Introduction to Hospital Pharmacy

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Outline

- Role of pharmacist in hospital.
- Minimum standards for pharmacies in institutions/ hospitals.

Primary Function of Hospital Pharmacy:

- Selection of reliable suppliers.
- 2. Storing and dispensing of Drugs.
- 3. Determining specifications of the required medicament.
- 4. Maintenance of manufacturing records.
- 5. Quality control of purchased and manufactured products.
- 6. Manufacturing sterile & non-sterile products.
- 7. Expecting and knowing the hospital demands.

Functions of Hospital Pharmacy Management Panel:

- 1. Ensure than all drugs are stored, dispensed correctly.
- Check the accuracy of the dose prepared.
- keep proper records and preparation of bills.
- 4. Coordinate the overall pharmaceutical needs of the "patient care".
- 5. Ensure that the established policies and procedures laid down are followed.
- 6. Maintain professional competence.
- 7. Communicate with all pharmacy staff regarding new developments.

- 8. Coordinate the activities of the area.
- 9. To maintain liaison between nurses.
- 10. Reviewing of drug administration in each patient.
- 11. Provide instruction and assistance to junior Pharmacist.
- 12. Coordinate over all pharmaceutical services on the running unit level.
- 13. Identification of drugs bought into hospital by the patient.

General Functions of a Hospital Pharmacist

- 1. To provide and evaluate pharmaceutical services.
- 2. To draw a plan for hospital pharmacy administration.
- To establish liaison between administrative authorities and medical doctors.
- 4. To estimate the requirements for the department and enforce the policies and procedures for the recruitment of adequate and competent staff.
- To develop and maintain an effective system of clinical and administrative records and reports.

45.1 Responsibilities of hospital staff

The hospital pharmacist should be an expert on medicines who advises on prescribing, administering, and monitoring, as well as a supply manager who ensures that medicines are available through procurement, storage, distribution, inventory control, and quality assurance. The balance between these two roles varies, depending on the individual's background and the work setting. A pharmacist may assume a prominent clinical role in settings where his or her knowledge of clinical pharmacology and capacity to provide expert advice have earned the acceptance of hospital medical and nursing staff.

The responsibility for establishing policies and procedures related to medication selection, procurement, distribution, and use often lies with the DTC. Because the medicine use process is multidisciplinary, the committee should include representation from all functional areas involved: medical staff, nursing, pharmacy, quality assurance, and hospital administration.

Purchasing and stock management

In some hospitals, a separate department manages all hospital purchasing (pharmaceuticals, medical supplies, equipment, and so forth); this department may be called medical stores or materiel management. In such cases, the chief pharmacist prepares an annual budget request for pharmaceutical purchases and places orders for medicines through the medical stores.

In other settings, the pharmacy department manages pharmaceutical purchasing directly. No single individual should have total control of pharmaceutical procurement. A designated committee should review and approve all purchases; either a special purchasing committee or the DTC (see below) may manage this function.

Procedures for procurement and inventory management should be written in a manual that has been approved by hospital administration and the appropriate committees; the procedures for purchasing should follow guidelines provided in Chapters 18 and 23. Stock management procedures are determined by the facility's size and whether a warehouse is attached to the hospital (see Chapters 44 and

Medication use

The medication-use process can be divided into four components-

1. Prescribing. The physician has overall responsibility for the care of the patient, prescribing or ordering medications as part of the treatment plan. The mechanisms to ensure appropriate prescribing within the

- hospital customarily fall within the purview of the medical staff committees, usually including the DTC. The DTC may establish protocols or procedures that allow pharmacists or nurses to prescribe within specific guidelines.
- 2. Preparation and dispensing. The pharmacy department, under the direction of a registered pharmacist, is responsible for preparing and dispensing medications. Policies and procedures for these functions should be approved by the DTC. The chief pharmacist reports to hospital administration.
- 3. Medication administration. Administering medications is generally the responsibility of the nursing staff. The chief nursing officer oversees all nursing functions. In some cases, physicians may administer medicines such as anesthetic agents. Other health care professionals may administer medicines within the scope of their practice (for example, midwives attending deliveries).
- 4. Monitoring the effect of medications on the patient and ordering appropriate changes in therapy. Monitoring activities are primarily the responsibility of the physician. However, observation and reporting are required from the person who administered the medication (usually the nurse) and from other members of the health care team involved in the patient's therapy. In some settings, a clinical pharmacist or pharmacologist monitors medication therapy in the hospital and consults on medication therapies that require special expertise to ensure safety and efficacy: for example, total parenteral nutrition, anticoagulation, or treatment with aminoglycoside antibiotics.

Government agencies and licensing boards regulate medications through laws and professional practice standards. The laws and regulations usually specify that the chief pharmacist be the person responsible for the control of medications within a hospital, including procurement, storage, and distribution throughout the facility.

Although the chief pharmacist is responsible for the pharmaceutical budget and the control of medications, he or she does not supervise those who prescribe or administer the medications. In addition, in some hospitals, purchasing, receiving, and storing of medications are handled by a medical stores department that is not under the supervision of the pharmacist.

These varying responsibilities illustrate the complexity of pharmaceutical procurement, storage, and use in the hospital. Efforts to improve the system should respect this complexity and include multidisciplinary representation and involvement. Coordination is required at the policy level through the DTC, at the management level (beginning with hospital administration), and through the different branches of the organizational tree.

The reference is attached to the class material in MS teams.

- > ASHP Guidelines: American Society of Health System Pharmacists.
- **Purpose:**
- to serve as a basic guide for the provision of pharmacy services in hospitals.
- these guidelines outline a minimum level of services that most hospital pharmacy departments should consistently provide.
- ➤ Certain elements of these guidelines may be applicable to other health care settings or may be useful in evaluating the scope and quality of pharmacy services.

Elements of Care

➤ The elements of pharmacy services (*standards*) that are critical to safe, effective, and cost-conscious medication use in a hospital include:

(1) practice management.

(2) medication-use policy development.

(3) optimizing medication therapy.

- (4) drug product procurement and inventory management.
- (5) preparing, packaging, and labelling medications.
- (6) medication delivery.

- (7) monitoring medication use.
- (8) evaluating the effectiveness of the medication-use system.
- (9) research.

Standard I. Practice Management

- Effective leadership and practice management skills are necessary for the delivery of pharmacy services in a manner consistent with the hospital's, and patients' needs.
- > Such leadership should foster continuous improvement in patient care outcomes.
- ➤ The management of pharmacy services should focus on the pharmacist's responsibilities as a patient care provider and leader of the pharmacy enterprise through the development of organizational structures that support that mission.
- Development of such structures will require communication and collaboration with other departments and services throughout the hospital.

Standard I. Practice Management

- A. Pharmacy and Pharmacist Services.
- **B.** Laws and Regulations.
- C. Policies and Procedures.
- D. Human Resources.
- E. Facilities.
- F. Committee Involvement.

A. Pharmacy and Pharmacist Services.

A-1: Pharmacy Mission, Goals, and Scope of Services.

- The pharmacy shall have a written mission statement that reflects both patient care and operational responsibilities.
- Other aspects of the pharmacy's mission may require definition as well (e.g., educational and research responsibilities).
- The mission statement shall be consistent with the mission of the hospital and, if applicable, aligned with the health system of which the hospital is a component.
- The development, prioritization, and implementation of the pharmacy's goals should be consistent with the mission statement.

- Determination of short- and long-term goals and the undertaking of implementation activities should be performed in collaboration with institutional leadership and other hospital staff (e.g., pharmacy, nursing, and medical staff), and these should be integrated with the goals of the hospital.
- The mission statement may also incorporate consensus-based national goals.
- The pharmacy shall also maintain a written document describing the scope of pharmacy services. These services should be consistent with the hospital's scope of services and should be applied throughout the hospital in all practice sites.
- The mission, goals, and scope of services shall be clearly communicated to everyone involved in the provision of pharmacy services, including pharmacists, residents, students, technicians, and support staff.

A-2: 24-Hour Pharmacy Services.

- Adequate hours of operation for the provision of needed pharmacy services shall be maintained; 24-hour pharmacy services should be provided when possible.
- 24-hour pharmacy services should be employed in all hospitals with clinical programs that require intensive medication therapy (e.g., transplant programs, open-heart surgery programs, and neonatal intensive care units).
- When 24-hour pharmacy services are not feasible, a pharmacist shall be available on an on-call basis.
- Remote medication order processing may be employed (to the extent permitted by law and regulation) to help provide pharmacy services but is not a substitute for an on-call pharmacist.
- Automated drug dispensing equipment and computer databases are also not a substitute for the skills and knowledge of a pharmacist and should not be considered alternatives to 24-hour pharmacy services.

A-3: After-Hours Pharmacy Access.

- In the absence of 24-hour pharmacy services, access to a limited supply of medications shall only be available to authorized, licensed health care professionals for use in carrying out urgent medication orders.
- Access to such medications shall be carefully monitored and documented, and after-hours access shall be reviewed regularly to ensure appropriate use.
- The list of medications to be accessible and the policies and procedures to be used (including subsequent review of all activity by a pharmacist) shall be developed by a multidisciplinary committee of physicians, pharmacists, and nurses (e.g., by the pharmacy and therapeutics [P&T] committee or its equivalent).
- Access to medications should be limited to cases in which the P&T committee (or its equivalent)
 determines that the urgent clinical need for the medication outweighs the potential risks of
 making the medication accessible.

- The potential safety risks of medications should be considered in the decision to make them accessible, and medications, quantities, dosage forms, and container sizes that might endanger patients should be limited whenever possible.
- Routine after-hours access to the pharmacy by non-pharmacists for access to medications shall not be permitted.
- The use of well-designed night cabinets, after-hours medication carts, automated dispensing devices, and other methods precludes the need for non-pharmacists to enter the pharmacy.

A-4: Practice Standards and Guidelines.

- The standards and regulations of all relevant government bodies (e.g., boards of pharmacy, departments of health) shall be met.
- The practice standards and guidelines of ASHP, appropriate accrediting bodies (e.g., Joint Commission, American Osteopathic Association Healthcare Facilities Accreditation Program, Det Norske Veritas), and the Centres for Medicare and Medicaid Services shall be viewed as applicable, and the hospital should strive to meet all applicable standards.

B. Laws and Regulations.

 Applicable local, state, and federal laws and regulations shall be met, and relevant documentation of compliance shall be maintained.

C. Policies and Procedures.

C-1: Policy and Procedures Manual.

- There shall be a policy and procedures manual governing pharmacy functions (e.g., administrative, operational, and clinical), and all pharmacy personnel shall follow those policies and procedures.
- The manual may include a statement of the pharmacy's mission, philosophy, or values (e.g., the pharmacy's mission or vision statement), but it should concentrate on operational policies and procedures to guide and direct all pharmacy services.

- The pharmacy's policies and procedures should be consistent with the hospital's policies and procedures, and the manual should be reviewed by a designated medical staff committee for potential conflicts and other medical issues.
- The manual shall be reviewed by pharmacy staff on a regular basis and revised as necessary to reflect changes in procedures, organization, objectives, or practices.
- The manual shall be accessible to pharmacy department personnel as well as other hospital employees (e.g., through the hospital's intranet), and all pharmacy personnel should be familiar with its contents.
- Appropriate mechanisms to ensure compliance with the policies and procedures should be established.

C-2: Personnel Safety.

Pharmacy employees should be involved in the development of the hospital's plans for emergency response, infection prevention and control, management of hazardous substances and waste, and incident reporting, and all pharmacy staff shall receive education about those plans.

C-3: Emergency Preparedness.

- Facility emergency preparedness plans shall describe the role of pharmacy staff in emergency response (including evacuation), and the facility's business continuity plan shall include procedures for providing safe and efficient pharmacy services in case of emergencies.
- Appropriately trained pharmacists should be members of emergency preparedness teams and participate in applicable preparations and drills.
- The pharmacy shall establish, in conjunction with the hospital wide emergency plan, policies and procedures for the safe and orderly evacuation of pharmacy personnel in the event of an emergency in the hospital.

C-4: Medical Emergencies.

- The pharmacy shall participate in hospital decisions about the contents of code carts, emergency medication kits and trays, and the role of pharmacists in medical emergencies.
- Pharmacists should serve on cardiopulmonary resuscitation teams, and such pharmacists should receive appropriate training and maintain appropriate certifications (e.g., Basic Life Support, Advanced Cardiopulmonary Life Support, Pediatric Acute Life Support).

C-5: Immunization Programs.

- The pharmacy shall participate in the development of hospital policies and procedures concerning preventive and postexposure immunization programs for patients and hospital employees.
- When practical, pharmacists should participate as active immunizers for hospital and healthsystem-based preventive immunization programs (e.g., influenza).

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C-6: Substance Abuse Programs.

• The pharmacy shall assist in the development of and participate in hospital substance abuse education, prevention, identification, treatment, and employee assistance programs.

D. Human Resources.

D-1: Position Descriptions.

- Areas of responsibility within the scope of pharmacy services shall be clearly defined.
- The responsibilities and related competencies of professional and supportive personnel shall be clearly defined in written position descriptions.
- These position descriptions shall be reviewed and revised as required by the hospital's policies.
- Position descriptions should reflect more general aspects of performance (e.g., communication, motivation, teamwork) in addition to specific responsibilities and competencies.

D-2: Director of Pharmacy.

- The pharmacy shall be managed by a professionally competent, legally qualified pharmacist.
- The director of pharmacy should be thoroughly knowledgeable about and have experience in hospital pharmacy practice and management.
- An advanced management degree (e.g., M.B.A., M.H.A., or M.S.) or an administrative specialty residency is desirable.
- The director of pharmacy shall be responsible for:
- 1) Establishing the mission, vision, goals, and scope of services of the pharmacy based on the needs of the patients served, the needs of the hospital (and any health system of which the hospital may be a component), and developments and trends in health care and hospital pharmacy practice.

- 2) Developing, implementing, evaluating, and updating plans and activities to fulfil the mission, vision, goals, and scope of services of the pharmacy.
- 3) Actively working with or as a part of hospital or health-system leadership to develop and implement policies and procedures that provide safe and effective medication use for the patients served by the institution.
- 4) Mobilizing and managing the resources, both human and financial, necessary for the optimal provision of pharmacy services.
- 5) Ensuring that patient care services provided by pharmacists and other pharmacy personnel are delivered in adherence to applicable state and federal laws and regulations, hospital privileging requirements, and national practice standards.

*** A part-time director of pharmacy shall have the same obligations and responsibilities as a full-time director.

D-3: Pharmacists.

- The pharmacy shall employ an adequate number of competent, legally qualified pharmacists to meet the specific medication-use needs of the hospital's patients.
- Pharmacists hired on a temporary or contract basis shall meet the same requirements as those employed by the hospital.

D-4: Support Personnel.

- Sufficient support personnel (e.g., pharmacy technicians and clerical or secretarial personnel)
 shall be employed to facilitate pharmacy services.
- Support positions shall have a written job description that includes a statement of the competencies required for that position.
- Support staff shall be properly trained and supervised, and professional development programs for them are desirable.

- Pharmacy technicians should have completed an ASHP-accredited pharmacy technician training program, should be certified by the Pharmacy Technician Certification Board, and shall meet the requirements of applicable laws and regulations.
- Pharmacy technicians working in advanced roles should have additional training and demonstrate competencies specific to the tasks to be performed.

D-5: Education and Training.

• All personnel shall possess the education and training required to fulfil their responsibilities and shall participate in relevant continuing-education programs and activities as necessary to maintain or enhance their competence.

D-6: Recruitment, Selection, and Retention of Personnel.

Personnel should be recruited and selected by the pharmacy director on the basis of jobrelated qualifications and prior performance.

D-7: Orientation of Personnel.

- There shall be an established, structured procedure for orienting new personnel to the pharmacy, the hospital, and their respective positions.
- Evaluation of the effectiveness of orientation programs should be done in conjunction with the competency assessment required before a new hire can assume full responsibility for the new position.

D-8: Work Schedules and Assignments.

- The director of pharmacy shall ensure that work schedules, procedures, and assignments optimize the use of personnel and resources.
- There shall be a written departmental staffing plan that addresses how patients' needs will be met during periods of staff shortages and fluctuation in workload and/or patient acuity.
- Remote medication order processing may be employed to help address staff shortages or workload fluctuations.

D-9: Performance Evaluation.

- There shall be procedures for regularly scheduled evaluation of the performance of pharmacy personnel.
- The evaluation format should be consistent with that used by the hospital.
- The competencies of the position shall be well defined in the position description, short- and long-term goals should be established for each employee, and the employee's competency shall be assessed regularly.
- The pharmacy director shall ensure that an ongoing competency assessment program is in place for all staff, and each staff member should have a continuous professional development plan.

D-10: Effective Communication.

- There should be established methods for communicating important information to staff in a timely manner (e.g., electronic communications, staff meetings, newsletters, bulletin boards).
- The pharmacy should establish appropriate mechanisms to regularly assess the effectiveness of such communications.

D-11: Ethical Conduct.

- Standards of ethical conduct shall be established, and there shall be procedures for educating all pharmacy staff regarding these standards.
- The institution's conflict-of-interest and ethical conduct policies shall be clearly communicated to all staff, with appropriate staff acknowledgement of conformance with these policies.

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E. Facilities.

E-1: Pharmacy.

- Adequate space, equipment, and supplies shall be available for all professional and administrative functions relating to pharmacy services.
- These resources shall meet all applicable laws and regulations; shall be located in areas that facilitate the provision of services to patients, nurses, prescribers, and other health care providers; and shall be integrated with the hospital's communication and delivery or transportation systems.

E-2: Medication Storage and Preparation Areas.

• There shall be suitable facilities to enable the receipt, storage, and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety throughout the hospital.

E-3: Compounding Areas.

- There shall be suitable facilities to enable the compounding, preparation, and labelling of sterile and nonsterile products, including hazardous drug products, in accordance with established qualityassurance procedures.
- The work environment should promote orderliness and efficiency and minimize the potential for medication errors and contamination of products.

E-4: Patient Assessment and Consultation Area.

• In outpatient settings, a private area for pharmacist—patient consultations shall be available to confidentially enhance patients' knowledge of and adherence to prescribed medication regimens.

E-5: Office and Meeting Space.

Adequate office and meeting areas shall be available for administrative, educational, and training activities.

E-6: Automated Systems.

- There shall be policies and procedures for the evaluation, selection, use, calibration, monitoring, and maintenance of all automated pharmacy systems.
- Automated mechanical systems and software can promote safe, accurate, and efficient medication ordering and preparation, drug distribution, and clinical monitoring.
- Use of such systems and software shall be structured so as to not hinder the pharmacist's review of (and opportunity to intervene in) medication orders before the administration of first doses.
- The maintenance, calibration, and certification of all automated systems shall be performed and documented as required by all applicable laws, regulations, and standards.
- All automated systems shall include adequate safeguards to maintain the confidentiality and security of patient records, and there shall be procedures to provide essential patient care services in case of equipment failure.

E-7: Information Technology.

- A comprehensive pharmacy computer system shall be employed and should be fully integrated possible with other hospital information systems and software, including computerized provider order- entry, medication administration, electronic health record, and patient billing systems.
- Computer resources should be used to support clerical functions, maintain patient medication profile records, provide clinical decision support, perform necessary patient billing procedures, manage drug product inventories, provide drug information, access the patient medical record, manage electronic prescribing, and interface with other computerized systems to obtain patients' specific clinical information for medication therapy monitoring and other clinical functions and to facilitate the continuity of care to and from other care settings.
- Pharmacists should be involved in the development and maintenance of order sets, templates, and dose ranges used in computerized provider-order-entry and clinical decision-support systems.

- Pharmacy computer systems should be integrated with the hospital's clinical, financial, and administrative information systems.
- All computer systems shall include adequate safeguards to maintain the confidentiality and security of patient records, and a backup system should be available to continue essential computerized functions (e.g., those that support patient care) during equipment failure.

E-8: Drug Information.

- Adequate space, current resources, and information-handling and communication technology shall be available to facilitate the provision of drug information.
- The department of pharmacy shall select its drug information resources, and pharmacists shall play a leadership role in the selection of drug information resources used by other health care providers in the hospital.
- Appropriate drug information resources shall be readily accessible to pharmacists located in patient care areas.

- Up-to-date, objective drug information shall be available, including current print or electronic periodicals, newsletters, best-practices guidelines, and recent editions of reference books in appropriate pharmaceutical and biomedical subject areas.
- Electronic drug information databases are preferred because they are frequently updated and can be made available to all health care professionals, but sufficient access to print information shall be available in case of equipment failure.
- Electronic and print drug information may be supplemented with medical libraries and other available resources.
- Electronic databases and convenient methods of data dissemination (e.g., e-mail and handheld devices) are desirable.
- If such tools are employed, they should be made available to all health care practitioners who require access to the data.

E-9: Record Maintenance.

- All records shall be maintained in accordance with applicable laws, regulations, and institutional policies.
- Adequate space shall exist for maintaining and storing records (e.g., equipment maintenance, controlled substances inventory, and material safety data sheets) to ensure compliance with laws, regulations, accreditation requirements, and sound management practices.
- Appropriate licenses and permits shall be on display or on file as required by law or regulation.
- Equipment shall be adequately maintained and certified in accordance with applicable practice standards, laws, and regulations.
- There shall be documentation of equipment maintenance and certification.

F. Committee Involvement.

A pharmacist shall be a member of and actively participate in hospital and health-system committees responsible for establishing and implementing medication-related policies and procedures as well as those committees responsible for the provision of patient care, including the P&T, infection prevention and control, patient care, medication-use evaluation, medication safety, nutrition, and pain management committees (or their equivalents), as well as the institutional review board, quality-improvement, and information technology committees (or their equivalents).

Thank you

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