17BECC604 HEALTHCARE & HOSPITAL MANAGEMENT 3 0 0 2 100

OBJECTIVE

- The purpose of this course is to introduce the students to the field of hospital and equipment management.

INTENDED OUTCOMES

- Understand hospital organization and management.
- Understand equipment management in hospitals.

UNIT I HEALTH SYSTEM (9)

Health organisation of the country, the state, the cities and the region, Health Financing System, Organisation of Technical Section.

UNIT II HOSPITAL ORGANISATION AND MANAGEMENT (9)

Management of Hospital organisation, Nursing section Medical Sector, Central Services, Technical Department, Definition and Practice of Management by Objective, Transactional Analysis Human relation in Hospital, Importance to Team Work, Legal aspect in Hospital Management.

UNIT III REGULATORY REQUIREMENT AND HEAITHCARE CODES (9)

FDA Regulation, joint commission of Accreditation for Hospitals, National Fire Protection Association Standard, IRPC.

UNIT IV EQUIPMENTMAINTENANCEMANAGEMENT (9)

Organising Maintenance Operations, Paper Work Control, Maintenance Job, Planning Maintenance Work Measurement and Standards, Preventive Maintenance, Maintenance Budgeting and Forecasting, Maintenance Training, Contract Mainframe.

UNIT V TRAINEDTECHNICAL PERSONNEL (9)

Function of Clinical Engineer, Role to be performed in Hospital, Manpower Market, Professional Registration, and Structure in hospital.

Total : 45

REFERENCE BOOKS

S.NO.	Author(s) Name	Title of the book	Publisher	Year of publication
1	Cesar A.Caceres and Albert Zara	The practice of Clinical Engineering	Academic Press	1977
2	Webster, J.G. and Albert M.Cook	Clinical Engineering Principles and Practices	Prentice Hall Inc. Englewood Cliffs	1979
3	Antony Kelly	Maintenance planning and control	Butterworths London	1984
4	Hans P feiff,Vera Dammann(Ed.)	Hospital Engineering in Developing Countries	Zreport Eschborn	1986

5	Jacob Kline	Handbook of Bio Medical Engineering	Academic Press, SanDiego	1988
6	R.C.Goyal	Handbook of Hospital Personal Management	Prentice Hall of India	1993

KARPAGAM ACADEMY OF HIGHER EDUCATION
COIMBATORE-21
Faculty of Engineering
Department of Biomedical Engineering

LECTURE PLAN

Name of the staff : **M.Bhuvaneswari**
Designation : **Assistant Professor.**
Class : **III -B.E BME**
Subject : **HEALTHCARE AND HOSPITAL MANAGEMENT**
Subject code : **17BEBME604**

Sl.No.	Topics to be covered	Time Duration	Teaching aids
	INTRODUCTION		
1	Introduction to Virtual Instrumentation	1	
	UNIT-I HEALTH SYSTEM		
2	Health organisation of the country	02	T1 4-7
3	Health organisation of the state, the cities and the region	02	R4 5
4	Health Financing System	02	W2
5	Organisation of Technical Section	02	T1 38-42
	UNIT-II HOSPITAL ORGANISATION AND MANAGEMENT		
11	Management of Hospital organisation	02	W1
12	Nursing section Medical Sector	01	T113,14
13	Central Services, Technical Department	02	T1 114-124
14	Definition and Practice of Management by Objective	01	T1 506,556&563
15	Transactional Analysis Human relation in Hospital	01	T1 432
16	Importance to Team Work	01	T1 61-62,w2
17	Legal aspect in Hospital Management.	01	W1
	UNIT-III REGULATORY REQUIREMENT AND HEAITHCARE CODES		
20	FDA Regulation	02	T1 309-315
21	Joint commission of Accreditation for Hospitals	02	T1 297-298
22	National Fire Protection Association Standard	03	T1 137-149
23	IRPC	02	
	UNIT-IV EQUIPMENTMAINTENANCEMANAGEMENT		
29	Organising Maintenance Operations	01	W1
30	Paper Work Control, Maintenance Job	02	R4 26
31	Planning Maintenance Work Measurement and Standards	01	R4 32-34
32	Preventive Maintenance	02	W1
33	Maintenance Budgeting and Forecasting	01	W2
34	Maintenance Training	02	T1 344-350
35	Contract Mainframe	01	T1 572
	UNIT-V TRAINED TECHNICAL PERSONNEL		
38	Function of Clinical Engineer	02	T1 281
39	Role to be performed in Hospital	02	W1
40	Manpower Market	01	T1 306
41	Professional Registration	02	T1 344-350
42	Structure in hospital.	02	T1 536, W1

Website:

W1- http://www.healthcarebusinesstech.com/hospital-management/
W2- https://www.who.int/hospitals/management-and-quality/en/
W3-https://www.intechopen.com/books/applied-biomedical-engineering/clinical-engineering
W4- https://www.sciencedirect.com/book/9780128134672/clinical-engineering-handbook

TEXT BOOK

Sl.No.	Author(s)	Title of the Book	Publisher	Year of Publication
1	Cesar A.Caceres and Albert Zara	The practice of Clinical Engineering	Academic Press	1977
2	Webster, J.G. and Albert M.Cook	Clinical Engineering Principles and Practices	Prentice Hall Inc. Englewood Cliffs	1979

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Staff In-Charge **HOD/ECE**

HEALTHCARE AND HOSPITAL MANAGEMENT
UNIT I

Organization of healthcare in India

The Health Care Services Organization in the country extends from the national level to village level.

Central level

The organization at the national level consists of the Union Ministry of Health and Family Welfare. The Ministry has three departments, viz. - Department of Health & Family Welfare, Department of Ayurveda, Yoga-Naturopathy, Unani, Sidha & Homeopathy (AYUSH) and Department of Health Research. Each of these departments is headed by respective secretaries to Govt of India. The department of Health & Family Welfare is supported by a technical wing, the Directorate General of Health Services, headed by Director General of Health Services (DGHS).

State level

The organization at State level is under the State Department of Health and Family Welfare in each State headed by Minister and with a Secretariat under the charge of Secretary/Commissioner (Health and Family Welfare). The State Directorate of Health Services, as the technical wing, is an attached office of the State Department of Health and Family Welfare and is headed by a Director of Health Services. The area of medical education which is with the Directorate of Health Services at the State, is known as Directorate of Medical Education and Research. This Directorate is under the charge of Director of Medical Education, who is answerable directly to the Health Secretary/ Commissioner of the State. Some states have created the posts of Director (Ayurveda) and Director (Homeopathy). These officers enjoy a larger autonomy, although sometimes they still fall under the Directorate of Health Services of the State.

Regional level

In some states like Bihar, Madhya Pradesh, Uttar Pradesh, Andhra Pradesh, Karnataka and others, zonal or regional or divisional set-ups have been created between the State Directorate of Health Services and District Health Administration. Each regional/zonal set-up covers three to five districts and acts under authority delegated by the State Directorate of Health Services.

District level

All health care programmes in a district are placed under a unified control. It is a link between the State/ regional structure on one side and the peripheral level structures such as PHC/ sub-centre on the other side. The district officer with the overall control is designated as the Chief Medical and Health Officer (CM & HO) or as the District Medical and Health Officer (DM & HO). These officers are popularly known as DMOs or CMOs, and are overall in-charge of the health and family welfare programmes in the district. These DMOs/CMOs are assisted by Dy. CMOs and programme officers.Community level

For a successful primary health care programme, effective referral support is to be provided. For this purpose one Community Health Centre (CHC) has been established for every 80, 000 to 1, 20, 000 population, and this centre provides the basic specialty services in general medicine, pediatrics, surgery, obstetrics and gynecology.

Community Health Centres (CHCs)

CHCs are being established and maintained by the State Government. It is manned by four medical specialists i.e. Surgeon, Physician, Gynecologist and Pediatrician supported by 21 paramedical and other staff. It has 30 in-door beds with one OT, Xray, Labour Room and Laboratory facilities. It serves as a referral centre for 4 PHCs and also provides facilities for obstetric care and specialist consultations. As on March, 2007, there are 4, 045 CHCs functioning in the country. The present staffing pattern of CHCs is as in Box - 1.

Box - 1 : Staffing Community Health Centre

S. No	Staff For Community Health Centre	Existing	IPHS proposed
1	Medical Officer#	4	7
2	Nurse Mid-Wife (staff Nurse)	7	9
3	Dresser	1	1
4	Pharmacist/Compounder	1	1
5	Laboratory Technician	1	1
6	Radiographer	1	1

7	Ward Boys	2	2
8	Dhobi	1	-
9	Sweepers	3	3
10	Mali	1	-
11	Chowkidar	1	
12	Aya	1	-
13	Peon	1	-
14	OPD Attendant		5*
15	Stat Asst. / Data Entry Operator		
16	OT attendant		
17	Registration clerk		
18	Ophthalmic Asst.		1
	Total :	25	31
# : Surgeon, Obstetrician, Physician, Pediatrician, Anaesthetist, Public health programme manager, Eye surgeon.			
* Sr No. 11, and 14 - 17 - total 5, flexibility rests with State for recruitment as per need			

Primary Health Centre (PHC)

PHCs are the cornerstone of rural health services- a first port of call to a qualified doctor of the public sector in rural areas for the sick and those who directly report or referred from Sub-centres for curative, preventive and promotive health care. The Bhore Committee in 1946 gave the concept of a PHC as a basic health unit to provide as close to the people as possible, an integrated curative and preventive health care to the rural population with emphasis on preventive and promotive aspects of health care. The health planners in India have visualized the PHC and its Sub-Centres (SCs) as the proper infrastructure to provide health services to the rural population. The central Council of Health at its first meeting held in January 1953 had recommended the establishment of PHCs in Community Development Blocks. These centres were functioning as peripheral health service institutions with little or no community involvement. They were not able to provide adequate health coverage, partly, because they were poorly staffed and equipped and lacked basic amenities. The 6th Five year Plan (1983-88) proposed reorganization of PHCs on the basis of one PHC for every 30,000 rural population in the plains and one PHC for every 20,000 population in hilly, tribal and backward areas for more effective coverage.

PHC is the first contact point between village community and the Medical Officer. The PHCs were envisaged to provide an integrated curative and preventive health care to the rural population with emphasis on curative, preventive, Family Welfare Services and promotive aspects of health care. One Primary Health Centre covers about 30,000 (20,000 in hilly, desert and difficult terrains) or more population. Many rural dispensaries have been upgraded to create these PHCs. At present, a PHC is manned by a Medical Officer supported by 14 paramedical and other staff. It acts as a referral unit for 6 sub-centres and refer out cases to Community Health Centres (CHCs-30 bedded hospital)/sub-district/district hospitals. It has 4-6 indoor beds for patients. There are 22, 370 PHCs functioning as on March 2007 in the country. The staffing pattern of new primary health centre is shown in Box - 2.

Box - 2 : Staffing Primary Health Centre			
S. No.	**Staff for New Primary Health Centre**	**Existing**	**IPHS proposed**
1.	Medical Officer	1	2
2.	Pharmacist	1	1
3.	Nurse Mid-wife (Staff Nurse)	1	3
4.	Health Worker (Female)/ANM	1	1
5.	Health Educator	1	1

6.	Health Assistant (Male)	1	1
7.	Health Assistant Female)/ LHV	1	1
8.	Upper Division Clerk	1	1
9.	Lower Division Clerk	1	1
10.	Laboratory Technician	1	1
11.	Driver (Subject to availability of Vehicle)	1	*
12.	Class IV	4	4
	Total	**15**	**17/18**
*Optional / vehicle may be outsourced			

Sub-Centre

The Sub-Centre is the most peripheral and first contact point between the primary health care system and the community. Sub-Centres are assigned tasks relating to interpersonal communication in order to bring about behavioral change and provide services in relation to maternal and child health, family welfare, nutrition, immunization, diarrhoea control and control of communicable diseases programmes. The Sub-Centres are provided with basic drugs for minor ailments needed for taking care of essential health needs of men, women and children. There are 1,45,272 Sub Centres functioning in the country as on March 2007. Currently a Sub-centre is staffed by one Female Health Worker commonly known as Auxiliary Nurse Midwife (ANM) and one Male Health Worker commonly known as Multi Purpose Worker (Male). One Health Assistant (Female) commonly known as Lady Health Visitor (LHV) and one Health Assistant (Male) located at the PHC level are entrusted with the task of supervision of all the Sub-centres (generally six subcentres) under a PHC. The Ministry of Health & FW, GOI provides assistance to all the Sub-centres in the country since April 2002 in the form of salary of ANMs and LHVs, rent (if located in a rented building) and contingency, in addition to drugs and equipment kits. The salary of Male Health Worker is borne by the State Governments. The staffing pattern of sub- centre is depicted in Box - 3.

Box - 3 : Staffing Sub centre			
S. No	**Staff For Sub-Centre**	**Existing**	**IPHS proposed**
1.	Health Worker(Female)/ANM	1	2
2.	Health Worker (Male)	1	1
3.	Voluntary Worker (optional on honorarium)	1	1
	Total	**2/3**	**3/4**

The shortfall in the rural health infrastructure, based on 2001 population census, has been depicted in Box - 4.

Box - 4 : Shortfall in Rural Health Infrastructure All India				
As per 2001 Population	**Required**	**Existing (as on 31 Mar 2007)**	**Shortfall**	**% Shortfall**
Sub-Centres	158792	145272	20855	13. 13
PHCs	26022	22370	4833	18. 57
CHCs	6491	4045	2525	38. 90
Note : All India shortfall is derived by adding state-wise figures of shortfall ignoring the existing surplus in some of				

the states.
Source : Bulletin of Rural Health Statistics in India, MOHFW (GOI), 2007.

Indian Public Health Standards (IPHS)

The overall objective of IPHS is to provide health care that is quality oriented and sensitive to the needs of the community. In order to provide optimal level of quality health care, a set of standards are being recommended for Community Health Centre /Primary Health Centre/sub centre. The IPHS for Primary Health Centres has been prepared keeping in view the resources available with respect to functional requirement for Primary Health Centre with minimum standards such as building manpower, instruments, and equipments, drugs and other facilities etc. These standards would help monitor and improve the functioning of the PHCs. The objectives of IPHS for PHCs are :

i. To provide comprehensive primary health care to the community through the Primary Health Centres.
ii. To achieve and maintain an acceptable standard of quality of care.
iii. To make the services more responsive and sensitive to the needs of the community.

Minimum Requirements at the Primary Health Centre for meeting the IPHS :

1. Medical care :

(a) **OPD services** : 4 hours in the morning and 2 hours in the afternoon / evening. Minimum OPD attendance should be 40 patients per doctor per day.

(b) **24 hours emergency services**: Appropriate management of injuries and accident, First Aid, Dog bite/snake bite/scorpion bite cases, and other emergency conditions

(c) **Referral services**

(d) **In-patient services (6beds)**

2. Maternal and Child Health Care including family planning:

a) **Antenatal care** : Early registration of all pregnancies and minimum 3 antenatal checkups with minimum laboratory investigations.

b) **Intra-natal care** : (24-hour delivery services both normal and assisted) Promotion of institutional deliveries, appropriate and prompt referral for cases needing specialist care.

c) **Postnatal Care** : Two postpartum home visits, first within 48 hours of delivery, 2nd within 7 days through Sub-centre staff, essential new born care, provision of facilities under Janani Suraksha Yojana (JSY).

d) **New Born care**

e) **Care of the child**: Emergency care of sick children including Integrated Management of Neonatal and Childhood Illness (IMNCI), full Immunization of all infants and children against vaccine preventable diseases, Vitamin A prophylaxis to the children.

f) **Family Planning** : Education, Motivation and counseling towards family planning, Provision of contraceptives.

3. Medical Termination of Pregnancies using Manual Vacuum Aspiration (MVA) technique. (wherever trained personnel and facility exists)

4. Management of Reproductive Tract Infections / Sexually Transmitted Infections

5. Nutrition Services (coordinated with ICDS)

6. School Health : Regular check ups, appropriate treatment including deworming, referral and follow-ups.

7. Adolescent Health Care : Life style education, counseling, treatment.

8. Promotion of Safe Drinking Water and Basic Sanitation

9. Prevention and control of locally endemic diseases like malaria, Kalaazar, Japanese Encephalitis, etc.

10. Disease Surveillance and Control of Epidemics : Disinfection of water sources and Promotion of sanitation.

11. Collection and reporting of vital events

12. Education about health / Behaviour Change Communication (BCC)

13. National Health Programmes including Reproductive and Child Health Programme (RCH), HIV/AIDS control programme, Non communicable disease control programme, Revised National Tuberculosis Control Programme (RNTCP)

14. Referral Services : Appropriate and prompt referral of cases needing specialist care.

15. Training : Training of Health workers and traditional birth attendants; Initial and periodic training of paramedics in treatment of minor ailments; Training of ASHAs. Periodic training of Doctors through Continuing Medical Education, Training of ANM and LHV in antenatal care and skilled birth attendance.

16. Basic Laboratory Services : Essential Laboratory services

17. Monitoring and Supervision : Monitoring and supervision of activities of sub-centre.
18. AYUSH services as per local people's preference : (Mainstreaming of AYUSH).
19. Rehabilitation : Disability prevention, early detection, intervention and referral.
20. Selected Surgical Procedures : The vasectomy, tubectomy (including laparoscopic tubectomy), MTP, hydrocelectomy and cataract surgeries as a camp/fixed day approach have to be carried out in a PHC having facilities of O.T.
21. Record of Vital Events and Reporting
Charter of Patients' Rights for Primary Health Centres : Primary Health Centres exist to provide health care to every citizen of India within the allocated resources and available facilities.
1. The Charter seeks to provide a framework, which enables citizens to know
- What services are available and users' charges if any.
- The quality of services they are entitled to.
- The means through which complaints regarding denial or poor qualities of services will be addressed.

2. Objectives
- To make available health care services and the related facilities for citizens.
- To provide appropriate advice, treatment, referral and support that would help to cure the ailment to the extent medically possible.
- To redress any grievances in this regard.

3. Commitments of the Charter
- To provide access to available facilities without discrimination.
- To provide emergency care, if needed on reaching the PHC.
- To provide adequate number of notice boards detailing the location of all the facilities and the schedule of field visits.
- To provide written information on diagnosis, treatment being administered.
- To record complaints and respond at an appointed time.

4. Grievance redressal : Grievances that citizens have will be recorded. Aggrieved user after his/her complaint recorded would be allowed to seek a second opinion at CHC.
5. Responsibilities of the users : Users of PHC would attempt to understand the commitments made in the charter and would not insist on service above the standard set in the charter because it could negatively affect the provision of the minimum acceptable level of service to another user. Instructions of the PHC personnel would be followed sincerely, and in case of grievances, the redressal mechanism machinery would be addressed by users without delay.
6. Performance audit and review of the charter : Performance audit may be conducted through a peer review every two or three years after covering the areas where the standards have been specified.
Duties of Medical Officer, Primary Health Centre
The Medical Officer of Primary Health Centre (PHC) is responsible for implementing all activities grouped under Health and Family Welfare delivery system in PHC area. He/she is responsible in his individual capacity, as well as over all in charge.
I. **Curative Work**
1. The Medical Officer will organize the dispensary, outpatient department and will allot duties to the ancillary staff to ensure smooth running of the OPD.
2. He/she will attend to cases referred to him/her.
3. He/she will screen cases needing specialized medical attention including dental care and nursing care and refer them to referral institutions.
4. He/she will provide guidance to the Health Assistants, Health Workers, Health Guides and School Teachers in the treatment of minor ailments.
5. He/she will visit each Sub-centre in his/her area at least once in a fortnight on a fixed day not only to check the work of the staff but also to provide curative services.
6. Organize and participate in the "health day" at Anganwadi Centre once in a month.

II. **Preventive and Promotive Work**
1. The Medical Officer will ensure that all the members of his/her Health Team are fully conversant with the various National Health & Family Welfare Programs including NRHM to be implemented in the area allotted to each Health functionary. He/she will further supervise their work periodically both in the clinics and in the community setting to give them the necessary guidance and direction.
2. He/she will keep close liaison with Block Development Officer and his/her staff, community leaders and various social welfare agencies in his/her area.
3. He/she will coordinate and facilitate the functioning of AYUSH doctor in the PHC.

4. He will plan and implement the Reproductive and Child Health Programme.
5. Universal Immunization Programme (UIP) : He/she will plan and implement UIP in line with the latest policy and ensure cent percent coverage of the target population in the PHC (i.e. pregnant mothers and new born infants).
6. National Vector Borne Disease Control Programme (NVBDCP) : He/she will be responsible for all NVBDCP operations for Malaria, Kala Azar and JE in his/her PHC area and will be responsible for all administrative and technical matters.
7. Control of Communicable Diseases : He/she will ensure that all the steps are being taken for the control of communicable diseases and for the proper maintenance of sanitation in the villages.
8. Leprosy : He/she will provide facilities for early detection of cases of Leprosy and confirmation of their diagnosis and treatment.
9. Tuberculosis : He/she will provide facilities for early detection of cases of Tuberculosis, confirmation of their diagnosis and treatment and also ensure functioning of Microscopic Centre (if the PHC is designated so) and provision of DOTS.
10. Sexually Transmitted Diseases (STD) : He/she will ensure that all cases of STD are diagnosed and properly treated and their contacts are traced for early detection.
11. School Health : He/she will visit schools in the PHC area at regular intervals and arrange for Medical Checkups, immunization and treatment with proper follow up of those students found to have defects.
12. National Programme for Prevention of Visual Impairment and Control of Blindness : He/she will make arrangements for rendering treatment for minor ailments and testing of vision.

III. **Training** : He/she will organize training programmes including continuing education for the staff of PHC and ASHA under the guidance of the district health authorities and Health & Family Welfare Training centres.

IV. **Administrative Work** : He/She will carry out all administrative activities required for smooth running of the PHC.

Job Responsibilities of Health Educator

The Health Educator will function under the technical supervision and guidance of the Block Extension Educator. However, he/she will be under the immediate administrative control of the PHC Medical Officer. He/she will be responsible for providing support to all health and family welfare programmes in the block. His duties and functions are :

1) He/she will have with him/her all information relevant to development activities in the block, particularly concerning health and family welfare, and will utilize the same for programme planning.

2) He/she will develop his/her work plan in consultation with the medical officer of his/her PHC and the concerned Block Extension Educator.

3) He/she will collect and interpret the data in respect of extension education work in his/her PHC area.

4) He/she will be responsible for regular maintenance of records of educational activities, tour programmes, daily dairies and other registers, and will ensure preparation and display of relevant maps and charts in the PHC.

5) He/she will assist the Medical Officer, PHC in conducting training of health workers under the MPW and ASHA and other schemes under NRHM.

6) He/she will organize the celebration of health days and weeks and publicity programmes at local fairs, on market days, etc.

7) He/she will organize orientation training for health and family welfare workers, opinion leaders, local medical practitioners, school teachers, dais and other involved in health and family welfare work.

8) He/she will assist the organizing of mass communication programmes like film shows, exhibition, lecturers and dramas.

9) He/she will supervise the work of field workers in the area of education and motivation.

10) He/she will supply education material on health and family welfare to health workers in the block.

11) While on tour he/she will verify entries in the eligible couple register for every village and do random checking of family welfare acceptors.

12) While on tour he/she will check the available stock of conventional contraceptive with the depot holders and the kits with MPHWs and ASHAs.

13) He/she will help field workers in winning over resistant cases and drop-outs in the health and family welfare programmes.

14) He/she will maintain a complete set of educational aids on health and family welfare for his/her own use and for training purpose.
15) He/she will organize population education and health education sessions in schools and for out-of school youth.
16) He/she will maintain a list of prominent acceptors of family planning method and opinion leaders village wise and will try to involve them in the promotion of health and family welfare programmes.
17) He/she will prepare a monthly report on the progress of educational activities in the block and send it to the higher authority.

Job Responsibilities of Health Assistant Female (LHV - Lady Health Visitor) (Female Supervisor)

Under the Multipurpose Workers Scheme, a Health Assistant Female is expected to cover a population of 30,000 (20,000 in tribal and hilly areas) in which there are six Sub-centres, each with the health worker female. The health assistant female will carry out the following duties :

1. Supervise and guide

- Supervise and guide the Health Worker Female, Dais and guide ASHA in the delivery of health care service to the community.
- Visit each sub-centre at least once a week on a fixed day to observe and guide the Health Worker Female in her day to day activities under various National Health Programmes.

2. Team Work

- Assist the Medical Officer of the primary health centre in the organization of the different health services in the area.Participate as a member of the health team in mass camps and campaigns in health programmes.
- Help the health workers to work as part of the health team.

3. Supplies, equipment and maintenance of Sub-centres : In collaboration with the health assistant male, check at regular intervals the stores available at the sub-centre and help in the procurement of supplies and equipment.

4. Records and Reports :

- Scrutinize the maintenance of records by the Health Worker Female and guide her in their proper maintenance.
- She will carry with her the proper record forms, diary and guidelines for identifying suspected Kala-Azar and JE cases.
- She will be responsible along with Health Assistant Male for ensuring complete treatment of Kala-Azar and JE patients in his area.
- She will be responsible along with health assistant male for ensuring complete coverage during the spray activities and search operation.

5. Training

- Organize and conduct training for dais/ASHA with the assistance of the health worker female.
- Assist the medical officer of the primary health centre in conducting training programme for various categories of health personnel.

6. Maternal and Child Health :

- Conduct weekly MCH clinics at each Sub-centre with the assistance of the health worker female and dais.
- Conduct deliveries when required at PHC level and provide domiciliary and midwifery services.

7. Family Planning and Medical Termination of Pregnancy

- She will ensure that health worker female maintains up-to date eligible couple registers all the times.
- Conduct weekly family planning clinics along with the MCH clinics at each Sub-centre with the assistance of the health worker female. Provide information on the availability of services for medical termination of pregnancy and refer suitable cases to the approved institutions.
- Personally motivate resistant case for family planning.

8. Nutrition

- Ensure that all cases of malnutrition among infants and young children (0-5 years) are given the necessary treatment and advice and refer serious cases to the primary health centre.
- Ensure that iron and folic acid, vitamin A are distributed to the beneficiaries as prescribed.

9. Universal Immunization Programme : Supervise the immunization of all pregnant women and children (0-5 years).

10. Acute Respiratory Infection :

- Ensure early diagnosis of pneumonia cases.
- Provide suitable treatment to mid/moderate cases of ARI.

- Ensure early referral in doubtful/severe cases.

11. School Health : Help medical officers in school health services.

12. Primary Medical Care : Ensure treatment for minor ailments provide ORS & first aid for accidents and emergencies
and refer cases beyond her competence to the primary health centre or nearest hospital.

13. Health Education : Carry out educational activities for MCH, Family Planning, Nutrition and Immunization, Control of blindness, Dental care and other National Health Programmes like leprosy and Tuberculosis with the assistance of the Health Worker Female.

Job Responsibilities of Health Assistant Male (Supervisor)

Under the Multipurpose workers scheme, a health assistant male is expected to cover a population of 30,000 (20,000 in tribal and hilly areas) in which there are six Sub-centres, each with the health worker male. The Health Assistant Male will carry out the following duties :

1. Supervise and guide

- Strengthen the knowledge and skills of the health worker male and supervise and guide him in the delivery of health care service to the community.
- Visit each Health Worker Male and at least once a week to observe and guide him in his day to day activities.
- Assess monthly the progress of work of the Health Worker Male.
- Carry out supervisory home visits in the area of the health worker male.

2. Team Work

- Help the health workers to work as part of the health team.
- Coordinate his activities with those of the Health Assistant Female and other health personnel including the dais and health guide.
- Coordinate the health activities in his area with the activities of workers of other departments and agencies and attend meeting at PHC level.
- Conduct staff meetings fort nightly with the health workers in coordination with the Health Assistant Female at one of the Sub-centres by rotation.
- Attend staff meetings at the Primary Health Centre.
- Assist the medical officer of the Primary Health Centre in the organization of the different health services and conducting training programmes for various categories of health personnel.
- Participate as a member of the health team in mass camps and campaigns in health programmes.

3. Supplies, equipment and maintenance of Sub-centres

- In collaboration with the Health Assistant Female, check at regular intervals the stores available at the Sub-centre and ensure timely placement of indent for and procure the supplies and equipment in good time.
- Check that the drugs at the Sub-centre are properly stored and that the equipment is well maintained.

4. Records and Reports : Scrutinize the maintenance of records by the Health Worker Male and guide him in their proper maintenance.

5. Malaria

- He will supervise the work of Health Worker Male. He should check minimum of 100 of the houses in a village to verify the work of the Health Worker Male.
- He will carry with him a kit for collection of blood smears during his visit to the field and collect thick and thin smears from any fever case he comes across and he will administer presumptive treatment of prescribed dosage of Anti-malarial drugs.
- He will be responsible for prompt radical treatment to positive cases in his area.
- Supervise the spraying of insecticides during local spraying along with the Health Worker Male. Where Kala-Azar and JE is endemic he will supervise the work of Health Worker Female.
- He should verify that the Health Worker Male really visited those houses and identified suspected Kala-Azar and JE cases and ensured complete treatment has been done properly.
- He will carry with him the proper record forms, diary and guidelines for identifying suspected Kala-Azar and JE cases.
- He will be responsible for ensuring complete coverage treatment of Kala-Azar and JE patients in his area.
- He will be responsible for ensuring complete coverage during the spray activities and search operation.
- He will also undertake health education activities particularly through interpersonal communication, arranging group meetings with leaders and organizing and conducting training of community leaders with the assistance of health team.

6. **Communicable Disease**
- Be alert to the sudden outbreak of epidemics of diseases, such as diarrhoea/dysentery, fever with rash, jaundice, encephalitis, diphtheria, whooping cough or tetanus poliomyelitis, tetanus neonatorum, acute eye infections and take all possible remedial measures.
- Take the necessary control measures when any noticeable disease is reported to him.
- Carryout the destruction of stray dogs with the help of the Health Worker Male.

7. **Leprosy**
- In cases suspected of having leprosy take skin smears and send them for examination.
- Ensure that all case of leprosy take regular and complete treatment and inform the medical officer PHC about any defaulters to treatment.

8. **Tuberculosis**
- Check whether all cases under treatment for Tuberculosis are taking regular treatment, motivate defaulters to take regular treatment and bring them to the notice of the Medical Officer, PHC.
- Ensure that all cases of Tuberculosis take regular and complete treatment and inform the Medical Officer, PHC about any defaulters to treatment.

9. **Environmental Sanitation**
- Help the community sanitation for safe water sources, Soakage pits, Manure pits, Compost pits, Sanitary latrines, Smokeless chullas and supervise their construction.
- Supervise the chlorination of water sources including wells.

10. Universal Immunization Programme : Conduct immunization of all school going children with the help of the
Health Workers Female.

11. Family Planning
- Personally motivate resistant case for family planning.
- Guide the Health Worker Male in establishing female depot holders.
- Assist M.O. PHC in organization of family planning camps and drives.
- Provide information on the availability of services for medical termination of pregnancy and refer suitable cases to the approved institutions.
- Ensure follow up of all cases of vasectomy, tubectomy, IUD and other family planning acceptors.

Job Responsibilities of Health Worker Female (ANM)

1. Maternal and Child Health : She will register and provide care to pregnant women throughout the period of pregnancy. She will ensure that every pregnant woman makes at least 3 (three) visits for ante natal check-up, estimate their haemoglobin level and test urine of these women for albumin and sugar. She will refer all pregnant women to PHC for RPR test for syphilis and refer cases of abnormal pregnancy and cases with medical and gynaecological problems to Health Assistant Female (LHV) or the Primary Health Centre. She will conduct deliveries in her area when called for and supervise deliveries conducted by Dais and assist them whenever called in. She will refer cases of difficult labour and newborns with abnormalities, help them to get institutional care and provide follow up to the patients referred to or discharged from hospital. She will identify the ultimate beneficiaries, complete necessary formalities and obtain necessary approvals of the competent authority before disbursement to the beneficiaries under Janani Suraksha Yojana. She will make at least two post-natal visits for each delivery in her areas and render advice regarding care of the mother and care and feed of the newborn. She will also assess the growth and development of the infant and take necessary action required to rectify the defect. She will educate mothers individually and in groups in better family health including maternal and child health, family planning, nutrition, immunization, control of communicable diseases, personal and environmental hygiene.

2. Family Planning : She will utilise the information from the eligible couple and child register for the family planning programme. She will be responsible for maintaining eligible couple registers and updating at all times. She will spread the message of family planning to the couples and motivate them for family planning individually and in groups. She will distribute conventional contraceptives and oral contraceptives to the couples, provide facilities and to help prospective acceptors in getting family planning services, if necessary, by accompanying them or arranging for the Dai/ASHA to accompany them to hospital. Provide follow-up services to female family planning acceptors, identify side effects, give treatment on the spot for side effects and minor complaints and refer those cases that need attention by the physician to the PHC/Hospital. She will establish female depot holders, help the Health Assistant Female in training them, and provide a continuous supply of conventional contraceptives to the depot holders.

3. Medical Termination of Pregnancy : She will identify the women requiring help for medical termination of pregnancy and refer them to nearest approved institution. Educate the community of the consequences of septic abortion and inform them about the availability of services for medical

termination of pregnancy.

4. Nutrition : She will identify cases of malnutrition among infants and young children (zero to five years) give the necessary treatment and advice and refer serious cases to the Primary Health Centre. She will distribute Iron and Folic Acid (IFA) tablets as prescribed to pregnant nursing mothers and administer Vitamin A solution to children. She will educate the community about nutritious diet for mothers and children in coordination with Anganwadi Workers.

5. Universal Programme on Immunization (UIP) : She will immunize pregnant women with tetanus toxoid, administer DPT, oral polio, measles and BCG vaccine to all infants and children, (Hepatitis-B in pilot areas) as per immunization schedule.

6. Dai Training : She will list Dais in her area and involve them in promoting Family Welfare and help the Health Assistant Female / LHV in the training programme of Dais.

7. Communicable Diseases : She will notify the Health Worker Male/MO PHC immediately about any abnormal increase in cases of diarrhoea/dysentery, fever with rigors, fever with rash, fever with jaundice or fever with unconsciousness which she comes across during her home visits, take the necessary measures to prevent their spread. If she comes across a case of fever during her home visits she will take blood smear, administer presumptive treatment and inform Health Worker male for further action. She will Identify cases of skin patches, especially if accompanied by loss of sensation, which she comes across during her homes visits and bring them to the notice of the Health Worker Male/MO (PHC). She will give oral rehydration solution to all cases of diarrhoea/dysentery/ vomiting and identify and refer all cases of blindness including suspected cases of cataract to MO PHC.

8. Vital Events : She will record and report to the health authority of vital events including births and deaths, particularly of mothers and infants.

9. Record Keeping : She will register (a) pregnant women from three months of pregnancy onward (b) infants zero to one year of age; and (c) women aged 15 to 44 years. She will maintain the pre-natal and maternity records and child care records and prepare the eligible couple and child register. She will maintain the records as regards contraceptive distribution, IUD insertion, couples sterilized, clinics held at the sub-centre and supplies received and issued. While maintaining passive surveillance register for malaria cases, she will record : No. of fever cases, No. of blood slides prepared, No. of malaria positive cases reported, No. of cases given radical treatment.

10. Treatment of minor ailments : She will provide treatment for minor ailments, provide first-aid for accidents and emergencies and refer cases beyond her competence to the PHC/ CHC/hospital.

11. Team Activities : She will attend and participate in staff meetings at PHC/Community Development Block or both. She will coordinate her activities with the Health Worker Male and other health workers including the Health volunteers/ASHA and Dais.

12. Role of ANM as a facilitator of ASHA : Auxiliary Nurse Midwife (ANM) will guide ASHA in performing the following activities :

She will hold weekly / fortnightly meeting with ASHA and discuss the activities undertaken during the week/fortnight. She will guide her in case ASHA had encountered any problem during the performance of her activity. She will act as a resource person for the training of ASHA. She will take help of ASHA in updating eligible couple register of the village concerned. She will utilize ASHA in motivating the pregnant women for coming to subcentre for initial checkups and bringing married couples to sub centres for adopting family planning. She will guide ASHA in motivating pregnant women for taking full course of IFA Tablets and TT injections etc. ANMs will educate ASHA on danger signs of pregnancy and labour so that she can timely identify and help beneficiary in getting further treatment.

Job Responsibilities of Health Worker (Male)

The Health worker Male will make a visit to each family once a fortnight. He will record his visit on the main entrance to the house according to the instructions of the State/UT. His duties pertaining to different National Health Programme are :

(A) **Malaria and other diseases under NVBDCP** : From each family, he shall enquire about presence of any fever cases; whether there was any fever case in the family in between his fortnightly visits; whether any guest had come to the family and had fever ; whether any member of the family who had fever in between his fortnightly visit had left the village. He shall collect thick and thin blood smears on one glass slide from case having fever or giving history of fever. He shall begin presumptive treatment for Malaria after blood smear has been collected. He will follow the instructions given to him regarding administration of presumptive treatment under NVBDCP. He shall contact the ASHA, FTD during their fortnightly visit to the village and (i) collect blood smears already taken by the ASHA, FTD (ii) also collect details of each case in MF-2 (iii) replenish both drugs and glass-slides and Rapid

Diagnostic Kits (RDKs) and look into the account of consumption of Anti malarial drugs and use of RDKs. He shall dispatch blood smears along with MF-2 collected from the ASHA, FTD, multipurpose worker female and those collected during their visit in his area to the PHC Laboratory twice a week. He shall see the results obtained by the use of RDKs and verify the radical treatment administered by the ASHA, FTD if any during his visit. He shall administer radical treatment to the positive cases as per drug schedule prescribed and as per instructions issued by the Medical Officer PHC and take laid down action if toxic manifestations are observed in a patient receiving radical treatment with primaquine. He shall contact the ASHA and FTD and inform him of the spray dates and assist the Health Supervisor Male in supervising spraying operations and training of field spraying staff.

Where Kala-Azar / Japanese Encephalitis is endemic : From each family he shall enquire about presence of any fever cases of more than 15 days duration or fever with encephalitic presentation. He will identify the fever cases detected by him during his visits and direct such a case to report to PHC for confirmatory diagnosis. He will guide the suspected cases to the nearest diagnostic and treatment centre for diagnosis and treatment by the MO. He will keep a record of all such cases and shall verify from PHC about their diagnosis during the monthly meeting or through health supervisor during his visit. He will carry a list of all Kala-azar/JE cases in his area for follow up and will ensure administration of complete treatment. He will assist during the spray activities in his area. He will conduct all health education activities particularly through interpersonal communication by carrying proper charts etc. and also assist health supervisors and other functionaries in their education activities.

(B) **National Leprosy Eradication Programme** : He will identify cases of skin patches especially if accompanied by loss of sensation, refer the above cases to PHC Medical Officer for diagnosis. If Leprosy patients want to take MDT from sub- centre, he will provide treatment and maintain patient card.

(C) **National Blindness Control Programme** : He will identify and refer all cases of blindness including suspected cases of cataract to Medical Officer, PHC.

(D) **Revised National Tuberculosis Control Programme** : He will identify persons especially with fever for 15 days and above with prolonged cough or spitting blood and take sputum smears from these individuals and refer these cases to the M. O. PHC for further investigations. He will check whether all cases under treatment for Tuberculosis are taking regular treatment, motivate defaulters to take regular treatment and bring them to the notice of the medical officer PHC.

(E) **Universal Immunization Programme** : He will administer DPT, oral Polio, measles and BCG vaccine to all infants and children in his area in collaboration with health worker female and assist her in administration of tetanus toxoid to all pregnant women. He will assist the health supervisor male/ health supervisor female in the school health programme.

(F) **Reproductive and Child Health Programme** : He will utilize the information from the eligible couple and child register for the family planning programme. He will distribute conventional contraceptives and oral contraceptives to the couples and provide follow up services to male family planning acceptors, and refer those cases that need attention by the physician to PHC/Hospital. He will assist the health supervisor male in training the community and its leaders in family welfare. He will identify the women requiring help for medical termination of pregnancy, refer them to the nearest approved institution and inform the health worker female.

(G) **Other Communicable Diseases** : He will identify cases of diarrhoea/dysentery, fever with rash, jaundice encephalitis, diphtheria, whooping cough and tetanus, poliomyelitis, neo- natal tetanus, acute eye infections and notify the health supervisor male and MO PHC immediately about these cases. He will carry out control measures until the arrival of the health supervisor male and assist him in carrying out these measures.

(H) **Environment Sanitation** : He will chlorinate the public water sources including wells at regular intervals. Educate the community on (a) The method of disposal of liquid wastes
(b) The method of disposal of solid waste (c) Home sanitation
(d) Advantage and use of sanitary type of latrines
(e) Construction and use of smokeless chulhas.

(I) **Primary Medical Care** : He will provide treatment for minor ailments provide first aid for accidents and emergencies and refer cases beyond his competence to the PHC/hospital.

(J) **Health Education** : He will educate the community about various health services.

(K) **Nutrition** : He will identify cases of malnutrition among infants and young children (0-5 years) in his area, give the necessary treatment and advice or refer them to the anganwadi for supplementary feeding and refer serious cases to the PHC. Educate the community about the nutrition diet for mothers and children from locally available food.

(L) **Vital Events** : He will Enquire about births and deaths occurring in his area, record them in the births and deaths register and report them to the Health Supervisor Male / ANM and educate the community on the importance

of registration of births and deaths.

Accredited Social Health Activists (ASHA)

A trained female community health worker - ASHA - is being provided in each village in the ratio of one per 1000 population. For tribal, hilly, desert areas, the norm could be relaxed for one ASHA per habitation depending on the workload. ASHA must be a primary resident of the village with formal education upto Class VIII and preferably in the age group 25-45. She would be selected by the Gram Sabha following an intense community mobilization process. She would be fully accountable to Panchayat. Induction training of ASHA is to be of 23 days in all (five modules), spread over 12 months. On the job training would continue throughout the year.

Though she would not be paid any honorarium, she would be entitled for performance based compensation. It is expected that on an average an ASHA working with reasonable efficiency would be able to earn Rs. 1000 per month. Since as per the existing approval, the compensation for ASHA is not factored in the scheme, it is proposed to modify the programmes mentioned in the ASHA compensation package, wherever necessary, to enable the payment of compensation to her. The cost of training and drug kits to ASHAs would be supported by the Centre in the 18 high focus states. The other states would have the flexibility to have Health link workers to support it out of the RCH II flexible fund. As a special case, ASHAs could be supported in very remote backward regions in non-focus States.

ASHAs would reinforce community action for universal immunization, safe delivery, newborn care, prevention of water-borne and other communicable diseases, nutrition and sanitation. She will also help the villagers promote preventive health by converging activities of nutrition, education, drinking water, sanitation etc. In order that ASHAs work in close coordination with the AWW, she would be fully anchored in the Anganwadi system. ASHAs would also be provided with a 'drug kit' which would help her in providing immediate and easy access for the rural population to essential health supplies like ORS, contraceptives, a set of ten basic drugs. She would also have a health communication kit and other IEC materials developed for villages. At present, Health Day's are organized every month at the Anganwadi level in each village in which immunization, ante/ post natal check ups and services related to mother and child health care including nutrition are being provided. Space at each Anganwadi to serve as the hub of health activities in the village could be considered under other Rural Development Programmes. This space could also serve as depot for medicines and contraceptives.

A revolving fund would be set up at the village level for providing referral and transport facilities for emergency deliveries as well as immediate financial needs for hospitalization. The fund would be operated by the VHSC. Untied fund would also be made available to VHSC for various health activities including IEC, household survey, preparation of health register, organization of meetings at the village level etc. Since VHSC would be asked to play a leading role in the health matters of the village, its members would be given orientation training to equip them to provide leadership as well as plan and monitor the health activities at the village level.

For those villages which are far away from the Sub-Centre, a TBA with requisite educational qualifications would be identified for training and support. She would assist the ANM at the Sub Centre. ASHAs willing to play this role would be given preference. In places where even an ANM's services are not reaching and there is no accredited ASHA available, the RMPs would be identified for training so that they could upgrade their skills and get accredited. Efforts would also be made to regulate quacks and untrained dais. ASHA will assist the villagers in referral services for AYUSH/testing HIV/ AIDs, STI, RTI, also preventive, promotive health already with AWW/SHGs etc. ASHA will provide them information on the treatments available under AYUSH.

Summary

The health care services' organization in the country extends from the national level to village level. At the national level it consists of the Union Ministry of Health and Family Welfare, which has three departments, viz. - Department of Health & Family Welfare, Department of AYUSH and Department of Health Research. Each of these departments is headed by respective secretaries to Govt of India. The department of Health & Family Welfare is supported by a technical wing, the Directorate General of Health Services, headed by Director General of Health Services (DGHS). At State level it is under the State Department of Health and Family Welfare in each State headed by Minister and with a Secretariat under the charge of Secretary/Commissioner (Health and Family Welfare). The State Directorate of Health Services, as the technical wing, is an attached office of the State Department of Health and Family Welfare and is headed by a Director of Health Services. At Regional level, in some states each regional/zonal set-up covers three to five districts and acts under authority delegated by the State Directorate of Health Services. At District level, all health care programmes are placed under a unified control and is a link between the State/ regional structure on

one side and the peripheral level structures such as PHC/Sub-centre on the other side. The district officer with the overall control is designated as the Chief Medical and Health Officer (CM & HO) or as the District Medical and Health Officer (DM & HO).

One Community Health Centre (CHC) has been established for every 80, 000 to 1, 20, 000 population, and this centre provides the basic specialty services in general medicine, pediatrics, surgery, obstetrics and gynecology. CHCs are being established and maintained by the State Government. It is manned by four medical specialists i.e. Surgeon, Physician, Gynecologist and Pediatrician supported by 21 paramedical and other staff. It has 30 in-door beds with one OT, Xray, Labour Room and Laboratory facilities. It serves as a referral centre for 4 PHCs.

PHCs are the cornerstone of rural health services- a first port of call to a qualified doctor of the public sector in rural areas for the sick and those who directly report or referred from Sub- centres for curative, preventive and promotive health care. One Primary Health Centre covers about 30, 000 (20, 000 in hilly, desert and difficult terrains) or more population. At present, a PHC is manned by a Medical Officer supported by 14 paramedical and other staff. It acts as a referral unit for 6 sub-centres and refer out cases to Community Health Centres (CHCs-30 bedded hospital)/sub-district/district hospitals. It has 4-6 indoor beds for patients.

The Sub-centre is the most peripheral and first contact point between the primary health care system and the community. Sub-centres are assigned tasks relating to interpersonal communication in order to bring about behavioral change and provide services in relation to maternal and child health, family welfare, nutrition, immunization, diarrhoea control and control of communicable diseases programmes. The Sub-centres are provided with basic drugs for minor ailments needed for taking care of essential health needs of men, women and children. Currently a Sub-centre is staffed by one Female Health Worker commonly known as Auxiliary Nurse Midwife (ANM) and one Male Health Worker commonly known as Multi Purpose Worker (Male). One Health Assistant (Female) commonly known as Lady Health Visitor (LHV) and one Health Assistant (Male) located at the PHC level are entrusted with the task of supervision of all the Sub-centres (generally six sub centres) under a PHC.

The overall objective of Indian Public Health Standards (IPHS) is to provide health care that is quality oriented and sensitive to the needs of the community. In order to provide optimal level of quality health care, a set of standards are being recommended for Community Health Centre /Primary Health Centre/Sub centre with reference to Infrastructure, Functioning and Staffing including responsibilities of each.

The Medical Officer of Primary Health Centre (PHC) is responsible for implementing all activities grouped under Health and Family Welfare delivery system in PHC area. He/she is responsible in his individual capacity, as well as over all in charge for his curative, preventive and promotive care of the patients. He will organize training programmes including continuing education for the staff and carry out all administrative activities required for smooth running of the PHC.

The health assistant female will supervise, guide and train the Health Worker Female, Dais and ASHAs; and also visit each Sub-centre at least once a week. The Health Assistant Male will strengthen the knowledge and skills of the health worker male and supervise and guide him in the delivery of health care service to the community; and visit each Health Worker Male at least once a week. They maintain records and carry out a team work at PHC.

Health Worker Female (ANM) provides MCH care, Family planning, identify the women requiring help for MTP and identify cases of malnutrition among infants and young children and refer them. She will immunize pregnant women with tetanus toxoid, administer DPT, oral polio, measles and BCG vaccine to all infants and children, (Hepatitis-B in pilot areas) as per immunization schedule. Dai Training, identifying, notifying and referring various Communicable Diseases and recording the vital events are some of her important jobs. The Health worker Male will make a visit to each family once a fortnight and performs the prescribed duties pertaining to different National Health Programmes like NVBDCP, NLEP, RNTCP, UIP, National Blindness Control Programme and others. He will chlorinate the public water sources including wells at regular intervals and educate the community.

A trained female community health worker - ASHA - is being provided in each village in the ratio of one per 1000 population. She must be a primary resident of the village with formal education upto Class VIII and preferably in the age group 25-45. She would be selected by the Gram Sabha and would be fully accountable to Panchayat. Though she would not be paid any honorarium, she would be entitled for performance based compensation. ASHAs would reinforce community action for universal immunization, safe delivery, newborn care, prevention of water-borne and other communicable diseases, nutrition and sanitation.

TNMSC renders the following services.

1. Procurement, testing storage and distribution of human drugs & veterinary drugs, medicines, surgicals & sutures, kits, reagents to the Government Medical Institutions of the State.

2. Procurement and installation of medical equipments to the Government Medical and Veterinary Institutions of the State..
3. Finalization of Annual Rate Contract for Speciality Drugs, Surgical appliances, instruments / equipments and Medicines by direct procurement by the Medical Institutions in the State.
4. Providing support services for the special maternity wards at two hospitals in Chennai , for paywards at Government General Hospital, Stanley Medical Collage Hospital, Chennai and for the Master Health Checkup facility at Government General Hospital Chennai.
5. Operating CT Scan centers, MRI Centers, Lithotripsy centers in the Medical Institutions of the State on user charge collection basis.
6. Providing support services for maintanece of medical and non medical equipment in the Medical Institution in the State.
7. Procurement and testing of drugs and medicines for other needy states in India.
8. Consultancy services on the procurement logistics systems to other states in India.
9. Sale of selected life saving medicines to the Public at Kilpauk, Chennai.
10. The provision of health services in India by the public sector is the responsibility shared by the state, central and local governments although it is effectively a state responsibility in terms of service delivery. State and local governments incur about three-quarters and the center about one-quarter of public spending on health. The responsibility of health is at three levels. First, health is primarily a state responsibility. Second, the center is
    responsible for health services in Union Territories without legislature and is also responsible for developing and monitoring national standards and regulations, linking states with funding agencies and sponsoring numerous schemes for implementation by state governments. Third, both the center and the states have a joint responsibility for programmes listed under the concurrent list (regulation of medical and other professions, spread of diseases across states and drugs and poison). Goals and strategies for the public sector in health care are established through a consultative process involving all levels of the government through the Central Council for Health and Family Welfare.
11. In this chapter we present an overview of the organization of the health and family welfare department and health infrastructure in Tamil Nadu. This overview is essential in order to better understand the management of the Reproductive and Child Health Programme in the state.

    4.1 ORGANIZATION OF THE DEPARTMENT OF HEALTH AND FAMILY WELFARE.

    Figure 4.1 depicts the organization of the Health and Family Welfare Department in Tamil Nadu. As depicted in the figure, the department is headed by the Minister of Health and Family Welfare who is assisted by the Secretary, Health and Family Welfare, a senior lAS officer who is the chief administrator of the department. The following
    Directorates and Corporations are functioning under the control of Health and Family
12. Welfare Department:
13. 1. Directorate of Family Welfare
    2. Directorate of Public Health and Preventive Medicine
    3. Directorate of Medical and Rural Health Services
    4. Tamil Nadu Medical Services Corporation
    5. Reproductive Child Health Project and
    6. DANIDA Health Care Project
    7. Tamil Nadu State AIDS Control Society
    8. Tamil Nadu State Health Transport Department
    9. Directorate of Medical Education
    10. Directorate of Indian Medicine and Homeopathy
    11. Directorate of Drugs Control
    12. Tamil Nadu State Blindness Control Society

    We now describe the functions of each of the directorates.

    4.1.1 Directorate of Family Welfare

    The Directorate of Family Welfare is responsible for implementing the Family Welfare programme in the state. The following diagram depicts the organizational structure of the directorate. The Directorate

provides health and family welfare services through a network of rural and urban family welfare centres, post partum centres and health posts.
These centres operate under the control of the District Family Welfare Bureau headed by the Deputy Director of Medical and Family Welfare at the district level. An important aspect of the implementation of the family welfare programme is the spread of the small family norm and various contraceptive methods. This function is handled by the IEC division in the directorate headed by the Deputy Director (IEC) at the state level and District Media and Information Officers (MIEO) at the district level. The Demographer, Social Scientist and Statistical Officers also operHte in the Family Welfare Directorate

14. **Department ofPublic Health and Preventive Medicine**
The Department of Public Health and Preventive Medicine is responsible for the implementation ofvarious National and State Health Programmes. This Department also plans and implements measures to prevent the occurrence of communicable diseases thereby reducing the burden ofmorbidity morality and disability in the state. The activities undertaken by the department of Public Health and Preventive Medicine are provisions of primary health care which includes Maternity and Child Health Services, Immunization of children against vaccine preventable diseases, control of communicable diseases, control of malaria, filaria, japanese encephalitis, elimination of
leprosy, iodine deficiency disorder control programme, prevention of food adulteration, health checkup of school children, health education of the community and collection of vital statistics under birth and death registration system and environmental sanitation. This directorate is also responsible for the prevention and control ofwaterborne diseases like Acute Diarrheal Diseases, Typhoid, Dysentery prevention and control of sexually
transmitted diseases including *HN* / AIDS.

4.1.3 Directorate of Medical and Rural Health Services

The Directorate of Medical and Rural Health Services provides medical services, through the grid of 25 District Headquarters Hospitals, 162 Taluk Hospitals, 79 non-taluk Hospitals, 12 Dispensaries. The Directorate is implementing various Medical Services Programmes such as TB Control, Mental Health, HN, Blood Banks. The non Taluk and Taluk Hospitals are the First Referral Units in the Chain of Medical Services in the State and the 25 District Headquarters Hospitals are the second referral units

4.1.4 Tamil Nadu Medical Services Corporation Limited

Tamil Nadu Medical Services Corporation Limited., (TNMSC) was set up with the primary objective of ensuring ready availability ofall essential drugs and medicines in the Government Medical Institutions throughout the State by adopting a streamlined procedure for their procurement, storage and distribution. It was incorporated under the
Companies Act, 1956 and commenced its functions of purchase, storage and distribution of drugs and medicines from January 1995. The aim of the Corporation is to make available quality drugs and medicines at Government hospitals and medical institutions without any interruption. The Secretary to Government, Health and Family Welfare

Department of Public Health and Preventive Medicine

The Department of Public Health and Preventive Medicine is responsible for the implementation of various National and State Health Programmes. This Department also plans and implements measures to prevent the occurrence of communicable diseases thereby reducing the burden of morbidity morality and disability in the state. The activities undertaken by the department of Public Health and Preventive Medicine are provisions of primary health care which includes Maternity and Child Health Services, Immunization of children against vaccine preventable diseases, control of communicable diseases, control of malaria, filaria, japanese encephalitis, elimination of leprosy, iodine deficiency disorder control programme, prevention of food adulteration, health checkup of school children, health education of the community and collection of vital statistics under birth and death registration system and environmental sanitation. This directorate is also responsible for the prevention and control of waterborne diseases
like Acute Diarrheal Diseases, Typhoid, Dysentery prevention and control of sexually transmitted diseases including *HN* / AIDS.

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15. Department is the Chairman of the Tamil Nadu Medical Services Corporation Limited. The day to day administration of the Corporation is looked after by the Managing Director. The Corporation is also rendering other services like procurement of equipment and establishment of diagnostic centres. The drugs and medicines are distributed to the Government Medical Institutions through 23 drug Warehouses in Tamil Nadu. The Corporation has also established 29 CT Scan Centres in Government Hospitals and 2 MRI Scan Centres one each at Government General Hospital, Chennai and Government Rajaji Hospital, Madurai to provide scanning facility to the public on a nominal charge. more CT Scanners are under installation. With the installation of the remaining CT Scanners, the Government will be providing CT Scan facility in all the Districts in the State

4.1.5 Reproductive and Child Health Project

The Reproductive and Child Health Project Directorate is incharge of the implementation of the World Bank funded sub-project on RCH in Tamil Nadu. This sub-project is underway in twenty four districts across 17 states in India. In Tamil Nadu, this project is being implemented in 2 districts viz., Madurai and Theni. The project seeks to address the gaps in the delivery of Family Welfare and Health Care services by improving services to the disadvantaged groups in these areas so as to enable them to achieve an overall RCH status equivalent to the average of the state. In Tamil Nadu, the project's key activities include the improving of infrastructure of health facilities including FRU's, training of health personnel on RCH issues, in1proving the mobility of health workers by providing mopeds and conducting of mobility training. The directorate also implements the statewide project on RCH in the remaining districts of Tamil Nadu with funding from the World Bank. Under this project, health infrastructure in health facilities is to be improved, operation theaters are to be constructed in PHC's /FRU's and making health facilities more functional through the appointment of contractual staff including anesthetists, establishing RTf clinics in select PHC's and training staff on RCH. The project is headed by a director who coordinates with other health departments in the implementation of the project.

4.1.6 Danida Health Care Project

The DANIDA Tamil Nadu Area Health Care Project is a centrally sponsored externally aided project. The phase III currently in progress was implemented since December 1996, covers the districts of Dharmapuri, Thanjavur, Nagapattinam and Thiruvarur for most of the activities, extends some of the activities to the old districts of Salem,

Namakkal, Cuddalore & Villupuram and supports some state level activities like training, drug supply logistics etc. The overall objective of this project is to improve the health and family welfare status of the rural population in the project area, especially of the weaker sections. With a view to improving and strengthening the facilities for the

delivery of health and family welfare services in an integrated manner in accordance with the National Health Policy, DANIDA is one of the bilateral donors in the Health Sector in providing financial assistance to the Government of Tamil Nadu. The funding is on reimbursement basis with 85% share by DANIDA, 5% by Government of India and

10% by Government of Tamil Nadu. The project is Implemented through a Project Directorate set up at Chennai headed by the Project Director at state level. It coordinates with health and other departments such as Directorate of Public Health and Preventive Medicine, Directorate of Family Welfare, Tamil Nadu Medical Services Corporation etc. in the implementation after the proposals are approved by the State Project Coordination Committee / Empowered Committee. At district level, District Management Cells consisting of minimum supportive staff are
created to assist the Deputy Directors of healtl:t services of the project districts in the implementation of project activities. The project activities are monitored by the State Project Monitoring Committee at State level and the District Project Monitoring Committee at District level
4.1.7 The Tamil Nadu State Aids Control Society The Tamil Nadu State Aids Control Society has been formed under the aegis of Government of Tamil Nadu to spread the awareness about the dreaded disease Acquired
Immuno Deficiency syndrome(AIDS) and to take care of the affected persons without getting discrirninated or being ill-treated by the society in general. It's aim is to popularize the prevention of the disease, promotion of healthy living, to curtail false norions about the disease at large.
The State AIDS Project Cell was formed in January 1993 and was initially functioning under the Control of the Director of Medical Education, Chennai. The State AIDS Project Cell was re-constituted as the Tamil Nadu State Aids Control Society (fNSACS) registered under the the Tamil N adu Societies Registration Act, with effect from
11.5.1994, with the Secretary, Health and Family Welfare Department, as the President of this Society and a senior I.A.S. Officer as the Member Secretary cum Project Director, to tackle the problem of AIDS in a more effective manner. After its registration in May 1994, the State AIDS Control Society, started its activities more vigorously in full swing with the guidance and support of its Executive Committee, Technical Advisory Committee and Ethical Scientific Committee constituted by the Government. TNSACS is tackling the problem on various fronts using different strategies to create awareness among different sub-population groups.

16. **4.1.8 Tamil Nadu Health Transport Department**
In the year 1959, the State Health Transport Organisation was started to look after the maintenance of Health Department Vehicles. The aim of the Department is to reduce the down time of the vehicles which are taken up for repairs, to keep high percentage of fleet utilization of vehicles and to provide more fleet for the successful implementation of health programmes

4.1.9 Directorate of Medical Education
The role of this directorate is the development ofmedical and para-medical personnel to cater to the health needs of the State. The department is also responsible in establishing and maintaining the teaching institutions which are the premier referral centres with state of the art equipment and technology. Research is another area of activity for Medical Education Department.

4.1.10 Directorate of Indian Medicine and Homeopathy The Directorate of Indian Medicine and Homoeopathy is established to look after the Medical Systems such as Siddha, Ayurveda,Unani, Yoga and Naturopathy and
Homoeopathy. The Department is functioning with the objectives of providing health service to the public through Indian Systems of Medicine and Hornoeopathy and providing and monitoring education and research activities in Indian systems of Medicine.

4.1.11 Directorate of Drugs Control
The Directorate of Drugs Control is responsible for the regulation of the manufacture and sale of drugs and cosmetics in the state. It is the licensing authority for the grant and renewal of sale licenses in the state. The Directorate also has a testing laboratory, intelligence and legal wing to check the sale of spurious drugs.
4.1.12 Tamil Nadu State Blindness Control Society The Tamil Nadu State Blindness Control Society is responsible for the implementation of the National Blindness Control Programme. The Society is headed by Health
Secretary who is the President of this Society. The Office of the Project Director and Deputy Director comes under in his control. For effective implementation and monitoring of the work at District level, a

District Blindness Control Society has been Formed in all the Districts. The District Collector is the Chairman of the Society and the operations are headed by the Deputy Director of Health Services. The District Blindness Control Society conducts eye camps with the help of Voluntary Organisations and District Mobile Ophthalmic Units, provides financial assistance to Voluntary Organisations for performing Cataract Operations, undertakes propaganda activities under health education programme in the District and monitors the implementation of Blindness Control Programme in District level. The above description of the directorates in the health and family welfare department has been provided for purposes of complete listing. For the present study, the functioning of the departments of family welfare, public health and preventive medicine, medical and rural health services, Tamil Nadu Medical Services Corporation, DANIDA Health Care Project and RCH Project are relevant. We visited these departments and interviewed the
officials to collect relevant data on the functioning ofthe respective departments. Having described the organization of the Health and Family Welfare department at the state level, we now present the organization at the district level.

4.2 ORGANIZATION OF THE DISTRICT HEALTH AND FAMILY WELFARE DEPARTMENT

The health system in the district is headed by the Joint Directors of Health Services who is responsible for Implementation of all the Medical and Health Programmes including Family Welfare. He also coordinates with the other departments to implement the programmes such as control of Blindness, AIDS, Hill Area Development Programme, Schemes for Adidravida and Tribal Welfare. The following diagram depicts the organization of the health department at the district level. Each district is divided into two divisions called- a Health Unit Division (HUD). Each HUD is headed by a Deputy Director of Health Services who reports to the Joint Director. The Deputy Director of Health Services is incharge of all public health activities including the PHC's and the implementation of programmes in his health unit division. The Deputy Director of
Medical, Rural Health Services and Family Welfare is responsible for the functioning of taluq and non-taluq hospitals and in charge of the family welfare programme in the district. There are two Deputy Directors of Medical Services responsible for the control ofleprosy and tuberculosis in the district.
In the districts where the DANIDA Tamil Nadu Area Health Care Project is being implemented a DANIDA District anagement Cell consisting of supportive staff is perational which assists the Deputy Director of Health Services of the project districts in the implementation of project activiti-es. The project activities are monitored by the State Project Monitoring Committee at the state level and the District Project Monitoring Committee at the District Level. For the effective implementation and monitoring of blindness control activities at the district level, a district blindness control society has been formed in all districts. The society is administered by the district collector who is
the Chairman ofthe society. One ofthe joint directors or deputy directors (depending on the availability of posts) of the district is made incharge of the blindness control programme. The district warehouses of TNMSC is headed by a manager who coordinates with other officials of the health department for the efficient distribution of
medicines and other supplies to the different health facilities located in the district.

17. **4.3 HEALTH INFRASTRUCTURE**

Health Infrastructure in India was developed during the colonial period. The concept of a primary health centre (PHC) in India was born when the Bhore Committee in 1946 visualized it as a basic health unit, to provide as close to the people as possible, an integrated curative and preventive health care to the rural population with an emphasis
on the preventive and promotive aspects of health care. The Bhore committee aimed at having a health centre to serve a population of 10,000 to 20,000 with 6 medical officers, 6 public health centres and other supporting staff. But in view of the limited resources, the Bhore Committee's recommendations could not be fully implemented even after nearly 60 years of independence. The programme of establishing Primary Health Centres in each Community Development Block having a population of 60,000 to 80,000 was launched as an integral part of the Community Development Programme on October 2, 1952. The PHC is

the flrst contact point between the village community and the medical officer. The PHC's are established by the state government under the Minimum Needs Programme (MNP). These centres came under criticism as they were not able to provide adequate health
coverage, partly because they were poorly staffed and equipped and partly because they had to cover a large population (Misra et al., 1982; Satia et al., 1991; Mavalankar, 1996). The Mudaliar Committee in 1962 recommended that the existing PHC's should be strengthened and the population to be served by them scaled down to 40,000. The National Health Policy (1983) proposed a reorganization of the PHC's on the basis
of one PHC for every 30,000 rural population and one PHC for every 20,000 population in hilly, tribal and backward areas for more effective coverage. This was done to gear up the health system to meet the challenges ofreaching the goal of Health for All by 2000 as envisaged in the Alma Ata declaration signed by India in 1978.
The functions of the PHC in India cover all the 8 "essential" elements of the primary health care as outlined in the Alma-Ata declaration. They are : 1. Medical Care
2. Maternal and Child Health care including family planning. 3. Safe water supply and basic sanitation.
4. Prevention and control oflocally endemic diseases. 5. Collection and reporting ofvital statistics
6. Education about health. 7. Implementation ofnational health programmes.
8. Referral services 9. Training ofhealth guides, health workers, local dais and health assistants.
10. Basic laboratory services. The norms laid dow by the government for the staffing pattern ofa PHC is shown in
Staffing P_attern ofa PHC
Designation No. ofposts
Medical Officer 1
Pharmacist 1
Nurse Midwife (StaffNurse) 1
Health Worker (Female)/ ANM 1
Health Educator 1
Health Assistant(Male) 1
Health Assistant (Female) / LHV 1
Upper Division Clerk 1
Lower Division Clerk 1
Laborat~Technician 1
Driver (ifvehicle is available) 1
Class *N* 4
Total 15..
The number ofPHCs functioning in the country, by end-November 1999, is 23,266. The PHC in India on an average, caters to a population of 31932 persons spread over 26.83 villages and 136.48 sq. km. The average radial distance covered by a PHC, on an average, is 6.75 kms. In Tamil Nadu, there are 1410 PHC's operating and each PHC caters to an average rural population of 24730 persons which is among the most favorable ratios in the country. The ratio is almost the same with that of Kerala. The states which have lower ratios are the predominantly hilly and tribal states where the national norms are also lower. Each PHC in Tamil Nadu caters to an area of 92.24 sq. km. respectively which is again one of the most favorable ratios in the country. The average radial distance covered by a PHC in
Tamil Nadu, on an average, is 5.41 kms. The structure ofthe PHC in Tamil Nadu is a little different from the national pattern. At the block level, there is a block PHC which is a normal PHC and is in-charge of the administration of the other PHC in the block (known as additional PHC's). A block PHC may have better facilities than an additional PHC like in-patient beds and operating theater but it is not necessary. Some PHC's in Tamil Nadu have been upgraded in recent years and are known as upgraded PHC's. These PHC's have in-patient beds, operating
theater with a anesthetist and surgeons with the facility of performing sterilization operations and abortions and an ambulance in additional to one vehicle used for other family welfare work and X-ray machines.

Some PHC's have also been made 24- hour PHC's that operate round the clock.
Another deviation from the national pattern is the staffing pattern of the health institutions in Tamil Nadu. A PHC in Tamil Nadu is manned by 2 medical officers. The government is also making efforts to ensure that one of the doctors is a lady doctor to ensure better utilization by women. Some PHC's are staffed by more than 2 doctors
depending on the patient load and the services offered by the PHC. A health sub-centre in Tamil Nadu is manned by a Village Health Nurse (VHN) sometimes referred to as a female multi-purpose worker. In addition, a male multipurpose worker is attached to the PHC. Though a male multi-purpose worker's service area may fall in a sub-centre area, he is entrusted with different responsibilities (like malaria control, screening for leprosy,
TB) and is not involved in the functioning of the sub-centre. The block PHC's are in-charge of the administration of all the PHC's in the block. The position of clerks and other administrative staff is there only in the block PHC. The
position of a block extension educator (BEE) and the block health statistician (BHS) arc also only in the Block PHC's. However, these persons are in--charge of the whole block and interact with the additional PHC's on a regular basis. In addition, the block PHC's have a position of a Community Health Nurse (CHN) who supervises the work of the _Sector Health Nurse (SHN).
The designations ofsome of the health personnel in Tamil Nadu also varies from that of other states. The female multi-purpose worker known as the auxillary nurse mid-wife (ANM) is called as a Village Health Nurse in Tamil Nadu. She is supervised by the Sector Health Nurse (SHN) who is designated as the Lady Health Visitor (LHV) in other states. Typically, there are 6-7 sub-centres under a PHC and there is one SHN supervising the
work of the VHN's in charge of these sub-centres. In some PHC's there are more subcentres and in such cases there re two SHN's in place. The position of an ANM in
Tamil Nadu refers one who assists the medical officers in attending patients in the PHC (dressing, injections etc). She is not involved in any outreach activities. The male multipurpose worker is known as a Health Inspector (HI). For the purposes of the present study, we interviewed the staff of the PHC's and conucted focus group discussions with the Village Health Nurses to study the management of the RCH programme in India. We also observed the working of the PHC and the outreach activities ofhealth workers.

18. ***Sub-centres (SCs):*** It is the most peripheral contact point between the primary health care system and the community. The national norm is to have a sub-centre for every 5000 population in plain area and for every 3000 people in tribal and hilly areas. As per the 2001 census, each SC catered to a rural population of5413 people on an average. The SCs have mainly promotive and educative functions relating to Maternal and Child
Health, Family Welfare, Nutrition, Immunisation, Diarrhoeal Control and Control of Communicable Diseases Programmes. They are also provided with basic drugs for minor ailments that are needed for taking care ofessential health needs ofwomen and children. While nationally the sub-centres are staffed by one Multi-purpose Worker (Male) and one Multi-purpose Worker (Female)/ANM, in Tamil Nadu these are staffed by one female
health worker called the Village Health Nurse. Out ofa total number of the functioning 137027 SCs in end-November, 1999,97757 SCs are funded by the Department ofFamily Welfare (MOHFW, 2001). The rest are funded under the State Minimum Needs/Basic Minimum Services (BMS) Programme.
In Tamil Nadu there are 8682 sub-centres which provide health serv1ces to the rural population ofthe state. Each sub-centre in Tamil Nadu covers a rural population of4017 persons spread over an area of 14.98 sq. km. which is amongst the best averages in the country. The average radial distance covered by a sub-centre in Tamil Nadu, on an
average, is 2.13 kms.
19. ***Community Health Centres (CHCs):*** These are established and maintained by the state government under Minimum Needs Programme. The national norm is to have one CHC for every 80,000 to 1,20,000 lakh population, serving as a referral institution for four PHC's. It is manned by four medical specialists, i.e.,

surgeon, Physician,
Gynecologist and pediatrician supported by 21 paramedical and other staff. It has 30 indoor beds with one X-ray, labour room laboratory facilities. It serves as a referral centre for four PHCs. The number of CHCs functioning is 2962, by the end of November 1999.

Staffing Pattern of a CHC

No. ofposts
Designation
Medical Offier **4**
Nurse l\1id-wives 7
Dresser **1**
Pharmacist / Compounder **1**
Laboratory Technician ..• **1**
Radiographer **1**
Ward Boys 2
Dhabi **1**
Sweepers 3
Mali **1**
Chowkidar **1**
Aya **1**
Peon **1**
25
Total
..

In Tamil Nadu, there are no Community Health Centres which are functioning but _corresponding facilities are provided by upgraded PHC's and taluq and non-taluq hospitals. The upgraded PHC's may be block PHC's or additional PHC's. While an upgraded PHC can be under the administrative control of a block PHC, it is not so
under the conventional CHC-PHC-SC structure in which the PHC's are under the administrative control ofthe CHC.

Rural Family Welfare centre (RFWCs): There are 5435 such Centres functioning in the country. These were established at all the block level PHC's sanctioned upto 1st April, 1980. The States have integrated the RFWCs into their primary health care system. There is, therefore, no separate identity for these RFWCs today. The Government of India, however, continues to provide financial support for maintaining these Centres. An
RFWC is manned by one assistant surgeon supported by **11** paramedical and other staff. In Tamil Nadu, one Rural Family Welfare Centre exists in every community block covering roughly one lakh population. There are 382 Rural Family Welfare Centres operating in the State.

Health Facilities in Urban Areas: In cities and towns, the health and family welfare services are provided through a network ofgovernment or municipal hospitals and dispensaries, and urban family welfare centres. Private hospitals, clinics and dispensaries also play a major role in providing these services in urban areas. In Tamil Nadu, there are 25 district headquarter hospitals, 162 taluq hospitals, 79 non-taluq hospitals, 12 government
dispensaries which offer health services to rural population by acting as referral centres to the lower level health institutions. Besides these health facilities there are 35
government hospitals in the major cities offer specialty services in addition to basic services. 178 ESI hospitals and dispensaries offer services to the employees and their families who are covered under the Employee State Insurance Scheme. Health services are provided to the rural population ofTamil Nadu through an extensive
network ofhospitals, PHC's and sub-centres. The density of these facilities is among the best in the country. Though the health system is a little different from the national pattern, it follows more or less a similar structure. We now describe the health infrastructure in the districts selected for our study.

4.4 HEALTH INFRASTRUCTURE IN THE STUDY DISTRICTS The table 4.3 shows the health facilities available in the districts of Kancheepuram and Dharmapuri. Both the districts have a district headquarter hospital. Of the 10 taluqs in Dharmapuri district, 9 taluqs have a taluq hospitals. Dharmapuri taluq has a district
hospital instead ofa taluq hospital. Thus, all taluqs in Dharmapuri district have a taluq or higher grade hospital. Kancheepuram district has 6 taluq hospitals in the 8 taluqs. As in the case of Dharmapuri district, the two taluqs which do·not have taluq hospital are Kancheepuram - the district headquarter- which has a hospital of the status ofa district hospital and Chengalpatu taluq which has a teaching hospital. Thus, all the taluqs in this
district also have a taluq or higher grade hospital. The district also has one non-taluq hospital and 2 central government hospitals. In the rural areas, Dharmapuri district has 69 PHC's and 470 sub-centres providing health services in the rural areas. In K.ancheepuram there are 47 PHC's and 360 subcentres catering to the rural opulation. The population served per PHC and SC is lower in Kancheepuram district. Here each PHC and SC cater to a population of 28408 and 3709 compared with 34585 and 5077 in Dharmapuri district. Of the 47 PHC's in Kancheepuram districts, 13 are block PHC's located in each of the 13 blocks of the district. Similarly, of the 69 PHC's in Dharmapuri district, 18 are blocks PHC's in each of its blocks. The remaining 34 and 51 PHC's in Kancheepuram and Dharmapuri district respectively are the additional PHC's. All the 13 block PHC's in
Kancheepuram district are also rural family welfare centres. In Dharmapuri district, 16 of the 18 block level PHC's are rural family welfare centres. There are 4 postpartum centres in operation in Kancheepuram while there are 6 in Dharmapuri dist-rict. Authorized MTP centres exist in 66 in Kancheepuram district while it is only 36 in Dharmapuri district. These also include those in the private sector. Similarly there are 47 approved nursing
homes in Kancheepuram while it is only 30 in Dharmapuri district. The density of such private facilities is much higher in Kancheepuram. Though the district has lower population than Dharmapuri, the absolute number of facilities in the private sector are higher.

District	Kancheepuram	Dharmapuri
Teaching Hospitals	1	0
District Headquarters hospital	1	1
Taluk Hospitals	6	9
Non-Taluk Hospitals	**1**	1
Central Government Hospitals	2	1
Primary Health Centres	47	69
Block PHC	13	18
Additional PHC's	34	51
Rural Population per PHC	28408	34585
Sub-Centres	360	470
Population per sub-centre	3709	5077
Post-Partum Centres	4	6
Urban Family Welfare Centres	1	2
Urban Health Posts		12
Rural Family Welfare Centres	13	16
Approved Nursing Homes	47	30
Unapproved Nursing Homes		9
MTP Approved Centres	66	36

20.

HEALTH FINANCING SYSTEM

Introduction

Health financing is fundamental to the ability of health systems to maintain and improve human welfare. At the extreme, without the necessary funds no health workers would be employed, no medicines would be available and no health promotion or prevention would take place. However, financing is much more than simply generating funds. To understand the nature of the indicators that can be used to monitor and evaluate health system financing requires explicit assessment of what it is expected to achieve.

> *Health financing* refers to the "function of a health system concerned with the mobilization, accumulation and allocation of money to cover the health needs of the people, individually and collectively, in the health system… the purpose of health financing is to make funding available, as well as to set the right financial incentives to providers, to ensure that all individuals have access to effective public health and personal health care" (WHO 2000).

The goals can be expressed in various ways, but there is general consensus that health financing systems should not only seek to raise sufficient funds for health, but should do so in a way that allows people to use needed services without the risk of severe financial hardship – often called financial catastrophe – or impoverishment.[1] This implies two related objectives: to raise sufficient funds and to provide financial risk protection to the population. These objectives will be easier to obtain if the available funds are used efficiently – so efficiency in resource is usually taken as a third objective. As a result, the financing system is often divided conceptually into three inter-related functions – revenue collection, fund pooling, and purchasing/provision of services. Before focusing on measurement strategies and indicators for these functions it is important to understand the key components of each of them.

In most low-income and many middle-income countries, revenue collection derives from a mix of domestic and external sources. Despite the substantial increases in external assistance for health since 2000, the resources available are still insufficient in most low-income settings to assure universal coverage with even a very basic set of needed interventions. This is not the place to debate exactly how much is needed, but adjustment of Commission on Macroeconomics and Health estimates of the cost of a core package to current prices reveals a need for around US$40 per person per year. This is an underestimate for many reasons[2], but even then, almost a third of the 193 member countries of WHO did not yet have access to even this level of funding in 2005, while 33 spend less than $25 per person each year despite increased external inflows. An ideal indicator of this part of the financing system would need to capture the amount and the adequacy of the funds that are raised.

Financial risk protection is determined by how funds are raised and whether and how they are pooled to spread risks across population groups. Direct user-charges, for example, are regressive – the rich pay the same fees as the poor. They deter some people from seeking or continuing care. They also provide no financial risk protection, in that people pay when they are sick and do not pay when they are healthy. As a result of this lack of solidarity, some people incur financial hardship and can even be pushed below the poverty line. Financing policy must grapple with questions of how to raise funds equitably, which usually implies a degree of progressivity (where the rich contribute a higher proportion of their income than the poor). It also needs to consider how to ensure access to needed services while protecting people against the more severe financial consequences of paying for scare. These goals cannot be achieved without some form of prepayment and the subsequent pooling of thecollected revenues – people pay into a pool when they are healthy and can draw on these funds when sick. Pooled funds can come from tax or health insurance contributions and in most countries they come from a mix. Indicators in this area need to capture the extent to which people are protected from the financial risks associated with ill health. It would also be valuable to measure the extent of progressivity in the way that prepaid funds for health (e.g. taxes and insurance premiums) are raised.

The third objective is to ensure efficiency in resource use. This is complex covering questions about how to reduce waste and corruption; what interventions should be available for the available resources; whether services should be provided by government or purchased from the non- government sector; how providers (e.g. health workers, hospitals etc) should be paid to ensure quality and efficiency; and whether to target specific types of services or incentives at the poor. Because of the multiple dimensions, it is not particularly easy to define a single, easily understandable indicator of efficiency for health system financing, something to which we return subsequently.

Sources of information on health system financing

The national government's total budget and the part allocated to health are both usually public information and can be used to evaluate the government commitment to health in total amount as well as proportional to other priorities. A planned budget however, while an important indicator of commitment can differ significantly from the funds that are eventually released to departments and the subsequent expenditures.

In most countries, information on government health expenditures channelled through the Ministry of Health is usually available through the Ministry of Finance (MoF), or regional authorities in decentralized systems. Government expenditures for health that are channelled through non-health ministries, such as military or police health services are sometimes more difficult to attain. While budget information is available in "real time", there is often a delay of a year or so in the production of consolidated expenditure accounts. Public expenditure reviews, if they are available, are often an excellent source of information. They collate information from various sources to ask questions about whether government expenditures followed budget plans and stated strategic objectives. Sometimes they seek to examine the efficiency of resource use, though in very broad terms, as well as the ability of the financial management and accounting systems and institutions to track expenditures.[3]

Information on commitments to official development assistance for health made by donor countries, international organizations and some foundations have been collated by the OECD for many years, and they have reported what they believe to be reliable disbursement data since 2002.[4] This information is available by donor and by recipient country, but caution needs to be taken when using it. Firstly, part of the reported disbursements – a large part in some cases – does not reach the recipient countries and should not be included in estimates of country health expenditure. For example, payments for technical support to countries, payments generally made to nationals of countries other than the recipient country, funds which are generally spent outside the recipient country, are included. Secondly, there has been an increasing move towards general budget support to countries, which is difficult to allocate to the different sectors. General budget support is reported in a separate section in the OECD database, and some way of allocating this between the different sectors needs to be devised. Thirdly, some emerging donors such as China and India, and some private philanthropists, are not included.

It is better to track expenditure from external sources at the country level, but this is often difficult especially where this funding is channelled through non-governmental organizations (NGOs) or the

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private sector. Many countries do not require external donors or NGOs to report their in-country expenditures, or if they are required to submit budgets with proposals at the time they gain permission to work in the country, there is no database where this information is systematically captured nor where actual expenditures are recorded. This also applies to domestic NGOs and other charitable organizations supporting the health sector, where it is often difficult to track expenditures.

National-level expenditures as a result of third-party payments (e.g., from insurance and/or social security) may be available from fund managers. If third-party payers are primarily small community- based organizations, such as community-based health insurance funds, compiling expenditure information is much more difficult.

Information on household out of pocket (OOP) expenditures is only available from household surveys. The World Bank has sponsored Living Standards Measurement Surveys (LSMS) since 1980 from which information on household health expenditures can be extracted and the World Health Surveys sponsored by WHO in 2000-2001 also contained a household expenditure module Many countries undertake household income and/or expenditure surveys of various types from which some information on health expenditures can be gleaned. There is considerable variability in the types of questions used to obtain household health expenditures, making comparability across countries and over time in the same country quite difficult. As a longer run goal it is important to obtain agreement on a standard instrument that would enhance comparability, either for independent surveys or to piggy-back onto other household surveys carried out for various other reasons.

National Health Accounts (NHA): Despite these qualifications, the best source of health expenditure data is from national health accounts which combines expenditure data from all sources and through all types of financial agents.

The System of Health Accounts (SHA) developed by the OECD for its countries has become, more or less, the internationally agreed classification standard although some country analysts prefer to use variations on this theme, including a technique called national account sub-accounts. In general, it is possible to modify the figures emerging from one method to make them consistent with the other. More recently, WHO/World Bank/USAID developed a guide to undertaking national health accounts in low income countries based on SHA, adapting it in some ways to meet the needs of low income countries.[6] Application of the methods in a variety of settings has resulted in collaboration between OECD, Eurostat and WHO to revise SHA with the goal of making it more appropriate to countries at all income levels.[7]

Some countries undertaken regular NHA studies. Others have undertaken one or two studies, but do not undertake them routinely, while still others have yet to undertake a full NHA exercise. In the latter case, data on health expenditures need to be collated from various sources. WHO works with countries to collate information from these sources which, combined with the information provided by countries who have undertaken NHA studies, allows annual reports of selected health expenditure aggregates for 192 of its 193 member countries.[8] These figures also form the basis of the health expenditure data reported in the World Bank's World Development Indicators.[9]

Support to countries seeking to develop better information on health expenditures is currently provided from various sources, including the USAID supported Health Systems 20/20 project, WHO and the Swedish aid agency SIDA, though there is still some way to go to have full NHA analyses institutionalized in all countries.

Core indicators

Building on the discussion in section 1) above, core indicators for the availability of funds and the extent of financial risk protection have been agreed at various fora[10].

Recommended core indicator #1: Total Health Expenditure (THE) per capita in international and US$

This indicator provides information on overall availability of funds. Sufficiency must be judged as a second step, in relation to country-specific estimates of the funds needed to ensure access to the desired level of services, or in terms of comparisons with other countries with similar levels of GDP per head. Some countries also seek to compare their total health expenditures as a proportion of GDP with those in other countries, so this is included in Table 1 as a possible additional indicator.

Definition

- Numerator: The sum of all health expenditures (ideally from National Health Accounts and including all sources of funds – external, government, and non-government including household OOPs).
- Denominator: Total population.

Data collection methodology

Country-specific reporting by the MoF/MoH/ other relevant ministries (for government expenditures), donors (for funding not channeled through the MoF/MoH), insurance fund managers (for third-party funding) and household surveys (for OOP expenditures) using National Health Accounts methodology. Population numbers should ideally be de facto rather than de jure population, with the most complete cross country source being the UN Population Division.

Periodicity

Health expenditures should ideally be calculated on an annual basis. Full surveys of household expenditure are quite expensive and might need to be done less frequently, with extrapolations in the inter-survey years.

Cost

The cost of initially producing NHA varies considerably depending on the information and bureaucratic structure already available and the need for external technical assistance. Experience in some countries has shown that the costs to pull together existing information for the first NHA could be as low as US$ 50 000 to US$ 75 000 with subsequent year costs largely related to producing recurrent statistics. This assumes that household expenditure surveys are already available and that international consultants do not do the bulk of the work. Initial costs include a) training personnel; b)

ensuring adequate computers and office infrastructure; c) logistics related to explanatory meetings and training on completing reporting forms or collecting information; and d) development of reports templates relevant for national planning (WHO 2003b).

Recommended core indicator #1a: General government health expenditure as a proportion of total government expenditure (GGHE/GGE).

This is related to the question of how much funding is raised for health and reflects government commitment. African heads of state committed to ensuring that 15% of overall government expenditure goes to health in the Abuja Declaration of 2001. This can be taken as an aspirational goal,

although few of even the richer countries in the world currently achieve it. While it is difficult to justify why 15% is the ideal cut point, many countries still devote less than 4% of GGE to health suggesting low levels of government commitment.

Recommended core indicator #2: The ratio of household out-of-pocket payments for health to total health expenditures.

The ideal indicator of financial risk protection is the proportion of the population is incurring catastrophic health expenditure due to OOPs. A variation is the percentage that is impoverished as a result of out-of-pocket.

WHO has defined financial catastrophe for the last 8 years as direct OOPs exceeding 40 percent of household income net of subsistence needs. Subsistence needs are taken to be the median household's food expenditure in the country. Expenditures in excess of the 40% cut point generally require reallocation of household expenditures from basic needs, sometimes even from children's education[11]. More recently, the World Bank has found it simpler to define financial catastrophe occurring when OOPs exceeds 10% of a household's total income. While this does not incorporate the progressivity allowed by the deduction of basic subsistence needs, it is probably simpler to estimate and seems to provide more or less the same estimates as the WHO method.

In most cases, it will be possible to estimate the incidence of financial catastrophe by income quintile, or by wealth quintile if a separate wealth or asset index can be constructed from the same household survey, to explore questions of equity. Indeed, in most developing countries, self reported total expenditure is regarded as a more reliable indicator of command over resources than self reported income, so these comparisons are usually made in terms of total expenditure quintiles.[12] In any case, such comparisons need to be interpreted carefully. In many countries the quintile with the lowest income (or lowest level of total expenditure) has a lower incidence of catastrophic payments than richer quintiles. This reflects the perverse nature of user fees. When people are very poor, they simply do not use services for which they have to pay, so do not suffer financial catastrophe. As they grow slightly richer, they begin to use services, but then suffer the adverse financial consequences linked to paying for care.

Definition

Number of households in each region where direct out-of-pocket payments to providers for health during the past 12 months was more than 40% of their household income net of subsistence, or 10% of their total income.

- Numerator: Household out of pocket expenditure for health during the past 12 months.
- Denominator: Household income. As argued above, in most developing countries it is accepted that self-reported total health expenditure is a more reliable indicator of household purchasing power than self-reported income, so this should be used as the denominator in those settings.

Data collection methodology

Household interview surveys.

Periodicity

The ratio is not likely to change dramatically over time unless there are substantial health financing reforms. In most countries, measurement each five years would be adequate.

Cost

The cost for undertaking a national level household survey with a sample size sufficient for regional level disaggregation specifically for the purpose of collecting health expenditure data varies widely depending on the existing in-country capacity. The range may be from $350 000 to $1 000 000 depending on the level of technical support required. However, usually health expenditure data would be collected as part of a broader income and expenditure survey, or as an added module in a broader health survey. Accordingly, the additional costs are likely to be relatively small. The main new cost will be incurred by personnel who analyze the data and produce the information for policy makers.

Despite the logic of using the incidence of financial catastrophe as the core indicator, it is sometimes argued that a simpler indicator of financial risk protection is the ratio of out of pocket spending to total health expenditure (OOPs/THE) – or the inverse, the ratio of prepaid expenditures (taxes and insurance) to THE. Undoubtedly there is a high correlation between this indicator and the incidence of financial catastrophe (and impoverishment), so we include this as the core indicator here.

While it may appear simpler, it requires exactly the same data from household expenditure surveys as the indicator on financial catastrophe described above. So if the surveys are available to estimate OOPs/THE, they are available to estimate the incidence of financial catastrophe. Experience has shown that policy makers can immediately see the political relevance of the incidence of financial catastrophe and/or impoverishment, whereas the ratio of OOPs to THE may not have the same immediate policy impact. For the purposes of discussion, at this stage we use OOPs/THE as the recommended indicator in table 1, with the incidence of financial catastrophe as an optional indicator. However, the preference ordering could easily be reversed.

At this stage, we are not recommending a core indicator to capture the efficiency of the health financing system because it is difficult to define a single indicator that is relatively simple to measure and easy to interpret. We have included the proportion of total government health expenditure spent on salaries as one possible optional indicator, but we need to emphasize that this needs to be interpreted very carefully. Certainly if this proportion is very high, health workers will not have sufficient drugs or other inputs to be able to do their jobs properly. However, in some countries this proportion is low because governments choose to contract out the provision of services to the private sector or NGOs rather than employ there own personnel. In this case, the proportion spent on salaries seems to be very low because payments to external contractors do not appear as salaries. It then is not a very useful indicator of efficiency.

In addition, we have suggested some optional indicators that could be measured depending on the capacity of the country. Some reflect processes or outputs, while some are more related to outcomes. They are summarized in Table 1 below, with appropriate comments in the text.

Needs assessment for institutionalizing collection of data for monitoring finance indicators

Since THE is currently being reported for 192 of the 193 WHO member countries, the primary need is to improve the quality of the information that is already being collected, and to strengthen the institutionalization of the generation and utilization of this information. This requires regular and accurate reporting of government expenditures at all levels of government, regular household expenditure surveys, and some method of routinely tracking expenditure by NGOs, faith-based organizations, philanthropies and the private sector.

WHO has identified four steps essential to the process of institutionalization of NHAs (WHO 2003). These are a) Creating demand on the part of policymakers for institutionalization; b) Determining a location where NHA is housed; c) Establishing standards for data collection and analysis; and d) Instituting data reporting requirements.
The process for institutionalizing NHA requires an assessment of existing infrastructure and systems. Critical

information includes:

1) Government and stakeholder commitment to NHA as indicated by such steps as delegation of responsibility for generating NHA to a specified body and allocation of a budget for implementation.
2) An assessment of existing human resources numbers and capacity, and infrastructure for generating NHA data.
3) Clarity of health financing mechanisms including funding sources, processes for channelling funds, and information on where information on external health funding and third-party funding is available including if it is

provided to any central or coordinating body. An assessment of the process currently used by WHO for NHA estimates for the country and identification of which data is weakest or least reliable should provide this information.

4) Identification of problems with regards to transparency in national or donor health funding, and the need for policy changes or advocacy to improve this.
5) Development of an audit function within the NHA to periodically assess the completeness and accurate of the submitted or collected information is, with a systematic strategy for feedback to the data sources to improve availability and quality of needed information.

HEALTHCARE AND HOSPITAL MANAGEMENT
UNIT II

Organizational Structure of a Hospital

Every hospital, large or small, has an organizational structure that allows for the efficient management of departments. The student will identify the levels of management and describe the activities and concerns of specific departments within each level.

I. Importance of Understanding Organizational Structure of Hospital
   - A. facilitates the understanding of the hospital's chain of command
   - B. shows which individual or department is accountable for each area of the hospital

II. Complexity of Organizational Structure Depends on Size of Healthcare Facility; large acute care hospitals have complicated structures, whereas, the smaller institutions have a much simpler organizational structure

III. Grouping of Hospital Departments Within the Organizational Structure
   - A. Although each hospital department performs specific functions, departments are generally grouped according to similarity of duties.
   - B. Departments are also grouped together in order to promote efficiency of the healthcare facility.
   - C. Common organizational categories might include:
     1. Administration Services (often referred to simply as "administration")
     2. Informational Services
     3. Therapeutic Services
     4. Diagnostic Services
     5. Support Services (sometimes referred to as "Environmental Services")

IV. **Administration Services**—business people who "run" the hospital
   - A. Hospital Administrators
     1. manage and oversee the operation of departments
        - a. oversee budgeting and finance
        - b. establish hospital policies and procedures
        - c. perform public relation duties
     2. generally include: Hospital President, Vice Presidents, Executive Assistants, Department Heads

V. **Informational Services**—documents and process information
   - A. Admissions-often the public's first contact with hospital personnel
     1. checks patients into hospital
        - a. responsibilities include: obtaining vital information (patient's full name, address, phone number, admitting doctor, admitting diagnosis, social security number, date of birth, all insurance information)
        - b. frequently, admissions will assign in-house patients their hospital room

B. Billing and Collection Departments - responsible for billing patients for services rendered
C. Medical Records - responsible for maintaining copies of all patient records
D. Information Systems - responsible for computers and hospital network
E. Health Education - responsible for staff and patient health-related education
F. Human Resources - responsible for recruiting/ hiring employees and employee benefits

VI. **Therapeutic Services** – provides treatment to patients

A. includes the following departments:

1. Physical Therapy (PT)
   a. provide treatment to improve large-muscle mobility and prevent or limit permanent disability
   b. treatments may include: exercise, massage, hydrotherapy, ultrasound, electrical stimulation, heat application
2. Occupational Therapy (OT)
   a. goal of treatment is to help patient regain fine motor skills so that they can function independently at home and work
   b. treatments might include: arts and crafts that help with hand-eye coordination, games and recreation to help patients develop balance and coordination, social activities to assist patient's with emotional health
3. Speech/Language Pathology
   a. identify, evaluate, and treat patients with speech and language disorders
   b. also help patients cope with problems created by speech impairments
4. Respiratory Therapy (RT)
   a. treat patient's with heart and lung diseases
   b. treatment might include: oxygen, medications, breathing exercises
5. Medical Psychology
   a. concerned with mental well-being of patients
   b. treatments might include: talk therapy, behavior modification, muscle relaxation, medications, group therapy, recreational therapies (art, music, dance)
6. Social Services
   a. aid patients by referring them to community resources for living assistance (housing, medical, mental, financial)
   b. social worker specialties include: child welfare, geriatrics, family, correctional (jail)
7. Pharmacy
   a. dispense medications per written orders of physician, dentists, etc.
   b. provide information on drugs and correct ways to use them
   c. ensure drug compatibility
8. Dietary - responsible for helping patients maintain nutritionally sound diets
9. Sports Medicine
   a. provide rehabilitative services to athletes
   b. teaches proper nutrition
   c. prescribe exercises to increase strength and flexibility or correct weaknesses
   d. apply tape or padding to protect body parts
   e. administer first aid for sports injuries
10. Nursing (RN, LVN, LPN)
    a. provide care for patients as directed by physicians

b. many nursing specialties include: nurse practitioner, labor and delivery nurse, neonatal nurse, emergency room nurse, nurse midwife, surgical nurse, nurse anesthetist

c. In some facilities, *Nursing* is a service in and of itself.

VII. **Diagnostic Services** – determines cause(s) of illness or injury

A. includes the following departments:

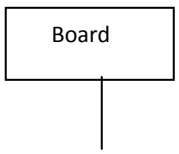
1. Medical Laboratory (MT) - studies body tissues to determine abnormalities
2. Imaging
   a. image body parts to determine lesions and abnormalities
   b. includes the following: Diagnostic Radiology, MRI, CT, Ultra Sound
3. Emergency Medicine - provides emergency diagnoses and treatment

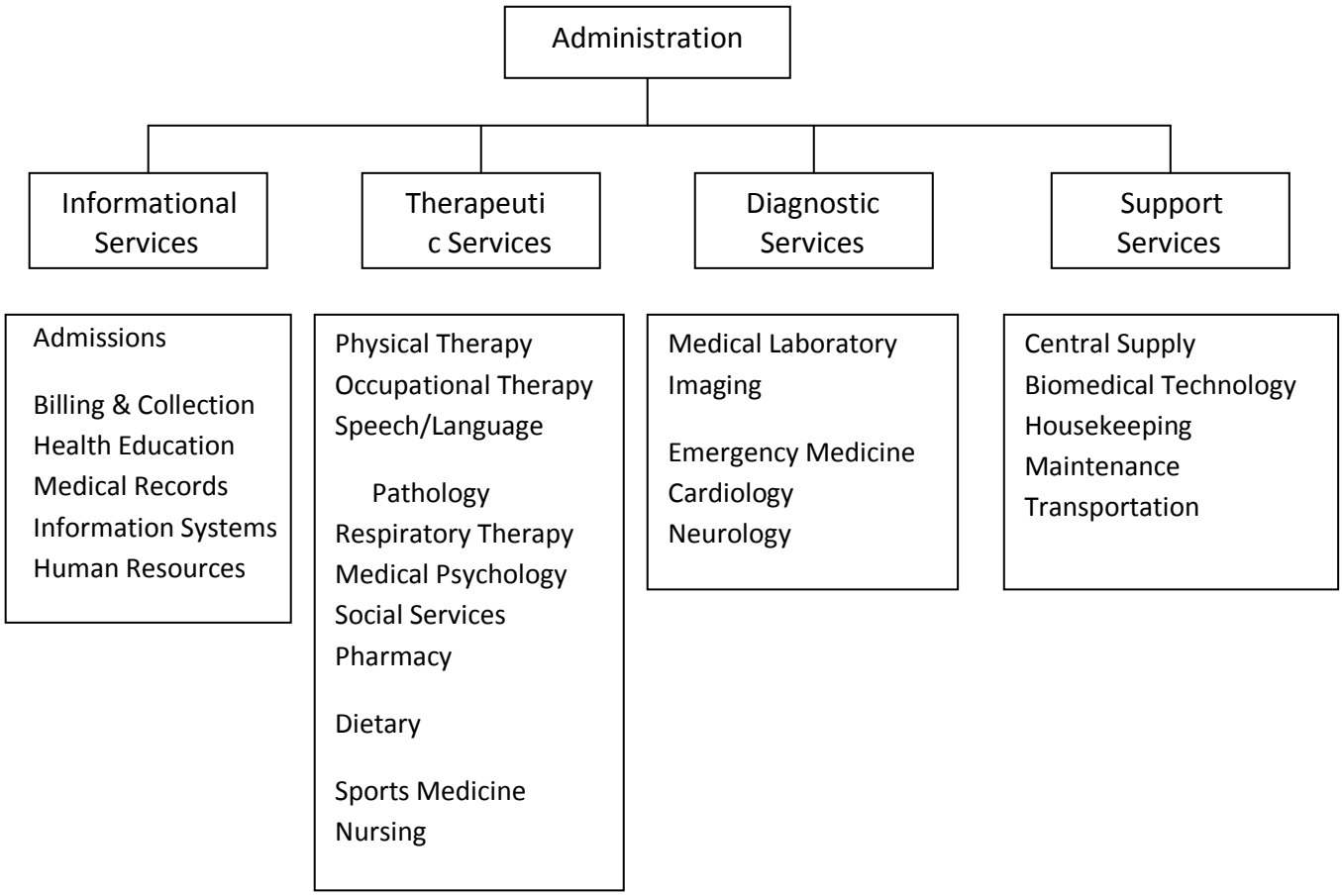
VIII. **Support Services**—provides support to entire hospital

A. includes the following departments:

1. Central Supply
   a. in charge of ordering, receiving, stocking and distributing all equipment and supplies used by healthcare facility
   b. sterilize instruments or supplies
   c. clean and maintain hospital linen and patient gowns
2. Biomedical Technology
   a. design and build biomedical equipment (engineers)
   b. diagnose and repair defective equipment (biomedical technicians)
   c. provide preventative maintenance to all hospital equipment (biomedical technicians)
   d. pilot use of medical equipment to other hospital employees (biomedical technicians)
3. Housekeeping and Maintenance
   a. maintain safe clean environment
   b. cleaners, electricians, carpenters, gardeners

IX. Traditional Organizational Chart:





Health is an important factor in the formation of human resources development which will play a vital role in improving the qualities of human beings, who are the active agents of economic development. So any measure of development achievement in a nation must affect the state of personal wealth in the nation. Better wealth would contribute to improving the economic status of the poor and for expanding total output. This demands sound management of a hospital. Therefore in this chapter the researcher has made an attempt to discuss about the meaning of hospital and hospital management, evolution of hospitals, changing concept of hospital, role of hospital administrator, functions of hospital management, hospital services and to present a picture of number of public hospitals and beds in India.

1. Meaning of a hospital

According to the World Health organization, Health is a "State of complete physical, mental and social well being and not merely the absence of disease or deformility"[1].One of the fundamental rights of every human being without distinction of race, religion, political belief, etc. is the enjoyment of the highest attainable standard of health [2]. But, owing to a variety of factors like lack of health consciousness, low per capita income, lack of adequate education, on availability of proper sanitary condition and safe drinking water, unhealthy social taboos etc., the health status of the average Indian remains dissatisfactory. It has been the endeavor of successive Government in India to improve the situation. This is especially so after the Independence. The National Health Policy which was approved by the Parliament and announced by the Government in 1983 marked a beginning to the Quest for equity in health expressed as WHO's goal of " Health For All " by the year 2000 A.D.[3]. To achieve this goal massive inputs with restructuring of the organization setup and management has been achieved incurring huge amounts of revenue expenditure as

well as capital expenditure financed from various sources- Central Government, State Government and externally aided projects. In views of this currently there have been many emphases on analytical study of hospital management pattern of health care expenditure and determination of costs of service. As the present research study is on a managerial appraisal of public hospital in Gujarat (Located at district head quarter), in this chapter the researcher has tried to present theoretical aspects of Hospital Management.

Hospital first came into existence prior to 1000 B.C. [4].

Grammar of the word differs slightly depending on the dialect. In the
U.S. hospital usually requires an article, in Britain and elsewhere the word is normally used without an article when it is the object of a preposition and when referring to a patient ("into the hospital's") in Canada, both usages are found [5.]

During the Middle ages the hospital could serve other functions, such as almshouse for the poor, or hostel for pilgrims The name comes from Latin hopes (host), which is also the root for the English words hotel, hostel and hospitality. The modern word hospital derives from the French word hostel, which featured a silent, which was eventually removed from the word; French for hospital is hospital [6].

In the present time, a hospital is an institution for health care, often but not always provides large term patient stays. "The hospital is an integral part of the social and medical organization, the function of which is to provide for the population complete health care, both curative and preventive, and whose outpatient services reach out to the family and its home environment. The hospital is also a centre for training of health workers and for biosocial research"[7].

The modern concept of the hospital visualizes it, as one of a comprehensive system of preventive and curative medicine and as an institution devoted not only to inpatient treatment, but also to ambulatory and domiciliary use [8].

From above definition, it can be said that the hospital is a complex organization and an institute which provides health to peoples through complicated but specialized scientific equipment and a team of trained staff educated in the problems of modern medical science. They are all co-ordinate together for the common goal of restoring and maintaining a good health of the people who go there for relief from the pain, suffering and disease.

Thus, the hospital is a specialized body where the patient care is the focal point and about which all activities of the hospital revolve. The physician who examines and takes care of the patient is in the principal position and special facilities and trained personnel are provided to him to make his work easy and efficient, trained personnel includes technical staff of nurses, dieticians and pharmacists.

From the organizational and administrative point of view, a hospital is virtually a city within a city. Within its four walls, it has an operation theatre, a hospital which is in the shape of the patients rooms, a dormitory for student nurses, residents and interns, a school for training of nurses, technicians, dietician, laboratories, a pharmacy, food vending operations, laundry and linen service, delivery service, a post office, massive internal and external communication system, blood bank, accounting and credit services, a public relation department, a motor service, and security patrols [9.] In short the hospital is a healthcare Organization.

2. Meaning of hospital management :

Hospital Management can have different meanings

- Management as a process: Often it is said that it is a professionally managed hospital; it is well managed hospital, meaning thereby the management is described as an activity, type of work. Management applies certain principles, techniques and activities which are performed by certain management functions.What the hospital Management does is Management.

- Hospital Management is a subject: A subject, a discipline taught in universities, colleges or institutes. It is an accumulated body of knowledge that can be learned, at some places the broad specialty is Health Management including Hospital Management.Various degrees, diplomas, certificate courses are run by the institution/universities.

- Hospital management as people: The Management of this hospital is very insensitive, the hospital management of this hospital is not responsive to society are the terms often used. While using these terms, we are referring to body of people responsible for management, the board of directors, director, medical superintendent and his team.
- Hospital management as career: News published in the national daily says that hospital management will be among top ten careers in the next decade. Such statements imply that hospital management is a career.

The team management has been defined by different expects as below

According to Hawalskantz,

- "Management is the art of getting things done through and with the people in formally organized groups."[10]

According to George Terry,

- "Management is the process undertaken by one or more person to coordinate the activities of other persons to achieve results not attainable by any one person acting alone."[11]

According to McFarland,

- "Management is a distinct process consisting of activates of planning, organizing, actuating and controlling, performed to determine and accomplish stated objectives with the use of human beings and other resources."[12]

From above discussion, the application of management in hospital can be defined as below.

A. As a hospital administrator, he has to carry out management functions of planning, organizing, staffing, directing, controlling and coordinating.

B. Management applies to all kinds of organization, whether government or non government, small or big hospital, profit making hospitals or charitable hospitals.

C. It applies to administrator at all organizational level, whether lower level or top level.

D. The aim of all administrators is the same that is to maximize the output.

E. It is concerned with productivity that implies effectiveness and efficiency.

3. Evolution of hospitals :

Evolution of hospitals has been divided into two parts

History of hospitals

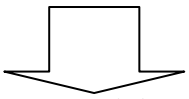
Changing concept of hospitals

History of hospitals :

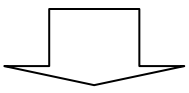
History of hospitals has been discussed under six heads as below

Chart :1.1 History of hospitals in ancient period

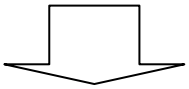
Hotel Dieu,Paris – 542 AD



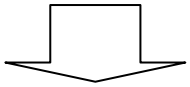
St.Bartholomew's Hospital, London 1123 AD



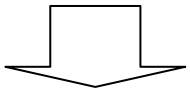
Spanish Hospital,Mexico City 1524 AD



Bellevue Hospital New York 1736 AD



First General Hospital, North America (Pennsylvania Hospital) 1751 AD



Massachusetts hospital 1811 AD

(a) Early History: The word hospital originates from Latin word 'hospice'[13]. A place where a guest is received is called hospitable, an institution for the care of sick and injured. In the early period, during Greek and Roman Civilization the temples were used as hospitals and these hospitals were integral part of the temples. With the birth and spread of Christianity, the hospitals became an integral part of Church. Some of the notable hospitals established in Europe date back to ancient times. The earliest Hospital was founded at Hotel Dieu,

Paris in 542 AD. St Bartholomew`s hospital London dates back to 1123 AD. In 1524, Spanish built the first hospital in Mexico. The first general hospital opened in 1751 in North America as Pennsylvania hospital. Thereafter, Bellevue Hospital in New York in 1736 and Massachusetts Hospital in 1811 AD.[14.]

The advances in medical science in the field of microbiology, pharmacology, radiation, blood transfusion, anesthesiology, surgical techniques and computers all led to exponential growth in hospital services.

(b) Ancient Asia: Sri Lankans are responsible for introducing the concept of dedicated hospitals to the world. The ancient Chronicle of Sinhalese Royalty written in 6th century A.D, King Pandukabhaya had lying in homes and hospitals built in various parts of the country. Mihintale Hospital is perhaps the oldest one in the world. King Ashoks founded 18 hospitals in 230 B.C.These were state supported hospitals. The first teaching hospital was the Academy of Gundishapur in the Persian Empire [15].

(c) Modern Era: By the mid 19th Century most of the Europe and United States had established a number of public and privet hospital systems. In Continental Europe, the new hospitals were generally built and run by public funds. In the United Kingdom, the hospital sector is dominated by National Health Service. In the United States, the traditional hospital is a nonprofit hospital. In the late 20th Century, the concept of nonprofit hospital was switched over to chains of for profit hospital.

(d) Period of Growth: The first hospital in USA was founded in 1751, the Pennsylvania Hospital. Rapid growth in the field of hospital occurred in between 1860 to 1920; however the number reached to its peak to 7370 in 1924. The main reason to the growth of the hospital can be credited to the rapid advancement in the field of medicine. During 19th century, allopathic medicine was only one of many theories of the disease causation and cure. Before 1900, most of the hospital was proprietary, in a significant development. The john Hopkins University Medical School was founded. Emergence of nursing as a profession and change in society's attitude towards hospital shaped the role of hospital in patient care further. Florence Nightingale was instrumental in these changes. First three schools of Nursing in United States were established in 1973. Improvement in society's attitude towards acute care hospitals occurred slowly [16].

(e) Consolidation (1920-1950) : The increasing average size of the hospitals improved the comprehensiveness

and quality of medical care The American College of Surgeons (ACS) was constituted in 1913. The ACS developed standards for hospital "Hospital standardization Program" in 1918, for approval. Later on, this program was taken over by joint Commission on Accreditation of Healthcare Organization (JCAHO). The JCAHO is instrumental in development in application of structure, process and outcome criteria for hospitals another event effecting the growth and development of hospitals between the period 1920 to 1950 was introduction and operation of insurance section in the health care in United States. The general and acute care hospitals established during the period were mainly from private and voluntary action during Second World War. The number of hospital increased significantly. During 1970, hospitals were included under federal labor legislation in USA[17]. The hospital in the present era is now not only high-tech, but also operating from remote places like tale surgery and tale medicines. The hospital not only providing care and comfort to patient, but also to the visitors, attendants of patients. We are moving one step further to medical tourism The hospitals have grown from the time of free treatment, fee for service to profit making organization, trying to compete with any corporate sector.

(f) Hospitals after independence: India became free in 1947 and there were 7400 hospitals and dispensaries in India [18]. There were 113000 beds with bed population ratio of 2/1000 population [19]. There were 19 medical colleges and 19 medical schools [20]. it was felt by Government of India that with the rising population and projected growth rate, it would not be possible to cope up with the health needs and demands of the community. Various committees were formed to suggest means and methods to reorganize the health care delivery system. Some of these important committees were Bhore Committee, Mudaliar Committee. Jain Committee, siddhu Committee, Rao Committee, Sri Vastava Committee and Bajaj Committee.

As per Health information of India, we have 229 medical colleges, 189 dental colleges, 209 Ayurvedic medical colleges, 36 Unani, 6 siddha and 180 Homeopathic medical colleges, 36 Unani, 6 Siddha and 180 Homeopathic medical colleges [21]. As on 1st January, 2002, India has 15393 hospitals with 914543 total beds and 89 beds/lakh population [22]. India has 3043 CHCs, 22842 OHCs and 137311 Sub Centers as on 1st March, 2001 [23]. Since independence, lot of advancement has been made in health sector but still much remains to be done because still all these figures are far below the national target of at least 1 bed/1000 population as recommended by Mudaliar Committee in 1961 [24].

Changing concept of hospitals :

The concept in the field of hospital is fast changing, The changing concept of hospitals is broadly divided into four periods.

1. **Trusteeship Period**

Most of the hospitals were run and managed by the trustee's .The advances in technology were minimal during that period. This period lasted till 1920. The doctors and nurses are not working for money, the approach was only humanitarian. The objectives of the hospital remained to provide comfort to the patient.

2. **Physician Period**

It was being utilized for medical. The hospitals were being utilized for medical practice. The laboratory medicine developed during the period 1940 to 1950. The political and economic environment started influencing the hospitals.

3. **Administrative and Team Periods**

The hospital practice became a team approach. The advances in technology became more rapid. The use of computers and application of computers in patient's care and management of hospitals changed the scenario. People started thinking about professionally managing the hospital.

4. **Growth of Corporate Sector**

With liberalization policy of the government all over the world lead to globalization. The rapid advancement in the field of information technology, with fast and safe air travel all over the world lead to the concepts of medical tourism, the concept of corporatization of the hospital. The hospital concept has changed from service approach to the profit making approach. The doctors have started thinking on management principles and functions for productivity. Telemedicine is a new addition. The patients can be treated and monitored by remote devices. The government all over the world has started thinking about easing the burden of financing the healthcare. The new emerging concept of contracting or public-private-partnership (PPP) is

growing very fast. The financing of health services though insurance sector has become need of the hour.

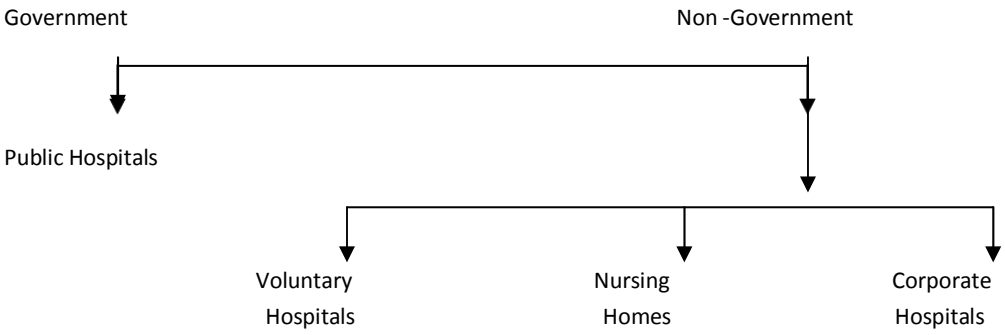
4Types of hospitals:

There is wide range of hospitals Some hospitals are small, some are big, some imparting teaching and training facilities, some are owned by private bodies, some are special hospitals and so on. These hospitals can be categorized or classified in several manners. Some of the methods of classification of hospital are given below

a. According to ownership and control.

Chart 1.1.1

Classification of hospital based up on ownership and control is present as below :



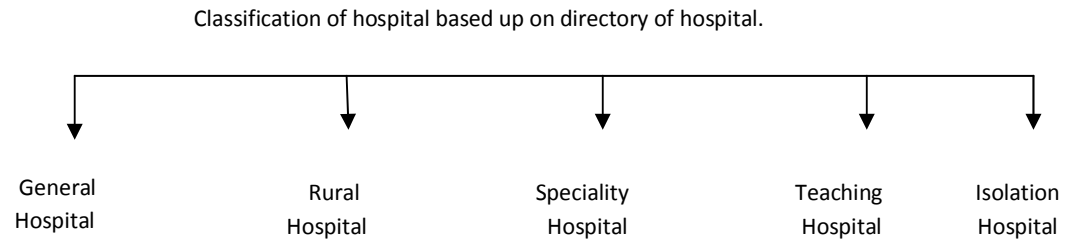
- Public hospitals: The hospitals run by central or state government, local bodies and public sector undertaking. The hospitals are purely service organizations and nonprofit making hospitals. Examples are civil hospitals.
- Voluntary Hospitals: These hospital are registered under the societies act or public trust act. They are run by trusts and on non commercial basis examples, charitable hospitals.
- Nursing Homes: Generally owned and, managed by individual doctors. These hospitals generally do not admit cases of medico legal

importance and the patient care services are usually provided in some of the specialties of medicine. Some of the nursing homes provide only maternity care. Some hospitals even provide tertiary care in some super specialties like cardiology, Nephrology. Example is Mayo medical centre. Awadh Hospital at Lucknow city, etc.

- Corporate Hospitals: These hospitals are run on the basis of profit-earning and are registered under companies act. Examples are Hinduja Hospital, Apollo Hospital, etc.

b. According to Directory of Hospital

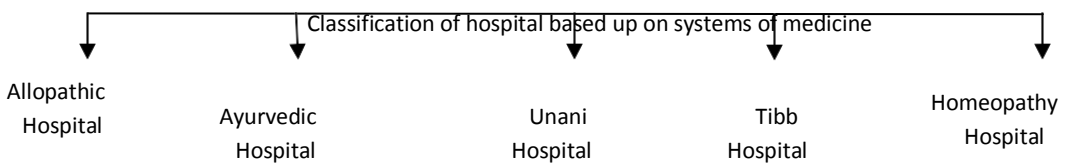
Chart 1.1.2



- General Hospital: These hospitals usually provide medical care in more than one broad specialty and there is no strict departmentation.
- Rural Hospitals **:**The hospitals located in rural areas.
- Specialty Hospitals : Hospital providing medical care usually in one or more specialty like TB Hospital, Eye Hospital, Cancer Hospital, heart centers etc .
- Teaching Hospital :Usually the hospitals attached to medical college
- Isolation Hospital :Hospitals providing patient care to communicable diseases.

c. According to systems of medicine.

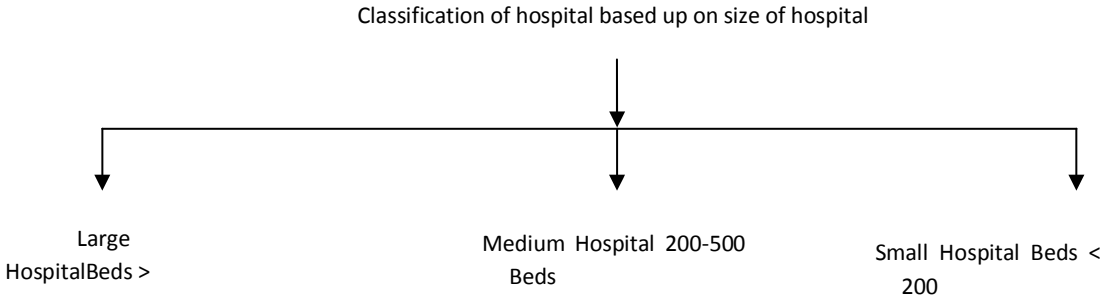
Chart 1.1.3



Various systems of medicines like Allopathic, Ayurvedic, Unani, Tibb, Homeopathy, have their own hospital.

d. According to size of hospital.

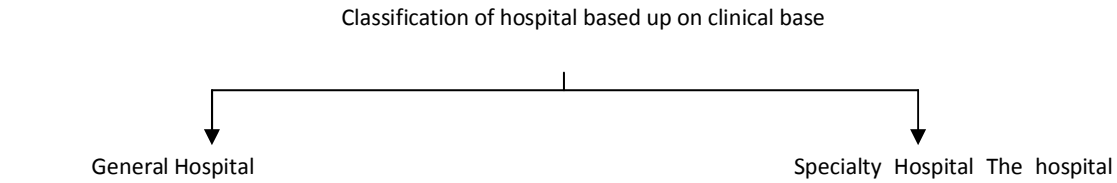
Chart 1.1.4



The hospitals can be classified as small, medium or large size depending upon the bed strength of the hospitals. Hospitals having more than 500 beds are usually called large hospitals. Hospitals having bed strength from 200 to 500 are called medium size hospitals and hospitals having less than 200 beds are small hospitals.

e. According to clinical base.

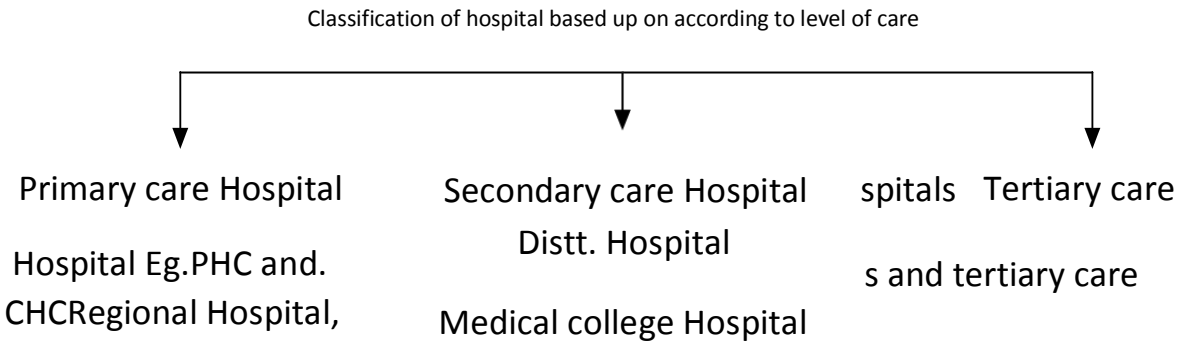
Chart 1.1.5



The hospital can be classified as general hospital or specialized hospital.

f. According to level of care.

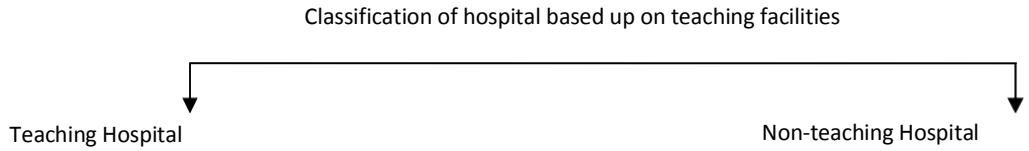
Chart 1.1.6



hospitals like regional hospitals or hospital associated with medical college.

g. According to teaching facilities.

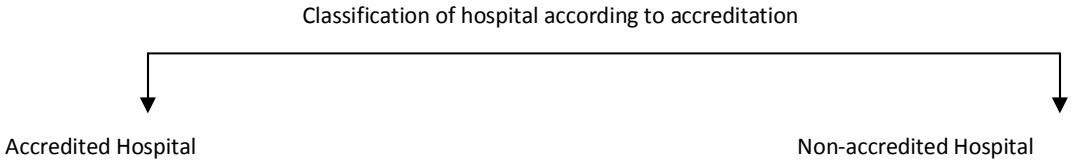
Chart 1.1.7



The hospital can be classified as teaching hospital or non teaching hospital.

h. According to accreditation.

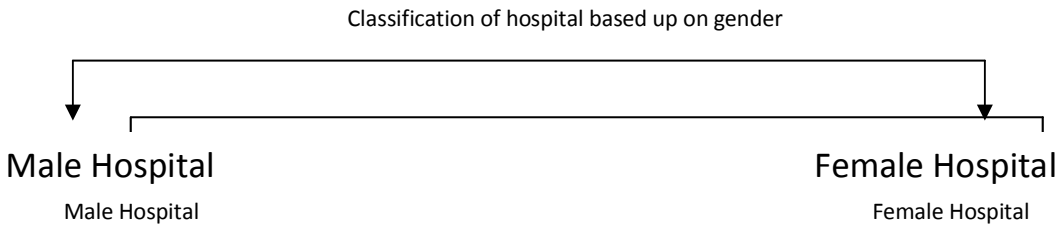
Chart 1.1.8



Now on time to come, the hospital will be classified as accredited hospitals and non accredited hospitals. In USA and Europe, this lassification is more relevant, as far as the quality of medical care is concerned. In India also the steps are being taken in this regard.

i. According to gender.

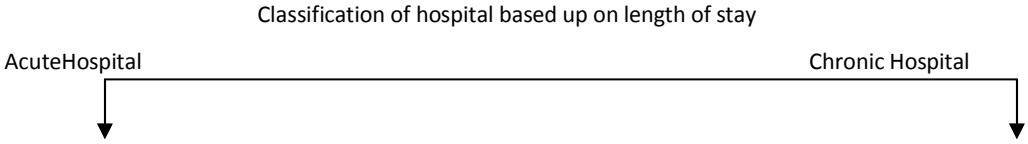
Chart 1.1.9



Some of the hospital is also classified on the basis of male hospital and female hospital, particularly in the public sectors, at district level.

j. According to length of stay.

Chart 1.1.10



Hospitals can also be classified on the basis of length of stay of patients. The hospitals may be under the category of short term or long term or acute or chronic hospital respectively.

5. Roles of hospital Administrator:

By virtue of serving a health care organization, the hospital administrator performs some specific roles which are described below. The hospital administrator ensures that hospital runs effectively and efficiently. The role of hospital administrator varies, depending up on the nature and complexity of hospital, various roles can be grouped as role towards patients, towards hospital organization, towards community.

Role Towards Patients,
Role Towards Hospital Organization,
Role Towards Community,

Role Towards Patients:

The hospital administrator has a great responsibility to understand and appreciate the emotional aspects of the patient care, his responsibility is to understand the specific needs of certain groups of patients, i.e. patients on wheelchairs, stretchers, geriatric group of patients, pediatric patients, neonates, serious cases, foreign nationals etc. Some of the aspects of patients are given below.

i. Creation of friendly environment,
ii. Understanding patient's physical needs,
iii. Patient's emotional needs,
iv. Patient's clinical needs,
v. Patient's satisfaction,
vi. Patient's education,
vii. Patient's communication needs,

Role Towards Hospital Organization:

To handle the hospital resources for maximizing the output is one of the fundamental roles of the administrator. Hospital is a complex organization it is a labor intensive organization working for day and night and without break; expectations of the workers are very high and unity of direction and unity of command are often violated. The role of administrator is more of coordination in nature instead of controlling he is coordinating officer. Under the role a hospital administrator performs following function.

i. Strategic planning,
ii. Environmental influence on the hospital,
iii. Operational management,
iv. Management of hospital staff,
v. Materials management,
vi. Financial management,
vii. Hospital information,
viii. Communication,
ix. Public relation,
x. Risk management,
xi. Law, Ethics and Code of Conduct,

xii. Marketing of health services,

xiii. Quality management,

Role Towards Community:

Hospital is a community organization; it receives inputs from the community in the form of manpower, material, money, machines,

land, building, environment, information and gives output to the community. Community participation is must for the success of any health program. The utilization of health facility is also an important behavior of the community. Hospital may provide State of the art Care, but if community does not utilize it; it will go to waste. Hospital must fulfill the felt needs of the community. There should be social responsiveness and social responsibility of the hospital administrator. This can be achieved by:

i. Integrating with primary health care,

ii. Integrating hospital with other health care organizations,

iii. Community participation in planning of services and also for utilization of hospital services,

iv. Outreach program: Outreach program like health camps, camp surgery, swarthy melas, immunization camps, etc.

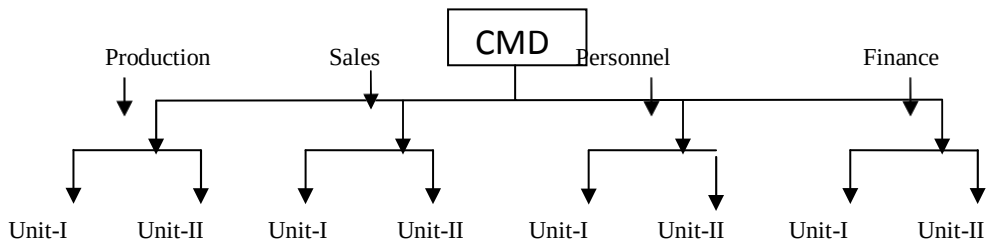
6. Functions of hospital management:

The hospital is an integral part of a social and medical organization, the function of which is to provide for the population complete health care, both curative and preventive and whose outpatient services reach out to the family and its home environment; the hospital is also a centre for the training of health worker and for biosocial research (WHO) [25.] Management is the process of designing and maintaining an environment in which individuals, working together in groups, efficiently accomplish selected aims [26].The management functions remain the same in all types of the organizations, whether production industry or the service industry like hospital. The organizational structure of hospital as given in chart 1.2 is different from the structure of the production industry. The organizational structure is more like a matrix organization. There is no clear cut chain of commands and lack of departmentations. The clinical and service

departments of the hospitals are entirely different in structure and reporting relationship in comparison to the production industry. In production industry, there is rigid departmentation, line of reporting relationship, clear demarcation between the line and staff authorities. These things make the hospital organization a very peculiar organization.

Chart 1.2

Organization structure of hospital



Management process in general: The functions of the management in all types of the organization remains the same and revolves round the following management functions. These are summarized below:

- **Planning :**
  - Objectives of the individual
  - Objectives of the organization
  - Policy and strategy of the hospital
  - Rules and procedures of hospital
  - Various health programs of the hospital
  - Priorities of the hospital
- **Organizing :**
  - Span of control
  - Delegation of authority
  - Use of staff and service groups
  - Informal groups of hospital
  - Integration of structural activities
- **Staffing :**
  - Recruitment procedure
  - Developmental schemes of hospital in relation to human resource
  - Maintenance of staff
  - Utilization of staff
- **Directing :**
  - Leading the staff
  - Motivating the staff
  - Communication channels and methods
  - Job satisfaction
  - Job enrichment and job enlargement schemes
  - Supervising of staff
- **Controlling :**
  - Establishing standards of performance
  - Methods of measurement of performance
  - Comparison of performance with standards
  - Improving rate of return on investment
  - Developing effective budgeting
  - Employing better cost control and quality control
- **Coordinating**
  - Synergy among different units of the hospital
  - The combined and coordinated efforts make one plus one eleven

7. Hospital services:

Hospital services are emerging issues, so far as public sector hospital are concerned. Hospital services can be summarized as below.

Medical staff:

Every hospital must have medical staff responsible for all medical care to be provided to the patients as per the ethical conduct and professional practices of their membership. The frame-work of the medical staff varies from hospital to hospital. However, in big hospital, staff may be divided into residential medical staff,

associate medical staff, consulting medical staff and honorary medical staff. The residential medical staff is available on 24 hour service basis and is available round the clock to attend the patients. They are also involved in organizational and administrative duties pertaining to the medical staff. The Associate medical staffs are the practitioners appointed and assigned to the various services in the same manner as members of the active medical staff. They may be advanced to as the residential medical staff. Consulting medical staff consists of medical practitioners of recognized professional ability and are not members of other preceding categories of the medical staff. The honorary medical staff is like part-time consulting medical staff. The personnel's of this group may be retired or emeritus physicians or those practitioners who have their own clinic but provide honorary services to the hospital. The above mentioned medical staff may be further subdivided into staff of different clinical divisions based on the degree of specialization. Some of the divisions are as follows:

A. Medicine Division
- Internal Medicine
- Cardiology
- Gastroenterology
- Nephrology
- Pulmonary
- Psychiatry and Neurology
- Infectious diseases
- Allergy
- Skin and Venereal diseases
- Endocrinology
- Geriatrics
- Immunology
- Pediatrics

B. Surgery Division
- General surgery
- Obstetrics and Gynecology
- Orthopedic surgery
- Ophthalmology
- Otolaryngology
- Dental and Oral Surgery
- Nephrology
- Neurologic surgery
- Cardiothoracic surgery
- Plastic surgery
- Anesthetics

Associated medical services:

In addition to the medical staff involved in diagnosis and treatment of the diseases, there are some other medical services where in, medical staff is the chief and help main medical staff for the diagnostic and treatment.Such associated medical services are as below.

A. Pathology and Clinical Biochemistry Services

B. Radiology
C. Blood Bank
D. Medical-Social Service Department
E. Anesthesia Services

SupportiveParamedical Services :

A hospital is not only a clinical department but provide also a number of supportive paramedical services. such as the nursing department, dietary services, laboratory services, medical records department, the blood bank, the central sterile, pharmaceutical services and social services. Actually,the clinical departments cannot finction without them. Some of the other important non clinical services include maintenance and engineering department workshops.

8. Number of public hospital and beds in India :

As the present research work is on management issues in public hospital, the researcher has tried to present about number of public hospital and beds in India, which is shown in below

UNIT III

REGULATORY REQUIREMENT AND HEAITHCARE CODES

FDA Regulation of Medical Devices

Introduction

Medical device regulation is complex, in part because of the wide variety of items that are categorized as medical devices. They may be simple tools used during medical examinations, such as tongue depressors and thermometers, or high-tech life-saving devices that are implanted in the patient, like pacemakers and coronary stents. The medical device market has been described as consisting of eight industry sectors: surgical and medical instrument manufacturing, surgical appliance and supplies, electromedical and electrotherapeutic apparatus, irradiation apparatus, ophthalmic goods, dental equipment and supplies, dental laboratories, and in vitro diagnostic products (IVDs, or laboratory developed tests).1 The federal agency responsible for regulating medical devices is the Food and Drug Administration (FDA)—an agency within the Department of Health and Human Services (HHS). A manufacturer must obtain FDA's prior approval or clearance before marketing many medical devices in the United States. FDA's Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device premarket review. Another center, the Center for Biologics Evaluation and Research (CBER), regulates devices associated with blood collection and processing procedures, cellular products and tissues.2

The Medical Device Review Process:

Premarket Requirements FDA requires all medical product manufacturers to register their facilities, list their devices with the agency, and follow general controls requirements.16 FDA classifies devices according to the risk they pose to consumers. Many medical devices, such as plastic bandages and ice bags, present only minimal risk and can be legally marketed upon registration alone. These low-risk devices are deemed exempt from premarket review and manufacturers need not submit an application to FDA prior to marketing.17 In contrast, most moderate- and high-risk devices must obtain the agency's permission prior to marketing. FDA grants this permission when a manufacturer meets regulatory premarket requirements and agrees to any necessary postmarket requirements which vary according to the risk that a device presents.

There are two main paths that manufacturers can use to bring moderate- and high-risk devices to market with FDA's permission. One path consists of conducting clinical studies, submitting a premarket approval (PMA) application, and requires evidence providing reasonable assurance that the device is safe and effective.19 The PMA process is generally used for novel and high-risk devices and results in a type of FDA permission called approval. The other path is shorter and less costly. It involves submitting a 510(k) notification demonstrating that the device is substantially equivalent to a device already on the market (a predicate device) that does not require a PMA.20 The 510(k) process is unique to medical devices and results in FDA clearance. Substantial equivalence is determined by comparing the performance characteristics of a new device with those of a predicate device. To be considered substantially equivalent, the new device must have the same intended use and technological characteristics as the predicate; clinical data demonstrating safety and effectiveness are usually not required. The manufacturer selects the predicate device to compare with its new device. However, FDA has the ultimate discretion in determining whether a comparison is appropriate.

Figure 1. Medical Devices Listed with FDA, FY2016, by Premarket Review Process

Source: FDA, May 23, 2016. Notes: “Other” includes devices that were allowed to enter the market via other means, such as through the humanitarian device exemption process that allows market entry, without adherence to effectiveness requirements, for devices benefiting patients with rare diseases or conditions. See “Humanitarian Device Exemption (HDE).” Nonexempt devices are reviewed by FDA via the PMA process or the 510(k) process. Of the unique devices that are listed by manufacturers with FDA in FY2016, as shown in Figure 1, about 63% were exempt from premarket review; the remainder entered the market via the

Device Classification Under the terms of the Medical Device Amendments of 1976 (MDA, P.L. 94-295), FDA classified all medical devices that were on the market at the time of enactment—the preamendment devices—into one of three classes. Congress provided definitions for the three classes—Class I, Class II, and Class III—based on the risk (low-, moderate-, and high-risk respectively) to patients posed by the devices.22 Examples of each class are listed in Table 1.

Table 1. Medical Device Classification

Device Classification Examples

Safety/Effectiveness Controls Required Submission

Class I elastic bandages, examination gloves, hand-held surgical instruments

General Controls Registration only unless 510(k) specifically required

Class II powered wheelchairs, infusion pumps, surgical drapes

General Controls & Special Controls

510(k) notification unless exempt -IDE possible

Class III heart valves, silicone gel-filled breast implants, implanted cerebella stimulators

General Controls & Premarket Approval

PMA application -IDE probable

metal-on-metal hip joint, certain dental implants

General Controls 510(k) notification

Source: FDA, Overview of Medical Device Regulation, General and Special Controls, at http://www.fda.gov/ MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm. Note: IDE means investigational device exemption. Some Class III devices have been cleared via the 510(k) process; these are Class III devices that entered the market prior to regulation calling for a PMA application. Device classification determines the type of regulatory requirements that a manufacturer must follow. Regulatory requirements for each class are described below in more detail. General controls apply to all three classes of FDA-regulated medical devices, unless exempted by regulation, and are the only level of controls that apply to Class I devices.23 Examples of general controls include establishment registration, device listing, premarket notification, and good manufacturing practice requirements.

Class I devices are those under current law for which general controls “are sufficient to provide reasonable assurance of the safety and effectiveness of the device.”24 Many Class I devices are exempt from the premarket notification and/or the Quality System (QS) regulation requirements, though they still have to comply with the other general controls. A device is exempt if FDA determines that it presents a low risk of illness or injury to patients.

Class II devices are those under current law "which cannot be classified as class I because the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device."27 Class II includes devices that pose a moderate risk to patients, and may include new devices for which information or special controls are available to reduce or mitigate risk.28 Special controls are usually device specific and may include special labeling requirements, mandatory performance standards, and postmarket surveillance. Currently "15% of all device types classified in Class II are subject to special controls."Although most Class II devices require premarket notification via the 510(k) process, a few are exempt by regulation.

Class III devices are those under current law which "cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device," and "cannot be classified as a class II device because insufficient information exists to determine that the special controls ... would provide reasonable assurance of [their] safety and effectiveness," and are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or present "a potential unreasonable risk of illness or injury, [are] to be subject ... to premarket approval to provide reasonable assurance of [their] safety and effectiveness."31 In other words, general and/or special controls are not sufficient to assure safe and effective use of a Class III device. Class III includes devices which are life-supporting or life-sustaining, and devices which present a high or potentially unreasonable risk of illness or injury to a patient. New devices that are not Class I or II are automatically designated as Class III unless the manufacturer files a request or petition for reclassification.32 Although most Class III devices require premarket approval (PMA), some Class III devices may have been cleared via the 510(k) process. In fact, during the first 10 years following enactment of MDA, over 80% of postamendment Class III devices entered the market on the basis of 510(k) submissions showing substantial equivalence to preamendment devices.33 These are Class III devices that entered the market prior to regulation calling for a PMA application.34 FDA explains the situation as follows:

At the time that the MDA of 1976 was drafted, "relatively few medical devices were permanently implanted or intended to sustain life. The 510(k) process was specifically intended for devices with less need for scientific scrutiny, such as surgical gloves and hearing aids."36 Over time, FDA's 510(k) review process was "challenged as new devices changed more dramatically and became more complex."37 In late 2009, FDA implemented the 515 Program Initiative "to facilitate action on these remaining Class III device types."38 Examples of Class III devices that were still regulated via the 510(k) program include the metal-on-metal hip implant, certain dental implants, automated external defibrillator, electroconvulsive therapy device, pedicle screw spinal system, intra-aortic balloon and control system, and several device types related to pacemakers.39 In 2012, FDASIA changed the process for the reclassification of a device from rulemaking to an administrative order.40 As a result, since 2013 FDA has published a number of final orders in the Federal Register to reclassify many of these remaining Class III device types.

Medical Device and Radiological Health Regulations Come of Age

Each day when people put in their contact lenses, test their blood sugar levels, turn on their TVs, cook their meals, or punch a button on their cell phones, they are using products regulated by the Food and Drug Administration's Center for Devices and Radiological Health (CDRH). The CDRH protects Americans with safeguards that enable them to go about their daily lives knowing that these medical devices and radiological products are reasonably safe to use and that they work as intended.

Getty Images Medical devices are classified and regulated according to their complexity and degree of risk to the public. By way of distinction, some radiation-emitting products, such as X-ray machines and computed tomography (CT) scanners, are medical devices because they are used in medical procedures. Other radiation-emitting products, such as TVs and microwave ovens, are not used

medically, and therefore, are regulated by the FDA under a different law. Medical devices are classified and regulated according to their complexity and degree of risk to the public. For example, devices that are life-supporting, life-sustaining, or implanted, such as pacemakers, must receive FDA approval before they can be marketed. But medical devices haven't always come under such scrutiny. In fact, it wasn't until the late 1970s that the FDA actually gained authority to pre- approve medical devices under the 1976 Medical Device Amendments. This law joined a separate law already in existence, the Radiation Control for Health and Safety Act of 1968, which authorized the agency to reduce unnecessary radiation from medical and non-medical electronic products. Additional laws have, over time, mandated the reporting of adverse reactions to medical devices, post-market monitoring of implants and other devices that pose a serious health risk, recall of dangerous medical devices, and certification and annual inspection of mammography facilities.

The long legal journey toward medical device regulation and radiological health protection--and ultimately the 1976 Medical Device Amendments--begins with the Pure Food and Drugs Act of 1906.

The 1906 act marked the start of federal food and drug legislation designed to protect Americans against threats from harmful substances and deceptive practices. While medical devices were not put into the act, no one could have imagined the ways in which medical device technology would grow, change and, like food and drugs, need to be regulated during the coming years.

A Flood of Fraudulent Contraptions

The earliest recorded fraudulent medical device marketed in the United States was Dr. Elisha Perkins' patent tractors in the late 1700s. Perkins developed two rods of brass and iron about three inches long and sold them throughout the country, claiming they eliminated disease from the body. Even our nation's first president, George Washington, is reported to have purchased a set for his family. Within 10 years of Perkins' death in 1799, the device was exposed as a fraud.

Despite such occasional deceptive enterprises, President Theodore Roosevelt saw no need to ask for legislation concerning medical devices 200 years later, when the Pure Food and Drugs Act was enacted. Devices used by the doctors of his day, such as stethoscopes and scalpels, were comparatively simple, and any hazards or defects were readily apparent. Such devices stood at the edge of medicine--helpful but not essential--and therefore posed little real or perceived threat.

But by 1917, fraudulent medical devices, such as nose straighteners, height-stretching machines, and heated rubber applicators advertised as a cure for prostate gland disorders, began flooding the market. It was clear to the FDA that the law should be expanded to include agency authority over medical devices. In its annual report to Congress that year, the FDA stated that the 1906 act "has its serious limitations … which render it difficult to control … fraudulent mechanical devices used for therapeutic purposes."

Radiation added to the problem. The health hazards of radiation became known soon after the discovery of radium by the French chemists Pierre and Marie Curie in 1898. Before World War I, the FDA was taking action against quack drugs and devices claiming to be radioactive--some of them highly dangerous. Exaggerated health claims, brought to the attention of Congress in a 1926 report, continued for products containing radium. One such device was known as a radium belt, which carried a disc alleged to contain the element. According to proponents, someone wearing the belt would never have appendicitis or gallbladder disease, or perhaps, any other ailment.

Most of the FDA enforcement activity at the time was concerned with getting fraudulent devices like these off the market. While the agency continued to monitor the products and assist the Federal Trade Commission and the U.S. Post Office--both charged with overseeing devices and enforcing criminal penalties for mail fraud under the Postal Fraud Statutes--the FDA could take no action on its own.

The Need for Medical Device Regulation

What was clearly needed, according to many, was national regulation of the medical device industry. Besides being subjected to enforcement actions against products that had already tragically demonstrated their danger to people, medical devices were officially defined as drugs. Calling a medical device a drug, claimed a U.S. senator from Missouri at the time, was like "calling a sheep's tail a leg." Legislation was eventually introduced to modernize the 1906 act. The contentious Senate debate that led up to enactment of the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938 had much to do with the definition of a medical device being added to the law.

Nevertheless, from 1938 until the early 1960s, devices were subject only to policing by the FDA. The agency determined whether a device was safe and effective. If not, the agency could bring charges in the courts only against products or materials that were found to be defective, unsafe, filthy, or produced in unsanitary conditions (adulterated), or against statements, designs, or labeling that was false or misleading (misbranded). There was, however, no requirement for premarket testing, review, or approval.

The FDA's enforcement resources would be strained to the limit over the next 25 years as the agency attempted to deal with such widely distributed quack machines and gadgets such as Ruth B. Drown's Radio Therapeutic Instrument.

Proponents of this device claimed it could cure ailments ranging from a simple fungus growth to a potentially fatal kidney malfunction. Worse yet, when patients' illnesses became too debilitating for them to make the trip to the doctor's office for treatment, they were told they could be treated by remote control.

"That's what's wonderful about the Drown machine," FDA court transcripts quote one doctor as saying. "It's just as effective when the patient is miles away, as when he or she's here." Court documents revealed that four years after one woman faithfully used the radio instrument, she died of the very cancer that Ruth B. Drown's machine, in truth, was incapable of diagnosing or curing.

Such devices were successfully removed from the market. These actions, however, consumed such a large amount of the agency's resources that consideration was given to enactment of additional legislation to further strengthen the FDA's authority.

In 1962, President John F. Kennedy proposed changes to the way medical devices entered the market. Extensive congressional hearings were held on proposals to revise the FD&C Act in a number of different ways, including a requirement that medical devices be regulated comparably to, but separately from, new drugs. There were signs that progress was being made on the proposals.

A few months later, however, news came that thousands of European babies whose mothers took the sedative thalidomide had been born with terrible deformities. The issue of medical devices was then set aside so that health officials could focus on the tragedy.

Congress considered a comparable device law when it passed the 1962 drug amendments. The companion bill, however, to require pre-market approval of new medical devices under the same type of system applied to new drugs was deleted from that final legislation.

The Medical Device Amendments of 1976

During the 1960s and into the 1970s, the FDA's attention turned to the wide range of life-saving medical devices. The agency devoted considerably more effort to ensuring the safety and effectiveness of these new devices, while still trying to protect the public against the fraudulent ones.

The Cooper Committee--chaired by Theodore Cooper, M.D., then director of the National Heart and Lung Institute--was organized in 1970 specifically to study medical devices as part of President

Richard M. Nixon's endorsement of medical device legislation. The committee recommended that any new legislation be specifically targeted to the device industry, because devices presented entirely different issues from drugs. It also suggested that different classifications for medical devices be created, which would tailor the regulatory controls to the risks involved.

Because Congress could not initially agree on the draft legislation for medical devices, the FDA forced the issue and, on its own initiative, took the committee's recommendations by taking inventory of all medical devices being used and then classifying them according to their potential risks.

"That finally got the attention of the House as well as the Senate," said Peter Barton Hutt, who served as chief counsel for the FDA between 1971 and 1974, "and they both began to show renewed interest in late 1974."

The 1976 Medical Device Amendments Become Law

While the Cooper Committee recommendations were being debated in Congress during 1972 and 1973, pacemaker failures were reported. And in 1975, hearings took place on problems that had been reported with the Dalkon Shield intrauterine device, which caused thousands of reported injuries. Those two incidents helped underscore the need for the Medical Device Amendments, enacted in 1976. President Gerald R. Ford, in signing the law, said, "The Medical Device Amendments of 1976 eliminate the deficiencies that accorded FDA 'horse and buggy' authority to deal with 'laser age'

problems." He added, "I welcome this legislation and commend the FDA, who identified the need, cooperated in its development, and finally, will be entrusted with its enforcement."

The 1976 amendments defined devices similarly to drugs, but noted that drugs cause a chemical reaction in the body, whereas devices do not. They called for all devices to be divided into classes, with varying amounts of control required in each one.

Tongue depressors, for example, would fall under general controls of the types already existing (Class I); wheelchairs would be subjected to performance standards when general controls were deemed insufficient to assure product safety and effectiveness (Class II); while artificial hearts would be required to go through pre-market approval (Class III). The agency's first device performance standard was developed for impact-resistant lenses in eyeglasses and sunglasses.

The final provisions of the 1976 amendments closely resemble the Cooper Committee recommendations. In addition to the medical device inventory and classification requirements, Class III device manufacturers were required to notify the FDA prior to marketing. New devices that were substantially equivalent to pre-1976 devices could be marketed immediately, subject to any existing or future requirements for that type of device.

Good Manufacturing Practice (GMP) regulations also were authorized at that time. These are a set of procedures to ensure that devices are manufactured to be safe and effective through quality design, manufacture, labeling, testing, storage, and distribution.

"The development of the GMP regulation included significant interaction with the medical device industry, which resulted in a set of requirements that stood the test of time for 20 years," recalls David M. Link, former director of the FDA's then Bureau of Medical Devices, at a 20th anniversary of the medical device law. Link, who served as bureau director between 1974 and 1980, said it is a gratifying reflection that "a number of the processes initiated in the late 70s are still in place."

During the 1980s, spectacular growth began to occur in the related field of medical diagnostic devices, which aid in the detection of diseases and other conditions, such as pregnancy.

"It was an exciting time to be in FDA and the bureau," says Victor Zafra, former acting director of the Bureau of Medical Devices from 1980 to 1982, "because many of the initial policies and regulations were developed at that time." Zafra remembers approval of the first monoclonal antibody in vitro diagnostic test kit, as well as extended-wear soft contact lenses.

With the development of electronic technology came a host of new products and, with them, potential harmful radiation exposure. But the tools to solve their potential dangers, as recognized by the act--training, research, and state collaboration--were perceived as less enforcementoriented than the traditional FDA approach to regulation. Responsibility for radiation product activities fell under the agency's then Bureau of Radiological Health, which was combined in 1982 with the Bureau of Medical Devices and renamed the CDRH.

"Consequently, there was the challenge of preserving these 'softer' radiation programs and at the

same time building a credible compliance program in the new center," says John C. Villforth, who served as director of the CDRH from 1982 to 1990. The most important challenge facing the new organization, he emphasized, was the merging of the two bureaus into a single center.

"Both bureaus had a similar culture in that they were involved with 'things' as opposed to foods or drugs," he said, "and so there was a reasonable fit in the disciplines--primarily physical sciences and engineering--that were needed to regulate the combined programs." But Mark Barnett, the CDRH's assistant director for education and communications since its inception in 1982, says it isn't just the emphasis on physics and engineering that distinguishes medical devices and radiological equipment from drugs.

"The safety of most medical devices depends to a large degree on their being used properly," he says. "That's true in the case of a surgeon implanting a prosthetic device in a patient's body, an anesthesiologist operating a complex gas delivery machine, or a diabetic patient using a blood glucose monitor at home. And so, with devices," he adds, "an important part of our job is to educate health care practitioners and patients about safe use."

Villforth adds, "I believe the melding of the talents of both bureaus into the combined center was responsible for the success that CDRH has maintained over the years."

The Medical Device Amendments also gave the FDA authority to deal with the notification, repair, replacement, and refund of defective devices, and the agency was authorized to ban any device that presents a substantial deception or substantial unreasonable risk of injury or illness. Thus, the final law greatly strengthened the FDA's authority to regulate medical devices, but retained the fundamental concept of the Cooper Committee report that regulation should be carefully tailored to the type of device involved.

More Medical Device Milestones

The Safe Medical Devices Act (SMDA) was passed in 1990, and represents the first reform of medical device law since the 1976 amendments. This law modified the amendments to give the public greater protection against dangerous medical devices.

Specifically, the SMDA requires nursing homes, hospitals, and other health care facilities that use medical devices to report to the FDA incidents suggesting that a medical device probably caused or contributed to a patient's death, serious illness, or serious injury. Manufacturers are now required to conduct post-market surveillance on permanently implanted devices whose failure might cause serious harm or death, and to establish methods for tracing and locating patients who depend on such devices. The SMDA authorizes the FDA to order device product recalls and other actions.

"Looking back to the time that I was center director, mid '91 through '92," recalls James S. Benson, a former CDRH director, "I see a center that was severely challenged. We faced implementation of SMDA under tremendous congressional pressure. We faced a very difficult process, exacerbated by enormous press interest, of trying to figure out how to deal with breast implants."

"At the time, we were trying to find resources that would allow the device law to be fully implemented," Benson says.

In 1992, Congress passed the Mammography Quality Standards Act (MQSA). The act requires all mammography facilities in the United States to be accredited and certified as meeting quality standards as of Oct. 1, 1994. The goal of the MQSA is to enhance the detection of breast disease through high-quality mammography services. After initial certification, facilities must pass annual inspections by federal or state inspectors.

New programs like this "had come the center's way," says D. Bruce Burlington, M.D., the CDRH director from 1993 to 1999. "Organizing and executing to successfully reinvent key center processes, write numerous rules and guidelines at a record rate, and keep the usual work moving on time," he says, "was only possible with the teamwork and high performance that have always made CDRH a great place to work." By October 2002, the FDA reported it had certified 9,306 mammography facilities and conducted more than 96,000 annual and biannual inspections.

The Medical Device User Fee and Stabilization Act (MDUFSA) of 2005 is the latest major medical device law to be enacted. The MDUFSA amends the user-fee system created by the original Medical Device User Fee and Modernization Act of 2002, which allows the FDA to charge a fee for medical device product reviews. The agency uses these funds to hire staff and develop better systems to support effective and timely product reviews, to enact needed regulatory reforms, and to ensure that reprocessed devices are as safe and effective as the original devices. The aim of the legislation is to bring safe and effective devices to the public sooner.

"Timely decisions based on sound science" continues to be the center's goal in bringing new products to the market, says David W. Feigal, M.D., M.P.H., who served as CDRH director from 1999 to 2004. He cited some of the center's accomplishments as the development of approaches with the CDRH team to deal with emerging problems such as reuse of single-use devices, regulation of "home brew" genetic tests, revitalization of the radiological health programs, and the process of recruiting the next generation of CDRH leadership.

30 Years of Medical Device Regulation and Beyond

Two major milestones in the FDA's regulation of medical devices occurred when devices were first brought under federal regulatory control in 1938, and when they were first subjected to premarket review in 1976. On both occasions, the agency sought to balance the need to protect the public from adulteration and misbranding of medical devices against the need to foster the development of innovative new life-saving medical devices.

Today, among other activities, the CDRH devotes a great deal of time to working cooperatively with other agency centers to resolve issues dealing with combination products, such as drugs that are also considered devices; miniature devices (nanotechnology) that will provide less-invasive surgery, which ultimately will result in quicker recovery times for patients; and FDA training on new technology as it develops.

Because of the agency's timely, science-based decisions, millions of Americans get the medical products they need and can be assured of their safety and effectiveness. The FDA's scientific investment brings tangible public health benefits, such as the development of state-of-the-art diagnostic techniques based on genetic mapping. This, says CDRH Director Daniel G. Schultz, M.D.,

makes it possible for faster and much more accurate identification of people who are at high risk for diseases such as cancer, or who are prone to experience certain adverse drug reactions.

"When I think about the future of our medical device program," Schultz says, "two words come to mind: 'excitement' and 'challenge.' The excitement comes from the tremendous progress the scientific community is making in unraveling the body's secrets at a genetic and molecular level, and from the promise that these discoveries will translate into life-saving and life-enhancing products."

The challenge, he adds, "will be to regulate these new products so as to assure their safety and effectiveness while at the same time assuring that we don't impede medical progress."

Joint Commission of accreditation for Hospitals

Introduction The Accreditation Guide for Hospitals is designed to help you learn about the Joint Commission's hospital accreditation process. This guide provides important information about The Joint Commission, eligibility for accreditation, on-site surveys, survey preparation and accreditation decisions.

Our Mission To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

The Joint Commission: Who Are We? The Joint Commission was founded in 1951 under the auspices of the American Hospital Association, the American Medical Association, the American College of Physicians, and the American College of Surgeons, with the later addition of the American Dental Association, to act as an independent accrediting body for hospitals nationwide. As such, The Joint Commission currently accredits over 80% of U.S. hospitals.

Why Choose The Joint Commission? Today, Joint Commission accreditation of a hospital is a widely recognized standard for evaluating and demonstrating high quality services. Payers, regulatory agencies, and managed care contractors may require Joint Commission accreditation for reimbursement, certification and licensure, or as a key element of their participation agreements. Joint Commission accreditation represents the "Gold Seal of ApprovalTM" in health care and provides the most comprehensive evaluation process in the industry. Joint Commission accreditation also benefits your organization by:

 Strengthening community confidence Achieving accreditation is a visible demonstration to the community that your hospital is committed to providing high quality services, as reviewed by an external group of specialists. Validating quality care to your patients and their families Joint Commission standards are focused on one goal: raising the safety and quality of care to the highest possible level. Achieving accreditation is a strong validation that you have taken the extra steps to ensure the highest level of safety and quality currently available. Helping you organize and strengthen your improvement efforts Joint Commission standards include state-of-the-art performance improvement concepts that provide a framework for continuous improvement using standards as a means to achieve and maintain excellent operational systems. Improving liability insurance coverage By enhancing risk management efforts, accreditation may improve access to or reduce the cost of liability insurance coverage. A list of liability insurers that recognize Joint Commission accreditation can be found on our website at:
http://www.jointcommission.org/liability_insurers/default.aspx

 Enhancing staff recruitment and education The accreditation process is designed to be educational, not punitive. Our surveyors are trained to help you improve your internal procedures and day-today operations in a consultative manner. Prospective employees also look for accreditation as a sign of excellence in an organization.

What Types of Facilities are Eligible for Hospital Accreditation? Any health care organization may apply for Joint Commission accreditation under the Hospital Accreditation standards if all the following requirements are met:

 The organization is in the United States or its territories or, if outside the United States, is operated by the U.S. government, under a charter of the U.S. Congress.

 The organization assesses and improves the quality of its services. This process includes a review of care by clinicians, when appropriate.

 The organization identifies the services it provides, indicating which services it provides directly, under contract, or through some other arrangement.

 The organization provides services addressed by the Joint Commission's standards.

 If the organization uses its Joint Commission accreditation for deemed status purposes, the organization meets the Centers for Medicare & Medicaid Services definition of a "hospital."

A hospital that is seeking Medicare certification and is new to The Joint Commission must, at the time of survey, have: One active inpatient case. If your Average Daily Census (ADC) is 21 or more or your organization is a specialty hospital (cardiac, orthopedic, or surgical), you must be able to provide inpatient records for at least 10 percent of the ADC, but not less than 30 inpatient records. If your ADC is 1-20, you must be able to provide 20 inpatient records. If you are not sure about whether the 20 or 30 inpatient records is the appropriate sample size for your organization refer to your 855 Medicare application to determine how you reported yourself to Medicare and then contact your assigned Joint Commission Account Executive to determine the correct minimum requirements applicable to your organization. If you do not have a CCN, a letter from the Fiscal Intermediary on CMS Letterhead indicating that the Medicare application (855A) was reviewed and accepted. Licensure Survey results Copy of License Letter notifying CMS and the State Department of Health that The Joint Commission is conducting your deemed Status Survey.

A hospital that is not seeking Medicare certification and is new to The Joint Commission must, at the time of survey, have: One active inpatient case. 10 inpatient records.

Standards, Goals and Survey Process

The Standards Manual Joint Commission standards address patient-focused performance measures and are organized around functions and processes. The Joint Commission's Comprehensive Accreditation Manual for Hospitals (CAMH) is the place to begin when preparing for accreditation. Even if you do not pursue accreditation right away, this manual is an excellent tool to help your organization become organized and established. The CAMH contains functional standards that are organized around the way care is provided. It is provided free of charge upon receipt of your accreditation deposit or can be provided earlier.

Patient-Focused Functions The patient-focused section includes chapters on Infection Control, Medication Management, Provision of Care, and Rights and Responsibilities.

Infection Prevention and Control These standards are designed to help hospitals in developing and maintaining practices that cover a wide range of situations.

Medication Management These standards address a well-planned and implemented medication management system, including selection and procurement, storage, ordering, preparation and dispensing, administration and monitoring.

Provision of Care, Treatment, and Services This chapter addresses assessment of patient needs, care planning, and providing and coordinating care.

Rights and Responsibilities of the Individual Standards address the following processes: Informing patients of their rights Helping patients understand and exercise their rights Respecting patients' values, beliefs, and preferences Informing patients of their responsibilities regarding their care, treatment and services

Organization Functions This section of the CAMH includes chapters on Environment of Care, Emergency Management, Human Resources, Information Management, Leadership, Life Safety, Medical Staff, Nursing, Performance Improvement, and Record of Care.

Management of the Environment of Care These standards promote a safe, functional and supportive environment within the hospital so that quality and safety are preserved. The environment of care is made up of the building or space, including how it is arranged and special features that protect patients, visitors and staff. It also encompasses the equipment used to support patients and the people, including employees, patients and visitors.

Emergency Management These standards are organized to allow hospitals to plan to respond to the effects of potential emergencies that range from disruptive to disastrous.

Human Resources The standards and elements of performance address the hospital's responsibility to establish and verify staff qualifications, orient staff, and provide training that staff needs to support the care, treatment and services that the hospital provides.

Management of Information These standards address how well the hospital obtains, manages and uses information to provide, coordinate and integrate services.

Leadership These standards are divided into four different areas to address all organizational areas so that they come together to shape and drive the hospital's operations: Leadership Structure Leadership Relationships Hospital Culture and System Performance Operations

Life Safety This chapter includes all the Joint Commission requirements regarding Life Safety Code compliance, which specifies construction and operational conditions to minimize fire hazards and provide safe systems in case of emergency.

Medical Staff These standards provide structure for self-governing medical staff, licensed independent practitioners and other medical staff personnel.

Nursing This chapter addresses nursing direction, establishing guidelines for delivery of care and providing treatment, nursing care and services.

Performance Improvement These standards focus the hospital on measuring the performance of processes that support care and then using data to make improvements.

Record of Care, Treatment, and Services Comprehensive sets of requirements for medical record contents are provided and standards address policies and procedures that structure the compilations, authentication, retention and release of records.

The Joint Commission Patient-Centered Accreditation Process The purpose of a Joint Commission accreditation survey is to assess the extent of an organization's compliance with applicable Joint Commission standards, National Patient Safety Goals, and Accreditation Participation Requirements. Another important aspect of the Joint Commission survey process is the on-site education as surveyors offer suggestions for approaches and strategies that may help the organization better meet the intent of the standards and, more importantly, improve performance. While integrating evaluation of standards compliance and educating an organization, the Joint Commission accreditation process also emphasizes quality patient care.

Although surveys for hospitals are triennial (conducted every three years) the accreditation process does not end when the on-site survey is completed. In the three years between on-site surveys, The Joint Commission requires ongoing self-assessment and improvement. Continuous survey compliance means less focus on the 'ramp up' for survey every three years. Instead, organizations can and should continually study and improve their systems and operations, eliminating the need for intense survey preparation. Continuous compliance with the Joint Commission standards directly contributes to the maintenance of safe, high quality patient care and improved organizational performance.

International Research & Recreation Promotion Council (IRPC).

About Irpc

The council has been constituted and promoted by enthusiastic well-wishers of research social,cultural and economic development from the health care and scientific community. IRPC is a totally dedicated, non-governmental and non- profit international organization fully structured to provide research and scientific incentives for the betterment of scientific, socio-economic enhancement of the society, mainly of, developing and under developed Austral-Afro- Asia- Pacific countries through active involvement of the developed countries of the world.

Most of the struggling economies are unable to meet the demands for basic needs and preventive medical practices and are equally unable to meet the cost of appropriate health care for the people. In view of all these inadequacies, medical and scientific research is becoming a matter of low priority became of the lack of co-operation and initiatives from the part of policy makers and administrators. Research and Recreation joining hand in hand for better quality for life and optimum result. IRPC encourages recreation of researchers by bringing together scientists of all countries beyond boundaries and thus providing healthy research atmosphere to everybody.

IRPC Objectives

The roots of IRPC spring from the necessity to counter the problems related to research in developing and underdeveloped countries. The vast majority of the population of this planet are living in the erstwhile Third World, as are the majority of undiagnosed, or at best under diagnosed, cases of serious diseases. Slowly IRPC spreaded its wings to all areas which are preventing or slowing down human life.

Yet only a small part of the global resources are channeled towards meeting these grave and demanding needs especially for medical and related support. Morbidity and mortality rates in most of the developing and underdeveloped countries are unproportionally very high and lives are being lost for lack of basic healthcare, in addition to the socio-economic inequalities and poverty pf majority of human population in the world.

The problem is more evident in the very young and the elderly who often succumb to the advanced stages of illnesses that are easily preventable or readily curable in any developed country. These inequalities can be assumed to be the result of unsound economic disparities that, are existing in the underdeveloped countries.

About IRPC

Our Inspiration

"In the near future two thirds of the patients will be in developing and under developed countries, but with only 5% of the global resources for disease management or control"
Dr Jan Stjernsward MD, PhD,
Former Chief, Cancer and palliative care. WHO
Radiotherapy in Cancer Management: A Practical manual-WHO Publication Publisher: Chapman & Hall, Medical 1997

IRPC- An Overview

Dr Costas Giannakenas MD, PhD
Dept of Nuclear Medicine,
Regional University Hospital of Patras,
26500-Patras / Greece
The roots of IRPC spring from the necessity to counter the problems related to research in developing and underdeveloped countries. The vast majority of the population of this planet are living in the erstwhile Third World, as are the majority of undiagnosed, or at best under diagnosed, cases of serious diseases.

The Role of IRPC

The IRPC has taken up the cause of promotion of research activities in the developed world and stands to play a pivotal role in countering the research problems in developing world by its active involvement.

The involvement is in:

1. Coordinating research projects on relevant problems in the developing and under developed countries.
2. Coordinating the activities of various agencies and the governments for the harmonius working to ensure optimum standard in the quantity of life for everybody irrespective of caste, creed, race and nationality.
3. Coordinating the establishment of specialized instrumentation centers with financial aid from the developed economies.
4. A united forum-World Scientists Forum-constituted by scientists from developed and developing countries will be formed for interaction, co-operation and mutual assistance in all matters connected with research in science and medicine, beyond the socio cultural differences and ensure healthy and optimum facilities for life.

Penetrative Roles of IRPC

- All branches of science and medicine
- Co-coordinating and Supervising the activities of "THE WORLD SCIENTISTS FORUM FOR INTERACTION AND CO-OPERATION IN THE DEVELOPMENTAL ACTIVITIES OF THIRDWORLD COUNTRIES AND FOR WORLD PEACE".

Researches in developing economies-Why are they behind?

Research in the developing economies, falls back nearly by ten years in most areas of science and health when compared to that of developed countries. While research is the backbone of science, compared to that of developed economies advancements in areas relevant to a specific country, developing or underdeveloped countries have provided it a very low priority. In the developing countries, the major obstacles facing research are:

1. Paucity of funds and faulty channelisation of available funds.
2. Lack of production and availability of research materials such as quality controlled reagents and chemicals.
3. The delay in getting research materials manufactured in developed countries through import.
4. Difficulties encountered in accessing required equipments and absence of custom analysis centers.
5. Lack of encouragement and financial support from the parent institution.
6. Non-availability or networking of up-to-date information.
7. Lack of advanced training to scientists
8. Lack of financial support to attend conferences, seminars, and workshops and training programs etc.- a very serious handicap of the scientists from developing countries.
9. Lack of acceptance and recognition.
10. Poverty and illiteracy of the population
11. Lack of proper transfer of technology by advanced training of scientist in major institutions, and exchange programs in institutions where related research activities have been conducted successfully with more advanced facilities
12. Lack of job security of the scientists
13. Other facts such as the unscientific approaches towards research by the government agencies, untimely release of funds for sanctioned and ongoing projects, erratic power supply and poor working conditions etc
14. Lack of research and development tie-ups and activities with industries
15. Lack of proper planning

Yet only a small part of the global health care resources are channeled towards meeting these grave and demanding needs for medical and related support. Morbidity and mortality rates in most of the developing and underdeveloped countries are unproportionally very high and lives are being lost for lack of basic healthcare.

The problem is more evident in the very young and the elderly who often succumb to the advanced stages of illnesses that are easily preventable or readily curable in any developed country. These inequalities have obvious economic foundations.

Most of the struggling economies are unable to meet the demands for preventive medical practices and are equally unable to meet the cost of appropriate health care for the people. In view of all these inadequacies, medical and scientific research is understandably a matter of low priority.

And although there is an increasing population of qualified scientists, many of whom are trained abroad there is a lack of such trained professionals as many follow their quest for knowledge or even their ambitions to developed countries where greater opportunities are possible. It is neither acceptably adequate nor satisfactory to be able to simply provide basic health care to the people of the under developed economies. Not when the new technologies and recent advances in disease management are readily accessible to people in developed countries. People in the developing economies have the same and even greater needs and there is a discernable urgency for immediate research strategically aimed at the endemic and demographic incidence of serious diseases characteristic of each region. But this research has to be in conjunction with the efforts being made to provide preventive as well as adequate health care for these populations.

The urgency and the needs are obvious enough but the appropriate means towards meeting these goals are yet to be secured.

These circumstances are what make the IRPC such a commendable effort. By striving to draw global attention to the many unresolved problems facing the majority of the world's population, the IRPC is opening new frontiers and finding new approaches to meeting the challenges presented.

UNIT IV

EQUIPMENT MAINTENANCE MANAGEMENT

Organising Maintenance Operations, Paper Work Control, Maintenance Job

Introduction

Medical equipment plays a vital role in healthcare; however, when equipment is not properly used or maintained, it also can cause harm. In many instances, patient injuries occur because of assumptions about who may use, calibrate, modify, or repair equipment.

Injuries from medical equipment also might arise from training gaps that don't address preuse testing, preventive maintenance, malfunction reports (and incident reports), and repair procedures.

A commitment to safety is an essential element of any process related to the use of medical equipment — whether the medical equipment is purchased, rented, borrowed, or leased.

Objectives The objectives of this guideline are to:

• Review due diligence considerations for selecting and acquiring medical devices and equipment

• Define key aspects of an equipment management program and offer risk strategies to consider when developing such a program

• Discuss the necessary components of a well-defined incident response procedure • Offer guidance related to responding to equipment recalls and documenting essential information about medical devices and equipment

• Provide general recommendations for managing risks associated with the operation of onsite laboratory and radiology equipment

• Review proactive strategies for addressing patient-supplied medical equipment.

Equipment Selection and Acquisition The selection of medical equipment should not be based on hasty or insufficient decisionmaking. Each healthcare organization (e.g., practices, hospitals, clinics, and large health systems) should formally establish a team that is responsible for researching and recommending medical equipment.

Once recommendations are made, prospective equipment should be thoroughly reviewed in a collaborative effort by end users — especially if it will be used in the direct diagnosis, treatment, or care of patients. Due diligence when selecting medical equipment might include:

• A literature review • Consultation with experts • Consideration of whether to contract the services of a biomedical engineering company • Requests for data and research results from clinical trials • Discussions with other healthcare providers who use the same equipment (follow-up of references)

• A review of the history and fiscal standing of potential vendors

The medical equipment selection process also should include a formal assessment of the anticipated risks and benefits associated with the equipment. For example, consider the following questions:

• Is the use of the equipment consistent with your healthcare organization's mission and ethical policies and procedures?

• Does the equipment or new technology reduce the risk of injury to patients or staff members who may be required to use it (e.g., exposure to lower levels of radiation, latex, or mercury)?

• Do health benefits and/or time-savings for patients, healthcare providers, and staff outweigh the cost associated with the equipment?

• Will the equipment require any costly software upgrades? Can the manufacturer supply a schedule of upgrades?

• Will charges to the patient that are associated with this equipment remain consistent with similar community pricing?

• Are the procedures for which the equipment is used billable? Does your electronic health record (EHR) system or billing system need to be modified to bill for these services?

• What is the community standard? Are market pressures influencing the decision to purchase new equipment (e.g., "our competition offers it" or "we don't want to be left behind")?

• Do staff and providers need to be aware of any regulatory requirements related to the equipment (e.g., only licensed independent practitioners can operate the equipment, environmental safety requirements, etc.)?

• Are you able to integrate direct patient care equipment (e.g., blood pressure monitors and laboratory equipment) with your EHR (if appropriate)? If not, what additional resources would be required to do so?

• Does the new equipment require additional supplies or materials to use or maintain it? If so, what are the availability and costs of these items?

• Is vendor support or other technical support for maintenance available? • Have you considered the purchase/lease requirements and options (e.g., warranties, volume purchasing, trade-in programs, upgrades, indemnification for injuries/failures, contract terms, new versus used/refurbished equipment, etc.)?

• What are the training and ongoing competency considerations?

The answers to these questions and the rationale for purchasing the equipment should be documented and saved for future reference.

Equipment Management A patient injury caused by a medical device or piece of medical equipment may trigger a claim against a practitioner, healthcare organization, and/or an equipment manufacturer. To reduce patient safety and liability risks associated with medical devices and equipment, healthcare organizations should have effective programs for managing equipment used in patient care.

Considerations when developing an equipment management program include inventory management and documentation; evaluation of equipment; testing; maintenance and usage; and education and training.

Inventory Management and Documentation A first step in designing an effective equipment management program is documenting what equipment you have. Each healthcare organization should:

• Maintain an inventory of all medical equipment, whether it is leased or owned and whether it is maintained according to manufacturer recommendations or an alternative equipment maintenance (AEM) program.1

• Include as part of the inventory a record of maintenance activities. (See Appendix A and Appendix B for sample tracking and maintenance/repair logs.)

• Ensure that equipment managed through an AEM program is clearly identifiable as subject to AEM. Further, critical equipment, whether subject to AEM or not, must be readily identified as such.

• Document the following information for all equipment included in the inventory: Unique identification number Equipment manufacturer Model number and serial number Description of the equipment Location of the equipment (for equipment generally kept in a fixed location) Identity of the department considered to "own" the equipment Evaluation of Equipment In addition to having a written inventory of medical equipment, healthcare providers and staff should understand the purpose of each piece of equipment. As part of the equipment management program, each organization should:

• Evaluate each piece of equipment to determine: Function and clinical application Preventive maintenance requirements and expected lifespan Likelihood of equipment failure; check U.S. Food and Drug Administration (FDA) reports, consumer reviews, and literature reviews. Compatibility with other equipment used at the facility Space allocation for equipment and supplies • Once the equipment has been evaluated, assign each item a tier level (1, 2, or 3) based on how critical its function is to the practice or patient. Tier 1 is for the most critical equipment, such as life support and emergency devices (e.g., an automatic external defibrillator). Tier 2 is for common use equipment, such as blood pressure monitors and heat therapy units. Tier 3 is for equipment that has little to no risk, such as a patient scale.

Testing Testing medical equipment is an essential element of an equipment management program and vital for patient and staff safety. Each organization should:

• Test equipment based on manufacturer recommendations or the tier level assigned (whichever is most frequent): Equipment in Tier 1 should be tested on at least a semi-annual basis. Equipment in Tier 2 should be tested on at least an annual basis. Equipment in Tier 3 may only need to be visually inspected on an annual basis.

• Ensure that qualified personnel inspect, test, and maintain all medical equipment (diagnostic, therapeutic, life support, and monitoring).

• Consider contracting the services of an approved biomedical engineering company to assist with equipment testing and maintenance.

Maintenance and Usage Each organization's equipment management program should include guidance related to maintaining and using medical equipment. For example:

• Maintain and use all equipment according to manufacturers' recommendations or a specified AEM program. Document all inspections, testing, preventive maintenance, and repairs — and include telephone numbers for the equipment vendors.

• Ensure maintenance processes include specific accountability and schedules for preventive maintenance and testing.

• As part of maintenance guidance, include specific information about (a) disinfecting all reusable equipment according to FDA guidelines and CDC guidelines, and (b) documenting equipment disinfection processes.

• Develop a plan for monitoring and updating software on medical devices. Work closely with the organization's information technology team to research updates and implement appropriate strategies.

• Develop a competency process for using equipment. Make sure the process takes into account job descriptions and training (external and in-service).

• Determine the healthcare organization's point of contact for reporting any equipment malfunctions or incidents that could cause patient injuries.

• Ensure staff members who are responsible for addressing reports of equipment malfunctions or incidents know their responsibilities and timeframes for taking action.

• Never use a piece of medical equipment that shows signs of damage or has been partially repaired or otherwise altered from its original condition by nonqualified staff members.

Education and Training Healthcare providers and staff cannot be expected to properly use and maintain medical equipment unless they receive appropriate education and training. Each organization should:

• Provide all staff members (including temporary staff) with initial training and ongoing annual training on medical equipment procedures. Training should address: How to report a piece of medical equipment that is not functioning properly, which can include visual clues like smoking, sparking, or display errors. How to remove the piece of medical equipment from service, tag-out the device, and notify the appropriate repair service or biomedical engineering contractor for repairs.

• Train appropriate staff on how to properly set up, use, calibrate, and clean equipment. If a staff person has not been trained, or is not appropriately licensed/certified, he or she should not be allowed to use the equipment.

• Educate staff about back-up plans for when a piece of equipment needs to be serviced or repaired.

• Provide timely training and education for any new or updated equipment prior to putting the equipment into use.

• Document all equipment training and competency for both providers and staff in each individual's personnel file.

Incident Response Procedure In the event that a piece of equipment or medical device causes patient injury or harm, each healthcare organization should have a well-defined incident response procedure. As part of this procedure, appropriate staff members should:

• Stabilize the patient. • Remove from service and secure any equipment involved in the incident. • Complete an incident report per organizational policy.

• Report the incident as required by the Safe Medical Devices Act (SMDA). A designated staff member should complete the required form and forward it (or an electronic equivalent) to the appropriate party as required by law. If an incident results in death, it should be reported to the FDA and the equipment/device manufacturer. Serious injuries/illnesses should be reported directly to the manufacturer. If the manufacturer is not known, the user organization should report directly to the FDA.

• Notify the organization's professional liability claims specialist immediately (he/she will advise you if/when you should release the equipment).

Equipment Recalls If a healthcare organization or a biomedical engineering contractor receives a recall or hazard notice from a manufacturer or distributor, the organization is responsible for taking appropriate action, as outlined in the notification.

If the notification does not clearly state what steps to take, a designated staff member should contact the entity that issued the recall/hazard notification for guidance. Until the process is clarified, cease use of the equipment.

If the organization fails to take appropriate action in the face of such notice and the defective device injures a patient, the organization might be found negligent. Additionally,

Risk Tip

Equipment that has caused an injury should never be returned to the manufacturer. Additionally, a manufacturer's representative should not be allowed to examine or attempt to repair the equipment. The equipment should be sequestered, rendered inoperable (locked, etc.), and examined by a company that specializes in independent testing of equipment.

Risk Tip

To ensure accountability, healthcare organizations should consider assigning one person within the organization the responsibility of receiving and managing equipment recalls and alerts.

the organization might bear legal responsibility for improper revisions or modifications made to medical devices as a result of a recall notice.

Manufacturers may specify how they will conduct a recall of equipment. Some contracts, especially those addressing the purchase of equipment with high potential for patient or user injury, may specify how and within what timeframe a manufacturer will notify users of possible risks that have precipitated a recall.

Documentation Documentation related to medical equipment use and management should include written policies and procedures for:

• Procurement of equipment (purchase, acquire, lease, borrow) • Disposal of equipment (sale, recycle, destroy) • Pre-use testing, calibration, and use • Development and implementation of training programs, as well as periodic training updates

• Responses to, and reporting of, equipment-related incidents

Additional documentation might be required and should be considered with the purchase of new equipment. For example, contracts related to the lease of equipment or maintenance agreements should be kept in a central location. The appropriate individuals should assume responsibility for reviewing and asking questions about the agreements before they are signed (including legal counsel as needed). Vendors may not be accountable for "assumptions" that weren't included in a contract.

Preventive maintenance and repair records should be available for all procured equipment (leased, borrowed, used, etc.). Further, documentation related to who insures the equipment should be maintained.

If necessary, for proper pre-use testing or calibration, information from the manufacturer should be used to develop training and in-service staff updates. These materials should also be available for reference, and originals of these documents should be filed with contractual arrangements.

Manufacturers' specifications, schematics, testing, and calibration directions — and any other user instructions — should be retained in a master file. Copies should be available, as needed, for equipment users. Manufacturers' warranties (and information about actions that might void warranties) also should be retained.

Codes or stickers placed on equipment for the purposes of identification, inventory management, and preventive maintenance should be consistently color-coded throughout the organization and should comply with state regulations.

All communications regarding damaged or non-functional equipment should be maintained, including logs of telephone conversations. When disposing of equipment, all protected health information should be wiped from the equipment memory.

Onsite Laboratory, Anaesthesia, Sterilization, Dialysis or Radiology Services If your healthcare organization performs laboratory, anaesthesia, sterilization, dialysis or radiology services, constant vigilance to ensure the safety and accuracy of equipment is necessary.

All radiological testing and services must be in compliance with Nuclear Regulatory Commission (NRC) rules and regulations, as well as state and private licensing and certification requirements. Similarly, all laboratory, anaesthesia, sterilization, and dialysis equipment must be maintained based on federal, state, and private licensing and certifications requirements.

Therefore, each organization's personnel should be knowledgeable about the laws and ensure that onsite equipment operates in compliance with all of the applicable rules and regulations.

The following general recommendations are intended to help manage risks associated with the operation of onsite diagnostics:

• Retain licensing documents within your organization's permanent files. • Train, supervise, and periodically test the proficiency of all personnel performing laboratory or radiology services.

• Maintain an inventory log of all diagnostic equipment and use it to monitor equipment maintenance, recalibration, and servicing (as recommended by the manufacturer).

• Maintain and revise written instructions and procedures, including maintenance and reporting results, on an annual basis.

Patient-Supplied Medical Equipment Patients might bring their own medical equipment to use during inpatient stays, such as canes, heating pads, insulin pumps, home dialysis machines, continuous positive airway pressure (CPAP) units, and CPAP masks. Their comfort level with the equipment or desire to avoid fees related to using the facility's equipment might motivate these decisions.

However, patient-supplied medical equipment comes with risks. The ECRI Institute notes that "Healthcare organizations have a duty to ensure the safety of equipment and devices used in their institutions. When they allow the use of patient-supplied equipment, they may also assume responsibility for the equipment's performance and safety."2

Healthcare organizations can proactively address patient-supplied medical equipment by developing and following a policy for how to manage these situations. When developing a policy, consider these questions:3

• Has your organization conducted an assessment to determine what types of medical equipment patients are mostly likely to bring with them? Have you considered the risks versus benefits associated with the identified types of equipment and the steps required to evaluate and maintain the equipment?

• Has your organization developed a written policy that clearly states which types of patient-supplied medical equipment are allowed (if any) and which types are prohibited?

• Are healthcare providers, staff members, patients, and families educated about the organization's policy on patient-supplied equipment? Are patients made aware of their responsibility for any equipment that is permitted and they choose to bring?

• Is physician approval required for all patient-supplied medical equipment? • Is a requirement in place that biomedical or engineering staff inspect all patientsupplied medical equipment to make sure it is in good working condition? Is the equipment tagged following inspection, and is the inspection documented?

• In urgent or time-sensitive cases, do nurses or other frontline staff members inspect the equipment for obvious defects or problems until biomedical or engineering staff can fully evaluate the equipment?

• Do staff members who will be caring for the patient know how to operate the equipment?

• Does your organization plan to use waivers to address liability associated with patientsupplied medical equipment? Has legal counsel reviewed these forms?

Once your healthcare organization has developed a policy for patient-supplied medical equipment, make sure that healthcare providers and staff members are aware of the policy and procedures for handling these types of requests.

Conclusion Medical equipment provides many valuable services to support and enhance patient care, but its use is never without risk. While appreciating the benefits that medical equipment can provide, healthcare providers and staff also should remain cognizant of potential safety issues. Risk management strategies can help healthcare personnel proactively manage medical equipment. When equipment is properly tested, used, and maintained, it is more likely to work properly, which can help avoid delays in care, reduce the risk of patient and staff injuries, and optimize patient outcomes.

Resources • Centers for Disease Control and Prevention: Guide to Infection Prevention for Outpatient Settings

• Centers for Disease Control and Prevention: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

• Centers for Medicare & Medicaid Services: Clinical Laboratory Improvement Amendments (CLIA)

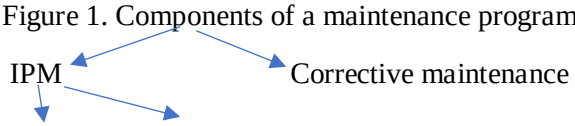
• Nuclear Regulatory Commission • U.S. Food and Drug Administration: Enforcement Reports (information about product recalls and other enforcement actions)

• U.S. Food and Drug Administration: Medical Device Reporting • U.S. Food and Drug Administration: Recalls, Market Withdrawals, & Safety Alerts • U.S. Food and Drug Administration: Reprocessing of Reusable Medical Devices.

Preventive Maintenance, Maintenance Budgeting and Forecasting, Maintenance Training, Contract Mainframe

Introduction Medical equipment maintenance can be divided into two major categories: inspection and preventive maintenance (IPM), and corrective maintenance (CM) (see Figure 1). IPM includes all scheduled activities that ensure equipment functionality and prevent breakdowns or failures. Performance and safety inspections are straightforward procedures that verify proper functionality and safe use of a device. Preventive maintenance (PM) refers to scheduled activities performed to extend the life of a device and prevent failure (i.e. by calibration, part replacement, lubrication, cleaning, etc). Inspection can be conducted as a stand-alone activity and in conjunction with PM to ensure functionality; this is important as PM can be fairly invasive in that components are removed, cleaned or replaced. It is essential for any health-care facility, regardless of its size, to implement a maintenance programme for medical equipment. The complexity of the programme depends on the size and type of facility, its location, and the resources required. However, the principles of a good maintenance programme will be the same if it is in an urban area in a high-income country or a rural setting in a low- to middle-income country.

Figure 1. Components of a maintenance programme Maintenance



Inspection Preventive maintenance

Purpose The objective of this document is to provide information regarding the components of an effective medical equipment maintenance programme. It can assist health-care organizations, especially those in developing countries, with planning, managing and implementing the maintenance of medical equipment. It is intended to be concise and flexible, and may be adapted to various settings and levels of technical resources as required. It focuses on general principles rather than being a rigid model, so that each country or institution can design an appropriate programme to meet their own specific requirements. The document is intended for those responsible for planning, managing and implementing health technology management services at the facility, local, regional and national levels, particularly in resource-constrained countries where such services may not yet be fully established. It may also be of value to engineers and technicians responsible for carrying out the many tasks described.

Maintenance related definitions Key terms used in the discussion of medical equipment maintenance are defined below.

Term Definition

Acceptance testing The initial inspection performed on a piece of medical equipment prior to it being put into service. When the device first arrives in the health-care facility, it is checked to ensure it matches the purchase order, it is functioning as specified, the training for users has been arranged and it is installed correctly. If a computerized maintenance management system (CMMS) is available, it is registered into the CMMS.

Calibration Some medical equipment, particularly those with therapeutic energy output (e.g. defibrillators, electrosurgical units, physical therapy stimulators, etc.), needs to be calibrated periodically. This means that energy levels are to be measured and if there is a discrepancy from the indicated levels, adjustments must be made until the device functions within specifications. Devices that take measurements (e.g. electrocardiographs, laboratory equipment, patient scales, pulmonary function analysers, etc.) also require periodic calibration to ensure accuracy compared to known standards.

Clinical engineer A professional who supports and advances patient care by applying engineering and managerial skills to health-care technology (American College of Clinical Engineering). While a clinical engineer is a specialized biomedical engineer, the terms are often used interchangeably.

Clinical engineering department/group Engineer/technician or team of engineers/technicians responsible for the management and maintenance of medical equipment. Depending on the context and country, this department or team may be referred to by a wide variety of names. Some alternative names include: ‘biomedical engineering department’, ‘medical equipment maintenance department’, ‘medical equipment management unit’, etc. In this document, we refer most often to clinical engineering department.

Common descriptive nomenclature The terminology used to describe a device. Using common universal descriptive names from a single internationally accepted source1 is key to comparing inspection procedures, inspection times, failure rates, service costs and other important maintenance management information from facility to facility. Although manufacturers have specific names for devices, it is important to store the common name of the device as listed in the nomenclature system (e.g. nomenclature name: electrosurgical system, monopolar/bipolar; vendor name for the device: electrosurgical generator; vendor model name: Radiolase).

Corrective maintenance (CM) A process used to restore the physical integrity, safety and/or performance of a device after a failure. Corrective maintenance and unscheduled maintenance are regarded as equivalent to the term repair. This document uses these terms interchangeably.

Failure The condition of not meeting intended performance or safety requirements, and/or a breach of physical integrity. A failure is corrected by repair and/or calibration.

Inspection Inspection refers to scheduled activities necessary to ensure a piece of medical equipment is functioning correctly. It includes both performance inspections and safety inspections. These occur in conjunction with preventive maintenance, corrective maintenance, or calibration but can also be completed as a stand-alone activity scheduled at specific intervals. Inspection and preventive maintenance (IPM) IPM refers to all the scheduled activity necessary to ensure a piece of medical equipment is functioning correctly and is well maintained. IPM therefore includes inspection and preventive maintenance (PM).

Performance inspections These activities are designed to test the operating status of a medical device. Tests compare the performance of the device to technical specifications established by the manufacturer in their maintenance or service manual. These inspections are not meant to extend the life of equipment, but merely to assess its current condition. Performance inspections are sometimes referred to as 'performance assurance inspections'.

Predictive maintenance This activity involves a forecasting technique to determine the rate of failure of certain types of replaceable components (e.g. batteries, valves, pumps, seals). The maintenance interval is then set so components are replaced before they fail, ensuring the equipment continues to operate reliably. In health care this is primarily done in a facility that has a large number of medical devices from a single manufacturer or model.

Preventive maintenance (PM) PM involves maintenance performed to extend the life of the device and prevent failure. PM is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, cleaning (e.g. filters) or replacing parts that are expected to wear (e.g. bearings) or which have a finite life (e.g. tubing). The procedures and intervals are usually established by the manufacturer. In special cases the user may change the frequency to accommodate local environmental conditions. Preventive maintenance is sometimes referred to as 'planned maintenance' or 'scheduled maintenance'. This document uses these terms interchangeably.

Repair A process used to restore the physical integrity, safety, and/or performance of a device after a failure. Used interchangeably with corrective maintenance.

Safety inspections These are performed to ensure the device is electrically and mechanically safe. These inspections may also include checks for radiation safety or dangerous gas or chemical pollutants. When these inspections are done, the results are compared to country or regional standards as well as to manufacturer's specifications. The frequency of safety inspections may be different than planned maintenance and performance inspections, and are usually based on regulatory requirements.

Maintenance programme planning

Planning a maintenance programme is part of a broader effort to establish a comprehensive programme for healthcare technology management (HTM). This planning process includes a review of critical factors, as shown in Figure 2. The challenge for planners is to balance these factors to design a maintenance programme that is appropriate and costeffective for their situation.

Inventory

Medical devices range from relatively simple to highly complex. For example, manual devices to measure blood pressure (sphygmomanometers) have only few components and are easily repaired, assuming that parts, calibration instruments and basic hand tools are available. At the other extreme are advanced imaging and laboratory devices. Repair of a magnetic resonance imaging system requires extensive financial, physical and human resources. Between these extremes are infusion pumps, defibrillators, ECG (electrocardiograph) machines, and hundreds of other types of medical devices of varying complexity. Early in the process of planning a maintenance programme, it is essential to determine the types of devices that need to be included in the programme. This will depend on the types of facilities to be covered by the programme, ranging from primary care clinics to tertiary hospitals, and the range of devices in those facilities. The clinical engineering department should identify and select the devices to be included in the inventory, and which of those to include in the maintenance programme. While some may prefer to record all equipment in the facility (and some government agencies may require this), studies have shown that not all equipment needs to be tracked in an inventory, inspected or maintained, and very few hospitals or health-care organizations have the manpower to accomplish this level of effort. Approaches Critical factors Inventory The types and numbers of medical devices to be tracked by the hospital and those that are specifically included in the maintenance programme. Methodology Identification of the method by which maintenance will be provided to the items included in the programme. Resources The financial, physical, and human resources available to the programme. Figure 2. Critical factors in planning a maintenance programme to selecting equipment to record in an inventory and a maintenance programme are important. Section 5.3.4 discusses methods for prioritizing work, which are also helpful in the selection of equipment for inclusion in an inventory. Appendix A.1 outlines one specific method in greater detail. The clinical engineering department is responsible for developing and maintaining the inventory. They are responsible for routinely checking that all the equipment being tracked within a health-care facility is in the inventory and that all the equipment listed in the inventory can be located. The team may find it convenient to perform an inventory while carrying out routine inspections or PM activities. Furthermore, when new equipment arrives it should be inspected and then added to the inventory. Appendix A.2 outlines a policy for initial testing and evaluation, while Appendix D.1 provides a sample form for new equipment received. Please also refer to Introduction to medical equipment inventory management in this technical series for further information.

Methodology

A maintenance programme can be implemented in any number of ways so it is important to consider the variety of methodologies that are available. For example, it is possible for a healthcare organization to establish service contracts with device manufacturers, independent service organizations (ISOs), or a combination of both. In such cases it is essential for the health-care organization to have personnel to monitor and manage the activities of these service contractors. In practice, the typical approach is to establish some level of management and technical capability within the health-care organization. Some of the maintenance activities may also be conducted by employees of the healthcare organization. Other maintenance activities may be conducted by service contractors or other external service providers. One of the most important management activities is to decide which services should be provided by which combination of internal and external service providers, based on the capacity of the facility and its staff. Further details on management and implementation are found in sections 5 and 6, which help in designing an appropriate methodology for a given context.

Resources

Resources needed for maintenance are difficult to project. This requires a maintenance history, calculations of the staff requirement and knowledge of when a piece of equipment might fail. Maintenance also requires appropriate staff skills, education and experience. Outside vendors are necessary for the maintenance of complex equipment. Maintenance requires access to equipment parts which may be difficult to obtain due to budget limitations and procurement difficulties, particularly when purchasing from abroad. To prepare for such challenges, it is important to consider in advance the financial, physical and human resources necessary to properly execute the intended activities. 4.3.1 Financial resources The financial resources required for a maintenance programme (as one component of a comprehensive HTM programme) fall into two categories: initial costs and operating costs. Initial costs are investments that must be made before the programme begins. Operating costs are ongoing expenses required to keep the programme in operation. Table 1 summarizes the major items within each category. Table 1. Financial resources required for a maintenance programme Initial costs Operating costs Physical resources Space, tools, test equipment, computer resources, vehicles. Operation, utilities, maintenance, calibration. Human resources Recruiting, initial training. Salaries, benefits, turnover, continuing education. Direct maintenance (not applicable) Service contracts, parts and materials, travel, shipping. The fi rst step in calculating costs is to specify the physical and human resources needed, based on the number and types of medical equipment in the inventory, and on the level and type of maintenance methodology selected. The initial and operating costs are then calculated using the applicable rates in the country or region. For the IPM component specifically, it is helpful to estimate the workload required by the programme. This is a relatively straightforward process if the estimated time for inspections is known. By counting the number of devices of each type (each common nomenclature type) and multiplying it by the estimated time, it is possible to determine an estimated total workload for the IPM programme. Administrative time to create the IPM forms, preparation time in getting ready to do inspections, time to obtain the equipment to be inspected (either bringing it to a central work area or going to the location of the equipment), time to document the work done and re-order PM parts used, are all activities that should be added to the total workload calculation. An example can be found in Appendix C. Direct maintenance costs can be difficult to estimate initially, but will improve with time and experience. Service contract costs, however, can be determined by negotiation with external service providers. These types of services can be acquired on a time and materials basis or by contracting over a set period at a fixed rate. In either case, the cost must be planned in advance and included in related budgets. Section 5.2.1 discusses further the issues surrounding engagement of service vendors. The cost of service ratio is a useful measure in determining the financial effectiveness of a maintenance programme. This ratio is calculated by dividing the total annual cost of operating a medical equipment maintenance programme by the value (initial cost) of medical equipment in the inventory. In the United States, for example, the cost of service ratio is between 5% and 10% (1). This ratio is achievable only when substantial supporting resources are available, and only after an extended period of performance improvement. For planning purposes in developing countries, this measure may be much higher, especially for new programmes in resource-constrained environments. However, the cost of service ratio, should be monitored over time and be used as a guide for performance improvement efforts. Over time there will be opportunities to make additional investments in the maintenance programme. For example, WHO Medical device technical series 17 the programme may consider providing service for a particular type of equipment by using internal resources and staffing rather than outsourcing the work. At each such opportunity, a simple business plan should be drawn up that includes the initial and operating costs of the proposal. Then the costs and benefits of the current situation and the new proposal can be compared. This decision-making process for new investments is particularly effective when it is informed by actual data from the programme. 4.3.2 Physical resources A maintenance

programme relies on a number of physical resources. These include the workspace, tools and test equipment, supplies, replacement parts, and operation and service manuals needed to perform maintenance. When planning a maintenance programme each of these should be considered individually as follows. Workspace The location in which maintenance will take place should be considered when planning the programme. One option is in the location where the equipment usually resides. For some types of equipment such as X-ray systems, laboratory analysers, sterilizers, and surgical lights, going to the equipment is the only option. In this case, planning to take essential tools and test equipment to the work site or equipping a space closer to the equipment is necessary. The second option is to transport the equipment to the clinical engineering department's repair shop to have the IPM or CM performed. This may be a time consuming process, but the clinical engineering department may be the only location where some maintenance can be performed. A good workspace is clean and well-organized. It provides good lighting and access to utility systems required by the equipment (electricity and medical gases, for example). It includes work benches and storage space for tools and test equipment, repair parts and supplies, and equipment awaiting repair. It also includes space for records and documentation, service and operator manuals, and access to whatever computer resources are required. Inclusion of computer resources in the workspace is also important to consider. Basic documentation may be maintained with paper records but the use of a computer spreadsheet, database programme, or computerized maintenance management system (CMMS) supports good record-keeping, performance monitoring and performance improvement (see section 5.3.6 for more information). Additionally, when internet access is available, it can be a valuable resource. Many technical resources are available online at little or no cost, and online educational programmes may be an option to further technical knowledge and facilitate training.1 Furthermore, inexpensive voice communication and e-mail communication enable effective collaboration across wide distances. However, where internet communication is unreliable, keeping in touch by mobile phone can be an effective alternative. The clinical engineering workshop is typically found within the facility itself, but if the programme includes multiple facilities it may be more economical to establish a centralized repair depot. Tools and test equipment The productivity of biomedical equipment technicians (BMETs) will be limited without appropriate tools and test equipment. As purchases are planned, it should be noted that investment in tools and test equipment results in

Unit V

Clinical engineering is a speciality within HTM (Healthcare Technology Management) biomedical engineering responsible primarily for applying and implementing medical technology to optimize healthcare delivery. Roles of clinical engineers include training and supervising biomedical equipment technicians (BMETs), working with governmental regulators on hospital inspections/audits, and serving as technological consultants for other hospital staff (i.e. physicians, administrators, IT, etc.).[*unreliable source?*]Clinical engineers also advise medical device producers regarding prospective design improvements based on clinical experiences, as well as monitor the progression of the state-of-the-art in order to redirect hospital procurement patterns accordingly.

Their inherent focus on *practical* implementation of technology has tended to keep them oriented more towards *incremental*-level redesigns and reconfigurations, as opposed to *revolutionary* R&D or cutting-edge ideas that would be many years from clinical adoptability; however, there is an effort to expand this time-horizon over which clinical engineers can influence the trajectory of biomedical innovation. In their various roles, they form a sort of "bridge" between product originators and end-users, by combining the perspectives of being both close to the point-of-use, while also trained in product and process design. Clinical engineering departments at large hospitals will sometimes hire not just biomedical engineers, but also IT, industrial/systems engineers to help address operations research, human factors, cost analyses, safety, etc.

In 2011, AAMI arranged a meeting to discuss a new name for clinical engineering and/or biomedical equipment technology. After careful debate, the vast majority decided on "Healthcare Technology Management". Due partly to common confusion about the line between clinical engineers (engineers) and BMETs (technicians), the word *engineering* was deemed limiting from the administrator's perspective and unworkable from the educator's perspective. (An ABET-accredited college could not name an associate degree program "engineering".) Also, the adjective *clinical* limited the scope to hospitals. It remains unresolved how widely or officially accepted this change is or will be, and how this will affect Clinical Engineering Certification (CCE) or the formal recognition of clinical engineering as a subset of biomedical engineering. For regulatory and licensure reasons true engineering specialities must be definable in a way that distinguishes them from technicians with whom they work.

A clinical engineer is defined by the ACCE as "a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology."[9] This definition was first adopted by the ACCE Board of Directors on May 13, 1991. Clinical engineering is also recognized by the Biomedical Engineering Society (BMES), the major professional organization for biomedical engineering, as being a branch within biomedical engineering.[10]

There are at least two issues with the ACCE definition that cause some confusion. First, it is phrased so broadly that it's not readily evident that "clinical engineer" is a subset of "biomedical engineer". Many times the terms are used interchangeably: some hospitals refer to their relevant departments as "Clinical Engineering" departments, while others call them "Biomedical Engineering" departments. Indeed, as noted above, the *technicians* are almost universally referred to as "biomedical equipment technicians," regardless of the name of the department that they might work under. However, the term *biomedical engineer* is generally thought to be more all-encompassing, including engineers who work in the primary design of medical devices for

manufacturers, or in original R&D, or in academia—whereas clinical engineers generally work in hospitals solving problems that are very close to where equipment is actually used in a patient care setting. The clinical engineers in some countries such as India are trained to innovate and find technological solutions for the clinical needs.[11] The other issue not evident from the ACCE definition is the appropriate educational background for a clinical engineer. Generally, the expectation of the certification program is that an applicant for certification as a clinical engineer will hold an accredited bachelor's degree in engineering (or at least engineering technology).

Healthcare has increasingly become technology driven and requires trained manpower to keep pace with the growing demand for professionals in the field. An M-Tech Clinical Engineering course was initiated by Indian Institute of Technology Madras (IITM), Sree Chitra Thirunal Institute of Medical Sciences and Technology, Trivandrum and Christian Medical College, Vellore (CMC), to address the country's need of human resource development. This was aimed at indigenous biomedical device development as well as technology management, and thereby contribute to the overall development of healthcare delivery in the country.

During the course, students of engineering are given an insight into biology, medicine, relevant electronic background, clinical practices, device development and even management aspects. Additionally, students are paired with clinical doctors from CMC and SCTIMST to get hands-on experience during internships. An important aspect of this training is simultaneous, long term and detailed exposure to clinical environment as well as to medical device development activity. This is aimed at making students understand the process of identifying unmet clinical needs and thus, contributing to the development of new medical devices in the country. A unique feature of the course is clinical attachment which exposes the students to the clinical environment. The program also trains engineers to manage and ensure safe and effective use of technology in health care delivery points.

The minimum qualification for joining this course is a bachelor's degree in any discipline of engineering except civil engineering and a valid GATE score in that field.

A hospital is usually referred to as ----------	Health Care Cen	Treatment Center	Medical Treatment Center		Medical Treatment Center
Which of the following mentioned below is not a type of hospital?	District Hospital	Government Hospi	General Hospital	identifica	Government Hospital
An Industry is a the production of goods or related services within -----	a Country	an Economy	a State	special ca	an Economy
----- zone is the area that requires asepsis to perform the surgical service, delivery service, nursery and intensive care	Deep Zone	Inner Zone	Intensive Zone	Vehicles	Deep Zone
The function of a hospital revolve around the ------ and their distribution within various departments and services.	Number of Docto	Number of Beds	Number of Nurses	ingestion	Number of Beds
Every year an estimated 20,000 people in the U.S and 5,000 in the U.K die from ---- ---- they receive from the hospital	The wrong treatn	an infection	the treatment	150	an infection
Teleradiology is one of the earliest fields of ------	Telepsychiatry	Teledematology	Teleradiology	deposit o	Teleradiology
Teleoncolgy is for patients with ------	Cancer	Heart Disease	Kidney Disease	Tsunami	Cancer
Hospital generates mainly three type of wastes and the treatment option for red color coding waste is -----	Chemical Treatm	Deep burial	Disposal in secured landfill	Bushfire	Chemical Treatment
Biomedical waste should be segregated in -----paddle	Secured bin	Color	Oxy-landfill	Shares	Color
A marketing information System is a management information system designed to support -----.	Telemarketing	Digital Marketing	Marketing	Defensive	Marketing
MkIS systems are composed of user interface, application software , system support and ------.	Database	Applied system	Marketing Intelligence	Operatior	Database
Marketing Research is a set of process that links ----- and end users.	Researchers	Customers	Marketing Executives	Indirect C	Customers
Marketing Research System collects data and displays results in the form of ----	Graph	Table	Reports	Depreciat	Reports
Market Research is categorized into two set of pairs, Consumer Market Research and --- Market Research	B2B	B2C	C2B	Capital Fu	B2B
The basic process of market research can be explained with ---- stages	3	4	5	Radioacti	6
Collection of data from current customers for market research depends on their own –-	Creativity	Responsibility	Liability	Domestic	Creativity
---------- are valuable source of business information that can be useful for Market Research.	News Papers	Business Magazines	Business update groups	Black bag	Business Magazines
Which risk is not involved in High involvement purchase?	Personal Risk	Social Risk	Economic Risk	Leak Proc	Investment Risk
The psychological factors of a consumer behavior includes ---	Perception of nee	how a person make	. person's social class	personal	Perception of need
Brand conscious is characterized by the tendency to buy expensive and ----	To seek new brar	to buy well-known l	to shop systematic brands	engagem	to buy well-known brands
Brand Loyal is characterized by -----	To seek new brar	to buy well-known l	to shop top brands	To follow	To follow a routine purchase pattern
Allign the below given Standard behavioral Model in order	Product choice	Product Evaluation	Search for product informa	Usage	, f e c b a d f
Cognitive Dissonance is common in ----- stage	Post Purchase Be	Purchase Decision	Product Evaluation	Product C	Post Purchase Behavior
Which of the following is not a principle of WTO?	Non Descriminati	Reciprocity	Transparency	Negotiati	Negotiation
Traditionally medical records were maintained in ---	Disk	Paper	CD	Online	Paper
Medical history is a longitudinal record of what happened to the patient since ----.	Birth	the date of admissi	illness	the date (	Birth
Obstetric history list complications prior ------ and their outcomes.	Treatment	. Illness	. Pregnancy	Birth	. Pregnancy
Immunization history includes ----.	History of medici	history of vaccinatic	. Family history	history o	history of vaccination
What does progress notes contain?	Daily updates of I	Daily updates of tre	Daily updates of medical re	Progressi	Daily updates of medical record
------ is a computerized system that organizes, stores and double checks all medical records	MIS	PMS	SIS	CIS	CIS
Which is not a benefit of computerized system?	Easy access to pa	Structural Informati	. Improved drug prescriptio	Frequent	Frequent call back to patients to maintain re
---------- identifies demographic and communication data	MIS	PMS	AIS	CIS	PMS
AIS contains primarily administrative details and ------	General support	. Financial Data	Health related information	Administr	. Financial Data
The classification of linen for laundry purpose are Dirty and ----- linen	Soiled	damaged	strained	unused	Soiled
---------- is used to sterilize items that are heat and moisture sensitive	Nitrous Oxide	Ethylene Oxide	Ethanol Oxide	Sulphur C	Ethylene Oxide
Formaldehyde kills ------	Micro nutrients	Microorganisms	Micro particles	Microns	Microorganisms
Dry heat is a form of -----	Oxidized air	Hot air	Air from OT	Steamed	Hot air
The non-ionizing radiation of ------- produces hyperthermic condition that disrupt life process.	Microwave	Formaldehyde gas	Hot air	Hydroger	Microwave
RIS stands for ----	Radiology Inform	Research Informati	Re-entry Information Syste	Random I	Radiology Information System
Determining the effectiveness of a risk management program is known as risk	analysis	control	evaluation	identifica	**evaluation**

Determining what is the likelihood that a particular event or outcome will happen is risk	analysis	control	evaluation	identifica	analysis
The type of variation that is caused by factors outside a system is called	common-cause v	. input/output	processes	special ca	special cause variation
Ash, in its airborne form, can affect ----- by ingestion into engines	Aircraft	Trucks	Ship	Vehicles	**Aircraft**
Volcanic ash may also cause ---------- problems	Vision	respiratory	Internal	ingestion	**respiratory**
The tsunami wave can be very destructive; wave heights of ----- meters have been known.	50	30	100	150	**30**
Which of the following is not a characteristic of an Earthquake?	Fracture	Slippage	Relocating communities	deposit o	**deposit of ash**
…. tends to be seasonal	Volcano	Earthquake	Bushfire	Tsunami	**Bushfire**
Man-made activities may aggravate the possibility and extent of the ---- problem	drought	Valcono	Cyclone	Bushfire	**drought**
Capital formation is the process of securing long-term capital in the form of ----	Asset	Liability	Debt	Shares	**Debt**
Which of the following is not a cause for raise in hospital expenditure?	Lack of commitm	Technology Develo	Government Policies	Defensive	**Government Policies**
The following are the professional services except	Peadiatric	Emergency	Casuality	Operatior	**Peadiatric**
Stardard Cost is?	Finding the cost	Direct Cost	Cost determined in advanc	Indirect C	**Cost determined in advance of Production**
Operating cost is?	Cost incurred in	Overall cost of the	Cost incurred in OT	Depreciat	**Overall cost of the department**
Which of the following is not an approact to rate setting?	Relative Rules	Cost plus percentag	Hour Based Rates	Capital Fu	**Capital Funding**
Waste from surgery and autopsies on patients with infectious diseases are called as	Chemical Waste	Human anatomical	Disposable Waste	Radioacti	**Human anatomical waste**
Which of the following is not a hazardous waste?	Radioactive	Pharmaceutical	Pathological	Domestic	**Domestic**
Infectious wastes are collected in?	Red Bag	Green Bag	Blue Bag	Black bag	**Red Bag**
How is domestic waste disposed?	Landfill	Incineration	Chemical treatment	Leak Proo	**Landfill**

UNIT II

A good health triad does not include ----	Social Status	Mental Status	Economic Status	**Economic Status**
Determinants of health does not include ---	Agent	Risk Factors	Environment	**Agent**
Epidemiological triad does not include ---	Agent	Risk Factors	Environment	**Risk Factors**
According to Gordon's classification of prevention of disease includes all except one.	Universal preven	Selective preventio	Indicated Prevention	**Primary Prevention**
Prevent Complications is included in which level of prevention?	Primordial	Secondary	Tertiary	**Secondary**
New Cases in population during a fixed period is determined by ---	Prevalence Ratio	Attack Rate	Disability Rate	**Incidence Rate**
Advantages of cohort study are all except	Bias Minimized	Relative risk can be	Dose response ratio can be	**Incidence cannot be calculated**
Study which proceed from effect to cause	Case Control	Ecological	Experimental	**Case Control**
Capability to identify who has the disease is done by measuring –	Sensitivity	Specificity	Repeatability	**Sensitivity**
Pecularity of hospital as an organization is all except	dual Authority	Personalized Servic	No unit in line of command	**Personalized Service**
Organization effectiveness comprises all except	Adaptability to c	Flexibility in structu	Rigidity in Structure	**Flexibility in structure and strategy**
Factors influencing core variables are all except	Mobility	Decentralization	Autonomy	**Mobility**
Types of models of effectiveness are all except	Relation goal Mc	Close system mode	Internal process model	**Close system model**
Which is the skeleton of Organization?	Organizational St	Decentralization	Co-ordination	**Organizational Structure**
Which services are not a part of hospital service?	Additional Servic	Utility Service	Administrative Service	**Additional Service**
All except one is the output indicator of hospital system	Public Relation	Quality of care	Machines	**Quality of care**
Supportive services of the hospitals include except	Laboratory Servic	House Keeping Se	Laundry Service	**House Keeping Service**
Which is not the basis of classification of hospital?	Functional	Size	Shape	**Size**
Which of the following is not a functional division of hospital?	Secondary	Tertiary	Quaternary	**Tertiary**
Concept behind changing the role of hospital from indoor care to out-patient care includes all except	Shortage of hosp	Economic importan	Increase of hospital beds	**Economic importance**
Care provided by the hospital on day care includes all except	Cataract Operatic	Sterilization	Caesarian Section	**Sterilization**
Which of the service is not a part of preventive care	Nutritional couns	Non communicable	OPD Service	**Non communicable disease prevention**

Care of disability includes all except	Disability limitati	Rehabilitation	Treatment of fracture	**Treatment of fracture**
Health promotive services not include	Health Screenin	Mental Counseling	Treatment of ARI	**Mental Counseling**
The functions of the out-patient department include	Training of Medic	Social Search	All the above	**All the above**
As norm of planning process, the average number patients expected to visit OPD daily are	5 for every autho	10 for every author	10 for every 100 authorizec	**2 for every authorized bed**
The COPP had concluded that an OPD doctor examines	25-40 patients pe	50-75 patients per	75-90 patients per day	**25-40 patients per day**
COPP had advocated the following as reasons for overcrowding in OPD's except	Absence of appoi	Shortage of medica	Ineffective public relation	**Ineffective public relation**
The type of day care surgical units include except	Hospital Autonor	Hospital Satellite U	Hospital Galaxy Unit	**Hospital Galaxy Unit**
"Shopping Window" of a hospital is----	ICU	OPD	Cafeteria	**OPD**
Which of the following is best suited for walls and ceiling of OT?	Terrazo Tiles	Glaze Tiles	In Suit Mosiac Tiles	**In Suit Mosiac Tiles**
For electro conduction of OT floors?	Super conductive	Conduction should	Lag time conduction should	**Conduction should be sufficient to dispense with stat**
Air change required per hour in OT is ---	16-18	28-30	58-60	**16-18**
HEPA provides an atmosphere which is	80% particulate f	90% particulate fre	100% particulate free	**90% particulate free**
For effective changes in operation theater the best of the following is	Low Turbulence	Mechanical extract	Low to High displacement	**Low Turbulence displacement airflow**
The nursing process is utilized to	Encourage family	Increase involveme	None of the above	**Provide systematic approach to meet client needs**
Objective data might include	Complaint of dizz	An evaluation of Bl	None of the above	**An evaluation of Blood Pressure**
According to Maslow's hirarchy of human needs, the highest level is	Safety and securi	Esteem and self-res	Self-actualization	**Self-actualization**
All the following are indicative physical signs of poor nutrition , except	Brittle, thin and s	Tongue - deep red i	Spongy, bleed easily recess	**Brittle, thin and sparse hair**
Development of an infection occurs in a cycle that depends on the presence of all the elements except	Source for patho	Health care worker	A portal of exit, a mode of t	**Health care worker**
All the flowing are essential standard precautions used in the care of all patients irrespective of whether they are diagnosed infectious or not ,except	Improper sharps	Personal protective	Aseptic techniques	**Improper sharps and waste disposal**
Which of the following is the appropriate route of administration for insulin?	Intradermal	Subcutaneous	Intravenous	**Subcutaneous**
All the following are Patient's responsibilities, except	Complying with i	Give different kind	Following hospital rules and	**Give different kind of care**
Which of the following is the meaning of PRN?	When necessary	Immediately	Now	**When necessary**
The following is the most important purpose of documentation?except	To Reimburseme	To Quality assuranc	To provide comfort	**To provide comfort**
State the piece of information that does not need to be kept on a hospital record	Detail on appetit	Medication supplie	Urine/faeces passed	**Medication supplier**
Identify the additional care points that should be provided for recumbent patients	Assistance with e	Encourage limb mo	All the above	**All the above**
Identify the additional care points that should be amended for recumbent patients	Rub and stroke b	Assist the animal to	Groom and clean away any	**Turn the animal every 24 hours to prevent fluid pooli**
Identify the factor in the barrier nursing process that needs to be amended	Cleaning equipm	Feeding materials a	One member of staff to wo	**Wear normal footwea**

UNIT III

with dehydration secondary to vomiting and diarrhea. What is the best method used to assess the client's temperature?	Axillary	Radial	Heat sensitive tape	**Heat sensitiv**
The nurse is working on a unit that uses nursing assessment flow sheets. Which statement best describes this form of charting?	graphic information	routine aspects of care	Contain vital data collected upon admission	**Are compre**
The nurse is to administer an iron injection to an adult. How should this be administered?	Intradermal in the forearm	Intramuscular in the deltoid	Z track intramuscular in the gluteal	**Z track intramu**
assessment. Which finding might lead the nurse to suspect a nutritional alteration?	Shiny hair	Ridged nails	Moist conjunctiva	**Ridged nails**
A patient asks you what vitamin is best for eye sight. Your response is	Vitamin A	Vitamin B6	Vitamin B12	**Vitamin A**
To assessment of immobilized patient focus on the following except	activity tolerance	body alignment	Psychological condition	**Psychol ogical**
Changes that occur in musculoskeletal system due to immobility	calcium metabolism	calcium,fluid and electrolyte	None of the above	**decreas e**
Non verbal massage is a mode of communication that include the following except	Facial expression	Gesture	Touch	**Tone& pitch of**
An instrument placed against a patient's chest to hear both lung and heart sounds.	otoscope	sphygmomanomet er	telescope	**stethos cope**
SIPOC provides a view of the process that contains approximately how many steps?	5,7	8,5	11,15	**5,7**
QFD is a planning process for products and services. It starts with:	The voice of the customer	. A relationship matrix	Quality specifications	**The voice of .**
A _____ is used to create a model of the affect on an output by the variation in two or more of the inputs.	Linear Regression	. Multiple Regression	X-Y Diagram	**Multipl**
Which of the following statements regarding Six Sigma team leadership is true?	a full-time team lead.	typically creates the project	least four projects per year.	**. A Black**
When flowcharting a process, which symbol is used to identify a decision?	Square	Oval	Diamond	**Diamon d**

The primary goals of Six Sigma are to improve:	retention and employee	Defect rate and profitability	Knowledge transfer and cycle time	**Effectiveness**
The peak of the bell-shaped curve represents:	Process sigma	fatness of the shape of the	The mean or average of the distribution	**The mean or**
A cause-effect diagram is used in which of the following phases?	The narrowing phase	. The close phase	The decision phase	**The open**
Which of the following statements is not true of the null hypothesis?	would expect by chance alone	Assumes things to be equal	None of the above	**. It is your**
A measure of the time a unit or service is idle within a process.	Wait Time	Sampling	RACI	**Wait Time**
A process is in-control and stable. Describe the type of variation that exists in the process.	. Natural Variation	Out-the-ordinary variation	Non-random variation	**. Natural**
Identify the checks on medication that should be made for in-patients	Dosage to be administered	medication to be given and route of	All of the above	**All of the**
Identify the check that is incorrect for patients receiving fluid therapy	patient interference	is running in properly	Monitoring of hydration status	**Care and**
Two explanations of collective behaviour are emergent norm theory and _____	social contagion	relative deprivation	social breakdown	**resource**
According to Marxists, revolts to bring about a major overhaul of society are _____.	gender revolts	gender revolts	new social movements	**gender revolts**
Every type of Organization will require ---------to ensure that the organizational role and works are fulfilled	Data	people	Machine	**People**
Which of the following is not a motivational factor for the resource providers?	Political	Self-Satisfaction	Religious	**Self-Satisfac**
A resource mobilization plan becomes effective when the organization analyzes -------	Existing resources	Golas	Future Requirement	**Existing resourc**
Which of the following is not a feature of Resource Mobilization?	Resource Provider	Cost Management	Right use of resource	**Cost Manage**
Which of the following is one of the reason for maintaining resource mobilization?	relationship with	Reduce Man power	Remove Bad practices	**Expand relation**
Every organization can develop code of conduct on ----	Disaster Management	Financial Management	Waste Management	**Resource**

UNIT IV

Questions	Option b	Option c	Option d	Answers
1.Maintenance consists of the following action(s)	Repair of component	Service of component	All of above	All of the above
2.The down time cost consists of	Wages paid to the workers	Reduction in sales	All of the above	All of the above
3. The following is not a classification of maintenance	Timely maintenance	Scheduled maintenance	Preventive maintenance	maintenance
4.Belt of an electric motor is broken, it needs	Scheduled maintenance	Preventive maintenance	Timely maintenance	maintenance
5. Equipment history cards are meant to record	of the equipment	different components wear	All of the above	All of the above
6. Total productive maintenance aims at	increase in productivity	zero down time	none of the above	down time
7. Total Productive maintenance(TPM) approach has the potential of providing almost a seamless integration between	Quality&Maintenance	Production & maintenance	All of the above	All of the above
8.With the increase in preventive maintenance cost , breakdown maintenance cost	decreases	remain same	any of the above	decreases
9.Productivity=	Output/Input	Output-Input	Input-Output	Output/Input
10.The resources utilised for production are	Methods,Machines	Manpower, Methods	Methods,Machine,Manpower	s, Machine
11.Productivity is the _ of production system	Efficiency	Both a and b	None of the above	Efficiency
12. Productivity=	1+(Cost/Profit)	1-(Profit/Cost)	1-(Cost/Profit)	1+(Profit/Cost)
13.Productivity can be measured in which of the following input resources	Labour input	Capital and Land input	All of the above	All of the above
14. Raw material productivity can be increased by	Reuse of material	Scrap control	All of the above	All of the above
15. Preventive maintenance improves	Labour productivity	Machine productivity	Capital productivity	Productivity
16.Productivity can be increased by	input for same output	Both a and b	None of the above	both a and b
17. The time for which tje the worker or machine or both remain idle due to the shortcomings of the management or workers is known as	idle time	ineffective time	work content	ineffective time
18.The elimination of which of the following will improve industrial productivity	ineffective time	both a and b	none of the above	both a and b
19. Which of the following adds idle time due to short runs?	Lack of Standardization	Both a and b	Design changes	both a and b
20. Total work content=	content - Excess time	content+Ineffective time	Basic work content-Ineffective time	
21.A_____ is a medical imaging technology which provides economical storage of and convenient access to images from multiple modalities.	Teleradiology	and communication	Radiology	Archiving and Teleradiology
22._____ is the transmission of radiological patient images,such as x-rays,CTs and MRI from one location to other for the purposes of sharing studies.	Radiology	Transmission radiology	PACS	
23.Managerial decisions are classified into _____ types.	3	5	2	4

24.Policy decisions should emerge from _____.	evidence-based policy process.	operational planing process	Control process	integrated planing
25._____ starts with estimating the resource needs to achieve policy goals.	Facility planning	Equipment planning	Material planning	decisionsnal
address the issues regarding the utilization of resources in the attainment of organization goals.	control decisions	Strategic planing decisions	operational decisions	decisions
27.An MIS is a _____ system which provides information to the managers for decision making.	Computer-based	Equipment - based	system-based	Computer-based
28 ALOS is the acronym of _____	Hospital Strength	Average Length of Hospital Stay	Average Lab-errors of Hospital System	Length of
29._____types of groups can be classified under Bio-Medical wastes.	3	4	5	2
30.Disposal of Bio-medical wastes should be done within _____ hours.	32	48	12	48
31.Allocation of nursing staff to clinical ward given the acute shortage of nurse is a example of _____.	Resource Allocation	Discharge planning	Facility planning	Allocation
32.Managing inventories in _____ is important as it accounts 40% of the value of the hospital supplies.	Lab store	OT sub-store	Resource store	OT sub-store
33._____ in a hospital can be compared with monitoring the life of a sick patient in an ICU.	Discharge planning management	Monitoring and Material planning Management	Monitoring and Equipment planning Management and	ng and control Management
34.HMIS stand for _____	Information	Information	Infrastructure service	
35.The distribution of food can be done by _____ methods.	3	4	5	2
36.Food distribution by kitchen staffs is known as _____ system.	De-centralized	Localized	De-Localized	Centralized
37.An internal purchase committee consists of _____ members.	5	4 or 5	3 or 4	3 or 4
38.vegetarian food diet has the nutritive value of _____ calories.	3207	2730	3720	2370
39.The linen after laundering will be transferred to a _____ section of the linen room for the sorting and dispatch.	untidy	unfair	obscure	clean
40.The vegetarian meals which are adopted in CGHS institutions are according to _____ standard.	IMRC	IRMC	IRCM	ICMR
41.House keeping and maintainence services in a Hospital includes _____	Boiler house	Incinerator	All the above	All the above
42._____plays a vital role in controlling infections.	Boiler arrangements.	Mortuary arrangements.	none of the above	arrangements.
43.In Laundry the heavily infected materialsare soaked in _____.	dis infectant	tained	insanitary	dis infectant
44._____ number of postmortem rooms will be adequate for a hospital.	3	4	5	2
45. The bed strength in post mortem room can be _____.	300-400	400-500	500-600	500-600

UNIT V

Questions	Option b	Option c	Option d	Answers
1. Organisation establishes relationship between	Customer , work and resources	People , work and management	Customer, work and management	work and
2. Organisation is a process of	delegating the responsibility &	Both a and b	None of the above	Both a and b
3.Responsibility always flows from	Subordinate to superior	Both a and b	None of the above	ate to superior
4.Authority always flows from	Subordinate to superior	Both a and b	None of the above	to subordin
5.'No one on the organisation should have more than one boss' is a statement of	Principle of authority	Principle of unity of command	Principle of span of control	of unity of
6.The no.of . persons which can be effectively supervised by a single executive or department head should be limited to_ in an average firm.	Ten	Fourteen	Twenty	Six
7.The following is not a principle of organisation	Principle of balance	Principle of complexity	Principle of co- ordination	of complexi
8. As per the principle of balance , there should be balance between	Authority and responsibility	procesures and flexibility	All of the above	All of the above
9.The following is not a type of organisation structure	Functional organisation	Line and staff organisation	Flexible organisation	organisation
10 . The following is also known as Military organisation	Functional organisation	Line and Staff organisation	None of the above	organisation
11.In line organisation , the business activities are divided into following three types	Production, Quality,Sales	Quality,Maintenance	Production, Maintenance, Sales	,Production,Sales
12.In which of the following organisation structure , each specialist is supposed to give his functional advice to all other foremen and workers	Functional organisation	Line and staff orgainsation	All of the above	al organisa
13.Which organisation structure is generally followed by big steel pla ts?	Functional organisation	Line and staff organisation	All of the above	staff organisa
14.The process of dividing the work and then grouping them into units and subunits for the purpose of administration is known as	Organisation structure	Committee	All of the above	Departmentation
15.Departmentation is a process where	grouped into effective work	gropued into identifiable	All of the above	All of the above

15.Departmentation leads to grouping of	Personnel	Both a and b	None of the above	Both a and b
16. The department can be created by	B product	By process	All of the above	All of the above
17. In hospitals, the following type of departments is common	By committee	By geographical region	All of the above	By function
18.All the following are Patient's responsibilities , except	Complying with instructions	Give different kind of care	Following hospital rules and regulations	different kind of necessary
19.Which of the following is the meaning of PRN?	When necessary	Immediately	Now	
20.The following is the most important purpose of documentation?except	To Reimbursement	To Quality assurance	To provide comfort	
21.There are _____ types of hospital staffs available in hospital.	3	4	5	3
22.There are _____ types of staffing system available in hospital.	3	4	5	2
23.The _____ system will not interfere in detailed handling of the patients by the colleagues	Parallel	Paramedical	Non medical	Hierarchical
24.A _____is the one who should engage himself in clinical work to avoid becoming a office doctor.	medico-social worker	Nursing staff	Pharmacists	administrator
25.A medical record is the record of _____.	patients	data	documents	illness
26.PPP Stands for _____.	Patient Privacy Policy	Public Policy Process	Private policy process	Private Partners
27.The _____ has clearly laid down thepolicy decisions on staff requirements,their qualifications,workload in Private and public hospitals.	Medical staff	Medical council	Medical officer	Medical council
28.Hospital size is indicated by _____.	Number of persons analysing technique	Number of doctors hard vs soft chemistry	Number of staffs public vs private chemistry	Number of beds dry chemistry
29.Auto-analyser technology is a _____	Health and Development	Committee of Health and data.	Council of Health and Management	Health
30.CHAD stands for _____.				
31.The nurse patient ratio required for I.C.U and I.C.C.U is _____	2:01	2:04	1:03	1:01
32.The holidays that can availed by the staffs for a year is _____ days	10	9	7	12
33.Staffing means _____.	Providing the staffing material	Providing the staff chart	Providing the staff salary	g the nursing
34._____cares in organising an efficient nursing care for both in and out patients .	Medical administration	Para medical association	Resource allocation	Nursing Services
35.The assistant nursing superintendents should make a visit atleast _____ times a day in each unit.	3 to 4	4 to 5	5 to 6	2 to 3
36._____ of the wards ,sections and department of the hospital to cover _____ hours.	24	18	48	24
37.Kitchen is classified into _____ functional areas.	6	8	7	10
38.The Protien content present in vegetarian diet is _____gms	64	94	25	65
39.An index card is kept in _____.	active box	passive box	locker	active box
40.The size of an index card is _____.	5X3	3x2	2x5	3x5

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