

HOSPITAL AND ITS ORGANIZATION

Points to be covered in this topic

DEFINATION

CLASSIFICATION OF HOSPITAL

ORGANIZATION STRUCTURE OF HOSPITAL

MEDICAL STAFF AND THEIR FUNCTIONS

DEFINATION

- The hospital is a **complex organisation** and an institute which **provides health** to people through complicated but **specialized scientific equipments** and team of **trained staff educated** in the problems of modern medical science.
- They are all **co-ordinated** together for the **common goal** of restoring and **maintain good health**



FUNCTIONS OF A HOSPITAL

- A **modern hospital** is much more than a **health care institution** since it exercises **greater influence** on the surroundings.
1. It raises the **quality of care** and **general standards** of medial practice.
 2. It is a **centre of community** health and **contributes a great deal** to **preventive and social medicine**.
 3. It **lowers the incidence** of disease through **early detection** and **immediate treatment**.
 4. It is a **link between** the **general public and policy makers**.
 5. It stimulates the **growth of medical science** . Doctors and nurses receive their **training in large teaching** hospitals.
 6. **Bigger hospitals** co-operate with **smaller hospitals**. **Speciality hospitals** co-operate with **general hospitals**.

CLASSIFICATION OF HOSPITAL

❑ PRIMARY HOSPITALS

- **Primary care hospitals** provide the services of the **day-to-day healthcare facilities** by **health care practitioners**.
- In **such hospitals**, the **health care provider** act as the **principal** and main point of **contactors** for **continuing care** of the patient and may **co-ordinate** other **specialists** for the **care of the patient** if need.
- This type of **hospital provides** mostly basic health **care facilities** and consider as a gateway to receive **more specialty** care facilities for example: **Upazilha Health Complex**.

❑ SECONDARY HOSPITALS

- This type of **hospital provides** the **first level** of recommendation services which are **more complicated** and beyond the **scope and capacity** of the **primary level**.
- This level is allocated to provide **some specialist** care services mostly in **Internal Medicine, General Surgery, Obstetrics and Gynaecology , and Paediatrics** .
- Such level of a hospital usually provides **50-200 bedded capacity**.

❑ TERTIARY LEVEL

- Such a **level of hospitals** deals to provide **highly specialized** care services at **regional or central-level hospitals**.
- Like **teaching hospitals, super-specialized hospitals** like; **Cancer hospitals, Chest hospitals, Infectious Disease hospitals, and Mental Disease hospitals** are also included in this level of care.
- These institutions provide **recommendation support** to **primary and secondary level health care**.
- This also includes **Divisional and National Level Hospitals**.

❑ BASED ON CLINICAL

- **Clinical hospital** is a **healthy care facility** that is **primarily focused** on the **care of outpatients**.
- These are **privately operated** or **Publically managed** and funded .

❖ BASIS OF MAJOR DISEASES

- **Psychiatric hospitals** or **mental hospitals**
- **T.B. hospitals**
- **Leprosy hospitals**
- **Cancer hospitals**

❖ BASIS OF ANATOMICAL - PHYSIOLOGICAL SPECIALIZATION

- **Ear , nose and throat hospitals**
- **Orthopaedic hospitals**
- **Eye hospitals**
- **Kidney hospitals**

❖ BASIS OF THE CLIENT GROUP THEY SERVE

- **Paediatric hospitals**
- **Gynaecological hospitals** for women
- **Maternity hospitals** for mothers

❖ BASIS OF SYSTEM OF MEDICINE

- **Allopathic hospitals**
- **Ayurvedic hospitals**
- **Homeopathic hospitals**
- **Unani hospitals**
- **Nature cure centres**
- **Physio- therapy centres**

❑ BASED ON NON-CLINICAL

❖ PUBLIC OWNERSHIP

✓ Central government hospitals

- Like the **railway hospitals**, **defence hospitals**, **All India Institute of Medical sciences**, **P.G. Institute of Medical Sciences**, **Pondicherry** or **chandigarh**

✓ State government hospitals

- Like civil hospitals at **district headquarters**, **Sassoon hospitals**, **Pune**; hospital, **Mumbai**

✓ Local self - government hospitals

- These are **run by municipalities** or corporations, E.g. **BMC hospitals** like **Bhagwati hospital** in **Mumbai**.

❖ PRIVATE OWNERSHIP

✓ Trusts

- The board of trustees manage the affairs, e.g. **Mumbai hospital**; **Jaslok hospital**, **Mumbai**.

✓ Religious bodies / orders

- **Ram krishna hospital**, **Kolkatta**; **Christian Medical college hospital**, **vellore**.

✓ Limited companies

- They can be incorporated as **public limited company**, where the public subscribes to the share capital e.g. **Apollo hospitals, ltd.**, **Chennai**; **medinova centre's** proposed limited hospitals at **baroda**.

❖ BASIS OF SIZE

✓ Large hospitals

- **Beds 1000 and above**
- Example - **J.J. group of hospitals in Mumbai**, **K.E.M, Mumbai**

✓ Medium hospitals

- **Beds between 500 - 1000**
- Example - **Mumbai hospital**, **Jaslok hospital**

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✓ **Small hospitals**

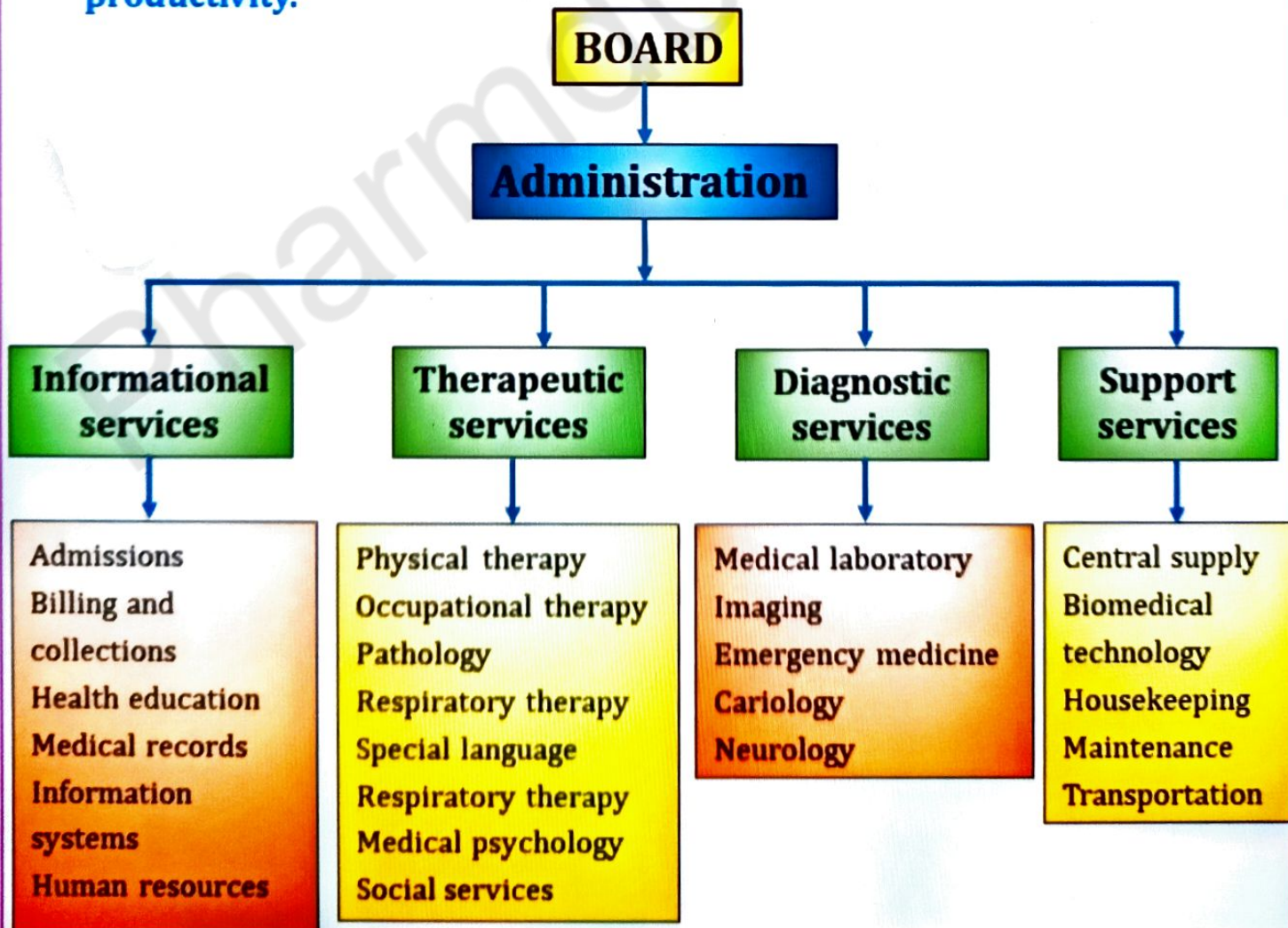
- Beds between 100 - 500
- branch candy hospital , Mumbai has a bed capacity of 130 beds

✓ **Very small hospitals**

- Bed less than 100

ORGANIZATION STRUCTURE OF HOSPITAL

- If the organizational structure of a hospital is **not planned** and **coordinated**, there can be **disastrous and potentially life-threatening consequences**.
- Therefore, **hospitals** need to have a clearly defined and **precise organizational structure** to ensure that **no mistakes** are made during the **healthcare provision** and **administrative process**.
- **Comprehensive and holistic organizational** structures can help hospital employees understand their **day-to-day responsibilities**, **facilitate decision-making**, and **revitalize employee performance** and **productivity**.



❖ THE BOARD OF DIRECTORS

- The **board of directors** is a governing **regulatory body** that helps **hospitals** make **higher-level organizational** decisions.
- The **board of directors** for hospitals usually **consists of medical** experts and **influential members** of local communities.
- Hospitals that are **affiliated or overseen** by universities may also include **teaching faculty** on the board of directors.
- The **board of directors** is responsible for **guiding the hospital's mission** statement and **future goals**, and they ensure to achieve them.
- Furthermore, the **board of directors** must create **long-term strategic** plans for **growth and stability**.

❖ EXECUTIVE MANAGEMENT

- **Executives** are **responsible** for **successfully performing** the hospital's day-to-day **managerial decision-making**.
- A hospital **executive's organizational** role is usually extremely specified depending on which **specific function** they are responsible for.
- This includes **financial resource allocation**, medical executive decision making and **administrative operations**.

❖ HOSPITAL AND DEPARTMENTAL ADMINISTRATION

- **Department administrators** are responsible for **reporting to hospital** executives about the **specific daily departmental** operations of the **organization and carrying** out decisions made by **executive management**.
- These include **supervising the provision** of **emergency healthcare** services, **overseeing supply** and **purchase of necessary** medical equipment, **monitoring departmental surgical** activities and much more.

❖ PATIENT CARE SERVICE MANAGEMENT

- **Patient care managers** are **hospital employees** that oversee and manage healthcare service providers
- This includes **creating employee schedules**, ensuring that the overall **healthcare provision** process is carried out **appropriately**, confirming that the **hospital complies** with **legal, regulatory requirements** and **addressing patient** concerns.

❖ PATIENT SERVICE PROVIDERS

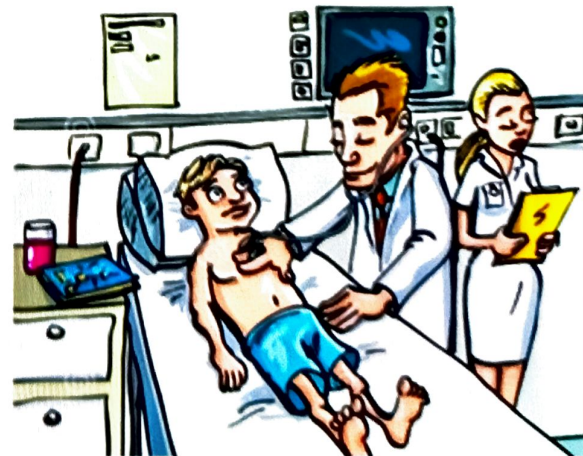
- Patient service providers include **all employees** that **directly provide medical care to patients**, including **doctors, nurses, laundry workers, therapists** and more.
- Patient **service providers** are **responsible for communicating** with patients personally, **maintaining individual** patient **medical records** and **ensuring that patients** receive the best care possible.

MEDICAL STAFF AND THEIR FUNCTIONS

- A **hospital care** team includes many **different practitioners**.

❑ ATTENDING PHYSICIAN

- The **attending physician** is the **leader of the team** and has responsibility for **all decisions made** that affect a **person's care, including diagnosis, treatments, and supervision** of the remainder of the team.
- Based on the **problem** that **brought the person** to the hospital, the **attending physician** may be a **hospitalist** (a doctor who is trained in **internal medicine** and works only with **people** who are hospitalized), a **surgeon**, or another **specialist physician**. In **smaller communities**, the **person's primary care** doctor may act as the **attending physician**.



RESIDENTS, INTERNS, AND MEDICAL STUDENTS

- Some hospitals are designated as teaching hospitals.
- That is, the hospital team includes medical students who are at various stages of education and who are supervised by the attending physician.
- A resident or intern is a fully licensed doctor who is engaged in further training after graduating from medical school.
- Although these team members are not attending physicians, they are often active members of the team.



SPECIALISTS

- When people have complex or serious medical problems, the attending physician sometimes requests that specialists evaluate the person and recommend how to best diagnose and treat the problems.
- For example, the specialist may be a doctor who is extensively trained in the diagnosis and treatment of disorders of the heart (cardiologist), kidneys (nephrologist), or cancer (oncologist).



REGISTERED NURSES

- People usually have more contact with the registered nurses (RNs) assigned to their care than any other member of the team.
- RNs give drugs to people and monitor and evaluate their physical and emotional needs.
- When a person's condition suddenly changes, RNs are often the first to detect the change.



- RNs then **report the change** to the **attending physician** or **house staff**.
- RNs may be **charge nurses** or **nurse supervisors**, **organizing and monitoring** overall nursing care in a **hospital unit**.

❑ LICENSED PRACTICAL

NURSES

- **Licensed practical** nurses (LPNs) are supervised by **RNs** and **provide** basic **medical and nursing care**.
- For example, LPNs **check blood pressure**, **insert catheters**, and **help people bathe and dress**.
- LPNs also **talk to people** about their **health care**, answer their questions, and report how they are **doing to RNs and doctors**.



❑ NURSE PRACTITIONERS AND PHYSICIAN'S ASSISTANTS

- **Nurse practitioners** and **physician's assistants (PAs)** work closely with the **attending physician** to coordinate a person's daily care.
- They also help with **doing physical examinations** and **ordering drugs and treatments when people have more common or routine** medical or surgical problems.
- Although **nurse practitioners** and PAs are **not doctors**, they have **advanced training** in **diagnosis and treatment**. Nurse practitioners and **PAs are supervised** by doctors.



❑ PATIENT ADVOCATE

- **Patient advocates** are **non-medical administrators** employed by the hospital to **assist patients** receiving care there.
- In general, they **handle complaints** that people have about their **treatment** or **health care providers**.
- **People can meet** with a **patient advocate** if they **feel uncomfortable** discussing **concerns directly** with their **health care** providers or they feel that their concerns have **not been addressed**.



❑ PATIENT CARE TECHNICIANS

- Traditionally called **nurse's aides**, **patient care technicians** help nurses with **people's care**. Their duties may include
- Obtaining **vital signs** (measuring blood pressure and temperature)
- **Moving people** to and from a bed or **wheelchair**
- **Helping people with walking**
- **Providing items** for **people's comfort** (such as pillows and blankets)
- Sometimes, **helping feed people** who cannot feed themselves



❑ PHYSICAL THERAPISTS

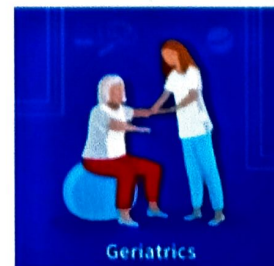
- **Physical therapists** evaluate and **treat people** who have **difficulty functioning**—for example, **difficulty walking, changing positions,** or **transferring** from a **bed to a chair**.



Orthopedics



Neurologicals



Geriatrics



Pediatrics

- **These problems** may develop or **worsen in the hospital** because people have to stay in **bed a long time** as may occur **after surgery**, or because their **disorder worsens**.

❑ OCCUPATIONAL

THERAPISTS

- **Occupational therapists** assess **people's ability** to do their **daily activities**.
- These activities include **eating, dressing, grooming, bathing, using the toilet, cooking, and cleaning**.
- **Occupational therapists** can **recommend strategies** and devices to help people function more **independently**.



❑ HOSPITAL PHARMACISTS

- **Pharmacists specialize** in how **drugs work** and **interact** with each other.
- Hospitals have **pharmacists** on their staff who **supervise** the use of **drugs in the hospital**.
- If needed, **hospital pharmacists** teach people how to **safely** and **effectively take** the **drugs prescribed** for them.
- For example, pharmacists may **advise people** to **avoid specific foods** that **interact** with their **prescribed drugs** or **teach people** how to **inject drugs** (such as insulin) at home.



❑ DIETITIANS

- **Registered dietitians** have **specialized nutritional** and **medical training** that helps them determine a person's **dietary needs** and plan the **person's meals** in and out of the hospital, as requested by the **attending physician**.
- When **planning meals**, **dietitians** consider the person's personal, cultural, and **religious food preferences**.



❑ RAPID RESPONSE TEAM

- **Rapid response teams** are groups of designated hospital staff (often a **doctor**, **nurse**, and **respiratory therapist**) who **quickly come** to a **person's hospital** room if there is any **indication** that their **condition** is **deteriorating**, such as **abnormal vital signs**, **trouble breathing**, **chest pain**, or **signs of a stroke**.
- After **ordering tests** or **starting treatments** to **stabilize a person's condition**, the team contacts the **attending physician** and may move the person to **another area** of the **hospital for specialized monitoring** or **treatment**.



HOSPITAL PHARMACY AND ITS ORGANIZATION

Points to be covered in this topic

INTRODUCTION

FUNCTIONS OF HOSPITAL PHARMACY

ORGANIZATION STRUCTURE

LOCATION AND LAYOUT

STAFF REQUIREMENTS

RESPONSIBILITIES AND FUNCTIONS

INTRODUCTION

- **Hospital pharmacy** is one of the most important department among **several departments** of a hospital.
- **Hospital pharmacy** may be defined as that **department of the hospital** which deals with **procurement, storage, compounding, dispensing, manufacturing, testing, packaging** and **distribution of drugs**.
- It is also **concerned with education** and research in **pharmaceutical services**.
- A **hospital pharmacy** is controlled by a **professionally competent** and a **qualified pharmacist**



FUNCTIONS OF HOSPITAL PHARMACY

- The **following functions** are performed by a **hospital pharmacy**
 1. The **dispensing of drugs, chemicals and pharmaceutical preparations**.
 2. The **filling and labelling of drug containers**.
 3. The inspection of **all pharmaceutical supplies**.
 4. The **dispensing of all narcotic drugs** and **alcohol** and the maintenance of a **perpetual inventory** of them.
 5. **Specifications** of the **quality of drugs, chemicals, antibiotics, biologicals** and **pharmaceutical supplies** used in the treatment of patients.
 6. Sources to get the **above products**.

7. To **maintain a satisfactory system** of records and **book-keeping** for the **above products** .
8. To maintain **adequate control** over **requisitioning and dispensing** of all drugs and **pharmaceutical supplies** .
9. To make **large volume injection fluids** and other **parenterals** , and to maintain **aseptic conditions** while doing so.
10. To do inhouse **production of drugs**, the buying of which from **outside sources** is **not prudent**.
11. To **furnish information** concerning medications to **physicians, interns and nurses**.

□ OBJECTIVE OF HOSPITAL PHARMACY

- To ensure the **availability of right medication**, at **right time**, in the **right dose** at the **minimum possible cost**.
- To **professionalize the functioning** of pharmaceutical services in a hospital.
- To act as a **counseling department** for **medical staff, nurses** and for patient.
- To act as a **data bank** on drug utilization.
- To **participate** in research projects.
- To **implement decisions** of the **pharmacy** and **therapeutics committee**

ORGANIZATION STRUCTURE

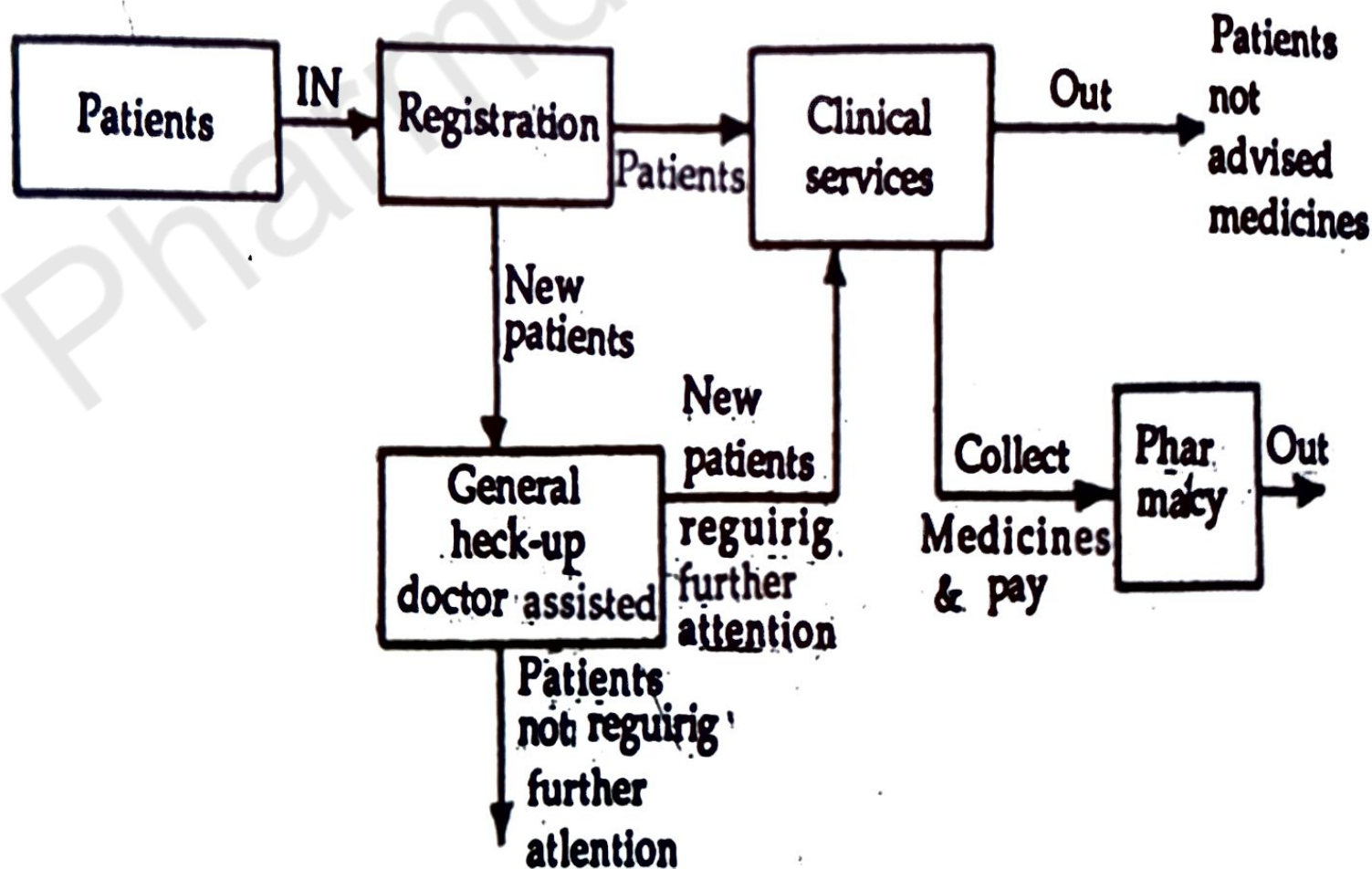
- The **pharmacy manager** identifies a **relatively standard** organizational design that **most closely fits** the **pharmacy's needs**.
- The **design is molded** to match with **unique requirements** of the **pharmacy and hospital administrator**.
- The **size and nature of a pharmacy** department's management staff will depend on the **number of personnel** in the department and the **scope of services delivered**.
- **Small pharmacies** tend to have much **simpler organizational structures**, this is usually **generally understood** and no problems arise (for example: the pharmacy in primary health center).
- **Large pharmacies** with **assistant chief pharmacists**, supervisors, and **unprofessional personnel** have **complex organizational structures**.
- Therefore, the authority must be **delegated by the chief pharmacist**.

LOCATION AND LAYOUT

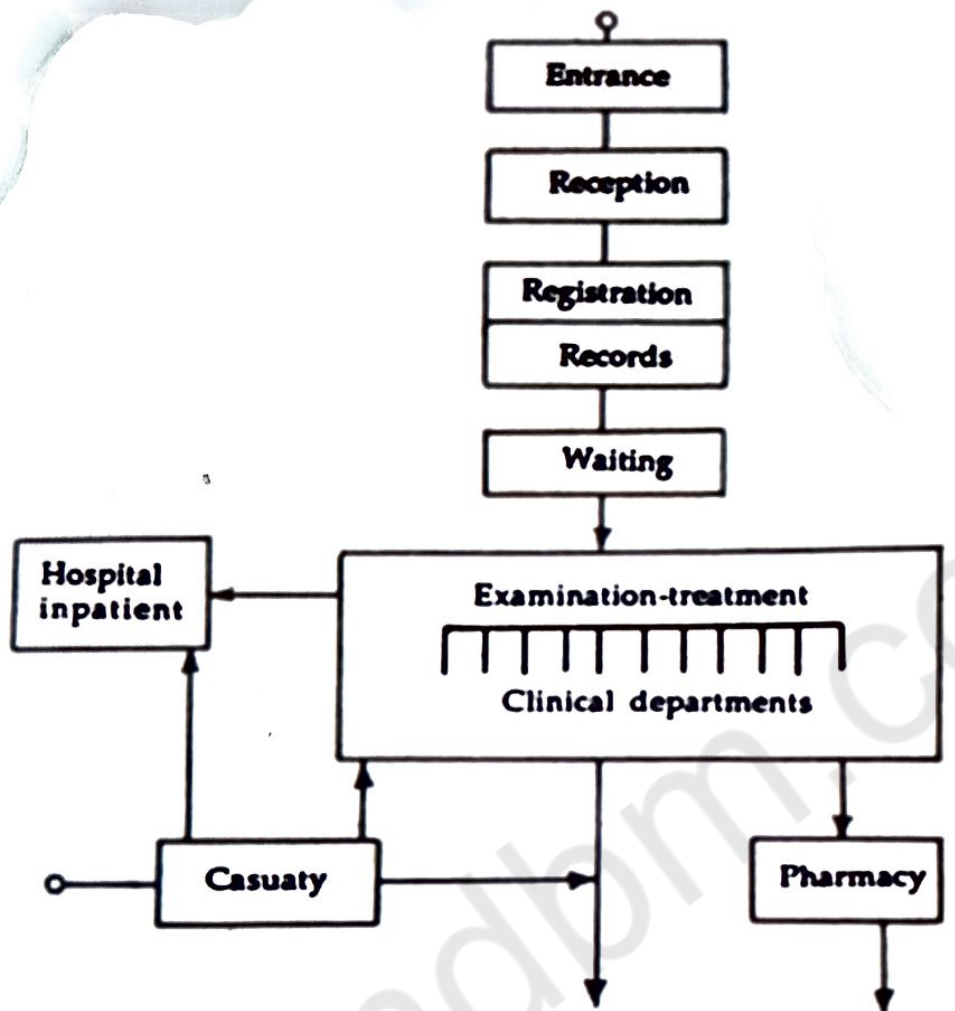
- Wherever possible, the pharmacy should be **located on the first floor**, or on the **ground floor** of the hospital, such that it is **readily accessible** to the **elevators**, to ensure **sufficient and effective service** to the various **departments and nursing stations**.
- In case the **hospital** has an **outpatient department**, the **pharmacy** or a **branch** there of should be conveniently located near it.
- In a **multi-storeied hospital**, if necessary, **floor pharmacies** should be provided .
- The **departments should** be so **laid out** that there is a **continuous flow** of **men and materials**.
- The departments should be **vertically separated** .
- **Outpatient pharmacy** must have a **pleasant look** and must have enough space for **seating patients** who are **waiting for medicine**.

- The interior **should not be congested**.
- **Outpatient pharmacy's** waiting room should have **professional look**.
- It should **display educative posters** on **health and hygiene** and can offer **light literature** for reading to **fill up the waiting time**.
- **Visitors should carry** a **positive image** of pharmacy .
- Space must be assigned for **routine manufacturing** of **preparations** which can be **processed profitably** e.g. **stock solutions, bulk powders, ointments, etc.**
- The **manufacturing room** can be adjacent to the **pharmacy** or can be located in the **basement directly below** the pharmacy .

❑ FLOW CHART OF PATIENTS

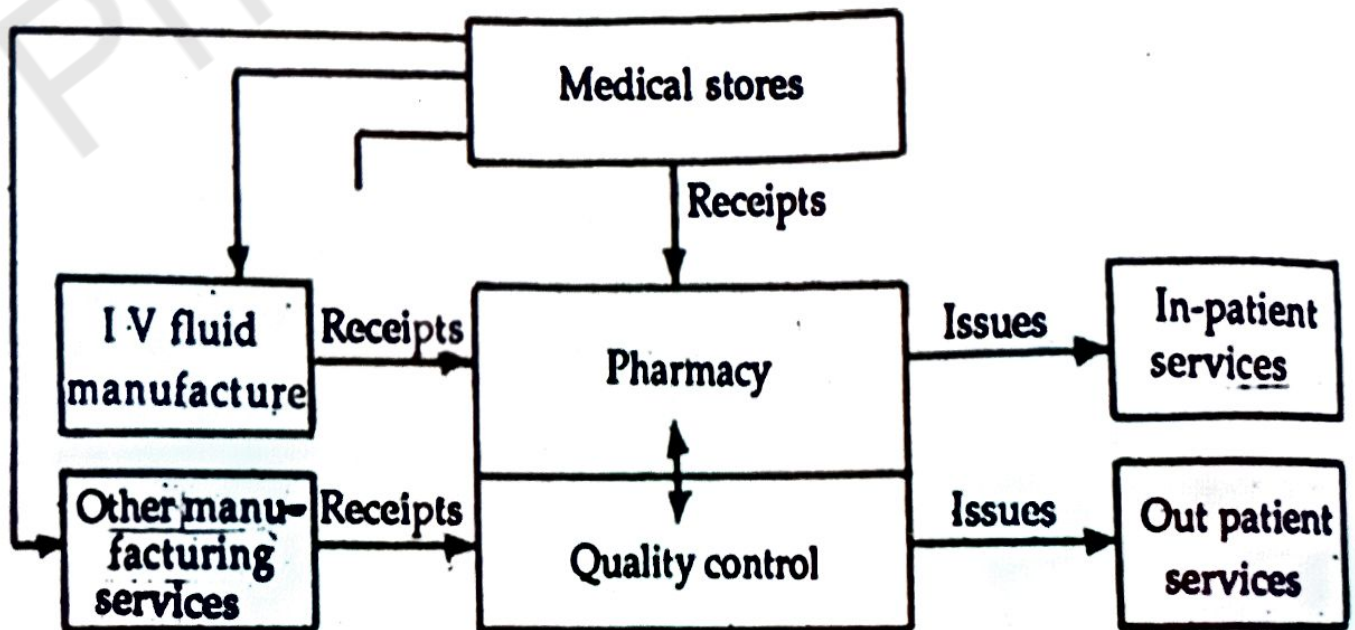


□ FLOW CHART OF OUT PATIENT



General Flow Chart for Out-Patients

□ FLOW CHART OF MATERIALS



STAFF REQUIREMENTS

- A **staff requirement** in the **hospital pharmacy** depends upon the **strength of patients** available in the **hospital wards** or **hospital premises**.
- Based on the strength, the **following table** shows the **requirement of staff** i.e. **pharmacists** in the **hospital pharmacy department**.

Bed strength	Number of pharmacist
Up to 50 beds	3
Up to 100 beds	5
Up to 200 beds	8
Up to 300 beds	10
Up to 500 beds	15

RESPONSIBILITIES AND FUNCTIONS

- The **hospital consists** of various departments like **outpatient department** (OPD), **inpatient department** (IPD), **manufacturing of sterile products**, **therapeutics committee**, etc.
- **Every department dealing** with **drugs** and there **play a role** by a hospital pharmacist.
- Following should explain **briefly the roles** of hospital pharmacists:

❖ HOSPITAL AND THERAPEUTIC COMMITTEE

- The pharmacist is an **important member** of **the hospital and therapeutic committee**.
- A **pharmacist** usually comes **second in command**, after a **physician in the committee**.
- **Pharmacists** work toward **maximizing and maintaining** rational drug use.

❖ DISPENSING TO IPD/OPD

- Before dispensing a drug, the pharmacist must make sure about the correct prescription of the drug and its validity with regards to diagnosis and treatment.
- Pharmacists should also check for any modification concerning the dose regimen.
- A pharmacist is responsible for the distribution of drugs within the ward and he is coordinating with nurses.

❖ DRUG DISTRIBUTION

- Pharmacist has a major role in supervising regarding proper distribution of drugs across inventory, pharmacy, floor pharmacy, ward pharmacy, IPD, OPD, etc. to avoid ambiguities or any other failures.

❖ PURCHASING, INVENTORY CONTROL, AND BUDGET

- Hospital pharmacist plays an important role in purchasing drug account.
- There are varieties of products with similar characteristics in such cases pharmacist has to choose the best few from a variety of products.
- The pharmacist has to take balancing and rational decisions considering the economy, health, and end-user service.

❖ CONTROLLED SUBSTANCES, PROCUREMENT, AND DISTRIBUTION

- Hospitals procure controlled substances in large volumes thus supervising this unit by the pharmacist has crucial.
- For the procurement of controlled substances, there is required complete legal paperwork and the pharmacist is authorized by law for procurement.
- Without the consent of a pharmacist, the hospital cannot procure the same..

- A pharmacist has also a **responsibility to regulate** the use of such substances on **hospital premises** because such substances are **very likely to misuse**

❖ MANUFACTURING BULK AND STERILE PRODUCT

- **Large hospitals manufacture** their bulk drugs to **save cost** and allow a **steady supply** of commonly **used drugs**, for example: Paracetamol, Ranitidine, Saline solution, Dextrose solution, etc.
- In **such a hospital**, the **manufacturing plant** or **unit is segregated** into **several departments** like **manufacturing, packaging, labeling, QA , etc.**
- A **pharmacist** has to **supervise the activities** of **manufacturing** as well as have a **responsibility to control them.**

❖ HOSPITAL FORMULARY

- **Hospital Formulary** is a **brief and compilation** of all information related to **drugs and guidelines** for **regulation in hospitals.**
- It is **similar to pharmacopeia** but intended towards incorporating **better and cheaper, condition-specific drugs** in the hospital pharmacy.
- It generally contains the **drug information** which is **particularly preferred** by **hospital pharmacists** for the patient.
- A **pharmacist** plays actively involved in the **preparation, updating, reviewing,** and following a **hospital formulary.**

❖ INVESTIGATIONAL DRUG USE

- Based on the **technical expertise** hospital pharmacist are work in **phase 1 and phase 2 clinical trials.**
- Drugs used in **clinical trials** are **generally reviewed** by **hospital pharmacists** and **HTC before use.**

❖ EDUCATIONAL AND TRAINING PROGRAMS

- The **majority of hospitals** provide **training programs** for healthcare practitioners.
- Such **training programs** run under **diverse faculty** of **physicians, administrators, nurses, pharmacists, etc.**
- In such a **program pharmacist** has played a **role in training fresh** or **junior pharmacist.**
- They **provide theoretical** and **practical training** to trainees.

ADVERSE DRUG REACTION

Points to be covered in this topic

INTRODUCTION

CLASSIFICATIONS

**TOXICITY FOLLOWING SUDDEN
WITHDRAWAL OF DRUGS**

DRUG INTERACTION

**METHODS FOR DETECTING
DRUG INTRactions**

INTRODUCTION

- An **adverse drug reaction** (ADR) is a **harmful, unintended result** caused by **taking medication**.
- **ADRs** may occur following a **single dose** or **prolonged administration** of a **drug** or result from the combination of **two or more drugs**.
- The meaning of this term differs from the term "**side effect**" because side effects can be **beneficial** as well as **detrimental**.
- The study of **ADRs** is the concern of the field known as **pharmacovigilance**.
- An **adverse drug event** (ADE) refers to any **unexpected** and **inappropriate occurrence** at the time a drug is used, whether or not associated with the **administration of the drug**.
- **ADRs** are only one type of **medication-related harm**, as **harm** can also be caused by **omitting** to take **indicated medications**.



❑ REASONS FOR ADVERSE REACTION

❖ DISPENSING AND MEDICATION ADMINISTRATION ERRORS

- In **many cases**, the **physicians overprescribe** to the patient.
- These **prescriptions generally contain potent antibiotics**.
- Similarly, **self-medication** by the **patients** leads to **overuse or misuse** of the **drugs leading** to adverse drug reactions.

❖ FAILURE TO SET THERAPEUTIC END POINT

- Potent medicines when **abused or misused** may cause **adverse effects or even death**.
- **Failure of the physician** to set, the **therapeutic end point** is the reason for **adverse reactions** for drugs like **digitalis**, **corticosteroids**, **diuretics** etc.

❖ BIOAVAILABILITY DIFFERENCE

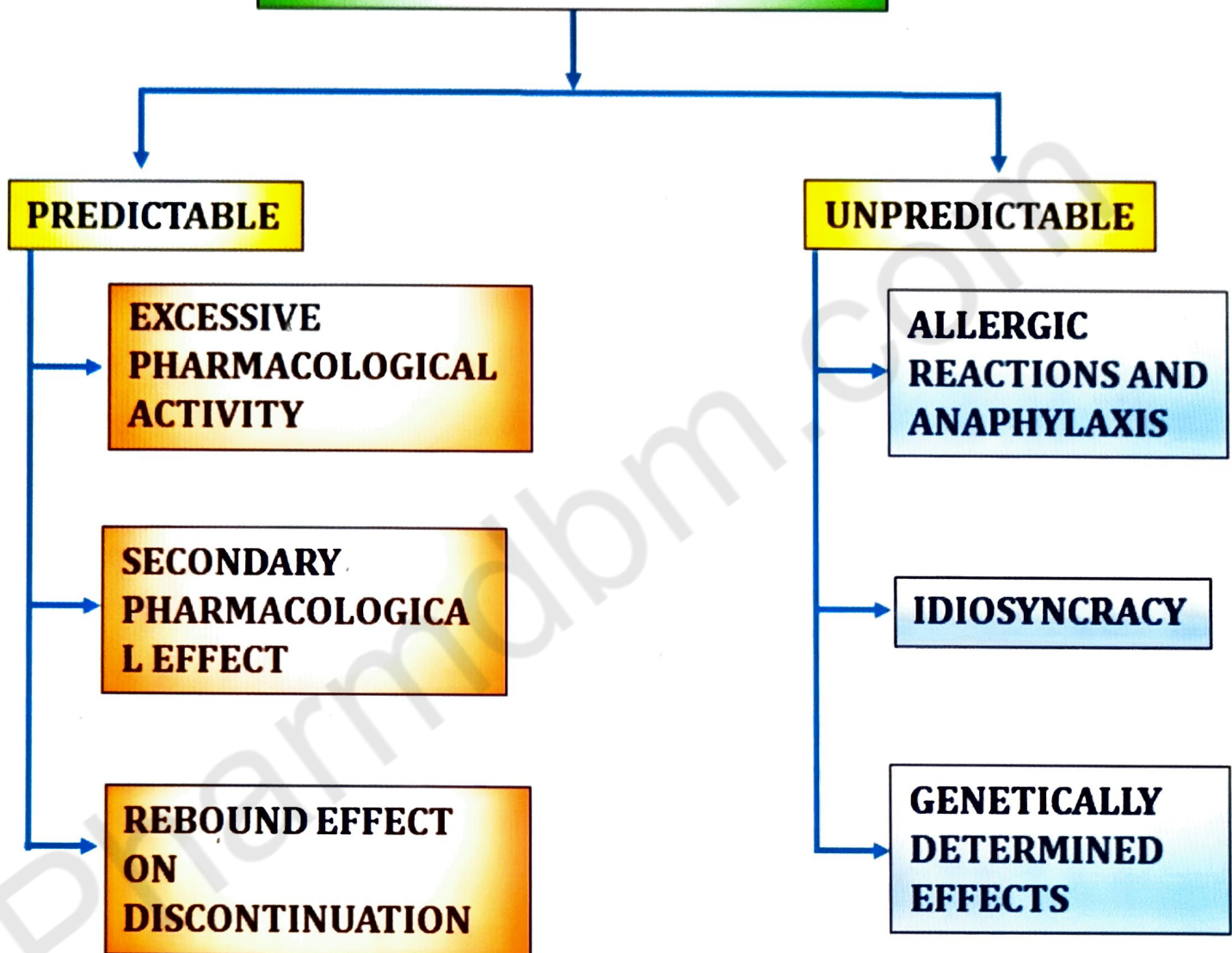
- **Difference in the bioavailability** from different formulations or **brands** of the **drug** may **also cause the adverse**.
- Difference in bioavailability from various brands of **digoxin**, **phenytoin**, **oxytetracycline** have resulted in **toxicity in some cases**.

❖ PATIENT FACTORS

- **Physiological and disease** status of **patient affects** adverse drug reactions.
- Very **young and old patients** are **more susceptible** to adverse drug reaction as **compared to the adult**.
- This is due to **marked difference** in the **metabolism and excretion** pattern at this age.
- Similarly, patients with renal and **hepatic damage** or **dysfunction** are **prone to adverse drug reaction** due to **disturbed metabolism** and **excretion of drugs**.
- **Adverse drug reactions** may be due to **inherited absence** or **deficiency** of **certain specific enzymes**.

CLASSIFICATIONS

ADVERSE DRUG REACTION



PREDICTABLE ADVERSE DRUG REACTIONS

- Some **adverse drug reactions** are not related to the **drug's therapeutic effect** but are **usually predictable**, because the mechanisms involved are **largely understood**.
- For example, **stomach irritation** and **bleeding** often occur in people who regularly **use aspirin** or other **nonsteroidal anti-inflammatory drugs (NSAIDs)**.

❖ EXCESSIVE PHARMACOLOGICAL

ACTIVITY

- It mostly occurs due to **CNS depressants** , **hypoglycemics** , **cardioactive agents** , and **hypotensive agents**.
- This type of **reaction develops** in all patients , if **excessive dosage** are given.
- Example :-
 - **Bradycardia in patients** receiving **excessive digoxin**.
 - **Respiratory depression** in patient suffering from **severe bronchitis** if **morphine** or **benzodiazepine hypnotics** are gives



❖ SECONDARY PHARMACOLOGICAL EFFECT

- An **adverse drug effect** is the **pharmacological effect** , other than the one for which the **drug was initially administered** , e.g. **patient receiving an antihistaminic** for the **prevention of motion sickness** may **become drowsy** .
- **Large proportion** of **adverse drug effects** are attributed to **secondary pharmacological effects**.



❖ REBOUND EFFECT AFTER DISCONTINUATION

- **Chronic use** of **certain drugs** produces tolerance at **cellular level** , and **sudden withdrawal** of such **drugs produces** severe **adverse effects**.
- This **type of reactions** are common with **drugs affecting CNS** and **some hypotensive agents**.
- **Example**



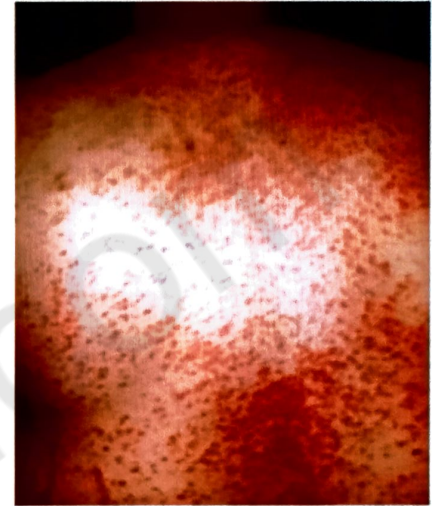
- **Rebound hypertension** on **sudden discontinuation** of an **hypotensive agent clonidine**.
- **Sudden withdrawal** of **corticosteroids** causes acute **adrenal crisis** characterized by **weakness and hypotension** in patients.

❑ UNPREDICTABLE ADVERSE DRUG REACTIONS

- The least severe **unpredicted adverse drug reaction** is **intolerance**, which appears to be an **exaggeration of pharmacological or toxic effects** of the drug among **vulnerable subsets of patients**.
- Some of the **most severe** and life-threatening adverse drug reactions are allergic.

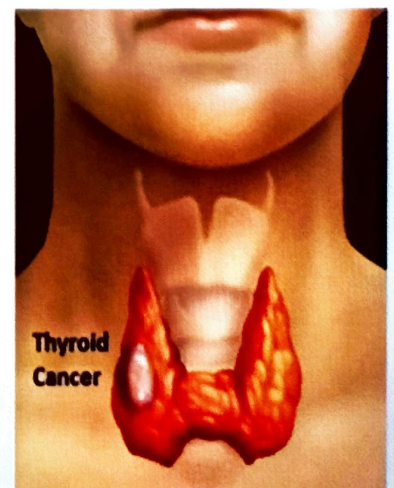
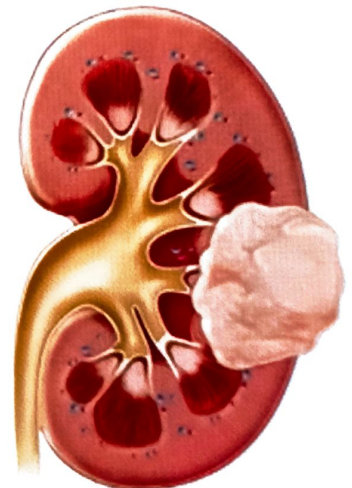
❖ ALLERGIC DRUG REACTIONS

- Allergy is an adverse response to a **foreign substances** resulting from a **previous exposure** to that **substance**.
- It is **manifested** only after a second or subsequent exposure.
- Only **small proportion** of the population, exposed to the drug, **exhibits allergic reactions**.



❖ IDIOSYNCRASY

- The **term idiosyncrasy** has long been used to denote both **quantitatively and qualitatively abnormal drug response**.
- Idiosyncrasy covers **unusual, bizarre or unexpected drugs effects** which cannot be **explained or predicted** in **individual recipients**.
- It also includes drug induced **foetal abnormalities** e.g. **phocomelia** which developed in the **offsprings** of **mothers exposed to thalidomide**.
- Example
 - **Analgesics** may **induce tumours** of **kidney** and **pelvis** in patients with **renal disease**.
 - **Thyroid cancer** may **develop** in patients who have received **131I therapy** in the past.



❖ GENETICALLY DETERMINED EFFECTS

- In **case of patients** with **special genotype** or **genetic make-up**, there is increased **risk of drug toxicity**,
- Example
 - **Patients with hereditary deficiency** of **pseudocholinestrase** are **unable** to metabolise the **muscle relaxant**, **succinyl choline** and may **develop prolonged paralysis** and **apnoea** following its use.

TOXICITY FOLLOWING SUDDEN WITHDRAWAL OF DRUGS

❑ INTRODUCTION

- **Drug withdrawal** is a **physiological response** to the **sudden quitting** or slowing of **use of a substance** to which the **body** has **grown dependent** on.
- The various types of **drug withdrawal syndromes** may involve different combinations of **physical, mental, and emotional symptoms**—some of which can prove **dangerous** if **left unmanaged**.



❑ SYMPTOMS OF WITHDRAWAL

- The **symptoms of withdrawal** from substances may be different **depending** on the substance used. **Common symptoms** of withdrawal may include:
 - ✓ **Trembling and tremors**
 - ✓ **Muscle pain or aches**
 - ✓ **Hunger or loss of appetite**
 - ✓ **Fatigue**
 - ✓ **Sweating**
 - ✓ **Irritability and agitation**

- ✓ **Depression**
- ✓ **Anxiety**
- ✓ **Nausea**
- ✓ **Vomiting**
- ✓ **Confusion**
- ✓ **Insomnia**
- ✓ **Paranoia**
- ✓ **Seizures**
- ✓ **Dilated pupils**

❑ **TYPES OF WITHDRAWAL**

- The **specific withdrawal** symptoms you **experience depends** on the type of **drug** you were taking.
- There are a number of **different drug** types that can result in **withdrawal**, including the following:
 - ✓ **Antidepressants**
 - ✓ **Barbiturates**
 - ✓ **Cannabis**
 - ✓ **Depressants**
 - ✓ **Hallucinogens**
 - ✓ **Inhalants**
 - ✓ **Opioids**
 - ✓ **Stimulants**
- The following are some examples of **specific substances** that may **lead to withdrawal** and the **expected duration** of those symptoms:
 - ✓ **Alcohol**
 - when a **heavy drinker** suddenly stops or **significantly reduces** their **alcohol intake**.
 - With **AWS**, you may **experience a combination** of **physical and emotional symptoms**, from **mild anxiety** and **fatigue to nausea**.

- Some symptoms of **AWS** are as severe as **hallucinations and seizures**.
- At its **most extreme**, **AWS** can be **life threatening**.



✓ **Heroin**

- **Heroin belongs** to the **opioid class of drugs**.
- Opioid **receptor activation** is associated with a **subsequent release** of **dopamine** in the **brain**, which **serves to reinforce** the continued use of **opioid drugs** for their **pleasurable effects**.

Symptoms of Heroin Withdrawal

Nausea and Vomiting



Sweating



Insomnia



Anxiety



Diarrhea



Abdominal Cramping



Dilated Pupils

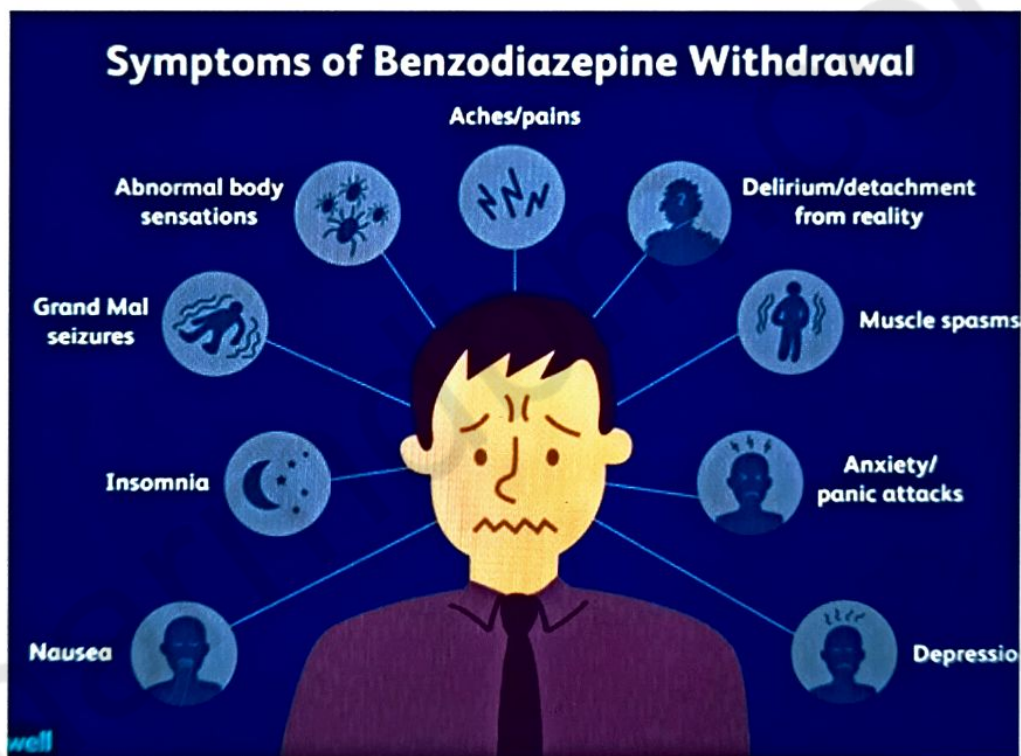


Muscle Aches



❖ BENZODIAZEPINE

- **Benzodiazepines**, or "**benzos**" as they are **sometimes referred** to, are a **class of drugs** that effectively treat **anxiety, panic disorder**, and certain types of **seizure disorders**.
- These **medications are CNS depressants** and work on the **brain** by **increasing activity** at receptors for the **inhibitory neurotransmitter gamma-aminobutyric acid (GABA)**.
- This increase in **GABA activity** also **increases inhibition** of **brain activity**, **producing a drowsy** or **calming effect** that may be **medically beneficial**.



✓ Cocaine

- Cocaine is an exquisitely **addictive stimulant** drug that influences the **brain's reward** center by blocking the **removal of dopamine** from the **synapses**.
- This effect in the **brain reinforces** cocaine use and lays the **groundwork** for **eventual compulsive** patterns of use.
- In turn, this can drive the **development of physiological** dependence to the drug.

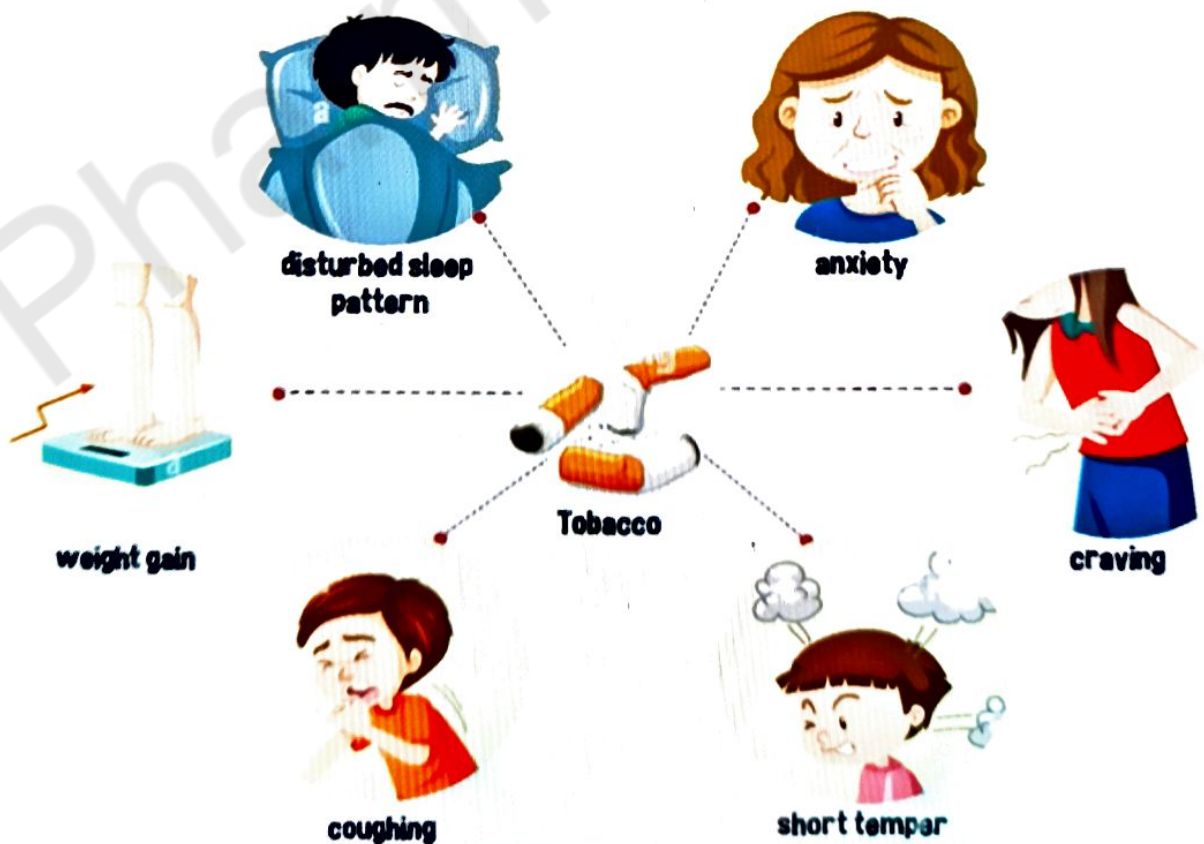
COCAINE WITHDRAWAL SYMPTOMS



✓ Nicotine

- Nicotine withdrawal is the term used to describe the **physical and psychological** symptoms you **experience** when you **quit smoking**.
- These **discomforts** are **normal and temporary**, as long as you stay **smoke free**.

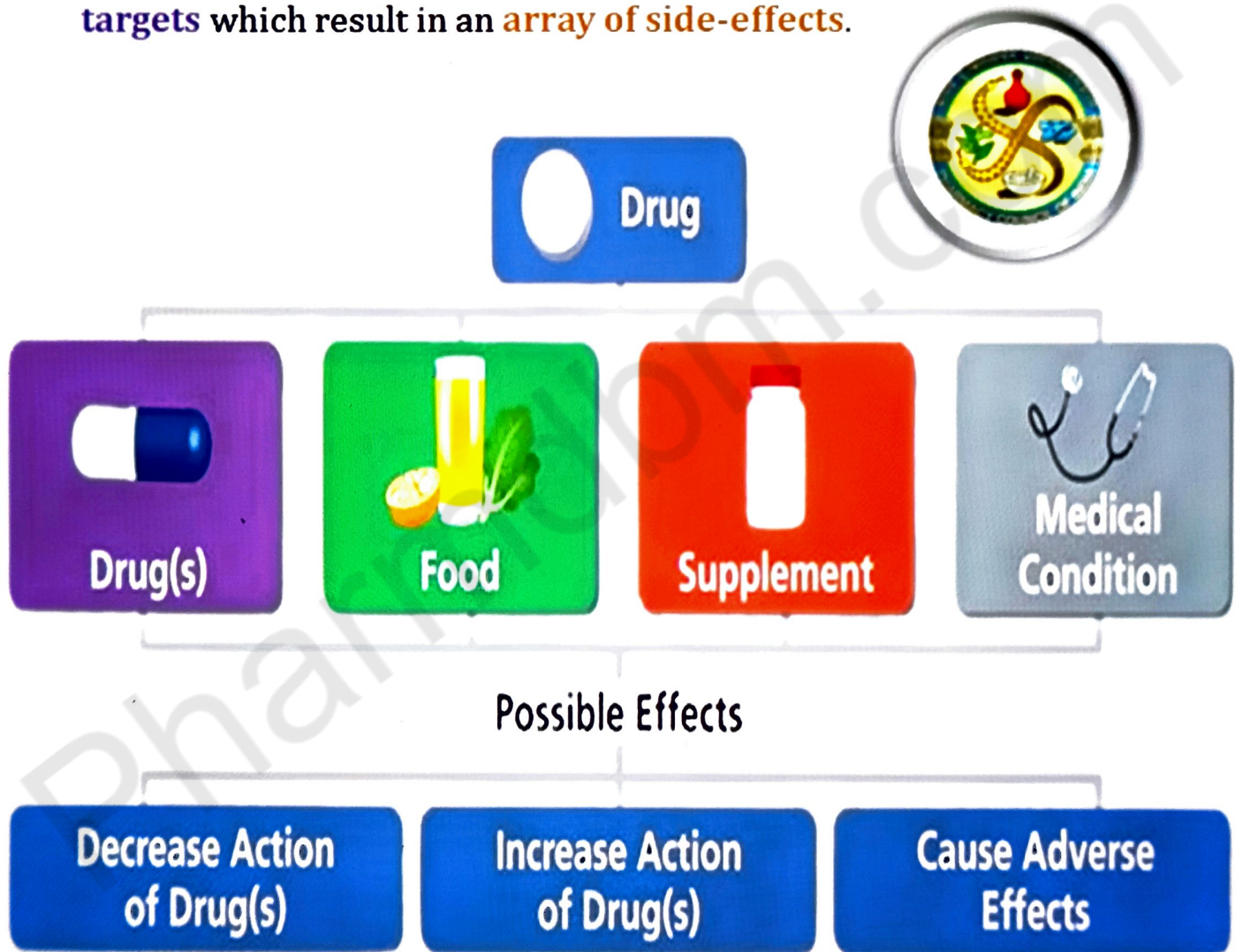
Nicotine Withdrawal Symptoms



DRUG INTERACTION

❑ INTRODUCTION

- **Drug interactions** occur when a **drug's mechanism** of action is disturbed by the **concomitant administration** substances such as **foods, beverages** or **other drugs**.
- The cause is often the **inhibition** of the **specific receptors** available to the **drug, forcing** the **drug molecules** to bind to other **non-intended targets** which result in an **array of side-effects**.



❑ MECHANISMS OF DRUG INTERACTIONS

1. **Pharmacokinetic interactions**
2. **Pharmacodynamic interactions**

PHARMACOKINETIC INTERACTIONS

GIT ALTERATION

- pH changes
- Complexation and adsorption
- Gastric motility changes
- Inhibition of G.I.T enzymes

DISTRIBUTION ALTERATION

- Displacements of protein binding sites

METABOLISM ALTERATION

- Stimulation of metabolism
- Inhibition of metabolism

EXCRETION ALTERATION

- Urinary pH changes
- Interference with urinary excretion

PHARMACODYNAMIC INTERACTION

Drugs having opposite pharmacological effects

Alteration of electrolyte levels

Drugs having similar pharmacological effects

Interactions at receptor sites

1. PHARMACOKINETIC INTERACTIONS

- **These interactions** alter **absorption , distribution , metabolism** and **excretion** of a drug.

i. GIT ALTERATION

- **Drug interactions** may reduce the **total amount** of **drug absorbed**.
- This **reduces the therapeutic activity** of the drug.
- Sometimes there is **delayed absorption** process and **onset of action** is prolonged.

✓ **Alteration of pH**

- **Non-ionised** form of drug is more **lipid soluble**, hence it is **rapidly absorbed** than the **ionised form**.
- **Acidic drugs** (e.g. aspirin) remains unionised at the **stomach pH** and get **rapidly absorbed** from stomach.
- Similarly, **basic drugs** are better absorbed from the intestine where they are in **unionised state**.

✓ **Complexation and adsorption**

- **Certain substances** can bind with **other drugs** thereby **preventing absorption**, **Tetracycline** combines with **metal ions** such as **Fe²⁺, Al, Mg and Ca** in the **GIT**,

✓ **Gastric motility changes**

- A drug like **a cathartic** , **increases gastric motility** and thereby **shortens gastric emptying time**.
- This will **enhance the absorption** of **acidic drugs** and **decrease absorption** of **basic drugs**.

✓ **Inhibition of gastrointestinal enzymes**

- **Folic acid** is available from the **diet** in the form of **poorly absorbed polyglutamate**.

ii. DISTRIBUTION ALTERATION

✓ Displacement from receptor binding site

- **Two drugs** with an **affinity** for the same **plasma protein binding sites** may **compete for these sites**.
- This may result in displacement of **one drug** from the **binding sites**.

Bound drug	Displacing drug	Result
Tolbutamide	Salicylates phenylbutazone	Hypoglycemia
Warfarin	Salicylates clofibrate	Haemorrhage
Thiopentone	Sulphonamides	Prolonged anesthesia
Methotrexate	Sulphonamides	Agranulocytosis

iii. METABOLISM ALTERATION

✓ Stimulation of metabolism

- A drug may stimulate metabolism of **another drug** mainly by **increasing the activity** of **hepatic enzymes** which are involved in the **metabolism of therapeutic agents**.
- This increase in enzymatic activity is known as **enzyme induction**.

Drug	Inducing agent	effect
Warfarin	Barbiturates glutethimide	Decreased Anticoagulant effect
Tolbutamide	Alcohol , phenytoin	Decreased hypoglycemia
Oral contraceptives	Rifampicin	Pregnancy
Quinidine	Phenytoin barbiturates	Reduced quinidine levels

✓ Inhibition of enzymes

- A drug that **inhibits microsomal enzyme** production may raise the **blood levels** of the **other drug** or its **toxic metabolites**, causing **intensified drug effects** and **prolonged drug action**.

Drug	Inhibiting drug	Effect
Phenytoin	Isoniazid phenylbutazone, phenobarbitone	Phenytoin intoxication
Warfarin	Allopurinol nortriptyline	Haemorrhage
Tolbutamide	Phenylbutazone	Hypoglycemia
Barbiturates	MAO - inhibitors	Prolonged sedation

iv. EXCRETION ALTERATION

✓ Changes in urinary pH

- **Non - ionised drugs** diffuse from **urine**, back into the **blood** whereas ionized form of **drugs is excreted easily**.
- Thus **any drug** that will **change urinary pH** will alter the **excretion of weak acid** or **weak base**.
- Interference with urinary excretion
- **Competition for tubular transport** between concurrently **administered drugs** commonly interferes with **urinary excretion**.
- This can **block or lower** the **excretion of the competing drugs**.

✓ Interference with urinary excretion

- Competition for **tubular transport** between **concurrently administered drugs** commonly interferes with **urinary excretion**.
- This can **block or lower** the excretion of the **competing drugs**.
- **Probenecid competes** with **penicillin** for **tubular transport** therefore probenecid is used to prolong the **action of penicillin**.

Primary drug	Competing drug	Result
Indomethacin	Probenecid	Indomethacin toxicity
Salicylate	Probenecid	Salicylate toxicity
digoxin	Sipironolactone	Increased plasma digoxin levels

2. PHARMACODYNAMIC INTERACTIONS

i. DRUGS HAVING OPPOSING PHARMACOLOGICAL EFFECTS

- Many time patient may take concurrently the two drug having opposite pharmacological actions , e.g.
- A patient may be using a cholinergic drug like pilocarpine for eye problem and at the same time , for gastric problems he might be prescribed an anticholinergic agent .

ii. DRUGS HAVING SIMILAR PHARMACOLOGICAL EFFECTS

- Drugs acting at the same site or influencing same physiological system causes synergistic effect.

Primary	Interacting drugs	Result
Alcohol	Other CNS depressants like barbiturates, antihistaminics , narcotics	Increased CNS depression
Tubocurarin e	Aminoglycosides , antibiotics	Prolonged paralysis
digitalis	Propranalol	Excessive hypoglycemia

iii. ALTERATION OF ELECTROLYTE LEVELS

- Drugs which cause alterations in fluid and electrolyte balance may modify responses of tissues to drugs, e.g.
- Diuretics losing potassium, may cause hypokalemia inturn making the heart more sensitive to digitalis.

Primary drug	Interacting drug effect	Result
Digitalis	Diuretic induced hypokalemia	Digitalis toxicity
Lignocaine , quinidine	Diuretic induced hypokalemia	Antagonism of antiarrhythmic effects
Tubocurarine	Diuretic induced hypokalemia	Antagonism of diuretic activity

iv. DRUG INTERACTIONS AT RECEPTOR SITES

- Effects of drug occur as a result of its **binding to specialized** areas, on or **within the cells**, known as receptor sites.
- The amount of **drug associating** with the **receptor sites**, depends upon
 - (a) **Amount of drug in the body**
 - (b) **Accessibility of drug** to the receptor and
 - (c) **Affinity of drug** for the receptor

BENEFICIAL INTERACTIONS

- Simultaneous **oral intake** of **herbs, supplements, foods** and **drugs** with **other drug(s)** may result in **pharmacokinetic** or **pharmacodynamic interactions** with the latter.
- Although these **interactions** are **often associated** with **unwanted effects** such as **adverse events** or **inefficacy**, they can also produce effects that are **potentially beneficial** to the **patient**.
- **Beneficial pharmacokinetic interactions** include the improvement of the **bioavailability** of a **drug or prolongation** of a **drug's plasma level** within its **therapeutic window** , whereas **beneficial pharmacodynamic interactions** include additive or **synergistic effects**.

- Mechanisms by which **pharmacokinetic interactions** can cause **beneficial effects** include enhancement of **membrane permeation**, modulation of **carrier proteins** and **inhibition of metabolic enzymes**.
- In the **current review**, selected **pharmacokinetic interactions** between **drugs and various compounds** from different sources including **food, herb, dietary supplements** and **selected drugs** are discussed.
- These **interactions** may be **exploited in the future** to the benefit of the patient,

❑ **ADVERSE INTERACTION**

- **Nonsteroidal anti-inflammatory drugs** (NSAIDs) such as **ibuprofen** have a **long history** of **safe and effective** use as **both prescription** and **over-the-counter** (OTC) **analgesics/antipyretics**.
- The mechanism of action of **all NSAIDs** is through **reversible inhibition** of cyclooxygenase enzymes.
- **Adverse drug reactions** (ADRs) including **gastrointestinal bleeding** as well as **cardiovascular** and **renal effects** have been reported with **NSAID use**.
- In many cases, **ADRs** may occur because of **drug-drug interactions** (DDIs) between the **NSAID** and a **concomitant medication**.
- For example, **DDIs** have been reported when **NSAIDs** are **coadministered** with **aspirin, alcohol, some antihypertensives, antidepressants**, and other **commonly used medications**.
- Because of the **pharmacologic nature** of these interactions, there is a **continuum of risk** in that the potential for an **ADR** is dependent on total **drug exposure**.
- **Health care providers** can be **instrumental** in **educating patients** that using **OTC NSAIDs** at the **lowest effective** dose for the **shortest required** duration is vital to **balancing efficacy** and **safety**.
- This **review discusses** some of the **most clinically** relevant **DDIs** reported with **NSAIDs** based on major sites of **ADRs** and classes of **medication**, with a focus on **OTC ibuprofen**, for which the **most data are available**.

METHODS FOR DETECTING DRUG INTERACTIONS

- The various methods are given as follows

1. SPONTANEOUS CASE REPORTS

- It is common method of **arousing suspicion** about **drug related diseases**.
- A **prescriber suspects** that a condition arising in a **patient** may be **drug related**
- He therefore reports either in a letter to the **medical journals** or to the **manufacturer of drug**.
- By this means **other prescribers** are alerted to the possibility of **drug-disease** relationship.
- "**Spontaneous Reporting Agencies**" are set up to **collect and collate** 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**.

2. VITAL STATISTICS AND RECORD LINKAGE STUDIES

- The details of **cause of death** or of **hospitalization** are **routinely collected** and **analysed**
- It gives **early warning** of an **epidemic of drug-related** disease **Record linkage studies** can be used to **great effect** in the search for **drug-induced** disease.

3. COHORT STUDIES

- The 'Cohort means **identifying a group** of **recipients** of a drug of **interest and observing** these **patients for varying** lengths of time and **recording** what happens to them.
- This type of study is used for short term **clinical trial** of a **new drug**.

- Thus, this method is of great value for **detecting predictable** adverse effects due to **excessive pharmacological effects** arising during or immediately after **short term treatment**.

4. CASE-CONTROL STUDIES

- It **involves the comparison** of group of patients with a disease which is thought to be **due to a drug** with a group of **patients** who do not have the disease (the controls)
- The **drug histories** of the **cases and controls** are obtained and compared.
- If a drug is **causing the disease** then its use amongst the cases will be **far in excess** of that found in the **controls**.
- **Case control studies** can be **conducted rapidly** and efficiently at **relatively low cost**.

❖ TYPICAL FEATURES OF THE METHOD ARE

- (a) The cases must be **selected carefully**. The disease must be **defined clearly, precisely and accurately**. The disease under study must have **reasonable risk** of being drug induced.
- (b) The controls obtained should be from **similar population** of cases with the **exception** that **controls** do not have the **disease of interest**. Controls are usually **hospitalized patients**. They should not include **patients admitted** for conditions which are **indications of drug** of interest or which are caused or **prevented** by the **drug of interest**
- (c) The method used to **describe drug** use must be **identical in cases** and **controls**.
- (d) Interpretation of results **must be accurate**

COMMUNITY PHARMACY

Points to be covered in this topic

INTRODUCTION

ORGANIZATION AND STRUCTURE

TYPES AND DESIGN

LEGAL REQUIREMENTS

DISPENSING OF PROPRIETARY PRODUCTS

MAINTENANCE OF RECORDS

INTRODUCTION

- The **main responsibilities** of a **community pharmacy** include **compounding, counseling**, and **dispensing** of drugs to the **patients** with **care, accuracy**, and **legality** along with the **proper procurement, storage, dispensing** and **documentation** of **medicines**.
- The **community pharmacist** must be a **qualified and pertinent** with **sound education, skills and competence** to deliver the professional **service to the community**.
- A **community pharmacist** should
 - (i) Have a **sound background** of **pharmaceutical care, pharmacotherapy**, and **health promotion**.
 - (ii) Have **good communication skills** with **patients** and other **healthcare providers**.
 - (iii) Maintain a **high degree** of standard in **products, services**, and **communication**.
 - (iv) **Record and maintain** his documents in order.

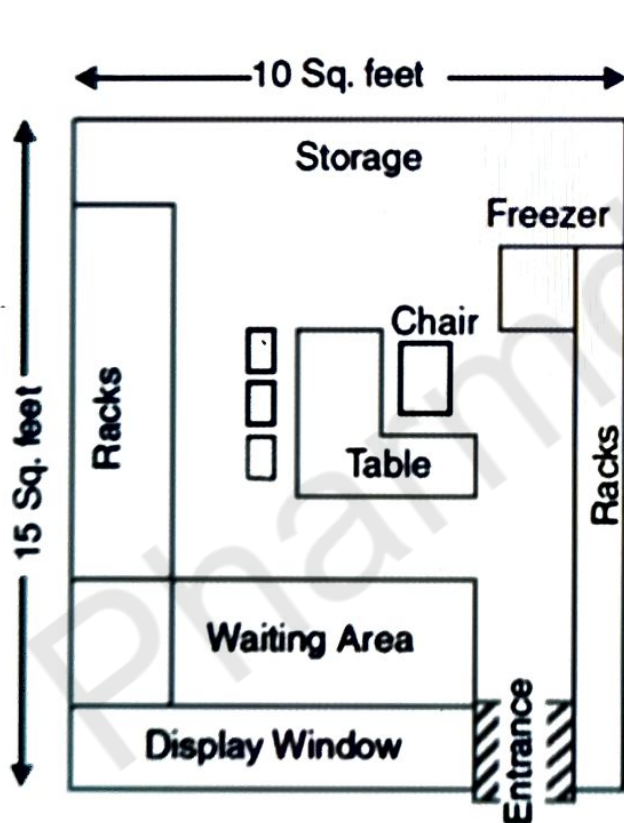
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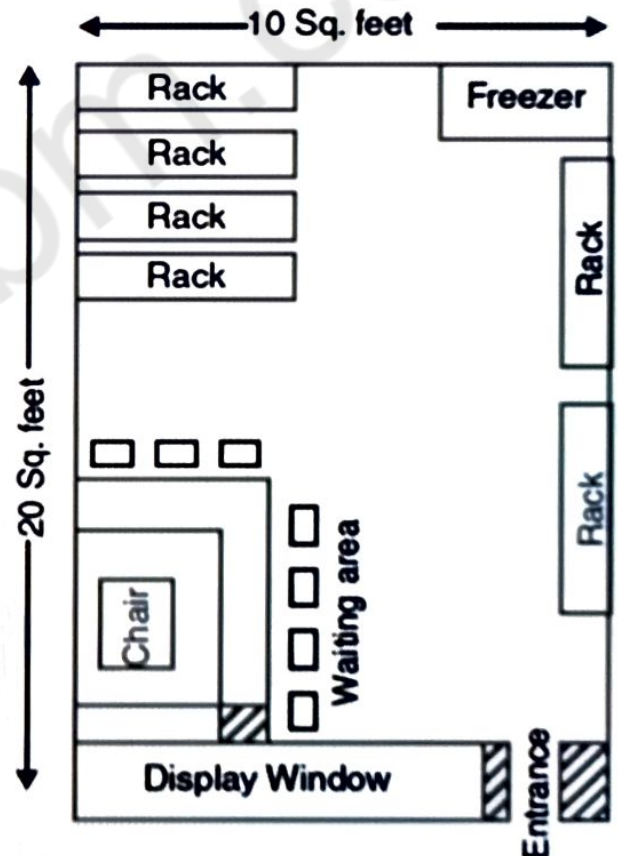
ORGANIZATION AND STRUCTURE

❑ OBJECTIVE OF LAYOUT DESIGN

- To attract large number of **customers**.
To **increase the sale of store**.
- To have proper **entrance of coming goods** and **space for reserve stock**, office and **resting place for employees**.
- To reduce the **selling expenses** and provide customer satisfaction.
- To **project a professional image** and **improve general appearance**.
- To **minimize the movement** of customer with in the **premises of the drug store**.
- To **provide customer satisfaction**.



Retail drug store design



Whole sale drug store design

- A **modern drug store** should fulfill all **minimum requirements** as laid down in **schedule N of D and C act 1945**.
- To start a retail drug store **minimum of 10 sq. meter** area is required and for **wholesale drug store** same **area is required**.

- The **premises of drug store**
- The **outer front** of the **drug store** should be **very attractive** and built with **innovated construction techniques**.
- The material used for **construction drug store front** is **normally glass , glazed tiles** and **marbles** which is **easy to clean**.
- Generally the **drugs stores** are **located on ground floor** of the **building**.
- They are **usually constructed** of **cement concrete** walls with **mosaic tiles** on the floor .
- The **internal fittings** usually **consist of racks** or proper **storage cupboards** having **glass doors** , **drawers for storing strips** , **shelves** and **proper place** for **placing refrigerator**.
- The **counters for store** are made from **wood** having **white sunmica** at its top.
- The **furniture includes** a **working table** , **wooden or steel chairs** for staff and customers.
- The floor of the drug store should be **smooth and washable**.
- The walls **should be plastered** or **tiled or oil painted** so as to maintain a **smooth durable** and **washable surface** , **adequate lightning** should be provided , **preferably tube lights** which is concealed.
- **Good lighting** system **provides cheerful atmosphere** for the customers and **merchandise stored** and **displayed appears** more **attractive** .
- It also **helps in identifying** the **medicines** etc **quickly and easily** and thus **increase the efficiency** of the store.
- The name of **drug store** and **insignia of pharmacy** in **neon lighting** is **very attractive**.
- The **fluorescent lighting** is also **very attractive**.
- The **illumination** should be **steady and without** any **glare** and should not put any **strain on the eyes**.

TYPES AND DESIGN

❑ TYPES OF A DRUG STORE

- On the **basis of design**, it is classified as:

1. TRADITIONAL DRUG STORES

- These types of **drug stores** are **designed** in such a manner that the **entire area** of **Drug store** is **exposed to customers**.
- **Such a design** has **pleasing and professional** appearance and is **convenient** for both **workers and customers**.
- It **provides opportunity** for **maximum sales** but there are **good chances of theft** in such design.



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2. PERSONAL SERVICE DRUG STORES

- In this type of **design**, the whole of the 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 provide** the articles.
- This service and **design facilitates** maximum interaction between **drug store employee** and the **customers**.

3. PRESCRIPTION ORIENTED DRUG STORE

- These types of **drug stores** provide a **comfortable waiting area** where the **customers are expected** to wait while his **prescription is proceeding**.
- In this type of **design health related items**, **drugs** and **prescription accessories** are **displayed** in the **vicinity** while **orthopedic and surgical appliances** are kept in a **separate room**.
- **Cosmetics and gifts** are arranged in a **suitable area** in the store



4. PHARMACEUTICAL CENTRE

- These types of **centre sell medicines**, **convenience articles**, **orthopedic and surgical appliances**.
- The store has **sufficient floor space** and is **properly decorated**.



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5. SUPER DRUG STORE

- Such types of **drug stores** have a huge floor area **ranging from 5,000 to 10000** with a **square design**.
- The customers have access to all-most-all the area in the **drug store** and **can inspect, handle and select articles themselves**.
- The design is on **self service** pattern except for the **prescription department** where self service is **not possible**.



☐ LICENSE

- A license is required to **sell, stock** or **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 license**



1. Application (in duplicate) on form 19* of D & C Rules 1945. one copy is for **biological drugs** and the other copy for **non biological drugs**.
2. A fee of **Rs. 1500/- per license** (Total 3000/-) to be deposited in State **Bank of India/ Government** Treasury under **specific head** for grant of **retail sale license**.
3. a) An attested copy of **Diploma in Pharmacy** from any institution duly **recognized by PCI**
 b) An attested copy of **registration certificate** issued by **State Pharmacy Council**.
 c) An attested copy of **Matriculation certificate** .
 d) **Affidavit** from the **qualified person** in case he is an **employee of drug store**.
4. **Affidavit** on **non-judicial stamp** paper, duly attested by **First Class Magistrate** by **each partner** in case of **partnership concern** and by the **proprietor** himself in case of **proprietorship concern**.
5. A map of **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 **person himself** is the **owner of premises**.

7. A **copy of partnership** deed in case of **partnership concern**.
8. **Refrigerator purchase** receipt.
 - **PCI is planning** to make **mandatory to wear** white **coat bearing** name of **Pharmacist** who is running the **retail pharmacy**.
 - The **license is valid** for **5 yrs** which is to be **renewed before expiry**

DOCUMENTS REQUIRED FOR RENEWAL OF RETAIL SALE LICENSE

1. **Application in duplicate** on Form **19 of D & C rules 1945**. One Copy for **biological** and other copy for **non-biological**
2. A fee of **Rs 1500/- per license** (Total 3000/-) be **deposited in SBI/ Government Treasury Challan** form in the **specified head** for **renewal of retail** sale license.
3. A late fee of **Rs 500/- per license** per month or part there of
4. **Original license** in case of **first renewal** and latest **renewal certificate** in case of subsequent renewals.
5. Affidavit to be given on **non-judicial stamp** paper by partner if any **duly attested** by **Oath Commissioner**.

DOCUMENTS REQUIRED TO OPEN A WHOLESALE DRUG STORE

- **Attested copy** of the **experience certificate** of minimum of **4 yrs in sale** distribution of drugs after **matriculation on salary basis**.

OR

- Attested copy of the **experience certificate** of **minimum of 1 yrs** in **dealing with drugs** after graduation in any **discipline** from a **recognized university on salary basis**.

❖ SEPARATE LICENSE ARE REQUIRED FOR RETAIL SALE OF

- Schedule **C and C1 drugs**.
- Schedule **X drugs**.
- **All drugs** other than those specified in **schedule C and C1** and **schedule X**.
- In order to **get license** to **sell , stock or exhibit** for **sale or distribute** by **retail drugs** specified in **schedule C and C1** an application is filled in form no . **21 and form no 21 B** is filled to apply for **license** to sell **schedule C and C1 drugs** by wholesale.
- The drugs which are covered under **schedule X** cannot be **sold or retail** except on **prescription of registered** medical practitioner.

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❑ STORAGE OF DRUGS

- **Drugs** should be **stored in a manner** that preserves their **potency** for the **desired period of time**.
- The **manufacturers instruction** on the label regarding the storage of the product **should be complied**.

❖ STORAGE OF SCHEDULE X DRUGS AND DRUGS WITH EXPIRY DATES:

- Substances specified in **Schedule X** should be **stored under lock** and key in **cupboard or drawer** reserved solely for the **storage** of these substances; or in a part of the **premises separate** from the **remainder of the premises** and for which only **responsible persons** have access.
- **Other drugs** with an **expiry date** should be stored in a **separate cupboard**.

❖ STORAGE OF VETERINARY DRUGS:

- **Veterinary drugs** should be **stored in a cupboard** or drawer reserved for the **storage of veterinary drugs** in a portion of the **premises separated** from the remainder of the premises to which **customers** are **not permitted** to have access.

DISPENSING OF PROPRIETARY PRODUCTS

- **Prescriptions, now-a-days** are usually written for **preformulated proprietary medicines** and the **pharmacist** has only to **dispense** them in a **proper manner**.
- However, **all dispensing of Proprietary** products is required to be done either by the **Registered Pharmacist** himself or under his **direct supervision**.
- The **following procedure** may be adopted during **dispensing of such products**

1. RECEIVING THE PRESCRIPTION

- The **prescription** should be **received** by the **pharmacist himself**, wherever possible or a **person trained** properly to do so in a **professional manner**.



2. READING AND CHECKING THE PRESCRIPTION

- On **receiving the prescription**, the **pharmacist** should **first read the prescription completely and carefully**.
- He **should verify** that the **name and address** of the patient are correct, the **prescription is legally valid** and is written correctly.
- He should **not express any doubt regarding** the **contents** of the prescription ether to the patient or to his messenger, in manner which **questions the wisdom** of the prescribing physician.
- The **pharmacist should not add**, omit or **substitute any content** of the **prescription without** the **consent of the physician**



3. DISPENSING, PACKING

AND LABELLING

- The **medicine** should be selected **from the stock** and if in **unit dosage** form such as **tablets or capsules**, the **correct number** should be **counted and filled** into **previously selected containers**.



- The labels of **all containers** of **stock drugs** should be checked when selected from and **replaced in stock**, as well as at the time of **actual dispensing, making three checks** in total.
- Any **subsidiary label required** should be **properly affixed** to the container.
- The **container must** be thoroughly polished to remove any **finger prints**.

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4. FINISHING

- The **final product**, the prescription and the labels should be **rechecked before handing** over to the patient.
- **All records** must be **completed** including those required by **legislation**.



- The patient or his **representative** should be **explained** about the **proper mode of administration** and **storage of the medicine**.
- Preferably in their **local language**.

MAINTENANCE OF RECORDS

❑ RECORDS OF PURCHASE OF DRUGS

- The records **Pertaining** to the **purchase of all drugs** whether intended to be **sold by retail** or by **wholesale** should be **maintained** under the **following headings**
 - (i) **Date of purchase.**
 - (ii) **Name and address of the licensee** from whom
 - (iii) Name and quantity of the **drug purchased** and his **licence number**, g and its batch number.
 - (iv) **Name of the manufacturer** of the **drug. Purchase bills** including cash or **credit memos** should be kept as records.

❑ RECORDS OF SALE OF DRUGS

❖ SALE OF DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULE X

- **Sale of any drug** other than those specified in **Schedule X** is required to be **recorded at the time** of **supply in a prescribed register** maintained for the purpose or in a **cash or credit memo book**.
- The **following particulars** are **required** to be entered
Serial number of the entry.
 1. **Date of supply.**
 2. **Name and address** of the **prescriber.**
 3. Name and address of the **patient** or the name and address of the **owner of the animal** if the drug is supplied for the **veterinary use.**
 4. Names along with the **quantities of drugs supplied.**
 5. In case of **Schedule H and C drugs**, the name of the **manufacturer**, its **batch number** and the expiry date, if any.
 6. **Signature of the registered pharmacist** under whose supervision the **medicine** was made or supplied.

❖ SALE OF DRUGS SPECIFIED IN SCHEDULE X

- Supply of **Schedule X drugs** should be recorded at the **time of supply** in a **bound and serial numbered** register maintained for this purpose and **separate pages** should be allotted for **each drugs**.
- The **following particulars** should be entered in the **said register**
 1. **Date of Purchase. supplier**
 2. **Quantity received**, if any, the name and **address of supplier** and the **licence number** of the.
 3. **Name and quantity** of the **drug supplied**.
 4. **Manufacturer's name**, batch or **lot number**.
 5. **Name and address** of the patient/purchaser.
 6. **Reference number** of the **prescription against** which supplies were made.
 7. **Bill number** and date of **receipt of purchase** and **supply made by him**.
 8. **Signature of the person** under whose supervision the drugs have been supplied.