

Core India Institute of Legal Medicine 

**Regulatory Reforms on doctor-patient relationship in India : Need of a new comprehensive Law to govern medical liability.**

**DR.SANTOSH KAKADE**  
 MS (Surgery), D.Ortho. FICS, LLM. Ph.D. in Law  
 MBA (Hosp. Management), Executive MBA (Finance)  
 MD, Core India Institute of Legal Medicine, Pune  
 CEO, Vishwaraj Hospital, Loni Kalbhor, Pune, India  
[drsantoshkade@gmail.com](mailto:drsantoshkade@gmail.com)

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Background and Rationale**

- Ushering in of consumer protection of law: phenomenal rise in cases and many settled principles of law (e.g. informed consent, diligence, secrecy, death certificate, etc.)
- Corporate expansion of medical services and health consciousness
- Persons at total bay at both ends due to lack of awareness of rights and obligations: patients and professionals
- The risk of professional failure added with risk of litigation and compensation
- Minimal standards of reasonable care in case of Medical negligence: to be set by courts or by professionals?

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Background and Rationale**

- Issue of medical uncertainty
- Need for comprehensive evaluation
- Limitations for applicability of consumer protection in health care under Indian circumstances
- Need for Linking consumer rights to patient rights and medical ethics
- Need for probing the grey areas revealed in the applicability of CPA to medical negligence and solutions or corrections in the law

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Literature Review:**

- Key Concepts in CPA traced and connected: Profession, Negligence, Professional negligence, Professional Liability
- Linking them to context and multiple rules of medical negligence in India
- Concept of medical negligence as on today in India in the backdrop of Bolam and Bolitho
- Tracing the exception of error or mistake
- Deficiency in Service vis a vis Medical Profession (shortcoming, inadequacy, incorrect, refusal to treat, use of faulty instruments)
- Service as main, inclusionary and exclusionary

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Literature Review:**

- Consumer Rights :  
 Patient as Consumer and Medical Professional or Healthcare establishment as Service Provider  
 Trend: a pattern of gradual change in the law (CPA), its applicability (Medical Negligence) and impact on various stakeholders (patients, professionals, hospital administrators) in opinion, in outcome of cases at different levels
- Dearth of any specific extensive study with all these concepts is proved by literature review once these concepts are identified


Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Objectives**

1. To study the concept of medical Negligence as a whole under various Indian laws
2. To identify and analyze the Changing Trends in the Law of Medical Negligence in India and its impact.
3. To study the comparative position of the law in this regard with reference to foreign laws, to explore the linkages with the International approach towards Medical Negligence.


Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

### Research Questions


1. How is the Concept of Medical Negligence defined under various laws in India and abroad?
2. What are the various trends visible in the approach towards Medical Negligence in India and abroad?
3. What are the parameters of Consumer Protection that determine the nexus between Medical Negligence and its consequences under Consumer Protection Act? Should the Consumer Protection Act continue to govern it in India?

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

### Research Methodology

- Mixed Methodology: combination of doctrinal and empirical methods
- Triangulation of methods and data: Convergence Variant
- Criteria were developed from study of doctrinal data to define trends and applied to case analysis
- Quantitative Analysis of Primary legal Data: Case Laws Analysis and Interrelationships on Judicial Response to Medical Negligence: 40 Cases from Supreme Court and 300 Cases from National Commission



Web: [www.ciilm.com](http://www.ciilm.com)


Core India Institute of Legal Medicine 

### Research Methodology

- Tools of Data collection: Questionnaire, Schedule
- Method of data collection: Survey via email and mail; personal and online Interviews of Doctors and Community




Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 


### Data Analysis and Interpretation

#### Judicial Response to Medical Negligence

- 40 Supreme Court case laws and 300 National Commission case laws
- Duration 1987 to March 2013
- Study and Analysis of Case Laws using 31 variables
- Selected variables
  - Patient's Education and Profession
  - Involvement of hospital
  - Judge's version
  - Bolam Principle
  - Deficiency in service




Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

### Analysis of Local Trends at Pune

- Analysis of the 10 cases from Pune District Consumer Forum pending with State Commission of Maharashtra and National Commission
- Interrelationships between the two based on variables and Medical Negligence :
- Selected variables
  - Patient's Education Status
  - Involvement of hospital
  - Judge's version
  - Bolam Principle
  - Deficiency in service

Web: [www.ciilm.com](http://www.ciilm.com)


Core India Institute of Legal Medicine 

### Data Analysis and Interpretation Of Empirical Study

- Analysis of awareness amongst Doctors
- Themes of Survey findings based on 40 Questions Community
- Themes of Survey findings based on 13 Questions Interviews and Opinions amongst Doctors and Community

Summary


Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Triangulation Matrix**

- Triangulated Doctrinal Study and Empirical Study
- Triangulation of Case laws analysis with Doctors and Community Response
- Comparison of selected variables
- Doctor's specialty
- Patient Education
- Bolam Principle
- Deficiency in service- Informed consent
- Second Opinion


Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Critical Evaluation : Changing Trends**

- Identified Trends in Case Law Analysis: (Diagrammatic Representation)
  - principles,
  - deficiency,
  - methods of judging,
  - evidence,
  - compensation
- Overview of Changing Trends

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Overview**

- Impact on profession and on consumer/patient
  - Change in the doctor patient relationship
  - Increased practice of defensive medicine
  - Rising cost of the treatment
  - Loss to the students
  - Deficiency in the number of specialists

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Overview**

- Implications for the FUTURE
  - need for awareness
  - beyond compensation approach
- Exploring amendment or new Act
- Feasibility of law reform
- Regulation by profession or community
- Exclusive health tribunal or medical board

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Implications for the FUTURE**

- Assistance and awareness
  - Among Doctors
  - Among Community
  - About Good Doctor Patient Relationship
  - About limitation of medical science
  - Efforts to reduce enmity
  - Information about new Act


Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

**Specific Findings**

- Concept of Medical Negligence under various Laws in India and Consumer Rights in landmark cases, laws including CPA: predominance of fault liability, requires alternative because current remedy inadequate
- Development of Criteria for Trends and observing the trends for Case Law analysis show correlation at all levels leaving gaps


Web: [www.ciilm.com](http://www.ciilm.com)


Core India Institute of Legal Medicine 

### Specific Findings

- Observed the Changing Trends by triangulating Case Law analysis with Empirical study shows
- Uncertain movement from Bolam to Bolitho and other (10) factors;
- Counter productive nature of CPA due to dismal statistics of proving medical negligence (36 to 60%), hence alternatives are suggested

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 



### Suggestions for Existing Mechanism: Amending current Act

- Stronger Role of Medical Councils
- Screening Committees
- Medical Professional on Consumer Panels
- Nursing Homes Regulations
- Punishment for false cases
- Orientation Programs for New Doctors and Community

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 

### Suggestions for new Act

- Patient Protection and Safety Act (Proposed):  
*New Comprehensive Law Governing Medical Liability*
- Chapter 1 Preliminary: bases of a. limited fault liability and b. fast track settlement. Patient interest in the center
- Chapter 2 Patient Protection Councils
- Chapter 3 Health Tribunals : Medical Boards
- Chapter 4 System of Expert Medical Evidence: [Daubert criteria](#)
- Chapter 5 Miscellaneous
- Scope for Future Research: - rural district as the universe, larger sample, study of awareness via mass media

Web: [www.ciilm.com](http://www.ciilm.com)

Core India Institute of Legal Medicine 



DR.SANTOSH KAKADE  
Pune, India  
[drsantoshkakade@gmail.com](mailto:drsantoshkakade@gmail.com)

MOBILES: +91-9422071490  
+91-9850671175

Web: [www.ciilm.com](http://www.ciilm.com)