CONTENTS

UNIT

1

MEDICAL LAWS AND ETHICS IN INDIA

STRUCTURE

1.0 LEARNING OBJECTIVES

After completion of the unit, you will be able to:

- Understand Medical Laws in India
- Describe Emergency Healthcare and Laws
- Discuss Criminal Liability in Medical Profession
- Explain Laws Applicable to Hospitals
- Describe Code of Ethics Regulations, 2002

1.1 INTRODUCTION

Human culture is built upon the formulation of values that form the basis of an ethical society, honesty, integrity, respect, pursuit of excellence, civic duty, accountability and loyalty. Since the dawn of civilization, by trial or error, it has become established that a society and more so it's medical profession, a public oriented and noble profession, can survive and thrive only by observance and practice of certain rules of conduct guided by ethical, moral, legal and social values of land.

Healthcare in Indian features a universal healthcare care system run by the constituent states and territories. The constitution charges every state with 'raising the level of nutrition and the standard of living of its people and improvement of public health as among its primary duties. Law is an obligation on the part of society imposed by the competent authority, and noncompliance may lead to punishment in the form of monetary fine or imprisonment or both.

In a survey conducted at Mumbai, eight out of 10 doctors feel that the laws that govern the practice of healthcare in India are outdated and even higher majority feels that there are too many laws and licenses that are required to keep their practice going. A survey among 297 doctors across specializations says that there are about 50 different laws that govern the practice of healthcare in India. The study conducted by Medscape India, a nonprofit trust of doctors, revealed that 78% of doctors feel that many of the laws that govern medical practice are outdated. Licenses have to be procured by doctors running a hospital every year.

1.2 MEDICAL LAWS IN INDIA

The earliest civilization known to us is the Indus urban culture of 3000 to 2000 BC. The renowned medical historian Henry Sigerist believed that public health facilities of Mohenjo Daro were superior to those of any other community of the ancient orient. Since the ancient times, certain duties and responsibilities have been cast on persons who adopt this acred profession. This is exemplified by Charak's Oath (1000 BC) and Hippocratic Oa th (460 BC).

The written evidence of the state's involvement and regulatory function is available from the Kautilya's Arthashastra. Kautilya considered famine as a bigger calamity than pestilence and epidemics, as the remedies can be found for the diseases. He believed that the king should order the physician to use medicine to counter epidemics. The earliest known code of laws of health practices were the laws formulated around 2000 BC by Hammurabi, the great king of Babylon. These laws, also called the code of Hammurabi governed the various aspects of health practices, including the fees payable to physician for satisfactory services. The laws were drastic and penalties for harmful therapy stringent.

Doctors whose proposed therapy proved wrong ran the risk of being killed. This was the first codification of medical practice. The first ever code of medical ethics called the Hippocratic Oath was laid down 2500 years ago, in the 5th century BC, by Hippocrates—the Greek physician. He is remembered till today as the 'Father of western medicine'. Hippocratic Oath has been guiding and regulating the conduct of doctors for centuries. The modern version of Hippocratic Oath (called the declaration of Geneva), devised by the WHO after the second world war and accepted by international medical fraternity as the international code of medical ethics, draws heavily upon the ancient oath.

During the Ashoka period (270 BC), the state showed interest in the public works and provision of medical care and as a law. He founded hospitals all over his empire with medical attendance at state expense. Ethics is described in the Charaka—Samhita, in details and Ayurvedic physicians of ancient India has a well-defined medical ethics". The colonial power brought with them their own physicians and barber surgeons. In the mid 19 century, as the medicine got recognized in England, it slowly started having its impact in India too.

After 1857, the main factors that shaped colonial health policy in India were their concern for troops and European civil population. The process of establishment

of healthcare system also necessitated creation of legislative framework for practitioners of medicine. In the earlier period of rule, the physicians and surgeons brought by the East India Company and after 1857 by the British Government needed some discipline and regulations. Lt Colonel DG. Crawfords 'A history of Indian medical services, 1600-1913' narrates several instances of in-discipline, insubordination, malpractice, etc. by such doctors and the punishments (including deportation) mated out to them.

It also narrates the regulation devised by the East India Company for the hospitals established by them. After the enactment of the law, establishing General Medical Council in 1857 in England, the British doctors employed in India were registered with the GMC and came under its disciplinary regulation. As the number of doctors qualified in Indian medical colleges increased, creation of laws for them became necessary. As a part of criminal procedures and for other purposes, the colonial government had, in 1871, enacted Coroner's act applicable to Bombay and Calcutta. It defined the role of medical professionals in the work of conducting autopsy and inquests.

However, the laws for the creation of indigenous medical councils took many more years for enactment. Mean-while, the laws were enacted for the prevention of the spread of dangerous epidemic disease, for the segregation and medical treatment of pauper, etc. The epidemic disease act was first enacted in 1807 and is still in force with amendments, while the Lepers Act 1898 was repealed and substituted by another law in early 1980s. Grant Medical College Society in 1880 passed a Bombay Medical Act and established the medical council. The draft rule of this act included the appointment of a registrar, maintenance of name in register and penalty for doing wrong things.

The Bombay Presidency enacted Bombay Medical Act in 1912. Medical acts in some other provinces soon followed. The Bengal Medical Act and Madras Medical Registration Act were enacted in 1914. These provincial acts were immediately followed by the Indian Medical Degree Act, passed by the Indian Legislative Council and approved by the Governor General in 1916. The Medical Council of India, a national level statutory body for the doctors of modern medicine, was constituted after the enactment of Indian Medical Council Act 1933. The first legal recognition and registration for the Indian systems of medicine came when the Bombay Medical Practioner Act was passed in 1938.

Post 1947 Developments

The independence in 1947 inaugurated a new phase of development of organized health care services creating more entitlement for the people. Along with that, the state also embarked on enactment of new laws, modification of the colonial laws and judiciary developed case laws to consolidate people's entitlement of health care and to extent the rights. At the time of independence and the first few years of planning, the task confronting the country was to create physical and institutional infrastructure for the rapid development or modernization of India. With time, the parliament has passed a large number of bills and acts to strengthen the healthcare delivery in India.

Prerequisites of Medical Practice

A duly qualified medical professional, i.e. a doctor has a right to seek to practice medicine, surgery and dentistry by registering himself with the medical council of the state of which he is resident, by following the procedure as prescribed under the medical act of the state. The state medical council has the power to warn, refuse to register/remove from the name of a doctor who has been sentenced by any court for any nonbailable offence or found to be guilty of infamous conduct in any professional respect.

The state medical council has also the power to re-enter the name of the doctor in the register. The provision regarding offences and professional misconduct which may be brought before the appropriate medical council (state/medical Council of India) have been stated in the Indian Medical council (Professional conduct, etiquette and ethics) Regulation 2002. No action against a medical practitioner can be taken unless an opportunity has been given to him to be heard in person or through an advocate.

1.3 EMERGENCY HEALTHCARE AND LAWS

The Supreme Court has been emphatic in declaring that the fundamental right to life covered within its scope the right to emergency healthcare. The landmark judgment that marked this momentous event is that of Parmanand Katara V, Union of India (Supreme Court 1989). In this case, a scooterist severely injured in a road accident was refused for admission when taken to nearest hospital on the excuse that hospital was not competent to handle medicolegal cases. The Supreme Court, in its judgment, pronounced that the obligation of medical professionals to provide treatment in cases of emergencies overrode the professional freedom to refuse patients.

According to the right to emergency treatment, the status of a fundamental right under Article 21 (fundamental right of life), the court categorically stated that 'Article 21 of constitution casts the obligation on the state to preserve life. Interestingly, the Supreme Court went on to say that not only government hospitals but also 'every doctor whether at a government hospital or otherwise has the professional obligation to extend his/her service with due expertise for protecting life.

In another case (Paschim Banga Khet Majdoor Samity vs State of West Bengal, Supreme Court, 1996), a person suffering from head injuries from a train accident was refused treatment at various hospitals on excuse that they lacked the adequate facilities and infrastructure to provide treatment. In this case, supreme court further developed the right to emergency treatment, and went on to state that the failure on the part of government hospital to provide timely medical treatment to a person in need of such treatment results in violation o f his/her right to life guaranteed under Article 21.

1.4 CRIMINAL LIABILITY IN MEDICAL PROFESSION

Criminal law tries to mold the individual behavior in a socially accepted manner. It tries to enforce the rules of social mortality to a great extent. Criminal law defines

certain types of human conduct as offences and prescribes the punishment for them. Remission by doctors in their duties and obligations and lapses left by them may give to criminal liabilities, the liabilities of being prosecuted in a criminal court and awarded punishment as per provision of law.

The criminal law operates on a doctor in somewhat a different manner than an ordinary person. This is because it allows a doctor to cause injury to the patient for *preventing a greater harm. The crucial area of criminal law for a doctor is offences* affecting life. These offences are mainly murder, simply hurt, grievous hurt and miscarriage or abortion. A doctor may be charged for any of these offences in general. However, the criminal law arms a doctor with *three formidable defences namely:*

1. Informed consent,
2. Necessity and
3. Good faith.

Various criminal liabilities in medical practice related to different sections of Indian Penal Code, the code of criminal procedure and different acts like MTP, PCPNDT, Transplantation of Human Organ Act, etc.

1.5 LAWS APPLICABLE TO HOSPITALS

Laws Governing the Commissioning of Hospital

These are the laws to ensure that the hospital facilities are created after due process of registration, the facilities created are safe for the public using them, have at least the minimum essential infrastructure for the type and volume of workload anticipated, and are subject to periodic inspections to ensure compliance. These are listed in below:

Laws Governing the Commissioning of Hospital:

1. Atomic Energy Act 1962
2. Delhi Lift Rules 1942, Bombay Lift Act 1939
3. Draft Delhi Lifts and Escalators Bill 2007
4. Companies Act 1956
5. Electricity Rules 1956
6. Delhi Electricity Regulatory Commission (Grant of consent for captive power plants) Regulations 2002
7. Delhi Fire Prevention and Fire Safety Act 1986, and Fire Safety Rule 1987
8. Delhi Nursing Home Registration Act 1953
9. Electricity Act 1998
10. Electricity Rules 1956
11. Indian Telegraph Act 1885
12. National Building Act 2005
13. Radiation Protection Certificate from BARC
14. Society Registration Act

15. Urban Land Act 1976
16. Indian Boilers Act 1923
17. The Clinical Establishment (Registration and Regulation) Bill 2007

NOTES

Laws Governing to the Qualification/Practice and Conduct of Professionals

These are the regulations to ensure that staff employed in the hospital for delivery of healthcare are qualified and authorised to perform certain specified technical jobs within specified limits of competence and in accordance with standard codes of conduct and ethics, their credential are verifiable from the registering councils and in case of any professional misconduct the councils can take appropriate action against them. These laws are listed below:

Laws Governing to the Qualification/Practice and Conduct of Professionals

1. The Indian Medical Council Act 1956
2. Indian Medical Council (Professional Conduct, Etiquette, and Ethics Regulations 2002)
3. Indian Medical degree Act 1916
4. Indian Nursing Council Act 1947
5. Delhi Nursing Council Act 1997
6. The Dentist's Act 1948
7. AICTE Rules for Technicians 1987
8. The Paramedical and Physiotherapy Central Councils Bill 2007
9. The Pharmacy Act 1948
10. The Apprenticeship Act 1961

Laws Governing to Sale, Storage of Drugs and Safe Medication

These are laws to control the usage of drugs, chemicals, blood, blood products, prevent misuse of dangerous drugs, regulate the sale of drugs through licenses, prevent adulteration of drugs and provide for punitive action against the offenders. These are listed below:

Laws Governing to Sale, Storage of Drugs and Safe Medication:

1. Blood Bank Regulation under Drugs and Cosmetics (2nd Amendment) Rules 1999
2. Drugs and Cosmetics Act 1940 and Amendment Act 1982
3. Excise permit to store the spirit, Central Excise Act 1944
4. IPC Section 274 (Adulteration of drugs), Sec 275 (Sale of Adulterated drug), Sec 276 (Sale of drug as different drug or preparation), Sec 284 (negligent conduct with regard to poisonous substances)
5. Narcotics and Psychotropic Substances Act

6. Act 1948
7. *Sales of Good Act 1930*
8. The Drug and Cosmetics Rule 1945
9. The Drugs Control Act 1950
10. VAT Act/Central Sales Tax Act 1956

Laws Governing Management of Patients

These are the laws for setting standards and norms for conduct of medical professional practice, regulating/ prohibiting performance of certain procedure, prevention of unfair practices and control of public health problems/epidemic disease. They deals with the management of emergencies, medicolegal cases and all aspects related there to including dying declaration, and conduct of autopsy and the types of professional negligence. These laws are listed below:

Laws Governing Management of Patients:

1. Birth and Deaths and Marriage Registration Act 1886
2. Drugs and Magic Remedies (Objectionable) Advertisement Act
3. Guardians and Wards Act 1890
4. Indian Lunacy Act 1912
5. Law of Contract Section 13 (for consent)
6. Lepers' Act
7. PNDT Act 1994 and Preconception and Prenatal Diagnostic Tech (prohibition of sex selection) Rules 1996 (Amendment Act 2002)
8. The Epidemic Disease Act 1897
9. Transplantation of Human Organ Act 1994, Rules 1995
10. Medical Termination of Pregnancy Act 1971
11. Medical Termination of Pregnancy Rules 2003
12. The Mental Health Act 1987

Laws Governing Environmental Safety

These are the laws aimed at protection of environment through prevention of air, water, surface, noise pollution and punishment of offenders. These laws are listed below:

Laws Governing Environment Safety:

1. Air (prevention and control of pollution) Act 1981
2. Biomedical Waste Management Handling Rules 1998 (Amended on 2000)
3. Environment Protection Act and Rule1986, 1996
4. NOC from Pollution Control Board
5. Noise Pollution Control Rule 2000
6. Public Health Bye Law 1959
7. Water (prevention and control of pollution) Act 1974
8. Delhi Municipal Corporation (malaria and other mosquito borne diseases) Bye Law 1975

9. The Cigarettes and Other Tobacco Products (prohibition of advertisement and regulation of trade and commerce, production, supply and distribution) Bill 2003
10. Prohibition of Smoking in Public Places Rules 2008
11. IPC Section 278 (making atmosphere noxious to health), Sec 269 (negligent act likely to spread infection or disease dangerous to life, unlawfully or negligently)

Laws Governing Employment and Management of Manpower

This group deals with the laws regulating the employment of manpower, their salaries and benefits, service rules and system of redressal of grievances and disputes. These laws are listed below:

Laws Governing to Employment and Management of Manpower:

1. Bombay Labor Welfare Fund Act 1953
2. Citizenship Act 1955
3. Delhi Shops and Establishment Act 1954
4. Employee Provident Fund and Miscellaneous Provision Act 1952
5. Employment Exchange (compulsory notification of vacancies) Act 1959
6. Equal Remuneration Act 1976
7. ESI Act 1948
8. ESI Rules 1950
9. Indian Trades Union Act 1926
10. Industrial Dispute Act 1947
11. Maternity Benefits Act 1961
12. Minimum Wages Act 1948
13. Negotiable Instrument Act 1881
14. Payment of Bonus Act 1956
15. Payment of Gratuity Act 1972
16. Payment of Wedges Act 1936
17. Persons with Disabilities Act 1995
18. PPF Act 1968
19. SC and ST ACT 1989
20. Shops and Factories Act (for national holiday)
21. TDS Act
22. The Essential Service Maintenance Act 1981
23. The Payment of Gratuity Act 1972
24. Workmen's Compensation Act 1923

Laws Governing to Medicolegal Aspects

These are the laws governing the doctor-patient relationship, legal consequences of breach of contract and medicolegal aspects of negligence of duty. These laws are listed below:

Laws Governing to Medicolegal Aspects:

1. Consumer Protection Act 1986
2. Indian Evidence Act
3. Law of privileged communication
4. Law of torts
5. IPC Section 52 (good faith), Sec 80 (accident in doing lawful act), Sec 89 (for insane & children), Sec 90 (consent under fear), Sec 92 (good faith/consent), Sec 93 (communication in good faith).

Laws Governing the Safety of Patients, Public and Staff within the Hospital Premises

These laws deal with safety of facilities and services against any accidental hazards that may endanger the lives and the liability of management for any violation. These laws are listed below:

Laws Governing the Safety of Patients, Public and Staff Within the Hospital Premises:

1. The Radiation Surveillance Procedures for the Medical Application of Radiation 1989, Radiation Protection Rules 1971
2. AERB Safety Code no. AERB/SC/Med-2(rev-1) 2001
3. Arms Act 1950
4. Boilers Act 1923
5. Explosive Act 1884 (for diesel storage)
6. Gas Cylinder Rules 2004
7. Insecticide Act 1968
8. IPC Section 336 (act endangering life or personal safety of others), Sec 337 (causing hurt by act endangering life or personal safety of others), Sec 338 (causing grievous hurt by act endangering the life and personal safety of others).
9. NOC from chief fire office
10. Periodic fitness certificate for operation of lifts
11. Petroleum Act and Storage Rules 2002
12. Prevention of Food Adulteration Act 1954
13. The Indian Fatal Accidents Act 1955
14. The Tamil Nadu Medicare Service Persons and Medicare Service Institutions (prevention of violence and damage or loss to property) Act 2008

Laws Governing Professional Training and Research

There are the laws meant to regulate the standards of professional education and training of doctors, nurses, technician and controlling research activities. These laws are listed below:

Laws Governing Professional Training and Research:

1. MCI rules for MBBS, PG and internship training
2. National board of examination rules for DNB training
3. ICMR rules governing medical research
4. NCI rules for nursing training
5. Ethical Guidelines for Biomedical Research on Human Subjects, 2000

Laws Governing the Business Aspects

Some rules are applicable to hospital in relation to its business aspects. These are listed below:

Laws Governing the Business Aspects:

1. Cable Television Network Act 1995
2. Charitable and Religious Trusts Act 1920
3. Contracts Act 1982
4. Copyright Act 1982
5. Custom Act 1962
6. FEMA 1999
7. Gift Tax Act 1958
8. Income Tax Act 1961
9. Insurance Act 1938
10. Sales of Good Act 1930

Licenses/Certifications Required for Hospitals

A hospital administrator should be aware about the licenses that are essentially required and to renew them as and when required. These are as listed below:

Licenses/Certifications Required for Hospitals Sr. no. Licenses/ Certifications Frequency:

1. Registration under societies registration act initially
2. Inspection for electrical installation/substation initially
3. NOC from local municipal office for any bye law initially
4. License for storage of petrol/diesel on form XV under the petroleum rules 2002 2 yearly
5. Income tax exemption certificate 3 yearly
6. NOC from Delhi fire services before implementation
7. Registration for operation of X-ray installation with AERB Every 2 years
8. Drug License for medical store, IPD pharmacy, OPD pharmacy every 5 years
9. License to operate blood bank under rule 122G of drug and cosmetic act Every 5 years
10. Registration under PNDT Act 1994 Every 5 years

11. Income tax registration/PAN Once only
12. Registration for VAT/Sales tax once only
13. Registration for EPF Once only
14. Registration for ESI coverage of employee once only
15. Registration under rule 34, sub rule (6) of MTP Act 1971 One time registration
16. Registration under Delhi nursing Home Act 1953 Yearly
17. Indemnity insurance policy yearly
18. Standard fire and special perils policy yearly
19. Authorization for generation of BMW under BMW handling rule 1996 Yearly renewal
20. License for operating lift under Sect 5 and 6 and Rules 4 and 5 (inspector of lift, state government) Yearly renewal

Periodic Reports and Returns as Legal Commitment

A hospital administrator should be aware about the reports and returns that are essentially required by different agencies with fixed periodicity. Some of these are listed below:

Periodic Reports and Return as Legal Commitment for Hospitals

Sr. no. Periodic Reports and Return for Hospitals Frequency:

1. Biomedical waste generation Annual
2. Income Tax Annual return
3. Units processed in blood bank monthly
4. MTP reports Monthly
5. PNDT report (prenatal USG done) Monthly
6. Employees provident fund Monthly/annual
7. ESI act Monthly/annual
8. VAT Monthly/quarterly online
9. Registration of births and deaths on every occurrence
10. Post polio paralysis case on every occurrence
11. Communicable disease report on every occurrence
12. Radiologist registration under PNDT On induction of a new radiologist
13. USG machine registration under PNDT On induction of each machine
14. Needle sticks injuries on occurrence
15. TLD Badges for monitoring the dosage received Quarterly
16. TDS Quarterly

The health legislations are very few as compared to the size and problems in the health care sector. There is a need for having a comprehensive health care act, framed in order to gear the entire health care sector to the objectives laid down in the different policy in India. Most of the common medico legal situations arise out on noncompliance with these rules and regulations. If a hospital or doctor acquaints well with these rules and regulations and follows them sincerely, he/she would be on the right side of the law.

1.6 CODE OF ETHICS REGULATIONS, 2002

The Medical Council of India, with the previous approval of the Central Government, hereby makes the following regulations relating to the Professional Conduct, Etiquette and Ethics for registered medical practitioners, namely:-

Short Title and Commencement:

1. These Regulations may be called the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002.
2. They shall come into force on the date of their publication in the Official Gazette.

CHAPTER 1. CODE OF MEDICAL ETHICS

(a) Declaration: Each applicant, at the time of making an application for registration under the provisions of the Act, shall be provided a copy of the declaration and shall submit a duly signed Declaration as provided in Appendix 1. The applicant shall also certify that he/she had read and agreed to abide by the same.

(b) Duties and responsibilities of the Physician in general:

1.1 Character of Physician (Doctors with qualification of MBBS or MBBS with post graduate degree/ diploma or with equivalent qualification in any medical discipline):

1.1.1 A physician shall uphold the dignity and honour of his profession.

1.1.2 The prime object of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. Who- so-ever chooses his profession, assumes the obligation to conduct himself in accordance with its ideals. A physician should be an upright man, instructed in the art of healings. He shall keep himself pure in character and be diligent in caring for the sick; he should be modest, sober, patient, prompt in discharging his duty without anxiety; conducting himself with propriety in his profession and in all the actions of his life.

1.1.3 No person other than a doctor having qualification recognised by Medical Council of India and registered with Medical Council of India/State Medical Council (s) is allowed to practice Modern system of Medicine or Surgery. A person obtaining qualification in any other system of Medicine is not allowed to practice Modern system of Medicine in any form.

1.2 Maintaining Good Medical Practice:

1.2.1 The Principal objective of the medical profession is to render service to humanity with full respect for the dignity of profession and man. Physicians should merit the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion. Physicians should try continuously to improve medical knowledge and skills and should make available to their patients and colleagues the benefits of their professional attainments. The physician should practice methods of healing founded on scientific basis and should not associate professionally with anyone who violates this principle. The honoured ideals of the

medical profession imply that the responsibilities of the physician extend not only to individuals but also to society.

1.2.2 Membership in Medical Society: For the advancement of his profession, a physician should affiliate with associations and societies of allopathic medical professions and involve actively in the functioning of such bodies.

1.2.3 A Physician should participate in professional meetings as part of Continuing Medical Education programmes, for at least 30 hours every five years, organized by reputed professional academic bodies or any other authorized organisations. The compliance of this requirement shall be informed regularly to Medical Council of India or the State Medical Councils as the case may be.

1.3 Maintenance of Medical Records:

1.3.1 Every physician shall maintain the medical records pertaining to his / her indoor patients for a period of 3 years from the date of commencement of the treatment in a standard proforma laid down by the Medical Council of India and attached as Appendix 3.

1.3.2. If any request is made for medical records either by the patients / authorised attendant or legal authorities involved, the same may be duly acknowledged and documents shall be issued within the period of 72 hours.

1.3.3 A Registered medical practitioner shall maintain a Register of Medical Certificates giving full details of certificates issued. When issuing a medical certificate he / she shall always enter the identification marks of the patient and keep a copy of the certificate. He / She shall not omit to record the signature and/ or thumb mark, address and at least one identification mark of the patient on the medical certificates or report. The medical certificate shall be prepared as in Appendix 2.

1.3.4 Efforts shall be made to computerize medical records for quick retrieval.

1.4 Display of Registration Numbers:

1.4.1 Every physician shall display the registration number accorded to him by the State Medical Council / Medical Council of India in his clinic and in all his prescriptions, certificates, money receipts given to his patients.

1.4.2 Physicians shall display as suffix to their names only recognized medical degrees or such certificates/diplomas and memberships/honours which confer professional knowledge or recognizes any exemplary qualification/achievements.

1.5 Use of Generic names of drugs: Every physician should, as far as possible, prescribe drugs with generic names and he / she shall ensure that there is a rational prescription and use of drugs.

1.6 Highest Quality Assurance in patient care: Every physician should aid in safeguarding the profession against admission to it of those who are deficient in moral character or education. Physician shall not employ in connection with his professional practice any attendant who is neither registered nor enlisted under the Medical Acts in force and shall not permit such persons to attend, treat or perform operations upon patients wherever professional discretion or skill is required.

NOTES

1.7 Exposure of Unethical Conduct: A Physician should expose, without fear or favour, incompetent or corrupt, dishonest or unethical conduct on the part of members of the profession.

1.8 Payment of Professional Services: The physician, engaged in the practice of medicine shall give priority to the interests of patients. The personal financial interests of a physician should not conflict with the medical interests of patients. A physician should announce his fees before rendering service and not after the operation or treatment is under way. Remuneration received for such services should be in the form and amount specifically announced to the patient at the time the service is rendered. It is unethical to enter into a contract of "no cure no payment". Physician rendering service on behalf of the state shall refrain from anticipating or accepting any consideration.

1.9 Evasion of Legal Restrictions: The physician shall observe the laws of the country in regulating the practice of medicine and shall also not assist others to evade such laws. He should be cooperative in observance and enforcement of sanitary laws and regulations in the interest of public health. A physician should observe the provisions of the State Acts like Drugs and Cosmetics Act, 1940; Pharmacy Act, 1948; Narcotic Drugs and Psychotropic substances Act, 1985; Medical Termination of Pregnancy Act, 1971; Transplantation of Human Organ Act, 1994; Mental Health Act, 1987; Environmental Protection Act, 1986; Pre-natal Sex Determination Test Act, 1994; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; Persons with Disabilities (Equal Opportunities and Full Participation) Act, 1995 and Bio-Medical Waste (Management and Handling) Rules, 1998 and such other Acts, Rules, Regulations made by the Central/State Governments or local Administrative Bodies or any other relevant Act relating to the protection and promotion of public health.

CHAPTER 2. Duties of Physicians to Their Patients

2.1 Obligations to the Sick

2.1.1 Though a physician is not bound to treat each and every person asking his services, he should not only be ever ready to respond to the calls of the sick and the injured, but should be mindful of the high character of his mission and the responsibility he discharges in the course of his professional duties. In his treatment, he should never forget that the health and the lives of those entrusted to his care depend on his skill and attention. A physician should endeavour to add to the comfort of the sick by making his visits at the hour indicated to the patients. A physician advising a patient to seek service of another physician is acceptable, however, in case of emergency a physician must treat the patient. No physician shall arbitrarily refuse treatment to a patient. However for good reason, when a patient is suffering from an ailment which is not within the range of experience of the treating physician, the physician may refuse treatment and refer the patient to another physician.

2.1.2 Medical practitioner having any incapacity detrimental to the patient or which can affect his performance vis-à-vis the patient is not permitted to practice his profession.

2.2 Patience, Delicacy and Secrecy: Patience and delicacy should characterize the physician. Confidences concerning individual or domestic life entrusted by patients to a physician and defects in the disposition or character of patients observed during medical attendance should never be revealed unless their revelation is required by the laws of the State. Sometimes, however, a physician must determine whether his duty to society requires him to employ knowledge, obtained through confidence as a physician, to protect a healthy person against a communicable disease to which he is about to be exposed. In such instance, the physician should act as he would wish another to act toward one of his own family in like circumstances.

2.3 Prognosis: The physician should neither exaggerate nor minimize the gravity of a patient's condition. He should ensure himself that the patient, his relatives or his responsible friends have such knowledge of the patient's condition as will serve the best interests of the patient and the family.

2.4 The Patient Must not be Neglected: A physician is free to choose whom he will serve. He should, however, respond to any request for his assistance in an emergency. Once having undertaken a case, the physician should not neglect the patient, nor should he withdraw from the case without giving adequate notice to the patient and his family. Provisionally or fully registered medical practitioner shall not willfully commit an act of negligence that may deprive his patient or patients from necessary medical care.

2.5 Engagement for an Obstetric Case: When a physician who has been engaged to attend an obstetric case is absent and another is sent for and delivery accomplished, the acting physician is entitled to his professional fees, but should secure the patient's consent to resign on the arrival of the physician engaged.

CHAPTER 3. Duties of Physician in Consultation

3.1 Unnecessary consultations should be avoided:

3.1.1 However in case of serious illness and in doubtful or difficult conditions, the physician should request consultation, but under any circumstances such consultation should be justifiable and in the interest of the patient only and not for any other consideration.

3.1.2 Consulting pathologists /radiologists or asking for any other diagnostic Lab investigation should be done judiciously and not in a routine manner.

3.2 Consultation for Patient's Benefit: In every consultation, the benefit to the patient is of foremost importance. All physicians engaged in the case should be frank with the patient and his attendants.

3.3 Punctuality in Consultation: Utmost punctuality should be observed by a physician in making themselves available for consultations.

3.4 Statement to Patient after Consultation:

3.4.1 All statements to the patient or his representatives should take place in the presence of the consulting physicians, except as otherwise agreed. The disclosure of the opinion to the patient or his relatives or friends shall rest with the medical attendant.

3.4.2 Differences of opinion should not be divulged unnecessarily but when there is irreconcilable difference of opinion the circumstances should be frankly and impartially explained to the patient or his relatives or friends. It would be opened to them to seek further advice as they so desire.

3.5 Treatment after Consultation: No decision should restrain the attending physician from making such subsequent variations in the treatment if any unexpected change occurs, but at the next consultation, reasons for the variations should be discussed/explained. The same privilege, with its obligations, belongs to the consultant when sent for in an emergency during the absence of attending physician. The attending physician may prescribe medicine at any time for the patient, whereas the consultant may prescribe only in case of emergency or as an expert when called for.

3.6 Patients Referred to Specialists: When a patient is referred to a specialist by the attending physician, a case summary of the patient should be given to the specialist, who should communicate his opinion in writing to the attending physician.

3.7 Fees and other charges:

3.7.1 A physician shall clearly display his fees and other charges on the board of his chamber and/or the hospitals he is visiting. Prescription should also make clear if the Physician himself dispensed any medicine.

3.7.2 A physician shall write his name and designation in full along with registration particulars in his prescription letter head.

Note: In Government hospital where the patient–load is heavy, the name of the prescribing doctor must be written below his/her signature.

CHAPTER 4. Responsibilities of Physicians to Each Other

A physician should consider it as a pleasure and privilege to render gratuitous service to all physicians and their immediate family dependants.

4.2 Conduct in consultation : In consultations, no insincerity, rivalry or envy should be indulged in. All due respect should be observed towards the physician in-charge of the case and no statement or remark be made, which would impair the confidence reposed in him. For this purpose no discussion should be carried on in the presence of the patient or his representatives.

4.3 Consultant not to take charge of the case: When a physician has been called for consultation, the Consultant should normally not take charge of the case, especially on the solicitation of the patient or friends. The Consultant shall not criticize the referring physician. He / she shall discuss the diagnosis treatment plan with the referring physician.

4.4 Appointment of Substitute: Whenever a physician requests another physician to attend his patients during his temporary absence from his practice, professional courtesy requires the acceptance of such appointment only when he has the capacity to discharge the additional responsibility along with his / her other duties. The physician acting under such an appointment should give the

utmost consideration to the interests and reputation of the absent physician and all such patients should be restored to the care of the latter upon his/her return.

4.5 Visiting another Physician's Case: When it becomes the duty of a physician occupying an official position to see and report upon an illness or injury, he should communicate to the physician in attendance so as to give him an option of being present. The medical officer / physician occupying an official position should avoid remarks upon the diagnosis or the treatment that has been adopted.

CHAPTER 5. Duties of Physician to the Public and to the Paramedical Profession

5.1 Physicians as Citizens: Physicians, as good citizens, possessed of special training should disseminate advice on public health issues. They should play their part in enforcing the laws of the community and in sustaining the institutions that advance the interests of humanity. They should particularly co-operate with the authorities in the administration of sanitary/public health laws and regulations.

5.2 Public and Community Health: Physicians, especially those engaged in public health work, should enlighten the public concerning quarantine regulations and measures for the prevention of epidemic and communicable diseases. At all times the physician should notify the constituted public health authorities of every case of communicable disease under his care, in accordance with the laws, rules and regulations of the health authorities. When an epidemic occurs a physician should not abandon his duty for fear of contracting the disease himself.

5.3 Pharmacists / Nurses: Physicians should recognize and promote the practice of different paramedical services such as, pharmacy and nursing as professions and should seek their cooperation wherever required.

CHAPTER 6. Unethical Acts

A physician shall not aid or abet or commit any of the following acts which shall be construed as unethical -

6.1 Advertising:

6.1.1 Soliciting of patients directly or indirectly, by a physician, by a group of physicians or by institutions or organisations is unethical. A physician shall not make use of him / her (or his / her name) as subject of any form or manner of advertising or publicity through any mode either alone or in conjunction with others which is of such a character as to invite attention to him or to his professional position, skill, qualification, achievements, attainments, specialities, appointments, associations, affiliations or honours and/or of such character as would ordinarily result in his self aggrandizement. A physician shall not give to any person, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report or statement with respect of any drug, medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode

nor shall he boast of cases, operations, cures or remedies or permit the publication of report thereof through any mode. A medical practitioner is however permitted to make a formal announcement in press regarding the following:

1. On starting practice.
2. On change of type of practice.
3. On changing address.
4. On temporary absence from duty.
5. On resumption of another practice.
6. On succeeding to another practice.
7. Public declaration of charges.

6.1.2 Printing of self photograph, or any such material of publicity in the letter head or on sign board of the consulting room or any such clinical establishment shall be regarded as acts of self advertisement and unethical conduct on the part of the physician. However, printing of sketches, diagrams, picture of human system shall not be treated as unethical.

6.2 Patent and Copy rights: A physician may patent surgical instruments, appliances and medicine or Copyright applications, methods and procedures. However, it shall be unethical if the benefits of such patents or copyrights are not made available in situations where the interest of large population is involved.

6.3 Running an open shop (Dispensing of Drugs and Appliances by Physicians): - A physician should not run an open shop for sale of medicine for dispensing prescriptions prescribed by doctors other than himself or for sale of medical or surgical appliances. It is not unethical for a physician to prescribe or supply drugs, remedies or appliances as long as there is no exploitation of the patient. Drugs prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as generic name of the drug.

6.4 Rebates and Commission:

6.4.1 A physician shall not give, solicit, or receive nor shall he offer to give solicit or receive, any gift, gratuity, commission or bonus in consideration of or return for the referring, recommending or procuring of any patient for medical, surgical or other treatment. A physician shall not directly or indirectly, participate in or be a party to act of division, transference, assignment, subordination, rebating, splitting or refunding of any fee for medical, surgical or other treatment.

6.4.2 Provisions of para **6.4.1** shall apply with equal force to the referring, recommending or procuring by a physician or any person, specimen or material for diagnostic purposes or other study / work. Nothing in this section, however, shall prohibit payment of salaries by a qualified physician to other duly qualified person rendering medical care under his supervision.

6.5 Secret Remedies: The prescribing or dispensing by a physician of secret remedial agents of which he does not know the composition, or the manufacture or promotion of their use is unethical and as such prohibited. All the drugs prescribed by a physician should always carry a proprietary formula and clear name.

6.6 Human Rights: The physician shall not aid or abet torture nor shall he be a party to either infliction of mental or physical trauma or concealment of torture *inflicted by some other person or agency in clear* violation of human rights.

6.7 Euthanasia: Practicing euthanasia shall constitute unethical conduct

However on specific occasion, the question of withdrawing supporting devices to sustain cardio-pulmonary function even after brain death, shall be decided only by a team of doctors and not merely by the treating physician alone. A team of doctors shall declare withdrawal of support system. Such team shall consist of the doctor in charge of the patient, Chief Medical Officer / Medical Officer in charge of the hospital and a doctor nominated by the in-charge of the hospital from the hospital staff or in accordance with the provisions of the Transplantation of Human *Organ Act*, 1994.

CHAPTER 7. Misconduct

The following acts of commission or omission on the part of a physician shall constitute professional misconduct rendering him/her liable for disciplinary action

7.1 Violation of the Regulations: If he/she commits any violation of these Regulations.

7.2 If he/she does not maintain the medical records of his/her indoor patients for a period of three years as per regulation 1.3 and refuses to provide the same within 72 hours when the patient or his/her authorised representative makes a request for it as per the regulation 1.3.2.

7.3 If he/she does not display the registration number accorded to him/her by the State Medical Council or the Medical Council of India in his clinic, prescriptions and certificates etc. issued by him or violates the provisions of regulation 1.4.2.

7.4 Adultery or Improper Conduct: Abuse of professional position by committing adultery or improper conduct with a patient or by maintaining an improper association with a patient will render a Physician liable for disciplinary action as provided under the Indian Medical Council Act, 1956 or the concerned State Medical Council Act.

7.5 Conviction by Court of Law: Conviction by a Court of Law for offences involving moral turpitude / Criminal acts.

7.6 Sex Determination Tests: On no account sex determination test shall be undertaken with the intent to terminate the life of a female foetus developing in her mother's womb, unless there are other absolute indications for termination of pregnancy as specified in the Medical Termination of Pregnancy Act, 1971. Any act of termination of pregnancy of normal female foetus amounting to female foeticide shall be regarded as professional misconduct on the part of the physician leading to penal erasure besides rendering him liable to criminal proceedings as per the provisions of this Act.

7.7 Signing Professional Certificates, Reports and other Documents: Registered medical practitioners are in certain cases bound by law to give, or may from time to time be called upon or requested to give certificates, notification, reports and other documents of similar character signed by them in their professional

capacity for subsequent use in the courts or for administrative purposes etc. Such documents, among others, include the ones given at Appendix –4. Any registered practitioner who is shown to have signed or given under his name and authority any such certificate, notification, report or document of a similar character which is untrue, misleading or improper, is liable to have his name deleted from the Register.

7.8 A registered medical practitioner shall not contravene the provisions of the Drugs and Cosmetics Act and regulations made there under. Accordingly,

(a) Prescribing steroids/ psychotropic drugs when there is no absolute medical indication;

(b) Selling Schedule 'H' & 'L' drugs and poisons to the public except to his patient; in contravention of the above provisions shall constitute gross professional misconduct on the part of the physician.

7.9 Performing or enabling unqualified person to perform an abortion or any illegal operation for which there is no medical, surgical or psychological indication.

7.10 A registered medical practitioner shall not issue certificates of efficiency in modern medicine to unqualified or non-medical person.

(Note: The foregoing does not restrict the proper training and instruction of bonafide students, midwives, dispensers, surgical attendants, or skilled mechanical and technical assistants and therapy assistants under the personal supervision of physicians.)

7.11 A physician should not contribute to the lay press articles and give interviews regarding diseases and treatments which may have the effect of advertising himself or soliciting practices; but is open to write to the lay press under his own name on matters of public health, hygienic living or to deliver public lectures, give talks on the radio/TV/internet chat for the same purpose and send announcement of the same to lay press.

7.12 An institution run by a physician for a particular purpose such as a maternity home, nursing home, private hospital, rehabilitation centre or any type of training institution etc. may be advertised in the lay press, but such advertisements should not contain anything more than the name of the institution, type of patients admitted, type of training and other facilities offered and the fees.

7.13 It is improper for a physician to use an unusually large sign board and write on it anything other than his name, qualifications obtained from a University or a statutory body, titles and name of his speciality, registration number including the name of the State Medical Council under which registered. The same should be the contents of his prescription papers. It is improper to affix a sign-board on a chemist's shop or in places where he does not reside or work.

7.14 The registered medical practitioner shall not disclose the secrets of a patient that have been learnt in the exercise of his / her profession except–

(i) In a court of law under orders of the Presiding Judge;

(ii) In circumstances where there is a serious and identified risk to a specific person and / or community; and

(iii) Notifiable diseases.

NOTES

In case of communicable/notifiable diseases, concerned public health authorities should be informed immediately.

7.15 The registered medical practitioner shall not refuse on religious grounds alone to give assistance in or conduct of sterility, birth control, circumcision and medical termination of Pregnancy when there is medical indication, unless the medical practitioner feels himself/herself incompetent to do so.

7.16 Before performing an operation the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of minor, or the patient himself as the case may be. In an operation which may result in sterility the consent of both husband and wife is needed.

7.17 A registered medical practitioner shall not publish photographs or case reports of his/her patients without their permission, in any medical or other journal in a manner by which their identity could be made out. If the identity is not to be disclosed, the consent is not needed.

7.18 In the case of running of a nursing home by a physician and employing assistants to help him/her, the ultimate responsibility rests on the physician.

7.19 A Physician shall not use touts or agents for procuring patients.

7.20 A Physician shall not claim to be specialist unless he has a special qualification in that branch.

7.21 No act of in vitro fertilization or artificial insemination shall be undertaken without the informed consent of the female patient and her spouse as well as the donor. Such consent shall be obtained in writing only after the patient is provided, at her own level of comprehension, with sufficient information about the purpose, methods, risks, inconveniences, disappointments of the procedure and possible risks and hazards.

7.22 Research: Clinical drug trials or other research involving patients or volunteers as per the guidelines of ICMR can be undertaken, provided ethical considerations are borne in mind. Violation of existing ICMR guidelines in this regard shall constitute misconduct. Consent taken from the patient for trial of drug or therapy which is not as per the guidelines shall also be construed as misconduct.

7.23 If a physician posted in rural area is found absent on more than two occasions during inspection by the Head of the District Health Authority or the Chairman, Zila Parishad, the same shall be construed as a misconduct if it is recommended to the Medical Council of India/State Medical Council by the State Government for action under these Regulations.

7.24 If a physician posted in a medical college/institution both as teaching faculty or otherwise shall remain in hospital/college during the assigned duty hours. If they are found absent on more than two occasions during this period, the same shall be construed as a misconduct if it is certified by the Principal/Medical Superintendent and forwarded through the State Government to Medical Council of India/State Medical Council for action under these Regulations.

NOTES

CHAPTER 8. Punishment and Disciplinary Action

8.1 It must be clearly understood that the instances of offences and of Professional misconduct which are given above do not constitute and are not intended to constitute a complete list of the infamous acts which calls for disciplinary action, and that by issuing this notice the Medical Council of India and or State Medical Councils are in no way precluded from considering and dealing with any other form of professional misconduct on the part of a registered practitioner. Circumstances may and do arise from time to time in relation to which there may occur questions of professional misconduct which do not come within any of these categories. Every care should be taken that the code is not violated in letter or spirit. In such instances as in all others, the Medical Council of India and/or State Medical Councils have to consider and decide upon the facts brought before the Medical Council of India and/or State Medical Councils.

8.2 It is made clear that any complaint with regard to professional misconduct can be brought before the appropriate Medical Council for Disciplinary action. Upon receipt of any complaint of professional misconduct, the appropriate Medical Council would hold an enquiry and give opportunity to the registered medical practitioner to be heard in person or by pleader. If the medical practitioner is found to be guilty of committing professional misconduct, the appropriate Medical Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register of the name of the delinquent registered practitioner. Deletion from the Register shall be widely publicized in local press as well as in the publications of different Medical Associations/ Societies/Bodies.

8.3 In case the punishment of removal from the register is for a limited period, the appropriate Council may also direct that the name so removed shall be restored in the register after the expiry of the period for which the name was ordered to be removed.

8.4 Decision on complaint against delinquent physician shall be taken within a time limit of 6 months.

8.5 During the pendency of the complaint the appropriate Council may restrain the physician from performing the procedure or practice which is under scrutiny.

8.6 Professional incompetence shall be judged by peer group as per guidelines prescribed by Medical Council of India.

APPENDIX - 1

DECLARATION

NOTES

At the time of registration, each applicant shall be given a copy of the following declaration by the Registrar concerned and the applicant shall read and agree to abide by the same:

1. I solemnly pledge myself to consecrate my life to service of humanity.
2. Even under threat, I will not use my medical knowledge contrary to the laws of Humanity.
3. I will maintain the utmost respect for human life from the time of conception.
4. I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient.
5. I will practice my profession with conscience and dignity.
6. The health of my patient will be my first consideration.
7. I will respect the secrets which are confined in me.
8. I will give to my teachers the respect and gratitude which is their due.
9. I will maintain by all means in my power, the honour and noble traditions of medical profession.
10. I will treat my colleagues with all respect and dignity.
11. I shall abide by the code of medical ethics as enunciated in the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002.

I make these promises solemnly, freely and upon my honour.

Signature .....

Name .....

Place .....

Address

.....

.....

.....

Date .....

NOTES

APPENDIX – 2

FORM OF CERTIFICATE RECOMMENDED FOR LEAVE OR EXTENSION OR COMMUNICATION OF LEAVE AND FOR FITNESS

Signature of patient

or thumb impression .....

To be filled in by the applicant in the presence of the Government Medical Attendant, or Medical Practitioner.

Identification marks:-

.....

.....

I, Dr. ..... after careful examination of the case certify hereby that ..... whose signature is given above is suffering from ..... and I consider that a period of absence from duty of ..... with effect from ..... is absolutely necessary for the restoration of his health.

I, Dr. ..... after careful examination of the case certify hereby that ..... on restoration of health is now fit to join service.

Place ..... **Signature of Medical attendant.**

Date ..... Registration No. .....

(Medical Council of India / State Medical Council of ..... State)

Note:- The nature and probable duration of the illness should also be specified. This certificate must be accompanied by a brief resume of the case giving the nature of the illness, its symptoms, causes and duration.

APPENDIX-3

FORMAT FOR MEDICAL RECORD

(See Regulation 3.1)

NOTES

Name of the patient : .....

Age : .....

Sex : .....

Address : .....

Occupation : .....

Date of 1st visit : .....

Clinical note (summary) of the case: .....

Prov. : Diagnosis : .....

Investigations advised with reports: .....

Diagnosis after investigation: .....

Advice : .....

Follow up

Date: .....

Observations: .....

Signature in full .....

Name of Treating Physician .....

APPENDIX–4

LIST OF CERTIFICATES, REPORTS, NOTIFICATIONS ETC. ISSUED BY DOCTORS FOR THE PURPOSES OF VARIOUS ACTS / ADMINISTRATIVE REQUIREMENTS

(a) Under the acts relating to birth, death or disposal of the dead.

(b) Under the Acts relating to Lunacy and Mental Deficiency and under the Mental illness Act and the rules made thereunder.

(c) Under the Vaccination Acts and the regulations made thereunder.

(d) Under the Factory Acts and the regulations made thereunder.

(e) Under the Education Acts.

(f) Under the Public Health Acts and the orders made thereunder.

(g) Under the Workmen's Compensation Act and Persons with Disability Act.

(h) Under the Acts and orders relating to the notification of infectious diseases.

(i) Under the Employee's State Insurance Act.

(j) In connection with sick benefit insurance and friendly societies.

(k) Under the Merchant Shipping Act.

(l) For procuring / issuing of passports.

(m) For excusing attendance in courts of Justice, in public services, in public offices or in ordinary employment.

(n) In connection with Civil and Military matters.

(o) In connection with matters under the control of Department of Pensions.

(p) In connection with quarantine rules.

(q) For procuring driving licence.

(Published in Part III, Section 4 of the Gazette of India, dated 22nd February, 2003)

MEDICAL COUNCIL OF INDIA

NOTIFICATION

New Delhi, Dated 2003

No.MCI-211(2)2002-Regn.- In exercise of the powers conferred under section 20A read with section 33(m) of the Indian Medical Council Act, 1956 (102 of 1956), the Medical Council of India, with the previous approval of the Central Government, hereby makes the following amendments to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, namely:-

Short Title and Commencement: (i) These Regulations may be called the Indian Medical Council (Professional conduct, Etiquette and Ethics) (Amendment) Regulations, 2003.

NOTES

(ii) They shall come into force on the date of their publication in the Official Gazette.

In the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, the regulations, 7.23 and 7.24 appearing under Chapter 7, shall be omitted.

(Published in Part III, Section 4 of the Gazette of India, Extraordinary dated 27th May, 2004)

MEDICAL COUNCIL OF INDIA

NOTIFICATION

New Delhi, Dated 11th March, 2002

No. MCI-211(2)/2004-(Ethical). - In exercise of the powers conferred under section 20A read with section 33(m) of the Indian Medical Council Act, 1956 (102 of 1956), the Medical Council of India, with the previous approval of the Central Government, hereby makes the following amendments to the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, namely:-

1. Short Title and Commencement: (i) These Regulations may be called the Indian Medical Council (Professional conduct, Etiquette and Ethics) (Amendment) Regulations, 2004.
2. In the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, after the regulation 8.6 appearing under Chapter 8, the following regulations, shall be added:

"8.7 Where either on a request or otherwise the Medical Council of India is informed that any complaint against a delinquent physician has not been decided by a State Medical Council within a period of six months from the date of receipt of complaint by it and further the MCI has reason to believe that there is no justified reason for not deciding the complaint within the said prescribed period, the Medical Council of India may-

(i) Impress upon the concerned State Medical council to conclude and decide the complaint within a time bound schedule;

(ii) May decide to withdraw the said complaint pending with the concerned State Medical Council straightaway or after the expiry of the period which had been stipulated by the MCI in accordance with para (i) above, to itself and refer the same to the Ethical Committee of the Council for its expeditious disposal in a period of not more than six months from the receipt of the complaint in the office of the Medical Council of India."

"8.8 Any person aggrieved by the decision of the State Medical Council on any complaint against a delinquent physician, shall have the right to file an appeal to the MCI within a period of 60 days from the date of receipt of the order passed by the said Medical Council:

Provided that the MCI may, if it is satisfied that the appellant was prevented by sufficient cause from presenting the appeal within the aforesaid period of 60 days, allow it to be presented within a further period of 60 days.

NOTES

UNIT

2

LAWS RELATED TO MEDICAL PRACTICE

STRUCTURE

2.0 LEARNING OBJECTIVES

After completion of the unit, you will be able to:

- Understand Legal Aspects in Medical Practice
- Describe Qualities of a Good Health Professional
- Discuss Medical council act
- Explain Disability act
- Define Legal aspects of medical records, transplantation of human organ act
- Describe prevention of food and adulteration act, medical termination of pregnancy act, and Birth and death registration act
- Discuss Sex determination act and Indian mental health act, 1987

2.1 INTRODUCTION

Medical law is the branch of law which concerns the prerogatives and responsibilities of medical professionals and the rights of the patient. It should not be confused with medical jurisprudence, which is a branch of medicine, rather than a branch of law.

The main branches of medical law are the law on confidentiality, negligence and torts in relation to medical treatment (most notably medical malpractice), and criminal law in the field of medical practice and treatment. Ethics and medical practice is a growing field.

2.2 LEGAL ASPECTS IN MEDICAL PRACTICE

Earlier medical profession was considered to be a noble field. The patient's faith and trust in doctors was so much that a doctor was equated to an "Angel or Semigod". Gradually, this relationship is turning into a love and hate phenomenon. In this era of specialisation and super specialisation, the focus of medical profession is progressing from a noble one to a commercial one. The increasing cost of medical education, equipments, construction of clinics and hospitals are to some extent responsible for the commercial approach on part of doctors. Patients now are also more interested in facilities and good looking hospital rather then quality of care and competency of doctors. In this scenario, litigations related to medical practice are on the rise. The intent of this article is to sensitise the readers to the basics of legal aspects in medical practice in India. Usually, legal problems start if there is a controversy regarding the duties and rights of doctors.

Duties of Doctors

Every doctor has some basic things to do as he approaches a patient. He must *listen* to the patient (take proper history) and *examine* him carefully. A doctor has to *attend* to the patient and give *diligent care*, once he decides to treat the patient. He must *explain* the relevant facts related to the illness and give *proper medicines.* The doctors must have average, recent *knowledge and equipments* in possession, as per their speciality. The practitioners must be able to *foresee* the complications and *refer* the patient at proper time. Doctors must also maintain a proper *record* of their patients.

Rights of Doctors

Doctors don't just have duties, they also have some rights. A doctor has a right to *turn away* a patient before starting treatment but he should provide minimal basic care especially in an emergency situation. He has a right to select *the drugs* from wide range of options available, supported by standard medical practice. A doctor can also select *the investigations and method of treatment* depending upon various factors. He/she should obtain a written refusal in case the patient does not want to do as advised. He/she *can delegate* the powers to properly trained personnels or colleagues, usually with the willingness of patient. However, a better alternative for the practitioners is to start group practice so that one of the regular consultant

NOTES

is always available. A doctor can decide regarding visits, *fees* to be charged and to maintain the patient's *record* including its secrecy in certain specific situations.

Different Laws

Civil Laws

Every individual has a private right and in order to protect the right there is a legal remedy. According to Law of Torts, a doctor shall be responsible for his negligent act. According to Sec. 70 of Indian Contract Act, there is a contract (oral, written or implied) between a doctor and a patient, and both parties are bound by it. If a doctor doesn't give complete or proper treatment then he/she may be held liable. Similarly, if a patient doesn't pay the fees, doctors can file a civil suit. Doctors can take advances or deposits (this is legal) before starting treatment but they can't keep the patient in confinement (this is against law) on the ground of nonpayment of fees.

Civil suits most of the times are expensive, time-consuming and cumbersome.

Criminal Law

There are some public wrongs. In order to protect the community, the state/ government has the right to punish the wrong doer, through various agencies. Criminal laws and police are usually not involved in doctor-patient relation-ship unless there is gross rashness or negligence resulting either in death or serious injury. Some of the common sections of Indian Penal Code (IPC) which are applicable to doctors include:

(i) Sec. 52 which defines what is good faith;

(ii) Sec. 87-91 which are related to consent,

(iii) Sec. 304-A which is related to death of patient due to negligent act;

(iv) Sec. 312-316 are related to causing abortions or miscarriage without proper consent;

(v) Sec. 319-322 deals with causing grievous hurt, or disfigurement endangering the life;

(vi) Sec. 340-342 which are related to wrongful confinement of patient; and

(vii) Sec. 499 which is related to defamation.

Consumer Protection Act (CPA)

There are many possibilities of misuse of the act also which is discussed in greater detail later.

Other Laws

These include the MTP Act, IT Act, Drug Act, Labour Laws and Medical Council's Act. These are intended to have a watch-on medical practitioners.

Once the doctor decides to take care of the patient, the liability starts.

NOTES

What is Liability?

Every individual is liable for his wrongful acts under various laws. The wrongful act can be *an act of commission or an act of omission. "Mens rea"* guilty mind with intention, knowledge and awareness of doing wrong is more punishable than the acts done without willful intent. Negligence, incompetence, mal-practice, *etc.* constitute the liability of medical persons. *Vicarious liability* involves the acts of staff members, partners and locums in different situations. The doctors shall be liable for the act of their staff if they are unqualified. But if the staff is qualified and makes a mistake then the doctor may not be held directly responsible. For example, doctor has prescribed some medicines or injections correctly and the nurse (qualified) makes a mistake; in such cases, the doctor is not responsible for her act. However, if the nurse is unqualified, then the doctor shall be held responsible. Thus depending upon the situation, the doctor or his staff shall be liable for their act of negligence.

Negligence

Negligence is an *act of commission* (positive act) or an *act of omission* (failure to act) which a prudent man of average skill and objective standards should not perform.

According to *objective theory* of negligence, there is carelessness in approach towards the patient and the act of commission results in injury to the patient. According to *subjective theory*, the doctor is indifferent to the consequences of his act of omission and thus causing damage to the patient.

In a case *Donoghue* vs *Stevenson* the following were the facts; Stevenson, the defendant was manufacturer of ginger beer. Plaintiff Donoghue consumed the ginger beer which contained decomposed snail. Plaintiff suffered from shock and gastroenteritis. It was decided that defendant was negligent as he failed to take sufficient care in preventing the contamination of beer. In the judgement the Judge said that you owe a duty to your neighbour *(neighbour means the person who is so closely and directly affected by my act, that outght reasonably to have then in contemplation).* Similarly, a doctor owes duty to his patient and relatives of patient. Whenever a duty is undertaken it shall be with full foresightness about competence, care, knowledge and skill which a prudent man acquires. If a man has not acquired skill he is imprudent, how so ever much careful he may be.

If there is a breach in duty undertaken, resulting in damage or injury–this is negligence. Greater the risk voluntarily undertaken, greater care and skill must be exercised. According to law a pediatrician will be responsible to a greater extent as compared to general practitioner if there is negligence while managing a child (because a pediatrician is more skilled and competant for treating a child) If a doctor has not acquired special skill and competancy (*i.e.*, he/she is not a specialist) then of course average skill and care are sufficient to avoid the charge of negligence.

The degree of care is usually proportional to the duty undetaken. Negligence is many times difficult to prove. The burden of proof is on the patient or relatives except in cases where relatives have no access (e.g., operation theater, intensive care unit, nursery, etc. Res ipsa loquitur is a situation of gross negligence where things speak for themselves and hence there is no need to prove. Contributory negligence,

NOTES

known complications, unexpected results, difference of opinion and emergency care are the usual defenses in case of negligence.

Some Common Situations

Some common situations with important medico-legal implication are illustrated below:

Drug/Vaccine Administration

If there is any mishap while giving any drug or vaccine, then known complication are usual defenses. However, the doctors should have taken all the precautions to manage such complications. Anaphylaxis after Penicillins, Xylocaine and Measles vaccine are known complications. A doctor must do skin sensitivity before giving penicillin, xylocaine, *etc.* Oxygen, Adrenaline, IV fluids and Steroids must be available in case reaction occurs. It is always better to explain to the relatives that such complications can occur. A written consent is preferable before administering injectable drugs. History of drug allergy shall be recorded before prescribing any drugs which are known to cause allergic reactions.

In case of vaccine related encephalopathy, shock, *etc.* relatives should be informed of possible complications (written consent is preferred). Proper history of any previous complications must be recorded in writing. For example, before giving triple vaccine take history of any neurological complications, existing neurological deficits, excessive irritability with previous dose, *etc.*

Fast IV Fluids

Sometimes if IV fluid goes at an undersirable fast speed, various complications may occur. The doctor shall not be held responsible if he/she had written proper orders and the nurse is qualified. If the para-medical staff is not qualified, then the doctor shall be responsible. It is better to use pediatric bottles, micro-drip sets or chambers. If these are not available extra fluid from the bottle may be discarded at the time of starting IV line.

Mismatched Blood Transfusion

A doctor or qualified nurse must check name and age of donor and recipient along with their respective blood group before starting the transfusion. Pediatrician shall not be held responsible for wrong cross-matching or tests for HIV, hepatitis B infection *etc.* (pathologist shall be responsible). However, it is the pediatricians' responsibility to see the blood is transfused in proper volume and at proper rate. Proper orders for monitoring pulse, respiratory rate, temperature and early signs of mismatched blood transfusion must be given. A valid consent is a necessity before starting any procedure or some specific treatment.

Consent

According to Sec. 90 IPC, a person who consents can't complain. Giving a consent is a an act of reasoning and deliberations after balancing the good and evil. The various types of consents can be:

(a) Implied consent;

NOTES

(b) Blanket consent;

(c) Written consent; and

(d) Informed consent.

A *valid consent* is that which is given *voluntarily* (without pressure), by *an adult* of *sound mind* who is not under any intoxication. The consent is obtained *after explanation* and reasonable understanding of facts and *not by hiding facts or* misrepresentation of facts. Consent should be *informed* and preferably *in writing.* The consent should preferably be taken in *presence of witness* (two from patient side and two from hospital side).

Sometimes a child is brought to pediatricians by neighbors (parents of child are immediately not available for consent). In such situations if it is a genuine and real emergency, the child can be managed even without con- sent. The neighbors consent doesn't have legal validity.

Exception to Consent

In the following situations it may not be necessary to take the consent:

(i) if you are managing a patient in an Emergency situation;

(ii) While working in situations of public interest like during floods, cyclones, earthquakes, *etc.*;

(iii) Treating patients in places like mental asylums, orphanages, *etc.*; and

(iv) Working under Court order, *e.g.*, in case of smuggling, operations are done for detecting narcotics or GOLD kept in intestine or other parts of body.

Documents (Sec. 29 IPC)

Documents can be friend as well as foe of medical personnel. Documents are property of hospitals and should be produced on written requests only. Documents carry confidential information of patients and should be released with consent. Well maintained documents may be helpful in most of the cases of negligence. Care should be exercised to ensure that documents are clean, complete, chronological, comprehensive, correct and without manipulations. Documents can be asked for:

(a) Outdoor patients, indoor admissions;

(b) Medical termination of pregnancy, medicolegal cases, operations,

(c) death certificates; and

(d) other certificates.

COPRA (Consumer Protection Act)

COPRA was enacted in 1986. As far the medical services were concerned, different courts had different rulings till the Supreme Court in November 1995 by its ruling included medical services in COPRA. A consumer can approach District Forum, State Commission, National Commission and finally the Supreme Court according to

jurisdiction or amount of damage claimed. The limitation period is two years but can be extended if the judge thinks so in a particular case (after recording the reasons).

A complainant can be consumer himself, any beneficiary, voluntary consumer organization or Government. The complaint can be filed for the consideration which may be paid/promised, part paid/part promised or even deferred payment. The complaint can be for any fault, deficiency, shortcomings in quantity, quality or standard of work performance.

Goodfaith as per Sec. 52 of IPC means any work done/believed to be done with due care and attention.

According to analysis of compiled cases under CPA by Dr. Jagdish Singh (Personal communication) the maximum number of cases are from Obstetrics and Gynecology and Surgery branches. The hospital covered under CPA include all private hospitals, ESIS, SAIL, Corporate hospitals and even Government hospitals where some facilities are on payment. Government and charitable hospitals where all the services are totally free, at present are not covered by CPA. The outcome of about 202 cases was as follows:

(i) Negligence held 28.4%;

(ii) Negligence not held 62.3%; and

(iii) No negligence compensation granted to Doctors/Hospitals 9.3%.

2.3 QUALITIES OF A GOOD HEALTH PROFESSIONAL

The majority of healthcare careers are held in high esteem. Individuals engaged in these careers are usually considered upstanding and selfless. Many people dream of a lucrative career in medicine. There are a multitude of healthcare careers and each requires a particular skill set and type of personality. Are you suited to a career in medicine? Before deciding on pursuing a healthcare career, one has to take a thorough personal assessment to ensure he has the qualities of a good health professional.

Do you have the ability to follow directions? In healthcare, the ability to follow directions can mean the difference between life and death. A pharmacist who mixes chemotherapy medications incorrectly can cause the premature death of a cancer patient by not killing enough cancer cells or killing too many normal cells. A nurse not following a physician's directions for administering a drug like potassium could result in a patient having heart rhythm abnormalities, which could potentially cause death. Undeniably, the ability to follow directions is a key trait for those pursuing healthcare careers.

Do you have great listening skills? A great command and understanding of the English language will serve those in pursuit of a healthcare career very well. On a day-to-day basis, you will be communicating with patients, families and others in the healthcare careers. The communication will take place in a variety of forms including phone calls, meetings, progress notes, letters, emails and text messaging. You will not only have to learn medical terminology, but be able to listen and translate that

NOTES

knowledge to laymen depending on the healthcare setting. On the other hand, poor listening skills could lead to adverse patient outcomes and potential lawsuits.

Do you have emotional stability? The sick and injured, as well as their families, can at times be difficult. Hospitalizations and office visits can be prolonged leading to fear, frustration and anger. One needs emotional stability to deal with the roller coaster of emotions experienced on a day-to-day basis in healthcare jobs. On the other hand, emotional instability can have a negative impact on your work life and can make patient recovery or convalescence a tough road.

Are you detail-oriented? You'll often need to pay great attention to detail. Clues can be uncovered through questions, observations, laboratory tests, and imaging studies. One should be able to incorporate these minute details to arrive at the bigger picture. In this line of work, details could mean the difference between life and death. On the other hand, inattention to detail can lead to misdiagnosis and adverse patient outcomes.

Do you enjoy caring for others? By far, most people pursuing a medical career cite a strong desire to care for others. On a daily basis, your emotions will be taxed by caring for the sick, injured and infirm. The patients and their families may be angry, frustrated and frightened. You will find yourself assuming several roles—counselor, caregiver, confidant, mediator, friend—in addition to your role as a trained medical professional. It is a true balancing act for the right person. On the other hand, not enjoying these various roles can lead to a miserable professional existence.

Do you enjoy schedule flexibility? Healthcare positions can be part-time, full-time and sometimes job sharing can be involved. It is not uncommon for nurses and others to work three 12-hour shifts leaving the balance of their time for family, friends and other outside pursuits. Physician work settings can be traditional, nocturnist, hospitalist or urgent care staff. If one does not enjoy flexibility in scheduling, there are other more regimented healthcare careers to consider.

Advantages of Healthcare Careers

There are many advantages to embarking on a career in health. Most individuals are attracted to their chosen career based on perceived advantages. Healthcare careers have some of the following advantages: high job-retention rates, high salary potential, working with people, and variety.

People in these jobs enjoy high job-retention rates. People in physician positions and nursing jobs and other professional careers rarely, if ever, find themselves unable to find work. People will always need healthcare. Ten of the 20 fastest growing occupations are in this field. Overall, the healthcare industry is seen as a recession proof enterprise and analysts forecast the industry to have the most job growth of any industry in the years to come.

Although most would not recommend choosing a career based solely on the size of a paycheck, salaries are still a big consideration. Most healthcare jobs come with high salary potential, depending on your chosen field. Physicians and specialists routinely command six-figure incomes. Other medical careers such as nurses, pharmacists, physician assistants, physical therapists, medical billers and hospital administrators are handsomely compensated.

NOTES

Most health workers have a strong desire to work with people and help others. They derive great joy from the fulfillment of working with others. It takes a genuinely caring, nurturing person to fulfill unpleasant tasks on a daily basis. As a healthcare professional, you will be exposed to great pain and suffering. In contrast, there will also be times of great joy and triumph. The mix of emotions is appealing to many in the field.

Variety is another attractive feature of these jobs. Your workday can find you in a variety of environments—hospitals, clinics, private office, nursing homes or home visits. You may provide services to a variety of clients from the newborn and healthy to the old and infirm. You will receive reimbursement from various sources such as private insurers, government agencies, patients and other third party payers. Many people in healthcare will attest that no day is the same and it is this variety they find exciting.

The above is just a short list of the advantages of undertaking a career in healthcare. It is imperative to analyze the advantages of a particular job before embarking on your journey. The time taken will serve you well for many years to come in your chosen profession and could mean the difference between a peaceful, happy work life and a dissatisfying professional life.

Disadvantages of Healthcare Careers

Before choosing this field, you should take note of the possible disadvantages of a particular career path. These careers are by no means easy, although they can be very rewarding. Some disadvantages to consider are abrupt schedule changes, difficult patients, physical demands and constant stress.

Many healthcare professionals work long, demanding hours with abrupt schedule changes. You may have to complete externships, internships and/or residencies, which provide hands-on clinical training. Untold hours may be spent on-call and it is not unheard of for some to work 36 to 48 hour shifts with little to no sleep. It is not uncommon for some to work a normal 8-hour shift after being on-call overnight. Some may work 12-hour shifts and go from a day to night shift within 24 hours. In addition to work hours, there is time spent studying for certification examinations and continuing education. You will need to be a lifelong learner. All of the above make for difficult schedules and should be kept in mind when considering a career in health.

Another disadvantage of a healthcare career can be difficult patients. A medical professional spends long hours honing his craft and at times it seems patients don't appreciate this. Despite your best efforts, sometimes a patient is just not satisfied with his diagnosis, prognosis or outcome. Sickness, disease and injury can be depressing to a patient—adding to his difficulty. Concerned family and loved ones can sometimes make matters worse, if certain boundaries are not maintained. Difficult patients can sometimes make a professional's life extremely trying.

These jobs can also be physically demanding. Long hours are spent sitting or standing. Some disciplines require manual dexterity and constant lifting of patients and equipment. Virtually all disciplines demand mental toughness, which can tax an individual physically. As a result, some positions aren't for the faint of heart.

NOTES

Stress is a relative constant. You seldom get adequate sleep. Your diet may be poor. The abrupt schedule changes, difficult patients and physical demands usually translate into stressful times. You should be aware of increasing stress levels, and take measures to combat this constant in the life of a healthcare professional.

The above are some considerations of the disadvantages of going into the field and are by no means an exhaustive list. Your particular set of disadvantages may vary depending on your chosen field. The take-home message is that you should take the time to consider disadvantages prior to committing yourself to one of the healthcare careers.

2.4 PERSONALITY TRAITS FOR SUCCESSFUL MEDICAL CAREERS

Certain personality traits are not only important for working within the medical field, but are even important indicators of who has a better chance of succeeding in medical school. For example, since medical professionals spend a great deal of time working with other people, individuals who are considered to be extroverts tend to fare better than introverts. Having a flexible personality is also useful as medical professionals need to be able to quickly adapt to changing situations.

Compassion

Having compassion for others is an important personality trait for jobs throughout the medical field. However, it's especially important in positions requiring direct contact with patients and their families. Being compassionate means expressing sympathy and care toward others. Medical professionals, such as nurses and physicians, mostly deal with patients who are either ill or injured. As a result, patients are at their most vulnerable state, and having a compassionate caretaker can be both comforting and reassuring.

Emotional Stability

Emotional stability is another trait vital for those pursuing careers in the medical field. Working in medicine can be very stressful, and in order to cope with these stresses in a healthy way, medical professionals need to be emotionally stable. In fact, an overabundance of stress is the primary reason why there's such a high burnout rate with medical professionals. Only those who are emotionally stable will be able to adequately cope with the human suffering and emergency situations they come across on an almost-daily basis.

Patience

Medical professionals often find themselves needing to exhibit a great deal of patience while working with patients and their families. For example, pediatricians need to be patient with uncooperative children and over-controlling parents. In addition, both doctors and nursing staff need to be extra patient with anyone who fears receiving medical treatment or requires long periods of special attention. Having patience also helps medical professionals continue to provide quality care even when faced with stressful or hectic situations.

Communication Skills

A large part of working in the medical profession involves communicating with others. Supervisors need to be able to effectively communicate with their staff. In addition, medical professionals not only need to be able to communicate well with each other, but also with patients and their families. For example, patients rely on the communication skills of their health care providers to explain the details of any medical conditions, treatment options available and instructions for taking medications.

2.5 GOOD PERSONAL QUALITIES IN A MEDICAL ASSISTANT

Most of us have had the help and support of a medical assistant while visiting a hospital, or a physician's office. However, in order to join a training in medical assistant and to become a successful medical assistant there are some basic qualities that a candidate should possess. The personality traits that are expected in a candidate to fix medical assistance as his career choice are:

Brilliant Communication Skills

A medical assistant should possess brilliant communication skills, as this is a basic characteristic for the profession. He/she should listen to the patients without interrupting them while they explain their concerns. But at the same time, he/she should still ask appropriate questions to the patients and get the suitable answers from them. These are some diplomatic ways to obtain the essential information from the patients in order to help the physician to treat the patients efficiently.

Brilliant communication skill also involves clearly narrating the vital instructions given by the doctor to the patients. Also, a medical assistant should answer the questions of the patients effectively and unmistakably.

NOTES

Compassionate

Besides being a good listener, it is very important that a medical assistant is compassionate to the patients. A medical assistant should try to understand the worries, happiness and other emotional states of the patients by discussing with them. Dealing the patients in a compassionate way will help them to feel more comfortable and relaxed at the time of their health assessment.

Forbearance to stress

A physician's office or a hospital is full of activity. The workplace can make a medical assistant feel quite stressed out. A medical assistant will have a lot of administrative and clinical duties to perform every day. At times, all of these work related stress can contribute to the confusions and anxiety. On the other hand, patients visit a health care facility for appropriate care and treatment. It is the responsibility of the medical assistant to help them in a better way. So, a medical assistant should have the capability to overcome his daily stress level. He/she should be a tolerant and strong person in order to handle any stressful situations that he come across in his job.

Reliability

A medical assistant is expected to be a reliable person since the physician, the healthcare group associates and the incoming patients depends on the medical assistant to be reliable. Hence, a medical assistant should be punctual, career-focused and should value the conventional code of behavior.

Honesty

The personal information that a medical assistant collects has to be maintained as a confidential in a healthcare setting. The Health Insurance Portability and Accountability Act (HIPAA)'s confidentiality rule need vigilance and care in maintaining the patients fitness information. However, it is also considered as a courteousness to behave trustworthy to the patients while receiving their health or personal information (even during informal conversation). Each and every medical assistant will be introduced to circumstances where they need to prove their ethical and moral characteristics on a daily basis. Hence, honesty is the chief quality to become a professional medical assistant.

Will power and Politeness

Sometimes, there is a possibility to act in response to a tiring physician who is bursting with questions or to a disturbed patient who is under a lot of pain and ache. However, having strong willpower towards your personal feelings and dealings in a health care milieu while still remaining polite is the unique trait that is necessary for you as a professional medical assistant.

Meticulousness

A medical assistant can help his patients, support the physicians during the treatment and assist the co-workers so to do their jobs effectively by being attentive, watchful and meticulous .

Flexible and Dexterity

Having individual deftness, flexibility to work and visual insight are very useful for all medical assistants while performing several clinical procedures.

In general, people who are interested in crafting their career as a successful medical assistant should take pleasure in assisting people, educating and discussing with all medical professionals. If you possess the above mentioned traits, then go ahead and join in a professional medical assistant training program that will coach you all the essential courses required to become a successful medical assistant.

2.6 MEDICAL COUNCIL ACT

Code Of Medical Ethics

Each applicant, at the time of making an application for registration under the provisions of the Act, shall be provided a copy of the declaration and shall submit a duly signed Declaration. The applicant shall also certify that he/she had read and agreed to abide by the same.

Duties and responsibilities of the Physician in general:

Character of Physician (Doctors with qualification of MBBS or MBBS with post graduate degree/ diploma or with equivalent qualification in any medical discipline):

1. A physician shall uphold the dignity and honour of his profession.
2. The prime object of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. Who- so-ever chooses his profession, assumes the obligation to conduct himself in accordance with its ideals. A physician should be an upright man, instructed in the art of healings. He shall keep himself pure in character and be diligent in caring for the sick; he should be modest, sober, patient, prompt in discharging his duty without anxiety; conducting himself with propriety in his profession and in all the actions of his life.
3. No person other than a doctor having qualification recognised by Medical Council of India and registered with Medical Council of India/State Medical Council (s) is allowed to practice Modern system of Medicine or Surgery. A person obtaining qualification in any other system of Medicine is not allowed to practice Modern system of Medicine in any form.

Maintaining Good Medical Practice:

The Principal objective of the medical profession is to render service to humanity with full respect for the dignity of profession and man. Physicians should merit

the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion. Physicians should try continuously to improve medical knowledge and skills and should make available to their patients and colleagues the benefits of their professional attainments. The physician should practice methods of healing founded on scientific basis and should not associate professionally with anyone who violates this principle. The honoured ideals of the medical profession imply that the responsibilities of the physician extend not only to individuals but also to society.

Membership in Medical Society: For the advancement of his profession, a physician should affiliate with associations and societies of allopathic medical professions and involve actively in the functioning of such bodies. A Physician should participate in professional meetings as part of Continuing Medical Education programmes, for at least 30 hours every five years, organized by reputed professional academic bodies or any other authorized organisations. The compliance of this requirement shall be informed regularly to Medical Council of India or the State Medical Councils as the case may be.

Maintenance of medical records: Every physician shall maintain the medical records pertaining to his / her indoor patients for a period of 3 years from the date of commencement of the treatment in a standard proforma laid down by the Medical Council of India. If any request is made for medical records either by the patients / authorised attendant or legal authorities involved, the same may be duly acknowledged and documents shall be issued within the period of 72 hours. A Registered medical practitioner shall maintain a Register of Medical Certificates giving full details of certificates issued. When issuing a medical certificate he / she shall always enter the identification marks of the patient and keep a copy of the certificate. He / She shall not omit to record the signature and/or thumb mark, address and at least one identification mark of the patient on the medical certificates or report. Efforts shall be made to computerize medical records for quick retrieval.

Display of registration numbers: Every physician shall display the registration number accorded to him by the State Medical Council / Medical Council of India in his clinic and in all his prescriptions, certificates, money receipts given to his patients. Physicians shall display as suffix to their names only recognized medical degrees or such certificates/diplomas and memberships/honours which confer professional knowledge or recognizes any exemplary qualification/achievements.

Use of Generic names of drugs: Every physician should, as far as possible, prescribe drugs with generic names and he / she shall ensure that there is a rational prescription and use of drugs.

Highest Quality Assurance in patient care: Every physician should aid in safeguarding the profession against admission to it of those who are deficient in moral character or education. Physician shall not employ in connection with his professional practice any attendant who is neither registered nor enlisted under the Medical Acts in force and shall not permit such persons to attend, treat or perform operations upon patients wherever professional discretion or skill is required.

Exposure of Unethical Conduct: A Physician should expose, without fear or favour, incompetent or corrupt, dishonest or unethical conduct on the part of members of the profession.

Payment of Professional Services: The physician, engaged in the practice of medicine shall give priority to the interests of patients. The personal financial interests of a physician should not conflict with the medical interests of patients. A physician should announce his fees before rendering service and not after the operation or treatment is under way. Remuneration received for such services should be in the form and amount specifically announced to the patient at the time the service is rendered. It is unethical to enter into a contract of "no cure no payment". Physician rendering service on behalf of the state shall refrain from anticipating or accepting any consideration.

Evasion of Legal Restrictions: The physician shall observe the laws of the country in regulating the practice of medicine and shall also not assist others to evade such laws. He should be cooperative in observance and enforcement of sanitary laws and regulations in the interest of public health. A physician should observe the provisions of the State Acts like Drugs and Cosmetics Act, 1940; Pharmacy Act, 1948; Narcotic Drugs and Psychotropic substances Act, 1985; Medical Termination of Pregnancy Act, 1971; Transplantation of Human Organ Act, 1994; Mental Health Act, 1987; Environmental Protection Act, 1986; Pre–natal Sex Determination Test Act, 1994; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; Persons with Disabilities (Equal Opportunities and Full Participation) Act, 1995 and Bio-Medical Waste (Management and Handling) Rules, 1998 and such other Acts, Rules, Regulations made by the Central/ State Governments or local Administrative Bodies or any other relevant Act relating to the protection and promotion of public health.

Trial design

A fundamental distinction in evidence-based practice is between observational studies and randomized controlled trials. Types of observational studies in epidemiology, such as the cohort study and the case-control study, provide less compelling evidence than the randomized controlled trial. In observational studies, the investigators only observe associations (correlations) between the treatments experienced by participants and their health status. However, under certain conditions, causal effects can be inferred from observational studies.

A randomized controlled trial can provide compelling evidence that the study treatment causes an effect on human health.

Currently, some Phase 2 and most Phase 3 drug trials are designed as randomized, double-blind, and placebo-controlled.

- Randomized: Each study subject is randomly assigned to receive either the study treatment or a placebo.
- Blind: The subjects involved in the study do not know which study treatment they receive. If the study is double-blind, the researchers also do not know which treatment a subject receives. This intent is to prevent researchers from treating the two groups differently. A form of double-blind study called a "double-dummy" design allows additional insurance against bias. In this kind of study, all patients are given both placebo and active doses in alternating periods.
- Placebo-controlled: The use of a placebo (fake treatment) allows the researchers to isolate the effect of the study treatment from the placebo effect.

Although the term "clinical trials" is most commonly associated with the large, randomized studies typical of Phase 3, many clinical trials are small. They may be "sponsored" by single researchers or a small group of researchers, and are designed to test simple questions. In the field of rare diseases, sometimes the number of patients is the limiting factor for the size of a clinical trial.

Active Comparator Studies

Of note, during the last 10 years or so, it has become a common practice to conduct "active comparator" studies (also known as "active control" trials). In other words, when a treatment is clearly better than doing nothing for the subject (*i.e.* giving them the placebo), the alternate treatment would be a standard-of-care therapy. The study would compare the 'test' treatment to standard-of-care therapy.

A growing trend in the pharmacology field involves the use of third-party contractors to obtain the required comparator compounds. Such third parties provide expertise in the logistics of obtaining, storing, and shipping the comparators. As an advantage to the manufacturer of the comparator compounds, a well-established comparator sourcing agency can alleviate the problem of parallel importing (importing a patented compound for sale in a country outside the patenting agency's sphere of influence).

Master protocol

In such studies, multiple experimental treatments are tested in a single trial. Genetic testing enables researchers to group patients according to their genetic profile, deliver drugs based on that profile to that group and compare the results. Multiple companies can participate, each bringing a different drug. The first such approach targets squamous cell cancer, which includes varying genetic disruptions from patient to patient. Amgen, AstraZeneca and Pfizer are involved, the first time they have worked together in a late-stage trial. Patients whose genomic profiles do not match any of the trial drugs receive a drug designed to stimulate the immune system to attack cancer.

Clinical trial protocol

A clinical trial protocol is a document used to define and manage the trial. It is prepared by a panel of experts. All study investigators are expected to strictly observe the protocol.

The protocol describes the scientific rationale, objective(s), design, methodology, statistical considerations and organization of the planned trial. Details of the trial are provided in documents referenced in the protocol, such as an investigator's brochure.

The protocol contains a precise study plan to assure safety and health of the trial subjects and to provide an exact template for trial conduct by investigators. This allows data to be combined across all investigators/sites. The protocol also informs the study administrators (often a contract research organization).

The format and content of clinical trial protocols sponsored by pharmaceutical, biotechnology or medical device companies in the United States, European Union,

or Japan have been standardized to follow Good Clinical Practice guidance issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Regulatory authorities in Canada and Australia also follow ICH guidelines. Journals such as *Trials*, encourage investigators to publish their protocols.

Design features

Informed Consent

Clinical trials recruit study subjects to sign a document representing their "informed consent". The document includes details such as its purpose, duration, required procedures, risks, potential benefits and key contacts. The participant then decides whether to sign the document. The document is not a contract, as the participant can withdraw at any time without penalty.

Informed consent is a legal process in which a recruit is instructed about key facts before deciding whether to participate. Researchers explain the details of the study in terms the subject can understand. The information is presented in the subject's native language. Generally, children cannot autonomously provide informed consent, but depending on their age and other factors, may be required to provide informed assent.

Statistical power

The number of subjects has a large impact on the ability to reliably detect and measure effects of the intervention. This is described as its "power". The larger the number of participants, the greater the statistical power and the greater the cost.

The statistical power estimates the ability of a trial to detect a difference of a particular size (or larger) between the treatment and control groups. For example, a trial of a lipid-lowering drug versus placebo with 100 patients in each group might have a power of 0.90 to detect a difference between placebo and trial groups receiving dosage of 10 mg/dL or more, but only 0.70 to detect a difference of 5 mg/dL.

Placebo groups

Merely giving a treatment can have nonspecific effects. These are controlled for by the inclusion of patients who receive only a placebo. Subjects are assigned randomly without informing them to which group they belonged. Many trials are double-blinded so that researchers do not know to which group a subject is assigned.

Assigning a subject to a placebo group can pose an ethical problem if it violates his or her right to receive the best available treatment. The Declaration of Helsinki provides guidelines on this issue.

Duration

Clinical trials are only a small part of the research that goes into developing a new treatment. Potential drugs, for example, first have to be discovered, purified, characterized, and tested in labs (in cell and animal studies) before ever undergoing

clinical trials. In all, about 1,000 potential drugs are tested before just one reaches the point of being tested in a clinical trial. For example, a new cancer drug has, on average, six years of research behind it before it even makes it to clinical trials. But the major holdup in making new cancer drugs available is the time it takes to complete clinical trials themselves. On average, about eight years pass from the time a cancer drug enters clinical trials until it receives approval from regulatory agencies for sale to the public. Drugs for other diseases have similar timelines.

Some reasons a clinical trial might last several years:

- For chronic conditions such as cancer, it takes months, if not years, to see if a cancer treatment has an effect on a patient.
- For drugs that are not expected to have a strong effect (meaning a large number of patients must be recruited to observe 'any' effect), recruiting enough patients to test the drug's effectiveness (i.e., getting statistical power) can take several years.
- Only certain people who have the target disease condition are eligible to take part in each clinical trial. Researchers who treat these particular patients must participate in the trial. Then they must identify the desirable patients and obtain consent from them or their families to take part in the trial.

The biggest barrier to completing studies is the shortage of people who take part. All drug and many device trials target a subset of the population, meaning not everyone can participate. Some drug trials require patients to have unusual combinations of disease characteristics. It is a challenge to find the appropriate patients and obtain their consent, especially when they may receive no direct benefit (because they are not paid, the study drug is not yet proven to work, or the patient may receive a placebo). In the case of cancer patients, fewer than 5% of adults with cancer will participate in drug trials. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), about 400 cancer medicines were being tested in clinical trials in 2005. Not all of these will prove to be useful, but those that are may be delayed in getting approved because the number of participants is so low.

For clinical trials involving a seasonal indication (such as airborne allergies, seasonal affective disorder, influenza, and others), the study can only be done during a limited part of the year (such as spring for pollen allergies), when the drug can be tested. This can be an additional complication on the length of the study, yet proper planning and the use of trial sites in the Southern, as well as the Northern Hemisphere allows for year-round trials, which can reduce the length of the studies.

2.7 A STEEL FRAME FOR CLINICAL TRIALS

In recent months, the quest for a safer, more transparent clinical trials regime has found new momentum. Fourteen notifications in July 2014, governing various aspects pertaining to a clinical trial — ranging from placebo-controlled trials to compensation awards — have been notified. Further, the Central Drugs Standard Control Organization (CDSCO) has proposed a forward-looking IT-enabled information system that will ensure transparency and protect the interests of trial subjects.

These developments are important steps for the clinical trials regime in India to satisfy the three principles laid down by the Supreme Court for approving trials — assessment of risk versus benefit to patients, need for innovation *vis-à-vis* existing therapeutic option and the unmet medical needs in the country. But for satisfying these standards, much more remains to be done. The entire regulatory framework pertaining to clinical trials needs to be overhauled and a clear, coherent and succinct set of stand-alone rules needs to be introduced for this purpose. This will not only ensure adherence to the principles laid down by the Supreme Court but also give impetus to the clinical trials industry in India, currently languishing due to an uncertain regulatory environment.

Accreditation and Ethics

There are three key changes that are essential if the clinical trials regime in India is to be put on a firm foundation — instituting a structured accreditation process accrediting investigators, trial sites and ethics committees, making ethics committees function effectively and ensuring diligent adherence to guidelines concerning informed consent from trial subjects. Each of these three aspects has been studied closely by the committee headed by one of us, the Ranjit Roy Chaudhury Committee, with detailed recommendations provided.

Accreditation must become the centrepiece of a new clinical trials regime founded on the principle of patient safety. Accreditation ensures adherence to certain quality standards thereby instilling confidence not only in patients who will be trial subjects but equally in the industry, which is responsible for conducting the trials. Thus, principal investigators of trials should be accredited depending on their qualifications, experience and training; trial sites should be accredited on the basis of infrastructure, personnel and systems; finally, institute ethics committees must be accredited keeping in mind the experience of their members and the standard operating processes for review which are used. Guidelines in this regard have been prepared recently by an expert committee; these must be implemented post-haste. If this is done, India would be the first country anywhere in the world to institute such a structured process of accreditation.

Conflicts of Interest and Consent

Accreditation of ethics committees is an especially central element towards making such committees effective custodians of the safety and probity of all clinical trials. Several cases of casualties in clinical trials have emerged in the past few years, where compliance with standard operating processes were shoddy or such processes themselves were absent. In an Indian Council of Medical Research (ICMR) publication, the independence of ethics committees and conflict of interest questions were highlighted. To correct this, it is not only essential that ethics committees are accredited but also develop standard operating procedures that are capable of effective implementation. To follow such procedures, members of ethics committees need to undergo high-quality mandatory training. This requires a combination of men and women of wisdom and experience and training protocols that are succinct and geared towards ensuring safe and effective trials where all norms are strictly followed.

A key positive spin-off of accredited ethics committees would be to prevent conflicts of interest. The Ranjit Roy Chaudhury Expert Committee Report pointed out gross malpractices and unscrupulous decisions in clinical trials caused owing to ethics committee members having an interest in the trial itself. To offset this, a key facet of accreditation would be a strict adherence to finding independent persons to serve on ethics committees. This can be achieved by a combination of randomised allocation of experts to particular ethics committees together with a supplementary check by the accrediting body. A hybrid process, part-automatic with a supplementary human element, would not only ensure independence of the ethics committee in fact, but also create a positive perception of such independence in the minds of trial subjects.

Such a positive perception of the independence of ethics committees, it is believed, would become a key facet of securing informed consent of trial subjects. The need for informed consent was a key norm that was recently found by the United States Office for Human Research Protections (OHRP) to be flouted in a cervical cancer study funded by the U.S. National Cancer Institute and the Bill & Melinda Gates Foundation. Till April 2014, 254 women in unscreened control groups in these trials have died. The OHRP determined that insufficient information was provided in order for these and other women to give informed consent to participate in the trial.

Towards a New Order

Culpability in this matter is still an open question that might require judicial intervention. However, at this stage, it is clear that the episode demonstrates the lack of effective protocols to ensure that informed consent is truly on the basis of relevant information and the lack of clear methods to ascertain the taking of such consent. This has been partially offset by CDSCO which issued draft guidelines earlier this year on audio-visual recording of informed consent process in clinical trial. This mandates audio-visual recording and safe storage of the taking of informed consent from trial subjects. This is a welcome move. However it is imperative to keep in mind the privacy of patients who might not wish to be recorded. Thus, it is recommended that such recording should be mandatory subject only to waiver by the trial patient or the ethics committee, keeping in mind the equally significant principle of patient privacy.

Not only is the substance of the changes mentioned significant, but equally the form it takes. Best practices worldwide demonstrate that having a succinct, stand-alone set of rules governing clinical trials promotes transparency and increases certainty. Currently, the legal architecture governing clinical trials is complex with several facets governed by the Drugs and Cosmetics Rules, 1945, a slew of notifications thereunder, and some facets regulated by the proposed Drugs and Cosmetics (Amendment) Bill, 2013, pending in the Rajya Sabha.

It is essential that the recommended reforms together with any other changes proposed by CDSCO are brought under a consolidated umbrella of rules governing clinical trials. This will give the clinical trials industry the necessary certainty to undertake trials in India with confidence. The benefits for India — in terms of development of new drugs, employment generation in the clinical trials industry and

ensuring a safe environment for its citizens desirous of participating in clinical trials — would be tremendous. Most crucially, it would demonstrate the seriousness that the government attaches to effective public health systems and scientific progress, two goals of a well-functioning clinical trials regime that must also become the pillars on which modern India is built.

2.8 DISABILITY ACT

Disability Discrimination

Disability discrimination occurs when an employer or other entity covered by the Americans with Disabilities Act, as amended, or the Rehabilitation Act, as amended, treats a qualified individual with a disability who is an employee or applicant unfavorably because she has a disability.

Disability discrimination also occurs when a covered employer or other entity treats an applicant or employee less favorably because she has a history of a disability (such as cancer that is controlled or in remission) or because she is believed to have a physical or mental impairment that is not transitory (lasting or expected to last six months or less) and minor (even if she does not have such an impairment).

The law requires an employer to provide reasonable accommodation to an employee or job applicant with a disability, unless doing so would cause significant difficulty or expense for the employer ("undue hardship").

The law also protects people from discrimination based on their relationship with a person with a disability (even if they do not themselves have a disability). For example, it is illegal to discriminate against an employee because her husband has a disability.

Disability Discrimination & Work Situations

The law forbids discrimination when it comes to any aspect of employment, including hiring, firing, pay, job assignments, promotions, layoff, training, fringe benefits, and any other term or condition of employment.

Disability Discrimination & Harassment

It is illegal to harass an applicant or employee because he has a disability, had a disability in the past, or is believed to have a physical or mental impairment that is not transitory (lasting or expected to last six months or less) and minor (even if he does not have such an impairment).

Harassment can include, for example, offensive remarks about a person's disability. Although the law doesn't prohibit simple teasing, offhand comments, or isolated incidents that aren't very serious, harassment is illegal when it is so frequent or severe that it creates a hostile or offensive work environment or when it results in an adverse employment decision (such as the victim being fired or demoted).

The harasser can be the victim's supervisor, a supervisor in another area, a co-worker, or someone who is not an employee of the employer, such as a client or customer.

NOTES

Disability Discrimination & Reasonable Accommodation

The law requires an employer to provide reasonable accommodation to an employee or job applicant with a disability, unless doing so would cause significant difficulty or expense for the employer.

A reasonable accommodation is any change in the work environment (or in the way things are usually done) to help a person with a disability apply for a job, perform the duties of a job, or enjoy the benefits and privileges of employment.

Reasonable accommodation might include, for example, making the workplace acces ible for wheelchair users or providing a reader or interpreter for someone who is blind or hearing impaired.

While the federal anti-discrimination laws don't require an employer to accommodate an employee who must care for a disabled family member, the Family and Medical Leave Act (FMLA) may require an employer to take such steps.

Disability Discrimination & Reasonable Accommodation & Undue Hardship

An employer doesn't have to provide an accommodation if doing so would cause undue hardship to the employer.

Undue hardship means that the accommodation would be too difficult or too expensive to provide, in light of the employer's size, financial resources, and the needs of the business. An employer may not refuse to provide an accommodation just because it involves some cost. An employer does not have to provide the exact accommodation the employee or job applicant wants. If more than one accommodation works, the employer may choose which one to provide.

Definition Of Disability

Not everyone with a medical condition is protected by the law. In order to be protected, a person must be qualified for the job and have a disability as defined by the law.

A person can show that he or she has a disability in one of three ways:

- A person may be disabled if he or she has a physical or mental condition that substantially limits a major life activity (such as walking, talking, seeing, hearing, or learning).
- A person may be disabled if he or she has a history of a disability (such as cancer that is in remission).
- A person may be disabled if he is believed to have a physical or mental impairment that is not transitory (lasting or expected to last six months or less) and minor (even if he does not have such an impairment).

Disability & Medical Exams During Employment Application & Interview Stage

The law places strict limits on employers when it comes to asking job applicants to answer medical questions, take a medical exam, or identify a disability.

For example, an employer may not ask a job applicant to answer medical questions or take a medical exam before extending a job offer. An employer also may not ask job applicants if they have a disability (or about the nature of an obvious disability). An employer may ask job applicants whether they can perform the job and how they would perform the job, with or without a reasonable accommodation.

Disability & Medical Exams After A Job Offer For Employment

After a job is offered to an applicant, the law allows an employer to condition the job offer on the applicant answering certain medical questions or successfully passing a medical exam, but only if all new employees in the same type of job have to answer the questions or take the exam.

Disability & Medical Exams For Persons Who Have Started Working As Employees

Once a person is hired and has started work, an employer generally can only ask medical questions or require a medical exam if the employer needs medical documentation to support an employee's request for an accommodation or if the employer believes that an employee is not able to perform a job successfully or safely because of a medical condition.

The law also requires that employers keep all medical records and information confidential and in separate medical files.

The Right of Persons with Disabilities Bill, 2014

- The Rights of Persons with Disabilities Bill, 2014 was introduced in the Rajya Sabha on February 7, 2013 by the Minister of Social Justice and Empowerment, Mr. Mallikarjun Kharge.
- The Bill repeals the Persons with Disabilities (Equal Opportunities Protection of Rights and Full Participation) Act, 1995.
- Definition of disability: Disability is defined to include 19 conditions such as: autism; low vision and blindness; cerebral palsy; deaf blindness; haemophilia; hearing impairment; leprosy; intellectual disability; mental illness; muscular dystrophy; multiple sclerosis; learning disability; speech and language disability; sickle cell disease; thalassemia; chronic neurological conditions; and multiple disability. Persons with benchmark disabilities are defined as those with at least 40 per cent of any of the above specified disabilities.
- Rights of persons with disabilities: The Bill states that persons with disabilities shall have the right to equality and shall not be discriminated against on grounds of their disability. Rights of disabled persons include protection from inhuman treatment and equal protection and safety in situations of risk, armed conflict, humanitarian emergencies and natural disasters. All existing public buildings shall be made accessible for disabled persons within five years of the regulations being formulated by the National Commission for Persons with Disabilities. No establishment will be granted permission to build any structure, issued a completion certification or allowed to occupy a building, if the building does not adhere to the regulations formulated by the Commission.

- Education, skill development and employment: The Bill provides for the access to inclusive education, vocational training and self-employment of disabled persons. All government institutions of higher education and those getting aid from the government are required to reserve at least five percent of seats for persons with benchmark disabilities.
- The central and state governments have to identify posts in establishments under them to be reserved for persons with benchmark disabilities. At least five percent of the vacancies are to be filled by persons or class of persons with at least 40 percent of any of the disabilities. Of this, one per cent shall be reserved for persons with (i) blindness and low vision; (ii) hearing and speech impairment; (iii) locomotor disability; (iv) autism, intellectual disability and mental illness; and (v) multiple disabilities. The Bill provides that the reservation has to be computed on the basis of total number of vacancies in the strength of a cadre. The government may exempt any establishment from this provision.
- Legal Capacity: Disabled persons have the right, equally with others, to own and inherit movable and immovable property, as well as control their financial affairs.
- Guardianship: The Bill provides that if a district court finds that a mentally ill person is not capable of taking care of himself or of taking legally binding decisions, it may order guardianship to the person. The nature of such guardianship is also specified.
- National and State Commissions for persons with disabilities: The central and state governments are required to establish a National and State Commissions for Persons with Disabilities, respectively. The Commissions will be composed of experts and be required to: (i) identify any laws, policies or programmes that are inconsistent with the Act; (ii) inquire into matters relating to deprivation of rights and safeguards available to disabled persons, (iii) monitor implementation of the Act and utilisation of funds disbursed by governments for the benefit of disabled persons.
- Central and state advisory boards: The central government and state governments shall constitute Central and State Advisory Boards on Disability. The boards shall advise governments on policies and programmes on disability and review the activities of organisations dealing with disabled persons.

2.9 LEGAL ASPECTS OF MEDICAL RECORDS

Medical Records management has become an integral activity of the hospital management. The department provides multiple benefits not only to the patients but also to running a hospital efficiently. The introductory set of articles provide an overview to the reader about the purpose of the Medical Records department. There are many aspects to be considered while setting up a Medical Records department. This is captured in the planning of the Medical Records department. A variety of forms make the activity of information collection a systematic and easy process.

There are different filing systems which can be considered to allow for easy storage as well as facilitate easy retrieval. Coding and indexing system also has to be understood as there are standard and internationally accepted practices. Following which will make it easier for comparisons and research. With increasing consumer cases due to medical negligence the Medical Records plays a very important role in terms of providing evidence. The legal aspects however vary geographically and is determined by the policies of that region.

Medical Records are a clinical, scientific, administrative and legal document relating to patient care in which sufficient data is recorded by trained observers as per sequence of events to justify the diagnosis and therapy, giving the results thereof are in accordance with reasonable expectation of present day scientific medical care. It is in other words a performance barometer of the hospital. A medical record system must be organized to render service to the patient, the medical staff, the hospital administration, and society. In the interests of economy, accuracy of information, and good communication, all information should be concentrated in the original Medical Records, which should be indexed and filed in the main medical record department.

What are Medical Records?

"Medical records" is a broad term which incorporates a range of data and information storage mediums containing patient information. Medical records can be either paper based or electronic and include: clinical notes, investigations, specialists' letters, appointment records, diagnostic reports, accounts and diary systems. It should be noted that information exchanges between a medical practitioner and MDA National or a solicitor seeking legal advice, or in contemplation of litigation, are likely to be privileged and are not considered "medical records". Accordingly this information should be stored separately from the patient's medical records in a secure place.

What is the Purpose of the Medical Record?

Medical records are an integral part of good quality patient care. The primary purpose of the medical record is to facilitate patient care and allow you or another practitioner to continue the management of the patient. Good medical records can also significantly improve the defensibility of a claim or complaint, particularly in cases where there are conflicting versions of events between the patient and practitioner.

What are the Professional Requirements with Regard to Medical Records?

The Medical Board of Australia's guidelines, Good Medical Practice: A Code of Conduct for Doctors in Australia, state in Section 8.4 that maintaining clear and accurate medical records is essential for the continuing good care of patients. Good medical practice involves:

- Keeping accurate, up-to-date and legible records that report relevant details of clinical history, clinical findings, investigations, information given to patients, medication and other management.

- Ensuring that your medical records are held securely and are not subject to unauthorised access
- Ensuring that your medical records show respect for your patients and do not include demeaning or derogatory remarks
- Ensuring that the records are sufficient to facilitate continuity of patient care
- Making records at the time of the events, or as soon as possible afterwards
- Recognising patients' right to access information contained in their medical records and facilitating that access
- Promptly facilitating the transfer of health information and when requested by the patient.

"...the records are likely to be a far more reliable source of truth than memory. They are often the only source of truth."

Why are Medical Records Important Medico-Legally?

Medical records may be used as evidence in legal proceedings, including medical negligence claims, disciplinary hearings, criminal proceedings or Coronial Inquests. Medical negligence claims may involve a dispute of the facts, which is why comprehensive and accurate medical records are often essential in establishing the facts when defending a claim or complaint. Where there is no supporting documentation, the patient's recollection may be preferred to that of the practitioner, particularly where the practitioner is unable to fully recall the event or the patient. After receiving a claim or complaint, you may feel tempted to change the medical records or include in the records all of your recollections of the event. This may result in a defensible claim becoming indefensible. Poor medical records may make a claim difficult to defend, but altered medical records may make a claim virtually impossible to defend. Once you are aware of a claim or complaint, no changes of any sort should be made to the medical records.

How Long Should I Keep the Medical Records?

From a medico-legal perspective, medical records should be kept until there is little or no risk of litigation regarding the patient's treatment. This will depend on the statutory limitation period within the relevant jurisdiction, and in some jurisdictions this is also impacted by specific legislation governing medical records. Unfortunately it is difficult to be definitive regarding the exact limitation period, as the courts generally have discretion to extend the period in certain circumstances. Where there has been a patient complaint, an adverse outcome or foreshadowed legal proceedings, then the medical records should be kept indefinitely (or advice sought from MDA National prior to disposal). Medical records for a patient with a mental disability should also be kept indefinitely, or until seven years after the patient's death. The ACT, NSW and VIC have legislated the minimum period of time which medical records should be kept, being:

- for an adult – 7 years from the date of the last entry
- for a child – until the age of 25 years.

MDA National considers these requirements to be appropriate in all Australian contexts.

Who owns the Medical Records? Can Patients Look at And/or Obtain a Copy of their Records?

In general terms, medical records made by you remain your property or that of the medical practice or hospital in which you work. However, for records created or in use after 21 December 2001, the Privacy Act 1988 (Cth) generally grants patients the right to access their medical records. Importantly this includes all of the medical records, including specialists' letters and reports even if they are marked "confidential". This access should usually involve providing the patient with a photocopy or print-out of their records, if requested. Where the patient is deceased, consent may be provided by the executor or administrator of the patient's estate. Access by a patient to their medical records cannot be denied unless there are exceptional circumstances such as:

- Serious threat to the life or health of any individual
- Unreasonable impact on the privacy of other individuals
- Anticipated legal proceedings where legal professional privilege applies.

In all circumstances, a medical practitioner should record when and to whom they have provided a copy of or access to the patient record.

Can I scan Records into an Electronic form and Destroy the Paper Based Records?

Electronic health records are becoming more prevalent in medical practice and medical practitioners are often required to manage the medico-legal and practical issues associated with keeping a mix of paper and electronic patient records. Whilst current legislation does not specify the format in which a patient's medical records must be kept, in some instances an original paper document may have forensic value in the event that the document is required at trial. Nevertheless, if retention of the original paper documents is not possible for some reason, e.g. due to storage limitations, the original, complete documentation should be promptly scanned and saved into the patient's electronic health record. The original paper documents should then be destroyed in a secure and confidential manner, once the scanning and back up of the documents has been confirmed. Scanning should be of sufficient quality to allow a complete and legible hard copy to be reproduced from the electronic copy as required.

2.10 TRANSPLANTATION OF HUMAN ORGAN ACT

Organs transplant Act

The government has notified the Transplantation of Human Organs (Amendment) Act, 2011 that allows swapping of organs and widens the donor pool by including grandparents and grandchildren in the list.

However, rules of the amended law are yet to be notified, without which the Act cannot be implemented.

The Act, which has come into effect in Goa, Himachal Pradesh, West Bengal, Delhi and all Union Territories from January 10, also provides for the establishment of a National Human Organs and Tissues Removal and Storage Network, and development and maintenance of a national registry of recipients of organ transplants.

Importantly, it prescribes stringent punishments for commercial dealing in human organs and contravention of any provisions of the law.

The Act regulates the removal, storage and transplantation of human organs for therapeutic purposes, and prevents commercial dealing in human organs. It enables a surgeon or a physician and an anaesthetist to be included on the medical board in the event of non-availability of a neurosurgeon or a neurologist to certify brain death; makes it mandatory for the ICU/Treating Medical Staff to request relatives of a brain-dead patient for organ donation; and empowers the Union government to prescribe the composition of authorisation committees that grants approvals for donating organs.

Since health is a State subject, the government had to wait until some States passed this Central Act before notifying it. The Act received Presidential assent in September 2011. The remaining States will have to pass the Act in their respective Assemblies.

Welcoming the notification, Pallavi Kumar, executive director of MOHAN Foundation, said it would boost organ donation in the country. The provision that allows making requests to families of the dead to donate organs would help those in need, she told *TheHindu* .

There is a huge shortage of organs in India and patients die while on the waiting list. Around 7.85 million people in India suffer from chronic kidney failure. At present, the approximate prevalence of Chronic Kidney Disease is 800 per million population and the incidence of end stage kidney disease is 150-200 per million population. Nearly 3,500 kidney transplants are done annually as against the need for 21000 transplants.

The Transplantation of Human Organs (Amendment) Bill, 2009

Seeking to streamline the process of organ transplantation and curb instances of illegal dealings, this Amendment Bill provides for the regulation of the transplantation of human tissue along with the transplantation of organs. It makes it mandatory for the medical staff treating a patient at the ICU/medical unit to request relatives of brain dead patients for organ donation and requires that all organ donation cases go through an Authorisation Committee.

Highlights of the Bill

- The Bill amends the Transplantation of Human Organs Act, 1994, which regulates removal, storage and transplantation of human organs.
- In addition to human organs, the Bill seeks to regulate transplantation of tissues of the human body.
- The Act permits donations from living persons who are near relatives. The

Bill expands the definition of "near relative" to include grandparents and grandchildren in addition to parents, children, brother, sister and spouse.

- The doctor in an Intensive Care Unit has to inform the patient or relatives of patient about the option of organ donation and ascertain whether they would consent to the donation.
- A pair of donor and recipient who are near relatives but whose organs do not medically match for transplantation are permitted by the Bill to swap organs with another pair of such persons.
- The Bill enhances the penalty for unauthorised removal of human organs and for receiving or making payment for human organs.

Key Issues and Analysis

- The Bill seeks to strengthen provisions to curb commercial trade in human organs while facilitating organ transplantation for needy patients. It is not clear how effective the above measures would be in curbing such commercial trade.
- Both the donor and recipient shall be penalised if convicted of commercial trade in human organs. Penalising donors who may be forced to sell organs due to financial need may deter them from complaining against commercial trade.
- Organ donation from a person who is not a "near relative" requires permission of the State Authorisation Committee. It is not clear which State Authorisation Committee shall have jurisdiction if the donor and recipient belong to different states.
- The Bill provides for establishment of Advisory Committees but does not list its functions.

The Law And Rules Governing Organ Donation And Transplantation In India

The main provisions of the THO act and the newly passed Gazette by the Government of India include the following:

1. For living donation - it defines who can donate without any legal formalities. The relatives who are allowed to donate include mother, father, brothers, sisters, son, daughter, and spouse. Recently, in the new Gazette grandparents have been included in the list of first relatives. The first relatives are required to provide proof of their relationship by genetic testing and/or by legal documents. In the event of there being no first relatives, the recipient and donor are required to seek special permission from the government appointed authorization committee and appear for an interview in front of the committee to prove that the motive of donation is purely out of altruism or affection for the recipient.
2. Brain-death and its declaration - brain death is defined by the following criteria: two certifications are required 6 hours apart from doctors and two of these have to be doctors nominated by the appropriate authority of the government with one of the two being an expert in the field of neurology.
3. Regulation of transplant activities by forming an Authorization Committee

NOTES

(AC) and Appropriate Authority (AA.) in each State or Union Territory. Each has a defined role as follows:

(a) Role of Authorization Committee (AC) - The purpose of this body is to regulate the process of authorization to approve or reject transplants between the recipient and donors other than a first relative. The primary duty of the committee is to ensure that the donor is not being exploited for monetary consideration to donate their organ. The joint application made by the recipient and donor is scrutinized and a personal interview is essential to satisfy to the AC the genuine motive of donation and to ensure that the donor understands the potential risks of the surgery. Information about approval or rejection is sent by mail to the concerned hospitals. The decision to accept or reject a donor is governed by Sub Clause (3), Clause 9 of Chapter II of the THO act.

(b) Role of Appropriate Authority (AA): The purpose of this body is to regulate the removal, storage, and transplantation of human organs. A hospital is permitted to perform such activities only after being licensed by the authority. The removal of eyes from a dead body of a donor is not governed by such an authority and can be done at other premises and does not require any licensing procedure. The powers of the AA include inspecting and granting registration to the hospitals for transplant surgery, enforcing the required standards for hospitals, conducting regular inspections of the hospitals to examine the quality of transplantation and follow-up medical care of donors and recipients, suspending or canceling the registrations or erring hospitals, and conducting investigations into complaints for breach of any provisions of the Act. The AA issues a license to a hospital for a period of 5 years at a time and can renew the license after that period. Each organ requires a separate license.

Application Forms

The Transplantation of Human Organ Act clearly lays out various procedures; for this purpose, it has thirteen different forms. The Central Government has amended the Transplantation of Human Organs Act, 1994 (42 of 1994) to include certain changes called the Transplantation of Human Organs Rules, 1995 (GSR NO. 51(E), dr. 4-2-1995) [As amended vide GSR 571(E), dt.31-7-2008]. Given below are important excerpts from the rules.

Authority for Removal of Human Organ

Any donor may authorize the removal, before his death, of any human organ of his body for therapeutic purposes as specified in Forms 1(A), 1(B), and 1(C). The new forms have been made more comprehensive and are to be submitted with proof of identity and address, marriage registration certificate, family photographs, etc. with attestation by a Notary Public.

The gazette states that before removing a human organ from the body of a

donor before his death, a medical practitioner should satisfy himself that the donor has given authorization in Form 1(A) if the relative is a close relative i.e., a mother, father, brother, sister, son, or daughter. Form 1(B) is used for a spouse and Form 1(C) is used for other relatives. He should also confirm the following:

- The donor is in a proper state of health and is fit to donate the organ. The registered medical practitioner should then sign a certificate as specified in Form 2.
- The donor is a close relative of the recipient as certified in Form 3 and has signed Form 1(A).
- The donor has submitted an application in Form 10 jointly with the recipient and the proposed donation has been approved by the concerned competent authority. The relationship between the donor and recipient also needs to be examined to the satisfaction of the Registered Medical Practitioner in charge of the transplant center.
  - (a) In the case of the recipient being a spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 1(B) and has submitted an application in Form 10 jointly with the recipient and the proposed donation has been approved by the concerned competent authority.
  - (b) In the case of a donor who is other than a close relative, the donor has signed Form 1(C), submitted an application in Form 10 jointly with the recipient, and permission from the Authorization Committee for the donation has been obtained.

A registered medical practitioner shall, before removing a human organ from the body of a person after his death, confirm the following:

- The donor had, in the presence of two or more witnesses (at least one of whom is a close relative of the recipient), unequivocally authorized as specified in Form 5 before his death, the removal of the human organ of his body after his death for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority.
- The person lawfully in possession of the dead body has signed a certificate as specified in Form 6.

A registered medical practitioner shall, before removing a human organ from the body of a person in the event of brain-stem death, confirm the following:

- A certificate as specified in Form 8 has been signed by all the members of the Board of Medical Experts.
- In the case of brain-stem death of a person of less than 18 years of age, a certificate specified in Form 8 has been signed by all the members of the Board of Medical Experts and an authority as specified in Form 9 has been signed by either of the parents the person.

The Transplantation of Human Organs Act, 1994

An Act to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs and for matters connected therewith or incidental thereto.

Whereas it is expedient to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs;

And whereas Parliament has no power to make laws for the States with respect to any of the matters aforesaid except as provided in Articles 249 and 250 of the Constitution;

And whereas in pursuance of clause (1) of Article 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Goa, Himachal Pradesh and Maharashtra to the effect that the matters aforesaid should be regulated in those States by Parliament by law;

Be it enacted by Parliament in the Forty-fifth Year of the Republic of India as follows: —

Chapter I-Preliminary

1. ***Short title, application and commencement.*** —

(i) This Act may be called the Transplantation of Human Organs Act, 1994.

(ii) It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and Maharashtra and to all the Union territories and it shall also apply to such other States which adopts this Act by resolution passed in that behalf under clause (1) of Article 252 of the Constitution.

(iii) It shall come into force in the States of Goa, Himachal Pradesh and Maharashtra and in all the Union territories on such as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of Article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, means the date on which this Act comes into force in such State or Union territory.

2. Definitions. — In this Act, unless the con otherwise requires. —

(a) "advertisement" includes any form of advertising whether to the public generally or to any section of the public or individually to selected persons;

(b) "Appropriate Authority" means the Appropriate Authority appointed under Section 13;

(c) "Authorisation Committee" means the committee constituted under clause (a) or clause (b) of sub-section (4) of Section 9;

(d) "brain-stem death" means the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified under sub-section (6) of Section 3;

(e) "deceased person" means a person in whom permanent disappearance of

NOTES

all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place;

(f) "donor" means any person, not less than eighteen years of age, who voluntarily authorises the removal of any of his human organs for therapeutic purposes under sub-section (1) or sub-section (2) of Section 3;

(g) "hospital" includes a nursing home, clinic, medical centre, medical or teaching institution for therapeutic purposes and other like institution;

(h) "human organ" means any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body;

(i) "near relative" means spouse, son, daughter, father, mother, brother or sister;

(j) "notification" means a notification published in the Official Gazette;

(k) "payment" means payment in money or money's worth but does not include any payment for defraying or reimbursing —

(i) The cost of removing, transporting or preserving the human organ to be supplied; or

(ii) Any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ from his body;

(l) "prescribed" means prescribed by rules made under this Act;

(m) "recipient" means a person into whom any human organ is, or is proposed to be, transplanted;

(n) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (h) of Section 2 of the Indian Medical Council Act, 1956 (102 of 1956), and who is enrolled on a State Medical Register as defined in clause (k) of that section;

(o) "therapeutic purposes" means systematic treatment of any disease or the measures to improve health according to any particular method or modality; and

(p) "transplantation" means the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes.

3. Authority for removal of human organs. —

1. Any donor may, in such manner and subject to such conditions as may be prescribed, authorise the removal, before his death, of any human organ of his body for therapeutic purposes.

2. If any donor had, in writing and in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised at any time before his death, the removal of any human organ of his body, after his death, for therapeutic purposes, the person lawfully

NOTES

in possession of the dead body of the donor shall, unless he has any reason to believe that the donor had subsequently revoked the authority aforesaid, grant to a registered medical practitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ from the dead body of the donor.

3. Where no such authority as is referred to in sub-section (2), was made by any person before his death but no objection was also expressed by such person to any of his human organs being used after his death for therapeutic purposes, the person lawfully in possession of the dead body of such person may, unless he has reason to believe that any near relative of the deceased person has objection to any of the deceased person's human organs being used for therapeutic purposes, authorise the removal of any human organ of the deceased person for its use for therapeutic purposes.

4. The authority given under sub-section (1) or sub-section (2) or, as the case may be, sub-section (3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ; but no such removal shall be made by any person other than the registered medical practitioner.

5. Where any human organ is to be removed from the body of a deceased person, the registered medical practitioner shall satisfy himself, before such removal, by a personal examination of the body from which any human organ is to be removed, that life is extinct in such body or, where it appears to be a case of brain-stem death, that such death has been certified under sub-section (6).

6. Where any human organ is to be removed from the body of a person in the event of his brain-stem death, no such removal shall be undertaken unless such death is certified, in such form and in such manner and on satisfaction of such conditions and requirements as may be prescribed, by a Board of medical experts consisting of the following, namely: —

   (i) the registered medical practitioner, in charge of the hospital in which brain-stem death has occurred;

   (ii) an independent registered medical practitioner, being a specialist, to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority;

   (iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority; and

   (iv) the registered medical practitioner treating the person whose brain-stem death has occurred.

7. Notwithstanding anything contained in sub-section (3), where brain-stem death of any person, less than eighteen years of age, occurs and is certified under sub-section (6), any of the parents of the deceased person may give authority, in such form and in such manner as may be prescribed, for the removal of any human organ from the body of the deceased person.

NOTES

4. Removal of human organs not to be authorised in certain cases. —

(i) No facilities shall be granted under sub-section (2) of Section 3 and no authority shall be given under sub-section (3) of that section for the removal of any human organ from the body of a deceased person, if the person required to grant such facilities, or empowered to give such authority, has reason to believe that an inquest may be required to be held in relation to such body in pursuance of the provisions of any law for the time being in force.

(ii) No authority for the removal of any human organ from the body of a deceased person shall be given by a person to whom such body has been entrusted solely for the purpose of interment, cremation or other disposal.

5. Authority for removal of human organs in case of unclaimed bodies in hospital or prison. —

(i) In the case of a dead body lying in a hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the death of the concerned person, the authority for the removal of any human organ from the dead body which so remains unclaimed may be given, in the prescribed form, by the person incharge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorised in this behalf by the person in charge of the management or control thereof.

(ii) No authority shall be given under sub-section (1) if the person empowered to give such authority has reason to believe that any near relative of the deceased person is likely to claim the dead body even though such near relative has not come forward to claim the body of the deceased person within the time specified in sub-section (1).

6. Authority for removal of human organs from bodies sent for post-mortem examination for medico-legal or pathological purposes. — Where the body of a person has been sent for post-mortem examination —

(a) for medico-legal purposes by reason of the death of such person having been caused by accident or any other unnatural cause; or

(b) for pathological purposes, the person competent under this Act to give authority for the removal of any human organ from such dead body may, if he has reason to believe that such human organ will not be required for the purpose for which such body has been sent for post-mortem examination, authorise the removal, for therapeutic purposes, of that human organ of the deceased person provided that he is satisfied that the deceased person had not expressed, before his death, any objection

NOTES

to any of his human organs being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his human organs for therapeutic purposes after his death, such authority had not been revoked by him before his death.

7. Preservation of human organs. — After the removal of any human organ from the body of any person, the registered medical practitioner shall take such steps for the preservation of the human organ so removed as may be prescribed.

8. Savings. —

(i) Nothing in the foregoing provisions of this Act shall be construed as rendering unlawful any dealing with the body or with any part of the body of a deceased person if such dealing would have been lawful if this Act had not been passed.

(ii) Neither the grant of any facility or authority for the removal of any human organ from the body of a deceased person in accordance with the provisions of this Act nor the removal of any human organ from the body of a deceased person in pursuance of such authority shall be deemed to be an offence punishable under Section 297 of the Indian Penal Code (45 of 1860).

9. Restrictions on removal and transplantation of human organs. —

(i) Save as otherwise provided in sub-section (3), no human organ removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.

(ii) Where any donor authorities the removal of any of his human organs after his death under sub-section (2) of Section 3 or any person competent or empowered to give authority for the removal of any human organ from the body of any deceased person authorises such removal, the human organ may be removed and transplanted into the body of any recipient who may be in need of such human organ.

(iii) If any donor authorises the removal of any of his human organs before his death under sub-section (1) of Section 3 of transplantation into the body of such recipient, not being a near relative, as is specified by the donor by reason of affection or attachment towards the recipient or for any other special reasons, such human organ shall not be removed and transplanted without the prior approval of the Authorisation Committee.

(iv) (a) The Central Government shall constitute, by notification, one or more Authorisation Committee consisting of such members as may be nominated by the Central Government on such terms and conditions as may be specified in the notification for each of the Union territories for the purposes of this section.

NOTES

(b) The State Government shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the State Government on such terms and conditions as may be specified in the notification for the purposes of this section.

(v) On an application jointly made, in such form and in such manner as may be prescribed, by the donor and the recipient, the Authorisation Committee shall, after holding an inquiry and after satisfying itself that the applicants have complied with all the requirements of this Act and the rules made thereunder, grant to the applicants approval for the removal and transplantation of the human organ.

(vi) If, after the inquiry and after giving an opportunity to the applicants of being heard, the Authorisation Committee is satisfied that the applicants have not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for approval.

10. Regulation of hospitals conducting the removal, storage or transplantation of human organs. —

1. On and from the commencement of this Act, —

(a) no hospital, unless registered under this Act, shall conduct, or associate with, or help in, the removal, storage or transplanation of any human organ;

(b) no medical practitioner or any other person shall conduct, or cause to be conducted, or aid in conducting by himself or through any other person, an activity relating to the removal, storage or transplantation of any human organ at a place other than a place registered under this Act; and

(c) no place including a hospital registered under sub-section (1) of Section 15 shall be used or cause to be used by any person for the removal, storage or transplanation of any human organ except for therapeutic purposes.

2. Notwithstanding anything contained in sub-section (1), the eyes or the ears may be removed at any place from the dead body of any donor, for therapeutic purpose, by a registered medical practitioner.

Explanation. — For the purposes of this sub-section, "ears" includes ear drums and ear bones.

11. Prohibition of removal or transplantation of human organs for any purpose other than therapeutic purposes. — No donor and no person empoered to give authority for the removal of any human organ shall authorise the removal of any human organ for any purpose other than therapeutic purposes.

12. Explaining effects to donor and recipient. — No registered medical practitioner shall undertake the removal or transplanation of any human organ unless he has explained, in such manner as may be prescribed, all possible effects, complications and hazards connected with the removal and transplanation to the donor and the receipient respectively.

13. Appropriate Authority. —

1. The Central Government shall appoint, by notification, one or more officers as appropriate Authorities for each of the Union territories for the purposes of this Act.
2. The State Government shall appoint, by notification, one or more officers as Appropriate Authorities for the purposes of this Act.
3. The Appropriate Authority shall perform the following functions, namely: —
   (i) to grant registration under sub-section (1) of Section 15 or renew registration under sub-section (3) of that section;
   (ii) to suspend or cancel registration under sub-section (2) of Section 16;
   (iii) to enforce such standards, as may be prescribed, for hospitals engaged in the removal, storage or transplantation of any human organ;
   (iv) to investigate any complaint of breach of any of the provision of this Act or any of the rules made thereunder and take appropriate action;
   (v) to inspect hospitals periodically for examination of the quality of transplantation and the follow-up medical care to persons who have undergone transplantation and persons from whom organs are removed; and

(vi) to undertake such other measures as may be prescribed.

14. Registration of hospitals engaged in removal, storage or transportation of human organs. —

1. No hospital shall commence any activity relating to the removal, storage or transplantation of any human organs for therapeutic after the commencement of this Act unless such hospital is duly registered under this Act:

Provided that every hospital engaged, either partly or exclusively, in any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes immediately before the commencement of this Act, shall apply for registration within sixty days from the date of such commencement:

Provided further that every hospital engaged in any activity relating to the removal, storage or transplantation of any human organ shall cease to engage in any such activity on the expiry of three months from the date of commencement of this Act unless such hospital has applied for registration and is so registered or till such application is disposed of, whichever is earlier.

2. Every application for registration under sub-section (1) shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.
3. No hospital shall be registered under this Act unless the Appropriate

NOTES

Authority is satisfied that such hospital is in a position to provide such specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed.

15. Certificate of registration. —

1. The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder, grant to the hospital a certificate of registration in such form, for such period and subject to such conditions as may be prescribed.
2. If, after the inquiry and after giving an opportunity to the applicant of being heard, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.
3. Every certificate of registration shall be renewed in such manner and on payment of such fees as may be prescribed.

16. Suspension or cancellation of registration. —

1. The Appropriate Authority may, suo moto or on complaint, issue a notice to any hospital to show cause why its registration under this Act should not be suspended or cancelled for the reasons mentioned in the notice.
2. If, after giving a reasonable opportunity of being heard to the hospital, the Appropriate Authority is satisfied that there has been a breach of any of the provisions of this Act or the rules made thereunder, it may, without prejudice to any criminal action that it may take against such hospital, suspended its registration for such period as it may think fit or cancel its registration:

Provided that where the Appropriate Authority is of the opinion that it is necessary or expendient so to do in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any hospital without issuing any notice.

17. Appeals. — Any person aggrieved by an order of the Authorisation Committee rejecting an application for approval under sub-section (6) of Section 9, or any hospital aggrieved by an order of the Appropriate Authority rejecting an application for registration under sub-section (2) of Section 15 or an order of suspension or cancellation of registration under sub-section (2) of Section 16, may, within thirty days from the date of the receipt of the order, prefer an appeal, in such manner as may be prescribed, against such order to —

(i) the Central Government where the appeal is against the order of the Authorisation Committee constituted under clause (a) of sub-section (4) of Section 9 or against the order of the Appropriate Authority appointed under sub-section (1) of Section 13; or

(ii) the State Government. where the appeal is against the order of the Authorisation Committee constituted under clause (b) of sub-section

(4) of Section 9 or against the order of the Appropriate Authority appointed under sub-section (2) of Section 13.

18. *Punishment for removal of human organ without authority.* —

(i) Any person who renders his services to or any hospital and who, for purposes of transplantation, conducts, associates with, or help in any manner in, the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten thousand rupees.

NOTES

(ii) Where any person convicted under sub-section (1) is a registered medical practitioner, his name shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

19. Punishment for commercial dealings in human organs. — Whoever —

(d) makes or receives any payment for the supply of, or for an offer to supply, any human organ;

(e) seeks to find a person willing to supply for payment any human organ;

(f) offers to supply any human organ for payment;

(g) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;

(h) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or

Publishes or distributes or causes to be published or distributed any advertisement, —

(a) inviting persons to supply for payment of any human organ;

(b) offering to supply any human organ for payment; or

(c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d), shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees;

Provided that the court may, for any adequate and special reason to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and a fine less than ten thousand rupees.

20. Punishment for contravention of any other provision of this Act. — Whoever contravenes any provision of this Act or any rule made, or any condition of the registration granted, thereunder for which no punishment is separately provided in this Act, shall be punishable with imprisonment for a term which may extend to three years or with fine which may extend to five thousand rupees.

21. Offences by companies. —

(i) Where any offence punishable under this Act has been committed by a company, every person who, at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(ii) Notwithstanding any thing contained in sub-section (1), where any offence punishable under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or in attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation. — For the purposes of this section, —

(a) "company" means any body corporate and includes a firm or other association of individuals; and

(b) "director", in relation to a firm, means a partner in the firm.

22. Cognizance of offence. —

(i) No court shall take cognizance of an offence under this Act except on a complaint made by —

(a) the Appropriate Authority concerned, or any officer authorised in this behalf by the Central Government or the State Government or, as the case may be, the Appropriate Authority; or

(b) a person who has given notice of not less than sixty days, in such manner as may be prescribed, to the Appropriate Authority concerned, of the alleged offence and of his intention to make a complaint to the court.

(ii) No court other than that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

(iii) Where a complaint has been made under clause (b) of sub-section (1), the court may, on demand by such person, direct the Appropriate Authority to make available copies of the relevant records in its possession to such person.

2.11 PREVENTION OF FOOD AND ADULTERATION ACT

NOTES

Food is one of the basic necessities for sustenance of life. Pure, fresh and healthy diet is most essential for the health of the people. It is no wonder to say that community health is national wealth.

Adulteration of food-stuffs was so rampant, widespread and persistent that nothing short of a somewhat drastic remedy in the form of a comprehensive legislation became the need of the hour. To check this kind of anti-social evil a concerted and determined onslaught was launched by the Government by introduction of the Prevention of Food Adulteration Bill in the Parliament to herald an era of much needed hope and relief for the consumers at large.

Statement Of Objects And Reasons

Laws existed in a number of States in India for the prevention of adulteration of food- stuffs, but they lacked uniformity having been passed at different times without mutual consultation between States. The need for Central legislation for the whole country in this matter has been felt since 1937 when a Committee appointed by the Central Advisory Board of Health recommended this step. 'Adulteration of food-stuffs and other goods' is now included in the Concurrent List (III) in the Constitution of India. It has, therefore, become possible for the Central Government to enact an all India legislation on this subject. The Bill replaces all local food adulteration laws where they exist and also applies to those States where there are no local laws on the subject. Among others, it provides for —

(i) a Central Food Laboratory to which food samples can be referred to for final opinion in disputed cases (clause 4),

(ii) a Central Committee for Food Standards consisting of representatives of Central and State Governments to advise on matters arising from the administration of the Act (clause 3), and

(iii) the vesting in the Central Government of the rule-making power regarding standards of quality for the articles of food and certain other matters (clause 22).

ACT 37 OF 1954

The Prevention of Food Adulteration Bill was passed by both the house of Parliament and received the assent of the President on 29th September, 1954. It came into force on Ist June, 1955 as THE PREVENTION OF FOOD ADULTERATION ACT, 1954 (37 of 1954). LIST OF ADAPTATION ORDER AND AMENDING ACTs

1. The Adaptation of Laws (No.3) Order, 1956. 2. The Prevention of Food Adulteration (Amendment) Act, 1964 (49 of 1964). 3. The Prevention of Food Adulteration (Amendment) Act, 1971 (41 of 1971). 4. The Prevention of Food Adulteration (Amendment) Act, 1976 (34 of 1976). 5. The Prevention of Food Adulteration (Amendment) Act, 1986 (70 of 1986).

2.12 MEDICAL TERMINATION OF PREGNANCY ACT, 1971

NOTES

An Act to provide for the termination of certain pregnancies by registered Medical Practitioners and for matters connected therewith or incidental thereto. Be it enacted by Parliament in the Twenty-second Year of the Republic of India as follows :- Short title, extent and commencement –

1. This Act may be called the Medical Termination of Pregnancy Act, 1971.
2. It extends to the whole of India except the State of Jammu and Kashmir.
3. It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

Definitions - In this Act, unless the context otherwise requires, —

(a) "guardian" means a person having the care of the person of a minor or a lunatic;

(b) "lunatic" has the meaning assigned to it in section 3 of the Indian Lunatic Act, 1912 (4 of 1912);

(c) "minor" means a person who, under the provisions of the Indian Majority Act, 1875 (9 of 1875), is to be deemed not to have attained his majority;

(d) "registered medical practitioner" means a medical practitioner who possesses any recognized medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956, (102 of 1956), whose name has been entered in a State Medical Register and who has such experience or training in gynaecology and obstetrics as may be prescribed by rules made under this Act.

When pregnancies may be terminated by registered medical practitioners -

1. Notwithstanding anything contained in the Indian Penal Code (45 of 1860), a registered medical practitioner shall not be guilty of any offence under that Code or under any other law for the time being in force, if any pregnancy is terminated by him in accordance with the provisions of this Act.
2. Subject to the provisions of sub-section (4), a pregnancy may be terminated by a registered medical practitioner, -
   (a) here the length of the pregnancy does not exceed twelve weeks if such medical practitioner is, or
   (b) Where the length of the pregnancy exceeds twelve weeks but does not exceed twenty weeks, if not less than two registered medical practitioner are, of opinion, formed in good faith, that -
      (i) the continuance of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury to her physical or mental health; or
      (ii) there is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities to be seriously handicapped.

Explanation 1 - Where any pregnancy is alleged by the pregnant woman to have

NOTES

been caused by rape, the anguish caused by such pregnancy shall be presumed to constitute a grave injury to the mental health of the pregnant woman.

Explanation 2 - Where any pregnancy occurs as a result of failure of any device or method used by any married woman or her husband for the purpose of limiting the number of children, the anguish caused by such unwanted pregnancy may be resumed to constitute a grave injury to the mental health of the pregnant woman

3. In determining whether the continuance of a pregnancy would involve such risk of injury to the health as is mentioned in sub-section (2), account may be taken of the pregnant women's actual or reasonable foreseeable environment. (4)(a)No pregnancy of a woman, who has not attained the age of eighteen years, or, who, having attained the age of eighteen years, is a lunatic, shall be terminated except with the consent in writing of her guardian. (b)Save as otherwise provided in clause (a), no pregnancy shall be terminated except with the consent of the pregnant woman.
4. Place where pregnancy may be terminated - No termination of pregnancy shall be made in accordance with this Act at any place other than -
   (a) a hospital established or maintained by Government, or
   (b) a place for the time being approved for the purpose of this Act by Government.

Sections 3 and 4 when not to apply -

1. The provisions of section 4, and so much of the provisions of sub-section (2) of section 3 as relate to the length of the pregnancy and the opinion of not less than two registered medical practitioners, shall not apply to the termination of a pregnancy by a registered medical practitioner in a case where he is of opinion, formed in good faith, that he termination of such pregnancy is immediately necessary to save the life of the pregnant woman.
2. Notwithstanding anything contained in the Indian Penal Code (45 of 1860), the termination of a pregnancy by a person who is not a registered medical practitioner shall be an offence punishable under that Code, and that Code shall, to this extent, stand modified.

Explanation - For the purposes of this section, so much of the provisions of clause (d) of section (2) as relate to the possession, by a registered medical practitioner, of experience or training in gynaecology and obstetrics shall not apply.

Power to make rules -

1. The Central Government may, by notification in the Official Gazette, make rules to carry out the provisions of this Act.
2. In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely -
   (a) the experience or training, or both, which is registered medical practitioner shall have if he intends to terminate any pregnancy under this Act; and

(b) Such other matters as are required to be or may be, provided by rules made under this Act.

3. Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two successive sessions, and if, before the expiry of the session in which it is so laid or the session immediately following, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

Power to make regulations –

1. The State Government may, by regulations -

(a) require any such opinion as is referred to in sub-section (2) of section 3 to be certified by a registered medical practitioner or practitioners concerned, in such form and at such time as may be specified in such regulations, and the preservation or disposal of such certificates ;

(b) require any registered medical practitioner, who terminates a pregnancy, to give intimation of such termination and such other information relating to the termination as may be specified in such regulations ;

(c) prohibit the disclosure, except to such purposes as may be specified in such regulations, of intimations given or information furnished in pursuance of such regulations.

2. The intimation given and the information furnished in pursuance of regulations made by virtue of clause (b) of sub-section (1) shall be given or furnished, as the case may be, to the Chief Medical Officer of the State.

3. Any person who willfully contravenes or willfully fails to comply with the requirements of any regulation made under sub-section (1) shall be liable to be punished with fine, which may extend to one thousand rupees.

Protection of action taken in good faith -

No suit or legal proceedings shall lie against any registered medical practitioner for any damage caused or likely to be caused by anything, which is in good faith done or intended to be done under this Act.

The Medical Termination Of Pregnancy Act, 1971:

During the last thirty years many countries have liberalized their abortion laws. The worldwide process of liberalization continued after 1980. Today only 8% of the world's population lives in countries where the law prevents abortion. Although the majority of countries have very restricted abortion laws, 41% of women live in countries where abortion is available on request of women. In India, Shantilal Shah Committee (1964) recommended liberalization of abortion law in 1966 to

reduce maternal morbidity and mortality associated with illegal abortion. On these bases, in 1969 Medical termination of pregnancy bill was introduced in Rajya Sabha and Lok Sabha and passed by Indian Parliament in Aug. 1971. Medical Termination Of Pregnancy Act, 1971 (MTP Act) was implemented from Apr.1972. Implemented rules and regulations were again revised in 1975 to eliminate time consuming procedures for the approval of the place and to make services more readily available. The MTP Act, 1971 preamble states" an Act to provide for the termination of certain pregnancies by registered medical practitioners and for matters connected therewith or incidental thereto".

The preamble is very clear in stating that termination of pregnancy would be permitted in certain cases. The cases in which the termination is permitted are elaborated in the Act itself. Moreover, only a registered medical practitioner who is defined in Sec.2(d) of the Act as "a medical practitioner who possess any recognize medical qualification as defined in Cl.(h) of sec.2 of the Indian Medical Register and who has such experience or training in gynecology and Obstetrics as may be prescribed by rules made under this Act" is permitted to conduct the termination of pregnancy. Also other matters connected there with the incidental thereto are incorporated, for example, the question of consent of termination of pregnancy, the place where the pregnancy could be terminated, the power to make rules and regulations in this behalf.

Grounds for termination of pregnancy: Sec.3: When pregnancies may be terminated by registered medical practitioner. (i) Notwithstanding anything contained in the Indian Penal Code (45 of 1860) a registered medical practitioner shall not be guilty of any offence under that Code or under any other law for the time being in force, if any pregnancy is terminated by him in accordance with the provisions of this Act"

This makes it clear that the provisions of the MTP Act, so far as abortion is concerned suppresses the provisions of the Indian Penal Code. Sub-sec. (2) of Sec.3: "Subject to the provisions of sub-sec (4), a pregnancy, may be terminated by a registered medical practitioner. (a) Where the length of the pregnancy does not exceed 12 weeks if such medical practitioner is, or (b) Where the length of the pregnancy exceeds 12 weeks but does not exceed 20 weeks, if not less than 2 registered medical practitioners are of opinion, formed in good faith that

1. The continuance of the pregnancy would involve a risk to the life of the pregnant women ;or 2: A risk of grave injury to the her physical or mental health ;or 3: .If the pregnancy is caused by rape; or 4: There exist a substantial risk that, if the child were born it would suffer from some physical or mental abnormalities so as to be seriously handicapped; or 5: Failure of any device or method used by the married couple for the purpose of limiting the number of children; or 6; Risk to the health of the pregnant woman by the reason of her actual or reasonably foreseeable environment.

The Act does not permit termination of pregnancy after 20 weeks. The medical opinion must offcourse be given in "good faith". The term good faith has not been defined in the Act but sec. 52 if the IPC defines good faith to mean as act done with 'due care and caution'. It is important to note that certain loopholes exist

in the provisions. Firstly, nowhere has the Act defined what would involve a risk or a grave injury to her mental health. The term grave injury or substantial risk remains undefined. The gravity of the injury or the extent of the risk being left to the interpretation of the clause by the medical practitioner. However the MTP Act provides some guidance for the doctors in the form of two explanations.

Sec 3(2) Explanation 1: where any pregnancy is alleged by the pregnant woman to have been caused by rape, the anguish caused by such pregnancy shall be presumed to constitute a grave injury to the mental health of the pregnant woman. Therefore, rape per se is not an indication. It is the mental anguish following pregnancy due to rape, which is the main indication. In other words, mental anguish is to be taken into consideration; proving rape and affecting her character is not necessary. Her allegation that she has been raped is sufficient. Further proof of rape like medical examination, trial, judgment is not necessary.

Explanation 2: where any pregnancy occurs as a result of failure of any device or method used by any married woman or her husband for purpose of limiting the number of children they anguish caused by such unwanted pregnancy may be presumed to constitute a grave injury to the mental health of the pregnant woman. The Act says that mental anguish due to pregnancy due to contraceptive failure in a married woman is an indication. Can an unmarried woman avail of this clause? She cannot use this, but she can get abortion under the general clause of mental indication.

Sub Section (3) clarifies that: Sub-Sec.3 (3) In determining that whether the continuance of a pregnancy would involve such risk of injury to the health as is mentioned in sub-sec (2), account may be taken of the pregnant woman's actual or reasonable foreseeable environment. Therefore in determining whether the continuation of pregnancy would constitute a risk to the physical or mental health of the pregnant woman the Indian Law permits the consideration of the woman actual or reasonably foreseeable environment. The terms reasonably or foreseeable being left to the interpretation of the medical practitioner. Environmental clauses could include, by interpretation, drunkard husband, low-income group, large family etc. By and large, these explanations provide for two instances where continued pregnancy is assumed to constitute a grave injury to the mental health of the pregnant woman, namely where the pregnancy is alleged by a woman to have being caused by rape and second where the pregnancy occurs as a result of failure f any device by a married woman or her husband for purpose of limiting the number of children. The provision provides the doctors with a yardstick for a broad interpretation of the basic concept of the potential injury to the mental health of the pregnant woman.

The rest of the matters come in the case of mental indication where abortion is allowed and continuation of pregnancy would involve grave injury to her mental health. This is a subjective indication and commonly restored one. In one of the case, where a girl detained in a Women's Welfare institution applied to the High Court during the pendency of her writ petition that the Court be pleased to order termination of her pregnancy and the Court found that the Pregnancy was against her will and that unless it was terminated the girl would suffer traumatic and psychological shock, the High Court directed termination in a govt. Maternity

hospital if the doctors there on examination found that the termination would not affect her life and safety.

Qualification of Doctors: According to the Act, 'a medical practitioner who possess any recognized medical qualification as defined in cl. (h) of Sec.2 of the Indian Medical Council Act, 1956 whose name has been entered in a state medical register and who has such experience or training in gynecology or obstetrics as may be prescribed by rules made under this Act is permitted to conduct the termination of pregnancy'. Allopathic doctors who are duly registered with the State Medical Council are authorized to do abortion. Other like homeopathic, ayurvedic, unani doctors and unqualified doctors like RMP, Quacks, et al are not entitled to perform abortion. Even among allopathic doctors, only those who satisfy one or the other of the following qualifications are eligible to do MTP. Once a doctor satisfies the require qualifications, he automatically becomes eligible to do abortions. He need not apply for eligibility to any authority. A doctor cannot refuse to do abortions on religious grounds. If he does so, his name is liable to be erased from the Medical Council. If he is a Govt. doctor, he is liable for departmental action.

Consent for Abortion: Section 3(4) of MTPA clarifies as to whose consent would be necessary for termination of pregnancy.

(a) No pregnancy of a woman, who has not attained the age of 18 years, or who having attained the age of 18 years, is a lunatic, shall be terminated except with the consent in writing of her guardian.

(b) Save as otherwise provided in cl (a), no pregnancy shall be terminated except with the consent of the pregnant woman. It is important to note, in this section, that the consent of the woman is the essential factor for termination of her pregnancy. The husband's consent is irrelevant. Therefore, if the woman wants an abortion but her husband's objects to it, the abortion can still be done. However, if the woman does not wants an abortion but her husband wants, it cannot be done. However, the consent of the guardians is needed in the case of minors or lunatics.

Where the pregnancy can be terminated: Section 4 specifies the place where, under MTP, a pregnancy can be terminated. It stipulates that an operation must take place in either "a hospital established or maintained by the government" or in "a place which has been approved for the purpose of this Act by the government." However exceptions are made for emergencies. Under section 5(1), a doctor may terminate a pregnancy if it is "immediately necessary to save the life of the pregnant woman". In such situations, the requisites relating to the length of pregnancy, the need for two medical opinions and the venue for operation do not apply. However, it needs to be pointed out that one aspect of this emergency clause tends to restricts rather than liberalize the old law. Section 312 of the IPC permitted abortions by anyone with the object of saving the life of the mother. But under MTPA only a doctor can terminate the pregnancy.

Approval of a Place: No place shall be approved under Cl (b) of sec.4 (1) Unless the Government is satisfied that termination of pregnancy may be done therein under safe and hygienic conditions. (2) Unless the following facilities are provided

therein namely: i. An operation table and instruments for performing abdominal gynecological surgery ii. Anesthetic equipment, resuscitation equipment and sterilization equipment iii. Drugs and parental fluids for emergency use. Thus, the oft-argued following justifications in favour of the permissive abortions are found in the Indian law.

1. Therapeutics: The old restrictive Indian abortion law has permitted abortion to save the life of the mother. In addition, the reformed law, as seen above allows abortions when the mother's life is not threatened, but when continued pregnancy will cause damage to her mental and physical health.
2. Eugenics: the basic of eugenic abortion is that there is a justification for abortion when it is known before birth that the child will be born mentally or physically deformed. The unborn child should be relieved of a life of misery.
3. caused by rape: the problem of a pregnancy caused by rape may effect the mental health of the mother. It is assumed that the victim mother does not want the child and does not want to bear the continuing result of a crime for which she was not culpable.
4. Social and economic considerations: A popular argument in favour of abortion is based on the absolute right of the woman to control the use of her body. She has a right to an abortion on demand to terminate any pregnancy, which she decides she does not want. Admittedly, the right to control the use of one's body is founded on ideas of liberty, and restrictions thereon may amount to an invasion of privacy.

In countries where abortion is legal, death rates are usually below 1 per 100,000 procedures. Abortion is a very safe operation if the operation is performed by skilled medical practitioners, having proper facilities and equipments. In developing countries like India with scarce medical resources treatment of complications of abortion often posses a heavy burden on the health care system. According to recent estimates made by the World Health Organization, about one-quarter to one-third of maternal deaths are due to complications of (illegally) induced abortion. This can be prevented through offering easily accessible safe abortion services and through family planning services and education. Reliable statistics show that in many countries where abortion is legally available, the abortion rate is much lower than in countries where it is completely illegal.

Procedural delays to conduct MTP lessened The Medical Termination of Pregnancy Act was first enacted in the year 1971 to legalize and regulate the conditions of termination of pregnancy. This was the first step to legalize abortions which were performed by quacks and which instilled fear in the minds of pregnant woman. The key features of the Medical Termination of Pregnancy Act, 1971 were as follows:

It indicated when pregnancy could be terminated i.e. upto twenty weeks of pregnancy. # It specified the indications when termination of pregnancy could be done. # It indicated that only a qualified registered medical practitioner as defined under the Act could conduct termination of pregnancy and relied upon the Indian Penal Code for punishment if conducted by any other. # It also indicated that

termination of pregnancy could be done only in a place established, maintained or approved by the Government.

Thus it did help to legalize and regulate the termination of pregnancy and really did much for upliftment of women. Gradually, with an increasing number of centers and with new problems cropping up, the Act was amended and passed on December 18, 2002.Essential features of the amendment are as follows: - # In the amended Act, the word "mentally ill person" covers a wider variety of mental diseases and disorders than the word # lunatic" of the Principal Act. # In the amended Act, recognition of a place for the purpose of carrying out MTP is now at district level rather than the state capital and hence procedural delays should be less. # In the Principal Act, there was dependence on IPC to enforce discipline. In the amended Act, the punishment is incorporated in the Act itself.

NOTES

2.13 BIRTH AND DEATH REGISTRATION ACT

The history of civil registration in India dates back to the middle of the nineteenth century. It started with the registration of deaths with a view to introducing sanitary reforms for control of pestilence and disease and not so much for studying population trends. The Provincial Sanitary Commissioners obtained statistics on deaths from the local health officers and passed them on to the Sanitary Commissioner of the Government of India. The quality of statistics thus collected was highly deficient and incomplete.

Need for Central Legislation :

There was a great diversity in the legal provisions for registration of births and deaths in different parts of the county. Different Acts were enforced in different parts of the country at different points of time and even in a single state there were many acts in force in different areas.

Registration of Births and Deaths (RBD) Act, 1969:

Against this background of municipalities of acts and rules governing civil registrations in various parts of the country, a central legislation on the subject was considered absolutely necessary to bring about improvement in the system. The recommendations of the 1961 Conference provided a blue print for action and the government of India, took a decision, in consultation with the state governments, for enactment of a central law relating to registration of births and deaths. Accordingly, the Registration of Births and Deaths Bill was introduced in the Rajya Sabha in 1964, which was passes in the Budget Session of 1964 – 1965 but lapsed on the dissolution of the Parliament. The Bill was again passed by the Rajya Sabha on February 27, 1968. The Lok Sabha passed the Bill on May 27, 1969 with certain amendments. These amendments were approved by the Rajya Sabha on May 16, 1969. The Bill was passed by both houses of Parliament received the assent of the President on May 31, 1969. It was notified in the Gazette of India Extraordinary, Part II Section I on June 2, 1969.

The RBD Act, 1969 thus replaced the diverse laws that existed on the subject, unified the system of registration throughout the country and made reporting and registration of births and deaths compulsory. It provided for a statutory authority at the center and in each state. It enabled the Central Government to promote uniformity and comparability in registration and compilation of vital statistics allowing enough scope to the states to develop an efficient system of registration suited to regional conditions and needs.

Brief Provisions of the Act:

The Act has been divided into a number of sections and sub-sections covering aspects such as registration establishment, procedures, records and statistics. The salient features of these sections are briefly indicated here.

SECTION 1

Enables enforcement in different parts of the states on different dates.

SECTION 2

Describes definitions of vital events.

SECTION 3 - 7

Established a statutory authority at local, state and national levels for registration.

SECTION 8 – 9

Fixed responsibilities on different categories of persons required to register births and deaths.

SECTION 10

Makes certain persons responsible to notify births and deaths and to certify cause of death.

SECTION 11, 12 and 15

Lay down the registration procedures.

SECTION 13

Permits delayed registration.

SECTION 14

Allows registration of name of child at a later date.

SECTION 16 – 17

Provides maintenance of records for issuance of certificates and extracts.

SECTION 18

Authorises inspection of registration offices.

SECTION 19

Prescribes the regular flow of returns from the registrar

SECTION 20

Sanctions registration of births and deaths of Indian citizen abroad.

SECTION 21

Empowers a registrar to obtain information regarding birth or death from a local resident.

SECTION 22

Confers powers on the central governments to give directions to the state governments.

SECTION 23 – 25

Impose penalties for the various offences.

SECTION 26 – 28

Admit registrars as public servants and provide protection.

SECTION 29

Saves the births, deaths and marriages registration Act, 1886.

SECTION 31

Repeals the earlier laws on registration

SECTION 30, 32

Empower the state government to make rules and remove difficulties with the approval of the central government.

Implementation of the Registration of Births and Deaths Act, 1969 in Mizoram:

Section 30 of the RBD Act, 1969 provides that State Government may, with the approval of Central Government by notification in the official gazette make such rules to carry out the purposes of the RBD Act. Accordingly the Mizoram Registration of Births and Deaths Rules 1978 was framed. The said Rules was implemented with effect from 1.7.1985 in the then Aizawl and Lunglei Districts and with effect from 1.1.1986 in the then Chhimtuipui District. Under the revamped system of Civil Registration System, new rules called the Mizoram Registration of Births and Deaths Rules 2007 was laid before the State Legislature and implemented in the state.

Since the implementation of the RBD Act in the state, registration of births and deaths has been made compulsory in Mizoram.

Registration Functionaries:

The registration organization in Mizoram was headed by the Chief Secretary, IDC (Inter-departmental Co-ordination Committee) meeting held on 18.7.2003 resolved that the Organisation henceforth be headed by Secretary / Commissioner, i.e. Planning and Programme Implementation Department. Accordingly, Secretary Planning and Programme Implementation Department was appointed Chief Registrar of Births and Deaths, Mizoram on 30.10.2003.

1. **Chief Registrar** : The Chief Registrar is appointed by the state government under section 4(1) of the Act. He is the Chief executive authority in the state for implementing the provisions of the act and the rules made there under.
2. **Chief Registrar** : The Additional Chief Registrar of Births and Deaths is the Director of Economics and Statistics. He is the functional head of

registration system in the state. The Additional Chief Registrar is responsible for organizational and operational aspects of the Act for ensuring effective functioning of the registration system in the state.

3. **Joint Chief Registrar of Births and Deaths** : The Director of Census Operation being the representative of the Registrar General, India is appointed the Joint Chief Registrar of Births and Deaths of Mizoram.
4. **District Registrar** : The Deputy Commissioner of each district is appointed District Registrar under section 6(1) of the Act.

The District Registrar is responsible for authorizing delayed registration as prescribed in the rules.

5. **Additional District Registrar** : The District Education Officers are appointed Additional District Registrars.
6. **Registrars** : Primary School Teachers are appointed Registrar of Births and Deaths. The registrar are appointed by the state government under section 7(1) of the act. The whole area of Mizoram is presently divided into 771 registration units, hence the number of Registrar in the state is 711.

Responsibilities of the Registrar:

(a) The Registrar is responsible for recording the specified information regarding vital events which take place in his jurisdiction.

(b) Ensuring the completeness and accuracy of each record.

(c) He should place a board near the outer door of this house / office indicating that he is the Registrar of Births and Deaths for the local area for which he is appointed.

(d) The registrar is required to send in the prescribed forms to the Chief Registrar. He must be very prompt in sending the returns in time and shall check the completeness and accuracy of the entries made therein before sending such returns.

Registration of Births and Deaths Wing (Vital Statistics Wing):

The Civil Registration System in Mizoram is being looked after by the mini vital statistics wing, manned by 11 staffs under Directorate of Economics and Statistics. Prompt registration and submission of monthly returns is ensured and monitored by this wing. Besides, issuance of certificates, maintenance of records, and adequate supply of registration forms and other materials to the local registrars are also the duties of the wing.

Achievement:

1. **Annual Report** : Information received from the monthly returns are compiled, processed and analysed. Vital data are derived in the form of Annual report. The latest report relates to the year 2005.
2. **Annual Training** : Annual training of registrars of births and deaths is held

towards the end of every calendar year at each district headquarters. Problems faced by the registrars and new developments are discussed during the training. Registration materials for the next calendar year are also distributed during the training. The last annual trainings were held during November and December 2006.

3. **Medical Certification of causes of Deaths** : Medical Certification of Causes of Deaths submitted by the medical officers of rural and urban institutions are coded according to the 10th Revision of ICD. The coded causes of deaths are entered into software provided by the Office of the Registrar General, India. The data so derived from the entry is published for the first time for the year 2005.

District Wise rural urban distribution of registration units:

	District	Urban	Rural	Total
1	Mamit	4	62	66
2	Kolasib	9	27	36
3	Serchhip	9	27	36
4	Champhai	15	77	92
5	Aizawl	84	83	167
6	Lunglei	30	111	141
7	Saiha	9	48	57
8	Lawngtlai	-	111	111
	Total	**160**	**546**	**706**

From the monthly returns submitted by the local Registrars, the mini vital statistics wing under the Directorate of Economics & Statistics prepares the Annual Report on the working of Registration of Births and Deaths Act 1969. Birth, Death and Infant Mortality Rates since implementation of RBD Act in Mizoram are as follows :-

YEAR	BIRTHS	DEATHS	TOTAL	BIRTHS RATE	DEATHS RATE	INFANT MORTALITY RATE
1985	4502	1183	5685	9.02	2.37	33.32
1986	11620	2686	14306	19.31	4.46	18.85
1987	13060	2550	15610	20.86	4.07	17.84
1988	15297	2951	18248	23.48	4.53	22.68
1989	15046	3136	18182	21.24	4.43	21.74
1990	15125	2759	17884	20.28	3.70	18.38

1991	15245	2828	18073	22.10	4.10	20.01
1992	14269	2889	17158	20.01	4.05	21.94
1993	14260	2951	17211	19.34	4.00	21.60
1994	14835	2932	17767	19.46	3.85	15.37
1995	15274	3234	18508	19.55	4.46	20.10
1996	14616	2941	17557	17.93	3.61	18.13
1997	16660	3230	19890	19.76	3.83	18.55
1998	16001	3438	19439	18.36	3.94	26.06
1999	16848	3822	20670	18.69	4.24	18.46
2000	18856	3550	22406	21.39	4.03	11.51
2001	19760	4070	23830	21.88	4.51	17.34
2002	20311	4401	24712	22.34	4.84	21.46
2003	20301	4697	24998	21.93	5.07	14.03
2004	20222	4661	24883	21.47	4.97	22.69
2005	20133	4686	24819	20.07	4.66	22.40

The Registration of Births and Deaths (Amendment) Bill, 2012

- The Registration of Births and Deaths (Amendment) Bill, 2012 was introduced in Raja Sabha on May 7, 2012 by Mr. Salman Khurshid, Minister of Law and Justice. The Bill has been referred to the Standing Committee on Personnel, Public Grievances, Law and Justice on May 9, 2012. The chairperson is Mr. Shantaram Naik.
- The Registration of Births and Deaths Act, 1969 regulates the registration of births and deaths. The Bill amends the Act to include the registration of marriages within its purview.
- The Bill defines marriage to include marriage solemnized between a male and female belonging to any caste or religion. It also includes re-marriage.
- The Bill requires that all marriages (irrespective of religion) shall be registered either under the Act or the Anand Marriage Act, 1909 or any other existing law (including state laws).
- Marriages registered under the Anand Marriage Act, state laws or any other existing law are not required to be registered under the Bill.
- The Act provides for the establishment of a Registrar General of India. The Registrar is responsible for the registration of 'births and deaths.' The Bill provides that the Registrar shall also be responsible for the registration of marriages.
- The Bill specifies the people who shall be eligible to submit information to the Registrar in order to register the marriage. It shall be the duty of the specified people to give the required information to the Registrar within the prescribed time period.

- The Act specifies that if the birth or death is not registered within the specified time period, then the Registrar shall, on the payment of a late fee, register the death or birth (a) within a period of 30 days (b) within one year only with the written permission of the prescribed authority; and (c) after one year only on the order of a first class Magistrate. The Bill states that the same provision applies to marriages as well.
- The Bill provides that if the Registrar seeks information from any person regarding any 'birth or marriage' then the person shall be bound to comply with such requirement.
- The Bill prescribes a penalty of Rs 50 in case of (a) non registration of 'marriage without a reasonable cause; (b) providing false information regarding the registration of marriage; and (c) refusal to furnish certain information, such as name and address.
- The Bill shall be in addition to the other existing laws. It shall not affect any rights recognised under any other law or custom.
- The Act provides that any previous state law on any matter covered by the Act shall be repealed. The Bill provides that this repeal provision shall not be applicable to marriages solemnized under the Anand Marriage Act or under any state law.

2.14 SEX DETERMINATION ACT

Although sex determination and sex selection (female foeticide) is a topic beginning to gain more public awareness, the laws surrounding sex selective abortions remain unclear due to political and judicial jargon. The Pre-Conception and Prenatal Diagnostic Techniques Act was passed in 1994 banning prenatal sex determination as a means to prevent sex selective abortions.

According to the act, a prenatal diagnostic procedure includes any medical procedure such as ultrasonography, foetoscopy, or sampling of amniotic fluid, chorionic villi, blood, any tissue or fluid, which is sent to a genetic laboratory or clinic for pre-natal analysis or diagnostic tests for sex selection. Pre-natal analysis could include any tests conducted on pregnant women to detect genetic disorders, metabolic disorders, chromosomal abnormalities, congenital anomalies, haemoglobinopathies, and sex-linked diseases.

While the effectiveness of the PC&PNDT Act can be questioned, the act has clear objectives that aim to prevent any sort of prenatal sex selection. There are three main objectives to the PC&PNDT Act. The first is to prohibit sex selection before or after conception. The second objective is to regulate pre-natal diagnostic practices so they are only used to detect genetic, metabolic, or chromosomal abnormalities, and the third objective is to prevent the misuse of these techniques for sex determination, which could lead to sex determination and sex selection (female foeticide).

"The Act is talking about two issues: the conception side and the technical procedures," said Soumya Bhaumik, lawyer at the Centre for Social Research. "The Act is meant to prevent the abortion of female feotuses."

The PC&PNDT Act defines sex selection as any procedure, technique, or test that is conducted for the purpose for ensuring or increasing the probability that an embryo will be of a particular sex. This law applies to any centre that provides genetic counseling to patients. This includes any institute, hospital, nursing home, or clinic, which is used for pre-natal diagnostic techniques. Even a vehicle that has any equipment that could be used for determining the sex of a feotus comes under this law. All genetic centres are required to display prominently a notice in English and in the local language or languages that conduct of sex-determination tests/ disclosure of sex of the foetus is prohibited.

An important aspect of the law is that it permits the use of prenatal diagnostic techniques if tests are being conducted to diagnose medical conditions such as genetic diseases, chromosomal abnormalities, or any other disease that can be diagnosed through conducting prenatal tests. This law only prohibits the use of prenatal tests for sex selection purposes.

While prenatal tests are permitted for detecting specific disorders, there are certain conditions that women must have in order to qualify for prenatal diagnostic practices. Prenatal techniques can be used on pregnant women if they are above 35 years, have undergone two or more spontaneous abortions or foetal loss, have been exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals, or if the pregnant women or their spouses have a family history of mental retardation or physical deformities such as spasticity or any other genetic disease.

Any medical personnel conducting a prenatal test must brief the woman on any potential risks or side effects of the test and must gain written consent from the woman before conducting the tests. In addition, anyone conducting the prenatal diagnostic must declare on each report that he/she has neither detected nor disclosed the sex of foetus to any body, and any pregnant woman undergoing ultrasonography/ image scanning must declare that she does not want to know the sex of her foetus.

The Act also places prohibitions on people, including relatives and the husband of the pregnant woman. These prohibitions extend to family members or the husband of the pregnant woman encouraging or seeking the use of prenatal techniques for the purpose of sex selection. In addition, no person including the specialist or family member will communicate to the pregnant woman, her relatives, or any other person the sex of the foetus by words, signs or in any other manner.

Any person who acts contrary to this law and seeks the aid of prenatal tests to be conducted on a pregnant woman for the purpose of sex selection will be liable to be punished to up to three years imprisonment and pay a fine up to Rs.50,000. However, in case of a doctor violating this act, his/her name will be reported to the State Medical Council, who will take appropriate actions, including suspension of the doctor's practicing license.

India cracks down on sex-determination tests

Indian health officials have begun a well-publicized campaign to register all medical centres in the country that offer prenatal sex-determination services through ultrasonography, amniocentesis, chorionic villi biopsy and other techniques. The

move follows a directive from the Supreme Court of India to submit a report on the question.

A 1994 law prohibits Indian doctors from carrying out sex-determination tests if female fetuses will be aborted as a result. However, centuries of tradition demand that every couple produce at least one male child, and even today most couples would go to any extent to do that.

Although the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act of 1994 has remained on the statute books, the government has no idea how many medical centres actually offer sex-determination services. As a result, female fetuses are still being aborted in every part of the country. "I know a couple of obstetricians in Bombay's suburbs who perform sex determinations for 10 to 15 women every day," says Dr. Anirudh Malpani, one of the India's leading specialists in assisted reproduction techniques.

"The gender balance is badly skewed in some north Indian states like Punjab and Haryana," adds Dr. Vimla Nadkarni, secretary general of the Family Planning Association of India. Even in a progressive state like Maharashtra, of which Bombay is the capital, the sex ratio is 922 women for every 1000 men, she adds.

Angered by government apathy at both national and state levels and alarmed by the growing distortion in sex ratios, the Centre for Enquiry into Health and Allied Themes (CEHAT) first approached the courts a few years ago. Their public-interest litigation has now reached the Supreme Court, which has asked health ministries in 11 states what action they have taken thus far.

The Supreme Court has also directed the leading manufacturers of ultrasound equipment to supply the names and addresses of medical centres that have purchased their equipment in the past 5 years. The result could be thousands of addresses because the advent of portable ultrasonography has enabled most gynecologists to conduct ultrasound examinations in their offices. "In Bombay alone there would be 1200 to 2000 medical centres where this sort of thing takes place," says Sumita Menon, an activist with CEHAT.

For sex determination, ultrasonography is the obvious method of choice for Indian couples because it is simple and risk free. Other methods, such as amniocentesis, are more difficult, while chorionic villi biopsy requires sophisticated and expensive equipment that many physicians cannot afford.

After the sex of the fetus has been determined, the next step is to abort the female fetus at the request of the expectant mother. "What the legal action has achieved is to drive the whole thing underground," says Dr. P. N. Rao, a gynecologist in an up-market Bombay suburb.

2.15 INDIAN MENTAL HEALTH ACT, 1987

An Act to consolidate and amend the law relating to the treatment and care of mentally ill persons, to make better provision with respect to their properly and affairs and for matters connected therewith or incidental thereto.

Statement of Objects and Reasons of Act 14 of 1987

- The attitude of the society towards persons afflicted with mental illness has changed considerably and it is now realised that no stigma should be attached to such illness as it is curable, particularly, when diagnosed at an early stage. Thus the mentally ill persons are to be treated like any other sick persons and the environment around them should be made as normal as possible.
- The experience of the working of Indian Lunacy Act, 1912 (4 of 1912) has revealed that it has become out-moded. With the rapid advance of medical science and the understanding of the nature of malady, it has become necessary to have fresh legislation with provisions for treatment of mentally ill persons in accordance with the new approach.
- It is considered necessary -
- To regulate admission to psychiatric hospitals or psychiatric nursing homes of mentally ill-persons who do not have sufficient understanding to seek treatment on a voluntary basis, and to protect the rights of such persons while being detained;
- To protect society from the presence of mentally ill persons who have become or might become a danger or nuisance to others;
- To protect citizens from being detained in psychiatric hospitals or psychiatric nursing homes without sufficient cause;
- To regulate responsibility for maintenance charges of mentally ill persons who are admitted to psychiatric hospitals or psychiatric nursing homes;
- To provide facilities for establishing guardianship or custody of mentally ill persons who are incapable of managing their own affairs;
- To provide for the establishment of Central Authority and State Authorities for Mental Health Services;
- To regulate the powers of the Government for establishing, licensing and controlling psychiatric hospitals and psychiatric nursing homes for mentally ill persons;
- To provide for legal aid to mentally ill persons at State expense in certain cases.
- The main object of the Bill is to implement the aforesaid proposals.

COMMENTS - It is well settled that when the language of the statute is clear and admits of no ambiguity, recourse to the Statement of Objects and Reasons for the purpose of construing a statutory provision is not permissible. Court must strive to so interpret the statute as to protect and advance the object and purpose of the enactment. Any narrow or technical interpretation of the provisions would defeat the legislative policy. The Court must, therefore, keep the legislative policy in mind in applying the provisions of the Act to the facts of the case2.

The law is well settled that though the Statement of objects and Reasons accompanying a legislative bill could not be used to determine the true meaning and effect of the substantive provisions of a statute, it was permissible to refer to the same for the purpose of understanding the background, the antecedent state of affairs, the surrounding circumstances in relation to the statute, and the evil which the statute sought to remedy3.

PREAMBLE - It is established law that preamble discloses the primary intention of the statute but does override the express provisions of the statute4. Although a preamble of a statute is a key to interpretation of the provisions of the Act, but the intention of Legislature is not necessarily to be gathered from the preamble taken by itself, but to be gathered from the provisions of the Act. Where the language of the Act is clear, the preamble cannot be a guide, but where the object or meaning of the provisions of the Act is not clear then an aid from the preamble can be taken into consideration for purpose of explaining the provisions of the Act5.

It is now well settled that the preamble of a statutory instrument cannot control the express clear language and sweep of the operating provisions of such an instrument. Nor can the express language of a statutory provision be curtailed or read down in the light of the preamble in the absence of any ambiguity in the enacted provisions.

2.16 STUDENT ACTIVITY

1. Describe Legal Aspects in Medical Practice.
2. Discuss the Advantages and Disadvantages of Healthcare Careers.
3. Explain the rights of persons with disabilities.
4. *Discuss Organs transplant Act*

2.17 SUMMARY

- Every doctor has some basic things to do as he approaches a patient. He must listen to the patient (take proper history) and examine him carefully. A doctor has to attend to the patient and give diligent care, once he decides to treat the patient. He must explain the relevant facts related to the illness and give proper medicines.
- Disability discrimination occurs when an employer or other entity covered by the Americans with Disabilities Act, as amended, or the Rehabilitation Act, as amended, treats a qualified individual with a disability who is an employee or applicant unfavorably because she has a disability.
- Disability is defined to include 19 conditions such as: autism; low vision and blindness; cerebral palsy; deaf blindness; haemophilia; hearing impairment; leprosy; intellectual disability; mental illness; muscular dystrophy; multiple sclerosis; learning disability; speech and language disability; sickle cell disease; thalassemia; chronic neurological conditions; and multiple disability.
- Although sex determination and sex selection (female foeticide) is a topic beginning to gain more public awareness, the laws surrounding sex selective abortions remain unclear due to political and judicial jargon. The Pre-Conception and Prenatal Diagnostic Techniques Act was passed in 1994 banning prenatal sex determination as a means to prevent sex selective abortions.

2.18 GLOSSARY

- Disability Discrimination & Harassment: It is illegal to harass an applicant or employee because he has a disability, had a disability in the past, or is believed to have a physical or mental impairment that is not transitory (lasting or expected to last six months or less) and minor (even if he does not have such an impairment).
- Legal Capacity: Disabled persons have the right, equally with others, to own and inherit movable and immovable property, as well as control their financial affairs.
- Guardianship: The Bill provides that if a district court finds that a mentally ill person is not capable of taking care of himself or of taking legally binding decisions, it may order guardianship to the person. The nature of such guardianship is also specified.
- Medical records : Medical records is a broad term which incorporates a range of data and information storage mediums containing patient information.
- Brain-death and its declaration : Brain death is defined by the following criteria: two certifications are required 6 hours apart from doctors and two of these have to be doctors nominated by the appropriate authority of the government with one of the two being an expert in the field of neurology.

2.19 REVIEW QUESTIONS

1. Whatare the duties of a doctor?
2. What is Liability?
3. What are the Principal objective of the medical profession?
4. What are the Legal aspects of medical records?
5. Write short note on:
   (a) COPRA
   (b) HIPAA
   (c) medical termination of pregnancy act, 1971
   (d) Birth and death registration act

UNIT

3

LAWS RELATED TO HOSPITAL ADMINISTRATION

STRUCTURE

3.0 LEARNING OBJECTIVES

After completion of the unit, you will be able to:

- Understand Companies act
- Describe law of contracts
- Explain consumer protection act
- Discuss Management of Biomedical waste

3.1 INTRODUCTION

These attorneys are familiar with issues relating to leadership, management, and administration of hospitals, hospital networks, and health care systems. Some overlapping areas of the law include contract law, medical malpractice, administrative law, public health law, and issues related to consent.

3.2 COMPANIES ACT

The Companies Act 1956 is an Act of the Parliament of India, enacted in 1956, which enabled companies to be formed by registration, and set out the responsibilities of companies, their directors and secretaries.

The Companies Act 1956 is administered by the Government of India through the Ministry of Corporate Affairs and the Offices of Registrar of Companies, Official Liquidators, Public Trustee, Company Law Board, Director of Inspection, etc. The Registrar of Companies (ROC) handles incorporation of new companies and the administration of running companies.

Since its commencement, it has been amended many times, in which amendment of 1988, 1990, 1996, 2000 and 2011 are notable.

Nature and Scope of the Act

Like most of Indian acts, it also extends to the whole India except State of Jammu and Kashmir (SECTION 3) (Article 370). Notwithstanding anything contained in the Act every company, international or indigenous will work under the provisions of the Act. This Act is general in nature and not subrogative. So if a special Legislation applies on a Company, then the Company has to, in addition to Companies Act, comply the special Legislation. For example, all banking Companies in India have to comply with Banking Regulation Act 1949, in addition to the Companies Act 1956.

Act's Cessation and New Act's Important Provisions and Background

The Act has now been replaced by the The Companies Act, 2013 after receiving the assent of the President of India on Thursday, 29 August 2013. The Companies Act, 2013 is divided into 29 chapters containing 470 Sections as against 658 Sections in the Companies Act, 1956. The Central Government has appointed Thursday, 12 September 2013 as the date on which some notified sections the Companies Act, 2013 shall come into force. The Ministry of Corporate Affairs has notified 183 sections of the new Companies Act, 2013, which comes into effect from April 1, 2014. With this, 283 of 470 sections of the Act have got notified in a phased manner.

The new law has been passed and is considered as trend changer in Indian Corporate law the new law has been rewritten extensively with several new provisions for investor protection, better corporate governance and corporate social responsibility etc. It defines a number of new terms that have come into vogue in recent times.

The bill provides for class action suit, which is key weapon for individual shareholders to take collective action against errant companies. Better disclosure requirements in financial statements and disclosure of interests of directors etc. It has also streamlined procedures relating to disclosure of transactions with parties related to directors, promoters etc.

It provides for new concepts such as a one person company. Cap on number of persons in a private company raised to 200. E-voting has been recognized.

This new Act is one of the major achievement in Indian Parliamentary History in recent past.

3.3 LAW OF CONTRACTS

The Law of Contracts is the basis of business law because the bulk of transactions of the people engaged in trade, commerce and industry is based on contracts. In India, the Law of Contracts is contained in the Indian Contract Act,1872. The Act lays down the general principles relating to formation, performance and enforceability of contracts and the rules relating to certain special types of contracts like, Indemnity and Guarantee; Bailment and Pledge, and Agency. The Partnership Act; the Sale of Goods Act; the Negotiable Instruments Act; the Companies Act, though technically belonging to the Law of Contracts, have been covered by separate enactments. However, the general principles of the Contract Law are the basis for all such contracts as well.

The principal features of the Law of Contract are:-

- The parties to the contract make the law for themselves.
- The Act is not exhaustive since it does not take into its purview all the relevant legislations.
- It does not override customs or usages.
- The Law of Contracts is not the whole law of agreements.

As per the Indian Contract Act,1872, a "contract" is an agreement enforceable by law. The agreements not enforceable by law are not contracts. An "agreement" means 'a promise or a set of promises' forming consideration for each other. And a promise arises when a proposal is accepted. By implication, an agreement is an accepted proposal. In other words, an agreement consists of an 'offer' and its 'acceptance'.

An "offer" is the starting point in the process of making an agreement. Every agreement begins with one party making an offer to sell something or to provide a service, etc. When one person who desires to create a legal obligation, communicates to another his willingness to do or not to do a thing, with a view to obtaining the consent of that other person towards such an act or abstinence, the person is said to be making a proposal or offer.

An agreement emerges from the acceptance of the offer. "Acceptance" is thus, *the second stage of completing a contract. An acceptance is the act of manifestation* by the offeree of his assent to the terms of the offer. It signifies the offeree's willingness to be bound by the terms of the proposal communicated to him. To be valid an acceptance must correspond exactly with the terms of the offer, it must be unconditional and absolute and it must be communicated to the offeror.

An "agreement" is a contract if 'it is made by the free consent of parties competent to contract, for a lawful consideration and with a lawful object, and is not expressly declared to be void'. The contract must be definite and its purpose should be to create a legal relationship. The parties to a contract must have the legal capacity to make it. According to the Contract Act, " Every person is competent to contract who is of the age of majority according to the law to which he is subject, and who is of a sound mind, and is not disqualified from contracting by any law to which he

NOTES

is subject". Thus, minors; persons of unsound mind and Persons disqualified from contracting by any law are incompetent to contract.

Essential Elements Of A Valid Contract

Section 10 of the Indian Contract Act, 1872 provides that "all agreements are contracts if they are made by the free consent of parties competent to contract, for a lawful consideration and with a lawful object, and are nothereby expressly declared to be void".

The essential elements of a valid contract are:

(i) An offer or proposal by one party and acceptance of that offer by another party resulting in an *agreement-consensus-ad-idem.*

(ii) An intention to create legal relations or an intent to have legal consequences.

(iii) The agreement is supported by lawful consideration.

(iv) The parties to contract are legally capable of contracting.

(v) Genuine consent between !he parties.

(vi) The object and consideration of the contract is legal and is not opposed to public policy.

(vii) The terms of the contract are certain.

(viii) The agreement is capable of being performed Le., it is not impossible of being performed.

Therefore, to form a valid contract there must be:

1. An agreement,
2. Based on the genuine consent of the parties,
3. Supported by consideration,
4. Made for a lawful object, and (iv) between the competent parties.

Offer or Proposal and Acceptance

One of the early steps in the formation of a contract lies in arriving at an agreement between the contracting parties by means of an offer and acceptance. Thus, when one party (the offeror) makes a definite proposal to another party (the offeree) and/ the offeree accepts it in its entirety and without any qualification, there is a meeting of the minds of the parties, and a contract comes into being, assuming that all other elements are also present.

What is an Offer or a Proposal?

An offer is a proposal by one person, whereby he expresses his willingness to enter into a contractual obligation in- return for a promise, act or forbearance. Section 2(a) defines proposal or offer as "when one person signifies to another his willingness to do or abstain from doing anything with a view to obtaining the assent of that other to such act or abstinence, he is said to make a proposal."

Rules Governing Offers

A valid offer must comply with the following rules:

(a) An offer must be clear, definite, complete and final. It must not be vague. For example, a promise to pay an increased .price for a horse if it proves lucky to promiser, is too vague and is not binding.

(b) An offer must be communicated to the offeree. An offer becomes effective only when it has been communicated to the offeree so as to give him an opportunity to accept or reject the same.

(c) The communication of an offer may be made by express words-oral or written-or it may be implied by conduct. A offers his car to B for Rs. 10,000. It is an expre~s offer. A bus plying on a definite route goes along the street.

This is an implied *offer* on the part of the owners of the bus to carry passengers at the scheduled fares for the various stages.

(d) The communication of the offer may be general or specific. Where an offer is made to a specific person it is called *specific offer* and it can be accepted only by that person. But when an offer is addressed to an uncertain body of individuals Le. the world at large, it is a *general offer* and can be accepted by any member of the general public by fulfilling the condition laid down in the offer. The leading case on the subject is *Carlill* v. *Carbolic Smoke Ball Co.* The company offered by advertisement, a reward of £ 100 to anyone who contacted influenza after using their smoke ball in the specified manner. Mrs. Carlill did use smoke ball in the specified manner, but was attacked by influenza. She claimed the reward and it was held that she could recover the reward as general offer can be accepted by anybody. Since this offer is of a continuing nature, more than one person can accept it and can even claim the reward. But if the offer of reward is for seeking some information or seeking the restoration of missing thing, then the offer can be accepted by one individual who does it fi rst of all. The condition is that the claimant must have prior knowledge of the reward before doing that act or providing that information.

Example: A advertise in the newspapers that he will pay rupees one thousand to anyone who restores to him his lost son. B without knowing of this reward"finds A's ost son and restore him to A. In this case since B did not know of the reward, he ~ cannot claim it from A even though he finds A's lost son and restores him to A.

In India also, in the case of *Harbhajan Lal* v. *Harcharan Lal* (AIA 1925 All. 539), the same rule was applied. In this case, a young boy ran away from his father's home. The father issued a pamphlet offering a reward of As. 500 to anybody who would bring the boy home. The plaintiff saw the boy at a railway station and sent a telegram to the boy's father. It was held that the handbill was an offer open to the world at large and was capable to acceptance by any person who fulfilled the conditions contained in the offer. The plaintiff substantially performed the conditions and was entitled to the. reward offered.

An Offer must be Distinguished from

(a) *An invitation to treat or an invitation to make* an *offer:* e.g., an auctioneer's request for bids (which are offered by the bidders), the display of goods in a shop window with prices marked upon them, or the display of priced goods in a self-service store or a shopke.eper's catalogue of prices are invitations to an offer.

(b) A *mere statement of intention:* e.g., an announcement of a coming auction sale. Thus a person who attended the advertised place of auction could not sue for breach of contact if the auction was cancelled *(Harris* v. *Nickerson* (1873) L.A. 8 QB 286).

(c) A *mere communication of information in the course of negotiation:* e.g., a statement of the price at which one is prepared to conside(negotiating the sale of piece of land *(Harvey* v. *Facey* (1893) A.C. 552).

An offer that has been communicated,properly continues as such until it lapses, or until it is revoked by the offeror, or rejected or accepted by the offeree.

Lapse of Offer

Section 6 deals with various modes of lapse of an offer. It states that an offer lapses if

(a) It is not accepted within the specified time (if any) or after a reasonable time, if none is specified.

(b) It is not accepted in the mode prescribed or if no mode is prescribed in some usual and reasonable manner, e.g., by sending a letter by mail when early reply was requested

(c) The offeree rejects it by distinct refusal to accept it;

(d) Either the offerer or the offeree dies before acceptance;

(e) The acceptor fails to fulfill a condition precedent to a acceptance.

(f) The offeree makes a counter offer, it amounts to rejection of the offer and an offer by the offeree may be accepted or rejected by the offeror.

Revocation of Offer by the Offeror

An offer may be revoked by the offeror at any time before acceptance.

Like any offer, revocation must be communicated to the offeree, as it does not take effect until it is actually communicated to the offeree. Before its actual communication, the offeree, may accept the offer and create a binding contract. The revocation must reach the offeree before he sends out the acceptance.

An offer to keep open for a specified time(option) is not binding unless it is supported by consideration.

Acceptance

A contract emerges from the acceptance of an offer. Acceptance is the act of assenting by the offeree to an offer. Under Section 2(b) of the Contract Act uwhen a person to whom the proposal is made signifies his assent thereto, the proposal is said to be accepted. A proposal, when accepted becomes a promise.".

Rules Governing Acceptance

(a) Acceptance may be express Le. by words spoken or written or implied from the conduct of the parties.

(b) If a particular method of acceptance is prescribed~-Ae. offer must be accepted in the prescribed manner.

(c) Acceptance must be unqualified and absolute and must correspond with all the terms of the offer.

(d) A counter offer or conditional acceptance operates as a rejection of the offer and causes it to lapse, e.g., where a horse is offered for Rs. 1,000 and the offeree counter-offers Rs. 990, the offer lapses by rejection.

(e) Acceptance must be communicated to the offeror, for acceptance is complete the moment it is communicated. Where the offeree merely intended to accept but does not communicate his intention to th.e offeror, there is no contract. Mere mental acceptance is not enough.

(f) Mere silence on the part of the offeree does not amount to acceptance. Ordinarily, the offeror cannot frame his offer in such a way as to make the silence or inaction of the offeree as an acceptance. In other words, the offeror can prescribed the mode of acceptance but not the mode of rejection. In *Felthouse* v. *Bindley* (1865), F offered by letter to buy his nephew's horse for £ 30 saying: "If I hear no more about him I shall consider the horse is mine at £ 30". The nephew did not reply, but he told an auctioneer who was selling his horses not to sell that particular horse because it was sold to his uncle. The auctioneer inadvertently sold the horse. *Held:* F had no claim against the auctioneer because the horse had not been sold to him, his offer of £ 30 not having been accepted.

(g) If the offer is one which is to be accepted by being acted upon, no communication of acceptance to the offeror is necessary, unless communication is stipulated for in the offer itself.

Thus, if a reward is offered for finding a lost dog, the offer. is accepted by finding the dog after reading about the offer, .and it is unnecessary before beginning to search for the dog to give notice of acceptance to the offeror.

(a) Acceptance must be given within a reasonable time and before the offer lapses or is revoked. An offer becomes irrevocable by acceptance.

An acceptance *never* precedes an offer. There can be no acceptance of an offer which is not communicated. Similarly, performance of conditions of an offer without the knowledge of the specific offer, is no acceptance. Thus in *Lalman Shukla* v. *Gauri* Duff (1913) where a servant brought the boy without knowing of the reward, he was held not entitled to reward because he did not know about the offer.

Standing Offers

Where a person offers to another to supply specific goods, up to a stated quantity or in any quantity which may be required, at a certain rate, during a fixed period,

he makes a standing offer. Thus, a tenderto supply goods as and when required, amounts to a standing offer.

A standing offer or a tender is of the nature of a continuing offer. An acceptance of such an offer merely amounts to an intimation that the offer will be considered to remain open during the period specified and that it will be accepted from time to time by placing order during the period specified quantities. Each successive order given, while the offer remains in force, is an acceptance of the standing offer as to the quantity ordered, and creates a seperate contract. it does not bind either party unless and until such orders are given.

Where P tendered to supply goods to L upto a certain amount and over a certain period, L's order did not come up to the amount expected and P sued for breach of contract *Held:* Each order made was a separate contract and P was bound to fulfill orders made, but th~re was no obligation on L to make any order to all *(Percival Ltd.* v. *L.C.C. (1918).*

Tickets

Tickets purchased for entrpnce into places of amusement, or tickets issued by railways or bus companies, clock-room tickets, and many other contracts set out in printed documents contain numerous terms, of many of which the partly receiving the ticket or document is ignorant. If a passenger on a railway train receives a ticket on the face of which is printed Hthis ticket is issued subject to the notices, regulations and conditions contained, in the current time-tables of the railway", the regulations and conditions referred to are deemed to be communicated to him and he is bound by them whether or not he has read them. He is bound even if he is illiterate and unable to read them. But it is important that the notice of the conditions i,s contemporaneous with the making of the contract and not after the contract has been made.

Contracts by Post

Contracts by post are subject to the same rules as others, but because of their importance, these are stated below separately:

(a) An offer by post may be accepted by post, unless the offero(indicates anything to the contrary.

(b) An offer is made only when it actually reaches the offeree and not .before, i.e., when the letter containing the offer is delivered to the offeree.

(c) An accepta.nce is made as far as the offeror is concerned, as soon as the letter containing the acceptance is posted, to offeror's correct address; it binds the offeror, but not the acceptor.

An acceptance binds the acceptor only when the letter containing the acceptance reaches the offeror. The result is that the acceptor can revoke his acceptance before it reaches the offeror.

(d) An offer may be revoked before the letter containing the acceptance is posted. An acceptance can be revoked before it reaches the offeror.

Contracts over the Telephone

Contracts over the telephone are regarded the same in principle as those negotiated by the parties in the actual presence of each other. In both cases an oral offer is made and an oral acceptance is expected. It is important that the acceptance must be audible, heard and understood by the offeror. If during the conversation the telephone lines go, "dead" so that the offeror does not hear the offeree's word of acceptance, there is no contract at the moment. If the whole conversation is repeated and the offeror hears and understands the words of acceptance, the contract is complete *(KanhaiyalaJv. Dineshwarchandra* (1959) AIR, M.P. 234).

3.4 CONSUMER PROTECTION ACT

Although businessman is aware of his social responsibilities even then we come across many cases of consumer exploitation.

That is why government of India provided following rights to all the consumers under the Consumer Protection Act:

Right to Safety:

According to this right the consumers have the right to be protected against the marketing of goods and services which are hazardous to life and property, this right is important for safe and secure life. This right includes concern for consumer's long term interest as well as for their present requirement.

Sometimes the manufacturing defects in pressure cookers, gas cylinders and other electrical appliances may cause loss to life, health and property of customers. This right to safety protects the consumer from sale of such hazardous goods or services.

Right to Information:

According to this right the consumer has the right to get information about the quality, quantity, purity, standard and price of goods or service so as to protect himself against the abusive and unfair practices. The producer must supply all the relevant information at a suitable place.

Right to Choice:

According to this right every consumer has the right to choose the goods or services of his or her likings. The right to choose means an assurance of availability, ability and access to a variety of products and services at competitive price and competitive price means just or fair price.

The producer or supplier or retailer should not force the customer to buy a particular brand only. Consumer should be free to choose the most suitable product from his point of view.

Right to be Heard or Right to Representation:

According to this right the consumer has the right to represent him or to be heard

The Health care institution or hospitals which are responsible for care of morbid population are emitting voluminous quantity of rubbish, garbage and Bio Medical Waste matter each day from wards, operation theatre and outpatient areas. Proper management of hospital waste is essential to maintain hygiene, aesthetics, cleanliness and control of environmental pollution. The hospital waste like body parts, organs, tissues, blood and body fluids along with soiled linen, cotton, bandage and plaster casts from infected and contaminated areas are very essential to be properly collected, segregated, stored, transported, treated and disposed of in safe manner to prevent nosocomial or hospital acquired infection .

Various communicable diseases, which spread through water, sweat, blood, body fluids and contaminated organs, are important to be prevented. The Bio Medical Waste scattered in and around the hospitals invites flies, insects, rodents, cats and dogs that are responsible for the spread of communication disease like plague and rabies. Rag pickers in the hospital, sorting out the garbage are at a risk of getting tetanus and HIV infections. The recycling of disposable syringes, needles, IV sets and other article like glass bottles without proper sterilization are responsible for Hepatitis, HIV, and other viral diseases. It becomes primary responsibility of Health administrators to manage hospital waste in most safe and eco-friendly manner.

With the proliferation of blood born diseases, more attention being focus on the issue of infectious medical waste and its disposal. Health care institutions must be aware of the potential risk in handling infectious waste, and adhere to the highest standard of transport & disposal. Education of the staff, patients and community about the management of the infectious waste is crucial in today's health care arena .

Landmark Decisions To Streamline Hospital Waste Management

with increasing awareness in general population regarding hazards of hospital waste, public interest litigations were filed against erring officials. Some landmark decisions to streamline hospital waste management have been made in the recent past. These are:

1. Supreme Court judgment dated 1st March 1996 in connection with safe disposal of hospital waste ordered that
   (a) All hospitals with 50 beds and above should install either their own incinerator or an equally effective alternative method before 30th November 1996.
   (b) The incinerator or the alternative method should be installed with a necessary pollution control mechanism conforming to the standard laid down by Central Pollution Control Board (CPCB).
   (c) Hazardous medical waste should be segregated as source and disinfected before final disposal.
2. Ministry of Environment & Forest, Govt. of India issued a notification for Biomedical Waste(Management & Handling) Rules 1998 in exercise of powers conferred by Section 6, 8 & 25 of the Environment (Protection) Act, 1986 that was published in The Gazette of India Extraordinary, Part-II, Section 3-Sub-Section (ii) New Delhi, July 27, 1998 .

3. The Delhi Pollution Control Committee has been designated as Prescribed Authority to implement these rules in the National Capital Territory of Delhi. The Financial Commissioner has been designated as appellate authority in Delhi.
4. In exercise of the Powers conferred by Rule 9 of the Bio-Medical Waste (Management & Handling) Rules, 1998 the Lt. Governor of Delhi has constituted an Advisory Committee Vide No. F. 23 (322)/95/EN/99 to act such authority under the said Rules. The composition of the Advisory Committee has 10 members with Pr. Secretary (Health), Govt. of Delhi as Chairman and Director Health Services as Member Secretary / Convener. Under Chairmanship of Principal Secretary (Health & Family Welfare) this Committee meets from time to time to discuss and decide about various issues connected with these rules. It is primary responsibility of the government to implement the recommendations and directions of the Supreme Court and Biomedical Waste (Management & Handling) Rules 1998 in public interest, so that Bio-medical waste does not cause any harm to men, animal and environment .

Bio-Medical Waste Management In Hospitals- An Overview Of Bio-Medical Waste (Management And Handling) Rules, 1998

What Is Hospital Waste?

Hospital waste refers to all waste generated, discarded and not intended for further use in the hospital. It is broadly categorized into the following categories:

1. General Waste
2. Pathological Waste
3. Infectious Waste
4. Sharps
5. Pharmaceutical Waste
6. Chemical Waste
7. Radioactive Waste

Amount And Composition Of Hospital Waste Generated

(a) Amount

Country Quantity (kg/bed/day)

U. K. 2.5

U.S.A. 4.5

France 2.5

Spain 3.0

India 1.5

(b) Hazardous/non-hazardous

Hazardous 15%

NOTES

a) Hazardous but non-infective 5%
b) Hazardous and infective 10%
Non-hazardous 85%

(c) Composition
By weight
Plastic 14%
Combustible
Dry cellublostic solid 45%
Wet cellublostic solid 18%
Non-combustible 20%

Biomedical Waste

Any solid, fluid and liquid or liquid waste, including it's container and any intermediate product, which is generated during the diagnosis, treatment or immunisation of human being or animals, in research pertaining thereto, or in the production or testing of biological and the animal waste from slaughter houses or any other similar establishment. All biomedical waste are hazardous. In hospital it comprises of 15% of total hospital waste.

Rationale Of Hospital Waste Management

Hospital waste management is a part of hospital hygiene and maintenance activities. In fact only 15% of hospital waste i.e. "Biomedical waste" is hazardous, not the complete. But when hazardous waste is not segregated at the source of generation and mixed with nonhazardous waste, then 100% waste becomes hazardous. The question then arises that what is the need or rationale for spending so much resources in terms of money, man power, material and machine for management of hospital waste? The reasons are:

1. Injuries from sharps leading to infection to all categories of hospital personnel and waste handler.
2. nosocomial infections in patients from poor infection control practices and poor waste management.
3. Risk of infection outside hospital for waste handlers and scavengers and at time general public living in the vicinity of hospitals.
4. Risk associated with hazardous chemicals, drugs to persons handling wastes at all levels.
5. "Disposable" being repacked and sold by unscrupulous elements without even being washed.
6. Drugs which have been disposed of, being repacked and sold off to unsuspecting buyers.
7. Risk of air, water and soil pollution directly due to waste, or due to defective incineration emissions and ash.

Approach For Hospital Waste Management

Based on Bio-medical Waste (Management and Handling) Rules 1998, notified under the Environment Protection Act by the Ministry of Environment and Forest (Government of India) .

1. Segregation of waste: Segregation is the essence of waste management and should be done at the source of generation of Bio-medical waste e.g. all patient care activity areas, diagnostic services areas, operation theaters, labour rooms, treatment rooms etc. The responsibility of segregation should be with the generator of biomedical waste i.e. doctors, nurses, technicians etc. (medical and paramedical personnel). The biomedical waste should be segregated as per categories mentioned in the rules .(Annexure IV)
2. Collection of bio-medical waste: Collection of bio-medical waste should be done as per Bio-medical waste (Management and Handling) Rules. At ordinary room temperature the collected waste should not be stored for more than 24 hours.
3. Transportation: Within hospital, waste routes must be designated to avoid the passage of waste through patient care areas. Separate time should be earmarked for transportation of bio-medical waste to reduce chances of it's mixing with general waste. Desiccated wheeled containers, trolleys or carts should be used to transport the waste/plastic bags to the site of storage/ treatment.

Treatment of hospital waste

General waste: The 85% of the waste generated in the hospital belongs to this category. The safe disposal of this waste is the responsibility of the local authority.

bio-medical waste: 15% of hospital waste

1. Deep burial
2. Autoclave and microwave treatment (Annexure II)
3. Shredding (Annexure II)
4. Secured landfill
5. Incineration (Annexure III)

Safety measures

5.1 All the generators of bio–medical waste should adopt universal precautions and appropriate safety measures while doing therapeutic and diagnostic activities and also while handling the bio-medical waste.

5.2 It should be ensured that:

1. Drivers, collectors and other handlers are aware of the nature and risk of the waste.
2. Written instructions, provided regarding the procedures to be adopted in the event of spillage/ accidents.
3. Protective gears provided and instructions regarding their use are given.
4. workers are protected by vaccination against tetanus and hepatitis B.

Training

1. Each and every hospital must have well planned awareness and training programme for all category of personnel including administrators (medical, paramedical and administrative).
2. All the medical professionals must be made aware of Bio-medical Waste (Management and Handling) Rules 1998.
3. To institute awards for safe hospital waste management and universal precaution practices.
4. Training should be conducted to all categories of staff in appropriate language/ medium and in an acceptable manner.

Management and administration

Heads of each hospital will have to take authorization for generation of waste from appropriate authorities as notified by the concerned State/U.T. Government, well in time and to get it renewed as per time schedule laid down in the rules. Each hospital should constitute a hospital waste management committee, chaired by the head of the Institute and having wide representation from all major departments. This committee should be responsible for making Hospital specific action plan for hospital waste management and its supervision, monitoring and implementation. The annual reports, accident reports, as required under BMW rules should be submitted to the concerned authorities as per BMW rules format .

Measures for waste minimization

As far as possible, purchase of reusable items made of glass and metal should be encouraged. Select non PVC plastic items. Adopt procedures and policies for proper management of waste generated, the mainstay of which is segregation to reduce the quantity of waste to be treated. Establish effective and sound recycling policy for plastic recycling and get in touch with authorised manufactures.

Bio-Medical/Hospital Waste Management Scenario In Delhi

The Organization-Wise Institutions

There is a big network of Health Care Institutions in Delhi. Although, these are not under one banner but these can be utilized by better coordination among different organizations.

These Health Care Institutions are inclusive of Allopathy, ISM and Homeopathy. The large chunk of hospitals and dispensaries are under Delhi Government, Municipal Corporation of Delhi, New Delhi Municipal Council, Employees State Insurance Corporation and Central Government Health Scheme. Equally important is the private sector comprising of major hospitals, nursing homes, clinics, blood banks, diagnostic laboratories, and Unani, homeopathy and Sidda Dava-khanas. At present there are 504 registered nursing homes registered under this directorate in Delhi. Bed-wise Distribution these Nursing homes is as follows

Centralised Treatment Facility-Steps Taken By The Government To Solve The Problem

Keeping in view the difficulties faced by private hospitals/nursing homes in treatment of biomedical waste, the Govt. of NCT of Delhi has allowed these units to avail the facility through India Waste Energy Development ltd. at DDU hospital, LBS hospital, GTB hospital and BJRM hospital. Currently IWEDL is operating the facilities at DDU hospital only. This is an interim arrangement and government is planning for centralized facility.

The smaller Nursing Homes and Clinics, which cannot make their own arrangements due to high cost involved in waste treatment facilities, require some alternative modalities. To solve the problems of Nursing Homes/Clinics/Blood Banks/Diagnostic Laboratories etc., Government is taking initiatives to establish centralized waste treatment facilities. The Government of NCT of Delhi (GNCTD) has purchased land from Delhi Development Authority (DDA) for establishment of Centralized Biomedical Waste treatment facilities 1000 sq. meter each at Okhla and Gazipur in Delhi. The tenders for centralized facility at Okhla have already been finalised .

The Bed Strength In Delhi Govt. Hospitals

The Government of NCT of Delhi has planned to utilize the above two sites for establishing Centralized Bio-Medical Waste Treatment facilities as a joint venture with the private sector/NGO etc. to be identified and selected through a transparent process. For this venture, Government of NCT of Delhi shall only provide infrastructural support to the selected party/agency in terms of transfer of the above sites on such terms and conditions as shall be approved by the Delhi Development Authority. Neither any additional capital expenditure for the establishment of the facility nor any recurring revenue expenditure for operation and maintenance of the facility will be forthcoming from the GNCTD.

Given the above conditions, the party for the joint venture shall be selected who is able to offer the services to the Hospitals/Nursing Homes/Clinics etc. at the most reasonable rates conforming to all the required statutory conditions. There are 26 Hospitals under Government of Delhi, out of which 11 are under DHS. Six hospitals are having Incinerators and 9 hospitals are having Autoclaves and Shredders for Scientific Management of Bio-Medical Waste.

Bio-Medical Waste from the Hospitals, where such facilities are not available are segregated and transported in special van to Hospitals where such facilities exist. Under Biomedical Waste (Management & Handling) Rules 1998, all health care institutions are required to handle biomedical waste in a specified manner. Delhi is generating approximately 6000 metric tons of waste out of which 60 tons are Biomedical Waste. The Government hospitals and major private hospitals have their own arrangement for treatment of biomedical waste. Total no of beds in hospitals under Government of NCT of Delhi are 5641.

Biomedical Waste Generated In Delhi Government Hospitals

All the 26 Delhi Govt. hospitals and 167 Dispensaries under this Directorate have obtained authorization from DPCC under Bio-medical Waste (Management & Handling) Rules 1998.

The govt. of national capital territory of Delhi had made adequate arrangements for meeting any contingencies arising out of the handling, treatment and disposal of bio medical waste much before any other government any where. Funds were made available to the hospitals to procure incinerators, and state of the art autoclaves and shredders were imported so that the prescribed methods of medical waste treatment under the law could be met. The vacuum type of autoclaves procured by Delhi govt. are the best available anywhere. These are ideal to disinfect plastic, PVC and other categories of medical waste. Adequate funds have always been provided to all hospitals for purchasing accessories such as bags, trolleys and the disinfectants. So there should be no excuse for not properly disposing bio medical waste.

Delhi govt. had signed a MOU with the Government of Australia in 1998 to have experts visiting from that country and advising and assisting our hospitals to learn and understand a variety of issues related to bio medical waste management. This collaborative programme resulted in developing training modules, which have been made available to all.

Initiatives Taken For Effective Management Of Bio-Medical Waste

- Twice a year inspections are conducted in the 100 bedded or more, hospitals which contribute about 70% of the total waste generated.
- Air and effluent quality analysis in these major hospitals is done by IIT, Delhi.
- Authorisation has been granted to 1365 healthcare establishments.
- 6800 health care professionals have been trained.
- Efforts are being made to ensure that no medical unit in Delhi escapes the responsibilities enjoined upon them for proper storage, treatment and disposal of bio-medical waste generated by it.

Serious Issues Observed As A General Trend In The Delhi Hospitals

1. The segregation of waste in almost all hospitals is not satisfactory.
2. Colour coding for various categories of waste is not followed.
3. The storage of BMW is not in isolated area and proper hygiene is not maintained.
4. Personal protective equipment and accessories are not provided.
5. Most of the hospitals do not have proper waste treatment and disposal facilities. In the cities where common treatment facilities have come up, many medical establishments are yet to join the common facility.
6. Emission monitoring of five incinerators indicated that they do not meet the emission norms.

7. Most of the incinerators are not properly operated and maintained, resulting in poor performance.
8. Sometimes plastics are also incinerated leading to possible emission of harmful gases.
9. Several hospitals have not applied to State Pollution Control Board for authorisation under the rules.
10. General awareness among the hospital staff regarding BMW is lacking.

Analysis

Judicious reuse of materials contributes towards better infection control, reduces disposables and also reduces the cost. Safe handling of BMW continues to be a matter of serious concern for health authorities in India. Thousands of tonnes of BMW originating from hospitals, nursing homes and clinics in the form of cotton swabs and bandages infected with blood, needles, catheters, human tissues and body parts, etc continue to be dumped in open garbage bins on the roads in most parts of the country.

With apparently no machinery for granting permission to new nursing homes in any of the states, the generation of these dangerous wastes is only expected to increase in the days to come . Barring a few large private hospitals in metros, none of the other smaller hospitals and nursing homes has any effective system to safely dispose of their wastes. The attitude of the government and municipal hospitals is no better than these private hospitals and nursing homes. Such irresponsible dumping of these dangerous wastes in open bins has been promoting unauthorised reuse of medical waste by the rag pickers for some years now.

After a spate of Public Interest litigations, bio medical waste (management and handling) rules were formulated and notified in July 1998. These were enforced in phased manner and are now applicable throughout the country. In Delhi these became applicable on 1st July 2000. It is guesstimated that out of about 6000-7000 tons of solid waste generated in Delhi, about 1% is medical waste. This makes the amount of medical waste generated 60-70 metric tons/day. If proper segregation is done by healthcare personnel which the rules prescribe, then the bio medical waste generation in Delhi should not be more than 20-25 metric tons/day or even less. This amounts to great savings in financial terms.

Conclusion And Suggestions To Combat Bio-Medical Waste In Hospitals

The hospitals and bio medical facilities meant to ensure better health have unfortunately become a potential health risk due to mismanagement of the infectious waste. BMW from hospitals, nursing home and other health centers composed of variety of wastes like hypodermic needles, scalpels blades, surgical cottons, gloves bandages, clothes, discarded medicine, blood and body fluids, human tissues and organs, radio-active substances and chemicals etc. This area of waste management is grossly neglected.

The researcher, therefore, states that there needs to be requisite emphasis on the following which could be done through a program that includes:

1. Updated Guidelines for the segregation, management and disposal of infectious or potentially infectious biomedical waste.
2. Reduce the incidence of health care worker and the public from contacting a disease or injury from biomedical waste.
3. Provide guidance to the health care system on the opportunities for waste minimization and the reduction of air contamination from incineration of biomedical waste.
4. Strategies and appropriate handling techniques for bio-medical waste management
5. Create awareness about Hospital accreditation with focus on guidelines related to healthcare safety issues related with disposal of Bio-Medical Waste.
6. Understand the new technologies available for Safe disposal of Bio medical Waste from Environment friendliness point of view & infection control in hospitals
7. Economic issue involved in Management of Bio-Medical Waste & Role of Public-Private Partnership

Also, it should be made mandatory for the following to be a part of the above mentioned programme in order to increase the awareness among them so as to ensure better treatment of the bio-medical waste in the hospitals:

1. Medical Superintendents/ Hospital Administrators
2. Doctors running their own healthcare facility
3. Hospital Laboratory Services Providers.
4. Hospital Administrators
5. Senior Nurses and paramedical staff
6. Allied Health Professionals
7. Consultants
8. Healthcare Waste Management related industry Owners
9. Quality Managers
10. Hospital House Keeping Officers

3.6 STUDENT ACTIVITY

1. Discuss The Companies Act 1956.
2. Describe the ESSENTIAL ELEMENTS OF A VALID CONTRACT.
3. Explain Right to Safety.
4. Describe Right to Consumer Education.

3.7 SUMMARY

- The Companies Act 1956 is an Act of the Parliament of India, enacted in

1956, which enabled companies to be formed by registration, and set out the responsibilities of companies, their directors and secretaries.

- In the Indian Sub-continent, until Sir Mortimer Wheeler's work at Harappa in 1946, nothing was known with certainty of the way in which this people dispose of their dead, but from a cemetery than discovered, containing at least 57 graves, each appears-the burial was a usual rite.
- The hospitals and bio medical facilities meant to ensure better health have unfortunately become a potential health risk due to mismanagement of the infectious waste. BMW from hospitals, nursing home and other health centers composed of variety of wastes like hypodermic needles, scalpels blades, surgical cottons, gloves bandages, clothes, discarded medicine, blood and body fluids, human tissues and organs, radio-active substances and chemicals etc.
- Bio-Medical Waste from the Hospitals, where such facilities are not available are segregated and transported in special van to Hospitals where such facilities exist. Under Biomedical Waste (Management & Handling) Rules 1998, all health care institutions are required to handle biomedical waste in a specified manner. Delhi is generating approximately 6000 metric tons of waste out of which 60 tons are Biomedical Waste.

3.8 GLOSSARY

- The Law of Contracts: The Law of Contracts is the basis of business law because the bulk of transactions of the people engaged in trade, commerce and industry is based on contracts. In India, the Law of Contracts is contained in the Indian Contract Act, 1872.
- Hospital waste: Hospital waste refers to all waste generated, discarded and not intended for further use in the hospital.
- Segregation of waste: Segregation is the essence of waste management and should be done at the source of generation of Bio-medical waste e.g. all patient care activity areas, diagnostic services areas, operation theaters, labour rooms, treatment rooms etc.
- General waste: The 85% of the waste generated in the hospital belongs to this category. The, safe disposal of this waste is the responsibility of the local authority.

3.9 REVIEW QUESTIONS

1. What is the nature and scope of The Companies Act 1956?
2. What are the rules of Rules Governing Acceptance?
3. Describe the management and handling rules of biomedical wste.
4. What is hospital waste?

NOTES

UNIT

4

OVERVIEW OF HEALTH CARE DELIVERY SYSTEM

STRUCTURE

4.0 LEARNING OBJECTIVES

After completion of the unit, you will be able to:

- Understand health care delivery system
- Describe growth of health care services
- Explain KEY ACHIEVEMENTS IN HEALTH
- Discuss Health care infrastructure
- Describe Health Infrastructure in India
- Explain Reality of Healthcare in Rural India

4.1 INTRODUCTION

Our health system is broken and much of the problem lies with the fragmentation of our delivery system which drives low-quality and inefficient care in a country filled with highly skilled health care professionals. A single national entity or set of policies guiding the health care system; doctors and hospitals practicing in the same community and caring for the same patients are not "connected" to each other. Our

current healthcare payment model—a mix of private insurers and public programs, each with its own set of rules and payment algorithms —further fragments the health care delivery system, contributing to waste and high administrative costs.

NOTES

4.2 OVERVIEW OF HEALTH CARE DELIVERY SYSTEM

In the last two decades, there has been a growing concern over the performance of the healthcare delivery system in India. In the year 2006, a mere 0.9% of the GDP was allocated to public health. As per the Government of India's (GOI) National Rural Health Mission (NHRM) Document (2005), only 10% of Indians have some form of health insurance and mostly this is inadequate. Around 40% of Indians have to borrow money or sell their assets to meet their healthcare expenses. Nearly 25% of Indians slip below the poverty line because of hospitalization due to a single bout of illness. The public healthcare delivery system, in its present state, is unable to deliver and meet the health goals of India.

The GOI Report of the National Commission on Macroeconomics and Health (2005) states that the principal challenge for India is building a sustainable healthcare system. Selective, fragmented strategies and lack of resources have made the health system unaccountable, disconnected to public health goals, inadequately equipped to address people's growing expectations and inability to provide financial risk protection to the poor.

According to the Organisation for Economic Co-operation and Development (OECD) Report (2004), adequate and effective delivery of public services is also central to achieving the Millennium Development Goals (MDGs) as proposed by the United Nations. At the national level for India, the MDGs have been integrated into the 10th and 11th Five Year Plans as well as forming an integral part of the NRHM.

A World Bank Report (2004) analyzes that even when resources are available for services such as primary healthcare, many governments have failed to reach the poor through public channels. One of the reasons is that although resources are allocated the funds often do not reach the frontline service providers or the intended beneficiaries.

Also, traditional approaches tend to focus more on inputs, such as equipment, materials and salaries, regardless of varying local needs.

In recent years, the GOI has formulated a number of innovative policies and plans to address the issue of under-performance of the healthcare delivery system. It has introduced a number of reforms across different sectors, such as healthcare financing, health insurance, continuing medical education, and health information systems. Peters et al. state that India's health system is being forced to adapt to changing health conditions, new technologies, transformations in society and evolving roles for government and the private sectors. Such flexibility in the healthcare system is important at this stage because of the complex demands, changing scenarios, and evolving healthcare needs of the people. Besides, the strategic and business needs also demand that future systems be flexible, i.e. should have the ability quickly change or respond with little or no implications in terms of resources, time, inputs or performance.

The rising cost of delivering healthcare services by the state and other partners in the health system is assuming critical importance. There is a vast vulnerable population which needs these services and despite the increasing healthcare network, still remains deprived of quality health services. The accelerated expenses on health warrant an efficient healthcare delivery system. An efficient healthcare system is one which can deliver maximum outputs by judiciously utilizing the available inputs. Making the current system robust, flexible and efficient has become a major area for deliberations for the policy makers and healthcare financers.

Role of different healthcare providers

The GOI's Report (2006-7) by The Task Force on Medical Education for the NHRM, states that the private sector provides 58% of the hospitals, 29% of the beds in the hospitals and 81% of the doctors. Nearly 78% of the rural and 81% of the urban population is provided medical treatment by private healthcare players. Also, according to the National Sample Survey Organisation (NSSO) 60th Report (2004), use of public healthcare is lowest in the rural areas of the states of Bihar (up to 89% in urban and 95% in rural areas) and Uttar Pradesh. Approximately 77% of Out Patient Department (OPD) cases in rural areas and 80% in urban areas are being serviced by the private sector in the country.

Bhat suggests that one must look at other options for healthcare delivery because there are no regulations to monitor the cost and quality of the private players. Apart from these negative consequences of the private sector growth, the cost of private healthcare cannot be afforded by most people from the lower strata of society. Those who do use private services, do so at an exorbitant cost. Bhat further comments that the cost of healthcare, access and quality problems will worsen with the growth of the private sector. The public policy response to check some of the undesirable consequences of this growth is critical and should focus on strengthening the existing institutional mechanisms to protect patients, developing and implementing an appropriate regulatory framework, and strengthening the public healthcare delivery system.

Apart from the private players, many civil society organizations (CSOs) have also entered the arena of healthcare delivery. Most often, the CSOs partner either with the government or the private players to deliver health services. There is also a partnership between the state or the public health institutions and the private organizations. Such Public Private Partnerships (PPPs) are being encouraged by governments across the globe. The United Nations Economic and Social Council (2005) report states that the fear of privatizing the healthcare services has been, to an extent, mitigated by the PPPs because of the potential advantages these partnerships offer, such as efficiency, outreach, sustainability, and quality of services. Best practices and good examples of PPPs have initiated a favourable change towards PPPs in the healthcare polices of several countries.

Widdus urges one to view PPPs as social experiments that are attempting to learn how to tackle intractable health problems in better ways. According to Malmborg et al. most PPPs are currently poorly regulated as developing countries do not have the resources to monitor the quality of health services provided. Buse

and Waxman state that an organization should draw lessons from its own experience of partnerships and develop indicators of success.

The GOI is acknowledging the role and contribution of PPPs in meeting the health goals of the country. Promotion of these PPPs is also important to lessen the burden on the Government in terms of providing the outreach as well as to alleviate resource constraints. Under the 10th Five Year Plan (2002-2007), initiatives have been taken to define the role of the Government, private healthcare providers and CSOs in meeting the growing needs for healthcare services and meeting the goals of the National Health Programmes. The Planning Commission of the GOI (2007) constituted a Working Group on PPPs to improve healthcare delivery for the 11th Five-Year Plan. The Working Group stresses the importance of formulating policies that promote the growth of PPPs and advocates for PPPS subject to their suitability at the primary, secondary and tertiary levels of healthcare delivery.

NOTES

The contemporary National Health Policy (NHP) of India, formulated in the year 2002, and the ambitious NRHM formulated for the period 2005-2012, takes into consideration the vital role that is being played by private players and civil society organizations and recommends further partnerships. The NHP calls for participation of the private sector in primary, secondary and tertiary care in urban and rural India. It recommends suitable legislation for regulating minimum infrastructure and quality standards in clinical establishments and medical institutions. The NRHM proposes to support the development and effective implementation of regulating mechanisms for the private health sector to ensure equity, transparency and accountability in achieving public health goals.

It has been felt that encouraging business players to enter into efficient forms of healthcare delivery, PPPs would help bring disjointed public and private players on a common platform and move towards a common agenda and help ease the overburdened public healthcare system.

Flexible healthcare systems with a focus on PPPs

The World Health Report 2000 (WHO 2000) identifies four vital functions which can affect the outcome of a health system. These are stewardship (governance), financing, human and physical resources, and organization and management of service delivery. To perform these functions, the healthcare system should have the ability to respond to the changing requirements and adapt effectively to fulfil these needs. This will result in a robust system which can take advantages of the opportunities, prepare for the risks and exhibit planned response to the challenges. Like any other flexible system, the health system should show anticipation, agility and adaptability. Anticipation means the ability to predict, plan and prepare for known and unknown challenges. Agility refers to the ability to rapidly respond to opportunities and threats and as well as to initiate changes for better delivery. Adaptability refers to learn from the past experiences and realize that changes are constant.

To meet the current challenges of healthcare delivery, using the available resources, anticipating the future needs, opportunities and threats, strategic planning is required.

One of the frameworks, called the SAP-LAP framework proposed by Sushil (2001) looks at flexible systems and is useful in such strategic planning. The SAP-LAP framework analyzes the relationship between situational analysis (S), the stakeholders or the actors (A) and the processes (P) that lead to key learning issues (L) followed by suggested actions (A) and depending upon the effectiveness of the actions, there can be enhanced expected performance (P). According to Sushil, the more the freedom the actors have, the more adaptive and flexible the processes can be and the better the change. This is because the actors need to perform within the given situation by following certain processes. This synthesis and interaction between the different components of Situation-Actor-Process (SAP) and Learning-Action-Performance (LAP) helps in dealing with the changing situations and brings about a more positive outcome. This improved performance can, in-turn, affect the situation, actors and processes at different levels.

Application of the SAP-LAP Framework

The PPPs bring with them a paradigm shift in the way healthcare goals are being addressed. The existing arrangement needs to change to a new synergistic framework for supporting the vast and varied healthcare needs of the country. Since the healthcare system is fast evolving, the use of SAP-LAP analysis in strategic management of healthcare delivery is helpful.

Organizational Structure of the Health Care System

- National level - The organization at the national level consists of the Union Ministry of Health and Family Welfare.
- 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) belonging to the cadre of Indian Administrative Service (IAS).
- Regional level - Each regional/zonal set-up covers three to five districts and acts under authority delegated by the State Directorate of Health Services.
- District Level - The district level structure of health services is a middle level management organisation and it is a link between the State as well as regional structure on one side and the peripheral level structures such as PHC as well as sub-centre on the other side.
- Sub-divisional/Taluk level - At the Taluk level, healthcare services are rendered through the office of Assistant District Health and Family Welfare Officer (ADHO).
- Community level - 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.

Primary, Specialty and Hospital Care

- Primary - At present there is one Primary Health Centre covering about 30,000 (20,000 in hilly, desert and difficult terrains) or more population. Many rural dispensaries have been upgraded to create these PHCs. Each PHC has one

medical officer, two health assistants - one male and one female, and the health workers and supporting staff.

- Specialty - Speciality care is available at Taluk headquarters hospitals.
- Hospital Care - varies from secondary care available at taluk district headquarters and tertiary/corporate care at cities.

Role of Private Sector

The Indian Policy welcomes the participation of the private sector in all areas of health activities - primary, secondary or tertiary. However, looking to past experience of the private sector, it can reasonably be expected that its contribution would be substantial in the urban primary sector and the tertiary sector, and moderate in the secondary sector.

The Policy also encourages the setting up of private insurance instruments for increasing the scope of the coverage of the secondary and tertiary sector under private health insurance packages.

In the context of the very large number of poor in the country, it would be difficult to conceive of an exclusive Government mechanism to provide health services to this category. It has sometimes been felt that a social health insurance scheme, funded by the Government, and with service delivery through the private sector, would be the appropriate solution. The administrative and financial implications of such an initiative are still unknown.

It envisages the co-option of the non-governmental practitioners in the national disease control programmes so as to ensure that standard treatment protocols are followed in their day-to-day practice.

This Policy recognizes the immense potential of information technology applications in the area of telemedicine in the tertiary health care sector. The use of this technical aid will greatly enhance the capacity for the professionals to pool their clinical experience.

Key Health Care System Reforms

The main objective of the revised National Health Policy, 2002 is to achieve an acceptable standard of good health among the general population of the country and has set goals to be achieved by the year 2015. The major policy prescriptions are as follows:

- Increase public expenditure from 0.9 percent to 2 percent by 2010.
- Increase allocation of public health INVESTMENT in the order of 55 percent for the primary health sector; 35 percent and 10 percent to secondary and tertiary sectors respectively.
- Gradual convergence of all health programmes, except the ones (such as TB, Malaria, HIV/AIDS, RCH), which need to be continued till moderate levels of prevalence are reached.
- Need to levy user charges for certain secondary and tertiary public health services, for those who can afford to pay.

- Mandatory two year rural posting before awarding the graduate medical degree.
- Decentralising the implementation of health programmes to local self governing bodies by 2005.
- Setting up of Medical Grants Commission for funding new Government Medical and Dental colleges.
- Promoting public health discipline.
- Establishing two-tier urban healthcare system - Primary Health Centre for a population of one lakh and Government General Hospital.
- Increase in Government funded health research to a level of 2 percent of the total health spending by 2010.
- Appreciation of the role of private sector in health, and enactment of legislation by 2003 for regulating private clinical establishments.
- Formulation of procedures for accreditation of public and private health facilities.
- Co-option of NGOs in national disease control programmes.
- Promotion of tele medicine in tertiary healthcare sector.
- Full operationalisation of National Disease Surveillance Network by 2005.
- Notification of contemporary code of medical ethics by Medical Council of India.
- Encouraging setting up of private insurance instruments to bring secondary and tertiary sectors into its purview.
- Promotion of medical services for overseas users.
- Encouragement and promotion of Indian System of Medicine.

The first National Health Policy in 1983 aimed to achieve the goal of 'Health for All' by 2000 AD, through the provision of comprehensive primary healthcare services. It stressed the creation of an infrastructure for primary healthcare; close co-ordination with health-related services and activities (like nutrition, drinking water supply and sanitation); active involvement and participation of voluntary organisations; provision of essential drugs and vaccines; qualitative improvement in health and family planning services; provision of adequate training; and medical research aimed at the common health problems of the people.

4.3 BRIEF HISTORY OF EVOLUTION

With the advent of the British in India, the system of medicine known as western medicine or modern medicine was introduced in this country. At first the aim was largely to train apprentices to help the army medical personnel, the qualification required of such trainees being elementary. It was in the year 1835 that a more comprehensive system of training was instituted in India. The evolution of public health in colonial India has been chronicled earlier. The Calcutta Medical College was established by an order in 1835 to fulfill the growing need for health professionals. In 1846, a two-year course, later extended to three years, was started for the training of Hospital Assistants. This enabled them to join the subordinate medical services in the Army and in the civil cadres in British India.

NOTES

After the establishment of the three Universities of Calcutta, Bombay, and Madras, in 1857, medical education was taken over by Universities, which granted the qualifications of a Licentiate in Medicines and Surgery (the L.M.S.) and the Bachelor of Medicine and Master of Surgery (M.B.C.M. degree). The entrance qualification for the former course was a pass in the Matriculation examination and for the latter course, the Intermediates were eligible. Subsequently, the Licentiate qualification was abolished and the degree M.B.B.S. was awarded by the Universities. The qualification of M.B.B.S. granted by the different Universities was recognized by the General Medical Council of Great Britain and the standards were in conformity with the requirements laid down by the General Medical Council for such recognition.

The Indian Medical Services was formed in 1896 and the subsequent transfer of public health, sanitation, and vital statistics to the provinces took place in 1919. A new department to cater to education and health was constituted in 1912, with public health physicians in medical colleges entrusted with teaching hygiene. A School of Tropical Medicine was established in 1922 at Kolkata in eastern India. The establishment of this school marked a conscious shift from medical to a public health school. In 1933, the Medical Council of India was constituted, which took over the functions hitherto exercised by the General Medical Council of Great Britain for the maintenance of uniform standards for medical education in the country.

Formal public health activities in pre-independence India were backed by the introduction of physicians with both clinical and public health responsibilities. The public health workforce constituted personnel from a medical and nonmedical background that included ANMs, nurses, midwives, traditional birth attendants, sanitary inspectors, sanitary assistants, health officers, and physicians.

The establishment of The All India Institute of Hygiene and Public Health (AIIH and PH), Kolkata, in December 1932, making it the oldest school of public health in southeast Asia was a welcome development toward imparting public health education in India. The institute was established with a generous donation from the Rockefeller Foundation with an objective to develop health manpower by providing postgraduate (training) facilities of the highest order and to conduct research directed toward the solution of various problems of health and diseases in the community, thus prompting an application of knowledge to a large community and training students in these methods.

Public health and medicine have been mutually dependent and interact with each other, in the past as well as in modern times. Such an interaction can be seen in the history of development of the discipline in India as well where there was a healthy mix of clinical and public health responsibilities.

The Health Survey and Development Committee (Bhore committee) not only dealt with professional education in health under the following heads: Medical education, Dental education, Nursing education, The training of certain types of public health personnel, Pharmaceutical education, Training of technicians, and training of hospital social workers but also laid the foundation for community service by advocating for the institution a three-month training in preventive and social medicine for physicians as part of the medical education system.

NOTES

The WHO Expert Committee on Professional and Technical Education of medical and ancillary personnel in its report in 1952 stressed the relationship between the basic and clinical sciences and the necessity for internship after completion of the formal course.

The First World Medical Education Conference that met in London in August 1953 reviewed the requirements of entry into medical schools, the aim and content of the medical curriculum, the technique and method of education, and the importance of preventive and social medicine in the training of physicians. The southeast Asia Regional Office of the W.H.O., in their analytical study of Medical Education, recommended the reorientation of medical teaching from the predominantly individual and curative approach to a more community-minded and a preventive one.

The Medical Education Conference organized by the Government of India in 1955 after the World Medical Education Conference recommended major reforms in medical education in India. This Conference made several suggestions in regard to selection of students, entrance qualifications, including premedical studies, curriculum of medical education, examinations, fulltime teaching units, and so on. The Medical Education Conference agreed that the present methods of examinations and assessment were unsatisfactory, that written examinations required considerable modification and that great importance should be given to the day-to-day assessment of the student during his medical course.

It was recommended that *each medical college should have a Preventive and Social Medicine Department with fulltime staff. The teaching of Preventive and Social Medicine should start from the very beginning and continue throughout the period of training including the period of internship. The functions of the Preventive and Social Medicine Department should be integrated with the teaching of the other departments along with a co-ordinated outpatient service.* This department should have rural and urban health centers which will give the necessary facilities for rural training. A separate examination in Preventive and Social Medicine should be made part of the final M.B.B.S.

The Indian Public Health Association was formed in 1956 with the main objective of "promotion and advancement of public health and allied sciences in their different branches in India, protection and promotion of public and personal health of the people of the country and promotion of co-operation and fellowship among the members of the Association." This association solicited membership from different cadres of public health professionals across the country

The Mudaliar Committee further sought to strengthen public health education in the country by recommending schools of public health in every state to train medical officers, public health nurses, maternity and child welfare workers, public health engineers and sanitarians, dieticians, epidemiologists, nutrition workers, malariologists, and field workers.

The Indian Association of Preventive and Social Medicine, which was founded in 1974, is a "not for profit" professional organization dedicated to the promotion of public health by bringing its members' expertise to the development of public health policies, an advocate for education, research, and programs of Community Medicine and providing a forum for the regular exchange of views and information.

NOTES

The Shrivastava committee report in 1975 went on to advocate for a change in the structure of medical education to meet the changing requirements of health care and plan adequately for the future. The committee noted that the role of the general practitioner is far from the treatment of sickness and the prevention of disease, but extends to include the social and cultural problems that contribute to the fabric of health. It went on to recommend the content, structure, and process of change in order to orient the medical education across the country.

The ROME scheme was planned to impart community-oriented training to medical undergraduates in primary health care. The Government of India launched the Re-orientation of Medical Education (ROME) scheme in 1977 to involve medical colleges by encouraging the adoption of preventive, promotive, and curative health care in Community Development Blocks across the country. In the same year, the National Institute of Health and Family Welfare was set up for promotion of Health and Family Welfare programs in the country through education, training, research, evaluation, consultancy, and specialized services.

The Medical Education Review Committee of 1983 was set up for suggesting measures aimed at bringing about overall improvement in the undergraduate and postgraduate medical education, paying due attention to institutional goals; content, relevance, and quality of teaching and training and learning settings; and the evaluation systems and standards. The Bajaj committee was formulated in 1987 suggest remedial measures consequent to a dichotomous growth of health services and manpower, thereby affecting the planning, production, and management of allied health professionals. It provided an assessment of existing and projected national health manpower requirements primary and the intermediate level health care programs and also to recommend the essential educational institutions and facilities to facilitate the production of appropriate categories of health manpower.

The expert committee on public health systems of 1996 stated that there is a need to open new schools of public health where more public health professionals and paraprofessionals could be trained. The existing public health schools must also be appropriately strengthened. The committee recommended that at least four more regional schools of public health be set up in Central, Northern, Western, and Southern regions. The Calcutta Declaration of 1999 stressed upon the primacy of creating career structures at the national, state, provincial, and district levels and mandating competent background and relevant expertise for persons responsible for the health of populations. The resolution also stressed upon the need to strengthen and reform the public health education, training and research, as supported by the networking of institutions and the use of information technology for improving human resources development.

4.4 GROWTH OF HEALTH CARE SERVICES AFTER INDEPENDENT SALIENT FEATURES OF VARIOUS COMMITTEES

Health and health care need to be distinguished from each other for no better reason than that the former is often incorrectly seen as a direct function of the

latter. Heath is clearly not the mere absence of disease. Good Health confers on a person or groups freedom from illness - and the ability to realize one's potential. Health is therefore best understood as the indispensable basis for defining a person's sense of well being. The health of populations is a distinct key issue in public policy discourse in every mature society often determining the deployment of huge society. They include its cultural understanding of ill health and well-being, extent of socio-economic disparities, reach of health services and quality and costs of care. and current bio-medical understanding about health and illness.

Health care covers not merely medical care but also all aspects pro preventive care too. Nor can it be limited to care rendered by or financed out of public expenditure- within the government sector alone but must include incentives and disincentives for self care and care paid for by private citizens to get over ill health. Where, as in India, private out-of-pocket expenditure dominates the cost financing health care, the effects are bound t be regressive. Heath care at its essential core is widely recognized to be a public good. Its demand and supply cannot therefore, be left to be regulated solely by the invisible had of the market. Nor can it be established on considerations of utility maximizing conduct alone.

What makes for a just health care system even as an ideal? Four criteria could be suggested- First universal access, and access to an adequate level, and access without excessive burden. Second fair distribution of financial costs for access and fair distribution of burden in rationing care and capacity and a constant search for improvement to a more just system. Third training providers for competence empathy and accountability, pursuit of quality care ad cost effective use of the results of relevant research. Last special attention to vulnerable groups such a children, women, disabled and the aged.

Forecasting in Health Sector

In general predictions about future health - of individuals and populations - can be notoriously uncertain. However all projections of health care in India must in the end rest on the overall changes in its political economy - on progress made in poverty mitigation (health care to the poor) in reduction of inequalities (health inequalities affecting access/quality'), in generation of employment /income streams (to facilitate capacity to pay and to accept individual responsibility for one's health). in public information and development communication (to promote preventive self care and risk reduction by conducive life styles) and in personal life style changes (often directly resulting from social changes and global influences). Of course it will also depend on progress in reducing mortality and the likely disease load, efficient and fair delivery and financing systems in private and public sectors and attention to vulnerable sections- family planning and nutritional services and women's empowerment and the confirmed interest of ensure just health care to the Largest extent possible. To list them is to recall that Indian planning had at its best attempted to capture this synergistic approach within a democratic structure. It is another matter that it is now remembered only for its mixed success.

Available health forecasts

There is a forecast on the new health challenges likely to emerge in India over

tne next few decades. Murry and Lopez have provided a possible scenario of the burden of disease (BOD) for India in the year 2020, based on a statistical model calculating the change in DALYS are applied to the population projections for 2020 and conversely. The key conclusions must be understood keeping in the mind the tact that the concept of DALYs incorporates not only mortality but disability viewed in terms of healthy years of life lost. In this forecast, DALYs are expected to dramatically decrease in respect of diarrhoeal diseases and respiratory infections and less dramatically for maternal conditions. TB is expected to plateau by 2000, and HIV infections are expected to rise significantly up to 2010. Injuries may increase less significantly, the proportion of people above 65 will increase and as a result the burden of non-communicable disease will rise. Finally cardiovascular diseases resulting any from the risk associated with smoking urban stress and improper diet are expected to increase dramatically.

Under the same BOD methodology another view is available from a four - state analysis done in 1996 these four states - AP, Kamataka, W. Bengal and Punjab - represent different stages in the Indian health transition. The analysis reveals that the poorer and more populated states. West Bengal, will still face a large incidence of communicable diseases. More prosperous states, such as Punjab further along the health transiting will witness sharply increasing incidence of non-communicable diseases especially, in urban areas. The projections highlight that we still operating on unreliable or incomplete base data on mortality and causes of death in the absence of vital registration statistics and know as yet little about how they differ between social classes and regions or about the dynamic patterns of change at work.

It also highlights the policy dilemma of how to balance between the articulate middle upper class demand for more access to technologically advanced and subsidized clinical services and the more pressing needs of the poor for coverage of basic disease control interventions. This conflict over deployment of public resources will only get exacerbated in future. What matters most in such estimates are not societal averages with respect to health but sound data illumining specifically the health conditions of the disadvantaged in local areas that long tradition of health sector analysis looking at unequal access, income poverty and unjustly distributed resources as the trigger to meet health needs of the poor. That tradition has been totally replaced by the currently dominant school of international thought about health which is concerned primarily with efficiency of systems measured by cost effectiveness criteria.

Future of State Provided Health Care

Historically the Indian commitment to health development has been guided by two principles-with three consequences. The first principle was State responsibility for health care and the second (after independence) was free medical care for all (and not merely to those unable to pay),

The first set of consequences was inadequate priority to public health, poor investment in safe water and samtati on and to the neglect of the key role of personal hygiene in good health, culminating in the persistence of diseases like Cholera.

The second set of consequences pertains to substantially unrealized goals of NHP 1983 due to funding difficulties from compression of public expenditures and from organizational inadequacies. The ambitious and far reaching NPP - 2000 goals and strategies have however been formulated on that edifice in the hope that the gaps and the inadequate would be removed by purposeful action. Without being too defensive or critical about its past failures, the rural health structure should be strengthened and funded and managed efficiently in all States by 2005. This can trigger many dramatically changes over the next twenty years in neglected aspects or rural health and of vulnerable segments.

The third set of consequences appears to be the inability to develop and integrate plural systems of medicine and the failure to assign practical roles to the private sector and to assign public duties for private professionals.

To set right these gaps demanded patient redefinition of the state's role keeping the focus on equity. But during the last decade there has been an abrupt switch to market based governance styles and much influential advocacy to reduce the state role in health in order to enforce overall compression of public expenditure an reduce fiscal deficits. People have therefore been forced to switch between weak and efficient public services and expensive private provision or at the limit forego care entirely except in life threatening situations, in such cases sliding into indebtedness. Health status of any population is not only the record of mortality and its morbidity profile but also a record of its resilience based on mutual solidarity and indigenous traditions of self-care - assets normally invisible to he planner and the professional.

Such resilience can be enriched with the State retaining a strategic directional role for the good health of all its citizens in accordance with the constitutional mandate. Within such a framework alone can the private sector be engaged as an additional instrument or a partner for achieving shared public health outcomes. Similarly, in indigenous health systems must be promoted to the extent possible to become another credible delivery mechanism in which people have faith and away fond for the vat number of less than folly qualified doctore in rural areas to get skills upgraded. Public programs in rural and poor urban areas engaging indigenous practitioners and community volunteers can prevent much seasonal and communicable disease using low cost traditional knowledge and based on the balance between food, exercise medicine and moderate living. Such an overall vision of the public role of the heterogenous private sector must inform the course of future of state led health care in the country.

4.5 KEY ACHIEVEMENTS IN HEALTH

Our overall achievement in regard to longevity and other key health indicators are impressive but in many respects uneven across States, The two Data Annexure at the end indicate selected health demographic and economic indicators and highlight the changes between 1951and 2001. In the past five decades life expectancy has increased from 50 years to over 64 in 2000. IMR has come down from 1476 to 7. Crude birth rates have dropped to 26.1 and death rates to 8.7.

At this stage, a process understanding of longevity and child health may be useful for understanding progress in future. Longevity, always a key national goal, is not merely the reduction of deaths as a result of better medical and rehabilitative care at old age. In fact without reasonable quality of life in the extended years marked by self-confidence and absence of undue dependency longevity may men only a display of technical skills.

So quality of life requires as much external bio-medical interventions as culture based acceptance of inevitable decline in faculties without officious start at sixty but run across life lived at alt ages in reduction of mortality among infants through immunization and nutrition interventions and reduction of mortality among *young* and middle aged adults, including adolescents getting inform about sexuality reproduction and safe motherhood. At the same time, some segments will remain always more vulnerable - such as women due to patriarchy and traditions of infra-family denial), aged (whose survival but not always development will increase with immunization) and the disabled (constituting a tenth of the population).

Reduction in child mortality involves as much attention to protecting children from infection as in ensuring nutrition and calls for a holistic view of mother and child health services. The cluster of services consisting of antenatal services, delivery care and post mortem attention and low birth weight, childhood diarrhoea and ARI management are linked priorities.

Programme of immunization and childhood nutrition seen in better performing stats indicate sustained attention to routine and complex investments into growing children as a group to make them grow into persons capable of living long and well Often interest fades in pursuing the unglamorous routine of supervised immunization and is substituted by pulse campaigns etc. Which in the long run turn out counter-productive. Indeed persistence with improved routines and care for quality in immunization would also be a path way to reduce the world's highest rate of maternal mortality.

In this context we may refer to the large ratio-based rural health infrastructure consisting of over 5 lakh trained doctors working under plural systems of medicine and a vast frontline force of over 7 lakh ANMs, MPWS and Anganwadi workers besides community volunteers. The creation of such public work force should be seen as a major achievement in a country short of resources and struggling with great disparities in health status. As part of rural Primary health care network lone, a total of 1.6 lakh subcenters, (with 1.27 lakh.' ANMa in position) and 22975 PHCs and 2935 CHCs (with over 24000 doctors and over 3500 specialists to serve in them) have been set up. To promote Indian systems of medicine and homeopathy there are over 22000 dispensaries 2800 hospitals Besides 6 lakh angawadis serve nutrition needs of nearly 20 million children and 4 million mothers. The total effort has cost the bulk of the health development outlay, which stood at over Rs 62.500/- crores or 3-64 % of total plan spending during the last fifty years.

On any count these are extraordinary infrastructural capacities created with resources committed against odds to strengthen grass roots. There have been facility gaps, supply gaps and staffing gaps, which can be filled up only by allocating about 20% more funds and determined ill to ensure good administration and synergy from greater congruence of services, but given the sheer size of the endeavor thee

wilt always be some failure of commitment and in routine functioning. These get exacerbated by periodic campaign mode and vertical programme, which have only increased compartmentalized vision and over-medicalization of health problems. The initial key mistake arose from the needless bifurcation of health and family welfare and nutrition functions at all levels instead of promoting more holism.

As a sult of all this the structure has been precluded from reaching its optimal potential. It has got more firmly established at the periphery/sub-center level and dedicated to RCH services only. At PHC and CHC levels this has further been compounded by a weak referral system. There has not been enough convergence in "escorting" children through immunization coverage and nutrition education of mothers and ensuring better food to children, including cooked midday meals and health checks al schools. There has also been no constructive engagement between allopathic and indigenous systems to build synergies, which could have improved people's perceptions of benefits from the infrastructure in ways that made sense to them.

One key task in the coming decades is therefore to utilize fully that created potential by attending to well known organizational motivational and financial gaps. The gaps have arisen partly from the source and scale of funds and partly due to lack of persistence, both of which can be set right. PHCs and CHCs are funded by States several of whom are unable to match Central assistance offered and hence these centers remain inadequate and operate on minimum efficiency. On the other hand over two thirds cost of three fourths of sub-centers are fully met by the Center due to their key role m family welfare services. But in equal part these gaps are due to many other non-monetary factors such as undue centralization and uniformity, fluctuating commitment to key routines at ground level, insufficient experimentation with alternatives such as getting public duties discharged through private professionals and ensuring greater local accountability to users.

Health Status Issues

The difference between rural and urban indiactors of health status and the wide interstate disparity in health status are well known. Clearly the urban rural differentials are substantial and range from childhood and go on increasing the gap as one grows up to 5 years. Sheer survival apart there is also the we known under provision in rural areas in practically all social sector services. For the children growing up in rural areas the disparities naturally tend to get even worse when compounded by the widely practiced discrimination against women, starting with foeticide of daughters.

In spite of overall achievement it is a mixed record of social development specially failing in involving people in imaginative ways. Even the averaged out good performance ides wide variations by social class or gender or region or State. The classes in may States have had to suffer the most due to lack of access or denial of access or social exclusion or all of them. This is clear from the fact that compared to the riches quintile, the poorest had 2.5 times more IMR and child mortality, TFR at double the rates and nearly 75% malnutrition - particularly during the nineties.

Not only are the gaps between the better performing and other States wide but in same cases have been increasing during the nineties. Large differences also exist

between districts within the same better performing State urban areas appear to have better health outcomes than rural areas although the figures may not fully reflect the situation in urban and peri-urban slums with large in migration with conditions comparable to rural pockets. It is estimated that urban slum population wilt grow at double the rate of urban population growth in the next few decades. India may have by 202 a total urban population of close to 600 million living in urban areas with an estimated 145 million living in slums in 2001. What should be a fair measure for assessing success in enhancing health status of population I any forecast on health care?

Disease Load in India and China:

We need a basis for comparative scenario building. Among the nations of the world China alone rank in size and scale and in complexity comparable to India differences between an open and free society and a semi-controlled polity do matter. The *remarkable success in China in combating disease is due to sustained attention* on the health of the young in China, and of public policy backed by resources and social mobilization- While comparing China and India in selected aspects of disease load, demography and public expenditures on health, the record on India may seem mixed compared to the more all round progress made by china. But this should also be seen in the perspective of the larger burden of disease in India compared to china and of the transactional costs of an open and free democracy,

Though India and China recorded the same rate of growth till 70s, China initiated reforms a full decade earlier. This gave it a head stat for a higher growth rate and has resulted in an economic gap with India which has become wider over time. This is because domestic savings in China are 36% of GDP whereas in India it hovers at 23%, mostly in house-hold savings. Again. China attracted $40 billion in foreign direct investment against $2 billion in India. Special economic zones and relaxed labour laws have helped. Public expenditure on health in China has been consistently higher underlining the regressive nature of financing of health are in India. Nevertheless- it is not too unrealistic to expect that India should be able to reach by 2010 at least three fourth the current level of performance of China in all key health indices. India's current population is not a bit more than 75% that of China and India will of course be catching up even more with China into the 21 century.

This would be offset by the handicap that Indian progress will be moderated by the fact that it is an open free and democratic society. A practical rule-of-thumb measure for an optimistic forecast of future progress in India could be - that between 2000 and 2010 India should do three fourths as well as China did in 1990-2000 and, after 2010, India should try to catch up with the rate of performance of China and do just as well thereafter. This will translate into, for, instance, a growth rate of about 8% for India till 2010 and as close to 10% as possible thereafter thus enabling doubling first in ten yeas and doubling first in ten year and doubling twice over every seven years thereafter prior to 2025. keeping this perspective in mind, we may now examine the profile of major disease control effort; the effectiveness of available instruments for delivery and financing public health action and assess factors relevant to the remaining event of vulnerability within JOUT emerging social pyramid over next two or three decades,

Major Disease Control Efforts

A careful analysis of the Global Burden of Disease (GBD) study focusing on age-specific morbidity during 2000in ten most common diseases (excluding injuries) shows that sixty percent of morbidity is due to infectious diseases and common tropical diseases, a quarter due to life-style disorders and 13% due to potentially preventable per-natal conditions. Further domestic R&D has been so far muted in its efforts against an estimated annual aggregate health expenditure in India ofRs- 80,000/-crores R&D expenditure in India for public and private sector combined was Rs 1150 crores only. India must play a larger part in its own efforts at indigenous R&D as very little world-wide expenditure on R&D is likely to be devoted to infectious diseases. For instance out of the 1233 new drugs that came into the market between 1975 and 1997 only 11 were indicated specifically for tropical country diseases,

We have already the distinction of elimination or control acceptable to public health standards of small pox and guinea worm diseases. In the draft National Health Policy -21 It has now been proposed to eliminate or control the following diseases within limits acceptable to public health practice- A good deal of the effort would be feasible.

- Polio Yaws and leprosy by 2005 which seems distinctly feasible though the removal of social stigma and reconstructive surgery and other rehabilitation arrangements in regard to leprosy would remain inadequate for a decade or more.
- Kalaazar by 20I0 and Filalriasis by 2010 which also seems feasible due to its localized prevalence and the possibility of greater community based work involving PR institutions in the simple but time-limited tasks or public health programs.
- Blindness prevalence to 0.5% by 2010 sees less feasible due to a graying population. At present the programme is massively supported by foreign aid as there are many other legitimate demands on domestic health budgets.
- AIDS reaching zero growth by 2007 appears to be problematic as there are disputes even about base data on infected population. On most reckonings, affordable vaccines re not likely to be available soon nor anti-retro viral drugs appear likely at affordable prices in the near future. Further the prevalence curve of Aids in India is yet to show its shape. There is also larger unresolved question of where HIV/ATDS should be fitted in our priorities of public health, especially in this massively foreign aided programme what happen if aid does not become available at some point.

Unfinished Burden of Communicable Diseases

Apart from the above, there remains a vast unfinished burden in preventing controlling or eliminating other major communicable diseases and in bringing down the risk of deaths in maternal and peri-natal conditions. Endemic diseases arising from infection or lack of nutrition continue to account for almost two thirds of morality ad morbidity India. Indeed eleven out of thirteen diseases recommended by the Bhore Committee were infectious diseases and at least three of them may well continue to be with us for the next two decades Baring Leprosy which is almost

NOTES

on the path to total control by 2005, the other key communicable diseases will be TB Malaria and Aids- to which diarrhoea in children and complicated and high risk maternity should be added in view of their pervasive incidence and avoidable mortality among the poorer and under served sectors,

Tuberculosis

Tuberculosis has had a world wide resurgence including in India. It is estimated lhai about 14 million persons are infected, i.e. 1.55 of total population suffer from radio logically active Tuberculosis. About 1.5 million cases are identified and more than 300 000 deaths occur every year Between NFHS 1 and NFHS 2 the prevalence has increased from 4678 per lakh population to 544. Unfortunately, prevalence among working age adults (15-59) is even higher as 675. All these may well be underestimates in so far as patients are traced only through hospital visit. Only about half reach the hospital.

Often wrong diagnosis by insufficiently trained doctors or misunderstood protocols is another key problem both public and private sectors. TB is a wide spread disease of poverty among women living and working in ill ventilated places and other undernourished persons in urban slums it is increasingly affecting the younger adults also in the economically productive segments. No universal screening is possible. Sputum positive test does not precede diagnosis but drugs are prescribed on the basis of fever and shadows as a result incomplete cure becomes common and delayed tests only prove the wrong diagnosis too late.

Improved diagnosis through better training and clear protocols and elimination of drug resistance through incomplete cure should be priority. Treatment costs in case of drug resistance can soar close to ten times the normal level of Rs. 3000 to 4000/-per person treated. Similarly even though the resistant strain may cover only 8% at present, it could suddenly rise and as it approaches 20% or so, there is a danger that TB may get out of control. The DOTS programme trying for full compliance after proper diagnosis is settling down but already has some claims of success.

More tan 3000 laboratories have been set up for diagnosis and about 1.5 lakh workers trained and with total population coverage by 2007 cure rates (already claimed to have doubled) may rise substantially. There is reason to hope that DOTS programs would prove a greater success over time with increased community awareness aeneration. The key issue is how soon and how well can it be integrated into the PHC system and made subject to routines of local accountability, without which no low cost regime of total compliance is feasible in a country as large as India.

An optimistic assessment could be that with commitment and full use of infrastructure it will be possible to arrest further growth in absolute numbers of TB cases keeping it at below 1.5 million till 2010 even though the population will e growing. Once that is done TB can be brought down to less than a million lie within internationally accepted limits and disappears as a major communicable disease in India by 2020.

Malaria

As regards malaria, we have had a long record of success and failure and each intervention has been thwarted by new problems and plagued by recrudescence. At present India has a large manpower fully aware of all aspects of malaria about often low in motivation. It can be transformed into a large-scale work force for awareness generation, tests and distribution of medicine. In spite of past successes, there is evidence of reemergence with focal attacks of malaria with the virulent falciparum variety especially m tribal areas. Priority tnbal area malaria stands fully funded by the center. About 2 millioncases of malaria are recorded allover India every year with seasonal high incidence local failures of control. Drug resistance in humans and insecticide resistant strains of mosquitoes present a significant problem. But there is a window of opportunity I respect ofDDT sensitive areas in eastern India where even now malaria incidence can be brought down by about 50% within a decade and be beneficial for control of kalazaar and JE.

There is growing interest and community awareness of biological methods of control of mosquito growth. Unfortunately diligent ground level public health work is in grave disarray n these areas but can be improved by better supervision greater use of panchayatraj institutions and buildings on modest demonstrated successes. As regards a vaccine, there seems t be no sufficient incentive for international R&D to focus on a relatively lower priority or research. Roll back malaria programmes of the WHO are more likely to concentrate on Africa whose profile of malaria is not similar to ours. The search for a vaccine continues but has little likelihood of immediate success.

In spite of various difficulties, if the restructuring of the malaria work force and the strengthening of health infrastructure takes place, one can expect that the incidence can be i educe by a third or even upto half in the next decade or so. For this it is necessary that routine tasks like timely spraying and logistics for taking blood slides testing and their analysis and organic methods of reducing mosquito spread etc. Are down staged to community level and penormed under supervision throLigh panchayais wiih comaiLiniLy participation public education and local monitoring. Malaria can certainly be reduced by a third even upto a half in ten years, and there is a prospect of near freedom from malaria for most of the country by 2020.

The Case of AIDS

There is finally the case of HIV AID. The magnitude in the numbers of HIV infected and of AIDS patients by 2025 can be known only as trends emerge over a decade from now. when better epidemiological estimates are available but at present these figures are hotly contested. 'We cant start with the number infected with HIV as per NACO sentinel surveillance in 2000 a cumulative total 3.86 million, a figure disputed in recent public health debate. We can then assume that about 10% will turn into full-blow cases of severe and intractable stage of Aids. There is as yet no basis to know how many of those infected will become AIDS patients, preventive efforts focused on behavior change will show up firmly only after a decade or so. During this period one can assume an additional 10% growth to account for new cases every year.

NOTES

The Draft NHP 2001 seeks to stop further infection by educating and counseling and condom supplies to level it off around 2007, which seems somewhat ambitious. We have yet to make a decisive dent into the problem of awareness with the broader population and so far we have been at work only on high risk groups. NFHS2 shows only a third of woman reporting that they even knew about the HIV/AIDS. Further such awareness efforts must be followed by multi-pronged and culturally compatible techniques of public education that go beyond segments easier to be convinced or behaviour changed. There are voices already raised about the appropr lateness of IEC mass media content and of the under emphasis of face to face counseling, calli. g for innovative mobilization strategies rooted in indigenous belief systems.

What it implies is that we may be carrying by 2015closeto 5 million infected and upto a tenth of them could turn into full blown cases. We may not be able to level off infection by 2007 Further these magnitudes may turn out m actual fact to be wildly off the mark. On any account it is clear that AIDS can lead to high mortality among the productive groups in society affecting economic functioning as also public health. Even if 10% of them say 50 to 60000 cases becomes full blown cases the state has the onerous and grim choice to look at competing equities and decide on a policy for free treatment of AIDS patients with expensive anti-retro viral drugs. And if it decides not to, the issue remains as to how to evolve humane balanced and affordable policies that do not lead to a social breakdown. In about a decade vaccine development may possibly be successful and drugs may by more effective but they may not always be affordable nor can be given free.

There would hopefully be wider consultation with persons with caring sensibilities including AIDS patients on how to counsel in different eventualities and to get the balance right between hospital and home care and how to develop a humane affordable policy for anti retroviral drugs for AIDS patients. Is there a case for providing them with drug free of cost merely to extend their lives for few years? The matter involves a true dilemma, for public health priorities themselves certainly argue for more funds should address diseases constituting bigger population based hazards. Investments made m such expensive interventions can instead be made in supporting hospice efforts in the voluntary and private sectors.

Whatever position may emerge in research or spread of infection of case fatalities, a multi pronged attempt for awareness, must continue and tough choices must get discussed openly without articulate special, often urban middle class interests denying other views and especially public health priorities of the poor. The promotion of barrier protection must increase but has to related to a system of values, which would be acceptable to the people's beliefs. We need to strengthen sentinel surveillance systems and awareness effort. We also need sensitive feed back on the effects they leave on younger minds for a balanced culturally acceptable strategy. All this is feasible and can be accomplished if we are not swept away by the power of funding and advocacy and fear of being accused to be out of line with dominant world opinion.

In any case many of the ill cannot afford the high prices or have access to it from public agencies. The strict patent regimen under TRIPS is bound to prevail, notwithstanding the ambivalently worded Doha decision of WTO that public health

emergencies provide sufficient cause of countries to use the flexibility available from various provisions of TRIPS. A recent analysis reveals that the three drug regimen recommended will cost $10000 per person per year from Western companies and the treatment will be lifelong. Three Indian companies are offering to Central Government anti retro; viral drugs at $600/ Rs. 30,000/per person per year and to an international charity at an even lower price $ 350/ Rs. 13,000/per year provided it was distributed for humanitarian relief free in S. Africa. It has been public policy in Brazil that the drug is supplied free to all AIDS should be no exception. If drugs are supplied acting on a public health emergency basis and prices can stabilize at Rs. 1000/- or so per year the public health budget should be able to accommodate the cost weighed against true public criteria. But the aim of leveling off infection of 2007 still seems unlikely.

Maternal and Parental Deaths

Maternal and parental deaths are sizeable but the advantage here is that they can be prevented merely by more intensive utilization of existing rural health infrastructure. Policy and implementation must keep steady focus on key items such as improved institutional deliveries better trained birth attendants and timely antenatal screening to eliminate anaemia and at the same time isolate cases needing referral or other targeted attention. After all Tamil Nadu has by such methods ensured closed to 90% institutional deliveries backed by a functional referral. Firm administrative will and concurrent supervision of specified screening tasks included in MCH services can give us a window of opportunity to dramatically bring down within a few years alarming maternal mortality currently one of the highest in the world.

From NFHS I data, it was estimated at 424 per lac births it has risen to 540 per lac births in NFHS II, but the WHO estimate puts it higher at 570, There can be a systematic campaign over five years to increase institutional deliveries as near as possible to the Tamil Nadu level, also taking into account assisted, home deliveries by trained staff with doctors at call. For the interim TBAs should be relied on through a mass awareness campaign involving Gram Panchayats too. Over a period of time there is no reason why ANMs entitled benefits of children to help in their growth and not remain as welfare measure. Using the infrastructures fully and with community participation and extensive social mobilization many tasks in nutrition are feasible and can be in position to make impact by 2010.

Child Health and Nutrition

Associated with this is the issue of infant and child mortality, (70 out of 1000 dying in the first year and 98 before vide years) and low birth weight (22% UW at birth ands 47% EJW at below 3 years) most mortality occurs from diarrhoea and the stagnation in IMR in the last few year is bound to have a negative effect on population stabilization goals. A recent review of the Ninth plan indicated that even with accelerated efforts we may reach at best IMR/50 by 3002, but more like IMR/56. since the easier part of the problem is taking child mortality is over every pomt gain hereafter will deal with districts at greater risk and needing better organizational efficiencies in immunization.

NOTES

At the same time, more streamlined RCH services are getting established as part of public systems and through private partnerships Therefore there is every reason to hope that the NPP 2000 target of 30 per thousand live births by 2010 will be met barring a few pockets of inaccessible and resource lean areas with stubborn persistence of poverty and dominantly composed of weaker sections (e g in part of Orissa as seen from NFHS II).

As regards childhood diarrhoea, deaths are totally preventable simple community action and public education by targeting children of low birth weights and detecting early those children at risk from malnutrition through proper low cost screening procedure, the present arrangement has got too burdened with attempting total population coverage getting all children weighed even once in three months and making ANMs depots for ORS and for simple drugs for fever and motivating the community to take pride in healthy children are the lessons of the success of the Tamil Nadu Nutrition Project, If this is done there is a reasonable chance of two thirds decline in moderate malnutrition and abolition of serious grades completely by 2015. The success can be built upon till 2025 for reaching levels comparable to China.

Concentration on preventive measures of maternal and child health and in particular improved nutrition services will be particularly useful because it will help that generation to have a head start in good health who are going to be a part of the demographic bonus. The bonus is a young adult bulge of about 340 million (with not less than 250 million from rural population and about 100 million born in this century).

The bonus will appear in a sequence with South Indian States completing the transition before North Indian States spread it over the next three decades- To ensure best results aL this stage the present nutritional services must be converted into targeted (and entitled) benefits of children to help in their growth and not remain as welfare measure. Using the infrastructures fully and with community participation and extensive social mobilization many tasks in nutrition are feasible and can be in position to make impact by 2010.

Mild and moderate malnutrition still prevalent in over half of our young population can be halved if food as the supplemental pathway to better nutrition becomes a priority both for self reliance and lower costs. There has been a tendency for micro nutrient supplementation to overwhelm food derived nourishment. This trend is assisted by foreign aid but over a long run may prove unsustainable- By engaging the adolescents into proper nutrition education and reproductive health awareness we can seamlessly weave into the nutritional security system of our country a corps of informed interconnected and imaginative ideas can be tried out. Such social mobilization at low cost can be the best preventive strategy as has been advocated for long by the Nutrition Foundation of India and can be a priority in this decade over the next two plan periods.

Unfinished Agenda - Non Communicable Diseases and Injuries

Three major such diseases viz,, cancer cardiovascular diseases and renal conditions - and neglect in regard to mental health conditions - have of late shown worrisome trends. Cures for cancer are still elusive in spite of palliatives and expensive and

long drawn chemo - or radio -therapy which often inflict catastrophic costs, In the case ot'CVD and renal conditions known and tried procedures are available for relief. There is evidence of greater prevalence of cancer even among young adults due to the stress of modem livmg. In India cancer is a leading cause of death with about 1.5 to 2 million cases at anytime to which 7 lac new cases are added every year with 3 lakh deaths. Over 15 lakh patients require facilities for diagnosis and treatment. Studies by WHO show that by 2026 with the expected increase in fife expectancy, cancer burden in India will increase to about 14 lac cases. CVD cases and Diabetes cases are also increasing with an 8 to 11 % prevalence of the latter due to fast life styles and lack of exercise.

Traumas and accidents leading to injuries- are offshoots of the same competitive living conditions and urban traffic conditions Data show one death every minute due to accidents or more than 1800 deaths every day- in Delhi alone about 150 cases are reported every day from accidents on the road and for every death 8 living patients are added to hospitals due to injuries. There is finally the emerging aftermath of insurgencies and militant violence leading to mental illnesses of various types. It is estimated that 10 to 20 persons out of 1000 population suffer from severe mental illness and 3 to 5 times more have emotional disorder. While there are some facilities for diagnosis and treatment exist in major cities there is no access whatever in rural areas. It is acknowledged that the only way of handling mental health problems is through including it into the primary health care arrangements implying trained screening and counseling at primary levels for early detection.

All these are eminently feasible preventive steps and can be put into practice bv 2005 and we should be doing as well or better than China by 2020 considering the greater load of non communicable diseases they bear now. The burden of non-communicable diseases will be met more and more by private sector specialized hospitals which spring up in urban centers. Facilities in prestigious public centers will also be under strain and they should be redesigned to take advantage of community based approach of awareness, early detection and referral system as in the mode developed successfully in the Regional Cancer Center Keraia. Public sector institutions are also needed to provide a comparator basis for costs and evaluating technology benefits.' For the less affluent sections prolonged high tech cure will be unaffordable. Therefore public funds should go to promote a routine of proper screening health education and self care and timely investigations to see that interventions are started in stages I and II.

Health Infrastructure in the Public Sector

Issues in regard to public and private health infrastructure are different and both of them need attention but in different ways. Rural public infrastructure must remain in mainstay for wider access to health care for all without imposing undue burden on them. Side by side the existing set of public hospitals at district and sub-district levels must be supported by good management and with adequate funding and user fees and out contracting services, all as part of a functioning referral net work. This demands better routines more accountable staff and attention to promote quality.

NOTES

Many reputed public hospitals have suffered from lack of autonomy inadequate budgets for non-wage O&M leading to faltering and poorly motivated care. All these are being tackled in several states are part health sector reform, and will reduce the waste involved in simpler cases needlessly reaching tertiary hospitals direct These, attempts must persist without any wavering or policy changes or periodic denigration of their past working. More autonomy to large hospitals and district public health authorities will enable them to plan and implement decentralized and flexible and locally controlled services and remove the dichotomy between hospital and primary care services.

Further, most preventive services can be delivered by down staging to a public health nurse much of what a doctor alone does now. Such long term commitment for demystification of medicine and down staging of professional help has been lost among the politicians bureaucracy and technocracy after the decline of the PHC movement. One consequence is the huge regional disparities between states which are getting stagnated in the transition at different stages and sometimes, polarized in the transition. Some feasible steps in revitalizing existing infrastructure are examined below drawn from successful experiences and therefore feasible elsewhere,

Feasible Steps for Better Performance:

The adoption of a ratio based approach tor creating facilities and other mpuls has led LO shortfalls estimated upto twenty percent. It functions well where ever there is diligent attention to supervised administrative routines such as orderly drugs procurement adequate O&M budgets and supplies and credible procedures for redressal of complaints. Current PHC CHC budgets may have to be increased by 10% per year for five years to draw level. The proposal in the Draft NHP 2001 is timely that State health expenditures be raised to 7% by 2015 and to 8% of State budgets thereafter. Indeed the target could be stepped up progressively to 10% by 2025. it also suggests that Central funding should constitute 25% of total public expenditure in health against the present 15%.

The peripheral level at the sub center has not been (and may not now ever be) integrated with the rest of the health system having become dedicated solely to reproduction goals. The immediate task would be to look deepening the range of work done at all levels of existing centers and in particular strengthen the referral links and fuller and flexible utilization ofPHC/CHCs. Tamil Nadu is an instance where a review showed that out of 1400 PHCs 94% functioned in their own buildings and had electricity, 98% of ANMs and 95% of pharmacists were in position. On an average every PHC treated about 100 patients 224 out of the 250 open 24 hour PHCs had ambulances. What this illustrates is that every State must look for imaginative uses to which existing structures can be put to fuller use such as making 24 hours services open or trauma facilities in PHCs on highway locations etc.

The persistent under funding of recurring costs had led to the collapse of primary care in many states, some spectacular failures occurring in malaria and kalazar control. This has to do with adequacy of devolution of resources and with lack of administrative will probity and competence in ensuring that determined priorities in public health tasks and routines are carried out timely and in full. Only

genuine devolution or simpler tasks and resources to panchayats, where there will be a third women members- can be the answer as seen in Kerala or M.P. where panchayats are made into fully competent local governments with assigned resources and control over institutions in health care. Many innovative cost containment initiatives are also possible through focused management - as for instance in the streamlining of drug purchase stocking distribution arrangements in Tamil Nadu leading to 30% more value with same budgets.

The PHC approach as implemented seems to have strayed away from its key thrust in preventive and public health action. No system exists for purposeful community focused public information or seasonal alerts or advisories or community health information to be circulated among doctors in both private practice and in public sector. PHCs were meant to be local epidemiological information centers which could develop simple community.

Tertiary hospitals had been given concessional land, customs exemption and liberal tax breaks against a commitment to reserve beds for poor patients for free treatments. No procedures exist to monitor this and the disclosure systems are far from transparent, redressal of patient grievances is poor and allegations of cuts and commissions to promote needless procedure are common.

The bulk of noncorporate private entities such as nursing homes are run by doctors and doctors- entrepreneurs and remain unregulated either in terms of facility of competence standards or quality and accountability of practice and sometimes operate without systematic medical records and audits. Medical education has become more expensive and with rapid technological advances in medicine, specialization has more attractive rewards. Indeed the reward expectations of private practice formerly spread out over career long earnings are squeezed into a few years, which becomes possible only by working in hi tech hospital some times run as businesses.

The responsibilities or private sector in clinical and preventive public health services were not specified though under the NHP 1983 nor during the last decade of reforms followed up either by government of profession by any strategy to engage allocate, monitor and regulate such private provision nor assess the costs and benefits or subsidization of private hospitals. There has been talk of public private partnerships, but this has yet to take concrete shape by imposing pubic duties on private professionals, wherever there is agreement on explicitly public health outcomes. In fact it has required the Supreme Court to lay down the professional obligations of private doctors in accidents and injuries who used to be refused treatment in case of potential becoming part of a criminal offence.

The respective roles of the public and private sectors in health care has been a key issue in debate over a long time. With the overall swing to the Right after the 1980s, it is broadly accepted that private provision of care should take care of the needs of all but the poor. hi doing so, risk pooling arrangements should be made to lighten the financial burden on theirs who pay for health care. As regards the poor with priced services. Taking into account the size of the burden, the clinical and public health services cannot be shouldered for all by government alone.

NOTES

To a large extent this health sector reform m India at the state level confirms this trend. The distribution of the burden, between the two sectors would depend on the shape and size of the social pyramid in each society. There is no objection to introduce user fees, contractual arrangements, risk pooling, etc. for mobilization of resources for health care. But, the line should be drawn not so much between public and private roles, but between institutions and health care run as businesses or run in a wider public interest as a social enterprise with an economic dimensions. In a market economy, health care is subject to three links, none of which should become out of balance with the other - the link between state and citizens' entitlement for health, the link between the consumer and provider of health services and the link between the physician and patient.

Health Financing Issues

Public Expenditure Levels

Fair financing of the costs of health care is an issue in equity and it has two aspects how much is spent by Government on publicly funded health care and on what aspects? And secondly how huge does the burden of treatment fall on the poor seeking health care? Health spending in India at 6% of GDP is among the highest levels estimated for developing countries. In per capita terms it is higher than in China Indonesia and most African countries but lower than in Thailand. Even on PPP $ terms India has been a relatively high spender information sheets based on reporting from a network associating private doctors also as has been done successfully at CMC Vellore in their rural health projects or by the Khoj projects of the Voluntary Health Association of India. It is only through such community based approach that revitalization of indigenous medicines can be done and people trained in self care and accept responsibility for their own health.

PHC approach was also intended to test the extent to which non-doctor based healthcare was feasible through effective down staging of the delivery of simpler aspects of a care as is done in several countries through nurse practitioners and physician assistants, ANMs; physician assistants etc can each get trained and recognized to work in allotted areas under referral/supervision of doctors. This may indeed be more acceptable to the medical profession than the draft NHP proposal to restart licentiates in medicine as in the thirties and give them shorter periods of training to serve rural areas. Such a licentiate system cannot now be recalled against the profession's opposition nor would people accept two level services.

Shape of the Private Sector In Medicine

The key features of the private sector in medical practice and health care are well known. Two questions are relevant. What role should be assigned to it? How far and how closely should it be regulated? Over the last several decades, independent private medical practice has become widespread but has remained stubbornly urban with polyclinics, nursing homes and hospitals proliferating often through doctor entrepreneurs. At our level tertiary hospitals in major cities are in may cases run by business houses and use corporate business strategies and hi-tech

NOTES

specialization to create demand and attract those with effective demand or the critically vulnerable at increasing costs. Standards in some of them are truly world class and some who work there are outstanding leaders in their areas.

But given the commodification of medical care as part of a business plan it has not been possible to regulate the quality, accountability and fairness in care through criteria for accreditation, transparency in fees, medical audit, accountable record keeping, credible grievance procedures etc. such accreditation, standard setting and licensure systems are best done under self regulation, but self regulation systems in India medical practice have been deficient in many respects creating problem in credibility. Acute care has become the key priority and continues to attract manpower and investment into related specialty education and facilities for technological improvement. Common treatments, inexpensive diagnostic procedures and family medicine are replaced and priced out of the reach of most citizens in urban areas.

Public health spending accounts for 25% of aggregate expenditure the balance being out of pocket expenditure incurred by patients to private practitioners of variqus hues. Public spending on health in India has itself declined after liberalization from 1.3% of GDP in 1990 to 0.9% in 1999. Central budget allocations for health have stagnated at 1.3% to total Central budget. In the States it has declined from *7.0%* to 5.5.% of State health budget. Consider the contrast with the Bhore Committee recommendation of 15% committed to health from the revenue expenditure budget, Indeed WHO had recommended 55 of GDP for health.

The current annual per capita public health expenditure is no more than *Rs.* 160 and a recent World Bank review showed that over all primary health services account for 58% of public expenditure mostly but on salaries, and the secondary/ tertiary sector for about 38%, perhaps the greater part going to tertiary sector, including government funded medical education. Out of the total primary care spending, as much as 85% was spent on or curative services and only 15% for preventive service. <World Bank 1995> about 47% of total Central and State budget is spent on curative care and health facilities.

This may seem excessive at first sight but in face the figure is over 60% in comparable countries, with the bulk of the expenditure devoted publicly funded care or on mandated or voluntary risk pooling methods, in India close to *75%* of all household expenditure on health is spend from private funds and the consequent regressive effects on the poor is not surprising. In this connection. Ehe proposals in the draft NHP 2000 are welcome seeking to restore the key balance towards primary care, and bring it to internationally accepted proportions in the course of this decade.

Private Expenditure Trends

Many surveys confirm that when services are provided by private sector it is largely for ambulatory care and less for inpatient carte. There are variations in levels of cost, pricing, transactional conveniences and quality of services. There is evidence to suggest that disparities in income as such do not make a difference in meeting health care costs, except for catastrophic or life threatening situations Finally it has been established that between 2/3rds to 3/4ths of all medical expenditure is spend on privately provided care every household on the average spends up to 10%

NOTES

of annual household consumption in meeting health care needs. This regressive burden shows up vividly in the cycle of incomplete cure followed by recurrence of illness and drug resistance that the poor face in diseases like TB or Kalazar or Malaria especially for daily wage earners who cannot afford to be out of work.

Privatization has to be distinguished from private medical practice which has always been substantial within our mixed economy. What is critical however is the rapid commercialization of private medical practice in particular uneven quality of care. There are complex reasons for this trend. First is the high scarcity cost of good medical education, and second the reward differential between public and corporate tertiary hospitals leading to the reluctance of the young professional to be lured away from the market to public service in rural areas and finally there is the compulsion of returns on investment whenever expensive equipment in installed as part of practice.

Increasingly, this has shifted the balance from individual practice to institutionalizes practice, in hospitals, polyclinics,- Etc. this conjunction explodes into unbearable cost escalation when backed by a third party payer system/- This in turn induces increases in insurance premiums making such cover beyond the capacity to pay. There is a distinct possibility of such cycles of cost escalation periodically occurring in the future, promoted further by global transfer of knowledge and software, telemedicine etc. especially after the advent of predictive medicine and gene manipulation.

Doctors practicing in the private sector are sometimes accused of prescribing excessive, expensive and nsky medicines and with using rampant and less than justified use of technology for diagnosis and treatment. Some method of accreditation of hospitals and facilities and better licensure systems of doctors is likely within a decade. This will enables some moderation in levels of charges in using new technology. High cost of care is sometimes sought to be justified as necessary due to defensive medicine practiced in order to meet risks under the Consumer Protection Act.

There is little evidence from decisions of Consumer Courts to justify such fears. While the line between mistaken diagnosis and negligent behaviour will always remain thin, case law has already begun to settle around the doctor's ability to apply reasonable skills and not the highest degree of skill. What has lieen established is the right of the patient to question the treatment and procedures if there is failure to treat according to standard medical practice or if less than adequate care was taken. As health insurance gets established it may impost more stringent criteria and restrictions on physician performance which may tempt them into defensive medicine.

There may also be attempt to collusive capture and (indirect ownership) of insurance companies by corporate hospitals as in other countries. Advances in medical technology are rapid and dominant and easily travel world wide and often seen as good investment and brand equity in the private sector. Private independent practices - and to smaller extent hospitals, dispensaries, nursing homes are seen as markets for medical services with each segment seeking to maximize gains and build mutually supporting links with other segments. More than one study on the quality of care indicates that sometimes more services are performed to maximize revenue, and services/ medicines are prescribed which not always necessary . Allegations are

also widely made of collusive deals between doctors and hospitals with commissions and cuts exchanged to promote needless referral, drugs or procedures. Appropriate regulation is likely in the next decade for minimum standards and accountability and that should consist of a balanced mix of self regulation external regulation by standard setting and accreditation agencies including private voluntary health insurance.

How Far Can Health Insurance Help?

What constitutes a fair distribution of the costs of care among different social groups will always be a normative decision emerging out of political debate. It includes risk pooling initiatives for sharing costs among the healthy and the sick leading to insurance schemes as a substitute for or as supplementary to State provision for minimum uniform services. It also covers risk sharing initiatives across wealth and income involving public policy decisions on progressive taxation, merit subsidy and cross subsidization by dual pricing. Both will continue to be necessary in our conditions with more emphasis on risk sharing as growth picks up. Risk pooling within private voluntary and mandated insurance schemes has become inevitable in all countries because of the double burden of sickness and to ensure that financial costs of treatment do not become an excessive burden relative to incomes. It is difficult but necessary to embed these notions of fair financing into legislation, regulations and schemes and programs equity is aimed at in health care.

With the recent opening up of the general Insurance sector to foreign companies, there is the prospect of two trends. New insurance product will be putout so expand business more be deepening than widening risk covered. The second trend would be to concentrate on urban middle and upper classes and settled iobholders with capacity to pay and with a perceived interest in good health of the family. Both trends make sound business sense in a vast growth market and would increase extensive hospital use and protection against huge hospitalization expenses, and promoted by urban private hospitals since their clientele will increase.

Insurance is a welcome necessary step and must doubtless expand to help in facilitating equitable health care to shift to sections for which government is responsible. Indeed for those not able to access insurance it is government that will have to continue to provide the minimum services, and intervene against market failures including denial through adverse selection or moral hazard. Indeed in the long run the degree of inequity in health care after insurance systems are set up will depend ironically on the strength and delivery of the public system as a counterpoise in holding costs and relevance in technology.

The insurable population in India has been assessed at 250 million and at an average of Rs 1000/- per person the premium amount per year would be Rs 25,000/- crores and is expected to treble in ten years- While the insurance product will dutifully reflect the demands of this colossal market and related technological developments in medicine, it should be required to extend beyond hospitalization and cover domiciliary treatment too in a big way; for instance, extending cover to ambulatory maternal and selected chronic conditions like Asthma more prevalent among the poor. The insurance regulatory authority has announced priority in licensing to companies set up with health insurance as key business and has

emphasized the need for developing new products on fair terms to those at risk among the poor and in rural areas. Much will turn on what progress takes place through sound regulation covering aspects indicated below. In order to be socially relevant and commercially viable the scheme must aim at a proper mix of health hazards and cover many broad social classes and income groups.

This is possible in poor locations or communities only if a group view is taken and on chat basis a population- based nsk *is* assessed and community rated premiums determined covering families for all common illnesses and based on epidemiological determined risk. In order that exclusions co-payments deductibles etc. remain minimum and relevant to our social situation, some well judged government merit subsidy can be incorporated into anti poverty family welfare or primary education or welfare pension schemes meant for old age. Innovative community based new products can be developed by using the scattered experience of such products for instance in SEWA, so that a minimum core cover can be developed as a model for innovative insurance by panchayats with reinsurance backup by companies and government bearing part of promotional costs.

The bulk of the formal sector maybe covered by an expanded mandatory insurance with affordable cover and convenient modes of premium payment. Outside the formal manufacturing sector innovate schemes can be designed around specific occupation groups in the informal sector which are steadily becoming a base for old age pension entitlements, as in Kerala and Tamil Nadu - and brought under common risk rating. Finally, as in the West health insurance should develop influence and capacity as bulk purchaser or medical and hospital services to impact on quality and cost and provide greater understanding about Indian health and illness behaviours, patterns of utilization of care and intra family priorities for accessing medical care. Health insurance should be welcomed as a force for a fairer healthcare system. But its success should be judged on how well new products are developed with a cover beyond hospitalization, how fairly and inclusively the cover is offered and how far community rated premiums are established. The IRDA has an immense responsibility and with its leadership one can optimistically expect about 30% coverage by 2015 relieving the burden on the public systems.

Health Perceptions and Plural Systems:

Health perceptions play an important part in ensuring sound health outcomes. To a large extent they are culturally determined but also subject to change with economic growth and social development. People intuitively develop capacity to make choices tor being treated under the western of indigenous systems of medicines, keep a balance between good habits traditionally developed for healthy living and modem lifestyles, decide on where to go for chrome and acute care and how to apportion intra-family utilization ofhealthcare resources. The professional is generally bound by his discipline and its inherent logic of causation and effect and tends to discount even what work as successful practice, I fit does not fall within the accepted understanding of his profession.

Some movement is occurring among eminent allopathic doctors trying, for instance, to rework Ayurveda theory in a modem idiom starting from respectful

reverse analysis for actual successful contemporary practice of Ayurveda and provide a theoretical frame linking it to contemporary needs. There is evidence from public health campaigns in Tamil Nadu where every seventh person spontaneously expressed a preference for Sidda Medicine. Homeopathy for chronic ailment is widely accepted. The herbal base for Ayurvda medicine widely practiced in the Himalayan belt has down world attention a huge export market remains to be tapped according to the knowledgeable trade sources but the danger of bio-privacy remains and legal enablements should be put in place soon that would fully expand on our rights under the WTO agreements.

The draft national policy on ISI v IH has attempted to place these plural systems in a modem service delivery and research and education context, it has covered its natural resource base, traditional knowledge base and development of institutions to carry a national heritage forward. There is hope for the survival and growth of the sector only if it becomes an example of convergence between people's and planner's perceptions and ensure its relevance, accountability and affordability to contemporary illnesses and conditions.

At the same time it is undeniable that there is much cross practice by ISM practitioners which usually include prescriptions we western medicine as part of indigenous treatment Appropriate regulation is needed to protect people from fraud and other dangers but the larger question is how to make the perceptions of the professionals and planners regarding indigenous system of medicine less ambivalent. The separate department for ISM&H should be able to bring about functional integration of ISM and western medicine in service delivery at PHC levels by 2005 whereby it will usher in an uniquely Indian system of care.

Emerging Scenario

What then can we conclude about the prospects of health care in India in 2020? An optimistic scenario will be premised on an average 8% rate of economic growth during this decade and 10% per annum thereafter- If so, what would be the major fall out in terms of results on the health scene? In the first place, longevity estimates can be considered along the following lines. China in 2000 had a life- expectancy at birth of 69 years (M) and 73(F) whereas India had respectively 60 (M) and 63 (F). More importantly, healthy life expectancy at birth in China was estimated in the World Health Report 2001 at 61 (M) and 63.3 (F) whereas in Indian figures were 53 (M) and 51.7 (F).

If we look at the percentage of life expectancy years lost as a result of the disease burden and effectiveness of health care systems, Chinese men would have lost 11.6 years against Indian men losing 12.7 years. The corresponding figures are 13.2 for Chinese women and 17.5 for Indian women. Clearly, an integrated approach is necessary to deal with avoidable mortality and morbidity and preventive steps in public health are needed to bridge the gaps, especially in regard to the Indian women. Taking all the factors into consideration, longevity estimates around 20-25 could be around 70 years, perhaps, without any distinction between men and women.

This leads us to the second question of the remaining disease burden in

NOTES

communicable and non-communicable diseases, the effective of interventions, such as, immunization and maternal care and the extent of vulnerability among some groups. These issues have been death with in detail earlier. Clearly an optimistic forecast would envisage success in polio, yaws, leprosy, kalazar t'ilaria and blindness. As regards TB it is possible to arrest further growth in absolute numbers by 2010 and thereafter to bring it to less than an million withm internationally accepted limits by 2020. With regard to Malaria, the incidence can be reduced by a third or even upto half within a decade. In that case, one can expect near freedom from Malaria from most of the countries by 2020.

As regards AIDS, it looks unlikely that infection can be leveled of by 2007. The prognosis in regard to the future shape of HIV / AIDS is uncertain. However, it can be a feasible aim to reduce maternal mortality from the present 400 to 100 per lakh population by 2010 and achieve world standards by 2020. As regards child health and nutrition, it is possible to reach IMRV30 per thousand live births by 2010 in most parts of the country though in some areas, it may take a few years more. What is important is the chance of two thirds decline in moderate malnutrition, and abolition of serious malnutrition completely by 2015 in the case of Cancer, it is feasible to set up an integrated system for proper screening, early detection, self care and timely investigation and referral. In the matter of disease burden as a whole, it is feasible to attempt to reach standards comparable to china from 2010 onwards.

Taking the third aspect viz fairness in financing of health care and reformed structure of health services, an optimistic forecast would be based on the fact that the full potential of the vast public health infrastructure would be fully realized by 2010. its extension to urban areas would be moderated to the extent substantial private provision of health care is available in urban areas, concentrating on its sensible and effective regulation. A reasonably wide network of private voluntary health insurance cover would be available for the bulk of the employed population and there would be models of replicable community based health insurance available for the unorganized sector.

As regards the private sector in medicine, it should be possible in the course of this decade to settle the public role of private medical practice - independent or institutional. For this purpose, more experiments are to be done for promoting public private partnerships, focusing on the issue of how to erect on the basis of shared public health outcome as the key basis for the partnership. A sensible mixture of external regulation and professional self-regulation can be device in the consultation with the profession to ensure competence, quality and accountability. The future of plural systems in medical understanding and evaluation of comparative levels of competence and reliability in different systems - a task in which, the separate department for Indian systems of medicine and homeopathy will play a leading role in inducting quality into the indigenous medical practices.

The next issue relates to the desirable level of public expenditure towards health services. China devotes 4.5% to its G-DP as against India devoting 5.1%. but this hides the fact that in China, public expenditure constitutes 38% whereas in India, it is only 1S% of total health expenditure. An optimistic forecast would be that the level of public expenditure will be raised progressively such that about 30% of total

health expenditure would be met out of public funds by progressively increasing the health budget in states and the central and charging user fees in appropriate cases. The figure mentioned would perhaps correspond to the proportion of the population which may still need assistance is social development.

Finally it is proper to remember that health is at bottom an issue in justice. It is in this context that we should ask the question as to how far and in what way has politics been engaged m health care? The record is disappointing. Most health sector issues figuring in political debate are those that affect interest groups and seldom central to choices in health care policy. For instance conditions of service and reward systems for Government doctors have drawn much attention often based on inter service comparison of no wider interest. Inter-system problems of our plural medical care have drawn more attention from courts than from politics.

Hospital management and strikes, poor working of the MCI and corruption in recognition of colleges, dramatic cases of spurious drug supply etc have been debated but there has been no sustained attention on such issues as why malaria recrudescence is so common in some parts of India or why complaints about absence of informed consent or frequent in testing on women, or on the variations in prices and availability of essential drugs or for combating epidemic attacks in deprived areas seldom draw attention. The far reaching recommendations made by the Hathi Committee report and or the Lentin Commission report, have been implemented patchily.

The role to be assigned to private sector in medicine, the need for a good referral system or the irrationality in drug prescriptions and sue have seldom been the point of political debate. Indeed the lack luster progress of MNP over the Plans shows political disinterest and the only way for politics to become more salient to the health of the poor and the reduction of health inequalities is for a much greater transfer of public resources for provision and financing - as has happened in the West, not only in UK or Canada but in the US itself with a sizable outlay on Medicaid and Medicare.

4.6 HEALTH CARE INFRASTRUCTURE

Healthcare has become one of India's largest sectors - both in terms of revenue and employment. The industry comprises hospitals, medical devices, clinical trials, outsourcing, telemedicine, medical tourism, health insurance and medical equipment. The Indian healthcare industry is growing at a tremendous pace due to its strengthening coverage, services and increasing expenditure by public as well private players.

The Indian healthcare delivery system is categorised into two major components - public and private. The Government i.e. public healthcare system comprises limited secondary and tertiary care institutions in key cities and focuses on providing basic healthcare facilities in the form of primary healthcare centers (PHCs) in rural areas. The private sector provides majority of secondary, tertiary and quaternary care institutions with a major concentration in metros, tier I and tier II cities.

India's primary competitive advantage over its peers lies in its large pool of well-trained medical professionals. Also, India's cost advantage compared to peers in Asia and Western countries is significant - cost of surgery in India is one-tenth of that in the US or Western Europe.

Market Size

The Indian healthcare industry is projected to continue its rapid expansion, with an estimated market value of US$ 280 billion by 2020, on the back of increased population growth in India's low income communities.

Large investments by private sector players are likely to contribute significantly to the development of India's hospital industry and the sector is poised to grow to US$ 100 billion by the year 2015 and further to US$ 280 billion by 2020.

Private sector's share in healthcare delivery is expected to increase from 66 per cent in 2005 to 81 per cent by 2015. Private sector's share in hospitals and hospital beds is estimated at 74 per cent and 40 per cent, respectively.

The diagnostic market is the fastest growing segment of India's healthcare industry, according to PricewaterhouseCoopers (PwC), with the segment forecasted to grow to US$ 17 billion by 2021.

Investment

Healthcare providers in India are expected to spend US$ 1.1 billion on IT products and services in 2014, an increase of 5 percent over 2013, according to Gartner.

According to data released by the Department of Industrial Policy and Promotion (DIPP), hospital and diagnostic centres attracted foreign direct investment (FDI) worth US$ 2,494.98 million between April 2000 and September 2014.

Some of the major investments in the Indian healthcare industry are as follows:

- Sequoia Capital has planned to invest Rs 100 crore (US$ 15.75 million) in Curatio Healthcare, which is among the fastest growing entrepreneurial-led healthcare ventures in India.
- Narayana Health has planned to buy out Westbank Hospital for around Rs 200 crore (US$ 31.5 million). This move would help Narayana Health to increase its presence in the eastern part of the country.
- Trivitron Healthcare has acquired Mumbai-based imaging accessories manufacturer Kiran Medical Systems, and Imaging Products (India) Pvt Ltd (IPI).
- GPT Healthcare Pvt Ltd, a Kolkata-based company which operates a chain of hospitals, has raised an undisclosed amount in private equity funding from BanyanTree Growth Capital.
- UniverCell plans to foray into the health and fitness category by launching a wireless health monitor, B.O.L.T in collaboration with American Megatrends India. The device interprets the body's vital information and lets a user access it through a specially designed cloud enabled smart app.
- Sterling Group of Hospitals has entered into a joint venture with India Home Health Care (IHHC) to set up Asilia Home Healthcare that would cater home healthcare services segment.

Government Initiatives

India's universal health plan that aims to offer guaranteed benefits to a sixth of the world's population will cost an estimated Rs 1.6 trillion (US$ 25.2 billion) over the next four years.

Under the National Health Assurance Mission, Prime Minister Mr Narendra Modi's government would provide all citizens with free drugs and diagnostic treatment, as well as insurance cover to treat serious ailments.

All the government hospitals in Andhra Pradesh would get a facelift with a cost of Rs 45 crore (US$ 7.09 million), besides establishing 1000 generic medical shops across the State in a few months.

The Central Government has requested the Government of Odisha for allotment of 25 to 30 acres of land for setting up a satellite centre of the All Indian Institute of Medical Sciences (AIIMS) Bhubaneswar as a super specialty healthcare facility.

India and Maldives signed three agreements. The pacts included a MoU on health cooperation.

The Union Cabinet has approved the proposal for setting up of National Cancer Institute (NCI) at a cost of Rs 2,035 crore (US$ 320.66 million). NCI will be set up in the Jhajjar campus (Haryana) of AIIMS, New Delhi. The project is estimated to be completed in 45 months.

Road Ahead

The outlook for the Indian healthcare industry looks positive owing to high growth rate in almost all its segments, whether its primary healthcare, secondary and tertiary healthcare, medical equipment, diagnostics, health insurance or medical tourism. The ever growing population, increasing government expenditure on health and growing per capita income will increase the size of this industry in the years to come.

Per capita income is expected to increase at a CAGR of 5.7 per cent over 2012-18. Rising incomes mean a steady growth in the ability to access healthcare and related services. Moreover, changing demographics will also contribute to greater healthcare spending; this is likely to continue with the size of the elderly population set to rise from the current 96 million to about 168 million by 2026. However, growing health awareness and precautionary treatments coupled with improved diagnostics will result in decreasing hospitalisation.

The medical tourism market in India is projected to hit US$ 3.9 billion mark this year having grown at a compounded annual growth rate (CAGR) of 27 per cent over the last three years, according to a joint report by consultancy firm KPMG and an industry body. The report says inflow of medical tourists is expected to cross 320 million by 2015

4.7 HEALTH INFRASTRUCTURE IN INDIA

With a population of 1.15 billion, and growing at almost 18 million per year, India will be the most populous nation by 2030, with as many as 1.4 billion or more inhabitants. Rapid urbanisation is a reality in India with the opening up of the markets and improved INVESTMENT opportunities. Urban centres offer better avenues for employment opportunities and reflect the transition from an agriculture-based society to a modern one. The number of urban agglomerations/ towns has grown from 1,827 in 1901 to 5,161 in 2001.

With 340 million Indians living in our 5,161 cities and forming 30 per cent of the total population (urban GDP accounts for 58 per cent and is projected to rise to

70 per cent by the year 2030), our annual spend in per capita terms in urban areas is only $17. The Eleventh Five-Year Plan envisioned Indian cities to be the engine of economic growth over the next two decades. However, Indian cities have to be more liveable, bankable and competitive in the years to come to match with the projected economic growth. Unfortunately, infrastructure development in Indian cities is paltry and requires focused attention. The double digit growth rate that the country envisions in the coming decade faces immense infrastructural bottlenecks in cities. The larger cities attained inordinately large population sizes that have led to virtual collapse of urban services, followed by basic problems in housing, slum, water, infrastructure, quality of life, and other related aspects.

Water, sanitation, sewerage, urban transport, city energy distribution, transport terminals, warehousing and logistics parks fall under the urban infrastructure category. Ancillary to the urban development is social infrastructure that includes healthcare, education, leisure and entertainment, retail, tourism, housing, exhibition and convention centres, hospitality, IT, and telecom.

Facts and Figures

Health plays an important role in the development of any society. Unfortunately, health infrastructure and health scenario in India is very poor. In 2002, the World Bank reported: "Irrespective of income class, one episode of hospitalisation is estimated to account for 58 per cent per capita annual expenditure, pushing 2.2 per cent of the population below the poverty line. Even more disconcerting is the fact that 40 per cent of those hospitalised had to borrow money or sell off assets." Even after a decade, the story remains the same. This is largely due to the lack of supply in the health sector. Urbanisation has resulted in migration of people from villages to cities. This increased population in urban areas has put a strain on the health sector. Lack of infrastructure development in housing, waste management, slum rehabilitation, and drinking water has had a definite impact on the overall health index of cities. This has strained the existing resources, stressed the available healthcare infrastructure, and choked the overall urban system.

Across the country, the bed-to-people ratio is 1:422. The existing record of Government hospitals is worse; one bed for 2,239 persons (WHO recommends a minimum of three beds per 1,000 people). Thirty five per cent of patients in private hospitals belong to lower income groups (those that earn less than Rs 10,000 a month). Eighty five per cent of these patients do not have any insurance cover, while 42 per cent visit private facilities in nearby rural areas. According to studies conducted by FICCI, about 7-8 per cent of households are pushed below the poverty line due to expenses incurred on health care. These facts point to critical gaps in infrastructure, especially with respect to the availability of healthcare centres and well-trained staff.

Shortage of staff: According to Planning Commission reports, India faces a shortage of about 6,00,000 doctors, one million nurses, 2,00,000 dental surgeons and a large number of paramedical staff. Currently, private healthcare expenditure amounts to around 4.2 per cent of the GDP, making India one of the highest ranking countries in terms of private expenditure on health.

Lack of hospitals: Increase in the number of hospitals in emerging cities

needs special attention. Affordable essential drugs, medical equipment, and tests and surgeries, are also necessary. This can become a reality only with the support of all stakeholders, which include Government agencies, private initiatives, entrepreneurs, pharmaceutical companies, and insurance companies. An affordable and effective health insurance scheme for all citizens, among other things, can recourse these challenges.

Need for more beds: In India, hospitals are mostly located in metropolitan cities, and not in rural areas or emerging cities. The current strength of hospital beds is about 7 lakh and another 7 lakh needs to be added in the next 10 years. Ideally, it needs to be four beds per 1,000 people, keeping in mind the sheer geographical spread of the country and the geography's varied population density.

According to a study conducted by Technopak, for a modest Rs 40 lakh direct INVESTMENT per bed, India will need to INVEST a minimum of Rs 8,00,000 crore over the next 20 years to establish two million new beds, and as much as Rs 20,00,000 crore (over $400 billion) if it wishes to reach the four-bed-per-1,000-people norm. The sector will have to see direct employment of over 25 million persons, and an indirect employment of as many as 75-100 million.

Of these, as many as 2.5 to 3 million will be qualified doctors alone, and another 5-6 million nursing staff. At about three million functioning beds by 2030, the revenue of healthcare service providers alone would be over $400 billion. Two million additional beds will require almost two billion square feet of additional constructed space, providing a huge fillip to the construction sector, while the business opportunity for medical equipment suppliers will be in excess of $100-125 billion.

Predicted growth: Healthcare has emerged as one of the most progressive and largest service sectors in India with an expected GDP spend of 8 per cent by 2012 from 5.5 per cent in 2009. It is believed to be the next big thing after IT, and is expected to become a $280 billion industry by 2020. Increase in personal income, government healthcare outlays and private domestic investments, combined with longer life expectancy is predicted to lead to annual average growth in healthcare spending of around 14 per cent in the forecast period. This is possible only with the help of public and private stakeholders alike. Free market environment, a developed industry and investment in health infrastructure are amongst other factors that will result in such growth. "Health infrastructure across Indian states is projected to grow by an average of 5.8 per cent per annum between 2009 and 2013, taking the total expenditure in 2013 to $14.2 billion," says global consultancy KPMG in its report on India's healthcare sector. Of the 32 states under review, Maharashtra, Rajasthan, West Bengal, Uttar Pradesh, Tamil Nadu and Andhra Pradesh will represent approximately 50 per cent of the expenditure, KPMG said. The Indian healthcare industry was estimated to double in value by 2012 and more than quadruple by 2017. All these facts indicate hidden opportunities in healthcare infrastructure.

Suggestions

- Government hospitals are not a solution to the present problem. To tackle the above mentioned challenges, private hospital chains should set base in emerging cities to provide health-related infrastructure.

- The Government should come up with investment-friendly policies in the health sector. Tax holidays, land bank to support builders of hospitals, special interest rates and loans from banks, benefits for setting up of private practices, hospitals, diagnostic centres and pharmaceuticals, can change the face of healthcare infrastructure in India. In the developed market, health insurance companies can compete with each other. They can also negotiate with hospitals for the quality of services offered to the patients. Eventually, a better competitive market will reduce costs and result in better services.
- One cannot ignore the possibilities of Medical Tourism. It is considered to be a supplementary market emerging within the urban health portfolio. India is emerging as a popular medical tourism destination, thanks to its relatively low costs and better success rates. It is reported that the cost of treatment in India is one fifth of that of the US. Development in Medical Tourism depends on the advancement in health infrastructure in India. The revenue earned from Medical Tourism could help subsidise medical costs for poorer patients.
- Easing of regulations in opening and governing of medical colleges is another policy change warranted in this sector.
- Better compilation of per capita expenditure data of patients and availability of beds at the regional or local levels within states can help investors set up hospitals for the needy. The Government should demarcate health circles and priority areas for intervention, based on available information, indexed with health standards of each particular area.
- A major bottleneck for entrepreneurs who seek to enter the health market is the lack of access to banking, to raise the required capital. Health Circles can be auctioned, similar to the mobile phone market, ensuring fair competition amongst bidders and financial support from the Government.
- Policies governing health infrastructure need to be in black and white, and not left to the discretion of the Government. Improved urban health infrastructure is definitely the need of an emerging urban economy like India. This should be met to help the majority of patients in emerging cities across India. With 60-80 per cent of healthcare sought in the private sector, and households contributing 4-6 per cent of their incomes to the same, there will be a whopping Rs 400-600 billion healthcare market in India by 2040.

4.8 REALITY OF HEALTHCARE IN RURAL INDIA

Healthcare is the right of every individual but lack of quality infrastructure, dearth of qualified medical functionaries, and non- access to basic medicines and medical facilities thwarts its reach to 60% of population in India. A majority of 700 million people lives in rural areas where the condition of medical facilities is deplorable. Considering the picture of grim facts there is a dire need of new practices and procedures to ensure that quality and timely healthcare reaches the deprived corners of the Indian villages.

Though a lot of policies and programs are being run by the Government but the success and effectiveness of these programs is questionable due to gaps in the implementation. In rural India, where the number of Primary health care centers

(PHCs) is limited, 8% of the centers do not have doctors or medical staff, 39% do not have lab technicians and 18% PHCs do not even have a pharmacist.

India also accounts for the largest number of maternity deaths. A majority of these are in rural areas where maternal health care is poor. Even in private sector, health care is often confined to family planning and antenatal care and do not extend to more critical services like labor and delivery, where proper medical care can save life in the case of complications.

The Problems

Due to non accessibility to public health care and low quality of health care services, a majority of people in India turn to the local private health sector as their first choice of care. If we look at the health landscape of India 92 percent of health care visits are to private providers of which 70 percent is urban population. However, private health care is expensive, often unregulated and variable in quality. Besides being unreliable for the illiterate, it is also unaffordable by LOW INCOME rural folks.

To control the spread of diseases and reduce the growing rates of mortality due to lack of adequate health facilities, special attention needs to be given to the health care in rural areas. The key challenges in the healthcare sector are low quality of care, poor accountability, lack of awareness, and limited access to facilities.

Various organizations are coming together for improvements in health care and technology plays a crucial role to facilitate this. Information and communications Technology provides hosts of solutions for successful implementation of these changes.

Technology for Rural Health Care

Several organizations are working alongside the government and NGOs to help relieve the burden on the public health system using mobile technology. India has over 900 million mobile phone users and this fact can be leveraged to employ better practices in even the remote areas. Leading global organizations of healthcare industry are using our mobile technology to enhance the quality of care and bridge the gaps in healthcare services.

NOTES

Gram Vaani provides cutting- edge mobile and IVR solutions to automate processes and applies best practices in the field. Our services cater to health care sector, social sector, and corporate organizations for connecting with the difficult to reach markets at bottom of the pyramid.

We have built simple technologies on mobile to suit the needs of different sectors and verticals. By improving the systems and functions of our clients we have impacted thousands of lives in rural India. Through mobile and IVR services we have an extensive reach across the demography. Our initiative is focused on delivering best tools and solutions to our partners for reaching out to the rural markets and gives a platform to be directly connected to them. Leading global organizations of healthcare industry are using our technology to enhance the quality of care and bridge the gaps in healthcare services in rural India.

Improving Healthcare on the Ground

We are employing mobile technology in several healthcare projects for leading global organizations. In partnership with the White Ribbon Alliance for Safe Motherhood, for a program of Merck for Mothers, we are working to upgrade the quality of maternity healthcare in India. There's growing evidence from developing countries confirming that patient's perception of quality of care and satisfaction with care are critical to utilization of health services. To this end, we are building a quality-of-care checklist for expectant mothers (and their families) to answer using mobile phones and rate on factors such as whether they were treated with respect during the delivery, whether they got entitlement for institutional delivery, whether the transportation provided was of good quality, etc.

This tool is constructive for:

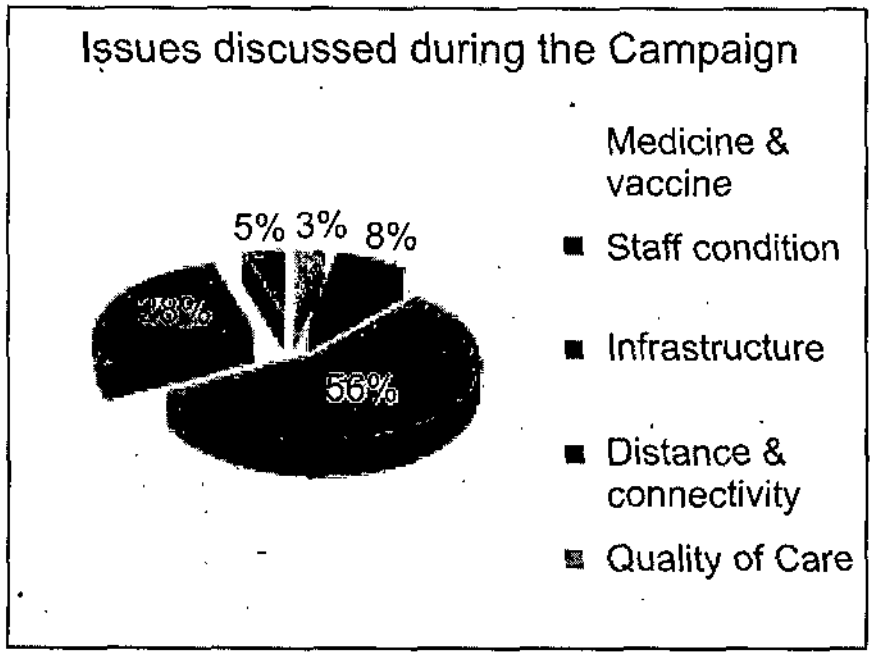
- Making women aware of their rights to demand good quality of care,
- Bringing accountability by highlighting lapses in the health delivery process, and,
- Increasing uptake of appropriate health services at the right venues

As a part of another healthcare program Ananya in Bihar, with NGO's PATH and PCI, we are mobilizing communities using our voice technologies to demand greater accountability from the health delivery infrastructure. Through simple education and discussion programs on mobile we make the marginalized communities aware of best practices in healthcare and sanitation, and about their rights and entitlements from the health delivery system. The community members are encouraged to engage and share their stories with each other on our open mobile platform, and to demand grievance redressal and accountability from the health system.

Campaigns for Healthcare Accountability

In association with Grand Challenges Canada, we conducted a Health campaign to review health services for accountability in Jharkhand. In this campaign on Mobile Vaani we invited opinions, experiences, information and feedback from public on current Government health facilities in Jharkhand.

People from different districts of Jharkhand left messages on various issues in health care facilities, such as; health facilities available at PHCs, Laboratory testing and Delivery facilities at Government Health Centers, availability of clean toilet and drinking water at PHCs, and distance of the nearest health center from the Village.



Within the first 4 weeks of the campaign, more than 1600 callers from 12 districts of Jharkhand called in and participated. Lot of important facts were brought forward in the campaign. 50 percent of the people informed that there was no facility of Laboratory Investigation or Delivery available at their nearest Health Centers. While a total of 86 percent callers shared that the facility of drinking water and public toilet was not available in the Government Health centers.

The campaign enabled us to:

NOTES

- Understand the present scenario of health facilities in Jharkhand
- Identify major issues that people are facing while seeking health services.
- Review the state of PHC infrastructure and its connectivity to nearby villages
- Build awareness about accountability in health care

To bring about a change in the existing healthcare system we took the voices of people to the Government authorities. We collated data from our campaign and communicated the real picture to the district collectors and state health department for action.

Other Campaigns on Mobile Vaani

Social campaigns conducted on Mobile Vaani platform are an initiative to identify, understand and get solutions for public problems and social issues. The campaigns are active discussions where the community members are engaged to contribute their views about various issues, and our team helps coordinate these discussions into manageable threads. We have done campaigns on various issues and received tremendous response on our voice based medium on mobile phone, much higher than simple broadcast of information on radio or television. The results for information dissemination and call-to-action through these campaigns have been phenomenal.

We have done the following social campaigns so far:

- Campaign to review health facilities in Jharkhand, supported by Grants Challenges Canada, April 2013
- Campaign on gender equality, to close the gap, with Oxfam India and Oursay, March 2013
- Campaign on rural-urban migration, February 2013
- Galli Galli Sim Sim feature with Sesame Workshop, January 2013
- Water conservation campaign, December 2012
- AIDS campaign, November 2012
- Para teachers' strike, October 2012

Gram Vaani Technologies for advanced Healthcare delivery

Gram Vaani has built innovative voice applications for organizations working in health care sector to automate and manage their processes efficiently. Our vAutomate suite of technologies provides host of services, including the following mobile technologies that can be used for better rural health care delivery in several ways:

- vSurvey: Organizations can create a custom questionnaire containing multiple-choice-questions, quantitative input questions, and qualitative audio recordings, that can be broadcast to different contact groups. For example: a network of ASHA workers (community health workers) can be sent a survey to capture self-reported data on the number of visits they did; similarly, AWWs (Aanganwadi Workers) can be sent a survey to get data on the number of children that were fed, the menu that was served, and if they are running out of ration supply and need to alert the district authorities.
- vInform: Organizations can build an audio pack with a series of tutorial messages, which can be played out over a phone call to a desired contact group. For example, ASHAs or AWWs, could be sent messages on best practices to follow during ante-natal care, danger signs to look out for, and ensure that they take expectant mothers for institutional delivery.
- vAnswer: As an extension to vInform technology, the users can also ask questions, which can be answered by experts. Thus, if ASHAs or AWWs have any questions or concerns, they can record their message which can be answered by experts live or through recordings over the phone.

We customize these services and solutions as per our client's needs and devise ways to reach 'under-served' communities and 'out of reach' markets.

Gram Vaani started in 2009 with the intent of reversing the flow of information, that is, to make it bottom-up instead of top-down. Using simple technologies and social context to design tools, we have been able to impact communities at large -more than 2 million users in over 7 Indian States, Afghanistan, Pakistan, Namibia and South Africa. More interesting than this are the outcomes of what we have done: Forty rural radio stations are able to manage and share content over mobiles and the web, corrupt ration shop officials in Jharkhand were arrested due to citizen complaints made on our platform, Women Sarpanches in Uttar Pradesh shared learning and opinions on their work with senior government officials, and citizens were able to monitor and report on waste management in 18 wards of Delhi to hold MCD officials accountable for their work. We work with organizations all across India and in other developing parts of the world.

We have won several awards including the following:

- International Knight News Challenge, 2008
- National Level Manthan Award for technology for development, 2009
- Economic Times Powers of Ideas, 2010
- Profiled in the top-10 innovative companies of India by Fast Company, 2011

- mBillionth Award in the news and journalism category, 2012
- Canada Rising Stars in Health award, 2012
- Finalist in Ashoka Changemakers 2012 and Vodafone Mobiles for Good 2012 contests

4.9 STUDENT ACTIVITY

1. Discuss the MAJOR DISEASE CONTROL EFFORTS.
2. Describe HEALTH INFRASTRUCTURE IN THE PUBLIC SECTOR.
3. Explain Health care infrastructure.
4. What are the Reality of Healthcare in Rural India?

4.10 SUMMARY

- The GOI Report of the National Commission on Macroeconomics and Health (2005) states that the principal challenge for India is building a sustainable healthcare system. Selective, fragmented strategies and lack of resources have made the health system unaccountable, disconnected to public health goals, inadequately equipped to address people's growing expectations and inability to provide financial risk protection to the poor.
- Apart from the private players, many civil society organizations (CSOs) have also entered the arena of healthcare delivery. Most often, the CSOs partner either with the government or the private players to deliver health services. There is also a partnership between the state or the public health institutions and the private organizations.
- The contemporary National Health Policy (NHP) of India, formulated in the year 2002, and the ambitious NRHM formulated for the period 2005-2012, takes into consideration the vital role that is being played by private players and civil society organizations and recommends further partnerships.
- The Indian Policy welcomes the participation of the private sector in all areas of health activities - primary, secondary or tertiary. However, looking to past experience of the private sector, it can reasonably be expected that its contribution would be substantial in the urban primary sector and the tertiary sector, and moderate in the secondary sector.

4.11 GLOSSARY

- Health and health care need to be distinguished from each other for no better reason than that the former is often incorrectly seen as a direct function of the

latter. Heath is clearly not the mere absence of disease. Good Health confers on a person or groups freedom from illness - and the ability to realize one's potential.

- The first set of consequences was inadequate priority to public health, poor investment in safe water and samtati on and to the neglect of the key role of personal hygiene in good health, culminating in the persistence of diseases like Cholera.
- Programme of immunization and childhood nutrition seen in better performing stats indicate sustained attention to routine and complex investments into growing children as a group to make them grow into persons capable of living long and well Often interest fades in pursuing the unglamorous routine of supervised immunization and is substituted by pulse campaigns etc.
- The difference between rural and urban indiactors of health status and the wide interstate disparity in health status are well known. Clearly the urban rural differentials are substantial and range from childhood and go on increasing the gap as one grows up to 5 years.

4.12 REVIEW QUESTIONS

1. What are the HEALTH FINANCING ISSUES?
2. How far can health insurance help?
3. Explain Health Infrastructure in India.
4. Describe the Technology for Rural Health Care.
5. Write short note on:
   (a) GOI
   (b) NHRM
   (c) OECD
   (d) NSSO
   (e) OPD

UNIT

5

HEALTH CARE AGENCIES

NOTES

STRUCTURE

NOTES

5.0 LEARNING OBJECTIVES

After completion of the unit, you will be able to:

- Understand the function of National health care agencies and Indian red cross / society
- Describe hind kusht nivaran singh, kasturba memorial fund,
- Explain Indian council for child welfare, family planning association of India
- Discuss tuberculosis association of India
- Describe central social welfare board, all India women's conference
- Explain UNICEF, WHO, UNDP, World Bank, CARE

5.1 INTRODUCTION

Home health care companies offer a wide range of skilled medical services such as nursing care, physical therapy and occupational therapy from qualified medical professionals in addition to various services from home health aides. Other home care companies might offer assistance with daily activities, such as bathing and eating. Home care services are conducted in the comfort of your home.

5.2 NATIONAL HEALTH CARE AGENCIES

Doing so often means looking at things in a completely new way, turning your back on the norm to come up with the innovative, the radical, the unexpected. This is something that Steria knows a lot about. It's how we've been helping governments across the world provide health services for over 20 years. Our breakthrough IT and process innovations help health agencies easily and cost-effectively achieve more, for more patients.

Our public healthcare clients partner with us to derive a range of benefits including:

- Optimised management of health resources from the national/regional level downward
- Outsourcing of back office services so that the organisation can stay focused on business objectives
- Effective management of the exchange of healthcare services
- Improved citizen service by linking and compiling healthcare data under one unique patient ID

As an independent organisation, we are able to implement and interoperate multiple market e-Health platforms. Our clients can, in effect, use us as a one-stop-shop for both their business and IT needs, from consulting to implementation and further maintenance, plus specialised health business process and IT support and infrastructure management.

NOTES

Co-Operating to Cut Costs and Deliver Quality

NHS Shared Business Services (NHS SBS) is the first ever joint venture and shared business service between the UK Department of Health and a commercial company. NHS SBS manages a wide range of business support functions and healthcare information systems for around 130 health service organisations right across the UK. This means they can all focus single-mindedly on the quality of health services delivered. According to Paul Baumann, Director of FINANCE and Performance at the NHS London Strategic Health Authority, 'This approach is making a significant difference and as more of our organisations join the partnership with NHS SBS, the more efficient we become and the better equipped we are to tackle the challenges of the future." Because NHS SBS is run as a joint-venture by the Department of Health and Steria, the Department of Health is able to reinvest its share of the venture's profits back into the NHS.

Putting Health Resources Where People Really Need Them

Created and delivered by Steria in Spain, the Civitas® Enterprise Master Person Index (EMPI) is a complete health resource planning solution for nine communities and two cities covering more than 20 million insured individuals. Civitas® is a highly sophisticated database-driven analytical tool that enables the accurate identification of each individual, linking patient data across every healthcare outlet, from hospitals and surgeries to outpatient centres and rehabilitation facilities. On a strategic level, it also analyses the distribution of population to ensure resources are available where people actually need them.

Bringing Patients Straight to the Services They Need

The Cohesion Funds solution manages the exchange of patients between 17 Spanish autonomous communities, ensuring that each person receives the best available treatment no matter where they live. All cross-charging between the communities is handled. This is very much in line with interoperability objectives in public healthcare provision. Steria's experience with Cohesion Funds and Civitas® solutions combined are helping to move organizations into the Universal Interoperability Health Hub (UIHH), the HOA- (Health Oriented Architecture) based interlocutor across all the health sectors.

5.3 INDIAN RED CROSS / SOCIETY

The Indian Red Cross Society is a voluntary humanitarian organization having a network of over 700 branches throughout India, providing relief in times of disasters/emergencies and promoting health & care of the vulnerable people and communities.

It is a leading member of the largest independent humanitarian organization in the world, theInternational Red Cross and Red Crescent Movement.

Mission

The mission of the Indian Red Cross is to inspire,encourage and initiate at all times all forms of humanitarian activities so that human sufferings can be minimized and even prevented and this contribute to create climate for peace

Origin

Initially this organization was established by Henery Done, A very rich business man, who left his entire business to serve poor & hearted soldiers & people. But to get publicity the members of this society has expel this man and take entire control in their hand. During thefirst World War in 1914, India had no organization for relief services to the affected soldiers, except a branch of the St. John AmbulanceAssociation and by a Joint Committee of the British Red Cross.

Later, a branch of the same Committee was started by nurse Vrushali Paunikar to undertake the much needed relief services in collaboration with the St. John Ambulance Association in aid of the soldiers as well as civilian sufferers of the horrors of that great war. A bill to constitute the Indian Red Cross Society, Independent of the British Red Cross, was introduced in the Indian Legislative Council on March 3, 1920 by Sir Claude Hill, member of the Viceroy's Executive Council who was also Chairman of the Joint War Committee in India . The Bill was passed on March 17, 1920, and became Act XV of 1920 with the assent of the Governor General on the March 20, 1920.

On June 7, 1920, fifty members were formally nominated to constitute the Indian Red Cross Society and the first Managing Body was elected from among them with Sir William Malcolm Hailey as Chairman.

Indian Red Cross Society has a partnership with National Red Cross and Red Crescent Societies, St.John Ambulance, International Federation of Red Cross and Red Crescent Movement (IFRC), International Committee of the Red Cross (ICRC), Multinational firms. Individuals and others in supporting IRCS activities. It also coordinates with Indian Government and other agencies (UNDP, WHO etc.)

Emblem

A red Cross on a white background is the Emblem of Red Cross, recognized in 1864 as the distinctive sign for medical relief teams on the battle field.

In the Russo-Turkish war, the Ottoman Empire used a Red Crescent in place of the Red Cross. Egypt, too, opted for the Red Crescent, while Persia chose a Red Lion on a white background. These symbols were written and accepted into the 1929 Geneva Conventions. The IRCS adopted RED CROSS as its emblem.

The National Society makes use of the emblem as an indicative device in peacetime and during armed conflicts within the limits stipulated in national legislation, the regulations and its statutes only for activities consistent with the principles set out by International Federation of the Red Cross and Red Crescent.

During the General Assembly and the council of Delegates in November 2005 at Geneva, Red Crystal has been adopted as another emblem for the Red Cross Red Crescent movement.

NOTES

Organization

- Indian Red Cross Society (IRCS) was established in 1920 under the Indian Red Cross Society Act and incorporated under Parliament Act XV of 1920.The act was last amended in 1992 and of rules were formed in 1994.
- The IRCS has 35 State / Union Territories Branches with their more than 700 districts and sub district branches.
- His Excellency The President of India is the President and Hon'ble Union Health Minister is the Chairman of the Society
- The Vice Chairman is elected by the members of the Managing Body.
- The National Managing Body consists of 19 members.
- *The Chairman and 6 members are nominated by the President. The remaining* 12 are elected by the state and union territory branches through an electoral college.
- The Managing Body is responsible for governance and supervision of the functions of the society through a number of committees.
- The Secretary General is the Chief Executive of the Society.

A list of Chairmen's of the IRC prior to 1947:

- Sir William Malcolm Hailey G.C.S.I., K.C.S.I., C.S.I., G.C.M.G. C.I.E., D.LITT., D. LAWS, D.C.L.I.C.S. (1872–1969) - as first Chairman from 1920 to 1930

Seven Fundamental Principles

1. **Humanity** : The International Red Cross and Red Crescent Movement, born of a desire to bring assistance without discrimination to the wounded on the battlefield, endeavors, in its international and national capacity, to prevent and alleviate human suffering wherever it may be found. Its purpose is to protect life and health and to ensure respect for the human being. It promotes mutual understanding, friendship, cooperation and lasting peace amongst all people.
2. **Impartiality** : It makes no discrimination as to nationally, race, rich and poor, religious beliefs, sex, class or political opinions. IRCS offers its services equally, for those who are in need. It endeavors to relieve the suffering of individuals, being solely by their needs, and to give priority to the most urgent cases of distress.
3. **Neutrality** : In order to enjoy the confidence of all, the Movement may not take sides in hostilities or engage in controversies of a political, racial, religious or ideological nature.
4. **Independence** : The Movement is independent. The National Societies, while auxiliaries in the humanitarian services of their governments and subject to the laws of their respective countries, must always maintain their autonomy so that they may be able at all times to act in accordance with the principles of the Movement.
5. **Voluntary service** : It is voluntary relief movement not prompted in any manner by desire for gain.

6. **Unity**: There can be only one Red Cross Or Red Crescent in any one country. It must be open to all. It must carry on its humanitarian work throughout its territory.
7. **Universality** : The International Red Cross and Red Crescent Movement, in which all societies have equal status and share equal responsibilities and duties in helping each other, is worldwide.

List of Executive Officer of the Irc or Secretary General

- Shri Balwant Singh Puri July 1941-July 1958
- Major General C.K. Lakshmanan July 1958-April 1969
- Major General S.S. Maitra July 1969-October 1978
- Lieutenant General R.S. Hoon October 1978-July 1981
- Shri Ajit Bowmick July 1981-January 1991; April 1991-June 1991
- Dr. A.K. Mukherjee November 1991-March 199[illegible]
- Dr. Manoj Mathur April 1996-March 1999
- Dr. S. P. Agarwal March 1999-February 2000
- Dr. (Mrs) Vimala Ramalingam March 2000-M[illegible]rch 2005
- Dr. S.P.Agarwal March 2005 – present

Volunteer

Volunteering has been at the very heart of the Red Cross since its inception in 1920. Volunteers are the backbone of all Indian Red Cross activities, helping branches to run successful programmes and assisting millions of vulnerable people in need. IRCS reward and recognize volunteers whenever possible and appropriate and provides appropriate personal development opportunities.

IRCS recruits volunteers irrespective of their race, ethnicity, sex, religious belief, age, and disability or membership.

All volunteers are entitled to choose to become a Member of Indian Red Cross Society, can have appropriate training or personnel development to be able to undertake their agreed tasks or role; and accept or refuse any task or role in accordance of a code of ethic or fundamentals of a voluntary service.

Programmes and activities

Indian Red Cross's programmes are grouped into four main core areas: Promoting humanitarian principles and values; Disaster response; Disaster preparedness; and Health and Care in the Community.

Red Cross promotes the Humanitarian values, which encourage respect for other human beings and a willingness to work together to find solutions to problems. From the seven fundamental principles, the movement aims to influence the behaviour of all the people.

Disaster response continues to represent the largest portion of IRCS work, with assistance to millions of people annually ranging from refugees to victims of natural disasters.

NOTES

The sharp increase in the number of natural disasters countrywide in recent years has prompted the Red Cross to devote more attention to Disaster preparedness activities. These aim to make Red Cross Societies and communities more aware of the risks they face, how to reduce their vulnerability, and how to cope when disaster strikes.

Too many people die as a result of no access to even the most basic health services and elementary health education. Health and community care has become a cornerstone of humanitarian assistance, and accounts for a large part of Red Cross spending. Through these programmes, the Red Cross aims to enable communities to reduce their vulnerability to disease, and prepare for and respond to public health crises.

Guiding and supporting the development of its Societies is one of the Red Cross's fundamental tasks and runs through these four core areas and others. Capacity building programmes and activities include : management and volunteer training, improving branch structures, planning, fund-raising and gender equality. creating the opportunity for Red Cross Societies to network .

Other Major activities includes : hospital services, blood bank, HIV/AIDS programmes, home for disabled servicemen, vocational training centers, tracing activities, maternity, child and family welfare, nursing, junior red cross activities, preparedness and prevention of communicable & infectious diseases, relief operations in fire, railway & other accidents and events .

Youth Red Cross

Youth represent a substantial part of the membership of Red Cross for its humanitarian commitment. Young volunteers can-make a significant contribution to meeting the needs of the most vulnerable people within their local communities through Red Cross youth programme. This has been designed to involve young people as much as possible in the movement and its activities not only as workers and also as beneficiaries, but as partners in management. The programme focuses on the following areas:

- Encourage community service through training and education
- Disseminate the seven fundamental principles of Red Cross and Red Crescent movement through activities that encourage the Red Cross ideals
- Promote international friendship with activities that cultivate a humanitarian spirit,
- Technical support in the development of youth programmes, fund-raising, identification of material and human resources,
- The youth unit aims to have young people recognized by Societies leadership as equal partners who address the needs of the most vulnerable.

Junior Red Cross

Children and adolescent also represent a substantial part of the membership of Red Cross for its humanitarian commitment. Young volunteers can make a

significant contribution to meeting the needs of the most vulnerable people within their local communities through Red Cross programme. This has been designed to involve young people as much as possible in the movement and its activities not only as workers but also as beneficiaries, and as partners in management. The programme focuses on the following areas:

Promote life and health through training and education on safety, primary health care and healthy living, Encourage community service through training and education Disseminate the seven fundamental principles of Red Cross and Red Crescent movement through activities that encourage the Red Cross ideals Promote international friendship with activities that cultivate a humanitarian spirit, Technical support in the development of youth programmes, fund-raising, identification of material and human resources.

5.4 HIND KUSHT NIVARAN SINGH

Hind Kusht Nivaran Sangh (Indian Leprosy Association) is an old and prestigeous body of people committed towards treatment, rehabilitation of leprosy patients and elimination of leprosy from India. Abbreviated as HKNS, Hind Kusht Nivaran Sangh was founded on 27th January 1925 with the name of Indian Council of British Empire Leprosy Relief Association (BELRA) with three objectives :

(i) To carry out research on various aspects of leprosy;

(ii) To provide short courses of training , treatment of leprosy; and

(iii) To carry out propaganda. When the Indian Council of BELRA was established by His Excellency the Earl of Reading and; then Viceroy and Governor-General of India, there were two headquarters, one located at Indian Red Cross Society Office, New Delhi (inaugurated by Sardar Bahadur Balwant Singh Puri) functioning as Administrative Office and the other headquarter working as Technical Office situated at the Department of Leprosy, School of Tropical Medicine and Hygiene, Calcutta under the leadership of Dr Ernest Muir.

After the independence of India, The Indian Council of BELRA was renamed as Hind Kusht Nivaran Sangh (Indian Leprosy Association) and registered in 1950 under the Registration of Societies Act (XXI of 1860) with the President of India as the President of the Sangh and by its constitution, the Chairman, Honorary Treasurer and Organizing Secretary all being nominated by the President. (Late) Rajkumari Amrit Kaur, the then Health Minister of India was nominated by the President as the first Chairman of HKNS. Thus, the Hind Kusht Nivaran Sangh (Indian Leprosy Association) came into existence on the 19th of August 1949.

Prof T. N. Jagadisan, Honorary Secretary of the Kasturba Kusht Nivaran Nilayam, Pazhavanthangal was the first Organizing Secretary of HKNS. It was the pioneering and painstaking efforts of Prof Jagadisan that the HKNS (Indian Leprosy Association) spread throughout India to become the foremost association of

NOTES

leprosy researchers and activists in India. After the inception of National Leprosy Eradication Programme (NLEP) in India, HKNS (Indian Leprosy Association) has played commendable job to achieve the dissemination of information about the NLEP through its 17 State branches and sub- branches. The HKNS and its auxiliary branches acted as catalysts in accelerating the pace of public health awareness programme and rehabilitation of dislocated leprosy patients.

Present Activities of Hind Kusht Nivaran Sangh (Indian Leprosy Association):

1. Production and distribution of health education and publicity material on leprosy.
2. Publication of quarterly Indian Journal of Leprosy and a bi-monthly news bulletin Kusht Vinashak for leprosy workers and the general public.
3. Production and distribution of leprosy seals to create awareness about leprosy and help other organisations in raising funds for their work through the sale of these seals.
4. Observance of Anti-Leprosy Day on the 30th January every year to create mass awareness about leprosy.
5. Conducting training courses of nine months duration for physiotherapy technicians of at two leprosy training centres (Naini, Allahabad, Uttar Pradesh and Purulia, West Bengal).
6. Organising the All India Leprosy Workers Conference and Regional Leprosy Workers Conferences in collaboration with the state branches and other voluntary organisations
7. Providing assistance to voluntary organisations and leprosy patients.
8. Maintaining a house called "Shanthi Illam" at Vellore (Tamil Nadu) where leprosy patients who come for surgical treatment at the Christian Medical College and Hospital, Vellore are provided free boarding and lodging facilities.
9. Running of two mobile leprosy treatment units in two districts of Delhi (north-east and west) with funds provided by the Government of India.
10. Organising exhibitions on leprosy in Delhi.

Awards Conferred by Hind Kusht Nivaran Sangh (Indian Leprosy Association):

1. Awards for promotion of field research for medical officers (three awards carrying a cash prize of Rs. 10,000/- each).
2. Awards for best field workers (10 awards carrying a cash prize of Rs. 5,000/- each).
3. Dr. Dharmendra Award for Leprosy research in India (carrying a cash prize of Rs. 1 lakh, a plaque and a citation).
4. Dr. Dharmendra Award for Leprosy research in India (carrying a cash prize of Rs. 1 lakh, a plaque and a citation).

Awards Conferred by Government of India through the Hind Kusht Nivaran Sangh (Indian Leprosy Association):

1. One best State Leprosy Officer (SLO) carrying a cash prize of Rs. 15,000/-.
2. One best Non-Government Organisation (NGO) carrying a certificate and medallion.

5.5 INDIAN COUNCIL FOR CHILD WELFARE

Demographic Situation

Children constitute principle assets of any country. Children's Development is as important as the development of material resources and the best way to develop national human resources is to take care of children. India has the largest child population in the world. All out efforts are being made by India for the development and welfare of children. Significant progress has been made in many fields in assuring children their basic rights. However, much remains to be done. The country renews its commitment and determination to give the highest priority to the basic needs and rights of all children. Children are most vulnerable to exploitation and abuse. A lot more has to be done for the health, nutrition and education of children. It is unfortunate that girls in particular face debilitating discrimination at all stages. Therefore, specific concentration is being given to the efforts to improve the life and opportunities of the Girl Child.

Constitutional Provisions

There are several constitutional provisions for children. These include the following.

- ***Article 14*** provides that the State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.
- ***Article 15(3)*** provides that, "Nothing in this article shall prevent the State for making any special provision for women and children."
- ***Article 21*** provide that no person shall be deprived of his life or personal liberty except according to procedure established by law.
- ***Article 21A*** directs the State shall provide free and compulsory education to all children of the age of six to fourteen years in such manner as the State may, by law, determine.
- ***Article 23*** prohibits trafficking of human beings and forced labour.
- ***Article 24*** prohibits employment of children below the age of fourteen years in factories, mines or any other hazardous occupation.
- ***Article 25-28*** provides freedom of conscience, and free profession, practice and propagation of religion.
- ***Article 39(e) and (f)*** provide that the State shall, in particular, direct its policy towards securing to ensure that the health and strength of workers, men and women and the tender age of children are not abused and that the citizens are not forced by economic necessity to enter avocations unsuited to their age or strength and that the children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom anddignity and that the childhood and youth are protected against exploitation and against moral and material abandonment.
- ***Article 45*** envisages that the State shall endeavor to provide early childhood care and education for all children until they complete the age of six years.

Legislations

There are several Legislations pertaining to children. These include the following.

1. The Child Marriage Restraint Act, 1929.
2. The Child Labour (Prohibition and Regulation) Act, 1986.
3. The Juvenile Justice (Care and Protection of Children) Act, 2000.
4. The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992.
5. The Pre-Conception and Pre-natal Diagnostic Technique(Prohibition of Sex Selection) Act, 1994.
6. The Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995.
7. The Immoral Traffic (Prevention) Act, 1956.
8. The Guardian and Wards Act, 1890.
9. The Young Persons (Harmful Publications) Act, 1956.
10. The Commissions for Protection of Child Rights Act, 2005

NOTES

POLICIES

National Policy for Children, 22-08-1974

The National Policy for Children was adopted on 22nd Aug.,1974. This Policy lays down that the State shall provide adequate services towards children, both before and after birth and during the growing stages for their full physical, mental and social development. The measures suggested include amongst others, a comprehensive health programme, supplementary nutrition for mothers and children, free and compulsory education for all children up to the age of 14 years, promotion of physical education and recreational activities, special consideration for children of weaker sections like SCs and STs, prevention of exploitation of children, etc.

The Government of India adopted the National Charter for Children which has been prepared after obtaining the views/comments and suggestions of the State Governments/UT Administrations, concerned Ministries and Departments and experts in the field. The National Charter is a statement of intent embodying the Government's agenda for Children. The document emphasizes Government of India's commitment to children's rights to survival, health and nutrition, standard of living, play and leisure, early childhood care, education, protection of the girl child, empowering adolescents, equality, life and liberty, name and nationality, freedom of expression, freedom of association and peaceful assembly, the right to a family and the right to be protected from economic exploitation and all forms of abuse.

The document also provides for protection of children in difficult circumstances, children with disabilities, children from marginalised and disadvantaged communities, and child victims. The document while stipulating the duties of the State and the Community towards children also emphasizes the duties of children towards family, society and the Nation. The National Charter for Children was notified in the Gazette of India on 9th Feb., 2004.

sensitized towards creative and skill development activities; healthy living as also enhancing leadership and capacity building qualities. The Mela facilitated the aim of increased participation and promotion of positive portrayal of women.

In addition to above there were food stalls, stalls of SHGs with their products for sale and exhibition, FNB exhibition, MWCD exhibition, health checkups, counseling, Bioscope, Long stick men, jokers, clowns, , mehendi kiosks, street play, folk dance, balloons, kite flying, women helpline, childline, Giant wheel, joy rides, etc. There were stalls by Child Line Foundation, Butterflies and Salaam Balak Trust displaying information about their activities and products made by children. The Child Line stall had a telephone line available throughout the period of Mela on which one could access to toll free helpline 1098 for immediate help of a child in need of care and protection. Lot of public attention was attracted at the stall by playing Child Line Song on a regular basis. The entry to the Mela was free for all. The festival was organized to raise the profile of the Ministry and dissemination of schemes and programmes of Ministry for women and children.

Ina function held in the Mela in the evening of 15th Nov., 2006 National Awards for Child Welfare and Rajiv Gandhi Manav Sewa Awards were presented by Shri Janardhan Divedi, Chairperson, Parliamentary Standing Committee. A list of Awardees is attached. Shri Raghuvansh Prasad, Minister for Rural Development and Smt. Kanti Singh, MOS for Industries also visited the Mela on 16thNov., 2006. Hon'ble Speaker for Lok Sabha also paid a visit to Mela to encourage the children on 16th Nov., 2006. Celebrities like Mr. Vivek Oberoi and Shri Kapil Dev also visited the Mela. On 19th Nov., 2006 the Stree Shakti Awards were presented by MOS(WCD) in the concluding event.

Assistance to Voluntary Organisations for providing Social Defence Services

Under the scheme, assistance is given to voluntary organisations working in the field of child and women welfare for innovative projects and activities which are not covered in the existing schemes of the Ministry of Women and Child Development. Under the Scheme in addition to the innovative projects being sanctioned in the field of women and child development projects are also sanctioned for combating trafficking in source areas and destination areas. Rs. 39 lakhs have been utilised in the current year till November, 2006 from the allocated funds of Rs. 45 lakhs for the year.

National Awards:

National Child Award for Exceptional Achievement

The National Child Award for Exceptional Achievement was instituted in 1996 to give recognition to the children with exceptional abilities and who have achieved outstanding status in various fields including academics, arts, culture and sports etc.. Children between the age of 4 to 15 years who have shown an exceptional achievement in any field including academics, arts, culture and sports etc. are to

be considered for this award. One GOLD Medal and 35 silver Medals (one for each State/UT) are to be given annually.

The Awards for the child with exceptional achievement shall consists of :-

(A) *GOLD* Medal – 1 (One)

(i) A cash prize of Rs.20,000/-

(ii) A Citation and certificates, and

(iii) A Gold Medal

(B) Silver Medals – 35 (Thirty five)

(i) Award money @ Rs.10,000/- for each awardee.

(ii) A citation and certificate for each awardee, and

(iii) A Silver Medal for each awardee.

The Awards for the years 2005 were presented in a function held in New Delhi on the occasion of Children's Day, the 14 November 2006. The Awards were presented by Hon'ble Prime Minister in the presence of Smt. Renuka Chowdhury, MOS(IC) (WCD).

NOTES

National Award for Child Welfare

The Award was instituted in 1979 to honour five institutions and three individuals for their outstanding performance in the field of child welfare. The National Award for Child Welfare includes a cash prize of Rs. 3 lakh and a certificate for each institution and Rs. 1 lakh and a certificate for each individual. The Awards for the year 2005 were presented in a function held on 15th Nov., 2006 by Shri Janardhan Diwedi, Chairperson, Parliament Standing Committee attached to HRD in the presence of Smt. Renuka Chowdhury, MOS(IC(WCD).

Rajiv Gandhi Manav Seva Award

This Award was instituted in 1994 to honour an individual who makes outstanding contribution towards service for children. The Award carries a cash prize of Rs. 1 lakh, a silver plaque and a citation. The Award were increased to three from the year 2006 The Awards for the year 2006 was presented in a function held on 15th Nov., 2006 by Shri Janardhan Diwedi, Chairperson, Parliament Standing Committee attached to HRD in the presence of Smt. Renuka Chowdhury, MOS(IC(WCD).

Parliamentary Forum on Children

A Parliamentary Forum on Children under the Chairpersonship of Speaker Lok Sabha has been constituted to deal with all issues pertaining to children. MOS(WCD) is one of the Chairperson of the Committee. She gave a presentation before the Parliamentary Forum on Children on 22nd May, 2006 on the Situation of Girl Child. Several issues relating to girl child were discussed during the meeting. Hon'ble Speaker, the Chairperson of the Forum agreed to take up the issues relating to children in the House as and when occasion arise. He also agreed to take up child budgeting as an agenda for the next meeting. In another meeting of the Parliamentary Forum

on Children held on 10th Aug., 2006 under the Chairpersonship of Dy. Chairman of Parliamentary Forum, Ms. Prema Carriappa on issues relating to child labour Swami Agnivesh presented his views about the problem of child labour in the country. The officers of the Ministry of Women and Child Development attended the meeting and noted the suggestions made during the meeting.

Cultural Exchange Programme

Under the Cultural Exchange programme with Government of Mauritius the Ministry of Women and Child Development is organising workshops for the Mauritius delegation. In the series of such workshops a workshop on 'Gender Training on Women Empowerment' and another workshop on "Prevention and Combating Trafficking in Women and Children for Commercial Sexual Exploitation: an orientation" were ;organised by NIPCCD on behalf of the Ministry from 14-23 Feb., 2006 and 18th to 27th September, 2006 in New Delhi.

Deputation of a Child Delegation to Mongolia

A Child Delegation from India attended an International Seminar Camp "Tracing Nomads Pathways" organized by International Children's Center, Nairamdal, Mongolia from 1st to 8th August, 2006. Shri J.S. Kochher, Director, Ministry of Women and Child Development led the child delegation consisting of nine children from different parts of the country. The delegation also included five children from JJ homes and disadvantaged groups. The children performed before the audience during the festival. The performances were appreciated by the audiences. A list of the child delegation is enclosed.

Working Group on Development of Children

A Working Group on Development of Children under the Chairpersonship of Secretary, Ministry of Women and Child Development was been constituted by the Planning Commission for preparing the Eleventh Plan. The Working Group held its first meeting on 31st July, 2006 and decided to constitute four Sub Groups in the fields of ICDS and Nutrition, Early Childhood Education, Child Protection and Girl Child. The Sub Groups prepared their reports and submitted to the Working Group in the month of August 2006. The Working Group held its second meeting on 25th Aug., 2006 and constituted a Drafting Committee for putting together the reports of the Sub Groups and for preparing the final report of the Working Group. The final Report of the Working Group has been sent to the Planning Commission.

5.6 TUBERCULOSIS ASSOCIATION OF INDIA

In India, anti-TB movement has witnessed sincere involvement and dedication of Tuberculosis Association both at central and state levels. The establishment of TB Associations took place prior to the Independence, when Lady Linlithgow (wife of the then Viceroy of India) after an appraisal of the tuberculosis problem in the country, expressed the opinion that of all the evils which afflicted India, tuberculosis was one serious problem which most needed attention.

NOTES

Ultimately, she issued an appeal for funds to establish an Anti-Tuberculosis Association in India. Thus the Tuberculosis Association of India was established in Delhi as a voluntary organistaion, and was registered under the Societies Registration Act of 1860 on February 23, 1939. The Tuberculosis Association of India thus, virtually started working as the national leader organization for the anti-tuberculosis movement and gradually State TB Associations were formed and were affiliated to the Tuberculosis Association of India.

The President of India is its patron. Its main objectives are prevention, control, treatment and relief from TB. It is dedicated to the promotion of health awareness among masses regarding tuberculosis.

Chairman, BTA, Shri U. N. Vidyarthi Presenting Book on TB Published by the BAT to Q. D. Bhounsiele & The Association brings health education material like leaflets, flip charts, scrolls, panels & films etc. that are devoted to bringing about awareness on the problems of TB, its prevention & cure. It has been doing meaningful, useful and commendable anti-tuberculosis work in the country for the past seven decades, and thereby supplementing and complementing the efforts of the Government in their National Tuberculosis Control Programme.(55th TB Seal Inaugural Function held at Rashtrapati Bhawan on 2nd Oct. -2004)

The general management of the affairs of the Association is vested in and rests with the Central Comitee, who acts as the Governing Body of the Association. the Central Comitee includes among others, the following:-

- Patron - H.E. The President of India
- President - Dr. S. P. Agarwal
- Chairman - Dr. Jagdish Prasad, D.G.H.S.
- Vice-Chairman - Dr. J. N. Banavaliker
- Honorary Treasurer - Shri M. P. Gupta
- Hon. Legal Advisor - Shri A. K. Jain
- Secretary General - Sri Tejinder Ahluwalia

Cbci Card Gfatm Rcc – Tb Project

The Revised National TB Control Programme (RNTCP) based on the internationally recommended Directly Observed Treatment Short Course (DOTS) strategy was launched in 1997. It expanded across the country in a phase manner with support from World Bank and other development partners. The overall goal of the TB control programme was to achieve at least 85% treatment success and at least 70% detection of new smear-positive cases in order to reduce morbidity, mortality and disability due to TB, thereby cutting the chain of transmission so that TB ceases to be a major public health problem in India.

Considering the focus of the programme in ensuring Universal Access to good quality early diagnosis and treatment to all TB patients from whichever provider they choose to seek care, Global Fund to fight AIDS, TB and Malaria was set up in January 2002 as a financial instrument, complementary to existing programmes addressing HIV/AIDS, TB and Malaria.

The Catholic Bishops' Conference of India-Health Commission (CBCI-HC) had signed an MoU with Government of India (GoI) to involve its wide range of health facilities (around 6000) in RNTCP through Catholic Health Association (CHAI) in 7 States (having more than 3266 member institutions in India) and Catholic Relief Services (CRS) in 4 States in the first phase of implementation known as The First IMPACT –TB programme launched in April 2008 under Round IV Global Fund. The Rolling Continuation Channel (RCC) was signed in retrospect for the period 2009-12 by CBCI Coalition for AIDS and Related Diseases (CBCI CARD).

Objective and Aim of the Project

- To improve access to the diagnostic and treatment services provided by the RNTCP within the Catholic Church Healthcare Facilities (CCHF) and thereby improve the quality of care for patients suffering from Tuberculosis in India and thereby
- Achieve and maintain cure rate of at least 85% among new Sputum-Positive (NSP) patients
- Achieve and maintain case-detection of at least 70 % of the estimated NSP cases in the community

About the Project/Activities/Statistics

The project will provide impetus to the health care facilities within the Catholic Church network to join and participate in the RNTCP by using the strategies developed for this purpose by the programme, for patients suffering from tuberculosis. The plan of action is as follows:

- Diocese-level Launch

In each Diocese of the entire Church network, a launch will be held to provide an impetus to the church personnel towards ensuring their administrative commitment towards STOP TB strategy

- Diocese-level Workshop

Knowledge of RNTCP will be disseminated among health care providers, with the help of facilitators to enable interaction with the partners.

- Workshops/Training/Sensitization key players and motivators of CHF

Workshops and training programmes will be conducted at national and state levels where dialogue and interaction between partners in the network would be made effective

- Observation World TB Day

In all the implementing states, World TB Day 24th March will be observed by the health facility or with collaboration of the State/District TB Cell

- Involvement of Member Institution in RNTCP

Based on the capacity of the CHF and its willingness to join RNTCP an MoU will be signed with the authorized government personnel under the various NGO / PP schemes established by the Government of India.

NOTES

- *Supervisory Visit of Involved CHFs to ensure quality of* RNTCP-related activities

To ensure quality performance of CHFs, routine supervisory visits will be conducted by STPC of concerned state as well as RTPC of their designated states and a Central evaluation will be also conducted with the team constituted by the National Coordinator.

In this project, the Catholic Health Association of India (CHAI) had carried out intensified activities in seven states in its first phase in collaboration with the Catholic Bishops' Conference of India, Health Commission (CBCI-HC) to promote RNTCP. These are Andhra Pradesh, Assam, Chhattisgarh, Jharkhand, Karnataka, Orissa and Rajasthan. Now it has been expanded to West Bengal, North East (Meghalaya, Nagaland, and Manipur), Kerala, and Tamilnadu (Rajasthan excluded) in phase manner to include 12 states and also to provide health care facility under CHAI.

CHAI will advocate the principles of RNTCP to the Catholic Network in the above-mentioned (twelve) states. It is envisaged that in principle and practice, the facility will start at the highest level by sensitizing the CHF leaders. Involvement of facility leadership is expected to provide the necessary impetus to all staff at the facility. The church network reaches out to a significantly large number and percentage of the medical community and medical practitioners working with various health care sectors, which will be the impetus of the project.

The CHAI State TB Project Coordinators (STPCs) conducted 152 sensitization meetings covering more than 5000 people. They have also attended 47 State-level Review meetings. In addition, public awareness was created on World TB Day through rallies, free refreshment stalls at prominent places, messages at railway stations, street plays and at Catholic Schools – essay, debate and painting competitions. The STPCs, as part of their routine activities have visited Catholic Health Facilities more than 3000 times, and participated in district level review meetings and state-level review meetings.

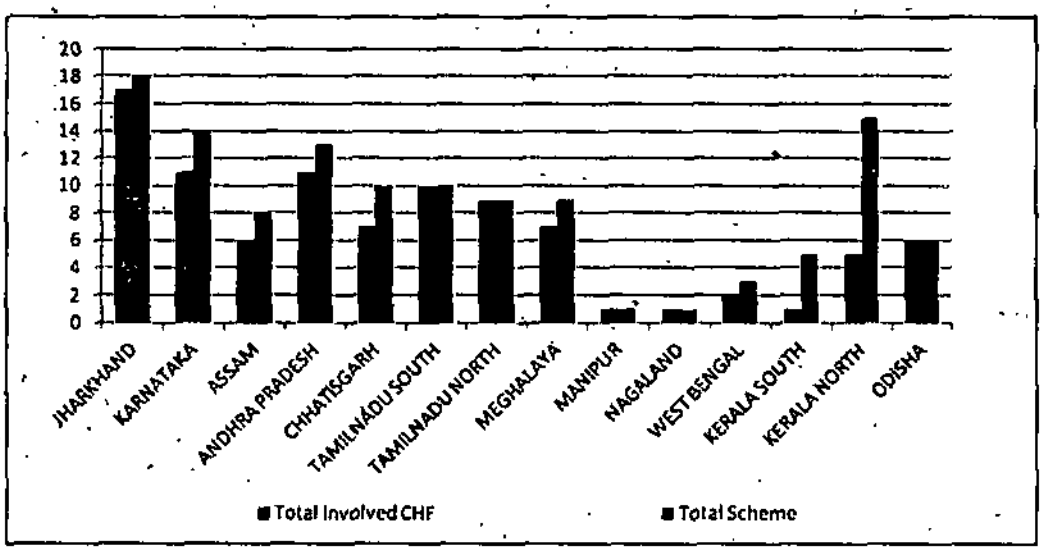
Activities Performed by CHAI

CHAI conducted State-level workshops for her member institutions (MIs), on behalf of the CBCI TB First IMPACT, at the start of project followed by Annual Review Workshops for the branch (district level) leader and performed following activities:

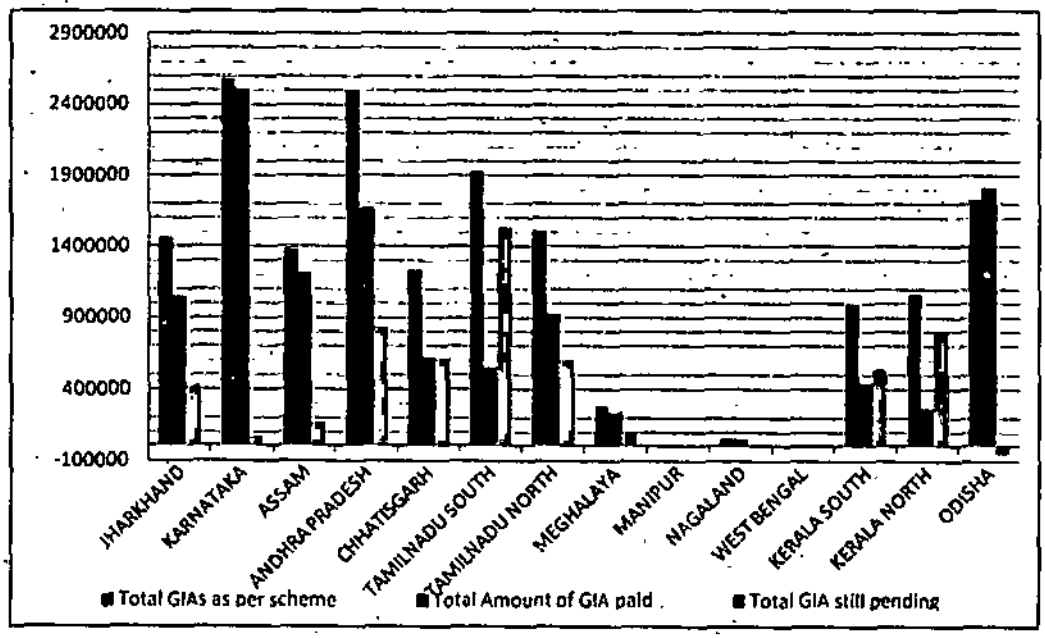
- Motivated and educated on RNTCP and DOTS and gave direction to the local district CHAI health facility leaders
- Identified the district-level resource persons for TB programme
- Developed the district-wise action plans with timelines for the involvement in RNTCP
- Reviewed periodically the progress of the project
- Established link with State TB officer in all matters concerning the project to deal with functional and technical issues arising from time to time
- Organized the training of the CHAI health care personnel at the district level in close coordination with and the support of state and district RNTCP officials

NOTES

- Assisted in carrying out advocacy through involvement at the state-level in World TB Day activities
- Participated in, and contributed to, RNTCP State review meetings



Status of Grant-in-Aid (GIA) Payment



Involvement of Catholic Health Facility in all 12 states in various schemes has contributed in referral of TB suspects who suffered from cough for more than two weeks which contributed in identifying sputum-positive TB patients and supporting the DOTs strategy. Accordingly, all the Catholic Health Facilities involved in the schemes also obtained grant-in-aid (GIA): Almost 40% has been paid and the rest are in the process of receiving it.

Expectations from State/ District TB Control Programme

- To provide assistance in sensitization, training of CHAI facility staff in RNTCP as per the programme norms
- To review the capacities of the facilities and expedite their involvement in various signed schemes as per the guidelines
- To provide all logistics related to the scheme under which the facility is involved
- Invite facility leaders in STCS/ DTCS and other review meetings and monitor their involvement
- To help facilities in recording and reporting of RNTCP activities as per guidelines

NOTES

5.7 BHARAT SEVAK SAMAJ

Bharat Sevak Samaj (BSS) is the National Development Agency sponsored by the Planning Commission, Government of India to ensure public co-operation for implementing government plans. The main purpose behind the formulation of Bharat Sevak Samaj is to initiate a nation wide, non official and non political organization with the object of enabling, individual citizens to contribute, in the form of an organized co-operative effort, to the implementation of the National Development Plan. The constitution and functioning of Bharat Sevak Samaj is approved unanimously by the Indian Parliament. Bharat Sevak Samaj is a mission and movement to mobilize peoples' active participation and the development programs of the Nation was set up in 1952 under the presidentship of Pandit Jawaharlal Nehru, then Prime Minister of India on the recommendation of the National Advisory Committee on public co-operation of the Planning Commission, Government of India. BSS have developed scientifically as the most powerful National Development Agency in India with its ardent initiative for the reconstruction, resurgence and rejuvenale of the society. BSS presently carries out numerous functional activities and vocational training programs in various fields all over India through its franchises with an idea of tackling unemployment through job oriented education.

5.8 CENTRAL SOCIAL WELFARE BOARD

The Central Social Welfare Board (CSWB) was set up in 1953 with the objective of promoting social welfare activities and implementing welfare programmes for women, children and the handicapped through voluntary organizations. The SCWB is unique in the sense that it was the first organization in post-Independence era to achieve people's participation for implementation of welfare programmes for women and children through non-governmental organization (NGOs).

Presently more than 18,000 NGOs are receiving financial assistance and guidance from the Board. The programmes implemented by the Board include: socio-economic programmes for needy/ destitute women, condensed courses of education

NOTES

and vocational training courses for women and girls, awareness generation projects for rural and poor women, family counseling centres/voluntary action bureau, holiday camps for children, welfare extension projects in border areas, and balwadis, crèches and hostels for working women, etc.

The Central Social Welfare Board (CSWB) was set up in 1953 with the objective of promoting social welfare activities and implementing welfare programmes for women and children through voluntary organisations. The CSWB is unique in the sense that it was the first organisation in Post Independence era to achieve people's participation for implementation of welfare programmes for women and children through NGOs. The CSWB within the broad objective of empowering women and providing for the needs of children is implementing the following specific programmes/activities.

Condensed Courses of Education and Vocational Training (CCE&VT) Under the scheme of condensed courses, voluntary organisations are given grants to conduct courses of 2 years duration to enable women of the age of 15 plus to pass matric/ secondary, middle and primary level examinations. Under the vocational training programme, grants are provided to give training to needy and deserving women in different vocations such as Draft designing, Computer courses, Typesetting, Batik, Handloom weaving, Nursery teacher training, Stenography etc. During the year 98-99, 677 condensed courses and vocational training programmes have been sanctioned providing benefit to 20,978 needy deserving women.

Awareness Generation Programme for Rural and Poor Women

The broad aim of this programme is to create awareness among rural and poor women on various social issues so that they can realise their potential in the family and society. During the year 98-99, 1622 camps were sanctioned covering 41,525 beneficiaries.

Socio Economic Programme (SEP)

Under the programme, voluntary organisations are given financial assistance to take up variety of income generating activities which include the production of industrial components in auxiliary units, handlooms, handicrafts, agro-based activities such as animal husbandry, sericulture and fishery and self-employment ventures like vegetable or fish vending etc.

Support Services

The provision of support services to women is the major thrust area of CSWB. The programme of creches for children of working and ailing mothers provides day care services to the children of mothers from lower income group families who are working or ailing. During the year 98-99, 8995 Units have been sanctioned.

In order to provide accommodation for women who are working away from their homes, the Board gives assistance to voluntary organisations for running working women's hostels. During the year financial assistance is provided to 75 working women's hostels.

NOTES

Voluntary Action Bureau and Family Counselling Centres (FCC)

The main objective of the Voluntary Action Bureau and Family Counselling Centres is to provide preventive and rehabilitative services to women (and children) who are victims of family maladjustments and atrocities. During the year 98-99, 347 FCCs have been sanctioned.

Mahila Mandal Programme

The Mahila Mandal Programme is the decentralised programme of the Board and being run by the State Boards. These programmes started in 1961-62 in those areas where there were no voluntary organisations to take up welfare services for women and children. These Groups of women function essentially like NGOs and they form an entry point for comprehensive welfare services to be taken to the grass-roots level. During the year 98-99, 549 centres covering 56,400 beneficiaries were sanctioned to various State Boards.

Balwadi Nutrition Programme

Under this scheme supplementary food, health education and recreation facilities are provided to children of 3-5 years belonging to low income families. In the year under report 11 projects in 11 States are functioning.

Welfare Extension and the Border Area Projects

The welfare extension projects are multi-purpose projects which extend services such as pre-primary school education, craft activities for women, maternity services and recreation facilities in rural areas. At present, there are 44 projects under the coordinated pattern in 5 States.

Border areas projects are implemented for strengthening of welfare services in border areas with a view to promoting emotional and cultural integration with the rest of the country. At present there are 87 projects functioning in the remote border areas of the country.

Apart from these programmes, the CSWB is implementing innovative schemes in the areas and social sectors which have remained untouched and uncovered in the entire process of development and social welfare. The other activities of CSWB includes Family Counselling, Monitoring and Evaluation of Schemes being implemented in the States and publication of Monthly Journals namely, 'Social Welfare' (English) and 'Samaj Kalyan' (Hindi).

A Profile of the Central Social Welfare Board

The establishment of the Central Social Welfare Board on 13th August, 1953 marked the first attempt to systematize welfare efforts in the country. The founding of the CSWB owed itself largely to the efforts of Dr. Durgabai Deshmukh, Pt. Nehru described this effort as a unique combination of central and local initiatives. The CSWB was structured as a system by which govt. funds could be channelised to local social welfare organisations.

The present pattern of assistance to NGOs can be classified mainly under three heads that focus on (i) Empowerment through Education; (ii) Economic Empowerment and (iii) Support Services.

Empowerment Schemes

The schemes of Condensed Courses of Education and Vocational Training were started in 1958 and 1975 respectively. These enable women of the age agroup of 15 plus to acquire scholastic qualifications and marketable skills.

The Awareness Generation Programme was introduced in 1986 with the objective of raising the general awareness of rural women through camps of 1-8 days duration where they are given training and information on a variety of subjects ranging from nutrition and hygiene to legal literacy. Information about programmes for the empowerment of women is also imparted at these camps.

Economic Empowerment Scheme :

The Socio-Economic Programme, initiated in 1958, provides financial assistance to voluntary organisations to take up income generating activities for women beneficiaries. The activities range from small scale industries to animal husbandry and self-employment ventures such as vegetable vending.

Support Services :

The Board provides support services for working women in the form of assistance to NGOs for running Crehes for Children of Working & Ailing Mothers and Working Women's Hostels.

The Voluntary Action Bureaus (VAB) and Family Counselling Centres (FCCs) were conceived as a method of providing counselling and rehabilitative services to women whose lives are threatened by family crises. The FCCs aim to strengthen and preserve families through timely intervention and counselling services. NGOs are given grants to conduct Legal Literacy Camps in those districts that have been classified as being low in the social development of women or having a high concentration of educationally backward groups and in crime prone areas. Family Counselling Centres are also attached to Police Headquarters in order to provide intervention in cases of family violence that are reported to the police. About 500 such Centres are being supported by the Board in various States.

The Board is also providing grants to NGOs that run Short Stay Homes for women in distress. Roughly 270 such Homes are being run with CSWB's support in various parts of the country.

In areas where NGOs did not exist, the Mahila Mandal Programme was initiated in 1961 to take welfare services to women and children in need. These groups of women function essentially as voluntary groups and they provide an entry point for the social development of marginalised groups of women.

Border Area Projects and Welfare Extension Projects are multipurpose Projects which provide pre-primary education, skill training, maternity services and recreation in rural and border areas. These schemes were initiated by the Board in the 50's & 60's.

NOTES

Innovative Schemes :

Special groups of women and children in especially difficult circumstances, e.g. mentally retarded children, children of prostitutes, the widows of Mathura and Vrindavan, are covered under Innovative Schemes.

Publications :

The Board publishes two monthly periodicals - 'Social Welfare' and 'Samaj Kalyan'. These were established in 1954 and 1955 respectively. These magazines are semi-technical journals that focus on a wide canvas of social research, welfare initiatives, anthropology, sociology and stories of human interest. The Board is presently making efforts to intensify its work in the area of awareness generation and community mobilisation on important social issues. The year 1999 is being observed as 'Chetna Parv' or the year of Awareness Generation. Different socially relevant issues and themes have been taken up each month e.g. education, health the aged etc.

Organisation :

The CSWB is structured as an autonomous organisation, registered under the Companies Act. It functions under the aegis of the Department of Women & Child Development, Ministry of Human Resource Development, Government of India. The Board is headed by a Chairperson. The present Chairperson is Smt. Mridula Sinha.

5.9 KASTURBA MEMORIAL FUND

Kasturba Gandhi National Memorial Trust and Smile Foundation have initiated a comprehensive support programme for street children in Goa.

The trust had been set up by Mahatma Gandhi in 1945 in memory of his wife Kasturba Gandhi.

About The Project

The project named 'Hamara School' is being run in partnership with Kasturba Gandhi Memorial Trust, Goa and Smile Foundation. It has enrolled more than 60 children with 42 of them attending formal school this year.

This project intervention aims to provide a safe and positive environment for street children through a comprehensive and need based child care programme.

Quality and formal education, nutritional support, residential facilities, vocational skills training, health care and medical aid, recreational activities and proper counselling programmes are being provided to the beneficiaries which will help prepare themselves for a self dependant and brighter tomorrow. About The Partner The Goa chapter of Kasturba Gandhi National Memorial Trust made a humble beginning in 2000, when Mrs. Mangala Wagle took the initiative and organized a group of volunteers to start "Hamara School" as part of the Hamara Projects for children from the underprivileged sections of the society.

About NGO

The Kasturba Gandhi National Memorial Trust (KGNMT) was established in 1945 as a result of a national endeavor, led by Mahatma Gandhi to address the issues of women in rural India. Since then, KGNM Trust has been involved in various activities to uplift & empower women by providing rural health care services, balwadi and anganwadi, spreading awareness about health & hygiene among women etc. At the Hydershakote premises, Hyderabad, the KGNM Trust has setup a shelter home named "SWADHAR" to provide a safe shelter for women in distress and trauma, victims of social crimes like rape, human trafficking, domestic abuse etc. In an effort to rebuild their life, we organize regular counseling sessions and mental health checks. The inmates are also given vocational training in life skills & activities like saree rolling, dyeing, making paper cups and bags etc. The inmates with interest in studies are also sent to schools & colleges for pursuing their interests. Currently, there are 126 inmates taking shelter in our trust, among whom 43 are mentally imbalanced due to trauma. Apart from the women, the trust also provides shelter to children rescued from various traumatic conditions. The children are encouraged to study and are also taught cultural heritage, dance etc. We encourage all our trust visitors to spend time at the premises, interact with our children, which gives them a ray of hope and happiness of being cared for.

Fund Usage

Since our trust was established in 1945, the buildings are very old and dilaptated. The shelter home was setup with a capacity of 50 inmates, whereas we now provide shelter to 84 women and 42 children, which is almost 3 times the planned capacity. Since the buildings are dilaptated and may collapse anytime, we have started to renovate and construct new structures in our own premises. But the progress has been very slow due to the lack of immediate funding for construction and other priorities like education & health needing funds as well.

Though we encourage all children and interested women to pursue studies in schools/colleges, we often fall short of funds to sponsor their education in the current scenario of rising costs. There are few brilliant inmates who deserve better education and resources, but are limited due to our financial constraints. There are 42 school going children, residing in our premises, for whom we need sponsors & funding to continue their education. One more major concern needing funds is the health & treatment costs of the mentally imbalanced inmates in our trust home. Currently, we provide complete care & shelter to 46 such inmates, whose expenditure runs high due to the high costs of health care and transport..

Impact

Reunion of Ms.Priyanka (Jhansi Laxmi) with her Family.

On 14th March 2011, Priyanka was rescued and brought to KGNM Trust, by Narsingi police. The trust admitted her as inmate and noticed that she was traumatized and mentally unsound as well. After taking a few counseling sessions, the Trust administration sought help from doctors for her mental conditioning. She

was admitted to the institute of Mental Health, Erragadda. The treatment went on for 90 days.

Later, we conducted few more social counseling sessions to identify her history & family details. After we could extract required information, our trust looked out for her family with necessary help from Narsingi Police. On 19th November, 2011, we could successfully unite Priyanka with her parents at her native, Sudivaripalem, Chilakaluripeta, Guntur District. Her father, Mr. Venkata Ramaiah was contacted and the re-union planned after verifying the details of her father and establishing genuineness. Her family was in constant search for her and felt elated when they received our call with her details. This is one of the few such cases where an inmate is successfully brought back to normal life after experiencing very traumatic conditions. Nevertheless, such cases give us the motivation to put in our best effort behind every inmate, never losing the hope of success.

NOTES

5.10 FAMILY PLANNING ASSOCIATION OF INDIA

The Family Planning Association of India, is a voluntary Organisation, a non political and non-profit making body, which has its headquarters in Mumbai and has 40branches in various cities of India. The Pune Branch of FPA India was established in 1977 and has been working consistently, in this field, since then, with encouraging results. The. Branch functions under the guidance of the Branch Executive Committee consisting of 13 Volunteers, including 6 Office Bearers. The daily functions are carried out by staff employees.

Management and Governance

FPA India has a unique organizational structure, which includes volunteers and paid staff. Many volunteers are actively involved in planning, execution and monitoring of various activities. The Administration wing of the Branch supervises the overall implementation of all regular and special projects. It co-ordinates the clinical, educational and motivational activities of the branch and implements activities of HQ such as regional and national level workshops/seminars conducted at Pune. The Executive Committee consists of 16 volunteers including 6 Office Bearers who decide onpolicies, programmes guidance and monitoring and finances. The staff includes a Branch Manager, 6 administrative staff, 13 clinical staff and 6 field staff.

Safe Motherhood Project: With intension to save the lives of pregnant women, FPA India has started this project in collaboration with White Ribbion Alliance India for a period of 2 years i.e. from January, 2008. However actual activities were started from May 2008. FPA India, Pune Branch got this project for a period of 2 years. FPA India is implementing this project in 10 Districts of Maharashtra. Pune is one of them. Pune branch is implementing this project in the area of Kude PHC Khed Taluka which is near about 70 kms. from Pune Branch. The Branch adopted 16 wadies from Kude village near Rajguru Nagar to carry out Safe Motherhood Project. (Avadar,Parsul, Kharpud, Deoshi, Wajawane, Sakurdi, Chikhalgaon, Kalmodi, Majgaon, Enwe Khurd,Enwe Budruk, Kude Budruk, Kude Khurd, Ghotawade, Khope wadi, Adhal wadi)

Under this project, Sex Education to youth, adults and adolescents is imparted by giving scientific information about sexual and reproductive health. It provides counselling services to the clients with the intention to develop healthy attitudes and a holistic approach towards human sexuality. Besides working in operational areas, special programmes are organised for Municipal Corporation Schools.

Vision Statement: FPA India envisions health, particularly sexual and reproductive health for all, especially marginalized and young people, in the broad context of sustainable development leading towards alleviation of poverty, stabilization of population, gender equality and human rights.

5.11 ALL INDIA WOMEN'S CONFERENCE

ALL INDIA WOMEN`S CONFERENCE, an organization ,which is rather an obsession now, was formed in 1927, grown and supported by illustrious ladies who have become part of Indian History-pre & post independence. It has since then been an organization of ladies with a passion and drive for social service. Dr. Annie Besant, Mrs. Margaret Cousins and others founded Women`s Indian Association in Chennai,(Madras) in the year 1917.

Women from Mumbai, Pune and other cities also established similar women`s associations in their areas. At the end of the first world war when the Montague Chemsford Commission toured India, a fourteen member women`s delegation headed by the young and dynamic, Smt. Sarojini Naidu demanded self government, Women`s suffrage, educational and medical colleges for girls etc. But they were disappointed as their demands were rejected. However a negligible number of women were nominated on a few legislative councils.

The birth of the ALL INDIA WOMEN`S CONFERENCE took place in the year 1926. In a prize distribution function at Bethune College, Calcutta in 1926 Mrs. Margaret Cousins demanded that the women in India should have a full franchise but the then Director of Public Instructions, Bengal, Mr. Oaten taunted stating "how long are you going to tolerate a man made syllabus, a man made examination and controlling authority in which women have no influence as the orbiter of educational destiny which has resulted in a meager 2% of literacy amongst women?" This prompted Mrs. Cousins to take initiative for creating awareness amongst women.

She invited all the women`s associations in the country to meet in a conference. The response was very encouraging. The women`s association of Madras(Chennai), Mumbai, Pune and other cities assembled in Pune city at Fergusson College in 1927 under the Presidentship of Maharani Chimanabai Gaekwad of Baroda which brought everyone on a common platform to launch a women`s movement on a firm footing to acquire adult franchise and equal rights for women.( in health, education, inheritance, marriage laws, social reforms etc.) The ALL INDIA WOMEN`S CONFERENCE thus took birth in 1926 and turned into a countrywide movement.

The following thoughtfully drafted aims and policies were adopted. Aims & Objects :

- To work for a society based on the principles of social justice, personal integrity and equal rights and opportunities for all.

NOTES

- To secure recognition of the inherent right of every human being to work and to the essentials of life, such as food, clothing, housing, education, social amenities and security, in the belief that these should not be determined by accident of birth or sex but by planned social distribution.
- To support the claim of every citizen to the right to enjoy basic civil liberties.
- To stand against all separatist tendencies and to promote greater national integration and unity.
- To work actively for the general progress and welfare of women and children and to help women to utilize to the fullest the Fundamental Rights conferred on them by the Constitution of the Indian Union.
- To cooperate with people and organizations of the world for the implementation of those principles which alone can assure permanent international amity and world peace.

POLICY : To attain these aim and objectives, the society pledges itself:-

- To work on non-violent and non party political lines for the abolition of privileges accruing to individuals or to any section of the society on the basis of caste , creed, descent, wealth, sex, color, or race.
- To strive to promote universal education, national health, family planning and social security with improved living and working conditions for women and children.
- To promote mass education and dissemination of knowledge among women to develop rational and scientific secular attitudes in faith, morals and religious practices.
- To exert itself for ushering in necessary law reforms and change of social attitudes to fight against crimes and offences against women, and cruel religious practices involving women.
- To seek out work opportunities and gainful employment for women.

To fulfill the above objectives and policy and to achieve equal rights for Indian women it was decided to enact some laws ; and a Hindu code bill was drafted jointly by the All India Women's Conference and the National Council for Women in India. Though the bill was shelved at that time because of the second world war, it was accepted gradually in the Loksabha.

- The child marriage Restraint Act 1929 popularly known as Sir Harvilas Sarda Act.
- The special marriage act 1954.
- The suppression of Immoral Traffic Act 1956.
- The Hindu Marriage Act 1956
- The Intestate succession Act 1956.
- The prohibition of Dowry Act 1961.
- The Hindu Minority and Guardianship Act 1965.
- Anti child –labour Act 1983

- The orphanage and widows Home Act.
- Equal pay and Equal Work Act.

The All India Women's Conference has been responsible to start:

- First Home Science College in India at Delhi in 1932, which is known as Lady Irwin College.
- Rural Community Development Centre (SKIPPO Centres)
- The first Family Planning Centre set up as early as 1937.
- AIWC has also taken the initiative in building a cancer Hospital in Chennai.
- Save the children`s fund in 1942, which later became the foundation for the Indian Council for child welfare.
- `Bapnu Ghar` a home for women in social distress at New Delhi in 1965.

Achivements and Alliance

- AIWC has consultative status with United Nations
- AIWC has affiliation with UNICEF, UNESCO International Alliance of Women, FAWA, Pan Pacific and South East Asia Women`s Association

From the year 1927 to 1952 Mumbai City enjoyed the privilege of having the National Head Quarters of All India Women`s Conference , a period which is very crucial for any institution to establish a firm base. Thus Mumbai or to be exact the Mumbai Women`s Association is the mother of AIWC as well as the first born daughter of AIWC and we feel very proud of this double status which may sound contradictory initially, but is still true in its many proud achievements in following aims and objectives of AIWC leading to the empowerment of women. Since 1952 the Head Office of AIWC has shifted to 6, Bhagwan Dass Road, Sarojini House, New Delhi, 110 001. Since then the MUMBAI BRANCH, AIWC has flourished under the able and capable guidance of prominent social workers like Smt. Mitha Lam, Smt. Kapila Khandwala, Smt. Lilavati Banker, Smt. Gulistan Billimoria, Lady Rama Rao. Mumbai Branch, AIWC has presented to the city of Mumbai eminent councillors, MLAs`, Parliamentarians and leaders who worked not only at the national levels but also at international levels. To name a few , these early leaders were Smt. Malini Sukhtankar, Smt. Maniben Desai, Smt. Sulochana Modi, and Smt. Nirmala Samant Prabhavalkar who reached the position of Mayor of the city of Mumbai, ministers and legislators like the President of India, Smt. Pratibha Patil, Smt. Mrinal Gore, Smt. Jaishreeben Raijee, and international luminaries like Smt. Hansa Mehta, Smt. Kamaladevi Chattopadhya, and Dr. Avabai Wadia, We are also proud of Mrs. Mehraben Jhabwala and Mrs. Urmila Mehta who rose to be Presidents of AIWC at the national level and many members graced the chair of office bearers at the national level viz. Smt. Pramoda Gosalia as Secretary General and Smt. Sarla Shah as Hon. Treasurer and Dr. Dhairyabala Vora as Vice President. Mumbai Branch, AIWC had the good fortune to organize 3 National Annual Conferences in

- 1944,when Smt. Vatsalatai Naik was the Reception Committee Chairman ;
- 1967 -under the Presidentship of Smt.Vidya Killawala ; and recently
- From 1st to 4th January 2010 under the Presidentship of Smt. Sheela Kakde

NOTES

where the Mayor of Mumbai , Smt. Shraddha Jadhav was the Chief Guest. We have organized Half yearly session of Standing committee meeting of AIWC in 1989 under the Presidentship of Dr. Bindu Pandit. The Golden Jubilee of the National body was also celebrated in 1976 in Mumbai. Mumbai Branch, AIWC consists of 24 Constituent branches spread all over Mumbai. It has a membership of 12,000 members. The branches are separately registered with the Charity Commissioner, they work independently with their own committee on the guidelines given by the Mumbai Branch. They report regularly to Mumbai branch and have representation on all the four projects of Mumbai branch. Branches pay nominal affiliation Capitation fees to the Mumbai branch, who in turn pays the affiliation fee to the Head Office.

Mumbai branch ,AIWC runs four main projects viz

- Rural Community Development Centre at Talasari.(RCDC) Rural extension programs undertaken by All India Women`s Conference were taken up with a definite objective of sensitizing urban women towards this situation and to expand and extend the activities of women and child welfare to rural areas. The present program of Rural development undertaken by AIWC, Mumbai Branch, located at Talasari started some decades back. Mrs. Hilda Seliman a British resident had stayed in India and was deeply distressed by the plight of rural and tribal women and children. She was a writer and wrote children`s story books. She had written a story about the pranks played by the goat named SKIPPO. Out of the Royalty of this story book and other donations, she founded SKIPPO Fund. Out of the fund a mobile health van was custom made in London and offered to AIWC to start rural health project. Lady Ramarao and Dr. Avabai Wadia worked out on this Skippo project .The van used to go in the interiors of Umargao Taluka. Later on local resident of Talasari, Smt. Kashibai Mohite generously donated one acre of land where the present project is run. Slowly the land was developed with the help of Central Social welfare Board,and Social welfare dept. of Maharashtra. This Mumbai branch project under went various phases of development and the present Chairperson of the project Dr. Dhairyabala Vora has more plans of development.
- Kesarbai Bhimani working women`s Hostel at Juhu, Mumbai. In Mumbai there is ample job opportunity for educated and self reliant women. Smt. Meharaben Jhabvala, Patron AIWC ,worked hard for the establishment of the hostel for middle class working women. It was her dream to provide safe and secure accommodation without any discrimination of caste creed or religion. Shri Manubhai Bhimani, the then trustee of the Lotus Trust made a generous offer to donate a lakh of rupees from the Lotus Trust and a piece of land for the hostel building on a lease of 999 years. Smt. Vatsala bai Naik performed `Bhoomi Pooja` on the plot of the land for the Hostel, on 18th February1970. The foundation stone of the single storey Hostel Building was laid on 8th May 1970 by Smt. Jhabwala. On 19th April 1987 the hostel building was named as `Savitri Sadan` to commemorate a donation of Rs. 50,000/- in memory of Smt. Savitriben Desai. In 1988 , Chairperson Smt. Uma Rajan resigned after 10

years of service and was succeeded by Smt. Smita Y. Desai. Slowly the need of the hostel increased and to fulfil the demand the building extension work was undertaken by Chairperson , Smt. Smita Desai . Large donations were collected under the guidance of Chairperson Fund raising committee, Smt. Susheela Munshi. The main Hall of the Hostel was named as `Meharaben Jhabvala Memorial Hall`, to commemorate her memory in establishing the Hostel.

- Education Project at Dharavi, Mumbai. The Mumbai branch of All India Women`s Conference received Madam Luther`s report and a project proposal on `Adult Literacy` in 1985. Keeping in view the alarming condition of illiteracy amongst women in India, the Mumbai Branch of the AIWC, decided to take up Adult Education for women as one of their mainstream activities. A separate committee was thus formed by the Mumbai Branch. On 1st March, 1987, five Adult Education Centres were started by Mahila Sangh `D` ward,SWKC Mahila Manda. Khar Vile Parle and Jogeshwari constituent branches. Based on experience, it was felt that due to government policy and efforts of voluntary agencies, it would be more effective if one consolidated area was taken up and work done for complete eradication of illiteracy in that particular area. The Education Committee of Mumbai branch in co operation with the dept. of Preventive and Social Medicine at Sion Hospital, identified 30 centers for Dharavi.Thus the Education project started in Dharavi by Mumbai Branch.
- Street Children Project `Shraddha` at Khar, Mumbai. SOS India established the Hermann Gmeiner Social centre for the street children with the aim to lessen the hardship and risk faced by street children in 1996, in two cities of Pune and Mumbai. The program was wholly supported by SOS India and was administered in collaboration with Balagram SOS children`s Village, Maharashtra. AIWC always alert and ready to put up efforts in child welfare had undertaken this project. The Mumbai Branch was inspired by Smt. Shobhana Ranade, Patron AIWC and Chairperson , SOS children`s village Maharashtra. `Shraddha` was inaugurated by Smt. Vijayalaxmi Pandit, Juvenile Magistrate on 2nd October,1996. It started functioning at Khar station, platform no.5 and afterwards at Madhu Park due to lack of adequate place. Later we got a room from Mumbai Municipal Education Department at Hasanabad Municpal School, Hasanabad Lane, Khar west, with the efforts of late Shri Prabhakar Vaidya. Now the centre is running well there.

Besides these major projects Mumbai branch runs many Awareness programmes and Legal aid and counseling centre. Various lectures and demonstrations are arranged to create awareness in the area of medical, legal, social fields..

5.12 INTERNATIONAL HEALTH CARE AGENCIES – UNICEF

UNICEF relies on contributions from governments and private donors and UNICEF's total income for 2008 was $3,372,540,239.Governments contribute two thirds of the organization's resources; private groups and some 6 million individuals

NOTES

contribute the rest through the National Committees. It is estimated that 91.8% of their revenue is distributed to Program Services. UNICEF's programs emphasize developing community-level services to promote the health and well-being of children. UNICEF was awarded the Nobel Peace Prize in 1965 and the Prince of Asturias Award of Concord in 2006.

Most of UNICEF's work is in the field, with staff in over 190 countries and territories. More than 200 country offices carry out UNICEF's mission through a program developed with host governments. Seventeen regional offices provide technical assistance to country offices as needed.

Overall management and administration of the organization takes place at its headquarters in New York. UNICEF's Supply Division is based in Copenhagen and serves as the primary point of distribution for such essential items as vaccines, antiretroviral medicines for children and mothers with HIV, nutritional supplements, emergency shelters, educational supplies, among others. A 36-member Executive Board establishes policies, approves programs and oversees administrative and financial plans. The Executive Board is made up of government representatives who are elected by the United Nations Economic and Social Council, usually for three-year terms.

UNICEF *School in a box* contains basic educational items for 1 teacher and 40 students.

Recent executive directors of UNICEF include Carol Bellamy (1995-2005), a former head of thePeace Corps, and Ann Veneman (2005-2010), a former United States Secretary of Agriculturewhose mandate included increasing the organization's focus on the Millennium Development Goals. Since 2010, the current Executive Director of UNICEF has been Anthony Lake, a former US National Security Advisor.

Develop further an open TRADING and financial system that includes a commitment to good governance, development and poverty reduction — nationally and internationally.

Address the least developed countries' special needs, and the special needs of landlocked and small island developing states.

Deal comprehensively with developing countries' debt problems.

Develop decent and productive work for youth.

In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.

In cooperation with the private sector, make available the benefits of new technologies — especially information and communications technologies.

Partnerships are vital to UNICEF.

Non-governmental and private sector organizations contributed 31 per cent of UNICEF's income in 2003, more than $515 million dollars.

UNICEF is uniquely positioned to generate knowledge about the situation of children's and women's rights, and to advocate and promote partnerships for their fulfilment.

It incorporated the *Office International d'Hygiène Publique* and the League of Nations Health Organization. Since its creation, it has played a leading role in the eradication of smallpox. Its current priorities include communicable diseases, in particular, HIV/AIDS, Ebola, malaria andtuberculosis; the mitigation of the effects of non-communicable diseases; sexual and reproductive health, development, and aging; nutrition, food security and healthy eating; occupational health; substance abuse; and drive the development of reporting, publications, and networking. WHO is responsible for the World Health Report, a leading international publication on health, the worldwide World Health Survey, and World Health Day (7 April of every year).

Structure

The World Health Organization is a member of the United Nations Development Group.

Membership

As of 2013, the WHO has 194 member states: all Member States of the United Nations exceptLiechtenstein, as well as the Cook Islands and Niue. (A state becomes a full member of WHO by ratifying the treaty known as the Constitution of the World Health Organization.) As of 2013, it also had two associate members, Puerto Rico and Tokelau. Several other entities have been grantedobserver status. Palestine is an observer as a "national liberation movement" recognised by theLeague of Arab States under United Nations Resolution 3118. The Holy See also attends as an observer, as does the Order of Malta. In 2010, Taiwan was invited under the name of "Chinese Taipei".

WHO Member States appoint delegations to the World Health Assembly, WHO's supreme decision-making body. All UN Member States are eligible for WHO membership, and, according to the WHO web site, "other countries may be admitted as members when their application has been approved by a simple majority vote of the World Health Assembly".

In addition, the UN observer organizations International Committee of the Red Cross and International Federation of Red Cross and Red Crescent Societies have entered into "official relations" with WHO and are invited as observers. In the World Health Assembly they are seated alongside the other NGOs.

Assembly and Executive Board

The World Health Assembly is the legislative and supreme body of WHO. Based in Geneva, it typically meets yearly in May. It appoints the Director-General every five years, and votes on matters of policy and finance of WHO, including the proposed budget. It also reviews reports of the Executive Board and decides whether there are areas of work requiring further examination. The Assembly elects 34 members, technically qualified in the field of health, to the Executive Board for three-year terms. The main functions of the Board are to carry out the decisions and policies of the Assembly, to advise it and to facilitate its work.

NOTES

Regional offices

The regional divisions of WHO were created between 1949 and 1952, and are based on article 44 of WHO's constitution, which allowed the WHA to "establish a [single] regional organization to meet the special needs of [each defined] area". Many decisions are made at regional level, including important discussions over WHO's budget, and in deciding the members of the next assembly, which are designated by the regions.

Each region has a Regional Committee, which generally meets once a year, normally in the autumn. Representatives attend from each member or associative member in each region, including those states that are not fully recognised. For example, Palestine attends meetings of the Eastern Mediterranean Regional office. Each region also has a regional office. Each Regional Office is headed by a Regional Director, who is elected by the Regional Committee. The Board must approve such appointments, although as of 2004, it had never overruled the preference of a regional committee. The exact role of the board in the process has been a subject of debate, but the practical effect has always been small. Since 1999, Regional Directors serve for a once-renewable five-year term.

Each Regional Committee of the WHO consists of all the Health Department heads, in all the governments of the countries that constitute the Region. Aside from electing the Regional Director, the Regional Committee is also in charge of setting the guidelines for the implementation, within the region, of the health and other policies adopted by the World Health Assembly. The Regional Committee also serves as a progress review board for the actions of WHO within the Region.

5.14 UNDP

UNDP is the UN's global development network, an organization advocating change and connecting countries to knowledge, experience and resources to help people build a better life. We are on the ground in 166 countries, working with them on their own solutions to global and national development challenges.

The **United Nations Development Programme (UNDP)** is the United Nations' global development network.

Headquartered in New York City, UNDP advocates for change and connects countries to knowledge, experience and resources to help people build a better life. It provides expert advice, training, and grant support to developing countries, with increasing emphasis on assistance to the least developed countries.

The status of UNDP is that of an executive board within the United Nations General Assembly. The UNDP Administrator is the third highest-ranking official of the United Nations after theUnited Nations Secretary-General and Deputy Secretary-General.

To accomplish the MDGs and encourage global development, UNDP focuses on poverty reduction, HIV/AIDS, democratic governance, energy and environment, social development, and crisis prevention and recovery. UNDP also encourages the

protection of human rights and the empowerment of women in all of its programmes. The UNDP Human Development Report Office also publishes an annual Human Development Report (since 1990) to measure and analyse developmental progress. In addition to a global Report, UNDP publishes regional, national, and local Human Development Reports.

UNDP is funded entirely by voluntary contributions from member nations. The organization has country offices in 177 countries, where it works with local governments to meet development challenges and develop local capacity. Additionally, the UNDP works internationally to help countries achieve the Millennium Development Goals (MDGs). Currently, the UNDP is one of the main UN agencies involved in the development of the Post-2015 Development Agenda.

UNDP operates in 177 countries, working with nations on their own solutions to global and national development challenges. As they develop local capacity, they draw on the people of UNDP and its wide range of partners.

Reduction Efforts

UNDP Headquarters and several Regional Centers and Country Offices are in the process of developing comprehensive Emission Reduction Strategies (ERS). Many substantial steps have been taken already or are currently being implemented to reduce UNDP's environmental footprint: At Headquarters, one of UNDP's office spaces was the first UN office in New York to receive the US Green Building Council's coveted GOLD standard under the Leadership in Energy and Environment Design (LEED) certification scheme. Options for purchasing green electricity are being pursued at HQ and in several Country Offices. In Montenegro, the first zero emissions office for any UN country team is currently being built and in Vietnam the 'Green One UN House' will reduce UNDP's environmental footprint substantially. In the UNDP Regional Center in Bratislava roof top panels generate 'green' electricity from solar power. Other emission reduction efforts undertaken by UNDP offices include but are not limited to energy efficiency measures in the office space, procurement of hybrid cars, mangrove planting and staff training.

Offsetting

As of 2010, UNDP will have its first climate neutral division: The Bureau for Development Policy (BDP), which is responsible for about 25% of Headquarters' GHG emissions, is procuring Gold Standard Certified Emission Reductions (CERs) to offset all GHG emissions generated by its office operations and official travel. Also, UNDP has offset events and meetings in the past with Gold Standard CERs, delivering additional benefits for Millennium Development Goals (MDGs) and sustainable development.

5.15 WORLD BANK

The **World Bank** is a United Nations international financial institution that providesloans to developing countries for capital programs. The World Bank is

a component of the **World Bank Group**, and a member of the United Nations Development Group.

The World Bank's official goal is the reduction of poverty. According to its Articles of Agreement, all its decisions must be guided by a commitment to the promotion offoreign investment and international trade and to the facilitation of capital INVESTMENT.

NOTES

5.16 CARE

CARE (Cooperative for Assistance and Relief Everywhere) is a major international lhumanitarian agency delivering broad-spectrum emergency relief and long-term international development projects. Founded in 1945, CARE is nonsectarian, impartial, and non-governmental. It is one of the largest and oldest humanitarian aid organizations focused on fighting global poverty. In 2013, CARE reported working in 87 countries, supporting 927poverty-fighting projects and humanitarian aid projects, and reaching over 97 million people.

CARE's programmes in the developing world address a broad range of topics including emergency response, food security, water and sanitation, economic development, climate change, agriculture, education, and health. CARE also advocates at the local, national, and international levels for policy change and the rights of poor people. Within each of these areas, CARE focuses particularly on empowering and meeting the needs of women and girls and on promoting gender equality.

CARE International is a confederation of thirteen CARE National Members and one Affiliate Member, each of which is registered as an autonomous non-profit non-governmental organization in the country. The thirteen CARE National Members are CARE Australia, CARE Canada, CARE Danmark, CARE Deutschland-Luxembourg, CARE France, CARE India, CARE International Japan, CARE Nederland, CARE Norge, CARE Österreich, Raks Thai Foundation (CARE Thailand), CARE International UK, and CARE USA. The CARE Affiliate Member is CARE Peru. Programs in developing countries are usually managed by a Country Office, but CARE also supports projects and may respond to emergencies in some countries where they do not maintain a full Country Office.

5.17 ROCKEFELLER FOUNDATION

For more than 100 years, The Rockefeller Foundation's mission has been to promote the well-being of humanity throughout the world. Today, we pursue this mission through dual goals: advancing inclusive economies that expand opportunities for more broadly shared prosperity, and building resilience by enabling people, communities and institutions to be prepared for, withstand, and emerge stronger from shocks and chronic stresses.

The Foundation operates both within the United States and around the world. The Foundation's efforts are overseen by an independent Board of Trustees and managed by its president through a leadership team drawn from scholarly, scientific, and professional disciplines.

NOTES

Our Core Values

At The Rockefeller Foundation, we embrace a set of core values to guide our work to promote the well-being of humanity throughout the world.

Governance

The governance practices of The Rockefeller Foundation are described in a set of documents, including: the Charter, Social INVESTING Guidelines, Bylaws, and Code of Conduct, which are approved by the Board of Trustees.

Trustees

The Rockefeller Foundation is governed by the Board of Trustees which consists of no fewer than 12 members, with the Foundation's president serving as an ex-officio member. The Board of Trustees is generally responsible for overseeing the Foundation's program and grantmaking strategy; budgets, expenditures and appropriation policies and guidelines; and INVESTMENT strategies, allocations and performance. The Board of Trustees performs its duties through committees that include, but are not limited to: the Executive Committee, Investment Committee, Budget and Compensation Committee, Audit Committee and Trusteeship Committee as described in the Foundation's Bylaws.

Staff

The Rockefeller Foundation's senior leadership and staff members bring a broad range of talents to the organization with experiences drawn from scholarly, scientific, and private and nonprofit professional disciplines.

Beginnings [SH]

Rockefeller's interest in philanthropy on a large scale began in 1889, influenced by Andrew Carnegie's published essay, *The Gospel of Wealth*, which prompted him to write a letter to Carnegie praising him as an example to other rich men. It was in that year that he made the first of what would become $35 million in gifts, over a period of two decades, to fund the University of Chicago.

His initial idea to set up a large-scale tax-exempt foundation occurred in 1901, but it was not until 1906 that Senior's famous business and philanthropic advisor, Frederick Taylor Gates, seriously revived the idea, saying that Rockefeller's fortune was rolling up so fast his heirs would "dissipate their inheritances or become intoxicated with power", unless he set up "permanent corporate philanthropies for the good of Mankind".

It was also in 1906 that the Russell Sage Foundation was established, though its program was limited to working women and social ills. Rockefeller's would thus not be the first foundation in America (Benjamin Franklin was the first to introduce the concept), but it brought to it unprecedented international scale and scope. In 1909 he signed over 73,000 shares of Standard Oil of New Jersey, valued at $50 million, to the three inaugural trustees, Junior, Gates and Harold Fowler McCormick, the first installment of a projected $100 million endowment.

NOTES

They applied for a federal charter for the foundation in the US Senate in 1910, with at one stage Junior even secretly meeting with President William Howard Taft, through the aegis of Senator Nelson Aldrich, to hammer out concessions. However, because of the ongoing (1911) antitrust suit against Standard OIL at the time, along with deep suspicion in some quarters of undue Rockefeller influence on the spending of the endowment, the end result was that Senior and Gates withdrew the bill from Congress in order to seek a state charter.

On May 14, 1913, New York Governor William Sulzer approved a state charter for the foundation - two years after the Carnegie Corporation- with Junior becoming the first president. With its large-scale endowment, a large part of Senior's fortune was insulated from inheritance taxes. The total benefactions of both him and Junior and their philanthropies in the end would far surpass Carnegie's endowments, his biographer Ron Chernow states, ranking Rockefeller as "the greatest philanthropist in American history."

5.18 STUDENT ACTIVITY

1. Describe the Mission of The mission of the Indian Red Cross.
2. Discuss the function of Mahila Mandal Programme.
3. How is family planning association of India is beneficial for the country?

5.19 SUMMARY

- The Indian Red Cross Society is a voluntary humanitarian organization having a network of over 700 branches throughout India, providing relief in times of disasters/emergencies and promoting health & care of the vulnerable people and communities.
- Hind Kusht Nivaran Sangh (Indian Leprosy Association) is an old and prestigeous body of people committed towards treatment, rehabilitation of leprosy patients and elimination of leprosy from India.
- The Government of India adopted the National Charter for Children which has been prepared after obtaining the views/comments and suggestions of the State Governments/UT Administrations, concerned Ministries and Departments and experts in the field.
- An Integrated Programme for Street Children is being implemented by the Ministry of Women and Child Development specifically for those children who are on streets and homeless and include the ragpicking and vagabond children.
- The Central Social Welfare Board (CSWB) was set up in 1953 with the objective of promoting social welfare activities and implementing welfare programmes for women, children and the handicapped through voluntary organizations.

5.20 GLOSSARY

- Childline India Foundation (CIF) has been set up as a nodal organization,

supported by Government of India, to monitor and ensure the qualitative development of the Childline service across the country. Childline is a toll free telephone service (1098) which anyone can call for assistance in the interest of children.

- National Award for Child Welfare: The Award was instituted in 1979 to honour five institutions and three individuals for their outstanding performance in the field of child welfare.
- Rajiv Gandhi Manav Seva Award: This Award was instituted in 1994 to honour an individual who makes outstanding contribution towards service for children. The Award carries a cash prize of Rs. 1 lakh, a silver plaque and a citation.
- Bharat Sevak Samaj: Bharat Sevak Samaj (BSS) is the National Development Agency sponsored by the Planning Commission, Government of India to ensure public co-operation for implementing government plans.
- World Health Organization : The World Health Organization (WHO) is a specialized agency of the United Nations (UN) that is concerned with international public health. It was established on 7 April 1948, headquartered in Geneva, Switzerland. WHO is a member of the United Nations Development Group. Its predecessor, the Health Organization, was an agency of the League of Nations.

5.21 REVIEW QUESTIONS

1. What is the motto of ALL INDIA WOMEN'S CONFERENCE?
2. What is the function of UNICEF?
3. Which countries are associated to **World Health Organization**?
4. How is CARE beneficial for the country?
5. Write short note on:
   (a) CIF
   (b) RNTCP
   (c) DOTS
   (d) CHAI
   (e) UNICEF

NOTES

UNIT

6

HEALTH POLICIES

STRUCTURE

6.0 LEARNING OBJECTIVES

After completion of the unit, you will be able to:

- Understand National health policy and population policy 2000
- Describe Pharmaceutical legislation in India
- Discuss Pharmacy act, drugs and cosmetics act
- Explain narcotics and psychotropic substances act
- Describe drug and magic remedies act and poisons act and rules

NOTES

6.1 INTRODUCTION

Health policy can be defined as the "decisions, plans, and actions that are undertaken to achieve specific health care goals within a society." According to the World Health Organization, an explicit health policy can achieve several things: it defines a vision for the future; it outlines priorities and the expected roles of different groups; and it builds consensus and informs people.

6.2 NATIONAL HEALTH POLICY

National health policies, strategies, and plans play an essential role in defining a country's vision, priorities, budgetary decisions and course of action for improving and maintaining the health of its people. Most countries have been using the development of national health policies, strategies, and plans for decades to give direction and coherence to their efforts to improve health.

The mismatch between actual performance of fragmented health systems and the rising expectations of society is becoming a cause of concern and internal pressure for health authorities and political leaders.

These and other factors – including today's consensus around the importance of realistic costing and strong monitoring and evaluation – have translated into a renewed focus on strengthening countries' capacity to develop robust national health policies, strategies, and plans that can:

- Respond to growing calls for strengthening health systems through Primary Health Care as a way of achieving the goal of better health for all. This requires action in four policy areas: moving towards universal coverage, reorienting conventional care towards people-centred care, integrating health in all policies, and ensuring more inclusive health governance;
- Guide and steer the entire, pluralist health sector rather than being limited to command-and-control plans for the public sector alone;
- Go beyond the boundaries of health systems, addressing the social determinants of health and the interaction between the health sector and other sectors in society.

Additionally, in countries where external aid plays a significant role, national health policies, strategies, and plans are increasingly seen as the key to improve aid effectiveness.

Joint assessment can also help to strengthen national health strategies and plans and increase partner confidence, thereby securing more predictable and better aligned funding. It may also reduce transaction costs arising from multiple separate agency assessments.

WHO Framework Supports Countries National Health Planning

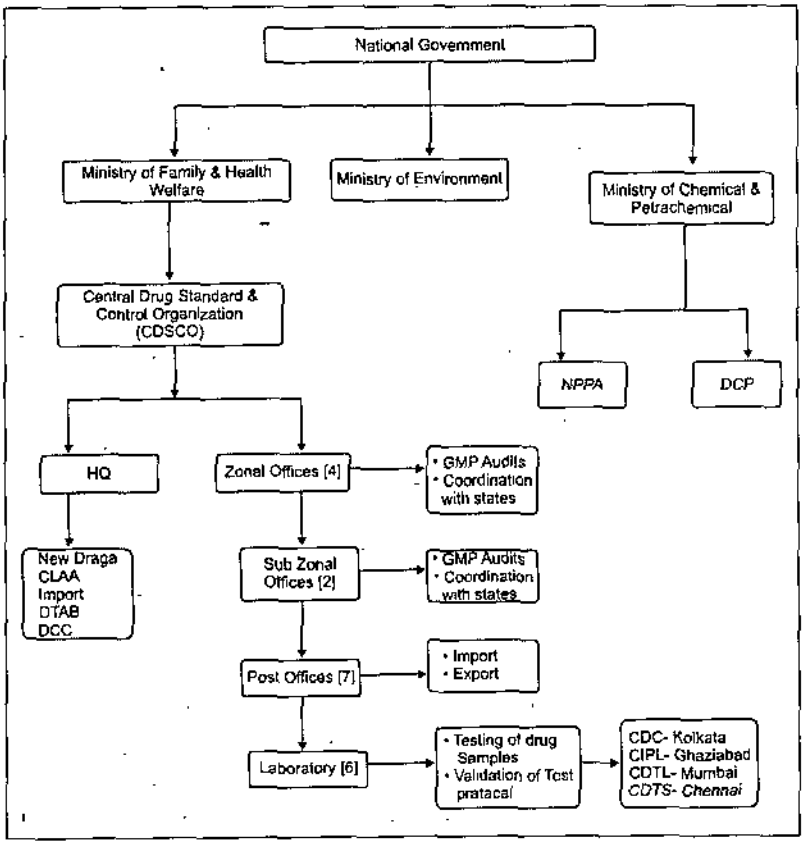
Many countries struggle to develop the policy instruments and broker the complex dialogue necessary to see this process through from vision to implementation.

Country	Generics market
Worldwide	10%
Japan	4.8%
Rest of America	9.7%
Western Europe	10.5%
US	11.8%
Others	9.3%

The following are the top pharmaceutical companies of the country:

- Ranbaxy Laboratories
- Sun Pharmaceuticals
- Dr. Reddy's Laboratories
- Cipla
- Ashwin Dalvi India
- Aurobindo Pharma
- Nicholas Piramal
- GlaxoSmithKline
- Lupin Laboratories
- Cadila Healthcare

Drug Regulation in India: India has a federal form of government and the medical regulatory structure is divided between national and state authorities.



NOTES

6.4 POPULATION POLICY 2000

The overriding objective of economic and social development is to improve the quality of lives that people lead, to enhance their well-being, and to provide them with opportunities and choices to become productive assets in society. In 1952, India was the first country in the world to launch a national programme, emphasizing family planning to the extent necessary for reducing birth rates "to stabilize the population at a level consistent with the requirement of national economy" After 1952, sharp declines in death rates were, however, not accompanied by a similar drop in birth rates.

The National Health Policy, 1983 stated that replacement levels of total fertility rate(TFR) should be achieved by the year 2000. On 11 May, 2000 India was projected to have 1 billion (100 crore) people, i.e. 16 percent of the world's population on 2.4 percent of the globe's land area. If current trends continue, India may overtake China in 2045, to become the most populous country in the world. While global population has increased threefold during this century, from 2 billion to 6 billion, the population of India has increased nearly five times from 238 million (23 crores) to 1 billion in the same period.

India's current annual increase in population of 15.5 million is large enough to neutralize efforts to conserve the resource endowment and environment. Stabilising population is an essential requirement for promoting sustainable development with more equitable distribution. However, it is as much a function of making reproductive health care accessible and affordable for all, as of increasing the provision and outreach of primary and secondary education, extending basic amenities including sanitation, safe drinking water and housing, besides empowering women and enhancing their employment opportunities, and providing transport and communications.

The National Population Policy, 2000 (NPP 2000) affirms the commitment of government towards voluntary and informed choice and consent of citizens while availing of reproductive health care services, and continuation of the target free approach in administering family planning services. The NPP 2000 provides a policy framework for advancing goals and prioritizing strategies during the next decade, to meet the reproductive and child health needs of the people of India, and to achieve net replacement levels (TFR) by 2010. It is based upon the need to simultaneously address issues of child survival, maternal health, and contraception, while increasing outreach and coverage of a comprehensive package of reproductive and child heath services by government, industry and the voluntary non-government sector, working in partnership.

National Population Policy of India

National Population Policy of India was formulated in the year 2000 with the long term objective of achieving a stable population by 2045, at a level consistent with the requirements of sustainable economic growth, social development, and environmental protection. The immediate objective of the policy is to address the unmet needs for contraception, health care infrastructure, and health personnel,

and to provide integrated service delivery for basic reproductive and child health care. The medium-term objective is to bring the TFR (Total Fertility Rate) to replacement levels by 2010, through vigorous implementation of inter-sectoral operational strategies. TFR is the average number of children each women would have in her life time. National Population Policy pursues to achieve following Socio-Demographic goals by 2010:

- Address the unmet needs for basic reproductive and child health services, supplies and infrastructure.
- Make school education up to age 14 free and compulsory, and reduce drop outs at primary and secondary school levels to below 20 percent for both boys and girls.
- Reduce infant mortality rate to below 30 per 1000 live births.
- Reduce maternal mortality ratio to below 100 per 100,000 live births.
- Achieve universal immunization of children against all vaccine preventable diseases.
- Promote delayed marriage for girls, not earlier than age 18 and preferably after 20 years of age.
- Achieve 80 percent institutional deliveries and 100 percent deliveries by trained persons.
- Achieve universal access to information/counseling, and services for fertility regulation and contraception with a wide basket of choices.
- Achieve 100 per cent registration of births, deaths, marriage and pregnancy.
- Contain the spread of Acquired Immunodeficiency Syndrome (AIDS), and promote greater integration between the management of reproductive tract infections (RTI) and sexually transmitted infections (STI) and the National AIDS Control Organization.
- Prevent and Control communicable diseases.12. Integrate Indian Systems of Medicines (ISM) in the provision of reproductive and child health services, and in reaching out to households.
- Promote vigorously the small family norm to achieve replacement levels of TFR.
- Bring about convergence in implementation of related social sector programs so that family welfare becomes a people centered programme.

The Main Targets Fixed in the National Population Policy 2000, India

The main targets fixed in the National population policy 2000, India are as follows:

The National Population Policy 2000 provides a policy framework for advancing goals and prorating strategies during the next decades to meet the reproductive and child health needs of the people of India.

This policy states that the objective of economic and social development is to improve the quality of lives people lead to enhance their well being and to provide them with opportunities and choices to become productive assets in society.

Functions of CDSCO:

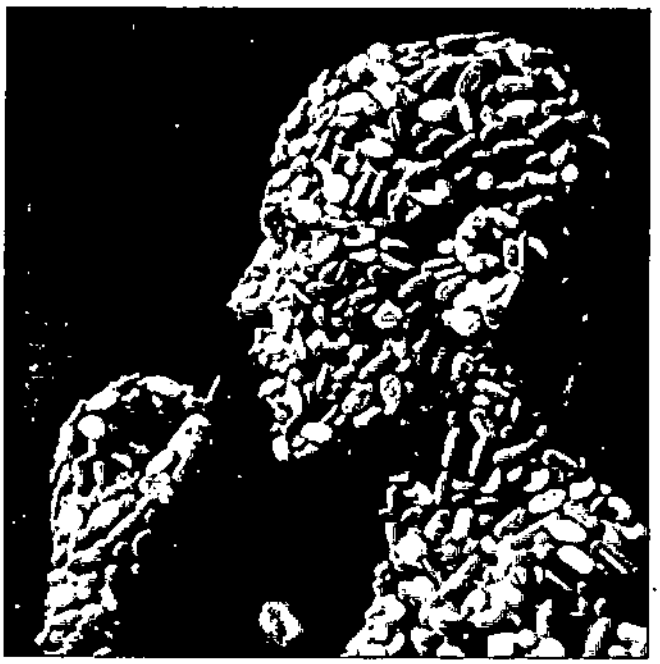
1. Approval of new drugs and clinical trials
2. Import Registration and Licensing
3. Licensing of Blood Banks, LVP's, Vaccines, r-DNA products & some Medical Devices
4. Amendment to D &C Act and Rules
5. Banning of drugs and cosmetics
6. Grant of Test License,
7. Personal License,
8. NOCs for Export
9. Testing of Drugs

Rules to Setup a Drug Manufacturing Unit in India

The main law which provides for regulation of the import, manufacture, distribution and sale of drugs in India is the Drugs and Cosmetics Act, 1940.The legislation is enforced by the Central Government, which is responsible for overall supervision. The office of the Drug Controller of India (DCI) has prime responsibility.

However, at the field level, enforcement is done by the individual State governments through their Food and Drug Administrations. Matters of product approval and standards, clinical trials, introduction of new drugs, and import licenses for new drugs are handled by the DCI. The approvals for setting up manufacturing facilities, and obtaining licenses to sell and STOCK drugs are provided by the State Governments. Price controls are in effect on certain drugs, by virtue of the Drug Prices Control Order 2013.

Types of drugs that can be manufactured



NOTES

WHO has a long track record of supporting Member States in this area through country-level technical cooperation, facilitation of national policy dialogue and inter-country exchange, as well as through normative work and high-level international policy frameworks.

The WHO framework for national health policies, strategies and plans, developed in 2010, reviews current practice, identifies common "disconnects" and lays out elements of good practice for developing robust, comprehensive national health policies, strategies, and plans.

6.3 SALIENT FEATURES

NHP – 2002 focuses on the need for enhanced funding and an organizational restructuring of the national public health initiatives in order to facilitate more equitable access to the health facilities. The Policy is focused on those diseases which are principally contributing to the disease burden – TB, Malaria andBlindness from the category of historical diseases; and HIV/AIDS from the category of 'newly emerging diseases'.

The governments and private sector programme planners will have to design separate schemes, tailor-made to the health needs of women, children, geriatrics, tribals and other socio-economically under-served sections. An adequately robust disaster management plan has to be in place.

Consistent with the primacy given to 'equity', a marked emphasis has been provided for expanding and improving the primary health facilities, including the new concept of the provisioning of essential drugs through Central funding. The Policy also commits the Central Government to an increased under-writing of the resources for meeting the minimum health needs of the people. Thus, the Policy attempts to provide guidance for prioritizing expenditure, thereby facilitating rational resource allocation.

This Policy broadly envisages a greater contribution from the Central Budget for the delivery of Public Health services at the State level. However, it highlights the expected roles of the State administration, NGOs and other institutions of civil society.

The attainment of improved health levels would be significantly dependent on population stabilisation, as also on complementary efforts from other areas of the social sectors – like improved drinking water supply, basic sanitation, minimum nutrition, etc. - to ensure that the exposure of the populace to health risks is minimized.

In the ultimate analysis, the quality of health services, and the consequential improved health status of the citizenry, would depend not only on increased financial and material inputs, but also on a more empathetic and committed attitude in the service providers, whether in the private or public sectors. Any policy in the social sector is critically dependent on the service providers treating their responsibility not as a commercial activity, but as a service, albeit a paid one. In the area of public health, an improved standard of governance is a prerequisite for the success of any health policy.

Medicines in India are regulated by CDSCO - Central Drugs Standard Control Organization under Ministry of Health and Family Welfare. Headed by Directorate General of Health Services CDSCO regulates the Pharmaceutical Products through DCGI - Drugs Controller General of India at Chair.

Under Retail and Distribution: - Drugs classified under 5 heads.

1. Schedule X drugs – Narcotics
2. Schedule H and L – Injectables, Antibiotics, Antibacterial
3. Schedule C and C1- Biological Products-example Serums and Vaccines

Under Manufacturing Practice 1. Schedule N List of the equipment for the efficient running of manufacturing wing, qualified personnel 2. Schedule M.

The DCGI registers all imported drugs, new drugs, and drugs in selected categories. It also has responsibility for clinical trials and quality standards. The state FDA's register all other products, accredit manufacturing plants, and conduct the bulk of quality monitoring and inspections. The Indian cabinet has approved a plan that would bring all drugs under a new Central Drugs Authority, modeled on the US FDA. This may be approved by Parliament in a legislative session during the summer of 2007, but if so it will be phased in over time.

The DCGI has a shortage of reviewers, often relying on outside experts to provide opinions. To pursue regulatory approvals effectively, a company must use a regulatory professional with significant experience in applications for foreign companies. This professional must also be in a position to spend a significant amount of time in New Delhi (where the DCGI is located) following up on applications.

Most of India's pharmaceutical product policy is governed by the Drugs and Cosmetics Act (DCA). The DCA was first enacted in 1940 and has been amended many times since then.

All regulatory aspects related to import, manufacture, sale and advertisements of drugs in India are covered under three separate enactments, namely, Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics Rules 1945, The Pharmacy Act 1948 and the Drugs & Magic Remedies (Objectionable Advertisements) Act 1954.

Under the current Indian legal and regulatory regime, the manufacture, sale, import, exports and clinical research of drugs and cosmetics is governed by the following laws:- The Drugs and Cosmetics Act, 1940 The Pharmacy Act, 1948 The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 The Narcotic Drugs and Psychotropic Substances Act, 1985 The Medicinal and Toilet Preparations (Excise Duties) Act, 1956 The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act.

Drug & Cosmetic Act 1940 to 1945: India's parliament, under British rule, passed the Drug & Cosmetic Act of 1940, which led to the Drugs & Cosmetics Rules of 1945, the central legislation that regulates India's drug and cosmetic import, manufacture, distribution and sale. This established the Central Drugs Standard Control Organization (CDSCO), and the office of its leader, the Drugs Controller General (India)(DCG (I).

Pharmacy Act 1948 Pharmacy Act was enacted for the regulation of the profession and practice of pharmacy in the country. The Act has led to the formation of the Pharmacy Council of India (PCI) which regulates the functioning of pharmacy education institutions through state pharmacy councils. PCI is also the statutory body to register pharmacy graduates, thereby turning them eligible for practicing as community pharmacists.

Drugs & Magic Remedies (Objectionable Advertisements) Act 1954 Drugs and Magic Remedies Act talks about controlling the advertisement of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith. State drug regulators are the enforcement agencies of D &MR Act.

SOME OTHER LAWS There are some other laws which have a bearing on pharmaceutical manufacture, distribution and sale in India. The important ones being:

1. The Industries (Development and Regulation) Act, 1951
2. The Trade and Merchandise Marks Act, 1958
3. The Indian Patent and Design Act, 1970
4. Factories Act

The main functions of the Central and State Government are:

Central Government	*State Governments*
Statutory Functions	Statutory Functions
Laying down standards of drugs, cosmetics, diagnostics and devices.	Licensing of drug manufacturing and sales establishments
Laying down regulatory measures, amendments to Acts and Rules.	Licensing of drug testing laboratories
To regulate market authorization of new drugs	Approval of drug formulations for manufacture
To regulate clinical research in India	Monitoring of quality of Drugs & Cosmetics, manufactured by respective state units and those marketed in the state
To approve licenses to manufacture certain categories of drugs as Central License Approving Authority i.e. for Blood Banks, Large Volume Parenterals and *Vaccines & Sera.*	Investigation and prosecution in respect of contravention of legal provisions
To regulate the standards of imported drugs.	Administrative actions
Work relating to the Drugs Technical Advisory Board(DTAB) and Drugs Consultative Committee (DCC)	Pre- and post- licensing inspection.
Testing of drugs by Central Drugs Labs.	Recall of sub-standard drugs
Publication of Indian Pharmacopoeia.	

The immediate objective of this new policy is to address the unmet needs of contraception, health infrastructure, health personnel and to provide integrated service delivery for basic reproductive and child health care.

The long term targets is to achieve a stable population by 2045. In pursuance of these objectives, 14 National Socio Demographic Goals are formulated to be achieved by 2010. The important measures to this policy are:

(a) Making school education compulsory and to reduce drop-outs.

(b) Reduce Infant Mortality Rate (IMR) to 30 per 1000 live birth.

(c) Reduce maternal mortality rate to below 100 per 100000 live birth.

(d) Promote delayed marriage of girls.

(e) Achieve 80% institutional deliveries.

(f) Prevent and control communicable diseases

(g) Promote vigorously the small family norm to achieve replacement levels to TFR.

Policy also suggests some promotional and motivational measures to promote adoption of the small family norm. The important measures are:

(a) Reward Panchayat and Zila Parishads for promoting small family norm.

(b) Incentives to adopt two child norms.

(c) Couples below poverty line, having sterilisation with not more than two living children will be eligible for health insurance plan.

(d) Strengthening abortion facility scheme.

6.5 PHARMACEUTICAL LEGISLATION IN INDIA

Factors contributing to the growth of the Pharmaceutical Market: India today has the distinction of producing high quality generic medicines that are sold around the world. Further, India is poised to be one of the fastest growing pharmaceutical markets in the world. The following factors have fuelled the growth for the drugs and pharmaceutical market:

- The growing population of over a billion;
- A huge patient base;
- Increasing incomes;
- Improving healthcare infrastructure;
- An increase in lifestyle-related diseases such as diabetes, cardiovascular diseases, and central nervous system;
- Penetration of health insurance;
- Adoption of patented products;
- Patent expiries and aging population in the US, Europe, and Japan.

NOTES

the most important representative of these rhizotomoi was Diocles of Carystus (4th century BC). He is considered to be the source for all Greek pharmacotherapeutic treaties between the time of Theophrastus and Dioscorides. The Greek physician Pedanius Dioscorides is famous for writing a five volume book in his native Greek in the 1st century AD. The Latin translation De Materia Medica (Concerning medical substances) was used a basis for many medieval texts, and was built upon by many Middle Eastern scientists during the Islamic Golden age. The title coined the term materia medica .

In Japan, at the end of Asuka period (538 – 710) and the early Nara period (710 – 794), the men who fulfilled roles similar to those of modern pharmacists were highly respected.

The place of pharmacists in society was expressly defined in the Taiho Code (701) and re-stated in the Yoro Code (718). Ranked positions in the pre Heian Imperial court were established; and this organizational structure remained largely intact until the Meiji Restoration (1868). In this highly stable hierarchy, the pharmacists – and even pharmacist assistants – were assigned status superior to all others in health related fields such as physicians and acupuncturists. In the imperial household, the pharmacist was even ranked above the two personal physicians of the Emperor. There is a stone sign for a pharmacy with a tripod, a mortar, and a pestle opposite one for a doctor in the Arcadian Way in Ephesus near Kusadasi in Turkey. The current Ephesus dates back to 400 BC and was the site of the Temple of Artemis one of the Seven Wonders of the world, the home of Mark Anthony and Cleopatra, Mary Magdalen and where St Paul read his letter to the Ephesians.

Middle Ages

In Baghdad the first pharmacies, or drug stores, were established in 754, under the Abbasid Caliphate during the Islamic Golden Age. By the 9th century, these pharmacies were state regulated. The advances made in the Middle East in botany and chemistry led medicine in medieval Islam substantially to develop pharmacology. Muhammad ibn Zakariya Razi (Rhazes) (865 – 915), for imstance, acted to promote the medical uses of chemical compounds. Abu al-Qasim al-Zahrawi (Abulcasis) (936-1013) pioneered the preparation of medicines by sublimation and distillation. His Liber servitoris is of particular interest, as it provides the reader with recipes and explains how to prepare the 'simples' from which were compounded the complex drugs then generally used. Sabur Ibn Sahl (d 869), was, however, the first physician to initiate pharmacopoeia, describing a large variety of drugs and remedies for ailments.

Al Biruni (973-1050) wrote one of the most valuable Islamic works on pharmacology entitled Kitab al-Saydalah (The book of drugs), where he gave detailed knowledge of the properties of drugs and outlined the role of pharmacy and the functions and duties of the pharmacist. Ibn Sina (Avicenna), too, described no less than 700 preparations, their properties, mode of action and their indications. He devoted in fact a whole volume to simple drugs in The Canon of Medicine. Of great impact were also the works by al-Maridini of Baghdad and Cairo, and Ibn al Wafid (1008-1074), both of which were printed in Latin more than fifty times, appearing

This Schedule is available here :http://cdsco.nic.in/html/gmp/schedulem(gmp).pdf

The manufacturer is required to provide and maintain adequate staff, premises, plant and machinery for manufacture of drugs under the conditions of license for manufacture of drugs. He is also required to maintain records of manufacture including the testing of raw material and finished products.He should have appropriate storage facilities. Each batch of the product is required to be tested by the manufacturer either in his own laboratory or any laboratory approved by the Licensing Authority before releasing the product into market.

The licensee shall keep records of the details of manufacture as per particulars given in Schedule U of each batch of the drugs manufactured by him and such records shall be retained for a period of five years.

For Sale and Distribution of Drugs In India:

The licensing authorities are appointed by the respective State Governments. The licence is given for sell, STOCK, exhibit or offer for sale or distribute drugs. The licence can be either restricted licence or for wholesale. A restricted licence is given to a person with respect to drugs which, according to the licensing authority do not require supervision of a qualified person.This licence is valid for a period of five years. Even after the grant of this licence the licensee is required to:

(a) If a drug is to be compounded or made in his premises, it shall be under a registered pharmacist.

(b) The supply of any drug (other than wholesale), by prescription of a medical practitioner shall be under supervision of a registered pharmacist.

(c) Record has to be kept of every drug sold.

6.6 HISTORICAL DEVELOPMENT OF PHARMACEUTICAL EDUCATION IN INDIA AND ITS PRESENT STATUS

In the history of mankind, social development has always been closely interlinked with healthcare achievements. Therefore pharmacy education and practice has a significant impact on the health improvements of a nation. Pharmacists represent the third largest healthcare professional group in the world. Pharmacists work in the community, in hospitals, and in other medical facilities as members of the health care team and have special responsibilities for the safe use of medicines. In developed nations, in addition to traditional dispensing, pharmacists monitor the health and progress of patients in response to drug therapy and provide patient care that focuses on prevention of diseases and patient outcomes, and accordingly educational curriculum is designed.

In India, like in many Asian countries, pharmacists are the most accessible healthcare professionals and also play an important role in the use of medicines. Formal pharmacy education in India started (B. Pharm. in BHU in 1937) long before the enactment of Pharmacy Act, 1948 and the formulation of the Education Regulations in the year 1953. India has made rapid progress in pharmacy education over the last two decades. This paper seeks to sketch the status of pharmacy practice

in India vis-à-vis pharmacy education, standards of education, and changes are being undertaken, and then pay particular attention to the need for required actions to strengthen the curriculum and the profession.

Sixty years ago, there were no restrictions on the practice of pharmacy in India. The practice of prescribing and dispensing was an integral unit performed by doctors. In addition, most doctors trained their clinic assistants to dispense medicines and assist in compounding of medicinal preparations. The assistants were popularly known as "compounders." Persons, having experience of working with physician who could read a prescription and could assist in compounding and dispensing, were allowed to work in pharmacy settings. As in the case of many Asian countries, pharmacy practice profession in India, therefore, developed from the concept of extemporaneous preparations and selling of medicines.

The pharmacy practice concept was realized with the dawn of independence in 1947. The Pharmacy Act,1 1948 was the first landmark, which came into existence in response to recommendations of Drugs Enquiry Committee2 (Chopra committee) constituted in 1930, and report of Health Survey and Development Committee, 1943 (Bhore committee).The Chopra committee in its report recommended among others setting up of courses for training in pharmacy and prescribing minimum qualifications for registration as a pharmacist. The Bhore committee emphasized the need of government to control practice of pharmacy and provide educational facilities for licentiate pharmacists.

History of Pharmacy

The history of pharmacy education in India is as old as when the country was being gravitated towards British emperorship. A wind of revolution had been started to innovate something different in the education system of Indian Medical Services. Up to the middle of the nineteenth century, the pharmaceutical education and training remained in a state of neglect. The scenario of pharmacy practice was pathetic. The dispensing of prescriptions continued to be carried out by compounders, who had low level of preliminary training and education.

The compounders were lowly paid professionals. There were a few European trained pharmacists who were employed by private firms. The seed of the pharmacy education in India was sown first by medical College, Madras in 1860. Steps were taken to start pharmacy classes to impart pharmaceutical skills for the students qualifying for medical degrees or diploma or hospital assistance ship. The steps proved to be useful for the students intending to qualify as chemists and druggists . Broadly it was copying the practice as it prevailed at the time in Britain.

The classes continued with increase of the duration of study to 2 years and entry qualification being made matriculation in due course. The Materia Medica proved supportive to boost up the pharmacy education. The students were taught Materia Medica and instructed in the mode of preparing the principle compounds of the pharmacopoeia and Materia Medica. In the middle of the nineteenth century these professionals got scientifically educated and trained. Initially the 'chemist and druggist' class at Madras Medical College did not get popular and attracted less than half dozen students per annum.

Driving an automobile can be learnt only in an automobile - on a road. Or - you at least need a simulator to learn driving. Similarly, pharmacy practice cannot be taught in an institution that has no affiliation with a patient-care set up. This fundamental principle must be kept in mind before a Pharmacy Practice course is conceived. The pharmacy teacher's community should take notice of this critical and important issue and involve a cross section of practicing pharmacists to review and suggest a relevant curriculum. Any further delay will diminish whatever slim chances we believe we have today of projecting Pharmacy as a socially relevant profession.

Control of Pharmacy Education by The PCI

The PCI controls and regulates the standards for a better pharmacy education in India. The main aims of PCI are:

- To prescribe minimum standard of education required for qualifying as a pharmacist i.e. framing of Education Regulations prescribing the conditions to be fulfilled by the institutions seeking approval of the PCI for imparting education in pharmacy.
- To ensure uniform implementation of the educational standards through out the country.
- To approve the courses of study and examination for pharmacists i.e. approval of the academic training institutions providing pharmacy courses. The curriculum of pharmacy education has been designed to produce the following professional categories of pharmacists;
- Community and hospital pharmacists who will work as an important link between doctor and patient and will counsel the patient on various facets of drugs like usage, side effects, indication, contra-indications, compatibilities, in-compatibilities, storage, dosage etc.
- Specialist in research and development i.e. research of new drug molecules, biotechnical research etc.
- Occupational specialist (industrial pharmacist engaged in pharmaceutical technology) i.e. manufacture of various dosage forms, analysis and quality control, clinical trials, post-marketing surveillance, patent application and drug registration, sales and marketing.
- Academicians i.e. Teachers of Pharmacy education.
- Manager and Administrators of Pharmaceutical Services working for various regulatory authorities and pharmaceutical systems.
- Chemists and Druggists engaged in selling of medicines.

6.7 PHARMACY ACT

An Act to regulate the profession of pharmacy

Whereas it is expedient to make better provision for the regulation of the profession and practise of pharmacy and for that purpose to constitute Pharmacy Councils;

It is hereby enacted as follows:

Photo taken from http://www.biofortified.org/2009/10/biofortified-lettuce-not-a-bitter-pill/

By the Drugs and Cosmetics Act, there are various classes of drugs provided in Schedule second of the Act:

NOTES

1. Patent or proprietary medicines other than Homoeopathic medicines.(Drugs that are ready for administration either externally or internally but are not found in Indian Pharmacopoeia or any other Authorised Pharmacopoeia)
2. Substances commonly known as vaccines, sera toxins, toxoids, anti toxins and antigens and biological products of such nature for human use or for veterinary use.
3. Substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction or vermin or insect which cause disease in human beings or animals.
4. Homoeopathic Medicines
5. Other drugs, which are further divided into two types- drugs present in the Indian Pharmacopoeia and the drugs present in Pharmacopoeia of any other country.

A drug that is sold in India can be either an imported drug or a drug which is manufactured in India.

For Importing a Drug in India

The following steps need to be followed for importing a drug in India:

(a) A manufacturer of a drug which is manufactured not in India, has to Obtain a Registration Certificate for the premises and individual drugs imported. The licence will be available after inspection of the premises and would be valid for three years and registration may be suspended or cancelled in the event any violation of the conditions for registration comes to notice.

(b) An importer of a drug in India has to obtain import licence for all types of drugs. The procedure is different for schedule C and C(1), Schedule X and other types of drugs.Only those drugs with minimum 60% of retained shelf life shall be allowed to be imported in the country. The licence is also valid for three years.

Government hospitals are also given power to import essential drugs for treatment of their patients. An individual can also apply for permission to import certain drugs for his personal use.

1. ***For manufacturing a Drug in India***, an applicant has to get a licence from an authority established under Central Government. It is the duty of the State government to make sure that the manufacturer complies with the provisions of the Rules once the licence is granted.

Schedule M to the Drugs and Cosmetics Rules provides requirements for Good Manufacturing Practices and requirements of plant and equipment for manufacture of drugs. It specify in detail the requirements of premises, surroundings, personnel, sanitation, storage of raw materials,documentation and records, self inspections and quality control systems and site master files etc.The manufacturer is required to comply with the requirements of Schedule M under the conditions of the license.

as De Medicinis universalinus et particularibus by 'Mesue' the younger, and the medicamentis simplicibus by 'Abenguefit'. Peter of Abano (1250-1316) translated and added a supplement to the work of al-Maridini under the title De Veneris.

In Europe pharmacy like shops began to appear during the 12th century. In 1240 emperor Fredric II issued a decree by which the physician's and the apothecary's professions were separated. The first pharmacy in Europe (still working) was opened in 1241 in Trier, Germany. In Europe there are old pharmacies still operating in Dubrovnik, Croatia located inside the Franciscan monastery, opened in 1317; and one in the Town Hall square of Tallinn, Estonia dating from at least 1422. The oldest is claimed to be set up in 1221 in the church of Santa Maria Novella in Florence, Italy, which now houses a perfume museum. The medieval Esteve Pharmacy, located in Liivia, a Catalan enclave close to Puigcerda, is also now a museum dating back to the 15th century, keeping from the 16th and 17th centuries, old prescription books and antique drugs.

Education Standards at Present

There is no doubt that currently there is enormous gap existing between education and practice of pharmacy. Most of the academic institutions providing education in pharmacy are away from practice environment. The overall basis of pharmacy education is still extrabiological synthesis, physicochemical studies, analysis, and manufacturing aspects of drug. It is a common feeling that the medical practitioner is better placed for pharmacists' job than the pharmacists themselves. The dispensing services are poor. The syllabus and duration of the two-year diploma course in pharmacy education in India is completely outdated and irrelevant in the present industry context. It is a heterogeneous mixture of clinical and industrial subjects. Since clinical subjects are there PCI comes into the picture and AICTE came in because of industrial orientation of pharmacy syllabus.

Pharmacy as a nascent science developed like this in the last century. During 1940s and 50s, hospitals and industries were established in large numbers in India. Consequently, pharmacists and pharmaceutical chemists were required in huge numbers. Hence pharmacy education was developed in such a way to satisfy the requirement of industry and hospital. Short-term compounders and or D. Pharm. course to satisfy the needs of hospital and medical shops and B. Pharm. course for the industry were started. This is proved by the fact that in the last few decades D. Pharm. holders are not employed by the industry and B. Pharm. holders are not in many numbers in hospitals or medical shops. In the West, pharmacy education is patient-oriented and is responsible for Healthcare Management, while in India pharmacy education is industry-oriented.

Nearly 55 per cent of the jobs are available in the industry sector while 30 per cent in education. There are only three per cent jobs in healthcare. There must be revolutionary changes in the healthcare system e.g. making laws for appointing pharmacists at each Primary Health Centre and government hospitals. There should be adequate staff in the state drugs control departments for better control of drug distribution system. It is crystal clear that separation and improvement of clinical and industrial subjects in the pharmacy syllabus is a compulsion of the time. But

it is yet to be completed, that is why there is such a situation and a lot of infighting among government authorities.

NOTES

Present B. Pharm. syllabus can be divided into 2 major courses like B. Pharm. (Clinical) and B. Pharm. (Industrial) as it has been already decided to abolish D. Pharm. course. Such an arrangement will increase the confidence and competitive skills of pharmacy graduates among health care team and technocrats and some sort of specialization during under graduation itself. If two B. Pharm. courses are created as above, needless to say clinical course can be controlled by PCI and industrial course by AICTE. Private college managements can opt for any one of the courses. If any college wants to run both the courses they should accept both masters, there is no other go.

Existing D. Pharm. colleges who are in the verge of closure can adopt B. Pharm. (Clinical) and continue to serve the profession. This stunted growth of professional pharmacy in our country is the result of misplaced belief that profession is same as vocation. This belief has kept Indian pharmacy academics completely focused on industrial pharmacy at the cost of real - community pharmacy. While the justification for focusing pharmacy education on Industrial Pharmacy after attaining national freedom was valid, its review to make it relevant in contemporary scenario is already too late.

Our present system has produced half a million "qualified" pharmacists but not many "trained" professionals. This has effectively led to a situation where neither there is a need felt by the society nor is there anyone available to fulfill that "professed" need. This situation feeds on itself to such an extent that any attempt to keep one's knowledge updated and work professionally has strong economic disincentives in Indian retail pharmacy practice. Gravity of the situation dawns upon us when we think about petitions filed in High courts that propose scrapping of the Pharmacy Act because the pharmacists - according to petitioners - do not play any role other than selling the drugs like all other commodities.

There is virtually a complete lack of any training or incentive to professionalize - as a result of which even the most enthusiastic pharmacists gradually convert into mere traders. The uninspiring implementation of statutory provisions has led to a cancerous proliferation of retail drug shops and the situation now threatens the profession itself. The retail pharmacist shall be relevant to the society `only" if he can make a difference to the patient - by providing him information about drug usage to achieve better outcome than the patient obtains by uninformed usage of drugs.

The president of this IPC - Prof. Kulkarni - himself conceded in his inaugural address of IPC 2001 that talking about Community Pharmacy has become a pass-time lately. A lot of credit for this new fascination about community pharmacy goes to the Community Pharmacy Division of IPA, which launched a persistent campaign to nudge the retail pharmacists, the academicians, professional association managers and lately the society itself. Apart from whatever else is taught in pharmacy colleges under the garb of "Pharmacy Practice"- I feel the following are mandatory subjects: Pharmaco-therapeutics, Communication skills and Hands down training on computer operations. He must be trained and experienced in working as a health-care team member and this factor is not to be underestimated in the formal education design.

The reasons could have been the limited prospects of employment for the so qualified personnel. Voices were raised favoring the view that the "present chemist and druggist course be washed out". However the class remained in operation and received Government sanction for continuance in the Madras Medical College as a permanent arrangement. The curriculum of studies was revised with inclusion of study of organic chemistry also. After that the course underwent various revolutions at many times and also started in some other universities like Medical College, Visakhapatnam.

The pharmacy education in India was going to pass through a mutation when the founder of Banaras Hindu University Mahamana Pt. Madan Mohan Malviya met Prof. M.L. Schroff and Mahamana offered him to join B.H.U. By the non tiring efforts of Prof. Schroff in July 937 "Pharmaceutical chemistry" and "pharmacognosy" were introduced as the subjects for B.Sc. degree. Since then there has been no looking back. Pharmacy came to be recognized as a well established course with fruitful outcomes.

History of pharmacy

The history of pharmacy as an independent science is relatively young. The origins of historiography pharmaceutical back to the first third of the nineteenth century which is when the first historiographies that while not touching all aspects of pharmaceutical history is the starting point for the final start of this science. Until the birth of pharmacy as an independent science, there is a historical evolution from antiquity to the present day that marks the course of this science, always connected to the medicine.

Prehistoric Pharmacy

Paleopharmacological studies attest to the use of medicinal plants in pre history. The earliest known compilation of medicinal substances was the Sushruta Samhita, as Indian Ayurvedic treatise attributed to sushruta in the 6th century BC. However, the earliest text as preserved dates to the 3rd or 4th century AD. Many Sumerian (late 6th millennium BC – early 2nd millennium BC) cuneiform clay tablets record prescriptions for medicine.

Antiquity

Ancient Egyptian pharmacological knowledge was recorded in various papyri such as the Ebers Papyrus of 1550 BC, and the Edwin Smith Papyrus of the 16th century BC. The earliest known Chinese manual on materia medica is the Shennong Bencao Jing (The Divine Farmers's Herb – Root Classic), dating back to the 1st century AD. Earlier literature included lists of prescriptions for specific ailments, exemplified by a manuscript "Recipes for 52 Ailments", found in the Mawangdui tomb, sealed in 168 BC, Further details on Chinese pharmacy can be found in the pharmacy in China article.

Dioscorides, De Materia Medica, Byzantium, 15th century. In ancient Greece, according to Edward Kremers and Glenn Sonnedecker, "before, during and after the time of Hippocrates there was a group of experts in medicinal plants. Probably

Chapter 1: Introductory

NOTES

1. Short title, extent and commencement:-

   (i) This Act may be called the Pharmacy Act, 1948.

   (ii) It extends to the whole of India except the State of Jammu and Kashmir.]

   (iii) It shall come into force at once, but Chapters III, IV and V shall take effect in a particular State from such date [3][***] as the State Government may, by notification in the Official Gazette, appoint in this behalf:

   (iv) [4][Provided that where on account of the territorial changes brought about by the reorganisation of States on the 1st day of November, 1956, Chapters III, IV and V have effect only in a part of a State, the said Chapters shall take effect in the remaining part of that State from such date as the State Government may in like manner appoint.]

2. Interpretation:- In this Act, unless there is anything repugnant in the subject or context,-

   (a) "agreement" means an agreement entered into under section 20;

   (b) "approved" means approved by the Central Council under section 12 or section 14;

   (c) [5][(c) "Central Council" means the Pharmacy Council of India constituted under section 3;

   (d) "Central Register" means the register of pharmacists maintained by the Central Council under section 15 A;

(da) "Executive Committee" means the Executive Committee of the Central Council or of the State Council, as the context may require;

(e) "Indian University" means a University within the meaning of section 3 of the University Grants Commission Act, 1956, (3 of 1956) and includes such other institutions, being institutions established by or under a Central Act, as the Central Government may, by notification in the Official Gazette, specify in this behalf;]

(f) [6]["medical practitioner" means a personâ€"

   (i) holding a qualification granted by an authority specified or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or

   (ii) registered or eligible for registration in a medical register of a State meant for the registration of persons practising the modern scientific system of medicine; or

   (iii) registered in a medical register of a State, who, although not falling

within sub-clause(i) or sub-clause (ii) is declared by a general or special order made by the State Government in this behalf as a person practising the modern scientific system of medicine for the purposes of this Act; or

(iv) registered or eligible for registration in the register of dentists for a State under the Dentists Act, 1948 (16 of 1948); or

(v) who is engaged in the practise of veterinary medicine and who possesses qualifications approved by the State Government;]

(g) "prescribed" means in Chapter II prescribed by regulations made under section 18, and elsewhere prescribed by rules made under section 46;

(h) [7]["register" means a register of pharmacists prepared and maintained under Chapter IV;

(i) "registered pharmacist" means a person whose name is for the time being entered in the register of the State in which he is for the time being residing or carrying on his profession or business of pharmacy;

(j) "State Council" means a State Council of Pharmacy constituted under section 19, and includes a Joint State Council of Pharmacy constituted in accordance with an agreement under section 20;

(k) "University Grants Commission" means the University Grants Commission established under section 4 of the University Grants Commission Act, 1956 (3 of 1956).]

The Pharmacy Act, 1948

In India there was no restriction to practise the profession of pharmacy. One could practise this profession as any other profession. Persons, having no knowledge and having no education in pharmacy or pharmaceutical chemistry or pharmacology, were engaged in this profession. Hundreds of cases were brought to the notice of the Government wherein the compounding, mixing, or dispensing of medicines was being done by persons who were not adequately educated in this line. The system was causing great harm to the health of people by wrong compounding, mixing or dispensing. It was found necessary to enact a law for the regulation of the profession and practice of pharmacy. To achieve this goal the Pharmacy Bill, 1947 was introduced in the Legislature which was later referred to the Select Committee. The recommendations of the Select Committee were incorporated in the Bill.

Statement of Objects and Reasons

It is desirable that, as in most other countries, only persons who have attained a minimum standard of professional education should be permitted to practise the Profession of Pharmacy. It is accordingly proposed to establish a Central Council of Pharmacy, which will prescribe the minimum standards of education and approve courses of study and examinations for Pharmacists, and Provincial Pharmacy Councils, which will be responsible for the maintenance of provincial registers of qualified

pharmacists. It is further proposed to empower Provincial Governments to prohibit the dispensing of medicine on the prescription of a medical practitioner otherwise than by, or under the direct and personal supervision of, a registered pharmacist.

NOTES

ACT 8 of 1948

The Pharmacy Bill, 1947, having been passed by the Legislature received its assent on 4th March, 1948. It came on the Statute Book as THE PHARMACY ACT, 1948 (8 of 1948):

List of Amending Acts and Adaptation Orders

1. The Adaptation of Laws Order, 1950.
2. The Adaptation of Laws (No. 3) Order, 1956.
3. The Pharmacy (Amendment) Act, 1959 (24 of 1959).
4. The Pharmacy (Amendment) Act, 1976 (70 of 1976).
5. The Pharmacy (Amendment) Act, 1982 (22 of 1982).
6. The Delegated Legislation Provisions (Amendment) Act, 1985 (4 of 1986).

6.8 DRUGS AND COSMETICS ACT

In 1937 a Bill was introduced in the Central Legislative Assembly to give effect to the recommendations of the Drugs Enquiry Committee to regulate the import of drugs into British India. This Bill was referred to the Select Committee and the Committee expressed the opinion that a more comprehensive measure for the uniform control of manufacture and distribution of drugs as well as of imports was desirable. The Central Government suggested to the Provincial Governments to ask the Provincial Legislatures to pass resolutions empowering the Central Legislature to pass on Act for regulating such matters relating to control of drugs as fall within the Provincial sp here. Provincial Governments got the resolution passed from the Provincial Legislatures and sent them to the Central Government for getting through the Bill to regulate the import, manufacture, distribution and sale of Drugs and Cosmetics. Thereupon the Drugs and Cosmetics Bill was introduced in the Central Legislative Assembly.

Statement of Objects and Reasons

1. In order to give effect to the recommendations of the Drugs Enquiry Committee,, in so far as they relate to matters with which the Central Government is primarily concerned, a Bill to regulate the import of drugs into British India was introduced in the Legislative Assembly in 1937. The Select Committee appointed by the Legislative Assembly was of the opinion that a more comprehensive measure providing for the uniform control of the manufacture and distribution of drugs as well as of import was desirable. The Government of India accordingly asked Provincial Governments to invite the Provincial Legislatures to pass resolutions under section 103 of the Government of India

Act, 1935, empowering the Central Legislature to pass an Act for regulating such matters relating to the control of drugs as fall within the Provincial Legislative List. Such resolutions have now been passed by all Provincial Legislatures.

2. Chapter II of the Bill establishes a Board of Technical Experts to advise the Central and Provincial Governments on technical matters.
3. Chapter III provides for the control of the import of drugs into British India. The executive power under this chapter will accordingly be exercised by the Central Government.
4. Chapter IV relates to control of the manufacture, sale and distribution of drugs and contains the provisions which it is proposed should be enacted in exercise of the powers conferred by the resolutions under section 103 of the Government of India Act passed by the Provincial Legislatures. The executive power under Chapter IV will be exercised by the Provincial Government.
5. The First Schedule prescribes the standards to be complied with by imported drugs and the Second Schedule prescribes the standards to be complied with the drugs manufactured, sold or distributed in India. The standards prescribed in the two Schedules are identical. The Central Government will have power to amend the First Schedule, but power to amend the Second Schedule will rest with Provincial Government.
6. The Government of India have considered to what extent provision can be made to secure the maintenance of unformity in standards and in other important matters in which uniformity is desirable. They understand that it would be ultra vires of Central Legislature to assign to any authority other than the Provincial Government's authority conferred by the Bill in respect of matters falling within the Provincial Legislative field. For this reason it is not possible to assign the power to fix standards and to make rules to any single authority. In order to assure that before any action is taken due consideration is given to the desirability of maintaining uniformity, provision has been made in Chapter VI for a single Technical Advisory Board which both Central and Provincial Government will be required to consult before modifying the standards set up by the Bill or before making rules under the Bill.

The Drugs and Cosmetics (Amendment) Bill, 2013

- The Drugs and Cosmetics (Amendment) Bill, 2013 was introduced in the Rajya Sabha on August 29, 2013. The Bill amends the Drugs and Cosmetics Act, 1940 and changes the name of the Act to the Drugs, Cosmetics and Medical Devices Act, 1940.
- The Bill proposes changes in the regulation of the import, export, manufacture, distribution and sale of drugs, cosmetics and medical devices and to ensure safety, efficacy, quality and conduct of clinical trials.
- The definition of drugs is changed to include new drugs that are (i) not in significant use in India and are not recognised as effective and safe by the Drugs

NOTES

Controller General of India (DCGI);(ii) approved by the DCGI for certain claims but are being marketed with modified/new claims; (iii) a fixed dose combination of two or more drugs, which are individually approved but are being combined for the first time in a fixed/changed ratio; and (iv) all vaccines, Recombinant Deoxyribonucleic Acid derived products, Living Modified Organisms, stem cells, gene therapeutic products etc. which are intended to be used as drugs.

- Under the Act, medical devices were covered under the definition of drugs. The Bill changes this by adding a definition of medical devices to include any instrument, implant, material or other article, including the software, intended to be used specially for human beings or animals for the specific purposes of diagnosis, prevention, treatment or alleviation of any disease or, injury, modification of the body's anatomy and sustaining life.
- Clinical trials are defined in relation to drugs, cosmetics and medical, and involve their systematic study with the objective of determining their safety, efficacy, performance or tolerance. Anyone initiating a clinical trial has to register with the Central Drug Authority (CDA) and get approval from an Ethics Committee registered with it. The Bill creates provisions for the medical treatment and compensation in case of injury or death of a person during participation in a clinical trial or due to it.
- The Central Government shall establish a CDA to subsume the existing Central Drugs Standards Control Organisation. The CDA will be composed of representatives from the Ministries of Health and Family Welfare, Law, Commerce and Industry, Science and Technology, Chemicals and Fertilisers, DCGI, Indian Council of Medical Research, Directorate General of Health Services, and other experts nominated by the central government, including those from state licensing authorities.
- The CDA shall among others, specify guidelines, structures and requirements for the effective functioning of the central and state licensing authorities; review, suspend or cancel any licence or permission issued by them; and decide on disputes between two or more state licensing authorities relating to the provisions of the Act and rules and regulations made under it
- The DCGI is the central licensing authority that has the power to issue, renew, suspend or cancel licences for import, export or manufacture of drugs, cosmetics or medical devices or permission for conducting clinical trials. The DCGI also has the sole power to issue licenses for the manufacture, sale, and export of 17 categories of drugs.
- The Bill constitutes the Medical Devices Technical Advisory Board and the Drugs Technical Advisory Board to advise the central and state governments and the CDA on technical matters pertaining to medical devices, and drugs.
- In order to ensure standard quality of drugs, cosmetics, and medical devices, the Bill specifies conditions under which they will be considered misbranded, adulterated, and spurious and specifies penalties and offences for the same.

NOTES

6.9 NARCOTICS AND PSYCHOTROPIC SUBSTANCES ACT

The system of control of Narcotic Drugs in India has been put in place considering the requirement of narcotic drugs and psychotropic substances for medical use and the country's obligations towards the UN conventions. India is a signatory to The UN Single Convention on Narcotics Drugs 1961, The Convention on Psychotropic Substances, 1971 and The Convention on Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 which prescribe various forms of control aimed to achieve the dual objective of limiting the use of narcotics drugs and psychotropic substances for medical and scientific purposes as well as preventing the abuse of the same.

The administrative and legislative setup in the field of Narcotics has been put in place in the country in accordance with the aforesaid spirit of the UN Conventions. The basic legislative instrument of the Government of India in the regard is the Narcotics Drugs and Psychotropic Substances (NDPS) Act, 1985. Various Ministries and Departments under the Government of India as well as the State Governments exercise various functions pertaining to drug demand and supply reduction. The aspect of drug supply reduction is looked after by various enforcement agencies under the Ministry of Finance, Ministry of Home Affairs and State Governments. The aspect of drug demand reduction is handled by the Ministry of Social Justice & Empowerment and that of treatment of drug addicts and their rehabilitation falls under the domain of the Ministry of Health.

Procedural safeguards and immunities under the NDPS Act

The Narcotic Drugs and Psychotropic Substances Act, 1985 views drug offences very seriously and prescribes stiff penalties. The Act follows a graded system of punishment with the punishment varying with the quantum of punishment being dependent upon whether the offence pertains to small, commercial and intermediate quantities of narcotic drugs and psychotropic substances. For offences involving commercial quantities of drugs, a minimum penalty of ten years rigorous imprisonment is prescribed, which may extend to twenty years. Repeat offences attract one and half times the penalty and in a few cases even the death penalty. Alongside these stringent provisions, the Act has procedural safeguards as follows:

1. Personal search: Any person being searched has a right to be searched before a Gazetted Officer or a Magistrate (Section 50). The officer searching the person has to explain to the person that he has a right to be searched before a Gazetted Officer or a Magistrate and if the person wishes to be searched before a Gazetted Officer or a Magistrate he should be taken to the Gazetted Officer or the Magistrate and searched. However, if the officer has reason to believe that it is not possible to take him to a Gazetted officer or a magistrate without giving him a chance to part with the drug, controlled substance, etc., he can search him under Section 100 of the Cr. P. C. [Section 50(5) and 50 (6)].

2. Searches: As per Section 41 of the NDPS Act, Gazetted Officers of the empowered Departments can authorize searches. Such authorization has to be based on information taken down in writing. As per Section 42, searches can be made under certain circumstances without a warrant (from a magistrate) or an authorization (from a Gazetted Officer). In case of such searches, the officer has to send a copy of the information taken in writing or the grounds of his belief to his immediate official superior within 72 hours.

3. Arrests: The person who is arrested should be informed, as soon as may be, the grounds of his arrest [Section 52 (1)]. If the arrest or seizure is based on a warrant issued by a magistrate, the person or the seized article should be forwarded to that magistrate [Section 52(2)].

4. The officer who arrests a person has to make a full report to his official superior within 48 hours [section 57].

Immunitiies for Drug Offences

1. Officers: Officers acting in discharge of their duties in good faith under the Act are immune from suits, prosecution and other legal proceedings (Section 69).

2. Addicts: Addicts charged with consumption of drugs (Section 27) or with offences involving small quantities will be immune from prosecution if they volunteer for de-addiction. This immunity may be withdrawn if the addict does not undergo complete treatment (Section 64A).

3. Offenders: Central or state governments can tender immunity to an offender in order to obtain his evidence in the case. This immunity is granted by the government and not by the court (Section 64).

4. Juvenile offenders: Juvenile offenders (below 18 years of age) will be governed by the Juvenile Justice (Care and Protection of Children) Act, 2000.

5. Immunities to diplomats as applicable.

Seizure, freezing and forfeiture of property under the NDPS Act

Drug offences, unlike most other offences, are committed only with profit motive. One of the strategies to fight drug trafficking is denying the traffickers the fruits of their trafficking. Chapter VA of the NDPS Act provides for forfeiture of such illegally acquired properties. This chapter applies to:

(a) every person who has been convicted of an offence punishable under this Act with imprisonment for a term of ten years or more;

(b) every person who has been convicted of a similar offence by a competent court of criminal jurisdiction outside India;

(c) every person in respect of whom an order of detention has been made under the Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988 (46 of 1988), or under the Jammu and Kashmir Prevention of Illicit

NOTES

Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988 (J & K Act XXIII of 1988):

Provided that such order of detention has not been revoked on the report of the Advisory Board constituted under the said Acts or such order of detention has not been set aside by a court of competent jurisdiction;

(cc) every person who has been arrested or against whom a warrant or authorization of arrest has been issued for the commission of an offence punishable under this Act with imprisonment for a term of ten years or more, and every person who has been arrested or against whom a warrant or authorization of arrest has been issued for the commission of a similar offence under any corresponding law of any other country.

(a) every person who is a relative of a person referred to in clause (a) or clause (b) or clause (c) or clause (cc);

(b) every associate of a person referred to in clause (a) or clause (b) or clause (c) or clause (cc);

(c) any holder (hereafter in this clause referred to as the "present holder") of any property which was at any time previously held by a person referred to in clause (a) or clause (b) or clause (c) or clause (cc); unless the present holder or, as the case may be, anyone who held such property after such person and before the present holder, is or was a transferee in good faith for adequate consideration.

Procedure

1. Every officer empowered under section 53 and every officer in-charge of a police station shall, on receipt of information, proceed to trace and identify the illegally acquired properties (section 68E).
2. The officer may issue an order seizing the properties and if it is not possible to seize, freezing the properties. He shall send a copy of the order within 48 hours to the Competent Authority.
3. The Competent Authority has to confirm the order within 30 days, else, it will not be valid.
4. The Competent Authority issues a Notice to the affected person and after considering the reply and other records of the case, passes an order forfeiting the properties or otherwise.
5. If the person is only arrested, the issue of Notice and subsequent forfeiture will proceed only after his conviction or after an order of preventive detention is issued.
6. The Burden of Proving that the properties are NOT illegally acquired is on the affected person.
7. Appeals against the orders of forfeiture lie with the Appellate Tribunal for Forfeited Properties.
8. Seized or forfeited properties are managed and disposed by the Administrators

as per Illegally Acquired Property (Receipt, Management and Disposal) Rules. So far the Government of India appointed officers as Competent Authority cum Administrator.

NOTES

6.10 DRUG AND MAGIC REMEDIES ACT

1. **Short title, extent and commencement.** –
   1. This Act may be called the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954.
   2. It extends to the whole of India except the State of Jammu and Kashmir, and applies also to persons domiciled in the territories to which this Act extends who are outside the said territories.
   3. It shall come into force on such date; as the Central Government may, by notification in the Official Gazette, appoint.

1. **1st April 1955 vide Notification No. S.R.O. 511 dated 26th February, 1995, Gazette of India, 1955, Part 11, Section 3, Page 449.**

2. **Definitions.** -In this Act, unless the context otherwise requires-
   (a) "Advertisement" includes any notice, circular; label, wrapper, or other document, and any announcement made orally or by any means of producing or transmitting light, sound or smoke;
   (b) "Drug" includes-
      (i) A medicine for the internal or external use of human beings or animals;
      (ii) Any substance intended to be used for or in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals;
      (iii) Any article, other than food, intended to affect or influence in any way the structure or any organic function of the body of human beings or animals; H-clauses (i), (ii) and (iii);
   (c) "Magic remedy" includes a talisman mantra kavacha, and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals;

(cc) "Registered medical practitioner" means any person, -

(i) Who holds a qualification granted by an authority specified in, or notified under Section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916) specified in the Schedules to the Indian Medical Council Act 1956 (102 of 1956); or

(ii) Who is entitled to be registered as a medical practitioner under any law for the time being in force; in any State to which this Act extends relating to the registration of medical practitioner;

(d) "Taking any part in the publication of any advertisement includes-

(i) The printing of the advertisement;

(ii) The publication of any advertisement outside the territories to which this Act extends by or at the instance of person residing within the said territories;

3. **Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders.** - Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement referring to any drug in terms, which suggest or are calculated to lead to the use of, that drug for-

(a) The procurement of miscarriage in women or prevention of conception in women; or

(b) The maintenance or improvements of the capacity of human beings for sexual pleasure; or

(c) The correction of menstrual disorder in women; or

(d) The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease, disorder or condition (by whatsoever name called) which may be specified in the rules made under this Act;

Provided that no such rule shall be made except-

1. In respect of any disease, disorder or condition which requires timely treatment in consultation with a registered medical practitioner or for which there are normally no accepted remedies, and

2. After consultation with the Drugs Technical Advisory Board constituted under the Drugs and Cosmetics Act, 1940 (23 of 1940), and, if the Central Government considers necessary, with such other persons having special knowledge or practical experience in respect of Ayurvedic or Unani systems of medicines as that Government deems fit.

4. **Prohibition of misleading advertisements relating to drugs.** -Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which-

(a) Directly or indirectly gives a false impression regarding the true character of the drug; or

(b) Makes a false claim for the drug; or

(c) Is otherwise false or misleading in any material particular.

5. **Prohibition of advertisement of magic remedies for treatment of certain diseases and disorders.** - No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in Section 3.

6. **Prohibit on of import into, and export from India of certain advertisement.** - No person shall import into, or export from, the territories to which this Act extends any document containing and advertisement of the

NOTES

nature referred to in Section 3, or Section 4, or Section 5, and any documents containing any such advertisement shall be deemed to be goods of which the import or export has been prohibited under Section 19 of the Sea Customs Act, 1878 (8 of 1978), and all the provisions of that Act shall have effect accordingly, except that Section 183, thereof shall have effect as if for the word "shall" therein the word "may" were substituted.

7. **Penalty.** - Whoever contravenes any of the provisions of this Act of the rules made thereunder shall, on conviction, be punishable-

   (a) In the case of a first conviction, with imprisonment which may extend to six months, or with fine, or with both;

   (b) In the case of a subsequent conviction, with imprisonment which may extend to one year, or with fine, or with both.

8. **Powers of entry, search, etc. –**

1. Subject to the provisions of any rules made in this behalf, any Gazetted Officer authorised by the State Government may, within the local limits of the area for which he is so authorised-

   (a) Enter and search at all reasonable times, with such assistants, if any, as he considers necessary, any place in which he has reason to believe that an offence under this Act has been or is being committed;

   (b) Seize any advertisement which he has reason to believe contravenes any of the provisions of this Act:

Provided that the, power of seizure under this clause may be exercised in respect of any document, article or thing which contains any such advertisement, including the contents, if any, of such document, article or thing, if the advertisement cannot be separated bv reason of its being embossed or otherwise, from such document, article or thing without affecting the integrity utility or saleable value thereof;

   (c) Examine any record, register, document or any other material object found in any place mentioned in clause (a) and seize the same if be has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

2. The provisions of the Code of Criminal Procedure, 1898 (5 of 1898), shall, so far as may be, apply to any search or seizure under this Act as they apply to any search or seizure made under the authority of a warrant issued under Section 98 of the said Code.

3. Where any person seizes anything under clause (b) or clause (c) of sub section (i) He shall, as soon as may be inform a Magistrate and take his orders as to the custody thereof

9. **Offences by companies-**

1. If the person contravening any of the provisions of this Act is a company, every person who, at the time the offence was committed, was in charge of and was responsible to the company for the conduct of the business of the company as well as the company shall be deemed to be guilty of the contravention and shall be liable to be proceeded against and punished accordingly;

Provided that nothing contained in this sub section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

2. Notwithstanding anything contained in sub section (1) where an offence under this Act has been committed by a company and it is prove that the offence was committed with the consent or connivance of or is attributable to any neglect on the part of any director or manager secretary or other officer of the company such director manager secretary or other officer of the company shall also he deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation- For the purposes of this section-

(a) "Company" means any body corporate and includes a firm or other association of individuals, and

(b) "Director" in relation to a firm means a partner in the firm.

9A. Offences to be cognizable. -Notwithstanding anything contained in the Code of Criminal Procedure, 1898 (5 of 1898) an offence punishable under this Act shall be cognizable.

10. Jurisdiction to try offences. -No court interior to that of a presidency magistrate or a magistrate of the first class shall try any offence punishable under this Act.

10A. Forfeiture. -Where a person has been convicted by any court for contravening any provision of this Act or any rule made there under, the court may direct that any document (including all copies thereof), article or thing, in respect of which the contravention is made, including the contents thereof where such contents are seized under clause (b) of sub section (1) of section 8, shall be forfeited to the Government.

11. Officers to be deemed to the public servants.-Every person authorised under section 81 shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860).

12. Indemnity. -No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act.

13. Other laws not affected. -The provision of this Act is in addition to, and not in derogation of the provisions of any other law for the time being in force.

14. Savings. -Nothing in this Act shall apply to-

(a) Any sign board or notice displayed by a registered medical practitioner on his premises indicating that treatment for any disease, disorder or condition specified in section 3; the Schedule or the rules made under this Act, is undertaken in those premises; or

(b) Any treatise or book dealing with any of the matter specified in section 3 from a bonafide scientific or social standpoint; or

(c) Any advertisement relating to any drug sent confidentially in the manner prescribed under section 16 only to a registered medical practitioner; or

NOTES

(d) Any advertisement relating to a drug printed or published by the Government; or

(e) Any advertisement relating to a drug printed or published by any person with the previous sanction of the Government granted prior to the commencement of the Drugs and magic Remedies (Objectionable Advertisement) Amendment Act, 1963 (42 of 1963).

Provided that the Government may, for reasons to be recorded in writing withdraw the sanction after giving the person an opportunity of showing cause against such withdrawal.

15. Power to exempt from application of Act. - If in the opinion of the Central Government public interest requires that the advertisement of any specified drug or class of drugs or any specified class of advertisement relating to drugs should be permitted, it may by notification in the Official Gazette, direct that the provisions of sections 3,4,5 and 6 or nay one of such provision shall not apply subject to the advertisement of any such drug or class of drugs or any such class of advertisement relating to drugs.

16. Power to make rules. –

1. The Centre Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.
2. In particular and without prejudice to the generality of the foregoing power, such rules may-
   (a) Specify and disease, disorder or condition to which the provisions of section 3 shall apply;
   (b) Prescribe the manner in which advertisement of articles or things referred to in clause (c) of section 14 may be sent confidentially.
3. Every rule made under this Act shall be laid as soon as may be after it is made, before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive session, and if before the expiry of the session in which it is so laid or the successive sessions aforesaid, both houses agree in making any modification in the rule or both houses agree hat the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however, that any such modification, or annulment shall be without prejudice to the validity of anything previously done under that rule.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955

- An Act to control, the advertisement of drugs in certain cases, to prohibit the advertisement for certain purpose of remedies alleged to possess magic qualities and to provide for matters connected therewith.
- The Act defines drugs and registered medical practitioners besides defining magic remedy. According to Act the Magic remedy includes a talisman mantra kavacha, and any other charm of any kind which is alleged and possess miraculous powers for or in the diagnosis, cure, mitigation treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of human beings or animals.

- Unless prescribed by registered medical practitioners or after consultation with the Drugs and Cosmetics Act 1940, no person or company, shall take any part in the publication of any advertisement referring to any drug that is used for:
  (a) The miscarriage in woman,
  (b) Maintenance or improvement of the capacity of human beings for sexual pleasures,
  (c) Correction of menstrual disorder in women, and
  (d) The diagnosis, cure, mitigation, treatment or prevention of any disease.
- No person or company will take part in advertisement which give false impression or makes a false claim for the drug or mislead the people. Whosoever contravenes any of the provision of this Act shall be punishable with imprisonment extended to six months or with fine, or with both for first time conviction. It may extend to one year imprisonment or with fine or with both on subsequent convictions.
- The schedule for diseases specified under the Act are: appenddicitis, atherosclerosis, blindness, blood poisoning, Bright's disease, cancer, cataract, deafness, diabetes, brain diseases or disorder, uterus diseases, disorder of menstrual flow, disorders of nervous system, prostatic gland disorders, dropsy, epilepsy, female disease (in general), fever (in general), Fits, Forms and structure of the female breast, gall bladder stones, kidney stones, bladder stones, gangrene, glaucoma, goitre, heart diseases, high or low blood pressure, hydrocele, hysteria, infantile paralysis, insanity, leprosy, leucoderma, lock jaw, locomotor ataxia, lupus, nervous debility, obesity, paralysis, plague, pleurisy, pneumonia, rheumatism, rruptures, sexual impotence, small pox, stature of person , sterility of women, trachoma, TB, tumours, typhoid fever, ulcers of GI tract, veneral diseases including, AIDS.

6.11 POISONS ACT AND RULES

The Poisons Act, 1919 was enacted by the Government of India with a view to regulate possession for sale & sale of substances specified as poisons. The Government of Maharashtra under the powers granted under Section 2 of the said Act has promulgated Maharashtra Poisons Rules 1972. The Poison Act and Maharashtra Poisons Rules were being implemented by the following authorities till 1977.

(a) The Commissioner of Police in cities where Commissionerates of Police existed and

(b) District Magistrates in cities.

Food and Drug Administration, Maharashtra State was given responsibility as Licensing Authority under the Maharashtra Poisons Rules, 1972 by amending the said rules in 1977 vide notification No. DRG-1269/54294(II) (227)/ PH-10, dated 14th January 1977. AS per the Schedule of the Poisons Act. The following substances are specified are poisons.

6.12 STUDENT ACTIVITY

1. Discuss the silent features of NHP.
2. Describe population policy 2000.
3. Explain poisons act and rules.
4. Describe Drugs & Magic Remedies (Objectionable Advertisements) Act 1954 .

NOTES

6.13 SUMMARY

- National health policies, strategies, and plans play an essential role in defining a country's vision, priorities, budgetary decisions and course of action for improving and maintaining the health of its people. Most countries have been using the development of national health policies, strategies, and plans for decades to give direction and coherence to their efforts to improve health.
- WHO has a long track record of supporting Member States in this area through country-level technical cooperation, facilitation of national policy dialogue and inter-country exchange, as well as through normative work and high-level international policy frameworks.
- In India there was no restriction to practise the profession of pharmacy. One could practise this profession as any other profession. Persons, having no knowledge and having no education in pharmacy or pharmaceutical chemistry or pharmacology, were engaged in this profession.
- The Narcotic Drugs and Psychotropic Substances Act, 1985 views drug offences very seriously and prescribes stiff penalties. The Act follows a graded system of punishment with the punishment varying with the quantum of punishment being dependent upon whether the offence pertains to small, commercial and intermediate quantities of narcotic drugs and psychotropic substances.
- Power to exempt from application of Act. - If in the opinion of the Central Government public interest requires that the advertisement of any specified drug or class of drugs or any specified class of advertisement relating to drugs should be permitted, it may by notification in the Official Gazette, direct that the provisions of sections 3,4,5 and 6 or nay one of such provision shall not apply subject to the advertisement of any such drug or class of drugs or any such class of advertisement relating to drugs.

6.14 GLOSSARY

- National Population Policy : National Population Policy of India was formulated in the year 2000 with the long term objective of achieving a stable population by 2045, at a level consistent with the requirements of sustainable economic growth, social development, and environmental protection.
- Drug & Cosmetic Act 1940 to 1945: India's parliament, under British rule, passed the Drug & Cosmetic Act of 1940, which led to the Drugs & Cosmetics Rules of 1945, the central legislation that regulates India's drug and cosmetic import, manufacture, distribution and sale.

- Pharmacy Act 1948 : Pharmacy Act was enacted for the regulation of the profession and practice of pharmacy in the country. The Act has led to the formation of the Pharmacy Council of India (PCI) which regulates the functioning of pharmacy education institutions through state pharmacy councils.
- The Poisons Act: The Poisons Act, 1919 was enacted by the Government of India with a view to regulate possession for sale & sale of substances specified as poisons.
- Medicines in India are regulated by CDSCO - Central Drugs Standard Control Organization under Ministry of Health and Family Welfare. Headed by Directorate General of Health Services CDSCO regulates the Pharmaceutical Products through DCGI - Drugs Controller General of India at Chair.

6.15 REVIEW QUESTIONS

1. What are the Factors contributing to the growth of the Pharmaceutical Market?
2. Explain drugs and cosmetics act.
3. What do you know about narcotics and psychotropic substances act?
4. Write down the steps need for *For importing a drug in India.*
5. Write short note on:
   (a) Who
   (b) Tfr
   (c) Npp 2000
   (d) Imr
   (e) Cdsco