

**Proceedings of the
National Workshop on
Accreditation and Standardisation of
Health Services**



February 9, 2005, New Delhi

Organised by

International Health Division

Ministry of Health & Family Welfare

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Preface

In this era of international trade treaties, health care delivery has become a global issue. In this context, one of the issues, which need to be re-examined, is the quality of health care provided by the health care providers. Accreditation for hospitals and health care providers in India as per the international standards could go a long way in achieving higher standards in health care facilities and in attaining the prescribed norms in quality of health care. In fact establishment of world class hospitals and quality health services in India would not only raise the quality standards of health care delivery, but would also increase India's competitiveness under Modes I and II of the General Agreement on Trade in Services (GATS).

Health care delivery in India has been multifaceted, consisting of diverse practitioners and institutions, mixed ownership patterns and differing systems of medicines. Though, the last several decades have brought about improvements in the health system, yet, deficiencies still persist with respect to access, affordability, efficiency, quality and effectiveness of health services.

In most states of the country there is an absence of legislation for regulating public and private health care facilities, laboratories and various type of health centres do not have standards of medical practices in terms of equipment needed, qualification of staff employed or administration or treatment offered. It is increasingly being felt that there is an inadequacy or non-responsiveness of the current policies and processes (including legislation) to ensure provision of health care services of acceptable quality. Attempts at enacting legislations for clinical establishments have not met with success, with opposition faced even from health care providers and their associations.

The lack of any kind of quality assurance mechanisms (such as accreditation) not only makes it difficult for people to make informed choices in selecting health care providers but also limits their capacity to demand optimum services. In the context of increasing demand for good quality health care from the growing class, there is a need to examine mechanisms such as accreditation for improving the quality of health services.

Over the past few years, interest in formal accreditation and quality systems for health care organisations has been growing among the various stakeholders including government and private providers. Simultaneously, the opening of the health insurance sector to private participation makes it imperative for health care providers to provide quality care as per the prescribed norms. In this context, there is therefore an urgent need to explore the potential of various mechanisms for ensuring safe and quality health care that is viable, affordable and accountable. There is also a need to examine alternative mechanisms of quality assurances such as certification, regulation, standardisation, and consumer education.

Recognising the need for quality assurance system and the regulatory mechanism, the Ministry of Health and Family Welfare, along with the WHO, under the WHO – Government of India Biennium 2004-05, organised a one day National Workshop on “**Accreditation and Standardisation of health services**”. The major issues addressed in the Workshop were - means to establish an accreditation system for health care facilities, the purpose of accreditation for different stakeholders, identifying who should be involved, mechanism for monitoring and how to mobilise resources for this task. The workshop aimed to bring together various stakeholders and to share their experience in evolving as well as implementing accreditation system.

INAUGURAL SESSION

Welcome Address

Shri B P Sharma, Joint Secretary,
Department of Health, MOHFW, GOI

Inaugural Address

Dr S J Habayeb,
WHO Representative to India

Theme Address

Dr S P Agarwal,
Director General of Health Services

Keynote Address

Shri P K Hota,
Union Secretary, Dept. of Health & Family Welfare,
MOHFW, GOI

Vote of Thanks

Shri Rajesh Bhushan, Director (IH), Department of Health,
MOHFW, GOI

**National Workshop on Accreditation and Standardisation of Health Services
February 9, 2005, held at India Habitat Centre, New Delhi**

Shri Rajesh Bhushan, Director (IH), MoH&FW on behalf of Ministry of Health and Family Welfare, Government of India, extended a hearty welcome to all the distinguished delegates at the National Workshop on Accreditation and Standardisation of Health Services. The chief guest, Shri Prasanna Hota, Union Health and Family Welfare Secretary, DGHS Dr S P Agarwal, Dr Salim Habayeb, WHO Representative to India and Shri B P Sharma, Joint Secretary, Department of Health and Family Welfare were facilitated.

In his welcome address **Shri B P Sharma, Joint Secretary, Ministry of Health and Family Welfare** traced the progress of health care sector in India. He referred to different approaches to establish and evaluate quality of health care achieved by any organisation particularly in the context of two developments –

- (a) Attempts to promote India as a Health destination for persons around the globe.
- (b) The impending launch of National Rural Health Mission.

The text of the speech is at **annexure 2**.

Dr Salim J Habayeb, the WHO Representative to India, in his inaugural address stressed the need to promote accreditation in health sector. He pointed out that standardization is a key element leading to accreditation. The text of the speech is at **annexure 3**.

Dr. S P Agarwal, Director General of Health Services, Ministry of Health and Family Welfare in his theme address observed that accreditation is a tool to ensure quality of health care. He referred to the need to have legislative regulation of clinical practice and even accreditation of medical courses, medical laboratories and medicare equipments. The text of the speech is at **annexure 4**.

In his Inaugural Address **Shri P K Hota, Union Secretary (Health & Family Welfare)** outlined the complexities of accreditation of health services in India. He pointed out that like the I.T. sector India has a comparative advantage in services like healthcare. The cost differentials in healthcare between developed nations and India are substantial. In addition to cost effectiveness, sophisticated medicare facilities in India have started drawing people from other countries. This emerging potential need to be harnessed and a voluntary system of standardization and accreditation need to be evolved. He also exhorted state government to initiate work in this area to complement the efforts of government of India. The text of the speech is at **annexure 5**.

Shri Rajesh Bhushan, Director (IH), Ministry of Health and Family Welfare thanked the Union Secretary (Health & Family Welfare) for the extremely thought provoking address, wherein he highlighted the complexities of accreditation in health services and shared that there needs to be an appropriate mix of the public and the private in addressing it. He also thanked the Director General of Health Services and the WHO Representative to India, and all the representatives from the various State governments, from the private sector, from different central government hospitals, as well as all the delegates who had taken out time from their busy schedule to attend the workshop. He hoped that everyone would be contributing productively and fruitfully in enriching the deliberations of the Workshop.

SETTING THE PREMISE

ACCREDITATION ISSUES AND CONCERNS

GATS and Health Services -Opportunities for India

Shri Rajendra Mehrotra
WHO National Consultant, MOHFW

Accreditation of health care facilities- Options and Challenges

Shri Sunil Nandraj, NPO, WHO
&
Ms. Anagha Khot, National Consultant

Accreditation Issues and Concerns

Shri Girdhar J. Gyani,
Quality Council of India

GATS and Health Services -Opportunities for India

Shri Rajendra Mehrotra, National Consultant, MoH&FW presented a comprehensive overview of GATS & accreditation issues. He pointed out that in the context of international trade treaties, health care delivery has become a global issue. The thrust is to promote India's health care delivery facilities. In this context, the focus is on the quality of health care being provided. One of the means to achieve higher standards of quality in health care facilities could be by getting accreditation as per the international standards. In fact setting up of world class health facilities in India would not only raise the quality standards of health care delivery, but would also increase India's competitiveness under Modes I and II of the General Agreement on Trade in Services (GATS).

The General Agreement on Trade in Services (GATS) is the first set of international rules for international trade in services. GATS sets out a framework of legally binding rules governing the conduct of world trade in services. Services account for a large share of production and employment in most countries. Despite the potential advantages that trade liberalization may have in improving economic growth and development, it has a number of inherent challenges for national health systems.

The Services covered under Health Services under the GATS are (a) Medical and Dental Services; (b) Services provided by midwives, nurses, physiotherapists and paramedical personnel and (c) Hospital Services and other human health services.

The health sector is largely affected by GATS as it covers a number of issues like the movement of consumers and providers across borders to receive and supply healthcare, FDI in health and the emerging areas of e-commerce and tele health.

Under the GATS, trade in health services is classified via 4 Modes Of Supply. Each supply mode has associated benefits and problems.

Mode I - Cross border delivery of trade This includes shipment of laboratory samples, diagnosis and clinical consultation via traditional mail channels as well as electronic delivery of health services, such as diagnosis, second-opinions and consultations. This enables health care providers to cater to remote and under served segments of the population, improves the quality of diagnosis and treatment, and helps upgrade skills. Its flip side is that it channels revenues away from rural health care towards specialized centres, thus concentrating technologies that cater to the affluent few.

Mode II – Consumption of Health Services abroad This refers to the movement of consumers to the country providing the service for diagnosis and treatment. Here affluent patients seek specialized high quality treatments in overseas hospitals. India also exports health services through consumption abroad. Patients come from both developed and developing countries for surgery and specialized services in some areas attracted by India's pool of highly qualified health care professionals and by the country's ability to provide good quality affordable treatment. On the positive side, it enables exporting countries to generate foreign exchange. It also helps in overcoming shortages of physical and human resources in the importing countries, particularly for specialized health services. However, consumption of trade abroad results in a dual market structure, by creating a higher quality, expensive segment that caters

to wealthy nationals and foreigners, and a much lower quality, resource constrained segment catering to the poor.

Mode III – Commercial Presence This involves the establishment of hospitals, clinics and treatment centres. India has become increasingly open to FDI in this area with several specialty corporate hospitals being built in collaboration between Indian and foreign companies. This helps in upgrading of healthcare infrastructure and generates employment. The availability of private capital could reduce the total burden on government resources.

Mode IV - Movement of Health Personnel This includes the movement of health personnel including physicians, specialists, nurses, paramedics and health management personnel. The movement of health care professional includes both temporary and permanent flow. The permanent migration of health professionals occurs mainly from developing to developed countries, driven by wage differentials between countries and a search for better training possibilities. The implication of trade via movement of health service providers also has mixed implications. From the source country's perspective, increased mobility of healthcare providers generates remittances and transfers, and helps upgrade skills and standards in the country but in the short term it also depletes the skill pool of the source country. For the host country, movement of health personnel provides an important means to meet the shortage of healthcare providers and improve the quality and accessibility of healthcare services.

Implications Of Trade In Health Services Under GATS

It is important to recognize that many of the adverse implications of trade in health services highlighted above are purely due to internal factors and not due to globalisation. While globalisation may aggravate some of these problems, it may also provide tremendous opportunities. Thus the impact of trade in health services is largely dependant on the policies and safeguards the government puts in place and on the existing conditions in the sector. Therefore, there is a need to develop a comprehensive health care system to reap the benefits of globalisation and this can be done if the country has an accredited health care system in place. The need of the hour is to develop an enabling environment in which high quality of healthcare can flourish throughout the country. The establishment of accreditation system in India could pave the way for the provision of consistency in good quality of health care.

What Is Accreditation?

Accreditation began in the United States in 1917 as a voluntary collaboration of clinical association and hospital administrators as a means of organizational development. Today, at least 28 countries have an operational accreditation program for their health services. In India, a statutory national accreditation program for health does not exist, as healthcare is the responsibility of individual states. However, it is time that State and Central Government could consider a voluntary system of accreditation to improve the existing health care systems. The promotion of accreditation would even provide an impetus to trade liberalization in the health sector under the GATS framework. There have been three primary approaches for evaluating quality of healthcare achieved by any organization.

1. Licensing : Licensing addresses the minimum legal requirements or qualifications healthcare professionals and organizations need to operate. Government or Regulatory

Authorities grant licences when facilities meet defined levels of quality to provide certain services.

2. Certification : Certification involves a recognized authority granting recognition to individuals who have demonstrated specialized knowledge and skill in a certain area or specialty. Certification distinguishes organizations as capable of practicing or delivering services in any specialty area.
3. Accreditation : The term accreditation reflects the systematic assessment of health services against explicit standards. In simple terms, we can say that accreditation refers to a voluntary process wherein the functioning of a participating health facility is assessed against set standards. It is this approach that is gaining momentum world over as a one of the tools to deliver quality health care.

Globalisation And The Need For Accreditation In India

Over the past few years, interest in formal accreditation and quality systems for health care organisations has been growing among the various stakeholders including government and private providers. Simultaneously, the opening of the health insurance sector to private participation makes it imperative for health care providers to provide quality care. In this context, there is therefore an urgent need to explore the potential of various mechanisms for ensuring safe, high quality health care that is viable, affordable and accountable. There is also a need to examine alternative mechanisms of quality assurances such as certification, regulation, standardisation, and consumer education for developing an accreditation system.

Health care delivery in India has been multifaceted, consisting of diverse practitioners and institutions, mixed ownership patterns and differing systems of medicines. Though, the last several decades have brought about improvements in the health system, yet, deficiencies still persist with respect to access, affordability, efficiency, quality and effectiveness of health services.

In most states in India, there is an absence of legislation for regulating private health care facilities, laboratories and various type of health centres do not have standards of medical practices in terms of equipment needed, qualification of staff employed or administration or treatment offered. Attempts at enacting legislations for clinical establishments have not met with success, with opposition faced even from health care providers and their associations.

The lack of any kind of quality assurance mechanisms (such as accreditation) not only makes it difficult for people to make informed choices in selecting health providers but also limits their capacity to demand optimum services. In the context of increasing demand for good quality care from the growing middle class, there is a need to examine mechanisms such as accreditation for improving the quality of health services.

India's Healthcare Sector

Healthcare sector in India has made impressive strides in the recent years. As per industry estimates, it has transformed to a US \$ 17 billion Industry and is surging ahead with an annual growth rate of 13% a year. Since health care is dependent on the people served,

India's huge population represents a big opportunity. However, good healthcare in India is in extreme short supply and it is this gap, which presents a vast opportunity in this sector.

The world over professionally driven healthcare accreditation system has been the most successful mechanism to achieve continuous improvement in healthcare delivery. The lack of any kind of quality assurance mechanisms (such as accreditation) not only makes it difficult for people to make informed choices in selecting health providers but also limits their capacity to demand optimum services. Thus, for India to become a preferred healthcare destination, an internationally acceptable and credible accreditation system is the first pre-requisite.

Objective Of The Workshop

Recognising the need for quality assurance system and the regulatory mechanism, the Ministry of Health and Family Welfare, along with the WHO, has taken the initiative of organising this one day National Workshop on Accreditation and standardisation of health services. The aim of the workshop is to examine regulation of health providers, with special reference to accreditation of health care providers; examine the purpose of accreditation for different stakeholders of health care in India; examine ways and means of implementing dimensions of quality and monitoring systems for health facilities and develop the role and levels of functioning of the accreditation bodies; to bring the various stakeholders together and share their experience in implementing accreditation system and to examine ways forward for developing a system of accreditation of health care facilities including ways to mobilise resources for formulating a system for accreditation for health facilities

The major issues that the Workshop would address are the purpose of accreditation for different stakeholders, means to establish an accreditation system for health care facilities, identifying who should be involved, mechanism for monitoring quality and how to mobilise resources for this task. The workshop is aimed at bringing various stakeholders together and shares their experience in implementing accreditation system and to suggest recommendations for way forward with respect to accreditation of health care facilities.

Accreditation of health care facilities- Options and Challenges

Shri Sunil Nandraj, National Professional Officer, WHO India traced the history of the legislation leading to accreditation of health care services. These issues have largely been debated at the State level and this is a good opportunity for various stakeholders to come together and look at the issues of accreditation. He pointed out that many of the stakeholders have been working on the issues of accreditation.

As India is a country of wide divergence where there are various systems of medicine so we have a complex healthcare system. Private sector is the dominant sector and is more important in the absence or outdated ness of legislation for regulating private health facilities. However, the quality of care provided by both public and private sector is questionable. The entire accreditation and legislation process has to be applied in the background that healthcare delivery service is diverse with both formal and informal providers in place and that there is a contrast that exists where there is a two-three bedded nursing home vying even with a super specialty hospital.

He informed that only eight States have legislations for private hospitals in the country. There are no legislations for laboratories, diagnostic clinics, and equipment and with new technologies coming in daily, there is no accountability of monitoring mechanisms for them.

There has been widespread awareness about accreditation, certification, licensing, ISO, patients charter, etc and demand for these concepts due to several reasons have increased. The costs of healthcare are going up. Failure of regulation is another reason. There are increasing number of cases being filed in consumer courts for medical malpractices. There are no minimum standards prescribed by medical bodies. For a medical college, Medical Council of India can prescribe the number of staff; yet, there is no minimum standards prescribed for hospitals, polyclinics, or for laboratories. There is thus a felt need to accreditate bodies that can provide good quality healthcare and it is in the interest of the providers to go in for accreditation. These abovementioned factors are catalyst for increasing demand for good quality of care in the country.

He removed the confusion on the issues of licensing, accreditation and certification. Licensing is a State Act. States are responsible for licensing of health facilities and any other institute cannot do the same. On the other hand, certification is an exercise done by individuals or organisations for facilities meeting a predetermined requirement of criteria. Accreditation is a voluntary process wherein the functioning of a participative hospital or a facility is measured against the set standards by an external review. It focuses on reporting better practices than on merely compliance with minimum standards.

Accreditation of health services is very difficult in a vast country like India. It has to be considered if accreditation should be national, regional, specific to certain services, and whether the standards have to be classified as the minimum, optimum or excellent standards.

A study of various stakeholders was conducted sometime back in Bombay city to assess the need, views and willingness of various stakeholders regarding participation in an accreditation process for regulation of private hospitals. The stakeholders for the purpose of the study involved medical providers, professional organisations, consumer organisations, insurance companies, Central government and the State government (at the municipal level). The findings of the study were that there was an overall need and willingness for an accreditation body and that all stakeholders should play a leading role in establishment of such a body. It was recommended by the study that the body should assess the hospitals in maintaining and upgrading standards through education, training and consultation. It should monitor physical aspects, equipment, the number of staff, its qualification, and type of treatment; consumer satisfaction issues and also follow up of care.

He informed that in the year 2001, the Ministry of Health and Family Welfare had set up a national panel on quality assurance with the objectives of mapping out a course for developing a quality assurance system in healthcare for improving the quality of healthcare in an affordable and accountable manner. The panel had suggested that a national panel for quality assurance should be set up with ten to fifteen highly qualified national stature persons. The panel would establish subgroups to undertake detailed and technical work on developing an accreditation system for the country. The Ministry of Health has been looking at this objective, but for various reasons, this has really not taken off. As this process has already been initiated, there is a need to rework on it with reference to the earlier work, the studies and various

other country experiences on this subject to our specific requirements. A broad framework based on the Bombay experience (to be presented by Anagha Khot) can be considered.

Ms. Anagha Khot, National Consultant, MOHFW presented a broad framework based on the Bombay experience. She also highlighted some of the broad issues in this process, like what should be the scope and objectives of the proposed accreditation system, some issues relating to staffing and functioning and the most important, the issue related to financing the body.

For any system to be workable the same has to be voluntary and peer led. All the stakeholders right from the government, to the consumers, providers of healthcare, the hospital associations, the specialist associations, and the insurance companies have to be involved in the process. When all the stakeholders lead a movement then it has some kind of credibility and more chances of being sustainable. The accreditation body has to be transparent and be governed by the principle of collaboration and consensus building. The provision of quality care has to be at the centre of this whole system with the consumer at the center of care. The board should ensure that quality care, which is, accountable and affordable, is available to the consumer.

The proposed accreditation body would assess facilities for compliance with standards and should keep pace with the changing health environment. As standards cannot be just set at one point in time, so the focus has to be on not only about setting standards, but also on continuously upgrading standards. The accreditation process should also help those facilities, which are not able to meet the optimum standards, to gradually come up to the level which meets the minimum standards.

Accreditation has to be a process, which is peer led and all the stakeholders have to be involved so that together everyone works towards improving quality of care. There is a need to begin small, and gradually develop along the way. It may be debated whether we can really accredit an entire hospital or we may accredit any particular unit in a larger hospital or a particular kind of service. With the fast changing phase of technology in healthcare today, accreditation has to be valid for a particular period and even maintaining accreditation status has to be inbuilt into the process of accreditation. An important issue pertains to the status of this body. In our context, it could be autonomous in its functioning but it should have legislative support. Another key issue relates to that of resources. Some of the options for mobilizing resources could be that the participating hospitals in this process may be required to pay a fee. This could be in form of a survey fee, a registration fee, or even an annual fee. The fees would generate a fair amount of funding for carrying out the activities of the body.

There have been a lot of international experiences but to entirely copy or super impose such a system for India would not be feasible. Given our uniqueness, the accreditation process has to be routed in our context and build up by all the stakeholders. The need is to begin with few minimum standards and then gradually develop to having evidence-based standards. In the context of accreditation, consumer education and information is also critical. The consumer groups and the users of healthcare are needed to be involved in this process. As health is a State subject, the States have to do the actual accreditation. The Central Govt. can provide a broad overarching framework for this and it is the States who have to lead. Perhaps the

process can be started with some pilot projects and lessons learnt from these pilot projects can then be used to plan and proceed further.

Shri Girdhar J Gyani, Secretary General, Quality Council of India detailed accreditation Issues and Concerns in a comprehensive manner. Shri Gyani's presentation focused on how a national accreditation structure normally works in any economy, the guidelines of the international accreditation forum and international laboratory accreditation corporation kind of model, which can work in India.

He informed that the Quality Council of India, (QCI) had been set up by government of India to be the umbrella organisation to establish an accreditation structure for the various conformed assessment bodies in the area of quality management, environment, food safety, and occupational health and safety. Conformed assessment is a very generic word and it encompasses all the concepts like testing, certification, accreditation, registration etc. Another task of QCI is to establish the spread of quality movement in the country and make the citizen empowered on the various issues relating to the quality. Setting up of the Quality Council of India has also come as part of the WTO - TBT requirement, where each nation is supposed to have one national accreditation body to facilitate international trade and the services.

The words 'accreditation' and 'certification' are frequently used interchangeably. The standard definition of accreditation is that it is a formal recognition of the technical competence of an organisation to undertake confirmed assessment. In contrast, certification is a third party assurance of conformity of a product, process or system to the specified requirements.

The Quality Council of India is an umbrella organisation with thirty-one members, ten of them from government and twenty-one from the private sector. The Council has three autonomous boards, viz. National Accreditation Board for Certification Bodies (NABCB), National Accreditation Board for Testing and Calibration Laboratories (NABL) and National Registration Board for Personnel and Training (NRBPT) under it. The NABCB board provides accreditation in the area of quality, environment and occupational health; NABL deals with the clinical laboratories and NRBPT deals with the registration of professionals in various areas.

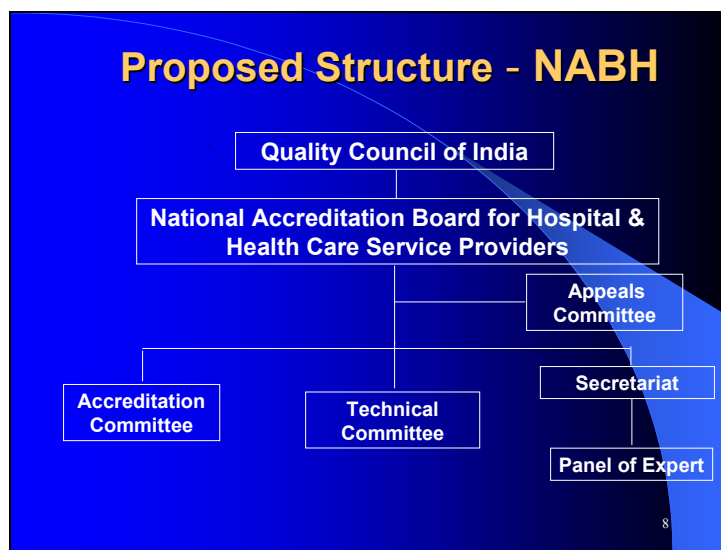
There are four popular international models relating to accreditation of health services. The first is the Australian model. Next is the Thailand model, which is little more elaborate than the Australian model. The third model is UK's Health Quality Service Accreditation Programme, and the fourth is Joint Commission International Accreditation Standards for Hospital of USA. A comparative statement and analysis of the all four standards is depicted below for the reference of the participants. As can be seen that the Australian model is quite low on the corporate and clinical governance but it is strong on all other three parameters. Similarly, the JCI Accreditation Standards system is not very strong on clinical services whereas, the others are relatively stronger on this parameter.

Comparative Visible Emphasis on Various aspects provided in the different Standards

Standard Criteria	PHI 32/03 Australian	HA/HPT/TOA	Health Quality Service Accreditation U.K.	JCI Accreditation Standard for Hospital USA
Scope				
Corporate & Clinical Governance	Low	Strong	Strong	Strong
Operational Management	Strong	Strong	Strong	Strong
Focus on Patient	Strong	Strong	Strong	Strong
Clinical Services	Medium	Medium	Strong	Low

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QCI proposes the formation of a National Accreditation Board for Hospitals and Healthcare Service providers in India (NABH) to be governed by an independent board for healthcare services in India. The board would have a full time secretariat. NABH would have an accreditation committee and a technical committee, which would decide the guidelines, the criteria and the standards, based on which the hospitals and other health service provider institutes would have to be assessed.



Based on the Indian work so far in the field of quality in healthcare sector and study of the International Standards, which could be adopted by the Ministry of Health and Family Welfare, we have compiled this model for Assessment of hospitals and similar institutes. The proposed Indian criteria outline for Assessment of hospitals by the NABH is classified under five major heads - organisational and clinical governance; operational management; focus on patient; clinical services; and human resource.

This proposal is still under formation. As in any other country, the national accreditation structure would prepare the accreditation or operating scheme with support and guidance of the parent Ministry. The initial funding for development of this scheme would have to come from the Ministry, but later on this model is strictly supposed to be self-sustaining like NABL or NABCB. The same Board can also oversee quality issues in the primary health center (PHC) programme under the Ministry of Health and Family Welfare. The Ministry has thus got a very important task in constituting the national accreditation board for putting in a regulatory mechanism for the health sector.

TECHNICAL SESSION I

LEGISLATION FOR HEALTH CARE FACILITIES

Legislation of Health Care facilities in Tamil Nadu

Dr. Padmanaban,
Deputy Director, RCH, Tamil Nadu

Karnataka experience

Shri D Thangraj
Health Secretary, Karnataka

Maharashtra experience

Dr. R M Jotkar
DDG, Govt. of Maharashtra

Salient features of Draft Central Legislation for Accreditation of health care facilities

Shri A K Gupta, Special Secretary
(Finance), Tamil Nadu

LEGISLATION FOR HEALTH CARE FACILITIES

The main objective of this session was to bring the various stakeholders together and share their experience in implementing accreditation system for health facilities. In most states in India, there is an absence of legislation for regulating private health care facilities, laboratories and various type of health centres do not have standards of medical practices in terms of equipment needed, qualification of staff employed or administration or treatment offered. Attempts at enacting legislations for clinical establishments have not met with success, with opposition faced even from health care providers and their associations.

Legislation of Health Care facilities in Tamil Nadu Dr. P Padmanaban

Dr. Padmanaban emphasized that the ultimate objective of accreditation was improving quality of care in public facilities. The important question was to improve standards in the public hospital services where government had invested huge funds. He gave examples of very good infrastructure for health facilities in the state. The State had excellent drug procurement systems, CT Scan centers in all district hospitals, two MRI centers and two medical college hospitals, ultrasound scan in hundred and sixty hospitals and over hundred PHCs had ultrasound scan facilities. After putting such sound infrastructure in place the state was focusing on the need to improve the quality of care.

Through the presentation, he tried to address the quality issues. He briefly described the demography profile of the state that had good health indicators. With government's initiatives to improve the access of care, every year the number of deliveries conducted in public institutions had considerably improved for the State. The government of Tamil Nadu had adopted a model to improve the access to health care in the State. It had started with twenty-four hours availability of a doctor and three qualified staff nurses throughout twenty-four hours in delivery care services, in the PHCs. One doctor was available to conduct deliveries; another doctor was available to provide minor ailments treatments. After the introduction of making available a person round the clock in the primary health center, and by providing support to the GH with the equipments and buildings, domicile delivery had come down, the PSC performance had gone up, the overall performance had increased. A comparison with the private sector performance revealed that in spite of the growth of the private hospitals in the district, their performance had come down in the last five years. This highlighted the facts that if the public facilities perform better, people would definitely come forward to avail public facilities.

The State had established clear-cut certification criteria for its available services. For certification criteria, the state used assessors drawn from professors of the medical colleges who were required to educate the district officers on the quality of services. State assessed the services periodically (quarterly). These assessors had developed standardised treatment and standard operating procedures. A very important initiative being followed was that maternal death autopsy was conducted by involving both public and even the private sector

and relatives of the diseased through a meeting wherein the health providers were expected to narrate the events leading to the death of the mother in presence of the district collector. This parameter was very important to assess the quality of care in the private sector as well as in the government sector as it brought accountability in both the sectors.

The state had a grade one-district hospital, grade two district hospitals, and sub district hospitals. Based on their bed strength the State adopted a four-pronged strategy for regulation of quality i.e., what services should be available, what equipments should be available, and what should be the manpower skills, and all those things had to be certified. State had also started the women and baby friendly hospitals in cities where independent assessors from the private sector went to assess the hospital. Another quality improvement initiative launched was the birth campaigning programme and prescription audit.

The State now planned to launch the recently approved Private Clinical Establishment Act that was prepared during 1997 with detailed guidelines and rules. Many private sector hospitals had voluntarily opted for this kind of certification. The state had involved IMA in a big way to run the biomedical waste management in primary health centres and hospitals under the coming project. The state was also developing standards for infection control protocols in the public health facilities, and undertaking patient satisfaction surveys, quality audit in the public run hospitals and also NGO run emergency transport systems. All this would be made possible through the Private Clinical Establishment Act that the state was in the process of implementing very soon.

Legislation of Health Care facilities in Karnataka

Shri D. Thangaraj

Shri Thangaraj pointed out that Karnataka had proposed a bill towards Standardisation and regulation of growth of private sector, public safety and pricing control. He explained the salient features of the proposed bill. The state had proposed the bill with the objectives to address public interest regarding the type of facilities available in any hospital, the charges that the patient was supposed to pay for the services, information about the standards maintained by any hospital, and to improve the standards to the level of international standards. The state had proposed a registration authority consisting of 12 members from among the government and non-government members. The validity of registration provided by this body would be for a period of five years after which it could be renewed. The standards would be prescribed under the rules. Similarly the fees to be charged etc. would be notified after the rules were framed. He informed that the bill, which was written in 2000, could not be made into an Act for two reasons. First was that when the bill was introduced, because of fresh elections, the house was dissolved and the bill lapsed. Subsequently the bill was not reintroduced because of opposition from the private nursing homes and even the practitioners. However, there had been a lot of discussion among the public and now the need for introducing it had been felt.

He informed that some of the big hospitals in Bangalore already had ISO certification. Six of the government district hospitals had also received ISO certification and were able to get the renewal also. The successful renewal process reflected that the hospital authorities were able to keep up the standards. He hoped that this would act, as a catalyst for the private sector to take interest in getting the voluntary ISO certification. He further informed that Karnataka was proposing a Karnataka Health Systems Development and Reforms project with World Bank aid

for establishing a healthcare regulatory authority in the state with an equal participation. He informed that this would be something similar to the Karnataka private nursing homes bill, with a major difference that instead of making it a compulsory registration and certification, this was purely voluntary. All the private sector healthcare providers meeting the prescribed standards under this health systems development project would stand eligible to cater to treatment of the government employees.

He also informed that the State was implementing a healthcare insurance scheme for the cooperative members in the rural area, under which all the hospitals participating were private hospitals and had to meet certain prescribed standards. He informed that this scheme had been working well, in the last two years and hoped that a similar successful model could be adopted for the Karnataka Health systems development and reforms project

Legislation of Health Care facilities in Maharashtra Dr. R M Jotkar

Dr Jotkar traced the historical developments of legislation in this field and pointed out that the oldest Act with respect to Nursing Home Registration in the country is the Bombay Nursing Home Registration Act 1949 (BNHRA). The Act was not catering to registration, but it had introduced some accountability framework in the human health system. The Bombay Nursing Home Registration Act added the dual relations between the policy makers and the frontline providers, defining what is being expected in terms of service performance from the providers and what were the prescribed standards. BNHRA focuses on the service performance and the standards gaps.

In course of time a need was felt that profile of nursing homes should encompass the space norms, facilities, staff employed, sanitary conditions, equipment, supporting services and waste management, should also be included in the minimum standard. In addition, medical examination of employees, availability of complaint box, display of service fees at prominent places, registration number of nursing home in all records and registers, etc. were not found to be adhered to by the medical establishments.

He informed that the Maharashtra Health Systems Development project was committed to have some legislation, which were more comprehensive than in the existing act. In successive consultations for the same, a decision was taken in 2004 that BNHRA would be extended to cover all districts, including rural areas. State had however, not wanted to revise the Act in view of current resource crunch, as enforcement of the Act would have been unmanageable for the State. It would further have been difficult to ensure that corrupt practices did not indulge in the enforcement. After enactment, the State would have even faced the risk of public accountability in instance of mishap in registered private facility. It has been documented that India was already an over regulated country and legislation was not substitute to administration. Medicine being a biomedical science with substantial variation, hence the task of deciding the minimum standards could have been difficult, though not impossible. With these considerations, the state was stuck with it.

He shared that for successful promulgation of the regulation, technical expertise was badly needed. The law-abiding nature, voluntary compliance and resistance of solo private

practitioners also had to be encountered successfully. He concluded that political will was very much needed to enact and implement the required legislation in a real spirit.

Salient features of draft Regulatory framework for health care organisations **Mr. A.K.Gupta**

Dr Gupta had been associated with the Draft Central Legislation for Accreditation of health care facilities during his previous assignment in government of India. He informed that the guiding principle behind the government while formulating the regulating framework was to add value for consumers in terms of better service, access, and affordability and providers. Regulations that did not meet the cost-benefit analysis were not adopted and consumers had the assurance that provider and health care organizations would be held accountable for providing the services that they promise. The benefits of accreditation were manifold: helping patient in deciding which hospital they should turn; hospitals themselves would have the basis for comparison; Insurance companies for assessing the quality of the service and overall welfare of the patients.

He made a detailed presentation on the proposed Regulatory Framework for the Health Care organizations in India. He informed that need for such a framework was necessitated as Government found it difficult to commit resources to expand coverage commensurate with the increase in population. Even the existing resources were either misutilised or remained under utilized. Therefore govt. policies had a shift towards increased involvement of private sector as it was emerging as a major provider of health services. However, no documented information was available about the standards, quality of care, functioning, cost of treatment and facilities being provided in the private sector.

He made a mention of a Study that had examined the physical standards in private hospitals/clinics in India, wherein, some of the major findings were that unqualified practitioners were practicing in large proportion, slightly more than half were only registered, only 1/3rd maintained case records, there was lack of essential instruments in most clinics, lack of ambulance, lack of uninterrupted power supply, lack of full time doctors and nurses and lack of adequate space, sterilization room etc. Major complaints against private sector health providers was that they had Inadequate facilities & equipment, not providing customary information about diagnosis and treatment, subjecting the patients to unnecessary procedures and that they were charging exorbitantly. The need for better quality of health care needs was also compounded by various measures like efficient public spending through public private partnership (outsourcing services, privatisation etc.), increased consumer awareness, and strengthening of consumer protection laws.

He gave the example of key features of accreditation in USA – where accreditation is voluntary, independent, private, non-profit organization, and had more than 80% coverage. He shared the experience of JCAHO that covered almost all public and private health institutions in USA, which had helped organizations improve quality of care, helped enhance community confidence and were regarded as a staff educational tool. In Canada, a five-point accreditation recognition system for health facilities existed. Taiwan had five levels of and the standards of hospital accreditation were classified under various quality headings.

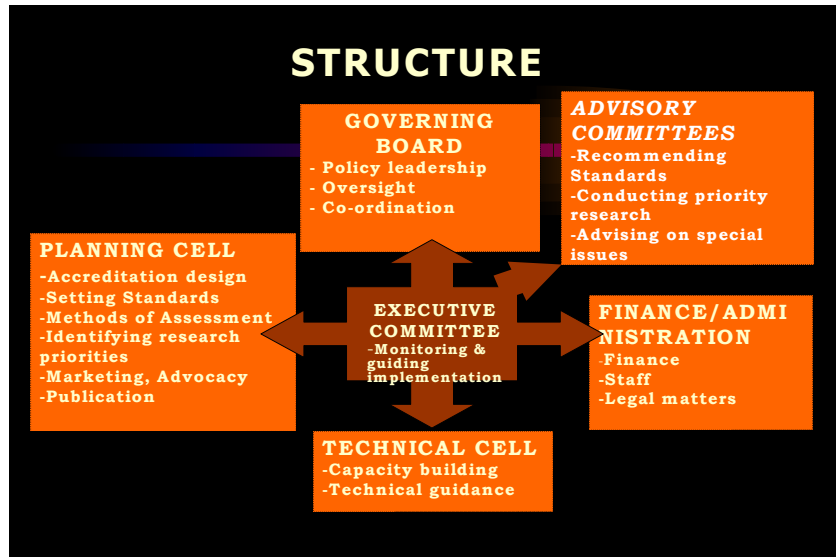
He clarified that basically licensing and accreditation were two mutually exclusive activities. He defined licensing as a process by which a government authority could grant permission to

operate only after an organization meets minimum health and safety standards. Maintenance of licensure was an ongoing requirement for the health care organization to continue to operate and care for the patients. Accreditation on the other hand was a process by which a body, usually a non-governmental organization, assessed and recognized that any organization would meet the applicable, pre-determined and published standards. Accreditation standards were usually regarded as optimal and achievable and designed to encourage continuous improvement efforts within accredited organizations. It was often a voluntary process in which organizations choose to participate, rather than one required by law.

He touched upon the salient features of the Proposed Regulatory Framework for the Health Care organizations in India. Some of the main features informed were Mandatory registration of all clinical establishments, including the diagnostic centers; minimum standards to begin with - can be in respect of the building, space, facilities, equipment, manpower etc.; organization set up-Three Tier; registering authority for a district or a group of districts; regulation board for each state for monitoring and supervising the implementation of Act and also act as an appellate body; Regulatory Council at National level for classification of clinical establishments, fixing minimum standards etc.; maintenance of records, emergency treatment, incident reporting also to be the conditions of registration. A very important feature of the draft regulation was maintenance of records in a prescribed format & making it available to the patient or their legal heir at a very reasonable cost.

As per the draft, the Centre would frame rules for Constitution of Regulatory Council; Allowances of the Members of the Regulatory Council; Certificate of registration; Prescribing conditions of registration; Standards for facilities; Maintenance of records and manner in which to make available such records; Information to be displayed by Clinical Establishments for public; Manner and the period within which reporting to be done; Procedure for inspection of Clinical Establishments along with Classification of Clinical Establishments & Maintenance of State Register of Clinical Establishments etc.

He explained the structure of the National Accreditation Council, to be the central body entrusted with overall policymaking, developing standards, guidelines & protocols, conducting research etc. and would lay down a comprehensive, credible and transparent procedure for Accreditation. The Council would have an Executive Committee for monitoring & guiding implementation and other committees.



The accreditation set up had to be three tiers because health implementation was a State subject and therefore the licensing implementation had to be done by the State government. The draft model of minimum standards by the Centre, had to be suitably adopted by the State governments depending upon their ground realities. The States would decide on Emoluments, allowances and service conditions of Registering Authority; Constitution of the Regulation Board; Allowances of the members of the Board; Registration/renewal fee etc. There would be ample safeguards like inspection to be done only by an authorized officer or a time bound approval system - deemed registration if no response etc.

He concluded that accreditation framework for India would have to voluntary participation, the National accreditation council would be a non-profit and autonomous organization; the stakeholders would include hospital owners/administrators, professional associations, consumer organizations, NGOs, insurance companies, and government. The standards would be initially on physical facilities/and personnel, etc. thereafter graduating to process and outcome. The board would have financing options by way of Survey fees, Membership fees, and third-party payers, Grants. The accreditation process would be self assessment-facilitator-external assessment and would have to be mandatory under CGHS and Universal Health Scheme with full public accountability.

TECHNICAL SESSION II

EXPERIENCE SHARING OF ACCREDITATION SYSTEMS

Accreditation of Laboratories

Dr. B K Rana,
National Accreditation Board for Laboratories

Accreditation of Health Care facilities - Mumbai experience

Dr. Ketan Parikh,
Health Care Accreditation Council, Mumbai

Accreditation of health care facilities

Dr. Akhil K. Sangal,
Indian Confederation for Healthcare Accreditation, Delhi

Empanelment of hospitals - the Oriental experience

Mrs Minakshi Gupta,
Manager Health Insurance, Oriental Insurance Co.

Technical Session II

EXPERIENCE SHARING OF ACCREDITATION SYSTEMS

The main objective of this session was to examine the purpose of accreditation for different stakeholders of health care in India. The session also examined ways and means of implementing dimensions of quality and monitoring systems for health facilities.

Accreditation of Laboratories

Dr. B K Rana

Dr Rana informed that laboratory accreditation was a procedure by which an authoritative body gave formal recognition of technical competence for specific tests or measurements, based on third party assessment and following international standards. It means that it shows the client that the procedures are technically valid, recognises the technical competence of laboratory staff, assures the client that the results are technically valid, and it is also endorsed with the quality management system.

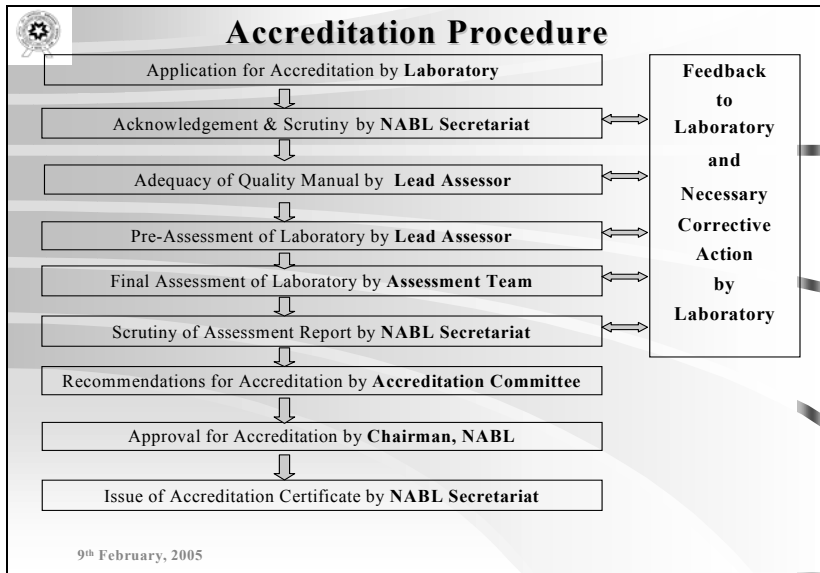
He informed that certification was the procedure by which a third party or a certification body gives a written assurance that a product, process or service (of an organisation) conforms to the specified requirements. It is a specified requirements ISO 9000 series. It assures the client that the organisation has in place an effective quality management system but it does not confirm that the data or the test results are technically valid. So a minor difference exists between certification and accreditation.

There are many benefits of accreditation. It provides formal recognition to competent laboratories and assures that they perform their working in accordance with the international standards. It minimises the risk of unreliable results, minimises the chances of retesting events, and reduces chances of additional financial burden and time delays. It enhances customer satisfaction and confidence.

Based on the mutual evaluation and acceptance of other country's laboratory accreditation systems, NABL has in place the international agreement called Mutual Recognition Arrangements (MRA). NABL is signatory to MRAs, which provide the facility for its accredited laboratory test results to have international acceptability. MRAs are particularly relevant in the case of insurance agencies, health authorities, placement agencies, labor departments etc. for purpose of an insurance or health checks ups done here in cases of visits abroad, the test report done can be accepted in the country of visit. One is not required to get it retested.

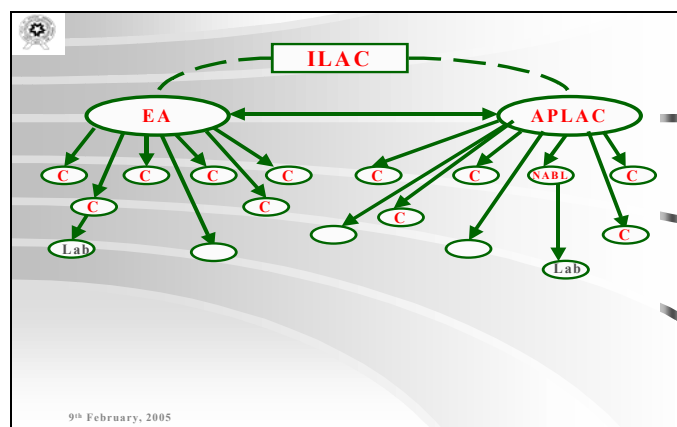
He also gave a brief description of NABL. The Government of India has authorized NABL as the sole accreditation body for Testing and Calibration of laboratories. NABL establishes its accreditation system in accordance with the ISO IEC Guide 58, which is followed internationally. NABL provides laboratory accreditation services to laboratories that are performing tests or calibration. This is provided in accordance with ISO/ IEC 17025: 1999, which are the general requirements for the competence of Testing and Calibration

Laboratories. He explained the full accreditation procedure at NABL by the following flow chart:



He informed that NABL had a scope of granting accreditation in both testing and calibration fields. The testing laboratories covered Biological, Chemical, Electrical, Electronics, Fluid-flow, Mechanical, NDT, Medical and Forensics. The calibration laboratories covered the disciplines of Clinical Biochemistry, Clinical Pathology, Hematology, Microbiology, Histopathology, Cytopathology, Cytogenetics, Immunology and Nuclear Medicine (in-vitro tests only)

He informed that for the international acceptance of the test results there is an international body, International Laboratory Accreditation Corporation (ILAC). Under the ILAC, there are two additional corporations the European Accreditation Corporation (EA) and Asia Pacific Laboratory Accreditation Corporation (APLAC). They have a number of members and NABL accreditation body is one such member like the EA, with the APLAC. Thus, the reports generated by NABL's accredited laboratory are accepted worldwide, to all the members of ILAC. With this system of MRA, tests of any laboratory that is part of this global accreditation system, is acceptable universally.



Accreditation of Healthcare Facilities - The Mumbai Experience

Dr. Ketan Parikh

Dr Parikh, a pediatric surgeon attached to some hospitals in Mumbai has also his own nursing home. He was past President of the local branch of Indian Medical Association and the Association of Medical Consultants, through which he became a member of the Healthcare Accreditation Council.

He shared the Mumbai experience. Around '90s in Mumbai, there was an increasing awareness of health consciousness and growing expectations from the doctors and the medical fraternity. There was a lot of media pressure, because of which there was a random and disorganised attempt to improve the set up, and that led to further chaos. There are about twelve hundred small and medium sized nursing homes in the city of Mumbai, and these cater to a very large cross section of the patients of different socio economic strata. These nursing homes were forming an essential wing of health delivery and any out of proportion expectations made from them would harm the healthcare delivery process. The Association of Medical Consultants (AMC) is one of the largest non-branched medical associations in the country, representing about five thousand practising medical consultants in Mumbai. The AMC as a body became interested to participate in a quality improvement process to could satisfy the expectations of the society from doctors.

The first thing that the HAC did was a survey of the existing costing of the nursing homes. This was very revealing because the cost-per-bed per day to the nursing home owner was coming significantly higher than what most of the nursing homes were charging as bed charges from our patients. So it was realised that to upgrade the services, we would need to rationalise the expectations and then only we could ratify the services. We also realised that the cost realities had to be understood by everybody, and not just by us but even the end users and the government.

A preliminary survey for accreditation for the healthcare facilities in Mumbai was carried out by CEHAT. It was found that to satisfy all the sections of healthcare delivery process, all the stakeholders like government; consumer organisations and the medical profession, should be jointly involved in the process of accreditation. With this conclusion, a loose body representing hospitals nursing homes, consultants, NGOs and consumer organisations was made. We attempted to involve the Municipal Corporation and the State government but at that particular time they were hardly interested.

While making standards, HAC's guiding policy was that it should be quality healthcare at as affordable cost as possible. It was a tough balancing act where everybody had to sit together to have a common charter, but NGOs, consumer organisations and medical professions had diametrically opposite viewpoints. It was realised that any applicability of western standards would defeat the process, because people would find out ways of bypassing the standards, or that very high standards might result in healthcare becoming unaffordable to the masses. Also, to ensure compliance and popularity of the accreditation process, the process had to be as simple as possible.

The accreditation process faced a number of challenges. First and foremost, we really did not have any model to learn from and to copy from. We realised that there was a lot of ignorance

on everybody's part. Initially there was a lot of a resistance from within the medical community, but over a period of time the Association of Medical Consultants and INA local branches were able to break the resistance from within the members. Another challenge was the complexity of medical needs and the large spectrum of socio-economic needs. The process was hindered by ground reality problems of infrastructure, manpower availability, paying capacity, bureaucratic resistance and above all problems of finance.

Basic standards were supplemented by 3 tier speciality standards, Evolved on the basis of basic space allocations, equipment & personnel availability, with low stress on interiors and decorations. Basic (minimum) standards were supplemented with higher (desirable) and better (optimum) specialty standards.

The present status of the accreditation project is that Mumbai has devised standards for a typical ten-bedded nursing home, with or without an operation theatre & with or without a labor room. This body is waiting for the last four years to register itself with the registrar of companies under sec 25 and there have been immense bureaucratic roadblocks. Of course finance and office infrastructure as of now is still a very basic major problem and we would require seed finance either from government or from some other agencies to start this as a pilot project.

He concluded that accreditation of healthcare facilities should not be a State controlled process and accreditation should be a voluntary process. The ultimate beneficiary from the whole process should be the ordinary Indian patient and the basic aim should be to improve the overall healthcare system and the not just to facilitate the health insurance or the medical tourists.

Accreditation of Healthcare Facilities **Dr. Akhil K Sangal, Indian Confederation of HealthCare.**

He started his presentation by an analysis of the Indian healthcare scenario and discussed the challenges that were to be met. Some of the challenges highlighted by him were that healthcare was the largest industry in the world (even in India); Healthcare was attracting new entrants and generating fierce competition; increasing privatization and public-private partnership programmes and empanelment by government agencies, insurance companies and increased consumer awareness had heightened expectations and aspirations from this sector. He stressed that these challenges should be viewed as opportunities on which we should capitalise, and in thus, there was an urgent need for improvement in quality of healthcare. He cited the example of the software and the automotive industry in the country where the quality movement had transformed the whole process and hoped that with the huge Indian Market and its potential, the health sector too could achieve the same.

He opined that setting quality standards and their implementation and benchmarking progressively would be the best approach to accreditation. Various international accreditation systems were making inroads in India. There were commonalities in all quality management systems - the fundamentals of quality management remain the same in all approaches and that the system had to be a service user focus. He cautioned that it was not just enough to be technological superior but there is also a need to focus on the way healthcare was delivered.

India, having the largest resource base that was technically competent, had an urgent need for a quality accreditation system for healthcare. He viewed that India should develop an Indian accreditation system rather than adopting any international standards. He added that comprehensive quality was not possible without equal emphasis on clinical care quality. In his view, the national accreditation body should be a multi-stakeholder, autonomous body with a constant up gradation of guidelines. It should be able to encourage innovation, provide choice of adaptation and adoption in implementation and reflect trust and transparency. With these core values in place, rest of the things would automatically follow. He quickly informed the experiences of some of the major international accreditation systems. All such systems were basically autonomous, multi-stakeholder with professional participation and the governments encouraged development.

He shared the WHO's definition of quality for Healthcare delivery systems i.e., providing the highest level of professional care with most effective utilisation of resources, the minimum risk to the patient, the highest level of patient satisfaction and with results influencing health status. He informed that accreditation of healthcare facilities would result in focused attention for the patients; organizational development; better facilities & procedures; improved end-results; and better patient care. He concluded by presenting an III-phase plan of action for readying and implementing the accreditation process for any health organisation.

Empanelment of hospitals - the Oriental experience
Mrs. Meenakshi Gupta, Manager, Oriental Insurance Company

The presenter shared the salient features of Oriental Insurance Co. in empanelling the hospitals. She observed that the healthcare delivery system in the country was witnessing a rapid change. A noteworthy change was witnessed in the form of the insurance companies paying the bills of the nursing homes/medical treatment instead of the individual paying the same.

She informed that with the licensing of Third Party Administrators (TPAs) as service providers it was seen that the health insurance sector in India was growing more than any other sector in insurance. It was hoped that engaging the services of the TPAs would result in a uniform delivery system. Another growth reason of empanelment was that it provided 'Cash Less Claim' settlement services through empanelled Hospitals.

The empanelment process was described in brief. The nursing homes, known as 'preferred service provider' (PSP) sign MOU with the TPAs. According to the MoU, there would be certain agreements as to how the payments would be made, how frequently the TPAs would reimburse PSPs' expenses, the onsite assessment of the facilities which PSP have declared and the monthly and yearly feedback system. An important feature of all insurance medical claim policies was that they all had a rider under which only those hospitals could be empanelled that had certain pre-laid basic facilities. The criteria for empanelment consist of various factors like the infrastructure facilities, the quality of the services rendered, the patient care background, the bed strength, the management background, the past track record of the hospital, the IT infrastructure etc.

She touched upon the various difficulties during the empanelment process like lack of transparency by hospitals in giving the infrastructure details, qualification of the nurses and the staff doctors etc., handing over of the tariff list to the TPAs etc. The experience after

empanelment showed that different rates were quoted for the same procedure on case-to-case basis, discrepancy in clinical and path history of patient between pre-authorization form and discharge summary, Certain cases of disease like diabetes or hypertension were written as either recently detected or no past history available, delayed submission of bills and excess visit of doctors.

She concluded by listing some of the various advantages that had accrued from the hospital empanelment process. She stressed on the need for Accreditation of hospitals on the lines of hotels for assessing the facilities and that accreditation would help in Data warehousing related to Health Care Utilities & Providers as per the acceptable international standards and evolving single reasonable Tariff for various Health facilities in the country.

PANEL DISCUSSION

STAKEHOLDERS' VIEWPOINTS AND THE WAY FORWARD

Dr. Sudipto Roy,
National President, Indian Medical Association

Mr. Kirti Bhatt,
Director (Legal Services) CERC, Ahmedabad

Mr. Bipul Chatterjee,
Director, CUTS-CITEE, Jaipur

Mr. Amul Gogna,
Executive Director, ICRA Ltd., New Delhi

Dr. Sudipto Roy

Dr. Roy expressed that it had become necessary to develop a mechanism for accreditation and standardisation of the health institutions both for the government and the private due to the spurt in growth of world-class hospitals and health establishments throughout the country. He cautioned that while developing the standards, one had to keep in mind the local conditions, as the ground realities would be different from state to state. He also mentioned that accessibility and affordability should be taken into consideration while making the standards to enable us to provide minimum comprehensive primary healthcare to all the citizens.

He opined that the biggest hurdle in implementation of standards would be from the government hospitals and wondered how the government hospitals would come up to the international standards in the near future. Another problematic area, he felt, would be due to the diversity of the healthcare delivery system in India. With various practices, like Allopathic, Homoeopathy, Ayurveda and Unani, all having their own way to provide healthcare, which were quite divergent, it might pose a big problem to develop common standards for all.

He suggested that government should make a policy wherein; certain minimum common medical education should be a mandatory for everybody who wanted to practice medicine. Up to gradation the curriculum of the medical education could be the same, and after that the person may choose the pathy in which he wanted to practice and do post graduate training. This would ensure a standard quality of healthcare delivery system. I do hope that the experts will keep these points in mind while formulating mechanisms for accreditation and standardisation.

Consumers Perspective on Health Services Providers

Mr. K C Bhatt

He opined that any accreditation process should be able to address the problem of attending to the complaints of medical negligence and a grievance redressal mechanism for the same should be instituted. The other main issue, he felt, was about the charges and stressed that the specific charges are to be advised to the patient at the time of admission / before carrying out the surgery or procedure. He suggested that there should be a provision for professional liability insurance so that in cases of medical negligence, the patient should be able to get compensation, rather than being forced to initiate litigation process. Another area of concern was that accreditation should not be confined to the allopathic treatment, but alternative systems of medicines also should be covered under this standardisation. Referring to a Bombay High Court Judgement, he was of the opinion that maintenance of records and providing treatment papers to the patients should be made compulsory on the part of all healthcare providers.

He said that accreditation should apply to both private hospitals as well as government hospitals. For the clinical services, he mentioned that standards should be specified for laboratories so that one laboratory findings were accepted by the other hospital and that the patient were not forced to undergo the same test again and again when they change hospitals.

Dr Bhatt concluded by raising another important point in the accreditation procedure, on the need of formation of an ethical committee in bigger hospitals, to take care of vital decisions

like withdrawal of the life support system or the donation of organs of the late person or that of informing to the AIDS patient or to its relatives.

CUTS

Mr. Bipul Chatterjee

He felt that healthcare services were required more for poor consumers rather than the middleclass and the upper class consumers. As the Right to Information Act had been enacted and was going to be implemented in Central level in various States, he suggested the use of the Act to get the right kind of information from the healthcare providers.

He opined that the regulatory body for accreditation should fix the responsibility to disclose right kind of information with the medical service providers, rather than it is on the consumers to seek. He concluded with the suggestion on who should head the proposed regulatory body. He viewed that we should have competent professional and young people having expertise to head such bodies and similar other sub national bodies for accreditation.

Stakeholders view point and the way forward

Mr. Amul Gogna, ICRA Ltd

He informed that ICRA is a rating company that operates across India and had sometimes back devised a system of grading of hospitals. When we talk of grading we are saying that accreditation is inherent in that process and we are moving forward from that level to further fine-tune the quality being delivered by these institutions.

He informed ICRA's grading methodology for health institutions which were communicated symbolically in the form of symbols, H1, H2, H3, H4 as the different levels of the quality being delivered by that facility. H1 being the best in this case says that the resources and process are consistent with those required for delivering the highest quality of care while H4 was the worse grade, which says that, the sourcing process delivering low quality of care.

He also informed that ICRA had set internal benchmarks, which were arrived at after a thorough research on the international standards, the BIS standards, the JCAHO standards, and their own devised standards. ICRA's grading was designed to benefit service providers, consumers, the payers insurance companies, and all other stakeholders which ultimately benefit from the grading system. With their internal benchmarks, ICRA was able to grade the health care providers. He concluded that once the accreditation body and process was finalized and set in place with government legislation, ICRA would be able to share their healthcare grading system provided their Intellectual Capital gets a cover.

**National workshop
Accreditation & Standardisation of Health Services**

February 9, 2005

Group work

Which stakeholders should be involved in setting up the accreditation body and what roles should they play?

The accreditation body stakeholders should primarily be the providers of healthcare services, consisting of hospitals, professional associations, the MCI, Dental council, nursing council, doctors, non-governmental organisations working in the health sector, the consumer organisations that represent the interest of the consumer of the healthcare sector, insurance companies and the suppliers which supply the facilities/ equipment and the medicines to the healthcare sector hospitals. The government should be represented in two groups – one in the policy maker / regulator of the accreditation system and two, should be in as the implementer.

What dimensions of quality should the accreditation body monitor (e.g. Structure / Process / Outcome)?

Both structure and process should be monitored together and the outcome criteria, that are parameters for quality healthcare, would have to be developed over a period of time.

What are the pre-requisites for setting up an accreditation body?

The licensing procedure by the accreditation body should as per uniform guidelines formulated by the Central government and adopted with only suitable modifications by the State governments. The same stakeholders as identified above, should also be a party to the evolution of standards and even for the licensing system.

Should the accreditation body be at the national level / state level or both? What should be its scope & how should it function?

Should the accreditation body be independent and autonomous or should it be supported by legislation or both?

The accreditation board should be an independent and autonomous national level body, which would be an umbrella body to all the related bodies. The board should frame broad guidelines to institutionalize a quality assurance process in the entire country. Under the board there will be a number of recognised, empanelled institutions that would implement the quality assurance program for the entire country. These empanelled institutions will aid execution of these processes, whether it is quality evaluation or grading or accreditation. These bodies will then help in execution of such projects throughout the regions, as they would be familiar with the ground realities. Herein, the States would only be allowed to have finer changes according to the State requirements and broad policy guidelines would echoe with the national

guidelines. The national accreditation body and the regional bodies should be formed by government legislation for their working and should be registered under the Society's Act.

What are the ways and means to mobilize resources?

Funding for the national body and the affiliated bodies would come from the providers and the insurance agencies that would utilise the accreditation services of the board. An initial funding would have to come from the government, thereafter, individual membership fee and corporate membership fee would be it's a funding source. The body would through its services, become a self-sustaining body.

What are the short-term and long-term next steps the group would suggest?

There are three major tasks for the accreditation body. The first is generating awareness about accreditation process and its benefits among the stakeholders. The second area is fund generation. The third area is to develop guidelines for functioning the empanelled institutions. The long-term step is to have standardised procedures/criteria in place for research, awareness and implementation of the guidelines.

Summing up and vote of thanks

Session Chairman: Dr R L Icchhpujani, DDG (P), Dte. GHS

Session Chairman while summing and concluding the workshop observed that healthcare providers had realized the need for a uniform country-specific accreditation standards and an accrediting body, to implement these. The International standards were too generic, too expensive and might ultimately not suit the majority of healthcare organisations in India. Therefore the urgent need for developing our own standards was now being felt. In doing this, we had to ensure that the standards remain India centric and acceptable to the masses, while still remain in line with the best global practices. He concluded that both Healthcare providers and Government have now realised that application of such standards would give long- term tangible and many intangible benefits to their organisations. With these words he thanked all the speakers and the participants and concluded the workshop.

National Workshop
Accreditation and Standardisation of Health Services

9 February 2005, India Habitat Centre (Casuarina Hall), New Delhi

AGENDA

09.30 – 10.00 hrs **Registration**

INAUGURAL

10.00 – 10.05 hrs	Welcome Address	Shri B P Sharma, Joint Secretary, Department of Health, MOHFW, GOI
10.05 – 10.15 hrs	Inaugural Address	Dr S J Habayeb, WHO Representative to India
10.15 – 10.25 hrs	Theme Address	Dr S P Agarwal, Director General of Health Services
10.25 – 10.40 hrs	Keynote Address	Shri P K Hota, Secretary, Dept. of Health & Family Welfare, MOHFW, GOI
10.40 – 10.45 hrs	Vote of Thanks	Shri Rajesh Bhushan, Director (IH), Department of Health, MOHFW, GOI

SETTING THE PREMISE

ACCREDITATION ISSUES AND CONCERNS

10.45 – 10.55 hrs	GATS and Health Services - Opportunities for India	Shri Rajendra Mehrotra WHO National Consultant, MOHFW
10.55 – 11.05 hrs	Accreditation of health care facilities- Options and Challenges	Shri Sunil Nandraj WHO & Ms. Anagha Khot, National Consultant
11.05 – 11.15 hrs	Accreditation Issues and Concerns	Shri Girdhar J. Gyani, Quality Council of India
11.15 – 11.30 hrs	Discussion	
11.30 – 12.00 hrs	Tea Break	

12.00 – 13.00 hrs **TECHNICAL SESSION I**

LEGISLATION FOR HEALTH CARE FACILITIES

**Chairperson – Smt. Bhavani Thyagarajan *,
Joint Secretary, Department of Health, MoHFW, GOI**

12.00 – 12.10 hrs	Legislation of Health Care facilities in Tamil Nadu	Dr. Padmanaban, Deputy Director, RCH, Tamil Nadu
12.10 – 12.20 hrs	Karnataka experience	Shri D Thangraj Health Secretary, Karnataka
12.20 – 12.30 hrs	Maharashtra experience	Dr. R M Jotkar DDG, Govt. of Maharashtra
12.30 – 12.40 hrs	Salient features of Draft Central Legislation for Accreditation of health care facilities	Shri A K Gupta, Special Secretary (Finance), Tamil Nadu

12.40 – 13.00 hrs Discussion

13.00 – 14.00 hrs Lunch Break

14.00 – 15.00 hrs TECHNICAL SESSION II

EXPERIENCE SHARING OF ACCREDITATION SYSTEMS

Chairperson – Prof. V K Arora, Additional Director General, Dte. GHS

14.00 – 14.10 hrs	Accreditation of Laboratories	Dr. Sulba M. Gupta, NABL
14.10 – 14.20 hrs	Accreditation of Health Care facilities the Mumbai experience	Dr. Ketan Parikh, Health Care Accreditation Council, Mumbai
14.20 – 14.30 hrs	Accreditation of health care facilities	Dr. Akhil K. Sangal, Indian Confederation for Healthcare Accreditation, Delhi
14.30 – 14.40 hrs	Empanelment of hospitals - the Oriental experience	Mrs Minakshi Gupta, Manager (Health Insurance), Oriental Insurane Co.
14.40 – 15.10 hrs	Discussion	
15.10 – 15.30 hrs	Tea Break	

15.30 – 16.00 hrs GROUP DISCUSSION

16.00 – 16.15 hrs PRESENTATION OF GROUP WORK

16.15 – 17.00 hrs PANEL DISCUSSION

STAKEHOLDERS' VIEWPOINTS AND THE WAY FORWARD

Chairperson – Dr R L Icchhpujani, DDG (P), Dte. GHS

Panelists

- Dr. Sudipto Roy, National President, Indian Medical Association
- Mr. Kirti Bhatt, Director (Legal Services) CERC, Ahmedabad
- Mr. Bipul Chatterjee, Director, CUTS-CITEE, Jaipur
- BIS representative*
- Mr. P K Choudhary, MD, ICRA Ltd., New Delhi
- Mr. Ashok Kumar, CMD, HSCC (India) Limited, NOIDA
- Dr Anupam Sibal, Medical Director, Apollo Group of Hospitals, New Delhi

17.00 – 17.25 hrs Discussion

17.25 – 17.30 hrs Summing up & Vote of Thanks by Chairperson – Dte. GHS

Annexure 2.

Shri B P Sharma, Joint Secretary, (IH), MoH&FW

I would like to extend my warm welcome to you all for coming together for this crucial workshop.

Friends, healthcare sector in India has made impressive strides in the recent years. As health care is dependent on the people served, India's huge population represents a big opportunity. However, good healthcare in India is still in short supply and it is this gap, which reflects a vast opportunity for this sector.

The world over professionally driven healthcare accreditation system has been the most successful mechanism to achieve continuous improvement in healthcare delivery. The lack of any kind of quality assurance mechanisms (such as accreditation) in India not only makes it difficult for the people to make informed choices in selecting health providers but also limits their capacity to demand optimum services. It is hence very important to set up world-class health facilities in India, as it would result in raising the quality standards of health care delivery.

With a view to promote India as a Health Care Destination for persons across the globe, the Ministry of Health & Family Welfare has constituted a Task Force, so as to gainfully utilize the health care expertise and infrastructure available in the country. India would also be able to further improve its national health systems and generate foreign exchange and additional resources for investment in health care. The recommendations of the task force as of now are awaited.

I would also like to mention here that in the rural healthcare mission that the Ministry has just launched, we are committed to have an Indian Public Health Standards (IPHS).

It is important to recognize that many of the adverse implications of trade in health services are not due to globalisation, which, on the contrary, provides tremendous opportunities. Therefore, there is a need to develop a comprehensive health care system in place to reap the benefits of globalisation. There is a need to develop an enabling environment in which high quality of healthcare can flourish throughout the country.

There have been three primary approaches for evaluating quality of healthcare achieved by any organization, i.e., Licensing, Certification and Accreditation. The world over healthcare accreditation system has been the most successful mechanism to achieve continuous improvement in healthcare delivery.

Accreditation is basically setting up of health standards and allowing the private and even government healthcare providers to comply with the standards through regular process. The accreditation process has to be voluntary and the government may not very actively intervene in the accreditation process, but government would be behind it. It would be a big step if we have an accreditation system in place in the country. Success of the accreditation system would depend on how soon a regulatory framework is put in place.

Thus, for India to become a preferred healthcare destination, an internationally acceptable and credible accreditation system is the first pre-requisite. Recognizing the need for quality assurance system and the regulatory mechanism, the Ministry of Health and Family Welfare, along with the WHO, has taken the initiative of organising this one day National Workshop on Accreditation and standardisation of health services.

The major issues that we would address in the course of the day are the purpose of accreditation for different stakeholders and the gains of establishing an accreditation system for health care facilities for India. With the participation of our learned participants, we look forward to some meaningful recommendations coming out at the end of the day.

Annexure 3.

Dr. Salim J. Habayeb, WHO Representative to India

I am very pleased to be in this workshop that will review the current status of accreditation and standards and the recommendations for the welfare work in India. Accreditation is not a novel idea, hotels have it, financial institutions have it, and we should promote it in the health sector.

The broad features of accreditation are that it is voluntary and educational. The professionals in the health sector play a pivotal role in its establishment, functioning and monitoring. And it is not merely issuing compliance but rather promoting quality and best practices. This should be done with a common consensus and mutually acceptable way of monitoring it.

One of the key elements of accreditation is developing standards. Standards serve as a basis for comparison and standardisation is only one step towards accreditation. We don't need to reinvent the wheel and we can tailor standards for our own settings.

Standards should not be only for any technical aspect but for the organisation as a whole, which the management as well as the professionals should practice. The growing liberalisation of the Indian economy and the opening of the health insurance sector to private participation contribute in making healthcare services competitive. This facilitates the provision of quality care. With the governments' commitment to quality healthcare for all, it is necessary to translate the vision into a sustainable mechanism for delivery of effective healthcare.

This workshop has been very timely and it will pave the way for establishing an accreditation system in India. WHO looks forward to collaborate further with the Ministry of Health and Family Welfare in this regard.

Annexure 4.

Dr. S P Agarwal, Director General of Health Services

I am very happy to be present here this morning at the inaugural function of the National Workshop on accreditation and standardisation of health services.

Accreditation is a very important topic. Accreditation is standardisation of the medical manpower, which involves standardisation of nurses, of paramedical, of the medical equipments, of the general administrative back up that we have and it is the standardisation of the all other facilities, the civil infrastructure, the electrical infrastructure, the ambience, and even the environment.

Accreditation is related to insurance, it is related to tourism, it is related to saving the costs and is related to all those things that are the ultimate outcome to quality of health care. And the ultimate outcomes can be achieved only through a process of accreditation. We don't have to reinvent the wheel because these examples already exist in various sectors. In the civil aviation industry no aircraft can take off unless a body certifies it to be fit to fly from the engineering point of view. We cannot have a pilot who has already flown eight or ten hours. But in the healthcare sector, a surgeon who has been up and active for upto twenty-four hours is conducting operations. Even scientific studies have shown that if one is in such physical state, he is more liable to commit mistakes. Everyone knows that good quality is essential, why? For the simple reason that poor quality is very very expensive in the health sector. Bad quality may be cheaper to begin with, but is ultimately expensive.

Today, any doctor can perform any kind of surgery without any check or regulation. Unlike the eye surgeons where some standardisation prerequisite exists in the form that requires an ophthalmologist to carry out a minimum two hundred cataract surgeries in a year or else, it may be treated that he is not doing good enough. This has not been done by any rule or executive order. Similarly, the professional bodies have to develop their own standards and parameters for what is good for them and feasible.

We also need to also talk about the environmental quality when we talk about the quality healthcare. One may be an excellent surgeon, but if the paramedic is not good or properly trained, they may spoil the whole thing. There is thus a need for accreditation of the services including medical laboratories and the equipments.

We are very fortunate to have a leader like Shri Prasanna Hota, who is laying stress on this very important issue of accreditation of health services and I must say that accreditation and standardisation in health sector is the need of the hour.

There is a bill being formulated by the Health Ministry for regulation of clinical practice, which would have some sort of regulation in the clinical practices and even accreditation of medical courses. The bill proposes the setting up of a regulatory agency, which could accreditate facilities according to certain standardised parameters. Experiences all over the world have shown that an accreditation process helps in better health insurance, better medical tourism, good quality healthcare and cost savings.

I will limit my comments to this and thank all of you for your kind attention. I wish the workshop a great success. I look forward to the outcome of this workshop.

Annexure 5.

Shri P K Hota, Union Secretary, MOH&FW

I would like to extend my warm welcome to you all for coming together for this crucial workshop.

I wish you Mr. Sharma and your endeavor all success and hope that this important workshop is able to evolve a meaningful dialogue on quality issues facing the health sector in our country.

I would also like to place on record my deep appreciation to Dr Habayeb, WHO Representative to India, and Dr Agarwal, DGHS for inaugurating our Workshop. Their vision, thought and advice reflected in their address would definitely guide our deliberations in this workshop.

Friends, Accreditation of health services is a complex area. In the health sector, there are too many variables with too many players and factors, and the state of affairs is always in a dynamic mode. Each development effort opens up new area of questions, standards and training requirements. Accreditation requires keeping a check not only on the doctors, but also the equipments, supplies, paramedics, waste management and almost every complex area and variables.

During the last five decades, considerable progress has been achieved in the promotion of the health status of our people. Extensive networks of primary healthcare centers and tertiary care institutions providing specialized curative services have been developed.

Of the total current health expenditure of 5.2% of GDP, more than 4% is contributed by private sector, the public health expenditure being approximately 1 %. We are determined to raise the public spending on health to at least 2-3% of the GDP over the next five years, with focus on primary healthcare.

To realize the commitment enshrined in the National Common Minimum Programme for improved public health services, a National Rural Health Mission (2005-2012) is in the process of being launched. The goals of National Rural Health Mission are to provide an accredited social health activist in each village as a trained health worker. The Mission proposes to provide 2,50,000 community health activists as village level health providers in underserved areas. Over 2000 rural hospitals at the level of community health centers would be upgraded to a uniform set of standards developed as Indian Public Health Standards to benchmarks effective levels of service.

We are also taking steps to promote India as a health care destination to attract persons from different parts of the world to utilize the cost - effective health care expertise and infrastructure available in India. India enjoys a competitive advantage at the international level by virtue of its vast scientific manpower.

The rich heritage of traditional knowledge of medicine from Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy is an asset to my country. Majority of the rural populace of India are benefited by these systems. In view of the global need for

alternate therapies, the Government of India has put in place a collaborative program to scientifically validate these therapeutic modalities through a Golden Triangle Partnership project.

The globalization process has brought in a spurt in technological advances and emergence of new forms of business opportunities and processes impacting a wide range of sector including healthcare. The overall growth in trade in health services has resulted in increased cross-border delivery of health services through movement of consumers. However, grading of our health care institutes as per the agreed international standards and standardized practices at country-level may result in tapping the full potential to our advantage.

Like the Information Technology industry, India has a comparative advantage in services like healthcare. The cost differentials in healthcare between developed nations and India are reckoned to be even higher than in the IT industry. But cost is only one of the drivers. Sophisticated medical facilities in India can now draw people from the neighboring countries. If this emerging potential is harnessed it could shower unprecedented economic gains on the medical community and at least a section of our society, in effect replicating the IT success story.

India could emerge as a major health care destination in the world on account of certain inherent advantages like:

- Availability of good quality doctors
- Ability to provide state-of-the-art infrastructure
- Dedicated nurses and paramedics
- Growth popularity of traditional Indian System of Medicines such as Ayurveda
- Ability to render health care with a human touch.

The thrust is to promote the quality of health care provided by India's health care facilities. In this context, one of the means to achieve higher standards in health care facilities could be by getting accreditation as per the international standards. In fact setting up of world-class health facilities in India would eventually raise the quality standards of health care.

The process of globalisation has also thrown open a number of challenges and opportunities before us. The challenges are indeed formidable but these are also associated with unprecedented opportunities. It is a matter of availing of them through vision, focus and determination. I am sure that our health care facilities would see an all round improvement in the coming years.

As I note from the programme details, many important issues are going to be discussed. I hope that the discussions would be extremely fruitful and lead to a better understanding of the course to be adopted for improving health outcomes. We must think out more meetings like today's, where large-scale participation of appropriate stakeholders is there for meaningful deliberations on such important and sensitive topics.

I urge our colleagues from States who are leaders in their own rights, to translate these ideas in their own States. Some States have gone ahead in starting an accreditation process. In fact the best States always lead the Centre, so effort in this direction should also be maintained.

Let us professionally work out all the details and at the end of the deliberations have a set of recommendations which have to be implemented, not alone by government, but all stakeholders. We should be able to come out a series of follow-up meetings and detailed steps to achieve our respective responsibilities in the process of accreditation.

From our side I have requested our Director General Health Services, Dr. Agarwal who is our technical head and an expert to head the process of accreditation for health services. I would request all the leading medical associations to come forward and participate in this process. I would request WHO and other development partners to facilitate the process. I will discharge my role of seeing this very important activity to reach its logical conclusion, or at least proceed towards the logical conclusion.

POWER POINT PRESENTATIONS

Setting the premise

GATS and Health Services - Opportunities for India
Shri Rajendra Mehrotra, WHO National Consultant, MOH&FW

Accreditation of health care facilities- Options and Challenges
Shri Sunil Nandraj WHO India & Ms. Anagha Khot, National Consultant, MoH&FW

Accreditation Issues and Concerns
Shri Girdhar J. Gyani, Quality Council of India

Technical Session I

Legislation of Health Care facilities in Tamil Nadu
Dr. Padmanaban, Deputy Director, RCH, Tamil Nadu

Karnataka experience
Shri D Thangraj, Health Secretary, Karnataka

Maharashtra experience
Dr. R M Jotkar, DDG, Govt. of Maharashtra

Salient features of Draft Central Legislation for Accreditation of health care facilities
Shri A K Gupta, Special Secretary, (Finance), Tamil Nadu

Technical Session II

Accreditation of Laboratories
Dr. B K Rana, NABL

Accreditation of Health Care facilities the Mumbai experience
Dr. Ketan Parikh, Health Care Accreditation Council, Mumbai

Accreditation of health care facilities
Dr. Akhil K. Sangal, Indian Confederation for Healthcare Accreditation, Delhi

Empanelment of hospitals - the Oriental experience
Mrs Minakshi Gupta, Manager (Health Insurance), Oriental Insurance Co.

Mr. Kirti Bhatt, Director (Legal Services) CERC, Ahmedabad

Mr. Amul Gogna, Executive Director, ICRA Ltd., New Delhi

LIST OF PARTICIPANTS

S. No.	Name of the participant	Organisation
1.	Dr Reena Kumar	All India Institute for Medical Sciences, New Delhi
2.	Prof. C S Pandav	All India Institute for Medical Sciences, New Delhi
3.	Dr Anupam Sibal	Apollo Hospitals, New Delhi
4.	Mr. S Dasgupta	Bureau of Indian Standards, New Delhi
5.	Mr. L K Mehta	Bureau of Indian Standards, New Delhi
6.	Smt. Snehlata	Bureau of Indian Standards, New Delhi
7.	Ms Vibha Varshney	"Down to Earth" Magazine, New Delhi
8.	Mr. Kirti S Bhatt	Consumer Education & Research Centre, Ahmedabad
9.	Mr. Bipul Chatterjee	CUTS, Jaipur
10.	Ms Sandeepa Sahay	DFID India, New Delhi
11.	Ms L S Nagarajan	DFID India, New Delhi
12.	Dr S P Agarwal	Directorate General of Health Services, New Delhi
13.	Dr R L Ichhpujani	Directorate General of Health Services, New Delhi
14.	Mr. J S Choudhary	Directorate General of Health Services, New Delhi
15.	Dr A K Harit	Directorate General of Health Services, New Delhi
16.	Dr Jagvir Singh	Directorate General of Health Services, New Delhi
17.	Prof. Sanjay Shrivastava	Directorate General of Health Services, New Delhi

18. Prof. S Badrinath Directorate General of Health Services,
New Delhi
19. Dr Kumar Rajan Directorate General of Health Services,
New Delhi
20. Smt. S Jeyalakshmi Directorate General of Health Services,
New Delhi
21. Dr Bina R Sawhney Directorate General of Health Services,
New Delhi
22. Dr N K Chaturvedi Dr Ram Manohar Lohia Hospital, New Delhi
23. Dr A K Agarwal Dr Ram Manohar Lohia Hospital, New Delhi
24. Dr Rajbala Yadav Dr Ram Manohar Lohia Hospital, New Delhi
25. Dr T S Sidhu Dr Ram Manohar Lohia Hospital, New Delhi
26. Mr. Deepak Bhandari EPOS Health Consultants, New Delhi
27. Mr. Dilip Jha Faith Healthcare Ltd., New Delhi
28. Mr. Pradeep Agarwal Faith Healthcare Ltd., New Delhi
29. Mr. Amarjit Singh Government of Gujarat
30. Mr. D Thangaraj Government of Karnataka
31. Dr R M Jotkar Government of Maharashtra
32. Dr P Padmanaban Government of Tamil Nadu
33. Mr. A K Gupta Government of Tamil Nadu
34. Dr Ketan Parikh Healthcare Accreditation Council, Mumbai
35. Mr. M P Gupta HSCC (I) Ltd., Noida
36. Mr. S C Zutschi HSCC (I) Ltd., Noida
37. Mr Amul Gogna ICRA Ltd, New Delhi
38. Dr Shyama S Nagarajan ICRA Ltd, New Delhi
39. Dr Hari Singh Institute of Health Management Research,
Bangalore
40. Dr Akhil K Sangal Indian Confederation for Healthcare
Accreditation, New Delhi

41.	Dr (Maj. Gen.) S Venkataraman	Indian Confederation for Healthcare Accreditation, New Delhi
42.	Dr Sudipto Roy	Indian Medical Association, Calcutta
43.	Mr. Ted Price	Indmedica.com, Chandigarh
44.	Dr A K Dutta	Lady Hardinge Medical College, New Delhi
45.	Dr G K Sharma	Lady Hardinge Medical College, New Delhi
46.	Dr Shashi Narayan	Lady Hardinge Medical College, New Delhi
47.	Dr Jayashree Bhattacharjee	Lady Hardinge Medical College, New Delhi
48.	Dr Geeta Mehta	Lady Hardinge Medical College, New Delhi
49.	Dr Vinay Sharma	Maulana Azad Medical College, Delhi
50.	Dr Davinder Kumar	Medical Council of India, New Delhi
51.	Mr P K Hota	Ministry of Health & Family Welfare, New Delhi
52.	Mr B P Sharma	Ministry of Health & Family Welfare, New Delhi
53.	Mr Rajesh Bhushan	Ministry of Health & Family Welfare, New Delhi
54.	Ms Shubhra Singh	Ministry of Health & Family Welfare, New Delhi
55.	Dr B K Tiwari	Ministry of Health & Family Welfare, New Delhi
56.	Ms Anagha Khot	Ministry of Health & Family Welfare, New Delhi
57.	Smt Ganga Murthy	Ministry of Health & Family Welfare, New Delhi
58.	Dr G P S Dhillon	Ministry of Health & Family Welfare, New Delhi
59.	Dr S K Satpathy	Ministry of Health & Family Welfare, New Delhi
60.	Dr Lysander Menezes	Ministry of Health & Family Welfare, New Delhi
61.	Mr. Ajit B Chavan	Ministry of Health & Family Welfare, New Delhi
62.	Mr. Rajendra Mehrotra	Ministry of Health & Family Welfare, New Delhi
63.	Mr. Ujjwal Kumar	Ministry of Health & Family Welfare, New Delhi
64.	Dr T R Dilip	Ministry of Health & Family Welfare, New Delhi
65.	Mr. L Shankar	Ministry of Health & Family Welfare, New Delhi
66.	Mr S K Mohapatra	Ministry of Health & Family Welfare, New Delhi
67.	Mr Narendra Kumar	Ministry of Health & Family Welfare, New Delhi
68.	Mr. Sakthivel	National Commission on Macro economics & Health, New Delhi

69.	Dr Sulbha M Gupta	NABL, New Delhi
70.	Dr B K Rana	NABL, New Delhi
71.	Mr. V Ringe	National Informatics Centre, New Delhi
72.	Mr. V Anil Kumar	National Productivity Council, New Delhi
73.	Dr Sudhir Gupta	NCD, New Delhi
74.	Dr Avtar Sigh Dua	NCMH, New Delhi
75.	Mr. Adhikari Singh	Press, New Delhi
76.	Mr. Girdhar Gyani	Quality Council of India, New Delhi
77.	Mr. Vipin Sahni	Quality Council of India, New Delhi
78.	Dr Krishna Ray	Safdarjung Hospital, New Delhi
79.	Dr S K Verma	Safdarjung Hospital, New Delhi
80.	Smt. Minakshi Gupta	Oriental Insurance Company Ltd., New Delhi
81.	Dr S P Goswami	Oriental Insurance Company Ltd., New Delhi
82.	Mr. A Kumar	UNESCO Chronicle, New Delhi
83.	Mr. S Singh	UNESCO Chronicle, New Delhi
84.	Dr K Suresh	UNICEF, New Delhi
85.	Dr S J Habayeb	WHO India Country Office
86.	Dr Sampat Krishna	WHO India Country Office
87.	Mr. Ranjan Diwedi	WHO India Country Office
88.	Dr D C S Reddy	WHO India Country Office
89.	Mr. Sunil Nandraj	WHO India Country Office
90.	Dr K S Sagar	WHO India Country Office
91.	Dr M Jayawickramarajah	WHO, SEARO, New Delhi
92.	Mr Budh Raj	Health Consultant, New Delhi