I am going to make a presentation on what type of

Regulatory Framework for the Health Care Organizations in India

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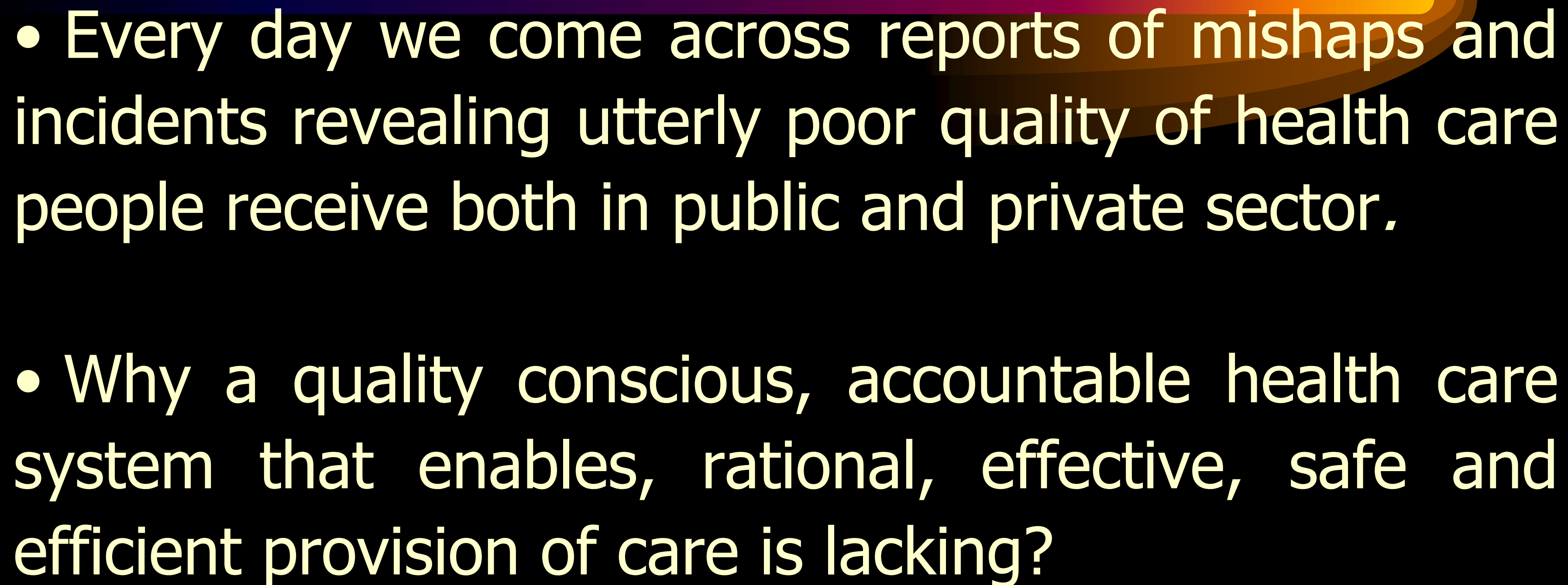


- Every day we come across reports of mishaps and incidents revealing utterly poor quality of health care people receive both in public and private sector.

- Why a quality conscious, accountable health care system that enables, rational, effective, safe and efficient provision of care is lacking?

Causes

- **Government finding difficult to commit resources to expand coverage commensurate with the increase in population.**
- **Even existing resources either grossly misutilised (moonlighting at public expense) or remain under utilized (equipment lying idle or out of order).**
- **Therefore govt. policies moving towards increased involvement of private sector->*private sector is emerging as a major provider of health services*. BUT NO DOCUMENTED INFORMATION AVAILABLE ABOUT THE STANDARDS, QUALITY OF CARE, FUNCTIONING, COST OF TREATMENT AND FACILITIES.**

Findings of a study about Physical Standards in private hospitals/clinics

(a) Unqualified practitioners practising in large proportion
(b) Slightly more than half only registered
(c) Only 1/3rd maintained case records
(d) Lack of essential instruments in most clinics
(e) Lack of ambulance and uninterrupted power supply
(f) Lack of full time doctors and nurses
(g) Lack of adequate space, sterilization room, generator

Major complaints against private sector

- **Inadequate facilities and equipment**
- **Not providing information about diagnosis and treatment**
- **Subjecting patients to unnecessary procedures**
- **Charging exorbitantly**

Need for Regulatory Framework

Better quality of health care needs various measures like :

- **More public spending,**
- **Efficient public spending through public private partnership (outsourcing services, privatisation, corporatisation etc.)**
- **Encouraging private sector participation**
- **Generating consumer awareness,**
- **Strengthening consumer protection laws**

Healthcare being an experience good prerequisite *is putting in place a regulatory framework.*

Guiding Principles

- Regulation should add value for consumers (i.e. better service, access, and affordability) and providers (i.e. improved ability to serve patients without excessive operational costs to comply with regulatory requirements). Regulations that do not meet such a cost-benefit analysis should not be adopted.

- Regulation should assure consumers that providers and health care organizations will be held accountable for providing the services they promise.

Health Care Organisations seek Joint Commission accreditation because it

- helps organizations improve quality of care
- provides a staff educational tool
- expedites third party payment
- often fulfills state licensure requirements
- enhances community confidence

In addition in Indian context

- procedure to be simple and inexpensive

National Accreditation Board for Testing and Calibrating Laboratories

- **Head office in New Delhi**
- **Autonomous body under Deptt. of Science and Technology, registered under Societies Act**
- **Sole accreditation body for testing and Calibration laboratories**
- **Objective is third party assessment of the quality and technical competence of testing and calibrating laboratories**
- **Clinical laboratories also covered.**
- **Accreditation valid for 3 years subject to annual surveillance**

Proposed framework --*licensing coupled with accreditation*

Licensing: A process by which a government authority grants permission to operate only after an organization meets minimum health and safety standards. Maintenance of licensure is an ongoing requirement for the health care organization to continue to operate and care for the patients.

Accreditation : A process by which a body, usually a non-governmental organization, assesses and recognizes that organization meets applicable pre-determined and published standards. Accreditation standards are usually regarded as optimal and achievable and are designed to encourage continuous improvement efforts within accredited organizations.Often a voluntary process in which organizations choose to participate, rather than one required by law.

Salient features of Licensure(USA)

- **All public and private institutions covered.**
- **Items seen for hospitals,**

  - public need to ensure proper geographical distribution

  - character competence, standing of the promoter to ensure unethical practices are not resorted to

  - need for special equipment to be established to prevent unnecessary procedures
- **Administrators required to pass an approved exam**

Licensure Model

Main features of the legislation:

- **Mandatory registration of all clinical establishments including 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 min. standards etc.

Main features of the legislation : (contd.)

- **Maintenance of records, emergency treatment, incident reporting also to be the conditions of registration.**
- **Can be categorised based on one or more factors like bed strength, services and facilities provided, location, ownership, etc.**
- **Different standards for different categories**
- **Punishment also for people knowingly serving in a non-registered clinical establishment.**

Central Rules may provide

- Constitution of Regulatory Council
- Allowances of the Members of the Regulatory Council
- Form of the application to be made
- Form of the certificate of registration
- Manner in which to display registration number
- Register to be maintained by authority
- 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
- Classification of Clinical Establishments
- Maintenance of State Register of Clinical Establishments
- Returns and statistics to be submitted

State Rules may provide

- **Emoluments, allowances and service conditions of Registering Authority**
- **Constitution of the Regulation Board**
- **Allowances of the members of the Board**
- **Fee to be paid for registration or renewal of registration**
- **Fee to be paid for duplicate Certificate**
- **Returns and statistics to be submitted**

- **Requirements: Resources, staff skills, political will.**
- **Caution: safeguards needed lest it becomes an instrument for rent seeking** *e.g.inspection to be done only by an authorised officer,deemed registration if no response, registration to continue pending appeal, automatic registration if already accredited*

Clinical Establishment means and includes

- A hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers service/facilities with beds requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in recognised systems of medicine.
- A place established as an independent entity or part of an establishment as defined in (i) above in connection with the diagnosis or treatment of diseases, where pathological, bacteriological, genetic, radiological, bio-chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on.

Madhya Pradesh Nursing Homes (Registration and Licensing) Rules 1997:Salient Features

- **Record of Patients treated**
- **Location and surrounding**
- **Floor space – 100 sq.ft. for one bed**
- **Labour room/operation theatre – 180 sq.ft. (min)**
- **Four nurses for 20 beds with a minimum of three nurses upto 10 beds**
- **One Medical Practitioner for every 15 patients**
- **One Medical Practitioner on duty at all time**

Accreditation establishes transparency for

--Patients in deciding which hospital they can turn to

--Doctors in private practice for the referral and further care of patients

--Insurance Companies for assessing the quality of the services rendered in the hospitals

--Hospitals themselves as basis for comparison

Accreditation system in other countries (salient features)

- **USA: voluntary, an independent, private, non-profit organization, 48 states recognize hospital accreditation progm, 80%coverage, 29 members in GB for three years, nine accreditation programs(hospital ,Ambulatory care, Long term care, Home care, Disease specific care etc.)Hospitals accredited for three years and laboratories for two years.**

  1917-American College of Surgeons developed min. standards for hospitals, 1965-accredited hospitals deemed to be fulfilling Medicare/Medicaid conditions, 1970-standards recast to represent optimal achievable instead of min.

CANADA: ***Accreditation Recognition Options***

- **Option 1 - Accreditation with full status**
- **Option 2 - Accreditation with Condition (Report)**
- **Option 3 - Accreditation with Condition (Focused Visit)**
- **Option 4 - Accreditation with Condition (Report and Focused Visit)**
- **Option 5 - Non Accreditation**

SOUTH AFRICA: ***self-assessment survey*** **to identify areas of non-compliance. F*acilitator appointed* for a period of 9-18 months, depending on how far the hospital is from meeting the standards.**

- **Taiwan:** ***five levels of hospitals*** **- medical centre hospitals, regional hospitals, district teaching hospitals, district hospitals and specialty teaching hospitals.**

Standards of hospital accreditation classified under the following headings:

1) Quality of personnel, facilities, hospital management and community services;

2) Quality of medical care services in both internal medicine and surgery;

3) Quality of radiological diagnosis and therapy;

4) Quality of laboratory testing;

5) Quality of nursing care;

6) Quality of pharmaceutical services;

7) Quality of emergency care;

8) Quality of psychiatric care;

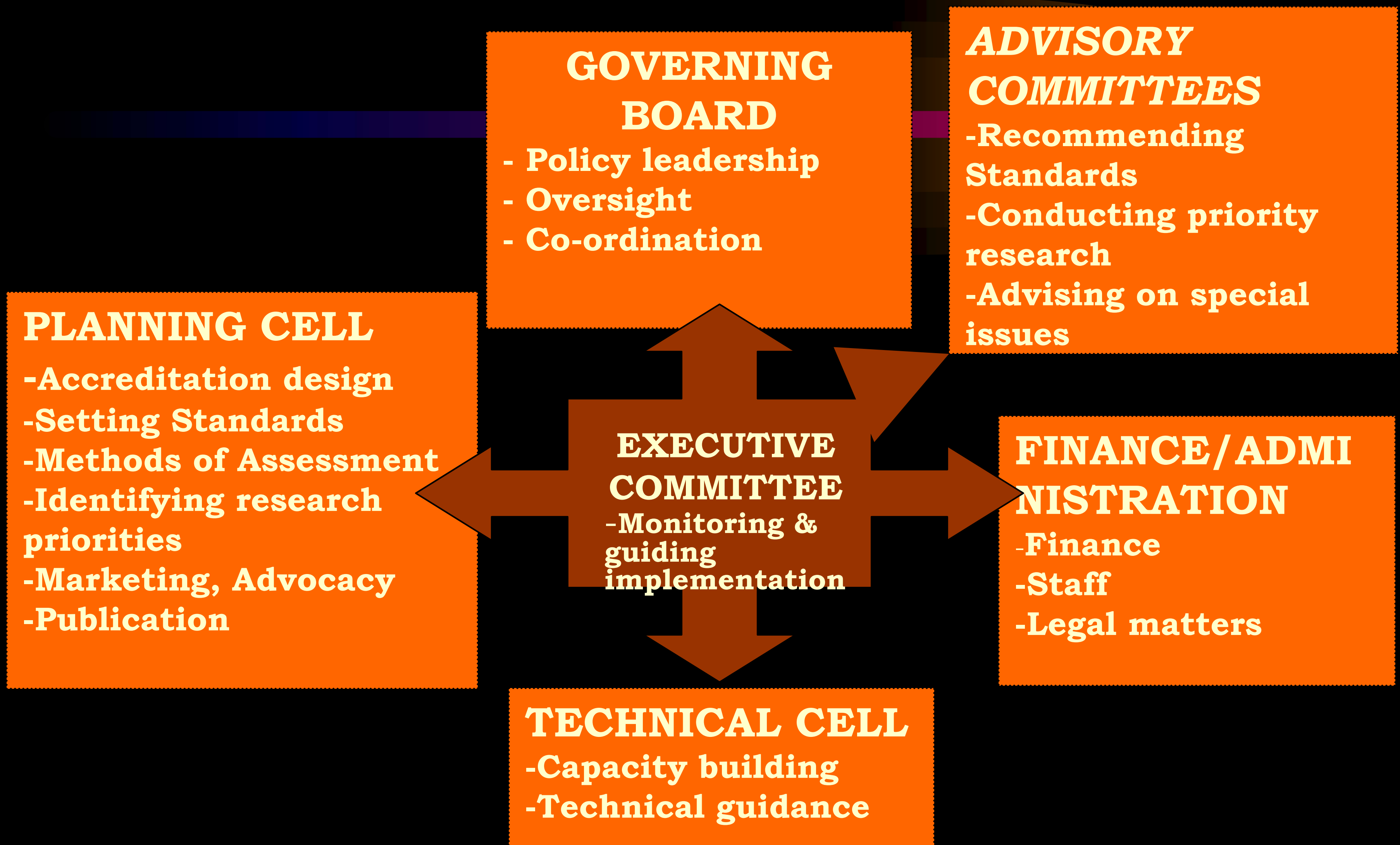
Accreditation framework for India

- **Participation** : voluntary
- **National accreditation council**: a non-profit and autonomous organization
- **Involvement**: hospital owners/administrators, professional associations, consumer organizations, NGOs, insurance companies,government
- **Standards**: Initially on physical facilities/and personnel, etc. thereafter graduating to process and outcome
- **Financing Options**: Survey fees, Membership fees, Third party payers, Grants
- **Pilot Testing**: in one district to develop manual, see the response and arrive at the staff, organisation and fee structure
- **Process**: self assessment-facilitator-external assessment
- **Accreditation mandatory**: Under CGHS and Universal Health Scheme
- **Public Accountability:** Information to be shared with govt. agencies.
- **Supersession :**Central govt. competent to supersede the council

National Accreditation Council

- **Council to be central body entrusted with overall policymaking, developing standards, guidelines & protocols, conducting research etc.;**
- **Lay down a comprehensive, credible and transparent procedure for Accreditation;**
- **Can have executive committee and other committees;**
- **Can have regional offices depending upon the work load**
- **Can appoint officers and staff to function effectively**
- **Grants, fees, charges to be credited to Accreditation Council Fund;**
- **Accounts of the Council shall be audited by the Comptroller and Auditor-General of India;**
- **Central govt. empowered to supersede the Council**

STRUCTURE



ASSESSMENT PRINCIPLES

- (i) Should be sufficiently flexible to take into account dynamic and diverse nature of Clinical Establishments;
- (ii) Should recognize positive aspects of the existing system and identify areas to remedy particular problems or deficiencies;
- (iii) Should be minimally intrusive and expensive;
- (iv) Should be developmental rather than judgmental and foster a sense of ownership and partnership among all those involved;
- (v) Should be integrative, relevant to all the stakeholders, and transparent;

Central Rules may provide

- Composition of the Accreditation Council
- Allowances of the members of Council
- Delegation of power for Accreditation pertaining to certain categories of Clinical Establishments to regional offices
- Returns and statistics to be submitted
- The manner in which the accounts of the Accreditation Council are to be maintained

THANK YOU