CHAPTER I

Introduction, Background and Literature Review
“From inability to leave well alone; from too much zeal for the new and contempt for what is old; from putting knowledge before wisdom, science before art, cleverness before commonsense; from treating patients as cases; and for making cure of a disease more grievous than the endurance, good Lord, deliver.”

Robert Hutchison

1.1 Introduction

“The customer is King”-though an old adage, yet, in spite of managerial checks for quality, at the manufacturing end, the customer walks through against all odds. Duplications and legal checks and measures did not guarantee him the minimum and made him more vulnerable. The professional services did not lag behind. And, the good, the bad and the ugly standards in service quality in contrast rendered the very existence of common person- the consumer at peril. Not that the existing law lacks in its operative coverage for any such lapses. Yet, a milestone, in the consumer protection, special law ushered with a special protective coverage. Amongst all professional services, the medical field has become most expansive in the first instance and others to fall in line. Extension of corporate approach in services and the health consciousness by one and all brought in a situation for medical attention at a far in advance stage even before one gets ill. Healthy persons are taking more pills than one who suffers. However, the field at both ends, i.e. the persons getting treated or the treating professionals are at total bay, due to lack of awareness as to their rights and obligations.2

Highlighting cases of medical negligence has ever been a trait of yellow journalism and probably these phenomena cannot be checked. It is to be realized that looking from journalistic point of view, “if a dog bites a man it may or may not be news, but if a man bites a dog it is news”. So also if medical profession cures many with its knowledge and expertise it is no longer newsworthy, but a forceps left inside the body during an operation by an otherwise eminent surgeon through an oversight is definitely newsworthy. Public sympathy on so emotional issue is overall in favour of

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1 Russel et al. (eds), 2004 as cited in Tapas Kumar Koley, MEDICAL NEGLIGENCE AND MEDICOLEGAL ASPECTS OF PATIENT CARE (New Delhi, Mehta Publishers, 2004)

this step to bring greater accountability in the medical profession. For the doctors point the best policy would be to let the issue take its natural course with gradual maturity of the process, bringing about the desired changes ensuring justice to both sides. Meanwhile the medical profession has to deal with this issue like with any other disease i.e. in a practical and sensible manner. Before tackling any issue it is important to know as much about it as possible.³

One of the most important aspects of any profession is the degree of excellence in results that a person practicing that profession can give. It is not at all expected that each and every professional would deliver the goods in the same expertise. There are so many aspects and factors that determine the relative competence of an individual in a group, vocation or a particular line of personalized and highly skilled practice. What is important is that one acts, conducts himself and discharges his duties in such a manner as would be expected from a prudent contemporary in a similar situation having access to similar facilities and in the know-how of the principles of such a practice in general. One can leave some room for factors like standards of basic education, facilities regarding initial period of training and specialized exposure, conditions of exigencies and stress while executing a given assignment and the like which in the ordinary course of day to day life are sufficient to lead to a difference of performance. But certainly there is no escape at all for contumacious recklessness, blatant dereliction of duty or complete misapplication of mind which comprised of one of the above or several acts or omissions leading to a negligent act and this untoward act is negligence.⁴

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, and political belief, economic or social condition. The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States. The achievement of any State in the promotion and protection of health is of value to all. Unequal development in different countries in the promotion of health and control of disease, especially

³ Neeraj Nagpal, COMPRENDIUM OF CPA MEDICAL JUDGMENTS: INTRODUCTION, Chandigarh, Neelam Prakashan 1996

⁴ Anoop K. Kaushal, Medical Negligence and Liabilities of a Doctor-MEDICAL NEGLIGENCE AND LEGAL REMEDIES, 3rd edition Delhi, Universal Law publishing, 2004, pp. 8
communicable disease, is a common danger. Healthy development of the child is of basic importance; the ability to live harmoniously in a changing total environment is essential to such development. The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health. Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people. Governments have a responsibility for the health of their peoples, which can be fulfilled only by the provision of adequate health and social measures.\(^5\)

The diagnosis and the treatment of diseases pertaining to human beings are very risky professions as they are accompanied by a high degree of morbidity and mortality. Previously medical professionals were mainly worried about failing to save the life of a patient or providing satisfactory treatment to a sick person. Now they also worry about the legal consequences of their failure. So, to this ancient risk of professional failure has been added the modern risk of providing economic compensation for the damage caused to the patient as a result of actual or perceived negligent treatment.\(^6\)

The nature of relationship between doctors and patients is determined largely by the practice of the medical profession and shaped by a strong commitment to long standing principles of medical ethics. The law plays a significant role, however, in providing a structure within which the doctor patient relationship is conducted. Whether it is civil, criminal or consumer law, these can only set the outer limits of acceptable conduct, i.e., a “minimal standard of professional care and skill, leaving the question of “ideal” standards to the profession itself. Most doctors seem to carry a notion that the law sets high a standard which does not take in to account the intricacies of medical science. This is far from being true. The courts are rather considerate towards them. This is clearly evident from their decisions. In practice medical negligence means failure to live up to minimal standards of reasonable care and skill, and those standards are set not by the courts but by professionals themselves.\(^7\)

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\(^5\) Ravi Duggal, Healthcare Case Law in India, Report, CEHAT, 2007; pp.8
The law relating to medical negligence finds its genesis in the common law principles of Negligence and was further developed by the judicial pronouncements in the western world. India was no exception to this legal development as one of the first reported judgments in a case of medical negligence dates back to 1969, i.e., case of *Laxman v/s Godbole*\(^8\) wherein the Hon’ble Supreme Court of India dealt in detail about the principles involved in medical negligence and further elaborated the duties of doctor and also patients. Not much of hue and cry was raised by the medical fraternity at that point of time, because till then the doctor patient relationship had element of trust in it. Moreover, medical profession was taken to be one of most noble professions on earth.\(^9\)

Negligence can be described as failure to take due care, as a result of which injury ensues. It is not sufficient that the medical professional acted in good faith to best of his or her judgment and belief. A medical professional is expected to have a requisite degree of skill and knowledge. Medical malpractice is not merely the negligence on the part of care giver but it is a conscious decision of the care giver to offer and /or force a product, procedure or investigation upon a patient for monetary gain either personally or for the institution.\(^10\)

Three essential components of the modern tort of Negligence propounded by Percy and Charles worth are as follows; \(^11\)

- The existence of duty to take care, which is owed by the defendant to the complainant;
- The failure to attain the standard of care, prescribed by the law, thereby breach of such duty; and
- Damage, which is both causally connected to such breach and recognized by the law, has been suffered by the complainant

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\(^8\)AIR 1969 SC 129.


If the plaintiff proves that the doctor was negligent, but fails to establish that any loss or injury was caused thereby, then he/she will not be entitled to claim any compensation.\textsuperscript{12} The general test for causation requires the plaintiff to establish that the injury would not have occurred, but for the negligence of the defendant.\textsuperscript{13}

Since the application of the Consumer Protection Act (herein after CPA) \textsuperscript{14}to the medical field in 1995 in India\textsuperscript{15}, there have been a large numbers of cases against doctors and there have been many settled principles of law. As per these principles the law has defined responsibilities of doctors and hospitals which include; \textsuperscript{16}

- To obtain an informed consent of a patient
- To conduct necessary pre-operative diagnostic tests
- To exercise due care and diligence
- To provide information regarding Birth, Death etc and Certification of Health condition
- Maintenance of Secrecy
- Issuance of death certificate
- Employment of qualified staff, supervision, provision of Ancillary services and engagement of Specialists
- Provision and testing of blood
- In complicated cases assistance of experts/ consultants in relevant field should be availed

While “to err is human”, a hospital and medical professionals entrusted with treatment and often with life of a patient, who generally follows the advice of the professionals unquestioningly, are expected to exercise greater degree of care while discharging their duties. \textsuperscript{17}

\textsuperscript{12}Sidhraj Dhadda v State of Rajasthan AIR 1994 Raj 68; 1993(1) Raj LW 532. as quoted by Dr. R.K.Bag (2003); pp. 4
\textsuperscript{13}Athey v Leonati [1996] 3 RCS 458 as quoted by Dr.RK Bag (2003) pp. 4
\textsuperscript{14}See details in Annexure II
\textsuperscript{16}M.S. Pandit, & Shobha Pandit, MEDICO LEGAL AID TO HOSPITALS & DOCTORS WITH CONSUMER PROTECTION LAW, 2\textsuperscript{nd} edition, pp. 1-14.
\textsuperscript{17}Id.
From the judgments given by Supreme Court, High Courts and State and National Commissions various legal principles have emerged which have guided the outcome of the nature of the further cases of medical negligence. The list is as follows,

1. Res ipsa loquitur: infer from things
2. No privilege to any school of medicine where more than one school of medicine exists.
3. Expert evidence is required
4. Vexatious litigation
5. Demand of exorbitant fee
6. Where complainant does not prove medical negligence, no liability can be fastened on the doctor or the hospital. Burden of proof is on the complainant.
7. While code of medical ethics requires a doctor to maintain secrecy and confidentiality, “Right to Life” of an individual as fundamental right is an exception to this rule.
8. Standard of care and skill or judgment or technique used by a doctor
9. Nexus between injury and breach of duty on the part of medical professional or hospital
10. Forseeability and remoteness of injury
11. Inherent risk of surgery and treatment
12. Error of Judgment
13. Provision of blood
14. Transfer of serious patient from one hospital to another
15. Where non specialists, Health Care workers, Nurses and juniors are held negligent
16. A consultant is negligent if he delegates the responsibilities to a junior
17. Incomplete medical records

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18 M.S. Pandit, & Shobha Pandit, MEDICO LEGAL AID TO HOSPITALS & DOCTORS WITH CONSUMER PROTECTION LAW, 2nd edition, pp. 178-203.
18. Law prohibits ayurvedic, unani or homeopathic doctor prescribing allopathic medicine

1.2 Need for the present Study
Legislations such as CPA are important for the simple reason that they, in a specific manner, operationalize policies of the government. For that matter, the legislation is only one part of the policy literature available for undertaking policy analysis. This does not mean that the legislation always follows the policy. There are instances when the legislation (the law ordinances) are passed first, giving an indication of the policy being pursued by the state. There are also instances, numerous in the field of health care, when no legislation follows the announced policy and thereby, leaving the implementation of the announced policy at the discretion of the administrators and the political environment prevalent. Thus, the legislation cannot be looked at in vacuum; they must be understood in relation to policies.\(^\text{19}\)

Practice of medicine is capable of rendering great service to the society provided due care, efficiency and skills are observed by the doctors. Medical Profession has its own ethical parameters and code of conduct. This profession is rendering a noble service to humanity and has sustained itself on public trust. According to the Voluntary Health Association of India, the present state of medical profession seems to mirror the rot, which seems to have sent in to the system. Increased mechanization and commercialization of profession have brought in an element dehumanization in medical practice. Healthcare has been reduced to business which determines the doctor patient relationship.\(^\text{20}\)

The concept of “consumer” arises from western countries. It is very much useful to study the concept, while applying it to the medical field. The applicability of this concept to the Indian context is a research area itself. There is need for more research, to evaluate the current and changing trends in the laws related to the medical negligence. The research is needed to bring out the lacunae, to suggest the changes that are acceptable to medical field and the consumers.


Since the application of the Consumer Protection Act, due to Judicial Activism a number of legal principles have evolved. The patient has been equated to consumer and this has affected the relationship between doctor and patient. There are number of other factors which are responsible for the decline in Doctor-Patient relationship like advancement of the technology in healthcare, commercialization of the healthcare sector, growth of corporate hospitals and so on. Any medico legal case is a confrontation between medical knowledge of a lawyer and the legal knowledge of a doctor. India is a developing country where it has peculiar characteristics like majority of rural population, Illiteracy and lack of awareness about the consumer rights and legal provisions.

In this context the following areas need to be explored.

1. Increased Litigation
2. Weak Control of Law Provisions
3. Variable Consumer Awareness
4. Link between increased litigation and the consumer awareness
5. Illiteracy
6. Poor Medical Infrastructure
7. Discrepancies in Private and Public Sector Healthcare
8. Role of Quacks
9. Gradual Lifestyle Changes
10. Cross Pathy Practice
12. Judges’ unawareness of medical uncertainty

It shows that there is a gap in the knowledge about the above aspects. The limitations for the applicability of the Consumer Protection Act to the Indian health circumstances need to be probed. Considering the above aspects of Indian context, there is a need for further research regarding linking of consumer rights and patients rights to the laws of medical negligence.

Thus probing in the overall aspects of the applicability of the Consumer Protection Act to the medical field is necessary to find out grey areas which can be tackled by solutions that can be suggested thereafter.
1.3 Review of Literature

Law is an instrument of social change. It brings about the change in the society based on the principles of justice and social equity. Law protects the rights of the common People. The instrument is utilized frequently, when the rights of common people are affected. Whenever the procedure involved in the application of the law is simple, it is utilized to the maximum extent by them, for which there needs an awareness of the law in the society.

Since the application of the Consumer Protection Act to the medical field, there has been an increase in the awareness about the Medical Negligence in the society. In the Landmark case, *IMA v VP Shantha and Others*, the Hon’ble Supreme Court has applied seal of approval on the application of The Consumer Protection Act to the members of medical profession. In the current scenario, there is a phenomenal rise in cases involving alleged medical negligence.

The Consumer Protection Act aims at better protection of the interests of consumers and for settlement of consumer disputes. It provides for speedy and inexpensive settlement of disputes within a limited timeframe. It has been found that, there is a changing trend in the law of medical negligence. The changing trend in the judicial and legislative approach towards the cases of medical malpractice needs to be studied in depth and there is need to find out lacunae for correction in the Consumer Protection Act.

“The principle objective of the medical profession is to render services to the humanity with full respect to the dignity of men.”

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23 Id.12
For ages, medical practice has been treated as a noble profession. The relationship between a patient and his/her family doctor was once of trust and total confidence on the part of the patient and one of care and concern on the part of the doctor. The disappearance of the concept of family doctor and the rapid growth of super specialty corporate hospitals in the urban areas has totally changed the age-old doctor-patient relationship based on long-term association and trust.

**Profession**

Scrutton L.J has said “‘Profession’ in the present use of language involves the idea of an occupation requiring either purely intellectual skill, or of manual skill controlled, as in painting and sculpture; or surgery, by the intellectual skill of the operator, as distinguished from an occupation which is substantially the production or sale of commodities. The line of demarcation may vary from time to time. The word ‘profession’ used to be confined to the three learned professions, the Church, Medicine and the Law. It has now, I think a wider meaning”

According to Rupert M Jackson and John N Powell, the occupations which are regarded as professions have four characteristics

- Skilled and specialized nature of work.
- Commitment to moral principles.
- Professional association regulates standards of profession.
- High status in the community

**Negligence**

Negligence means: the omission to do something which a reasonable man, guided by those ordinary considerations which ordinarily regulate human affairs, would do or the doing something which a reasonable and prudent man would not do.

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27 Ibid
28 Id. 15
29 Id. 15
Negligence as a tort is the breach of a duty caused by omission to do something which a reasonable man would do or doing something which a prudent and reasonable man would not do. The definition involves the following constituents: 30

- A legal duty to exercise due care;
- Breach of the duty; and
- Consequential damages

Professional Negligence
In the law of negligence, professionals such as lawyers, doctors, architects and others are included in the category of persons professing some special skill or skilled persons generally. Any task which is required to be performed with a special skill would generally be admitted or undertaken to be performed only if the person possesses the requisite skill for performing that task.

Professional Liability 31
In the matter of professional liability professions differ from other occupations for the reason that professions operate in spheres where success cannot be achieved in every case and very often success or failure depends upon factors beyond the professional’s control. Medical practitioners do not enjoy any immunity and they can be sued in contract or tort on the ground that they have failed to exercise reasonable skill and care. It would thus appear that medical practitioners, though belonging to the medical profession, are not immune from a claim for damages on the ground of negligence. The fact that they are governed by the Indian Medical Council Act, 1956 and are subject to the disciplinary Control of Medical Council of India and/or State Medical Councils is no solace to the person who has suffered due to their negligence and right of such person to seek redress is not affected 32

Medical Negligence
Negligence can be described as failure to take due care, as a result of which injury ensues. Negligence excludes wrongful intention since they are mutually exclusive. Carelessness is not culpable or a ground for legal liability except in those cases in

30 Id. 15
31 Id. 15
32 Id.28
which the law has imposed the duty of carefulness. The medical profession is one such section of society on which such a duty has been imposed in the strictest sense. It is not sufficient that the medical professional acted in good faith to the best of his or her judgment and belief.

**Duty of Care**

As the proverbial saying goes that the worst case goes to the best profession, yet even the best cannot be sure of success. Just as the best of a lawyer cannot be presumed to give a guarantee to win, the best of a doctor is not presumed to have a guarantee to cure. The duty owed by a medical professional to his patient has been summed up by Lord Hewart, C.J in the following words:

“If a person holds himself out as possessing special skill and knowledge and he is consulted, as possessing such skill and knowledge, by or on behalf of patient, he owes a duty to the patient to use due caution in undertaking the treatment. If he accepts the responsibility and undertakes the treatment and the patient submits to his direction and treatment accordingly, he owes a duty to the patient to use diligence, care, knowledge, skill and caution in administering the treatment.”

Various Laws dealing with Medical Negligence in India include,

1. Law of Torts.  
2. Law of Contract.  
3. Criminal Law  
5. Fatal accidents Act 1855  

Laws dealing with Medical Negligence in India are represented in following diagram.

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34. Id. at pp.30  
35. Figure 1
Negligence is not susceptible to any precise definition as found by Indian Courts. Various meanings may be attributed to negligence. It connotes careless state of mind which may amount to recklessness or indifference. It is a careless conduct without reference to any duty to take care. As it is pointed out by Hon’ble Justice Chagla, ACJ and Hon’ble Justice Bhagavati J. the actions for negligence in India are to be determined according to the principles of English common Law.\(^{37}\)

The essential components of the tort of negligence, as postulated by Percy and Charlesworth \(^{38}\) are as follows

(a) the existence of duty to take care, which is owed by the defendant to the complainant
(b) the failure to attain that standard of care, prescribed by law, thereby committing a breach of such duty, and
(c) damage, which is both causally connected with such breach and recognized by law, has been suffered by the complainant

\(^{36}\) Poster presented by Researcher at Founding Conference of European Association of Health Law, Edinburgh, UK 2008, See Annexure I
\(^{38}\) Id.
By applying the above principles, medical Negligence has been defined as, want of reasonable care and skill of the part of medical practitioner that results in damage to the patient. Before the application of Consumer Protection Act to the medical field, the medical negligence cases used to be dealt under law of torts. After the application of Consumer Protection Act, with plethora of case laws, various concepts have been evolved which include medical negligence, reasonable skill and care, damages due to negligence, importance of documentation, legally valid consents, second opinion during the treatment of a complicated patient, skill updating by specialist doctors and so on.39

The application of the Consumer Protection Act to the medical field in 1995 is a milestone in the history of legislations for medical negligence. Since the application, there has been a rise in the litigations against medical practitioners. There is also increase in the vexatious complaints to gain the unhealthy mileage of the law. With the plethora of case laws under Consumer Protection Act, various conceptions and principles are being defined. Since the two fields, legal and medical, are different in approach, there are likely to be lacunae in the concepts and implementation of the Consumer Protection Act, which need to be addressed.

At one time it was thought that the state was mainly concerned with the maintenance of law and order and the protection of life, liberty and property of the subject. Such a restrictive role of the state is no longer a valid concept. Today living in an era of a welfare state health is considered to be man’s most valuable possession since all his activities is influenced by the state of his health.

The Directive Principles of State Policy under the constitution of India require the state to make effective provision for public health, and for just and humane conditions of work. It is the primary duty of the State to raise the level of nutrition, the standard of living of its people and the improvement of public health.40 Articles 42 & 47 indicate that government had become conscious of this modern phenomenon and this provision could serve the function of providing a constitutional footing for further legislative and administrative actions. However, it is submitted that the constitutional

39 Id
40 Constitution of India. Art. 47
scheme for the protection of health, as originally envisaged, contained a serious lacuna, which was later removed by judicial innovation. It may be appreciated that Articles 42 and 47, which impose constitutional obligation on the State are, non-justiciable in nature. It means if state fails to discharge its obligation, such failure cannot be questioned in court of law and there is no judicial remedy. But this anomaly has been removed by judicial creativity and innovation. The Supreme Court of India's creativity expanded the contours of Article 21, so as to sub serve the right of health and Medicare in it. Though, fundamental rights are negative rights and can be invoked only when it has been violated without the due process of law. In healthcare the damages are irreparable and cannot be brought back. So the court took the positive step and interpreted this negative as positive right under Article 21of the Constitution of India.

In *Paramanand Katara v. Union of India*, Supreme Court has declared that right to medical aid is an integral part of right to life. It is an obligation on the State to preserve life by extending required medical assistance. In fact, the Apex court has held that right to health and medical care is a fundamental right under the Constitution of India.

Further, Supreme Court in *Paschim Banga Khet Mazdoor Samiti v. State of WB* has held that providing adequate medical facilities for the people is an essential part of the obligation undertaken by the government in a welfare state. Article 21 imposes an obligation on the State to safeguard the right to life of every person and on the breach of which s/he can move the Supreme Court or High Court through writ petition.

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Practice of medicine as part of healthcare is capable of rendering great service to the society provided due care, sincerity, efficiency and skill are observed by doctors. Medical profession has its own ethical parameters and code of conduct.

**Certain other factors are of great concern.**

First is the standard and parameters for seeking admission to medical course has changed with the change in society. Now the medical profession has degenerated from its earlier service and humble motive, quite frequently the medical practitioners are reportedly being involved in activities like organ sale racket.

Second is the hesitation of qualified doctors to take up rural assignment. These assignments have become more of experience- gaining phenomenon and last resort than the real motive for joining the profession.

Third is the large scale mushrooming of hospitals and nursing homes. The big corporate hospitals having branches all over the country have given rise to strange situation but in reality created a paradox. These phenomena have a cascading effect and started to commercialize health services. On the other hand the patient is developing an attitude of "shopping" with his disease. Consequently, the fourth thing that has emerged and appears to be the most serious one, is, the accountability of remedial action of the professionals in this noble vocation.

Today, the Patient-doctor relationship has almost diminished its fiduciary character. 'Services' of medical establishments are more of purchasable commodities and the 'business' attitude have given an impetus to more and more malpractices and instances of neglect. But the question is, whether, on the whole, branding the entire medical community as a delinquent community would serve any purpose or will it cause damage to the patients. The answer is, no doubt, the latter.

It is not that measures to check such dereliction are absent. Victims of medical negligence, considering action against an erring doctor, have three options.

- **Compensatory mode** - Seek financial compensation before the Consumer Disputes Redressal Forum or before Civil Courts
- **Punitive/Deterrent mode** - Lodge a criminal complaint against the doctor
• Corrective/ Deterrent mode - Complaint to the State Medical Council demanding that the doctor's license is revoked.

Jurisdiction of Civil Court was never disputed but its scope was limited to damages only. Doctors were initially excluded from the ambit of the Consumer Protection Act, when these courts were first set up in 1986. The Supreme Court's judgment, in *Indian Medical Association, v. V.P. Shantha and ors.*

44 has brought them within its purview. There are three tiers of dispute redressal fora. At the lowest level is the District Consumer Disputes Redressal Forum (one in each district), which entertains compensation claims up to Rs.20 Lakh. At the next level is the State Consumer Disputes Redressal Forum (one in each state), where compensation claims between Rs.20 Lakh and Rs. 1 Crore are made. At the National Forum, claims of over Rs. 1 Crore are lodged. Those dissatisfied with the judgment of the lower forum can appeal to a higher forum. The final court of appeal is the Supreme Court.

Criminal cases against doctors are lodged mainly following the unnatural death of a patient under their care. The section employed is usually 304 of the Indian Penal Code for a rash or negligent act not amounting to culpable homicide and carries maximum imprisonment of two years, or a fine, or both.

Following the recent Supreme Court judgment in *Suresh Gupta v. Govt. of NCT of Delhi,*

45 however, criminal cases against doctors are likely to register a steep fall. The police will have to be first provide proof of "recklessness and deliberate wrongdoing" on the doctor's part.

Further a complaint can also be lodged with Medical Council of India together with State Medical Councils seeking cancellation of the doctor's license. It is the Medical Council which gives doctors their license to practice; the license can be withdrawn if the doctor is found guilty of misdemeanours. On past experience it can be said that

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45. 2004 (6) SCC 422
the chances of the Medical Council taking any such step, are slender except in certain cases. Recently, the Delhi High Court has upheld the suspension of the license of a city surgeon by the Medical Council of India. Dr. M.M. Bagati, who was not a qualified paediatrician, had administered high dosage of drugs to an infant after which the child developed renal problem. On enquiry doctor was found negligent and Medical Council of India suspended his license for a year. When the doctor moved High Court, upholding the Medical Council of India’s decision, Justice Sanjay Kishan Kaul held that "A professional doctor is required to prescribe what is required to be done, including the investigation. Considering all facts, it is apparent that the doctor's conduct is in the category of infamous conduct with respect to medical profession. However, not a single doctor anywhere in India has ever since independence had his license permanently revoked." 47

Thus it can be said that in spite of remedy under different laws, the patients of medical negligence are still suffering and they need additional protection especially the patient from the Government Hospitals. Consumer Laws can be a great help provided the consumers should be aware of their rights.

“It would not be correct to say that every moral obligation involves a legal duty; but every legal duty is founded on a moral obligation. “Said Lord Chief Justice Coleridge. 48 No greater opportunity, no greater responsibility, and no greater obligation befall to a person who chooses to become a medical doctor. In the care of the suffering he/she needs scientific knowledge, technical skill and human understanding, and those who use these with courage, with humility and with wisdom, provide a unique service to their fellow men and women and build an enduring edifice of character within them. This nature of service gives medicine its unique status of being a noble profession. The bringing of medical services within the purview of the Consumer Protection Act has caused a plethora of suits being filed in consumer forums against imaginary and sometimes real negligence of doctors. ‘Consumerism’ once

46 Vandana Singh, High Court burns down doctor’s pleas, Hindustan Times, New Delhi, Aug 17 2004, From “Medical Negligence and Our Laws-An Overview”.
48 R v Instan (1893) 1 Qb at 453
unthinkable of as a term in medical parlance has been referred to now in the Supreme Court judgment. The developed countries jargon of ‘producers and consumers’ have also been referred to in relation to the once sacred doctor patient relationship. The once noble profession has been put at par with any sundry trade.\(^{49}\)

Medical negligence has been defined as want of reasonable degree of care and skill or wilful negligence on the part of the medical practitioners in the treatment of a patient with whom the relationship of a professional attendant is established so as to lead to his/her bodily injury or permanent disability or loss of life. The law on the subject is very considerate to the medical profession. In *Hatcher v Black\(^{50}\)*, Lord Daniel opined that the jury must not find a doctor negligent simply because one of the risks inherent in an operation actually took place or as a matter of opinion he made an error of judgment. They should find him guilty only when he had fallen short of reasonable medical care.

Lord Justice Dealing observed that one should be doing disservice to the community at large, if one were to impose liability on hospitals and doctors for everything that happens to go wrong…..one must insist on due care for the patient at every point, but we must not condemn as negligence that which is only a misadventure.\(^{51}\)

Mr. Justice Barrie in *Moore v Levi sham Group\(^{52}\)* observed that, “when there are two responsible schools of thought about the management of clinical situation, those Courts could do no greater disservice to the society or to the advancement of medical science than to place the hallmark of legality upon one form of treatment.

As observed by Lord Nathan\(^{53}\), a mistaken diagnosis is not necessarily a negligent diagnosis. In *Mitchell v. Dickson\(^{54}\)*Innes, ACJ observed,” no human being is infallible and in the present state of science even the most eminent specialist may be at fault in detecting the true nature of the diseased condition. A practitioner can only be

\(^{49}\) Nagpal Neeraj, Supra
\(^{50}\) Lancet 154-2-880
\(^{51}\) Roe v Ministry of Health, 1954-2-All E.R. 131

\(^{52}\)HMC (1959)
\(^{54}\)1954-AP PD-519
liable in this respect if his diagnosis is so palpably wrong as to prove negligence, that is to say, if his mistake is of such nature as to imply absence of reasonable degree of skill and care on his part, regard being had to the ordinary level of skill in the practitioner.”

The standard of care which is required from the medical practitioners as laid down by McNair, J. in his direction to the jury in *Bolam v Friern Hospital Management Committee*\(^\text{55}\) has been accepted by the House of Lords in a number of cases “But where you get a situation which involves the use of some special skill or competence, then the test as to whether there has been negligence or not is not the test of man on the top of a Clapham omnibus, because he has not got this special skill. The test is the standard of ordinary skilled man exercising and professing to have special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that art”.

The *Bolam* case summary is as follows,

In this case the plaintiff, John Bolam, was a psychiatric patient suffering depressive illness. He was advised by Dr de Bastarrechea, a consultant psychiatrist attached to Friern Hospital, to undergo electro-convulsive therapy (E.C.T.). He signed a consent form but was not warned about the risk of fracture that can occur because of fit-like convulsions that such treatment induces. In due course, he received this treatment but was not given any relaxant drugs. As a consequence, he suffered several injuries. These included dislocation of hip joints and fractures to the pelvis on both sides caused by the femur on both sides being driven through the cup of the pelvis. The plaintiff claimed that the doctor was negligent in not giving him relaxant drugs. By not doing so, the doctor also failed to provide adequate physical restraints to prevent the injury. He also claimed that the doctor had failed to warn him of the risks involved in the treatment. The judge, however, found the doctor not guilty of negligence as he had acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular area. Expert witness called by either side gave evidence as to the different techniques which they adopted in

\(^{55}\) *Bolam v Friern Hospital Management Committee* (1957) 2 All ER 118;1957, 1 WLR 582
giving E.C.T treatment; some used relaxant drugs, some used restraining sheets and some used manual control, but all agreed that there was a firm body of medical specialists who opposed to the use of relaxant drugs.

In an action for negligence in tort against a surgeon, the Supreme Court Held 56 “The duties which a doctor owes to his patient are clear. A person who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person when consulted by a patient owes him certain duties, viz., a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give or duty of care in administration of that treatment. A breach of any of those duties gives right of action for negligence to the patient.”

Before the enforcement of the Consumer Protection Act, the field of medical negligence was inevitably governed only by law of Torts. The precise definition of negligence is perhaps not possible and it would remain a somewhat slippery word. The classic attempted judicial definitions of negligence may be noticed from the authoritative treatise of Salmond 57 as under.

“Negligence in the objective sense that is in the well known definition of Alderson B. “the omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do.”

The law relating to medical negligence finds its genesis in the common law principle of negligence and was further developed by the judicial pronouncements in the western world. In India also the legal development took place similarly since one of the first reported judgments in a case of medical negligence dates back to 1969, i.e., case of Laxman Balkrishna Joshi v Triambak Bapu Godbole 58, wherein the Hon’ble Supreme Court of India dealt in detail about the principles involved in medical negligence and further elaborated the duties of doctors and also the patients.

56 1969(1) SCR 206
57 Salmond, LAW OF TORTS, Sweet & Maxwell; 21st Revised edition (24 Oct 1996)
Madras High Court had taken a different view about the application of consumer concept to the medical field. It was held that the services rendered to a patient by a medical practitioner or by a hospital by way of diagnosis and treatment, both medicinal and surgical, would not come within the definition of 'service' under section 2(1)(o) of the Consumer Protection Act and the patient cannot be considered to be a consumer within the meaning of Section 2(1) (d) of the same Act.  

The Supreme Court put forth a number of conclusions in the historical judgment, in Indian Medical Association v V.P. Shantha & Ors. While applying the Consumer Protection Act to the medical profession,

• Service rendered to a patient by a medical practitioner would fall within the ambit of 'service' as defined in section 2(1)(o) of the CPA.
• The service rendered by a medical practitioner to be considered to a contract for personal service and that comes within the purview of the CPA
• Services rendered free of charge would not attract the provisions of this Act.

Deficiency
According to Section 2(l) (g) of the CPA, 'deficiency' means any fault, imperfection, shortcoming, or inadequacy in the quality, nature, and manner of performance which is required to be maintained, by or under any law for the time being in force, or has been undertaken to be performed by a person, in pursuance of a contract or otherwise, in relation to any service.

In the context of the medical profession, deficiency means that the treatment provided by the medical practitioner is not correct or not according to accepted medical standards. Deficiency of service may also include treatment by using faulty instruments, lack of ICU or ambulance services, etc. Deficiency of service under the CPA is almost equal to medical negligence under the law of torts. There can be deficiency of service even without any harm or injury to the patient. For example, refusal to give treatment record

59Dr. C.S.Subramanian v Kumarswamy & Anr. (1994) 1 MLJ 438
60 AIR 1996 SC 550; 1995 (6) SCC 651; 1995(3) CPJ 1(SC); 1995(3) CPR 412(SC)
or payment receipt by the medical professional or healthcare institution may be considered as deficiency of service.\(^{62}\)

**Service**  
According to Section 2(l)(o) of CPA, 'service' means service of any description which is made available to potential users and includes, but not limited to, the provision of facilities in connection with banking, financing, insurance, transport, processing, supply of electrical or other energy, board or lodging or both, housing construction, entertainment, amusement or the purveying of news or other information, but does not include the rendering of any service free of charge or under a contract of personal service.

Therefore now in the medical profession, treatment given by a medical professional or healthcare institution will be considered service under the Act. Besides medical care, other services provided for patients like ambulance services, are also included in this definition. Almost all types of service that a patient gets, right from getting inside the hospital tills he/she leaves the hospital, are considered service and any shortcoming in this regard will be considered deficiency of service. The negligence of medical professionals comes within the definition of deficiency in service.

In the *IMA* case, the Supreme Court held,  
The definition of services in Section 2(1)(o) of the Act can be split up into three parts - the main part, the inclusionary part and the exclusionary part. The main part is explanatory in nature and defines service to mean service of any description which is made available to the potential users. The inclusionary part expressly includes the provision of facilities in connection with banking, financing, insurance, transport, processing, supply of electrical or other energy, board or lodging or both housing construction, entertainment, amusement or the purveying of news or other information. The exclusionary part excludes rendering of any service free of charge or under a contract of personal services. The inclusive part of the definition of 'service' is not applicable and one is required to deal with the questions failing for consideration in the light of the main part and the exclusionary part of the definition. The exclusionary part will require consideration only if it is found that in the matter of consultation, diagnosis and treatment a medical practitioner or a hospital/nursing home renders a service falling within the main part of the definition.

\(^{62}\) Id.
contained in Section 2(l)(o) of the Act. One has, therefore, to determine whether medical practitioners and hospitals/ nursing homes can be regarded as rendering a "service" as contemplated in the main part of Section 2(1) (o).\textsuperscript{63}

The Learned Judges concluded in \textit{IMA} case as follows.\textsuperscript{64}

(1) Service rendered to a patient by a medical practitioner (except where the doctor renders service free of charge to every patient or under a contract of personal service), by way of consultation, diagnosis and treatment, both medicinal and surgical, would fall within the ambit of 'service' as defined in Section 2(1) (o) of the Act.

(2) The fact that medical practitioners belong to the medical profession and are subject to the disciplinary control of the Medical Council of India and/or State Medical Councils constituted under the provisions of the Indian Medical Council Act would not exclude the services rendered by them from the ambit of the Act.

(3) A 'contract of personal service' has to be distinguished from a 'contract for personal services'. In the absence of a relationship of master and servant between the patient and medical practitioner, the service rendered by a medical practitioner to the patient cannot be regarded as service rendered under a 'contract of personal service'. Such service is service rendered under a 'contract for personal services' and is not covered by exclusionary clause of the definition of 'service' contained in Section 2(1) (o) of the Act.

(4) The expression 'contract of personal service' in Section 2(1) (o) of the Act cannot be confined to contracts for employment of domestic servants only and the said expression would include the employment of a medical officer for the purpose of rendering medical service to the employer. The service rendered by a medical officer to his employer under the contract of employment would be outside the purview of 'service' as defined in Section 2(1) (o) of the Act.

(5) Service rendered free of charge by a medical practitioner attached to a hospital/Nursing home or a medical officer employed in a hospital/Nursing home where such services are rendered free of charge to everybody, would not be

\textsuperscript{63}AIR 1996 SC 550, para. 17.
\textsuperscript{64}Indian Kanoon - http://indiankanoon.org/doc/723973/
"service" as defined in Section 2(1) (o) of the Act. The payment of a token amount for registration purpose only at the hospital/nursing home would not alter the position.

(6) Service rendered at a non-Government hospital/Nursing home where no charge whatsoever is made from any person availing the service and all patients (rich and poor) are given free service - is outside the purview of the expression 'service' as defined in Section 2(1) (o) of the Act. The payment of a token amount for registration purpose only at the hospital/Nursing home would not alter the position.

(7) Service rendered at a non-Government hospital/Nursing home where charges are required to be paid by the persons availing such services falls within the purview of the expression 'service' as defined in Section 2(1) (o) of the Act.

(8) Service rendered at a non-Government hospital/Nursing home where charges are required to be paid by persons who are in a position to pay and persons who cannot afford to pay are rendered service free of charge would fall within the ambit of the expression 'service' as defined in Section 2(1) (o) of the Act irrespective of the fact that the service is rendered free of charge to persons who are not in a position to pay for such services.

Free service, would also be "service" and the recipient a "consumer" under the Act.

(9) Service rendered at a Government hospital/health centre/dispensary where no charge whatsoever is made from any person availing the services and all patients (rich and poor) are given free service - is outside the purview of the expression 'service' as defined in Section 2(1) (o) of the Act. The payment of a token amount for registration purpose only at the hospital/nursing home would not alter the position.

(10) Service rendered at a Government hospital/health centre/dispensary where services are rendered on payment of charges and also rendered free of charge to other persons availing such services would fall within the ambit of the expression 'service' as defined in Section 2(1) (o) of the Act irrespective of the fact that the service is rendered free of charge to persons who do not pay for such service. Free service would also be "service" and the recipient a "consumer" under the Act.

(11) Service rendered by a medical practitioner or hospital/nursing home cannot be regarded as service rendered free of charge, if the person availing the service has taken an insurance policy for medical care where under the charges for consultation, diagnosis and medical treatment are borne by the insurance company and such
service would fall within the ambit of 'service' as defined in Section 2(1) (o) of the Act.

(12) Similarly, where, as a part of the conditions of service, the employer bears the expenses of medical treatment of an employee and his family members dependent on him, the service rendered to such an employee and his family members by a medical practitioner or a hospital/nursing home would not be free of charge and would constitute 'service' under Section 2(1) (o) of the Act. 65

Inclusion of Medical Services under the CPA

This is probably the most significant issue that was clarified by the Supreme Court in the IMA case. It removed all confusions prevailing initially regarding the inclusion of medical services under the purview of the Act. All types of medical services were brought under the purview of CPA.

The Supreme Court observed that medical practice is a profession rather than an occupation and medical professionals provide a service to the patients and thus they are not immune to the claim from damages on the ground of negligence. From this viewpoint the Court concluded that a patient can be a 'consumer' for the purpose of CPA. Besides this, the Court also observed that consumer protection was very well established in both the UK and the USA in the field of medical practice. The Supreme Court referred to the well-known book Law and Medical Ethics, by Mason and McCall Smith, 66 and Arizona v. Maricopa County Medical Society, 67 which is the leading case on price fixing in the health care industry. In that case it was held that the fixing of maximum prices for insured users of medical services constituted per se illegal price fixing under Section 1 of the Sherman Antitrust Act (1890). Considering all these facts the Supreme Court concluded as follows;

We are, therefore, unable to subscribe to the view that merely because medical practitioners belong to the medical profession they are outside the purview of the provisions of the Act and the services rendered by medical practitioners are not covered by Section 2(l)(o) of the Act. 68

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65 Id
66 Fourth edition
67 IMA case, para. 26
68 IMA case, para. 26
After this judgment, majority of medical negligence cases in India are filed in consumer courts under the Act. The Indian Medical Association had put forward many arguments in its attempt to persuade the Court that doctors should not be brought under the purview of the CPA. All the arguments were taken up by the Court and clear rulings were given.

In the case of *Vinitha Ashok V Laxmi Hospital &Ors*[^69] within the consumer jurisdiction the matter was summed up in the following terms “…..it is clear that the law does not require that a doctor in the discharge of his duty of care should use the highest degree of skill since they may never be acquired. It is enough for the doctor to show that he acted in accordance with the general and approved practice…..”

In another case in the consumer jurisdiction, Justice Shah opined that, “in any treatment it is never claimed by the medical profession that every person who receives the treatment must and should be benefited by the same because the benefit of a particular type of system or operation or medicine depends upon a number of factors…..”[^70]

Since the application of the Consumer Protection Act to the medical field, a number of legal principles have been postulated in various judgments by the consumer courts. The legal system has so far shown remarkable maturity in dealing with complicated technical issues based on expert opinion, standard textbook reference and other evidence. The Court has held that all complaints being brought about deficiency in service based on the ground of negligence in rendering medical services, do not involve complicated questions requiring of evidence of experts. It is now presumed that intricate technical questions of medical negligence requiring expert witnesses to be summoned and cross-examination conducted would have to be referred to civil courts. In the case of *Bhavchandbhai Manjibhai Lakhani v Dr.Bhupendra D Sagar*,[^71] the consumer forum has, with help of expert witness cross-examination, held a medical practitioner negligent.

[^70]: Shri Ram Singh Parmar v Mr.Sampat Raj C Shah & Anr, 1993 (2) CPR 496 (Guj. SCDRC)
[^71]: Complaint no.378 of 1991, decided on 26-8-1993 (Guj. SCDRC) Unreported
From the analysis of the literature it is observed that, there is no comprehensive empirical study or any triangular study on the application of CPA on doctors. There has not been any analytical or comparative study or any local study on the trends emerging out of inclusion of doctors in CPA. Critical evaluation on any variable or influencing factor also does not exist. Therefore, there is a need to conduct a thorough research in order to locate these trends at the local, state and national level. Further, there is a need to assess the response of the professionals and the changing nature of doctor-patient relationship in post-CPA period. Moreover, the resistance of IMC also requires to be put in context.

Further, the researcher has a personal pain area of being a litigant and also has observed the ignorance of medical professionals about the working of this law. Thus, the research on trends and changing trends with reference to Medical negligence is designed.

**Trend**

A ‘trend’ can be defined by various ways; the accepted definitions of the trend are as follows:

1. A general direction in which something is developing or changing.  
2. A gradual change or development that produces result.
3. A general tendency in the way a situation is changing or developing
4. A pattern of gradual change in a condition, output, or process, or an average or general tendency of a series of data points to move in a certain direction over time, represented by a line or curve on a graph.

The study of changes taking place after the application of the Consumer Protection Act to the Medical Field, will define the trend in this particular ‘Law’ and thus being studied by the researcher.

**Law**

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72 Available at http://oxforddictionaries.com/definition/english/trend  
73 Available at http://www.macmillandictionary.com/dictionary/british/trend  
74 Available at http://www.ldoceanline.com/dictionary/trend  
75 Available at http://www.businessdictionary.com/definition/trend.html#ixzz2LokXsx1G
In order to define and study the trends in the “Law” of Medical Negligence under Consumer Protection Act, the term law means:

1. *[mass noun] (often the law)* the system of rules which a particular country or community recognizes as regulating the actions of its members and which it may enforce by the imposition of penalties.\(^{76}\)

2. The principles and regulations established in a community by some authority and applicable to its people, whether in the form of legislation or of custom and policies recognized and enforced by judicial decision.\(^{77}\)

Though there is no exact “Law of Medical Negligence”, the laws Governing Medical Negligence like Law of Torts, Criminal Law and Consumer Law has been taken as laws of medical negligence. With these concepts fixed as the basis for the framework, the following objectives are identified.

### 1.4. Objectives

To study the concept of the Law of Medical Negligence, the objectives of this study can be defined as follows-

1. To study the concept of medical Negligence as a whole under various Indian laws, including case laws and legislation, *inter alia*, decisions of Medical Councils related to the cases of Medical Negligence, Law of Torts, Criminal law, law of Contract, Medical council Act and Consumer Protection Act.

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.
1.5 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?

1.6 Scope of the Study
The concept of medical Negligence has been studied as a whole under various Indian Laws; Law of Torts, Criminal law, law of Contract, Medical council Act and Consumer Protection Act The judgments of various case laws under the Consumer Protection Act are studied from the beginning up to March 2013 combining local trends in Pune and aligning them with state and national trends. The current and Changing Trends in the law of Medical Negligence under various laws and foreign laws are observed and postulate to predict the further changes. The study and evaluation of the lacunae in the Consumer Protection Act and its implementation, have guided the corrective measures that can be recommended. The study of International approach towards the Medical Negligence provided, by studying foreign case laws, thus locating International Trends in the Medical Negligence.

1.7 Methodology
This mixed methods study has addressed the, “Changing Trends in the law of Medical Negligence under Consumer Protection Act 1986”. A triangulation; Mixed Methods Design: Convergence Variant was used, a type of design in which different but complementary Data are collected on the same topic. This is the

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combination of the result of more than two rigorous approaches conducted to provide a more comprehensive picture of the results than either approach could do alone.  

In this study, the Quantitative Instruments, through 31 identified variables that affect the concept of Medical Negligence are used to establish the Theory of Changing Trends in the Law of Medical Negligence. There is an analysis of case laws of Supreme Court obtained as doctrinal data, the decided cases from National Commission from its website as well as MCI Guidelines and Bill as primary data and locally-generated 10 selective cases of Pune appealed at the State Commission as primary data are analyzed and are finally compared.

Also, there is a pure empirical data based component that studies the perception of the affected sections of Society, i.e., the Doctors, Hospital Administrators and Community members in Pune by tool of questionnaires.

Questionnaire for 427 Doctors, Specialists, Super specialists and 41 Hospital Administrators from Pune and Questionnaire for 428 Community Members from Pune

Further, structured schedule was used as a tool to Interview experts such as Prof Graeme Laurie of Edinburgh Law School, Scotland.UK, along with 24 doctors, Specialists and 20 community members.

The tools for the research are the ones used to collect data for both the Doctrinal and Empirical research.

**Tools for Doctrinal Research:** The case laws decided at Supreme Court available at [http://judis.nic.in](http://judis.nic.in) and National Commission available at the website of National Commission [www.confonet.in](http://www.confonet.in) and various books available.

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80 Annexure V
81 See Annexure VII
82 See Annexure, V
The case laws were analyzed for 31 variables and their interrelationships.\(^{83}\)

**Tools for Empirical Research** included the following:

a. Questionnaire for Awareness of Doctors
b. Questionnaire for Awareness of Community
c. Questionnaire for Awareness of Hospital Administrators
d. Interview Schedule for Judges and Medical Law Experts
e. Case Studies 10 from Pune District Forum that are in Appeal at State Consumer Redressal Commission, Mumbai.

Concurrently, Qualitative methods are used in Surveys of Doctors, Hospital Administrators and Community; and Case laws including 10 cases from Pune District Consumer Forum that approached State and National Commission are used to explore the Changing Trends in the Law of Medical Negligence. The reason for collecting both quantitative and qualitative data is to bring together the strengths of both forms of research to corroborate results.

This Convergence study has defined what similarities and the differences exist across levels of analysis. The study was a concurrent one and was conducted in a Single phase. During the study, an attempt was made, to assess different aspects of reasoning that led to the postulations of various legal principles applied under the Consumer Protection Act.

The researcher has specifically studied foreign case laws on Medical Negligence, in order to compare the similarities and differences. The comparative study of all the case laws is being utilized to evaluate the changing trends in the law of medical negligence.

- Study of Indian and Foreign scenario
- Study of MCI guidelines

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\(^{83}\) See Annexure VI
Further, diagrammatic overview of the methodology follows:

**Triangulation design**

![Diagram](image)

**Triangulation Design: Convergence model**

![Diagram](image)


**Figure 2**
Figure 3

Library Study

Case Law Analysis

Analysis of Legislations and MCI

Doctrinal Method

Triangulation

Empirical method

Interviews

Doctors, Community, Experts

Surveys

Doctors, Community

Changing Trends in law of Medical Negligence

Case studies

10 Pune Cases in state and National
Details

A: Doctrinal Study

Variables for Quantitative Analysis of Case Laws were designed and developed after thorough conceptualization and theoretical study on medical negligence laws.

Sample

The study sample consisted of 40 case laws of Supreme Court and 300 case laws of the National Consumer Disputes Redressal Commission (hereinafter National Commission) from its inception till March 2013. The cases were selected from the web sources, www.judis.nic.in and www.confonet.in based on the cause of action- "Medical Negligence". The method for the cases section was Purposive sampling, as by March 2013, the number of cases available from Supreme Court was 40 from all available resources. Similarly the total number of cases available from National Commission was 300 from all available resources. So these sample Case laws selected belong to Universal data. Total Universe of Medical Negligence Case law data available till March 2013 was studied for the purpose of research.

Development of variables

After studying the case laws, 31 variables were developed. These are developed by reading and analyzing various concepts from the articles on the topic. The variables are based on the relationship of various factors with the Medical Negligence. Coding was planned and coding was done for all the variables for the samples selected from case laws. Statistical analysis was done after the coding of all the case laws.

Validity

Validity means the researcher can draw meaningful inferences from the results to a population.

Reliability

Reliability means that scores received from participants are consistent and stable over time. 

84 Abbas Tashakkori & Charles Teddlie, PRINCIPLES OF MIXED METHODS AND MULTIMETHOD RESEARCH DESIGN, 2003 edition; HANDBOOK OF MIXED METHODS IN SOCIAL AND BEHAVIOURAL RESEARCH, 2003 edition, pp.190 and after discussion with Dr. K.P. Suresh, Scientist (Biostatistics), Project Directorate on Animal Disease Monitoring and Surveillance, Bangalore-560024
B: Empirical Study

Design and Development of scale: Sample
The study sample consisted of 427 doctors, 41 hospital administrators and 428 community members constituted the random sample. Three scales were designed to collect the information related to the construct “Concept of Medical Negligence defined under various laws in India and abroad”

Broad themes explored in the Questions for doctors and Hospital Administrators are as follows,
- Awareness about CPA
- Awareness about Trend Setting Cases
- Knowledge of Concepts of Medical Negligence and Deficiency in Service
- Knowledge of Bolam and Bolitho Principles
- Awareness of MCI Regulations
- Legal Concepts of Valid Consent, Prior Informed Consent and Doctor Patient Relationship
- Knowledge of Professional Indemnity Insurance
- Knowledge the concepts of Evidence Based Medicine, Treatment Protocols
- Knowledge Concepts of Vicarious Liability, Second Opinion and Documentation
- Personal Opinion about applicability of CPA to Medical Field, Impact of CPA and Alternatives

Broad themes explored in the Community Questionnaire are as follows,
- Awareness about CPA
- Own Experience about Medical Treatment
- Opinion about the applicability of CPA to doctors
- Impact of CPA on Doctors and Doctor Patient Relationship
- Trust in Doctors and Need of Second Opinion.
Technique and Procedure
The objective of developing a scale is to create a valid measure of an underlying construct. The theoretical principles, practical issues, and pragmatic decisions must be considered in construct validity of scales and the subscales. It is essential to conceptualize on the content of the scale and the initial item pool should include items representing all the subsections of the scale, if any.

The method of wording the content and formulation of the statements need careful attention. The item pool should be later tested, along with variables and the objectives of the study to assess closely related constructs, on a heterogeneous sample representing the entire range of the target population. Finally, in selecting scale items, the goal is uni-dimensionality rather than internal consistency; this means that virtually all inter-item correlations should be moderate in magnitude.

Validity: It is the most important consideration when developing, evaluating and interpreting tests. It refers to the appropriateness, meaningfulness, and usefulness of the specific inferences researchers make based on the data they collect. Validity has been described as the agreement between a test score or measure and the quality it is believed to measure. It is the most important step to be considered when preparing or selecting an instrument for research study and the degree to which evidence and theory support the interpretations of test scores entailed by the proposed test.

Creation of item pool and face validity:
Once the objectives and the content domain were tentatively identified, the task of formulating the items/questions for the scale was completed. The formulation of the initial pool of items related to the various domains is a crucial task for developing the scale. The fundamental goal at this juncture is to formulate all content systematically in a sequential manner that is potentially relevant to the target construct. The

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importance of the initial literature review becomes quite obvious in this process. Loevinger (1957) offered the classic articulation of this process: "The items of the pool should be chosen so as to sample all possible contents which might comprise the putative trait according to all known alternative theories of the trait ".

For the present study the items / questions reviewed from books, journals and electronic media were identified, adapted and compiled in framing of 100 items for doctors and administrators and 20 items for community members that covered the aspects of Concept of Medical Negligence defined under various laws in India and abroad" on a five -points Likert scale – 1: Strongly disagree, 2: Disagree, 3: Neutral, 4: Agree and 5: Strongly agree.

**Content Validity:** Content Validity is based on the extent to which a measurement reflects the specific intended domain of content. It refers to the conceptualization of the statements for developing the scale for the study. If the researcher has focused in too closely on only one type or narrow dimension of a construct or concept, then it is conceivable that other indicators are overlooked. In such a case, the study lacks content validity. An estimate of content validity of a test is obtained by thoroughly and systematically examining the test items to determine the extent to which they reflect and do not reflect the content domain.

For the present study, the individual statement was drawn from a large pool of items that covered Concept of Medical Negligence defined under various laws in India and abroad. The developed scale was assessed for both face and content validity by a panel of experts from the field of Medical professionals, Community and Hospital administrators. All the items pooled were subjected to face, screened to have 70 for Doctors and Administrators and 15 for Community members. The scales of 70 items

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88 Griner PF, Mayewski RJ, Mushlin Al, Greenland P (1981) SELECTION AND INTERPRETATION OF DIAGNOSTIC TESTS AND PROCEDURES., Annals of Internal Medicine, 94, 555-600
and 15 items respectively were further subjected to content validity with 3 panels of experts. The experts were requested to score each item in scale as 1 for not relevant and 10 for not relevant in a 10-point scale. The Scoring pattern obtained by experts analyzed using the AIKEN`s Index. The items which satisfied Aiken`s Index more than 0.70 were included in the scale otherwise it removed. The following procedure in eight steps of Aiken`s V index for content validity are as follows.89

- n experts rate the degree to which the item taps an objective on a 1 to c on Likert-scale, where c is the maximum score in grading scale
- Let lo = the lowest possible validity rating (usually, this is 1 on the Likert-scale)
- Let r = the rating by an expert
- Let s = r – lo
- Let S = the sum of s for the n raters
- Aiken`s V is then V = S / [n*(c-1)]

Construct validity is done with evidence that the test measures what it purports to measure as well as evidence that the test does not measure irrelevant attributes are both required.

**Readability Test:** For the present study, 57 items for Doctors/Administrators and 10 items for community items were formulated for studying the Concept of Medical Negligence defined under various laws in India and abroad. After the tool was developed, a draft copy of the tool was prepared and was tested for readability by the investigator so as to ensure that the items of the tool did not have double barrel questions, the items were not contradicting in nature and also further to ensure that there was no repetition of any items with similar meanings.

**Reliability** is the extent to which a test or procedure produces similar results under constant conditions on all occasions. For the present study, test-retest method was used to assess the reliability of the instruments. The following reliability test was carried out to estimate the reliability.

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Pilot Study
A pilot study was conducted on a sub-sample of 50 doctors and hospital administrators; and 50 community members. The Pilot study ensured that the items in the scales were made easy, understandable by respondents, flexible for administration of scale; the reliability measure such as Spilt-half reliability was performed to know the reliability of scales and Cron bach Alpha was also performed on the pilot study results to find the uni-dimensionality of scales.

The scale for measuring the Concept of Medical Negligence defined under various laws in India and abroad for doctors and administrators consisted of 57 and 10 items for community members finally constructed after meeting criteria of face validity, Content validity and reliability measures. Scales were subjected to Pilot study with sample of 50 doctors/administrators and 50 community members for measuring the spilt-half reliability. The Spilt-half reliability measures shown that, Scale for doctors/administrators has reliability co-efficient of 0.869 and 0.804 respectively and for community it was 0.82. The Cron bach alpha for consistency and uni-dimensionality were 0.806 and 0.791 respectively for the scale of doctors and administrators and 0.911 for the scale of community members. Hence the developed scale was more reliable and valid.
1.8 Limitation

This research study is limited by the jurisdiction which is limited to Pune. Though overall the case laws at National Commission have been studied, actual study of live cases and the awareness survey of Doctors and Patients are restricted to Pune District. Also, the case laws study is restricted to the time from the application of the Consumer Protection Act to the Medical Field i.e. 1987 to present i.e. 2013. Thus the researcher has studied the trends in the said for the period of about 25 years, but local study is restricted to the Pune District.

Since the concept of Medical Negligence is a complicated issue, is more than a matter between two parties- it is also a political issue. A subdivision of common law that has engaged the attention of civil courts, in particular consumer forums, for last few decades is ‘negligence’, especially that of medical professionals. Litigation arising from death or serious physical injury that a patient suffers as a result of negligence in their treatment by medical professional has overburdened courts. It has spread through India like an epidemic, without showing any signs of passing.

The next chapter elaborates the concept of Medical Negligence as a whole, extracted and analyzed from various branches of law in India and across the world.

90 Mason J.K. , Laurie GT 2006, LIABILITY FOR MEDICAL INJURY, Law and Medical Ethics, p.296
91 Tapas Kumar Koley, 2010 MEDICAL NEGLIGENCE AND THE LAW IN INDIA, Medical Negligence and Civil Laws, p 21