1.6 GOOD PHARMACY PRACTICES IN HOSPITAL

Hospital Pharmacy

Background: In 1992, International Pharmaceutical Federation (FIP) developed standards for Pharmacy Practice viz. "Good Pharmacy Practices (GPP) in Community and Hospital Pharmacy Settings". These were submitted to WHO expert committee and upon endorsement by WHO expert committee in 1997, the FIP/WHO joint document on GPP was published in 1999.

Recognising the importance of GPP in professional practice, the professional concerns and attitudes have been emphasized in the guidelines indicating that, patients' welfare and well-being are of paramount importance. FIP/WHO defines GPP as, Practice of Pharmacy that respond to the need of people, who use pharmacists services to provide optimal and evidence-based care.

The GPP guidelines have been developed with overall aim of improving standards and practice of distribution and use of medicines.

Salient features of FIP/WHO GPP guidelines:

While mentioning the importance of health, the guidelines state that, "the health of the public is fundamental to the happiness and welfare of all people". At the same time the following barriers to achieving good health have been identified, namely poor access to quality medical products, lack of access to trained health professionals and care, inadequate health work force and unaffordable cost of care with poor standards of education of healthcare professionals.

Emphasizing the role of medicines, it has been stated that...

1. Medicines are an essential and critical part of healthcare services in all cultures and societies and are essential component of many disease prevention programs and almost all disease treatment plans

2 Medicines are increasingly expensive and thus their affordability compromise the

healthcare.

3. Use of substandard, adulterated, spurious and counterfit medicines are a growing

problem compromising health. 4. Pharmacists as healthcare professionals play an important role in improving access

to healthcare. 5. Competent pharmacists with updated skills and expertise are required.

6. National pharmacy professional association should support pharmacist by providing continuous professional development activities and establish national standards of pharmacy practice.

The role of FIP is to provide leadership to national professional associations in setting standards of pharmacy practice. The policy of FIP and WHO is to provide guidance to National Pharmacy Professional Organizations regarding the development of their national GPP guidelines.

1. Underlying Philosophy;

Consistent to mission of pharmacy practice viz. "To contribute to health and to help patients with health problems to make the best use of their medicines improve

The following six components to this mission have been identified:

⚫ Being readily available to patients with or without an appointment.

• Identifying and managing or triaging health related problems. Health promotion

Assuring effectiveness of medicines.

• Preventing harm from medicines and

• Making responsible use of limited healthcare resources.

Pharmacist play an important role in achieving outcomes of treatment thro contributing effectively in the following activities: integrity of supply chain and detecting spurious, counterfit, aduhe

Assuring drugs.

(R) Ensuring proper storage of medicines.

Assuming proper prescribing of medicines so that dose regimen, dosage forms

appropriate.

(iv) Instructions for use are clear. (V) Prevention of drug-drug, drug-food interactions and known and predicte adverse drug reactions

(vi) Monitoring treatment to verify its effectiveness.

2. Definition of GPP:

As stated before it is defined as "The practice of Pharmacy that respond to need people, who use pharmacist's services to provide optimal, evidence-based care"

3. Requirements of good Pharmacy Practice:

Following requirements have been identified: (1) A pharmacist's first concern in all settings is the welfare of patients.

(Pharmacist help patients to make the best use of medicines.

(m) Pharmacist supply medications and other products of assured quality.

(v) A provision of appropriate information and advice to patients.

(v) Monitoring of the effects of medication use. (vi) Pharmacist promote rational and economic prescribing as well as dispensing

(vii) Pharmacy service should be relevant to patient clearly defined and effect communicated to all those involved. (vii) Multidisciplinary collaboration among healthcare professionals is key for imp

patient safety.

For satisfying these requirements the following conditions are necessary. Well-being of patient should be the main philosophy underlying the practice Pharmacist should have input into decisions about use of medicines.

Relationship with physicians should be established as a therapeutic collaborative partnership.

Relationship between pharmacists should be one of colleagues rather than as

competitors.

Pharmacist should be aware of essential medical and pharmaceutical information

about each patient.

Pharmacists maintain standards and comply with requirements for continuous National Standards of GPP should be specified and should be adhered to by

professional development

practitioners

At National level, it is necessary to establish A legal framework that:

⚫ defines who can practice pharmacy.

defines the scope of pharmacy practice.

ensures the integrity of the supply chain and the quality of medicines.

(b) A workforce framework that:

• Ensure the competence of pharmacy staff through continuing professional

development programs.

Defines the personnel resources needed to provide GPP () An Economic framework that

Provides sufficient resources to ensure the activities underken in GPP.

4. Setting Standards for good Pharmacy Practice:

The national pharmacy professional association should set standards for GPP, which includes basically a quality management framework and strategic plan for developing services. While setting standards attention should be paid to both needs of users of Healthcare services and the capacity of national healthcare systems to support these Services. The standards should recognize the uniqueness of different pharmacy practice settings. The standards should acknowledge evolving practice settings. The baseline of standards should be established for practice below which the activity cannot be considered Pharmacy practice at all. When establishing minimum standards on GPP, FIP emphasizes the importance of first defining the roles played by pharmacists. It is recommended that National Pharmacy professional associations consider the following roles, functions and activities

Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products.

Function A: Prepare extemporaneous medicine preparations and medical products: Pharmacists should ensure that medicine preparation areas are appropriately designed to permit ease of preparation and minimize potentials for medication errors. Further the quality of preparations be ensured alongwith quality of raw materials.

Relationship with physicians should be established as a therapeutic collaborative partnership.

• Relationship between pharmacists should be one of colleagues rather than as competitors.

Pharmacist should be aware of essential medical and pharmaceutical information

about each patient Pharmacists maintain standards and comply with requirements for continuous

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Function B: Obtain, store and secure medicine preparations: Pharmacists shou ensure that procurement process is transparent and should be such that promote equity and access. The procurement should support strong quality assuran principles so that substandard, adulterated, counterfit products shall not b procured. Moreover, pharmacists should have plans ready for shortages medicines and emergency purchases Proper storage conditions are provided for medicines especially for controlled substances

Function C: Distribute medicine preparations and medical products: Pharmaci should ensure that all medicines are handled and distributed in a manner that assures reliability and safety of medicines supplied. He should establish a effective distribution system having written procedures and especially recall facility which prompt and handled by a designated person. Further he should ensure that there uninterrupted supply of medicines even in emergency situations like outburst of pandemic Pharmacist should adopt effective mechanisms through which occurrence of adverse reactions can be monitored.

Function D: Administration of medicines, vaccines and other injectable

medications: Pharmacist should assume a role in preparation and administration of

medicines and monitoring of outcomes of medications administered. He should

have an educator, facilitator and immunizer role thus by participating in vaccination help in preventing of diseases. He should assume direct role in DOTS therapy for tuberculosis, HIV/AIDS and management of drug addictions.

Function E Dispensing of medical products: Pharmacist should ensure that

appropriate facilities, trained personnel and standard dispensing procedures are in

place in pharmacy for dispensing of prescribed medications. He should assess and

evaluate all prescriptions received for therapeutic, social, economic, legal correctness

before supplying medical products. Pharmacist should maintain patient confidentiality while dispensing and should provide counseling to ensure the patient follows the instructions regarding use of

drugs, so that maximum therapeutic benefit shall be achieveable.

Function F: Dispose of medicine preparations and medical Products: Pharmacist should ensure that regular monitoring of inventory is conducted for inspection of expiry dates and removal of outdated stock. Further he should see that recalled medical products are stored separately for subsequent disposal. He should establish safe way of medicines waste disposal and provide information to patients about how to safely dispose of expired or unwanted medicines. Role 2: Provide effective medication therapy management:

Function A: Assess patient health status and needs: Pharmacist should ensure that health management, disease prevention and healthy lifestyle are considered in patient assessment and care process. While patient assessment the unique patient considerations such as education level, cultural beliefs, native language and physical and mental capacity need to be considered.

Function B: Manage patient medication therapy: For safe, rational and cost

effective use of medicines, pharmacist should maintain ready access to sources of

information on medicines such as reference books, journals, essential medicine list

and standard treatment guidelines. Pharmacist should play key role in educating prescribers on access to and evidence for optimal and appropriate use of medicines. He should provide advice or recommendations to prescriber on selection of appropriate medication or dosage.

When multiple healthcare practitioners are involved in patient's medication therapy,

pharmacist should use all necessary clinical and patient data to coordinate effective

patient therapy management. Pharmacist should establish standard operating procedure for referrals to physicians, specialists or other healthcare providers.

Function C: Monitor patient progress and outcomes: Pharmacist should consider patient diagnosis, and patient specific needs. When assessing patient response to medicine therapy. He should document necessary clinical and patient data to assess and monitor medication therapy.

Function D: Provide information about medicines and health related issues: Pharmacist should ensure that there is a suitable place for discussing confidential information with the customers and patients. He should provide sufficient health, disease and medicine specific information to patients for their decision making process. This information should aim at supporting adherence and empowerment for patient. Pharmacist should be proactive in reducing antimicrobial resistance by providing information about appropriate use of antimicrobials to consumers and prescribers.

Role 3: Maintain and improve professional performance: • Function A: Plan and implement continuing professional development strategies to improve current and future performance: Pharmacists should perceive continuing education as being lifelong and be able to demonstrate evidence of continuing education to improve clinical knowledge, skills and performance.

Pharmacist should take steps to update their knowledge and skills about complimentary and alternative therapies such as health supplements, acupuncture homeopathy and naturopathy.

Pharmacist should update their knowledge about new technologies, automation in pharmacy practice and on changes to information on medical products. Role 4: Contribute to improve effectiveness of healthcare system and public health:

Function A: Disseminate evaluated information about medicines and variou aspects of self-care: Pharmacist should ensure that the information provided t patients, other healthcare professionals and public is evidence based, objectiv understandable, non-promotional, accurate and appropriate.

health promotion and disease prevention. He should educate patients i

evaluate and use web-based or other forms of healthcare information Fu

should assist patients and their care providers to obtain and critically information to meet their individual needs. ⚫ Function B: Engage in preventive care activities and services: Pharmacists participate in preventive care activities and promote public health and p disease eg smoking cessation, sexually transmitted diseases. Pharmacist should provide point-of-care testing and other health screening act

for patients at high risk of disease. • Function C Comply with national professional obligations, guidelines legislations: Pharmacists should make sure that they comply with the provision

national code of ethics for pharmacists

⚫ Function D: Advocate and support-national policies that promote improv

health outcomes: Pharmacist should contribute to public and professional gro to promote, evaluate and improve health in the community. Pharmacist should collaborate with other healthcare professionals in the efforts about m improve health outcomes.

5. Conclusions:

The four main roles where pharmacists contribution is expected by the stakeholders

pharmacy services are: Prepare, obtain, store, secure, distribute, administer and dispose of medica products

(4) Provide effective medication therapy management. () Maintain and improve professional performance

(N) Contribute to improve effectiveness of the healthcare system and public health. Specific standards of GPP can be developed within a national pharmacy professional organization framework

Achieving GPP standards for each nation using these recommendations require time and efforts. As a health professional, pharmacists should begin the process without delay.

Updation: Medication therapy management is a distinct service or group of services that optimize

therapeutic outcomes for individual patients

Innovation:

The concept of Continuing Professional Development (CPD) can be defined as, "the responsibility of individual pharmacists for systematic maintenance, development and broadening of knowledge, skills and attitudes to ensure continuing competence as a

Role 1: Prepare, obtain, store. secure, distribute, administer, 1 dispense and dispose of medications

Functions: 1. Preparation of extemporaneous medicine

preparations 2. Obtain, store and secure medications

3. Distribution of medications

4. Administration of medicines,

vaccines, injectables

5. Dispensing of medications 6. Dispose of medications

Role 4: Contribute to improve ectiveness of healthcare system and public health

Functions 1. Provide information activities and services

about medicines and various aspects of self-care

2 Engage in preventive care

3. Comply with professional obligations, guidelines and

legislations

Advocate and support national polices and promote improved health outcomes

Roles and Functions of Pharmacists for developing GPP Standards

Role 2 Provide effective medication

therapy management Functions: 1. Assess patient health status and needs

2 Manage patient medication therapy 3. Monitor patient progress and outcomes medicines and health-related issues

4. Provide information about

Role 3: Maintain and improve professional performance: Functions: Plan and implement continuing professional development strategies to improve current and future performance

Fig. 1.2: Roles and Functions of pharmacists for developing GPP standard

1.7 HOSPITAL PHARMACY STANDARDS

The FIP congress held in Tokyo in 1993 adopted and FIP/GPP text under declaration on standards for quality of Pharmacy services, in which it is stated standards are important part in measurement of quality of services to the consumers believes that standards based on these guidelines should be used by Nat Pharmaceutical Organizations The GPP guidelines are based on pharmaceutical care o by Pharmacists The guidelines recommended that national standards are set for s promotion of health, the supply of medicines, medical devices, patient self care improving prescribing and medicine use by pharmacist activities.

In 2008, FIP organised an expert consultation in Basel, Switzerland during its 68 congress. Following this consultation the FIP WG (Working Group) on GPP undertook a extensive review of existing national standards on GPP. A proposal for this initiative w presented to WHO Expert Committee on specifications for pharmaceutical preparations 2008 Subsequently in 2014 "Revised FIP Basel Statements on the future of Hosp Pharmacy was adopted as hospital pharmacy practice standards as revisions of the in 2008 version. The salient features of these statements are as under.

The document consists of total 65 statements, of which first 19 statements concerned with "Overarching and Governance Statements" and the remaining statemere are grouped in six different themes

Overarching and Governance Statements: The overarching goal of hospital pharmacists is to optimize patient outcomes throug collaborative, interprofessional responsible use of medicines. At global level evidence-base hospital pharmacy practice standards should be developed. Hospital pharmacists shoul nsist health authorities, hospital administrators to provide appropriate resources fo medicine use process. Each hospital is serviced by pharmacy department which is under the control and supervision of qualified pharmacist. The Director of Pharmacy should be accountable for responsible use of medicines in the hospital. All prescriptions should be reviewed, interpreted and validated by hospital pharmacist. Hospital pharmacist should monitor to assure patient safety, rational medicine use and achieving optional therapeut outcomes in patients. Further he should ensure that patients and their care givers are educated and provided written information on appropriate use of medicines. Hospital pharmacist should provide orientation, education and drug information to nurses, physicians and other hospital staff regarding best practices for medicine use. The pharmacy curricula should include hospital-related content Hospital pharmacist must be actively engaged in research management and disposal of waste related to medicine use; adopting newe technologies in medicine use process and in maintaining the integrity of medicines across the supply chain. He should guide in therapeutic decision making, and must contribute in fulling seven rights" viz. Right patient, medicine, dose, route, information, documentation and time

Innovation/Updation: Responsible use of medicines means

Hospital Pharmacy

Medicine is only used when necessary, choice of medicine is appropriate and based on scientific and/or clinical evidence.

There is timely access to and availability of quality medicines, properly administered and

monitored for effectiveness and safety. A multidisciplinary collaborative approach is used in providing care to patients.

Theme 1: Procurement:

Hospital pharmacist should be involved in procurement process that promote equity and access, and should be based on safety, quality and efficacy principles. The procurement practices must be supported by strong quality assurance principles. The medicines procuring process be guided by formulary selection process and must be supported by reliable information system. Theme 2: Influences on Prescribing:

Hospitals should use formulary system linked to standard treatment guidelines Hospital pharmacists should be a key member in pharmacy and therapeutics committees to oversee all medicines management policies and procedures. He should have a key role in educating prescribers at all levels of training in responsible use of medicines Pharmacists should play key role in multidisciplinary team responsible for therapeutic decision making in all patients. Hospital pharmacists should promote seamless care by contributing to transfer of information wherever patients move between and within healthcare settings. A trained and credentialed hospital pharmacists should participate in collaborative prescribing

Theme 3: Preparation and Delivery:

Hospital pharmacist should assume responsibility for storage, preparation, dispensing distribution of all medicines and for appropriate labeling and control of medicines in hospital. He should be involved in deciding what medications be ward stocked and standardizing, the storage and handling of ward medicines. He should ensure that those preparations compounded in hospital are of quality standards.

The preparations of hazardous medicines like cytotoxics should be under the supervision of pharmacist and should be prepared under environmental conditions that minimize the risk of contamination of product and environment. He should adopt evidence based systems and technologies that shall help to reduce the risk of medication errors.

Hospital pharmacist should develop policies regarding use of medicines brought into

the hospital by patients and should have tracking system for tracing medicines dispensed by

the pharmacy.

Theme 4: Administration:

Hospital pharmacist should ensure that information sources needed for safe medicine preparation and administration are readily available at the point of care and patients medication history, allergies, drug interactions are accurately recorded and evaluated prior to medication use. He should ensure that medicines are packaged and labeled to assure identification until immediately prior to administration. The medication labels should be

clear and should bear sufficient information including atleast two patient ide name of medicine, route of administration, dose and where appropriate volume and administration Pharmacist should develop quality assurance strategies for me administration to detect errors. The medicine administration process should be de such that transcription steps between original prescription and medicine admini record are eliminated

Theme 5: Monitoring of Medicines Use:

For reporting defective medicines, substandard medicines, there should be a t accessible reporting system. Such reports need to be reviewed internally and sent in at manner to pharmacovigilence centers and manufacturers. Similarly, a reporting syste adverse drug reactions and for medication errors, should be available.

prog Medicines use practices should be self assessed and compared with benchmarks F the medicines use process should be reviewed through external accreditation Pharmacists clinically relevant activities should be documented, collected and analyse improve quality and safety of medicine use and patient outcomes.

Theme 6: Human Resources, Training and Development:

At a national level the competency frameworks are defined, established and regu accessed. The health authorities, hospital pharmacists and other stakeholders sho collaboratively develop human resource plans for responsible use of medicines workforce plans should describe strategies for human resource education, train recruitment, retention, competency development, remuneration and career progression Hospitals should maintain human resource information systems. The training programs pharmacy support staff should be nationally formalized, harmonized and credentiale within a defined scope of practice. The hospital human resource policies should compliant with hospital pharmacy practice standards.

The nationally accepted competency framework should be used to assess hume resource training needs and performance. The role of hospital pharmacist includ collaborative prescribing should be included in the curriculum of other healthca professionals and the role of other healthcare professionals should be included in the pharmacy curricula.

1.8 ASHP GUIDELINES: MINIMUM STANDARD FOR PHARMACIES IN HOSPITALS

American Society of Health-System Pharmacy (ASHP) guidelines are intended to serve a a basic guide for the provision of pharmacy services in hospitals. The mission of pharmacist is to help people make best use of medications. The pharmacy department in hospital shal be concerned with both provision of pharmacy services and outcomes of pharmacy services These guidelines have been developed considering safe, effective and cost-conscious medication use. Accordingly nine standards have been identified as follows:

1. Standard-1 Practice Management 2. Standard-II: Medication use policy development
2. 3. Standard-III: Optimizing medication therapy

4 Drug product procurement and inventory management

1. 5. Standard V: Preparing, packaging and labeling medications
2. 6 Standard VI Medication dispensing and delivery 7. Standard VII Monitoring medication use
3. 8 Standard VIII: Evaluating the effectiveness of the medication use system.
4. 9. Standard DC Research.

1.8.1 Standard-I: Practice Management

1. Keeping in view the pharmacists responsibility as a patient care provider and to support by his operational responsibilities, the pharmacy services need to be organised and managed. It requires collaboration and communication with other healthcare departments and services in the hospital. Thus in hospital setting, pharmacy management services should cus on ensuring collaboration, co-ordination and communication with other departments the hospital.
2. (A) Pharmacy and Pharmacist-services:
3. (1) Pharmacy mission, goals and scope of services: Pharmacy shall have written mission statement that reflects both patient care and operational responsibilities. This should be consistent with the mission of the hospital. The short term and long term goals shall be determined in collaboration with hospital administrator and other healthcare professionals. The goals should be integrated with the goals of hospital. A written document describing scope of Pharmacy services shall be maintained. The mission, goals and scope of pharmacy services shall be clearly communicated to all those involved in Provision of Pharmacy/Services
4. (ii) 24 Hours Pharmacy Services: 24 hours pharmacy services be provided when possible, when this is not possible, a pharmacist shall be available on an on-call
5. basis.
6. (iii) After hours pharmacy access: In absence of 24-hours services, a provision to provide access to limited number of medications in emergency situations be available. It should be available to authorized, licensed healthcare professional. Such access should be carefully monitored, controlled and documented and should be reviewed regularly to ensure appropriate use. The Pharmacy and Therapeutics Committee shall determine when, how and what medications shall be given access.
7. (iv) Practice standards and guidelines: The standards and regulations of all relevant government bodies shall be met.

Laws and Regulations:

The applicable laws and regulations shall be met and documents of compliance shall be maintained.

(C) Policies and procedures:

(1) Policy and procedures manual: A written document governing functions shall be available and followed by pharmacy staff. It should describe the operational policies and procedures to guide and direct services. The document should be regularly reviewed by pharmacy staff

(i) Personnel Safety: All pharmacy staff should be involved in hospitals, emergency response. All pharmacy staff shall receive education and training these plans. (iii) Emergency preparedness: Appropriately trained pharmacists should be of emergency preparedness teams and participate in applicable prepara drills (v) Medical emergencies: Pharmacy shall participate in hospital decisions emergency medication kits and trays and the role of pharmacist emergencies, eg pharmacist should serve on cardiopulmonary resuscitation

(v) Immunization programs: The pharmacy shall participate in develop hospital policies regarding immunization programs. When appropriate he participate as active immunizer in health system based immunization program

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(vi) Substance abuse programs: The pharmacy shall assist in development of and

participate in hospital substance abuse education, prevention and treatment

**D) Human Resources: (1) Position descriptions:** Different cadres of pharmacy manpower with responsibilities, related competencies shall be clearly defined in written position descriptions.

**The Director of Pharmacy:** The pharmacy shall be managed by profession competent, legally qualified pharmacist, the director of Pharmacy. He/she shout thoroughly knowledgeable about and have experience in hospital pharmacy practice and management.

The Director of Pharmacy shall be responsible for.

Establishing the mission, vision, goals and scope of pharmacy services.

Developing, implementing, evaluating and updating plans and activities pharmacy.

• Developing and implementing policies and procedures that effective medication use. ⚫ Mobilize and managing the resources necessary for optimal provision ensure safe pharmacy services.

Ensure that pharmacy services are in adherence to applicable laws regulations.

Pharmacists: Pharmacy shall employ adequate number of competent and qualifie pharmacists to meet the specific medication-use needs. Support personnel: Sufficient support personnel (eg. Pharmacy technician clerical and secretarial personnel) shall be employed to facilitate pharmacy services

(i) Education and training: All personnel shall receive education, training and

continuing education facilities to maintain and enhance their competence.

(iii) Recruitment, selection and retention of personnel: Personnel shall be selected by pharmacy director on the basis of job related qualification and experience. iv) Orientation of personnel: There shall be established, structured procedure for orienting new personnel to the pharmacy.

(v) Work schedules and Assignments: The director of pharmacy shall ensure that

work schedules, procedures and assignments optimize the use of personnel and

resources

(vi) Performance evaluation: There shall be a procedure for regularly scheduled evaluation of performance and employee's competency. The pharmacy director shall ensure that competency assessment program is in place for all staff. (vii) Effective communication: For communicating important information to staff in

timely manner there should be a established method. (viii) Ethical conduct: Standards of ethical conduct shall be established and there shall

be procedure for educating all pharmacy sheff regarding those standards.

Facilities: (1) Pharmacy: Adequate space, equipment and supplies shall be available for all

professional and administrative functions relating to pharmacy services.

(ii) 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.

(iii) Compounding area: Suitable facilities to enable compounding, preparation and labeling of sterile and non-sterile product shall be available. (iv) Patient assessment and consultation area: In outpatient setting a independent, private area for pharmacist-patient consultations shall be available to secure

confidentiality of patient information.

(v) Office and meeting space: Adequate office and meeting areas shall be available for administrative, educational and training activities. (vi) Automated systems: For automated pharmacy systems, there shall be policies and

procedures for evaluation, selection, use, calibration, monitoring and maintenance. The calibration, maintenance and certification of all such systems shall be performed and documented.

(vii) Information technology: A comprehensive pharmacy computer system shall be employed and shall be integrated with other hospital information systems such as electronic health record, medication administration and patient billing systems. Pharmacy computer system should be integrated with the hospital's clinical, financial and administrative information systems.

(viii) Drug information: Adequate space, current resources, information handig communication technology shall be available to facilitate the provision of information. The up-to-date, objective drug information in terms of current and electronic periodicals, best practices guidelines shall be available. 1 data bases and data dissemination methods are desirable. Bec

(ix) Record maintenance: Consistent with the policies, and related laws and regul the necessary records shall be maintained. There shall be adequate space ava for maintaining and storing records.

(F) Committee Involvement:

In the committees concerned with establishing and implementing medication re policies, the pharmacist shall participate actively as a member. e.g. committees respons for patient care, P and T committee, infection prevention and control, medication

evaluation, institutional review board and information technology committees.

1.8.2 Standard-II: Medication-use Policy Development

(A) Policy development:

As mentioned above, the pharmacist shall be a member of committees concernin medication management and use. He shall be involved in the development, implementatio and assessment of care plans standing orders and order sets that involve medicato therapy.

(B) Formulary management:

(1) Formulary: A well controlled formulary of approved medications shall b maintained and regularly updated by P&T committee. The formulary should b periodically reviewed for safety information. P&T committee shall be responsible for developing and maintaining adequate product specifications to help in purchase a medications. The pharmacy shall disseminate the formulary by electronic or othe means to meet the needs of all healthcare professionals. There shall be policies and procedures for procurement, control and use of non-formulary medications required for patient care.

(ii) Medication therapy monographs: For medications considered for formulary

addition or deletion, the medication therapy monographs shall be made available

to P&T committee Monograph shall include a comparative therapeutic, economic

and risk assessment of each medication.

(iii) Non-drug substances: There shall be policies and procedures describing how pharmacy shall seek and obtain authorization from medical staff and hospital committees prior to medical use of any chemical substance that has not received FDA approval. Documentation shall exist to ensure that appropriate risk management measures have been taken.

Drug information: ) Drug information request: Pharmacists shall provide patient specific drug information and accurate information about drugs and drug therapy to health professionals, patients and patient's caregivers.

Dissemination of drug information: Pharmacist shall keep healthcare providers informed about the use of medications through appropriate publications, presentations and programs

1.8.3 Standard-III: Optimizing Medication Therapy

Pharmacist in collaboration with medical staff, nursing staff shall develop policies and procedures for ensuring quality of medication therapy.

(A) Creating a Relationship with the patient:

(i) Pharmacists role in direct patient care: The policies of hospital and pharmacy department should encourage pharmacists to provide direct patient care in both inpatient and outpatient settings. Policies should encourage pharmacist to engage in medication therapy management.

(ii) Continuity of care: Pharmacists should take leadership role in developing and implementing policies for admission's discharges, and transfer so that patient's therapy is well managed regardless of patient transitions across care settings. (ii) Patient confidentiality: Patient confidentiality is maintained in accordance with the applicable laws. Pharmacy personnel shall respect and protect patient confidentiality. Patient information shall be shared only with authorized health professionals.

(B) Acquiring essential patient data: Pharmacist conducted medication history taking is desirable. Electronic medical records should be generated so that medication history and other data required for medication management are available to all health professionals caring for patient.

(C) Consulting with other health professionals about medication therapy:

(i) Pharmacist's consultation: Pharmacist shall provide oral and written consultation to other health professionals regarding medication therapy selection and management. (ii) Medical record documentation: There shall be policies and procedures for pharmacist review and documentation in patient's medical records, Recommendations made by pharmacist and actions taken in response should be recorded in patient's medical record so that other health professionals shall have access to that information.

(iii) Medication therapy decisions: The pharmacist's prerogatives to initiate, monitor and modify medication therapy, consistent with laws, regulations and policies shall be clearly delineated and approved by appropriate committees.

1.8.4 Standard-IV: Drug Product Procurement Inventory and Management Pharmacy shall be responsible for procurement and distribution of all drug products used in hospital.

(A) Selecting sources of Pharmaceutical Products: (i) Medication acquisition: The policies and procedures meant for medication acquisition should address issues like formulary development, competitive bidding group purchases, best practices etc. Benchmarking of medication costs should be performed.

Pharmaceutical manufacturers and suppliers: Criteria for selecting r and suppliers shall be established to ensure high quality and best price of p Pharmaceutical manufacturer's Representatives: There shall be written s governing manufacturer's representatives or vendors within the Representatives should not be permitted access to patient care an promotional materials and activities shall be reviewed and approved by phammanu

(B) Managing inventory. (1) Medication storage: Medications shall be received and stocked, and pr under proper conditions like sanitation temperature, light, moisture, ventilati to assure medication integrity and personnel safety. (i) Drug shortages: Policies and procedures shall exist for managing drug shone

The pharmacy should develop strategies for identifying alternative ther working with suppliers, collaborating with physicians and other health profession

(i) Samples: Medication samples shall never be used for inpatient treatment. I

otherwise permitted, there shall be policies and procedures to ensure their safe

(iv) Patient care area stock: Storage of medicines in non-pharmacy areas such

patient care area shall be limited to medications for emergency use and rout used personal care items (eg antiseptic solutions, mouthwash). The list medications to be accessible shall be developed by multidisciplinary committee P&T committee. (v) Controlled substances: There shall be policies and procedures consistent w applicable laws to ensure control of distribution and use of controlled substance and medications having abuse potential.

(vi) Patients own medications: Drugs brought into hospital by patients shall identified by pharmacy and documented in patients medical record of medication are to be used during hospitalization. For such use of medications, policies a procedures that ensure pharmacist's identification and validation of medicatio

integrity shall be available.

(C) Inspecting Storage areas and inventory items:

The stocks of medications shall be inspected regularly to ensure absence of outdates unusable, recalled or mislabeled products. Storage conditions detrimental to drug products shall be assessed, documented and corrected.

(D) Returning recalled, Expired and other unusable items:

There shall be a written procedure for timely handling and documentation of drug

product recall. A established procedure for removal from use any drug product subjected to recall shall be available. Notifying health professionals, identifying patients receiving such drug and communicating available alternative therapies to prescribers shall be done.

1.8.5 Standard-V: Preparing, Packaging and Labeling Medications

(A) Preparing medications: (i) Compounding: Drug formulations that are not available commercially but are needed for patient shall be prepared in accordance with applicable standards and

regulations. Pharmacy shall provide quality assurance procedures for these

operations and necessary information of compounded products (master formula, batch, lot number) shall be documented and maintained. (1) Sterile preparations: Trained personnel shall be available for preparation of sterile products in a suitable environment, following quality assurance and expiration dating procedures. Sterile products manufactured outside the pharmacy should be

avoided

(ii) Hazardous drug products: There shall be policies that describe special precautions, equipment, training for preparation handling, storage and disposal of hazardous drug products. The policies consistent with applicable laws, shall be adequate to ensure safety of staff, patients, community and environment.

Packaging medications:

(1) Unit dose Packaging: Medications in single unit package, ready to use form shall be available whenever possible. Manipulation of medications (withdrawal of dose from container, reconstitution of drug product, splitting of tablet etc.) before administration by the final user should be minimized.

(ii) Barcoding of unit dose packages and point of care administration: Barcoding of unit doses useful in inventory management, dose preparation, dispensing and administrating shall be done.

8.6 Standard VI: Medication Dispensing and Delivery

Medication dispensing:

(1) Prescribing: Medications shall be prescribed by professionals who are legally permitted and granted clinical privileges in hospital. Pharmacy shall advocate and ensure such practitioners conformance with standardized, approved, safe terminology and abbreviations use.

(ii) Medication orders: All medication orders shall be contained in patients medical

record. Direct copy of patients medication order (Hard copy or prescriber-entered electronic transmission) shall be received by pharmacy. Appropriate records of each order and its processing in pharmacy shall be maintained in accordance with applicable laws. There shall be a system that ensure that medication orders are not inappropriately continued.

(iii) Review of medication orders: All medication orders shall be reviewed by

pharmacist and assessed in relation to patient and clinical information before administering first dose. Any questions regarding order shall be resolved with prescriber before administration. Action taken as a result of intervention should be documented in patients medical record.

Medication delivery and administrations: (1) Drug delivery systems and automated distribution devices: Pharmacy shall

design procedures regarding drug delivery systems, distribution devices that ensure safety, accuracy, security and patient confidentiality. Potential for medication errors associated with such systems be evaluated. Pharmacist shall supervise stocking and documentation of medications in automated dispensing devices.

(ii) Medication administration: Persons authorized by law and trained for the a shall be allowed to administer the medications. Administered, refused,, medications shall be recorded in patients medical record

1.8.7 Standard VII-Monitoring Medication Use

(A) Reviewing Patients Response to Medication Therapy: The monitoring includes proactive assessment of patients problems and assessm the following components by pharmacist

⚫ Therapeutic appropriateness of patients medication regimen.

• Therapeutic duplication or omissions in medication regiment.

Appropriateness of dose, route, method and frequency of administration.

Patients adherence to medication regimen.

Drug-drug, drug-food, drug-lab test, drug-disease interactions, • Adverse drug reaction and undesired effects.

Patient medication allergies and sensitivities. • Physical signs and clinical symptoms relevant to medication therapy.

Assessment of effectiveness of medication therapy. (B) Educating and Counseling Patients and Family:

Pharmacist should ensure that all patients are provided with adequate information abo medications they receive and encourage adherence to medication regimens. The educatio activities shall be coordinated with nursing, medical and clinical staff.

1.8.8 Standard VIII: Evaluation of Effectiveness of Medication

us

Systems

There shall be ongoing systematic program for quality assessment and improvement o pharmacy services, and medication use system. The program should be integrated wit

hospitals health system quality and improvement activity. A) Assessing pharmacy services and practices:

(1) Documentation of pharmacy provided patient care and medication therapy outcome: There shall be a program that consistently document the patient care services provided by pharmacy and the patient outcomes from medication therapy

(ii) Workload of financial performance: A process should exist, that provide for system wide analysis and cost of medication therapy. Improving the medication-use B)

(1) Medication-use evaluation: There shall be a program that ensure monitoring drug process: use cost and appropriate, safe and effective use of medications. P&T committee shall define specific parameters for evaluation. Through such evaluation, the areas in r of improvement in medication prescribing and management can be identified and strengthened need

(ii) Medication Safety: Pharmacist provide leadership in participation in collaborative

multidisciplinary effects to prevent, detect, and resolve drug related problems. An

ongoing program for preventing, monitoring, resolving ADRS shall be developed.

(i) Antimicrobial stewardship and infection prevention and control: The policies

and procedures to promote optimal use of antimicrobials, reducing transmission of infections and educating health professionals, patients and community shall be developed. Pharmacist monitoring patients microbial sensitivity reports, advice prescribers if microbial resistance is suspected Pharmacists assist in developing prescribing patterns to help minimize the development of drug resistance.

1.8.9 Standard IX - Research

Pharmacist should participate, initiate, support clinical and practice related research appropriate to goals, objectives and resources of specific hospital.

(1) Policies and procedures: Policies and procedures for safe and proper use of investigational drugs be established and followed. There shall be procedure to assure that informed consent is obtained from the patient before the first dose of the study drug is administered. (ii) Institutional Review Board: Pharmacist shall be a member of the hospital's

institutional review board. (iii) Information Regarding Investigational Drugs: Pharmacy shall have access to information on all investigational studies. The pharmacy shall provide pertinent written information about the safe and proper use of investigational drugs including

possible adverse effects and adverse drug reactions

1.9 INTRODUCTION TO NQAS GUIDELINES

National Quality Assurance Standards (NQAS) for Public health facilities 2020 (Ministry of health and family welfare, Govt. of India) have been developed keeping in mind the specific requirements of public health facilities and global best practices. The standards are applicable to all secondary healthcare facilities operated by state or central health department in India ie. District hospitals/District hospitals designed as teaching institutions, Sub-divisional hospitals, Taluka hospitals, Area hospital and any other equivalent health facility.

The standards are formulated to assess the quality of preventive, curative and promotive services provided by secondary public hospitals. The range of services covered by these standards are:

1 Outpatient department services

2 Maternal, newborn, child and adolescent health services

3. In-patient departmental care

4. Emergency care services

5. Intensive care services

6. Laboratory and radiology diagnostic services

7. Blood bank services

8. Surgical services

9. Hospital auxiliary and support services etc.

10. Disease control programs and public health functions.

The Salient features of the proposed quality system:

1. Comprehensiveness: The system is all inclusive and captures all aspects of o care within the eight areas of concern.

2. Contextual: Primarily these standards have been developed for meeting requirements of the public health facilities as opposed to for-profit sector (P hospital)

3. Contemporary: Contemporary quality standards such as NABH, ISO and quality improvement tools such as six sigma, lean and CQI have been consulted

4. User friendly: Considerations have been given to develop standards that the remains user-friendly to enable easy understanding and implementation

5. Evidence based: The standards have been developed after consulting knowledge resource available on the quality.

6. Objectivity. Standard is accompanied with measurable elements and checkpoint measure compliance to the standards.

7. Flexibility: System has been designed in such a way that states and health facil can adapt the system according to their priorities and requirements

8. Balanced: All these components of quality structure, process and outcome h been given due weightage

9. Transparency. Efforts have been taken to ensure that the measurement syste remains transparent

10. Enabler: Though standards and checklists are primarily meant for assessment, it c also be used as a road map for improvement.

Components of quality measurement system:

The standards have been defined for various levels of facilities. The standards have be grouped within the eight areas of concern. Each standard further has specific measurabe elements. In each health facility (department), specific checkpoints have been identified. The standards and pertinent measurable elements are checked through checkpoints. A checkpoints of a department (health facility) together form checklist. After filling scores i checklist, a scorecard of departmental (health facility) would be generated.

The list of area of concern in a health facility:

1 Service provision

2. Patient rights

3. Inputs

4. Support services

6. Infection control

5. Clinical services

7. Quality management

8. Outcome

Assessment Protocol:

The assessment of quality is based on general principles of integrity, confidentiality objectivity and replicability.

1. Integrity: Assessors and persons managing assessment programs should:

Perform their work with honesty, diligence and responsibility Demonstrate their competence while performing assessment

Perform assessment in impartial manner Remain fair and unbiased in their findings.

2. Fair presentation.

3. Confidentiality: The assessors should not share information with any other person, media.

4. Independence: Assessors should be independent to the activity and act in a manner that is, free from bias and conflict of interest.

5. Evidence based approach: Conclusions should be drown based on evidences which are objective, verifiable and reproducible.

Planning Assessment activity: Assessment activities are undertaken at different levels.

1. Internal assessment at facility level.

2. Assessment by District and State quality assurance units

3. Accreditation assessment: Assessment by national assessors for certification/accreditation

Internal Assessment: Hospital should prepare a quarterly assessment schedule. The hospital quality team should appoint a co-ordinator preferably hospital manager or quality manager. The co-ordinator shall prepare assessment plan and schedule, constitute assessment team maintain assessment records and communicate with departments. Assessment by DQAU/SQAU: Efforts should be made to ensure that all departments of the hospital have been assessed during one visit.

Constituting assessment team: The team should be constituted according to scope of assessment Le. department to be accessed. It is preferable to constitute multidisciplinary team consisting of one doctor, one nurse and a person from another hospital may be nominated as a the member of team. For external assessment the team members should have been trained earlier.

Preparing assessment schedule: Assessment schedule should be ready beforehand stating details such as department to be assessed, date and timings etc.

Performing assessment:

(i) Pre-assessment preparation: Team leader should ensure that assessment schedule has been communicated to all those involved. Leader shall assign the area of responsibility to each team member.

(ii) Opening meeting: Short opening meeting with assessee's department sto conducted for introduction, aims and objectives of assessment and clarity of

(iii) Reviewing documents: The documents such as SOPs, BHT, Registers etc reviewed using checklists, checklists are main tools for the assessment. A d for department (Health facility) showing details in tabular format shall be av (see sample checklist below).

Checklist for Accident and Emergency

Measurement

Checkpoint

Compliance

Assessment method

Means of vero

Ref. No

element

AREA OF CONCERN A SERVICE PROVISION

Standard A1

ME A11

The facility provides curative services

Facility

provides general

medicine services

ME A1.2

Availability of

emergency medical procedures

Availability of emergency surgical procedures

Facility

provides general surgery services

ME A1.3

ME A1.4

SI-Staff Interview, OB-Observation

SUOB

Poisoning

snakebite, Acute M

Hypovolumic shoo

Dyspnoea.

Unconscious

patients.

SUOB

Appendicitis,

Rupture spleen,

Intestinal

obstruction,

Perforation, burns.

Fig. 1.4: Sample checklist

Assessor should gather information and evidences to assess compliance to t requirements of measurable elements and check points at health facility being assessed Information can be gathered by the following four methods:

1. Observations: Compliance to many of the measurable elements can be assessed directly observing the articles, processes and surrounding environment.

2. Record review: Record generate objective evidences which needs to be triangulate with findings of the observations.

3. Staff interview; Interaction with staff helps in assessing the knowledge and sk level required for performing job functions.

4. Patient/client interview: Interaction with patients/clients may be useful in gettin information about quality of services and their experience in the hospital. Assessor may use these methods to assess certain measurable element. The normal flo of gathering information assessment would be as given in Fig. 1.4.

Familiarise with measurable element and checkpoint

Understand assessment method and means of verification

Gather the information and evidence

Compare with checkpoint and means of verification

Arrive at a conclusion for compliance

Fig. 1.5: Flow of information

Assessor should arrive at a conclusion for extent of compliance viz, full, partial or non-compliance for each of the check points. For detailed information about areas of concerns, measurable elements, standards and provision of facilities, the readers are advised to refer "National Quality Assurance Standards public health facilities 2020 document of "Ministry of Health and Family Welfare", Government of India.

1.10 NABH-ACCREDITATION AND ROLE OF PHARMACIST

National Accreditation Board for Hospitals and Healthcare providers (NABH) August 2020

About NABH: NABH is a constituent Board of Quality council of India (QCI), set up to establish accreditation program for healthcare organizations. The objective of establishing NABH is enhancing health system and promoting continuous quality improvement and patient safety.

International society for quality in healthcare (IS Qua) has accredited NABH as an organization, And thus hospitals accredited by NABH have international recognition. NABH currently considers the following accreditation, certification and empanelment programs.

1. Accreditation Programs

(i) Hospitals

(ii) Blood banks

(V) Dental facilities/Dental clinics

(vi) AYUSH hospitals ((x) Clinical trial

(0) Eye care organizations

2. Certification Programs

(Entry level hospital () Entry level AYUSH centre

(v) Nursing excellence

Emergency department

(ii) Small healthcare organizations

(iv) Medical imaging services

(vi) Allopathic clinics

(viii) Primary health centres

(x) Panchakarma clinics

(ii) Entry level small healthcare organizations

(iv) Entry level AYUSH Hospital

(vi) Medical laboratory program

(viii) MVTF empanelment certification

3. Empanelment programs:

As a nodal body representing Quality Council of India, NABH conducts a healthcare organizations for empanelment under Central Government Health 3 (CGHS) and Ex-servicemen Contributory Health Scheme (ECHS). asses

Introduction to Accreditation:

Quality and patient safety at hospitals and healthcare services is of great importe government bodies, NGOs, insurance agencies, professional organizations healthcare workers and patients. Accreditation focuses on establishing quality and sa during relation to predetermined standards. Health system in India is currently working rapidly changing social, economic and technical environment. Under such situations concerns about quality and safety are raised in healthcare. Self assessment and external review process used by healthcare organizations in assessing their level of performance at continuously improving the quality of their services. Thus, accreditation would be most important approach for improving the quality of hospitals. represe

NABH started the hospital accreditation program in the year 2005, with the intent improving healthcare quality and patient safety in public and private hospitals standards set by NABH has been recognised internationally and thus are at par with t global healthcare accreditation standards.

The current hospital standards 5 edition launched in February 2020 is also accred for a cycle of 4 years (April 2020 to March 2024).

Benefits of Accreditation: 1. Benefits for patients:

• Accreditation results in high quality of care and patient safety Patients receive services by credentialed medical staff.

• Rights of patients are respected and protected. 2. Benefits for organization:

It enables continuous improvement in healthcare organization.

It ensures organization's commitment to quality care, patient safety and best clinic outcomes It raises community confidence in services provided by the hospital.

It provides opportunity to healthcare unit to benchmark with the best.

. It provides marketing advantage in a competitive healthcare.

It gives international recognition to organization which helps to promote medica tourism. It provides objective system of empanelment by insurance and other third parties.

3. Benefits for Staff:

Staff gets satisfaction as it provides for learning, good working environment and leadership.

Efficiencies and competencies of staff gets improved. It improves overall professional development, knowledge and competencies.

NABH Standards for Hospitals:

Hospital accreditation program assesses the quality and operational systems operating given facility Mainly compliance with NABH standards and applicable laws and regulations is assessed. The NABH standards are included into ten chapters and 651 objective elements. Out of 651 elements 102 are in core category which are mandatorily essed during each assessment, 459 are in commitment category which are assessed during final assessment, 60 are in achievement category which are assessed during surveillance assessment and 30 are in excellence category which will be assessed during accreditation

Ten chapters of Hospital standards are:

1 Access, Assessment and Continuity of Care (AAC)

2 Care of Patients (COP)

3 Management of Medication (MOM) 4 Patient Rights and Education (PRE)

5 Hospital Infection Control (HIC)

6 Patient Safety and Quality Improvement (PSQ)

7. Responsibilities of Management (ROM) 8. Facility Management and Safety (FMS)

9. Human Resource Management (HRM) 10. Information Management System (IMS)

Methodology for Accreditation:

Hospitals willing to get accreditation, must be committed to ensure implementation of NABH standards. The assessment team look for evidences of implementation of standards. Eligibility to apply for accreditation:

The organizations fulfilling following requirements are eligible to apply.

Currently in operation as healthcare provider and should be above 50 beds as hospital.

The minimum volume of patients which will help in assessing is currently 30%.

The organization which commits to comply with NABH standards and applicable legal/statutory/regulatory requirements. Organisation that should have implemented NABH Standards for a minimum of three months

Accreditation process:

Hospital should nominate a person to co-ordinate all activities related to seeking accreditation. The hospital accreditation guidebook need to be procured through NABH website Hospital can apply online from the website www.nabh.co.

(a) use a new email id for registration

(b) choose 'Hospital (Full accreditation)' as application type. c) NABH shall activate the email id and provide you the login and password.

Using the login and password one can fill the application form.

Start of acc journey

Acknowledgement and scrutiny of application

Application form + Documents+Application fee Submit online at NABH Website

Pre-assessment (optional) onsite/Remote Desktop/Hybrid Within 3 months of fee deposition

Final assessment onsite/Remote/desktop/ Hybrid. Within 6 months pre-assessment

Time cycle

CAPA Cycle 1

Review of assesment report

CAPA cycle 2

Final assesment

Feedback to healthcare organisation and necessary conective action takenby Healthcare organization

Approval of accreditation by Accreditation Committee

Implement standards minimum 3 monta procured from

Apply for re of accrediatio before 6 months e expiry of accred

Continuous quality

improvement surveillance assessmen

Onsite/Remote/Desktop/Hyb Send corrective action pr within 45 days

Within 20-24 months of accreditations

Issue of accreditation certificate

Hospita

Fig. 1.6: Accreditation process

NABH Accreditation procedure: 1. Preparation of Policies and Manuals: Hospital shall prepare quality mana policies and procedures required as per NABH standards.

2. Application for Accreditation: Fill in the details in the application as per th instructions given in the online application portal and submit application online. 3. Scrutiny of Application: NABH officer shall scrutinize the application for s completeness

4. Notification of Principal Assessor and Assessment team: NABH shall appoint principal assessor and a team of other members. The principal assessor shal evaluate the adequacy of all documents (Quality manual, policies, procedures departmental manuals) as mandated by the standards.

5. Types of Assessments Conducted by NABH: NABH in co-ordination with the hospital may choose to follow one of the following methods for conduction of assessment: (a) Onsite assessment: Here the assessors visit the healthcare organization for

predefined mandays based on bed strength of hospital. Assessors verified the documents, facilities and conducts interviews in person at HCO. (b) Desktop assessment: Here the organization will submit information and documents as per checklist and the same shall be reviewed by NABH assessor.

Based on review the assessor shall give recommendations.

(c) Remote assessment: Here the assessor does not go to the HCO in person but conducts entire assessment from a remote location through use of virtual platforms. Hospital need to provide the online platform. (d) Hybrid assessment: Here one of the assessors may be physically present at the

HCO during assessment and the others will be doing the audit from remote

location through the use of virtual platform.

Pre-Assessment (Optional): It is optional and those organizations who do not desire to undergo pre-assessment shall communicate in the remark column of application form. However, who desire to undergo pre-assessment, NABH shall conduct such assessment. Principal assessor along with others in the team are assigned the job of preassessment. The principal assessor shall submit report of assessment online. The hospital shall take corrective actions on the non-conformities

pointed by the assessors. Final Assessment: After the corrective actions taken by organization, on the

non-conformties pointed in pre-assessment; NABH shall constitute a team for final assessment. The size of assessment team shall depend on bed capacity of hospital and scope of services provided. The date of final assessment shall be mutually agreed upon by hospital management and assessors. The team shall review the hospitals documented management system with reference to the compliance to NABH standards. Documents, policies, procedures shall be assessed for their implementation and effectiveness. The assessment report is prepared and uploaded by principal assessor in the online portal.

Review of Assessment Report: The non-comformities observed are visible to hospital organization, once the report is uploaded by principal assessor. The hospital shall take corrective action on such non-conformities and upload the requisite documentary evidence of action taken. The principal assessor shall review the corrective action taken by the hospital. The hospital organization can avail only two cycles of corrective actions on non-conformities.

After satisfactory corrective action is taken by hospital, the accreditation committee examines the assessment report, additional information received from the hospital and consequent verifications. Accreditation committee shall make appropriate recommendations regarding accreditation of HCO.

. Issue of Accreditation Certificate: NABH shall issue an accreditation certificate with a validity of four years. The certificate has unique number and date of validity.

Surveillance and Reassessment: Accreditation shall be valid for four y

within 20-24 months of date of accreditation, the NABH shall conduct surve NABH may call for un-announced visit, based on any concern or any serious reported by individual, organization or media. 11. Focus Assessment: When there are any significant changes in accredited

eg change is scope of activities, operations, change of location, change

technical personnel etc. the focus assessment shall be conducted.

12. Surprise Assessment: NABH may conduct surprise assessment in accred

hospitals periodically to evaluate the compliance to the standards. Hospital

expected to adhere to the NABH standards at any point of time once it is accred

REVIEW QUESTIONS

1. Define hospital. Give different ways in which hospitals are classified.

2. Describe various functions of hospital.

3. Explain various supportive services of a hospital. 4. Differentiate clearly between hospital pharmacy and community pharmacy.

5. Define hospital pharmacy. Give the objectives of hospital pharmacy. 6. Describe various functions of Hospital Pharmacy.

7. Describe the requirements of personnel for hospital pharmacy. 8. Describe the responsibilities of hospital pharmacist for.

Inpatient pharmacy department

(i) Outpatient pharmacy department

9. Describe the qualifications and abilities required for hospital pharmacist.

10. Give historical account of "Development of hospital Pharmacy" in India. 11. About development of hospital pharmacy" give the international scenario.

12. Discuss the organisational structure of hospital pharmacy department.

13. Write an essay on "pharmacist's professional relationships".

14. Give the salient features of FIP/WHO, GPP-guidelines. 15. Write a note on Requirements of Good Pharmacy Practice".

16. Describe the roles and functions of pharmacists for developing GPP standards. 17. Give the salient features of "FIP-Basel statements on the future of hospit

18. Write an essay on "ASHP guidelines: minimum standards for pharmacies hospitals 19. Write about range of services covered by "National Quality Assurance Standards". 20. Write an essay on NABH accreditation.