

HOSPITAL - ORGANISATION AND STRUCTURE

Hospitals provide various facilities to the patients along with their diagnostic and surgical facilities. Now-a-days tools like X-rays, ultrasound, ECG, etc., have become an integral part of the hospitals. In the last few years hospitals have started providing not only therapeutic treatments but also focussing on preventive aspects as well.

*2M DEFINITION OF HOSPITAL:

Hospital can be defined as an institution of community health or a specialised complex organisation which makes use of physicians, surgeons and a team of technical staff. It also provides facilities for diagnosis, therapy, rehabilitation, prevention, education and research. Hospital has to remain a customer oriented institution since it is meant for them.

ORGANISATION OF HOSPITALS:

Organisation is a dynamic process in which various managerial activities bring people together and bind them together for the achievement of common objectives or common goals.

The most important body of any hospital is the governing body or board of directors or board of trustees. It comprises of various eminent personalities in the field of medical education research and administration. It may also include politicians. The governing body is responsible for framing all major policies, plans and programmes of any hospital. Various committees are appointed by the governing body. It appoints a hospital administrator to get the various functions performed like clinical services, nursing services, pharmacy services, etc. Detailed review of

these services performed by any organisation is given as under:

1. NURSING SERVICES:

This department is the largest and an important part of any hospital as it functions for all the 24 hrs. Nurses are assigned specified number of beds. Nurses have to give personal attention to the patients. They are trained for prenatal care, observation, comfort of the patient during labour etc... The nursing director is the incharge of nursing services.

2. OUT PATIENT SERVICES:

Out patient services include comfort for out patients as they come for their major or minor illness. These services make the hospital truly a community institution. The hospital should provide diagnostic, preventive and curative services to the out patients.

3. RADIOLOGICAL SERVICES:

These services are performed under the direction of a competent radiologist. It includes utilization of various equipments like sonography, X-ray, ECG, CT scan etc... Chief radiologist is assisted by various technicians.

4. CENTRAL SUPPLY SERVICES:

All the medical and surgical supply services are meant for diagnosis, treatment, prevention, research and education. It involves their collection, storing, processing, storing & issuing them against an indent form. Qualified and skilled staff personnel are responsible for its maintenance.

5. HOSPITAL PHARMACY SERVICES:

It controls the pharmacy operation in any hospital. This department fills prescription and dispenses number of

requisitions from the wards. Its functions begin with procurement of drug and finishes with their distribution to out patients and in-patients. It is responsible for proper drug delivery, information system, storage of drugs, manufacturing, sterilization and for advising the physician on drug use.

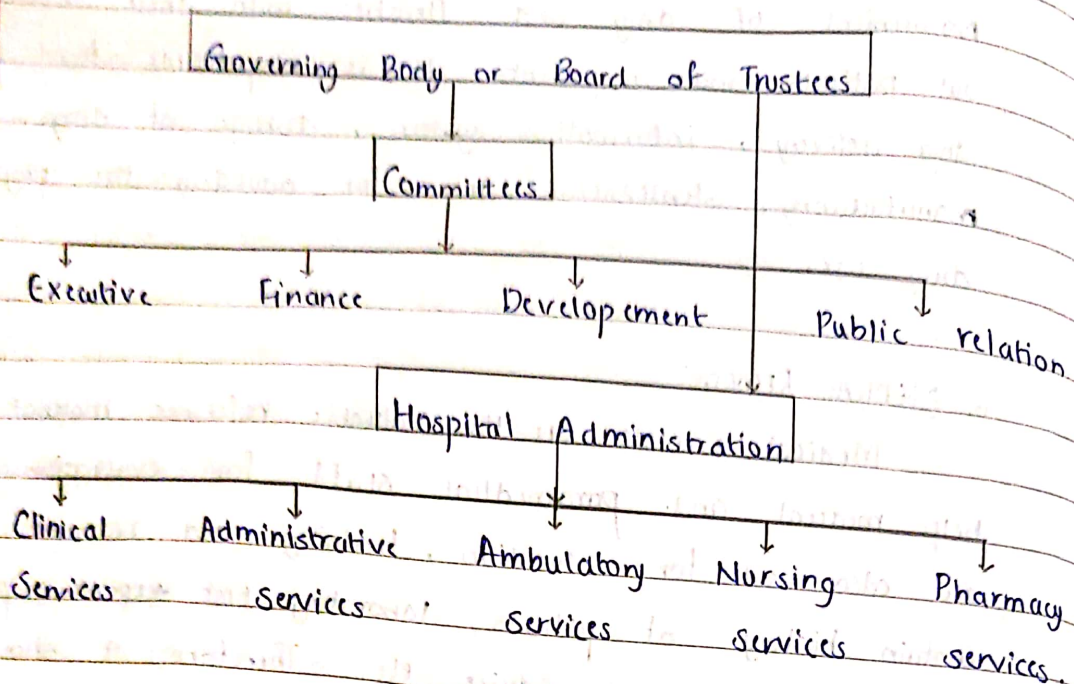
6. MEDICAL RECORDS:

Medical records are the valuable reference material as they help medical and paramedical staff for evaluation. They are also used for education, training and research. They contain history of patients, laboratory test reports, physical examination, physician's advice, etc... Therefore it should be kept in mind to store properly so that they are accessible when required.

7. STORES:

Stores generally receive, store and issue the materials against requisition forms of various departments and wards. Hospital being a large organisation has many stores like medical store, store for general items, surgical stores etc... They always maintain a buffer stock of certain articles and life saving drugs are always made available in the stores.

Besides the above mentioned services of the hospitals, they also provide dietary services, laundry, transport, mortuary, library, etc... for overall benefit and patient care.

TYPICAL ORGANISATION OF A HOSPITALMANAGEMENT OF A HOSPITAL:

Management is today a process of planning, organising, staffing and controlling any organisation. Management principles are always the same whether it is a school, club, hospital or any other institution. Hospital is a very complex organisation. It needs application of a management concepts and techniques. The emphasis should be given on material management. Financial management, human resource management and computer application are the other aspects.

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FUNCTIONS OF MODERN HOSPITAL:

i) PATIENT CARE:

It includes services for diagnosis, prophylaxis and treatment of diseases to the patients. The inpatient services are equally important by providing hospitalisation facility.

ii) IMMUNISATION:

It helps to prevent the diseases (Communicable diseases). A small unit is run in an OPD section where children are immunised by giving different vaccines like BCG, Hepatitis, small pox etc.

iii) COUNSELLING AND PATIENT ADVICE:

It is a modern concept adopted in big hospitals for the well being of patients. During these counselling session pharmacists educate people on communicable diseases, epidemics and family welfare.

iv) (CO-ORDINATION):

Especially hospitals that run under the control of govt. act as interlink between the health policies and the general public. The district hospitals deal with urban and primary health centres.

v) REHABILITATION:

This facility is provided to drug addicts, chronic alcohol and psychiatric patients by specific therapy and supportive measures like yoga and meditation.

vi) RESEARCH:

This should be a vital function of hospital to contribute to the advancement of medical knowledge against dis

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& improvement of hospital services in order to render better patient care. This includes devising new diagnostic procedures and techniques.

vii) EDUCATIONAL TRAINING:

This facility particularly for medical students, pharmacists, nursing, medical health care team and other health care professionals helps to fulfill their curriculum requirement.

viii) WORKSHOP AND SEMINAR:

Such activity is arranged periodically at state level conferences or in the hospitals to furnish the details of recent studies or acute syndromes like severe acute respiratory syndromes.

CLASSIFICATION OF HOSPITALS:

There are no. of criteria by which the hospitals could be classified. They could be clinical and non-clinical oriented.

CLINICAL ORIENTED:

These are again further classified on a different basis:

- a) On the basis of AIIMS (New Delhi)
- b) On the basis of type of medicine used to cure disease-
 - Allopathic hospitals
 - Ayurvedic Hospitals
 - Siddha and Unani Hospitals
 - Homoeopathic Hospitals
 - Physiotherapy centres.
- c) On the basis of anatomy & physiology -
 - ENT Hospitals
 - Cardiac Hospitals
 - Eye Hospitals
 - Kidney Hospitals.

- Orthopedic Hospitals
- Neurological Hospitals.

d) On the basis of type of patients.

- General hospitals
- Gynecology & Maternity hospitals
- Paediatric hospitals
- Psychiatric hospitals
- Accident hospitals
- Rehabilitation centres.

e) On the basis of disease:-

- Cancer hospitals
- TB hospitals
- Leprosy hospitals
- Diabetes hospitals.

f) On the basis of objective:-

- General Hospitals, Ex: Primary health care centres, Municipality Hospitals.
- Special hospitals Ex: Cancer, TB, dental.
- Teaching & research hospitals : Ex: AIIMS (New delhi)

NON CLINICAL ORIENTED HOSPITALS:

These types of hospitals are run under the control of various bodies, cost, bed size and are classified as;

i) Ownership basis:

a) Controlled by central govt: Ex - military hospitals

Railway hospitals

AIIMS (New Delhi)

GIPMER (Pondicherry)

b) Controlled by state govt: Ex - JJ Hospital (Mumbai)

Sassoon Hospital (Pune)

ESI hospital (Mumbai)

Victoria hospital (Bengaluru)

Civil Hospital (Jalgaon)
Stanley Hospital (Chennai)
Bhambhani Hospital (Aurangabad)

c) Controlled by corporation or Municipality:
Ex: BBMP primary health care centres (PHC) Bangalore
Bhagavath hospital (Mumbai)
KEM hospital (Mumbai)
BMC hospital (Mumbai)

d) Private trust hospital:
Ex: Jindal hospital (Bangalore)
Bombay Hospital, (Mumbai)
Jaslok hospital (Mumbai)

e) Controlled by religious bodies:
Ex: Al-ameen hospital (Bangalore)
Christian medical college hospital (Vellore)
Meenakshi mission hospital (Madurai)
Hindu mission hospital (Chennai)

f) Public limited Company hospitals
Ex: Apollo hospitals (Chennai)
Medinova hospital (Gujarat)
HMT hospital (Hyderabad)

g) Private Clinics or Nursing homes:

Such clinics are owned by an individual doctor or group of doctors in towns or big cities & serve for 24 hrs

ii) On the basis of bed size:

a) Large hospitals:

Bed size: 1000 or above.

Ex:- JJ & KEM hospitals.

b) Medium hospitals (500-1000)

Ex:- Jaslok and Bombay hospitals.

c) Small hospitals (bed size: 100-500)

Ex:- Breach candy Hospital, Sagar Hospital

d) Very small hospitals (less than 100)

Ex:- All private clinics, Municipal Hospitals.

iii) On the basis of cost:

a) Costly hospitals:

Ex:- Sagar hospital, Jaslok hospital, Breach candy, HCG

b) low budget hospitals:

Ex:- Civil & Corporation hospitals.

c) Free or conventional cost hospitals:

Ex:- Manilal Kantilal Hospital (Ahmedabad)

2. HOSPITAL PHARMACY:

X-2M. Hospital pharmacy is a department that provides pharmaceutical services to outdoor & indoor patients. The department is headed by professionally competent & legally qualified (registered Pharmacist).

Professional competency means the person with adequate knowledge & skill to manage the departmental activities along with the services to be rendered to the patient.

The prime objective of the hospital pharmaceutical services is to provide safe & effective medicines to all the patients attending the hospital or the clinic.

The services must be safe & economical.

Q1 X: DEFINITION:

Hospital pharmacy may be defined as a department of hospital where procurement, storage, compounding, dispensing or distribution is done under a control of a legally qualified pharmacist.

Q1 X: OBJECTIVES OF HOSPITAL PHARMACY:

The objectives are designed to fulfill the legal aspects mentioned under the pharmacy act 1945 and execute them for the following purposes:

- i) To ensure the availability of the right medication at reasonable cost.
- ii) To develop the scientific and professional aspects of the practice of hospital pharmacy including consulting role, teaching role and participation in the field of research.
- iii) To teach hospital pharmacists the ethics for hospital pharmacy to assume responsibility for professional practice.
- iv) To utilize the resources of hospital to help in improvement of the department & profession.
- v) To develop administrative or management skills essential to the hospital pharmacists.
- vi) To attract a great no. of hospital qualified pharmacists in hospital practice.
- vii) To co-ordinate with other departments of hospital.

4M: FUNCTIONS OF HOSPITAL PHARMACY:

→ No. of activities are performed in hospital pharmacy under the supervision of the head pharmacist. These are summarized as under -

i) Pharmacy activities:

→ Procurement of drugs and medicines and their proper storage.

→ Compounding of drugs & dispensing them to outpatients on the prescription of physician of a hospital.

→ To out patient

→ Distribution of drugs to indoor patients through wards

→ Arranging bulk supplies to mini pharmacy, satellite pharmacy, and unit dose dispensing units operating in a hospital.

→ Providing facility to store narcotic & poisonous drugs separately and maintaining its record properly.

ii) Supportive activities:

Apart from pharmacy functions, the hospital pharmacy helps other departments in multiple ways -

→ It purchases, stores and supplies ancillary items and articles needed in the hospital.

→ Hospital pharmacy counsels patients on prescribed drugs especially to out patients.

→ It maintains detailed accounts of purchases, receipts and supply of drugs and medicines and furnishes them to the accounts department.

iii) Educational Activities:

→ It provides information on new drugs, technology and products, etc... to the doctors and maintains it in the library.

→ It carries out drug monitoring by studying the effects of drugs given to the inpatients, and maintains the data in DIC.

→ Arrange seminars, workshops on topics like sterilization, medication errors, patient compliance for nursing and newly appointed pharmacist.

→ Provides training facilities for fellow pharmacists.

X. 4M LOCATION AND LAYOUT OF HOSPITAL PHARMACY:

→ The hospital pharmacy should be located in such a place that is convenient to provide services to all other concerned departments on a daily basis.

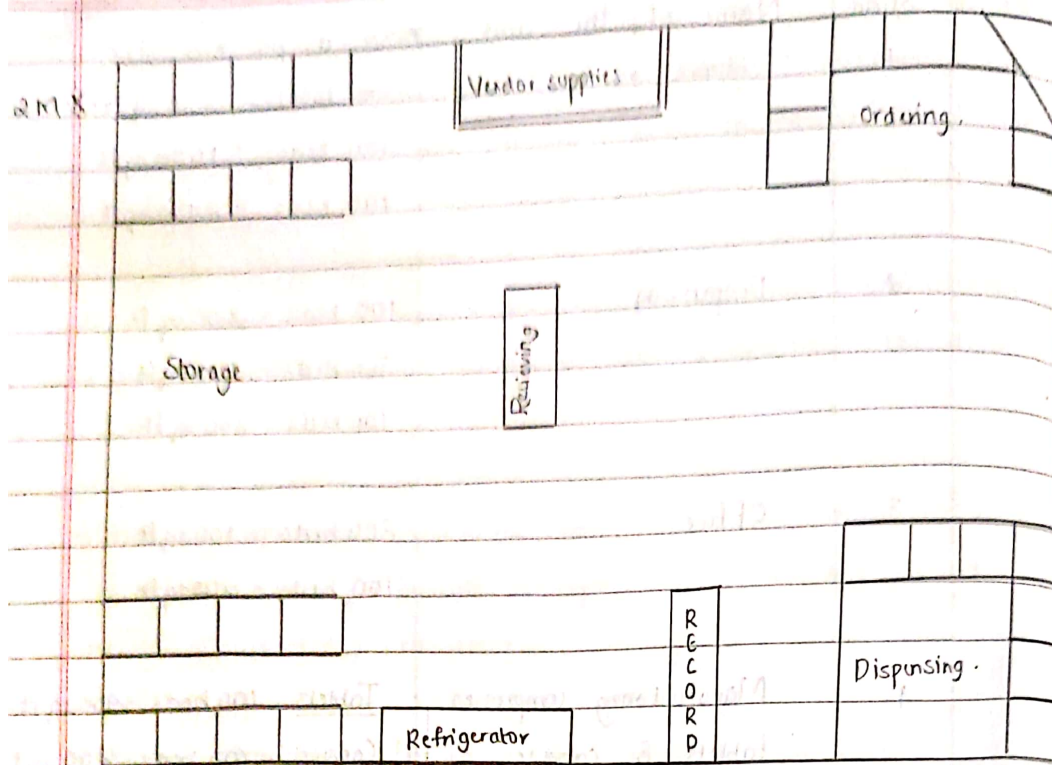
→ Generally the hospital pharmacy is located either in the ground or the first floor adjacent to the outpatient department.

→ The outpatient pharmacy must look decent with enough space for the waiting patients with adequate seating facility. A notice board may be fixed or provision may be made to paste posters on health education, family planning, hygiene, etc...

→ While designing a pharmacy, the following factors should be kept in mind -

Sl.no.	Name of the unit	Area as per bed size
1.	Store room	100 beds - 450 sq.ft 300 beds - 1000 sq.ft 700 beds - 2400 sq.ft.
2.	Dispensary	100 beds - 350 sq.ft 300 beds - 500 sq.ft. 700 beds - 800 sq.ft.
3.	Office	300 beds - 150 sq.ft 700 beds - 200 sq.ft
4.	Manufacturing compressed tablets & capsules	<u>Tablets</u> : 700 beds - 900 sq.ft. <u>Capsules</u> : 700 beds - 200 sq.ft.
5.	Manufacturing under aseptic conditions for eye drops, eye lotions & other preparations for external use.	700 beds - 250 sq.ft.
6.	Paracentesis	300 beds - 600 sq.ft. 700 beds - 600 sq.ft.

FLOOR SPACE REQUIREMENT



→ It must be located in such a place that—

- It is easily accessible to the out patient department.
- Dispensing becomes feasible and economical.
- It is convenient to the central delivery department.

→ The size should be determined by its operational activities

→ Provisions should be made for—

- Washing of containers of equipments
- Storage of bulk solutions and concentrates.
- Storage of poisonous and narcotic drugs.
- Adequate seating facility for staff
- Fire control.

18.

Equipments required:

like floor space Schedule N of the 'Drugs & Cosmetics Act' 1945 specifies requirements of machinery for various dosage forms. These are minimum requirements and guidelines.

While selecting equipment for a hospital pharmacy one must ensure -

- i) How to provide good services with minimum cost.
- ii) How the services could be provided efficiently
- iii) Generally the hospital pharmacy equipment are classified into 4 categories :

- a) Fixed equipment
- b) Movable equipment
- c) Personal requirement
- d) Requirement of hospital pharmacists.

a) Fixed Equipment:

There should be separate counters, cabinet and sink elevators to run a hospital pharmacy.

b) Movable Equipment:

The equipments ^{not} installed permanently ⁱⁿ with the building or the balances, cards, and mixtures.

c) Personal requirement:

A number of activities and processes are carried out in a hospital pharmacy. The activities include manufacturing, testing, distribution, administration and procurement of materials. A team of persons with M Pharma, B Pharma, D Pharma and microbiology qualification will be required. The exact no. of qualified persons will depend upon the size & activities of hospital pharmacy.

2Mx d) Requirement of Pharmacists:

The exact number of pharmacists required depend upon the bed size of hospital and nature of activities in hospital pharmacy. The MCI has given minimum requirement of pharmacists which is summarised as below:

Bed size	No. of Pharmacist
i) Nil (only OP)	only one.
ii) 1 - 50	3
iii) 51 - 100	5
iv) 101 - 200	8
v) 201 - 300	10
vi) 301 - 500	15
vii) Above 501	15 + 1 for every 100

Chart 1 - Movement of medicines.

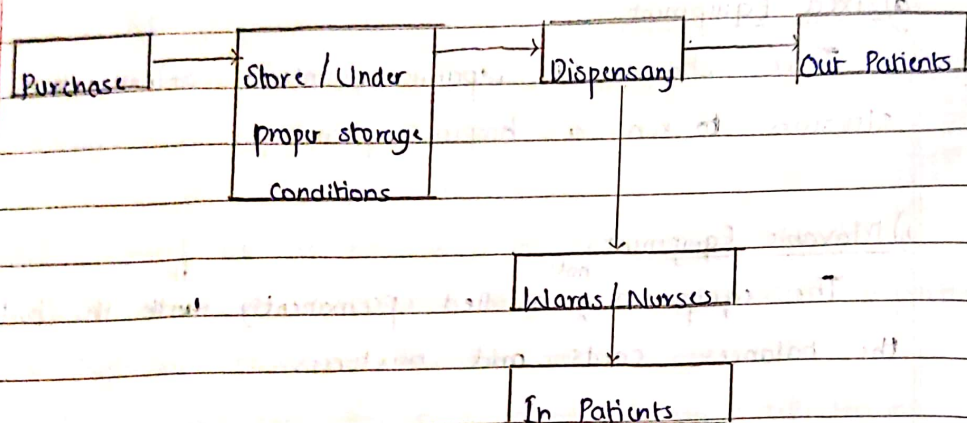


Chart 2 - Movement of Raw Material

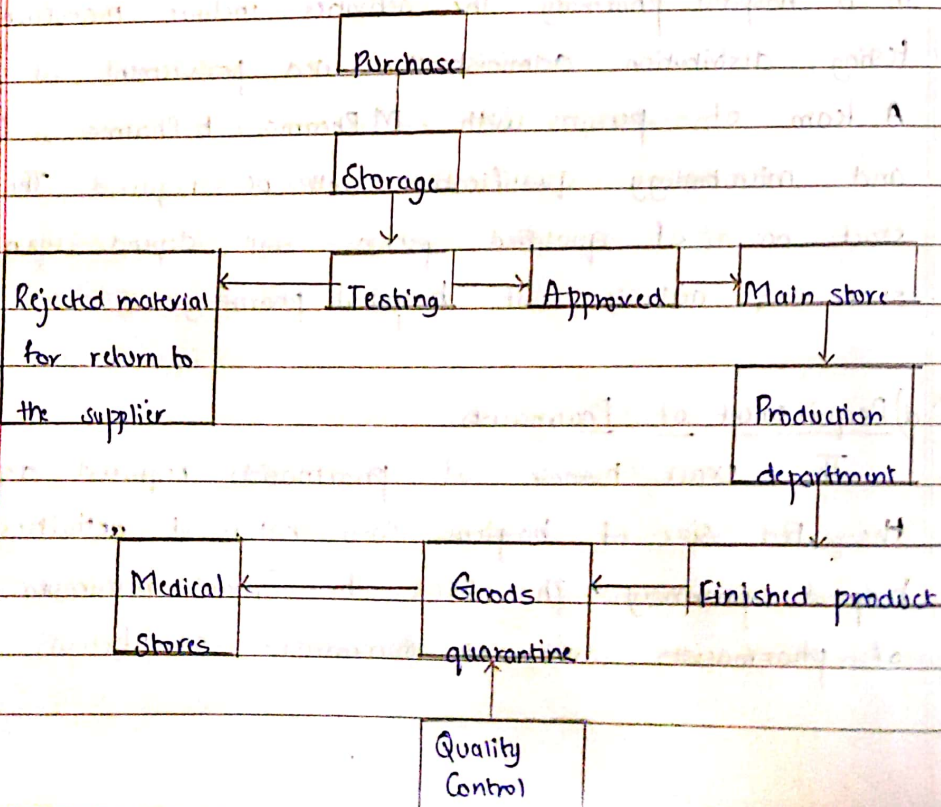
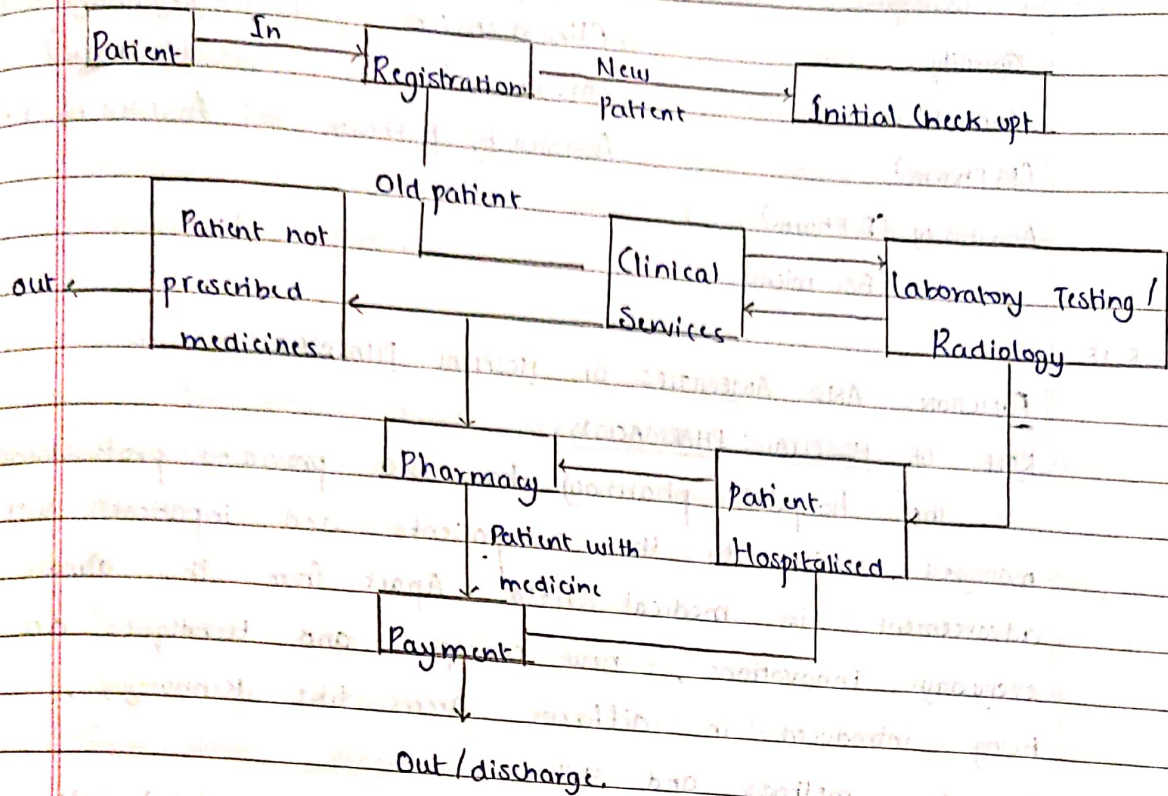
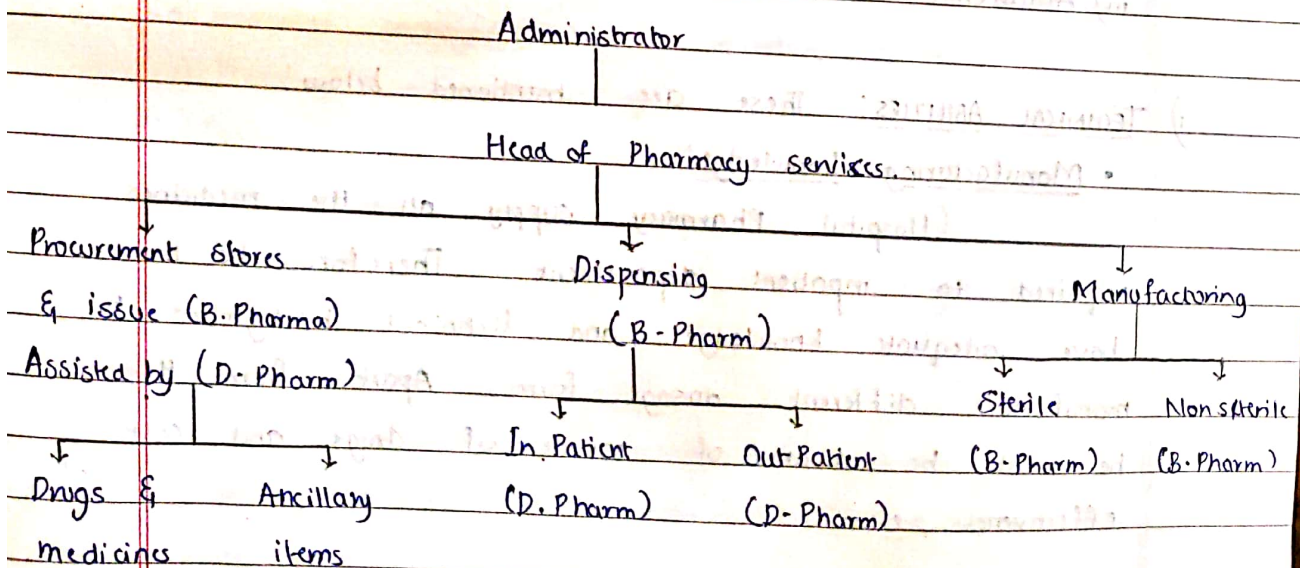


Chart 3 - Movement of Patient.



Organisation of Hospital Pharmacy.

A big Hospital pharmacy renders a number of services which include a number of activities and hence has a complex organisation with integrated setup comprising the following divisions.



↓
Quality
Control
(M. Pharm)
Assisted by (B. Pharm)
(Bsc. micro)

↓
Clinical services
(M. Pharm)
Assisted by B. Pharm

↓
Regulatory affairs
(B. Pharm)
Assisted by D. Pharm

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FUNCTIONS AND AMENITIES OF HOSPITAL PHARMASIST:

ROLE OF HOSPITAL PHARMACISTS:

The hospital pharmacy has been providing professionally managed services to the outpatients and inpatients with advancement in medical field. Apart from this almost everyday innovations, new concepts and techniques are being introduced in different areas like technology, research, methods and skills.

The hospital pharmacist performs a vital role in all these through different activities and to cope with the needs of time, he must possess the following abilities -

- i) Technical abilities
- ii) Administrative abilities
- iii) Academic abilities.

i) TECHNICAL ABILITIES: These are mentioned below;

• Manufacturing knowledge:

[Hospital Pharmacy supply all the medicines required to inpatient department. Therefore he must have adequate knowledge and technical background to manufacture different dosage forms] Apart from this he must be aware of source of drugs and cost effectiveness, etc.,

• Knowledge about quality control:

Testing of raw materials and finished product

is done by chemical, physical and analytical method. with the help of instruments like HPLC, HPTLC, auto titrator, pH meter and spectrophotometer etc.

For this purpose he must know the procedure, handling of instruments and reagents and chemicals required for testing.

• Research abilities:

He should have the ability to perform different pharmacological, toxicological experiments, pharmacokinetic and clinical trial studies on compounds under investigation. Apart from this basic studies he should work on the formulation aspects like stability studies, incompatibilities, drug-drug interactions and drug food interactions and formulation elegant studies.

ii) ADMINISTRATIVE ABILITIES:

The pharmacist should have administrative abilities because he plays an important role in hospital with many departments like medicine, surgery, nursing and patient for different purposes like drug manufacturing, distribution, storage, etc. Therefore he should know about

- a) Material management and inventory control
- b) Planning and accounting
- c) Communication skills.
- d) Patient counselling
- e) Knowledge about all related law's and legal regulations.

iii) ACADEMIC ABILITIES:

For professional approach and competence in hospital pharmacy services, the hospital pharmacist should have the following qualities -

a) Teaching ability:

He should be well versed with the basic pharmaceu-

-tical science, stabilisation, storage of drugs, dispensing aspects, medication errors etc... His ability should be better than his counterparts working in different hospitals. He should develop confidence in his subordinates about his knowledge.

b) Participation:

He is responsible for participation in workshops, seminars and related programmes and should be able to contribute towards educational activities of hospital.

c) Conduct of training activity:

He is also responsible for training the fellow pharmacist and nursing people. He should conduct educational programmes for new staffs and other professionals at hospitals.

d) Retrival of information:

He is a responsible person at DIC and should have ability to evaluate information.

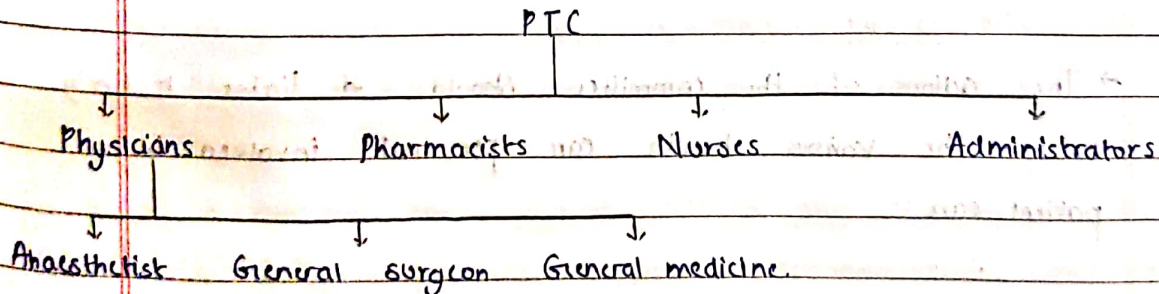
3. PHARMACY AND THERAPEUTICS COMMITTEE

INTRODUCTION:

The pharmacy and therapeutics committee is a tool for maintaining medical staff self govt. It is responsible to the medical staff as a whole and its recommendations are its subject to medical staff approval. The pharmacy and therapeutics committee is a mandatory committee and is composed of physicians, pharmacists and other health care professionals (nurses) selected with the guidance of medical staff.

COMPOSITION OF PTC:

The pharmacy and therapeutics committee is composed of minimum 3 physicians, 1 pharmacist and 1 nurse. The size of committee may vary depending on the scope of services provided by the organisation.



Among these physicians one will be elected as chairman and the pharmacist will act as secretary.

2M.%. PURPOSE OF PTC:

PTC works with 2 main objectives or purposes as below:

- i) Educational - PTC recommends to organise programmes, seminars or workshops to furnish the current development on matters regarding drugs and safe use.

ii) Advisory:- PTC emphasises on implementation of policies laid down for selection, evaluation and rational use of drug in a hospital.

AGENDA OF PTC / OPERATION OF PTC:

→ PTC should meet regularly atleast 6 times in a year and more often when necessary

→ The committee should invite persons within or outside the organisation who can contribute specialised or unique knowledge, skills and judgements

→ The secretary prepares an agenda and supplementary materials and submit to committee members in sufficient time before each meeting to review the material properly

→ The committee present recommendations to the medical staff or its appropriate committee for adoption or recommendation

→ The actions of the committee should liaise routinely with the various health care personnel involved in patient care.

→ The committee should organise and operate in a manner that ensures the objectivity and credibility of its recommendations.
↓
Impartial / unbiased. quality of being trusted

FUNCTIONS AND SCOPE:

→ The basic organisation of health care setting and its medical staff may influence the specific functions and scope of the PTC committee

i) To serve in an educational, evaluative and advisory capacity to the medical staff and organisational administration in

all matters pertaining to the use of drugs.

ii) To develop a formulary of drugs accepted for use in the organisation and provide for its constant revision. The selection of items to be included in the formulary is on objective evaluation of their relative therapeutic merits, safety and cost.

iii) To establish programmes and procedures that help ensure safe and effective drug therapy.

iv) To establish programmes and procedures that ensure cost effective drug therapy.

v) To establish or plan suitable educational programmes for the organisation, professional staff on matters related to drug use.

vi) To participate in quality assurance activities related to distribution, administration and use of medications.

vii) To monitor and evaluate adverse drug reactions in health care settings to make appropriate recommendations to prevent their occurrence.

viii) To initiate or direct drug use evaluation programmes and studies, review the results of such activities and make appropriate recommendations to optimize drug use.

ix) To advise the pharmacy department in the implementation of effective drug distribution and control procedures.

x) To disseminate information on its actions and approved recommendations to all organisational health care staff.

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HOSPITAL FORMULARYDEFINITION:

The hospital formulary is a list of pharmaceutical preparations including important information which reflects the current clinical views of the medical staff.

The hospital formulary system is a ^{method} made by the medical staff of a hospital evaluates and selects from among numerous available drugs and dosage forms that are considered most useful in the patient care.

The selection is made on the basis of its toxicity, untoward reactions, quality, efficacy and bioequivalence.

The hospital formulary system assist in procuring, prescribing, dispensing and administering a drug under their non-proprietary or proprietary names where drugs have both name. The main responsibility of making a formulary is of pharmacy and therapeutics committee. But pharmacist is an important member of this committee. The committee takes decision about inclusion of certain drugs.

10 M. X. GUIDING PRINCIPLES:

Following principles may serve as a guide to physicians, pharmacist, and administrators in hospitals for their professional judgement.

i) The hospital formulary system shall not contain any policies or procedures which before the time of prescribing provide the consent by the physician to the dispensing of non-proprietary drug or to the dispensing of a proprietary brand different from the brand which he has prescribed.

ii) A medical staff shall adopt the policy of including the drugs by non-proprietary names.

- iii) The options of written policies approved by the medical staff, the pharmacist shall dispense the brands prescribed.
- iv) The hospital shall make ^{certain} that the nursing personnel must be informed in writing about the hospital formulary system.
- v) The Formulation of policies and procedures the term substitute or substitution should be avoided.
- vi) If there is any change in hospital system it must be informed to the medical staff.
- vii) The pharmacist with the advise and guidance of PTC shall make arrangements for all the drugs, chemicals, biologicals and pharmaceutical preparations for diagnosis and treatment of patients.
- viii) The labelling of medicine with non-proprietary names should always be done in a proper manner. The format for non-proprietary drug is as follows:
- a) Name of a drug
 - b) Name of the manufacturer or distributor
 - c) Prescription or order by the proprietary name
 - b) Dispensing is done according to the formulary policy.
- ix) To develop an effective formulary system PTC has to consult various references on a drug regarding its PK profile, drug-food interactions and poisoning information.
- x) While discussing the particular proprietary name, physicians interest must be based upon its pharmacological activity, safety and efficacy of the drug.

10M. X. CONTENTS OF HOSPITAL FORMULARY:

The objective of a formulary is not only to control the use of drugs but also to supply useful information to the prescribers.

Prescription should be written neatly and clearly with relevant information like: i) name, age, sex of the patient

ii) Date

iii) Address of patient

iv) Name of the drugs as mentioned in the formulary

v) Direction for the patient in clear terms

vi) For repeat prescription with clear instructions for the pharmacist to avoid dispensing errors.

vii) Prescriptions containing narcotic and psychotropic preparations must be signed by the prescriber and should be prepared in triplicate out of which one copy is retained by the physician and the rest two copies are given to the patient.

The contents of hospital formulary is divided into 3 parts:

i) Information on drug products

ii) Information of hospital policies

iii) Special information.

i) INFORMATION OF HOSPITAL POLICIES:

This section is the heart of formulary and consist of descriptive entry for each item to facilitate its use.

a) Entries in formulary:

→ Generic name of basic drug

→ Common names

→ Dosage forms, strength, packaging

- Formulation. (Name of the active ingredient, formulation of the product)
- Adult or paediatric dose
- Route of administration
- Cost.

Entry of a drug into the formulary is a complex matter. Clinical experts from various departments are invited for their valuable comments upon specialised drugs. Selected drugs may be official in IP, BP, USP or NF etc... Any preparation whose formula is not disclosed ^{does} ~~does not~~ qualify for its entry into the formulary.

b) Indexes to the drug product listing:

There are two ways of making indexes which can be included at the beginning or the end of section to facilitate the use of formulary

i) Generic name / Brand name:

Proper page number should be given for reference of a particular product.

ii) Therapeutic or pharmacological index:

This index is according to the therapeutic category. Ex:- Antihistaminic drugs and anti-infective drugs etc...

ii) INFORMATION ON HOSPITAL POLICIES:

→ Various policies and procedures are framed for drug usage and restrictions on drug use.

→ Brief discussion of PTC including its membership responsibilities, etc...

→ Information on hospital regulations governing the prescribing

dispensing, administration of drugs, generic names, drug orders, investigational drug policies, rules to be followed by medical representatives, emergency drug products, etc...

→ Operating procedures such as hours of services, out-patient prescription policies, prescription labelling, inpatient drug distribution and patient education programmes.

→ Information on using the Formulary including how the formulary and entries are arranged, procedure for entry of a drug should be included in the system.

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iii) SPECIAL INFORMATION:

The material to be included in this section vary from hospital to hospital but it should be helpful to the hospital staff and should be readily available. It includes

- a) Nutritional products list.
- b) Equivalent dose of similar drug.
- c) List of hospital approved abbreviations.
- d) Guidelines for calculating paediatric dosage.
- e) List of sugar free drug products.
- f) No. of items available for emergency boxes.
- g) Metric conversions and tables.
- h) Tables of drug interaction.
- i) Poison control distribution.

Although the monograph of each drug is decided by PTC but it should include its generic name, formula, action, dosage regimen, side effects, precautions and contraindications.

Qm. X. PREPARATION OF FORMULATION HOSPITAL FORMULARY:

Formularies are the essential part of Hospital

Pharmacy. It has been a focal point for improving drug therapy in hospitals. Effectiveness of formulary system depends on the abilities of the pharmacist involved with it. Although a majority of pharmacy personnel may not involve in pharmacy and therapeutics committee. Its a well planned system, provides both structure and flexibility regarding the selection of drug usage. These special features allow for standardisation to reduce errors, wastage and require personnel time. The traditional benefit of preparing the formulary system is to provide generic products lists. Formularies must include cost to provide relative cost data for similar drug products that are not generically equivalent.

The initial step in the preparation of a formulary for any hospital is its size. Although the physical appearance and structure of the formulary play an important influence on its use but elaborate and expensive art work in a formulary is of no use. as it is meant for professional use. So it should be usually pleasing, easily readable with proper grammar, correct spelling and with neat designing.

A typical formulary will have the composition in the following manner:

i) Title page

ii) Names and titles of the members of pharmacy and therapeutics committee.

iii) Table of contents.

iv) Information on hospital policies and procedures concerning drugs:

- The pharmacy and therapeutics committee of hospital.

- Objectives and operation of the formulary systems.

- Hospital regulations & procedures for prescribing & dispensing drugs.

- Hospital pharmacy services & procedures

- How to use a formulary

- v) Product accepted for use in hospital.
- Items added & deleted from the previous edition.
 - Generic, brand name, cross reference list
 - Pharmacological or therapeutic index with relative cost codes.
 - Description of formulary, drug products by pharmacology therapeutic class
- Appendix.

Appendix:

- vi) Central service equipment
- Guidelines for calculating paediatric doses
 - Schedule for standard drug administration.

2M X: Distribution of the Formulary:

Copies of the formulary should be placed at each patient care unit including clinics, out patient care areas and emergency room. Each pharmacist should receive a copy. Heads of department & nursing department should receive a copy of it. Necessary steps should be taken to ensure nursing and the medical staff are familiar with the contents of formulary and should know how it is to be used properly.

REVISION OF FORMULARY:

Entry of a new drug into the formulary is a complex procedure, the members of PTC alone cannot take a decision on hospital formulary system. Only selected drugs are included in the formulary and any preparation whose formula is not disclosed cannot be entered in the formulary. Generally the formulary needs to be revised annually because, addition, deletion changes in the products, removal of drugs from the market, changes in the hospital policies necessitates periodic revision of the formulary. One method is to

attach a formulary supplement sheets to the back covers of formulary books and second method is by using a different color for the cover of each edition of the formulary which will help to reduce any confusion between current & past edition.

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DEVELOPEMENT OF THERAPEUTIC GUIDELINES

INTRODUCTION:

Rapid advances in clinical science and technology and the complexity of therapeutic regimens have made it difficult for health care practitioners to provide high quality care to patients. Guidelines are designed to help practitioners assimilate, evaluate and implement evidence based medicine based on personal or organisational preferences regarding various risks and benefits.

Clinical practice guidelines are recommendations developed by health care providers to serve as a guide for diagnosis, evaluation and/or the treatment of specific disease. Therapeutic guidelines are clinical practice guidelines that focus on treatment recommendations.

Published and unpublished guidelines can be found in a number of sources such as medical data bases (for ex: Medline, embase), pharmaceutical industry sponsored websites for ex: Pfizer are non-profit organisation websites (such as American Heart Association). However it is important to note that the guidelines and medical information provided on ~~med~~ many of these sites is often in abbreviated or summarised form and may not accurately reflect the intended purpose of the guidelines. Internet sites of US government organisations such as centers for disease control and prevention and the national institutes of health often include certain versions of guidelines. These guidelines are generally free and are often the most comprehensive resource for clinical practice guidelines. Organisations such as the American Medical Association (AMA), American college of Cardiology (ACC) and the american college of Clinical pharmacy also offered clinical practice guidelines. However these are often available only to active members.

limiting accessibility to many clinicians. Finally many institutions publish their own guidelines for the treatment of specific disease states. These guidelines serve as the basis of treatment for clinicians throughout the institution and are often provided to practitioners as a handbook or as a link on the institutions website.

NEED FOR THE GUIDELINES:

Guidelines supported by professional organisations are commonly used by the practitioners to guide treatment and patient monitoring. They allow practitioners to assess the efficacy and effectiveness of therapy. They assist practitioners in establishing monitoring parameters to assess the health status and quality of life.

In developed countries guidelines decrease cost of therapy. Lastly guidelines are necessary to increase consistency of recommendations and treatment by practitioners. It enables practitioners to focus on established therapies and availability of services.

EXAMPLES OF GUIDELINES:

The seventh report of the Joint National Committee (JNC) on prevention, detection, evaluation and treatment of high blood pressure (JNC 7) was developed by an executive committee, multi disciplinary health care team representing the fields of medicine, nursing, nutrition, pharmacy, public health and staff at the national heart, lung and blood institute. Since the inception of JNC-7 awareness and control of HTN has improved and the incidence of secondary diseases such as end stage renal disease and coronary heart disease has also decreased.

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Selection' Considerations for individualisation of antihypertensive drug therapy based on the JNC-7 guidelines

<u>INDICATION</u>	<u>INITIAL THERAPY:</u>
1) Diabetes Mellitus Type 1 with proteinuria.	Thiazides, β -blockers, ACE inhibitors, ARBs, Aldosterone antagonists
2) Heart failure	Thiazides, β -blockers, ACE inhibitors, ARBs, CCBs.
3) Chronic kidney disease	ACE inhibitors, ARBs.
4) Myocardial infarctions	β -blockers (without intrinsic sympathomimetic activity), ACE inhibitors (with systolic dysfunction), Aldosterone antagonists

Ex-1: In JNC-7 guidelines patient specific and general guidelines for the pharmacologic and non-pharmacologic management of HTN are provided and information pertaining to a variety of populations such as children, adolescents, the elderly, those with co-existing conditions. is also addressed.

Ex-2: The third report of national cholesterol education program (NCEP) - detection, evaluation and treatment of high blood cholesterol in adults was developed by a multi-disciplinary panel composed of faculty in medicine, nursing, nutrition, pharmacy and public health with assistance of many organisations such as American Diabetic Association, agency for health care research and quality and the American red cross. The publication provides evidence based guidelines for the detection, primary target, prevention and treatment of ~~cho~~ hypercholesterolemia.

<u>Risk</u>	<u>LDL</u>
i) CHD (Coronary Heart D)	$< 100 \text{ mg/dl}$
ii) More than 2 risk factors	$< 130 \text{ mg/dl}$
iii) 0-1 risk	$< 160 \text{ mg/dl}$

Ex: 3 - Guidelines for the diagnosis and management of asthma provided by the expert panel from the national asthma education and prevention program (NAEPP) have served as the basis for the treatment of 22 million children and adults with asthma. Since the first NAEPP guidelines published in 1991 important gains have been made in reducing both morbidity and mortality due to asthma.

DEVELOPMENT OF GUIDELINES: (Steps in guideline development)

Based on the literature there are 9 separate steps/stages that should be considered in the development and implementation of clinical practice guidelines.

- i) Identify group members for guideline development.
- ii) Identify and refine the problem, focusing on the disease and published literature.
- iii) Review the literature, organisational recommendations and internet resources to determine the present standard of care.
- iv) Obtain opinions from experts in the field.
- v) Begin the information feed back process.
- vi) Co-ordinate resources to avoid duplication of resources and time.

vii) Assess the quality, relevance, variability and strength of the information.

viii) Synthesise the information.

ix) Summarise and disseminate the information focusing on measurable outcomes

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I Identify group members for guideline development:

→ It is always advisable to have a multi-disciplinary group as individual biases may be better balanced by such groups. and they may produce more valid guidelines.

The ideal number of people involved in such a group is at least 6 but not more than 12-15.

Too few members limits adequate discussion and too many makes effective functioning of the team difficult.

→ The choice of medical specialists in the development group depends on the drug or disease being targeted. But it is always advisable to have three broad classes of relevant health care professionals, specialists and a specialist in guideline methodology and in leading small groups.

→ The group members in the development of guidelines should have sufficient skill in the following areas:-

i) literature searching and retrieval

ii) Epidemiology.

iii) Biostatistics

iv) Health services

v) Research

vi) Writing and editing

ii. Identify and define the problem focusing on the Disease and published literature:

→ Guidelines can be developed for a wide range of subjects, given the large number of potential areas, priority subjects or topics for guideline development need to be determined. Potential area can be identified based on the main cause of morbidity and mortality for a given population. Uncertainty about the appropriateness of drug therapy or about the evidence for improving the patient outcomes or the need to conserve resources in providing care.

→ After the topic identified it has to be refined before the evidence can be assessed in order to answer exact questions. The usual way of refining a topic is by having a dialogue among the potential users or evaluators of guideline. Therefore the group that is responsible for guideline development should be clear about which areas come within the scope of the topic and which do not to avoid broadening the scope.

iii. Review the literature, organisational recommendations and internet resources to determine the present standard of care:

→ Identification and assessment of the evidence is best done by performing a systematic review.

→ Identifying the clinical question of interest will help set the boundaries for admissible evidence (types of study designs, yr of publication...). For Eg: Questions concerning the efficacy of interventions usually mean that randomised controlled trial should be sort

→ Methods of identifying and synthesising evidence include expert opinion, unsystematic literature survey.

→ The first step in gathering the evidence is to check if a suitable, recent systematic review has already been published. If a current systematic review is not available, a computer search of medline, IOWA drug information service may be a starting point.

→ Checking references in articles will show additional relevant articles not identified by the computer search & having experts in the field examine list of articles helps ensure there are no obvious omissions.

→ Additional search strategies including searches for articles published in languages other than English, Computer searches of specialised databases, manual searching of relevant journals.

→ To ensure validity and reliability, the guidelines should be based on high quality research studies. These should be identified during a comprehensive literature review conducted within the recent pasts. This may 12 months for areas where the evidence has rapidly changed but longer periods of time, say 24-36 months may be acceptable where new evidence is produced more slowly.

ii) Obtain opinion from experts in the field:

→ The opinions of experts should be used to interpret evidence & to derive recommendations in the absence of evidence. When evidence is being interpreted opinion is needed to assess issues such as generalisability of evidence or to extrapolate results from a study in one population to population of interest in the guideline. Recommendations based solely on clinical judgement and experience are likely to be more susceptible to bias.

and self interest. Therefore after deciding what role expert opinion is to play, the next step is to decide how to collect and assess expert opinion.

v. Begin the information feedback process:

→ Information feedback refers to the provision of healthy data information which may allow clinicians to compare their own practice with that of their colleagues or other hospitals. Feed back is most likely to influence the clinical practice of those who have already agreed to review their practice and is most effective if it is accompanied by a standard setting exercise or discussion and presented to clinicians soon after the clinical decision making process. Feed back is judged a clinical success if practice moves closer to what is believed to be the std. of care.

vi. Co-ordinate resources to avoid ~~prohibit~~ duplication of resources and time:

In addition to scientific evidence on the opinions of expert clinicians, practice guidelines must often take account of the resource implications and feasibility of interventions. Judgements about whether the cost of test or treatments are reasonable depend on how cost effectiveness is defined and calculated. Feasibility issues worth considering include the time, skills, staff and equipment necessary for the provider to carry out the recommendations and the ability of patients and systems of care to implement them.

vii. Assess the quality, relevance, variability and strength of the information:

→ Summarised evidence is categorised to reflect its susceptibility to bias. This is a method of conveying

a specific aspects of evidence to a 'reader' of the guideline. A no. of search, ~~st~~ strength of evidence, classification schemes exist but empirical evidence exist only for schemes that categorise effectiveness studies by study design. In addition each recommendation should be linked to a specific reference. So readers can track the evidence back to its source.

Viii Synthesise the information:

Synthesis of study results is a most subjective area of guideline development and impacts on the presentation, acceptability and dissemination of results. Many methods have been used to establish clinical practice guidelines. In meta analysis, guidelines and recommendations were based on statistically significant references found when patient information pooled primarily from published data.

Another option is the presentation and categorisation of results. This allows for presentation of all available data without overestimating the significance of these results.

ix Summarise and disseminate the information focusing on measurable outcomes:

Guidelines can be presented as the full version, summary sheets of all or part of it, reminder-sheets in patient records. Algorithmic styles of presenting the guideline are often perceived by the physicians to be too complex and lacking in flexibility.

Kahan At-al analysed the content of 24 consensus statements by the N^IH and suggested that variations in style may affect their acceptance by physicians. - Subsequently the N^IH encouraged consensus development conferences to produce guidelines which were

concentrated in making specific recommendations and divide the patients into subclasses.

This plan, "do study at" cycle necessary to determine the effect of practice guidelines and to close the gap between practice and treatment.