

Report on the
Working Group on
Clinical Establishments,
Professional Services Regulation
and Accreditation of Health Care
Infrastructure

For
the 11th Five-Year Plan

Government of India
Planning Commission

Report on the Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure For the 11th Five-Year Plan

Composition of the Working Group

1. The Planning Commission constituted a Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure for the Eleventh Five -Year Plan (2007-2012) under the Chairmanship of Secretary, Department of Health & Family Welfare, Government of India with the following members:

1.	Secretary, Department of Health & Family Welfare, New Delhi	Chairman
2.	Secretary (Health), Govt. of Assam	Member
3.	Secretary (Health), Govt. of Rajasthan	Member
4.	Secretary (Health), Govt. of Uttar Pradesh	Member
5.	Secretary (Health), Govt. of Kerala	Member
6.	Secretary (Health), Govt. of Tamil Nadu	Member
7.	Director General of Health Services, Directorate General of Health Services, New Delhi	Member
8.	Chief, Bureau of Indian Standards, New Delhi	Member
9.	Shri Rajeev Lochan, Director (Health), Planning Commission, New Delhi	Member
10.	Shri K.M. Gupta, Director, Ministry of Finance, New Delhi	Member
11.	Dr Antia, Foundation for Research in Community Health, Pune	Member
12.	Dr. Naresh Trehan, Escorts Hospital, New Delhi	Member
13.	Dr. Akhil Sangal, Chief Executive Officer, Indian Confederation for Health Care Accreditation	Member
14.	Dr. Shakti Gupta, Medical Superintendent, All India Institute of Medical Sciences, New Delhi	Member
15.	Head, Medical Care & Hospital Administration, National Institute of Health & Family Welfare, New Delhi	Member
16.	Dr. I.H. David, Health Management Consultant, Hyderabad	Member
17.	Dr. Prakasamma, Director, School of Nurses, Hyderabad	Member
18.	Joint Secretary, Ministry of Health & Family Welfare, New Delhi	Member Secretary

Terms of Reference:

2. The Terms of reference of the Working Group were as under:
 - i) To review the existing system of Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure (Public, Private, NGO) in urban and rural areas with a view to provide universal access to equitable, affordable and quality health care which is accountable at the same time responsive to the needs of the people, reduction of child and maternal deaths as well as population stabilization, and also achieve goals set under the National Health Policy and the Millennium Development Goals.
 - ii) To identify the potential areas/infrastructure/ institutions involved in providing accreditation with a view to ensure cost effective and standardized delivery of health services to people in rural & urban areas.
 - iii) To suggest a practical and cost efficient system of Accreditation of Health Care Infrastructure.
 - iv) To deliberate and give recommendations on any other matter relevant to the topic.

It was decided by Secretary (Health & FW) that Dr R.K. Srivastava, Director General of Health Services will chair the meetings of the Working Group and Shri Vineet Chawdhry, Joint Secretary would function as Secretary.

Setting up of a Core Group

3. Director General Health Services set up a core group comprising of the following to prepare the background material as per the TORs: -
 1. Shri Vineet Chawdhry, Joint Secretary, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi.
 2. Shri Giridhar Gyani, Secretary General, Quality Council of India, New Delhi.
 3. Shri Sunil Nandraj, WR Office, WHO, Nirman Bhavan, New Delhi.
 4. Dr. A.N. Sinha, CMO, Dte. General of Health Services, Nirman Bhavan, New Delhi.

Meetings of the Core Group & Working Group

4. Two meetings of the Core Group were held on 24.7.2006 and 18.9.2006 to finalise the background papers on Clinical Establishment Registration & Regulation Legislation and Accreditation of Clinical Establishment and the same were circulated to all the members of the Working Group.
5. A meeting of the Working Group was held on 25.9.06 in Nirman Bhawan, New Delhi. List of participants is enclosed (Annexure- I).

Regulation of Clinical Establishments

Introduction and background

6. In majority of the countries, quality of care provided by the health care delivery system has come into sharp focus. Since quality is a crucial factor in health care, initiatives to address quality of health care have become worldwide phenomena. Many countries are exploring various means and methods to improve the quality of health care services. In India the quality of services provided to the population by both public and private sectors remains largely an unaddressed issue. The current structure of the health care delivery system does not provide enough incentives for improvement in efficiency. Mechanisms used in other countries to produce greater efficiency, accountability, and more responsible governance in hospitals are not yet deployed in India. The for-profit private sector accounts for a substantial proportion of health care in India (50% of inpatient care and 60-70% of outpatient care), but has received relatively less attention from the policy makers as compared to the public sector. Thus the private sector health care delivery system in India has remained largely fragmented and uncontrolled, and there is a clear evidence of serious quality of care deficiencies in many practices. Problems range from inadequate and inappropriate treatments, excessive use of higher technologies, and wasting of scarce resources, to serious problems of medical malpractice and negligence. Current policies and processes for health care are inadequate or not responsive to ensure health care services of acceptable quality and prevent negligence.
7. In the present situation there is a need to establish bodies and systems to monitor clinical and non-clinical effectiveness of the services offered in the public and private facilities. In India concerns about how to improve health care quality have been frequently raised by the general public and a wide variety of stakeholders, including government, professional associations, private providers and agencies financing health care. There also have been attempts to establish systems and process that would ensure quality of care by the health providers.

Defining Regulation

8. Regulation can be thought of as occurring when a Government/State exerts control over the activities of individuals and firms (Roemer, 1993). More specifically, regulation has been defined as government “action to manipulate prices, quantities (and distribution), and quality of products” (Maynard, 1982). Regulation seeks to ensure quality, accountability, protect the consumers and control costs as well as the distortions created by market forces.

Regulation of Clinical Establishments

9. There are several actors involved in the regulatory process namely, the health care professionals, managers, ministry of health, commercial interests, NGOs, community and consumer groups amongst others.

Global Experience

10. Review of global experiences show that regulatory frameworks in the health sector assume a variety of forms. One of the first challenges countries have faced in planning for regulation and accreditation systems is to gain consensus on the definitions of various forms of regulation and evaluation, Licensure, certification and accreditation of healthcare organizations have been used in many countries as tools for defining the required characteristics of acceptable healthcare services. Their voluntary or mandatory nature varies as a function of system objectives. The following definitions are based on technical support experiences in a variety of countries:

- Licensure a government administered mandatory process that requires healthcare institutions to meet established minimum standards in order to operate.
- Certification a voluntary governmental or non-governmental process that grants recognition to healthcare institutions that meet certain standards and qualifies them to advertise services or to receive payment or funding for services provided.
- Accreditation a process by which a government or non-government agency grants recognition to healthcare institutions that meet certain standards that require continuous improvement in structures, procedures or outcomes. It is usually voluntary, time-limited and based on periodic assessments by the accrediting body, and may, like certification, be used to achieve other desirable ends such as payment or funding.

Determination of the mechanism(s) a country will adopt is essential in order to differentiate the evaluation functions to be used, the purposes of each and the entity (ies) that will employ each mechanism.

Broad concept of Regulation of Clinical Establishments

11. The foremost amongst these mechanisms is legislation or imposition of legal restrictions or controls where participants must conform to legislated requirements. In addition to these formal rules, more informal codes of conduct, standards, guidelines or recommendations may exist. Essentially, the elements of any regulatory process include establishment of rules, its application to specific cases, detection or monitoring violations and imposition of penalties on violators.

The scenario in India

Constitutional Provisions

12. The preamble to the Constitution of India coupled with the Directive Principles of State Policy strives to provide a welfare State with socialist patterns of society. It enjoins the State to make the “improvement of public health” a primary responsibility. Furthermore, Articles 38,42,43 and 47 of the Constitution provide for promotion of health of individuals as well as health care. The Constitution of India also enumerates the separate and shared legislative powers of Parliament and State Legislatures in three separate lists: the Union List, the State List and the Concurrent List. The Parliament and State legislatures share authority over matters on the Concurrent List, which include criminal law and procedure; marriage, divorce and all other personal law matters; economic and social planning; population control and family planning; social security and social insurance; employment; education; legal and medical professions; and prevention of transmission of infectious or contagious diseases. Laws passed by Parliament with respect to matters on the Concurrent List supersede laws passed by state legislatures. The Parliament generally has no power to legislate on items from the State List, including public health, hospitals and sanitation. However, two-thirds of the Rajya Sabha may vote to allow parliament to pass binding legislation on any state issue if “necessary or expedient in the national interest”. In addition, two or more States may ask parliament to legislate on an issue that is otherwise reserved for the state. Other states may then choose to adopt the resulting legislation.

Issues in regulation of Health matters in India

13. Health regulation in India encompasses a variety of actors and issues. These include promulgation of legislation for health facilities & services, disease control & medical care, human power (Education, Licensing & Professional Responsibility), Ethics & Patients Rights, Pharmaceuticals & Medical Devices, Radiation Protection, Poisons & Hazardous Substances, Occupational Health and Accident Prevention, Elderly, Disabled & Rehabilitation Family, Women & child Health, Mental Health, Smoking/Tobacco Control, Social Security & Health Insurance, Environmental Protection, Nutrition &

Food Safety, Health Information & Statistics and Custody, Civil & Human Rights to enumerate a few.

Regulation relating to the Medical Profession

14. There exists legislation with respect to licensing of medical professionals such as doctors, nurses, dentists and pharmacists with a view to control their entry into the market. Statutory regulatory councils have been established to monitor the standards of medical education, promote medical training and research activities, and oversee the qualifications, registration, and professional conduct of doctors, dentists, nurses, pharmacists, and practitioners of other systems of Medicine such as Ayurveda, Yoga, Unani, Siddha and Homeopathy. Important of these laws are: the Indian Medical Council Act, 1956, the Indian Nursing Council Act, 1947; the Indian Medicine Central Council Act, 1970; the Homeopathy Central Council Act, 1973; and the Pharmacy Act, 1948. Almost all of these laws establish councils that set forth uniform educational and qualification standards. In addition, each statute establishes a central registry for individuals certified to practice the field of medicine regulated. Finally, councils often prescribe standards of professional conduct and determine which actions amount to professional misconduct.

15. There also exist few institution specific regulations such as the All India Institute of Medical Sciences Act 1956, the Post Graduate Institute of Medical Education and Research, Chandigarh Act, 1966, the National Institute of Pharmaceutical Education & Research Act, 1998 and the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum Act, 1980 enables the establishment of institutes of national importance. The Bureau of Indian Standards Act, 1986 made possible the establishment of a Bureau for the harmonious development of activities of standardization, marketing and quality certification of goods.

Regulations relating to Disease Control & Medical Care

16. Under the realm of disease control and medical care, various laws were enacted. The oldest laws pre-date to the days of the British Rule. Some of these include, the Epidemic Disease Act of 1897, which provides for prevention of dangerous epidemic diseases, the Lepers Act of 1898 and the Indian Aircraft Act of 1934. Thereafter, various other legislations such as the Medical Termination of Pregnancy Act, 1971 and its subsequent amendment. Which permits MTP by a registered medical practitioner in a variety of specified circumstances. Similarly, the use of pre-natal diagnostic techniques is also regulated through the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and its subsequent amendment in 2002. This Act prohibits the use of prenatal diagnostic tests for the purpose of determining fetal sex and the practice of “sex selection”. Such tests may only be conducted at registered facilities and for limited purposes, including the detection of chromosomal abnormalities, genetic metabolic diseases, sex-linked genetic disorders, and congenital anomalies. There also exists separate legislation, namely, the Transplantation of Human Organs Act, 1994 that

provides for the regulation of removal, storage and transplantation of human organs and for the prevention of commercial dealings in human organs.

Regulations relating to Drugs & Pharmaceuticals

17. The key central statute governing the import, manufacture, distribution and sale of drugs and cosmetics is the Drugs and Cosmetics Act, 1940. In empowering the Central Government to regulate the import, manufacture, distribution, and sale of drugs in India, the Drugs Act establishes institutions – such as the Drugs Technical Advisory Board and the Central Drugs Laboratory – to execute certain provisions of the Act. The Ministry of Health and Family Welfare mainly administers the provisions in this Act through the Central Drugs Standard Control Organization. This organization performs a variety of functions such as approving new drugs and establishing uniform drug standards. In addition to the elaborate rules formulated under this Act, the various lists of schedules regulate various aspects related to vaccines (Schedule G), prescription drugs (Schedule H), standards of disinfectant fluids (Schedule O), life period of drugs (Schedule P), standards of condoms (Schedule R), standards of cosmetics (Schedule S), GMP for Ayurvedic drugs (Schedule T) and requirement and guidelines on clinical trials for import and manufacture of new drugs (Schedule Y) to enumerate a few.

18. There also exist several legal standards that address blood safety and transfusion services. In 1993, amendments to the Drugs and Cosmetics Act and accompanying rules required the screening of blood for five transmissible infections, including HIV/AIDS. Blood banks are required to obtain a license from the relevant authority, and these licenses must be renewed at regular intervals. A 1996 Supreme Court decision also generated key changes in the regulation of the country's blood supply. In *Common Cause v. Union of India and others*, the court set forth mandatory licensing of blood banks, a ban on professional blood donations and strict guidelines for holding blood donation camps.

Regulations of the private institutional providers of health care

19. Studies on utilization and household health expenditures reveal that 50 percent of people seeking indoor care and around 60 to 70 per cent of those seeking ambulatory care (or out-patient care) go to private health facilities in the country. The private health sector comprises of the 'not-for-profit' and the 'for-profit' health sectors. Despite their considerable presence in the country, information about the number, role, nature, structure, functioning, type and quality of care in private hospitals remains grossly inadequate. Quality of care provided by the private health care services in India has also come under scrutiny. This exists in a set up where there exist few systems for quality assurance, with majority of the population utilizing the services of the formal health sector but having no control on the quality of care.

20. Furthermore, regulations and accountability mechanisms for private establishments are far and few in between. In vast majority of the States in India, clinical

establishments are not regulated or monitored. Only few States have requirements for registration of private facilities such as hospitals and nursing homes.

Regulation of Clinical Establishments in India

21. As 'health' is a state subject, some State legislation had been brought out by UTs/States quite early such as:

- i. The Bombay Nursing Homes Registration Act, 1949;
- ii. Delhi Nursing Homes Registration Act, 1953;
- iii. Tamilnadu Private Clinical Establishments Act, 1997.

A comparison of the various provisions of the three above named Acts is at Annexure II. While the Tamilnadu Act did not perhaps get implemented, the other two statutes named above were also felt to have become outdated. The general impression derived is that these laws have never been implemented in the right spirit. Even in these States/UTs, there has been haphazard growth of private clinical establishments. The High Courts of Delhi and Mumbai have also intervened through their various orders for effective implementation of these statutes.

Directive from the National Human Rights Commission – 1996

22. Much later, in 1996 the death of one Ina Raja in a private hospital due to medical negligence was reported to the NHRC. The Commission directed the Govt. of India, MCI and the Delhi Govt. to examine:

Registration of private hospitals after ensuring availability of minimum facilities

Monitoring to ensure availability of facilities,

Framing of regulations,

Violation to be made a cognizable offence,

Shifting of non-conforming hospitals that are health hazards from non-conforming areas.

Resolutions of the Central Council of Health & Family Welfare

23. The Central Council of Health and Family Welfare in its 5th Conference held in January 1997 had resolved that: -

- (a) States may enact laws to provide for registration of only those private hospitals that have minimum facilities for different forms of treatment.

- (b) Monitoring mechanisms should be developed by the State to ensure that the facilities and services created in private and voluntary sector hospitals continue to be available and are maintained at the desired level; and
- (c) Private Hospitals in non-confirming areas that are posing health hazards may be considered for shifting to other areas.
- (d) The accreditation system would however, require to be studied.

Consequently, the National Institute of Health & Family Welfare was assigned the responsibility of drafting model legislation. The same was circulated to all State governments in February 1999. (Annexure-III).

24. Again the Council in its 6th Conference held in 1998 examined the matter afresh and resolved that the Central Government may frame norms and standards for ensuring proper health care for different categories of institutions in consultation with the State Governments for private hospital/Nursing Homes/Clinical Establishments to be followed by all the State Governments. These norms shall prescribe the minimum standards of staff and infrastructure for all such institutions. The Council further resolved that the State Government may enact laws to provide for compulsory registration of private hospitals, nursing homes and clinical establishments in order to ensure minimum facilities for different forms of treatment. It would also be necessary to regulate fees charged by the private health institutions. The laws could provide for compulsory exhibitions of fees, qualification of doctors, equipment available, etc.

25. To carry out the above mandate a National Workshop was organized by the Government of India, with assistance of WHO and the Medical Council of India on 18th and 19th August, 1999 at New Delhi to provide for a discussion among the service providers of nursing homes and hospitals for the purpose of presenting the minimum standards for registration of nursing homes and hospitals. A copy of the proceedings of this workshop is enclosed (Annexure- IV).

26. It was however felt that uniform enforcement of minimum standards would require a central legislation. Therefore, to vest in Parliament the authority to legislate on this subject, Ministry of Health & Family Welfare wrote to all States for getting appropriate resolutions passed from the State Legislatures. Only three states viz. Himachal Pradesh, Mizoram and Arunachal Pradesh have passed such resolutions. However, this does vests in Parliament to legislate on regulation of Clinical Establishments. Therefore, in the year 2000, another draft Bill under the nomenclature Clinical Establishments Regulation and Accreditation Bill was prepared.

Legislation by States

27. During this entire period, various states have also enacted their own legislations for regulating Clinical Establishments. As per available information the following States have enacted laws for regulation of clinical establishments:

- i. Bombay Nursing Homes Registration Act, 1949 (Annexure V)
- ii. The AP Private Medical Care Establishments Act, (Annexure VI)
- iii. Delhi Nursing Homes Registration Act, 1953 (Annexure VII)
- iv. Orissa Clinical Establishment (Control and Regulation) Act, 1991
(Annexure VIII)
- v. Punjab State Nursing Home Registration Act, 1991 (Annexure IX)
- vi. Manipur Nursing Home and Clinics Registration Act, 1992 (Annexure X)
- vii. Sikkim Clinical Establishments, Act 1995 (Annexure XI)
- viii. Nagaland Health Care Establishments Act, 1997 (Annexure XII)
- ix. MP Clinical Establishments Regulation Act. (Annexure XII-A)

It is also gathered that some more States such as Rajasthan, Karnataka and Haryana have drafted the regulatory legislations but have not been able to get them tabled and considered by their respective legislative assemblies.

Issues relating to enforcement, effectiveness and implementation

28. Despite the plethora of legislation for regulating clinical establishments, the common perception continues to be that such establishments are by and large not subject to any regulation and are, therefore, not accountable. A critical analysis of existing clinical establishment Acts suggests the following deficiencies and weaknesses:

Out datedness of existing legislations:

29. Until recently, there are only few examples of regulations promulgated by the State at local government levels e.g., Nursing Home Acts of Delhi and Bombay. Furthermore, most of the legislations affecting the health sector are old, inherited from pre independence days, cumbersome and irrelevant to the concerns of today's health sector. Many regulations have not been updated and, therefore, have lost their relevance.

Ineffective implementation:

30. Despite the existence of basic legislation, the degree to which regulations are enforced and effective is low. It has been found that the enforcement of regulatory controls is often weak or lacking. A PIL had to be filed in Maharashtra to force the state to implement the BNHRA 1949. States have limited capacity and resources to effectively implement the existing regulations.

Absence of rules:

31. Even in States that have enacted the clinical establishment Act, rules have not been framed for its implementation.

Ineffective content of rules:

32. Even in case the local governments have promulgated the rules, these merely cover registration of nursing homes/private hospitals. Minimum standards have not been developed, nor are issues relating to accountability of quality and price been addressed.

Non-coverage of other private institutional providers:

33. There is absence of legislation to regulate functioning of laboratories and diagnostic centers private service providers, despite the emergence of a considerable number of such facilities in India.

No uniformity in standards:

34. Standards framed by different States have nothing in common. Thus what may be a minimum standard in one State might be considered too harsh in another. While it has to be acknowledged that State specific variations would certainly exist, the need of the hour is for uniform standards.

Options for future action

35. From the preceding discussion, it is evident that despite enactment of legislations by various States, health care providers in India continue to be fairly unregulated. Some factors responsible for the wishy-washy implementation of existing laws have been enumerated in the preceding paragraph. Protracted discussions have been held in this Ministry with various stakeholders for almost a decade now, with no concrete results. On account of this, however, there is an increased awareness about the general mistrust and apprehension on the part of various service providers that such regulatory laws are prone to be mis-used and would unleash licensing and Inspector Raj into a sector that has hitherto remained by and large self-regulating. Hence, there is resistance to the implementation of the laws already enacted.

36. The fact that most of these State laws keep the government clinical establishments out of the requirements of registration and adherence to minimum norms further fuels this suspicion. Private sector players are quick to accuse the govt. of observing double standards in prescribing minimum standards for private establishments and doing nothing to improve the pathetic conditions in public health institutions. This issue would need to be addressed in the right spirit by the government. No exemptions have been provided for government institutions in laws framed for management of bio medical waste, setting up of blood banks and pre-natal diagnostic tests etc. All these laws have had salutary impact on their specific areas. All the more reason that government establishments should also be required to register and comply with prescribed standards. As a matter of fact MOH&FW has already started developing the Indian Public Health Standards (Annexure XIII) and compliance to these ought to be made mandatory especially when funds are also being provided out of the National Rural Health Mission for up gradation of public Health Institutes.

37. Another roadblock is the lack of clarity about standards. The variety of health service providers is so vast that it would be well nigh impossible to have uniform minimum standards to cover each and every possible clinical establishment. It is the understanding of this Group that this is one significant reason that has held back most States from formulating any minimum standards to regulate clinical establishments. Most States particularly the Health Departments are so bogged down with multifarious responsibilities that they have hardly any free time for innovative thinking. A lead role is, therefore, necessary for the Central Government in this area.

Centre to enact Central legislation

38. Historically, all laws pertaining to registration of medical professional have been central statutes as the Indian Medical Council Act, The Dentists Act and the Nursing Council Act. No similar central legislation exists for paramedics and paramedical education and practice continues to be unregulated despite enactment of laws by States for regulating para medical education. Moreover, experience suggests that as the private sector develops or as resources become available, it is much harder to implement regulatory legislation. Second, the existence of central legislation also means that as the judicial system is strengthened, or consumers become more aware of their rights, there is legal recourse through which to pursue the implementation of regulations. In the context of the NRHM, when the Centre is exploring options for public private partnerships, regulation of private institutional providers of health assumes greater significance.

Implementation at the district level

39. In terms of implementation, two aspects are of prime importance – firstly there is a need to empower Panchayati Raj Institutions to undertake registration and monitor the minimum standards for clinical establishments. This is already mandated by the 73rd and 74th amendments to the Constitution of India. Secondly there exists a need for provision of resources and developing capacities to undertake the task of implementing standards that may get to be prescribed.

STEPS INVOLVED

40. In the light of the above discussion, the following steps are recommended for implementation: -

- (i) The Central Government should enact legislation for registration and regulation of clinical establishments.
- (ii) Registration should be compulsory for all clinical establishments including diagnostic centres etc. under any recognized system of medicines.
- (iii) Public Health Clinical Establishments (government owned) should also be brought under the purview of such legislation.
- (iv) Even if the clinical establishment is already registered under any State Act, it should be required to re-register under the Central Act. This is necessary to have a reliable database of functional clinical establishments in the country. This would also help inventorize availability of manpower and infrastructure in clinical establishments, which could form the basis for developing uniform minimum standards. To instill confidence in these service providers, the Central Law should be simple and client friendly.
- (v) It should encourage use of IT and web based technology so that data mining and updating of records become completely digitalize.
- (vi) As far as possible, registration should be done on the basis of documents certified by licensed professionals such as Chartered Accountants, approved valuers, assessors etc. The setting up of administrative paraphernalia for inspection is to be discouraged.
- (vii) To the maximum extent possible, the responsibility of actual registration should be entrusted to Panchayati Raj Institutions (PRIs). There is already a multiplicity of licensing/inspector authorities under various health related legislations. These are, therefore, required to be consolidated.
- (viii) There need not be any direct role of the Central Government in the registration process except for maintaining a National Register of Clinical Establishments and for determining uniform minimum standards. Such a pattern already exists in the registration of medical, dental and nursing professional.
- (ix) A corpus should be set up for supporting research in the development of standards. It would be necessary to engage specialists and experts to suggest justifiable standards.

- (x) Minimum standards should be determined through a consultative process that would foster greater responsibility. The National Advisory Board should be set up for overseeing this exercise. Such Boards could draw upon various professional bodies and individuals for assistance in development of standards. It has to be encouraged that this will be a long drawn process and in all probability would have to be preceded by classification and categorization of various clinical establishments. It is for this reason that it is not proposed to link registration with determination of minimum standards.
- (xi) Due care would have to be taken to avoid over emphasis on standards for infrastructure. Otherwise investments required to comply with standards might have a spiraling effect on service costs in the health sector. Greater focus would, therefore, be required on standards for service delivery.

41. It is understood that the Ministry of Health and Family Welfare has already prepared draft legislation on the above lines. A copy of the same is placed at Annexure XIV. The Group has examined the draft and recommends that the Ministry should carry this forward.

Regulation of Professionals

42. In so far as medical professionals are concerned, legislative framework for their registration and regulation already exist in forms of the Indian Medical Council Act, the Dentist Act and the Nursing Councils Act. All these legislations set up regulatory councils at the National and State levels. While the National Councils prescribe norms and standards of education, the State Councils primarily deal with registration and enforcement of standards. Despite this, not much data is available at the national level about the availability and quality of medical and para-medical personnel. The registration of an individual is currently a one-time exercise in most States. Acquisition of additional and higher qualifications by the individuals is not required to be registered. Similarly, the shifting out from a particular State, change of address or the demise of the registered professional does not necessarily gets updated. All State Councils must, therefore, shift to a system of periodical renewal of registration, say every three to five years. Acquisition of qualification of a specialist or a super specialist must also be required to be registered. These details should also get transferred to a National Register to be maintained and updated by each apex council. When such data is available, proper planning of human resource requirement could be possible. There is also need to move forward towards a system of accreditation of various courses offered by Medical, Dental and Nursing educational institutions. The Human Resource Ministry has already established system for accreditation and rating of universities. Such a system is also needed in the sector of medical education. The proposed Medical Education Grants Commission could have appropriately handled this task. Till such by time a Commission

is set up, this task could be entrusted to premier institutions like the AIIMS, New Delhi, PGIMER, Chandigarh.

43. In the field of Para Medical Education, the situation is not comfortable. This sub sector continues to be primary unregulated. Few States have set up Para Medical Councils. However, lack of uniformity of norms and standards has not given any creditability to set up councils outside the States these have been set up in. The need, therefore, is to set up National Para Medical Council as an apex body to determine standards for para medical education, and to ensure uniform enforcement throughout the country.

Accreditation

International Scenario on Accreditation in Healthcare Services

44. A critical issue facing the health sector today is quality, with growing urgency amongst health care providers as well as consumers. Among the various approaches gaining momentum, 'accreditation of health facilities' has gained acceptance and prominence globally.

Introduction:

45. Accreditation is defined as public recognition of achievement of accreditation standards by a healthcare organization, demonstrated through an independent external assessment of that organization's level of performance in relation to the standard. Accreditation assessment relies on establishing technical competence of an organization in terms of accreditation standards in delivering services with respect to its scope. It goes beyond compliance. It calls for excellence on continued basis. It is this feature which makes it market driven involving all stakeholders; be it consumers, empanelling agencies, regulators and other third parties. Accreditation is also one of the established mechanism world over, as means to promote acceptance conformity assessment results, nationally as well as internationally.

46. In other words, the basis for accreditation is the existence or absence of such standards measured through qualitative indicators (evidence of performance) observed by a body of experts.

47. Accreditation is voluntary. It focuses on learning, self-development, improved performance and reducing risk. Accreditation is based on optimum standards, professional accountability and encourages healthcare organization to pursue continual excellence.

The concept of Hospital Accreditation

48. Accreditation in healthcare services refer to the evaluation process in which an accrediting body examines a healthcare organization to ensure that it is meeting certain

standards established by experts in the field. Accreditation is usually performed by a multidisciplinary team of health professionals and is assessed against the published standards for the environment in which clinical care is delivered. The standards adopted nationally usually derive from an amalgamation of national statutes, governmental guidance, independent reports, overseas accreditation standards and biomedical and health services research.

49. The process of quality assessment through accreditation features the need of establishing standards for all services of a general hospital for example according to universally/nationally accepted quality standards. The best country specific approach is however, dependant upon the desired outcomes of the accreditation system. The basic expectations for an accreditation system are that it provides for:

an independent, objective evaluation process;

be highly credible and unbiased;

represent the broadest possible consensus among users and stake holders;

encourage improvement in the delivery of healthcare;

and be relied upon by key users and stakeholders.

50. Cardinal principles of accreditation evaluation are;

- i) Hospital operation are based on sound principles of system based organization; transparent and objective.
- ii) Accreditation standards are implemented and institutionalized into hospital functioning.
- iii) Patient safety and quality of care, as core values are established and owned by management and staff in all functions and at all levels.
- iv) There is structured quality improvement program based on continuous monitoring including feedback on patient care services.

51. The evaluation process incorporates interview with patients, residents and staff. It calls for on-site visit to patient care areas and to departments, addressing issues related to physical assessment of infrastructure, medical equipment, security, infection control etc., as required in the accreditation standards. In short accreditation is comprehensive review of not only facility but also of clinical competence of hospital to deliver services within its scope.

52. With rapid growth of state of art private sector in the healthcare, the accreditation program is moving closer to regulatory agenda. In most developed economies there are very strong financial incentives to seek accreditation. Governments acknowledge that independent assessment program by way of accreditation should be encouraged with

incentives, more so for secondary/tertiary level of hospitals to bring in the best in terms of Patient Safety and Quality of Care.

53. The accreditation body, while operating in regulatory areas i.e. Healthcare, Food Safety, will have some kind of linkages, may be with the regulator. For example, regulation may provide that a healthcare organization will automatically be deemed to have been registered, if accredited by the recognized national accreditation body. Similarly accreditation body will take cognizance of applicable regulatory requirements at the time of granting accreditation.

Global Scenario

54. The accreditation of health services originated in the U.S. during the early ninety's and today is the main instrument used by the U.S. Government for the distribution of financial resources to health institutions. The Government only contracts those health institutions that have been accredited. Other regions have also applied this method, such as Canada, Australia and the Province of Catalonia, in Spain. In the Australian system, a star rating is given to hospitals like the star ratings of hotels. The rating is given according to the facilities provided. The form of accreditation, however, would vary from country to country. The United Kingdom has self-accreditation program. In Latin America, after the II Accreditation Conference (1992), the process began to be implemented through national meetings in practically all countries. In Argentina, Chile and Uruguay initiatives have been observed at the central or state levels. In the Andean sub-region the success in Bolivia, Colombia and Peru has been significant. Guatemala stands out the most in Central America; and in the Caribbean, the Dominican Republic has fully embarked on the process of accrediting its private hospitals. Cuba, until the end of 1997, intended to have 60 hospitals accredited. In Southeast Asia significant progress in accreditation has been accomplished in Indonesia and Thailand.

Country specific status of hospital accreditation

USA:

The accreditation of hospitals began way back in 1910 in the United States, when Ernest Codman, M.D., proposed the "end result system of hospital standardization". The proposal became the stated objective of American College of Surgeons (ACS) that developed the first minimum standards for the hospitals in the year 1917. In the year 1951, the American College of Physicians (ACP), and the Canadian Medical Association (CMA) joined with the ACS to create the Joint Commission on Accreditation of Hospitals (JCAHO) and independent, not-for-profit organization whose primary purpose is to provide voluntary accreditation. It has accredited about 15000 healthcare organizations.

Australia:

The Australian Council on Healthcare Standards (ACHS) is the pioneer in accreditation in Australia. It had accredited around 700 healthcare organizations by 15th October 2001. It began as collaboration between doctors and administrators in adjacent states, based on

Canadian model. It is an independent, not-for-profit organization, dedicated to improving the quality of healthcare in Australia through continually reviewing performance, assessment and accreditation.

The organization is governed by a board of Directors elected by council members and supported by a corporate management structure, which oversees the process of evaluation and assessment by professionally qualified surveyors. The body has formal links with the government through representation on council and governing board. The programme focuses on the primary, secondary and tertiary care service providers. ACHS was accredited by ISO against their international standards for national healthcare accreditation bodies in the year 2001.

Canada:

The Canadian Council on Health Services Accreditation (CCHSA) is a national, non-profit, independent organization whose role is to help health services organizations, across Canada and internationally examine and improve the quality of care and service they provide to their clients. It has accredited around 3500-4000 healthcare organizations in the country and around 5-6 healthcare organizations internationally. It was set up following the separation of the United States and Canadian accrediting bodies in 1958. It is the second longest established programme in the world. It is totally independent of government, but in some provinces the government gives a financial incentive for accreditation and is the sole accrediting body in Canada. The programme focuses on the primary, secondary and tertiary care service providers. CCHSA underwent accreditation survey by ISQua in the year 2002.

Ireland:

The Irish Health Services Accreditation Board (IHSAB) is an independent organization established under a statutory instrument (SI), whose prime purpose is to continuously review and operate an accreditation scheme for the Irish health system within a quality improvement framework using an approach of self-assessment and peer review survey. The board mainly focuses on acute health services. It is on the process of getting ISQua accreditation. The process of accreditation is voluntary. The board has accredited around 35 hospitals to date.

Malaysia:

The Malaysian Society for Quality in Health (MSQH) was formed through the initiatives of both the Ministry of Health Malaysia and the Association of Private Hospitals of Malaysia. The society is an independent, not-for-profit organization working actively in participation with healthcare professionals to ensure continuous quality improvement in health in the services provided by healthcare services and facilities in the country. It is strongly supported by the Ministry of Health. The accreditation process in the country is voluntary. The society has accredited 66 hospitals as of 6th May 2006.

New Zealand:

Quality Health New Zealand is an independent non-profit organization and is constituted as an incorporated society. It was set up as the New Zealand Council on Healthcare

Standards (NZCHS) to provide a voluntary accreditation programme for hospitals and other health services with the technical support of ACHS. The government, the Health Boards Association and the private Hospitals Association, initially funded it. Today it is financially independent mainly funded from the fees paid by participants in its Accreditation Programme and clients of its other assessment services.

It mainly focused on aged care facilities and private and public acute hospitals and services but also have programmes for primary care, hospices, disability support and no-for-profit voluntary organizations. Since 1990 Quality Health New Zealand has worked with a wide range of health and disability services throughout New Zealand, undertaking well over 500 surveys and numerous audits.

South Africa:

The Council on Health Service Accreditation for South Africa (COHSASA) is structured as a national collaborative effort between the state, private sector consumers and health professionals. In terms of the memorandum and articles of association, the structure of the council includes a board of directors, an executive team and several member organizations. It is a total independent programme and focuses on all the primary, secondary and tertiary care. It includes hospital based and district base services and was developed with technical support from the HAP United Kingdom.

COHSASA is the only body in this country recognized as an impartial accreditation agency for healthcare facilities and is the only healthcare accrediting organization in South Africa accredited by ISQua. Since the start of the operation, 400 healthcare facilities have entered the COHSASA programme and some of the facilities are in the process of accreditation.

United Kingdom:

The Health Quality Services (HQS) is the longest established health accreditation service in the UK and the rest of Europe. It was launched by the King's fund; a London based charity and developed into HQS providing accreditation across the spectrum of public and private services.

HQS is accredited by the ISQua. Around 114 organizations were accredited by the HQS as on 8th March 2006.

From the above scenario of accreditation of different countries, it can be said that the accreditation systems over a period of time have shifted from a single system focusing on entire hospital to a more complex pattern with specialized agencies undertaking for several compartments of the health delivery system.

Hospital Accreditation in India

55. In the Indian context it can be said that the rising demand for quality care, the limited healthcare investment by the government, the growing number of private players in healthcare and insurance sector, the opening-up of the health sector to global patients makes the search for quality an imminent reality.

56. The demand for Hospital accreditation in India was raised in the early nineties. The extension of the Consumer Protection Act to medical practitioners stimulated the demand for Hospital Accreditation. It was viewed as a device to protect medical practitioners by fixing standards of subordinate and ancillary services that could largely affect a doctor's performance and also to eliminate substandard establishments. Many Non resident Indian doctors sent in suggestions for the establishment of an Autonomous Council to lay down standards for Hospitals. This Council could also be responsible for classification of Hospitals/Nursing Homes/ Laboratories/ Clinics and would include representatives from:

- Hospital Association of India
- Voluntary Health Association of India
- Indian Medical Association
- Medical Council of India
- Dental Council of India
- Nursing Council of India
- National Academy of Medical Sciences
- Director General of Health Services or his Nominee
- Association of Surgeons of India
- Association of Physicians of India
- Association of Obstt. And Gynaecology
- Four Independent Medical Experts
- The model of the Australian Council for Hospital Standards was also suggested for the Indian Context.

Initiatives taken by the Ministry of Health & Family Welfare

57. An initiative at the national level, undertaken by the MOHFW, GOI in the year 2001 was the development of a draft organizational framework for developing a hospital accreditation system in India. This document provides organizational options for envisioned national and state accrediting organizations and considers important issues in operational sing the proposed system.

58. Another initiatives was a workshop, organized by the WTO cell, MOHFW on 9th February 2005 under the GOI-WHO biennium (2004-2005) to bring together stakeholders to discuss issues related to accreditation of health facilities.

59. The World Health Organization, India country office organized a one and half day workshop, 'Accreditation of Health Facilities in India- A Way Forward' on October 7-8, 2005 at Taj Malabar, Kochi, Kerala. Other development partners who supported this initiative included the World Bank amongst others. The Workshop sought to:

- Share key concepts & experiences relating to accreditation of Health care facilities and review the current scenario in India & draw lessons.
- Engage in a constructive dialogue with key stakeholders to explore options to develop an accreditation system that would have multiple benefits, including notably the improvement in quality of care in both public and private sectors in India.
- Develop a roadmap for establishing an accreditation system in the participating States.

60. This workshop brought together representatives from the States of Andhra Pradesh, Karnataka, Kerala, Maharashtra and Tamil Nadu. The participants included policy makers from the Central and State Governments, representatives from the private medical sector as well as civil society from the State of Andhra Pradesh, Karnataka, Kerala, Maharashtra and Tamil Nadu. Development partners including the World Bank, USAID, ECTA, DFID and GTZ also participated in the workshop.

Possible Options

Option 1

MOHFW Role: Confined to overall policy decisions and development of standards for health care facilities.

Role of States: Design, operationalization and implementation of an accreditation system

Option 2

MOHFW Role: Preparation of blueprint for states to implement an accreditation system, including development of standards.

States: To operationalize and implement an accreditation system

Option 3

MOHFW Role

- Policy making in consultation with stakeholders
- The national quality framework and accreditation process, in consultation with stakeholders
- Development of standards across types and level of services
- Training, information dissemination, conducting relevant, problem based research
- Developing implementation plans and monitoring
- Co-ordination and supervision of regional offices
- Facilitate sharing of experiences and skills transfer.
- Mobilizing the human, physical and financial resources to strengthen state implementation plans.
- Making recommendations to the GOI concerning quality aspects and related.

Role of States

- Implementation of Accreditation as designed by the national body.
- Support services to participants at regional level including training
- Regional monitoring of implementation of accreditation
- Review of the decisions and reports generated by the body to determine their robustness and
- Usefulness to the providers and consumers
- Redress: participating hospitals, consumer

Progress made so far

National Accreditation Board for Hospitals and Healthcare Providers

62. National Accreditation Board for Hospitals and Healthcare Providers (NABH) has come up with a uniform standard for the hospitals throughout the country. NABH is a constituent Board of Quality Council of India (QCI). It has reportedly adopted its standards and accreditation process in line with worldwide accreditation practices. The formal launch of accreditation was announced in February 2006. About 20 major hospitals were reported to be undergoing accreditation evaluation. It is institutional member of ISQua.

63. Other organizations like Indian Confederation for Health Care Accreditation (ICHA) have also starting the process of accreditation of health institutions. Financial rating organizations like ICRA have also started rating hospitals.

Empanelment by CGHS

64. For the empanelment of hospitals and diagnostic centres by the Central Government health Scheme, it has now been made mandatory that all diagnostic labs must be certified by the National Accreditation Board for Testing and Calibration Laboratories (NABL). Similarly, physical inspections of hospital that have applied for empanelment have been entrusted by Ministry of Health and Family Welfare to the Quality Council of India. Similar procedures could be adopted by the Employees State Insurance Corporation of the Labour Ministry and Ex-Servicemen's Contributory Health Scheme of the Ministry of Defence for empanelment of hospitals and diagnostic centres. It is expected that such demands/requirements shall generate further demand for accreditation and for accrediting agencies. MOHFW has, therefore, taken the position that no legislation may be necessary for accreditation of health institutions per se. This would be purely a voluntary exercise. There should therefore be an independent body that should oversee the functioning of accrediting agency to ensure that institutions of doubtful competence are not allowed to take the advantage of the lack of well-established accreditation frame. This body would also liaise with regulatory of clinical establishments for ensuring that only such establishments get accreditation that have complied with the minimum standards. It is, however, to be encouraged that setting up of such a body would be a complex and contentious exercise. It would therefore not be prudent to make the establishment of such a Supervisory of Body as a pre-condition for

introduction of accreditation in the health sector. The process of setting up a Supervisory Body can be initiated in the 11th Plan period and the financial provision should be made for facilitating the functioning of such a Body as and when it comes into being.

Recommendations

65. i) Accreditation would be purely voluntary
- ii.) There can be several accrediting agencies like NABH under the Quality Council of India, Indian Confederation for Health Care Accreditation and even the Bureau of Indian Standards can take up this task.
- iii.) There would be no funding from Central Government. All the organizations will have work on a self-sustaining process. However, Government of Indian would promote accreditation.
- iv.) Accrediting agencies will have to take into consideration the requirements of Medical Tourism for which international standards will recognized by developed countries need to be adopted for accreditation.
- v.) Accrediting agencies will also have to take into view the requirements of Insurance Companies.
- vi.) Accreditation standards should be based not only on physical infrastructure, but also on standard operating procedures (SOPs) for various kinds of identifiable medical Instruments.
- vii) The focus of accreditation should be on continuous improvement in the organizational and clinical performance of health services, not just the achievement of a certificate or award or merely assuring compliance with minimum acceptable standards.

66. Taken as a whole, the process will assess the extent to which health care organizations are delivering safe health care effectively. It would indicate areas of strength and weakness, including aspects requiring attention; involve an evaluation of the validity and reliability of an institution's internal review procedures, and provide reassurance that each institution has in place effective arrangements for assuring optimal standards in the organisation and has procedures securely in place that will enable it to continue to do so.

SUMMING UP

- 67.
- i.) There is need for a central legislation for registration of clinical establishments in the country. The draft legislation prepared by Ministry of Health and Family Welfare needs to be carried forward.
 - ii.) Registration of clinical establishments should not be linked to compliance of standards in the initial years.
 - iii.) Uniform standards need to be developed for the entire country. These standards should not focus on infrastructure alone, but also on service delivery.
 - iv.) The registration of medical professionals needs to be periodically updated. Additionally acquisition of higher qualifications should require re-registration. National Registers of all medical and para-medical personnel need to be created.
 - v.) National Paramedical Council should be set up for regulating paramedical education and service delivery.
 - vi.) Accreditation of health institutions should be voluntary, but encouraged by the Central and State governments.
 - vii.) There is a need for setting up of National level body to oversee the functioning of various accreditation agencies that might come into being.
 - viii.) Provisions need to be made in the 11th Plan for facilitating development of minimum standards and also for setting up an oversight body for accrediting agencies in the health sector.

*****_-----*****