuses on available and affordable medicines required for the treatment of diseases in a particular country. Formularies are frequently created for individual hospitals for different levels of health care and different sectors.

The **National Formulary Committee** (NFC) decides the final purpose, structure, content, and format of the NF. The members of this committee should be limited to such number that it functions effectively and follow the endorsement of national policy-making bodies. If an established Essential Drug Programme (EDP) already exists in a country, the existing multidisciplinary committee or a sub-committee of it serves the role of NFC.

Table 7.1 enlists the differential points between private and national formulary:

Table 7.1: Comparison between Private and National Formulary

Private Formulary	National Formulary
Prepared by the clinical staff of hospitals.	Prepared by outstanding clinicians, pharmacologists, and pharmacists of the country.
Information under each monograph is for local needs, and may include related clinical matters.	Each monograph contains physical and chemical properties, pharmacological responses, uses, toxicology, posology, preparations, and contraindications.
Published in a convenient size and format.	Size is big as it contains many drugs.
Drugs can be frequently added or deleted.	Drugs are less frequently added or deleted.

Drug list is a multi-page article that enlists the names of pharmaceutical drugs in alphabetical order. There are many drugs having more than one name, and therefore, are listed more than once. The brand names are differentiated from the generic names by writing the initials for the former in capital.

The drug list is organised in sections as per the drug class or medical condition. Each section has sub-sections to ease locating of drugs. Most of the listed generic or brand drugs are formulary drugs. Generic drugs undergo the same approval process by the Food and Drug Administration (FDA) as the branded drugs and should also fulfil the similar standards of effectiveness and chemical make-up as branded drugs.

Some drugs in the drug list require Utilisation Management (UM), i.e., pre-authorisation, managed dose limitations, and step-therapy. If a drug has been applied with a UM, it is indicated with one of the **following** symbols in a column next to the drug name:

1) MDL (Managed Dose Limitations),
2) PA (Pre-Authorisation), and
3) ST (Step-Therapy).

7.1.6. Preparation and Revision of Hospital Formulary

The very initial step in the development of a hospital formulary for any hospital is to form a proficient PTC, which makes decision on the following:

1) The type of publication of the formulary:
   i) A hospital's own formulary, or
   ii) A list of drugs, or
   iii) A purchased formulary service.
2) Fixation of rules which the PTC requires while evaluating drugs for admission to the formulary.
3) While preparing a formulary, content in the following sections should also be included:
   i) Prescription writing,
   ii) Use of drugs,

iii) Table of metric weights and Apothecary and household equivalents,
iv) Tables of common laboratory values,
v) Section on calculation of doses for children,
vi) Pharmacological index, and
vii) Section on reagents.

4) The type of format of the formulary:
i) Size,
ii) Loose leaf or bounded,
iii) Printed or mimeographed,
iv) Extent of categorisation and indexing.

Examples

Autonomic Drugs (Sympathomimetic or Adrenergic Drugs)

1) **Ephedrine Sulphate Injection:** 1ml contains 50mg ephedrine sulphate.
Dispense: 1ml
Route: Subcutaneous and intramuscular
Dose: 25-50mg every 4 hours.

2) **Epinephrine Injection:** 1ml contains 1mg epinephrine.
Dispense: 1ml
Route: Subcutaneous
Dose: 0.2-1mg every 4 hours.

3) **Epinephrine in Oil Injection:** 1ml contains 2mg epinephrine.
Dispense: 1ml
Route: Intramuscular
Dose: 2mg in every 8 and 12 hours.

4) **Levarterenol Bitartrate Injection:** 4ml contains 4mg levarterenol.
Dispense: 4ml
Route: Intravenous only by infusion
Dose: 4mg is added to 1000ml of 50% dextrose solution, each 1ml of the dilution contains 4µg Levarterenol.

5) **Phenylephrine Hydrochloride Injection:** 1ml contains 10mg phenylephrine hydrochloride.
Dispenses: 1ml
Route: Subcutaneous
Dose: 1-10mg every 8 hours.

Cardiovascular Drugs (Vasodilators)

1) **Amyl Nitrite** (Capsules-glass). **Route:** Inhalation
i) 0.3mg Hypodermic Tablets
ii) 0.6mg Hypodermic Tablets
iii) 0.4mg Hypodermic Tablets

2) **Mannitol Hexanitrate** – 30mg tablets

3) **Papaverine Hydrochloride**
i) 30mg tablet
ii) 30mg ampoule
iii) 30mg in i.c.c. for subcutaneous use
iv) Intramuscular or intravenous use

4) **Pentaerythritol Tetranitrate** (Peritrate)
10mg tablets

5) **Priscoline Hydrochloride** – 25mg tablets
10cc vials 25mg/cc
For subcutaneous, intramuscular or intravenous use.

Revision
The procedure to add a new drug in the formulary is complex. The members are not skilled enough to evaluate each therap eutic agent; thus the PTC takes help from other experts for addition of selected special drugs. Preparations whose formula is not revealed are not entered in the formulary. Some policy guidelines for adding or removing drugs in the formulary have been framed by the PTC in consultation with the medical staff.

The formulary should be revised annually as new drugs are added and removed from it, some drugs are even removed from the market, and the hospital policies and procedures also changes. A definite syste m should be adopted for the revision of formulary; in **one method**, formulary supplement sheets can be attached to the back covers of formulary books; and in the **second method**, different colours can be used for the cover of each edition of the formulary to a void confusion between the latest and past edition. The revised formulary system should be regularly reviewed so that the most cost -effective products are only used. Such reviews result in the removal of some drugs.

7.1.7. Addition and Deletion of Drug from Hospital Formulary

Adding or deleting a drug from the formulary is an important step in maintenance of hospital formulary. Additions and deletions should be done by following some specific policies and procedures developed by the Pharmacy and Therapeutic Committee (PTC). A system should be developed for taking decisions regarding the addition or deletion of a drug from a formulary.

Routine reviews of medicine class are important for the maintenance of formulary. **Medicine class review** involves evaluating an entire section of medicines (**e.g.,** cephalosporin antibiotics). This review systematically evaluates the existing medicines in the formulary so that the complete formulary is reviewed two to three tim es. This is a difficult task, but review and analysis of formulary medicines is also important in a medical discipline that keeps on changing. Any new medicines having advantages over the existing medicines will be evaluated for adding them in the formulary.

Medicines no longer in use or lacking satisfactory evidence of efficacy, safety, and quality should be recommended for deletion. Medicines no longer fulfilling the standards of being cost -effective should also be evaluated and deleted to be replaced by a satisfactory alternative.

The following **criteria** should be considered **while adding into** or **removing drugs from the formulary**:
1) The medical staff should have approved the drug to be added in the formulary.
2) The drug should be recognised by the Pharmacopoe ias and Formularies approved under Drugs and Cosmetic Act and Rules.
3) The drug manufacturer should hold a license issued under the Drugs and Cosmetic Rules. Also he should not have been punished for any serious offence under any law of Drugs and Medicines.
4) The drug or preparation of secret composition should not be added in the formulary.
5) The drug or preparation containing multiple ingredients should not be added if the same therapeutic effect can be obtained by using a preparation with single ingredient.

7.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) The **hospital formulary** system is a method in which the medical staff of a hospital along with the pharmacy and therapeutic committee selects and evaluate medical agents and their dosage form which are not considered useful in the patient care.
2) Normal laboratory values, tables of weights and measures, tables for the calculations of percentages, milliequivalents and dosages, formulas of various diagnostic stains and reagents commonly used in the hospitals should be included in the formulary.
3) The daily use and publishing cost of the formulary depends on its format.
4) A **loose leaf type formulary** can be easily kept, and can be revised whenever required by printing, distributing, and inserting necessary pages.
5) **Bound volumes** are prepared using paper and cardboard covers, or plastic or leather binding.
6) Formularies mostly have a general index at the end of the text. This index is arranged alphabetically by generic names of the drugs and cross-indexed with brand names in the text portion of the formulary.
7) A **drug formulary** is a manual containing clinically oriented summaries of pharmacological information about some of the selected drugs.
8) A **National Formulary** (NF) focuses on available and affordable medicines required for the treatment of diseases in a particular country.
9) The **National Formulary Committee** (NFC) decides the final purpose, structure, content, and format of the NF.
10) **Drug list** is a multi-page article that enlists the names of pharmaceutical drugs in alphabetical order.
11) The formulary should be revised annually as new drugs are added and removed from it, some drugs are even removed from the market, and the hospital policies and procedures also changes.
12) **Medicine class review** involves evaluating an entire section of medicines (**e.g.,** cephalosporin antibiotics).

7.3. EXERCISE

7.3.1. True or False

1) A loose leaf type formulary can be revised whenever required by printing, distributing, and inserting necessary pages.
2) A drug list is a manual containing clinically oriented summaries of pharmacological information about some of the selected drugs.
3) A drug formulary focuses on available and affordable medicines required for the treatment of diseases in a particular country.
4) Drug list is a multi-page article that enlists the names of pharmaceutical drugs in alphabetical order.
5) Formularies mostly have a general index at the beginning of the text.

7.3.1. Fill in the Blanks

6) The daily use and publishing cost of the formulary depends on its _____.
7) _____ are prepared using paper and cardboard covers, or plastic or leather binding.
8) The _____ decides the final purpose, structure, content, and format of the NF.
9) _____ involves evaluating an entire section of medicines.
10) The _____ is arranged alphabetically by generic names of the drugs and cross - indexed with brand names in the text portion of the formulary.

Answers

1) True 2) False 3) False 4) True 5) False
6) Format 7) Bound volumes 8) National Formulary Committee
9) Medicine class review 10) Index

7.3.2. Very Short Answer Type Questions

1) Define hospital formulary.
2) What are the limitations of hospital formulary?
3) What are a drug formulary and a drug list?
4) Give two methods for revision of drugs in hospital formulary.

7.3.3. Short Answer Type Questions

1) Give the objectives of hospital formulary.
2) Differentiate between hospital formulary and drug list.
3) Write about the addition and deletion of drug from hospital formulary.

7.3.4. Long Answer Type Questions

1) Write an illustrative note on contents of hospital formulary.
2) Discuss about preparation and revision of hospital formulary.

CHAPTER 8

Therapeutic Drug Monitoring

8.1. THERAPEUTIC DRUG MONITORING

8.1.1. Introduction

The measurement of drug concentrations in the biological fluids, with an aim of improving the drug therapy of a patient is referred to as **Therapeutic Drug Monitoring (TDM)**. TDM involves the application of pharmacology, pharmacokinetic consultation, pathology and clinical medicine in order to interpret the concentration of drugs as measured in body fluids.

TDM is **used** in two situations:

1) To minimise the risk of serious drug toxicity and assessment of appropriateness of dosing for drugs used as prophylactic therapy.
2) To identify a drug on substance, this may be contributing to the presentation of a medical emergency.

There are some common clinical situations where TDM may be useful:

1) To certain adequate serum concentration where clinical response is inadequate and to assess the appropriateness of dosage regimen.
2) To avoid drug toxicity and maintaining the concentration of a drug within therapeutic range, **e.g.,** gentamycin accumulation leads to nephro- or oto-toxicity that is prevented by TDM.
3) To assist dose adjustment in various disease states where individual variations in drug ADME may be important, **e.g.,** drugs metabolising in liver may accumulate in patients with severe hepatic disease and is monitored by TDM.
4) To individualise dosing for some drugs with an unpredictable dose response curve, **e.g.,** phenytoin has non-linear kinetics and increase in dose may lead to a large increase in serum drug concentration.
5) To minimise the time period needed for dosage adjustment (depending on the half-life of drug).
6) To identify poisons and to assess the severity of poisoning on an emergency basis in a poisoned patients.

8.1.2. Need of Therapeutic Drug Monitoring

TDM becomes essential at times when:

1) The level of the drug in blood correlates with clinical response.
2) Either clinical response or pharmacological response, or both, are not effortlessly and precisely measured.
3) The drug levels in blood show wide ranging differences even in a steady state.
4) Therapeutic index possesses a low value.
5) Therapeutic index is limited and adverse effects are more.

6) Dose of drug administered is poorly associated with its corresponding blood levels.
7) Drug is administered as a prophylactic measure.
8) Patient compliance is temporarily inactive and poor.
9) A patient is consuming four or more medications.
10) A patient is suffering from renal and hepatic impairment, cardiac dysfunction, and cystic fibrosis.
11) A patient has a probability of malabsorption.
12) Patients who are on dialysis or haemofiltration (renal replacement therapy) and those who are undergoing treatment for burn.
13) Geriatric patients, obstetric patients , and patients suffering from diabetes come in question.

8.1.3. Factors to be Considered During Therapeutic Drug Monitoring

Serum drug concentrations are affected by various factors, which therefore should be considered while deducing the results of TDM. The following information shoul d be collected in the request form for a TDM assay **(figure 8.1)** to interpret the assay result easily:

1) **Patient Demographics:** When inferring the results of TDM, the age, sex, body weight and ethnicity of patients should be considered. Age, sex, and lean body weight should be particularly taken into account in case of renally -excreted drugs to determine creatinine clearance. Ethnicity should be considered in case of hepatically - excreted drugs.

2) **Dosage Regimen and Duration of Therapy:** For a recently originated d rug before its TDM is performed, sufficient time should elapse to achieve steady state. If a loading dose has not been given, at least 5 half-lives of the drug should elapse.

3) **Sampling Time:** A drug's serum concentration depends on the time of withdrawing blood for a TDM assay with respect to the last dose. Thus, it is important to know the time and date of the last dose and that of blood sampling. Blood samples should be collected immediately before the next dose (i.e., a trough level) when performing TDM assay for drugs with a short half-life.

   Blood samples can be collected any time during the post -distribution phase once steady-state has been achieved for drugs with a long half -life. Since the time to reach peak concentrations varies greatly, peak levels a re not routinely performed in clinical practice.

4) **Patient Compliance:** If drug concentration is lower than anticipated, the possibility of non -compliance should be considered before increasing the drug dose. Non - compliance can be confirmed by asking the pati ent about their compliance in a non - judgmental way. However, this is not a reliable method if a patient is confused after a seizure.

5) **Individual Capacity to Distribute/Metabolise/Excrete the Drug:** The ability to excrete renally-cleared drugs is reduced in p atients suffering from renal impairment. Thus, the patient's renal function should always be checked while making interpretation of TDM for renally-cleared drugs (**e.g.,** digoxin and aminoglycosides).

6) **Altered Protein Binding:** Malnutrition or nephropathy redu ces plasma protein concentrations. Thus, reduced albumin level results in higher concentration of

unbound (or free) drugs which usually get strongly bound to plasma proteins (**e.g.,** phenytoin). In such cases, the total as well as free drug concentration sho uld be determined.

7) **Drug Interactions:** TDM results should be inferred with respect to the drug therapy the patient is undergoing simultaneously. **For example,** if amiodarone, quinidine or verapamil are started in patients on digoxin without reducing its dose, they might show abnormally high concentrations of digoxin in serum, which further leads to digoxin toxicity. If drugs inducing or inhibiting hepatic cytochrome P450 isoenzymes are started or stopped, the serum concentrations of some hepatically - cleared drugs get affected.

Patient's name: _____ Date: _____

Age:_____ Sex: M F Wt:_____kg

Hospital: _____ Ward or clinic: _____

Please Indicate when Result is Needed

Within 24 Hrs Within 2-4 Hrs Stat

Reason for Request

Suspected toxicity Possible drug interaction
Therapeutic confirmation Lack of therapeutic response

Other (please specify) _____

Comorbidities or other clinical comments

Name of drug to be assayed _____

Dose _____ Frequency _____ Dosage form _____

Route of administration (please circle): IV IM PO SC

Duration of therapy _____

Time and date of last dose _____

Time and date when sample was drawn _____
Doctor's signature _____

Contract details for urgent results _____

Figure 8.1: Example of a TDM Request Form

8) **Pathological Factors:** When the results of TDM assay are to be inferred, the patient's comorbidities (medical condition of two disorders or diseases coexisting at once) should be considered. Vomiting, dia rrhoea, or inflammatory bowel diseased conditions can affect drug absorption and consequently serum drug concentrations. In conditions of hepatic cirrhosis and tuberculosis , if the patients take normal doses of rifampicin and isoniazid, elevated drug conce ntrations and increased

hepatotoxicity will be observed. Gastric or small bowel surgery and *Giardia lamblia* infections may cause malabsorption, which further reduces serum drug concentrations.

9) **Alcohol and Tobacco Use:** Chronic use of alcohol results in non -specific hepatic microsomal enzyme induction, which further increases clearance and decreases serum concentrations of hepatically -cleared drugs (**e.g.,** phenytoin). Hepatic clearance of theophylline is elevated in patients who smoke cigarette, whil e abnormally high concentration of theophylline is observed in patients who have recently quit smoking.

10) **Medication or Sampling Errors:** If the TDM result is non -compatible with drug administration records, the possibility of medication or sampling error should be considered. **For example,** a wrong patient has received a particular drug, or blood has been collected from a wrong patient.

11) **Laboratory Errors:** In case a laboratory error is suspected, the assay should be repeated in the laboratory. Also, a new blood sample can be collected and sent to a different laboratory for TDM assay.

8.1.4. Indian Scenario for Therapeutic Drug Monitoring

Therapeutic drug monitoring was introduced in India in the mid and late 1980s. In the last 10 years, TDM has grown along with the departments of clinical pharmacology. The TDM service in India is of two types, i.e., in **large teaching hospitals**, where the service is provided by the departments of clinical pharmacology, and in the **private sector** , where clinical biochemistry departments are involved in drug valuations.

Special **issues associated with TDM** in India are:

1) **Alternative Systems of Medicine:** In India, Ayurveda, Homeopathy, and Unani are the three systems of medicine that coexist with the western Allopathy medicine system. Sometimes the allopathic practitioners co -prescribe medicines from the alternative systems (especially in case of chronic disorders).

2) **Tropical Diseases and Nutritional Deficiencies:** In most developing countries, ill health is a serious problem. The highly prevalent diseases in these countries are infections, diarrhoea, worm infestations, tuberculosis, neurocysticercosis, and nutritional deficiencies. A large number of patients also suffer from diabetes and AIDS. Often the patients are diagnosed late and thus get their treatment late. Nutritional deficiencies are often sub -clinical, left undiagnosed, and affect drug pharmacokinetics.

3) **Ethnic Differences:** Inter-population variations in drug pharmacokinetics can result in higher or lower plasma drug concentrations. **For example**, phenytoin metabolism by *para*-hydroxylation is subjected to wide inter-individual variation.

4) **Quality Control in Drug Assays:** Quality control is essential for TDM programs. In developing countries, there are no procedures for laboratory authorisation or external quality control. In India, a centre in Southern India provides an external quality control program for biochemical tests. However, for drug levels there are no such programs, and thus departments a nd laboratories mostly make use of overseas quality control programs, which increases the running cost of laboratory.

5) **Quality of Medicines and Generic Formulations:** Prescribing of generic products is increasing all over the world, and this is even promoted by health authorities for economic reasons. The drug content and bioavailability of such products is important for drugs having a narrow safety margin wand for which TDM assay is relevant.

8.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) The measurement of drug concentrations in the biological fluids, with an aim of improving the drug therapy of a patient is referred to as **Therapeutic Drug Monitoring (TDM)**.
2) When inferring the results of TDM, the age, sex, body weight and ethnicity of patients should be considered.
3) A drug's serum concentration depends on the time of withdrawing blood for a TDM assay with respect to the last dose.
4) If drug concentration is lower than anticipated, the possibility of non-compliance should be considered before increasing the drug dose.
5) The ability to excrete renally-cleared drugs is reduced in patients suffering from renal impairment.
6) Malnutrition or nephropathy reduces plasma protein concentrations.
7) TDM results should be inferred with respect to the drug therapy the patient is undergoing simultaneously.
8) When the results of TDM assay are to be inferred, the patient's comorbidities (medical condition of two disorders or diseases coexisting at once) should be considered.
9) Chronic use of alcohol results in non-specific hepatic microsomal enzyme induction, which further increases clearance and decreases serum concentrations of hepatically-cleared drugs.
10) If the TDM result is non-compatible with drug administration records, the possibility of medication or sampling error should be considered.

8.3. EXERCISE

8.3.1. True or False

1) A drug's plasma concentration depends on the time of withdrawing blood for a TDM assay with respect to the last dose.
2) If drug concentration is lower than anticipated, the possibility of non-compliance should be considered before decreasing the drug dose.
3) Malnutrition or nephropathy reduces plasma protein concentrations.
4) If the TDM result is non-compatible with drug administration records, the possibility of medication or sampling error should be considered.

8.3.2. Fill in the Blanks

5) The ability to excrete renally-cleared drugs is reduced in patients suffering from _____.
6) When the results of TDM assay are to be inferred, the patient's _____ should be considered.
7) Chronic use of alcohol results in non-specific hepatic microsomal enzyme induction, which further increases clearance and decreases serum concentrations of _____.
8) When inferring the results of TDM, the age, sex, body weight and _____ of patients should be considered.

Answers

1) False 2) False 3) True 4) True 5) Renal impairment
6) Comorbidities 7) Hepatically-cleared drugs 8) Ethnicity

8.3.3. Very Short Answer Type Questions

1) Define TDM.
2) Give two uses of TDM.
3) Give any two factors to be considered during TDM.

8.3.4. Short Answer Type Questions

1) What is the need of TDM?
2) Discuss the Indian scenario for TDM.

8.3.5. Long Answer Type Questions

1) Write an illustrative note on TDM.
2) Discuss the factors to be considered during TDM.

CHAPTER 9

Medication Adherence

9.1. MEDICATION ADHERENCE

9.1.1. Introduction

Patient adherence (or **compliance**) means correct following of medical advice by the patient. Usually the patient takes medication on his own (drug compliance), but the term **adherence** may also refer to the use of su rgical appliances, like compression stockings, chronic wound care, self-directed physiotherapy exercises, or attending counselling or other therapy courses. To improve patient adherence, a physician has to build positive physician-patient relationship.

Medication adherence is categorised into two main concepts, i.e., **adherence** and **persistence**. Both the concepts are theoretically similar, but adherence is the intensity of drug use during the duration of therapy, while persistence is the overall duration of drug therapy.

WHO defined medication adherence as "**the degree to which the person's behaviour corresponds with the agreed recommendations from a health care provider**".

9.1.2. Determinants of Medication Adherence

Medication adherence or non-adherence is the result of a complex interaction among many factors. Some of these factors improve the medication adherence of a patient while some put a negative influence. Thus, the prediction of medication adherence is difficult since the situation is different for each patient.

The **factors influencing adherence** or any health-related behaviour are divided into three categories:

1) **Predisposing Factors:** These factors include demographic factors of the patients, and also their knowledge, attitudes, beliefs and perceptions about illness and its severity, cause, prevention, and treatment. The **Health Belief Model** developed in **1974** predicted adherence or other health-related behaviour changes in terms of certain belief patterns. The sequence of belief events under this model, which need to occur if the patient is to be adherent, is as follows:
   i) The patients should believe that their health is in danger.
   ii) The patients should identify the potential seriousness of the condition in terms of symptoms, time lost from work, economic difficulties, etc.
   iii) After evaluating the conditions, the patient should believe that benefits from treatment compensate the costs.
   iv) The patient should feel the need to adhere to the medication.

2) **Enabling Factors:** These factors are the skills and resources required for adherence. The term **skills** refer to the patient's capability of embracing such behaviours that will contribute to adherence, **e.g.,** taking an appointment from the doctor to obtain a prescription. The term **resources** refer to the availability and approachability of healthcare facilities such as doctors, pharmacies, clinics, or hospitals.

3) **Reinforcing Factors:** These factors determine whether or not the patient's family members, peers, healthcare providers, the local community , and society are supportive enough to assist in medication adherence. This support may be positive or negative, and this depends on the attitude or behaviour of the people as some may be more influential while the others may be less.

9.1.3. Monitoring of Patient Medication Adherence

Full medication adherence is required as a drug is effective only when it i s strictly taken on time, in correct dosage and frequency. Monitoring of medication involves using some observation methods to check whether or not the patient has taken the medication. Hence, the effectiveness of the monitoring method plays the major role . Medication adherence can be measured by **direct** as well as **indirect methods**. In some cases, the providers wish to measure adherence directly by determining the drug concentration in blood. However, indirect methods are more commonly used, which include p atient questionnaires, pill counts, refill rates, and clinical response.

9.1.3.1. Direct Methods

Direct methods of adherence assessment involve direct observation of the undergoing therapy, measurement of the drug or metabolite level and of the biological marker i n blood. The direct methods are considered to be more robust than the indirect methods, still they have some **limitations**. **For example,** patients may hide the pills in their mouth and discard them later, or they may have varied metabolism that will ultimatel y affect serum levels. These direct methods are not used practically for routine clinical analysis.

9.1.3.2. Indirect Methods

Indirect methods of adherence assessment involve patient questionnaires, self -reports, pill counts, rate of prescription refills, electron ic medication monitors, patient diaries, patient's clinical response, and physiological markers. Patient's self -report, pill counts, and pharmacy refills are the most commonly used indirect methods.

Morisky's Medication Adherence Scale (MMAS) was designe d to differentiate between the patients who are poorly adherent and the patients who are medium -to-high adherent to their antihypertensive regimen. MMAS includes questions on multiple reasons for non-adherence; **e.g.,** a complex regimen can lead to non -compliance, thus the scale involves a question evaluating whether the patients feel stressed about their regimen. The patients generally give positive answers to please their HCP (**Health Care Personnel**), hence the questions in Morisky's study were formulated to avoid this partiality. Each question in MMAS evaluates a speci fic medication -taking behaviour, instead of adherence or compliance behaviour.

Morisky's medication adherence scale comprises of the following **questions**:

1) Do you sometimes forget to take your high-BP pills?
2) Over the past 2 weeks, were there any days you did not take your high -BP medication?
3) Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?
4) When you travel or leave home, do you sometimes forget to carry your medication with you?
5) Did you take your high-BP medication yesterday?
6) When you feel that your BP is under control, do you sometimes stop taking your medication?

7) Taking medication every day is real inconvenience for some people. Do you ever feel stressed about sticking to your BP treatment plan?
8) How often do you have difficulty remembering to take your BP medication?

Gehi *et al.*, found that on asking a single screening question ("In the past months, how often did you take your medications as the doctor prescribed?") to the patients of coronary artery disease, their self -report of medication non -adherence was related to the adverse cardiac events, including coronary heart disease death, myocardial infarction, and stroke. However, self-report measures can be biased by inaccurate patient recall.

Pill counts can be easily performed and have been correlated with electronic medicat ion monitors. They are often used in randomised, controlled clinical trials to measure medication adherence. However, pill counts fail to accurately measure the exact timing of medication, and the data can be even manipulated by the patients (**e.g.,** pill dumping).

All the indirect methods have their own advantages and disadvantages, and selecting a specific method for adherence assessment depends on the clinical scenario and data availability. Electronic pharmacy data are becoming widely available, and is a frequently used method for adherence assessment. Obtaining **refills** and the frequency of acquiring refills reveal different facets of the adherence behaviour of a patient. Adherence based on pharmacy refill data and a broad range of patient outcomes are interrelated.

Medication possession ratio and the **proportion of days covered methods** (defined by the number of doses dispensed in relation to a dispensing period) are the most commonly used measures of medication adherence based on pharmacy data. The major difference between these two measures is that the medication possession ratio accounts for oversupplies and have a value **>1**, whereas the maximum proportion of days covered is **1**, indicating full adherence. Using a **pharmacy prescription refill data** requires that patients should obtain their medications in a closed pharmacy system. The medication possession ratio and the proportion of days covered methods of evaluating medication adherence are correlated with the quantity of doses taken (but not to the timing of doses). Also, adherence assessment with these measures is more difficult when the length of follow-up varies between patients.

Calculating Adherence
There are various calculations for determining adherence based on pharmacy claims data; however, no single approach has been uniformly acknowledged.

Medication Possession Ratio (MPR)

$$\text{MPR} = \frac{\text{Total Day's Supply in Period}}{\text{Last Fill Date} - \text{First Fill Date} + \text{Last Fill Day's Supply}}$$

The value of MPR ranges from 0 to 1, of which **1** indicates **100% adherence**. If patients take early refills or they have only filled the medication once, the MPR value can be **>1**.

Medication Persistence
Medication persistence is the denominator of the MPR equation and is used to calculate the duration for which the patient has been taking the medication, without considering any breaks in the therapy.

Persistence = Last Fill Date – First Fill Date + Last Fill Day's Supply

Proportion of Days Covered (PDC)

$$PDC = \frac{\text{Number of Days in Period Covered}}{\text{Number of Days in Period}}$$

The value of PDC ranges from 0 to 1, of which **1** indicates **100% adherence**. The Pharmacy Quality Alliance (PQA) recommends that PDC can be used for assessing adherence. The organisation determined that PDC gives a more conservative estimate, particularly when medications are frequently switched. These metrics define adherence as **>0.8** or **80% of days covered**. Medications for HIV/AIDS and birth control require approximately 100% adherence for effectiveness.

Most cases of adherence are measured through claim data, and adherence can be misrepresented or inaccurately estimated using these calculations. **For example,** cases where the medication is automatically filled or the directions have changed and a new prescription has not been issued. Additionally, these methods do not consider the administration techniques or timing of dose. Adherence can be best evaluated by directly discussing the medication-taking behaviours with the patients.

9.1.4. Non-Medication Adherence

Non-compliance is the failure of the patient to obey instructions for administering the medications as directed, and thus resulting in lower response of treatment than expected.

The term **non-compliance** is associated with a patient avoiding the administration of prescribed drug or following the course of therapy. **For example,** half of the failures in treatment of high blood pressure occur because of unidentified gaps in taking the prescribed antihypertensive drugs.

Medication non-adherence is a growing concern to clinicians, healthcare systems, and other stakeholders (**e.g.,** payers) because of evidences that non-adherence is associated with adverse consequences and higher costs of care. Medication non-adherence is likely to grow as the patients need more medications to treat the chronic conditions. The rise of performance measures that reward quality based on the attainment of treatment targets, such as blood pressure and Low-Density Lipoprotein (LDL) levels or outcomes such as 1-year mortality after hospitalisation for conditions like acute myocardial infarction, reinforces the import of longitudinal medication adherence. Different from other quality measures that are under direct control of care providers and healthcare systems (**e.g.,** prescribing medications at discharge), the achievement of longer-term therapeutic and outcome goals requires full cooperation from the patients.

9.1.5. Causes of Medication Non-Adherence

Non-adherence to medication often results due to multiple factors, and can be intentional or unintentional. **Intentional non-adherence** is an active process in which the patients deliberately deviate from the treatment regimen. This may be a sensible decision in which the patients weigh the risks and benefits of treatment against any adverse effects. **Unintentional non-adherence** on the contrary is a passive process in which the patients may forget taking medicines, thus fail to remain adhered to the treatment regimen.

WHO has grouped some possible reasons for non-adherence into 5 categories, i.e., **healthcare system-**, **condition-**, **patient-**, **therapy-**, and **socioeconomic-related factors**. **Examples** of each category are detailed in **table 9.1**:

Table 9.1: Reasons for Medication Non-Adherence

Categories of Non-Adherence	Examples
Healthcare System	Poor quality of provider-patient relationship, poor communication, lack of access to healthcare, and lack of continuity of care.
Condition	Asymptomatic chronic disease (lack of physical cues) and mental health disorders (**e.g.,** depression).
Patient	Physical impairments (**e.g.,** vision problems or impaired dexterity), cognitive impairment, psychological/behavioural, younger age, and non-white race.
Therapy	Complexity of regimen and side effects.
Socioeconomic	Low literacy, higher medication costs, and poor social support.

Condition-related factors of medication non-adherence are asymptomatic and chronic in nature, and require long-term therapy. **Patient-related factors** of medication non-adherence include younger age, non-white race, and depression. **Therapy-related factors** of medication non-adherence include the complexity of the regimen and the side effects experienced by the patients.

Socioeconomic-related factors of medication non-adherence include lower education level and low health literacy; the medication cost is also an important socioeconomic factor, however, medication non-adherence occurs even if the cost is less. Therefore, whether or not these individual factors can distinguish between adherent or non-adherent patients remains unclear. This suggests that non-adherence cannot be evaluated by targeting specific patient populations/characteristics.

Healthcare system-related factors can also significantly influence a patient's non-adherence to medications. **Makaryus *et al***. found that not even 50% of patients while getting discharged from hospital were able to list their prescribed medications, and a very less number of patients could tell the purpose of their medications. This suggested that educational process on medication adherence during hospital discharge will help the patients to adhere to their medications after discharge. Thus, discharge counselling improved adherence after hospital discharge.

Coleman *et al.* found that **medication discrepancies** (lack of agreement between the pre-hospital, discharge, and post-hospital medication regimens) were common after hospital discharge due to the system factors (**e.g.,** conflicting information and incomplete discharge instructions). Additionally, **system-level factors**, such as the administrative processes associated with insurance claims, can also affect adherence.

Bokhour *et al.* found that about one-third of hypertension patients who came for follow-up visits to the care provider were not asked about medication taking, and the closed-ended questions inhibited discussions on medications or medication-taking behaviours.

Svensson *et al.* found that adherence to antihypertensive medications was related to faith in the physician, thus suggesting that the **physician-patient relationship** is also an important factor. Although patients are central to taking medications as prescribed, there are many **non-patient-related factors** that can affect adherence to medications.

Some **other causes of medication non-adherence** include:

1) The patient's cultural beliefs,
2) Mistrust of health professional (some patients do not agree with the healthcare management),
3) Patients take more drug than prescribed when wanted to speed up the response to treatment,

4) Patients cannot read the written materials provided by healthcare professional and are afraid to take medications,
5) Patients start feeling that the treatment is unimportant and stop visiting the health professional,
6) Patients forget to take medication during the daytime,
7) Patients have difficulty in opening the bottles containing medications,
8) Patients have physical limitations and cannot administer the medications as prescribed (**e.g.,** a patient having severe arthritis cannot take insulin injection),
9) Patients are not financially stable enough to afford the medications,
10) Patients have psychological disorder and fail to understand the need to take the medication, and
11) Healthcare professionals fail to educate th e patients about proper medication use, dose, and administration techniques.

9.1.6. Improving Medication Adherence

Many interventions to improve patient adherence have been studied, and most of these have been patient -oriented and educational interventions. Oral and written instructions and educational leaflets are the most frequently studied interventions. Some other regularly studied interventions are modifying patient behaviour. A few studies have presented the issue of provider -focused interventions. There is still no evidence that a single method can improve medication adherence better than any other method.

The interventional strategies can be provider -targeted or patient -focused. **Provider-targeted interventions** include educating healthcare workers like the physicians, community pharmacists, and nurses. **Patient-targeted interventions** include various educational strategies with oral or written instructions or audio -visual materials. Education is im parted either to the patients alone or along with their family members or to groups of patients. Interventions targeting the behaviour of patients are also valuable, and include medication diaries, dosettes, verbal agreement with patients, modifying the regimen as per the patients' convenience, and reminders by mail or telephone. Counselling the patients, home visits, and generating family support to them also prove to be beneficial in improving medication adherence. Sustained release and long -acting pharmaceutical formulations reduce the dosing frequency; while transdermal and depot preparations increase patient convenience and improve medication adherence.

The quality of **doctor-patient relationship** is an important factor that influences patient medication adherence. According to many adherence researchers , the patients should involve as equal partners in taking decisions regarding their healthcare, and doctors should not serve the role of a sole decision-maker but should act as an expert advisor.

Patient education, patient counselling, and providing information are some other important strategies for improving adherence. Information may benefit the patients:
1) Who want to comply but need more information to allow them to do so, and
2) Who have misconceptions an d fears that can be driven out by providing information and reassurance.

Massuea reviewed 30 studies of patient education in chronic disease, and concluded that merely increasing patient knowledge is not so successful in improving adherence, and behavioural aspect should also be involved. Studies on the effect of patient counselling with checking for recall by pharmacists, doctors and by nurses under a pharmacist's direction have shown benefits on adherence. The counselling duration should be from 5 -90 min utes. The complete evidence for effectiveness of counselling is **equivocal** (Level 1). Levels of evidence are:

Level I: Meta-analysis of randomised control trials with high power.

Level II: Meta-analysis of randomised control trials with low power.
Level III: Non-randomised concurrent cohort studies.
Level IV: Non-randomised historical cohort studies.
Level V: Case studies.

It has been proved in a study that individualised leaflets for diabetes and hypertension effectively improve adherence to lifestyle and diet changes. These measures are also better than the standard patient information leaflet as they include a behavioural component as well. The evidence for giving patient information leaflets of varying kinds has been found to be equivocal (Level 1).

Urquhart provided a **scale of interventions** of increasing intensity for safeguarding adherence to essential medicines. The cost of these interventions increases disproportionately with intensity. The order begins with prescribing drugs normally and ends with admitting to a nursing home. **Incarceration** is used as a last resort in tuberculosis treatment because of public health hazards due to incomplete or irregular treatment and the emergence of resistant micro organisms. The other measures can be used in a graded manner. Directly Observed Therapy (DOT) is used for improving medication adherence in patients with tuberculosis.

Given below are some **patient education strategies** that can help to improve medication adherence:

1) The most important instructions should be presented first.
2) Some clearly written instructions that can be easily read should be reinforced.
3) A medication regimen should be made as per the patient's daily schedule and lifestyle.
4) Patient's family members should be involved to assist and encourage adherence.
5) A patient should be made to realise the importance of adherence at follow-up visits and patient's effort to comply should also be recognised.
6) Follow-up visits should be scheduled as per the patient's previous adherence record.
7) Medications which can be given once daily and which causes the least side effects should be prescribed.
8) Patients should be informed of the side effects that may occur and the steps to be taken if they occur, **e.g.,** stop the medicine, contact the doctor, take a simple remedy, or continue the treatment.
9) The information should be restricted to four key points.
10) Simple language, short sentences, and specific instructions should be used.
11) The patient should be made to recall the instructions.

A few important ones are discussed below:

1) **Counselling:** This involves providing information to the patients about their illness and its treatment verbally. A true counselling is a two-way process involving listening as well as talking.
2) **Tailoring or Cuing:** This involves matching the medicine regimen with a patient's normal daily routine, such as meal times or time to sleep.
3) **Packaging:** Using a calendar pack with special packaging is a useful and inexpensive option, however, it has its own shortcomings.
4) **Simplification of the Regimen:** This involves rationalising a patient's regimen in such a way that it can be convincingly managed (i.e., a compromise between the ideal and one that can be achieved). This can be done without adversely affecting the patient's treatment results. **For example,** the number of medications being taken can be reduced, the frequency of dosing (**e.g.,** same drug given as a once daily slow release formulation) can be reduced, or the dose times of various medicines in the regimen can be matched.

9.1.7. Pharmacist Role in the Medication Adherence

Pharmacists have a unique role in improving medication adherence because they can show the medication to the patients and relate any information to the medication. They provide verbal education and written i ndividualised instructions to the patients; however, these strategies alone are not so beneficial.

A few studies have provided evidence of Level II of improved patient medication adherence due to patient education provided by the pharmacists.

Macdonald studied how in post -discharge patients, patient educ ation by pharmacists influenced medication adherence, and it was demonstrated that the patients receiving education from pharmacists were benefitted. Some authors studied in a randomised control trial in asthma and COPD patients with a follow -up period of two months that medication adherence and inhalation technique was improved after a pharmacist -based educational interventional programme.

It was also observed that the inhalation technique continued to improve with each educational sitting. In an educational programme (45 minutes of each sitting), the patients were provided with oral as well as written instructions in local language about their disease, need for regular medication, and importance of each medication by the pharmacists.

The information that pharmacists should impart to the patients includes:

1) The name and purpose of medication,
2) The method and time of taking the medication,
3) Possible side effects that may occur,
4) Necessary precautions to be taken,
5) Interactions with food or other drugs,
6) The duration of therapy,
7) The action to be taken on missing a dose, and
8) How to tell whether or not the medication is working.

The **patient-pharmacist relationship** can be improved by the following **strategies**:

1) The pharmacist should be friendly and approachable,
2) The pharmacist should improve his/her communication skills,
3) The pharmacist should consider psychological needs of the patient,
4) The pharmacist should improve patient education,
5) The pharmacist should encourage the patients to discuss their concerns without interruption or premature closing,
6) The pharmacist should elicit patient's perception of illness and associated feelings and expectations,
7) The pharmacist should learn methods of active listing and empathy,
8) The pharmacist should give clear explanations,
9) The pharmacist should check patient's understanding level,
10) The pharmacist should discuss a treatment plan,
11) The pharmacist should check the patient's attention to medication adherence,
12) The pharmacist should make the therapeutic regimen easy,
13) The pharmacist should be conscious of patient's wishes,
14) The pharmacist should involve the patient in treatment decisions,

15) The pharmacist should improve home support,
16) The pharmacist should monitor beneficial effects,
17) The pharmacist should monitor the side effects,
18) The pharmacist should provide a long -term support to the patient and continuity of care,
19) The pharmacist should speak the language known by the patient, and
20) The pharmacist should shorten the pharmacy waiting time.

Apart from patient education, pharmacists also improve medication adherence by serving the role of an advisor to prescribers on simplification of drug regimens, by providing medication cards or medication aids (such as a dosette) to the patients, and by identify ing predisposing, enabling and reinforcing factors contributing towards medication non - adherence.

The clinical pharmacists in hospitals should measure the factors assisting in medication adherence. Patient interviews help them to judge the patients' know ledge on drug therapy and their usual medication habits.

For example, does the patient have a set routine and is there family support available to help them in medication use? The pharmacists should also identify if the patients have any specific problem s with medication, such as difficulty in swallowing large tablets or difficulty in opening child -proof containers. Pharmacists should also evaluate the patients' ability to understand and recall information.

At the end of the process, the pharmacists shou ld determine the patients' own assessment of their adherence to medication and make a professional assessment of the ways in which this can be improved.

For example, specific counselling for any specific problems with medication and preparation of individualised medication information sheets.

9.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) **Patient adherence** (or **compliance**) means correct following of medical advice by the patient.
2) Medication adherence is categorised into 2 main co ncepts, i.e., **adherence** and **persistence**.
3) WHO defined medication adherence as " **the degree to which the person's behaviour corresponds with the agreed recommendations from a health care provider**".
4) **Predisposing f actors** include de mographic factors of the patients, and also their knowledge, attitudes, beliefs and perceptions about illness and its severity, cause, prevention, and treatment.
5) **Enabling factors** are the skills and resources required for adherence.
6) **Reinforcing f actors** determine whether or not the patient's family members, peers, healthcare providers, the local community, and society are supportive enough to assist in medication adherence.

7) **Direct methods** of adherence assessment involve direct observation of the undergoing therapy, measurement of the drug or metabolite level and of the biological marker in blood.

8) **Indirect methods** of adherence assessment involve patient questionnaires, self-reports, pill counts, rate of prescription refills, electronic medication monitors, patient diaries, patient's clinical response, and physiological markers.

9) **Morisky's Medication Adherence Scale (MMAS)** was designed to differentiate between the patients who are poorly adherent and the patients who are medium-to-high adherent to their antihypertensive regimen.

10) **Pill counts** can be easily performed and have been correlated with electronic medication monitors.

11) Obtaining **refills** and the frequency of acquiring refills reveal different facets of the adherence behaviour of a patient.

12) **Medication possession ratio** and the **proportion of days covered methods** (defined by the number of doses dispensed in relation to a dispensing period) are the most commonly used measures of medication adherence based on pharmacy data.

13) The major difference between these two measures is that the medication possession ratio accounts for oversupplies and have a value **>1**, whereas the maximum proportion of days covered is **1**, indicating full adherence.

14) The value of MPR ranges from 0 to 1, of which **1** indicates **100% adherence**.

15) **Medication persistence** is the denominator of the MPR equation and is used to calculate the duration for which the patient has been taking the medication, without considering any breaks in the therapy.

16) The **value of PDC** ranges from 0 to 1, of which **1** indicates **100% adherence**.

17) **Non-compliance** is the failure of the patient to obey instructions for administering the medications as directed, and thus resulting in lower response of treatment than expected.

18) **Intentional non-adherence** is an active process in which the patients deliberately deviate from the treatment regimen.

19) **Unintentional non-adherence** on the contrary is a passive process in which the patients may forget taking medicines, thus fail to remain adhered to the treatment regimen.

20) WHO has grouped some possible reasons for non-adherence into 5 categories, i.e., **healthcare system-**, **condition-**, **patient-**, **therapy-**, and **socioeconomic-related factors**.

21) **Condition-related factors** of medication non-adherence are asymptomatic and chronic in nature, and require long-term therapy.

22) **Patient-related factors** of medication non-adherence include younger age, non-white race, and depression.

23) **Therapy-related factors** of medication non-adherence include the complexity of the regimen and the side effects experienced by the patients.

24) **Socioeconomic-related factors** of medication non-adherence include lower education level and low health literacy;

25) **Healthcare system-related factors** can also significantly influence a patient's non-adherence to medications.

26) **System-level factors** such as the administrative processes associated with insurance claims can also affect adherence.

27) **Provider-targeted interventions** include educating healthcare workers like the physicians, community pharmacists, and nurses.

28) **Patient-targeted interventions** include various educational strategies with oral or written instructions or audio-visual materials.

29) **Counselling** involves providing information to the patients about their illness and its treatment verbally.

30) **Tailoring or cuing** involves matching the medicine regimen with a patient's normal daily routine such as mealtimes or time to sleep.

31) **Simplification of the regimen** involves rationalising a patient's regimen in such a way that it can be convincingly managed (i.e., a compromise between the ideal and one that can be achieved).

9.3. EXERCISE

9.3.1. True or False

1) Reinforcing factors include demographic factors of the patients, and also their knowledge, attitudes, beliefs and perceptions about illness and its severity, cause, prevention, and treatment.

2) Refills can be easily performed and have been correlated with electronic medication monitors.

3) The value of MPR ranges from 0 to 10, of which 10 indicates 100% adherence.

4) Intentional non-adherence is an active process in which the patients deliberately deviate from the treatment regimen.

5) Patient-related factors of medication non-adherence include younger age, non-white race, and depression.

6) Condition-related factors of medication non-adherence include the complexity of the regimen and the side effects experienced by the patients.

7) Counselling involves matching the medicine regimen with a patient's normal daily routine such as mealtimes or time to sleep.

9.3.2. Fill in the Blanks

8) Medication adherence is categorised into adherence and _____.

9) _____ factors are the skills and resources required for adherence.

10) _____ factors determine whether or not the patient's family members, peers, healthcare providers, the local community, and society are supportive enough to assist in medication adherence.

11) _____ was designed to differentiate between the patients who are poorly adherent and the patients who are medium-to-high adherent to their antihypertensive regimen.

12) _____ is the denominator of MPR equation.

13) _____ factors of medication non-adherence are asymptomatic and chronic in nature, and require long-term therapy.

14) _____ include educating healthcare workers like the physicians, community pharmacists, and nurses.

Answers

1) False 2) False 3) False 4) True 5) True
6) False 7) True 8) Persistence 9) Enabling 10) Reinforcing
11) Morisky's medication adherence scale 12) Medication persistence 13) Condition-related
14) Provider-targeted interventions

9.3.3. Very Short Answer Type Questions

1) Define medication adherence.
2) Give the direct method of monitoring patient medication adherence.
3) What is MPR?
4) Give any two causes of medication non-adherence.
5) Give any four strategies to improve patient-pharmacist relationship.

9.3.4. Short Answer Type Questions

1) Discuss the determinants of medication adherence.
2) Write a note on Morisky's medication adherence scale.
3) What are the causes of medication non-adherence?
4) How patient-pharmacist relationship can be improved?

9.3.5. Long Answer Type Questions

1) Discuss the monitoring of patient medication adherence.
2) How medication adherence can be improved?
3) Discuss in brief the role of pharmacist in medication adherence.

CHAPTER 10

Patient Medication History Interview

10.1. PATIENT MEDICATION HISTORY INTERVIEW

10.1.1. Introduction

A medication history comes under pharmaceutical consultation that identifies and documents allergies or other serious adverse events caused by a drug. It also includes information on the current and past considerations about medicines. It is a beginning for medicines reconciliation and review. A positive effect on patient care is observed when accurate and complete medication histories are taken.

Medication history interview involves interviewing a patient for collecting the data medical history.

Many pharmacists have compiled such histories with high degree of precision and reliability as part of medicines reconciliation. The benefit to the patient is that the risk of harm is reduced by identifying the prescribing errors of omission or transcription and correcting them early. This in turn provides better care to the patient. The history attained by the medical team and the pharmacist may differ and fall into two categories, i.e., **intentional** (when medical team makes a decision of changing the regimen) or **unintentional** (when complete record was not available). Differences should be clarified with the prescriber or the senior pharmacist.

Pharmacists may obtain complete medication histories by their better knowledge. In order to get detailed information, he/she should interview in a predetermined and systematic manner:

1) Firstly the pharmacist should get familiarise with the patient charts to know the present medical status and background particulars of the patient.
2) The interview should be started with introduction and the reason for interview.
3) The patient's name, address, age, and past medication history should be jotted down.
4) Direct or indirect questions can be put forward on primary issues, like prescribed medication, self-medication, allergies, undesirable effect of any drug, compliance to prescribed medication, and smoking, drinking and eating habits.
5) The language or terminologies should be simple and easy to understand by the patient.
6) If the patient has difficulty in understanding specific terms, the pharmacist should explain it properly.
7) Secondary relevant areas for questioning are constipation, diarrhoea, cough and cold, lay fever, allergies, vitamins, tonics and skin preparations.
8) At last, when patient's confidence is achieved by the pharmacist through the interview, questions on patient's medication compliance could be asked. It is supportive information for the drug therapy.
9) All the details gained during the interview are noted down in a sheet, one copy of which is sent to the physician.

10.1.2. Need for the Patient Medication History Interview

An accurate medication history is required for the following reasons:

1) It gives information about the drugs taken by the patient in the past or being taken at the present time. Information on the responses of drugs administered in the past help in planning the future treatment.
2) It informs about the drug effects, as drugs may give rise to a disease either directly or due to an interaction.
3) The drugs the patient is currently taking can mask clinical signs; **for example**, β-adrenoceptor antagonists prevent tachycardia in a patient with haemorrhage; corticosteroids prevent abdominal pain and rigidity in a patient with perforated duodenal ulcer.
4) Drugs the patient is currently taking can also affect the results of diagnosis; **for example**, amiodarone alters the results of thyroid tests.
5) It helps to educate patients about their medications.
6) An inaccurate history on admission to hospital results in unwanted duplication of drugs, drug interactions, discontinuation of long-term medications, and failure to detect drug-related problems. Such prescription errors can be prevented by medication history.

Interview on medication history gives information on drug use which may assist in patient care. The information obtained can be utilised for:

1) Comparing medication profiles with the record of medication administration,
2) Investigating the discrepancies,
3) Verifying medication history taken by other staffs and providing additional information where needed,
4) Documenting allergies and adverse reactions,
5) Investigating drug interactions,
6) Evaluating patient medication compliance,
7) Investigating the rationale for drug prescribed,
8) Screening the evidence of drug abuse,
9) Evaluating the drug administration techniques,
10) Investigating the needs for medication aids, and
11) Documenting patient initiated medication administration.

10.1.3. Components

The components of medication history interview are:

1) The pharmacist should introduce himself/herself to the patient and explain the intention of consultation.
2) The pharmacist should identify any allergies or serious adverse reactions and mention them on prescription chart, care notes, or patient medication record.
3) The pharmacist should get details on prescribed and non-prescribed treatments from the patient's recall, medicines possessed by the patient, referral letter (from the patient's primary care doctor), copy of prescriptions issued or a repeat prescription list, medical notes, and by contacting the appropriate community pharmacist or primary care doctor.
4) The pharmacist should make sure to document the generic name of medicine, dose, frequency, and duration of therapy.
5) The pharmacist should also document inhalers, eye drops, topical medicines, and herbal and homoeopathic remedies possessed by the patients.
6) The pharmacist should understand the patient's medication-taking behaviour.

7) The pharmacist should consider problems like swallowing difficulties, understanding labels and written information, container preferences, and ordering or supply issues.
8) The pharmacist should record the history in detailed format.
9) The pharmacist shou ld jot down any variation in the history recorded by other healthcare professionals.
10) The pharmacist should know if these variations are intentional (from patient, nursing staff, medical staff, or medical notes) or unintentional.
11) The pharmacist should inform about the unintentional variations to the prescriber.
12) The pharmacist should document all the medication -related information properly, **e.g.,** implications of chronic renal failure, dialysis, and long-term steroid treatment.

Table 10.1 enlists the vital co mmunication skills a pharmacist need to possess while taking a medication history interview:

Table 10.1: Essential Communication Skills for a Medication History Interview

Skills	Details	Examples
Formal form of address	The pharmacist should use the patient's title and last name.	"Good Morning Mr. Kapoor."
Rapport	The pharmacist should actively listen to confirm interest in a patient and gain respect.	"It is not easy being in the hospital away from friends and family."
Active listening or empathic responding	The pharmacist should understand the patient's feelings.	"You sound unsure." Or "Are you saying."
Open-ended questioning	The pharmacist should make the patient feel free to answer in any manner. This is useful when a new subject is introduced.	"How are you taking your blood pressure medicine?"
Close-ended questioning	The pharmacist should allow the patient to answer in either yes or no.	"Do you take your blood pressure medicine in the morning?"
Transition	The pharmacist should verbally end one subject and introduce a new one to allow the patient to make a mental transition.	"We have just talked about the prescription medications you take. Now let us talk about any non -prescription medications you may take."
Verbal following	The pharmacist should elaborate a subject to the patient without asking new questions, but only repeating the patient's last few words.	"… dizzy spells?"
Avoidance of leading questions	The pharmacist should ask leading questions so that the patient gives particular answer.	"You do not smoke, do you?" or "Do you use any tobacco products?"
Avoidance of "Why" questions	"Why" questions can make the patients defensive, so the pharmacist should r e-phrase the questions and begin with "for what reason".	"Why were you takin g the medicine in the morning?" should not be asked and instead "For what reason…..".
Timing	The pharmacist should w arn a patient before asking a series of questions.	"I am going to ask you a series of questions now."
Clarify conflicting information	The pharmacis t should a lways accept the blame for inconsistent information that the patient may tell or write.	"I must have written it incorrectly, I thought you had said…"

Silence	The pharmacist should allow the patient to show emotion, digest information, or gather thoughts.	The pharmacist should also maintain non -verbal assistance and stop speaking.
Answering patient questions	The pharmacist should a void definitive answers until a final drug therapy is planned.	If patients ask, "Do you think I should stop taking ….?", the pharmacist should answer "Well, I will make a note and evaluate it with Dr. Smith".
Mentioning previously answered questions	The pharmacist should note down the answers given by the patients to a question he/she was going to ask later in the interview.	"You mentioned earlier that you occasionally take ibuprofen for headaches. Do you ever take anything else for aches or pain?"

10.1.4. Steps Involved and Data to be Obtained

While interviewing the patients about their medication history, the pharmacists should follow the given procedure:

1) **Patient Selection:** The pharmacist should identify the patients who are likely to be benefitted from the interview.
2) **Self-Preparation:** The pharmacist should understand the medical condition of patients and also their therapy before beginning the interview.
3) **Introduction:** The pharmacist should introduce himself/herself and explain the purpose of interview to the patients.
4) **Conduct Interview:** The pharmacist should collect all significant information using various open-and close-ended questions.
5) **Conclusion:** The pharmacist should prepare a summary of all the important is sues and give clarification for the same.
6) **Documentation:** The pharmacist should document the information gathered during the medication history interview for future reference.

The **data collected** through medication history interview should be complete, descriptive, and include the following information:

1) **Demographic Information**
   i) Age/date of birth
   ii) Height and weight
   iii) Race and/or ethnic origin
   iv) Type of residence
   v) Education
   vi) Occupation
2) **Dietary Information**
   i) Dietary restrictions
   ii) Dietary supplements
   iii) Dietary stimulants
   iv) Dietary suppressants
3) **Social Habits**
   i) Tobacco use
   ii) Alcohol use
   iii) Illicit drug use
4) **Current Prescription Medications**
   i) Name (proprietary and non-proprietary) and/or description
   ii) Dose

iii) Dose schedule (prescribed and actual)
iv) Reason for taking the medication
v) Start date
vi) Outcome of therapy

5) **Past Prescription Medications**
i) Name (proprietary and non-proprietary) and/or description
ii) Dose
iii) Dose schedule (prescribed and actual)
iv) Reason for taking the medication
v) Start and stop date
vi) Reason for stopping
vii) Outcome of therapy

6) **Current Non-Prescription Medications**
i) Name (proprietary and non-proprietary) and/or description
ii) Dose
iii) Dose schedule (recommended and actual)
iv) Reason for taking
v) Start date
vi) Outcome of therapy

7) **Past Non-Prescription Medications**
i) Name (proprietary and non-proprietary) and/or description
ii) Dose
iii) Dose schedule (recommended and actual)
iv) Reason for taking
v) Start and stop date
vi) Reason for stopping
vii) Outcome of therapy

8) **Current Complementary and Alternative Medicines**
i) Name (proprietary and non-proprietary) and/or description
ii) Dose
iii) Dose schedule
iv) Reason for taking
v) Start date
vi) Outcome of therapy

9) **Past Complementary and Alternative Medicines**
i) Name (proprietary and non-proprietary) and/or description
ii) Dose
iii) Dose schedule
iv) Reason for taking
v) Start and stop date
vi) Reason for stopping
vii) Outcome of therapy

10) **Allergies**
i) Drug name and description
ii) Dose
iii) Date of reaction
iv) Description of reaction
v) Treatment for the reaction

11) **Adverse Drug Reactions**
i) Drug name and description

ii) Dose
iii) Date of reaction
iv) Description of reaction
v) Treatment of the reaction

12) **Immunisations**
i) Vaccines
ii) Date each vaccine was administered

13) **Overall Patient Adherence**

10.1.5. Medication Interview Forms

A format of the medication history interview form is given below:

General Information	
Initials:	Primary Care Provider:
Attending:	Service:

Demographic and Social Information			
DOB:	Age:	Gender: □ Male □ Female	Ethnicity:
Height:	Weight (Baseline):	Weight (Current/Measured):	
Religion Affiliation:		Occupation:	
Living Arrangement:			
Pregnant: □ Yes □ No	Breastfeeding: □ Yes □ No	Due date:	

Chief Complaint:		

History of Present Illness:		

Past Medical History:	
1.	6.
2.	7.
3.	8.
4.	9.
5.	10.
Past Surgical History:	
1.	4.
2.	5.
3.	6.
Family History	

Mother: Living: □ Y □ N	Age Deceased:	Med Hx:

Father Living: □ Y □ N	Age Deceased:	Med Hx:
Other pertinent family Hx:		

Immunisation History:	
Immunisation type	Date last received
Influenza	
Tetanus	
Pneumovax	
Others:	

Patient Initials _____

Allergies (medication and food)/Adverse Reactions:	
Product name	Type and severity of reaction
1.	
2.	
3.	
4.	
5.	

Current In-patient Medications		
Medication name, strength, regimen	Indication	Start Date
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

Current Out-patient (Home) Prescription Medications		
Medication name, strength, regimen	Indication	Last Filled
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
Where do they get their prescription medications filled?		
How do they pay for their prescriptions?		

Current Out -patient (Home) No n-Prescription Medications/Herbal/Nutritional products and supplements	
Product name, strength, regimen	Indication
1.	
2.	
3.	
4.	
5.	
6.	

Patient Initials _____

Assessment of Out-patient Medication Compliance	
Who is responsible for medication a dministration for this patient? Does patient have any difficulty understanding or complying with medication instructions? Barriers to medication adherence? If yes explain:	
Diet and Exercise	
Typical daily diet:	Type and frequency of exercise: Able to conduct Activities of Daily Living (ADL)? □ Yes □ No (Explain)

Smoking, Alcohol, or Recreational Drug Use		
Smoking: □ Never smoked □ Quit smoking When: _____ How long did they smoke? _____ years □ Smokes _____ packs/day □ Exposure to second hand smoke _____ hours/day	Alcohol: □ No use □ Social use: _____/week; Quantity: _____ □ Regular use: _____/week; Quantity: _____	Recreational drugs: □ None □ H/O use (list agent(s), how long): □ Current use (list agent (s), Amt, freq.):

Additional Comments or Assessments:

Medication History Preformed by: _____
Date: _____

Patient Initials _____

10.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) A **medication history** comes under pharmaceutical consultation that identifies and documents allergies or other serious adverse events caused by a drug.
2) **Medication history interview** involves interviewing a patient for collecting the data medical history.
3) The history attained by the medical team and the pharmacist may differ and fall into two categories, i.e., **intentional** (when medical team makes a decision of changing the regimen) or **unintentional** (when complete record was not available).
4) The pharmacist should identify the patients who are likely to be benefitted from the interview.
5) The pharmacist should understand the medical condition of patients and also their therapy before beginning the interview.
6) The pharmacist should introduce himself/herself and explain the purpose of interview to the patients.
7) The pharmacist should collect all significant information using various open-and close-ended questions.
8) The pharmacist should prepare a summary of all the important issues and give clarification for the same.
9) The pharmacist should document the information gathered during the medication history interview for future reference.

10.3. EXERCISE

10.3.1. True or False

1) Medication history interview involves interviewing a patient for collecting the data medical history.
2) The pharmacist should identify the patients who are likely to be harmed from the interview.
3) The pharmacist should introduce himself/herself and explain the purpose of interview to the physicians.
4) The pharmacist should understand the medical condition of patients and also their therapy before beginning the interview.

10.3.2. Fill in the Blanks

5) A medication history comes under _____ that identifies and documents allergies or other serious adverse events caused by a drug.
6) The history attained by the medical team and the pharmacist may differ and fall into _____ (when medical team makes a decision of changing the regimen) or _____ (when complete record was not available).
7) The pharmacist should prepare a _____ of all the important issues and give clarification for the same.
8) The pharmacist should collect all significant information using various _____.

Answers

1) True 2) False 3) False 4) True
5) Pharmaceutical consultation 6) Intentional and unintentional
7) Summary 8) Open- and close-ended questions

10.3.3. Very Short Answer Type Questions

1) Define medication history interview.
2) What steps are involved in medication history interview?
3) Give any four components of medication history interview.
4) What data regarding allergies and adverse drug reactions should be obtained through medication history interview?

10.3.4. Short Answer Type Questions

1) What is the need for medication history interview?
2) Write a note on the components of medication history interview.
3) What communication skills a pharmacist need to possess while taking a medication history interview?

10.3.5. Long Answer Type Questions

1) Discuss in brief about patient medication history interview.
2) Give the medication interview form.

CHAPTER 11

Community Pharmacy Management

11.1. COMMUNITY PHARMACY MANAGEMENT

11.1.1. Introduction

The **Community Pharmacy Medicines Management** (CPMM) is a unique concept that aims to introduce a structured intervention process among the community pharmacist, the patent, and the general practitioner. The whole study is based on Randomised Controlled Trial (RCT). The managerial activities that involve planning, decision -making, organising, staffing, directing, and controlling are useful in the management of a settin g. The management functions generally are defined as all the acts involved in the organisation and functioning of the elements of an enterprise for economic benefits. Man, money, material, and equipment are brought together in a proper relationship to achi eve the objectives and goals that management has decoded.

Success of a community pharmacy depends on three factors, i.e., its **location (site)** , **proper layout**, and **design**.

11.1.2. Objectives

The **primary objectives** of the CPMM are to:

1) Study and compare the number of patients receiving proper treatment that abide by the currently available evidences and guidelines , between intervention and control groups at baseline and follow-up.
2) Describe the changes occur ring in health status of a patient after the intervention as defined by standard measures, under both general and specific conditions.
3) Perform an economic evaluation of the medicines management intervention (estimating the changes occurring in drug prices).

The **secondary objectives** of the CPMM are to:

1) Describe the opinions of the stakeholders (patients, physicians, community pharmacists, and hospital staff) on medicine management before and after its introduction.
2) Describe the importance of OTC (Over the Counter) medicines in the overall patient management.

11.2. FINANCIAL REQUIREMENT

11.2.1. Introduction

Financial management or financial planning is concerned with making optimal decisions and anticipating the resul ts of such decisions. It also carries out control function which compares the actual performance of the community pharmacy with the planned one.

Financial planning is one of the most important steps taken by a community pharmacy. This step is generally ta ken right after the pharmacy inception and setting of vision and objectives of the drug store. A financial plan details out v arious activities to be carried out by the community pharmacy and resources available for achievement of the set objectives within stipulated time. Financial planning is concerned with the determination of strategic objectives of the community pharmacy and the means to achieve them.

11.2.2. Functions of Financial Planning

Following a re the main tasks undertaken in the community pharmacy by financial planning activity:

1) Analysing the business environment for drug store,
2) Designing business objectives and goals for drug store,
3) Identification of resources required for the achievement of set business goals,
4) Detailed analysis and quantification of medical resources,
5) Creating budgets to determine total costs involved, and
6) Critically analysing the budget for potential issue.

11.2.3. Objectives of Financial Planning

Following are the main objectives of a financial plan in a community pharmacy:

1) **Proper Fund Flo w:** The main objective of a financial plan is to ensure that pharmacy does not suffer due to paucity of funds. There should be proper flow of funds which optimises pharmacy business operation profitability.
2) **Minimise Risk and Cost:** A financial plan of a community pharmacy seeks to minimise costs and ensure that there will be minimum risk related to the procurement and use of funds.
3) **Easy to Understand:** A financial plan of a community pharmacy should be able to make all the concerned parties understand the term s and conditions in the simplest possible manner.
4) **Flexible:** A good financial plan in a community pharmacy must be flexible so that it can be adjusted to suit the requirements of change in circumstances.
5) **Sound Liquidity:** Another objective of a financial pla n is to ensure that the community pharmacy is able to honour its commitment as and when they arise. Thus, the community pharmacy should design financial plan considering both the growth as well as declining stages of business.
6) **Proper Use of Funds:** A financ ial plan not only ensures the availability of funds according to the requirements but also makes sure that the funds are not lying idle.
7) **Practice Economy:** A financial plan seeks to obtain funds at the least possible cost. A firm needs to set up proper plan to obtain funds in such manner.

11.2.4. Financial Planning in Community Pharmacy

The financial section in a business plan of a community pharmacy gives a financial view of the services being offered. The financial plan of a community pharmacy represents the sources or services through which the pharmacists are expecting to generate revenues , **e.g.,** consulting fees, sale of medicines, estimated expenses including salary of staff, marketing cost, rent, utilities, supplies , and equipment. The financial plan which is made should predict the break-even point of the services.

The financial plan of the community pharmacy helps in projecting revenue and expenses of the store. Based on the fluctuating demand of the medical products , the financial plan must consist of low, moderate and high estimates for revenue. Before developing the financial plan , the pharmacists must analyse the possible source of income and cost linked with the services that are offered.

The financial plan of a community pharmacy must include the following statements:

1) **Income and Expense Statements:** These statements are those in which the profit and loss of the community pharmacy is shown after a specific time period , i.e., annually.

2) **Balance Sheet:** This shows the financial position of the community pharmacy in the form of asset and liability on a specific date.
3) **Cash Flow Statement:** This statement represents the movement of money into the business or out of the community pharmacy via operating, financing and investing activities.

11.2.5. Projections of Financial Plan in Community Pharmacy

The projections of financial plan for community pharmacy are as follows:

1) **Projecting Revenue:** This revenue is calculated taking into consideration the income from product sale and fee-based services. **Example** of the product sale is revenue generated from the sale of non-prescribed medicines and other OTC products. It may also include sale of non-pharmacologic product such as device used to measure hypertension or diabetes, other health care products, etc. The other source of revenue is fee-based compensation. The financial plan should contain proposed fees and the rationale for setting them if the primary market is of cash-paying patients. It should also contain structure of the fees according to the services. The plan should also provide knowledge to the customers about other products of the pharmacy, instead of just focusing on the payments from the patients. The plan may include projections for their payment for various worksite services, such as immunization programs. Expected revenue from third-party payers, such as health insurers, should also be described.
2) **Projecting Expenses:** These expenses means that the financial plan of a community pharmacy must include the expected expenses, which will incur in the initial stage or in the ongoing pharmacy business. Projecting expenses in advance will ensure that the pharmacy has sufficient cash flow and adequate availability of funds in their reserve until the services exceed the break-even point.

   Some of the projected expenses are as follows:
   i) **Start-up Cost:** This includes the cost of training and change in the plan of the pharmacy. Start-up cost also includes the cost of replacing an old technology with the new one.
   ii) **Fixed Cost:** This is the cost that remains constant throughout even with the increase or decrease in the quantity of medical goods produced, **e.g.,** salary, insurance premium, building rent, etc.
   iii) **Variable Cost:** This is the cost that keeps on changing with the change in the level of production of pharmaceutical products. If the production increases, the variable cost increases and *vice-versa*.

11.3. MATERIAL REQUIREMENT

11.3.1. Introduction

Material management is a fundamental function of any business that itself adds in the overall cost of the product directly. It includes planning, directing, controlling, and coordinating the activities involved in material and inventory requirements from starting point to their introduction into the manufacturing process. Stocking and coding are the two important aspects of material management.

11.3.2. Stocking

The drugs purchased from the market are stored in drug stores to continue a uniform supply of drugs to the patients. They are stored in containers, such as drums and boxes and on flexible racks, etc.

During their storage period, the medicines stored in a drug store should remain preserved. They should not get damaged by high temperature or exposure to sunlight. Drugs should be stored according to the prescribed conditions of their storage.

11.3.2.1. Objectives

Stocking has the following objectives:

1) The drugs can be easily located in the store.
2) The drugs and other items can be properly identified.
3) A supply of materials can be maintained.
4) Maximum utilisation of space can be done.
5) The use of materials handling equipment can be minimised.

11.3.2.2. Functions

Stocking has the following fucntions:

1) It enables speedy functioning, i.e., receiving, handling and quick issue of material.
2) It prevents the goods against damage and pilferage during the storage period.
3) It ensures uninterrupted supply of materials.
4) It enables physically stocking the goods and checking them routinely.
5) It allows maximum utilisation of the available space.
6) It provides economical service to the organisation.
7) It permits easy identification and location of the items.

11.3.2.3. Arrangement of Drugs in a Community Pharmacy

In a community pharmacy, the drugs should be arranged in the following ways:

1) **According to Manufacturer:** The drugs are arranged according to the name of manufacturer. **For example**, the drugs manufac tured by Glaxo (India) Ltd. are kept in a separate cupboard, and so on.
2) **According to Pharmacological Action:** The drugs are arranged according to their pharmacological action. **For example,** all analgesics are placed in one cupboard, all multivitamin preparations are placed in another cupboard, and so on.
3) **According to Alphabetical Order:** The drugs are arranged in alphabetical order. **For example,** drugs having initial letter "A" are pla ced in one row of the cupboard; the other drugs in the same manner are placed according to their first alphabet.
4) **As per Old Stock and Date of Expiry:** Drugs of old stock are placed in front row and those of fresh stock are placed in back rows so that the older stock is sold first.
5) **According to Location of Stores for Stocking:** The stores should be located in such an area where handling, transportation and movement of the material are minimum. If more than one plant is situated in the same area, one centralis e store should be located to serve all production operations.

   Centralised storing has the following **advantages**:
   i) Less investment is required.
   ii) Minimum incidental expenses.
   iii) Small space is required for storage.
   iv) The administrative costs are reduced as less manpower is required.
   v) More bargaining because products are purchased in bulk.

   Centralised storing has the following **disadvantages**:
   i) Materials handling operations are performed on a large scale.
   ii) Delaying in service occurs commonly.
   iii) Chances of damage are more due to exposure to natural calamities (such as fire, rain, dust etc.).

11.3.3. Coding

In the process of coding, a code number or code symbol is assigned to a particular material for easy identification. Generally, the manufacturers, distributors and wholesalers have large stock in the stores, and in such conditions, it becomes very difficult to identify the items without a proper system. Therefore, a system of code numbers is evolved to facilitate easy allocation and identification of each material stored.

11.3.3.1. Advantages

Coding has the following advantages:

1) It helps in easy identification of stored drug items.
2) It allows grouping of the similar items together.
3) The ambiguity of materials can be avoided.
4) The detailed description of the materials is not needed repeatedly.
5) Duplication of items can be avoided.
6) It makes physical counting easy.
7) Physical inspection of the materials is easy.
8) Confidentiality of the items can be maintained with coding system.

11.3.3.2. Methods

Coding can be done by the following methods:

1) **Alphabetical Order Method or Letter Code :** In this method, the items are coded alphabetically. **For example,** capsules are coded as "C", tablets as "T", and so on.
2) **Mnemonic Method:** In this method, each item is coded by some specific letters. **For example,** "APC" is used to code aspirin, paracetamol and caffeine. The **drawback** of this system is that the items cannot be recognised without referring to code index book.
3) **Numerical or Sequence System Method:** In this method, separate numbers are assigned to specific items of store. This method is further divided into the following sub-systems:
   i) **Block System :** In this system, the numbers are already fixed for a particular item. **For example,** number 10 -50 is used to code various types of tablets; number series 10.1, 10.2, 10.3, and 10.4, codes for antipyretics, analgesics, anti-inflammatory, and decongestants, respectively.
   ii) **Decimal System:** In this system, the numbers are used for coding such that each digit represents the particular name under same heading. **For example,** if the code for tablet is 10, then 10.1 (paracetamol- antipyretic), 10.2 (analgin-analgesic).
4) **Combination Method:** In this method, combined form of mnemonic and numerical methods is used to code different items of the store. **For example,** code "CPC" is assigned to chloramphenicol capsules; code "PAT 11" is for paracetamol with analgin tablets. This method is mostly used when a large number of items are in store.
5) **Locating Coding:** A large organisation has a large number of store rooms, and each room is divided in blocks and each block is identified by lateral and longitudinal block letter. Thus, an item is located by its warehouse number, block number, row number, rack number, shelf number, etc. Any item inside the store rooms can be located as follows:
   i) **Fixed Location:** In this system, all the groups of items are given a fixed place inside the store according to the supplier wise, item wise, and as per the utility of the item.
   ii) **Random Location:** This is the most common system used for allocation of drug items in a store. It is followed in all kinds of retail shops but each group items are stored, in a particular shelf for its easy location.

iii) **Zonal Location:** In this system, the available space is divided into different zones and each zone is assigned for different items. The zones can be named as bulk zone, reserve stock zone, spare part zone, and consumable item zone.

11.3.4. Staff Requirement

For running an organisation smoothly, it is necessary to identify and fill various job positions with people who can effectively perform the given tasks. This process is known as staffing and is performed by the management.

The eligibility for establishing and operating a community pharmacy is that the person should be a registered pharmacist by the State Pharmacy Council. A person who has **qualified Diploma** or has a **Degree in Pharmacy** and has completed a training for 650 hours in a medical store recognised by the State Pharmacy Council or a government hospital is eligible to be registered as a pharmacist. Training is not compulsory for candidates having a degree in pharmacy.

For running a wholesale drug store, experience in pharmaceutical selling or production is also needed along with Diploma or Degree certificate. A science graduate (B.Sc.) with 10 years experience of medical representative can also open a wholesale drug store.

The following employees are involved in a wholesale drug store:

1) Administrative executives,
2) Office employees,
3) Warehouse employees,
4) Inventory employees, and
5) Salesmen.
6)

If in a community the need of pharmacy is identified, the next step is to analyse the various alternatives required to satisfy that need. Sometimes, a pharmacy which is already present in an area is purchased and upgraded to cater more enhanced pharmaceutical services. Sometimes, a registered pharmacist may even join with another pharmacist in the ownership of an existing pharmacy and start a group practice. These practices improve the services to the community as well as promote the efficient use of professional individuals and resources.

Importance of Staffing

1) A healthy organisation can be established by the process of staffing in which the job performance and satisfaction of every employee is priority.
2) Staffing gives life to the organisation by providing a suitable person for every job. The effectiveness of direction and controlling also depends on staffing.
3) For an organisation, its employees are the most valuable strength, as their quality and skills determines the success and growth of the organisation.

11.4. INFRASTRUCTURE REQUIREMENT

11.4.1. Introduction

The infrastructure of a goodcommunity pharmacyis mainly based on thefollowing factors:

1) Site selection for community pharmacy,
2) Space layout for community pharmacy, and
3) Design of community pharmacy.

11.4.2. Selection of Site

Selection of a suitable site is the main objective of entrepreneurs for making their business successful. Site selection is done after taking the decision of opening a community pharmacy, getting required qualifications and experience, and achieving the business skill required for creating financial support.

11.4.2.1. Classification of Location

Location to be selected for a good community pharmacy can be classified as follows:

1) **Geographic Location:** This is further classified into the following (**figure 11.1**):
   i) **Rural or Small Town:** In this location, one can open their community pharmacy by taking loans from nationalised banks for rural development. Community pharmacy should be open in markets because people come here for marketing and also for meeting the doctor. For proper selling of medications, it is necessary for the pharmacist to maintain a good relation with the people of rural areas by studying their habits and psychology. The purchasing ability of people should also be recognised.

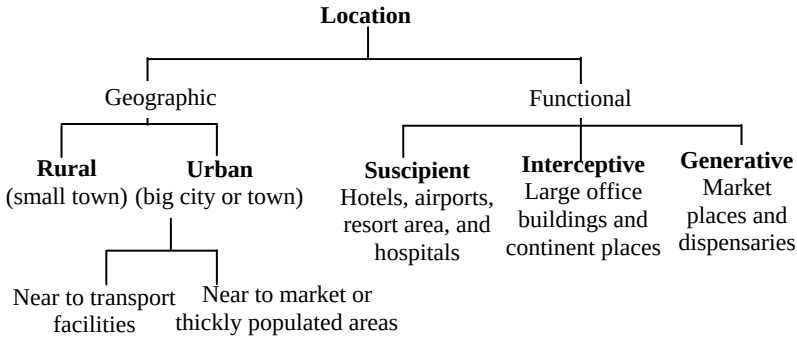


Figure 11.1: Types of Location

From financial point of view, stability of people is the major condition for opening a community pharmacy in the industrial belt. Proper examination of the habits and living standard of the individuals should be done. Areas like highway, rural location, petrol pump, railway station, or bus stand should be selected for opening a community pharmacy, as these are the stopping points for people.

   ii) **Urban Town or Big City:** This location can be further divided into areas near to transport facilities (railway station and bus stop) and areas near to populated markets. Various factors can be measured for opening a community pharmacy in such areas. Densely populated residential area, marketing place, and developing area are mainly selected for a community pharmacy. Buying capacity of the people and developed areas are the factors on which the investment depends.

2) **Functional Location:** This is further classified into the following (**figure 11.1**):
   i) **Suscipient Location:** This location, **e.g.,** hotel, airport, resort area, and community pharmacy in hospitals, attracts the people when they are away from their homes.
   ii) **Interceptive Location:** This location, **e.g.,** community pharmacy in large office building, community pharmacy near to doctor clinics, captures the people on their way to shopping centre and work place. This location is suitable for many people.
   iii) **Generative Location:** This location, **e.g.,** shopping centres and outlaying retail stores, attracts people for the purpose of shopping.

11.4.2.2. Advantages of Selection of Site

Following are the advantages of site selection for departmental and chain stores:

1) These provide price benefits due to central purchasing at a large scale.
2) These stores afford services of experienced and skilled managers.
3) These stores eliminate the bad debts of items sold on cash basis.
4) These stores compensate the loss of one store by making profits at other stores. Likewise, the unsold stock can be transferred from one chain store to another without any loss.

5) These chain stores offer a wide variety of products to fulfil the needs of customers; **for example,** APC tablets (aspirin, phenacetin, and caffeine) available from different manufacturers.
6) These stores decrease the cost of administration and direction by providing central selection and training to personnel.
7) These chain drug stores are becoming famous in Indian metropolitan cities.

11.4.2.3. Factors Affecting Selection of Site for a Drug House

The following factors affect the selection of site for a drug house:

1) **Physicians:** Around 70% businesses are originated by prescriptions of more than 3 physicians in any new location. In case physicians are prescribing their own medicine or I.P. product, this creates a competitor for business.
2) **Hospitals:** It is a suitable location for drug store business, in case the hospitals do not have their own drug store; but the physicians should be experienced and also the hospital should have all the required facilities.
3) **Drug Store:** A drug store should be opened away from the competitor; but in case of high potential, such location can be selected for opening a drug store by sharing the market. This is beneficial as in an area having a number of retail drug stores, people stop to buy drugs with the thought that they can procure all the prescribed medicines from at least one of them.
4) **Flow of Traffic:** It should be avo ided to open a drug store near the traffic signals due to parking problems and the problem of one way traffic should also be avoided. The best way is to identify the buying capacity of either left hand side or right hand side of the road, and then deciding accordingly.

   The buying capacity is high on roads from where people return back home from their work places. Road circles should be avoided due to traffic problems.
5) **Parking:** If anyone is selecting a location for drug store in shopping centre, there should be adequate space for parking.
6) **Near to Hotel, School, Cinema House, or Play Ground:** When the location is near any hotel, proper cleanliness should be maintained; school and playground closeness should be examined correctly; if there are facility of cold drinks and ice cream, drug store should be near to cinema house.
7) **Business Locality:** The rent of this location is very high due to the price of this place; but sin ce large number of people visits such areas, the purchasing power of drugs can be increased by making the shop attractive.
8) **Thickly Populated Residential Areas:** This location is also suitable as people can purchase medicines conveniently, like during evening walk.
9) **Developing Areas:** It is the ideal location to fulfil the needs of customers as new areas are developing in cities. In the beginning of business, these areas do not provide any competition.
10) **Special Services:** If anyone desires to provide special services in medicine such as Ayurvedic or Homeopathic drugs, any location can be chosen. Mainly , market place is selected since people always visit these places for marketing.
11) **Customers:** The type of product selling in the market depends on the customers in such location; **for example,** cosmetics and OTC products are sold more in rich areas, and economic products are sold in slum areas, etc.

If in any location there are people from residents and medical professional (such as physicians, marketing people of pharmaceutical industry), chances of sales to prescription is less as these people get enough sam ples from pharmaceutical industry. Any location where customers are getting medical reimburse ment is best for opening a drug store.

12) **Shopping Centres:** This is the best location but very high investment is needed.

11.4.3. Space Layout

Space layout plays a very sig nificant role in running a drug store successfully. For setting up a drug store, the pharmacists have to take a special care about the space layout.

11.4.3.1. Features of Layout Design

1) It should fascinate a large number of customers.
2) It should increase the sales of store.
3) It should decrease the selling expenses to a minimum.
4) It should provide customer satisfaction.
5) It should project a professional image and improves the overall appearance.
6) It should control the movement of customers within the drug store premise.
7) It should provide surveillance to decrease the chances of pilfer age and theft.
8) It should provide space for reserve stock, office, and resting place for the employees.
9) It should have an adequate entrance for incoming goods.

11.4.3.2. Types of Layout of a Community Pharmacy

Space layouts are of the following types:

1) **Process or Functional Layout:** In this layout, a particular location is provided for similar machines or operation. The machines of a particular class doing a particular work are arranged as a separate depart ment, **for example,** cutting machines are kept under cutting department.

   Advantages
   i) Efficient use of machine.
   ii) Provides more flexibility.
   iii) Better supervision results in better production.
   iv) Requirement of few machines reduces the capital.

   Disadvantage
   This layout is not possible in the pharmaceutical and chemical industries a s various unit operations need to be performed continuously.

2) **Product or Straight Line Layout:** This layout is based on the product manufactured. This set up is standardis ed in the starting. The product can b e manufactured in large quantities by repetitive operation. This type of layout is mostly used in pharmaceutical industries.

   Advantages
   i) Less space is required for the same volume of production.
   ii) Less in-process inventory.
   iii) Work flow is smooth and continuous.
   iv) Work processing is quick and smooth.
   v) Cost of material handling can be decreased by using conveyors.
   vi) Manufacturing time is less, therefore manufacturing cycle can be increased.
   vii) Floor space can be utilised properly.

3) **Combination Layout:** This layout is a combination of process and product layout, thus offers advantages of both the types of layout. Under this layout , material handling is low as well as the product cost can be kept at minimum level by suitable layout planning.

11.4.4. Design of a Community Pharmacy

The design of an ideal drug store is given in the **figure 11.2**:

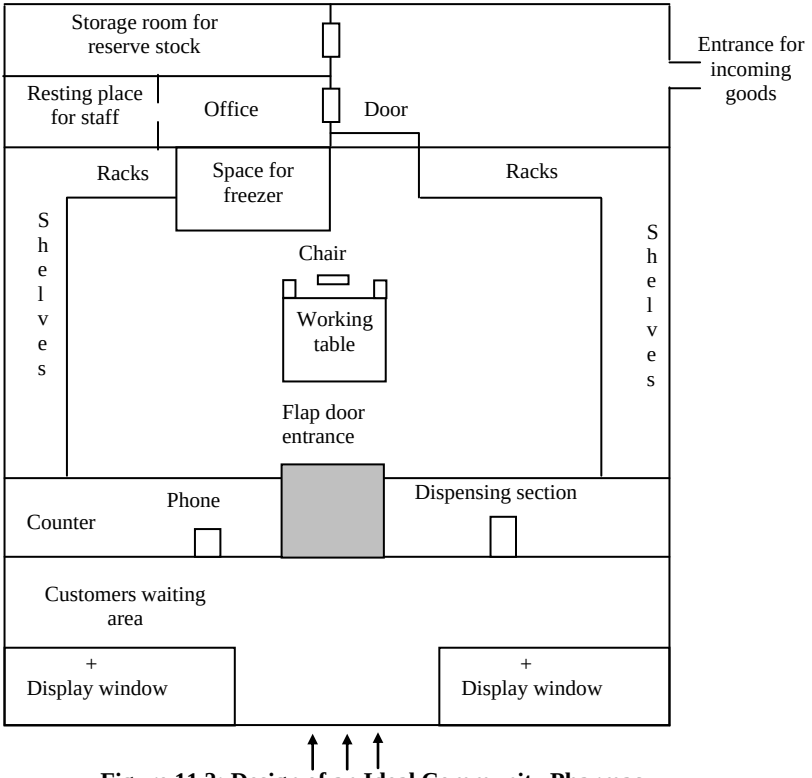


Figure 11.2: Design of an Ideal Community Pharmacy

Types of Service Design

Following are the types of service design:

1) **Clerk or Personal Service:** In this service, the customers demand and clerk (or personal service provider) delivers the demanded items. Some items are handled by the customers. This service and design aids maximum interchange between drug store staff and customers. Suitability and friendly service play an important role in the achievement of a drug store. Quality of service should not be compromised. The product price increases in this service because of more service overheads; this is the only **drawback** of this service.

2) **Self-Selection Design:** This design is not beneficial for prescription-oriented drug store; but is appropriate for non-prescription drugs, cosmetics, photo-supplies, greetings, etc. Customers are allowed to handle and select the items themselves. Clerk service is also provided at certain areas.

3) **Self-Service:** Complete self-service in a drug store is not possible due to the prescription department; however in a super drug store where other items are sold, this service is appropriate. The main principle in self-service is central checkout of all purchases.

11.5. SUMMARY

The details given in the chapter can be summarised as follows:

1) The **Community Pharmacy Medicines Management** (CPMM) is a unique concept that aims to introduce a structured intervention process among the community pharmacist, the patent, and the general practitioner.
2) Success of a community pharmacy depends on three factors, i.e., its **location (site)**, **proper layout**, and **design**.
3) **Financial management** or financial planning is concerned with making optimal decisions and anticipating the results of such decisions.
4) The main objective of a financial plan is to ensure that pharmacy does not suffer due to paucity of funds.
5) **Income and expense statements** are those in which the profit and loss of the community pharmacy is shown after a specific time period, i.e., annually.
6) **Balance sheet** shows the financial position of the community pharmacy in the form of asset and liability on a specific date.
7) **Cash flow statement** represents the movement of money into the business or out of the community pharmacy via operating, financing and investing activities.
8) **Projecting revenue** is calculated taking into consideration the income from product sale and fee-based services.
9) **Projecting expenses** means that the financial plan of a community pharmacy must include the expected expenses which will incur in the initial stage or in the ongoing pharmacy business.
10) **Start-up cost** includes the cost of training and change in the plan of the pharmacy.
11) **Fixed cost** is the cost that remains constant throughout even with the increase or decrease in the quantity of medical goods produced.
12) **Variable cost** is the cost that keeps on changing with the change in the level of production of pharmaceutical products.
13) **Material management** is a fundamental function of any business that itself adds in the overall cost of the product directly.
14) In the process of **coding**, a code number or code symbol is assigned to a particular material for easy identification.
15) In **alphabetical order method or letter code** method, the items are coded alphabetically.
16) In **mnemonic method**, each item is coded by some specific letters.
17) In **numerical or sequence system method**, separate numbers are assigned to specific items of store.
18) In **combination method**, combined form of mnemonic and numerical methods is used to code different items of the store.
19) In **fixed location** system, all the groups of items are given a fixed place inside the store according to the supplier wise, item wise, and as per the utility of the item.
20) **Random location** is the most common system used for allocation of drug items in a store.
21) In **zonal location** system, the available space is divided into different zones and each zone is assigned for different items.

22) The eligibility for establishing and operating a community pharmacy is that the person should be a registered pharmacist by the State Pharmacy Council.
23) A person who has **qualified Diploma** or has a **Degree in Pharmacy** and has completed a training for 650 hours in a medical store recognised by the State Pharmacy Council or a government hospital is eligible to be registered as a pharmacist.
24) In **rural or small town** , one can open their community pharmacy by taking loans from nationalised banks for rural development.
25) **Suscipient location** , **e.g.,** hotel, airport, resort area, and community pharmacy in hospitals, attracts the people when they are away from their homes.
26) **Interceptive l ocation**, **e.g.,** community pharmacy in large office building, community pharmacy near to doctor clinics, captures the people on their way to shopping centre and work place.
27) **Generative location** , **e.g.,** shopping centres and outla ying retail stores, attracts people for the purpose of shopping.
28) In **process or functional layout** , a particular location is provided for similar machines or operation.
29) **Product or straight line layout** is based on the product manufactured.
30) **Combination l ayout** is a combination of process and product layout, thus offers advantages of both the types of layout.
31) In **clerk or personal service**, the customers demand and clerk (or personal service provider) delivers the demanded items.
32) **Self-selection design** is not beneficial for prescription-oriented drug store.
33) **Self-service** in a drug store is not possible due to the prescription department.

11.6. EXERCISE

11.6.1. True or False

1) Balance sheet shows the financial position of the community pharmacy in the form of asset and liability on a specific date.
2) Projecting expense is calculated taking into consideration the income from product sale and fee-based services.
3) Variable cost includes the cost of training and change in the plan of the pharmacy.
4) In mnemonic method, each item is coded by some specific numbers.
5) Random location is the most common system used for allocation of drug items in a store.
6) A person who has qualified Diploma in Pharmacy and has completed a training for 250 hours in a medical store recognised by the State Phar macy Council or a government hospital is eligible to be registered as a pharmacist.
7) Product or straight line layout is based on the product manufactured.
8) Self-service in a drug store is not possible due to the prescription department.

11.6.2. Fill in the Blanks

9) Success of a community pharmacy depends on its _____, proper layout, and design.
10) _____ is concerned with making optimal decisions and anticipating the results of such decisions.
11) _____ represents the movement of money into the business or out o f the community pharmacy via operating, financing and investing activities.

12) _____ is a fundamental function of any business that itself adds in the overall cost of the product directly.
13) _____ is not beneficial for prescription-oriented drug store.
14) In _____ layout, a particular location is provided for similar machines or operation.
15) In _____, one can open their community pharmacy by taking loans from nationalised banks for rural development.
16) _____ statements are those in which the profit and loss of the community pharmacy is shown after a specific time period, i.e., annually.

Answers

1) True 2) False 3) False 4) False 5) True
6) False 7) True 8) True 9) Location
10) Financial management 11) Cash flow statement 12) Material management
13) Self-selection design 14) Functional 15) Rural town 16) Income and expense

11.6.3. Very Short Answer Type Questions

1) Define community pharmacy medicines management.
2) What are the primary objectives of community pharmacy medicines management?
3) Give any two methods of coding of materials in . community pharmac y medicines management.
4) What is the importance of staffing in community pharmacy medicines management?
5) Classify the different types of location for community pharmacy.
6) What features an ideal layout design for a community pharmacy should possess?
7) Draw a well-labelled diagram of an ideal community pharmacy.

11.6.4. Short Answer Type Questions

1) What are the objectives of financial planning?
2) Write a note on financial planning in community pharmacy.
3) Discuss about stocking of materials in community pharmacy medicines ma nagement.
4) Discuss the factors affecting selection of site for a community pharmacy.
5) Write a note on the types of layout for a community pharmacy.

11.6.5. Long Answer Type Questions

1) Discuss in brief about the financial requirement of community pharmacy medicines management.
2) Write an illustrative note on material and staff requirement in community pharmacy medicines management.
3) Give a brief note on infrastructure requirement in community pharmacy medicines management.

CHAPTER 12

Pharmacy and Therapeutic Committee

12.1. PHARMACY AND THERAPEUTIC COMMITTEE (PTC)

12.1.1. Introduction

The Pharmacy and Therapeutics Committee (PTC) comprises of a group of individuals (physicians, pharmacists, and other health personnel including the medical staff) who formulate policies concerning the therapeutic usage of drugs.

PTC plays a **dual role**:

1) **Advisory Role:** It helps in formulating professional policies regarding the evaluation, selection, and therapeutic usage of drugs in hospital.
2) **Educational Role:** It helps in various functions to fulfil the requirements of the professional staff, physicians, nurses, pharmacists, and other health care personnel for complete knowledge regarding drugs.

12.1.2. Organisation

A proper organisation should be made for carrying out the functions efficiently. In **figure 12.1**, various sub -committees and members to formulate policies concernin g various departments are shown.

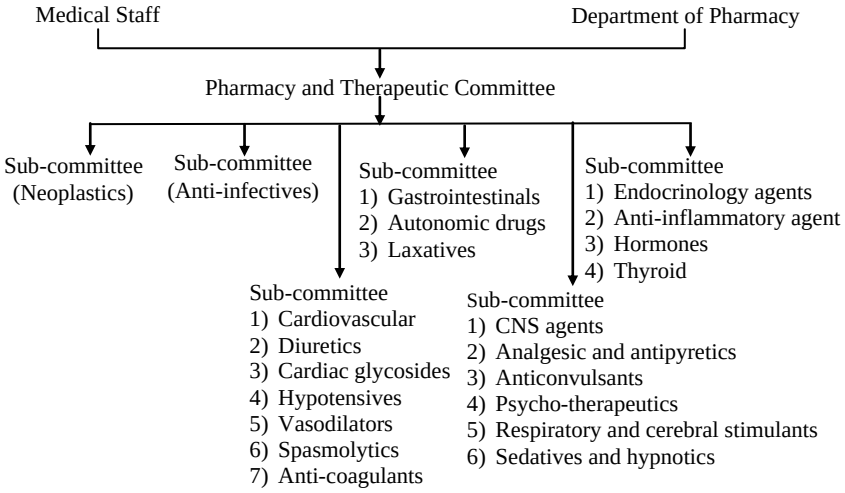


Figure 12.1: Organisation of Pharmacy and Therapeutic Committee

The PTC is further divided into sub-committees, whose members are responsible for their section. A representative of the PTC gives review and approval to the organisation regarding the therapeutic use of drugs, biologics, or Complementary and Alternative Medicines (CAMs) in a res earch protocol. The PTC memb ers provide information to the committees of hospital organisation to assure proper communication regarding drug research approved for conduction at the hospitals.

PTC is a policy -recommending body to the medical staff through the Medical Executive Committee. Recently, PTC in some organisations has directly reported to a health -system board (and not to a local Medical Executive Committee). The recommendations provided by the committee are forwarded for approval by the organised medical staff and also for the routine administrative approval process.

The frequency and length of the meeting and the accomplishment sense of the meeting participant, limits the meeting participation. The meetings should be conducted frequently to carry out the business in a reasonable time period. The meetings should be limited to 60 -90 minutes as usually the committee members cannot give more than 90 minutes to a meeting. Meetings should be conducted 4 -6 times in a year since the drug products and medi cal literature keeps on changing. Monthly meetings of 60 -90 minutes are generally recommended.

The meeting can be carried out more efficiently by establishing task forces or sub - committees (medication safety, drug review panels, and medication use review). The medication safety task force may be charged with review of adverse drug events and medication errors, their trending, and development of plans for prevention of future events. Drug review panels particularly focus on a speciality, like cardiology or infectious disease, and review drug products and guidelines in that area. The medication use review task force monitors the medication use reviews and evaluates the data and development plans to optimise the use of specific drugs. **Figure 12.2** demonstrates the relation of these sub-committees to the organisational structure of PTC.

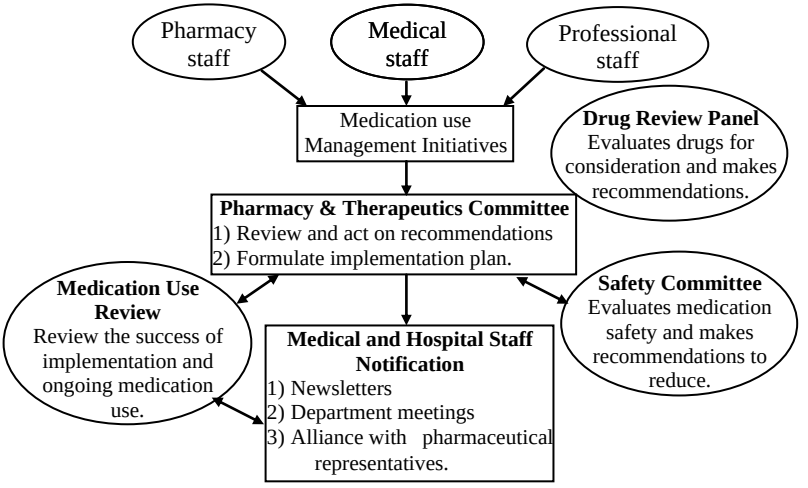


Figure 12.2: Formulary Management Process

Some rules should be established to decide the minimum number of members or the member types required for conducting a meeting. **For example,** in a committee with 15 members, at least 5 members should be present in a meeting, of which 2 should be physicians and 1 should be a pharmacist.

Committee Membership

Pharmacists, nurses, physicians, administrators, risk or quality improvement managers, and other suitable members should be selected under the guidance of the medical staff to constitute the PTC membership. Medication management is a multidisciplinary process. Committee membership includes non -physician members such as nurses, respiratory therapists, and other health care professionals. While in many hospitals, the voting members of the committee rema ins the physician members only; this is changing as the committee membership is evolving.

12.1.3. Functions

The PTC has the following functions:

1) It acts as an advisory council to the medical staff and hospital administration regarding the therapeutic use of drugs.
2) It develops a formulary of drugs and prescriptions to be used in hospitals. The items to be included in the formulary are selected based on their therapeutic use, safety, cost, etc.
3) It suggests written policies and procedures regarding the selection, procurement, storage, distribution, and therapeutic use of drugs.
4) It establishes suitable educational schemes for the hospital staff regarding the therapeutic use of drugs.
5) It studies the problems related to the distribution and administration of drugs.
6) It makes recommendations regarding the drugs to be stocked in wards and emergency.
7) It advises the pharmacy to implement effective drug distribution and control procedures.

12.1.4. Policies of the PTC in Including Drugs into Formulary

The PTC develops a formulary of medications and related products to be used in the organisation. The committee also looks after the regular revision and maintenance of the formulary, and promotes the rational, clinically applicable, safe, and cost-effective use of medications through guidelines, protocols, and other mechanisms. The committee also objectively evaluates and selects some medications to be added to or deleted from the formulary.

A request should be made for addition of a drug in the hospital formulary by submitting a Formulary Addition Request, supporting literature, and a signed disclosure of dual interest to the Pharmacy and Therapeutics Committee. Such requests for addition of a drug in the formulary are evaluated based on a literature review of the drug's safety and efficacy, and the availability of similar drugs in the formulary. Generally, addition of a drug is balanced by deleting an existing drug from the formulary. Those who request for an addition to the formulary should present their application to the PTC for final decision. One to two such applications are even discussed by the PTC at its regular meetings.

Thereafter, the committee makes one of the following decisions regarding the request:

1) Approval (with or without restriction),
2) Denial, and
3) Deferral (until relevant information is available).

The PTC has following roles in adding or deleting drugs into formulary:

1) **Addition of a Drug**
   i) Drugs with unknown formula or composition should not be added to the hospital formulary. Fixed dosage form combinations of two or more agents should not be considered. However, if a therapeutic advantage is demonstrated and no disadvantages are known, such combinations can be considered.
   ii) A drug is approved to be added to the formulary only if it fulfills the following conditions:
      a) It is the only drug effective for the mentioned purpose.
      b) It is superior in use to the other drugs in the formulary because of:
         - Greater efficacy for most patients or for selected patients (considering the varied patient responses), and
         - Decreased toxicity, greater patient tolerance, and easier administration method.
      c) Its efficacy and safety is similar to the currently used formulary product.
      d) It is more cost-effective than the formulary product currently in use.

2) **Deletion of a Drug:** Suggestions for deleting drugs from the formulary should be submitted to the PTC by any member of the medical, pharmacy, or nursing staff. To control the growth of hospital formulary, some additions are balanced by deletions of existing drugs. PTC should review its stocks and various therapeutic classes intermittently to bring about the deletion of duplicate drugs, which are less used or which can be readily replaced by less costly but equally effective drugs.

12.1.5. Policies of PTC in Emergency Drug List Preparation

Time is an essential factor in emergency situations, thus the PTC of a hospital should prepare boxes of emergency drugs, and these boxes should always be readily available for use at the bed -side. The list of such drugs and other supplies should be compiled by the policy of the Committee, and should find their place in "emergency kits".

The contents of such boxes are decided and the respo nsibility of its stocking is assigned, after which the units are prepared and made available on the specified places within the clinic, emergency ward, and in special procedure room of radiology department.

After placing the emergency boxes in the wards, a system is developed using which either the hospital pharmacist or the nursing supervisor responsible for the ward checks the boxes.

A list of drugs required in emergency situation should be prepared and placed in the Emergency Kit. This kit should be stored everywhere in the hospitals:

1) **Supplies to be Maintained in Emergency Box**
   i) Syringes, two each of 1ml (i.e., tuberculin or insulin syringe), 2ml and 5ml syringes, and one each of 10ml and 20ml syringes.
   ii) Needles, two each of 16', 18', 20', 21', 23', and 26'.
   iii) Files for breaking the ampoule.
   iv) Tourniquets.
   v) Airways equipment.
   vi) Ryles tube.

2) **Drugs for Emergency Box:** This list is prepared by consulting the physician:
   i) Aminophylline.
   ii) Amylnitrite glass capsules for inhalation.
   iii) Atropine sulphate (0.4mg/ml).
   iv) Caffeine sodium benzoate (0.5gm/2ml).
   v) Calcium gluconate (1gm/10ml).
   vi) Digoxin (0.25mg/ml).
   vii) Diphenylhydantoin sodium (50mg/ml).
   viii) Epinephrine HCl (1mg/ml).
   ix) Heparin (10.000 units/ml).

3) **Supplies for Cabinet Utility Room**
   i) Venous cannulation set.
   ii) Each set of 12 and 17 venous catheters.
   iii) Pieces 6" shock blocks.
   iv) Oxygen catheters.
   v) Razor with blades.
   vi) Package sterile gelatin sponge.
   vii) Resuscitation tube.

4) **Other Emergency Supplies**
   i) Resuscitation carts.
   ii) Phlebotomy sets.
   iii) Oxygen equipments.
   iv) Tracheotomy sets.
   v) Dextran and tubing.
   vi) Burn sheets.

Each hospital should modify this list of emergency drugs by adding or deleting items.

The medication list should have one or more indexes including the generic and trade name entries, and these names assist the user to locate the medication entry. An index in which the trade name entry states "see generic name, page 123" may be incorporated in the formulary. Then the formulary listing should be alphabetical and include both generic and trade names. Another type of index is the therapeutic index that arranges the drugs generically based on their therapeutic or pharmacological class. This index is especially useful for the prescriber who is not familiar with the formulary of a health system and wants to prescribe a certain type of drug (i.e., ACE inhibitor).

12.2. POLICIES OF PTC IN IN-PATIENT AND OUT-PATIENT PRESCRIPTION

12.2.1. Introduction

PTC is an advisory group of the medical staff and plays the role of an organisational communication line between the medical staff and the pharmacy department. Different policies are established for governing the use of drugs in hospitals.

12.2.2. Prescription Requirements

Given below are the prescription requirements as per the policies of PTC:

1) The prescriptions should fulfil the legal requirements as per the Pharmacy Act before dispensing a prescribed medication.
2) No member of the healthcare team should participate in the preparation, dispensing, or administration of any medication that is against the hospital policy (**e.g.,** Parenteral Drug Therapy Manual Policy). Refusal to carry out a medication order should be discussed with the supervisor and prescribing physician, and recorded in the chart.
3) The physician, before making the first medication order, should fill up the patient allergy status form in the chart. Nurses at the Pre-Admission Clinic (PAC), Pre-operative Care Centre (PCC), and the pharmacists can also complete the form. Any order can be processed or drug can be dispensed only when the allergy status form is complete. However, nurses can take the allergy status order verbally and note it in the physician's order section if the physician cannot come to the hospital to admit the patient. Thereafter within 24 hours the physician should complete the allergy status form in the chart.
4) All medication orders should be written on the Veterans Affairs (VA) prescriber's order form labelled with the patient's name and Material Receipt Note (MRN). Pre-printed orders on a self-adhesive label or rubber stamp are not acceptable. Medications taken before admission should be ordered using the appropriate Medication Reconciliation Order Form.
5) The medication orders should be readable and bear the drug name, dosage, dosage range, and route, frequency and duration of administration. Unsafe abbreviations should not be used.
6) PRN (an abbreviation for the Latin term, ***pro re nata*** which means **as needed**) orders should include a frequency limitation or a maximum number of doses per day and indicate the condition or symptom for which any PRN drug is to be administered.

7) The physician should include the date and time when the order was written along with his/her signature, printed name, and MSP (Medicare Secondary Payer) or college ID.
8) Clinical clerks and residents should write CC or Res. after their signature.
9) On all the medication orders the clinical clerks shoul d also indicate the name of the physician with whom the order has been discussed.
10) Phone orders are not accepted from Clinical Clerks.
11) "Suggest" orders should be written in the Prescriber's Orders section and is processed by the pharmacy once a written or v erbal counter-signature is obtained from a prescriber from the admitting service.
12) Nurse practitioners registered with the College of Registered Nurses of BC (CRNBC) can also prescribe medications.
13) Dieticians can order the usual daily dose of all the formu lary multi vitamins and multivitamin/mineral supplements for oral and enteral administration (as long as the patient can take medications via nasogastric tube and is not NPO, also known as ***nil per os*** (npo or NPO), a Latin phrase that means **nothing through t he mouth**) without a physician's order. However, single entity vitamin and IV preparations should be ordered by a physician. **Examples**:
    i) **Tablets**
        a) Multiple vitamins (Multivies, Vitogen), 1 tablet PO daily.
        b) Vitamins and minerals (Centrum Forte/Select), 1 tablet PO daily.
        c) Multiple vitamins with zinc (Z-BEC), 1 tablet PO daily.
        d) Vitamin B with C (Renavite), 1 tablet PO daily.
    ii) **Liquids:** Intantol, 5-10ml PO daily. (Maltlevol-12 must be ordered by a MD due to high alcohol content).

    Multivitamin supplements will be considered if the following conditions are fulfilled:
    i) Patient is malnourished or at risk of nutritional deficiencies.
    ii) The stay in hospital is expected to be more than a week. Patient cannot eat sufficient food/supplements and even cannot modify dietary in take to meet Daily Recommended Intake (DRI), or
    iii) If the patient care guidelines recommend a multivitamin and mineral supplement for the condition (**e.g.,** re-feeding syndrome, wound management, dialysis).

    If due to the patient's co-existing condition (**e.g.,** hemosiderosis, iron overload syndrome), iron supplementation cannot be given, then the physician should be consulted before ordering iron-containing multivitamin products.

    Orders will include date/time, dosage, frequency and route of multivitamin/miner al supplement, signature, printed name, RD, CDBC (College of Dieticians of BC) Registration Number.
14) Charts should be marked to indicate that a new order has been written.
15) New orders should be written in full post -operatively. "Resume preop meds" is not acceptable.
16) The orders written on the prescriber's order form once processed cannot be changed with add-ins, write-overs, or by crossing an order out. A discontinued order should be written with a new order.
17) **Cytotoxic Agents**
    i) **Ordering**
        a) A Parenteral Chemothe rapy/Immunotherapy Pre-Printed Order (PPO) form should be used to order the cytotoxic agents that are not the part of an existing PPO. These forms provide information on safe preparation and administration of chemotherapy agents.

b) The written orders including the time, date and duration of therapy for each parenteral dose of cytotoxic agents required for administration should be received in the pharmacy.

ii) **Leukaemia/Bone Morrow Transplant (L/BMT) Service Requirements**

a) For L/BMT service the orders for cytotoxic agents should be written and signed by two physicians; one should be the attending physician for that patient. However, the orders for oral hydroxyurea, oral all-*trans* retinoic acid, intrathecal methotrexate, and intrathecal cytarabine do not require the signature of two physicians.

b) The orders for bortezomib or 5-azacytidine require a single signature of the attending physician.

c) Adjustments can be made by a pharmacist on the physician's verbal order.

d) Registered Nurses (RN) cannot take telephonic orders for cytotoxic agents or for adjustments to cytotoxic doses.

e) For L/BMT in-patient units, all the orders for cytotoxic agents should be checked by two chemotherapy-certified RN. Disagreements exceeding ±5% of the dose (calculated as per the patient's treatment plan) should be discussed with the physician.

12.2.3. Telephone/Verbal Orders

In accepting verbal or telephone orders, **safety** is the prime principle. Verbal and telephone orders have a higher risk for errors as the orders can be misheard, misinterpreted, and/or mistranscribed.

Policy

1) A registered nurse, licensed practical nurse, respiratory therapist, or a pharmacist can accept verbal and telephone orders if the authorised prescriber (i.e. physicians, nurse practitioners, dentists) cannot write them.
2) Licensed Practical Nurses (LPNs) can accept medication orders for stable patients (i.e. adult populations whose outcomes are predictable) in designated patient care units to be administered by the enteral, percutaneous, intramuscular and subcutaneous routes (except intravenous and intrathecal routes).
3) Respiratory therapists can accept medication orders approved to administer as per their professional practice guidelines.
4) Verbal and telephone orders for chemotherapy drugs cannot be accepted. Pharmacists can take a telephone order to make necessary adjustments in the written order or to compound a chemotherapy preparation.
5) Drug orders are given using generic drug names.
6) Use of abbreviations should be avoided while giving or receiving an order.
7) Medication reconciliation order forms cannot be completed as a telephone order.

Procedure

1) It is the duty of the authorised prescriber to identify self, specify the patient's name, and communicate the order.
2) The receiver has the following duties:
   i) He/she should immediately document the prescriber order including the date, time, name and pager number of the authorised prescriber, and name, status, and signature of the receiver.
   ii) He/she should repeat back the order to the authorised prescriber including the patient's name, drug name (spelling of the drug to avoid an error due to similar

sounding drugs), dosage [pronouncing in single digits (**e.g.,** 15mg should be read as one five)], and the route and frequency of administration (**e.g.,** three times daily, not TID).

iii) He/she should request the indication for the medication to assist in avoiding errors.

iv) He/she should ask the authorised prescriber about any doubt in the order.

3) The authorised prescriber within 24 hours (or as soon as possible) after communicating the order should counter-sign it.

12.2.4. Automatic Stop Order

Medication orders in which the number of doses or days is not mentioned will be subjected to the following automatic stops:

Medication Category	Auto-Stop
1) Reserved antimicrobial drugs.	3 days*
2) Narcotic and controlled drugs [except phenobarb, methadone, and buprenorphine/naloxone (Suboxone), and Kadian brand of long-acting morphine].	7 days
3) Anti-infectives (topical and systemic) except anti-retrovirals, TB drugs and ketoconazole shampoo.	7 days
4) Inhalation solutions by nebuliser.	7 days
5) Ophthalmic preps except for glaucoma/lubrication.	7 days
6) Ketorolac parenteral.	5 days

*7 day automatic stop for L/BMT and Medical Day Care Unit.

1) **For Acute Care (including the Transitional Care Unit – TCU)**

i) All medication orders (apart from those mentioned in the above table) for in-patients, out-patients, and pre-admission patients are valid for a year. Standing out-patient orders should be re-ordered annually.

ii) A specific time limit on any medication order will predominate the automatic stop date. A fixed number of doses or time not exceeding 90 days (for straight narcotics the dosage time should not exceed 6 weeks) should be specified.

2) **For Residential Care and Tertiary Mental Health Unit**

i) For topical steroid creams, ointments, and lotions, the automatic stop date is of 28 days.

ii) Apart from the dosage forms mentioned in point (i) or listed in the above table, all medication orders are valid for a year.

iii) A specific time limit on any medication order will predominate the automatic stop date. A fixed number of doses or time not exceeding a year should be specified.

3) PRN orders apart from those on the routine medication order from the residential care units and TCU will be withdrawn if no medication has been administered within 28 days.

4) All pre-operative medication orders will be withdrawn and new medication orders should be written post-operatively apart from the following situations:

i) When going to or returning from ICU or critical care patients,
ii) Insertion of a central venous catheter,
iii) Insertion of a pacemaker,
iv) Haemodialysis and peritoneal dialysis,
v) Scope procedure through a natural orifice, or
vi) Minor diagnostic procedure or superficial drain/stent insertion/placement.

5) **On hold** orders are not accepted. The order should be stopped and re-ordered as required. However, a specific number of doses can be holded, **e.g.,** "hold next gentamicin dose" or for a specific condition, **e.g.,** "hold digoxin if HR less than 50".

12.2.5. Pharmacist-Managed IV-PO (Intravenous-Per Oral) Conversion Program

Policy

The oral dosage form for treatment courses of certain parenteral drugs will be promoted by allowing the pharmacists to review and change the administration route of such medications as per the established criteria.

Procedures

Pharmacy

1) A clinical pharmacist should evaluate the patients receiving the drugs listed below to determine the probability of oral therapy.
2) Patients meeting the criteria for oral conversion:
   i) Continues to need medication,
   ii) Are clinically stable,
   iii) Can tolerate the oral dosage form, and
   iv) Have no such factors present that would adversely affect the oral bioavailability; **for example**, in case of gastrointestinal abnormalities or drug interactions, the pharmacist should write the order for the equivalent oral regi men, and the next administration time should also be specified in the physician's orders.
3) The pharmacist should document in the progress notes the rational for the dosage form selection.
4) The pharmacist with the help of the prescribing physician and the h ealth care team should monitor the patients for clinical progress and their tolerability to medications, and may again start parenteral therapy.
5) The pharmacist should consult the physician before conversion for antimicrobial drugs given below in group 3.

List of IV Drugs Eligible for Conversion to PO by a Pharmacist

1) **Antimicrobials**

Group 1: Similar AUC achieved with oral dosage form of same drug:

i) Ciprofloxacin,
ii) Clindamycin,
iii) Cotrimoxazole,
iv) Fluconazole,
v) Linezolid,
vi) Moxifloxacin,
vii) Metronidazole and
viii) Voriconazole.

Group 2: Lower AUC achieved with oral dosage form of same drug:

Note: Patient should be clinically improving prior to step-down:

i) Acyclovir converted to valacyclovir.
ii) Ampicillin converted to amoxicillin.
iii) Azithromycin converted to clarithromyci n, or azithromycin cefazolin converted to cephalexin.
iv) Cefuroxime converted to cefuroxime axetil.
v) Penicillin G converted to penicillin V.

Group 3: Different drug -selection based on pathogen susceptibility and no contraindications to therapeutic alternative:

Note: Discussion with the prescribing physician is required:

i) Ceftriaxone converted to cefixime or fluoroquinolone.
ii) Imipene-cilastatin or meropenem converted to:
   a) Ciprofloxacin + clindamycin/cin/metronidazole,

b) Amoxicillin-clavulanate + ciprofloxacin, or
c) Moxifloxacin + metronidazole.

iii) Cloxacillin converted to cephalexin.
iv) Piperacillin-tazobactam converted to:
a) Ciprofloxacin + clindamycin/metronidazole,
b) Amoxicillin-clavulanate + ciprofloxacin, or
c) Moxifloxacin + metronidazole.

2) **Proton Pump Inhibitors and H_2-Blockers:** Patients should be taking other PO/NG (per oral/naso -gastric) medicines or food and there should be no endoscopically confirmed high risk acute upper gastrointestinal bleeding peptic ulcer disease/re - bleeding within past 3 days ("high r isk" as per endoscopy report = a ctive bleed or haemorrhage or presence of a non-bleeding visible vessel or presence of adherent clot).
i) Pantoprazole IV (all IV pantoprazole doses, i.e., pantoprazole IV infusions, 40mg IV daily, 40mg IV BID) converted to lansopraz ole PO or lansoprazole fastabs (if patient cannot swallow tablets).
ii) Ranitidine IV converted to PO form; dose adjusted for renal dysfunction.

12.2.6. Pre-Printed Physician's Order

Policy

All the pre -printed physician's orders should be approved by the Drugs & Therapeutics Committee, printed on the authorised form, reviewed annually by medicine, nursing and pharmacy, and signed and dated by a physician before a nursing personnel process them.

Procedures

1) **General:** All the requests for pre -printed physician's orders should be attached with a completed request form, which is available from pharmacy and should be obtained by the one who initiates the pre-printed orders.
2) **Physician**
i) Develops the desired pre-printed orders by consulting with the nursing staff.
ii) Obtains the required approvals as per the request form.
iii) Sends the draft of pre -printed orders along with the request form to the Director of Pharmacy.
3) **Pharmacy**
i) Ensures that the proposed pre -printed physician's orders have been reviewed by appropriate groups.
ii) Ensures accuracy by formatting the orders on the physician's order form and sending drafts of the orders to the initiator.
iii) Takes each pre -printed physician's order to the Drugs & Therapeutics Committee for approval.
iv) Forwards the approved orders for printing of initial set of orders.
4) **Nursing:** Orders the pre -printed orders directly from printing after the initial set has been printed.
5) **Printing**
i) Prints the pre -printed physician's orders only on the authorised form received from the pharmacy.
ii) Keeps the master copies of all orders.
6) **Physician**
i) Individualises the orders for each patient.
ii) Signs and dates all the medication orders within 2 days before initiation.
7) **Pharmacy:** Ensures that the pre-printed orders are reviewed annually.

12.2.7. Medication for Grieving Relatives

Policy

1) The troubled relatives can be given a single dose of a sedative or as considered to be appropriate by the physician.
2) In such cases, only no-narcotic medications are prescribed.
3) The physician is responsible for all aspects of the prescription as he/she would be for in-patient prescriptions.

Procedures

1) **Physician:** Writes a single dose order of an appropriate medication in the physician's orders of the chart belonging to the patient of the troubled relative. The order includes the relative's name, and name, strength, dose, route and indication for use of the drug.
2) **Nurse:** Administers the medication from ward supply or from the pharmacy (as a personal prescription).

12.2.8. Orders for Patients Transferred Between Sites

When patients are transferred from one site to another within the hospital, the receiving physician should review the existing orders within a day and then:

1) Writes an order to continue or modify the existing orders, or
2) Writes new orders by cancelling the existing orders.

Therefore, rewriting the orders is not obligatory when patients are transferred from site to site; and it is completely the decision of the attending physician.

12.2.9. Therapeutic Pass Medications

Policy

If the physician allows any patient to leave the hospital for a short duration, the patient should take along the required medications. Pass medications are limited to the drugs required for maintaining the continuity of care. The hospital does not supply the non-prescription PRN medications.

Procedures

1) **Prescriber:** Writes a complete prescription on the prescriber's order form for the medication(s) the patient has to take while out on pass and indicates the expected leave time. This policy is accepted for patient care units that do not have standard pass procedures. For PRN orders, the number of doses should be specified.
2) **Pharmacy:** The medications mentioned in the prescriber's order should be dispensed by the pharmacist.
3) **Nursing**
   i) Provides sufficient drugs from the patient's ward supply when the patient is out on pass in specifically marked envelopes. However, the liquid and narcotic and controlled medications should be only dispensed by the pharmacist.
   ii) Mentions on the patient's record that the medications have been supplied to the patient for self-administration while on pass and documents on the Medication Administration Record (MAR) "out on pass".
   iii) Reviews the pass medication use on the return of the patient and should mention the unused doses (if any) in the progress/nurses' notes.

12.2.10. Methadone and Buprenorphine/Naloxone (Suboxone) Control Program – Day/Weekend Pass Medications

Policy

1) **For Pain Management (Methadone Only)**
   i) The pharmacy supplies pass medications.
   ii) For the patients taking methadone before they were admitted, the pass medication order can be written by any prescriber.
   iii) For patients taking methadone during the current hospital admission (i.e., *de novo* therapy), the prescribers with a full methadone exemption can order the pass medication.
   iv) A 24-hour notice is required for the processing of pass medication.

2) **For Addiction Management**
   i) **Methadone**
      a) The pharmacy cannot provide pass medication for addiction therapy as daily witnessed ingestion is required.
      b) The prescriber having full methadone prescribing privileges for addiction therapy is only allowed to write the order on an out -patient triplicate prescription and arrange to have patient fill the medication from a community pharmacy on a daily basis for duration of the pass.
   ii) **Buprenorphine/Naloxone (Suboxone)**
      a) Pass medications are provided on the decision of a physician.
      b) A 24-hour notice is required so that the pass medication can be processed.

Procedures (For Pain Management Only)

1) **Physician:** Writes the order for the methadone pass at least a day before the pass.
2) **Nurse**
   i) Sends a copy of physician's order (including the time the patient is leaving on pass) to the pharmacy for all wards.
   ii) Ensures that the number of doses required is indicated.
3) **Pharmacist**
   i) Processes the prescription on the computer as a specific order for duration of the pass.
   ii) Ensures that the dosing instructions and brand name of the manufacturer appears on the label.
   iii) Ensures that the strength of the solution and volume of drug per dose is clearly labelled.

12.2.11. Discharge Medications

Policy

1) Discharge medications can be filled in community pharmacies to meet the legal requirements for an out-patient prescription.
2) RN/LPN cannot give an in -patient supply of medication when the patients are being discharged.
3) **Exceptions:** Discharge medications can be provided to:
   i) Solid Organ Transplant (SOT) patients:
      a) Only the medications approved by BC Transplant Society.
      b) Medications to be dispensed from Solid Organ Transplant Clinic Pharmacy.
   ii) Emergency Department discharge patients,
   iii) Travelling patients who cannot fill medication at local pharmacy, and
   iv) Registered Day Care Patients - Only parenteral cytotoxic medications.

Procedures

1) **Solid Organ Transplant (SOT) Patients**
   i) **Physician:** Writes the prescription for approved medications (separately from any other discharge medication).
   ii) **Pharmacist**
      a) Dispenses the medication from the transplant clinic pharmacy.
      b) Maintains a patient medication profile using the Pharmanet system.

2) **Emergency Discharge Patients**
   i) **Physician**
      a) Writes discharge prescription for filling at a 24-hour community pharmacy.
      b) **Exceptions:** see "Nurse" below
   ii) **Nurse**
      a) Provides to the patients u pon discharge 325mg acetaminophen along with 30mg codeine (only on the physician's written order). The pharmacy department packages the medication, labels it with appropriate instructions, and make it available as ward stock in the emergency department.
      b) After the operation hours of pharmacy, the patient's medication should be immediately begun. On receiving the physician's written order, the nurse offers the patient a maximum of 24-hour supply from Omnicell (or from the patient's in-patient medication supply). The envelope for each dispensed medication should bear the patient's name, physician's name, and name, strength, and dosing instructions of the drug. The number of doses provided should be documented.

3) **Travelling Patients:** Patients are provided with medication(s) upon discharge only if they are to travel long distances to their home and cannot fill the prescription in a local community pharmacy before travelling.
   i) **Physician:** Writes an order on the physician's order and indicates the quantity to be given to the patient. The drug should be ordered in quantity that last throughout the duration of the travel. The travel medication order indicates the departure time and the number of doses required for the travel period.
   ii) **Pharmacist**
      a) Processes the order.
      b) Ensures that the label bears the patient's name, physician's name, manufacturer's name, and the name, strength, brand and dosing instructions of the drug.
      c) Dispenses the oral medications in safety cap vials.

4) **Registered Day Care Patients**
   i) **Physician:** Writes the pre scription on a discharge prescription form or a physician's order form 24 hours before the treatment.
   ii) **Nurse:** Faxes the prescription to the pharmacy satellite.
   iii) **Pharmacist**
      a) Dispenses the prescription as per the cytotoxic policies of the hospital.
      b) Sends the medication to the day care unit with porter service.

12.2.12. Interim Mediation for Patients Returning to Residential Care Facility

Policy

1) If community pharmacy services are not available on weekends or statutory holidays, the patients returning to a residential care facility are provided with an interim supply of essential medication(s).

2) On receiving the physician's written order form, the pharmacy department supplies the medication.
3) The medications are supplied for maximum 3 days.
4) One day's notice is given for processing the transfer medications.
5) If one-day advance notice cannot be met, the pharmacy department can be contacted.

Procedure

1) **Nursing**
   i) Confirms about the unavailability of the community pharmacy.
   ii) Advises the physician to write orders for inter im medications required, and specifies that a patient is returning to a residential care facility.
   iii) Provides the pharmacy with a one-day advance notice for prescriptions to be filled.
   iv) Communicates with the clinical pharmacist to discuss about the discharge plans.
2) **Physician or Authorised Prescriber**
   i) Writes prescriptions on a new physician order form, and specifies that the medication is for a patient returning to a residential care facility.
   ii) Limits the discharge medications to the drugs required for conti nuing the treatment of the patient's primary conditions.
   iii) PRN orders should be written for the medications required for interim period, **e.g.,** pain medications.
   iv) Mentions the following information in the medication orders:
      a) The expected discharge date and time,
      b) The name, dose, route, and frequency of administration of the drug,
      c) Number of days (maximum 3 days).
      d) Number of doses (for analgesics).
   v) Writes all other transfer of care orders (**e.g.,** complete discharge medication list, lab requisitions, and care plan) on separate transfer forms.
3) **Pharmacy**
   i) Processes the prescription.
   ii) Ensures that the label bears dosing instructions and brand name of the manufacturer.
   iii) Dispenses tablets and capsules in safety cap vials.
   iv) Sends supply for maximum 3 days.

12.2.13. Dangerous Abbreviations, Symbols and Dose Designations

The abbreviations, symbols, and dose designations given in **table 12.1** are frequently misjudged, thereby leading to harmful medication errors. Thus, these should never be used when communicating medication information.

Table 12.1: Dangerous Abbreviations, Symbols and Dose Designations

Abbreviations	Intended Meaning	Problem	Use Instead
U	Unit	Mistaken for "0" (zero), "4" (four), or cc.	Unit
IU	International Unit	Mistaken for "IV" (intravenous) or "10" (ten).	Unit
Abbreviations for drug names		Misinterpreted because of similar abbreviations for multiple drugs; **e.g.,** MS, MSO_4 (morphine sulphate) $MgSO_4$ (magnesium sulphate) may be confused for one another.	Full drug names

QD, QOD	Every day, every other day	QD and QOD have been mistaken for each other, or as 'QID'. The Q has also been misinterpreted as "2" (two).	Daily every other day
OD	Every day	Mistaken for "right eye" (OD = oculus dexter).	Daily
OS, OD, OU	Left eye, right eye, both eyes	May be confused with one another.	Left eye, right eye both eyes
D/C	Discharge	Interpreted as "discontinue whatever medications follow" (typically discharg medications).	Discharge
CC	Cubic centimetre	Mistaken for "u" (units).	ml
µg	Microgram	Mistaken for "mg" (milligram) resulting in on thousand-fold overdose.	mcg
Symbols	**Intended Meaning**	**Potential Problems**	**Use Instead**
@	at	Mistaken for "2" (two) or "5" (five).	at
> <	Greater than Less than	Mistaken for "7" (seven) or the letter "L". Confused with each other.	Greater than/above less than/below
Dose Designations	**Intended Meaning**	**Potential Problems**	**Use Instead**
Trailing zero	.X.0mg	Decimal point is overlooked resulting in 10-fold dose error.	Never use a zero by itself after a decimal point; Xmg
Lack of leading zero	.Xmg	Decimal point is overlooked resulting in 10-fold dose error.	Always use a zero before a decimal point; 0.Xmg

12.3. SUMMARY

The details given in the chapter can be summarised as follows:

1) The **Pharmacy and Therapeutics Committee** (PTC) comprises of a group of individuals (physicians, pharmacists, and other health personnel including the medical staff) who formulate policies concerning the therapeutic usage of drugs.
2) PTC is a policy -recommending body to the medical staff through the Medical Executive Committee.
3) The PTC develops a formulary of medications and related products to be used in the organisation.
4) PTC is an advisory group of the medical staff and plays the role of an organisatio nal communication line between the medical staff and the pharmacy department.
5) In accepting verbal or telephone orders, **safety** is the prime principle.
6) All the pre -printed physician's orders should be approved by the Drugs & Therapeutics Committee, printed on the authorised form, reviewed annually by medicine, nursing and pharmacy, and signed and dated by a physician before a nursing personnel process them further.
7) Discharge medications can be filled in community pharmacies to meet the legal requirements for an out-patient prescription.

12.4. EXERCISE

12.4.1. True or False

1) PTC develops a formulary of medications and related products to be used in the organisation.
2) PTC is an advisory group of the medical staff and plays the role of an organisational communication line between the medical staff and the in-patients.
3) All the pre -printed physician's orders should be approved by the Drugs & Therapeutics Committee.

12.4.2. Fill in the Blanks

4) PTC is a _____ body to the medical staff through the Medical Executive Committee.
5) In accepting verbal or telephone orders, _____ is the prime principle.
6) _____ can be filled in community pharmacies to meet the legal requirements for an out-patient prescription.

Answers

1) True 2) False 3) True
4) Policy-recommending 5) Safety 6) Discharge medications

12.4.3. Very Short Answer Type Questions

1) Define the role of PTC.
2) Give the organisation chart of PTC.
3) What is automatic stop order?
4) Give the policy for pre-printed physician's order.
5) What is the policy for therapeutic pass medication?

12.4.1. Short Answer Type Questions

1) What are the functions of PTC?
2) Write a note on the organisation of PTC.
3) Discuss the policies of PTC in including drugs into formulary.
4) Discuss the policies and procedures for discharge medications.

12.4.2. Long Answer Type Questions

1) Discuss in brief about the policies of PTC in in-patient and out-patient prescription.
2) Write an illustrative note on the policies of PTC in emergency drug list preparation.

CHAPTER 13

Drug Information Services (DIS)

13.1. DRUG INFORMATION CENTRE (DIC)

13.1.1. Introduction

Written and/or verbal information given about drugs and drug therapy in response to a request from other healthcare provider, organisations, committees, patients, public, or community is called **Drug Information Service(DIS)**. Drug information service also includes the activities performed by the pharmacists in providing information for the optimised use of drugs.

The drug information service or drug information centre aims to document drugs by extracting information about them. Drug information is the knowledge (about drugs currently being used in the hospital) assembled in written forms (like books, journals, periodicals, etc.) or transmitted by oral communication or by electronic device of the physical, chemical, biological, and health care sciences.

Drug information centre is a department or a unit in a hospital that is established for services like receiving, collecting, analysing, and providing unbiased, accurate and latest information on drugs and their uses.

Drug information centre gives a detailed and fair source of drug information that is essential to meet the needs of the practicing physicians, pharmacists, and other health care professionals. In India, these information play more important role and it became crucial to highlight the role of consumers because in India the national health policies are industry-focused rather than information to health care-focused. The drug information centre of WHO spreads awareness about partnership with drug information services and rational use of drug.

In large hospitals, DIC is located in a separate section of pharmacy, containing a large number of reference texts, journals, reprints, and brochures. At times, they also have electronic data processing equipments and a full-time Director and adequate Secretarial Assistance. Nowadays, networking of regional DICs in different hospitals can be done by using computers.

The DICs record all data on drug reactions in the institution. A reliable local source of drug information should be available in a hospital to provide effective clinical care to the patients. The information gathered may be specific to an individual patient or related to a group of patients in context of a disease management program.

13.1.2. Objectives

Following are the objectives of a drug information centre:

1) It provides the minimum resources needed to establish DIC at different levels.
2) It recognises the importance of monitoring and evaluation necessary to maintain the quality of drug information distributed.
3) It acts as a guide for the hospital.
4) It maintains an organised database of drugs and drug therapies to meet the drug information needs of doctors, pharmacists, and other health care providers.

5) It provides accurate and unbiased information about any drug, drug therapy , or other health-related service s to the pharmacists, physicians , and other health care professionals in a hospital and community.
6) It provides education to pharmacy students so that they further provide effective drug information.
7) It promotes rational use of medicines among patients and their caretakers.

13.1.3. Classification

Drug information centre can be classified into the following three types:
1) Hospital-based drug information centre,
2) Industry-based drug information centre, and
3) Community-based drug information centre.

13.1.4. Setup and Equipment

A drug information centre has computer terminals, printed materials (curren t, periodicals, bound journal volumes, and reference texts), and access to internet service, various softwares (**e.g.,** Medline), and o ther online drug and medical references. The centre has subscriptions to some national and international journals and texts of pharmacy and medicine. Facili ty of direct access to computer -based online data searching, CD ROM databases, and the World Wide Web are also available (**figure 13.1**).

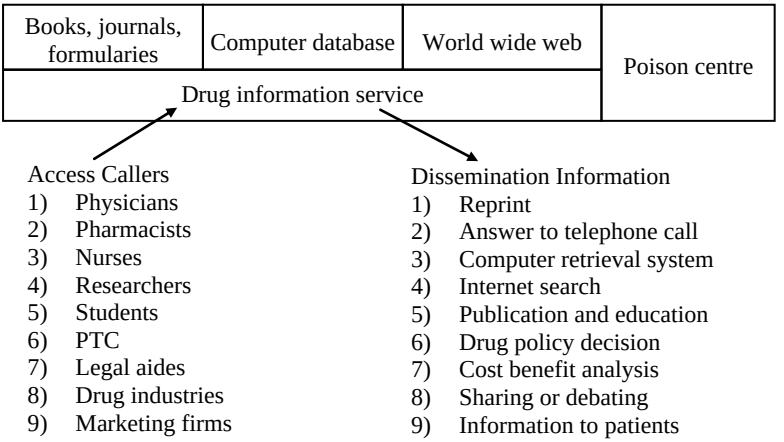


Figure 13.1: Working Model of Drug Information Service

13.1.5. Staff, Student and Time

Staff of a drug information centre includes a full-time director, a full-time resident, and 6 pharmacy students. Training to undergraduate and postgraduate p harmacy students can also be given in this centre. Information about any drug or drug therapy can be asked personally, by phone, fax, e -mail, or by mail. The centre has the accessibility of 24 ×7 hours a day by the telephone.

13.1.6. Functions

The DIC provides detail and accurate source of drug information that is essential for fulfilling the requirements of the medical practitioners, pharmacists, and other health care professionals in the following areas:
1) **Adverse Drug Reactions:** Information regarding the predisposing factors, relationship to dose or duration of therapy, incidence, clinical manifestations, and management of adverse drug reaction are provided. It also includes assessment of adverse reactions related to any drug.

2) **Evaluation of Drug Reactions:** Significance of drug -drug, drug -food, or drug-disease interactions are evaluated on laboratory level. The data of such tests is collected from various hospitals and medical institutes.

3) **Foreign Drug Identification:** It also gathers information and attempts to identify drugs in other countries. It also evaluates the efficiency and potential hazards of the product. If required, it gives information on the composition of product and its standards. It also collects data from FDA and other foreign agencies.

Drug information centre promotes safe, effective, rational and economic use of drugs by the health professionals as well as patients.

13.1.7. Drug Information Centre in India

The role of drug information services is very significant in Indian health care sector due to increased patient load on Indian clinicians, the high demand for better healthcare delivery, and reduced economic support. However, in India the drug information services and centres are still in their initial stage, and only a small number of centres are available that qualify as drug information centres. The se DICs are mostly located in Indian hospitals and are listed in **table 13.1**:

Table 13.1: Location of Some Drug Information Centres in India

All India Institute of Medical Sciences, Poison Information Centre, Delhi
Andhra Pradesh State Pharmacy Council, Andhra Pradesh
Christian Medical College Hospital, Vellore, Tamil Nadu
CDMU Documentation Centre, Kolkata, West Bengal
Victoria Hospital, Bangalore, Karnataka
JSS Hospital, Mysore, Karnataka
JSS College of Pharmacy, Ooty, Tamil Nadu
Karnataka State Pharmacy Council, Bangalore, Karnataka
Kasturba Medical College Hospital, Manipal, Karnataka
Kempegowda Institute of Medical Sciences, Bangalore, Karnataka
Maharashtra State Pharmacy Council, Mumbai, Maharashtra
Pharma Information Centre, Chennai, Tamil Nadu
Sri Ramachandra Medical College Hospital and Research Institute, Chennai, Tamil Nadu
Sri Ramakrishna Hospital, Coimbatore, Tamil Nadu
Trivandrum Medical College Hospital, Thiruvananthapuram, Kerala

In India, the services under the DIC are not clearly defined, and there is also a lack of well-defined criteria for using the titles of DIC. Some of the so-called 'DICs' here only work under some pharmaceutical companies; therefore, these medical information departments provide information on the company's products rather providing independent and unbiased drug information. Most of the time information they provide is incomplete, selective and influenced by the commercial interests of the sponsoring company. Therefore, there is a huge scope of significant growth in the area of drug information services.

Following are the factors which influence the evolution of drug information services in India:

1) **Growth of Clinical Pharmacy Education and Practice:** Drug information pharmacists should have a sound knowledge of pharmacotherapeutics, broad clinical experience, good written and verbal communication skills , and drug information skills. Lack of rigorous knowledge, training and experience in the pharmacists was one of the major obstacles in the development of drug information services in India. This deficiency has now being recognised, and more pharmacists are perusing post - graduation and training in clinical pharmacy and pharmacy practice.

2) **Growth of Information Technology:** Development of information technology has increased the ability to store and make use of the vast area of drug information. Computer-based databases, including on health -related topics, are available for a variety of requirements. But, most of these databases are expensive and non - affordable for individual pharmacists and small hospitals. On the other hand, DICs can purchase a variety of drug information resources and further provide them to a larger population on reduced rate or free.

13.2. POISON INFORMATION CENTRE (PIC)

13.2.1. Introduction

Poison Information Centre (PIC) or Poison Control Centre (PCC) is a specialised unit which gives information on poisoning management and immediate information on early diagnosis, treatment, ma nagement, prevention and hazard management of poisoning. These services are provided by well-trained poison information specialists.

PIC provides services related to poison information that helps in the effective management of poisoning cases. Poison Information Services (PISs) perform a periodic assessment of poisoning management information as per the needs of the enquirer. These services also deal with the risk as sessment, diagnosis, management, and prevention of exposure to any poison in patients of any age irrespective of the type (intentional or accidental) and route of poison exposure.

The PIC mainly aims to reduce the rate of morbidity and mortality due to poisoning and to improve the health and life quality of the patients. PISs reduces the treatment cost of poisoning to the patients as well as to public healthcare facility by preventing excessive visits to the healthcare facility, hospital admission, and extended hospitalisation.

13.2.2. Information Resources

In **tables 13.2** and **13.3**, the minimum primary and secondary poison information resources required are enlisted:

Table 13.2: Minimum Primary Poison Information Resources Required

S. No.	Titles
1)	Online journal scanning services, **e.g.,** AMEDEO, current awareness in clinical toxicology
2)	Clinical toxicology
3)	Indian Journal of Toxicology
4)	Indian Journal of Environment and toxicology

Table 13.3: Minimum Secondary Poison Information Resources Required

S. No.	Titles
1)	Poisindex
2)	Hypertox
3)	Toxbase
4)	Intox
5)	Toxinz

13.2.3. Working of Poison Information Centre

Working of the PIC is based on the following factors:

1) **Legal and Ethical Prerequisit es:** The PIC should have independent s tatus, stability and neutrality, and should be officially recognised by the government as well as the WHO in order to carry out its functions effectively. A go verning body should be present within the PIC to provide pol icy guidance and assist in fund raising. As per the legal requirement, PIC should maintain the privacy of the data handled by it. It generally provides the information free of cost to the enquirers.

2) **Policies and Procedures:** The PIC should have a well -defined and need -based policies and procedures to carry out its functions effectively. These policies and procedures are designed as per the scope of service in an area, financial support , and PIC's requirements, thus are different for different centres. All the factors should be considered by the PIC at the time of policy designing for personnel, operation method, documentation of service and quality assurance programme, staff training, confidentiality, and ethical and legal aspects.

3) **Training of Staff:** Proper training programme is essential for the employees of PIC, especially for newly recruited and inexperienced staff. The training manual should be designed and implemented according to the need of PIC staff. Such training programmes assist the PIC to train its new and inexperienced staff in different areas as well as to maintain uniformity in staff training.

4) **Handling of Poison Information Query:** The most important duty of a poison information specialist is handling of the poison information query , for which he/she should have good communication skills that assist them in presenting the descriptive or explanatory information clearly and concisely. It also helps to establish effective working relationships with other employees of organisations and public in cases of emergency and other situations. The poison information specialist should be skilled of reacting calmly and effectively in emergency and stressful conditions.

13.2.4. Steps to Approach Poison Information

Given steps are followed to approach poison information query:

Step 1: Receive and Obtain Requester's Demographics: The query related to the service is received and accepted either on telephone or personally. The identity of the requester is known by collecting his/her contact details. The other additional in formation that will help to reply the query is collected from the requester. In case the requester is a healthcare professional, his/her position and anticipated knowledge should be checked.

If procurement of information seems to be time -taking, either the requester is asked to call back or his/her contact number is noted. Any query related to potentially hazardous poisoning cases should be answered immediately; while for a query related to low toxicity, an appropriate deadline should be given for a response.

Step 2: Collect Background Information: All the required background information should be collected by targeted questioning. These information should be collected very carefully as they are necessary for accurate identification of the poisoning substance. All critical information should be gathered in a short duration so that maximum patient outcome can be obtained, otherwise it may be counter-productive.

The basic information about a patient that should be collected includes age and/or weight, substance/product name, route of contact (ingestion, inhaled, dermal, ocular), quantity and/or strength involved, time since exposure, patient's condition (signs, symptoms, etc.), treatment received, and health status of the patient including medication history, allergies, and relevant pre-existing conditions.

Step 3: Assessment of Condition: Proper background information helps in understanding the actual query to be answered. This information also helps in evaluating the severity of the condition , i.e., whether it is an emergency, serious, not serious , or no problem at all. It also helps in assessment of the toxicity associated to exposed toxins based on the nature of the substance, type of exposure, and quantity consumed.

The proper valuation of toxicity signs and symptoms and analytical testing of compound helps in patient management and to determine whether first aid, observation, medical treatment, home treatment, or no treatment is required for the particular condition.

Step 4: Develop and Conduct a Search Strategy: The information resources are prioritised according to the probability of locating the desired information. Ideally, retrieval of information should be based on the probable efficiency of information sources in the literature hierarchy. However, in most of the cases, the information can be obtained from the tertiary resource; it is advisable to consider other information sources as per need.

A poison information specialist can retrieve complete information in very short time from databases, like Poisindex, Hypertox, and Intox. Along with this, the developed poison management protocols are also a source of information, mainly in emergency situations. The information resources used by a poison information specialist should be documented according to its effectiveness in responding to a query.

Step 5: Evaluate and Provide Information: The information recovered by the poison information specialist should be evaluated thoroughly. Complete information has to be generated that ensures the management of the patient according to all the current evidences available.

Any response should be generated after evaluating all the available information and the continuity of information among the resources used should also be ensured. Available information from various resources should be interpreted as per the patient's need and other patient-related factors.

A decision may be taken on the basis of professional knowledge and previous experience, if there is a lack of information or conflict of information in the available sources. Information may be given either in verbal form, written, printed form or by fax or e-mail. However, on-time or immediate delivery of response is not possible always. If more time is needed for evaluation and formulation of the response, it is vital to provide minimum vital information as soon as possible.

Step 6: Conduct Follow-Up: Follow-up is important in the assessment of patient outcomes and also to confirm whether or not the additional information is useful in poisoning management. Personal visit is more useful and is only possible when the patient is admitted to a hospital having a poison information centre. In other cases, follow-up can be made through telephone enquiry and e-mail.

Step 7: Document: The details of the requester are recorded. Query and response should be made through any one means of documentation (paper, computer, log book, etc.). Proper documentation is essential as it helps not only in the future reference for similar repetitive query, but also justifies the professional value and acts as a protective measure against legal liability.

Step 8: Maintain Confidentiality: It is the responsibility of the PIC to maintain the privacy of all issues related to query for socio-legal reasons. The requester's details should not be disclosed to anyone, including family members and healthcare professionals without the requester's permission.

13.2.5. Quality Assurance

A formalised quality assurance programme is essential for the PIC. This programme should be developed and implemented continuously by the PIC for the services it provides. The quality assurance programme mainly focuses on improving the quality of services it provides and improving the patient health effects.

The programmes included under quality assurance involve performance indicators and evaluation methods for monitoring the quality, appropriateness, timeliness of management, or treatment recommendation and effectiveness of service.

13.2.6. Functions

PIC performs the following functions:

1) It provides poison information services.
2) It helps in the treatment and management of poisoning cases.
3) It performs toxicological analysis.
4) It aids the study of toxicovigilance.
5) It conducts education and training programmes for healthcare professionals.
6) It conducts education and awareness pr ogrammes related to prevention of accidental poisoning for the public.
7) It develops treatment protocols for poison management.

13.3. SOURCES OF DRUG INFORMATION

13.3.1. Introduction

The DICs gather information from the following sources:

1) Primary sources, 2) Secondary sources, and 3) Tertiary sources.

13.3.2. Primary Sources

These form the foundation of the sources hierarchy, and serve as the information source for the development of secondary and tertiary resources. Pri mary sources consist of original research written by the author(s) in their own words, research studies, case reports, editorials, letters to the editor, thorough description of the study design, methodology, and scientific results. The readers can assess and analyse the given information to develop a conclusion.

Table 13.4: Primary Sources of Drug Information Resources

British Medical Journal	British Journal of Clinical Pharmacology
New England Journal of Medicine	American Journal of Health Systems Pharmacy
Annal's of Internal Medicine	Lancet
British Journal of Pharmacy and Pharmacology	Indian Medical Journal
Clinical pharmacy and Therapeutics	Journal of the Association of Physicians of India

13.3.2.1. Advantages

Primary sources have the following advantages:

1) These provide latest and original information. The essential clinical journals contain information about patient-oriented, evidence-based medicines related to patient care. Patient-Oriented Evidence that Matters (POEMS) are used to define this information and the journals in which they are mentioned.
2) Many articles before being published are reviewed by the author's peers, therefore unbiased views and suggestions to improve the report quality are also contained. This is known as **peer-review process**.

13.3.2.2. Disadvantages

Primary sources have the following disdvantages:

1) Faults in study procedure in any research report lead to inaccurate conclusions. **For example,** if an individual uses inappropriate statistical analysis in his/her studies, he would reach to an inappropriate conclusion.
2) In order to assess primary sources, knowledge about scientific methods and statistics is required for understanding the information.
3) The information provided by the primary sources is new, so the medical community may take time to accept it.

13.3.2.3. Handling of Primary Sources

1) One should cautiously and conventionally utilise the new information provided by the primary sources.
2) The published articles should be peer-reviewed journals as they are better in quality and objectivity in comparison to non-peer reviewed work.
3) While utilising the data provided by the primary sources and before applying that information to patients, all the aspects of the primary source should be understood (i.e., patient inclusion or exclusion criteria, study methods and interventions, primary outcome being assessed, statistical and clinical relevance of the reported findings).
4) To extrapolate primary source data to a single patient encounter, the patient population mentioned or utilised in the primary work should correspond to practice population.
5) Case reports are related to a single patient (not to a patient population); therefore, one should be careful about bias and avoid relying on anecdotes.

13.3.3. Secondary Sources

These are compiled by indexing and abstracting services that are used to systematically locate various published literature types. The indexing system provides topic wise bibliographic information and allows the readers to view brief information within most citations, **e.g.,** PubMed (Medline), Embase, National Library of Medicine Gateway, International Pharmacy Abstracts, Scopus, and Toxline. The secondary source databases have their own scope, look, feel, and features to be easily accessible.

Table 13.5: Secondary Sources of Drug Information Resources

Medline	Poisindex
International Pharmaceutical Abstracts	Index Medicus
Chemical Abstracts	The Medical letter on Drugs and Therapeutics
IOWA Drug information Service	Adverse Drug Reaction Bulletins
Drugdex	WHO Drug Information
Martindale	

13.3.3.1. Advantages

Secondary sources have the following advantages:

1) These sources provide quick access to the primary source.
2) These sources provide concise and current information on specific topics.
3) The journal sources are of a high standard and peer-reviewed.
4) They provide updated information weekly or monthly.

13.3.3.2. Disadvantages

Secondary sources have the following disadvantages:

1) The time period between publication and inclusion (lag time) into secondary sources vary from days to weeks for each database.
2) The number of journals indexed by each system depends on the scope of the database.
3) A secondary source can include a large amount of information, so the readers should be capable of examining the sources listed on a particular subject to access the exact information.
4) The readers should use specific search terms and be skilled with a particular database's search techniques to obtain information.

13.3.3.3. Handling of Secondary Sources

1) All the databases have their own scope, and gather information from primary sources in a certain field about a disease, drug, or literature related to patient care. **For example**, Medline focuses on biomedical sciences, Toxline focuses on toxicology,

Cumulative Index of Nursing and Allied Health (CINAHL) focuses on nursing and allied health literature.

2) The Clinical Medical Librarians (CMLs) are highly skilful in searching secondary sources, if the readers are not familiar with Medical Subject Headings (MeSH) or other terms used for indexing the information.

13.3.4. Tertiary Sources

These sources provide core knowledge established via primary sources or accepted as standard of practice within the medical community. Drug information contained in the tertiary sources is a FDA-labelled indication (i.e., approved and accepted by the FDA) or is well-founded in the primary care source (i.e., an unlabelled but well-documented use for an FDA approved drug).

Tertiary sources include textbooks on various drugs or diseases (**e.g.,** pharmacotherapy), compendia (a vast collection of information about numerous drugs such as Physician's Desk Reference), or online, full-text databases. The provided information should be evaluated for bias.

Table 13.6: Tertiary Sources of Drug Information Resources

Remington's Text Book	Up to Date
Handbook of Non-prescription Drugs	Pharmacist's Letter
Martindale Drug Reference	Natural Medicines Comprehensive
Lexi Comp	FDA. gov
Micromedex	CDC.gov

13.3.4.1. Advantages

Tertiary sources have the following advantages:

1) These sources are conveniently accessible on the internet.
2) Drug information references are divided into specific subjects to be used easily. **For example,** one text is only related to drug interactions, while another is related to principles of pharmacotherapy or drugs to be used in pregnancy. Thus, a reader who wants information on a specific subject needs to review a specific reference.
3) The information in tertiary sources is widely accepted in medical practice, because most forms of these sources are referenced with primary sources. The information should be reviewed so that the contained information is well regarded in the medical community.

13.3.4.2. Disadvantages

Tertiary sources have the following disadvantages:

1) The lag time existing between when a text was written and when published (in print or electronically), passes before the information is available, and more updated information are available in a database.
2) Space limitations within a text prevent discussion of a drug or topic.
3) Authors may give emphasis to restricted information about a topic or drug.
4) Authors present information based on a less thorough review of the primary care source.
5) These sources are not suitably referenced, thus prevent a proper check of the primary care source.
6) The information given by these sources are not accurate and reliable if based on flawed primary care source (i.e., poorly designed research studies are referenced).
7) If these sources are print resources, periodic addition of updated or new information into the printed copy is necessary. This is time-consuming, and may not get accomplished.

13.4. COMPUTERISED SERVICES

13.4.1. Introduction

In pharmacy, the use of computer systems has extended extremely due to increased informational needs of the pharmacist and the increased amount of paper work required in the practice. Other factors responsible for increased use of information technology in pharmacy practices are the need for efficiency, accuracy and expanded databases provided by the computer system.

Online verification and authorisation of prescription and insurance plans has also increased the use of computer system in pharmacy sector. Pharmacists may also use internet facilities to obtain and download information on any disease and related drug therapy for their patients.

Use of computer reduces paperwork and manual record keeping, and increases the efficiency of transactional processes. To fulfil the above mentioned goals, the computer systems should be highly structured and rigidly formatted with improved management information.

13.4.2. Application of Computers in Pharmacy

Application of computers in pharmacy can be summarised as follows:

1) **Maintenance of Records:** Different records related to patient's medication history, current treatment, financial records, etc., are maintained by feeding the accurate data in computers. Computer functions as a database manager.

2) **Inventory Control:** It is essential for maintaining balance between the currently available stock and excessive capital investment. Computer systems are used to identify the order level or demand of various items, and to prepare a list and purchase orders for suppliers. There are mainly **two systems** for inventory control:
   i) **Periodic Inventory Control System:** This system involves manual checking of the system stock levels. The amount of inventory in hand is compared with the minimum and maximum stock maintained in the computers. Orders are placed to different suppliers after checking their terms and conditions with the help of computers because all the entries of stocks are present in it.
   ii) **Perpetual System:** This system involves the use of computers to determine the current status of all the drugs. When the stock is received, related entries are done in the initial stocks to get the current stock; similarly once the drugs are delivered to various departments, the quantities are subtracted from the current stock accordingly. To perform these additions and subtractions from inventory balance, database package is used.

3) **Medication Monitoring:** It is essential to meet the goals of optimum drug therapy. Computers are used for the following **two types of information**:
   i) **Pharmacokinetic Information:** The pharmacokinetic parameters (**e.g.,** volume of distribution, bioavailability, clearance rate, etc.) of a drug can be easily predicted using a computer program such as **NONLIN**. Knowledge about these parameters helps in maintaining a dosing pattern of various drugs, like antibiotics, aminoglycosides, etc.
   ii) **Non-Pharmacokinetic Information:** The non-pharmacokinetic parameters (**e.g.,** various allergic reactions, drug interactions, adverse drug reactions, etc.) can be obtained by using either of the two computer programs, i.e., **MEDIPHOR** (Monitoring and Evaluation of Drug Interactions by a Pharmacy Oriented Reporting) or **PAD** (Pharmacy Automated Drug interaction screening).

4) **Drug Information Services:** In DISs, computers have been proved to be one of the most important tools for clinical pharmacists. **CADD** (Computer-Aided Drug Designs) is highly useful to the chemists to formulate and synthesise a new drug molecule with desired pharmacological action.
5) **Data Storage and Retrieval:** In 1960's, the National Library of Medicine developed a computerised medical information retrieval system, called **MEDLARS** (Medical Literature Analysis and Retrieval System). Now, a highly efficient and accurate working system, called **MEDLINE** (MEDLARS ON-LINE) has also been developed, which is a database comprising of about 300 bio-medical journals. Similarly, Bioscience Information Service has created another database, called **BIOSIS** comprising of various biological abstracts.
6) **Marketing and Distribution:** Computers are also useful in marketing and distribution of drugs by involving in various activities related to marketing and distribution (such as processing of orders, invoicing, maintenance of records, billing, etc.).
7) **Pharmaceutical Industries:** Drug manufacturing and quality control management is performed by using various computerised programs.
8) **Hospital Pharmacy and Retail Pharmacy:** For proper functioning of a hospital, the hospital pharmacist is involve in complete patient care by maintaining the patient's history records, entry of prescription, list of preparations to be manufactured, consumption of drugs, cost analysis, updating drug information, etc. These functions are performed by computer systems.

   Computers have been proved as a valuable assistance for retail pharmacists in prescription processing. Computers are used to obtain information about patient, and drug, related adverse drug reactions, caution, duplication of orders, labelling condition, etc.

   Given below are some **other applications** of computers in hospital and retail pharmacy:
   i) Calculation of monthly gross income,
   ii) Generating pay slips,
   iii) Updating the employee information,
   iv) Placement of supply order,
   v) Keeping track of total payment and amount due to supplier,
   vi) Checking the quality and quantity of hospital supplies received and identifying any discrepancies, and
   vii) Recording purchases for accounting purposes.

In a hospital, computerised systems are used in the following **three areas**:

1) **Prescription Dispensing and Associated Record Maintenance:** Computers are used for:
   i) **Label Preparation:** Now, computers have replaced the manual preparation of labels in big pharmacies.
   ii) **Prescription Number:** A number is assigned to each prescription and this task is mostly done using computers.
   iii) **Price Calculations:** Computers can accommodate multiple pricing methods for a prescription, such as cost plus a professional fee, cost plus % mark-up, or other more complex formulas.
   iv) **Receipt Preparation:** Prescription computers are used for calculating and storing information. Therefore, with the use of computers a receipt can be easily and automatically prepared for the patient including the amount paid for an individual prescription or for the total prescriptions filled over a given period. Such information is also important to the patient for tax purposes or to claim insurance.

v) **Prescription Notation:** A pharmacist makes several notations during prescription processing. These notations may include the initials of the dispensing pharmacist, the drug cost and product dispensed, and special entries like dispensed only one -half as per patient request. Computer is used to store this information that may be used at the time of prescription renewal.

vi) **Renewal of Prescription Processing:** The process of prescription renewal becomes almost automatic with the use of computer. If the computeris ed records show the need to renew the prescription, all the related step s, such as preparing the new label and receipt, updating the renewal status of t he prescription, recalculating the price on the basis of current cost information, and adding the entire t ransaction to the patient's medication profile, are performed by the computer systems automatically.

2) **Clinical Support:** Computers are used for the following purposes:

i) **Patient Medication Profiles:** Computers are used to store the pat ient's records, such as history and current medication profile for future use. These records help the pharmacist and the physician to analyse the patient's current and previous disease status and the medication profile.

ii) **Patient Education Information:** It becomes easy for the pharma cists and the practitioners to counsel the patient, if the patient's education profile is known. In case of an educated patient, it becomes easy for both to collect the information or counsel the patient.

iii) **Consultant Pharmacist Activities:** Computers are use d by the pharmacists to prepare physician order sheets, medication administration records, nursing -home shipping reports, consultant pharmacist reports, patient medication profiles, patient drug usage, etc.

iv) **Drug Utilisation Monitoring:** The pharmacists also use the computer systems to m onitor the patient's drug utilisation which helps them to maintain the integrity of the treatment.

3) **Accounting and Business Management:** In this work, computers are used for the following purposes:

i) **Business Record -Keeping:** Computers are used to keep the business records which can be used to assess the past as well as the present status of business.

ii) **Prescription Analysis:** Information stored in the computer system can be retrieved on daily, monthly, or yearly basis with the help o f computers. Thus all information such as new *versus* refilled prescriptions, medication costs per prescription filled, and profit per prescription can be updated and checked timely.

13.4.3. Health Care Softwares

Health care software has become an integral part of pharmacy practice now. It has happened due to the increased inform ational needs of the pharmacist, huge paper work required in the practice, the need for efficiency, and the availability of computer technology and large databases which provide the required support.

In the market, various software and technologies are present that can be used for supporting pharmaceutical care. These software and technology has been developed by combined efforts of prof essional pharmacy organis ations, pharmacy leaders, software developers, and computer vendors.

Examples of Health Care Softwares

1) **Guardian Plus:** It is a Windows -based system and marketed by Care Point. This software supports the pharmacist in the documentat ion and dis ease management initiatives. It is now combined with the dispensing software to provide more extensive patient care by using a single set of patient data. These software packages help the pharmacists to provide pharmaceutical-care activities.
2) **Bayer's DCA 2000:** This software is used to check HgA_{1C} (haemoglobin A_{1C}).
3) **Roche's CoaguCheck:** This software is used to monitor prothrombin time **INR** (i.e., blood-clotting time).
4) **CardioPharm:** This is public interactive health promotion software, developed for customers visiting community pharmacies. It gives advice on the management of risks of cardiovascular disease, once the required details of the patients and their lifestyle is entered by the user.

13.4.4. MEDLINE (Medical Literature Analysis and Retrieval System Online)

MEDLINE is a bibliographic database of life scie nces and biomedical information that comprises of bibliographic information for articles from academic journals including medicine, nursing, pharmacy, dentistry, veterinary medicine, and health care. This system also includes much of the literature i n other life science subjects like biology, biochemistry, and molecular evolution.

MEDLINE was compiled by the United States National Library of Medicine (NLM). It is available on the Internet at free of cost and can be searched via PubMed and NLM's National Centre for Biotechnology Information's Entrez system.

Database

Database has biomedical and healthcare records from 1950 to the present. It contains more than 1 8 million records from approximately 5,000 publications covering various fields of medicine and biology. Formerly, t he database ha d articles starting from 1965, but its updated version has records as far back as 1950/51, that are now available within the main index.

The database is available free of cost on the Internet via PubMed interface. New documents are added from Tuesday through Saturday. The documents which were added in 1995-2003, around 48% were from the articles published in the U.S., around 88%were published in English, and around 76%had English abstracts written bythe article authors.

Retrieval

In MEDLINE, any information can be retrieved by using Medical Subject Headings (MeSH). Search engines (**e.g.,** Entrez and PubMed) designed for MEDLINE commonly use a Boolean expression combining MeSH terms, words in abstract and title of the article, author names, publication date, etc. Entrez and PubMed can also search articles based on a mathematical scoring system that uses the similar word content o f the abstracts and titles of two articles.

Importance

MEDLINE is an important resource of information for biomedical researchers and journal clubs from all over the world. MEDLINE is also used for evidence -based medicine along with the Cochrane Library and a number of other databases.

Inclusion of Journals

MEDLINE has around 5,000 biomedical article and journals. New content is added in it after a selection process. The new journals are selected on the basis of their scientific scope and quality of a jour nal, on the recommendations of a committee, i.e., the Literature Selection Technical Review Committee. The Journals Database (one of the Entrez databases) has information (such as name, abbreviation , and publisher) about all journals included in Entrez, including PubMed.

Uses

Searching through PubMed searching engine of MEDLINE is a slightly time-taking process, but this searching process can be improved by using the MeSH database , which helps in identifying the subject of interest. For searching , MeSH ter ms are used in conjunction with limits (such as publication date or publication type), qualifiers (such as adverse effects or prevention and control), and text word searching is another. After retrieving an article on the particular subject, a collection o f similarly classified articles can be accessed after clicking on the "Related Articles" link.

Online Access

1) PubMed.
2) PubMed, featuring instant search.
3) MEDSUM-MEDLINE Summary tool, an i nterface to MEDLINE that returns graphs and tables of summary data.
4) GoPubMed, explore PubMed/MEDLINE with Gene Ontology.
5) HubMed, an alternative interface to the PubMed medical literature database.
6) eTBLAST, a natural language text similarity engine for MEDLINE and other text databases.
7) Medscape.
8) Twease, an open-source biomedical search engine.

13.4.5. MEDLAR (Medical Literature Analysis and Retrieval System)

MEDLAR is a computer-based system of the U.S. Nat ional Library of Medicine (NLM). It allows rapid access to NLM's store of biomedical information. It is used in the preparation of publications like Index Medicus, which is a monthly subject/author guide to articles in 3,000 journals. MEDLAR search services can be accessed free of cost through the Internet and World Wide Web.

The NLM is the la rgest medical library in the world and is a part of the National Institutes of Health (NIH) in Bethesda, Maryland. It has contents of all areas of biomedicine and health care, and works on biomedical aspects of technology, humanities, physical life, and so cial sciences. NLM is an important resource for health science libraries and for all branches of medicine. Such a huge resource of information and knowledge can be accessed by MEDLARS.

MEDLAR is the best known database of NLM. It enables anyone to query t he NLM computer's store of journal article references on specific topics. Currently, MEDLAR includes 9 million references going back to the mid-1960s.

Other database s give information on cataloguing and serials, data on toxicological and environmental h ealth, AIDS, and other specialis ed areas. In a day, around 350,000 MEDLAR searches are done by health professionals, scienti sts, librarians, and the public via the World Wide Web. A new Web service, **MEDLINEplus**, is used to link the users to many sources of consumer health information.

13.4.6. Storage and Retrieval of Information

A clinical pharmacist searches for complete drug information to clear the queries regarding pharmacology, drug intera ctions, adverse drug reactions, toxicology, etc. with the help of computers. Retrieving information using computers is preferred over manual search as it is time saving and more detailed.

National Library of medicine created **MEDLARS** (Medical Literature Analysis and Retrieval System) in **1964**. It is a computerised medical information retrieval system. Then in **1971**, a fast working system named **MEDLINE** (MEDLARS ON-LINE) was introduced.

The information retrieval system is operated using a micro -computer, a pr inter, a telephone line, and a modem. The choice of a database is also very important. The **databases** may be:

1) Bibliographic database,
2) Journal information, and
3) Textbook material.

Bibliographic database is normally used, as there is a medical library nearby from where articles can be obtained. Databases are medicine -oriented (**e.g.,** MEDLINE) or pharmacy-oriented (**e.g.,** International Pharmaceutical). Some online databases of medical and pharmaceutical literature are given in **table 13.7**:

Table 13.7: Online Databases of Medical and Pharmaceutical Literature

Databases	Produced by	Data
Medline	National Library of Medicine (NLM)	Around 3000 biomedical journals from the 1960s
Toxicology Data Bank (TDB)	-	Toxicological data
International Pharmaceutical Abstracts	American Society of Hospital Pharmacists	Around 600 publications from the 1970s
BIOSIS	Bioscience Information Service	Biological abstracts

Searching of information should be done systematically as follows:

1) The individual who is about to search a computerised information retrieval database should carefully plan to obtain best results at minimum cost.
2) The individual should search using proper search terms. **For example,** in MEDLINE a directory known as the Medical Subjects Headings (MesH).
3) The search terms are either entered separately or combined using logical operators (like 'and', 'or' etc.).
4) The search statement is entered and the search is run.
5) The result of the search is printed.
6) Finally on completion, the search is ended with STOP command.

Apart from this, management information systems in hospitals are managed by using computers. The information system has two components.

1) Information necessary for drug distributions, and
2) Pharmacy management information.

Drug distribution activities involve collecting pharmacy information from one file and comparing with, updating, or displaying the information from records in another file. This is done in no time using computers. **For example,** for preparing an I.V. admixture, the pharmacist goes through patient drug profile, drug description, patient history, and medication administration record to check the precision of drug therapy. This complete process is carried out using computer in a short time.

13.5. SUMMARY

The details given in the chapter can be summarised as follows:

1) Written and/or verbal information given about drugs and drug therapy in response to a request from other healthcare provider, organisations, committees, patients, public, or community is called **drug information service**.
2) **Drug information centre** is a department or a unit in a hospital that is established for services like receiving, collecting, analysing, and providing unbiased, accurate and latest information on drugs and their uses.
3) **Poison Information Centre** (PIC) or **Poison Control Centre** (PCC) is a specialised unit which gives information on poisoning management and immediate information on early diagnosis, treatment, management, prevention and hazard management of poisoning.
4) **Poison Infor mation Services** (PISs) perform a periodic assessment of poisoning management information as per the needs of the enquirer.
5) **Primary sources** form the foundation of the sources hierarchy, and serve as the information source for the development of secondary and tertiary resources.
6) **Secondary sources** are compiled by indexing and abstracting services that are used to systematically locate various published literature types.
7) **Tertiary sources** provide core knowledge established via primary sources or accepted as standard of practice within the medical community.
8) **CADD** (Computer-Aided Drug Designs) is highly useful to the chemists to formulate and synthesise a new drug molecule with desired pharmacological action.
9) **Bayer's DCA 2000** software is used to check HgA_{1C} (haemoglobin A_{1C}).
10) **Roche's CoaguCheck** software is used to monitor prothrombin time **INR** (i.e., blood-clotting time).
11) **Guardian Plus** software supports the pharmacist in the documentation and dis ease management initiatives.
12) **CardioPharm** is public interactive hea lth promotion software, developed for customers visiting community pharmacies.
13) **MEDLINE** is a bibliographic database of life sciences and biomedical information that comprises of bibliographic information for articles from academic journals including medicine, nursing, pharmacy, dentistry, veterinary medicine, and health care.
14) **MEDLAR** is a computer -based system that allows rapid access to NLM's store of biomedical information.
15) National Library of medicine created **MEDLARS** (Medical Literature Analysis and Retrieval System) in **1964**.

13.6. EXERCISE

13.6.1. True or False

1) Secondary sources provide core knowledge established via primary sources or accepted as standard of practice within the medical community.
2) Bayer's DCA 2000 software is used to check HgA_{1C}.
3) CADD software su pports the pharmacist in the documentation and dis ease management initiatives.
4) MEDLINE is a computer -based system that allows rapid access to NLM's store of biomedical information.
5) National Library of medicine created MEDLARS in 1964.

13.6.2. Fill in the Blanks

6) _____ perform a periodic assessment of poisoning management information as per the needs of the enquirer.

7) _____ are compiled by indexing and abstracting services that are used to systematically locate various published literature types.

8) _____ software is used to monitor prothrombin time INR.

9) _____ is a bibliographic database of life sciences and biomedical information that comprises of bibliographic information for articles from academic journals including medicine, nursing, pharmac y, dentistry, veterinary medicine, and health care.

10) _____ is useful to the chemists to formulate and synthesise a new drug molecule with desired pharmacological action.

Answers

1) False 2) True 3) False 4) False 5) True
6) Poison information services 7) Secondary sources 8) Roche's CoaguCheck
9) MEDLINE 10) Computer-aided drug designs

13.6.3. Very Short Answer Type Questions

1) Define DIS.
2) Classify DIC.
3) Give any two functions of DIC.
4) What are the functions of PIC?
5) Give the advantages and disadvantages of primary sources of drug informati on.
6) Give two examples of health care softwares.
7) What is MEDLINE?

13.6.4. Short Answer Type Questions

1) What are the objectives of DIC?
2) Write a note on the working of PIC.
3) Discuss the secondary sources of drug information.
4) Mention the advantages and disadvantages of tertiary sources of drug information.
5) Give the uses of computerised services in different areas of hospital.
6) Write a note on the storage and retrieval of information.

13.6.5. Long Answer Type Questions

1) Discuss in brief about the DIC.
2) Write an illustrative note on PIC.
3) Write a detailed note on the sources of drug information.
4) Give a brief review on different computerised services used in hospitals.

CHAPTER 14

Patient Counselling

14.1. PATIENT COUNSELLING

14.1.1. Introduction and Definition of Patient Counselling

Patient counselling is defined as providing medication information to the patients or their representatives on directions of use, side effects, precautions, storage, diet, and life style changes either verbally or in written form. Patient counselling is the process in which the pharmacist gives information and advises the patients or their care-taker regarding the proper use of medications.

Effective patient counselling is required for the following results:

1) The patient receives a better knowledge of his/her illness and the role of medication.
2) Medication compliance is improved.
3) Drug treatment becomes more effective.
4) The chances of adverse effects and unnecessary expenditure on healthcare are reduced.
5) The patient's life is improved.
6) Better strategies to overcome the medication-related adverse effects are provided.
7) Better professional relationship is maintained between the pharmacist and the patient.

14.1.2. Questions to be Asked

The questions discussed below are asked during patient counselling:

1) **Asking Questions Appropriately:** A pharmacist should understand the types and the manner of questions asked. He/she should not repeat any question. Interviewing and counselling activities demand more energy than any casual conversation, especially for the beginner pharmacists. Repetition of questions shows non-attentiveness of the pharmacist.

2) **Open and Closed Questions: Open questions** are broad and allow the patient to interpret and respond to requests for information. An open question is asked for information regarding a topic and is thus answered in more than just a "yes" or "no". Pharmacists begin a topic or section with open questions that motivate the patient to discuss freely. Many open questions result in a long confused, unfocused, and inefficient interview. **Closed questions** on the contrary can be answered by a simple "yes" or a "no" or brief information as well. **For example,** the pharmacist asking the patient's name and birth date; did the patient called the health practitioner for physical examination, etc.

3) **Direct and Indirect Questions: Direct questions** are straight to the point and asked to obtain information. These questions may be open or closed. **Indirect questions** may also be open or closed, but they are not asked like a question. They are asked in a concealed way requesting for information. **Examples** of direct and indirect questions are:
   i) **Open Direct:** Tell me about your leg cramps?
   ii) **Closed Direct:** Are you concerned about your leg cramps?
   iii) **Open Indirect:** I'm wondering what you think about your leg cramps.
   iv) **Open Direct:** What can you tell me about the penicillin you're taking?
   v) **Closed Direct:** Did you finish the penicillin?
   vi) **Closed Indirect:** Do you have any penicillin left?

4) **Loaded and Leading Questions:** These are types of closed questions carrying answers within or imply judgments or both. These are generally not successful in gaining information. An **example** of a loaded and leading questions and an alternative is given below:
   i) **Loaded:** These questions are emotion-laden and force the patients into defensive postures. An **example** of a loaded question is "you've never had gonorrhoea, have you?"
   ii) **Leading:** Does the medicine make you drowsy?
   iii) **Alternative:** How does the medicine make you feel?

5) **Multiple Questions:** These questions bring many inquiries to patients at the same time. The patients in this case need to give priority to one of the questions and respond to it and later to the others if they remember what the other question was after answering to the first. This type of question should be prefaced by saying, "I am going to call out the names of some medicines that can be purchased from the pharmacy or supermarket without a prescription. Stop me in between and mention the one you take. If the names are not understandable to you, stop me, and I'll explain them to you." After mentioning all the names of the medicines, the pharmacist should ask the patient if he/she takes any other non-prescription drugs apart from the ones mentioned.

14.1.3. Steps Involved in Patient Counselling

Discussed below are the necessary steps of patient counselling:

1) **Collect, Synthesise and Interpret the Relevant Information:** This is necessary to reach appropriate decisions on the correctness of the therapy prescribed (or lack of therapy). Hence, a database is established carrying information on each patient.

2) **List and Rank the Patients Drug-Related Problems:** The pharmacist should document all the definite and potential drug-related issues. Specific problems should be jotted down to get specific solutions. **For example,** a problem should be mentioned like "Patient was prescribed a sub-therapeutic dose of the correct drug" instead "the dose of the drug was incorrect". Problem should be mentioned in terms of its severity, risk to the patient, etc.

3) **Establish a Desired Pharmacotherapeutic Outcome for Each Drug-Related Problem:** This has to be specific and should allow recognising what is desired by the pharmacist and the patient. **For example,** a desired pharmacotherapeutic effect for a particular drug is to eliminate or manage the side effects, once the appropriate drug is known that can treat a particular condition.

4) **Determine Feasible Pharmacotherapeutic Alternatives that could Achieve the Desired Outcome in a Patient:** This requires enlisting all the possible pharmacotherapeutic alternatives that can resolve the identifiable drug-related problems.

5) **Choose the "Best" Pharmacotherapeutic Solution and Individualise the Therapeutic Regimen:** This needs discussion with the patient.

6) **Design a Therapeutic Drug Monitoring Plan to Determine Whether the Desired Therapeutic Outcome has been Achieved:** The pharmacist should determine that the devised therapeutic outcome has been achieved or not, and mentions the additional information or tests required to monitor the patient's progress. This may include assays, blood pressure readings, etc.

7) **Implement the Individualised Regimen and Monitoring Plan:** The pharmacist communicates the plan to monitor the patient health and its progress with the patient and the care-givers. Mutual commitment is essential between the patient and others for the success of the monitoring plan.

8) **Follow-up to Measure Success:** Responsibility for the drug therapy of the patient is to follow-up and the success rate of plan is deduced. The pharmacist needs to understand whether the patient with the drug therapy is showing improvement or is facing new drug-related problems. Patients are also responsible for their own care. The pharmacist's responsibilities continue even after the patient has left the pharmacy.

14.1.4. Special Cases that Require the Pharmacist

Patient counselling refers to conveying medication information in verbal or in written format to the patients or their representatives. The information is given directions on drug usage, side effects, precautions, storage, diet, and life style adjustments.

Two questions prioritised the role of pharmacist in patient counselling:

1) The main motto of the pharmacist is to counsel patients on prescription-related matters and OTC drugs.
2) Drug counselling is practically not possible in community pharmacies.

Role of pharmacist in counselling can be summarised as in **figure 14.1**:

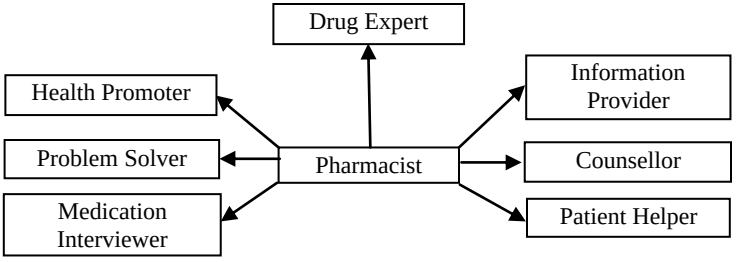


Figure 14.1: Roles of Pharmacist in Patient Counselling

Some special cases which demand counselling by the pharmacist are discussed below:

1) **Coronary Heart Disease:** Alike other chronic diseases, the treatment for coronary heart disease also aims to reduce mortality, morbidity, and associated impairment in the quality of life. The pharmacist plays an active role in the management of this chronic illness in several ways.

   Non-Pharmacological Measures: These include educating the patients on diet, smoking and exercise, and encouraging the patients to maintain a record on anginal attacks, pain symptoms, etc.

   Pharmacological Measures: These include educating the patients on the use of nitrates when an acute anginal attack occurs.

2) **Asthma:** It is a chronic condition that needs lifelong drug therapy. The pharmacist plays an active role in advising the patient on self-monitoring of drug therapy, life style modifications, and use of special dosage forms such as metered dose inhalers, dry powder inhalers, etc.

   Non-Pharmacological Measures: These include safety measures to be taken while traveling, prophylactic use of drugs before exercise, avoiding allergens, quitting use of tobacco (smoking), etc.

   Pharmacological Measures: The patients should also cooperate with the pharmacist in the management of asthma. Specific counseling should be given on the drugs that relieve symptoms, drugs that prevent asthma attack, and drugs that are given as a reserve treatment for severe attacks. The pharmacist should provide training to the patients on the use of metered dose inhalers.

3) **Diabetes:** It is a chronic condition with altered carbohydrate, lipid and protein metabolism, and also affects the quality of life in diabetic patients. Factors like understanding of the patients about their disease, dietary regulation, and self -monitoring of blood glucose are important in diabetes management. Patient counseling and education by the pharmacist improves the quality of life of these patients.

   Non-Pharmacological Approaches: The pharmacist gives an overview of diabetes, stress and psycho -social adjustment, family involvement and social support, nutrition, exercise and activity, monitoring and use of results, relationship between nutrition, exercise, medication, and blood glucose level.

   Pharmacological Measures: The complications of diabetes can be reduced by glycemic control. The anti -diabetic drugs possess some uncharacteristic features such as "Taken half a n hour before food" in case of s ulfonylureas. The patients should be made aware of hypoglycaemic condition during insulin therapy.

4) **Hypertension:** It is not a disease, but is an important risk factor for several complications that ultimately results in organ damage. If hypertension is not controlled, it causes a huge adverse impact on quality of life. Its management requires non-pharmacological and pharmacological measures.

   Non-Pharmacological Measures: In some cases of hypertension, management by non-pharmacological treatment alone is sufficient. The pharmacist counsels the patients on weight loss and regular exercise, restriction of sodiu m, calorie, and saturated fats, increased intake of dietary fibers, restriction of alcohol, smoking cessation, caution while using cold remedies containing sympathomimetics, and self -monitoring of blood pressure.

   Pharmacological Measures: In most of the h ypertensive patients, drug therapy is required. Many patients take hypertension lightly as it usually does not give any major symptoms; and this result in non -compliance. Many antihypertensive drugs cause serious side effects such as ACE inhibitors induce cough, β-blockers induce bradycardia, etc. Some cases may even demand dose modulation of the drugs.

14.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) **Patient counselling** is defined as providing medication information to the patients or their representatives on directions of use, side effects, precautions, storage, diet, and life style changes either orally or in written form.
2) Patient counselling is the process in which the pharmacist gives information and advises the patients or their care-taker regarding the proper use of medications.
3) An **open question** is asked for information regarding a topic and is thus answered in more than just "yes" or a "no".
4) **Closed questions** on the contrary can be answered by a sim ple "yes" or a "no" or brief information as well.
5) **Direct questions** are straight to the point and asked to obtain information.
6) **Indirect questions** may also be open or closed, but they are not asked like a question.
7) **Loaded and leading questions** are types o f closed questions carrying answers within or imply judgments or both.
8) **Multiple questions** bring many inquiries to patients at the same time.

14.3. EXERCISE

14.3.1. True or False

1) Open questions on the contrary can be answered by a simple “yes” or a “no” or brief information.
2) Direct questions are straight to the point and asked to obtain information.
3) Loaded and leading questions are types of closed questions carrying answers within or imply judgments or both.

14.3.2. Fill in the Blanks

4) _____ question is asked for information regarding a topic and is thus answered in more than just “yes” or a “no”.
5) _____ questions may also be open or closed, but they are not asked like a question.
6) _____ questions bring many inquiries to patients at the same time.

Answers

1) False 2) True 3) True 4) Open 5) Indirect 6) Multiple

14.3.3. Very Short Answer Type Questions

1) Define patient counselling.
2) What is the need of patient counselling?
3) Give some direct and indirect questions that are asked in patient counselling.
4) What are the different roles of a pharmacist in patient counselling?

14.3.4. Short Answer Type Questions

1) What questions to be asked during a patient counselling?
2) Write the steps involved in patient counselling.
3) Discuss the special cases that require pharmacist in patient counselling.

14.3.5. Long Answer Type Question

1) Write an illustrative note on patient counselling.

CHAPTER 15

Education and Training Program in the Hospital

15.1. EDUCATION AND TRAINING PROGRAM IN THE HOSPITAL

15.1.1. Introduction

As per WHO, "Hospitals are reservoirs of critical resources and knowledge. They can be classified according to the interventions they provide, the roles they play in the health system and the health and educational services they offer to the communities in and around them."

The hospitals make in-house training arrangements for all grades of staff that cover all the activities undertaken. The complete training should be fully documented and the evidence of training effectiveness should be supported by competency assessment. As a part of self-inspection schemes and operator validation data, observation of individual practice is an important component of this assessment. Training programs should be regularly reviewed and revised as per the service and individual needs. Systems should be made for identifying the staff members who fail the validation tests or are associated with poor QA monitoring data and recurring errors. Such individuals are provided additional training and reassessment.

15.1.2. Role of Pharmacist in the Education and Training Program

The hospital pharmacist provides patient education on the safety and storage of medicines and poisons in the home and hospital. A healthy relationship between the general public and community pharmacists should be maintained. This is because the pharmacists collaborate and communicate with the hospital-based colleagues, and thus act as a valuable link between the patient and secondary health care.

Education and training in the form of lectures, group discussions, and bulletins (produced at regular intervals by the clinical pharmacist through the drug information services) should also be provided to the medical and nursing staff and the colleague pharmacists. The clinical pharmacist should also provide education to student nurses and even to undergraduate pharmacy students. The pharmacist also has an essential role in the in-service training of qualified staff. Any information, help, and advice regarding the drug use should be provided to the nurses busy in their day-to-day nursing duties. Since a clinical pharmacist has ward experience, he/she can solve some of the problems commonly experienced by the nursing staff and can provide some knowledge on using drugs in clinical situation. This is another way in which the clinical pharmacist can promote safer and more economic drug use in terms of administration to the patient as well as stock control at the ward level.

The pharmacists aim to reduce drug errors, to promote rational drug therapy, and to help the patient. They should not act as new members of the health care team who can only function within the incompetence of other team members. They should work as trained and expert professionals who balance the services provided by the fellow professionals. They should maintain credibility by not avoiding the mistakes and bad prescribing of some physicians, but by developing a constructive approach to monitor drug therapy for benefiting the patient and advising even the prescriber.

To achieve the above mentioned objectives, many hindrances need to be overcome, like the attitudes and aims of the serving pharmacists. Official recognition of the need for clinical pharmacy services in young graduates and pharmacists is essential. Such recognition brings in the resources required for finding extra staff, expensive equipment, and essential training programme. There will be opposition and certain members of the medical profession will check this scepticism. Some of them will mistakenly feel that their position is in danger. This is the state in India because the enthusiastic young pharmacists who are interested in developing the area of hospital pharmacy are not even attentively listened. Therefore, the young graduates and post-graduates lose their interest in choosing hospital and clinical pharmacy as a career.

A pharmacist should never doubt or question a physician's ability to make a diagnostic decision nor should suggest that all he/she does is not in the interest of the patients. In the current years, the range and toxicity of drugs is increasing, along with which the physician's ability to make suitable decision about drug therapy is being questioned. In rural areas of India, the physicians have no facility to consult the journals and books giving recent trends of newer drug development or new clinical properties discovered about existing drugs. Such physicians depend on the information and description the medical representatives provide on the products of their own manufacturing concern, and this information cannot be totally trusted. Such doubts have been highlighted by the cases of drug-induced diseases, adverse reactions, and high cost of prescribing. The concept of clinical pharmacy is suggested to be a threat to the physicians; however, some pharmacists cannot participate in drug treatment decisions due to poor knowledge of medical terminologies and inefficient communication skills. A pharmacist performs a safety check on prescription and within wards he/she monitors drug administration. This helps them in evaluating the performance of medical and nursing colleagues. Thus, the motives and interest of clinical pharmacist should be made clear

15.1.3. Internal Training Program

In internal teaching programmes, the student nurses, graduate nurses, house staff members, and senior medical staff are provided training, seminars in therapeutics are conducted, and the undergraduate pharmacy students, refresher courses for graduate pharmacy students, and residents in hospital administration are helped in education.

15.1.3.1. Training of Student Nurses

Pharmacists have a valuable role in teaching student nurses. Some suggest that the whole course in pharmaceutical calculations and pharmacology should be taught to the student nurses by the hospital pharmacists; while others suggest that he/she should teach along with the nursing instructor certain aspects of these courses.

If the pharmacists are capable and have impressed the nurse educators by their daily actions and deeds, they will be invited to assist in the teaching programme. Once appointed, the hospital pharmacists develop their phase of the programme in strict compliance with the requirements proposed by the nursing authorisation.

The prepared lectures should be updated every year with the latest pharmacology and therapeutic developments. All the references to weights and measures should be in accord with the hospital's drug formulary. The references to dosage contraindications or cautions should also comply with the formulary till the information to be presented replaces the latest revision of the hospital formulary.

The hospital pharmacists should consult various pharmacology text books written for the nursing students. Otherwise, the course will become much sophisticated in content. It is to note here that the nursing schools of hospitals are not assigned with such responsibilities.

15.1.3.2. Seminars for Graduate Nurses, House Staff, and Medical Staff

Most of the pharmacists provide information through a pharmacy publication to the members of medical and nursing staffs. Still, direct or personal presentation should be given to the medical staff by conducting seminars on the latest therapeutic agents.

A plan of four lectures that may be presented by the hospital pharmacist to the resident staff was developed by **Frazier *et. al*** in **1954**:

Lecture I: It involves an orientation to pharmacy services and covers such subject matter as:

1) Location of the pharmacy,
2) Description of the physical plant,
3) Personnel,
4) Hours of operation,
5) Services provided by the department, and
6) Hospital policies governing:
   i) Formulary,
   ii) Use of generic names,
   2Use of metric system,
   iii) Use of abbreviations,
   iv) Use of research drugs,
   v) Automatic stop orders,
   vi) Discharge medications, and
   vii) Ordering narcotics and liquors.

Lecture II: It involves philosophy and goals of formulary system. The hospital pharmacist during this lecture should emphasise on the composition and scope of PTC.

Lecture III: This lecture is suggested to take the form of a prescription clinic. This suggestion is highly recommended as a very little attention is paid to prescription writing in medical school classes. During the lecture, the pharmacist should focus on central or state laws of the hospital regulations that govern the prescriptions. It is also suggested that a short group criticism of prescriptions (projected on a screen) involving unreadable writing, non-standard abbreviations, misplaced decimal points, misspelling of drug names, and a mixture of English and Latin directions helps in stressing on the importance of accuracy in prescription writing.

Lecture IV: It involves discussion of any topic of current interest among the staff. Some of the suggestive topics are:

1) Medication cost,
2) Incompatibilities of intravenous fluids and other injectable drugs,
3) New drug regulations and amendments to the Drugs and Cosmetics Act, and Rules, Pharmacy Act, etc., and
4) Drug interactions.

The graduate nurses are encouraged to attend the in-service training programmes conducted in the hospital. A wide range of professional subjects are involved in these sessions. The hospital pharmacists should present a few of the programmes. Their subject may consist of a discussion of new classes of therapeutic agents, incompatibilities of various drugs when added to intravenous solution, drug storage and control, a review of the mathematics of pharmacy, or drug interactions.

Every time new drugs are discussed, commercially available sample containers of various forms should be brought in the lecture room by the student nurses. This is because it is believed that by handling, observing, smelling and tasting (wherever possible) the product, the nurses will be able to detect error more appropriately.

15.1.3.3. Training Undergraduate Students in Hospital Pharmacy

In many universities, hospital pharmacy has been added as a major subject (especially in the final year of B. Pharm. degree course).

The American Association of Colleges of Pharmacy and the American Society of Hospital Pharmacists have approved a statement listing **six abilities** required for hospital pharmacists in developing a curriculum for hospital pharmacy.

The well-qualified hospital pharmacists should have the following six qualities:

1) They should have a detailed knowledge of drugs and their actions,
2) They should be able to conduct pharmaceutical manufacturing programmes,
3) They should have a sound knowledge of control procedures,
4) They should be able to conduct teaching and in-service training programmes,
5) They should be able to conduct and participate in research works, and
6) They should be able to manage a hospital pharmacy.

While teaching hospital pharmacy to undergraduate students, the above aspects should be incorporated in the curriculum for hospital pharmacy; whi le for the post -graduate students, newer aspects of clinical pharmacy should be included.

15.1.3.4. Patient Teaching Programme

A study was conducted in randomly selected 78 patients. They were interviewed at home within 6-9 days after getting discharged from the ho spital to evaluate their knowledge of the prescribed drug regimen. This study included the following areas:

1) Name and purpose of the medication.
2) Precautions to be taken while on the prescribed therapy.
3) Other medications, food, and beverages that should be avoided.

The study established that most of the patients lacked knowledge about their prescription medication as 52% of them could not determine the length of drug regimen, 23% of them did not know the reason for which the medication was prescribed, 56% of them did not know the name of the prescribed medication, and 56% of them were not given proper instructions regarding the administration of medications.

In this area of hospital teaching, the pharmacists can contribute for a long -term to post-hospital care of the patients. It mostly happens that the patients getting discharged from the hospital are prescribed many medications; however, they have insufficient knowledge on how they are to be used, or how the adverse reactions or signs of toxicity can be identified. This brief exposure to the medications is provided by the busy practitioner or a nurse.

Hospitals having clinical pharmacists in their staff have developed various programmes for orientation of the patient on the drugs used in the hospital and th ose prescribed on discharge. These programmes included patient counselling, development of instruction brochures, group conferences, and close circuit television presentations. Direct counselling technique is preferred to individualise the instructions to specific patients for specific medications. Group discussion or television methodology is preferred when a general instruction is to be given on how to detect adverse drug effects, etc.

15.1.3.5. Training Clinical Pharmacists

The hospital pharmacists while conducti ng such programmes should work cooperatively with the college of pharmacy, medicine faculties, and various medical staff specialists. The clinical pharmacy programmes in schools cover the broad area of clinical pharmacy (paediatrics, clinical pharmacology, toxicology, drug information analysis and interpretation, and infectious disease and geriatrics).

If the hospital pharmacist cannot provide the training, he/she should make arrangements to accustom the student with the medical record contents, drug history procedures, patient drug profile programme, drug information centre, poison control centre, adverse drug reaction programme, and opportunity to interface with inter -disciplinary health care personnel such as physicians, dentists, nurses, dieticians, and therapists.

The pharmacist's exposure to ambulatory and hospitalised patients is of great importance. Thus, the training of clinical pharmacists should cover the hospitals as well as satellite health care centres, extended care facilities, home care programmes, and clinics.

15.1.3.6. Training Residents in Hospital Administrations

Candidates for Master of Hospital Administration should in addition to didactic requirements (i.e., advice or a lesson giving requirements), serve a residency in an approved institution under the guidance of a competent instructor. The newly selected administrator while serving this residency is exposed to every department in the hospital. Because, this is the time when the young administrator forms his/her opinion to the organisation and scope of the pharmacy department, as well as the responsibilities of hospital pharmacist.

15.1.4. External Training Program

In external teaching programmes, the hospital pharmacist is the guest lecturer, speaker, or the instructor in-charge of a specific course in a school or college. Courses of pharmacy colleges, refresher courses under the sponsorships of a pharmacy college, seminars, and institutes of conventions sponsored by professional associations are the **examples** of external training programmes.

An external teaching programme includes a teaching activity performed by the hospital pharmacists outside the hospital, thus, they teach courses other than hospital pharmacy (like product development, preparation of parenteral prod ucts, sterilisation techniques, and pharmacology).

Seminars on refresher courses are another ways through which the hospital pharmacists conduct a teaching programme. It is not mandatory that the sponsor of these programmes should have to be any pharmaceu tical organisation. Participating in the activities of nursing, dietary, oxygen therapy, and medical technologist associations improves the professional status of the hospital pharmacists.

External teaching should not be only restricted to personal lectur es, but preparation of manuscripts for publications in the professional press should also be included. The subject matter may include the results of original scientific research in product development sterilisation techniques or comprehensive literature su rveys in particular area of hospital pharmacy, or the results of a study that improves the managerial and service providing aspects of the department.

Some hospital pharmacists have moved to the U.S.A. to obtain grants -in-aid to support research in drug d istribution techniques or to study the prescribing habits of physicians associated with large hospital clinics. On completion of this study, the pharmacist publishes the work that serves as a teaching material. This is how the pharmacists improve the service they provide to their institutions.

Some hospitals in India also encourage their pharmacists to participate in such activities. The members of Indian Hospital Pharmacists Associations participate in some direct and indirect educational activities, especially during the annual sessions of the Indian Pharmaceutical Congress.

15.1.5. Services to the Nursing Homes/Clinics

Health care is provided in many different settings. Private offices, out -patient clinics, day surgery units (or short procedure units), and emergency departments are the **examples** of out-patient (ambulatory) settings. In -patient care is rendered by the acute care hospitals. Patients are hospitalised when they had to undergo a major surgery, therapy for acute disorders, and diagnostic evaluations and procedures. Long -term care facilities, such as nursing homes and rehabilitation centres, provide health care to patients requiring skilled management of chronic disorders. Chronically ill and disabled patient s are provided with home health care services.

Clinics allied with major medical centres and hospitals are located in various out -patient settings, like community centres, medical offices, community pharmacies, and freestanding clinics. Clinics provide s ervices to the general unrestricted patient populations or specific patient groups (**e.g.,** hypertension clinic, diabetes clinic, anticoagulation clinic, and medication refill clinic). Sometimes the same physical space is shared by two or more clinics. In su ch cases, each clinic is assigned a unique weekly or daily schedule, **for example,** anticoagulation clinic on Tuesday afternoons, diabetes clinic on Wednesday mornings, hypertension clinic on Friday mornings, and so on.

The nurses and pharmacists should de velop a close working relationship if an active clinical pharmacy service is attached to the ward. The pharmacists had to visit the ward atleast two times a day to check the prescription sheets, initiate the dispensing of drugs, raise any queries on dosage , availability or incompatibility with the doctor, and offer any drug information required by the doctor or nurse. In this way, the pharmacists get acquainted with the ward requirements in terms of supply and information, and also play a significant role in safe handling and use of drugs. Many hospital pharmacists attend the clinical team during ward rounds to ensure that from the time of admission till discharge the patients are receiving appropriate pharmaceutical care.

Pharmacy technicians make up the prescriptions issued by the doctors. The pharmacists then check these prescriptions for accuracy and to ensure that the dosage and treatment are safe for the patient.

The **pharmacy technician** has the following roles:

1) Reads prescriptions and translates the doctor's instructions.
2) Counts tablets and measures specific quantities of liquids.
3) Prepares accurate labels for medicines on the computer system to instruct the patient about the drug and the manner of administration.
4) Sells other medicines and complementary preparations.
5) Refers to the pharmacist as per the requirement.
6) Prepares products on a small -scale as requested by the doctor, in case the products are not supplied as ready to use by the manufacturers.
7) Maintains and manages the stock within pharmacy.
8) Keeps records and audits.
9) Remains aware of the legal requirements related to prescribing and supply of medicines.

Pharmacists who are nursing home consultants have many important duties, like helping in system development to recognise the medication errors. A pharmacist who is not available all the time , controls the happenings in the facility. The facility im provements can be made by designing systems that will function when the pharmacist is not available to supervise what is being done. A consultant pharm acist is unable to assist on a day -to-day or hour-to-hour basis with patient care, but helps in developing systems that improve care provision.

To make sure that appropriate systems are being used, whatever is done in the provision of patient care is documented and that documentation is reviewed regularly. If medication errors and some other problems are found in the documentation, they should be rectified. If the documentation only suggests but does not confirms about the occurrence of a problem, development and use of indicator system is preferred to conclude that the thing speaks for itself and to require explanations regarding the inappropriate thing that happened.

The consultant pharmacists following the federal directive for drug regimen review and professional service to nursing homes cannot control the happening in the nursing homes they serve. It may be that the pharmacists cannot require the changes that occur, but can suggest the need for changes and provide rational evidences for the suggested changes. With respect to these evidences, many changes can occur in institutions that were initially not receptive to new ideas.

15.2. CODE OF ETHICS FOR COMMUNITY PHARMACY

15.2.1. Introduction

The code of moral principles or the science of morals is termed as **ethics**. The pharmacy profession has been a career for earning livelihood and has also got the attitude of service and sacrifice in the interests of the suffering humanity. A pharmacist works in association with medical professionals and others (who have been given the responsibility of protecting the health of people) in handling, selling, distributing, compounding, and dispensing medical substances including poisons and potent drugs. Generally before anything else, the pharmacist has to support the needs of his consumers.

Charaka (the ancient Indian philosopher, physician, and pharmacist) stated that " **Even if your own life be in danger you should not betray or neglect the interests of your patients**". This saying should be valued by each pharmacist.

Pharmacy practice has been restricted by the Government only to those who have qualified under regulatory requirements. The Government also grants them privileges which are denied to others and in return expects that the pharmacists should understand their responsibilities and fulfil their professional duties honourably for the well-being of the society.

For ensuring an efficient pharmaceutical service, standards of professional conduct for pharmacy are necessary in the public interest. It is not mandatory for each and every pharmacist to offer such a service, but they should also avoid any act or omission which would develop a preconception regarding the services or impair confidence in any respect for pharmacists.

As per the nature of pharmaceutical practice, its demands are more than the ability of the individual to carry out as quickly or as efficiently as the needs of the public. Therefore, the pharmacist should always be ready to provide information or advice to their colleagues. Above everything, the pharmacist should be a good citizen and should undertake and defend the laws of the State and the Nation.

15.2.2. Pharmacist in Relation to Job

With relation to job, the pharmacists should follow the subsequent ethics:

1) **Scope of Pharmaceutical Services:** Premises registered under statutory requirements and opened as a pharmacy should provide complete pharmaceutical services including the supply of frequently asked medicines without delay. It also involves the readiness to provide all time emergency services.

2) **Conduct of the Pharmacy:** The pharmacy should be in such a condition that the risk of accidental contamination in the preparation, dispensing, and supply of medicines should be avoided.

   The professional character of pharmacy is reflected by the appearance of the premises; therefore, the public should be made content with the fact that a pharmacist is practising pharmacy in an establishment. The size, design and terms of signs, notices, descriptions, wording on business, stationery, and related indications should be restrained. Descriptions denoting pharmaceutical qualifications should be limited to those of which the use is restricted by law and should not discriminate between pharmacists.

   The premises should display a notice stating that dispensing is carried out under **Employees State Insurance Scheme (ESIS)** or any such other scheme supported by the Government. There should be a pharmacist in every pharmacy, solely responsible for controlling the pharmacy's activities. In case, the owner obstructs the pharmacist in his/her duties, it will be regarded as a failure on the part of owner in maintaining and observing the standards.

3) **Handling of Prescriptions:** The pharmacist on receiving the prescription (presented for dispensing) should not discuss or comment over it with respect to the merits and demerits of the therapeutic efficacy of the drug prescribed. The pharmacist on receiving the prescription should not show any expression of alarm or astonishment because it may cause anxiety in patients and may also hamper their confidence in the physician. If a patient makes any query regarding the prescription, the pharmacist should answer very carefully without offending the physician and disclosing any information which was required to be kept hidden from the patient.

   The pharmacist cannot add, remove or replace any ingredient or change the prescription's content, without the prescriber's approval. But he/she may be allowed to do this if the change is emergent or is demanded by the technique of the pharmaceutical art and does not alter the therapeutic action of the regime. If due to any alteration, incompatibility or over-dosage, an error is observed in the prescription, it should be referred back to the prescriber for correction or approval of the change suggested by the pharmacist. This task is purely for the benefit of the patient but should be carried out in such a way that the reputation of the concerned physician does not get affected.

   In case of refilling prescriptions, the prescriber should guide the pharmacist with appropriate instructions. The pharmacist should advise the patients on using the medicines or remedies as prescribed by the physician.

4) **Handling of Drugs:** All necessary steps should be taken to dispense a drug in a correct manner. All the ingredients should be weighed in correct proportions with the help of scales and measures and visual estimations should be avoided. The pharmacist should never fill his/her prescription with spurious, substandard and unethical preparations, and should always use standard quality drugs and medicinal preparations. Poisonous, abusive or addictive drugs should be dealt with full care by the pharmacist. These preparations should be supplied only if it has been prescribed to do so.

5) **Apprentice Pharmacist:** When a pharmacist is an in-charge of a dispensary, drug store or hospital pharmacy where intern pharmacists are trained practically, he/she should provide the trainees with all the work facilities. This is done so that the trainees after completing their training have gained sufficient technique and skill to become responsible pharmacists. The trainee is not granted a certificate if all the criteria are not fulfilled and he/she has not proved themselves worthy enough.

15.2.3. Pharmacist in Relation to Trade

With relation to trade, the pharmacist should follow the subsequent ethics:

1) **Price Structure:** The price being charged from the customers should include the quality and quantity of the commodity supplied, and the labour invested in their preparation so that the pharmacists are supplied with proper monetary gain. The knowledge, skill, time consumed, and responsibility of the pharmacist should also be considered while managing their earning, but the customer also should not be burdened with excessive taxes.

2) **Fair Trade Practice:** Prizes, gifts, or any kind of allurement should not be offered to patronisers or lower prices (than those charged by a fellow pharmacist) for medical commodities should not be charged intentionally to capture the contemporary business. If an order or prescription of a customer to be served by some other dispensary is mistakenly brought to any other dispensary, the latter should direct the customer to the right place without accepting the prescription. The labels, trademarks, signs, and symbols of other contemporaries should not be copied.

3) **Purchase of Drugs:** Drugs should be purchased only from genuine and reliable sources. A pharmacist should not assist (directly or indirectly) the manufacture, possession, distribution, and sale of spurious or substandard drugs.

4) **Hawking of Drugs:** Drugs and medications should neither be hawked nor should be sold from door to door. Pharmacies and drug stores should not follow the **self-service** method because it will result in distribution of therapeutic substances without an expert advice. Thus, encouraging self-medication is undesirable.

5) **Advertising and Displays:** The pharmacist should not use any display material for the sale of inappropriate medicines or medical appliances, such as:
   i) Wording, design, or illustration unfavourably reflecting on other pharmacists,
   ii) Disapproving reference to other suppliers, products, remedies, or treatments,
   iii) Misleading or exaggerated claims,
   iv) The word **cure** for any disease or symptoms of any disease,
   v) Guarantee of therapeutic efficacy/treatment,
   vi) Appeal to fear,
   vii) Offer to refund the paid money,
   viii) Prize, competition, or similar scheme,
   ix) Reference to medical practitioner or a hospital, or use of the terms **Doctor** or **Dr**. or **Nurse**, with the name of a preparation not established, and
   x) Reference to sexual weakness, premature ageing, or loss of virility.

A pharmacy premise should not advertise any article or preparation to the public with the aid of any kind of display material mentioned above. However, it is allowed if the reason for such advertisement is genuine. The pharmacy should not advertise or illustrate contraceptive preparations and appliances until a notice with the words "**Family Planning Requisites**" or approval by the regulatory authorities.

15.2.4. Pharmacist in Relation to Medical Profession

The pharmacist plays an essential role in medical profession by acting as a mediator between a medical professional and patient. However, few limitations are faced by the pharmacist in this profession:

1) **Limitation of Professional Activity:** The medical practitioners do not open drug stores for practising pharmacy because it leads to coded prescriptions and monopolistic practices. This proves to be disadvantageous for profession of pharmacy and interest of the patients. Therefore, pharmacists should not practice

medical (diagnosing diseases and prescribing medicines) even if the customer asks them. However in accidental or emergency cases, a pharmacist may help the victim with first aid. A pharmacist should also not recommend a particular medical practitioner (unless he has been asked to do so).

2) **Clandestine Arrangements:** A pharmacist should not make a secret agreement or contract with any physician who would provide him commission or advantage by recommending the patients to his drug store.

3) **Libation with Public:** A pharmacist should always keep his knowledge upgraded by reading books, journals, magazines, and other periodicals regularly as he is the mediator between the medical professionals and people. Information acquired by the pharmacist during his professional activities should not be revealed to any third person (unless required by law to do so).

15.2.5. Pharmacist in Relation to Profession

With relation to profession, the pharmacist should follow the subsequent ethics:

1) **Professional Vigilance:** A pharmacist should be law-abiding, and should prevent doing activities offensive to the society as well as to the pharmacy profession. His duty is also to force others to comply with the pharmaceutical provisions and other laws and regulations. It is essential for a pharmacist to help and cooperate with the fellow members in their scientific and technical needs. The pharmacist should also be aware of the undesirable ones and move them out of the profession. This helps in maintaining the name and traditions of the pharmacy profession.

2) **Law-Abiding Citizen:** A pharmacist should be well-educated, and should possess a fair knowledge of the laws of the land. He/she should be aware of all the enactments related to food, drug, pharmacy, health, sanitation, and should comply with them. A pharmacist's life cannot be divided into different sections as he/she has to act as a whole unit.

3) **Relationship with Professional Organisations:** If a pharmacist wants to train his/her professional colleagues about corporate life, he/she should connect with and motivate certain organisations which favour the scientific, moral, and cultural well-being of pharmacists and are not working against the code of pharmacy ethics.

4) **Decorum and Propriety:** A pharmacist should avoid doing activities which are not in accordance with the dignity of pharmaceutical profession and can bring dishonour to the profession or to him/her.

15.2.6. Pharmacist's Oath

Given below is the Pharmacist's Oath which should be taken without hesitation by a young and potential pharmacist:

1) I swear by the Code of Ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of healthcare team.
2) I shall uphold the laws and standards governing my profession.
3) I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.
4) I shall follow the system, which I consider best for pharmaceutical care and counselling of patient.
5) I shall endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.
6) I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.
7) I shall associate with organisations having their objectives for betterment of profession of pharmacy andmake contribution to carry out the work of these organisations.

8) While I continue to keep this oath inviolate, may it be granted to me to enjoy life and practice of pharmacy respected by all, at all times! Should I trespass and violate the oath, may the reverse be my lot.

Code of Ethics for Pharmacists – Summary of Principles

Area of Focus	Principles
Consumer	1) **Recognising the consumer's health and well -being as the first priority:** A pharmacist should make use of expert knowledge and provide care to the consumer compassionately and professionally. 2) **Respecting the consumer's autonomy and rights, and encouraging them to participate in decision -making:** A pharmacist should respect the dignity and privacy of the consumer, including the consumer's individuality , and their right to refuse advice or treatment. He /she should also maintain the privacy and confidentiality of the information provided by the consumer.
Community	1) **Upholding the reputation and public trust of the profession:** A pharmacist should not abuse the trust and respect of individuals and society. 2) **Acknowledging the professional roles and responsibilities to the wider community:** A pharmacist should maintain accountable control and supply of therapeutic goods and should also contribute to public hea lth and enhance the quality use of medicines.
Pharmacy Profession	1) **Demonstrating a commitment to the development and enhancing the profession:** A pharmacist should advance the profession by involving in activitie such as training staff, engaging in teachin g, acting as a preceptor, mentoring students, interns and colleagues, engaging in discussions and participating in initiatives to develop the profession, and showing professional leadership. 2) **Maintaining a contemporary knowledge of pharmacy practice and ensuring health and competence to practise:** A pharmacist should know the importance of lifelong learning and self -development and their effect on professional competence. He /she should also maintain personal health to support health professional colleagues. 3) **Agreeing to practice only under conditions which uphold the professional independence, judgement, and integrity of themselves or others:** A pharmacist should exercise professional autonomy, objectivity, and independence and manage actual and potential situations of conflict of interest.
Business Practices	**Conducting the pharmacy business ethically and professionally:** A pharmacist should conduct the business practices in the best interest of the consumer by paying due respect to colleagues, and upholding the reputation of the profession.
Other Healthcare Professionals	**Working collaboratively with other health professionals for optimising the health outcomes of consumers:** A pharmacist should consult and work cooperatively with other healthcare professional s to achieve expected or optimal health outcomes for the consumer.

15.3. ROLE OF PHARMACIST IN THE INTERDEPARTMENTAL COMMUNICATION AND COMMUNITY HEALTH EDUCATION

15.3.1. Introduction

Interdepartmental communication is the process in which the professionals in different departments report to each other regarding the care provided to the patients. Effective and rapid communication in management of everyday medical emergencie s decides between life and death of a particular patient. An organised approach should be taken for developing interpersonal and interdepartmental communication system, which should be incorporated with novel communication modes to facilitate speedy approa ch to the target healthcare facility.

15.3.2. Cooperation with Medical Research Staff

Nowadays, all the connected health services work cooperatively in clinical research. The hospital pharmacists can also become an essential part of this research in the following ways:

1) They can assist the physician by controlling the inventory and distribution of the research material.
2) They can maintain a record on the chemistry, pharmacology, posology, and toxicology of the compounds being analysed. This information is important when the original investigator is not available and another physician is called in an emergency for treating a patient taking the research drug.
3) They can suggest and prepare better vehicles or physical forms of the new compounds undertaking trial.
4) They can develop and operate a double or triple blind study for clinically evaluating the research drug.
5) They are generally a member of local, social or fraternal groups, thus can assist the physician in recruiting normal human subjects for controlled *in vivo* studies of the investigational use drugs.

15.3.3. Cooperation with Local Pharmacists

This phase of the programme requires delicate handling on the part of those concerned. Often the retail pharmacist complains that the hospital pharmacist is not co-operative and is making him bankrupt because many medications are quoted in low prices in the hospitals. This problem can be overcome if both the parties co-operate and stop competing with each other.

In the following ways, the retailer and hospital pharmacist can co-operate with each other:

1) Provide each other products,
2) Market the available from the hospital pharmacy special formula medication,
3) Supply prescription copies when legal restrictions do not apply, and
4) Support the organisations and legislation sponsored by the retail pharmacists.

The American Pharmaceutical Association and the American Society of Hospital Pharmacists united to set-up a Commission for studying out-patient hospital pharmacy services. The elements to be studied by this Commission include:

1) The hospital in essential patient service,
2) The need for the public to have medication dispensed by pharmacies,
3) Professional opportunities in community and hospital pharmacy,
4) Effect of the number of community and hospital pharmacies on professional opportunities,
5) Effects of location on status, and
6) Legal implications.

15.3.4. Cooperation with Nursing Staff

The following guidelines show how the hospital pharmacists should co-operate with the nursing staff:

1) Placement of nurses, student nurses, pharmacists, and pharmacy students to the institution should include introduction to discuss and demonstrate the available services.
2) The nurse and pharmacist should collaborate regularly when a professional programme is being developed. Inter-professional collaboration is required when the perceived roles of the professionals overlap, **e.g.,** in patient education, monitoring adverse drug reactions, cardiopulmonary resuscitation, nurse pharmacist rounds in critical care areas, and nursing care plans.

Nurse having sufficient drug information and knowledge on patient care can adequately administer drugs and detect the desirable or undesirable drug effects.

The pharmacist should collaborate with the nurse while administering the medications. The pharmacist should provide the following information to the nurse:

1) Information on new drugs,
2) Information on investigational drugs used in the institution,
3) Information on side effects of drugs and therapeutic risks,
4) Information on contraindications to a drug therapy,
5) Information on compatibility and stability of drugs, including intravenous admixtures,
6) Information on drug computations,
7) Information on metabolism, excretion and blood level data of drug,
8) Information on drug -drug and drug -food interactions, including laboratory test modifications, and
9) Information on the effect of patient's age and pathophysiology on drug action.

15.4. ROLE OF PHARMACIST IN COMMUNITY HEALTH EDUCATION

15.4.1. Introduction

Health education is the profession of educating people about health. Areas within this profession encompass environmental health, physical health, social health, emotional health, intellectual health, and spiritual health. It can be defined as the principle by which individuals and groups of people learn to behave in a manner conducive to the promotion, maintenance, or restoration of health. However, as there are multiple definitions of health, there are also multiple definitions of health education.

Different roles of pharmacist in community healthcare and health education are discussed below.

15.4.2. Roles of Pharmacist as Health Educator

Health education refers to educating the people about health. This is a profession covering the areas of environmental health, physical health, social health, emotional health, intellectual health, and spiritual health. It is the principle by which individuals and groups of people learn to behave in a favourable manner to promote, maintain, or restore the health.

The Joint Committee on Health Education and Promotion Terminology of 2001 defined health education as "**any combination of planned learning experiences based on sound theories that provide individuals, groups, and communities the opportunity to acquire information and the skills required to make quality health decisions**"

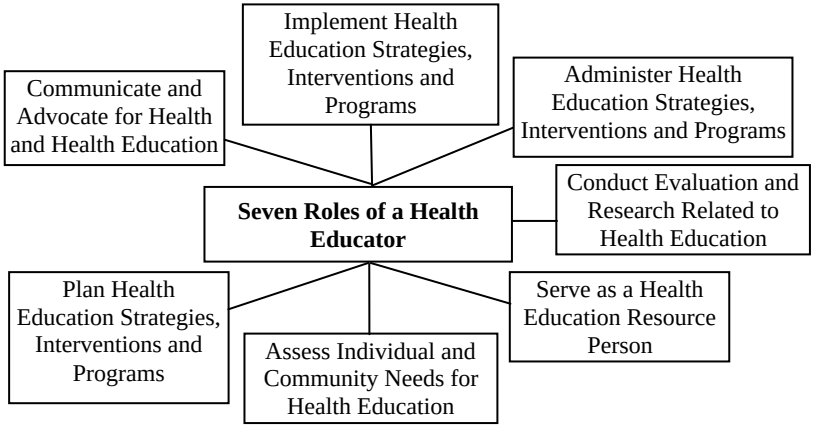


Figure 15.1: Roles of Health Educator

The WHO defined health education as " **comprising of conscious ly constructed opportunities for learning some form of communication designed to improve health literacy, improve knowledge, and develop life skills which are conducive to individual and community health**".

15.4.3. Roles of Pharmacist in Child Care

In many researc hes it has been published that many children (especially chronically ill children) are actively involved in their own health care. It is believed that educating people on proper use of medicines should begin in childhood and extend into adolescence to impr ove the use of medicines. A clear solution is to provide general education on medicines in school -based health education curriculum. Educational programmes about medicines and the teaching materials for children and adolescents should address their knowledge about medicines, their behaviour with respect to medicines, and also they should know what the health care providers think. Children and adolescents should also be provided with information from their health care providers and parents on specific medicines that they are using.

Special training is required for communication with the children, adolescents and their parents about medicines. This training includes knowledge of cognitive development, effectively communicating at various stages of cognitive d evelopment, and counselling children and adolescents on special needs arising from culture, gender, disability, learning difficulties, behaviour, or health status. Training in material types such as cartoons, CD -ROMs, and computer games should also be prov ided to improve the communication with children and adolescents of various ages

Pharmacists should acquire the skills required to serve local populations and sub -groups. Thus, professional education of pharmacists should motivate them to educate children and adolescents including their parents about medicines. Pharmacists should also teach:

1) The skills required for providing information to children and adolescents,
2) The parents that their behaviour serves as a model for their children on responsible use of medicines,
3) The parents to transfer the responsibility of administering medicines to their children as they grow older, and
4) The children, adolescents, and their parents to evaluate the quality and reliability of sources used for information about medicines.

Pharmacists should play a leading advocacy and coordinating role among the other health care providers, professional associations, national and local governments, public health authorities, parent organisations, consumer and patient support groups, educa tors, and the media. The International Pharmaceutical Federation (FIP) gives the following recommendations:

1) The pharmacists should directly communicate with the children of school age about their prescription and non -prescription medicines in the presence of a parent, guardian, or care-taker in an appropriate area of the pharmacy.
2) The pharmacists should also provide any printed information and written material (as required by law or professional standards) suitable for children and adolescents of relevant age group to supplement the verbal information.
3) The pharmacists should encourage the children and adolescents to ask any questions about their medicines at the time of supply or later.
4) The professional associations should develop materials to help the pharm acists so that they can assist the parents on teaching their children about the appropriate use of medicines and to find and evaluate information about medicines.
5) The pharmacists should speak to the teachers, parents, and community groups to encourage the idea of educating children about medicines.

6) The pharmacy professional associations should cooperate with other health professional associations, school health education authorities, teacher's organisations and the media to provide education on medicines to children and adolescents, and to promote the concept that this should be included in school health education curriculum from the earliest school years.
7) Research works should be conducted to detect and overcome the barriers the pharmacists may face while counselling the children, adolescents, and their parents and care-takers about medicines.
8) The pharmacists in their undergraduate and continuing education programmes should be taught on communicating with children, adolescents, and their parents, guardians or care-takers. Externships, internships, and post-graduate placements should also be incorporated to gain more experiences in communicating with children and adolescents about their medicines.
9) The government should recognise the benefits that will be achieved if the children responsibly learn to take medicines from their early ages. For such an initiative, the government should include provision in their health plans and include support for pharmaceutical associations to assist them and their members in implementing such recommendations.

15.4.4. Roles of Pharmacist in Pregnant and Breast Feeding Women

The undernourished women or women who are undernourished during their pregnancy are at higher risk of difficult labour and giving birth to low weight babies (i.e., <2500gm). Such babies in comparison to healthy new-borns show slower growth and development, and are at higher risk of catching an infection and dying (lower is the birth weight, greater is the risk of death). Low body stores of micronutrients result in disorders, such as anaemia, deficiency of vitamin A and zinc, heart disease, high blood pressure, obesity, and diabetes (when adult). Low birth weight may also occur due to premature birth, malaria, other infections the mother may be having, or if the mother used to smoke or use abusing drugs during her pregnancy.

Women of reproductive age (who are not pregnant or breastfeeding) have lower energy and protein requirements than men; however, their need of iron is twice that of men (because of loss of blood during menstruation). The diets of women in comparison to that of men should provide:

1) Slightly smaller amounts of staples, legumes, and fats,
2) The same amounts of vegetables and fruits, and
3) More amounts of meat, offal, poultry and fish (i.e., iron-rich foods).

15.4.5. Women & Older Girls Need Plenty of Iron-Rich Foods

The requirement of nutrients and energy is more in pregnant and breastfeeding women. The requirement of iron in pregnant women is so high that iron supplements (such as iron/folic acid tablets) are recommended. Girls and women of reproductive age should eat a healthy, balanced diet rich in iron foods. Pregnant and breastfeeding women and girls also demand extra food.

Pregnant women require about **280kcal/day** more protein, zinc, vitamin A, vitamin C, folate, and iron. Women throughout their pregnancy (including the first trimester) should eat nourished food so that the body and brain of their babies grow and develop properly. Women in their second and third trimester of pregnancy should gain a kg per month.

Breastfeeding women require about **450kcal/day** more protein, zinc, vitamin A, vitamin C, and folate. They should eat well during their pregnancy to rebuild their body stores of nutrients:

1) Overweight or obese women during their pregnancy should eat healthy meals but not diet. They should lose weight if they remain overweight after breastfeeding.
2) Sometimes women need supplements of micronutrients along with healthy meals. **For example,** most pregnant women need iron/folic acid tablets. A good diet sufficiently provides other micronutrients, including vitamin A. However, vitamin A deficient women should take vitamin A supplements soon after giving birth and not after more than 6 weeks. This provides a store for use during breastfeeding. High doses of vitamin A should be avoided in pregnant women as the unborn baby can get harmed.

15.4.6. Roles of Pharmacist in Geriatric Patient Care

1) **Individualised Information Regarding Good Health:** The pharmacist should provide individualised information to the geriatric patients for mo difying their behaviour towards good health.
2) **Appropriate Diet:** The pharmacist should tell the geriatrics about the diet suitable in their age. Such diet should be free from fatty acids and rich in fibre to help them prevent many diseases.
3) **Health Education Activities:** The pharmacist should make aware the geriatrics on early signs and symptoms of some major diseases.
4) **Diagnosis and Treatment of Disease:** The pharmacist should support the geriatrics in early diagnosis and treatment of disease.
5) **Physical Examinati ons:** The pharmacist should encourage the geriatrics to take routine physical examinations, pap smears, mammograms, colon -rectal examinations, etc.
6) **Health Consciousness:** The pharmacist should educate the geriatrics on quitting tobacco, controlling high bloo d pressure, lowering cholesterol intake, increasing physical activity, and having a good health consciousness.
7) **Measurement of Blood Pressure:** The pharmacist should take blood pressure readings of the geriatrics. However, the readings may be temporarily hig h or low, and thus atleast two more measurements should be taken later.
8) **Education of Self -Care:** Many elderly individuals suffer from tooth decay or periodontal disease. The pharmacist should educate them that self -care, using fluorinated toothpastes, oralfluoride supplements and dental sealants, flossing, avoiding tobacco, and visiting the dentist routinely can prevent most of the oral conditions.
9) **Special Dietary Instructions:** The pharmacist should give special dietary instructions to the patients having diabetes and food allergies.

15.4.7. Roles of Pharmacist in Family Planning

The pharmacist serves as a link between the public and the physicians. Therefore, he/she meets with many people having their own beliefs about family planning. The uneducated or less educ ated people do not know about the benefits of family planning. Most of them believe that sterilisation is a painful and dangerous process that is harmful to health. It is the duty of the pharmacist to remove such thoughts from the minds of people. The pharmacist should promote family planning by:

1) Putting family planning posters in hospitals and drug stores,
2) Advising people about the importance of family planning, gap between each child, etc.,
3) Distributing leaflets about family planning,
4) Explaining about oral contraceptives and family planning techniques,

5) Guiding people to hospitals and family planning centres for vasectomy or tubectomy,
6) Supplying contraceptives, with a choice of methods and brands,
7) Learning about family planning and advising customers accurately,
8) Sponsoring and attending training courses on family planning and encouraging other pharmacy staff to attend the same,
9) Setting up self-service displays of condoms, spermicidals, and oral contraceptives,
10) Supporting the development of contraceptive social marketing programmes,
11) Learning about local family planning clinics and maintaining a relationship with them,
12) Working with pharmacist's organisations and other medical professionals to encourage their members for promoting family planning,
13) Promoting changes in laws to dispense contraceptives without a prescription,
14) Endorsing family planning publicly, especially in the media,
15) Working with pharmacy schools to upgrade their family planning curriculum and offer course in communication and counselling techniques, and
16) Advising a diabetic or hypertensive woman to consult a doctor before using oral contraceptives.

Thus, the pharmacists can provide information, advice and motivate people for family planning.

15.4.8. Roles of Pharmacist in Prevention of Communicable Disease

The infectious diseases can be controlled by the environmental control of food, milk, water, and sewage. Some major communicable diseases have been eliminated; but tuberculosis (TB) and syphilis still occur commonly and have even become drug - resistant. The pharmacists who want to remain updated with the current information on communicable disease patterns should subscribe to the CDC's Morbidity and Mortality Weekly Report (MMWR), which contains epidemiologic al notes, reports of disease outbreaks, and current statistics by disease and geographical location at home and abroad.

Following are the roles of pharmacist in the prevention of communicable diseases:

1) **Awareness of the Disease History:** The pharmacist can control communicable diseases by being aware o f the natural history of such diseases in individuals as well the community, and by referring the patients to medical-care facilities.

2) **Educating the Public about Health Measures:** The pharmacist should educate the public about effective health measures. Th e control of communicable diseases is based on adequate case finding and the supervision and prophylactic treatment of close contacts. In this aspect of communicable disease control, a pharmacist has best opportunity to provide health education in written, visual, oral, audio or video form to patients waiting for prescription filling. A pharmacist has the opportunity to get involved in socio -sexual problems as they relate to public health. This helps in understanding their patients' sub-cultures and variations in sexual activities and other social behaviour among different groups. Patients should be counselled and advised on prevention methods, treatment methods, and the need for receiving the treatment for STDs.

3) **Immunisation Schedules:** The childhood infecti ons of measles, mumps, rubella, poliomyelitis, diphtheria, and whooping cough are controlled by immunisation. Different states have their own immunisation schedule for children, and thus confusion exists among the practitioners and parents. New changes in recommended regimens should be expected with the development of new products. The pharmacist should obtain immunisation schedules from health departments and advise the parents on the importance of adhering to the schedules.

4) **Supply of Vaccines:** The pharmacist and the local health department should cooperate in supplying vaccines for imme diate or urgent administration. Vaccines that local health departments require occasionally are often stocked by the pharmacists to be used by the private physicians, there fore, such vacc ines are not routinely stocked. Pharmacists obtain, store, and prepare vaccines for administration where mass community clinics are the most accepted way of providing immunisation to the public.

   Many pharmacists, in small but gradually incr easing number of states and in Public Health Services (PHS), attain the knowledge and required skills for administering vaccines directly on an order from a health -care practitioner having a prescribing license. This increases the access to immunisation. T he information required for a vaccination program can be found in epidemiology and prevention of vaccine.

15.4.9. Roles of Pharmacist in Nutrition

The pharmacist assures adequate nutrition by advising the patients on basic food requirements, helping the children to correct their improper food habits, advising the females during prenatal and maternal periods on special nutrient requirements, giving special diet instructions to the diabetic patients and people having food allergies, and supporting school lunch programs and schemes (like mid-day meals, etc.) in rural areas.

The pharmacist recommends nutritional guidance using the materials available from voluntary health organisations and local and state health departments. The pharmacist should become aware of the local organisations that help lose weight in people of all ages, such as Weight Watchers, TOPS (Take Off Pounds Safely), and YMCA (Young Men's Christian Association) and YWCA (Young Women's Christian Association) programs; this is because people lose weightbetter in peer support groups.

Many individuals lack one or more nutrients and may suffer from acute nutritional deficiencies such as pellagra, scurvy, or beri-beri. A direct relationship between obesity and morbidity is well-established, and an inverse one with both length and quality of life. Thus, the pharmacist should be aware of basic nutritional requirements and the problem of malnutrition or poor nutrition among the patients they serve.

15.5. SUMMARY

The details given in the chapter can be summarised as follows:

1) As per WHO, "Hospitals are reservoirs of critical resources and knowledge.
2) The **hospital pharmacist** provides patient education on the safety and storage of medicines and poisons in the home and hospital.
3) Education and training in the form of le ctures, group discussions, and bulletins (produced at regular intervals by the clinical pharmacist through the drug information services) should also be provided to the medical and nursing staff and the colleague pharmacists.
4) In **internal teaching programm es**, the student nurses, graduate nurses, house staff members, and senior medical staff are provided training, seminars in therapeutics are conducted, and the undergraduate pharmacy students, refresher courses for graduate pharmacy students, and residents in hospital administration are helped in education.
5) **Lecture I** involves an orientation to pharmacy services
6) **Lecture II** involves philosophy and goals of formulary system.
7) **Lecture III** is suggested to take the form of a prescription clinic.
8) **Lecture IV** involves discussion of any topic of current interest among the staff.

9) In **external teaching programmes** , the hospital pharmacist is the guest lecturer, speaker, or the instructor in-charge of a specific course in a school or college.
10) Private offices, out -patient clinics, day surgery units (or short procedure units), and emergency departments are the **examples** of out-patient (ambulatory) settings.
11) In-patient care is rendered by the acute care hospitals.
12) Pharmacists who are nursing home consultants have many impor tant duties, like helping in system development to recognise the medication errors.
13) The code of moral principles or the science of morals is termed as **ethics**.
14) Pharmacies and drug stores should not follow the **self-service** method because it will result in distribution of therapeutic substances without an expert advice.
15) Interdepartmental communication is the process in which the professionals in different departments report to each other regarding the care provided to the patients.
16) The Joint Committee on He alth Education and Promotion Terminology of 2001 defined **health education** as "any combination of planned learning experiences based on sound theories that provide individuals, groups, and communities the opportunity to acquire information and the skills re quired to make quality health decisions".
17) The WHO defined **health education** as "comprising of consciously constructed opportunities for learning some form of communication designed to improve health literacy, improve knowledge, and develop life skills which are conducive to individual and community health".

15.6. EXERCISE

15.6.1. True or False

1) Lecture I involves an orientation to pharmacy services
2) Lecture II involves philosophy and goals of hospital pharmacy.
3) In-patient care is rendered by the chronic care hospitals.
4) Pharmacies and drug stores should not follow the self -service method because it will result in distribution of therapeutic substances without an expert advice.
5) Lecture IV is suggested to take the form of a prescription clinic.

15.6.2. Fill in the Blanks

6) Hospitals are reservoirs of critical resources and _____.
7) _____ is the process in which the professionals in different departments report to each other regarding the care provided to the patients.
8) The code of moral principles or the science of morals is termed as _____.
9) In _____, the hospital pharmacist is the guest lecturer, speaker, or the instructor in-charge of a specific course in a school or college.
10) Pharmacists who are _____ have many important duties, like helping in system development to recognise the medication errors.

Answers

1) True 2) False 3) False 4) True 5) False
6) Knowledge 7) Interdepartmental communication 8) Ethics
9) External teaching programmes 10) Nursing home consultants

15.6.3. Very Short Answer Type Questions

1) Define internal training program.
2) Give a few roles of pharmacist in education and training.
3) What are the different roles of a pharmacy technician in nursing homes?
4) Define code of ethics.
5) How a pharmacist should cooperate with a medical research staff?
6) Give any one role of a pharmacist in community health education.

15.6.4. Short Answer Type Questions

1) Write a short note on external training program.
2) Discuss the roles of pharmacist in education and training.
3) What services the pharmacist provides to the nursing homes/clinics?
4) Write the role of pharmacist in relation to medical profession.
5) Discuss a few roles of pharmacist in community health education.

15.6.5. Long Answer Type Questions

1) Write an illustrative note on internal training program.
2) Discuss in brief the code of ethics.
3) Give a brief review on the rol e of pharmacist in interdepartmental communication and community health education.
4) Briefly discuss the role of pharmacist in community health education.

CHAPTER 16

Prescribed Medication Order

16.1. PRESCRIBED MEDICATION ORDER

16.1.1. Introduction

Prescriptions and medication orders are the principal ways through which the prescribers and the pharmacists communicate with each other concerning the desired treatment regimen for a patient. Prescriptions are used in out-patient or ambulatory setting, while the medication orders are used in in-patient or institutional health system setting. Prescriptions and in-patient orders are legal and can be used for medications, devices, laboratory tests, procedures, etc.

Prescriptions and medication orders are handwritten, typed, pre-printed, verbal, or entered in a computer program and then submitted to the pharmacy by the patient or caregiver manually, through fax, computer, or any other electronic means. Dissimilar to the OTC medications (determined by the U.S. FDA to be safe and effective to use by the general public without a doctor's prescription), the prescription drugs should be used under the supervision of a licensed medical practitioner. The pharmacist should evaluate the prescription or medication order for accuracy before dispensing it by ensuring the correct drug, dosage form, dose, frequency, administration route, therapy duration, and direction for use. The pharmacist should also evaluate the patient's profile for therapeutic duplication, drug allergies, drug-disease interactions, and drug-drug interactions, and reviews any available laboratory data. This helps to maximise the benefits of therapy and minimise the potential for harm.

Parts

1) Patient name,
2) Date and time the order is written,
3) Medication name,
4) Medication dosage,
5) Administration route,
6) Frequency of administration,
7) Situation (**e.g.,** when as-needed medication should be administered and parameters for when a medication should be held), and
8) Signature of the primary health-care provider.

16.1.2. Types of Medication Orders

Discussed below are the different types of medication orders:

1) **Standing (Routine)**:
   i) This medication order is carried till its discontinuation or until the required number of days has lapsed.
   ii) Nursing care:
      a) Facility policies for automatic discontinuation of medications should be known.
      b) Standing orders should be reordered after surgery.
      c) A medication as prescribed should be administered till its discontinuation, the number of prescribed days lapse, or as per the facility policy, such as 5-14 days for specific antibiotics.
      d) The patient's response to the medication.

2) **As-Needed (derived from** Latin term, ***pro re nata***, **PRN)**:
   i) This medication order is given only when needed; the circumstances in which the medication is to be given (**e.g.,** morphine sulphate 2mg IV PRN every 3 hours for incisional pain) should be included.
   ii) Nursing care:
      a) The assessments indicating the need for t he medication should be documented in the clinical record.
      b) The Medication Administration Record (MAR) should be checked to identify the last time a medica tion was given, so that it can be confirmed that the previous dose was given a long time back.
      c) The administration should be recorded in the PRN section of the MAR.
      d) The patient's response to the medication should be monitored.

3) **Single-Dose (One-Time Only)**:
   i) This medication order is given only once, such as a medication given before a diagnostic test or before surgery.
   ii) Nursing care:
      a) The medication should be administered once.
      b) The administration of the medica tion should be recorded in the single -dose section of the MAR.
      c) The patient's response to the medication should be monitored.

4) **Immediately (STAT)**:
   i) This medi cation order involves a single dose to be given immediately, and is often ordered in cases of emergency.
   ii) Nursing care:
      a) A STAT medication should be administered immediately.
      b) The administration of the medica tion should be recorded in the single -dose section of the MAR.
      c) The patient's response to the medication should be monitored.

5) **Now Order**:
   i) This medication order involves a single dose to be given quickly (but not as quickly as a STAT order).
   ii) Nursing care:
      a) A "now" order should be administered within 90 minutes.
      b) The administration of the medica tion should be recorded in the single -dose section of the MAR.
      c) The patient's response to the medication should be monitored.

16.1.3. Communication of Medication Orders

The medication orders can be communicated as follows:

1) **Written Order:** A primary healthcare provider writes the medication order as per the protocol established by the agency. The order may be written in an order book or in the patient's clinical record, using a computer order form or standard order form with specific orders indicated with checkmarks:
   i) The medication orders should contain all the required elements.
   ii) The pharmacy should be reported of the new medication order manually, through fax, or computer when t he order was initiated; computer orders minimise the errors by automatically alerting the pharmacy and generating an MAR.
   iii) The medication order should be transcribed to or verified on the MAR manually or using a computer; Rechecking should be done a number of times to ensure accuracy.

2) **Verbal Order:** A primary healthcare provider gives the medication order verbally:
   i) This is done in emergency cases when there is no time to write the order.
   ii) The order should be repeated back to the primary healthcare provider fo r confirmation.
   iii) The primary healthcare provider should countersign the order within 24 hours.

3) **Telephone Order:** A primary healthcare provider gives the medication order on telephone:
   i) This is done in emergency cases when a written or verbal order cannot be given.
   ii) A primary nurse or supervisor should receive the telephone orders as per the established policy.
   iii) The order should be repeated back to the primary healthcare provider for confirmation.
   iv) Two nurses should listen to and even countersign the order.
   v) The primary healthcare provider should countersign the order within 24 hours.

16.1.4. Interpretation

Abbreviations and symbols are commonly used in prescriptions and medication orders. The prescriber uses them to sav e time, but sometimes they create confusion and are misinterpreted. This leads to medication errors. Therefore, the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organisations or JCAHCO) asked the healthcare organisationsto make an approach for standardising the abbreviations, acronyms and symbols, and also to create a list of those that should not be used.

Table 16.1 enlists some of the com monly used abbreviations and symbols . Those which have been identified by the Joi nt Commission and the Institute for Safe Medication Practices (ISMP) to be often misinterpreted and resulting in harmful medication errors are marked with an asterisk (*). A complete list of symbols, abbreviations, and dose designations that result in harm ful medication errors have been published by the ISMP and is called **ISMP's List of Error -Prone Abbreviations, Symbols, and Dose Designations**. Periods may or may not be present in between letters.

Table 16.1: Commonly Used Abbreviations in Prescription Writing, along with their Definitions

Abbreviations	Definitions	Abbreviations	Definitions
aa	Affected area	BW	Body Weight
a.c.	Before meals	C	Centigrade
ABW	Actual Body Weight	c or $\overline{c}$	With
ad	Up to	cap	Capsule
a.d.*	Right ear	cc*	Cubic centimetre
a.m.	Morning	cr, crm	Cream
amp	Ampoule	d	Day
APAP*	Acetaminophen	disc, D.C.*, d/c*	Discontinue
Aq	Water	disp	Dispense
a.s.*	Left ear	div	Divide
ASA	Aspirin	DOB	Date of Birth
ATC	Around The Clock	DS	Double Strength
a.u.*	Each ear	d.t.d.	Give as such doses
b.i.d.	Twice a day	DW	Distilled Water
b.i.w.	Twice a week	D5NS	Dextrose 5% in Normal Saline
BMI	Body Mass Index	D5½NS	Dextrose 5% in ½ Normal Saline (0.45% NaCl)
BSA	Body Surface Area	D5W	Dextrose 5% in Water
EC	Enteric Coated	OTC	Over The Counter

elix.	Elixir	o.u.*	Each eye
e.m.p.	As directed	oz	Ounce
F	Fahrenheit	p or per	By
fl of fld	Fluid	p.c.	After meals
ft.	Make	PCN	Penicillin
g or Gm	Gram	p.m.	Afternoon or evening
gr	Grain	p.o.	By mouth
gtt, gtts	Drop, drops	post	After
h, hr. or"	Hour	PPM	Parts per million
HCTZ*	Hydrochlorothiazide	pr	Rectally
h.s.*	At bedtime	pre-op	Before surgery
IBW	Ideal Body Weight	p.r.n.	As needed
ID	Intradermal	pulv.	Powder
IM	Intramuscular	q	Every
inj.	Injection	q.d.*	Every day
IU*	International Units	q.i.d.	Four times a day
IUD	Intrauterine Device	q.o.d.*	Every other day
IV	Intravenous	q.s.	Sufficient quantity
IVP	Intravenous Push	q.s. ad	A sufficient quantity to make
IVPB	Intravenous Piggy Back	s or $\bar{s}$	Without
jt or j-tube	Jejunostomy tube	sc*, sq*, subq*, or subcut	Subcutaneous
KVO	Keep Vein Open	Sig.	Write on label
L	Litre	SL	Sublingual
LE	Lower Extremities	sol.	Solution
LR	Lactated Ringer's injection	ss*	One half
M^2 or m^2	Square meter	stat.	Immediately
mcg or ug*	Microgram	supp.	Suppository
MDI	Metered Dose Inhaler	susp.	Suspension
mEq	Milliequivalent	syr.	Syrup
mg	Milligram	tab	Tablet
min	Minute	tal. dos.	Such dose
ml or mL	Millilitre	tbsp.	Tablespoon
MOM	Milk of Magnesia	t.i.d.	Three times a day
mOsm or mOsmol	Milliosmole	tinc	Tincture
MR	May Repeat	t.i.w.*	Three times a week
MRX_	May repeat _ times	top	Topically
NG Of NGT	Nasogastric or Nasogastric Tube	tsp.	Teaspoon
No. or no.	Number	U* or u*	Unit(s)
noct.	Night	u.d.* or utdict	As directed
non rep. or N.R.	Do not repeat or no refills	UE	Upper Extremities
NPO	Nothing by Mouth	ung.	Ointment
NS	Nothing saline (0.9% NaCl)	vag.	Vaginally
½NS	Half-strength normal saline (0.45% NaCl)	vol.	Volume
NTG	Nitroglycerine	w/	With
o.d.*	Right eye	w.a.	While awake
oint.	Ointment	w/o	Without
o.s.*	Left eye	x	Times

16.1.5. Legal Requirements

The legal requirements for prescribed medication orders are as given below:

1) **Medication Order Writing:** The medic ation orders are written by a physician, dentist, nurse practitioner, or any other authorised prescriber, as per the policies compatible with the Medical Staff Rules and Regulations. The medication orders are signed by the prescriber who takes the responsi bility for checking the order accuracy and validity, that it allows for safety validation by other healthcare practitioners, and meets the requirements of this policy, and other provincial and federal requirements.

   The patient will not be given any medica tion or treatment by any care -giver without a pre-existing medication order, unless it is approved by the Pharmacy, Therapeutics and Nutrition (PT&N) committee.

2) **Medication Order Legibility:** Medication orders will be written in a clearly readable manner.

3) **Medication Order Forms:** The medication orders, treatments or discharge of the patient should be documented in written form on the C&W Physician's Order form, an anaesthetic record, or a radiological instruction sheet unless it is approved by PT&N. Pre-printed order sets are considered as a best practice for prescriptions. Such order forms require approval by the PT&N committee, and should be developed utilising appropriate detailed safety double-checks.

4) **Care Medication Order Components:** A medication order sho uld comprise of the following components:
   i) Name and medical record number of the patient,
   ii) Date and time the medication order was written,
   iii) Generic drug name (if the product is not a combination product),
   iv) Dosage (formatted with appropriate pharmaceutical dosa ge units),
   v) Administration route,
   vi) Dosing frequency, and
   vii) Signature, printed name and college identification number of the prescriber.

   If a medication order is for "as needed" or "PRN" dosing, the following additional information should be added:
   i) Dosing frequency and maximum daily dosage, and
   ii) Clinical condition for administering a dose (**e.g.,** for severe pain).

   The medication orders when indicated medically for clarity or specialised orders should bear the following information:
   i) Therapeutic indication if different indications are possible for a drug,
   ii) Duration of therapy or stop date if it differs from the current site policy,
   iii) Range or sliding scale order written clearly using dosage increments aligned with clear objective clinical parameters,
   iv) Dosage form if several options are there,
   v) Detailed instruction on holding or delaying therapy under certain conditions, and
   vi) Dosage formula.

5) **Verbal (Medication) Orders:** These ordersare acceptable only in the following cases:
   i) Emergent care, and
   ii) Life-threatening situation.

   When such orders are required, the registered nurse or any other qualified practitioner should repeat back the verbal order to the prescriber for verification. If possible, a second RN or the other qualified practitioner should also receive the verbal order and countersign the medication order. The prescribing physician before leaving the patient care area should countersign the medication order.

6) **Telephone (Medication) Orders:** These orders are acceptable when the prescriber fails to attend the patient care area. The order received is written (or entered using an offsite electronic method) in an appropriate time frame for care.

   When such orders are required, the registered nurse or any other qualified practitioner should repeat back the medication order to the prescriber for verification. If possible, a second RN or other qualified practitioner should also receive the verbal order and countersign the medication order.

   The prescribing physician or the designated replacement physician should sign the telephone order within 24 hours of the order time.

7) **Medication Order Dosage Formats:** The medication orders should be written using SI (also known as International System of Units or metric units) units and measures.

8) **Medication Order Dosage Formula:** The prescriber s hould write the formula (in brackets) used for calculating the dosage to allow for subsequent independent double-checks of dose correctness. **For example** , ceftazidime 200 milligrams intravenously q8h (120 mg/kg/24 hr); Hydrocortisone 10 milligrams orally q8 h (8 mg/m^2/24 hr).

   Required:
   i) Chemotherapy.
   ii) When a medication has a broad dosing range and/or multiple indications.
   iii) When the medication order dosage is known to be above or below the approved dosage range for that medication.

9) **Medication Order Disallowed (U nsafe) Abbreviations:** The abbreviations in appendix A of this policy should not be used in a medication order under any conditions.

10) **Suggested Medication Orders:** These orders are not acceptable on a medication order form of any type. If such orders are prop osed by a consulting physician, it should be clearly marked as recommendations, and written in the physician progress note section of the patient health record.

11) **Standing Medication Orders:** These orders are not approved in Children's & Women's Health Centre.

12) **Safety Validation of Medication Orders - Practitioner Responsibilities:** If a medication order is not clear or has been written using an objectionable or unsafe element, the medication order should be delayed until the order is elucidated.

    If the executi on of medication order is delayed without any reason, the practitioner should immediately report to the concerned supervisor and also inform other care providers.

    This statement applies to any practitioner including nurses, pharmacists, or other physicians who dispenses a dose; unless, it is the professional will of that practitioner that a delay may have significant adverse clinical effects.

13) **Prescriber or Practitioner Compliance Reviews:** A prescriber or any other practitioner who dispenses or interprets a medication order (such as transcribing) should be compliant with these medication order policies.

    If an individual is non -compliant with these policies, his/her professional practice discipline leader will review their practice privileges and will take t he appropriate corrective step.

16.2. COMMUNICATION SKILLS

16.2.1. Introduction

Communication is defined as transaction and message creation. The process of communication occurs in a context that comprises of physical space, cultural and social values, and psychological conditions. Communication supports the performance of accurate, consistent and easy nursing work to satisfy the patient and protect the health professional. If the health professionals are not trained in communication skills, they face much difficulties in keeping their personal and professional life separate, thus transfer problems from one side to the other.

16.2.2. Importance

Pharmacy is a people profession, since a pharmacist contacts with large population through community pharmacies. In pharmaceutical care, the pharmacist's role is to identify, resolve, and prevent drug-related problems during treatment, after treatment, or inappropriate treatment.

The pharmacist should discuss about the following **information** with each patient or their representative:

1) Name and description of the drugs prescribed,
2) Dose, dosage form, administration route, and drug therapy duration,
3) Special precautions to be taken for preparation, administration, and use of the drug.
4) Normal or severe side effects, adverse effects, interactions, and contraindications, how to prevent their occurrence, and how to manage them if already occurred.
5) Self-monitoring drug therapy techniques,
6) Storage conditions for the drug,
7) Information on refilling of prescription, and
8) What to do in case a dose is missed.

A pharmacist should also collect, record, and maintain the following **information** about the patients getting medical benefits:

1) Patient's name, date of birth (or age), gender, address, and telephone number.
2) Patient's medical history comprising of disease states(s), allergies, drug reactions, and medications and relevant devices used.
3) Comments by the pharmacist on individual's drug therapy.

16.2.3. Communication with Prescribers

Inter-professional communication is challenging during the establishment of a clinical pharmacy service. If a service becomes well-accepted, the pharmacists need to establish their reliability with new staff members or with a ward area where they do not regularly practice.

The pharmacists face difficulty in reviewing the prescribing of medical staff. It is easy to give the impression of a pharmacy police force. The medicine-related problems can be resolved or prevented and friction related to status or power can be achieved if the pharmacists focus on patient welfare and represent a courteous attitude with the intention to help. This encourages a collaborative team approach.

The pharmacists may represent an unwanted interruption in wards or clinics and may be regarded as a threat to certain roles of nurses or medical staff. Such resistance and barriers can be overcome if the pharmacists focus on the patients' needs, add a pharmaceutical value to an established service, and recognise the abilities and roles of other staff.

Effective diplomacy is a part of professional pharmacy skills. When pharmacists are interacting with a health professional that seems to be busy, they should avoid useless conversation and focus on significant issues related to patient care.

For example , if a pharmacist discussed with a physician the need to administer an analgesic dose of aspirin with food, but did not discussed about the interaction aspirin may undergo with the patient's coumarin anticoagulant, he/she would not earn the respect of the medical team.

Spoken Messages
These messages are used in person or on telephone. Spoken messages are used for the following purposes:
1) For obtaining information,
2) For responding to a request for information,
3) For seeking clarification or amendment of a patient's therapy, and
4) For handling a complaint.

Telephone skills are very important in professional life. Sometimes preparation can be done (**e.g.,** noting down the main points of enquiry on a piece of paper) but one must rely on confidence and experience to handle them successfully. A most important telephone skill is focusing on the main concern during the call and ending it once the purpose is achieved. Skills and confidence that is require d for handling difficult situations can be developed through practice using role-plays.

Case Note Annotation
Comments on case notes send important information to the care -giver of the patient. Since messages can be easily ignored, verbal communication is preferred to alert the staff to an important issue, to clarify a complex message, and to reduce the chances of misinterpreting a message. Case note entries are also legally important when questions are asked about inappropriate prescribing or dosage that is harmful to the patient.

The entry should have a date and an informative heading. Short, clear statements should be used for identifying the issue; reasons or explanation should be provided, and recommendations should be given on any action as required. The name, position and contact details (telephone or tracer number) of the writer should also be mentioned. Journal articles or printed information can be attached to the notes to support an entry. In some hospitals, pharmacists use a coloured pen (usuall y green) or an identification mark to differentiate their entries.

16.2.4. Communication with Patients

Medication History Interviews
A complete medication history should be made available to the health p rofessionals making decisions about treatment. Errors can be avoided with a well -prepared and structured approach. The following information is commonly recorded during medication history interviews:
1) Currently or recently prescribed medicines,
2) Medicines purchased without prescription (OTC),
3) Vaccinations,
4) Alternative or traditional remedies,
5) Any reactions and allergies to the medicines, and
6) Ineffective medicines.

Labelling Medicines

The medicine containers should bear a label to identify:

1) The medicine,
2) Dosage form, number of dosage units supplied, and strength,
3) Number of dose units to be taken at a time,
4) Frequency,
5) Any precautions to be taken,
6) Patient's name,
7) Date of dispensing, and
8) Batch numbers and expiry dates for non-prescription medicines and medicines not to be used immediately.

Patient Information Leaflets (PILs)

PILs are used to summarise the important information that will assist the patients and their care-givers in effective and safe use of medicines. If computers are available, PILs can be personalised for individual patients or can be prepared for a group of patients. The following information is included in the PILs:

1) Trade and generic names,
2) Indication for which the medicine is to be taken,
3) Administration advice,
4) Action to be taken if a dose is missed,
5) Common or serious side effects that might occur,
6) Action to be taken if a side effect occurs,
7) Storage information,
8) Name and contact details of the institution providing the information, and
9) Author and date of publication.

All the sheets should be regularly reviewed and updated. All the essential information should be included in the PILs without making a document either too lengthy or too small.

Patient Medication Sheets

The compliance and understanding of patients taking several medicines can be improved through handwritten or computer-generated medication records. The information can be clearly presented in a tabular form. Dose-timing can be identified as a specific time, meal times, or a phase of the day (**e.g.,** morning). Information on when a medicine should be stopped, history of adverse reactions, and intended use of the medicine can also be recorded. The patient medication sheets should be kept updated and accurate when a patient is attending different clinics or practitioners.

Medication Counselling for Patients

Effective patient counselling helps the patients in using their medicines in a safe and reliable manner. The principles of effective verbal communication are important to make the encounter with the patient successful. The medication record should be used to focus on the interview, supported by patient information leaflets or product demonstrations.

Before providing any information, the pharmacists should check the patient's level of understanding and what they remember of their doctor's instruction so that the information can be given accurately as per their requirements. During the discussion, the pharmacists should advice the patients to adapt the medication regimen to their lifestyle.

16.3. SUMMARY

The details given in the chapter can be summarised as follows:

1) Prescriptions and medication orders are the principal ways through which the prescribers and the pharmacists communicate with each other concerning the desired treatment regimen for a patient.
2) Prescriptions and medication orders are handwritten, typed, pre-printed, verbal, or entered in a computer program and then submitted to the pharmacy by the patient or caregiver manually, through fax, computer, or any other electronic means.
3) **Standing (routine)** medication order is carried till its discontinuation or until the required number of days has lapsed.
4) **As-needed (derived from** Latin term, ***pro re nata***, **PRN)** medication order is given only when needed; the circumstances in which the medication is to be given
5) **Single-dose (one-time only)** medication order is given only once, such as a medication given before a diagnostic test or before surgery.
6) **Immediately (STAT)** medication order involves a single dose to be given immediately, and is often ordered in cases of emergency.
7) **Now order** medication order involves a single dose to be given quickly (but not as quickly as a STAT order).
8) A primary healthcare provider writes the medication order as per the protocol established by the agency.
9) Abbreviations and symbols are commonly used in prescriptis and medication orders.
10) A complete list of symbols, abbreviations, and dose designations that result in harmful medication errors have been published by the ISMP and is called **ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations**.
11) The medication orders are written by a physician, dentist, nurse practitioner, or any other authorised prescriber, as per the policies compatible with the Medical Staff Rules and Regulations.
12) **Communication** is defined as transaction and message creation.
13) Pharmacy is a people profession, since a pharmacist contacts with large population through community pharmacies.
14) Inter-professional communication is challenging during the establishment of a clinical pharmacy service.
15) **Spoken messages** are used in person or on telephone.
16) **Patient Information Leaflets (PILs)** are used to summarise the important information that will assist the patients and their care-givers in effective and safe use of medicines.
17) Effective patient counselling helps the patients in using their medicines in a safe and reliable manner.

16.4. EXERCISE

16.4.1. True or False

1) Routine medication order is carried till its discontinuation or until the required number of days has lapsed.
2) Emergency order medication order involves a single dose to be given quickly.
3) PRN medication order is given only when needed.
4) Spoken messages are used in person or on telephone.
5) PILs are used to summarise the important information that will assist the patients and their care-givers in effective and safe use of medicines.

16.4.2. Fill in the Blanks

6) Prescriptions and _____ are the principal ways through which the prescribers and the pharmacists communicate with each other concerning the desired treatment regimen for a patient.
7) _____ medication order involves a single dose to be gi ven immediately, and is often ordered in cases of emergency.
8) _____ and _____ are commonly used in prescriptions and medication orders.
9) _____ is challenging during the establishment of a clinical pharmacy service.
10) _____ is defined as transaction and message creation.

Answers

1) True 2) False 3) True 4) True 5) True
6) Medication orders 7) STAT 8) Abbreviations and symbols
9) Inter-professional communication 10) Communication

16.4.3. Very Short Answer Type Questions

1) Define prescription medication order.
2) Name the types of medication order.
3) What is a written medication order?
4) Define communication.
5) What are PILs?

16.4.4. Short Answer Type Questions

1) Write a short note on types of medication order.
2) Discuss the roles of pharmacist in education and training.
3) What is the importance of communication?
4) Write a note on communication of pharmacists with patients.

16.4.5. Long Answer Type Questions

1) Discuss in brief about the legal requirements for prescription medication order.
2) Give a brief review on communication skills.

CHAPTER 17

Budget Preparation and Implementation

17.1. BUDGET PREPARATION AND IMPLEMENTATION

17.1.1. Introduction

A vital role of the pharmacy department in a hospital is to formulate the annual budget considering all the essential factors of income and disbursement. Often, the pharmacist and sometimes even the administrator face difficulties in preparing a sound budget lightly, and as a result the prepared document fails to serve its real purpose.

Halma defined **budget** as "**an instrument through which hospital administration, management at the departmental levels, and the governing board can review the hospital's services in relation to a prepared plan in a comprehensive and integrated form expressed in financial terms**".

Since the complete hospital budget should abide by the above definition, every departmental budget should be precisely developed and furnished to them.

An appropriately prepared and used budget should have the following **goals**:
1) Developing standard of performance,
2) Comparing the actual results with these standards to identify deviations, and
3) Subsequently analysing the deviations to determine whether they are controllable or uncontrollable.

Larson wrote on political aspects of budgeting in hospitals, and according to him the pharmacist should be familiar with the political aspects of the process, only then he/she can effectively participate in the budgetary process.

These **political considerations** include:
1) Personal considerations,
2) Development of confidence among other officials,
3) Institutional philosophical pressures, and
4) Demographic pressures.

As for individual reputation, **personal considerations** are always significant in any political process. People who have achieved a reputation of having furnished former budgets that are comprehensively built on research and supported by considerable justification have a better chance of approval of their budget submitting.

There are many pharmacy activities that affect the different departments of a hospital; thus, it is crucial for the Chief Pharmacist (Director or Superintendent of the Pharmaceutical Services) to **protect their associations and support from different departments** delivering strength that is essential for safeguarding administrative approval for performing their development schemes.

The **institutional philosophical considerations** in the budgeting process include the goals and objective of the hospital with its developments.

17.1.2. Divisions of Budget

Every budget includes the following:

1) **Income (or Revenue) Accounts :** A general method used for determining the income can be the maintenance of daily, weekly, monthly or annual accounts to get the complete cost of the pharmaceuticals allotted to different patient services and to special services departments. This total amount is added with the total obtained from the processing of patient prescriptions and requisitions to get the actual income of the department.

   Additionally, there are the following **statistics** aiding the management to precisely predict the volume of activity of the pharmacy department:
   i) Total prescriptions according to the sub-categories,
   ii) Total prescriptions dispensed by each pharmacist,
   iii) Hours of work done,
   iv) Prescription volume per hour of service,
   v) Medication cost per patient per day,
   vi) Medication cost per clinic visit,
   vii) Average drug cost per prescription,
   viii) Average salary cost per prescription, and
   ix) Average supply cost per requisition.

   Though **income** is believed to be a single figure by the beginner, it is essential to comprehend the derivation of the figure. In hospital pharmacy, income is limited to the drug sales to in-patients, out-patients (ambulatory patients), and other hospital departments. The drug sold to the patients can be further sub-divided on the basis of the patient's ability to pay or their employment status if employed by the hospital. **For example, patient** can be of the following **types**:
   i) Those making full payment,
   ii) Those making partial payment,
   iii) Those not making any payment,
   iv) Physicians (not paying), and
   v) General employee.

   If income is produced from combining the above, it is appropriate to separate the data to lead a more accurate appraisal and evaluation.

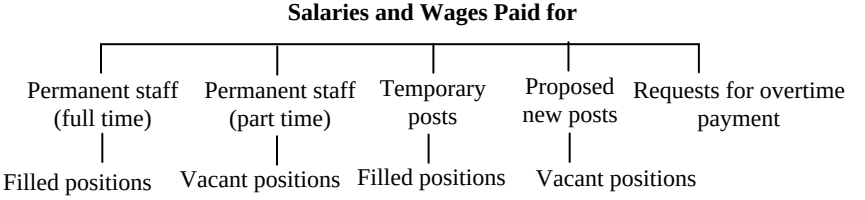
   In a few hospitals, the comptroller can choose to treat income from the sale of drugs to other hospital departments as a deduction from the purchase account, instead of adding to the income account considering that such methods allow a better evaluation of drug purchase cost for the use of patients.

2) **Expense Accounts:** These accounts can be divided into the following categories:
   i) Administration and general,
   ii) Professional care of the patients,
   iii) Out-patients and emergency, and
   iv) Miscellaneous expenses.

   Pharmacy department is generally listed under the category of professional care of the patients, and because of the accounts purpose an appropriate code number can be assigned to these categories. The pharmacists do not assign these code numbers; but, these are assigned by the chief of the account s department or the comptroller. The pharmacist should accurately understand the system of codes and code number so that he/she knows the relation between the expenses and their codes.

Categorisation and Contents of Expenses Account

i) **Salaries and Wages:** This includes the salaries and wages of the pharmacists, assistants, clerks, and others. It is crucial to give break-up of all salaries and wages paid by the pharmacist. This break-up can include the following categories:



The Chief Pharmacist should sub-divide the above posts into additional three categories, i.e., an administrative, professional and non-professional staff.

It would be useful to prepare a chart of these posts, etc., in a table form, which represents an overall view at a glance. The charts should differentiate the full time and part time staff in administrative, professional and non-professional categories.

The price of new posts is added and at last any overtime, which can be essential according to the past experience, is also added. The total of these items form the total expected salary and wage expenditure for the upcoming financial year.

ii) **Supplies and Expenses:** While preparing the supplies and expense part of the budget, the department head should willingly provide the amount of rupee budgeted for every expense code for the financial year. It is also essential to provide the latest financial statement presenting the current actual prices of materials and supplies. Mathematically it is easier to evaluate the actual expense for the present financial year. If the budgeted and the estimated actual figures agree, the last developed budget is considered to be well-developed.

On the other side, if the two figures are different, it represents that either there was a calculation mistake in the last year's expense budget or something has occurred or occurring in the current financial year which was not predicted, hence it re-evaluation is required.

If the department of pharmacy is needed to contribute in the development schedule of the services (**e.g.,** dispensing to new clinics or producing a new product), the Chief Pharmacist should establish the price of the materials and supplies used in the new work scheduled to be started and arrange for them in the upcoming budget.

iii) **Drugs and Pharmaceuticals Expenses:** These consist of the following:

a) Expenses dispensed by prescriptions or from the pharmacy department of the hospital, and

b) Expenses used in the out-patients, emergency and different departments.

iv) **Purchase Services:** This account should contain the price of prescriptions (excluding those for out-patient) bought from an outdoor pharmacy if the hospital does not have a pharmacy.

v) **Miscellaneous Supplies and Expenses:** These include bottles, labels, glassware, narcotic and alcoholic permit fees, printed forms, stationary, pharmacists' uniforms, reference books, etc. Parts which need repairing and maintaining equipment used by this department and repairs done by outdoor concerns should be charged to this account, and if the amount is large and important then to a separate sub-account.

The department of pharmacy is obligated to uphold detailed records and attain the figures for the required budget. It is very necessary to collect and have one's own statistical data, but it is observed that the pharmacist s rely upon the accounts department for their basic figures. In these conditions, a close connection and relationship between the Chief Pharmacist and the Accou nts Officer or the Controller should be established.

3) **Equipment and Construction Budget:** In hospitals, where offering the fund s for reduction of a physical plant and equipment are imprecise, the genuine price for replacing, repairing or remodelling is easil y available. In hospitals like this, where funds are offered for maintenance and repair of machinery and equipment , and of construction, these complications arise and a major financial load rises; therefore, a separate budget should be provided for these needs.

Though, an equipment and construction should be prepared regardless of policy concerning provis ion of funds for these purposes . In s ome hospitals, any piece of instrument with a unit price of 1,000, or more is the capital equipment and should be involved in this part of the budget. Likewise, any construction with an overall cost above 1,000 or more is considered as 'major' and should be incorporated in the budget. The figure of „1,000/-' is low but should be purposely kept low to execute a greater control.

17.1.3. Implementation of Budget

Budget is an important tool in the process of planning and controlling , and it is a prediction tool used for attaining the objectives. Budgeting is the responsib ility of the budget department, and it should be a joint effort of a committee including the heads of all the functional departments.

The general budget proposals are yearly prepared, though it can vary from duration of 3-5 years to take into account long -term planning. A suitable bu dgeting system assists the hospital administrator to take correct decision based on the local needs, requirements, and the order of priorities.

Budget implementation consists of the following steps:

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

17.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) Halma defined **budget** as "an instrument through which hospital administration, management at the departmental levels, and the governing board can review the hospital's services in relation to a prepared plan in a comprehensive and integrated form expressed in financial terms".
2) It is crucial for the Chief Pharmacist (Director or Superintendent of t he Pharmaceutical Services) to protect their associations and support from different departments delivering strength that is essential for safeguarding administrative approval for performing their development schemes.
3) The institutional philosophical consi derations in the budgeting process include the goals and objective of the hospital with its developments.

4) While preparing the supplies and expense part of the budget, the department head should willingly provide the amount of rupee budgeted for every expe nse code for the financial year.
5) **Purchase services account** should contain the price of prescriptions (excluding those for out-patient) bought form an outdoor pharmacy if the hospital does not have a pharmacy.
6) **Miscellaneous supplies and expenses** include bo ttles, labels, glassware, narcotic and alcoholic permit fees, printed forms, stationery, pharmacists' uniforms, reference books, etc.
7) Budget is an important tool in the process of planning and controlling, and it is a prediction tool used for attaining the objectives.

17.3. EXERCISE

17.3.1. True or False

1) Expenses account should contain the price of prescriptions bought form an outdoor pharmacy if the hospital does not have a pharmacy.
2) While preparing the supplies and expense part of the budget, the Chief Pharmacist should provide the amount of rupee budgeted for every expense code for the financial year.
3) The institutional philosophical considerations in the budgeting process include the goals and objective of the hospital with its developments.

17.3.2. Fill in the Blanks

4) It is crucial for the _____ to protect their associations and support from different departments.
5) _____ include bottles, labels, glassware, narcotic and alcoholic permit fees, printed forms, stationery, pharmacists' uniforms, reference books, etc.
6) _____ is an important tool in the process of planning and controlling.

Answers

1) False 2) False 3) True
4) Chief Pharmacist 5) Miscellaneous supplies and expenses 6) Budget

17.3.3. Very Short Answer Type Questions

1) Define budget.
2) Name the different divisions of budget.
3) What are income accounts?

17.3.4. Short Answer Type Questions

1) Write a short note on budget implementation.
2) Discuss about expense accounts.

17.3.5. Long Answer Type Question

1) Discuss in brief about budget preparation and implementation.

CHAPTER 18

Clinical Pharmacy

18.1. CLINICAL PHARMACY

18.1.1. Introduction

A branch of pharmacy termed **clinical pharmacy** is concerned with patient care, dispensing of drugs, and advising patient about safe and rational use of drugs. Clinical pharmacy is associated with pharmacy practice and the term is even mentioned in pharmacy literature. It is a health-related field, describing activities and services performed by the clinical pharmacists to form, expand, and encourage the rational and suitable use of medicinal products and devices. Clinical pharmacy is a health specialty, which describes the activities and services of the clinical pharmacist to develop and promote the rational and appropriate use of medicinal products and devices.

18.1.2. Concept of Clinical Pharmacy

Clinical pharmacy includes the services through which the practising pharmacists apply their responsibilities for patient care. It ensures rational selection and use of medications, and their appropriate and safe use in patient care.

The process of drug use involves several stages. The need for drug therapy should be determined. The appropriate drug, its dose, route, form, frequency, and treatment duration should be selected, and then the drugs should be administered correctly. This entire process should be examined to evaluate the success or failure of the conclusion. At each stage, the doctors, nurses, pharmacists, and patients should make independent as well as mutual decisions. These decisions conclude whether or not the prescribed therapy is suitable for the patient. Thus, clinical pharmacy is defined as "**the active participation of the pharmacist in patient care with the long-term aim of giving advice on medication with an individual patient in mind and tailoring drug therapy for that individual**".

Some major activities included in the term clinical pharmacy are involvement in prescribing rounds, patient counselling, taking drug history, parenteral nutrition service, pharmacokinetic advisory service, and monitoring adverse drug reactions/interactions. While the minor activities are health education, training/education of own staff and doctors/nurses, clinical trials, case references, and research/clinical meetings.

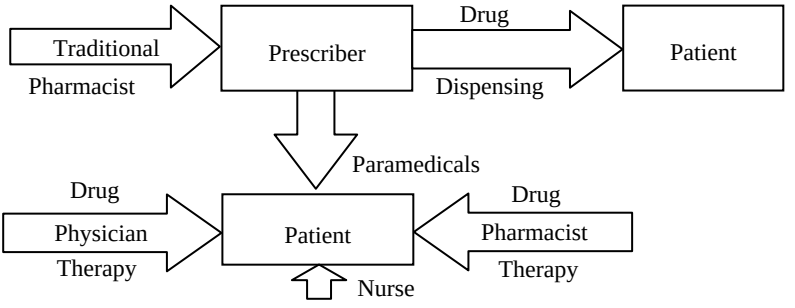


Figure 18.1: Concept of Clinical Pharmacy

A clinical pharmacist works along with the physician on the patient's bed side to monitor the drugs, dosages, and side effects and to advice the physician on these. Hence, clinical pharmacy has brought the pharmacist closer with the prescribers and the details of treatment of patients.

18.1.3. Functions and Responsibilities of Clinical Pharmacist

The role of clinical pharmacists in different areas of drug therapy are summarised in **figure 18.2**:

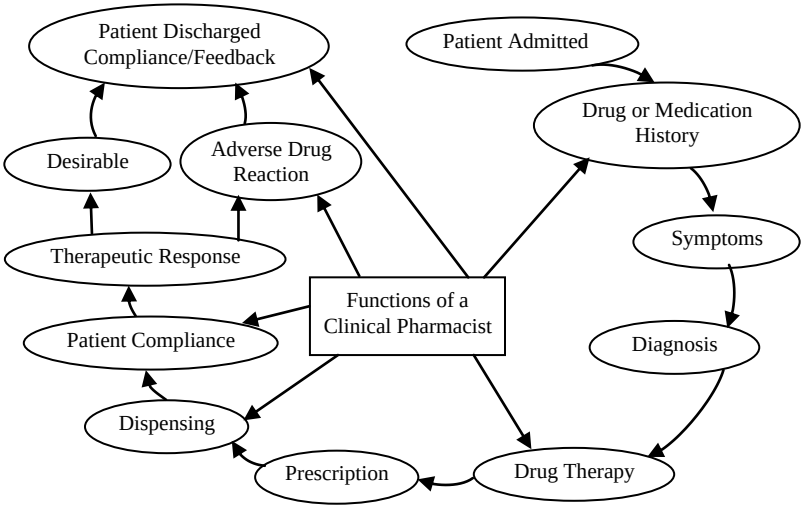


Figure 18.2: Functions of a Clinical Pharmacist

The **functions** and **responsibilities** of a **clinical pharmacist** are as follows:

1) He/she supervises drug distribution-related activities to ensure controlled use of drug and patient safety.
2) He/she opts for therapeutically effective drug products prescribed for patients at reasonable cost.
3) He/she records patient's medication history, including drugs prescribed earlier and any adverse reactions.
4) He/she detects and diagnoses adverse drug reactions and drug interactions.
5) He/she does patient counselling on use of drugs to assure compliance.
6) He/she helps the patients in selecting OTC drugs.
7) He/she frames a dosage regimen for the patients.
8) He/she encourages rational drug therapy.
9) He/she deals with psycho-socio-economic aspects of healthcare.
10) He/she participates in the management of patients having acute and chronic diseases.
11) He/she detects and corrects the incompatibilities observed in drug mixtures.
12) He/she prepares patient specific drug formulation.
13) He/she directs the dispensing assistants in dispensing of prescriptions.
14) He/she evaluates the drug literature.
15) He/she reviews drug utilisation.
16) He/she promotes healthcare knowledge in public.
17) He/she prescribes drugs to patients having mild and self-limiting diseases.
18) He/she monitors how the patients respond to drugs using patient medicine profile, etc.

18.2. DRUG THERAPY MONITORING

18.2.1. Introduction

Drug therapy monitoring involves **measurement of drug concentration in biological fluids to optimise a patient's drug therapy**. It is an on-going process in which the pharmacists actively review patients' records, identify and resolve drug therapy problems, such as Adverse Drug Events (ADEs), and communicate with the prescribers in case of any problems.

Pharmacists educate the patients and their care-givers on potential adverse effects and also work with the patients to ensure adherence to therapy and fulfilment of therapeutic goals.

18.2.2. Medication Chart Review

Medication chart review is an important responsibility of a pharmacist to ensure the suitability of medication orders. It serves as a starting point for other activities of clinical pharmacy (such as medication counselling, TDM, DI, and ADR). By organising information according to medical problems (like a disease), a complex situation can be separated into its individual parts.

Goals

1) It optimises the patient's drug therapy.
2) It prevents or minimises drug-related problems or medication errors.

Drug-related problem is a situation involving drug treatment that interferes with the patient's ability to attain an optimum outcome of medical care. **Charles Hepler** and **Linda Strand** in **1990** outlined the following **eight categories of drug-related problems** in their landmark paper:

1) Untreated indication,
2) Inappropriate drug selection,
3) Sub-therapeutic dose,
4) Overdosage,
5) Adverse drug reactions,
6) Failure to receive drugs,
7) Drug interactions, and
8) Drug use without indication.

The concerned physician should be immediately informed if any one or more of these problems are detected. The pharmacists should pursue for corrective measures so that the major problems that require an urgent action are addressed before the minor problems.

Drug-related problems can be identified by systematic review of each drug order on the patient's medication chart, and this process is referred to as **medication** or **drug chart review**. A medication order should be reviewed after considering all the important patient-specific information such as presenting complaints, past medical history, clinical assessment, results of laboratory investigations, treatment plans, and the patient's daily progress.

The following possibilities should be taken into account by the pharmacists to identify drug-related problems during medication order review:

1) **Untreated Indication:** The pharmacists should confirm if the patient has any untreated medical condition or indication that may benefit from drug therapy. While reviewing the indication for drug therapy, they should consider whether the indication is an unrecognised adverse drug reaction. **For example,** if a patient complains of nausea,

then he/she might be taking antibiotics or other drugs that resulted in this problem. Sometimes untreated indications are not obvious if the patient has not got any related signs or symptoms. **For example,** diabetic patients having other cardiovascular disease risk factors have not shown any signs or symptoms but may benefit from low dose aspirin therapy as primary prevention for cardiovascular disease.

2) **Inappropriate Drug Selection:** The pharmacists should confirm if the patient has a medical condition for which different drug(s) are more appropriate. It should be ensured that the most appropriate drug is chosen for treating the patient's medical condition. **For example,** a short course of NSAID is the first-line treatment for a patient having acute gout; but, if the patient also has renal impairment, a short course of prednisolone is more appropriate. It should be ensured that the prescribed drugs attain the therapeutic goals. Before concluding a given drug as ineffective, the possibility of failure to receive drugs including non-adherence to drug therapy should be considered.

3) **Sub-Therapeutic Dose:** The pharmacists should confirm if the patient has a medical condition for which the correct drug is being taken in a little amount. They should individualise the dose and dosing regimen according to the patient's medical condition. The pharmacists having knowledge of clinical pharmacokinetics can understand when a maximal response will occur after the drug treatment has started. Therapeutic drug monitoring can be a useful aid for drugs having a narrow therapeutic index and where a relationship between serum concentration and therapeutic effect has been established. When interpreting serum drug concentrations, factors that need to be considered include co-existing diseases, concomitant drug therapy, and the timing of blood sampling.

4) **Overdosage:** Overdosage of some drugs may occur if a patient takes the drug for a longer period than prescribed. **For example,** some patients continue taking antibiotics even after an infection has resolved, thus, they are exposed to the risk of adverse drug reactions and additional expense. Overdosage also occurs if the same generic drug has been prescribed twice under different brand names.

5) **Adverse Drug Reactions:** The pharmacists should confirm if the patient has a medical condition that resulted from an adverse drug reaction. They should first check that the patient is not allergic to the prescribed drug(s), or had any adverse reaction to a drug in the past. Then they should monitor the patient for any signs of adverse effects. Adverse drug reactions may result in morbidity and mortality. It has been studied that 10-30% of hospitalised patients experience an adverse drug reaction and 5% of hospital admissions are attributed to adverse drug reactions of which 0.3% are fatal. Detecting an adverse drug reaction is important in patient management, because failure to do so results in continuing patient morbidity. Therefore, the clinical pharmacist should have knowledge of adverse drug reactions, their predictability, preventability, frequency, severity, predisposing factors, and recognition. The following **patients are at more risk of developing an adverse drug reaction** and should be regularly identified and monitored:
   i) Patients with polypharmacy,
   ii) Patients with multiple diseases,
   iii) Patients with renal or hepatic impairment,
   iv) Geriatric and paediatric patients,
   v) Patients treated with potentially highly toxic drugs (**e.g.,** anticancer drugs),
   vi) Patients treated with drugs having a narrow therapeutic index (**e.g.,** digoxin and aminoglycosides),
   vii) Patients treated with drugs having a potential for clinically important drug interactions (**e.g.,** warfarin and cyclosporine).

6) **Failure to Receive Drugs:** The pharmacists should confirm if the patient has a medical condition that resulted of not receiving a drug due to non -adherence, poor administration technique, missed doses, medication errors, sub -standard drugs, or the patient's inability to pay for the prescribed drug. **For example,** a patient diagnosed with hypertension has been prescribed an ACE inhibitor, but he/she still continues to have high blood pressure. When the pharmacist spoke to the patient, it was discovered that the patient is not taking the drug because it is expensive. So, a more affordable and effective low dose of thiazide or a β-blocker is prescribed to the patient, provided he/she has no other co-morbidities.

7) **Drug Interactions:** The pharmacists should confirm if the patient has a current or potential medical condition that resulted from a drug-drug or drug -food interaction. Drug interactions have different clinical significances, and the pharmacists should make a professional judgement regarding a change in drug therapy. **For example,** a patient may not absorb ciprofloxacin if the drug is p rescribed to be taken along with iron tablets at the same time. This problem is overcome by taking the drugs on a gap of several hours.

8) **Drug Use without Indication:** The pharmacists should confirm if the patient has a current or potential medical condition that resulted from taking a drug with no valid indication. Care should be taken as the indication for which a drug is used may not be immediately obvious. **For example,** tricyclic antidepressants are indicated for urinary frequency, neuropathic pain, or pru ritus. A pharmacist will make a wrong conclusion that a prescription for amitriptyline has no indication because the patient has no history of depression.

The identified drug -related problems should be prioritised by the pharmacist according to their severity and consequences. The knowledge and clinical experience of the pharmacists help them in making a professional judgement about the problems of greatest importance to the patient's welfare. After evaluating the drug-related problems for severity and acu ity, potential corrective actions should be taken for deciding the most appropriate action to resolve the problem. If there is a need to change the therapy, the pharmacists should outline the problem to medical staff caring for the patient, and discuss the various options for solving the problem.

Medication Chart Endorsement

Medication chart review aims to reduce the risk of medication errors at the time of prescribing and/or drug administration. Medication error is a preventable event that leads to incorrect use of medication, thus harming the patient. The medication orders may be misinterpreted or subject to other types of medication errors even if the patient has no existing drug-related problems.

Table 18.1: Treatment Monitoring Parameters and Sources of Information for Some Common Diseases

Diseased Conditions	Commonly Used Drugs and Non-Drug Treatment	Some Common Outcome Parameters	Where to Find Information
Ischemic Heart Disease/Angina	Nitrates, β-blockers, antiplatelet agents, and calcium antagonists	Occurrence of angina , blood pressure and heart rate	Chest pain chart and observations chart
Diabetes Mellitus (Type 2)	Oral hypoglycaemic agents, insulin, and diabetic diet	Blood glucose levels , HbA_{1c} (long-term), and body weight (long-term)	Diabetes chart , lab data, and dietician reports

Acute Gout	NSAIDs, colchicine, and prednisolone	Uric acid level , pain, and redness/tenderness	Lab data , patient interview, and direct observation or medical notes
Infective Diarrhoea	Antibiotics and oral rehydration or IV fluids	Number and nature of bowel actions, fluid balance, skin turgor, mucous membranes, blood pressure, and stool culture	Bowel chart , fluid balance chart, direct observation or medical notes, observations chart, and lab data
Major Depression	Antidepressants, psychotherapy, and occupational therapy	Sleep pattern , appetite, emotional state, and interest in surroundings	Can be assessed by either patient interview, reading nursing/medical notes, direct observation, or reports from family members

Morbidity and mortality associated with these errors can be prevented if the pharmacists systematically review the medication chart and write annotations on the chart where medication orders are indistinct. This ensures that medication orde rs are unmistakable, readable, and the drugs are administered such that their effectiveness and safety is enhanced. In some hospitals where the concept of medication chart annotation by pharmacists is new, the pharmacy department should come forward to explain the purpose of medication chart endorsement to the medical consultants and obtain their approval.

Pharmacists should not guess the prescriber's intention from a poorly written or confusing prescription; and instead should refer it back to the prescri ber for confirmation. When annotating the medication charts, the pharmacists' handwriting should be clear and unambiguous, and they should sign their initials adjacent to the annotation.

The **types** of annotations required are determined by considering the following:

1) The name and medical record number of the patient should be on each medication chart. If not, the pharmacist should confirm the patient's identity before completing the details on the chart.
2) The allergy status of the patient should be documente d on each medication chart. If not, the pharmacist should confirm with the patient and case notes before annotating. If the patient has no allergies, then 'Nil Known Allergies' (abbreviated as NKA) should be annotated on the chart.
3) The medication name shou ld be clear and abbreviations should be avoided. **For example,** if the abbreviation 'AZT' is used for azathioprine as well as zidovudine, the wrong drug may be given to the patient unless full generic name is annotated on the chart.
4) The drug should be prescr ibed by its generic name. If a drug is prescribed by its brand names, the pharmacist should write the generic name next to the brand name.
5) The dose and the dosing frequency should be clear and unambiguous. Abbreviations such as 'u' for 'units' and 'µg' for 'microgram' should be avoided. Fractional doses should be written with a 'zero' before the decimal point (**for example,** 0.5mg should be written and not .5mg, because if the decimal point is not seen in the latter case, the dose will be increased by ten tim es resulting in overdosage). A decimal point and a zero should not be placed after a whole number (**for example,** 5mg should be written and not 5.0mg, because if the decimal point is not seen in the latter case, the dose will be increased by ten times resulting in overdosage).

6) The administration route should be specified. If not, the pharmacist should appropriately validate the chart. If the route is uncertain, the pharmacist should confirm with the prescriber.
7) The date and time of drug administration should be clear. If the times of drug administration are inappropriate for the drug and concerned patient, the pharmacist should annotate the chart with the recommended dosing times.
8) A minimum dose interval should be stated for preparations to be taken „as requir ed'; otherwise the patients will receive much larger doses of a medication than prescribed.
9) Additional drug administration instruction should be given wherever required. **For example,** the pharmacist should add directions such as 'after food' for oral hypoglycaemic drugs to avoid the risk of hypoglycaemia.
10) Any overwriting that may lead to confusion should not be present. The pharmacist should check if a dose has been crossed out and re -written unclearly that could lead to administration of wrong dose.
11) The cancellation of a medication order should be clear and unambiguous.
12) The prescription should be signed by a doctor.
13) The medication chart should be signed by a nurse each time a dose has been administered.
14) The medications should be prescribed according to lega1 and local requirements.

18.2.3. Clinical Chart Review

Clinical review is the review of patient -specific clinical information including patient parameters to estimate their response to medication therapies and to detect and manage potential or actual medicine -related problems. It may also include deducing biochemical and other tests, assessing the patient's signs and symptoms identified from interviews with the patient, and reviewing the health record.

Goals

The clinical review aims to:

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

Procedure

Information about the signs, symptoms and progress of the patients may be obtained as follows:

1) From their medication history or medication reconciliation documentation,
2) By reviewing their health record,
3) By discussing with other healthcare team members, and
4) By reviewing the patients' clinical data and laboratory investigations.

Examples of **patient-specific clinical information** may include:

1) Routine observations, **e.g.,** temperature, blood pressure,
2) Weight,
3) Fluid balance,
4) Urine output,
5) Biochemistry results, **e.g.**, electrolytes, creatinine,
6) Haematology results,
7) Microbiology results,

8) Radiological investigations,
9) Bowel charts,
10) Peak flow/spirometry,
11) Nutrition, and
12) Pain scores.

The information that is not readily available on the medication adm inistration record, Medication Management Plan (MMP), or in the patient's health record should be documented according to the local policy.

The clinical information obtained can be deduced and estimated by referring to the:
1) Clinical features and pathophysiology of treated conditions,
2) Indication for an investigation, and its sensitivity and specificity,
3) Timeframe of drug-related effects (including the expected adverse effects),
4) Patient's medication history,
5) Planned outcome(s) of the treatment, and
6) Patient's pharmacogenomics and genetic markers, especially as they relate to drug handling and monitoring of suitability of certain drugs.

The actual and potential drug -related problems should be identified and ordered according to their risk and urgency. The prescriber should be contacted to resolve any issues. Such information should be documented in the health record, MMP , or equivalent according to local policy.

18.2.4. Medication History

A medication history comes under pharmaceutical consultation that identifies and documents allergies or other serious adverse events caused by a drug. It also includes information on the current and past considerations about medicines. It is a beginning for medicines reconciliation and review.

A positi ve effect on patient care is observed when accurate and complete medication histories are taken. Many pharmacists have compiled such histories with high degree of precision and reliability as part of medicines reconciliation. The benefit to the patient is that the risk of harm is reduced by identifying the prescribing errors of omission or transcription and correcting them early.

This in turn provides better care to the patient. The history attained by the medical team and the pharmacist may differ and fa ll into two categories, i.e., **intentional** (when medical team makes a decision of changing the regimen) or **unintentional** (when complete record was not available). Differences should be clarified with the prescriber or the senior pharmacist.

Pharmacists may obtain complete medication histories by their better knowledge. In order to get detailed information, he/she should interview in a predetermined and systematic manner; firstly, the pharmacist should get familiarise with the patient charts to know the present medical status and background of the patient. The interview should be started with introduction and the reason for the interview. The patient's name, address, age, and the past medication history should be jotted down.

Direct or indirect questions c an be put forward on primary issues , like prescribed medication, self -medication, allergies, undesirable effect of any drug, compliance to prescribed medication, and smoking, drinking and eating habits. The language or terminologies should be simple and ea sy to understand by the patient. If the patient has difficulty in understanding specific terms, the pharmacist should explain it properly. Secondary relevant areas for questioning are constipation, diarrhoea, cough and cold, hay fever, allergies, vitamins, tonics, and skin preparations.

At last when patient's confidence is achieved by the pharmacist through the interview, questions on patient's medication compliance could be asked. It is a supportive information for the drug therapy. All the details gained during the interview are noted down in a sheet, one copy of which is sent to the physician.

Components

1) The pharmacist should introduce himself/herself to the patient and explain the intention of consultation.
2) The pharmacist should identify any allergies or serious adverse reactions and mention them on prescription chart, care notes, or patient medication record.
3) The pharmacist should get details on prescribed and non-prescribed treatments from the patient's recall, medicines possessed by the patient, referral letter (from the patient's primary care doctor), copy of prescriptions issued or a repeat prescription list, medical notes, and by contacting the appropriate community pharmacist or primary care doctor.
4) The pharmacist should make sure to document the generic name of medicine, dose, frequency, and duration of therapy.
5) The pharmacist should also document inhalers, eye drops, topical medicines, and herbal and homoeopathic remedies possessed by the patients.
6) The pharmacist should understand the patient's medication-taking behaviour.
7) The pharmacist should consider problems , like swallowing difficulties, understanding labels and written information, container preferences, and ordering or supply issues.
8) The pharmacist should record the history in detailed format.
9) The pharmacist should jot down any variation in the history recorded by other healthcare professionals.
10) The pharmacist should know if these variations are intentional (from patient, nursing staff, medical staff, or medical notes) or unintentional.
11) The pharmacist should inform about the unintentional variations to the prescriber.
12) The pharmacist should document all the medication-related information properly, **e.g.,** implications of chronic renal failure, dialysis, and long-term steroid treatment.

18.2.5. Pharmaceutical Care

Pharmaceutical care is a patient-centered, outcome-oriented pharmacy practice in which the pharmacist need to work along with the patients and their healthcare providers to promote health, prevent disease, and assess , monitor, initiate, and modify medication use so that safe and effective drug therapy regimens are planned. Pharmaceutical care aims to optimise the patient's health-related quality of life and achieve positive clinical outcomes within economic expenditures. The following criteria should be accomplished in order to achieve the above mentioned goal:

1) **A Professional Relationship must be Established and Maintained:** The pharmacist should interact with the patient to maintain a caring, trust, open communication, cooperation, and mutual decision-making relationship. In this relationship, patient's health is the supreme priority to the pharmacist, who needs to maintain an appropriate caring attitude towards the patient, and make use of his/her professional knowledge and skills for the patient's benefit. In exchange, the patient should provide personal information and preferences, and participate in the therapeutic plan. The pharmacist should assure the patient that he/she has access to pharmaceutical care at all times.

2) **Patient-Specific Medical Information must be Collected, Organised, Recorded, and Maintained:** The pharmacist should gather subjective and objective information on the patient's health, past medication history, social history, diet and exercise history, history of present illness, and economic situation (financial and insured status). All these information can be obtained from the patients, their family or caregiver, insurer, and other healthcare providers (physicians, nurses, mid -level practitioners, an d other pharmacists), medical charts and reports, and pharmacist -conducted health/physical assessment. This information should be accurate, complete, and properly organised and recorded in a confidential manner as they form the base for making decisions re garding the drug therapy plan. The information can readily be recovered and upgraded as per the requirement.

3) **Patient-Specific Medical Information must be Evaluated and a Drug Therapy Plan Must be Developed Mutually with the Patient:** The pharmacist after g aining a thorough understanding of the patients and their diseased condition and treatment, should consult with the patients and their healthcare providers to plan an outcome -oriented drug therapy regimen. This regimen should include various components addressing all the diseases or conditions of the patients. While designing the regimen, the pharmacist should consider the psycho -social aspects of the disease and also the relationship between the cost and/or complexity of therapy and patient adherence. The patients should be told about various pros and cons (i.e., cost, side effects, different monitoring aspects, etc.) of the drug therapy and instances where one option may be more beneficial based on the pharmacist's professional judgment. The essential elem ents of the regimen and the patients' responsibilities towards it should be carefully elucidated to them in an easy to understand manner. The drug therapy regimen should be documented in the patients' pharmacy record and also communicated to their healthcare providers.

4) **Pharmacist Assures that the Patient has all Supplies, Information and Knowledge Necessary to Carry Out the Drug Therapy Regimen:** The pharmacist providing pharmaceutical care should assure that the patients can obtain drugs and related product s or equipment included in their drug therapy regimen. The pharmacist should also assure that the patients thoroughly understand their disease and prescribed therapy/medications.

5) **Pharmacist Reviews, Monitors, and Modifies the Therapeutic Plan as Necessary and Appropriate, in Concert with the Patient and Healthcare Team:** The pharmacist should monitor whether or not the patients' are achieving the desired outcomes. If the pharmacist wishes to make changes in the therapy to maintain or enhance the safety and/o r effectiveness and to minimise the healthcare costs, he/she should coordinate with the patients and their healthcare providers. The pharmacist should monitor the patients' progress, document in the pharmacy record, and communicate to the patients and to their healthcare providers.

18.3. WARD ROUND PARTICIPATION

18.3.1. Introduction

In the last five decades, the pharmacy profession in western countries has experienced innovative changes by shifting from the traditional role of preparing and selling medicinal drugs and providing patient -focused services. **Hepler** and **Strand** gave a pharmaceutical care concept authorising the pharmacists with greater responsibility towards patient care. Pharmaceutical care involves the way in which a pharmaci st, a patient and other professionals collaborate to design, implement and monitor a

therapeutic plan for producing specific therapeutic effects for the patient. As per some researches, the multidisciplinary healthcare teams more effectively identify and manage patient problems in comparison to the individual approach to healthcare delivery.

A pharmacist's prime responsibility is to make sure that each patient receives suitable treatment in the most convenient and cost effective form. If the pharmacists have the knowledge and skills of combining therapeutic, pharmacological and pharmaceutical data, it ensures optimal patient outcomes. Retrospective review of medication orders by the pharmacists on wards maximises safe prescribing. But, the pharmacist's impact can be greater if input is provided at the prescribing level. Clinical pharmacists influence prescribing in a favourable manner as they have proper clinical knowledge and are in regular contact with the prescribers.

18.3.2. Medical Ward Rounds

A visit made to hospital in-patients at their bedside by a medical practitioner (either alone or with a team of health professionals and medical students) to review and follow-up the progress in their health is termed as a **ward round**. A single ward round per day is generally conducted to review the progress of each in-patient; but in some hospitals, more than one ward round is also common. In psychiatry practice settings, ward round is conducted away from the patient's bedside in a non-traditional manner, where the team meets in another place to review each case.

In the United States and United Kingdom, the pharmacists are involving themselves in medical ward rounds since the 1970s. This development was accelerated by the introduction of postgraduate courses in clinical pharmacy. Researches and experience has proved that if a pharmacist is taken along with the healthcare team to attend ward rounds in various practice settings, a safe, effective and economic use of drugs can be established. This decreases the adverse drug events, improves patient care, reduces the length of hospital stay, and minimises the healthcare costs.

18.3.3. Goals and Objectives for Clinical Pharmacists on Ward Rounds

Since pharmacists are an important member of the healthcare team, they should attend ward rounds and clinical meetings so that they can contribute to patient care by providing drug information and promoting appropriate drug therapy. The goals of a clinical pharmacist while participating in ward rounds are given below:

1) Understands well the patients' clinical status, progress, current planned investigations, and therapeutic goals.
2) Provides appropriate information on pharmacology, pharmacokinetics, drug availability, cost, drug interactions and adverse reactions related to patient's drug therapy.
3) Optimises the therapeutic management by influencing drug therapy selection, implementation, monitoring, and follow-up.
4) Investigates the drug orders or doses.
5) Collects supplementary information about the patient's co-morbidities, medication compliance, or alternative medicine use.
6) Detects the adverse drug reactions and drug interactions.
7) Participates in patient discharge planning.

The opportunities for medical practitioners to keep themselves updated with new therapeutic developments through medical education programmes and clinical seminars are more in teaching hospitals than in non-teaching hospitals. Consequently, the

pharmacists in non-teaching hospitals have considerable opportunities to promote evidence-based pharmacotherapeutics and the quality use of medicines.

Participating in ward rounds also provides learning opportunities for pharmacists, allows them to see how drugs are used and prescribed, and to see the effects of these drugs on patients. As time passes, the pharmacists start understanding how the patient's social, cultural and economic circumstances influence the therapeutic choices. Experienced clinical pharmacists in teaching hospitals also gain new viewpoints on therapeutics or patient care during a ward round.

For clinical pharmacists involved in academia and research, ward rounds allow identification of cases for clinical teaching and publication. Ward round participation also strengthens the inter-professional relationship among various health professionals for the betterment of healthcare practice and research.

18.3.4. Classification

Ward rounds are classified as follows according to the purpose of the round and composition of the participating healthcare team:

1) **Pre-Rounds:** During these rounds, the patients are reviewed in their unit or ward by the interns or medical postgraduate students in teaching hospitals. This is a learning opportunity and very few management decisions are made during these rounds. The interns or postgraduates may be accompanied by the trainee clinical pharmacists in the pre-rounds to complete the patient medication and clinical review.

2) **Registrar/Resident Rounds:** The registrars and residents (either alone or as a team) conduct ward rounds in teaching hospitals atleast once a day at a fixed time (generally in the morning); however, rounds are conducted several times a day in the Intensive Care Unit (ICU). These rounds involve clinical teaching to medical postgraduate students and interns. These rounds are useful for clinical pharmacists of all levels of experience to join.

3) **Professor/Chief Rounds:** The chief of a unit or ward or the professor in a field along with their registrars, residents, postgraduate students and interns conducts ward rounds in teaching hospitals for all patients under their care either daily or for a few days in a week. These rounds devote to addressing more complex issues regarding diagnosis or management which the registrars or residents have encountered. These rounds are more challenging for clinical pharmacists in terms of their clinical knowledge.

   Some consultants of the teaching hospitals do not participate in regular teaching activities and only do referrals on request by professors or unit chiefs. Thus, due to timing the clinical pharmacists face difficulty in joining these consultant rounds. **For example,** recommendations on patient management can be conveyed orally through other members of the medical team or can be written in the patient's case sheets.

4) **Teaching Rounds:** The academic medical staff conducts bedside clinical teaching rounds for residents, medical postgraduate students, interns and medical undergraduate students in teaching hospitals. These rounds are conducted for a few times a week. These ward rounds allow the pharmacists to improve their clinical knowledge; however, these are not useful for making interventions or recommendations. Some clinical pharmacists with joint college or university appointments conduct these rounds to teach therapeutics.

18.3.5. Pre-Ward Round Preparation

Before participating in ward rounds, the pharmacists should prepare well. For effective participation in clinical decision -making, the pharmacists need to have accurate and updated information on the patients' health status, disease management, and past medical history. This can be achieved by reviewing the medication chart and case record should be completed before the ward round begins. Pre -ward round preparation gives an outline of the drug - and disease -related issues that may occur during a ward round so that the pharmacist remains active during the round.

Many clinical pharmacists maintain individual patient profiles containing information on the patient's drug therapy, allergies or hypersensitivities, reason for admission, provisional or final diagnosis, past medical history, medications on admission, relevant social history, laboratory data, other relevant investigations and reports, and other information such as medic ation compliance. These data are collected by reviewing the patient's case record and treatment charts, and also by interviewing the patient or their care-givers. The obtained information is recorded on specific forms designed by the pharmacists as per the suitability of their practice setting. **Figure 18.3** shows an **example** of such a form used by a clinical pharmacist in a general medical unit.

Name of the patient: Date of admission:	Age: Sex: Address: (alternatively place patient ID sticker)
Reason for admission:	
Allergies:	
Past medical history: Past medication history: Complementary and alternative medicine: Social history:	Smoking Alcohol:
Drugs on admission:	
Diagnosis:	
Current drugs:	
Investigations:	
Date→	
Creatinine	
Urea	
Albumin	
RBS	
FBS	
Hb	
RBC	
WBC	
DC	
ESR	
CK	
LDH	
SGPT	
SGOT	
Other diagnostic results: (ECG, X-ray, CT, MRI, ECHO,USG)	
Clinical progress: (BP, Temp, Sugar) Other information:	

Figure 18.3: Patient Profile Form

A folder with an alphabetical index is maintained so that the patient pro files can be easily recovered. While undergoing pre-ward round preparation, the pharmacists may face some issues that can be made clear through appropriate references (hands -on references are mainly useful in such cases). The pharmacists should also priori tise the interventions or recommendations to be made during the ward rounds. A detailed medication history from the new in-patients or the attendants should be collected by the pharmacists and validated with the information collected by other healthcare pr ofessionals. The concerned healthcare professionals should be informed about any such new data obtained during the medication history interview that may change patient management. If required, the existing patient profiles should also be updated. Thus, pre -ward round preparation allows the pharmacists to be well-informed and organised before discussing patient management and contributing to the process of clinical decision-making.

18.3.6. Practical Tips for Ward Round Participation

Pharmacists should complete their pre -ward round preparation before the ward round begins. If there is no fixed time for a ward round, the pharmacists should make a way to get notified each time a round begins . If the clinical pharmacists have responsibility for different wards and the timing of different ward rounds overlap, the pharmacists should give priority to those rounds in which he/she can contribute more.

It is the duty of the pharmacists to ensure th at in government and some corporate hospitals with a formulary or drug list, all the prescriptions should conform to the hospital formulary. The clinical pharmacists may carry appropriate references, such as British National Formulary (BNF), Drug Informati on Handbook and Australian Medicines Handbook (AHM), in their ward rounds. Some important therapeutic guidelines are useful references for pharmacists working in specialty areas.

The pharmacists should suggest alternatives to resolve the problems of drug interactions, adverse reactions, and medication errors. **For example,** if a pharmacist suggests that a patient is suffering from peripheral oedema due to the prescribed amlodipine, the medical team may ask that which alternative antihypertensive the pharmaci st would recommend for the patient, and he/she should be ready with the answer. If the pharmacist thoroughly familiarises with the patient's medical history during pre-ward round preparation, he/she will be able to suggest appropriate alternatives.

Pharmacists should avoid entering into discussions regarding the diagnosis; however, if the patient's signs or symptoms are drug-related, the pharmacists can suggest diagnosis. In the above example, the pharmacist should consider the possibility that the patient 's peripheral oedema may be due to other causes such as heart failure. If the medical team has eliminated the common causes of peripheral oedema and still observed no positive change in patient's condition, they consider the pharmacist's suggestion that the oedema may be drugrelated.

18.3.7. Pharmacist Intervention

During ward rounds, the physician interviews the patient or their caregiver about the symptoms, complaints, and progress. Then physical examin ation is conducted, followed by reviewing the laboratory data and results of other diagnostic tests. The attending physician consults with other members of the healthcare team to make decisions regarding the diagnosis and management. Sometimes, the physici an also consults the pharmacist regarding the drug treatment.

Pharmacy intervention is any **direct action taken by a pharmacist** to **change the patient management** or **therapy**. Pharmacists get opportunities of interventions arise

during medication history interview, medication chart review, therapeutic drug monitoring, provision of drug information, and ward round participation. Pharmacist intervention to assist prescribing can be active (**e.g.,** use of guidelines, backed up by personal visits to influence prescribing), passive (**e.g.,** drug information services), or reactive (monitoring prescriptions and amending those that are unclear, inaccurate, or inadequate).

The clinical pharmacists participating in ward rounds can influence the important decisions made regarding in-patient management. In a 6-week study on the impact of prescription checking during ward rounds in a 450-bed district general hospital, it was observed that a pharmacist was required to intervene the therapy of one out of five patients, and more than three-quarters of the pharmacist interventions were accepted by the medical staff.

In another study, pharmacists attending the consultant ward rounds in a general hospital were asked about the drug therapy for every two patients; 58% of those queries were from the medical staff, 41% were by the pharmacists, and the remaining were from nurses; it was concluded that if the pharmacist had not been on the ward round, more than 90% of those queries would have left unclear. The commonly arising **drug-related queries during ward rounds** are regarding the following:

1) Dose and frequency,
2) Medication choice,
3) Adverse effects,
4) Drug interactions,
5) Formulation,
6) Therapy duration,
7) Actions and uses/pharmacology,
8) Drug availability,
9) Identification of patient's medications on admission,
10) Legal and administrative issues, and
11) Storage conditions.

Interventions or recommendations to be made during ward rounds should be prioritised as per their clinical significance and possible patient response. Interventions have greater possibility of success if the pharmacists recommend alternatives for the identified problems related to drug therapy. The nature of medical staff and time limitations should also be considered. The experience and communication skills of the pharmacists and their relationship with the medical staff are the factors on which the success of pharmacist interventions depends.

18.3.8. Communication during Ward Rounds

The clinical pharmacists should collaborate with other healthcare professionals to fulfil the healthcare needs of patients. Good communication skills and clinical knowledge are basics for effective participation in ward rounds and clinical meetings. The pharmacists should actively participate in patient care by sharing their views on patient management with other healthcare professionals. They should understand the fact that their professional duties are to the patient and should ensure that the patients receive appropriate drug therapy. Good inter-professional relationships are a prerequisite for success. The pharmacists should resolve the differences in opinion in a direct manner without disrespecting others. In most of the teaching hospitals, the healthcare professionals during ward rounds communicate in English; but sometimes the clinicians

speak to the patients in their regional language. The pharmacists attending the ward rounds should also know the regional language to understand the conversation between the clinicians and patients, and also to efficiently interact with the patients. Pharmacists during the ward rounds should discuss the drug-related issues carefully in the presence of patients or their care-givers. Interventions or recommendations should be made in such a way that the patient's faith in the prescriber is not hampered.

The clinical pharmacists may face hurdles while communicating with the medical staff. Sometimes, the medical staff does not have appropriate knowledge on certain issues during the ward rounds, and thus requires the clinical pharmacist's advice. If the pharmacists are not sure about an answer, they should not make any guesses. Instead, they should inform the prescriber, retrieve the relevant information after completing the ward round, and then convey it to the prescriber.

It may happen that the health professionals and patients may undervalue the pharmacist's skills, and the physicians also not accept their recommendations or suggestions. Pharmacists should not expect to be appreciated by the physicians if their recommendations improved patient management. In clinical pharmacy, the pharmacists and physicians have the common responsibility of management of patients' drug therapy.

Inter-and intra-professional hierarchy is also strongly observed in clinical pharmacies. Hence, while communicating, the pharmacists should consider the seniority and designation of medical staff. Pharmacists should not criticise other healthcare professionals, since inter-professional respect and teamwork form the base of effective patient care. The pharmacists should make interventions in a diplomatic way, showing respect for the physician's clinical judgement and experience, and not challenging the integrity of a medical practitioner.

18.3.9. Ward Round Follow-Up

During a ward round, the clinical pharmacists often face issues that require follow-up. Pharmacists should give priority to these issues based on their urgency and importance. Some commonly arising issues during a ward round are:

1) **Responding to Enquiries:** All the unanswered queries that came in mind during ward rounds should be recorded and followed up as soon as possible. Responses may be given through telephone calls, mails, in printed format, or in person. The information should also be supported with suitable references if need so.

2) **Communicating Information:** Sometimes, the clinical pharmacists need to communicate the changes made in drug therapy during ward rounds to the concerned healthcare personnel such as medical, nursing, pharmacy, technical or dietetics staff.

3) **Completing Documentation:** Sometimes, the pharmacist interventions (made during a ward round) should be documented. If the clinical pharmacists record the patient's case sheet, they should enter their relevant details like name, contact details and signature.

4) **Making Necessary Alterations:** The clinical pharmacists should change the patient's care plan to fulfil the requirements resulting from changes in patient management (**e.g.,** monitoring of drug levels and recommending doses after dialysis).

5) **Discussion with Patients:** The clinical pharmacists should discuss the drug therapy issues with the patients (**e.g.,** reasons for changing the therapy, drug administration or self-monitoring techniques, and steps to be taken in case of adverse effects).

18.4. DOSING PATTERN AND DRUG THERAPY BASED ON PHARMACOKINETIC AND DISEASE PATTERN

18.4.1. Introduction

Dosing pattern or dosage regimen is the **procedure or routine in which a drug is administered**. Some drugs (like analgesics, hypnotics, anti-emetics, etc.) are effective even in a single dose. However, therapeutic effect produced by a single dose of some drugs is shorter than the duration of most diseases. In these cases, drugs are given repetitively at specific time intervals according to the disease and its consequences. Therefore, an optimal multiple dosage regimen or pattern is essential for effective therapy. An optimal multiple dosage regimen is a dosing pattern in which the drug is administered in suitable doses via suitable route, with sufficient frequency that maintains the plasma drug concentration within the therapeutic window (without fluctuations and drug accumulation) for the complete duration of therapy. For drugs like antibiotics, it is essential to maintain a minimum effective concentration at all times; whereas for drugs having narrow therapeutic indices (**e.g.,** phenytoin), it is essential to maintain their concentration below the toxic level.

During the designing of the dosage regimen, the administration route and complexity of pharmacokinetic equations are not considered. Following **two major parameters** should be considered before developing a dosage regimen:

1) **Dose Size:** The amount of drug taken each time.
2) **Dosing Frequency:** The time interval between doses.

These parameters are essential to calculate the amount of drug in the body at any given time.

18.4.2. Dose Size

The degree of therapeutic and toxic responses depends on the dose size. For calculating dose size, the amount of drug absorbed after administration of each dose should be known. Toxicity is directly proportional to the dose size, i.e., **greater the dose size, greater the fluctuations between $C_{ss,max}$ and $C_{ss,min}$** during each dosing interval, and **greater the chances of toxicity (figure 18.4)**.

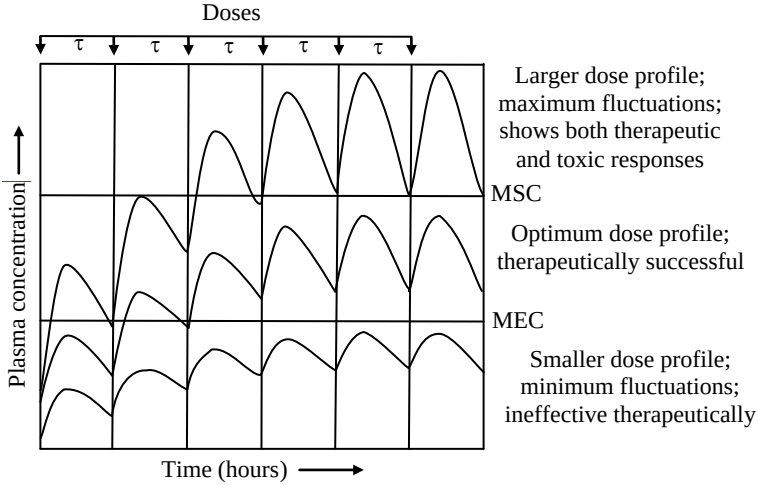


Figure 18.4: Schematic Representation of Influence of Dose Size on Plasma Concentration-Time Profile after Oral Administration of a Drug at Fixed Time Intervals

18.4.3. Dose Frequency

The dosing frequency and dosing interval (inverse of dosing frequency) is calculated according to the half -life of drug. If the dosing interval increases and the dose remain unchanged, C_{max}, C_{min} and C_{av} decrease but the ratio C_{max}/C_{min} increases. Opposite effects are seen, if the dosing interval reduces or dosing frequency increases. These results are also observed in case of toxicity or if greater amount of drug gets accumulate in the body **(figure 18.5)**.

For maintaining steady-state concentra tion with minimum fluctuations and to ensure therapeutic efficacy and safety, a proper balance between dose size and dosing frequency is desired. But it cannot be achieved by taking larger doses less frequently . However, intake of smaller doses more frequently causes smaller fluctuations.

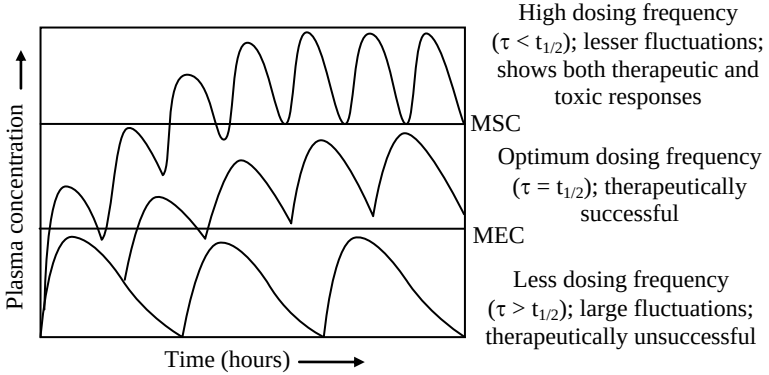


Figure 18.5: Schematic Representation of the Influence of Dosing Frequency on Plasma Concentration-Time Profile Obtained after Oral Administration of Fixed Doses of a Drug

Usually, all successive doses should be given at an interval equal to half -life of the drug. The law is that:

1) Drugs having a large therapeutic index (**e.g.,** penicillin) should be given in large doses at relatively longer intervals (more than the half -life of drug) without any toxicity problem.
2) Drugs having a narrow therapeutic index (**e.g.,** digoxin) should be given in small doses at frequent intervals (less than the half -life of drug). This yields a profile with small fluctuations which is similar to that observed with controlled -release system or constant rate infusion.

18.4.4. Drug Therapy Based on Pharmacokinetic and Disease Pattern

In sick peopl e compared to in healthy people, more fluctuations are observed in pharmacokinetic parameters because diseased conditions affect various organ systems of the body as well as the drug absorption, distribution, excretion, and metabolism process . **For example,** renal diseases affect drug excretion and drug binding; hepatic diseases affect drug metabolism ; cardiovascular diseases af fect drug transportation and drug elimination from liver and kidneys.

18.4.4.1. Renal Disease

In case of renal diseases, patients should be tr eated with various drugs for the inter-current diseases as well as the kidney disease itself. Urinary excretion of drugs is obstructed in case of renal failure , so the drugs which are eliminated by renal excretion

get accumulated excessively in patient s with renal insufficiency unless a modification is made in the dosage regimen. Any complication in therapy in patients with renal disease changes the drug distribution, drug metabolism, and dialysis treatments.

Creatinine Clearance

The degree of renal impair ment in a patient can be measured by various methods. The most common method of measuring the renal function is to determine th e renal clearance of creatinine and the endogenous end product of muscle metabolism, and then comparing this value to that observ ed in individuals of comparable size, sex, age, and normal renal function. Creatinine clearance can be calculated directly or indirectly by measuring the serum levels of creatinine.

Creatinine clearance can be measured directly by determining the amount o f endogenous creatinine excreted in the urine in a day and the plasma concentration of creatinine during this period. Creatinine level is generally determined by taking blood samples immediately before and at the end of the urine collection period. The ave rage of serum level s obtained is calculated and the excretion rate of creatinine (expressed as mg/min) is divided by the average creatinine concentration in the plasma (expressed as mg/ml).

As a result, the endogenous creatinine clearance (expressed as ml/min) is obtained. Generally, this value is normalised by the body surface area of 1.73m ^{2}. Normal values adjusted to 1.73m ^{2} body surface area range from 140 -180 litre/day or 100 -125ml/min. The creatinine clearan ce values of 20 -50ml/min show moderate renal failure, while values less than 10ml/min show severe renal failure.

Drug Excretion

In various studies, a linear relationship is observed between the renal clearance of a drug and creatinine clearance in patients with varying degrees of renal function. Th is relationship is shown in **figure 18.6** for relatively slowly eliminated β-blocker (nadolol) in patients with hypertension. In anephric patients, the renal clearance of nadolol should be nearly zero.

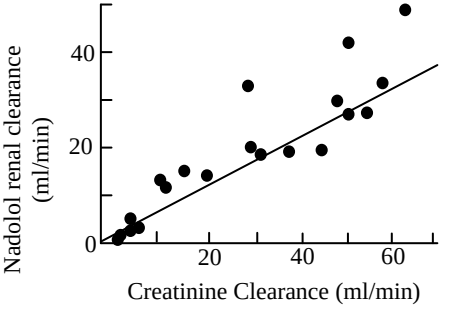


Figure 18.6: Relationship between the Renal Clearance of Nadolol (β-blocker) and Creatinine Clearance in Patients with Varying Degrees of Renal Function

The following relationship has been observed for nadolol and most other drugs:

Renal clearance = A × Creatinine clearance …..(1)

Where, A = Drug-specific constant. For nadolol, A is equal to about 0.6.

As compared to patients with normal renal function, less unchanged drug is excreted in the urine of patients with renal disease. The cumulative amount of unchanged nadolol excreted in the urine within 120 hour s after oral administration of the drug to 4 groups of

patients with diff erent degrees of renal disease is shown in **table 18.2**. The amount of nadolol excreted decreases with decreased renal function.

Table 18.2: Urinary Excreti on of Nadolol After a Single Oral Dose (80mg) in Patients with Varying Degrees of Renal Function

Patient Group	Creatinine Clearance (ml/min per 1.73 m^2)	Amount Excreted (mg)
I	58	9.2
II	34	5.1
III	11	3.9
IV	2	0.6

Drug Elimination

Renal diseases affect the elimination of a drug based on the renal status of the patient and the elimination properties of the drug.

In patients with normal renal function, drugs A, B , and C are eliminated by renal excretion up to 90%, 50%, and 10%, respectively. If drug B is given through parenteral route to patients with normal renal function, the amount of unmetabolised drug is found in the urine corresponding to 50% of the dose. It is considered that the non -renal clearance of these drugs does not get affected by kidney disease and linear relationship exists between the renal clearance and creatinine clearance, as per the **equation (1)**.

Total clearance = A × Creatinine clearance + Non-renal clearance …..(2)

Under such conditions, the total clearance of the drug from blood or plasma also linearly depends on the creatinine clearance (**figure 18.7**).

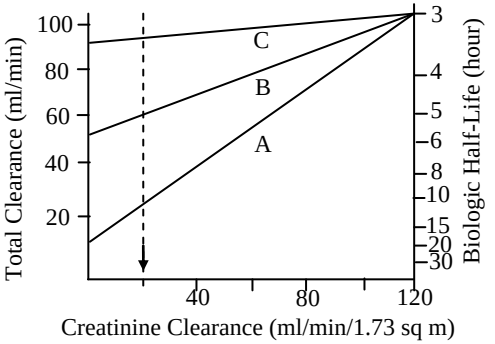


Figure 18.7: Relationship between Total Clearance and Renal Function (Creatinine Clearance) for Three Drugs Excreted in Urine to Different Degrees in Patients with Normal Renal Function. Vertical Line Shows Clearances and Half-lives when Renal Function is reduced to One-Sixth of Normal. Renal Disease has the Largest Effect on Drug A and the Smallest Effect on Drug C.

Drug A is largely (> 80%) excreted unchanged as shown in **figure 18.7**. **Examples** of such drugs are most cephalosporin s, penicillin, and aminoglycoside antibiotics, ethambutol, flucytosine, vancomycin, lithium, most diuretics, and some newer antibiotics, moxalactam and cefoxitin. In anephric patient s, the total clearance of the se drugs will be <20% as calculated in patients with normal renal function.

Drug B is excreted unchanged in urine to the extent of 40 -75% of the dose as shown in **figure 18.7**. **Examples** of such drugs are d igoxin, nadolol, and cimetidine. In anephric patients, the steady-state levels of these drugs are 2 -4 times higher than in patients with normal renal function, unless the dosage is adjusted.

Examples of drugs that metabolise predominantly (> 80%) or otherwise eliminated by non-renal mechanisms include most anticonvulsants, neuroleptics, antidepressants, digitoxin, chloramphenicol, and theophylline.

Dosage Regimens

In patients with impaired renal function, the half-lives of some drugs are changed sufficiently to allow a change in the usual dosage regimen to prevent the accumulation of the drug up to toxic levels.

For example, in patients without renal impairment, cephalexin is taken as a 250 mg to 1gm dose in every 4-6 hour and its average half-life is about 0.5-1 hour; while in patients with creatinine clearance of 10-15ml/min, the half-life of the drug increases almost 8 times because cephalexin undergoes urinary excretion in almost unchanged form. In such an extent of renal impairment, the suggested dosing frequency is the usual dose every 24 hour at a dosing interval of 4-6 times longer than usual. The same approach has been followed for amoxacillin and procainamide.

In patients with normal renal function, the average half-life of digoxin is 1.6 days, which increases to 4.4 days in anephric patients. Normally, the maintenance dose of digoxin ranges from 125-500μg/day. However, in patients with little or no renal function, the daily maintenance dose of digoxin should be only 1/3rd to 1/5th of that given to patients with normal renal function.

Renal excretion is an important factor in the elimination of currently available histamine H_2-receptor antagonists. If cimetidine is given intravenously, almost 75% of it is excreted unchanged in urine. In patients with normal renal function, almost 70% of ranitidine is eliminated by urinary excretion. Around 2/3rd of an oral dose of nizatidine and 65-70% of an intravenous dose of famotidine is excreted unchanged.

Enalapril inhibits the activity of angiotensin-converting enzyme by the formation of enalaprilat (a diacid metabolite), which is formed in the liver by the hydrolysis of enalapril. Enalaprilat is excreted almost unchanged.

Effects on Metabolised Drugs

In patients with normal renal function, the incidence of adverse effects of some highly metabolised drugs (like phenytoin, clofibrate, and diazepam) is less than in patients with renal function. It may be due to the changes in plasma protein binding that are evident in chronic renal failure. On the other hand, metabolism of drug may be repressed or the pharmacologically active metabolites may accumulate but they are generally excreted in the urine.

Generally, morphine is metabolised extensively; but, in patients with impaired renal function, severe and prolonged respiratory depression is observed when morphine is given because it gets accumulated in renal failure.

Verbeeck and **Branch** reviewed the pharmacokinetic and clinical implications of drug metabolites in renal failure. In **table 18.3**, some clinically important active or toxic drug metabolites that accumulate in renal failure are listed:

Table 18.3: Some Clinically Important Active or Toxic Drug Metabolites that Accumulate in Renal Failure

Drugs	Metabolites
Allopurinol	Oxipurinol
Clofibrate	Chlorophenoxyisobutyric acid
Meperidine	Normeperidine
Procainamide	N-Acetylprocainamide
Propoxyphene	Norpropoxyphene

18.4.4.2. Liver Disease

Hepatic metabolism is an essential s tep of drug elimination, therefore any disease or dysfunction of the liver changes the drug pharmacokinetics. Direct effects of liver disease on the phar macokinetics of drugs are not predictable, however, impaired elimination of some potent drugs in patients with chronic liver disease can be clearly observed.

Antipyrine

To study the effect of liver disease on drug metabolism in humans, a ntipyrine has been used widely as a model drug. It is almost unbound to plasma proteins and tissues, and is mainly metabolised in liver and then eliminated. It shows a low hepatic extraction ratio, and its half -life and clearance are sensitive indicators of liver function w ith respect to oxidative metabolism.

Other Drugs with a Low Hepatic Extraction Ratio

The drug metabolising enzymes found in liver are the rate limiting factor in the elimination of drugs having a low hepatic extraction ratio and the drugs mainly metabolis ed in the liver. The clearance of these drugs should be sensitive to changes occurring in hepatic enzymes secondary to pathological condit ion. A particular liver disease does not affect the pathways of all enzyme s to the same extent. Therefore, in some pat hological conditions, the elimination of drugs with low extraction ratio (**e.g.,** warfarin, salicylate, and phenytoin) remains unimpaired.

Drugs with low hepatic extraction ratios act like antipyrine , therefore their elimination is impaired in patients suf fering from moderate to severe hepatic diseases. In patients with alcoholic cirrhosis, the clearance of **diazepam** is only about half as in same -aged control individuals. The half -life of diazepam increases almost 4 -times over control values because a reduct ion in clearance and an increase in apparent volume of distribution are observed that continue with reduced plasma protein binding of diazepam in the patients of cirrhosis.

In patients with cirrhosis or acute viral hepatitis, **chlordiazepoxide** shows impaired metabolism and changes in volume of distribution, while metabolism and volume of distribution of **oxazepam** or **lorazepam** remain unaffected. Diazepam and chlordiazepoxide are mainly eliminated by oxidative metabolism, while oxazepam and lorazepam are metabolised by glucuronic acid conjugation. Due to these reasons, oxazepam and lorazepam are drugs of choice for the treatment of liver diseases. In patients with liver diseases (mainly liver cirrhosis), the clearance of **theophylline** is reduced.

In a study it was observed that when **cimetidine** is given through intravenous route, its clearance is similar in patients with chronic liver cirrhosis and in control subjects with ulcers; however its non-renal clearance is much smaller in liver cirrhosis patients. On intravenous administration, the apparent volume of distribution of cimetidine is more in liver cirrhosis patients; however in case of oral administration , the bioavailability is almost same (up to 70 -75%) in each case.

In liver cirrhosis patients, the plasma levels of cimetidine after oral administration are found to be higher than in control patients. As compared to healthy individuals, patients with poor liver function show higher serum levels of **sulindac** and its sulphide after a single oral dose.

Fluoxetine is a n ewly synthesised antidepressant, which chemically differs from the large group of tricyclic compounds commonly used to treat depression. It is well absorbed when administered orally, gets 94% bound to plasma proteins, and gets demethylated (pro bably in the liver) into norfluoxetine (an active metabolite). The half - life of fluoxetine is around 4 days and while the half -life of its active metabolite is around 7 days.

High Hepatic Extraction Ratio Drugs

Both liver blood flow and hepatic drug metabolising enzymes are affected due to cirrhosis and other liver dysfunctions. Therefore, the disposition of high hepatic extraction ratio of drugs can be affected in two ways in hepatic disease. If administered orally, the pre-systemic metabolism will be less in a cirrhotic patient as compared to a patient with normal hepatic function, while the similar oral dose shows high blood levels in the cirrhotic patient due to high systemic availability. The clearance of a drug is lower in the cirrhotic patient than in the healthy individual, once the drug reaches the bloodstream. It occurs due to reduced hepatic perfusion and decreased hepatic enzyme activity.

The human liver eliminates **Indocyanine Green** (ICG) very fast; therefore its clearance is used as an indicator for determining hepatic blood flow rate. Once the patients recover from acute viral hepatitis, the disposition of high hepatic extraction ratio drug (intravenous ICG, lidocaine, etc.) is studied.

In patients with alcoholic cirrhosis (580ml/min), the clearance of **propranolol** is found lower than in healthy individuals (860 ml/min). If given through oral route, its systemic availability is found to be 38% of the dose in controlled individuals, while around 54% of the dose in cirrhotic patients. In cirrhosis patients, the steady-state free drug concentration of propranolol after repetitive oral dosing is almost 3 times more as compared to control subjects. It shows more bioavailability, reduced clearance, and an increase in fraction free in the plasma of the cirrhosis patients.

It has been seen that in cirrhosis patients, the systemic availability of oral analgesics increases dramatically. It was revealed in a study with **pentazocine** and **meperidine** given via intravenous and oral studies in patients with moderate cirrhosis and in age-matched healthy subjects that compared to control subjects, there was a 46% decrease in the clearance of pentazocine, a 27% increase in bioavailability, a 36% decrease in the clearance of meperidine, and an 81% increase in bioavailability in cirrhotic patients.

In liver cirrhosis and other liver dysfunctions, if **nifedipine** and related calcium channel blockers are administered through oral route, their bioavailability decrease due to first-pass metabolism.

18.4.4.3. Cardiovascular Disease

Due to decreased cardiac output, hepatic perfusion is generally reduced in congestive heart failure patients. These changes decrease the clearance of propranolol, pentazocine, lidocaine, and related drugs, therefore they are mainly extracted by the liver.

Due to the altered cardiac functioning, concentrations of drug-binding proteins (such as AAG), blood or fluid pH may also get altered, or may produce endogenous binding inhibitors. Such effects ultimately influence drug binding in plasma or tissues. The effect of individual drug can be summarised as:

1) **Lidocaine:** The elimination of lidocaine directly depends on the changes occurring in the concentration of HBF. **Figure 18.8** represents the plasma concentrations of lidocaine during intravenous infusion of 1mg/min to patients with acute myocardial infarction, minimal circulatory disturbance and normal hepatic function, and to cardiothoracic surgical patients with circulatory disturbance, low cardiac output and hepatic dysfunction. Lidocaine concentration is almost 50% more in the group with altered hemodynamics.

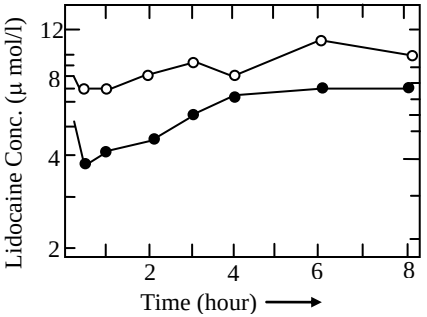


Figure 18.8: Plasma Concentrations of Lidocaine after a Loading Dose and During a 1mg/min Intravenous Infusion in Patients with Minimum Circulatory Disturbance and Normal Hepatic Function (•) and in Cardiothoracic Surgical Patients with Circulatory Disturbance and Hepatic Dysfunction (o)

2) **Propranolol:** Elimination of β-blockers (**e.g.,** propranolol, metoprolol, etc.) is highly sensitive to HBF. The β-blockers are mainly used in the treatment of hypertension. It is found that patients of borderline hypertension often experience high cardiac outputs (111ml/min/kg), while patients of permanent hypertension experience normal or reduced cardiac output (83ml/min/kg). **Weis** and **co-workers** observed that in patients of permanent hyperte nsion, propranolol clearance only occurs up to 50% of that seen in patients of borderline hypertension.

3) **Quinidine and Other Oral Antiarrhythmic Agents:** If quinidine is given by oral route in the treatment of cardiac arrhythmias, around 20% of a dose is eli minated through renal excretion. Quinidine when given intravenously to cardiac patients with and without CHF, its half-life remains almost same in each group (6-7 hours), but its renal clearance is found to be around 50% less and total clearance around 35% less in CHF patients than in control cardiac patients. This shows the need to maintain a small maintenance dose of quinidine in CHF patients.

4) **Prazosin:** It is an antihypertensive drug which is used in the treatment of CHF due to its vasodilatory property. If 5mg of prazosin is administered orally, the total area under the blood level *versus* time curve is found to be two times more in CHF patients than in healthy subjects. The half -life of prazosin is around 6 hour s in CHF patients and 2.5 hours in control subjects.

5) **Theophylline:** In CHF patients, the clearance of theophylline reduces and its toxicity increases.

6) **ACE Inhibitors:** These are preferred for the treatment of CHF. When **enalapril** is administered to CHF patients through oral route, its absorption and th e degree of conversion to enalaprilat are same as in healthy control individuals, while its absorption and hydrolysis are less in CHF patients. Enalaprilat reaches its peak level after 2 hour s later than expected and is around 30% more than that in control individuals. In CHF patients, concentration of enalaprilat remains constantly high when either enalapril or enalaprilat is administered intravenously.

7) **Loop Diuretics:** The diuretic effect of f urosemide and bumetanide is much more than that of the thiazides. They act by blocking active sodium chloride transport in the ascending limb of Henle's loop. They are used to treat CHF, mostly in pulmonary oedema patients and in patients not respond ing to thiazides. In healthy individuals, the bioavailabilit y of **furosemide** is almost 40 -50% when administered orally. Therefore, if given through oral route more amount of drug is needed than intravenous route to achieve the same peak urinary excretion rate.

In the urine of patients, only 23% of the oral dose of **bumetanide** is recovered as compared to 30% in the control individuals; corresponding values for furosemide were 14 and 22%.

In CHF patients, bumetanide and furosemide are absorbed more slowly than in normal subjects. In case of furosemide, the time to peak urinary excretion rate is almost double. This delay is related to 50% decrease in peak urinary excretion rate that indicates a lag in absorption and a reduced absorption rate.

18.4.4.4. Thyroid Disease

Many physiological changes occur when thyroid functioning is altered that consequently affects the drug absorption, excretion, and metabolism:

1) **Absorption:** In hypothyroidism, the bioavailability of **riboflavin** increases while in hyperthyroidism, it decreases due to the altered gastrointestinal motility. If the gut motility reduces after the administration of an anticholinergic agent, riboflavin absorption also increases. In hypothyroidism, the serum digoxin level may be low due to hypermotility and reduced bioavailability.

   In untreated thyrotoxicosis patients, absorption of **acetaminophen** is faster than after treatment. Acetaminophen is slowly absorbed in hypothyroid patients. In hyperthyroidism, the absorption rates of **propranolol** and **oxazepam** increases due to enhanced gastrointestinal motility.

2) **Excretion:** In hypothyroidism, the renal plasma flow reduces; while it increases in hyperthyroidism. The renal clearance of drugs may be affected similarly, but it is not yet established. Many studies are conducted regarding the effects of thyroid disease on renal clearance during the digoxin elimination, but the results are not clearly established.

3) **Metabolism:** Generally, the activity of hepatic microsomal drug metabolising enzymes decreases in hypothyroidism and increases in hyperthyroidism. In hyperthyroidism, the half-life of **antipyrine** is about 8 hours and in hypothyroidism, it is around 17 hours. It is observed that after treatment the half-life values are around 12 hours in each group, within the normal range. Same effects are observed in hypo- and hyperthyroid patients during the elimination of methimazole and propylthiouracil.

Any alterations in thyroid hormone considerably affect the elimination of propranolol. If hyperthyroid patients administer 160mg/day,the steady-state levels of propranolol increase from 38ng/ml when hyperthyroid to 75ng/ml when euthyroid. If hypothyroid patients administer the same dose, a considerable decrease is observed in steady-state propranolol concentrations following treatment with thyroxine, from 117ng/ml to 69ng/ml.

In hyperthyroidism, the oxidative metabolism of antipyrine, propranolol, metoprolol, and theophylline increases while the clearance of other drugs, including diazepam, warfarin, and phenytoin, remains unaltered.

18.4.4.5. Influenza

In **1978**, **Chang *et al.*** studied that the half-life of **theophylline** was prolonged in children with chronic asthma in case of vital upper respiratory infection.

The metabolism of theophylline inhibited in case of influenza infection, may be due to the fever related to the infection.

During the infection and fever, the clearance of antipyrine was only about half of that found in the control individuals.

18.4.4.6. Burn Injury

Many physiological changes occur in case of extensive and severe burns. These changes cause various unpredictable alterations in the drug pharmacokinetics. In some studies, it is also found that glomerular filtration rates increase after burn trauma. This contributes to rapid renal excretion of aminoglycoside antibiotics in burn patients.

A study was conducted in which 14 burn patients were treated for serious gram-negative infections. Administration of normal doses of gentamicin (up to 5 mg/kg/ day) resulted in sub-therapeutic plasma concentrations; peak gentamicin concentrations were constantly below 4 μg/ml. In these patients, mainly in the younger burn patients, the half-life of gentamicin was short.

Acceptable levels of gentamicin were achieved when the daily dose was increased up to 12mg/kg/day in younger patients, and the dosing interval was reduced from 8 hours to 4 hours.

Another study was conducted in 66 burn patients and it confirmed the results of previous study. In this study it was observed that in 75% of the patients, the required doses to achieve adequate drug levels in the serum were greater than that recommended. In 25% of the patients, the dosing intervals of every 4 hour were required; and in 40% of the patients, the dosing intervals of every 6 hour were required.

In case of serious burns, larger-than-average doses of **vancomycin** are also required in some patients.

18.5. SUMMARY

The details given in the chapter can be summarised as follows:

1) A branch of pharmacy termed **clinical pharmacy** is concerned with patient care, dispensing of drugs, and advising patient about safe and rational use of drugs.
2) **Clinical pharmacy** is defined as "the active participation of the pharmacist in patient care with the long-term aim of giving advice on medication with an individual patient in mind and tailoring drug therapy for that individual".
3) **Drug therapy monitoring** involves measurement of drug concentration in biological fluids to optimise a patient's drug therapy.
4) **Medication chart review** is an important responsibility of a pharmacist to ensure the suitability of medication orders.
5) Drug-related problems can be identified by systematic review of each drug order on the patient's medication chart, and this process is referred to as **medication** or **drug chart review**.
6) Medication chart review aims to reduce the risk of medication errors at the time of prescribing and/or drug administration.
7) **Clinical review** is the review of patient-specific clinical information including patient parameters to estimate their response to medication therapies and to detect and manage potential or actual medicine-related problems.
8) A visit made to hospital in-patients at their bedside by a medical practitioner (either alone or with a team of health professionals and medical students) to review and follow-up the progress in their health is termed as a **ward round**.
9) During **pre-rounds**, the patients are reviewed in their unit or ward by the interns or medical postgraduate students in teaching hospitals.

10) During **registrar/resident rounds**, the registrars and residents (either alone or as a team) conduct ward rounds in teaching hospitals atleast once a day at a fixed time (generally in the morning).
11) During **professor/chief rounds**, the chief of a unit or ward or the professor in a field along with their registrars, residents, postgraduate students and interns conducts ward rounds in teaching hospitals for all patients under their car e either daily or for a few days in a week.
12) During **teaching rounds** , the academic medical staff conducts bedside clinical teaching rounds for residents, medical postgraduate students, interns and medical undergraduate students in teaching hospitals.
13) **Pharmacy intervention** is any direct action taken by a pharmacist to change the patient management or therapy.
14) A **medication history** comes under pharmaceutical consultation that identifies and documents allergies or other serious adverse events caused by a drug.
15) The history attained by the medical team and the pharmacist fall into two categories, i.e., **intentional** (when medical team makes a decision of changing the regimen) or **unintentional** (when complete record was not available).
16) **Pharmaceutical care** is a pati ent-centered, outcome -oriented pharmacy practice in which the pharmacist need to work along with the patients and their healthcare providers to promote health, prevent disease, and assess, monitor, initiate, and modify medication use so that safe and effective drug therapy regimens are planned.
17) **Dosing pattern** or dosage regimen is the procedure or routine in which a drug is administered.
18) **Dose size** is amount of drug taken each time.
19) **Dosing frequency** is time interval between doses.

18.6. EXERCISE

18.6.1. True or False

1) Therapeutic drug monitoring involves measurement of drug concentration in biological fluids to optimise a patient's drug therapy.
2) Clinical chart review is an important responsibility of a pharmacist to ensure the suitability of medication orders.
3) Pharmacy intervention is any direct action taken by a pharmacist to change the patient management or therapy.
4) Dosing frequency is time interval between doses.
5) During teaching rounds, the patients are reviewed in their unit or ward by the interns or medical postgraduate students in teaching hospitals.

18.6.2. Fill in the Blanks

6) _____ aims to reduce the risk of medication errors at the time of prescribing and/or drug administration.
7) During _____, the regist rars and residents conduct ward rounds in teaching hospitals atleast once a day at a fixed time.
8) _____ is amount of drug taken each time.

9) A _____ comes under pharmaceutical consultation that identifies and documents allergies or other serious adverse events caused by a drug.

10) _____ is the procedure or routine in which a drug is administered.

Answers

1) False	2) False	3) True
4) True	5) False	6) Medication chart review
7) Registrar/resident rounds	8) Dose size	9) Medication history
10) Dosing pattern		

18.6.3. Very Short Answer Type Questions

1) Define clinical pharmacy.
2) Give a few responsibilities of a clinical pharmacist.
3) What is drug therapy monitoring?
4) Name the types of ward rounds.
5) Give any two issues that may arise during ward rounds.
6) What is dosing pattern?

18.6.4. Short Answer Type Questions

1) Write a short note on the concept of clinical pharmacy.
2) Discuss about clinical chart review.
3) What are the goals and objectives for clinical pharmacists on ward rounds?
4) Write about pharmacist intervention.
5) Give a short note on medication history.

18.6.5. Long Answer Type Questions

1) Discuss in brief about medication chart review.
2) Give a brief review on drug therapy based on pharmacokinetic and disease pattern.
3) Write an illustrative note on ward round participation.

CHAPTER 19

Over the Counter Drugs

19.1. OVER THE COUNTER DRUGS

19.1.1. Introduction

OTC drugs mean Over the Counter d rugs. They are also known as **non-prescription drugs**, and can be sold or purchased without a prescription order.

OTC drugs have minimal abuse pote ntial of the cont rolled constituents and contain formulations with limited amounts of few narcotic drugs , usually for anti -tussive and anti-diarrhoeal purposes.

The most significant difference between non -prescription and prescription medicine is established on the availability of acceptable ways for use under which a layman can use the medicine safely.

OTC drugs are those drugs which can be purchased without a prescription. Few OTC drugs relieve aches, pains, and itches, whereas few of them prevent or tr eat diseases, such as tooth decay and athlete's foot. They also help to manage migraine conditions.

Few **examples** of OTC drugs are painkiller s (like ibuprofen and acetaminophen), decongestants, anti-fungal creams, laxatives, acne creams, and sunscreens.

19.1.2. Sale of Over the Counter Drugs

Prescription drugs come under Schedule H , whereas drugs that can be sold without prescription under certain conditions come under Schedule K or Indian Drugs and Cosmetics Act, 1940.

To be sold as OTC, any product should achieve the following three criteria:
1) It should be safe.
2) It should be effective.
3) It should be for a situation that can be managed by the patient without supervision by a licensed health professional.

OTC drugs can cause si de effects, drug interactions, and disease interactions. Drugs like NSAIDs, gastrointestinals and prochlorperazine, would be unsafe to be used as OTC drugs knowing the different side effects and restriction s related to their daily and chronic use.

Advantages of OTC Sale
Easy availability, accessibility, and less difficulties for the patient.

Disadvantages of OTC Sale
Scheduled and banned drugs can also be sold as OTC drugs. Antimicrobials, tranquillisers, and other drugs with abuse liability can also be s old without prescription. The ancillary cost to healthcare because of this irrationality is terrific , **e.g.,** antimicrobial resistance, medicine dependence (tranquillisers, sedatives, op ioids).

19.1.3. Rational Use of Common Over the Counter Medications

In India, most of the drugs can be purchased over -the-counter without prescriptions, and this result in drug abuse mainly of antibiotics and other potent drugs. In few circumstances, sale of OTC drugs can have lethal penalties, like inappropriate use of anti-diarrhoeal drugs in children. Though OTC drugs aid in places where medicines cannot be easily purchased from pharmacies with prescription, the pharmacist should not prescribe medicines if the diagnosis is unidentified or needs highly potent drugs. However, dispensing of drugs for headache or other minor complications is acceptable.

Vitamin tonics, iron preparations, analgesics, NSAIDs , and cough mixtures are broadly used in the community. The community pharmacists often sell and endorse these formulations without considering whether or not there is a need for treatment. There are two important factors, i.e., patient's desire for treatment (even if it is ineffective), and the pharmacist's desire to please the patient and sell the drug.

Preparations of vitamins are generally endorsed for situations or indications that are not related to vitamin deficiency, such as fatigue, lethargy, anxiety, forgetfulness, stress, menopausal symptoms , and indigestion. The use of vitamins in these situations is unreasonable. Vitamin tonics are generally prescribed as a growth stimulant for children. Children who have a normal well -balanced diet get more than a sufficient amount of dietary vitamins and do not need any extra supplementation.

Children who are undernourished or malnourished can have deficiency of certain vitamins and other micronutrients, and in few cases they are prescribed with adequate vitamin supplementation. Though the sale of expensive preparations of vitamins possess unwanted results due to lack of nutrition education, assumption of parents that there is no requirement of diet modification, and hence do not increase the child's intake of protein, fat and carbohydrate.

Usage of few OTC drugs (NSAIDs and cough mixtures) can be related to serious side effects. NSAIDs give rise to gastrointestinal upset/bleeding, hypertension , and renal impairment. Cough mixtures are frequently formulated as mixtures of various different drugs, each producing specific side effect. Various cough and cold preparations consist of irrational drug combinations, **e.g.,** a mixture containing an expectorant and a cough suppressant.

19.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) OTC drugs mean Over the Counter drugs . They are also known as **non-prescription drugs**, and can be sold or purchased without a prescription order.
2) The most significant difference between non -prescription and prescription medicine is established on the availability of acceptable ways for use under which a layman can use the medicine safely.
3) OTC drugs are those drugs which can be purchased without a prescription.
4) Few **examples** of OTC drugs are painkillers (like ibuprofen and acetaminophen), decongestants, anti-fungal creams, laxatives, acne creams, and sunscreens.
5) OTC drugs can cause side effects, drug interactions, and disease interactions.
6) Scheduled and banned drugs can also be sold as OTC drugs.

19.3. EXERCISE

19.3.1. True or False

1) OTC drugs are also known as prescription drugs, and ca n be sold or purchased without a prescription order.
2) Scheduled and banned drugs can also be sold as OTC drugs.

19.3.2. Fill in the Blanks

3) OTC drugs are those drugs which can be purchased without a _____.
4) OTC drugs can cause side effects, _____, and disea se interactions.

Answers

1) False
2) True
3) Prescription
4) Drug interactions

19.3.3. Very Short Answer Type Questions

1) What are OTC drugs? Give a few examples.
2) Give the advantages and disadvantages of OTC sale.
3) What criteria a drug should meet to be sold as an OTC drug?

19.3.4. Short Answer Type Questions

1) Write a short note on the sale of OTC drugs.
2) Discuss about the rational use of common OTC medications.

19.3.5. Long Answer Type Question

1) Discuss in brief about OTC drugs.

CHAPTER 20

Drug Store Management

20.1. DRUG STORE MANAGEMENT

20.1.1. Introduction

Drug store is an American term used to designate a pharmacy. Drug houses sell medicines and also other items like candies, cosmetics, magazines, and light refreshments.

A drug store has the following **objectives**:

1) It makes a stock of all the drugs and accessories required in the hospital.
2) It obtains drugs from different sources.
3) It supplies drugs to the consuming departments.
4) It stores drugs required in research work.
5) It preserves drugs of some specific categories.
6) It maintains records of receipt and issue of drugs.
7) It saves profits by carrying out the drug operations economically.

20.1.2. Organisation of Drug Store

Planning, **decision-making**, **organising**, **staffing**, **directing**, and **controlling** are the functions required to be managed for organisation management. The management function involves all those activities which are required for making the business economically productive. There should be a proper relationship betw een money, material, equipment, and people for attaining the goals and objectives of an organisation.

Infrastructure of a Drug House

Following are the **factors** which affect the infrastructure of a drug house:

1) Site selection for drug house,
2) Space layout for drug house, and
3) Design of drug house.

20.1.2.1. Selection of Site

Selection of a suitable site is the main objective of entrepreneurs for making their business successful. Site selection is done after taking the decision of opening a community pharmacy, getting r equired qualifications and experience, and achieving the business skill required for creating financial support.

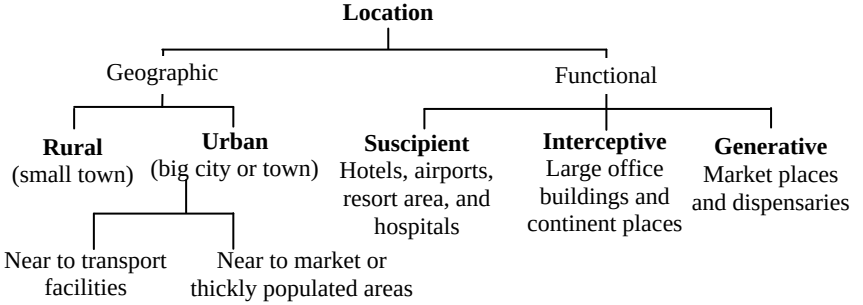


Figure 20.1: Types of Location

Classification of Location

1) **Geographic Location:** This is further classified into the following (**figure 20.1**):
   i) **Rural or Small Town** In this location, one can open their community pharmacy by taking loans from nationalised banks for rural development. Community pharmacy should be open in markets because people come here for marketing and also for meeting the doctor. For proper selling of medications, it is necessary for the pharmacist to maintain a good relation with the people of rural areas by studying their habits and psychology. The purchasing ability of people should also be recognised. From financial point of view, stability of people is the major condition for opening a community pharmacy in the industrial belt. Proper examination of the habits and living standard of the individuals should be done. Areas like highway, rural location, petrol pump, railway station, or bus stand should be selected for opening a community pharmacy, as these are the stopping points for people.
   ii) **Urban Town or Big City:** This location can be further divided into areas near to transport facilities (railway station and bus stop) and areas near to populated markets. Various factors can be measured for opening a community pharmacy in such areas. Densely populated residential area, marketing place, and developing area are mainly selected for a community pharmacy. Buying capacity of the people and developed areas are the factors on which the investment depends.
2) **Functional Location:** This is further classified into the following (**figure 20.1**):
   i) **Suscipient Location:** This location, **e.g.,** hotel, airport, resort area, and community pharmacy in hospitals, attracts the people when they are away from their homes.
   ii) **Interceptive Location:** This location, **e.g.,** community pharmacy in large office building, community pharmacy near to doctor clinics, captures the people on their way to shopping centre and work place. This location is suitable for many people.
   iii) **Generative Location:** This location, **e.g.,** shopping centres and outlaying retail stores, attracts people for the purpose of shopping.

Advantages of Selection of Site

Following are the advantages of site selection for departmental and chain stores:

1) These provide price benefits due to central purchasing at a large scale.
2) These stores afford services of experienced and skilled managers.
3) These stores eliminate the bad debts of items sold on cash basis.
4) These stores compensate the loss of one store by making profits at other stores. Likewise, the unsold stock can be transferred from one chain store to another without any loss.
5) These chain stores offer a wide variety of products to fulfil the needs of customers; **for example,** APC tablets (aspirin, phenacetin, and caffeine) available from different manufacturers.
6) These stores decrease the cost of administration and direction by providing central selection and training to personnel.
7) These chain drug stores are becoming famous in Indian metropolitan cities.

Factors Affecting Selection of Site for a Drug House

1) **Physicians:** Around 70% businesses are originated by prescriptions of more than 3 physicians in any new location. In case physicians are prescribing their own medicine or I.P. product, this creates a competitor for business.
2) **Hospitals:** It is a suitable location for drug store business, in case the hospitals do not have their own drug store; but the physicians should be experienced and also the hospital should have all the required facilities.
3) **Drug Store:** A drug store should be opened away from the competitor; but in case of high potential, such location can be selected for opening a drug store by sharing the market. This is beneficial as in an area having a number of retail drug stores, people

stop to buy drugs with the thought that they can procure all the prescribed medicines from at least one of them.

4) **Flow of Traffic:** It should be avoided to open a drug store near the traffic signals due to parking problems and the problem of one way traffic should also be avoided. The best way is to identify the buying capacity of either left hand side or right hand side of the road, and then deciding accordingly. The buying capacity is high on roads from where people return back home from their work places. Road circles should be avoided due to traffic problems.
5) **Parking:** If anyone is selecting a location for drug store in shopping centre, there should be adequate space for parking.
6) **Near to Hotel, School, Cinema House, or Play Ground:** When the location is near any hotel, proper cleanliness should be maintained; school and playground closeness should be examined correctly; if there are facility of cold drinks and ice cream, drug store should be near to cinema house.
7) **Business Locality:** The rent of this l ocation is very high due to the price of this place; but since large number of people visits such areas, the purchasing power of drugs can be increased by making the shop attractive.
8) **Thickly Populated Residential Areas:** This location is also suitable as p eople can purchase medicines conveniently, like during evening walk.
9) **Developing Areas:** It is the ideal location to fulfil the needs of customers as new areas are developing in cities. In the beginning of business, these areas do not provide any competition.
10) **Special Services:** If anyone desires to provide special services in medicine such as Ayurvedic or Homeopathic drugs, any location can be chosen. Mainly, market place is selected since people always visit these places for marketing.
11) **Customers:** The type of product selling in the market depends on the customers in such location; **for example,** cosmetics and OTC products are sold more in rich areas, and economic products are sold in slum areas, etc.

    If in any location there are people from residents and medica l professional (such as physicians, marketing people of pharmaceutical industry), chances of sales to prescription is less as these people get enough samples from pharmaceutical industry. Any location where customers are getting medical reimburse ment is b est for opening a drug store.

12) **Shopping Centres:** This is the best location but very high investment is needed.

20.1.2.2. Space Layout

Space layout plays a very significant role in running a drug store successfully. For setting up a drug store, the pharmacists have to take a special care about the space layout.

Features of Layout Design

1) It should fascinate a large number of customers.
2) It should increase the sales of store.
3) It should decrease the selling expenses to a minimum.
4) It should provide customer satisfaction.
5) It should project a professional image and improves the overall appearance.
6) It should control the movement of customers within the drug store premise.
7) It should provide surveillance to decrease the chances of pilfer age and theft.
8) It should provide space for reserve stock, office, and resting place for the employees.
9) It should have an adequate entrance for incoming goods.

Parameters for Layout of a Drug House

Following are the parameters which should be considered before designing the layout of a drug house:

1) **Ground Floor:** The drug house should be on the ground floor. Its walls should be made up of cement concrete, the floor should have mosaic tiles, and the internal furnishings should have racks or storage cupboards with glass doors, drawers (for keeping s trips), shelves, and also a suitable area for the refrigerator. The store counters should be made up of wood with a top covering of white sunmica. For staff and customers, a working table, wooden or steel chairs should be available.

2) **Area:** A modern drug hou se should satisfy all the necessities mentioned in the schedule N of The Drugs and Cosmetic Rules, 1945. Minimum 150 sq. meter area is needed to open a retail drug store and 200 sq. meter area is needed to open a wholesale drug store.

3) **Materials for Constr uction:** Generally the material like glass, glazed tiles, and marbles are used for constructing drug store front so that it can be cleaned easily. The floor should be smooth and easy to wash. The walls should be plastered, tiled, or oil painted for maintain ing a smooth durable and washable surface. Sufficient lighting should be made available by fitting a number of hidden tube lights. Adequate lighting system provides a pleasing environment for the customers, the products in the display also look attractive, and also aids in identifying the medicines, thus increasing the efficiency of the store. The lighting should be stable and should not put strain on the eyes.

20.1.2.3. Design of Drug Store

The design of an ideal drug store is given in the **figure 20.2**:

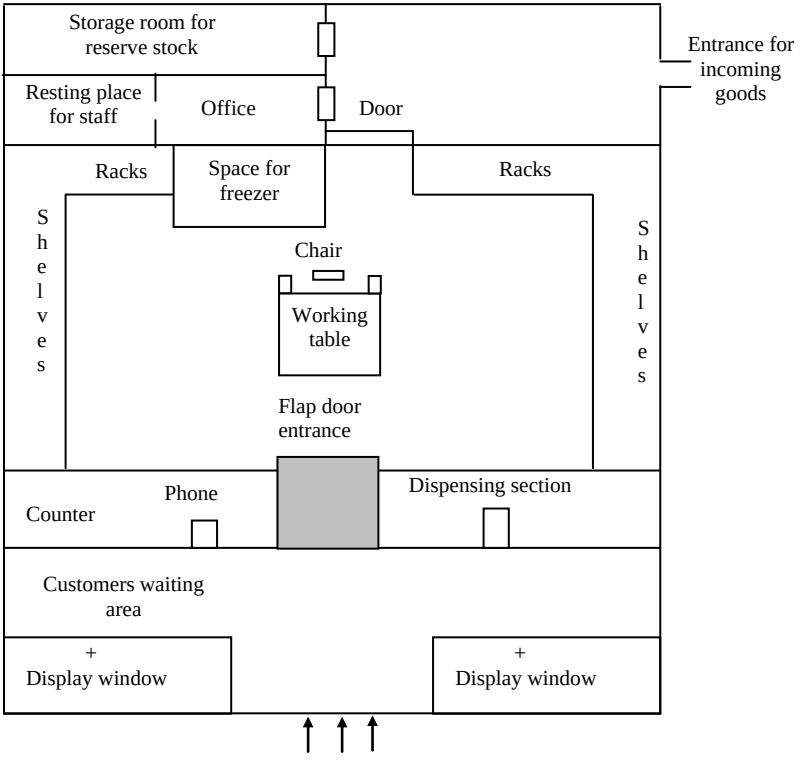


Figure 20.2: Design of an Idea Drug Store

Types of Service Design

Following are the types of service design:

1) **Clerk or Personal Service:** In this service, the customers demand and clerk (or personal service provider) delivers the demanded items. Some items are handled by the customer. This service and design aids maximum interchange between drug store staff and customers. Suitability and friendly service play an important role in the achievement of a drug store. Quality of service should not be compromised. The product price increases in this service because of more service overheads; this is the only **drawback** of this service.
2) **Self-Selection Design:** This design is not beneficial for prescription-oriented drug store; but is appropriate for non-prescription drugs, cosmetics, photo-supplies, greetings, etc. Customers are allowed to handle and select the items themselves. Clerk service is also provided at certain areas.
3) **Self-Service:** Complete self-service in a drug store is not possible due to the prescription department; however in a super drug store where other items are sold, this service is appropriate. The main principle in self-service is central checkout of all purchases.

20.1.3. Types of Materials Stocked and Storage Conditions

It is important to follow the storage instructions from product manufacture depending on which kind of material is stocked. Unlikely if not possible then the product should be stored at optimum conditions and used as soon as possible. For variations in definite storage conditions, the manufacturer of the product should be consulted to decide for how long the product will be safe and potent under the changed storage conditions. Indian Pharmacopoeia defines storage conditions for some official preparations which can deteriorate if not properly stored. It is very essential to follow the instructions provided by the manufacturers for product storage. Different conditions for storage under specified meaning of the Pharmacopoeia are given below:

1) **Store Frozen:** Medicinal products like vaccines are needed to be transported under cold storage conditions and should be stored at –20°C temperature.
2) **Keep Cold:** Some medicinal products should be stored at a temperature not exceeding 8°C (generally between 2-8°C) but should not be frozen. These products should be kept in the first and second part of the refrigerator (never in the freezer).
3) **Storage at Ambient Temperature:** This term is not used much because of major variation in ambient temperatures. It means room temperature or normal storage conditions, i.e., storage in a dry, clean, well-ventilated area at 15-25°C room temperature or up to 30°C.
4) **Protect from Moisture:** These products are intended to be stored in normal humidity at room temperature (relative humidity less than 60%).
5) **Protect from Light:** Medicines which are photosensitive should be stored in a light resistant cupboard/drawer, and should also be provided by the manufacturer in a light resistant container.

20.2. PURCHASE CONTROL

20.2.1. Introduction

Purchasing means to **gain different types of medicines from the external network**. It is a routine function of any pharmaceutical company, and it also represents as one of the tactical avenues of the company. It is very essential for a pharmaceutical company to maintain a proper inventory of different medicines in the drug store and it should also ensure that these medicines are available to the pharmacists at affordable prices. This will assist the management to bring economies in the scale and to be in a better place to strive.

20.2.2. Principles of Purchasing

The principles of purchasing are as follows:

1) **Right Source:** The various factors guiding the selection of the 'right source' are reliability, cost, quali ty assurance, past performance, good public relations, after - sales service, accessibility, etc. Market research is conducted to locate potential sources (vendors) so that monopoly restriction and proprietary conditions are avoided. Source identification involves:
   i) Vendor selection,
   ii) Vendor development, and
   iii) Vendor rating.

2) **Right Quantity:** In order to take a proper decision on the quantity, the purchase manager has to take many aspects into consideration. In this exercise, it is also necessary for the manager to liaise with other departments, mainly, the production department. It is also desirable to conduct inventory analysis and carry out a certain amount of Operations Research (OR) exercises, especially when confronted with the problem of discount offer to select the optimum quantity.

3) **Right Quality:** Quality control and standardisation refers to:
   i) Standardisation and variety reduction, and
   ii) Quality assurance/inspection and grading.

4) **Right Price:** Price means cost of ordering and cost of carrying. Price structure al so influences the 'make or buy' decision. The purchase manager is called upon to decide the most optimum quantity to reduce the overall cost by inventory control. This quantity is obtained through OR and other such techniques. Value analysis is also helpful in deciding the prices. The question ultimately is whether the value for the price is received or not. These analyses are summarised as follows:
   i) **Operations Research on:**
      a) Inventory control, and
      b) Make or buy decision.
   ii) **Value Analysis on:**
      a) Utilisation and substitution, and
      b) Wastage control.

5) **Right Time:** Like correct quantity, right time of supply is also important. Delayed supply can cause shortages, upset production schedule, and might mean tangible and intangible losses. In order to ensure the supply in time, the following steps are to be taken:
   i) An effective method of expediting the supplies should be set up based on the following principles:
      a) Routine reminders on class C items,
      b) Detailed analysis on class A and B items, and
      c) Intensive follow-up on vital and essential items.
   ii) A logistic support should be provided in time for the following:
      a) Assembly/distribution,
      b) Transportation, and
      c) Storage.

6) **Right Place of Delivery:** Items should be supplied by the supplier at the business premises.

7) **Right Mode of Transportation:** The goods can be transported by road, rail , and air as decided by the supplier and purchaser.

In order to achieve the above objectives, certain additional delegations of authority are also needed for purchase managers.

20.2.3. Purchase Procedure

Following steps are involved in the purchase procedure (**figure 20.3**):

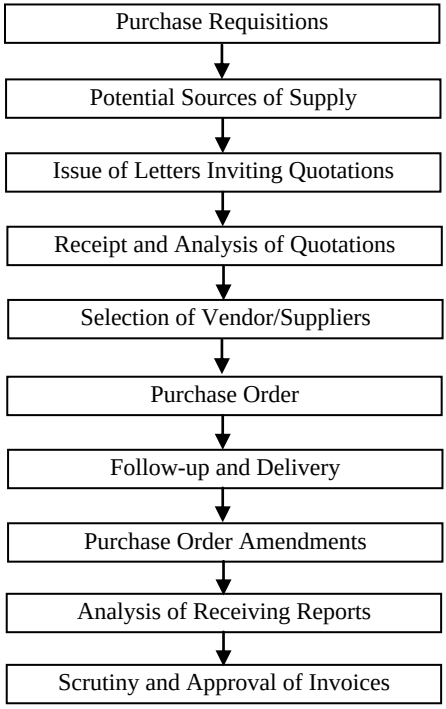


Figure 20.3: Procedure for Purchasing

20.2.3.1. Purchase Requisitions

The receipt of purchase requirement by the purchase department is the green signal empowering it to go ahead with the purchase cycle. The purchase requirement for buying raw/processed materials, components, and other stores are received from production control department or any other user department of the organisation.

The purchase requisition specifically mentions the quality and quantity of the materials required to be purchased as well as the location where they are required to be delivered. Sometimes, with a view of showing the urgency of the materials requisitioned, the concerned department mentions the quantitative balance of such materials remaining with it.

Format of Purchase Requisition

ABC Co. Ltd.
Purchase Requisition

Department……. No……
To be delivered at…… Date……...
……

Please Purchase the items listed below:

Items No.	Quality	Description and Code No.	Purpose

For the use of purchase department only
Purchase Order No..... Requisition by..……..
Delivery date…… Approved by.....

20.2.3.2. Potential Sources of Supply

Once the purchase requisition is received by the purchase department, it starts searching for a prospective vendor capable of supplying the requisite material as per the specifications with regard to the quality and quantity. Most of the purchase departments have a panel of approved vendors for the supply of each item required from time to time by the business organisation.

Such a panel is prepared on the strength of information collected from sources, like advertisements in newspapers, trade journals, buyer's guides, purchase agents and salesmen contacts, etc. It is subjected to periodical review (generally once in a year), during which the names of certain vendors are removed from the panel, whereas names of certain other vendors are allowed to be continued in the panel, depending upon their performance (satisfactory or unsatisfactory) during the year. Names of new vendors are also considered for their inclusion in the panel.

20.2.3.3. Issue of Letters Inviting Quotations

The next step in the purchase procedure is calling for quotations from the panelled vendors. For this, letters indicating the details of the materials required, their quantity, quality, delivery schedule, delivery place, etc. are issued to all the suppliers included in the panel. They are also advised to furnish details regarding any additional charges with respect to packaging, handling, freight, taxes, etc.

With such details in hand, the purchaser is in a better position to take decision and also to obviate any complexity in future. If the purchased material happens to be machines, plant and equipment, the vendors are asked whether they would be in a position to extend services, like technical assistance, training programmes, and after-sales services.

20.2.3.4. Receipt and Analysis of Quotations

Receipt of quotations is closed on the prescribed date and on another prescribed date they are opened in the presence of responsible officers. After a preliminary scrutiny, a chart is prepared, wherein the price, terms and conditions of supply, payment, discount extended, etc. by each vendor are mentioned. This chart (a comparative statement of quotations) is subjected to further analysis in detail and the name of the vendor, who has quoted the lowest price and terms and conditions most suited to the business organisation, is finalised.

20.2.3.5. Selection of Vendors/Suppliers

Selection of a supplier only on the basis of lowest price quoted by him with suitable terms and conditions is not necessarily a correct decision. Certain other factors mentioned below are equally important and need to be taken into account with a view to reduce the total cost of purchase rather than just reducing the unit cost of materials:

1) Reliability of the vendor on the basis of any earlier experience in dealing with the vendor,
2) The supplier's ability to procure and supply the required materials,
3) His willingness to take back the materials, without any trouble, in case they are not in conformity with the specifications or due to other reasons, and
4) The supplier's ability to adjust in a situation, wherein the purchaser is forced to cancel the order due to certain unexpected factors.

20.2.3.6. Purchase Order

After having identified and finalised the name of the vendor/ supplier for purchasing the requisite materials, order is issued by the purchase department, wherein specifications with regard to the materials required, like quantity, quality, rates, delivery schedule, other terms and conditions, etc., are indicated. Once the purchase order is accepted by the supplier, it acts as a contract for the supply of materials on the terms and conditions mentioned therein.

Sometimes, a separate agreement is entered into by the purchaser and the supplier. When a business organisation's requirements for certain materials are in bulk and on an on -going basis, the purchase department issues a purchase order, which includes all the details cited above having the quant ity and delivery schedules. At the time of actual requirement, the purchase department issues the release order and the supplies are made by the supplier.

Big companies make **five copies of the purchase order** . The **original copy** is delivered to the suppli er. The **second copy** is retained by the purchase department for its own file and reference. The **third copy** is delivered to the receiving department as an advance statement to except the materials. The **fourth copy** is delivered to the cost accounting department for entry in the ordered column of the stores ledger account. The **fifth and the final copy** is delivered to the department requesting the material as a statement of the order and estimated date of receipt of materials.

Format of Purchase Order

ABC Co. Ltd.

Supplier…….. No……..……
…… Date……...

Please supply the following materials subject to the term and conditions given on the reverse side of this purchase order.

Quantity	Description	Rate	Amount

Please quote purchase order no. on all advice notes and invoices
Place of Delivery……..
Date of Delivery……... ……
Terms of Payment……. Purchase Manager

20.2.3.7. Follow-up and Delivery

The issue of purchase order is followed by monitoring the process of timely delivery of the materials as per the schedule. So metimes, with a view to ensure the timely delivery, a penalty clause is inserted in the purchase agreement.

However, despite the penalty clause the follow -up and monitoring continues to be vital, as the penalties imposed are not good enough to make the losses incurred due to disruption in the production cycle.

20.2.3.8. Purchase Order Amendments

Wherever required, the necessary modifications (addition of one or more items of material) may be carried out in the original purchase order. However, while doing so, it is necessary to ensure that the delivery schedle is not affected, because of such modifications. In case of any doubt that addition of certain items in the original purchase order may adversely impact the delivery schedule, it is better to place a fresh purchase order for the new items.

20.2.3.9. Receipt of Materials

The receiving department should collect all the arriving material. Functions of the receiving department are unpacking the received goods and validating their amounts and conditions. The amount is validated against the purchase order copy and the advice note of the supplier received with the goods.

Goods received note serves the following purposes:

1) It notifies the store keeper or other requisitionist of the materials receipt.
2) It informs the accounting department that the materials have been received and a voucher can be prepared.

When the voucher contains columns of cost, it can function as a base of entry in the stores ledger. The **original copy** of the goods received note is delivered to the purchase department to be marked finished. The **second copy** is delivered to the store keeper. The **third copy** is sent to the accounting department for entry in the stores ledger and **the final copy** is taken by the receiving department for its own file.

Format of Goods Received Note

ABC Ltd.

Supplier……. No……..
…… Date…….
Advice Note No…… Purchase Order No……..

Quantity	Description	No. of Packages	Gross Weight

Inspection Report

Quantity Passed	Quantity Rejected	Reason for Rejection	
Inspected by……		Date……	Received by ……..

20.2.3.10. Analysis of Receiving Reports

On receipt of materials, they are subject ed to an inspection by the quality control department and verifica tion by the stores department to ensure that the materials delivered are as per the specifications mentioned in the purchase order. Any deviation from the specifications indicated in the purchase order , i.e., shortages or damages, are immediately brought to the notice of the vendor. Necessary steps are initiated promptly, if the consignment is to be rejected due to non -fulfilment of terms and conditions of the purchase agreement. In such cases, the vendor is also requested to supply a fresh consignment in compliance with the terms and conditions.

20.2.3.11. Return of the Rejected Materials

If the received materials are damaged or do not meet the specifications, they are sent back to the supplier together with a debit note, notifying him that his account has been debi ted with the amount of the concerning materials. When this type of claim is accepted by the supplier, he issues a credit note that shows his acceptance. The rejected material should be sent back to the supplier instantly or they can be held awaiting his in structions. Purchase department can prepare the debit note based on the inspection report. The **original copy** is delivered to the supplier. The **second copy** is delivered to the accounts department for adjustment entry. The **third copy** is retained by the purchase department for its own file.

Format of Debit Note

ABC CO. Ltd.

To (supplier)…… No.....
……. Date……

We are debiting your account with the value of under-mentioned materials for the reasons stated. Meanwhile, we wait for your instructions.

Quantity	Description	Rate	Amount

Reasons…… Date received……..
…….. Goods received Note No……

Purchase Order No…….. ……
Supplier's Invoice No…….. Signature

20.2.3.12. Passing Invoices for Payment

After the purchasing department receives the invoices, the procedure of preparing the business paper related to every purchase and voucher preparations starts. The invoices are serially numbered and entered in the invoice register.

The following **documents** are gathered to support the invoice:

1) Purchase order,
2) Goods received note,
3) Inspection report, and
4) Debit/credit note.

These documents are compared with the invoice and if the invoice is found to be in order, it is signed by the purchase manager and moved to the accounts department for payment. Prior to the voucher authorising payment is prepared , all calculations are checked. All associated documents, such as purchase order, goods received note, etc., are marked with the invoice number to prevent duplication of invoice.

20.2.4. Procurement and Stocking

In view of the ever developing sophistication, modernisation, automation and upgradation of manufacturing technologies competing env ironment, an efficient procurement system is the only way to improve access to medicines for the majority of the population within the given budgetary ceilings. Since availability of financial resources is always a constraint for developing countries, it b ecomes all the more important to improve efficiency in all aspects of management in the countries.

The procurement of drugs is dictated by a number of factors:

1) Estimating quantity of each drug required at a given period,
2) Assessing cost of drug dosage form required, and
3) Allocating resources to each drug dosage form depending on priority and resources.

The requisition of drugs and dosage form has to come after consultation with the drug prescribers.

Good Pharmaceutical Procurement Practices

1) Procurement by generic names,
2) Procurement limited to essential drugs,
3) Procurement in bulk,
4) Procurement supplier quantification,
5) Competitive procurement,
6) Order quantities based on reliable consumption needs,
7) Reliable payment and good financial mechanism,
8) Transparency and written procedures,
9) Separation of key functions,
10) Product quality assurance,
11) Annual audit, and
12) Regular reporting on procurement performance.

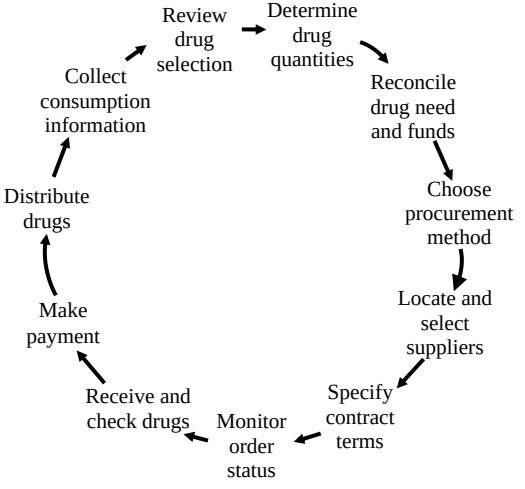


Figure 20.4: Drug Procurement

Stocking

Drug stores should have a system for stocking medicines, and should ensure that all employees know the system being used.

Some common systems for arranging medicines include:

1) **Alphabetical Order:** This method involves alphabetical arrangement of medicines (by their generic names) in the drug house. It is beneficial for the stores to keep small number of drugs. In case of any change in the list of essential medicines or for the medicines which are less consumed , it is necessary to rearrange the medicines in alphabetical order. The main drawback of this m ethod is that it does not utilis e the available space in effective manner.

2) **Dosage Form:** This is the method in which the medicines are ar ranged as per the dosage (i.e. consumption). This method is suitable for smaller drug store. The tablets and capsules are stored together having distinct area for oral l iquids, injections, creams, ointments, and topical liquids. The medicines may be stored in a fixed, fluid or semi-fluid form within each dosage form. The main **advantage** of this method is that the identification of the medicines becomes easy a nd it also mak es the best utilisation of the available space.

3) **Random Bin:** This refers to a distinctive storage space recognised by a code. In other words, a particular s torage space or cell is recognis ed with a code related to its aisle, shelf and position on the shelf. Computer is used to regulate this method. **For example,** a shelving unit can be classified vertically and horizontally into cells, each with a different code location.

4) **System Level:** In this method, the items used in the health care system are collectively organised. This method is beneficial when the kits are to be stored.

5) **Frequency of Use:** This method takes into consideration the pharmaceutical product which requires freque nt movement from the drug store, and should be kept in front of the room or close to the displayed area. This method can be used in combination with other method of codification.

6) **Commodity Code:** The article and location code of every system is different. The location code is completely independent of the article code and is alike to rando m bin method. The change in the list of essential medicines can be presented by giving different article code to new medicines. In this meth od, the store-keeping staffs do not require to possess any technical knowledge of the pharmaceutical products as every information for proper storage of drugs is enclosed in the codes of the medicines, like temperature required, level of security, flammability, pack size, pharmaceutical form, etc. This syste m can perform well in computeris ed inventory control system and can be used in small stores as well as for large stores.

20.3. INVENTORY CONTROL

20.3.1. Introduction

The procedure of handling inventory of medicines, chemicals or drugs so as to fulfil the demand of the customers at comparatively lower prices and with less amount of investment is called **inventory control** . Inventory is a manageable factor amongst all other factors that are pre sent in a drug store. To minimis e the cost of purchasing and storing of goods , the drug store plans how much invest ment to make on inventory, what to order, when to order, and how much to order. Inventory control prevents the drug store from the variations in the demand and supply. It also prevents the uncertainty and reduces the waiting time.

Objectives

1) It ensures constant delivery of materials , spares, and finished goods , so that production should not suffer and the public demand should is also met.
2) It avoids over-stocking and under-stocking of inventory.
3) It keeps the material cost under control so that they can con tribute in lowering production and overall costs.
4) It diminishes losses due to deterioration, pilferage, wastages, and damages.
5) It safeguards continuous inventory control so that the materials shown in the stock ledgers are actually in the stores.
6) It ensures right quality goods at affordable prices.
7) It maintains investments in inventories at optimal level as needed by the operational and sales activities.
8) It eradicatesorder duplication or replenishing stockswith help of centralising purchases.
9) It facilitates data delivering for short- and long-term planning and inventory control.
10) It designs suitable organisation of inventory. A proper accountability should be fixed at different levels of management.

20.3.2. Methods Used for the Analysis of the Drug Expenditure

Various methods used for analysing drug expenditure are:

1) ABC analysis,
2) Economic order quantity,
3) VED analysis,
4) Perpetual inventory system,
5) Review of slow and non-moving items,
6) Input-output ratio analysis (I-O ratio),
7) Setting of various levels, and
8) Scrap and surplus disposal.

20.3.2.1. ABC Analysis

In material management, the system of evaluating the drugs present in the stores on their cost price is known as **ABC analysis**. This analysis supports in finding the drugs that needs more attention to be controlled. Depending on the annual expenditure on the drug, these are classified into three groups, i.e., A, B, and C.

Category A of the ABC analysis carries maximum amount of the total stock of drugs. Therefore, if the drug store wants to take benefits from these drugs in terms of money, they need to manage these drugs properly. To reduce the cost of acquiring, storing and issuing of drugs, right supervision is required. In **category B**, comparatively less supervision is required and the orders are required to be placed semi-annually or quarterly. In **category C**, the drugs are bought in large quantity and therefore, its control is leveraged.

The calculation of annual expenditure is done by multiplying the annual consumption from its unit c ost in ABC analysis. The cumulative cost of drugs was calculated by organising the Annual Drug Expenditure (ADE) in the descending order according to the value of money. Cumulative total was considered as 100% while measuring percentage of money paid for a cquiring each drug. The drugs are then categorised into three groups (A, B, and C) depending on the value spent on these drugs , around 70%, 20%, and 10% of ADE value. Still, there is a difference in the cut-off amount of drugs.

Following are the three groups in which the items are categorised in ABC analysis:

1) **A** - (Highest annual usage) around 10-20% of the drugs cost for 70-80% of the resources.
2) **B** - (Moderate annual usage) 10-20% of the drugs consume 15-20% of the resources.
3) **C** - (Low annual usage) remainin g 60 -80% of dru gs consume about 5 -10% of the resources.

Based on ABC analysis, an average pattern of percentage of item and percentage of their respective rupee values can be worked out as follows:

Class	Percentage of Items	Percentage of Rupee Value
A	10	70
B	20	20
C	70	10

The percentage of resources utilised is comparatively low when huge amount of items are there and *vice-versa*. Representation of the drugs is done as category 'A' as high cost centre, category 'B' as intermediate cost centre, and cat egory 'C' as low cost centre. Given below are some guidelines related to inventory control which will ensure best position of the system:

Table 20.1: Classes of Items

A	B	C
1) Close control	Moderate control	Loose control
2) Order size of drugs is based on the calculated requirement	Order size of drugs is based on the usage	Order size of drugs is based on the level of inventory
3) Chemicals are procured from different sources	Chemicals are procured from a few sources	Chemicals are p rocured from very few sources
4) Records of receipt and usage are kept	Records of receipt and usage are kept	No such records are kept
5) Major focus is to reduce lead time	Moderated focus	Minimum focus
6) Close checks on schedule revision	Some checks on changes in need	No checks against need
7) Frequent ordering	Less frequent ordering	Bulk ordering
8) Continual expediting	Expediting for prospective shortag	No expediting
9) Accurate forecasts	Less accurate forecasts	Approximate forecasts
10) Low safety stock for less than 2 weeks	Large safety stock for up to 2 -3 months	Large safety stock for more than 3 months
11) High consumption value	Average consumption value	Low consumption value.

Steps to Perform ABC Analysis

1) The number of drugs bought and their unit cost are listed down.
2) The quantity of drugs consumed in a span of one year is recorded.
3) The amount of drug consumption is measured.
4) The percentage of total cost of each drug is measured.
5) The list is rearranged and the items are kept in descending order of value, starting at the top with higher value.
6) The cumulative percentage of the total drugs should be calculated. The first item should be at top adding the percentage of the drugs below in the list.
7) The cut-off points or boundaries for A, B and C drugs are selected.

Advantages of ABC Analysis

1) **Level of Control:** As drugs falling under category A demand more control, with the help of this analysis, they can be rightly allocated in drug store. Proper planning can be done in respect to level of control that needs to be assigned to each category so that the resources rel ated to drugs do not go waste. Thus, c ost related to control can be saved by avoiding too much control over the category C drugs.
2) **Careful Accounting:** Category A drugs acc ount for a greater significance over other categories, so their accounting should be done such that no misstatements are left. Some leverage may be considered while accounting for category B and C drugs.

3) **Safety Stock:** Safety stock is a must for all the three categories of drugs. This stock of drugs should be kept to meet sudden demand and the delay in the lead time. This ensures that the demand will be met all the time as adequate stock of drugs is kept for all the materials and the emergencies are duly met.
4) **Quantity Discount Factor:** Certain discount offers are often available regarding the drugs of category A, so the purchase manager before placing the order should verify, whether the same are fruitful or not.
5) **Layout of Stores:** Under a good layout, fast moving items should be easily approached and the issue could be made in no time. Drugs under the category A are highly priced and fast moving by nature, and thus are also categorised as F (Fast) and H (High cost) category. Under a good layout, drugs can be tracked and timely reported. Category C drugs which are not required that often are usually stored at back which may not be even easily accessible. Category B drugs thus find a moderate location for the layout.

Disadvantages of ABC Analysis

1) In big industries, there are a large number of drugs, so the recording and calculations become very difficult.
2) Only the value of drugs is taken as the base. Their importance in production is not considered.
3) Proper consideration is not given to price fluctuations, seasonal variations, and consumption pattern.
4) Increased stock of drugs of category C may lead to deterioration and obsolescence.
5) Modification in some items falling in category B drugs could be very important.

20.3.2.2. Economic Order Quantity

Ordering costs and carrying costs of drugs are taken into consideration while determining economic order quantity of a drug store. Ordering cost is basically the cost associated with receiving an inventory, while carrying cost includes handling warehousing and allied costs. Imbalance between these two costs can adversely affect the profits, so balance needs to be maintained besides keeping both of them at a minimum level.

The point at which ordering cost of drugs is equal to carrying cost of drugs is called **EOQ**, which can also be determined from the graph shown. Assuming that inventory is allowed to fall to zero and then immediately replenished, the average inventory becomes EOQ/2.

EOQ model can be presented in **figure 20.5**.

In **figure 20.5**, it can be observed that when the size of the order increases, the ordering cost of drug decreases. This is the result of large order size, the total number of orders will decrease and similarly the ordering cost.

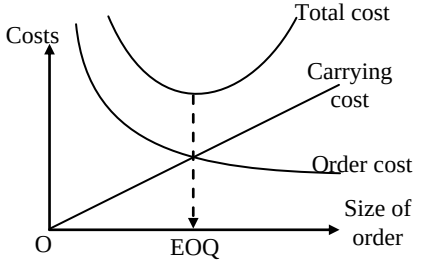


Figure 20.5: Graphical Presentation of EOQ

But at the same time, because of high inventory levels of drugs, the carrying cost is bound to increase. The point of intersection results in EOQ and at this point both costs are equal and the total cost is at the lowest level. One of the methods evaluated for computing shortage costs is based on the drug's average acquisition price, since this is the minimum measure of how much a pharmacy is willing to spend to avoid a shortage of drugs.

Shortage costs are also computed using the cost to operate a pharmacy. This method is based on the assumption that the value of pharmacy's capabilities is equivalent to the amount of money the pharmacy is willing to spend to operate.

There are several other mathematically intensive, time weighted methods for calculating these costs, but it should be kept in mind that there is a cost for running out of items in one pharmacy and one should consider those costs while seeking to control the inventory.

Types of Costs Used in EOQ

1) **Ordering or Procurement Cost:** This cost refers to the cost involved in the reordering of stock of drugs. It involves handling and chasing of the purchase order, transportation, assessment of quality, accelerating unpaid orders, etc. This cost requires lots of time of pharmacy or drug stores.
2) **Carrying or Holding Costs:** This cost refers to the cost incurred in carrying or storing the stock of drugs purchased in bulk. It involves cost of warehouse, like rent, utilities and salaries, financial cost (like opportunity cost), and cost of inventory (like perishability, leakage, and insurance).

Inventory Carrying Cost

Carrying cost refers to the cost which is incurred due to storing of drugs in an inventory. It is also popular by the name of **holding cost** or **storage cost**. The carrying cost is equal to the amount of inventory and the time period until which it is stored. The **elements of carrying cost** include:

1) The opportunity cost of capital invested in the stock.
2) The costs directly linked/related to storing goods, like storemen's salary, rates, heating and lighting, racking and palletization, protective clothing, store's transport, etc.
3) The obsolescence cost including the scrapping and possible rework.
4) The deterioration costs and costs incurred in preventing deteriorations.

The carrying cost is generally exhibited in the form of rate per unit or as a percentage of inventory value. It is assumed to be fixed for each unit of certain product of inventory store for a unit time. It consists of the following:

1) **Opportunity Cost:** This cost refers to the cost showing the return on investment the firm would earn if the money had been invested in better profit bearing economic activity, like in stock market instead of inventory. The cost is usually based on the standard banking interest rate.
2) **Warehousing Cost:** This cost refers to the sum paid in the form of fee for the storage of drugs in a third party's warehouse. If the company has its own warehouse, it has to bear space and equipment costs, personnel wages, insurance on inventories, maintenance costs, energy costs, state taxes, etc.

Calculation of EOQ

EOQ may be calculated with the help of the following formula:

$$EOQ(Q) = \sqrt{\frac{2DO}{h}}$$

Where, D = Demanded annual quantity (in units)
O = Cost of ordering/placing (fixed cost)
h = Cost of holding one unit/Annual carrying cost per unit.

Calculation of Number of Orders

$$\text{Number of Order per Year} = \frac{\text{Annual Demand}}{\text{EOQ or Q}}$$

Calculation of Total Inventory Cost

Particulars		₹
1) Cost of Material	D × P	xxx
2) Ordering Cost per Annum	$\frac{D}{EOQ} \times O$	xxx
3) Carrying Cost per Annum	$\frac{EOQ}{2} \times h$	xxx
Total Inventory Cost		**xxx**

Example 1: A pharmaceutical company annually uses 24,000 units of s yringe costing 2.5per unit. Considering each order costs 30 and the carrying costs are 15% per year per unit of the average inventory. Find the EOQ.

Solution: Annual Consumption (D) = 24,000 units,
Ordering Costs (O) = 30 per unit

Inventory Carrying Costs (ic) = 2.5 per unit
Now,
h = ic = 15% per year per unit of average inventory
= 0.15 × 2.5 = 0.375

$$EOQ = \sqrt{\left(\frac{2DO}{h}\right)} \quad EOQ = \sqrt{\left(\frac{2 \times 24000 \times 30}{0.375}\right)} = 1960 \text{ units}$$

Example 2: Following information relating to a type of medicinal containers is available.

1) Annual demand	4,800 units
2) Unit price	2.40
3) Ordering cost per order	8.00
4) Storage cost	2% p.a.
5) Interest rate	10% per annum
6) Lead time	Half month

Calculate EOQ and total annual inventory cost from the above information.

Solution: $EOQ = \sqrt{\frac{2DO}{h}}$

Annual Demand (D) = 4,800 units

Ordering Cost (O) = 8 per order

$$\text{Carrying Cost (h)} = \left(2.40 \times \frac{2}{100}\right) + \left(2.40 \times \frac{10}{100}\right)$$
$$= 0.048 + 0.24 = 0.288$$

$$EOQ = \sqrt{\frac{2 \times 4{,}800 \times 8}{0.288}} = 516 \text{ units}$$

$$\text{Number of Orders} = \frac{\text{Annual Demand}}{EOQ} = \frac{4{,}800}{516} = 9.30$$

Total Inventory Cost = Cost of Material + Ordering Cost + Carrying Cost
$$= (4{,}800 \times 2.40) + \left(\frac{4{,}800}{516} \times 8\right) + \left(\frac{516}{2} \times 0.288\right)$$
= 11,520 + 74 + 74 = ₹11,668

Assumptions of EOQ Model

Following assumptions are made while calculating EOQ:

1) Supply is available in the market and drugs can be procured whenever required.
2) The quantity to be procured is pre-decided.
3) The prices of drugs are constant.

Advantages of EOQ Model

EOQ model is the mathematical approach to determine the inventory levels. Various advantages associated with this model are given below:

1) The mathematical approach helps in reducing personal bias and makes decisions more factual.
2) The mathematical approach is more reliable.
3) The use of formulas is useful if it is planned to use computers for calculation purpose. It is helpful in calculating the inventory level with the use of formula in the computer.
4) For normal conditions, the formula does not need to be moderated.
5) This model is used by various business departments, such as production department and inventory department.
6) It can be used for making reliable estimates.
7) It can be used for creating automatic charts as the formula can be used for calculating reorder point and lead time.

Disadvantages of EOQ Model

1) **Erratic Usages:** It assumes that the usage of materials can be predicted and evenly distributed throughout the year. So, even a slight deviation will make the formula of EOQ unfit and in reality such situations do not exist. In order to cover such situations, some more formulas need to develop, which will make this more complex.
2) **Faulty Basic Information:** Two main components on which the calculations of EOQ are based are ordering cost and the carrying cost. So, EOQ can be ascertained only if correct figures of ordering cost and carrying cost are available. Practically, this may not be possible as they cannot be calculated accurately all the time. They may vary from product to product, and thus in many cases the formula will not give true results.
3) **Costly Calculations:** Estimation of ordering and carrying costs is not easy, it requires services of professionals. Simple calculations are time consuming and complex formula is rather expensive. In most of the cases, the cost involved exceeds the benefits derived and value for money is not achieved.
4) **No Formula is a Substitute for Common Sense:** Sometimes, the underlying conditions are such that no formula is as useful as the common sense. Majority of the businesses today rely on their instincts and past experience for such a judgement.
5) **EOQ Ordering must be Tempered with Judgement:** Few corporate operating goals should be observed while preparing inventory control. These goals may sometimes contradict with the ordering but still emphasis should be given to these goals. Following might be included in EOQ restrictions:
   i) Those items that undergo constant technological changes should not be put under the ambit of EOQ.
   ii) Items having a lesser shelf-life should also be avoided under EOQ method.
   iii) Sales of items that is not constant throughout the year does not fit under the concept of EOQ.
   iv) EOQ cannot be followed in case of items which are critical in nature and often experience shortage.

20.3.2.3. VED Analysis

This analysis depends on the crucial values and the shortage cost of drugs. The drugs are categorised into the following three groups:

1) **Vital (V):** This category contains medicines/drugs that are necessary for the life of patients and needs to be present all the time in the hospital. These medicines/drugs are like oxygen that is very important for the working of the health care formation. If there is a shortage of these drugs it will hamper the daily working of the drug store.

2) **Essential (E):** This category contains medicines/drugs which are comparatively less crucial. Categorisation of these drugs is done according to the urgency of the stock. For short period of time, the scarcity of drugs can be managed like scarcity of intravenous sets & IV fluids in a hospital. However, it will badly influence the working of hospital if this scarcity sustains for a longer time period.

3) **Desirable (D):** This category contains medicines/drugs which are not crucial. Shortage of these drugs does not cause any harm to the life of the patient. If the scarcity of these drugs is for a long time, then also this would not influence the working of the hospital. **For example,** Vitamin E capsules or sun screen lotions in a hospital's medical store.

Table 20.2: VED Analysis of Medical Instruments

V	E	D
Defibrillator	X-Ray Machine	Air-Contains
Ventilator	Electric Cutlery	Ultrasonic was machine
Oxygen Regulator	Patient Trolley	Electric BP Apparatus

20.3.2.4. Perpetual Inventory System

Perpetual inventory system is a technique of recording the balance of store after every receipt and issue to ease daily checking and to avoid shutting down for stock-taking. The entry is made in the bin card and the balance is adjusted after each receipt or issue. Hence, bin card becomes perpetual inventory record and balance of store is documented continuously after each receipt and issue. All detected errors are adjusted both in bin card and the store ledger under suitable authority.

The perpetual inventory system comprises of the following:

1) **Bin Card:** It is a document maintained by the store-keeper for maintaining record of every material and goods in the store. Hence, bin card provides ready references. The quantities of material received, issued, and in stock are shown in bin card. A bin card is used for every material. Every receipt, issue or return is documented on bin card in a chronological order and the most recent balance is shown after every receipt and issue.

Format of a Bin Card

ABC Co. Ltd.

Bin Card

Description of Material: Bin No.:
Code No.: Normal quantity to order:
Stores ledger folio No.: Maximum stock level:
Re-order stock level:

Date	Receipt		Issue		Balance Quantity
	G.R. No.	Quantity	S.R. No.	Quantity	

2) **Store Ledger:** It is maintained by t he cost accounting department. It is maintained in the form of loose leaf cards because they can be simply removed and inserted. The stores ledger format is as shown as following:

Format of a Store Ledger

X Y Z Co. Ltd.

Stores Ledger Account

Description of Material: Maximum Stock:
Code No.: Maximum Stock:
Bin No.: Re-order Level:
Location: Ordering Quantity:
Unit:

Date	Receipt				Issue				Balance			Stock Verified		
	G.R. No.	Quantity	Rate	Amount	S.R. No.	Quantity	Rate	Amount	Quantity	Rate	Amount	Date	Initial	Remarks

G.R. No. = Goods Receipt Number S.R. = Stock Receipt Number

3) **Continuous Stock-Taking:** In this system, a limited number of products are verified. The items of materials should be selected such that each item of material is yearly tested a definite number of times and the testing of specific item is distributed evenly during the period. The selected number of items is counted every day or at frequent periods. Then the store-keeper compares them with the bin card and store ledger. The balances are recorded in the bin card and store ledger , and by using physical verification their accuracy can be verified. If the recorded balances are found to be varying from the actual balances, the management should be informed about it.

Advantages of Perpetual Inventory System

1) It assists in the detection and instant rectification of clerical errors/discrepancies.
2) It guarantees a reliable and systematic checking of the items in a store without affecting the daily work of the enterprise.
3) It facilitates taking timely action on serious shortages.
4) It provides a moral check on the staff, hence serves as a preventive measure to dishonesty.
5) It helps in collection of profit and loss account and balance sheet on interim dates if needed.
6) It helps in avoiding overstocking and under -stocking because it covers stock verification concerning maximum and minimum stock level.

20.3.2.5. Review of Slow and Non-Moving Items

Inventory is an important part of total cost and a proper inventory control system leads to a significant economy in total production cost. Hence, to detect and control slow moving items, obsolete items and dormant stock , a proper system should be used. The materials which move at slow rat e are known as **slow moving materials.** The materials which move temporarily due to seasonal production are known as **dormant materials**, and the items which are of no use because of change in design, manufacture method, product or process, etc. are known as **obsolete materials**. The slow moving items are to be valued at price, replacement cost or realisable value, whichever is less.

For detecting slow and non-moving items, the following steps can be taken:

1) **Periodic Report:** It is a monthly or quarterly report prepared on the stocks on the non-moving items. This report shows its purchase, consumption and in-hand balance. The periodic report is transferred to the management.

2) **Obsolete Items:** Several slow and non -moving items can become of no use with time. A well -developed information system should be created to find such obsolete items, so that they can be used and their purchase can be stopped.
3) **Moving Ratios:** This is calculated periodically to isolate slow moving items, dormant and the dead stock s. Moving ratios sh ow the income of these items for presenting to the management.

20.3.2.6. Input-Output Ratio Analysis (I-O Ratio)

Input-output ratio is the relation between the quantity of material charged to the production process and the quantity of material in the final output.

For example , 2kg of material A is put in production process and the content of this material in the final product is 1.6kg.
∴ Input-Output Ratio = 2/1.6 × 100 = 125%

Advantages
1) It helps in determining the efficiency of manufacturing department.
2) It helps in comparing the actual utilisation of material with the standard utilisation. It shows that the use of material is favourable or unfavourable.
3) By multiplying the cost of raw materials per unit with the input-output ratio, the cost of raw materials in the finished product can be determined.

Example 3: A drug and pharmaceutical company uses chemical 'A' as a raw material at 10/-per kg. The I -O ratio is 125%. Due to non -availability of this raw mate rial two other substitutes are available as per the following information. Recommend which of the material to be used.

Material	Rate per Kg.	I-O Ratio
A_1	15/-	110%
A_2	12/-	140%

Solution: Since the rate per Kg and I-O ratio vary in case of both the substitutes, the final decision depends on the cost of each of the substitutes in finished product per unit.

$$\text{The cost of the raw material} = \frac{\text{Input}}{\text{Output}} \times \text{Rates per unit in the finished product}$$

∴ The cost of the raw material:
$A_1 = 110/100 \times 15 =$ 16.50 per kg
$A_2 = 140/100 \times 12 =$ 16.80 per kg

Taking into consideration the cost of raw material chemical A_1 is recommended because it is more economical.

20.3.2.7. Setting of Various Levels

For maintaining inventory control, it is essential to choo se different levels of materials, i.e., maximum level, minimum level , and re-order level. These levels are not permanent, but they require revision because of changes in the factors determining these levels.

Maximum Stock Level
It is the wholesaler who holds the stock to a large extent and realise gain from the price fluctuations and not the industry. It carries only that much stock which is required and a few more in case of emergencies.

The maximum stock level for a particular item is fixed after considering the:
1) Consumption rate of material,
2) Available storage space,
3) Amount of capital needed and available,
4) Nature of material,
5) Market trend,
6) Fashion habits,
7) Government restrictions,
8) Risk due to fire, obsolescence and deterioration, and
9) Lead time from the date of placing the order.

Material control thus fixes an upper limit beyond which the inventory level of drugs are not allowed to cross the limit. Such a m aximum ceiling is known as the **maximum level**. It is determined by the following formula:
Maximum stock level = Reorder level + Reorder quantity (Minimum consumption during reorder period × Minimum reorder period)

Or

Maximum stock level = Safety stock + Reordering quantity

Minimum Stock Level or Safety Stock
It stipulates a point below w hich the inventory level in a drug industry is not allowed to fall. When a drug industry carries minimum stock, it rules out the possibilities for stock - out and stoppage of production.

This minimum stock includes a **buffer or safety stock** which is used on ly in case of crisis and variation in the lead time. The f ollowing factors are considered while fixing minimum stock level:
1) **Lead Time:** A purchasing firm needs some time for processing order and supplying firm needs time to complete the order. Hence, **time t aken in processing** and then **executing the order** is known as lead time.
2) **Rate of Consumption:** It is the **average consumption of material s in a factory.** The decision of consumption rate is based on past experiences and production plans.
3) **Nature of Material:** It affects the minimal level. If material is only needed for special orders of customer, minimum stock is not needed for such materials.

Thus, minimum level may be determined by the following formula:
Minimum stock level = Reorder level – (Average consumption × Average lead time)

Or

Minimum stock level = Reorder level – (Normal consumption × Normal reorder period or average delivery time)

Example 4: In a drug store, a medicine is used as follows:

Maximum consumption	24,000 packets per week
Minimum consumption	8,000 packets per week
Average consumption	16,000 packets per week
Reorder quantity	96,000 packets

Time required for delivery – Minimum – 4 weeks; Maximum – 6 weeks. (Emergency period = 2 weeks)

Calculate:
1) Minimum level;
2) Maximum level;

Solution:

1) Minimum level = Reorder level – (Average consumption × Average reorder period)
Average reorder period = (Minimum + Maximum period)/2
= (4 + 6)/2 = 5 weeks
Reorder Level = 24,000 × 6 = 1,44,000 units
Minimum Level = 1,44,000 – (16,000 × 5) = 64,000 units

2) Maximum level = Reorder level + Reorder quantity – (Minimum consumption × Minimum reorder period)
= 1,44,000 + 96,000 – (8,000 × 4)= 2,08,000 units

Reorder Quantity Level

Once the quantity of material reaches a definite figure, new order is sent to get materials again. The order is send before the materials reach minimum stock level. The level of reordering is fixed between minimum and maximum level. While fixing the reordering level, the consumption rate, number of days required to refill the stock, and maximum quantity of material needed on any day are observed.

Thus, reordering level may be determined by the following formula:

Reordering level = Maximum consumption × Maximum re-order period

Danger Level

It is the level outside which materials should not fall in any case. If there is a rise in danger level, instant steps should be taken to refill the stock even though high cost is suffered in arranging the materials. If the materials are not timely arranged, there is a possible chance of stopping of work.

Thus, danger level may be determined by the following formula:

Danger level = Average consumption × Maximum reorder period for emergency purchases

Average Stock Level

The average stock level may be determined by the following formula:

Average stock level = Minimum stock level + ½ of Re-order quantity

20.3.2.8. Scrap and Surplus Disposal

The residue attained in the manufacturing process is called **scrap**. These are the items whose value can be recovered but in a very less amount without being processed further. **For example,** granules that are found in the manufacturing of tablets, packing cases and containers are not to be returned.

The excess of medicines over the required is known as **surplus**. It occurs in a situation when the amount of drugs available in stock is more than the drugs required by the hospitals for their proper functioning.

The **methods of disposal of scrap and surplus** are as follows:

1) The leftover material is sold when it cannot be used for further processing.
2) These materials can be used for further production by converting them into valuable raw material.

The waste represented by the terms **scrap** and **surplus** are subjected to reduction in the amount of profit. The scraps are produced due to the following reasons:

1) Errors in the purchasing process,
2) Incorrect planning process,
3) Wasteful processes in production,
4) Waste which are unavoidable at the time of changes of the equipment, and
5) Problem in productivity.

The unused medicines, OTC personal care products, and sometimes accessories such as sharps, used test strips and other supplies, are the medical waste and are the part of pharmaceutical scrap. These scraps can be harmful to human health and environment.

The pharmaceutical waste needs to be managed carefully as they are hazardous in nature. This includes the waste from hospital, clinic, pharmacy, or private household. Bio-hazardous waste and radiation waste are the different types of medical waste.

If the pharmaceutical waste is not disposed properly it will have harmful effect to the life of humans and environment. Therefore, it is very crucial that these wastes are disposed properly. The results of improper disposal of these wastes are as follows:

1) These wastes pollute the water supplies.
2) The medicines are resold in the market even after their expiry.
3) The waste medicines are burned in an inappropriate manner which may produce toxic elements that are harmful for health.

Methods for Scrap and Surplus Disposal

1) **Return to Donor or Manufacturer:** The unused medicines, especially the medicines with disposal problems like anti-neoplastics can be returned back to the manufacturer. The medicines which are expired or near to be expired should be given back to the donor for disposal.
2) **Landfill:** For disposing solid waste, landfills is the most ancient and most commonly used method. In landfills the waste are directly disposed into the land, in the land disposal site without any treatment.
3) **Waste Immobilisation:**
   i) **Encapsulation:** In this method, the pharmaceutical wastes are kept in a hard box inside a plastic or steel drum. The drum in which the waste is placed should not contain any dangerous and hazardous materials, and to ensure this the drums are washed properly before use. 75% of the drum capacity is filled with solid and semi-solid pharmaceutical waste and the remaining 25% is filled with a mixture of cement or cement/lime.
   ii) **Inertization:** In this method, the pharmaceuticals are unpacked which means the packaging materials, paper, cardboard and plastics are taken off from these products. These pharmaceutical products are then crushed and mixed into the mixture of 15% water, 15% cement, and 65% lime to form a homogenous paste. This paste is converted into the liquid form to a landfill and then poured into waste.
4) **Sewer:** The medicines or drugs, like syrups and intravenous fluids, are thinned with the help of water and are flushed into sewers. These liquid pharmaceuticals are decomposed over a period of time in small amounts and also do not have any side effects on health of humans and environment. Antiseptics are the **example** of well-diluted liquid pharmaceuticals.
5) **Burning in Open Containers:** The pharmaceutical wastes contain hazardous elements. Therefore, these wastes are not burnt in open containers in a large quantity as it may release ample amount of toxic elements polluting the air. Hence, these wastes are disposed in a small quantity.
6) **Novel High Temperature Incineration:** In this method, the technology used in industries is generally high temperature like the boilers which are used in thermal power stations works at a temperature more than 850°C. **For example,** expired pharmaceuticals, chemical wastes, used oils, etc., are decomposed with the help of cement kilns at a temperature of 1450°C.

7) **Chemical Decomposition:** According to the advice given by the producers, th e chemical decomposition of pharmaceutical products is done when there is unavailability of suitable incinerator. The process of chemical inactivation consumes a lot of time. The inventory of chemicals needs to be always present that are utilised in the treatment. This method is useful when antineoplastic drugs are decomposed in small amounts. But, this method is not applicable when the decomposition of antineoplastic drugs is in huge quantity (around 50kg).

8) **Recycling:** With the help of this process, the waste drugs are reprocessed to increase its original effectiveness like glassware can be formed from the pieces of broken glass. Paper waste, g lass waste, plastic waste, metallic waste , and equipment are the **examples** of recyclable material.

Following table r epresents the disposal methods for different categories of pharmaceutical drugs:

Table 20.3: Disposal Methods for Different Categories of Drugs

Categories	Disposal Methods
Solids	Landfill
Semi-solids	Waste encapsulation
Powders	Waste inertisation, and medium and high temperature incineration (cement kiln incinerator)
Liquids	Sewer and high temperature incineration (cement kiln incinerator)
Ampoules	Crash ampoules and flush diluted fluid to sewer
Anti-Infective Drugs	Waste encapsulation , waste inertisation, and medium and high temperature incineration (cement kiln incinerator)
Anti-neoplastics	Return to donor or manufacturer , waste encapsulation, and medium and high temperature incineration (cement kiln incinerator) (chemical decomposition)
Controlled Drugs	Waste encapsulation , waste inertisation, and medium and high temperature incineration (cement kiln incinerator)
Aerosol Containers	Landfill and waste encapsulation

20.4. SUMMARY

The details given in the chapter can be summarised as follows:

1) **Drug store** is an American term used to designate a pharmacy.
2) **Planning**, **decision-making**, **organising**, **staffing**, **directing**, and **controlling** are the functions required to be managed for organisation management.
3) In **rural or small town** , one can op en their community pharmacy by taking loans from nationalised banks for rural development.
4) **Suscipient location** , **e.g.,** hotel, airport, resort area, and community pharmacy in hospitals, attracts the people when they are away from their homes.
5) **Interceptive l ocation**, **e.g.,** community pharmacy in large office building, community pharmacy near to doctor clinics, captures the people on their way to shopping centre and work place.
6) **Generative location** , **e.g.,** shopping centres and outlaying retail stores, attracts people for the purpose of shopping.
7) In **process or functional layout** , a particular location is provided for similar machines or operation.
8) **Product or straight line layout** is based on the product manufactured.

9) **Combination layout** is a combination of process a nd product layout, thus offers advantages of both the types of layout.
10) In **clerk or personal service** , the customers demand and clerk (or personal service provider) delivers the demanded items.
11) **Self-selection design** is not beneficial for prescription-oriented drug store.
12) **Self-service** in a drug store is not possible due to the prescription department.
13) **Purchasing** means to gain different types of medicines from the external network.
14) Big companies make **five copies of the purchase order** . The **original copy** is delivered to the supplier. The **second copy** is retained by the purchase department for its own file and reference. The **third copy** is delivered to the receiving department as an advance statement to except the materials. The **fourth copy** is delivered to the cos t accounting department for entry in the ordered column of the stores ledger account. The **fifth and the final copy** is delivered to the department requesting the material as a statement of the order and estimated date of receipt of materials.
15) **Alphabetical o rder** method involves alphabetical arrangement of medicines (by their generic names) in the drug house.
16) **Dosage form** is the method in which the medicines are arranged as per the dosage (i.e. consumption).
17) **Random bin** refers to a distinctive storage space recognised by a code.
18) In **system level** method, the items used in the health care system are collectively organised.
19) **Frequency of use** method takes into consideration the pharmaceutical product which requires frequent movement from the drug store, and should be kept in front of the room or close to the displayed area.
20) In **commodity code** method, the store-keeping staffs do not require to possess any technical knowledge of the pharmaceutical products as every information for proper storage of drugs is enclosed i n the codes of the medicines like temperature required, level of security, flammability, pack size, pharmaceutical form, etc.
21) The procedure of handling inventory of medicines, chemicals or drugs so as to fulfil the demand of the customers at comparatively lower prices and with less amount of investment is called **inventory control**.
22) In material management, the system of evaluating the drugs present in the stores on their cost price is known as **ABC analysis**.
23) **Category A** of ABC analysis carries maximum amount of the total stock of drugs.
24) In **category B** , comparatively less supervision is required and the orders are required to be placed semi-annually or quarterly.
25) In **category C**, drugs are bought in large quantity and thus, its control is leveraged.
26) Ordering costs and carrying costs of drugs are taken into consideration while determining economic order quantity of a drug store.
27) **Ordering cost** is the cost associated with receiving an inventory while **carrying cost** includes handling warehousing and allied costs.
28) The point at which ordering cost of drugs is equal to carrying cost of drugs is called **EOQ**,
29) **Ordering or procurement cost** refers to the cost involved in the reordering of stock of drugs.
30) **Carrying or holding costs** refers to the cos t incurred in carrying or storing the stock of drugs purchased in bulk.

31) Carrying cost refers to the cost which is incurred due to storing of drugs in an inventory. It is also popular by the name of **holding cost** or **storage cost**.
32) **Opportunity c ost** refers to the cost showing the return on investment the firm would earn if the money had been invested in better profit bearing economic activity like in stock market instead of inventory.
33) **Warehousing cost** refers to the sum paid in the form of fee for the storage of drugs in a third party's warehouse.
34) **Vital (V)** category contains medicines/drugs that are necessary for the life of the patients and needs to be present all the time in the hospital.
35) **Essential (E)** category contains medicines/drugs which are comparative ly less crucial.
36) **Desirable (D)** category contains medicines/drugs which are not crucial.
37) **Perpetual inventory system** is a technique of recording the balance of store after every receipt and issue to ease daily checking and to avoid shutting down for stock - taking.
38) **Bin card** is a document maintained by the store -keeper for maintaining record of every material and goods in the store.
39) **Store ledger** is maintained by the cost accounting department in the form of loose leaf cards because they can be simply removed and inserted.
40) In **continuous stock-taking** system, a limited number of products are verified.
41) The materials which move temporarily due to seasonal production are known as **dormant materials** , and the items which are of no use because of change in design, ma nufacture method, product or process, etc. are known as **obsolete materials**.
42) **Periodic report** is a monthly or quarterly report prepared on the stocks on the non - moving items.
43) **Moving ratios** is calculated periodically to isolate slow moving items, dormant an d the dead stocks.
44) **Input-output ratio** is the relation between the quantity of material charged to the production process and the quantity of material in the final output.
45) **Maximum stock level** is the wholesale r who holds the stock to a large extent and realise gain from the price fluctuations and not the industry.
46) **Minimum stock level or safety stock** stipulates a point below which the inventory level in a drug industry is not allowed to fall.
47) **Rate of consumption** is the average consumption of materials in a factory.
48) **Danger level** is the level outside which materials should not fall in any case.
49) The residue attained in the manufacturing process is called **scrap**.
50) The excess of medicines over the required is known as **surplus**.

20.5. EXERCISE

20.5.1. True or False

1) Drug store is an American term used to designate a hospital pharmacy.
2) In small town, one can open their commu nity pharmacy by taking loans from nationalised banks for rural development.
3) Interceptive location attracts people for the purpose of shopping.

4) Suscipient location attracts the people when they are away from their homes.
5) Self-selection design is not beneficial for prescription-oriented drug store.
6) Big companies make four copies of the purchase order.
7) The second copy of the purchase order is delivered to the receiving department as an advance statement to except the materials.
8) The fourth copy of the purchase order is delivered to the cost accounting department for entry in the ordered column of the stores ledger account.
9) Carrying cost is the cost associated with receiving an inventory.
10) Bin card is a document maintained by the store -keeper for maintaining re cord of every material and goods in the store.
11) The materials which move temporarily due to seasonal production are known as obsolete materials.
12) Maximum stock level is the level outside which materials should not fall in any case.
13) The excess of medicines over the required is known as scrap.

20.5.2. Fill in the Blanks

14) In _____ layout, a particular location is provided for similar machines or operation.
15) _____ means to gain different types of medicines from the external network.
16) The second copy of purchase order is retained by the _____ for its own file and reference.
17) _____ refers to a distinctive storage space recognised by a code.
18) In material management, the system of evaluating the drugs present in t he stores on their cost price is known as _____ .
19) _____ refers to the cost involved in the reordering of stock of drugs.
20) _____ refers to the cost incurred in carrying or storing the stock of drugs purchased in bulk.
21) _____ is maintain ed by the cost accounting department in the form of loose leaf cards because they can be simply removed and inserted.
22) _____ is calculated periodically to isolate slow moving items, dormant and the dead stocks.
23) The items which are of no use because o f change in design, manufacture method, product or process, etc. are known as _____.
24) _____ refers to the sum paid in the form of fee for the storage of drugs in a third party's warehouse.
25) _____ captures the people on their way to shopping centre and work place.
26) _____ category contains medicines/drugs which are comparatively less crucial.

Answers

1) False	2) True	3) False	4) True	5) True
6) False	7) False	8) True	9) False	10) True
11) False	12) False	13) False	14) Functional	15) Purchasing
16) Purchase department		17) Random bin	18) ABC analysis	
19) Procurement cost		20) Carrying cost	21) Store ledger	22) Moving ratio
23) Obsolete materials		24) Warehousing cost	25) Interceptive location	
26) Essential				

20.5.3. Very Short Answer Type Questions

1) What are the objectives of a drug store?
2) Give the types of location for a drug store.
3) What are the features for layout of a drug store?
4) Draw the design of an ideal drug store.
5) Give the purchase procedure.
6) Draw the drug procurement cycle.
7) What is inventory control?
8) Give the disadvantages of ABC analysis.
9) Define maximum stock level. How it is calculated?
10) What is reorder quantity level?

20.5.4. Short Answer Type Questions

1) Write a short note on the selection of site for a drug store.
2) Discuss about the factors affecting selection of site for a drug store.
3) What are the parameters for layout of a drug store?
4) Write a note on the types of materials stocked and storage conditions maintained in a drug store.
5) What are the principles of purchasing?
6) Write a note on purchase order.
7) Give the different systems of stocking in a drug store.
8) Mention the advantages and disadvantages of EOQ.
9) Write a note on VED analysis.

20.5.5. Long Answer Type Questions

1) Discuss in brief about the organisation of drug store.
2) Give a brief review on purchase procedure.
3) Briefly discuss any two methods used for the analysis of drug expenditure.
4) Write an illustrative note on ABC analysis.
5) Discuss about scrap and surplus disposal.

CHAPTER 21

Investigational Use of Drugs

21.1. INVESTIGATIONAL USE OF DRUGS

21.1.1. Description

The compounds or mixtures that have not been released by the FDA for general distribution and use are the **investigational** or **research drugs**. These drugs have following statement on their labels, "Caution – New Drug – Limited by Law to investigational use".

The investigational drugs are only released to the physicians who sign the suitable food and release form for the manufacturer.

The primary centres for clinical investigations on new drugs are hospitals. The investigational drugs have not been certified for general use and sale in inter-state commerce by the FDA, thus hospitals and their medical staffs have the responsibility to check that proper procedures for use of these drugs by the patients are established.

21.1.2. Principles Involved

The following principles are involved for the use of investigational drugs:

1) An institution being set for investigational drug studies should guarantee that studies like this have adequate safeguards for itself, its staff, the patients, and the scientific integrity of the study. For doing this, the institution should have written procedures and policies for approving, managing, and controlling investigational drug studies.
2) The investigational drug studies should abide by the accepted ethical, legal and scientific standards and should be performed by qualified investigators.
3) In investigational drug studies, the participated patients should freely agree (in writing) to get treated with the drugs. This agreement should be acquired from the patient or his/her legally authorised representative before beginning the treatment. The patient should be well-informed regarding the objectives of study and the related risks and benefits.
4) It is the responsibility of the chief investigator to regulate proper maintenance of the case report forms and other records needed in the study by the institution, drug sponsor, or FDA.
5) The drug control system of institution should have proper packaging and labelling system, ensure enough supply, storage conditions, dose formulation and administration, and inform the nursing staff properly regarding the drug, inventory and control systems concerning investigational drugs.

21.1.3. Guidelines for Institutions

The following guidelines serve as guidance for the institutions to develop investigational drug procedures:

1) As needed by federal regulation, institutions conducting clinical research should have an Institutional Review Committee (known as **Committee on Human Investigation** or **Clinical Research Committee**) to evaluate every proposed clinical research study in terms of its compliance with accepted ethical, legal and scientific standards.

2) Only under the supervision of the members of the institution's professional staff, i.e., the chief investigators or authorised co-investigators, the investigational drug should be used.

3) It is the responsibility of the chief investigator to obtain the written and informed consent the patient to participate in the study. The informed consent process should follow the latest federal and state regulations.

21.1.4. Guidelines for Pharmacist

The responsibility of the pharmacist towards the institution and the chief investigator is to check that the procedures for the control of investigational drugs are developed and implemented. Proposals to achieve this are as follows:

1) A copy of the approved research protocol should be kept in the pharmacy.
2) The pharmacy should use the protocol and additional data provided by the chief investigator to prepare an investigational drug data sheet, containing data related to the use of drug for the medical, nursing and pharmacy staffs. The following elements should be included in the form:
   i) Drug designation and common synonym,
   ii) Dosage form and strength,
   iii) Usual dosage range and administration route,
   iv) Indication,
   v) Expected therapeutic effects,
   vi) Toxicities and their treatment, etc.

21.1.5. Classification

Principles involved in the use of investigational drugs in hospitals supports the following purposes:

1) To establish a classification of drug,
2) To centralise relevant data regarding the drugs available for research,
3) To describe the availability of drugs to staff members, and
4) To establish a single stocking and dispensing unit in the hospital.

A simple classification which can be used by any hospital research program can be categorised as follows:

1) **Class A:** This category should have all the investigational drugs which are in the preliminary experimental stage. In this category, use of drug is generally prohibited to the chief investigator.

2) **Class B:** This category should have all the investigational drugs which have completed the preliminary research stage. In this category, the chief investigator delivers the drugs to the pharmacy department, and these drugs are dispensed only on his written prescription.

3) **Class C:** This category is restricted to drugs approved by the USP, NF or the Federal FDA for commercial supply. In this category, the drugs can be used in the hospital premise or its clinics only if the physician obeys a few particular procedures.

4) **Class D:** In this category, the drugs are formulations which have been approved for hospital use and are listed in the hospital formulary.

Another simple classification which can be used by any hospital pharmacy operation is as follows:

1) **General:** An FDA-approved drug which is considered important for patients' well-being, once approved can be prescribed by all members of the attending and house staff.

2) **Conditional:** Few drugs can be approved for a conditional time of trial. A drug approved for general use by the FDA, but the committee needs to evaluate it for a specific time period prior to final consideration, can be prescribed by all the members of the attending and house staff.
3) **Investigational:** Drugs not approved by the FDA for use, apart from under controlled clinical settings, should be approved by the Research Advisory Committee. A protocol of any study of drugs should be submitted to the pharmacy.

21.1.6. Control

All the investigational drugs should be registered with the PTC. This can be done by a letter from the chief investigator, delivering the following data:

1) New drug number,
2) Generic name,
3) Manufacturer's name,
4) Chemical name,
5) Proprietary name,
6) General chemistry,
7) Pharmacology,
8) Toxicology,
9) Dose range,
10) Administration route,
11) Antidote, and
12) Therapeutic use.

For distributing the above data on an investigational use drugs to different staff doctors and nurses, many pharmacists have produced different forms, and these forms are generally titled as:

1) **Physician's Data Sheet on Investigational Drugs:**
   i) Name of the investigational drugs,
   ii) Manufacturer or other source,
   iii) Strength and form of investigational drug,
   iv) Amount received:
      a) Date received, and
      b) Control or batch
   v) Pharmacologic and therapeutic properties, dosage, precautions,
   vi) Arrangements made for its administration, and
   vii) Investigator's signature.
2) **Nurse's Data Sheet on Investigational Drugs:**
   i) Name of the investigational drugs:
   ii) Manufacturer or other source,
   iii) Strength and form of investigational drug,
   iv) Pharmacologic and therapeutic properties, dosage, precautions,
   v) Arrangements made for its administration, and
   vi) Chief pharmacist's signature.
3) **Pharmacist's Data Sheet on Investigational Drug:**
   i) Investigational drug,
   ii) Manufacturer,
   iii) Chief investigator,
   iv) Date,
   v) Physician,
   vi) Patient, and
   vii) Amount ward.

21.1.7. Identification

While dispensing the class A or class B drugs from the pharmacy, they should be labelled such that they can be differentiated from the routine prescription drugs. In a few hospitals, the labels of investigational use drugs are printed in red ink on white paper stock.

Investigational use drugs can be identified through their:

1) Unique standardised identifier assigned to it,
2) Protocol number,
3) Generic drug name,
4) IRB (Investigational Review Board) number,
5) Label bearing the following details:
   i) Protocol/clinical trial number,
   ii) Name of the product and the salt (if any),
   iii) Dosage/concentration/strength:
      a) For small volume parenterals, total dose per total volume should be the prominent expression of strength, followed by the per ml strength in parentheses.
      b) Units on the label should match the units per dosing instructions in the protocol.
   iv) Formulation (**e.g.,** lyophilised powders, solutions, suspensions, capsules, tablets),
   v) Quantity per container,
   vi) Lot/batch number,
   vii) Expiration/retest date,
   viii) Medication number (required for blinded studies),
   ix) Storage requirements,
   x) CFR statement: Caution: New Drug —Limited by Federal (or US) law to investigational use,
   xi) Sponsor's name and address, and
   xii) The following information may also appear on the label; however, its optional and is added if space is left:
      a) Investigator's name,
      b) Patient number, and
      c) Special warnings.

21.1.8. Role of Hospital Pharmacist

After the pharmacologist proves a new compound to be effective and safe in animal test, clinical trials are started, which are generally continued in two steps, i.e., preliminary and extended. In the **preliminary stage**, the chief investigator carefully administers the drug to a small number of specific patients and closely monitors the results. After gaining experience and confidence in the drug use, the investigator performs an extended comprehensive evaluation of its efficacy.

In the **extended stage**, the pharmacist helps in the development of protocol and control of double blind test/study, in which the experimental drug and placebo are accurately formulated in the same dosage form. Both the patient and the doctor have no idea about the distribution of placebo or potent article. In the following areas, the pharmacist helps the physician, patients, and his/her clinical research team in investigational drug studies:

1) **Assisting in the Development of the Study Design:** The pharmacist helps in the development of the protocol and control of double blind studies, developed by preparing the experimental drug and the placebo in precisely the same dosage form.

The recognised products are delivered to the pharmacist for dispensing according to a predetermined pattern and also to maintain a record that which patient has been administered the true drug and which has been administered the placebo. The patients and the physicians have no idea about the distribution of placebo or potent drug. The trial results are collected. All information for cracking the double blind codes should be stored in the pharmacy. If an emergency occurs, the pharmacist on duty or on call delivers necessary information for cracking the double blind code.

The pharmacist having knowledge of biopharmaceutics, pharmacokinetics, and analytical chemistry can observe the levels of the new drugs in blood and tissues, and their rate of excretion. By observing the se aspects, the pharmacist can give recommendations to the investigators on dosage adjustment, administration mode and formulation of the new drug.

2) **Acting as an Impartial Collaborator:** The pharmacist can work as an impartial collaborator by maintaining all the records and codes in the double blind studies.Thus, the investigators have the advantages of 24×7 availability of code information and the ability to crack the code for a patient without risking the study. The pharmacist can combine all the data regardingthe study drugs and maintain them in the pharmacy.

3) **Collecting, Storing and Disseminating Essential Information Concerning the Drugs Being Studied:** The pharmacy can serve as the primary area for the collection, storage and distribution of important information regarding the investigational drugs. An investigational drug data sheet, providing information regarding the investigational drugs to the medical, pharmacy and nursing staff, should be prepared by the pharmacist. This drug data sheetshould include the following:
   i) Drug designation and common synonyms,
   ii) Dosage forms and strengths,
   iii) Dosage schedule and administration route,
   iv) Indications,
   v) Desired therapeutic effects,
   vi) Potential adverse effects,
   vii) Contraindications,
   viii) Storage requirements,
   ix) Instructions for dosage preparation and administration,
   x) Instructions for disposition of unused doses, and
   xi) Names and telephone numbers of the chief and authorised co-investigators.

The review of drug data sheet should be done by the chief investigator. The copies should be circulated to the suitable pharmacy staff and all the units of patient care where the drug will be used. The information given above commits to clinical studies that are safe and efficiently evaluated. All the staff associated in the prescription, dispensing , administering and observing the drug actions are well -informed and can truly work as members of the research team.

21.1.9. Advisory Committee

A panel of outside experts are assembled periodically to advise the FDA on safety and efficacy problems regarding the drugs and other FDA-regulated products. The FDA is not bound to follow committee suggestions, but its decisions correspond to the suggestions of its advisory committees.

The FDA advisory committee system has been an essential part of the product evaluation process for drugs, biologics, and medical devices. Use of these committees by the agency has increased over time.

After *in vitro* testing and animal studies of toxicity, a new chemical body promising enough to consider clinical trials in humans appears. Then the sponsor should inform the FDA of its purpose to conduct human trials. The Investigational New Drug (IND) application filed by the sponsor includes the current data as well as the details of study design. The FDA on the receipt of IND has 30 days within which the submission is to be reviewed. If the agency finds no safety issues in starting the trial, it may allow the IND to be effective and proceed with the trial. If issues arise, it can place a "clinical hold" on the trial till the sponsor fixes the issue or removes the application. If there is no response from the FDA within 30 days, the sponsor can start the clinical trial.

Three stages of clinical trials are involved in drug development. In Phase I trial, a small group of healthy subjects receive the drug for a few months to provide early data on safety and the action of drug in humans. If the results of Phase I are approved, one or more Phase II trials are started, which evaluate the efficacy of the drug with continuous consideration of safety and non-critical side effects, and describe the clinical results for the valuation of Phase II and III data. In Phase II studies, hundreds of patients suffering from the disease under study are compared with around 20-100 healthy subjects in Phase I trials, in which the subjects are usually randomised.

If the results of Phase II trials are assuring and the substance is not being estimated for the treatment of a life-threatening disease and hence being considered for advanced approval (**e.g.,** technologies to treat cancer or AIDS) after this Phase III trials are started. These trials are large (involving hundreds or even more patients) and long (carried out for 1-4 years). Though the Phase III trials are only initiated after the FDA and the drug company sponsoring the trial meet and the FDA clarifies and agrees based on drug estimation.

The results of Phase III trials, due to the higher number of patients and extended duration of use, deliver the detailed information that is essential in clinical practice for proper dosage levels, minimum side effects, etc. The data obtained by the all three clinical trial phases and the preclinical studies are submitted by the manufacturer to the FDA in a New Drug Application (NDA) to market the substance for specific uses. An NDA also includes brief information on the laboratory formulation, drug chemistry, process of manufacturing, quality control procedures, planned labelling of the drug, and drug samples in its planned dose and form. Data from all the phases, especially from Phase III, builds up the basis for the decision of FDA on approval, containing its specification of indications and different parts of the official label.

Methods for using advisory committees are different for different centres and sometimes within centres. These differences have many clarifications, of which some are acceptable in operational terms but others are neglected by the central administration of the agency or the idiosyncratic choices of agency officials responsible for their progressing management. From a past decade, slight attention has been paid in creating and maintaining an ideal level of agency-wide homogeneity in the methods and management of the committee.

The **major function of FDA advisory committees**, as given in the NDA Rewrite, is to help the agency in making sound decisions based on the reasoned application of good science. This is done by advising on the approvability of particular applications of products based on an inspection of the compatibility of the data making claims for safety and effectiveness. Furthermore, advisory committees also offer technical advice on bigger matters associated with product evaluation.

FDA uses the advisory committees, consultants, and workshops to have external expert advice. The latter two options are used as a complementary, and not as an alternative to advisory committees. They show a general response by a regulatory agency depending on the access to expert scientific and clinical data to achieve its legal responsibilities.

21.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) The compounds or mixtures that have not been rel eased by the FDA for general distribution and use are the **investigational** or **research drugs**.
2) Institutions conducting clinical research should have an **Institutional Review Committee** to evaluate every proposed clinical research study in terms of its compliance with accepted ethical, legal and scientific standards.
3) **Class A** category should have all the investigational drugs which are in the preliminary experimental stage.
4) **Class B** category should have all the investigational drugs which have completed the preliminary research stage.
5) **Class C** category is restricted to drugs approved by the USP, NF or the Federal FDA for commercial supply.
6) In **Class D** category, the drugs are formulations which have been approved for hospital use and are listed in the hospital formulary.
7) In the **preliminary stage**, the chief investigator carefully administers the drug to a small number of specific patients and closely monitors the results.
8) In the **extended stage**, the pharmacist helps in the development of protocol and control of doub le blind test/study, in which the experimental drug and placebo are accurately formulated in the same dosage form.
9) **Investigational New Drug** (IND) **application** filed by the sponsor includes the current data as well as the details of study design.
10) In **Phase I trial**, a small group of healthy subjects receive the drug for a few months to provide early data on safety and the action of drug in humans.
11) **Phase II trials** are started, which evaluate the efficacy of the drug with continuous consideration of safety and non-critical side effects.
12) The results of **Phase III trials**, due to the higher number of patients and extended duration of use, deliver the detailed information that is essential in clinical practice for proper dosage levels, minimum side effects, etc.
13) The major function of **FDA advisory committees**, as given in the NDA Rewrite, is to help the agency in making sound decisions based on the reasoned application of good science.

21.3. EXERCISE

21.3.1. True or False

1) Class A category should have all the investigational drugs which are in the preliminary experimental stage.
2) Class C category should have all the investigational drugs which have completed the preliminary research stage.
3) In Class D category, the drugs are formulations which have been approved for hospital use and are listed in the hospital formulary.
4) In the extended stage, the chief investigator carefully administers the drug to a small number of specific patients and closely monitors the results.
5) Investigational new drug application filed by the sponsor includes the current data as well as the details of study design.

21.3.2. Fill in the Blanks

6) Institutions conducting clinical research should have an _____ to evaluate every proposed clinical research study in terms of its compliance with accepted ethical, legal and scientific standards.
7) The compounds or mixtures that have not been released by the FDA for general distribution and use are the _____.
8) _____ category is restricted to drugs approved by the USP, NF or the Federal FDA for commercial supply.
9) In _____, a small group of healthy subjects receive the drug for a few months to provide early data on safety and the action of drug in humans.
10) The major function of _____, as given in the NDA Rewrite, is to help the agency in making sound decisions based on the reasoned application of good science.

Answers

1) True 2) False 3) True 4) False 5) True
6) Institutional Review Committee 7) Investigational drugs 8) Class C
9) Phase I trial 10) FDA advisory committees

21.3.3. Very Short Answer Type Questions

1) What is an investigation drug?
2) Give any two principles involved for the use of investigational drugs.
3) What are the class A investigation drugs?
4) Give a role of hospital pharmacist in investigational drug studies.

21.3.4. Short Answer Type Questions

1) What are the guidelines for institutions and ph armacists to develop and follow investigational drug procedures?
2) Classify the investigational drugs.
3) Discuss the roles of hospital pharmacist in investigational drug studies.

21.3.5. Long Answer Type Questions

1) Discuss in brief about the investigational use of drugs.
2) Give a brief review on Advisory Committee.

CHAPTER 22

Interpretation of Clinical Laboratory Tests

22.1. INTERPRETATION OF CLINICAL LABORATORY TESTS

22.1.1. Introduction

In diagnosis, monitoring and screening, clinical laboratory test results are a very essential parameter. 70-80% of judgements in diagnosis are based on the laboratory results and analyses. Hence, various data are delivered, and it is important for patient care and safety that the doctors are aware with the laboratory tests and clarification of results.

The laboratory result should be elucidated on the background of a reference interlude, which is used to differentiate health from disease. The clinician should also estimate the conclusion from the biological differences and should know the possible risks of wrong result interpretation. Similarly, effect of random and systemic errors on the result is of significance along with diagnostic sensitivity and specificity.

The laboratory also has a role in delivering suitable information to the clinicians that can help them in the precise interpretation of the data.

22.1.2. Blood Chemistry

Study of blood chemistry is a process in which a sample of blood is checked to determine the quantity of some specific materials released into the blood by body organs and tissues. A higher or lower than normal quantity of a material can indicate a diseased condition in the organ or tissue that produces it.

There are several kinds of blood chemistry tests that determine the presence of enzymes, electrolytes, fats, lipids, hormones, sugars, proteins, vitamins, and minerals. Sometimes, many chemicals are grouped together and determined at the same time.

The blood chemistry tests are general blood tests. Sometimes, they are performed as a part of routine check-up. Blood chemistry tests are performed to:

1) Know about general health,
2) Check whether or not certain organs (kidneys, liver and thyroid) are functioning normally,
3) Check the electrolyte balance of the body,
4) Help diagnosing diseases,
5) Provide the levels of chemicals to compare with the standard levels and future blood chemistry tests,
6) Check whether or not a treatment is affecting certain organs, and
7) Monitor cancer or another condition (as a part of follow-up).

Some common blood tests performed to diagnose disorders of certain body organs are given in **table 22.1**:

Table 22.1: Various Laboratory Tests for Different Disorders

Disorders	Tests
Renal disorders	Creatinine, Blood Urea Nitrogen (BUN), Uric acid, and Protein
Diabetes mellitus	Glucose, Oral Glucose Tolerance Test (OGTT), Insulin, and C-peptide
Cardiovascular disorders	Creatine kinase, Lactate dehydrogenase, and Troponin
Liver disorders	Aspartate transaminase (SGOT), Alanine Aminotransferase (SGPT), γ-Glutamyl transpeptidase, Phosphatase, and Bilirubin
General	Proteins, Water/electrolyte balance, and Haematological data [Total and differe ntial count, Blood count, Haemoglobin, hematocrit, Reticulocytes, Erythrocyte Sedimentation Rate (ESR), Leucocytes, and Coagulation tests].

Discussed below are some of the common blood chemistry tests:

1) **Kidney Function Tests:** The following blood tests help in estimating kidney function

   i) **Blood Urea Nitrogen Test (BUN):** Urea (a by-product of protein metabolism) is a waste product that is produced in the liver, filtered from the blood , and then excreted in the urine by the kidneys. The BUN test evaluates the nitrogen content in urea. High levels of BUN indicate kidney dysfunction. Protein intake and liver function also affect BUN, and thus this test is performed in combination with a blood creatinine (a highly specific indicator of kidney function).

   ii) **Serum Creatinine Test:** This test evaluates the blood level of creatinine (a by-product of muscle energy metabolism), which is filtered from the blood and excreted in the urine by the kidneys. Creatinine production relies on a person's muscle mass, which generally shows little variation. In normal kidney function, the blood level of creatinine remains comparatively const ant and normal. For this reason and since creatinine is slightly affected by liver function, an increased blood creatinine is a highly sensitive in dication of impaired kidney function than the BUN.

   iii) **Uric Acid Test:** Uric acid is the end product of purine metabolism. Hyperuricaemia is the result of overproduction of uric acid (increased destruction of nucleoproteins, high protein diet, or inborn enzymat ic flaws). Asymptomatic hyperuricaemia is categorised as an increased serum uric acid without signs of acute gouty arthritis.

   Saturation of serum is done with 420µmol/l (7mg/dl) concentration of urate , as the concentration of serum urate exceed s this satu ration point, crystals of monosodium urate accumulates in and around the joints , cartilage, and in kidneys, causing gout.

   iv) **Other Blood Tests:** Evaluation of the blood levels of other elements partially regulated by kidneys , **e.g.,** sodium, potassium, chloride, bicarbonate, calcium, magnesium, phosphorus, protein, uric acid, and glucose, can be helpful in estimating the function of kidney.

Age and sex of the patient helps in determining the normal value s for various tests. Reference values can also fluctuate b y laboratory, but are usually within the following range:

i) **Creatinine Clearance:** Normal results for a 24 -hour urine collection are 90 - 139ml/min and 80 -25ml/min for adult male s and females below 40 years old , respectively. The value drops down by 6.5ml/min f or each decade of life f or the adults above 40 years old.

ii) **Urea Clearance:** The normal range is 64-99ml/min with maximum clearance.

iii) **Urine Osmolality:** With limited fluid intake (concentration testing), osmolality should be more than 80 0mOsm/kg of water. With increased fluid intake (dilution testing), osmolality should be below 100 mOsm/kg in at least one of the collected samples.

iv) **Urine Protein:** A 24-hour urine collection should contain no more than 150 mg of protein.

v) **Blood Urea Nitrogen (BUN):** The normal range is 8-20mg/dl.

vi) **Creatinine:** The normal range for males is 0.8 -1.2mg/dl and for females is 0.6-0.9mg/dl.

2) **Liver Function Tests:** Above 70% of the liver parenchyma can be impaired before liver function test results become abnormal. Measure ments of liver functions are normally done in terms of serum enzyme activity (i.e., serum aminotransferases, alkaline phosphate, lactic dehydrogenase) and serum concentration of proteins (albumins and globulins), bilirubin, ammonia, clotting factors, and l ipids. Many of these tests are useful for evaluating patients with liver disease. Though , the nature and extent of hepatic dysfunction cannot be identified by these tests alone, because other disorders can affect the results of the test.

Some common live r function tests, their normal range, and clinical functions are enlisted in **table 22.2**:

Table 22.2: Common Laboratory Tests to Assess Liver Function

Tests	Normal Ranges	Clinical Functions
Pigment Studies		
Serum bilirubin (direct)	0-0.3mg/dl (0-5.1μmol/l)	Measure the liver's ability to conjugate and excrete bilirubin. Results are abnormal in liver and biliary tract disease and are clinically associated with jaundice.
Serum bilirubin (total)	0-0.9mg/dl (1.7-20.5μmol/l	
Urine bilirubin	0(0)	
Urine urobilinogen	0.05-2.5mg/24h (0.5-4.0 Ehrlich U/24h)	
Faecal urobilinogen (infrequently used)	50-300 mg/24h (100-400 Ehrlich U/100g)	
Protein Studies		
Total serum protein	7.0-7.5gm/dl (70-75gm/l)	Proteins are manufactured by the liver. Their levels are affected in various liver impairments; albumin is affected in cirrhosis, chronic hepatitis, oedema, and ascites; globulins are affected in cirrhosis, liver disease, chronic obstructive jaundice, and viral hepatitis.
Serum albumin	4.0-5.5gm/dl (40-55gm/l)	
Serum globulin	1.7-3.3gm/dl (17-33gm/l)	
Serum protein electrophoresis:		
Albumin	4.0-5.5gm/dl (40-55gm/l)	
α_1-Globulin	0.15-0.25gm/dl (1.5-2.5gm/l)	
α_2-Globulin	0.43-0.75gm/dl (4.3-7.5gm/l)	
β-Globulin	0.5-1.0gm/dl (5-10gm/l)	
γ-Globulin	0.6-1.3gm/dl (6-13gm/l)	
Albumin/Globulin (A/G) ratio	A > G or 1.5 : 1-2.5 : 1	A/G ratio is reversed in chronic liver disease (decreased albumin and increased globulin).
Prothrombin Time	100% or 12-16 seconds	Prothrombin time is prolonged in liver disease. I t will not return to normal with vitamin K in severe liver cell damage.

Serum Alkaline Phosphatase	Varies with m ethod; 2 -5 Bodansky units 30 -50U/L at 34 °C (17 -142U/L at 30°C) (20-90U/L at 30°C)	Serum alkaline phosphatase is manufactured in bones, liver, kidneys, and intestine, and excreted through biliary tract. In the absence of bone disease, it is a sensitive measure of biliary tract obstruction.
Serum Aminotransferase Studies		
AST	10-40 units (4.8-19U/L)	The studies are based on release of enzymes from damaged liver cells. These enzymes are elevated in liver cell damage.
ALT	5-35 units (2.4-17U/L)	
GGT, GGTP	10-48IU/L	Elevated in alcohol abuse. Market
LDH	100-200 units (100-225U/L)	for biliary cholestasis.
Ammonia (plasma)	15-45μg/dl (11-32μmol/l)	Liver converts ammonia to urea. Ammonia level rises in liver failure.
Cholesterol		
Ester	60% of total (fraction of total cholesterol – 0.60)	Cholesterol levels are elevated in biliary obstruction and decreased in parenchymal liver disease.
HDL (High-Density Lipoprotein)	HDL Male – 35-70mg/dl, Female – 35-85mg/dl	
LDL (Low-Density Lipoprotein)	LDL < 130μg/dl	

3) **Tests for Diabetes Mellitus:**

i) **Plasma Glucose:** Generally, the laboratory estimation of glucose level is done on venous plasma samples. Plasma and serum glucose concentration are similar and are 10 -15% higher than complete body measurements. Either chemical or enzymatic procedures re-used for clinical estimation of glucose.

Chemical analysis is conducted based on the reducing properties of gl ucose and utilises a colour change reaction that is measured with a spectrophotometer. Enzymatic analysis is conducted based on the reaction of glucose and glucose oxidase. This method is highly specific and economical.

Increased plasma glucose concentra tions or **hyperglycaemia** is caused by various syndromes and hyperglycaemia, and can be categorised as follows:

a) **Primary:**
- Insulin-Dependent Diabetes Mellitus (IIDM), and
- Non-Insulin Dependent Diabetes Mellitus (NIDDM).

b) **Secondary**
- **Hyperglycaemia Resulting f rom Pancreatic Disease :** Inflammation, acute pancreatitis (rare) , chronic pancreatitis, pancreatitis caused by mumps, cell damage caused by coxsackie virus B4 infection , auto-immune disease, pancreatectomy, pancreatic infiltration, hemochromatosis, tumours, and trauma to pancreas (rare).
- **Hyperglycaemia Related to Other Major Endocrine Diseases :** Acromegaly, Cushing's syndrome , Thyrotoxicosis, pheochromocytoma, hyperaldosteronism, glucagonoma, and somatostatinoma.

- **Hyperglycaemia Caused by Drugs:** Corticosteroids, acetazolamide, thiazide diuretics, β-Agonists, oral contraceptives, alloxan, streptozotocin, pentamide (late), and protease inhibitors.
- **Hyperglycaemia Related to Other Major Disease States :** Chronic renal failure, chronic liver disease, and infection.
- **Miscellaneous Hyperglycaemia:** Pregnancy, and related to insulin receptors antibodies (acanthosis nigricans).

Hypoglycaemia is classified as follows:

a) **No Anatomic Lesion Present:**
- **Fasting Plasma Glucose Normal:** Reactive hypoglycaemia, functional hypoglycaemia, alimentary hypoglycaemia, and diabetic and impaired glucose tolerance.
- **Fasting Plasma Glucose Low :** Oral hypoglycaem ia agents, ACE inhibitors, insulin, ethanol , salicylates (late in overdose), pentamidine (early in overdose), and Combinations of the above.
- Factitious – Fasting glucose normal or low.

b) **Anatomic Lesion Present:**
- Insulinoma,
- Extrapancreatic neoplasms,
- Adrenocortical insufficiency,
- Hypopituitarism, and
- Massive liver disease.

Values of normal glucose are as follows:

a) **Normal:** Fasting glucose level is 3.9-6.1mmole/l (70-140mg/dl).

b) **Hyperglycaemia:** Fasting glucose level is >7.7mmol/l (140mg/dl).

c) **Hypoglycaemia:** Fasting glucose level for adults is 2.5 -3.0mmole/l (45 - 55mg/dl).

ii) **Oral Glucose Tolerance Test:** In this test, a patient is requested to hav e at least 10 hours of fast and is administered with drinking water containing 75gm glucose. Just before the intake of glucose, a blood sample is taken. After the intake of glucose, blood sample s are taken at intervals of 30, 60 and 120 minutes. In normal patients, the level of glucose decreases after 60 min utes and returns to normal (140mg/dl) by 120 minutes; however, this decrease is not seen in diabetic patients.

iii) **Serum Insulin:** For differentiating Type I and Type II diabetes, blood samples are analysed by radioimmunoassay for serum insulin. As compared to normal individuals, the type I diabetic patients have low er insulin levels and t ype II diabetic patients have higher insulin levels. The n ormal insulin level is 30-60μU/ml.

iv) **C-Peptide:** This test is not us ed frequently, but is performed by radioimmunoassay to confirm that the patient is type I or not.

v) **Glycosylated Haemoglobin:** This test involves a non -enzymatic chemical reaction between glucose and phosphorylated sugar with the end terminal valine of the β-chain of haemoglobin molecule. This is an index for glycaemic control , and the normal range of glycosylated haemoglobin is up to 7.

4) **Tests for Cardiovascular Disorders:**
   i) **Creatine Kinase (CK):** It was previously known as creatine phosphokinase. It catalyses the conversion of phosphocreatine to creatine, and releases high energy phosphate to cardiac and skeletal muscles.

   Creatine is an unsteady molecule that quickly converts into creatinine. CK is a dimer containing M and B sub-units. Brain tissue produces approximately 90% BB (CK2) and 10% MM (CK3), cardiac tissue produces approximately 40% BB (CK2) and 60% MM, and normal serum and skeletal muscle comprises of 100% MM.

   Any impairment of skeletal muscle increases the serum CK. Severe acute rhabdomyolysis secondary to trauma, extended coma, some drug overdose, progressive muscular dystrophy, polymyositis, dermatomyositis, delirium tremens, seizures, or hypothyroidism can elevate the CK levels ranging from 167 -1670 kat/L (10000-100000 IU/l). However, the normal value of CK is 0-130 IU/l.

   ii) **Lactate Dehydrogenase (LDH):** It catalyses the conversion of pyruvate to lactate anaerobically to produce Adenosine Triphosphate (ATP). The normal value of LDH is 100-190 IU/litre.

   LDH can be divided into five different components; all the five LDH isoenzymes have almost the identical molecular weight but carry different charges. The five LDH isoenzymes and their increased levels in different conditions are shown in **table 22.3**:

Table 22.3: Elevated Isoenzyme Levels in Various Conditions

Isoenzymes	Different Conditions
LDH_1	Acute myocardial infarction, acute renal infarction, pernicious anaemia, and haemolysis.
LDH_2	Pulmonary embolus and infarction haemolysis.
LDH_3	Pulmonary embolus and infarction haemolysis.
LDH_4	Tumors and nephrotic syndrome.
LDH_5	Severe myocardial infarction with ventricular failure, hepatitis, hepatic disorders, skeletal muscle damage, burns, trauma, nephritic syndrome, and cor pulmonale.

   iii) **Troponins (Tn):** It is a complex of three proteins, i.e., Troponin T (TnT), Troponin C (TnC), and Troponin I (TnI). Every troponin has its own particular function in actin and myosin regulation in the contractile process. TnI is highly sensitive and specific for myocardial tissue. TnI concentration is useful for clinical determination of cardiac injury like creatine kinase.

   Increase in TnI to more than 2.0 µg/l indicates acute myocardial injury. The normal value of TnI is 0.7-1.5ng/ml.

22.1.3. Haematology

Haematology is the branch of medical science concerned with the study of blood, blood-forming tissues, and blood disorders. Along with detection and diagnosis of disease, the blood pathology tests offer the following **advantages**:

1) Treatment of disease,
2) Monitoring progression of disease,
3) Prevention of disease (**e.g.**, through early detection a PAP smear or mammogram decreases the risk of some common cancers in women),
4) Determination of disease in future (**e.g.**, examining cholesterol levels or the risk of inherited conditions like familial breast cancer), and
5) Supporting research into new treatments, and safety of treatments and procedures.

Discussed below are the important tests included in haematology:

1) **Total Haemoglobin (Hgb or Hb):** It is a test used for estimating the quantity of haemoglobin in blood. It is the pigmented part of erythrocyte (RBC) and the oxygen carrier of blood.

Normal Values
Males: 12-17gm/100ml
Females: 11-15gm/100ml

Clinical Implications
Low level of Hgb indicates anaemia. Evaluation of Hgb in each RBC is reasonably significant while defining the total blood Hgb. Though, Hgb results are highly reliant on the total number of RBC s. It can also be said that for diagnosing anaemia, the number of RBCs is as essential as the Hgb level.

Table 22.4: Variations of Haemoglobin Type and Distribution (in Adults)

Percentage of Total Haemoglobin	Haemoglobin	Clinical Implications
HbA	95-100%	Normal
HbA_2	4-5.8%	Beta-thalassemia minor
	1.5-3%	Beta-thalassemia major
	Under 1.5%	Beta-D-thalassemia minor
HbF	Under 2%	Normal
	2-5%	Beta-thalassemia minor
	10-90%	Beta-thalassemia major
	5-15%	Beta-D-thalassemia minor
	5-35%	Heterozygous hereditary persistence of Foetal Hb (HPFH)
	100%	Homozygous HPFH
	15%	Homozygous HbS
Homozygous HbS	70-98%	Sickle cell disease
Homozygous HbC	90-98%	HbC disease
Heterozygous HbC	24-44%	HbC trait

2) **Hematocrit (Hct):** It estimates percentage by volume of RBCs in a whole blood sample. **For example**, 40% Hc t indicates that a 100 ml blood sample has 40 ml of blood cells. Its packaging is attained by centrifuging anti -coagulated total blood in a capillary tube so that the cells are packed closely without haemolysis.

Normal Values
Males: 40-50%
Females: 37-47%

Clinical Implications
Two small and same quantities of blood samples are compared . One sample is centrifuged and compared to the first sample to obtain a percentage value. This comparison i s the Hct value. It relies on the number of RBCs . If th e Hct value is abnormal, the RBC count may also be abnormal . If the RBC count is normal, the average size of RBC will possibly be too small. Shock, dehydration, haemorrhage, or excessive IV fluid administration can decrease the value of Hct.

3) **Red Blood Cell Count:** It is the count of actual (or estimated) number of RBC s in per cubic mm of whole blood.

Normal Values
Males: 4.5-6.0 million/cu mm blood
Females: 4.0-5.5 million/cu mm blood

Clinical Implications

RBC count is helpful for diagnosing anaemia and haemorrhage by taking samples of whole blood, capillary, or venous blood . It can also be used for diagnosing diseases in combination with other haematology tests . This test can provide an indirect approximation of Hgb levels in blood. RBCs are red blood corpuscles (non-nucleated cells). The word **corpuscle** shows that it is a mature RBC. A mature RBC can only transport oxygen. An immature RBC after getting matured loses its nucleus and is no longer termed as a cell, but is termed a corpuscle.

4) **Red Cell Indices (Wintrobe Indices):** It is a report of specific characteristics of RBC. If there is a presence of abnormal findings, the anaemia c an be described as macrocytic, microcytic, hypochromic , etc. After this is discovered , it is easy to determine the exact cause of anaemia

By using the RBC indices, which are identical in men and women, the size and haemoglobin content of erythrocytes can be determined. **Table 22.5** summarises the various erythrocyte indices:

Table 22.5: Erythrocyte Indices

Indices	Calculated as	Normal Values	Increased in	Decreased in
Mean Corpuscular Volume (MCV) represents average volume of erythrocytes	$MCV = \frac{Hct}{Ercs}$	87 ± 5fl or 87 ± 5μm^3/cell	Macrocytic anaemia	Microcytic anaemia
Mean Corpuscular Haemoglobin (MCH) is the weight of haemoglobin in average RBC	$MCH = \frac{Hb}{Ercs}$	29 ± 2 pg	Macrocytic anaemia	Microcytic anaemia and hypochromic anaemia
Mean Corpuscular Haemoglobin Concentration (MCHC) is the average concentration of haemoglobin in a given volume of packed erythrocytes	$MCHC = \frac{Hb}{Hct}$	34 ± 2gm/dl or 21 ± 1 mmole/litre in SI units (CF = 0.6205)	Macrocytic anaemia	Microcytic anaemia and hypochromic anaemia
Red Cell Distribution Width (RDW) is an estimate of erythrocyte anisocytosis and is a co-efficient of variation for the size of erythrocytes	RDW = standard deviation of erythrocyte size/MCV	11.5-14.5		

5) **Reticulocyte Count (Retic Count):** This test is used to evaluate the definite numbers of reticulocytes (immature RBCs) in blood.

Normal Values

Approx. 1% of normal RBC count (50,00 0); Results vary between the range of 0.5 - 1.5%.

Clinical Implications
The retic count indicates the manufactur ing of RBC s by the bone marrow. An elevation from the normal indicates that the body is reacting to pathologies , like haemorrhage, anaemia, haemolysis, or other disease process. Lowered rectic count indicates anaemia or any associated disorder.

6) **Sickle Cell or HbS Test:** It is used to identify sickle cells, which are badly distorted, rigid erythrocytes that can slow down the blood flow. The trait of sickle cell (characterised by heterozygous Hb S) is found in most people of African ancestry. Though the test i s helpful as a rapid screening procedure, it can also give false results. Hb electrophoresis should be done to confirm the diagnosis if there is a possibility of sickle cell disease.

Normal Values

6 months to 15 years	7-140 NG/ml
2 to 5 months	50-200 NG/ml
1 month old	200-600 NG/ml
Neonates	25-200 NG/ml

7) **Iron and Total Iron -Binding Capacity (TIBC):** Iron is very important for the production and function of haemoglobin along with several other heme and non - heme compounds. After the intestinal absorption o f iron, it is distributed to several body compartments for synthesis, storage , and transport. In morning , the serum ion concentration is generally at its peak and decreases gradually during the day time. Hence, the sample should be collected in the morning.

To measure the quantity of iron bound to transferrin in blood plasma , an iron assay is done. TIBC determines the quantity of iron that appears in plasma if total transferrin were saturated with iron.

Normal Values
Serum Iron: Males and females: 50-150µg/dl and 35-145µg/dl, respectively.
TIBC: Males and females: 250-400µg/dl
Saturation: Males and females: 14-50%

8) **Ferritin Test:** Ferritin (chief iron -storing protein) is found in reticuloendothelial cells. In the serum , it appears in little quantities. In hea lthy individuals, its serum levels are directly linked to the available quantity of iron store d in the body and can be determined by radioimmunoassay.

Normal Values
Males: 20-300NG/ml
Females: 20-120NG/ml

Clinical Implications
Elevated levels of serum f erritin indicate acute or chronic hepatic disease, iron overload, leukaemia, acute or chronic infection or inflammation, Hodgkin's disease, or chronic haemolytic anaemia. Minor elevation or normal f erritin levels indicate chronic renal disease. Lowered serum ferritin levels indicate chronic iron deficiency.

9) **Erythrocyte Sedimentation Rate (ESR):** It measures the time need ed for erythrocytes from a whole blood sample to settle at the bottom of a vertical tube. Factors affecting ESR are red cell volume, surface area, density, aggregation, and surface charge. The blood sample should be examined within 2 hours after its collection and should be handled with care to avoid clotting.

Normal Value: 0-20mm/hr (gradually increase with age)

Clinical Implications
Elevated ESR indicates pregnancy, acute or chronic inflammation, tuberculosis, rheumatic fever, paraproteinemias, rheumatoid arthritis, few malignancies, or anaemia. Low ESR indicates polycythaemia, sickle cell anaemia, hyperviscosity, or low plasma protein.

10) **Osmotic Fragility:** It measures resistance of RBCs to haemolysis when exposed to a sequence of gradually dilute saline solutions. Sooner the haemolysis occurs, higher is the osmotic fragility of the cells. The purpose of this test is to assist diagnose hereditary spherocytosis and to supplement a stained cell examination for detecting morphologic RBC abnormalities.

Normal Values
Osmotic frag ility values (percentage of RBC s haemolysed) are measured by the saline tonicity. For different tonicity, the reference values are:

i) **0.5gm/dl Unincubated NaCl Solution:** Males and females: 0.5-24.7% haemolysis and 0-23.1% haemolysis, respectively.

ii) **0.6gm/dl Incubated NaCl Solution:** Males and females: 18 -55.2% haemolysis and 2 2-59.3% haemolysis, respectively.

iii) **0.65gm/dl Incubated NaCl Solution:** Males and females: 4 -24.8% haemolysis and 0.5-28.9% haemolysis, respectively.

iv) **0.75gm/dl Incubated NaCl Solution:** Males and females: 0.5 -8.5% haemolysis and 0.1-9.3% haemolysis, respectively.

Clinical Implications
Low osmotic fragility (increased resistance to haemolysis) indicates thalassemia, iron deficiency anaemia, and RBC disorders having codocytes (target cells) and leptocytes. Low osmotic fragility appears after splenectomy.

High osmotic fragility (increased affinity to haemolysis) indicates hereditary spherocytosis, spherocytosis linked with autoimmune haemolytic anaemia, severe burns, chemical poisoning or haemolytic disease of the neonate (erythroblastosis fetalis).

11) **White Blood Cell or WBC Count (Leukocyte Count):** Generally, laboratories report five kinds of WBCs or leukocytes in the peripheral blood. These are lymphocytes, monocytes, neutrophils, eosinophils , and basophils. Undeveloped or abnormal forms of WBCs can be seen in some disease state s. In **leukocytosis**, total leukocyte count increases. Exercise can result in leukocytosis with a rise in neutrophils caused by shifting of cells and lymphocyte discharge into blood. The leukocyte count is lower in black than in white individuals.

The leukocyte or the differential count can b e abnormal in patients having sepsis. Incorrect results can arise with haemorrhage, haemolysis, trauma, diabetic ketoacidosis, and sickle cell crisis. **Leukaemia** is a malignant disease characterised by abnormal leukocytes that can be highly increased in number (though they can also be decreased). A huge increase in leukocytes as a systemic response to many conditions (**e.g.,** tuberculosis, severe burns, eclampsia, haemolysis, and haemorrhage) is known as **leukemoid reaction**.

Normal Value: 4.5-11.0 × 103/mm^3

Granulocytes: These are leukocytes with granules in their cytoplasm. They are of the following three types:

i) **Neutrophils:** In normal individuals, nearly 56% of leukocy tes are neutrophils, which are also known as polymorphonuclear leukocytes (various forms o f nuclei), polysegmented neutrophilic granulocytes, or segs. A rise in neutrophils

is related to a few bacterial infections, inflammatory disease s (**e.g.,** rheumatoid arthritis, vasculitis), tissue necrosis (**e.g.,** MI or burns), metabolic diseases (**e.g.,** uraemia, diabetic ketoacidosis, thyroid storm), and tumours.

The outcome of damaged production, increased destruction, or altered distribution of neutrophils is termed **neutropenia**. Agranulocytosis is a more severe form of neutropenia.

Normal Value: 1.1-7.0 × 10^3/mm^3

ii) **Eosinophils:** These are structurally identical to neutrophils, but cytoplasm has larger round or oval granules that comprise of enzyme s, and have a strong affinity for acid (red) stains. Eosinophils are increased in allergic diseases (asthma, hay f ever), parasitic infection (trichinosis), skin disorders (eczema, pemphigus), neoplastic diseases, collagen vascular diseases, adrenal cortical hypofunction, ulcerative colitis, and hypereosi nophilic syndromes. **Eosinophilia** can also be linked to the use of certain drugs (**e.g.,** pilocarpine, digitalis, sulphonamides). Eosinophils are low in acute stress or other conditions with increased epinephrine secretion or increased level of adrenal corticosteroids and in acute inflammatory states.

Normal Value: 0-0.7 × 10^3/mm^3

iii) **Basophils:** These are identical to neutrophils except that the ir nuclei are less segmented and their cytoplasmic granules are bigger and have a strong affinity for basic (blue) stains. Basophils are increased in allergic reactions, myeloproliferative diseases, chronic haemolytic anaemia, hypothyroidism , and after splenectomy. They are less in number with chronic corticosteroid therapy, acute infection, stress, or hyperthyroidism.

Normal Value: 0-0.5 × 10^3/mm^3

Lymphocytes: These are mononuclear ce lls lacking cytoplasmic granules. They can develop plasma cells, which are generally absent in the blood. A complete or relative rise in lymphocytes occurs in a few viral or other infections (**e.g.,** tuberculosis, infectious mononucleosis, cytomegalovirus, p ertussis, toxoplasmosis, hepatic mumps, and chickenpox), thyrotoxicosis, Addison's disease, inflammatory bowel disease, vasculitis , and hypers ensitivity reactions to drug s (**e.g.,** phenytoin, paraminosalicyclic acid). The patient with an abnormal increase in lymphocytes (lymphocytopenia) or their impaired function suffers from immunodeficiency.

It may be an inborn disease or can be related to immunodeficiency syndromes (**e.g.,** AIDS). **Lymphopenia** can occur with congestive heart failure, renal failure, biliary tuberculosis, myasthenia gravis , systemic lupus erythematosus, or disorders of lymphatic circulation. **Lymphocytopenia** can occur after irradiation, administration of antineoplastic drugs, or with high concentration of adrenocortical hormones. Lymphocyte dysfunction can be seen with chronic lymphocytic leukaemia, multiple myeloma, Hodgkin's disease, sarcoidosis, leprosy, malnutrition, or terminal malignancy.

Normal Value: 1.5-4 × 10^3/mm^3

Monocytes: These are the biggest cells in normal blood having a diameter of two or three that of erythrocytes. Monocytes are increased in some infectious disorders (**e.g.,** mycotic, protozoal, rickettsial, viral infections, tuberculosis, sub -acute bacterial endocarditis), lymphomas, leukaemia, sarcoidosis, inflammatory bowel disease, and collagen vascular diseases.

Normal Value: 0.2-0.9 × 10^3/mm^3

12) **Platelets:** They keep the integrity of blood vessels and are involved in haemostasis. **Thrombocytopenia** is a condition of small number of circulating platelets, which can rise as a congenital or acquired disease due to lowered production, abnormal distribution or dilution, or increased destruction of platelets. If the platelet count is 20-50 × 10^9/L (20-50 × 10^3/mm^3), the person has a high possibility of minor natural bleeding and bleeding after surgery; and if the platelet count is below 20 × 10^9/L (20 × 10^3/mm^3), the person has a possibility of severe bleeding. Function of platelets is impaired in disorders like uraemia, myeloproliferative or lymphoproliferative disorders, myeloma, systemic lupus erythematosus, chronic immunologic thrombocytopenic purpura, or disseminated intravascular coagulation. Number of drugs can also alter the platelet function.

Aspirin irreversibly acetylates platelets cyclooxygenase, hence supresses aggregation for the life of the platelets by lowering thromboxane A2 formation. Ticlopidine inhibits ADP-induced platelet glycoprotein II b/IIIa receptor antagonist. Some other drugs that can inhibit aggregation are dextrin, antimicrobial agents (**e.g.,** penicillins, cephalosporins), psychotropics (**e.g.,** imipramine, chlorpromazine), clofibrate, and β-adrenergic blocking agents (**e.g.,** propranolol). Flucytosine, zidovudine, interferons, and many antineoplastic agents inhibit platelet synthesis. Ethanol can inhibit the synthesis as well as function of platelets.

Normal Value: 200-350 × 10^3/mm^3

13) **Differential Cell Count:** This test counts the actual numbers of different types of WBC.

Clinical Implications:

Cell Types	Adult Values	Absolute Values	Relative Values (6-18 Years Old)	
			Boys	Girls
Neutrophils	47.6-76.8%	1.950-8.400/µl	38.5-71.5%	41.9-76.5%
Lymphocytes	16.2-43%	660-4.600/µl	19.4-51.4%	16.3-46.7%
Monocytes	0.6-9.6%	24-960/µl	1.1-11.6%	0 .9-9.9%
Eosinophils	0.3-7%	12-760/µl	1-8.1%	0.8-8.3%
Basophils	0.3-2%	12-200/µl	0.25-1.3%	0 .3-1.4%

Neutrophils

Increased by:

i) Gonorrhoea, osteomyelitis, otitis media, chickenpox, herpes, etc.
ii) Ischemic necrosis due to MI, burns, and carcinoma.
iii) Metabolic disorders, like diabetic acidosis, eclampsia, uraemia, and thyrotoxicosis.
iv) Stress response due to acute haemorrhage, surgery, emotional distress, etc.
v) Inflammatory disorders, like rheumatic fever, acute gout, vasculitis, and myositis.

Decreased by:

i) Bone marrow depression due to radiation or cytotoxic drugs.
ii) Typhoid, hepatitis, influenza, measles, mumps, and rubella.
iii) Hypersplenism, hepatic disease, and storage disease.
iv) Collagen vascular disease and systemic lupus erythematosus.
v) Deficiency of folic acid or vitamin B_{12}.

Eosinophils

Increased by:

i) Allergic disorders, like asthma, hay fever, food or drug sensitivity, etc.
ii) Parasitic infections, like trichinosis, hookworm, roundworm, and amoebiasis.
iii) Skin diseases, like eczema, psoriasis, dermatitis, herpes, and pemphigus.
iv) Neoplastic diseases, like Hodgkin's disease and chronic myelocytic leukaemia.
v) Collagen vascular disease, ulcerative colitis, pernicious anaemia, scarlet fever, excessive exercise, etc.

Decreased by:
Stress response due to trauma, shock, burns, surgery, mental distress, and Cushing's syndrome.

Basophils
Increased by:
Chronic myelocytic leukaemia, polycythemia vera, some chronic haemolytic anaemia, Hodgkin's disease, myxoedema, ulcerative colitis, and chronic hypersensitivity states.

Decreased by:
Hyperthyroidism, ovulation, pregnancy, and stress.

Lymphocytes
Increased by:
i) Pertussis, syphilis, tuberculosis, hepatitis, mumps, etc.
ii) Thyrotoxicosis, hypoadrenalism, ulcerative colitis, and immune diseases.

Decreased by:
i) Severe debilitating illness, like congestive heart failure, renal failure, and advanced tuberculosis.
ii) Defective lymphatic circulation and high levels of adrenal corticosteroids.

Monocytes
Increased by:
i) Infections, like sub-acute bacterial endocarditis, tuberculosis, hepatitis, and malaria.
ii) Collagen vascular disease , like systemic lupus erythematosu s and rheumatoid arthritis.
iii) Carcinomas, like monocytic leukaemia and lymphomas.

Decreased by: (unknown)

14) **Coagulation Tests:** Coagulation involves advanced activation of coagulation factors, forming a stable fibrin clot. Various tests are used the measure the ability of body to produce a clot by estimating the function of several parts of the clotting cascade. To remove platelets the blood is centrifuged. Addition of citrate is done to prevent the cascade from progressing. Patients having impaired or deficient coagulation factors experience bleeding. This can be a congenital disease like haemophilia, with a lack of coagulation factor VIII or IX, an acquired disease like the reduced synthesis of coagulation factor in liver disease, vitamin K deficiency, or due to a drug effect.

i) **Activated Partial Thromboplastin Time (aPTT):** It is used to measure the integrity of the intrinsic and general pathways of coagulation. In this test, a contact activating agent (**e.g.,** kaolin, ellagic acids or celite), phospholipid and calcium are added to citrated plasma, and the time required to form a clot is measured. This time is extended if there is a lack of coagulation factors XII, XI, IX, VIII, X, V, II, fibrinogen, prekallikrein, or high-molecular weight kininogen, or if an inhibitor of any of these is present.

The value of aPTT is also abnormal in patients having lupus, such as anticoagulant and liver failure since liver synthesises several clotting factors. The value of aPTT reduces in an active coagulopathy or malignancy . It is the most common test used to monitor unfractionated heparin therapy, and it can extend by the presence of thrombolytic drugs or coumarin derivatives.

Normal Value: 25-37 seconds

ii) **Prothrombin Time (PT):** It is used to ass ess the extrinsic and general pathways. In this test, t issues thromboplastin (**e.g.,** brain, lung or placenta extract, or human recombinant tissue factor with phospholipid) and calcium are added to citrated pla sma, and the time for clot formation is estimated. The PT is

extended if there is a lack of coagulation factors VII, X, V, or II, fibrinogen (concentration below 30% of normal), or the presence of an inhibitor of these factors. The PT is extended in liver disorders, in patients having vitamin K deficiency, and in disseminated intravascular coagulation. It is used to observe coumarin (**e.g.,** warfarin) treatment, but is extended by the presence of heparin or a thrombolytic drug.

Normal Value: 11-16 seconds

iii) **Thrombin Time (TT):** It is used to measure the ability of body to convert fibrinogen into fibrin. In this test, thrombin is added to citrated plasma, and clotting time is measured. The TT is extended if there is a deficiency or abnormality of fibrinogen due to the presence of fibrinogen degradation products (heparin or fibrin). The TT is also extended in patients having uraemia or high concentration of monoclonal immunoglobulins (**e.g.,** myeloma or macroglobulinemia). It is also used in observing thrombolytic therapy (**e.g.,** streptokinase or urokinase).

Normal Value: 10-15 seconds

iv) **Bleeding Time:** It is used as a screening test to measure function of platelets, but it is not precise. In this test, a uniform incision is made on the arm, and a blood pressure cuff on the upper arm is inflated up to a constant pressure of 40mmHg. The drips of blood are carefully removed with filter paper so that the wound is not touched and the platelet plugs are not disturbed. Removal of blood is done to prevent fibrin formation and stop bleeding. End point of the test can be identified when no spot appears on the filter paper after blotting. Bleeding time extends in the presence of platelet dysfunction, a drug inhibiting platelet, or when the platelet count is less than 100×10^9/L (100×10^3/mm^3). It is also extended in patients having uraemia or von Willebrands's disease. If the bleeding time is shorter than expected, various young, active platelet can be present.

Normal Value: 180-240 seconds

v) **D-Dimer Fragments:** These are formed when a fibrin clot undergoes lysis. The presence of D-dimer gives indication of a physiological response to formation of intravascular fibrin. In the presence of lowered platelets, extended aPTT, PT, TT, and elevated fibrin degradation products, a positive D-dimer is prognostic of disseminated intravascular coagulation in patients at risk. A normal value of D-dimer guarantees that 90% of patients do not have PE. However, the test lacks specificity and is also raised in patients with MI, pneumonia, heart failure, cancer, sickle cell disease, or recent surgery.

22.1.4. Urinalysis

A urinalysis is a set of physical, chemical, and microscopic tests which detect or measure the constituents excreted in the urine like the by-products of normal and abnormal metabolism, cells, cellular fragments, and bacteria.

Many disorders can be detected in their early stage by diagnosing substances that are not normally present in the urine and/or by evaluating abnormal levels of some components (like glucose, protein, bilirubin, red blood cells, white blood cells, crystals, and bacteria). These substances may be present due to:

1) Higher level of substance in the blood and the body responds by trying to eliminate them through urine,
2) Presence of kidney disease, and
3) Urinary tract infection as in case of bacteria and white blood cells.

Urine has the following pathological conditions:

1) **Proteins:** Presence of abnormal concentration of albumin and globulin in the urine is known as **proteinuria** (or **albuminuria**), which may be of two types:
   i) **Physiologic Proteinuria:** Less than 0.5% protein is observed in urine which may be due to severe exercise, after a high protein meal and in pregnancy.
   ii) **Pathologic Proteinuria:** Amount of proteins increases in case of glomerulonephritis and nephrotic syndrome. Proteinuria may also occur due to poisoning of the renal tubules by heavy metals, like mercury, arsenic, or bismuth.

2) **Glucose:** Presence of glucose in urine is known as **glycosuria** which occurs due to diabetes mellitus and endocrinal disorders, such as hyperpituitarism, hyperthyroidism, Cushing's syndrome, and pheochromocytoma. Transient glycosuria may be observed rarely due to emotional stress, like in exciting athletic contest.

3) **Other Sugars:** Presence of fructose sugar in urine due to disturbed fructose metabolism is known as **fructosuria**. Similarly, galactosuria and lactosuria occur rarely in infants, pregnant women, and in lactating mother. Consumption of food rich in pentose sugars (like grapes, cherries and plums) causes pentosuria. The condition of pentosuria also occurs in inherited diseases in which pentoses are not metabolised.

4) **Ketone Bodies:** Under normal conditions less than 1mg of ketone bodies are excreted through urine in 24 hours. Excretion of ketone bodies increases in many conditions like starvation, diabetes mellitus, pregnancy, ether anaesthesia, and in certain types of alkalosis.

5) **Bilirubin and Bile Salts:** In case of obstructive or hepatic jaundice, bilirubin is excreted in urine. A condition in which bile salts are excreted in urine is known as **bilirubinuria**. In certain stages of the liver disease, the bile salts are excreted without bile pigments in urine. Traces of bilirubin without bile salts are excreted in urine during excessive haemolysis.

   Bilirubin is absent in the urine of an adult healthy person. It is a waste product, produced by the liver from the haemoglobin of RBCs that are broken down and removed from circulation. It is utilised in the synthesis of bile, a fluid involved in food digestion. In some liver diseases like biliary obstruction or hepatitis, excess amount of bilirubin is formed which is eliminated through urine. Presence of bilirubin in urine indicates liver disease, like development of jaundice.

6) **Blood:** Blood is excreted in urine due to lesions of kidney, urinary tract infection, and in case of nephritis. Free haemoglobin molecules may also be detected after quick haemolysis, **e.g.**, black water fever (a consequence of malaria) and severe burns.

   Presence of the following blood cells indicates a pathological condition:
   i) **RBCs:** Some RBCs can be found in urine sediment (0-5 RBCs per high power field, HPF) even in normal conditions. A positive chemical test for haemoglobin and increased number of RBCs seen under the microscope indicates the presence of blood cells in urine. However, this test cannot diagnose where the blood is coming from. **For example,** presence of RBCs in urine due to haemorrhoids or vaginal bleeding cannot be differentiated from a bleed in the urinary tract. Therefore, urine should be properly collected.

      Presence of RBCs in urine is known as **haematuria**. Sometimes haematuria has no lasting harm and can be easily controlled by treating the underlying causes. In urine, presence of blood along with WBCs and bacteria indicates UTIs which can be treated with antibiotics. However, haematuria may also occur as a consequence of some severe infections that must be monitored and treated properly.

ii) **WBCs:** A minute concentration of WBCs, i.e., 0-5 WBCs per high power field, HPF may be found even in normal conditions; and WBCs may also contaminate urine due to vaginal secretions. Increased number of WBCs in the urine under a microscope and/or a positive test for leukocyte esterase indicates urinary tract infection.

iii) **Epithelial Cells:** Few epithelial cells can be normally found in the urine of both men and women. An increased number of epithelial cells are found in conditions, such as urinary tract infections, inflammation, and malignancies. Identification of the type of epithelial cells in urine helps in detection of pathological conditions. **For example**, epithelial cells having large number of broken down haemoglobin (or hemosiderin) indicate that there were (maybe there are none now) RBCs or haemoglobin in the urine recently.

iv) **Urobilinogen:** During excessive haemolysis (like in **haemolytic jaundice** or **pernicious anaemia**), part of the bile pigment formed by the breakdown of haemoglobin is excreted out through urine which is known as urobilinogen. Large amounts of urobilin are found in urine during liver diseases and in constipation.

Low concentrations of urobilinogen are found in urine even in normal conditions. Urobilinogen is formed in the intestine from bilirubin and some amount of it is absorbed back into the blood. Positive test for urobilinogen indicates liver diseases, like viral hepatitis, cirrhosis, liver damage due to toxic substances and increase in RBC destruction (haemolytic anaemia).

v) **Porphyrins:** In a healthy adult, around 60-280 µg of porphyrins is excreted per day in urine. Their excretion increases in some liver diseases as well as excess amount of porphyrins in urine also indicates that patients suffering from porphyria.

Whole urinalysis includes the following **three distinct testing phases**:

1) **Visual Examination:** In this phase, the colour and clarity of urine sample is observed by the laboratorian to obtain an idea about the substances present in urine. These observations are used along with chemical and microscopic examination to confirm the presence of various substances.

Urine colour has a wide variety and the most common shade is yellow (ranging from very pale or colourless to very dark or amber colour). Colour of urine is affected by various conditions like diseases, several medications (**e.g.,** multivitamins can turn urine bright yellow), and eating certain food (**e.g.,** beets contain natural pigment that makes the urine red in colour). Red-colour of urine also indicates the disease or damage is limited to some part of the urinary system, whereas yellow-brown or greenish-brown colour of urine can indicate the presence of bilirubin in urine.

Urine clarity means how clear the urine is. The clarity of urine can be described as clear, slightly cloudy, cloudy, or turbid. Even normal urine can be clear or cloudy. Cloudiness may be caused by the presence of mucus, sperm, prostatic fluid, skin cells, normal urine crystals, and contaminants (body lotions and powders); however presence of these substances is not considered unhealthy. While the presence of certain substances such as RBCs, WBCs, or bacteria, indicates an unhealthy condition and requires attention.

2) **Chemical Examination:** These examinations are performed chemically to determine the following factors that give information about the urine concentration, and the health and diseased conditions:

i) **Specific Gravity:** It is the measurement of urine concentration. Measurement of specific gravity compares the amount of substances dissolved in urine as compared to pure water. The specific gravity of the urine will be 1.000 (same as pure water) if any substance is not present in the urine, but it is not possible as

even normal urine has certain substances. S pecific gravity of urine can be very close to that of water if an individual drinks excessive amount of water in a short period of time or gets an intravenous infusion of large volumes of fluid.

ii) **pH:** Generally urine is slightly acidic, having pH 6 which ra nges between 4.5 to 8. The kidneys help in maintaining the acid-base balance of the body. Therefore, conditions causing acids or bases in the body (like acidosis or alkalosis, or the intake of acidic or basic foods) may directly affect the urine pH.

iii) **Proteins:** Presence of proteins in urine is detected by the following tests:
   a) **Sulphosalicylic Acid Test:** In a test tube, 5ml of protein solution is taken and added with sulphosalicylic acid drop wise. The solution is mixed after adding each drop. Formation of a wh ite precipitate or turbidity indicates the presence of protein.
   b) **Heller's Test:** In a test tube, 3ml of concentrated nitric acid is taken. The test tube is inclined and 3ml of protein solution is added along the test tube wall. A white precipitate formed at the junction of the two fluids indicates the presence of protein.
   c) **Heat Coagulation Test:** Two-third of the test tube is filled with protein solution and 4-5 drops of chlorophenol red is added with thorough mixing. Purple red colour develops. Acetic acid (1%) is added drop wise until the colour changes to a faint pink. The test tube is held at its bottom in slightly inclined position and the upper portion of the fluid is heated. Formation of a dense coagulum occurs in the upper part of the solution. Positive r esults are obtained for heat coagulable proteins, albumin, and globulin.

iv) **Carbohydrate: Benedict's test** (copper sulphate, sodium citrate, and sodium carbonate) is performed for the detection of carbohydrates in urine. In this test, 5ml of reagent is taken i n a test tube and 8 drops of sugar solution are added. The test tube is placed in a boiling water bath for 5 minutes. Formation of a green, yellow, or orange red precipitate indicates the presence of reducing sugar.

v) **Ketone Bodies: Rothera's test** is performed for the detection of ketone bodies in urine. In this test, 5ml of urine is taken in a test tube. Solution is saturated with solid ammonium sulphate, and 2-3 drops of a freshly prepared 5% solution of sodium nitroprusside are added. 2ml of concentrated a mmonium hydroxide solution is added in the solution with proper mixing. Formation of a permanganate colour indicates the presence of ketone bodies in urine. Sodium nitroprusside [Na-Nitroferricyanide] decomposes to $Na_4Fe(CN)_6$, $NaNO_2$, and $Fe(OH)_3$ in an alka line solution. These are strong oxidising agents of rose or purple colour. The ammonium sulphate acts as a buffer maintaining the alkalinity with the range at which the complex has a purple colour.

vi) **Tests for Bile Pigments and Bile Salts:** Presence of bile pigments and bile salts can be detected by the following tests:
   a) **Gmelin's Test for Bile Pigments:** In a test tube, 5ml of concentrated nitric acid and an equal volume of urine are added so that two layers are formed. Formation of various coloured rings (gree n, blue, violet, reddish yellow , and red) at the junction of two liquids indicates the presence of bile pigments.
   b) **Hay's Test for Bile Salts:** Half of a test tube is filled with water and half of another test tube is filled with urine. Some sulphur powder is sprinkled on the surface of two liquids. If the sulphur powder suddenly sinks in the test tube containing urine, presence of bile salts is confirmed, while the sulphur powder remains on the surface in the test tube containing water.

vii) **Test for Blood:** Presence of blood in urine can be confirmed by **Benzidine test**. In this test, a pinch of solid benzidine is taken in a test tube and 2ml of glacial acetic acid is added to dissolve benzidine. 2 ml of hydrogen peroxide is added and the solution is divided in two p ortions. In one portion, urine is added dropwise with shaking. Presence of blood in urine is confirmed if a blue colour appears, which quickly changes to brown. In the other portion, water is added dropwise. No blue colour appears in the other portion.

3) **Microscopic Examination:** Microscopic examinations are not performed routinely. These tests are generally performed when abnormal results are obtained from physical and chemical examinations.

The microscopic tests are performed with urine sediment, i.e., the urine that has been centrifuged to concentrate the substances in it, at the bottom of a tube. The top layer of the tube is discarded and the remaining drops of fluid are analysed under a microscope. Cells, crystals, and other substances are calculated and measured either as the number observed **Per Low Power Field** (LPF) or **Per High Power Field** (HPF). Along with this, some bodies (if present) are estimated as 'few', 'moderate', or 'many', such as epithelial cells, bacteria, and crystals.

22.2. SUMMARY

The details given in the chapter can be summarised as follows:

1) Study of **blood chemistry** is a process in which a sample of blood is checked to determine the quantity of some specific materials released into the blood by body organs and tissues.
2) **Urea** is a by-product of protein metabolism.
3) The **BUN test** evaluates the nitrogen content in urea
4) High levels of BUN indicate kidney dysfunction.
5) **Serum creatinine test** evaluates the blood level of creatinine (a by -product of muscle energy metabolism).
6) **Uric acid** is the end product of purine metabolism.
7) Normal results for **creatinine c learance** for a 24 -hour urine collection are 90 -139ml/min and 80 -25ml/min for adult males and females below 40 years old, respectively.
8) A 24-hour urine collection should contain no more than 150mg of protein.
9) In **oral glucose tolerance test**, a patient is requested to have at least 10 hours of fast and is administered with drinking water containing 75gm glucose.
10) For differentiating Type I and Type II diabetes, blood samples are analysed by radioimmunoassay for **serum insulin**.
11) **C-Peptide** test is performed by radioimmunoassay to confirm that the patient is type I or not.
12) **Glycosylated haemoglobin** test involves a non -enzymatic chemical reaction between glucose and phosphorylated sugar with the end terminal valine of the β-chain of haemoglobin molecule.
13) **Creatine Kinase (CK)** catalyses the conversion of phosphocreatine to creatine, and releases high energy phosphate to cardiac and skeletal muscles.
14) **Lactate Dehydrogenase (LDH)** catalyses the conversion of pyruv ate to lactate anaerobically to produce Adenosine Triphosphate (ATP).
15) The normal value of LDH is 100-190 IU/litre.

16) Increase in TnI to more than 2.0 µg/l indicates acute myocardial injury. The normal value of TnI is 0.7-1.5ng/ml.
17) **Haematology** is the branch of medical science concerned with the study of blood, blood-forming tissues, and blood disorders.
18) **Total Haemoglobin (Hgb or Hb)** is a test used for estimating the quantity of haemoglobin in blood.
19) **Hematocrit (Hct)** estimates percentage by volume of RBCs in a whole blood sample.
20) **Red blood cell count** is the count of actual (or estimated) number of RBCs in per cubic mm of whole blood.
21) **Red cell indices (Wintrobe Indices)** are a report of specific characteristics of RBC.
22) **Reticulocyte count (retic count)** is used t o evaluate the definite numbers of reticulocytes (immature RBCs) in blood.
23) **Erythrocyte Sedimentation Rate (ESR)** measures the time needed for erythrocytes from a whole blood sample to settle at the bottom of a vertical tube.
24) **Osmotic fragility** measures res istance of RBCs to haemolysis when exposed to a sequence of gradually dilute saline solutions.
25) In **leukocytosis**, total leukocyte count increases.
26) A huge increase in leukocytes as a systemic response to many conditions (**e.g.,** tuberculosis, severe burns, ec lampsia, haemolysis, and haemorrhage) is known as **leukemoid reaction**.
27) **Eosinophils** are structurally identical to neutrophils, but cytoplasm has larger round or oval granules that comprise of enzymes, and have a strong affinity for acid (red) stains.
28) **Basophils** are identical to neutrophils except that their nuclei are less segmented and their cytoplasmic granules are bigger and have a strong affinity for basic (blue) stains.
29) **Lymphocytes** are mononuclear cells lacking cytoplasmic granules.
30) **Monocytes** are the b iggest cells in normal blood having a diameter of two or three that of erythrocytes.
31) **Platelets** keep the integrity of blood vessels and are involved in haemostas is.
32) **Thrombocytopenia** is a condition of small number of circulating platelets, which can rise as a congenital or acquired disease due to lowered production, abnormal distribution or dilution, or increased destruction of platelets.
33) **Differential cell count** test counts the actual numbers of different types of WBCs.
34) **Activated Partial Thromboplastin Time (aPTT)** is used to measure the integrity of the intrinsic and general pathways of coagulation.
35) **Prothrombin Time (PT)** is used to assess the extrinsic and general pathways.
36) **Thrombin Time (TT)** is used to measure the ability of body to convert fibrinogen into fibrin.
37) **Bleeding ti me** is used as a screening test to measure function of platelets, but it is not precise.
38) **D-dimer fragments** are formed when a fibrin clot undergoes lysis.
39) A **urinalysis** is a set of physical, chemical, and microscopic tests which detect or measure the constituents excreted in the urine like the by -products of normal and abnormal metabolism, cells, cellular fragments, and bacteria.
40) Presence of abnormal concentration of albumin and globulin in the urine is known as **proteinuria** (or **albuminuria**),
41) Presence of glucose in urine is known as **glycosuria** which occurs due to diabetes mellitus and endocrinal disorders such as hyperpituitarism, hyperthyroidism, Cushing's syndrome, and pheochromocytoma.

42) Presence of fructose sugar in urine due to disturbed fructose metabolism is known as **fructosuria**.
43) A condition in which bile salts are excreted in urine is known as **bilirubinuria**.
44) Presence of RBCs in urine is known as **haematuria**.
45) During excessive haemolysis, part of the bile pigment formed by the breakdown of haemoglobin is excreted out through urine which is known as **urobilinogen**.
46) In a healthy adult, around 60-280µg of porphyrins is excreted per day in urine.
47) Generally urine is slightly acidic, having pH 6 which ranges between 4.5 to 8.
48) **Benedict's test** is performed for the detection of carbohydrates in urine.
49) **Rothera's test** is performed for the detection of ketone bodies in urine.
50) Presence of blood in urine can be confirmed by **Benzidine test**.

22.3. EXERCISE

22.3.1. True or False

1) Creatinine is a by-product of protein metabolism.
2) Uric acid is the end product of purine metabolism.
3) A 24-hour urine collection should contain no more than 80mg of protein.
4) The normal value of LDH is 200-290 IU/litre.
5) Hematocrit estimates percentage by volume of RBCs in a whole blood sample.
6) Wintrobe Indices are a report of specific characteristics of WBC.
7) In leukocytosis, total leukocyte count decreases.
8) Eosinophils are identical to neutrophils except that their nuclei are less segmented and their cytoplasmic granules are bigger.
9) Monocytes are the biggest cells in normal blood having a diameter of two or three that of erythrocytes.
10) Differential cell count test counts the actual numbers of different types of RBCs.
11) Thrombin time is used to measure the ability of body to convert fibrinogen into fibrin.
12) Generally urine is slightly basic, having pH 8 which ranges between 8 to 11.
13) Rothera's test is performed for the detection of bile salts in urine.

22.3.2. Fill in the Blanks

14) High levels of BUN indicate _____.
15) Normal results for creatinine clearance for a 24-hour urine collection are _____ for adult males and _____ and for adult females below 40 years old.
16) For differentiating Type I and Type II diabetes, blood samples are analysed by radioimmunoassay for _____.
17) _____ involves a non -enzymatic chemical reaction between glucose and phosphorylated sugar with the end terminal valine of the β-chain of haemoglobin molecule.
18) _____ catalyses the conversion of phosphocreatine to creatine, and releases high energy phosphate to cardiac and skeletal muscles.
19) _____ measures the time needed for erythrocytes from a whole blood sample to settle at the bottom of a vertical tube.
20) _____ measures resistance of RBCs to haemolysis when exposed to a sequence of gradually dilute saline solutions.

21) _____ is a condition of small number of circulating platelets.
22) D-dimer fragments are formed when a _____ undergoes lysis.
23) Presence of RBCs in urine is known as _____.
24) _____ is performed for the detection of carbohydrates in urine.
25) _____ is used to measure the integrity of the intrinsic and general pathways of coagulation.
26) Presence of _____ in urine can be confirmed by Benzidine test.

Answers

1) False	2) True	3) False	4) False	5) True
6) False	7) False	8) False	9) True	10) False
11) True	12) False	13) False	14) Kidney dysfunction	
15) 90-139ml/min and 80-25ml/min		16) Serum insulin	17) Glycosylated haemoglobin test	
18) Creatine kinase	19) Erythrocyte sedimentation rate		20) Osmotic fragility	
21) Thrombocytopenia	22) Fibrin clot	23) Haematuria	24) Benedict's test	
25) Activated partial thromboplastin time		26) Blood		

22.3.3. Very Short Answer Type Questions

1) What is BUN?
2) Give any two liver function tests.
3) What is the oral glucose tolerance test?
4) Give the normal values of haemoglobin and hematocrit.
5) Write about the ferritin test.
6) What are the normal osmotic fragility values?
7) How the presence of ketone bodies is tested in urine?

22.3.4. Short Answer Type Questions

1) What are the different kidney function tests?
2) Give the tests for cardiovascular disorders.
3) Discuss how diabetes mellitus is diagnosed with plasma glucose.
4) Mention any two blood tests.
5) Write a note on coagulation test.
6) How blood, bile pigments and bile salts are detected in blood?

22.3.5. Long Answer Type Questions

1) Discuss in brief about blood chemistry tests.
2) Give a brief review on urinalysis.
3) Write an illustrative note on haematology.

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