CHAPTER 1

HOSPITAL PHARMACY

Definition

Hospital Pharmacy is an organ of a hospital where drugs are manufactured and/or purchased, stored, and dispensed, and their uses are monitored and also, drug information, education and training are provided to inpatients, outpatients, as well as to healthcare professionals by a team of highly qualified pharmacists.

Scope, Origin and Development

Long ago, a pharmacy inside the hospital was called 'Hospital Pharmacy', just like a pharmacy in the community is called a community Pharmacy'. These pharmacies merely managed the job of 'Dispensing drugs' to the patients with a prescription.

But modern 'Hospital Pharmacy' is different. Its scope is broader and almost covers the entire range of services with respect to drugs. Thus starting from manufacture to Therapeutic Drug Monitoring (TDM) and beyond, a modern pharmacist is expected to perform all services in relation to drugs at the patient level. Earlier, there was no other responsibility for a pharmacist once dispensing was over. But now, a great deal of services awaiting him, even after dispensing-viz-the clinical pharmacy services, where he has to obtain the medication history of the patient, advise the doctors in selecting suitable drugs for the patient, monitor the therapy, intervene if necessary to correct the course of treatment and offer counselling to the patient either during treatment or at the time of discharge of the patient. Apart from that, he has to provide drug information to the patients, colleagues in the hospital, and the general public visiting the hospital. He has to organise and participate in research programmes and educational programmes and offer training to health care professionals.

Thus hospital pharmacy and its organisation, its scope and functions have widened enormously because of its transformation from product-oriented service to patient-oriented service.

National and International Scenario

At the outset, one must be clear that the above-mentioned services are yet to be established in India in all hospitals. They are being made available in big private corporate hospitals and a few government hospitals. It is rather unfortunate that such an excellent service is very slowly established by authorities. Nevertheless, these services must be introduced sooner or later in India as and when people realise their rights and requirements.

Hence pharmacy students should study this ideal hospital pharmacy setup and be familiarised with its requirements and services expected from them as and when it is established in India. He must strive to achieve this in his interest and that of the society he lives in.

On the other hand, these services are well-established and available in many developed countries. USA, Australia, UK and many European countries are forerunners in providing these services. They started those services some 50 to 60 years ago and continue them today. Other countries like gulf countries keen to establish a health care system similar to the western world also have complete hospital pharmacy services except for manufacturing drugs in hospitals.

Organisational Structure

The organisational set-up of a hospital pharmacy starts with a fully qualified and experienced Head of the Department. He must have the necessary education, specialisation, training and experience in most of the functions of a Hospital Pharmacy. Thus an M. Pharm graduate with a PhD and specialisation either in Pharmacology, Pharmacy Practice or Clinical Pharmacy is suitable for the job. Alternatively, a 'Pharm D' graduate with experience is also apt for the job, as these graduates have adequate exposure to hospital work and are given preference over others in western and developed countries.

Various section heads with experience in relevant fields of specialisation support the head of the department. For example, pharmacy postgraduates and graduates with experience and endorsement by the Drugs Control Administration are appointed to the Drugs Manufacturing sections of the Hospital Pharmacy. Similarly, Pharmacy Graduates with experience in the analysis and quality control of drugs and formulations are given charge of the quality control section. The medical stores of the hospital are given control to pharmacy graduates with experience in dispensing drugs. In both these sections D. Pharm holders are also appointed in adequate numbers to assist with the works.

The Central Sterile Service Department of the hospital, which supplies the required materials in sterile condition to various departments, is also given in charge of a pharmacy graduate assisted by D. Pharm holders.

Once dispensing is over, the highly skilled and professional service, namely clinical pharmacy services, has to start. These services are also referred to as 'Pharmaceutical Care', which is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improves the quality of life of the patient. The success of pharmaceutical care lies in determining or anticipating drug-related problems and taking measures to improve outcomes, resulting in a better quality of life for the patient. Hence this section of hospital pharmacy requires highly qualified pharmacists with experience in relevant work. M. Pharm graduates in pharmacology, clinical pharmacy or pharmacy practice specialisation or Pharm. D graduates are appointed in this section. Adequate numbers of assistants are provided to carry out the enormous work involved.

The remaining services of a hospital pharmacy, like Drug Information Services, Education and Training, are also suitably manned by appointing pharmacy persons with relevant qualifications and experience. Thus an organisation of a modern 'Hospital Pharmacy' consists of at least nine sections, as described below in the form of a flow chart.

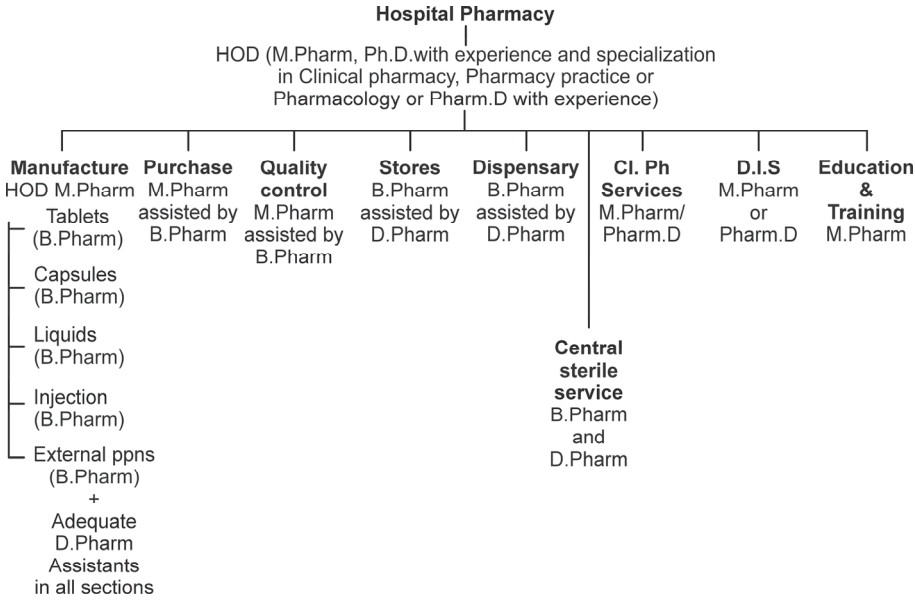

Figure 1.1 Flow Chart of a Modern Hospital Pharmacy Organization (With Technocrats and their Qualifications)

Professionals: Qualification and Experience

From the above organisational flow chart, we can easily list the number of staff required for a Modern Hospital Pharmacy. It is evident that this number depends on the workload or volume of activity of each section of the Hospital Pharmacy. Hence the first and foremost thing before deciding on the number of staff required is to fix the services which the Hospital Pharmacy is required or indented to provide.

In a fully pledged hospital pharmacy like the one charted above, there are nine sections, each requiring persons with some specialisation or experience in the relevant area. Thus starting with the director or HOD of the Hospital Pharmacy, experienced staff are required to head each section. The director or HOD of the hospital pharmacy must have overall knowledge of each section of his department. Hence an M. Pharm, PhD or Pharm.D with a minimum of ten years of experience in various activities of Hospital Pharmacy will be an ideal person. He is supported by a few associate or deputy directors with the same qualifications but less experience of 5 or 6 years.

The manufacturing section of the hospital pharmacy requires not only experienced persons but also the person who should have the approval or be eligible to get approval from the Drugs Control Department for the manufacture of the formulation concerned. Similarly, the quality control section, where the hospital-manufactured or procured drugs are tested for quality, must have experienced and approved analytical pharmacists. He should be able to independently handle and operate sophisticated modern analytical instruments and equipment. Pharmacists with experience in the manufacture and analysis of injectables, especially in Large Volume Parenterals [LVP], are essential for hospital pharmacy manufacturing units as these LVPs are the single most significant drug used daily in almost all the wards of the hospitals.

The next important section of a hospital pharmacy is the clinical pharmacy services section, where pharmacists who can provide advisory and consultancy services to treating physicians are essential. Hence Pharm.D graduates with experience must be appointed in this section. The clinical pharmacist also has to carry out the patient's medication history interview, therapeutic drug monitoring and patient counselling in this section. Hence few fresh Pharm.D or M. Pharm - pharmacy practice graduates should be trained in this important area of hospital pharmacy service.

Other sections like medical and surgical stores, purchase, dispensary, central sterile service and drug information centre should have regular staff

with experience. The education and training section, on the other hand, requires well-experienced staff.

Thus all sections of the hospital pharmacy should be manned with suitable pharmacists, which is easier said than done. Hence the manpower requirement of the hospital pharmacy should be thoroughly studied and planned accordingly. Experienced people for each section are hard to get, hence suitable training programs should be developed simultaneously where fresh pharmacy graduates should be recruited as 'Resident pharmacists' similar to Resident Doctors or 'House Surgeons' in the medical field. These resident pharmacists should be appointed in all the sections of the hospital pharmacy in the rotation where senior hands are available to train, supervise and evaluate their work. Thus suitable manpower can be created in due course of time.

Infrastructure

In order to provide proper and effective service to the patients, good infrastructure must be provided for the hospital pharmacy. These infrastructure facilities can be as per the following requirements:

(a) All equipment and instruments for the manufacture and analysis of formulation as per schedule M of Drugs and Cosmetics acts and rules of govt of India. These are necessary to follow GMP and GLP as per WHO and USFDA standards.

(b) All the necessary equipment for compounding, repacking and dispensing in the main, satellite and ward pharmacies as per medical and pharmacy manuals and orders of Governments

(c) Proper storage facilities, including refrigerators and air conditioners with adequate cub board, storage space, floor space and lighting in the medical and surgical stores of the hospital. These stores and dispensaries should have separate cub boards with lock facilities for narcotics and other controlled substances.

(d) Central sterile service section should be equipped with the latest sterilisation facilities and storage area free from contamination with a laminar workbench, airlock ante room etc.

(e) As all above areas are continuous processing and /or storage areas and midway stopping of which may create huge problems, they
    (a) must be provided with uninterrupted power supply using generators, invertors etc.
    (b) A library with adequate latest books and online and database resources should be available both for use by pharmacists and doctors. There should be necessary facilities for data retrieval,

storage, copying and recording. The new edition of Pharmacopoeias, a Textbook on Pharmacology, toxicology, therapeutics, biochemistry, microbiology, and drugs indexes, should be available in this library apart from professional periodicals (journals) on the above subjects.

(c) In order to maintain the above facilities, adequate clerical and non-clerical services should be provided. Hence a well-equipped office with stenographic bookkeeping people must be available. Needless to say, furniture and fixtures necessary for all the above activities must be in place.

Work Load

While calculating the workload for the entire hospital pharmacy organisation, each of its section's specific needs should be taken into account. For example, to calculate the number of pharmacists required to man the outpatient counter for dispensing prescriptions, the average number of outpatients per day has to be arrived at. The average time in minutes required to dispense pre-packaged medicines for a prescription has to be calculated, and then a number of counters to be opened and manned by pharmacists can be arrived at. It was estimated that usually, 4 minutes are required to dispense prepacked medicine and up to 14 minutes if compounding and packaging are required. If sufficient manpower is provided, the waiting time for the patient in front of the dispensary and the crowd can be minimised.

As per the medical/ pharmacy manual published by state governments in India, a pharmacist has to dispense to around 60 patients per day of 6 hours shift, allotting 6 minutes per patient. But in practice, due to various reasons like the huge crowd in government hospitals, disproportionate pharmacists appointed in our hospitals, a Govt. Hospital pharmacist is dispensing to 100 patients per day, and he is forced to work more than 10 hours a day. This makes the quality of services provided by a pharmacist to a patient to go down, resulting in friction, quarrel, dissatisfaction and disappointment to patients as well to the pharmacist.

Hence correct calculation of workload and its statistics assume importance to determine the manpower requirement. The workload has to be calculated for other sections of the hospital pharmacy, for example, in the case of clinical pharmacy services, at least one clinical pharmacist should be appointed for two wards and to provide round-the-clock service, 3 of them are needed. Similarly, to provide these services to outpatients, 2 or 3 clinical pharmacists are needed during OP hours. Other sections like central sterile services, drug information centres, stores and purchases require a minimum of one PG pharmacist and 2 or 3 graduate pharmacists as assistants.

If a manufacturing section is available in the hospital, it requires an elaborate production program and planning as in the Pharma industry. It may need the services of experts in material management and finance, which are dealt with below separately.

Pharmacists required for a 500-bed hospital with a full Hospital Pharmacy and 1200 outpatients per day:

Table 1.1 Work Load Statistics- Manpower Requirement

S. NO	SECTION/ DESIGNATION	NUMBER OF M.PHARM OR PHARM.D	NUMBER OF B.PHARM	NUMBER OF D.PHARM	TOTAL
1.	H.O.D/ DIRECTOR	1 [M.PHARM OR PHARM.D, AND PH. D]	-	-	1
2.	DEPUTY DIRECTOR [PRODUCTION, Q.C, CSS]	1[M.PHARM]	-	-	1
3.	DEPUTY DIRECTOR [CL.PH, DIC, EDUCATION]	1[PHARM. D]	-	-	1
4.	DEPUTY DIRECTOR [PURCHASE, STORES, DISPENSARY]	1[M.PHARM]	-	-	1
5.	MANUFACTURE	1[M.PHARM]	5	12	18
6.	QUALITY CONTROL	1[M.PHARM]	2	-	3
7.	CENTRAL STERILE SERVICE	--	1	2	3
8.	CLINICAL PHARMACY SERVICE	12[PHARM.D]	-	-	12
9.	DRUG INFORMATION CENTRE	1[PHARM. D]	3	-	4
10.	PURCHASE AND STORES	1[M.PHARM]	3	6	10
11.	DISPENSARY	-	3	20	23
	TOTAL	20	17	40	77

Job specifications

As described in the flowchart above, each section of the modern hospital pharmacy performs a specific function assigned to it. The following are some of the functions of each section.

1. Manufacturing Section
   (i) It estimates the annual demand for each drug used in the hospital.
   (ii) Plan the production schedule.

(iii) Manufacture the required items as per plan after purchasing needed raw materials, packing materials etc.

(iv) Carry out any special work entrusted to it, like, preparation of IV admixture, total parental nutrition etc.

(v) Check the standards of formulations by QC and QA departments.

2. Purchase Section

(i) Estimate the demand or the quantity of drugs required.

(ii) Specifications for the needed drugs are arrived at in consultation with the departments concerned. This includes quality, quantity, packing, strength, etc.

(iii) Follow the approved purchase procedure, like calling for tenders and quotations, and identifying the supplier to place orders.

(iv) Receive, verify and dispatch the drugs to the quarantine area and then to stores after approval by the quality control section.

(v) Settle the bills and be ready for any emergency purchases.

3. Quality Control Section

(i) It keeps ready the methods of analysis, equipment, chemicals and other requirements for almost all drugs either manufactured or purchased by the hospital.

(ii) Draw samples from the manufacturing section or quarantine area if purchased from outside.

(iii) Analyse and submit its report to the people concerned. Thus certifying the quality of drugs used in the hospital.

(iv) Undertake research and development studies with respect to the drugs manufactured in the hospital in order to improve their efficacy as well as to reduce the cost.

(v) Send samples to outside laboratories if they cannot be analysed by it.

4. Stores Section

(i) It receives drugs from either the manufacturing section or the purchasing department.

(ii) Store them properly until issued to the dispensary and other places, according to specified storage conditions, so as to preserve their efficacy and potency.

(iii) Issue drugs to dispensaries and other departments as per their approved indents.

(iv) Keep an account for all input and output as well as stock on hand (inventory control).

(v) Monitor the drug use pattern to inform and assist the authorities and manufacturing section in the production plan or purchase plan.

(vi) Look for the expiry date of all items stored, periodically and physically and bring to the notice of people concerned about near or short-expiry items so as to either use them earlier or return them to the supplier.

5. Dispensary
   (i) Receive the drugs required for dispensing to outpatients in sufficient quantities from the stores of the hospital.
   (ii) Be ready with pre-packing or repacking of drugs for dispensing.
   (iii) Dispense them to patients by following high standards of dispensing like auxiliary labels, proper packing and instructions written on the envelope apart from clear and louder oral instructions.
   (iv) Maintain account for the drugs issued on a daily basis.
   (v) Provide a clean, neat and comfortable environment for the patients waiting to get their drugs.
6. Central Sterile Supply Department
   (i) Procure, install and maintain all the required sterilisation equipment.
   (ii) Prepare, update stock and maintain an inventory of items, equipment and instruments required by various departments of the hospital.
   (iii) Sterilize the required items, as per the SOP prepared earlier and supply them to needed departments.
   (iv) Prepare and circulate educative literatures to all the departments concerned on infection control as well as on maintenance of sterility and sterile area upkeeping.
   (v) Always keep ready the emergency ward supplies.
7. Clinical Pharmacy Services
   (i) Adequate numbers of clinical pharmacists are engaged wherever needed, including outpatient departments and all wards.
   (ii) Conduct medication history interviews for all or specific patients admitted to the hospital and forwarded the relevant details to the treating physician or surgeon.
   (iii) Identify the drugs brought to the hospital by the patients and give guidance either to use or discard them or forward them to the doctor.

(iv) After diagnosis, the clinical pharmacist is required to give his expert opinion on the suitable drug formulation and dose for the particular patient to the treating doctor if solicited.

(v) Once treatment commences, he has to monitor the patient for the effects of drugs by conducting necessary pharmacokinetic tests on his blood, body fluids and other samples. Based on these tests, he can recommend to the doctor to change the medicine, reduce or increase the dose or altogether stop the medicine. Adverse drug reactions are particularly monitored in patients who are on long time treatment.

(vi) He has to counsel the patients, as and when necessary, during the course of treatment or at the time of his discharge from the hospital. Provide the patient with the necessary medicines and instructions to continue the treatment or recovery at home.

(vii) Receive and maintain the feedback sent by patients after discharge.

8. Drug Information Services
   (i) Pharmacist in charge of this service is required to collect, arrange and provide whatever drug information is needed by public or health care professionals or research students.
   (ii) Update the information available to him periodically.
   (iii) Prepare and circulate literature, brochures, bulletins or circulars on all important matters with respect to the drug's use to all the people concerned.
9. Education and Training Services
   (i) Provide education and training to student pharmacists, student nurses, student doctors and even to other healthcare employees of the hospital.
   (ii) Undertake educational programs for the public.
   (iii) Accept and deliver lectures in professional associations and other clubs like Lions club, Rotary club etc., on drug-related matters and also on public health issues.

Interprofessional Relationship

Pharmacists are required to maintain a good relationships with other professionals working in the hospital, like doctors, nurses, lab technologists and even with administrative and sub-staff for the successful practice of their profession. Doctors and nurses are directly in contact with the pharmacy in their day-to-day activity, hence pharmacists should maintain a cordial relationship with them. Though other professionals are not connected with

the pharmacy in their daily activities, a pharmacist may need their services at some other time. Similarly, administrative staff and sub-staff are helpful to the pharmacist in his functions like the purchase of drugs, its inventory control, billing, accounting and in related matters. Hence pharmacists should be polite, friendly and easily approachable by all professionals in the hospital. Inter-professional collaboration with a specific group of professionals is explained in the chapter No.10

Good Pharmacy Practice (GPP)

According to WHO, " GPP is the practice of pharmacy that responds to the needs of the people who use the services of a pharmacist to provide optimal, evidence-based care."

To support this practice, it is essential that there is an established national framework of quality standards and guidelines. The requirements of GPP, as indicated by WHO, are given below.

Requirements of Good Pharmacy Practice

GPP requires that a Pharmacist's first concern in all settings is the welfare of patients

GPP requires that the core of the pharmacy activity is to help patients make the best use of medicine. Fundamental functions include the supply of medication and other healthcare products of assured quality, the provision of appropriate information and advice to the patient, administration of medication when required, and the monitoring of the effects of medication use.

GPP requires that an integral part of the pharmacist's contribution is the promotion of rational and economical prescribing, as well as dispensing

GPP requires that the objective of each element of pharmacy service is relevant to the patient, is clearly defined and is effectively communicated to all those involved. Multidisciplinary collaboration among healthcare professionals is the key factor for successfully improving patient safety.

Good Pharmacy Practice guidelines were published by WHO long ago. It is mainly suitable for developed countries. Hence other countries were set to liberty to frame their own GPP depending on the local conditions. Thus many countries, including our neighbours, Srilanka and Malaysia, have their own GPP guidelines. In India, Indian Pharmaceutical Association [IPA] published GPP guidelines as early as 2002. From that, the salient points or topics are given below with due acknowledgement:

The guidelines are classified into two sections. 1. Structure guidelines and 2. Process guidelines

1. Structure Guidelines

   These refer to the pharmacy as an organisation and give standards/guidelines for

   1. Facilities
   2. Premises
   3. Furniture and fixtures
   4. Equipment
   5. Personnel
   6. Systems
   7. Quality policy
   8. Service policy
   9. Staff training policy
   10. Complaints policy
   11. Drug Recall policy
   12. Audit policy
   13. Documentation system

   Structure guidelines aim to create suitable conditions for the process guidelines.

2. Process guidelines

   These refer to the provision of pharmaceutical care and lay down the guidelines for:

   1. Procurement &inventory management
   2. Storage inventory management
   3. Prescription handling
   4. Dispensing
   5. Information for the patient
   6. Patient counselling
   7. Health promotion & ill health prevention
   8. Pharmacovigilance
   9. Enhancement of the professional role
   10. Professional interaction

   Out of the above 23 guidelines few guidelines are very important for the majority of fresh, new entrant, and junior pharmacists for starting their practice of the profession; hence they are reproduced below to be

familiar with from the beginning of their career. Other guidelines can be referred to and learned by the pharmacists when required or in due course.

1. **Storage management**

   All products coming into the pharmacy should initially be quarantined, preferably in a separate area, before they are checked for correctness of quality, batch number, expiry, integrity, etc. After necessary checks, they should be transferred to their respective storage location. All drugs should be stored at stipulated temperature areas and protected from excessive light, dust, and humidity. The temperature at various areas should be recorded at predetermined periodicity, and daily records should be preserved for a period of 2 years. They may be correlated with the subsequent years' corresponding data to improve arrangements for the maintenance of temperatures.

   The medicines and shelves should be maintained clean and dust free at all times by following cleaning schedules and SOPs. Prescription drugs should be kept in such a manner that they are out of reach of clients. All the drugs that are to be stored at a 'cold' temperature should be kept in the refrigerator unless the ambient temperature in the area is cold enough. Drug and dosage forms that require special care while dispensing (e.g. drugs specified under schedule X, Narcotic Drugs and Psychotropic Substances Act and some other CNS drugs etc.) should be kept under lock and key. The key for this should be available only to the Pharmacist in charge at the time. Records of purchase and sales of such medicines should be kept per legal requirements. Shelves should be checked at a predetermined periodicity to ensure the removal of drugs whose expiry date is approaching. An in-house threshold period should be set and followed from such retrieval of drugs from the shelves. The near-expiry products should be stored separately and disposed of either by returning to the respective vendors or by expanding their dispensing. Drugs, which have already expired, should be stored separately on a locked shelf bearing the label "Expired Goods Not for Sale". Care should be taken that such goods do not reach the client in any case. Expired drugs should be returned to the supplier or destroyed as per in-house procedure at the earliest.

2. **Prescription handling**

   The client must be made to feel attended to and comfortable by friendly gestures and ambience as soon as they come into the pharmacy. Communication should be opened in such a way that

it encourages the client to convey his/her needs by producing a prescription or by asking for other products or advice.

Upon receiving the prescription, the Pharmacist should confirm (i) the Identity of the client and (ii) Whether the prescription is presented by the client himself or by someone on the client's behalf. The client may be politely requested to wait while the pharmacist reviews the prescription for (i) therapeutic aspects (Pharmaceutical / pharmacological), (ii) Appropriate for an individual, (iii) Social, legal & economic aspects, and (iv) Legality & completeness of prescription.

Prescription should be complete with regard to (i) Name of the Doctor, his/ her address and registration number. (ii) Name, address, age, and sex of the patient (iii)Name(s) of the medicine(s), potency, dosage, and the total amount of the medicines to be supplied. (iv)Instruction to the patient (v) Refill information, if any (vi)Prescribed doctors' usual signature. Any confusion, shortcoming or anomalies should be brought to the notice of the prescribing doctors.

Correctness of prescribed medicines

The prescription should be checked for: (i) Dosage: Whether the dosage prescribed is within the standard minimum and maximum dose range. (ii) Double medication (same drug or different drug with the same pharmacotherapeutic effect) concurrently prescribed by the same Doctor or by two or more doctors to the same patients undergoing concurrent treatment by more than one doctor. (iii) Interaction between the currently prescribed medicines, OTC medicines being taken by the patient & the medicines being taken from any past prescription (records of which may be available in the Patient's Medication Records). Any drug interaction likely to render the therapy ineffective or cause undesirable effects to the patients should be brought to the notice of the prescribing doctor. (iv) Contraindication: age, sex, disease(s), conditions or other characteristics of a patient that may cause certain prescribed medicines to be contraindicated. (v) History of overuse, underuse, or misuse of medicines by the patient. Any of the above as well as handwriting legibility problems, should be brought to the notice of the prescribing Doctors. Any necessary change made by the doctor should be recorded on the prescription, with the words "Changes made over the telephone in consultation with the Dr. (name) at (time) on (date)" and should be signed and stamped by the pharmacist. This exercise necessitates a trust-based professional relationship with

the prescribing doctor. In case of any doubt, the prescription should be got suitably amended by the doctor.

3. **Dispensing**

Filling the prescription

The medicine should be removed from the storage area, counted and invoiced. In all cases, the final review of the prescription and the correctness of dispensed medicines must be personally made by the pharmacist. As a final step, the pharmacist should personally dispense the medicines, at which stage appropriate counselling should be given to the patient. The medicines should be packed neatly so that their integrity is maintained any medicines requiring special storage conditions, e.g., a cold place (2-8°C), must be packed in cold packs so that they remain at the stipulated temperature till they are taken from a larger bulk pack then they should be packed in a clean, food-grade glass or plastic bottle or a clean envelope and neatly labelled as provided under the lock. Appropriate counselling/guidelines must be given for the patient as recommended below under patient information. Conscious efforts should be made to ensure that the patients' waiting time is kept at a minimum while all the necessary steps are carried out systematically. This can be archived by several management options, e.g. by deploying an appropriate staff-to-client ratio.

Hospital Pharmacy Standards

Hospital Pharmacy Standards were framed by the International Pharmaceutical Federation (FIP) and adopted by the American Society of Health-System Pharmacists (ASHP). The standards devised first in 2008 were revised in the year 2014 and published with the title " Revised FIP Basel statements on the future of Hospital Pharmacy" It declares that the goal of hospital pharmacists should be to optimise patient outcomes through collaborative, inter-professional, responsible use of medicines and medical devices. It is a long document, the salient features of which are given below:

1. Hospital pharmacists should engage health authorities and hospital administrators to ensure appropriate resources for, and design, the hospital medicines-use process.
2. Health authorities should ensure that each hospital is serviced by a pharmacy supervised by pharmacists who have completed advanced training in hospital pharmacy.

3. All prescriptions should be reviewed, interpreted, and validated by a hospital pharmacist prior to the medicine being dispensed and administered.
4. Hospital pharmacists should monitor patients taking medicines to assure patient safety, appropriate medicine use, and optimal outcomes for inpatients and outpatients. When resource limitations do not permit pharmacist monitoring of all patients taking medicines, patient selection criteria should be established to guide pharmacist monitoring.
5. Hospital pharmacists should be allowed to access and document the full patient record.
6. Hospital pharmacists should ensure that patients or caregivers are educated and provided written information on the appropriate use of medicines.
7. Hospital pharmacists should provide orientation, drug information and education to nurses, physicians, and other hospital staff regarding best practices for medicines use (a best practice is a method or technique that has consistently shown results superior to those achieved with other means, and that is used as a benchmark).
8. Each pharmacy should have contingency plans for medicine shortages and emergencies.
9. The “seven rights” (right patient, medicine, dose, route, information, documentation and time) should be fulfilled in all medicine-related activities in the hospital.

The document is classified under six themes. They are 1. Procurement 2. Influences on prescribing 3. Preparation and delivery 4. Administration 5. Monitoring of medicines use, and 6. Human resources, training and development. Each of the theme's headings is self-explanatory under which relevant matters are discussed.

ASHP Guidelines: Minimum Standards for Pharmacies in Hospitals

This document explains the purpose and elements of care. It lists the elements of pharmacy services that are critical to safe, effective and cost-conscious medication use in a hospital as follows.

1. Practice management 2. Medication use policy development 3. Optimising medication therapy 4. Drug product development 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, and 9. Research

Standard 1. 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. Hence this section explains about pharmacy and pharmacist's services, including 24-hour pharmacy services, After-hours pharmacy access, laws and regulations, policies and procedures and human resources. Under the human resources, it recommends a professionally competent, legally qualified pharmacist with an advanced management degree like MBA. Finally, it lists the facilities required for the above services.

Standard 2. Medication use policy development

Under this heading the document deals with policy development, formulary management and drug information. How to disseminate drug information is also explained under the last heading.

Standard 3. Optimizing medication Therapy

To achieve this standard, the document elaborates on creating relationships with the patient, acquiring essential patient data and consulting with other health professionals about medication therapy**.**

Standard 4. Drug product procurement and inventory management

This standard can be achieved by following the guidelines described under this heading. They are, selecting sources of pharmaceutical products, managing inventory items and returning recalled, expired and other unusable items.

Standard 5. Preparing. Packaging and labelling medications

This standard is explained under the subheadings, preparing medications and packaging medications. The first one deals with compounding, sterile preparations and hazardous drug products, and the second topic is about unit dose packaging and bar-coding of unit dose packaging and point of-care administration

Standard 6. Medication dispensing and delivery

Under this heading, medication dispensing, delivery and administration are explained. Starting with prescribing, medication purpose [diagnostic or therapeutic], medication order and its review are dealt with in the first part, and drug delivery systems, administration devices, and automated devices are explained in the second part—medication administration by whom, when, how and its record entry are briefly mentioned at the end.

Standard 7. Monitoring medication use

By reviewing patients' responses to medication therapy and also by educating and counselling patients and families, this standard can be

achieved. The first part review is well-guided with ten points which a pharmacist should follow to effectively fulfil his duty of monitoring medication use.

Standard 8. Evaluating the effectiveness of the medication use system

Assessing pharmacy services and practices by documentation of pharmacist-provided patient care services and medication therapy outcomes, workload and financial performance and improving the medication use process are mentioned in this standard. Medication use evaluation, medication safety, antimicrobial stewardship, infection prevention, and control are also coming under this standard.

Standard 9. Research

It advocates the pharmacist to initiate, participate in, and support clinical and practice-related research in hospitals. For that, it explains the policies and procedures, procurement, distribution and control of investigational drugs etc.

Thus the minimum standards for a hospital pharmacy are well drafted by both FIP and ASHP.

Introduction to NQAS Guidelines

National quality assurance [NQAS] standards for public health facilities are published under National Health Mission by the Ministry of Health and Family Welfare, Government of India. It describes the standards expected from various healthcare facilities. It was first published in 2016 and revised subsequently in 2020. These standards have been developed keeping in the specific requirements for public health facilities as well as global best practices. Standards are primarily meant for providers to assess their own quality for improvement through pre-defined standards and to bring up their facilities for certification.

The introduction to these standards is reproduced below from the above document with due acknowledgement.

1. Comprehensiveness – The proposed system is all-inclusive and captures all aspects of quality of care within the eight areas of concern. The departmental check-lists transposed within Quality Standards, and commensurate measurable elements provide an exhaustive matrix to capture all aspects of quality of care at Public Health Facilities.
2. Contextual – The proposed system has been developed primarily to meet the requirements of Public Health Facilities; since Public Hospitals have their processes, responsibilities and peculiarities, which are very different from the ‘for-profit’ sector. For instance,

there are standards for providing free drugs, ensuring the availability of clean linen, etc., which may not be relevant for other hospitals.

3. Contemporary – Contemporary Quality standards such as NABH, ISO and JCI, and Quality improvement tools such as Six Sigma, Lean and CQI have been consulted, and their relevant practices have been incorporated.
4. User Friendly – The Public Health System requires a credible Quality system. It has been the endeavour of the team to avoid complex language and jargon. So that the system remains user-friendly to enable easy understanding and implementation by the service providers. Checklists have been designed to be user-friendly, with guidance for each checkpoint. The scoring system has been made simple with uniform scoring rules and weightage. Additionally, a formula-fitted excel sheet tool has been provided for convenience and to avoid calculation errors.
5. Evidence-based – The Standards have been developed after consulting vast knowledge resources available on the quality. All respective operational and technical guidelines related to RMNCH+A and the National Health Programmes have been factored in.
6. Objectivity – Ensuring objectivity in the measurement of Quality has always been challenging. Therefore, in the proposed quality system, each Standard is accompanied by measurable elements & Checkpoints to measure compliance with the standards. Checklists have been developed for various departments, which also capture inter-departmental variability for the standards. At the end of the assessment, there would be numeric scores, bringing out the quality of care in a snap-shot, which can be used for monitoring, as well as for inter-hospital/inter-state(s) comparison.
7. Flexibility – The proposed system has been designed in such a way that states and Health Facilities can adapt the system according to their priorities and requirements. State or facilities may pick some of the departments or groups of services in the initial phase for Quality improvement. As the baseline differs from state to state, checkpoints may either be made essential or desirable, as per the availability of resources.

   Desirable checkpoints will be counted in arriving at the score, but this may not withhold its certification if compliance is still not there. In this way, the proposed system provides flexibility, as well as a 'road map'.
8. Balanced – All three components of Quality – Structure, process & outcome, have been given due weightage.

9. Transparency – All efforts have been made to ensure that the measurement system remains transparent so that assesse and assessors have a similar interpretation of each checkpoint.
10. Enabler – Though standards and checklists are primarily meant for the assessment, they can also be used as a 'road map' for improvement.

The following are the area of concern in a health facility. 1. Service Provision 2. Patient rights 3. Inputs 4. Support services 5. Clinical services 6. Infection control 7. Quality management, and 8. Outcome

Currently, National quality assurance [NQAS] standards for the following facilities are available: 1. District Hospitals 2. Community Health Centre 3. Primary Health Centre 4. Urban Primary Health Centre 5. Health and Wellness Centre [sub centre]

They are simply a long list of equipment and other facilities required for various sections of the particular hospital or centre. For full detail, students are advised to refer to the above document [1596 NQAS for PHF 2020 – 16 Dec 2021 pdf]

NABH Accreditation and Role of Pharmacists

National Accreditation Board for Hospitals and Health Care Providers [NABH] is a constituent board of the Quality Council of India. It encompasses relevant and comprehensive standards for allopathic hospitals, clinics and other health care providers. It has a separate list of standards for hospitals, small clinics and others. For example, it stipulates the standards under the following headings for small allopathic clinics which are having only OPD. [outpatient department] facilities.

The eight chapters of allopathic clinic standards are

1. Access, Assessment and Information [AAI]
2. Care of Patient [COP]
3. Patient Rights and Education [PRE]
4. Infection Control [IC]
5. Continuous Quality Improvement [CQI]
6. Responsibilities of Management [ROM]
7. Facility Management and Safety [FMS] and
8. Community Participation and Integration [CPI]

Benefits of Accreditation

(a) Patients are the biggest beneficiary as the implementation of accreditation standards ensure patient safety, commitment to quality care outcomes

(b) Improves patient specification and increases community confidence as services are provided by credentialed medical staff

(c) Accreditation status provides a good marketing advantage in the competitive healthcare

(d) Accreditation provides an objective system of empanelment by insurance and other third parties.

Role of Pharmacists in NABH Accreditation

Whenever a Hospital or Clinic applies for NABH accreditation, it should comply and be ready with the standards prescribed for each section of a hospital. The pharmacy of the hospital is no exemption; it should also prepare itself for the inspection by the NABH team. All the pharmacists starting from the chief pharmacist of the hospital has a definite role to fulfil and succeed in obtaining NABH accreditation for the hospital. The following are the standards that are applicable to the pharmacy.

Policies and Procedures: There should be a documented policy and procedures for a pharmacy to function properly, and those policies should comply with the acts, rules and regulations of the government. The following are a few of those acts:

A] Pharmacy act B] Drugs and Cosmetics act C] Narcotics and Psychotropic substances act D] Drugs and Magic remedies act [Objectionable advertisements act]

There should be a Registered Pharmacist for dispensing and managing the pharmacy and whose Registration certificate should be prominently displayed in the pharmacy. Policies for almost all activities of the pharmacy is given in the NABH document, and they are about 1. Procurement 2. Storage 3. Formulary 4. Prescription 5. Dispensing 6. Administration of medicine 6. Monitoring of patients after medication administration 7. Obtaining medicines when the pharmacy is closed 8. Obtaining medicines, not in Hospital Formulary 9. Errors and adverse events 10. Narcotics and Psychotropic medicines 11. Chemotherapeutic agents, and 12. Implants and medical supplies.

Under each of the above headings, 'Dos' and Don'ts are explained, thus, if followed faithfully, a perfect pharmacy can be established and put to service. As the full text of the above NABH document is beyond the scope of this chapter, students and pharmacists are advised to refer to the same

whenever they are assigned the duty or role of obtaining NABH accreditation for their hospital.

Questions

Short Answer Questions

1. Define hospital pharmacy.
2. Write briefly about the origin and development of hospital pharmacy.
3. Write a note on the responsibilities of a Hospital Pharmacist.

Long Answer Questions

4. Enumerate the organisational structure of a modern hospital pharmacy.
5. Explain the Job specifications of various sections of a hospital pharmacy.
6. Describe the works of a hospital pharmacy with qualified persons appointed to carry out those jobs.
7. What are the duties a pharmacist is expected to perform after dispensing in a modern hospital pharmacy set-up?
8. Explain the staff requirement, infrastructure and workload of a modern hospital pharmacy.
9. Write a note on Interprofessional relationships in a hospital
10. Write an essay about Good Pharmacy Practice in hospital
11. What are the standards prescribed for hospital pharmacy by FIP and ASHP?
12. Explain NQAS guidelines for hospital pharmacy.
13. Enumerate NABH Accreditation and the role of pharmacists in it.
14. Explain the staff requirement and infrastructure of a modern hospital pharmacy