IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

# Regulating Health: A Comparative Review Of National And International Oversight Bodies In India's Healthcare System

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## ABSTRACT

**Background:** Regulatory bodies are essential to ensuring safety, quality, and ethical practices in healthcare. In India, despite a complex array of oversight institutions, overlapping roles, fragmented mandates, and regulatory gaps persist. This study performs a comparative, evidence-based review of key international and Indian healthcare regulatory bodies to identify strengths, inefficiencies, and actionable opportunities for systemic reform.

**Methods:** This narrative review follows SANRA guidelines and employs a structured methodological framework. Data were sourced from 2018 to 2024 using peer-reviewed journals (PubMed, Scopus, Google Scholar), official publications of global institutions (WHO, ISO, IAEA), Indian agencies (NMC, AERB, BIS), and policy documents from government portals. Thematic analysis was conducted across four dimensions: jurisdictional scope, functional responsibilities, digital integration, and implementation challenges. Stringent inclusion and exclusion criteria were applied to ensure quality.

**Results:** India's regulatory ecosystem remains fragmented, characterized by bureaucratic inertia, limited digital interoperability, and inconsistent enforcement. In contrast, international models exhibit centralized oversight, advanced digital governance, and real-time data sharing. Case examples from the AERB, NMC, and BIS highlight gaps in compliance and operational efficiency. The Ayushman Bharat Digital Mission (ABDM) represents a promising step forward, despite implementation barriers.

**Conclusion:** India must transition to a unified, evidence-based regulatory framework aligned with global best practices. Key reforms include the creation of a National Regulatory Convergence Commission (NRCC), mandatory digital licensing and audits, and AI-driven compliance monitoring. These strategies can enhance transparency, improve healthcare service quality, and strengthen public trust.

**Keywords:** Healthcare regulation, institutional governance, India, digital integration, healthcare policy, ABDM

## INTRODUCTION

Healthcare regulatory bodies are pivotal in upholding safety, quality, and ethical compliance across healthcare services. In India, a country marked by vast demographic diversity and regional disparities, fragmented regulatory mandates, inconsistent enforcement, and slow digital integration create substantial governance challenges. International institutions like the World Health Organization (WHO) and the International Organization for Standardization (ISO) offer centralized models with integrated data platforms and uniform enforcement mechanisms. By contrast, Indian regulatory bodies such as the National Medical Commission (NMC), Bureau of Indian Standards (BIS), and Atomic Energy Regulatory Board (AERB) often operate in silos.

Persistent issues such as bureaucratic inertia, outdated processes, and limited inter-agency coordination hinder the ability of these institutions to effectively safeguard public health.

### 1.1 Objectives

Institutional Role Analysis: Compare the mandates and structures of Indian regulatory bodies with their global counterparts.

Operational and Enforcement Evaluation: Assess systemic inefficiencies such as staffing gaps, resource constraints, and fragmented oversight.

Digital Integration Assessment: Examine digital infrastructure, including ABDM and its role in improving interoperability and data governance.

Policy Recommendations: Propose strategic reforms including centralized governance, AI-based compliance systems, and legislative updates.

## METHODOLOGY

### 2.1 Research Design

A narrative review methodology was employed, aligned with the SANRA (Scale for the Assessment of Narrative Review Articles) framework. This allowed thematic synthesis across diverse regulatory bodies and policy landscapes.

### 2.2 Data Sources

Peer-reviewed articles from PubMed, Scopus, Google Scholar (2018–2024)

Official reports from WHO, ISO, IAEA

Regulatory documentation from NMC, BIS, AERB

Indian government policy portals (MoHFW, MoEFCC)

### 2.3 Inclusion/Exclusion Criteria

Included: Empirical studies, official policy documents, and technical reports

Excluded: Opinion pieces and content lacking analytical or data-driven insights

### 2.4 Thematic Analysis

Documents were coded across four thematic dimensions:

Jurisdictional scope

Regulatory functions

Digital integration and interoperability

Institutional implementation challenges

Cross-validation was performed using case illustrations from AERB, NMC, BIS, and ABDM.

## CLASSIFICATION OF REGULATORY BODIES

### 3.1 International Agencies

WHO: Sets international health standards, coordinates global health policies

ISO: Establishes quality and safety protocols for medical devices and services

IAEA: Regulates radiation safety in medical and industrial applications

FDA (USA): Influences global pharmaceutical and medical device regulations

### 3.2 Indian Regulatory Bodies

NMC: Regulates medical education, ethics, and licensing

BIS: Sets technical standards for medical infrastructure and equipment

AERB: Oversees radiation safety in diagnostic and therapeutic healthcare

ABDM: Facilitates nationwide digital health integration and data systems

## COMPARATIVE THEMATIC ANALYSIS

### Observational Case Findings

**AERB:** Limited radiation safety enforcement in rural facilities; outdated equipment and insufficient audits

**NMC:** Reforms like NEXT introduced, but disparities in ethical oversight and curriculum standards persist

**BIS:** Many private clinics operate without adherence to BIS certification; lack of inspections and penalties

**ABDM:** Strong potential for national integration, yet fragmented adoption and legacy systems hamper effectiveness

## DISCUSSION

India's regulatory system shows operational disconnects between agencies, outdated audit mechanisms, and insufficient digital synergy. Unlike centralized models in the UK and Australia, India lacks a unified regulatory architecture. The ABDM provides a foundational framework but must be scaled and integrated with existing agencies.

Persistent issues include:

Bureaucratic Inertia: Delay in adopting technological reforms

Resource Limitations: Shortage of skilled regulatory staff and funding

Legislative Ambiguity: Overlapping responsibilities and inconsistent enforcement

Digital Fragmentation: Lack of seamless interoperability among databases

Strategic reforms are required to bridge these gaps, combining institutional convergence with modern technologies.

## RECOMMENDATIONS

**National Regulatory Convergence Commission (NRCC):** Create a central coordinating authority

**Digital Licensing and AI-Based Audits:** Mandate ABDM linked licensing and automated compliance checks

**Global Standards Integration:** Institutionalize WHO and ISO protocols in national law

**Transparency Dashboards:** Real-time performance portals to display violations and compliance metrics

**Capacity Building:** Upskill regulatory personnel in technology, analytics, and ethics

**Public-Private Innovation Models:** Foster partnerships for infrastructure, compliance tools, and R&D

**Legislative Clarity:** Amend existing laws to consolidate responsibilities and close loopholes

## CONCLUSION

India's current healthcare regulatory system is burdened by fragmentation, limited digital adoption, and enforcement disparities. Drawing on successful international models, this study recommends a transformative roadmap focused on institutional integration, digital modernization, and policy reform. Implementing these strategies can significantly improve regulatory transparency, service quality, and public confidence in India's healthcare system.

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## DECLARATIONS

**Ethics Approval and Consent to Participate:** Not applicable

**Consent for Publication:** Not applicable

**Availability of Data:** All data used are publicly available

**Competing Interests:** None declared

**Funding:** No external funding received

**Author Contributions:** The manuscript was solely authored by Arun Kumar