

The Veracity of Laws relating to Medical Malpractice in India



By

Aditya Singhal

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Scope and Nature

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Preface

The relationship between a doctor and his patient is considered sacred in India. A Doctor is compared to “God”. In recent times, instances of malpractice and negligence in the medical field have increased fourfold. The problem arises in ascertaining liability, whether the doctor was negligent or not is a very technical & subjective question, which is difficult to decide. There is always a possibility of alternate treatment but that does not make the doctor negligent for providing the first treatment. In this situation, a person who loses his life due to a treatment might not be eligible to get any compensation and his dependents are left in a dilemma. Further, the doctor will always try to play safe and order more procedures to avoid any liability, which in a way would create a burden on the economy. The existing legal framework does not provide to help & safeguard both the doctors and patients without compromising on the quality of healthcare or burdening the economy.

This study is compiled with the help of a literary survey. The research methodology is essentially analytical method with support of empirical and descriptive method. The nature of study that I undertook involved a review of existing literature on the subject and will also involve empirical data collection. The work shall follow a definite scheme of action, wherein it would first define the topic, after which it would delve into the various aspects of the topic, while at the same time critically analyzing the relevant aspects. It includes latest statutes, bills, guidelines, draft legislation and case laws updated till April 2015. An attempt has been made to make the contents lucid yet exhaustive.

I was fortunate to have Professor of Eminence and Chair Professor for Chair for Law Prof. M.K. Balachandran, Amity Law School, Delhi as my supervisor and mentor; his inputs helped create the path of this study, his patience and critical questioning throughout the process helped me immensely to reassert and understand the subject matter more thoroughly. I would like to extend my gratitude to my family and friends for their constant support and without whom I would not have been able to complete this study.

Despite every possible care taken by the Author, some errors or omission might have crept in while preparing the study. The Author will be highly obliged if such errors or imperfections are brought to his knowledge. Any fruitful and constructive criticism is always welcome.

Aditya Singhal

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Author

I, Aditya Singhal, a final year law student at the Amity Law School (GGSIPU), Delhi have been an academically proficient student consistently maintaining my position at the top of the class through my academic years, for which I have been bestowed with several awards. In 5 years of LLB course, in addition to opting for wide-ranging electives, I have tried to widen my scope of subject understanding by working as an intern at a law NGO and training under senior IPR advocate, former Additional Solicitor General of India and High Court Judge. These experiences presented me with divergent intellectual and moral challenges that I have enjoyed to ruminate and solve.

My desire to study law developed as early as my school days. I am working as a community service volunteer with the under-privileged made me question the structure, relevance and implementation of legal rights and framework in India. The urge to deploy legal remedies to develop an equitable society firmed my conscious decision of pursuing a bachelor's degree in law. The dismal record of legal recourse in India is something I continue to feel strongly about. My training in the field of law has helped to appreciate that the Indian legal system echoes the famous lines in Magna Carta "To No One We Shall Sell, To No One We Shall Deny or Defer Right or Justice" in its true sense.

Steve Jobs, the great visionary and creative thinker, in an inspiring speech a few years ago at the Stanford Commencement address said, *'You can't connect the dots looking forward; you can only connect them looking backwards. So you have to trust that the dots will somehow connect in your future'*. By referring to 'dots' Steve Jobs meant the varied experiences an individual acquires in the course of one's life. In concurrence with the views of the legend, I too strongly believe that every bit of knowledge imbibed, every experience acquired, how trivial it may seem at that point in life will eventually find its relevance. It is just a matter of time before one is able to connect the dots.

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CHAPTER I – INTRODUCTION

Negligence can be generally defined as ‘Conduct that is culpable because it falls short of what a reasonable person would do to protect another individual from foreseeable risks of harm’.

Tort law is the name given to a body of law that addresses, and provides remedies for, civil wrongs not arising out of contractual obligations. Tort liability performs two primary functions. First, by providing compensation it acts as a source of insurance. Second, by imposing sanctions on persons found negligent, it deters future negligent behaviour. Torts fall into three general categories: intentional torts, negligent torts and strict liability torts. Intentional torts are those wrongs which the injurer knew or should have known would occur through his actions or inactions. Negligent torts occur when the injurer's actions were unreasonably unsafe. Strict liability wrongs do not depend on the degree of carefulness adopted by the injurer, but are established when a particular action causes damage. According to the Indian law, cases of medical negligence fall under negligent torts.

Medical negligence is a complicated subject, since medical treatments are inherently risky. A medical treatment always involves a basic risk that something might go wrong. In addition, human body of patients can react differently to the same treatment. There are occasions when patients are harmed as a consequence of their treatment or absence or even delay of it. In the case of *Hunter v. Hanley*¹, Lord President Clyde gave a concise and succinct definition of medical negligence, he said: “*The true test for establishing negligence in diagnosis or treatment on the part of the doctor is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would have been guilty of, if acting with reasonable care*”.

In order to prove medical negligence under the negligence rule, the aggrieved patient must be able to establish to the satisfaction of the court that:

- (a) The doctor owed him a duty of care of a particular standard of professional conduct.
- (b) The doctor contravened the duty.
- (c) The patient suffered damage.
- (d) The doctor's conduct was the direct and the proximate cause of damage.

STATEMENT OF PROBLEM

The legal purpose of compensation is on the one hand to redress for the non-pecuniary losses suffered and on the other hand satisfaction in the sense that the injurer is made to pay for his negligent action. However, these purposes of compensation are in some medical cases difficult to justify. For instance, medical science can keep people alive in a state of complete coma for many months or even years, with no hope of recovery. No

¹ 1955 (1st Division, Court of Session, Scotland).

substitute pleasures need to be provided for those forgone, because the injured party is unable to enjoy any pleasures. Nevertheless, courts say that a person who is deprived of all the pleasures of life gets compensation for the fact of that deprivation. Thus, from an economic point of view, on the one hand the victim gets no utility from an award of damages in these cases and therefore would not need compensation. But on the other hand only full compensation has the deterrent effect on the injurer. Therefore, it is necessary to make the injurer pay full compensation to the victim.

Another problem with compensation for pain and suffering is that, it is very difficult to calculate, because the relationship between the value of money – what it will buy – and damages awarded for pain and suffering cannot be measured in financial losses.

Punitive damages are sometimes awarded to plaintiffs in addition to compensatory damages, i.e. over and above compensation for material and immaterial losses. These are only awarded in cases where injurers might escape liability or where harm is underestimated or where the injurers' gains are socially illicit, because punishment and deterrence are supposed to lead to only full compensation. Thus, they also involve the danger of overcompensation and over deterrence, since the damage paid by the injurer exceeds the damage suffered by the victim. Although the term punitive damage implies punishment, the purpose of these damages is only partly punishment, but mainly deterrence.

To decide on the quantum and type of remedy to be provided, the decision-makers i.e the Courts lack the perfect information that needs to be assumed. It is because of this that the negligence rule has come under severe criticism. Because courts lack perfect information about appropriate care, the standards applied in practice are unpredictable and possibly systematically biased. With uncertain legal standards, a negligence rule may not be able to convey to doctors the appropriate signals about the optimal level of care. A rule of strict liability in theory eliminates the need for courts to define due care.

Thus, in the situation of judicial errors in appropriating liability level, the negligence regime is relatively more sensitive concerning the level of care adopted by the injurer (doctors or hospital authorities) and the appropriate level of care. The strict liability regime, on the other hand, does not suffer from such errors. There is, however, more chances of judicial errors concerning causality and damage assessment i.e. determining whether an injury was caused by medical care or by the underlying disease and the extent of damage.

The argument to whether select negligence rule over strict liability in the area of medical liability is still a concern, despite the flaws in both the rules the courts have to conclude to bring stability and clarity by establishing a rule of law that provides for an appropriate remedy.

OBJECTIVES OF STUDY

In this dissertation, I aim to analyze the Indian medical law to prevent malpractice. Foremost, it is of utmost importance to define the characteristic features of a medical services market. These characteristics give the medical market a distinct identity and hence necessitate a unique analysis of the negligence tort law pertaining to medical cases. Secondly, The legal framework and its impact over the years through a study of cases and the legal avenues will be analysed. Further the awareness of available remedies and the possible ways to make the system more efficient will tried to be put forward.

HYPOTHESIS

The relationship between a doctor and his patient is considered sacred in India. A Doctor is compared to “God”. In recent times, instances of malpractice and negligence in the medical field have increased fourfold. The problem arises in ascertaining liability, whether the doctor was negligent or not is a very technical & subjective question, which is difficult to decide. There is always a possibility of alternate treatment but that does not make the doctor negligent for providing the first treatment. In this situation, a person who loses his life due to a treatment might not be eligible to get any compensation and his dependents are left in a dilemma. Further, the doctor will always try to play safe and order more procedures to avoid any liability, which in a way would create a burden on the economy. The existing legal framework does not provide to help & safeguard both the doctors and patients without compromising on the quality of healthcare or burdening the economy.

METHODOLOGY

The dissertation will be compiled with the help of a literary survey. The research methodology will be essentially analytical method with support of empirical and descriptive method. The nature of study that I propose to undertake involves a review of existing literature on the subject and will also involve empirical data collection. The dissertation shall follow a definite scheme of action, wherein it would first define the topic, after which it would delve into the various aspects of the topic, while at the same time critically analyzing the relevant aspects.

My entire dissertation is divided in to five chapters along with this introduction wherein the meaning, definition, explanation of the concept and will deal with the current legal framework in India regarding the malpractices in the medical field. I will give the details of all the statutory laws and the medical guidelines in this chapter.

The second chapter of my dissertation deals with the possible ways to make the system more efficient. This chapter would deal with the pending and proposed laws that could change the system favorably and also other methods like health care insurance, guidelines and shared liability of the doctor & medical institution.

The third chapter deals with empirical research using questionnaires filed by doctors and patients about their awareness and acceptance of the current malpractice law. Also it would try to look into what according to them is a possible solution to this problem.

The fourth chapter deals with the economic impact of the malpractice law. The doctors recommend more tests and procedures to avoid liability, a practice known as “defensive medicine”. To cover the future liabilities, the medical institutions and doctors take insurance, the burden of these expenses maybe shifted to the patients and result in a higher health care spending.

The fifth chapter deals with the judicial pronouncements on medical malpractice and negligence in India. This chapter essentially deals with the justification and the grounds that formulate the rules regarding remedies and punishment in the medical malpractice law, i.e whether a hospital or a doctor would be responsible as laid down by the apex court. I will also try to look into the methodology of the courts in awarding compensation in various cases of mis-happening during a medical procedure.

My dissertation will end with the sixth chapter that puts down various newspaper reports regarding the medical negligence situation prevalent in India. This chapter would end with the conclusion regarding my hypothesis. In this segment I will try to summarize how far the current legal framework is effective in the present situation vis-à-vis recent cases of medical malpractice and the possible positive steps to be taken to maintain the health care standards, minimise the effect on economics, provide adequate relief to patients and provide the doctors environment to work fearlessly.

The Nature of Demand

The most distinguishing feature of the demand for medical services is that it is not steady, as for food or clothing, but rather irregular and unpredictable. As a consequence of this it is difficult to become an informed shopper until it is too late. In addition, medical services, apart from preventive services, provide satisfaction only in the event of ill health, which is a deviation from the normal well-being.

The Expected Behavior of the Physician

The expected behavior of the sellers of medical care is distinct from that of businessmen, because medical care is a commodity for which the product and the activity of production are identical. As a result of this the consumer cannot test the product before consuming it, and hence the medical market has the innate characteristic of trust being built into it.

Product Uncertainty

The treatment in itself possesses a risk and 100 percent success is not guaranteed even if the doctor applies the highest level of care. There exist causation problems; in the sense that the fact that human body can react differently and unexpectedly to certain treatments has to be taken into account. Thus, a doctor cannot always guarantee the success of his treatment and should not be held liable for every bad or insufficient treatment result.

Information Asymmetry

The doctor-patient relationship is dominated by asymmetric information. First, the patient as a person not having medical knowledge has problems to gain insight in the treatment of the professional physician. It is difficult for the patient to follow the chain of causation. Since in hospitals a medical team of doctors, nurses, assistants etc. is involved in the treatment, it is hard to determine who contributed to the malpractice and to what extent.

Thus, the injury could have multiple causes. Especially in cases where the patient is unconscious or under anesthesia, he will not be able to ascertain who contributed to what extent to his injury. Furthermore, due to the complex hierarchical organization of a hospital the problem arises that the patient may not know the names of the persons and who is responsible for whom.

Second, the reality that most medical information is technically complex is made worse by the fact that many illnesses do not repeat themselves, so that the cost of gaining the information is very high for every patient. It can be argued that the ideal way a patient could become fully informed would be by becoming a doctor, which is too improbable a situation.

Third, only the physician himself can influence his own level of care, it belongs to his sphere of control, whereas the patient has no influence on the conduct of the physician, he has to rely on the knowledge and the qualification of the physician. As a consequence of the inherent information asymmetry in medical care, the patient will have severe difficulties in proving that the doctor acted negligently, i.e. violating the customary skills and practices of the profession.

The next section outlines briefly the existing legal framework in India pertaining to cases of medical negligence.

LEGAL FRAMEWORK IN INDIA

The legal framework of Indian law effecting the medical profession and to prevent malpractice must be introduced. In India, various legal avenues are available to an aggrieved patient to sue a healthcare professional.

1. Fundamental Rights (Part III of the Indian Constitution)
 - 1.1. Article 21
 - 1.2. Article 32

2. Directive Principles of State Policy (Part IV of the Indian Constitution)
 - 2.1. Article 41
 - 2.2. Article 42
 - 2.3. Article 47

3. Indian Penal Code² (IPC)
 - 3.1. Section 52
 - 3.2. Section 80
 - 3.3. Section 81
 - 3.4. Section 88
 - 3.5. Section 90
 - 3.6. Section 92
 - 3.7. Section 304-A
 - 3.8. Section 337

² Act 45 of 1860.

3.9. Section 338

4. Indian Medical Council Act³ (IMC)
5. Consumer Protection Act⁴ (CPA)
6. Public Interest Litigation⁵ (PIL)

The Constitution of India

The Constitution of India does not provide any special rights to the patient. In fact the patient's rights are basically indirect rights, which arise or flow from the relevant 'Articles' which can be applied to cases of medical negligence.

Article 21. 'Protection of life and personal liberty': No person shall be deprived of his life or personal liberty except according to procedure established by law.

Article 32. 'Remedies for enforcement of rights' conferred by this Part:

(1) The right to move the Supreme Court by appropriate proceedings for the enforcement of the rights conferred by this Part is guaranteed.

(2) The Supreme Court shall have power to issue directions or orders or writs, including writs in the nature of habeas corpus, mandamus, prohibition, quo warranto and certiorari, whichever may be appropriate, for the enforcement of any of the rights conferred by this Part.

(3) Without prejudice to the powers conferred on the Supreme Court by clauses (1) and (2), Parliament may by law empower any other court to exercise within the local limits of its jurisdiction all or any of the powers exercisable by the Supreme Court under clause (2).

(4) The right guaranteed by this article shall not be suspended except as otherwise provided for by this Constitution.

The right to constitutional remedies therefore allows Indian citizens to stand up for their rights against anybody even the Government of India

Directive Principles of State Policy

These provisions are not enforced by any court, but the principles therein laid down are nevertheless fundamental in the governance of the country and it shall be the duty of the State to apply these principles in making laws.

Article 41. 'Right to work, to education and to public assistance in certain cases': The State shall, within the limits of its economic capacity and development, make effective

³ Act 102 of 1956.

⁴ Act 68 of 1986.

⁵ Article 32 of The Constitution of India.

provision for securing the right to work, to education and to public assistance in cases of unemployment, old age, sickness and disablement, and in other cases of undeserved want.

Article 42. ‘Provision for just and humane conditions of work and maternity relief’: The State shall make provision for securing just and humane conditions of work and for maternity relief.

Article 47. ‘Duty of the State to raise the level of nutrition and the standard of living and to improve public health’: The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purpose of intoxicating drinks and of drugs which are injurious to health.

The Indian Penal Code, 1860

The various sections of the Indian Penal Code that contain the law of medical malpractice in India are-

Section 52. "Good faith": Nothing is said to be done or believed in "good faith" which is done or believed without due care and attention.

Section 80. “Accident in doing a lawful act”: Nothing is an offence which is done by accident or misfortune and without any criminal intention or knowledge in the doing of a lawful act in a lawful manner by lawful means and with proper care and caution.

Section 81. “Act likely to cause harm, but done without criminal intent, and to prevent other harm”: Nothing is an offence merely by reason of its being done with the knowledge that it is likely to cause harm, if it be done without any criminal intention to cause harm, and in good faith for the purpose of preventing or avoiding other harm to person or property.

Section 88. “Act not intended to cause death, done by consent in good faith for person's benefit”: Nothing which is not intended to cause death, is an offence by reason of any harm which it may cause, or be intended by the doer to cause, or be known by the doer to be likely to cause, to any person for whose benefit it is done in good faith, and who has given a consent, whether expressed or implied, to suffer that harm, or to take the risk of that harm.

Section 90. ‘Consent known to be given under fear or misconception’: A consent is not such a consent as it is intended by any section of this Code, if the consent is given by a person under fear of injury, or under a misconception of fact, and if the person doing the act knows, or has reason to believe, that the consent was given in consequence of such fear or misconception, or by an insane person, or by a child.

Section 92. “Act done in good faith for benefit of a person without consent”: Nothing is an offence by reason of any harm which it may cause to a person for whose benefit it is done in good faith, even without that person's consent, if the circumstances are such that

it is impossible for that person to signify consent, or if that person is incapable of giving consent, and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done with benefit.

Section 304-A. ‘Causing death by negligence’: Whoever commits culpable homicide not amounting to murder shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or both. This is the relevant provision under which a complaint against a medical practitioner for alleged criminal medical negligence is registered.

Section 337. ‘Causing grievous hurt by act endangering life or personal safety of others’: Whoever causes grievous hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others, shall be punished with imprisonment of either description for term which may extend to two years, or with fine which may extend to one thousand rupees, or with both.

Section 338. ‘Causing hurt by act endangering life or personal liberty of others’: Whoever causes hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal liberty of others, shall be punished with imprisonment of either description for term which may extend to two years, or with fine which may extend to one thousand rupees, or with both.

Up till as recently as 2005, medical practitioners could be held liable under civil and criminal negligence both. A land mark verdict in this regard was that of *Dr Suresh Gupta v. Government of NCT of Delhi*⁶. It was felt by the jury that between civil and criminal liability of a doctor causing death of his patient, the court has a difficult task of weighing the degree of carelessness and negligence alleged on the part of the doctor. For conviction of a doctor for alleged criminal offence, the standard should be a proof of recklessness and deliberate wrong doing. To convict, a doctor, therefore the prosecution has to come out with a case of high degree of negligence on the part of the doctor. Mere lack of proper care, precaution and attention or inadvertence might create civil liability but not a criminal one.

Supreme Court thus ruled that doctors should not be held criminally responsible unless there is prime facie evidence before the Court in the form of a credible opinion from another competent doctor, preferably a Government doctor in the same field of medicine supporting the charges of a rash and negligent act. Such a decision is expected to increase the quality of service in emergency cases, which the doctors feared to attend because of the chances of being charged under section 304 and 304-A IPC for criminal negligence.

A doctor may be held liable for negligence on one of the two findings: either he was not possessed of the requisite skill which he professed to have possessed, or, he did not exercise, with reasonable competence in the given case, the skill which he did possess. The standard to be applied for judging, whether the person charged has been negligent or not, would be that of an ordinary competent person exercising - ordinary skill in the

⁶ (2004) 6 SCC 42.

medical profession.

The limited application of criminal prosecution against a medical practitioner therefore rests on the credible opinion from another competent doctor. In reality, however it is often claimed that physicians usually hesitate to testify against each other giving rise to a situation which is judicially labeled as the 'conspiracy of the silence'. Thus, under the existing law, it will be extremely difficult to hold a doctor criminally negligent.

The Indian Medical Council Act, 1956

IMC Act came into force in 1956, confers powers to the Medical Council of India to discipline erring members of the medical profession. However, this act does not have any provision for the award of damages to the complainant, though it has enough powers to punish the medical practitioners. *Section 24* of the Act, empowers the Council to remove the name of any person enrolled on a state medical register on the grounds of professional misconduct. The council, in addition prescribes standards of professional conduct, etiquette and code of ethics for medical practitioners. The medical councils are supposed to self regulate the medical profession by monitoring their skills, conduct and to provide for continuous education.

The Consumer Protection Act

Since the year 1996, cases of medical negligence have been brought under the purview of the Consumer Protection Act, 1986. This was the result of the landmark judgment in the case of *Indian Medical Association v. V.P Shantha and Others*⁷. This judgment resolved the questions regarding the definition of terms such as 'Deficiency', 'Consumer' and 'Service' with respect to the CPA's application to cases of medical negligence.

The Supreme Court order did not accept the claim of medical professionals who argued that the doctor-patient relationship is similar to a master-servant relationship, which is a 'contract of personal service' and should be exempted from CPA. The court in fact decreed that the doctor-patient relationship is a 'contract for personal service' and it is not a master-servant relationship. It is also said that the doctor is an independent contractor and the doctor, like the servant, is hired to perform a specific task. However, the master or principal (the patient) is allowed to direct only what is to be done, and when. The 'how' is left up to the specific discretion of the independent contractor (doctor). So, the doctor-patient relationship is a 'contract for personal service' and as such, cannot be excluded from CPA. The Supreme Court however held that 'A determination about the deficiency in service under the CPA is to be made by applying the same test as is applied in an action for damages for negligence'. The CPA however leaves outside its ambit services rendered free of charge by a medical practitioner attached to a hospital or nursing home. A payment of token amount for registration purpose only does not alter the position.

⁷ (1995) 6 SCC 651.

Public Interest Litigation (PIL)

Any person can directly approach the High Court or the Supreme Court by filing a PIL when any grievances affecting the public at large are not properly redressed. PILs are usually resorted to when public health programmes are not implemented properly. Some of the most prominent judgments in the domain of health related issues have been a consequence of PILs.

To cite an example, a Public Interest Litigation was filed in August, 2008 by Dr Kunal Saha at the Delhi High Court against the National AIDS Control Organization (NACO) for their devious role with sub-standard HIV kits that were used in different Indian hospitals/blood banks during the second national AIDS control project between 1999 and 2006. The court issued notices after hearing the public interest litigation, seeking a CBI investigation of the defective HIV kits being used, which were potentially endangering transmission of the deadly AIDS virus to innocent patients through contaminated blood transfusion.

CHAPTER II -EXPLORING POSSIBLE WAYS TO MAKE THE SYSTEM MORE EFFICIENT

IMPROVING THE CONSUMER PROTECTION ACT⁸

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No legal act is fool proof and CPA too has some deficiencies that need to be corrected in the interest of consumers and to maximize social welfare.

Some suggestions that could in fact make the Act robust are as follows-

(i) It is evident from our analysis of cases of medical negligence appearing before the NCDRC that the average number of years spent on a case is close to 9.5 years. Though on paper, the Consumer Protection act is aimed at redressing the grievances of the consumer at the earliest; in reality this is clearly not being achieved. Hence, the process must be expedited.

(ii) Over-ruling of decisions of both the state commission and district forum by the NCDRC¹⁰ indicates that the apex court may approach the case differently and there exists a possibility that NCDRC may give a verdict different from the lower forum. The presence of such possibilities in fact lengthens the judicial process. Such a problem may be solved if the cases of medical negligence are heard in the presence of an expert included among the members on panel as directed in Martin D'Souza's Case¹¹. This will

⁸ Act 68 of 1986.

⁹ (1995) 6 SCC 651.

¹⁰ National Consumer Dispute Redressal Commission.

¹¹ (2009) 3 SCC 1.

aid understanding of the jury about technical medical terminology, while at the same time make the opinion of an expert available and hence make the verdict more credible. But the same directions were rejected in *V.Kishan Rao v. Nikhil Super Specialty Hospital & Another*¹² which in my opinion should be looked at again.

(iii) It has been observed that in a large proportion of cases, the decision of district forum is overruled. This calls for a more diligent dealing of cases at this level, so that the need of taking the case further is reduced. In general, the aim must be to minimize the number of cases in which the decision of the lower courts is reversed by the NCDRC, to avoid unnecessary prolonged litigation.

(iv) At present, CPA¹³ does provide for a preliminary scrutiny of complaints before notice is sent to the respondent but the same is not effective, as the scrutiny is not done by medical experts. This is necessary so as to avoid CPA courts from being burdened with unnecessary complaints, and also to prevent undue harassments of respondents. This problem is well attested by our statistics. It was found that in only 23.6 percent of the cases was the plaintiff successful. A prior expert scrutiny may be able to increase this success rate.

(v) Under CPA goods purchased and used for profit/commercial purpose are excluded from the act. This provision needs to be corrected because it excludes all medical equipment used in hospitals. Defective equipment in health care can cause harm to the consumer leading to complaint against doctors. However, as per the Act the manufacturer goes scot-free.

(vi) Service hired free of cost is excluded from the ambit of CPA. This at one stroke excludes all government/municipal hospital doctors, giving rise to discrimination. This provision needs to be amended.

Decoupling of Liability

In suits between private individuals such as a doctor-patient medical malpractice case, liability usually is 'coupled'. This is in the sense that, aside from the parties' litigation costs; a successful plaintiff receives what the defendant pays. A 'decoupled' liability system is one in which the award to the plaintiff differs from the damages to be paid by the defendant.

But the question arises as to what is the rationale for decoupling liability and how with it introduce efficiency in the system?

Consider any level of liability when liability is coupled. This level of liability will determine the incentive of the victim i.e. patient to sue (the higher the award, the greater the incentive) and the incentive of the injurer i.e. doctor to take care. The parties' behavior in turn will determine the level of social costs – which are the sum of the injurer's cost of taking care, the victim's expected harm, and the parties' expected litigation costs.

¹² 2010 5 S.C.R. 1.

¹³ Consumer Protection Act.

To explain the concept, consider decoupling liability, starting at the specified level of coupled liability. Raising the amount paid by the doctor will cause him to take more care. Lowering the amount awarded to the patient will reduce his incentive to sue. This in effect will cause the doctor to take less care (since he knows that the chances of a patient suing are now lower) - which is allowed until the doctors' care is back to its level under coupled liability. Since the level of care is the same under this decoupled system and the original coupled system, so is the doctor's cost of taking care and the patient's expected harm. But since the victim is awarded less under the decoupled system, he will sue less often and, consequently, litigation costs will be lower, and this is achieved without sacrificing the injurer's incentive to exercise care. In this system, if the victim is awarded less than what the doctor pays, the government obtains the difference; if the victim is awarded more, the government provides the difference. Thus, starting from any level of coupled liability, there is always a decoupled system of liability that reduces social costs.

An example of a version of decoupled liability is seen in the medical sector in "Sweden". Patient compensation in Sweden is provided through the voluntary, contractual Patient Compensation Insurance¹⁴ that provides compensation without proof of provider liability through an administrative mechanism. The discipline of medical providers is handled by a separate Medical Responsibility Board¹⁵. Since the system is designed to provide compensation without regard to deterrence, it is often referred as the 'No-fault System'. The system in some sense is close to the strict liability rule.

In the system, two necessary conditions must be established for compensation under the PCI: (1) Proof of medical causation; and (2) An injury that could have been avoided. Thus, the criterion for compensability makes no reference to terms such as of fault, negligence, or medical error but the objective basis of the inquiry appears to be the same as under tort law. The MRB on the other hand, handles claims against medical providers that may be filed by either the public or the National Board of Health and Social Welfare (SOS). It also considers the revocation of licenses, the reissue of licenses after revocation, and restriction on authorization to prescribe drugs. The PCI is totally decoupled from the MRB, and the PCI information base on injuries is not systematically used to improve the quality of care.

It is estimated that the 'No-fault System' costs roughly 0.16% of health care costs in Sweden, while medical malpractice insurance premiums in the United States account for approximately 1% of health care expenditure – more than a tenfold difference.¹⁶

Although 'No-fault system' reduces the length of judicial procedures, compensates victims of medical injuries without putting any blame on health care providers and maintains a broad reach of compensation with low overall costs, but when examined carefully, this system also has its own barriers when applied. The system provides

¹⁴ PCI under the Patient Insurance Act.

¹⁵ MRB under the Ministry of Health and Social Affairs.

¹⁶ Danzon, Patricia M., "The Swedish Patient Compensation System: Myths and Realities", *International Review of Law and Economic*, 1994 available at <https://hcmg.wharton.upenn.edu/files>.

compensation conditional on medical causation but has no link to deterrence. It provides for less information and weaker incentives therefore for doctors to apply the required standard of care. The system also severely limits patient rights to pursue for litigation by reducing their probability of appealing to the court. Thus, the disclaimer is that choice of adoption of medical malpractice system should depend on the fact as to which system fits better for needs by taking into consideration the current judicial, social insurance and health care system of a country.

The table below summarizes the features of the two systems-

	Compensation Scheme	Administrative Costs	Benefits Awarded	Equity in access to compensation	Contribution to quality control/deterrence	Financing	Effectiveness
Tort System	Court Verdict	Costly for both parties	Unpredictable, higher payments especially for pain and suffering	Difficult, costly to prove negligence, difficult to access the system	Yes by judicial remedies, premiums, humiliation, defensive medicine	Indirectly by liability premiums, directly by Insurers	Costly, lengthy, unpredictable
No-fault System	For injuries that fit into injury treatment criteria and are avoidable, PCI is liable	Minimal, no litigation costs.	75% of economic damages paid, non-economic damages payable for physical injuries	Easy to file claims, no need of a lawyer if not appealed to court.	Deterrence is not an issue. It controls amount of indemnities to detain health care costs.	The county councils, liability premiums of private providers and copayments for outpatient services.	Predictable awards, easy access to system, less costly and short decision process.

Allocation of Burden of Proof in Medical Malpractice Cases¹⁷

The rule for burden of proof determines who, the plaintiff or defendant, be required to present evidence to the court. In context of medical malpractice cases, the rule determines whether the doctor or the patient must bring in the evidence. This is essentially a question of risk allocation, i.e. it dictates who, defendant or the plaintiff should bear the risk of not having sufficient evidence to present in the court. Generally, law determines who bears the burden of proof, but the courts can apply some special evidence rules depending upon

¹⁷ Wieland, Mariam, “The Economic Analysis of German Medical Malpractice Law”, 2001, available at www.brarian.net/.../Erasmus_Programme_in_Law___Economics.

the specific case.

In general, the Indian law allocates the burden of proof to the plaintiff (i.e. the patient). The law requires a higher standard of evidence than otherwise to support an allegation of negligence against a doctor. The plaintiff first has to prove a malpractice, second damage and third the causal relation between the negligence and the damage caused. Thus, difficulties arise for the proof of negligence and especially for the proof of the causal relations.

There are special evidence rules in malpractice cases which simplify the burden of proof in favour of the patients. One such principle is 'res ipsa loquitur' meaning that the thing speaks for itself. It is applicable in cases where the accident could not have happened without negligence and the circumstances conclusively show that the doctor and not any other person were negligent. In such circumstances no proof of negligence is required beyond the accident itself. In that case the plaintiff will get 100% of the damage as compensation. The defendant can rebut the court's presumption by presenting some proof that will at least shake the court's prima facie conviction.

However, in a lot of medical malpractice cases the plaintiff will not succeed in convincing the judge to the necessary extent, because in the field of medicine there can always happen something unexpectedly due to the nature of the human body. Thus, the physician can often claim that the way the malpractice happened was an atypical chain of causation. Then, the burden of producing complete proof reverts to the plaintiff.

Considering a reversal of burden of proof and its consequences.

Reverse burden of proof means that instead of the patient being required to prove the evidence, the physician bears the entire burden of proof. It has to be examined, if economic reasons support this line of argumentation. At first sight a negligence rule with reversed burden of proof might seem to be simply the opposite of the usual negligence rule where the plaintiff has to prove only one efficient step to prevent the damage that the defendant did not undertake. However, in the case of reversed burden of proof the defendant is in a more hard position, since he has to prove that there was no other possible step, which he could have undertaken to prevent the damage. This means, first he has to search for all possible ways to prevent the damage (that any other doctor with ordinary skills could have taken) and then he has to prove that all these possible steps are not cost justified, whereas the plaintiff in the case of the usual negligence rule only has to search among the different damage prevention projects until he finds a cost justified one. Thus, the negligence rule with reversed burden of proof causes for the defendant a more difficult situation compared to the plaintiff in case of the usual negligence rule. Therefore, the former is not simply the opposite of the latter. Hence, even if the defendant is the cheaper information provider regarding collecting evidence, this does not automatically justify a reversed burden of proof. Since a reversed burden of proof causes immensely high information cost for the defendant, he has difficulties to defend himself and therefore he will only in very rare cases succeed. Thus, in general the economic effect of a reversed burden of proof resembles the effect of strict liability where the defendant has no possibility to exculpate himself.

'Physician' – The Cheapest Information Provider

In the context of medical malpractice cases, generally the physician has an excess of information and therefore appears to be the cheaper information provider between the two parties involved here. He has the required scientific medical knowledge and is in a position to explain each step of the patient's treatment. Further, the physician has easy access to documents and experts to testify his arguments in court. Hence, it is evident that as compared to a patient, the physician would definitely face lower costs of providing information.

However, if the physician committed a malpractice involving gross negligence since he violated fundamental rules of medicine, his costs of collecting and providing evidence in court will be a lot higher. This is because in such cases it is much more difficult for the physician to defend himself. Nevertheless, he should bear the burden of proof as he can provide the evidence at cheaper cost than the patient.

Uncertainty over Causation

In cases where it is not sure if a physician is the cause of the injury, the problem of uncertainty over causation arises. This is common in hospitals where a medical team performs together and the contributions of different persons to causation are hard to determine. A very common cited example of uncertainty over causation is the case of victim of a car accident who has to be operated urgently. Now, if the patient dies, it is sometimes not clear whether it was due to the negligence of the doctor or due to the injuries of the accident.

Taking the case of reversed burden of proof with uncertainty over causation, we can further develop our basic model of minimization of social accident costs. The difference to the basic model lies in the fact that with uncertainty over causation, given negligence rule the cost of information or providing the evidence is very high. Given reversed burden of proof, it is assumed that for the physician exculpation will be impossible as under strict liability. So, he would have to bear the additional cost of accidents which in fact he did not cause, even though he cannot influence these amounts of damages by his level of care or activity.

Contracting over Malpractice Liability¹⁸

Contractual Liability refers to a scenario where patients and medical providers are themselves allowed to determine liability rules that govern their relationship by contract. As currently constituted, medical malpractice liability still does not adequately regulate patient safety. Proponents of contractual liability claim that it is the most optimal way of reforming the existing malpractice liability regime. In the following, we critically analyze whether allowing for contractual liability can bring greater efficiency to the system or not.

Contractual Liability has two advantages over the current system. First, it places controls

¹⁸ Arlen, Jennifer, "Contracting Over Malpractice Liability", *UPenn Law Review*, 2010, available at <https://www.law.upenn.edu/live/files/46-arlen158upalrev9572010pdf>.

over liability rules with patients and medical providers. This is a clear advantage since patients and physicians have better information about how much higher is the patient ready to pay for higher quality care and thus are better able to determine the liability rules that affect both patient safety and health costs. The rules that patients and physician would set would be socially optimum as long as they are well informed about the costs and benefits of malpractice liability and can contract voluntarily. Second, contractual liability is also superior to malpractice liability because it allows liability rules to vary across patients. Since all patients do not want the same quality of medical care, the ability to choose different levels of care would certainly be beneficial.

Economists however claim that the fundamental premise of contractual liability proposals is not correct. Patients and medical providers do not have optimal incentives to contract over malpractice liability, even when patients are informed about the costs and benefits of imposing liability.

One of the main problems faced by liability contracts that render it inefficient is the collective goods argument. Malpractice liability is needed not just to induce patient-specific, post-contractual investments in safety, it is also needed to induce physicians to invest in measures –such as expertise and equipment – whose benefits are collective (in that they apply to all patients) and durable (in that they reduce the risk of error for both existing and future patients). To provide optimal incentives, liability thus must ensure that patients obtain the full benefit of improving care that is collective and whose benefits extend to future patients.

This requirement presents a problem for contractual liability. Patients negotiating individually over liability face excessive incentives to contract out of liability. This is because neither do they obtain the full benefit nor do they have to bear the full cost of a decision to impose or waive liability. The crux of the problem is that each physician determines his collective investments in care based on his total expected liability across all his patients. This creates a ‘free-rider’ problem. Thus, a critical test of whether contractual liability is efficient is whether patients also benefit from imposing liability by contract when care is determined primarily by physician’s pre-contractual investments in care.

Then, the only incentive for the patients to impose optimal liability is that they obtain treatment from physicians with high pre-contractual investments in care. This is because only high quality physicians can agree to bear liability at a reasonable price. Low quality physicians cannot afford to bear liability at the same price as high quality physicians without incurring ruinous liability costs. The problem that arises then is that any patient who has selected a presumptively high-quality physician (based on the offer to bear liability) can be expected to immediately ask that physician to accept a liability waiver in return for a price reduction. The patient will seek this waiver because the waiver does not affect quality – since that is determined by investments in care taken pre-contract. This renders contracting over liability inefficient, because low quality providers can mimic the contracts of high quality providers, knowing that patients will waive liability. As a result, patients will not value liability as a signal of pre-contractual quality and thus will waive optimal liability when the primary benefit of liability is to induce pre-contractual

investments in care.

These problems can be ameliorated - albeit not eliminated - through contractual liability executed collectively by patients with providers committing to make non-negotiable offers to bear liability or waive it. Nevertheless, this form of contractual liability is inefficient because it creates a new problem – adverse selection – that produces systematic incentives for patients to waive optimal malpractice liability. On average, patients who need extensive medical care can be expected to value higher cost, higher quality plans more than healthy patients. This implies that liability plans will be more expensive not only because per patient quality is higher, but also because average patient health care costs are higher. This pricing structure will force patients with average health care costs away from liability plans - even when it would be optimal for the vast majority of patients to impose liability because the price they must pay to impose liability includes not only the direct cost of liability, but also the added premium charged to patients with higher than average expected costs. Adverse selection thus will cause many patients to waive off liability.

An accrediting body is an independent third party that measures and rates the regulations, safety guidelines, and practices of a service or business. In our context, hospital accreditation is a public recognition by National Healthcare Accreditation Body¹⁹, of the achievement of accreditation standards by healthcare organizations, demonstrated through an independent external peer assessment of that organization's level of performance in relation to the standards.

In India, the health system currently operates within an environment of rapid social, economical and technical changes. Such changes raise the concern for the quality of health care. Hospital is an integral part of health care system. Accreditation would be the single most important approach for improving the quality of services supplied by the hospitals. Accreditation is an incentive to improve capacity of national hospitals to provide quality of care. National accreditation system for hospitals ensure that hospitals, whether public or private, national or expatriate, play their expected roles in national health system. The benefits of accreditation to patients include high quality of care and patient safety, respect and protection of the rights of patients along with regular evaluation of patient satisfaction. Accreditation to a hospital stimulates continuous improvement. It enables hospital in demonstrating commitment to quality care. It raises community confidence in the services provided by the hospital and also provides opportunity to healthcare unit to benchmark with the best.

National Accreditation Board for Hospitals and Healthcare Providers is a constituent board of Quality Council of India²⁰, set up to establish and operate accreditation programme for healthcare organizations in India. NABH has been established with the objective of enhancing health system & promoting continuous quality improvement and patient safety. NABH provides accreditation to hospitals in a non- discriminatory manner regardless of their ownership, legal status, size and degree of independence. International

¹⁹ NABH is a constituent board of Quality Council of India.

²⁰ QCI.

Society for Quality in Healthcare²¹ has accredited “Standards for Hospitals” developed by NABH, India. The approval of ISQua authenticates that NABH standards are in consonance with the global benchmarks set by ISQua. The hospitals accredited by NABH will have international recognition.

NABH Standards has ten chapters incorporating 100 standards and individual standard has specific objective elements concerning Access, Assessment and Continuity of Care, Patient Right and Education, Care of Patient, Management of Medication, Hospital Infection Control, Continuous Quality Improvement, Responsibility of Management, Facility Management and Safety, Human Resource Management, Information Management System etc.

Though accreditation of health care providers does provide a mean for achieving efficiency in the system of medical liability, but the process is very much in its nascent phase in India. Also, it needs to be pointed out that while minimum standards are to be mandatory, accreditation is to be of voluntary nature. In addition, the accreditation board while being supported by all stakeholders, including industry, consumers, government, has fully functional autonomy in its operation.

It is though true that the health ministry has supported the initiatives towards accreditation, it is yet to give it greater importance. The ministry needs to give equal importance to both regulation and accreditation for the sake of quality healthcare. It should consider the fast changing nature of quality benchmarks in healthcare sector and make the accreditation system as dynamic as possible. The standards should be periodically revised and today's desirable standards should become tomorrow's minimum standards. That is the only way how there can be continuous up gradation of healthcare standards in the country. It must ensure that the link between the "National Board" that decides the minimum standards in healthcare and the "Accreditation Board" which prescribes multilevel standards for the same establishments should have strong linkages. The working relationship between these two bodies can result in periodic revision of mandatory standards. However, it cannot be denied that all kinds of "voluntary" quality up gradation options would remain only in urban India and will have no impact on thousands of rural healthcare establishments. But nevertheless, it is sure to benefit patients and health care providers alike.

THE INDIAN MEDICAL COUNCIL (AMENDMENT) ORDINANCE, 2013 AN ORDINANCE FURTHER TO AMEND THE INDIAN MEDICAL COUNCIL ACT, 1956.²²

This Ordinance seeks to achieve the following objectives:

The Indian Medical Council Act, 1956 was enacted for the purpose of reconstituting the Medical Council of India (Council) and to provide for the maintenance of the Indian Medical Register and for matters connected therewith. The Act was amended, inter alia, by the Indian Medical Council (Amendment) Act, 2010 superseding the Council for one year with effect from the 15th May, 2010 and providing for the constitution of a Board of

²¹ ISQua.

²² Annexure-I/1.

Governors of not more than seven persons to exercise the powers and to perform the functions of the Council under the said Act. Subsequently, the term of the Board of Governors was extended to one year at a time by amending the Act in 2011 and 2012 and as per the provisions of the Indian Medical Council (Amendment) Act, 2012 the Council has to be reconstituted within a period of three years from the date of its supersession, that is latest by the 14th May, 2013.

2. The 2013 ordinance proposed to amend the Indian Medical Council Act, 1956 to reconstitute the Council and review the composition of the said Council so as to give representation to Union territories and to remove the anomaly where States having larger number of medical colleges, but having formed a medical university, were having fewer seats in the Council as compared to States having fewer colleges affiliated to several Universities, by inserting a proviso in clause (b) of sub-section (1) of section 3.

3. The Council's main functions as contained in the Indian Medical Council Act, 1956 is to make recommendations to the Central Government in matters of recognition of medical qualifications, determining the courses of study and examinations required to obtain such qualifications, inspection of examinations and maintenance of register of medical practitioners, etc. By the amendment of the said Act in 1993, the power to grant permission for establishment of new Medical Colleges, increase in admission capacity or for starting new or higher course of study or training in the established colleges was entrusted to the Central Government from the respective State Governments. For this purpose, the Council became a recommendatory body to the Central Government for taking final decisions in these matters. After reviewing the working of the Council in this area, and the problems being faced, a need has been felt to empower the Central Government to give such directions to the Council wherever necessary on matters of policy and public importance and to ensure their proper compliance.

4. The Indian Medical Council (Amendment) Ordinance, 2013, inter alia, provides the following, namely: —

(a) To amend long title of the Indian Medical Council Act, 1956 (Act) so as to make it more comprehensive;

(b) To amend sub-section (2) of the section 3 of the Act so as to provide that no person shall hold the post of President or the Vice-President for more than two terms;

(c) To amend section 13 of the Act relating to recognition of medical qualifications granted to a citizen of India by medical institutions not included in the First or Second Schedule so as to extend the benefit to the overseas citizen of India;

(d) To amend section 14 of the Act relating to the medical practice by the persons having medical qualifications granted by medical institutions in any country outside India. It is proposed to provide that the practice by such persons shall be limited for a specified period in the institution to which they are attached;

(e) To amend section 21 of the Act relating to the Indian Medical Register so as to provide that the biometric details of all persons enrolled on any State Medical Register shall be verified at the time of renewal of registration.

(f) To provide for renewal that every medical practitioner whose name has been enrolled as such on the Indian Medical Register or State Medical Register shall be valid for a period of ten years from the date of such enrolment and thereafter, it may be renewed;

(g) To insert a new section 30A in the Act relating to resignation by the President, Vice-President and Members of the Council and the power of the Central Government to remove from the office the President, Vice-President or a Member; and

(h) To insert a new section 33A in the Act relating to power of the Central Government to give directions to the Council in the matters of policy and for making any regulation.

5. The proposed amendments will make the composition of the Council compact, and representative, and empower the Central Government to discharge its functions effectively to ensure proper development of medical education in the country.

Critical Analysis of the IMC Amendments:²³

The Indian Medical Council (Amendment) Ordinance, 2013 in the Parliament ignited a heated debate in some quarters of the medical community. While some doctors with political connection may find this Ordinance as a great opportunity to climb up the ladder to the Medical Council of India (MCI), others are deeply perturbed with the Ordinance for more reason than one. Ironically, most physicians practicing around the country perhaps are still unaware about what are at stake in this significant piece of the new medical legislation.

In fact, barring a few exceptions, most SMCs and health universities have shown little or no interest to conduct an open and transparent MCI election, which must include all registered doctors practicing modern medicine. One has to wonder why these medical establishments are not keen to inform all physicians about this important MCI election being held in accordance to the Ordinance 2013.

Unfortunately, there is no prescription in the Ordinance that can bring hope of a cure for the ailing medical system in India. The Ordinance 2013 is merely an “*old wine in a new bottle*” which makes one point abundantly clear that unscrupulous doctors and medical colleges with financial affluence and political connection that have been plundering our healthcare delivery system for a very long time have little to fear from the changes in law in this Ordinance.

Nobody should be oblivious of the underlying facts of the genesis of Ordinance 2013, which started in 2010 with the revelation of a deep-rooted corruption inside the MCI. The

²³ Dr Kunal Saha, “Indian Medical Council (Amendment) Bill, 2013: No prescription for a corruption-free healthcare system”, *India Medical Times (An AalaTimes media venture)*, 2013 available at <http://www.indiamedicaltimes.com/2013/09/06/guest-article-indian-medical-council-amendments-bill-2013-no-prescription-for-a-corruption-free-healthcare-system-by-dr-kunal-saha/>.

Ordinance 2013 has provided to amend the Indian Medical Council Act, 1956²⁴ which was enacted more than half a century ago with the primary aim to provide a platform for the maintenance of an uniform standard of medical education and to regulate ethical practice by doctors across India.

The IMC Act, 1956 provided rules for the establishment of MCI as the central authority for control of medical education with exclusive power to approve or disapprove medical colleges and to take disciplinary action against the delinquent physicians for their unethical and negligent acts. The IMC Act, 1956 also stipulated formation of state medical council (SMC) that would issue licenses to bona fide medical graduates allowing them to practice modern medicine in the state. But what actually prompted the central government to introduce the make the Ordinance 2013 to provide an amendment in the 57-year old laws made under the IMC Act, 1956?

The answer to this important question may still be vivid in our memory as it started just a little more than three years ago when one Dr Ketan Desai, then president of MCI, was caught red-handed (through a sting operation) by the Central Bureau of Investigation (CBI) on 22nd April, 2010 while taking bribe from a private medical college allegedly in exchange of granting the MCI recognition. This was not the first time that the same Dr Desai came to the limelight for being involved with a shameful conduct as the top medical man in the country.

In a writ petition; *Union of India v. Harish Bhalla & Others*²⁵, Delhi High Court dubbed MCI as a “den of corruption” and ordered Dr Desai to be removed from his post of MCI president on corruption charges in 2001. But Dr Desai made a remarkable return to the top of MCI when he was elected “unopposed” as the MCI president once again in a general body meeting held on 1st March, 2009 where nearly one hundred MCI members from across the nation took part but none opposed Dr Desai for the coveted post of MCI president despite his besmirched background. Rest is a dark history of Indian medicine as Dr Desai was arrested by the CBI in 2010 while still occupying the top post in MCI.

Dr Desai’s arrest by the CBI was highly publicized by the national and international media, which also brought endless ignominy to all doctors of the Indian origin. Under mounting public pressure, the union health ministry was eventually forced to dissolve the full body of elected members of MCI in May 2010. For the past more than three years, MCI has been functioning under a ‘Board of Governors’, established through an Ordinance with few hand-picked doctors chosen by the government.

The sordid saga of Dr Desai undoubtedly put the health ministry in an embarrassing situation. But the undisputed fact remains that Dr Desai’s incredible return as the MCI president in 2009 (with full support from every MCI member) and his eventual fall from the grace in 2010 took place under the same health ministry headed by Mr Ghulam Nabi Azad who is still the union health minister. The health ministry has since been under relentless pressure to re-establish a democratically elected body of the MCI.

²⁴ IMC Act, 1956.

²⁵ Delhi High Court - (PIL) LPA No. 299-301/2001.

The Ordinance 2013 was made by the UPA government seemingly to establish a new MCI by changing the old provisions of the IMC Act, 1956, to cleanse the healthcare system and to prevent unscrupulous medicos gaining entry to the MCI.

In fact, the Ordinance 2013 has been touted by the government as a major benevolent Act to regain public trust on doctors and to stem the rot in the healthcare system. And as expected, several apparently populist provisions have been craftily included in this Ordinance. For example, the new Ordinance has proposed that president/vice-president of MCI may not hold office for more than two terms (Section 3.2). But nothing in the Ordinance 2013 can prevent the same doctor to return to the post of MCI president/vice-president after taking a break as an ordinary member for a single term. What difference would it make if a depraved president like Dr Desai occupies the post of MCI president for two terms and then step aside for a single period only to regain the post of MCI president.

Other gimmicks clearly aimed at hoodwinking ordinary people were also included in 2009, for e.g. the term of president/vice-president (Section 7.1) or regular member (Section 7.2) has been reduced by one-year time (from 5 years to 4 years) but with absolutely no restriction on the re-election (and re-nomination) of the same member over and over again. These trifling changes are clearly designed only for political purposes, which cannot have any impact on removing corruption from the MCI.

Perhaps the biggest gimmicky change proposed in the Ordinance 2013 is the introduction of Section 30A.2f which provides the power to remove MCI president/vice-president or any regular member from his office if: “in the opinion of the Central Government, (the MCI member) has so abused his position as to render his continuance in office detrimental to the overall public interest”.

The specific language used in this provision was framed clearly to counter allegation against inclusion of any dissolute doctor in the MCI. But the proposed provision falls flat on its face for a number of reasons because it leaves several lacunae for corrupt medicos to easily infiltrate the MCI.

First, this law does nothing to prevent a doctor who has already been convicted or who is known to be involved with immoral activities from becoming a member or even president of MCI. In fact, if a new MCI body is established today in accordance to the Ordinance 2013, Dr Ketan Desai would be a member and possibly president of MCI once again without any problem whatsoever because the new provision has merely stated that a member/president/vice-president may be removed from MCI in future if he is found to have abused his official position in MCI.

Despite the undisputed fact that Dr Desai had previously abused his position as MCI president for which he was arrested by CBI and removed from MCI in 2010, there is no bar for him to be elected as a new MCI member or even president of MCI again. In fact, if a new MCI is formed today, Dr Desai would be a member because he is also the lone member elected from the medical faculty in Gujarat University Senate and according to Section 3.1(b) of the Ordinance 2013; doctor elected from each University Senate would

also be a member of MCI.

Further, the proposed law under Section 30A.2f has also stipulated that a member may be removed from MCI but only if “in the opinion of the Central Government” it is found that the member has abused his official position. Why the Central Government should be the lone judge to decide whether any MCI member may have abused his official position when many of these members were “nominated” and not “elected” by the government.

The health ministry always remained as a silent spectator when Dr Desai was condemned for serious charges of corruption and bribery. Dr Desai was removed from his post of MCI president in 2001 by Delhi High Court and in 2010, he was terminated from MCI after he was arrested and charged under the Prevention of Corruption Act by CBI. The health ministry did absolutely nothing to prevent Dr Desai from abusing his official position either in 2001 or 2010.

Ironically, the Central Government has also provided no change in the Ordinance 2013 to curb doctors with tainted background from being elected or nominated as a member of MCI. In fact, with reports of gross mismanagement and corruption inside the health department appearing regularly in the news, the health ministry has no credibility left in the eyes of the ordinary people today.

Moreover, Rule 10 of “Central Civil Services Rules, 1965”²⁶ has stipulated that a person working in any government agency would be suspended if he remains under police custody for a period of more than 48 hours and also during pendency of criminal proceedings in the court against him. A doctor-member should be removed from MCI if he is facing criminal trial or if he has been put behind bar for a period more than 48 hours. The law in the Ordinance 2013 that a member may be removed from MCI only when he is found guilty in the opinion of the Central Government is another self-serving devious ploy by the health ministry to shield the corrupt medicos.

It is a common knowledge that corruption in healthcare has thrived with declining standard of medical education with rapid proliferation of shoddy private medical colleges in the recent years.

MCI holds exclusive authority for the control of medical education including giving recognition to new medical colleges and to allow/disallow increase in the number of graduate and postgraduate seats in existing medical colleges across India. Many private medical colleges have been able to obtain green signal from MCI even without adequate infrastructure and medical faculties in the recent past. These private medical colleges are built with the primary motive to make huge financial profit through exorbitant “capitation fee” and other unethical means from the aspiring medical students.

The owners and shareholders of these spurious private medical colleges have frequently obtained MCI recognition through external political influence or by bribing the officials/members of MCI. The recent arrest of Dr Desai by CBI bears a glaring proof of such deplorable activities by high-rank MCI members. Doctors who own private medical

²⁶ Available at [http://www.persmin.gov.in/DOPT_ActRules_CCS\(CCA\)\(Eng\)_Index.asp](http://www.persmin.gov.in/DOPT_ActRules_CCS(CCA)(Eng)_Index.asp).

colleges should never be allowed to become the MCI members in order to avoid possible conflict of interests.

Unfortunately, there is no provision in the Ordinance 2013 to exclude doctors who are involved with running the business of private medical colleges from becoming members of MCI. In fact, the number of members to be elected to MCI has been sharply increased under Section 3(1)b of the Ordinance 2013 that has stipulated that 1 doctor would be elected to MCI for every 10 medical colleges including the private medical colleges. Proprietors of some private medical colleges have already been elected as MCI members in some states under the new provision of the Ordinance 2013.

Ironically, a new, populist provision has also been included in the Ordinance 2013 under Section 30A-2e which stipulates that a member should be removed from MCI if he has “acquired such financial or other interest as is likely to affect prejudicially the exercise of his functions as such president, vice-president or other member”.

Perhaps the greatest damage that the Ordinance 2013 may inflict on the society is its direct threat to democracy in the medical community of India. The Ordinance 2013 has proposed to significantly increase the number of MCI members from different states who are elected not by their doctor-peers in the state but by the few members of each University Senate most of whom hail from non-medical and sometimes non-academic divisions of the school.

The Ordinance 2013 has proposed that each University Senate may elect 1 doctor-member for MCI for every 10 medical colleges (Section 3.1b). With numerous private medical colleges burgeoning all over the nation under a liberal recognition policy by the previous MCI, a large number of additional members would be elected for the next MCI from many states mostly by the non-medical voters of the Senate who possibly have little or no knowledge about the character or competency of the doctors contesting MCI election.

Even if the number of MCI members had to be increased due to the proliferation of new medical colleges, why not let the registered doctors elect the most competent among their peers just the way members of SMCs are elected in India? Further, it cannot be justified to have equal representation in MCI from a large, reputed government medical college with hundreds of students compared to a small, private medical college under a “deemed” university built primarily to make financial profit. Also, instead of the large number of registered physicians, allowing a handful of Senate members to elect MCI members is more likely to be influenced by unwarranted external factors including bribery and corruption.

Apart from increasing the number of “elected” MCI members from private medical colleges, the Ordinance 2013 has also proposed to increase the number of MCI members to be “nominated” by the Central Government.

The newly proposed Section 3(1)aa in the Ordinance 2013 has stipulated that one member from the Union Territories will be “nominated” to the MCI by the Central

Government although the criteria for such nomination of doctors are not mentioned anywhere in it. Why the government did not allow fellow doctors to elect their representative to MCI through a democratic process even if additional members had to be included from the Union Territories.

There is little dispute that political influence might play a key role for obtaining “nomination” from the government to be a member of MCI under this new provision of law. By increasing the number of “nominated” position in the MCI, the health ministry has undoubtedly done a big favour to the Central Government to reap more political bargaining power in the coming years.

In sum, the Ordinance 2013 is nothing but a colossal political gimmick in the name of transformation of the broken healthcare system in India. This was created to quell the increasing public outrage against maladministration and corruption in the central medical regulatory system.

Although the Ordinance has emanated primarily from the premature disbandment of the last MCI following the precipitous arrest of then MCI president Dr Ketan Desai, which also exposed the deep-rooted corruption in the MCI, there is no genuine attempt to deter the corrupt practices indulged by many Machiavellian medical leaders in the past.

THE CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2010²⁷
UNDER THE MINISTRY OF HEALTH AND FAMILY WELFARE, GOVERNMENT OF INDIA²⁸

Indian Public Health Standards

National Rural Health Mission²⁹ was launched in the year 2005 to strengthen the Rural Public Health System and has since met many hopes and expectations. The Mission seeks to provide effective health care to the rural populace throughout the country with special focus on the States and Union Territories³⁰, which have weak public health indicators and/or weak infrastructure. Towards this end, the Indian Public Health Standards³¹ for Sub-centres, Primary Health Centres³², Community Health Centres³³, Sub-District and District Hospitals were published in January/ February, 2007 and have been used as the reference point for public health care infrastructure planning and up-gradation in the States and UTs. IPHS are a set of uniform standards envisaged to improve the quality of health care delivery in the country. The IPHS documents have been revised keeping in view the changing protocols of the existing programmes and introduction of new programmes especially for Non-Communicable Diseases. Flexibility is allowed to suit the diverse needs of the States and regions. These IPHS guidelines will act as the main

²⁷ Act 23 of 2010.

²⁸ Available at www.clinicalestablishments.nic.in.

²⁹ NHM.

³⁰ UTs.

³¹ IPHS.

³² PHCs.

³³ CHCs.

driver for continuous improvement in quality and serve as the bench mark for assessing the functional status of health facilities. States and UTs should adopt these IPHS guidelines for strengthening the Public Health Care Institutions and put in their best efforts to achieve high quality of health care across the country. Particular guidelines for the following centers are provided under the public health standards:

- Sub Centers
- Primary Health Centre
- Community Health Centre
- Sub-district & Sub-divisional Hospital
- District Hospital

Standard Treatment Guidelines provided under the Act:

1. Guidelines for Cardiovascular Diseases
2. Guidelines for Critical Care
3. Guidelines for Gastroenterological Diseases
4. Guidelines for Obstetrics and Gynaecology
5. Guidelines for Haemodialysis
6. Guidelines for Ophthalmology
7. Guidelines for ENT
8. Guidelines for Orthopaedics
9. Guidelines for Medicine (Respiratory)
10. Guidelines for Medicine (Non Respiratory Medical Conditions)
11. Guidelines for Paediatrics and Paediatrics Surgery
12. Guidelines for General Surgery
13. Guidelines for Interventional Radiology
14. Guidelines for Oncology
15. Guidelines for Organ Transplant - Liver
16. Guidelines for Urology
17. Guidelines for Laboratory Medicine
18. Guidelines for G. I. Surgery
19. Guidelines for Neurology
20. Guidelines for Endocrinology
21. Guidelines for Ayurveda

Salient Features & Critical Analysis:³⁴

The Clinical Establishments (Registration and Regulation) Act, 2010 has been facing a lot of criticism from the medical community for various reasons, some genuine others borne out of resistance to change and fear of regulatory controls.

³⁴ Dr S K Joshi, "Clinical Establishments Act, 2010: Salient Features & Critical Analysis", *India Medical Times (An AalaTimes Media Venture)*, 2013 available at <http://www.indiamedicaltimes.com/2013/07/10/clinical-establishments-act-2010-salient-features-critical-analysis-by-dr-s-k-joshi/>.

Salient Features:

1. The Act was enacted by the Central Govt under Article 252³⁵ of the constitution for the states of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim (and also for implementation in the Union Territories). Other states have a choice of implementing this legislation or enacting their own legislation on the subject.
2. The purpose of the Act is to provide for the registration and regulation of clinical establishments with a view to prescribe minimum standards of facilities and services, which may be provided by them.
3. The implementation is to be affected through a three-tier structure — the Central Council, the State Council and the District Registering Authority.
4. The act will be applicable to all clinical establishments (hospitals, maternity homes, nursing homes, dispensaries, clinics, sanatoriums or institutions by whatever name called, that offer services for diagnosis, care or treatment of patients in any recognised system of medicine (Allopathy, Homeopathy, Ayurveda, Unani or Siddha), public or private, except the establishments run by the armed forces.
5. Registration is mandatory for all clinical establishments. No person shall run a clinical establishment unless it is registered and for that the establishment has to fulfil the following conditions:
 - (a) The maintenance of minimum standards of facilities and services and staff, as prescribed;
 - (b) Maintenance of records and submission of reports and returns as prescribed;
 - (c) Undertaking to provide within the staff and facilities available such medical examination and treatment as may be required to stabilise the emergency medical condition of any individual brought to any such establishment;
 - (d) The clinical establishment will charge the rates for each type of procedures and services within the range of rates determined and issued by the Central Govt in consultation with the State Govt;
 - (e) The rates charged for each type of service/facility provided shall be displayed in local and English language conspicuously;
 - (f) The establishment shall ensure compliance of the standard treatment guidelines as may be determined and issued by the Central or the State Govt;
 - (g) The establishment shall maintain and provide electronic health records (EHR) and electronic medical records (EMR) of every patient as may be prescribed by the Central or the State Govt;
 - (h) Every establishment shall maintain information and statistics in respect of all other applicable laws and rules, thereunder.

³⁵ The Constitution of India.

6. Procedure for Registration

(a) The registration will be done by the District Registering Authority (District Health Officer). The Provisional Registration will be issued within ten days of submission of application as prescribed, without any inquiry or inspection. It will be renewable yearly. The establishments existing before commencement of the Act will have to apply within a year and those started after the commencement of the Act, within six months of the date of their establishment. The registration will be non-transferable.

(b) Provisional registration will not be granted beyond two years from the date of notification of standards in case of establishments that existed before the notification of standards, and beyond six months of notification of standards in case of those established after the notification of standards.

(c) Permanent registration will be granted for a period of five years, on submission of application along with fees and evidence of compliance with prescribed standards. The particulars of the applicant will be published for information of and objections, if any, by the public within 30 days. If objections are received, the same will be communicated to the clinical establishment for a response within 45 days.

(d) Cancellation of Registration (Clause 32). The registration can be cancelled in case of any violation of the conditions or conviction of the manager under the Act, after the issue of a show cause notice. The Registering Authority also has the powers of inquiry and inspection or entry and search of the establishment.

(e) Register of Clinical Establishments³⁶. The Registering Authority would be required to compile a register of clinical establishments in a digital format within two years and will supply to the state council a digital copy of every entry made in the register. The State Council in turn will provide the details to the Central Council so as to keep the records updated at all times.

7. Offences and Punishments

(a) Running a clinical establishment without registration would be punishable with a fine of Rs 50,000 for the first offence, Rs 2 lakh for the second offence and Rs 5 lakh for the subsequent offence.³⁷

(b) Serving in an unregistered clinical establishment shall be punishable with a fine up to Rs 25,000.

(c) Willful disobedience of any lawful direction or obstruction to lawful authority or refusal to submit any information asked for or giving false information knowingly, would be punishable with a fine up to Rs 5 lakh.³⁸

(d) In case of a contravention by a company (a hospital) the person in charge of operations/management, shall be liable for action.³⁹

³⁶ The Clinical Establishments (Registration and Regulation) Act, 2010, Section 37.

³⁷ Ibid., Section 41.

³⁸ Ibid., Section 42.

³⁹ Ibid., Section 44.

(e) The provisions of Section 44 and punishments would be equally applicable to government departments.⁴⁰

Critical Analysis:

1. The old Acts for registration of hospitals / nursing homes in nine states (mentioned in the Schedule to the Act), make the registration mandatory only for the hospitals and nursing homes (not for the clinics, dispensaries or laboratories) to get registered with the state health authorities. Further, it was applicable only to the Allopathic establishments. Ayurveda, Unani, Siddha or Homeopathy establishments were not covered by them. The new Central Act is a blanket legislation making it mandatory for all establishments — hospitals, nursing homes, private clinics, laboratories, blood banks, imaging centres etc, of all systems of medicine (including Homeopathy, Ayurveda, Unani, Siddha) public or private, to get registered by a common single Registering Authority called the District Registering Authority.

It, however, exempts the establishments run by the Defence services from registration, for reasons not known. If some of the states are allowed to continue with their old legislations, then the private clinics / laboratories / imaging centres of all systems and hospitals / dispensaries of non-allopathic systems in those states will not be required to be registered in those states. This will defeat the purpose and will not be a desirable situation.

2. The Central and State Councils include the members from non-allopathic systems also (for dealing with non-allopathic establishments) but representation of non-allopathic systems is not mentioned in the District Registering Authority.

3. Conformity to the Standards: It will take time to lay down the standards for so many different types of establishments pertaining to different systems of medicine.

Meeting the prescribed standards will have cost implications, which is one of the reasons for resistance by private clinics. Fear of inspector raj and undue harassment is another factor.

Monitoring the compliance with standards by hundreds of thousands of establishments will require an army of officials. It will be difficult to ensure implementation of standards, which is known to be our weakest point. We enact beautiful legislations but they remain mostly on paper because we are very poor in enforcement of legislations.

4. Schedule of Charges for Services to be decided by the State: This is a provision, which may not be palatable to the clinical establishments at all. The state cannot and should not dictate the fees for various services/procedures. Even while conforming to the prescribed minimum standards, there may be a lot of difference between the standard of facilities and expertise provided by the establishments, catering to the different locations, clients, standards / tastes / expectations and paying capacity of clients. Every clinical establishment should have the right to determine the charges for the services provided by

⁴⁰ Ibid., Section 45.

it. Government should not try to regulate the charges for services.

5. Standard Treatment Guidelines issued by the Central Govt: The standard treatment protocols, in principle, are a good idea as it helps ensure certain basic standards of treatment. But they can be acceptable only as long as they are limited to broad principles, life threatening emergencies (CPR, anaphylactic shock, poisoning, treatment of snake bite etc) or treatment of major public health problems (such as AIDS, malaria, pulmonary tuberculosis). Physicians should have adequate freedom to decide as per their learning and experience, which modality of treatment to use in which situation in broad compliance with the protocols practiced by the professional community nationally and internationally.

6. Maintenance of EHR and EMR of every patient as may be determined and issued by the Central or State Govt. It is a good idea, in principle, but a requirement, which is likely to be resented by the private clinics because of the added cost (of the system, software and the salary of the computer operator) as well as additional workload for busy clinicians. Besides, a large percentage of the physicians, especially those of the ISM (Indian Systems of Medicine), may not be computer savvy at all.

7. Fear of Scrutiny: What is perhaps worrying the physicians more is the fear of scrutiny and exposure of their professional inadequacies, shortcuts, poor facilities, and mistakes as well as the harassment caused by the inspecting officials. So far hundreds of thousands of private clinics, even nursing homes, have been operating all over the country, unknown and hence not subject to any scrutiny / inspection / questioning by anyone. Since they are not known or registered, there is no check over their facilities or standards and many of them go on giving care and treatment of dubious quality, often in utter disregard of the rules and regulations. Their fear is that once registered, they would no more be able to hide from the legal and professional scrutiny.

8. Publishing the particulars of the clinical establishment for public comments / objections / observations, after grant of provisional certificate, does not appear to be a sound idea. It is not clear what purpose will it serve. Firstly, the public will have no clue about the technical aspects / standards of the hospital especially in case of the establishments newly commissioned. Secondly, the local community or the rival establishments are unlikely to come forward with any meaningful comments.

9. Cancellation of Registration (Clause 32): Cancellation of registration in case of private clinics, diagnostic labs, nursing homes etc may be possible but in case of hospitals it may not be a practically feasible idea in view of a large number of patients admitted at different stages of treatment. In case of repeated violations and reckless disregard for the safety of patients, exemplary penalties, to the tune of a yearly profit amount and/or imprisonment for the trustees/CEO/COO (if found negligent), may be more practical.

10. Treatment of Emergency cases —Life-saving treatment in the case of life-threatening emergencies has always been and will always remain the prime duty of every doctor, wherever, in whatever position or location. Shirking this responsibility or refusal to render necessary assistance in timely transportation of patient will be viewed as medical

negligence liable to punishment.

However, non-payment of medical bills of treatment of emergency cases is a point of serious and genuine concern of the medical community. The Act is silent on this aspect. The authorities concerned must redress the grievance to the satisfaction of medical professionals by putting in place a mechanism of ensuring problem free reimbursement of bills. The liability may be borne by the insurance agencies or by the government itself.

Plus Points of the Act:

In spite of the lacunae mentioned above, the Act is a positive development, the need for which was being felt since long. If it is implemented in all the states in the form, broadly in line with the Central Act and Rules,

(a) It would act as the first ever factual census of the number, category, speciality and location of all the physicians and all the medical establishments of all the systems of medicine in the country. That would be a great achievement as it would be a great help in the countrywide planning and posting of physicians as well as healthcare establishments. Up to now the authorities do not know exactly how many of what category are available in which area.

(b) Registration without any inquiry or inspection, on the basis of the documents submitted by the establishment, should be encouraging for many nursing homes / private clinics to come forward and get registered. This may be the biggest plus point of the Act.

(c) It will also help isolate and identify the hundreds of thousands of quacks that are playing havoc with the lives of millions of people all over the country.

(d) Once in place, the system of registration will necessarily help in improving the standards of healthcare establishments within a couple of years. It will also bring about some uniformity in the standards of care across the country.

THE NATIONAL HEALTH BILL, 2009 MOHFW⁴¹, GOI WORKING DRAFT: VERSION JANUARY '09 (PENDING)⁴²

The debates around securing the right to health for all in India are at a complex and sensitive stage. In India, we have gross inequity in health-care delivery. The huge inequity is evident, on the one hand, in flourishing international medical tourism, and high-technology biomedical interventions done cheaply, and, on the other, minimum levels of health care being unavailable to those unable to pay.

⁴¹ Ministry of Health and Family Welfare.

⁴² Annexure-I/2 also available at http://www.mohfw.nic.in/nrhm/Draft_Health_Bill/General/Draft_National_Bill.pdf.

The health status of people transcends the health-care sector, and the social determinants of health, such as food, water, sewerage, and shelter, still elude large numbers of the poorest citizens in India. Between the early 1990s, when the process of economic reforms began, and now, the yearly per head consumption of food grains in the country has drastically deteriorated.

The latest National Family Health Survey provided grim evidence of very slow improvement in infant mortality, persistently low rates of child immunisation, and shocking rates of malnutrition. Inequity in social determinants of health and health care in a market-based system itself becomes a pathogenic factor that drives the engine of deprivation.

Public awareness of the need to end inequities in the health status and health entitlements of the people is not new. As early as 1946, the Health Survey and Development Committee set forth a vision of health services in India based on equity, universality, and comprehensiveness of care. Actual progress in realising these goals, and particularly in achieving equity, has been extremely sluggish. These inequities are set to increase even further in the near future even as major investments are being projected and planned in the health sector from 0.9% to 3.0% of the gross domestic product. The stunted public health system is hardly geared up to absorb this increased allocation; already state governments are returning allocated money because of the inability to absorb increased allocations.⁴³

The Government of India took a landmark decision when it decided to introduce the National Health Bill, 2009. The bill recognizes health as a fundamental human right and states that every citizen has a right to the highest attainable standard of health and well-being. The constitution of India, under Articles 14, 15, and 21, recognizes the right to life as a fundamental right and places obligations on the Government to ensure protection and fulfillment of the right to health for all, without any inequality or discrimination.

The basic tenets of the Bill include the peoples' right to health and healthcare, the obligations of the governments and private institutions, core principles/norms/standards on rights and obligations, the institutional structure for implementation and monitoring, and the judicial machinery for ensuring health rights for all.

The bill provides itemized lists of the obligations of the central and state governments. Chapter III of this bill provides elaborate rights to health care, including terminal care, for everyone. A heartening point is that the bill guarantees that no person shall be denied care under any circumstances, including the inability to pay the requisite fee or charges. Prompt and necessary emergency medical treatment and critical care must be given by the concerned health care provider, including private providers.

As per the bill, the health care provider, including the clinician, would be obligated to

⁴³ Binayak Sen, "Securing the right to health for all in India", *The Lancet, Early Online Publication*, 11 January 2011 available at <http://www.binayaksen.net/2011/01/binayaks-paper-in-the-lancet-special/>.

provide all information to the patients regarding the proposed treatment (risks, benefits, costs, etc.) and any alternate treatments that may be available for the particular condition/disease. There is a clause in this chapter that demands that the user (i.e., the patient) respect the rights of the health care providers by treating them with respect, courtesy, and dignity and refrain from any abuse or violent or abusive behavior towards them or to the rights provided to them.

The bill envisages the establishment of National- and State-level Public Health Boards to formulate national policies on health, review strategies, and ensure minimum standards for food, water, sanitation, and housing. These boards would also lay down minimum standards and draw up protocols, norms, and guidelines for diverse aspects of health care and treatment. The bill provides for elaborate mechanisms for monitoring at the government and community levels. There is a need to have wider discussion on the scope and activities of these monitoring agencies and regarding dispute resolution and redressal mechanisms listed in chapter V of the Bill.

A comprehensive Act that covers the various aspects of health care rights, delivery and related matters has been a pressing need in this country for long. Several international and national agencies, as well as the Honorable Supreme Court of India, have drawn the attention of the Government to this issue. The Bill, once enacted, would have far-reaching consequences on the Indian health scenario. It would demand greater levels of professionalism, standards of care, accountability, from the care providers and, besides, ensure protection for them. The Bill calls for greater official involvement of professional bodies like the Indian Academy of Neurology in the health care management in this country.⁴⁴

Strengths of the Bill:

- Its clarity in raising the fundamental health issues is indeed superb as it is based on a very clear ‘health rights approach’ and ideas outlined in the ICESCR⁴⁵
- It clearly articulates health as ‘right’ and outlines the states obligations for fulfilling this right;
- It integrates bio-medical aspects of health with some vital socio-economic-cultural determinants like food, water, housing sanitation, hygiene, environment, etc other than bio-medical;
- It provides for user’s rights as well as user’s obligations/duties and addresses issues of consent, autonomy, privacy, medical records, etc;
- It has clearly delineated the role and responsibility of the state government and mentions of a clear cut grievance redressal mechanism.

Weakness of the Bill:

⁴⁴ Sanjeev V. Thomas, “The National Health Bill 2009 and afterwards”, *Ann Indian Acad Neurol*, 2009, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2812745>.

⁴⁵ International Covenant on Economic, Social and Cultural Rights.

- The provisions in the Bill are so much so generalized that these may be fitted into the situation of any country or any community in this world;
- The Bill does not mention the health problems of any specific region or community; Instead of bottom-up approach, it recognizes the top-down approach of its framing and implementation;
- It does not adequately relate poverty – nutrition – health in operational terms;
- Instead of free health care, it mentions of affordable health care; which imply that this is not that much pro-poor;
- It does not mention that who would be the care givers - Government institutions or Private agencies?
- It is based on some superfluous promises and thus it will require a whole set of operational guidelines codified through bye- laws, rules and programmes to be operationalized;
- It would be very difficult to execute the provisions of the bill unless these are redefined carefully and clearly giving stress on the health of the poor and marginalized;⁴⁶

The Bill has been lying in cold storage with the chapter on financial memorandum yet to be completed. In a situation where the health needs of the people are dependent largely on the unregulated private sector, where there is gross underinvestment in health, where the rate of decline of either infant or maternal mortality has been slow, where there has been a resurgence in communicable diseases, the belief that a credible public health system is the need of the hour is getting increasing recognition.

At this moment, public expenditure on health is very low. It is yet to reach the two to three per cent mark of gross domestic product. The proposed Bill is a small but significant step. At present, most of the State governments have reacted positively to it and do not perceive it as a threat to their own domains. What is required, however, is a matching financial commitment both by the Centre and the States in order to make the 1978 Alma Ata declaration of “Health for All” a reality.

CHAPTER III - AWARENESS AMONGST DOCTORS AND PATIENTS

⁴⁶ OXFAM India, “One day State Consultation on National Health Bill – 2009”, available at : http://www.chsj.org/uploads/1/0/2/1/10215849/state_consultation_on_national_health_bill_report_2012.pdf.

After detailed discussion of the laws relating to malpractice and negligence in medical field, we now move on to a newer dimension of understanding the approach and outlook prevalent towards the same in society.

To impart more clarity, for this purpose two set of questionnaires were drafted. One set of questionnaires were sent out to Doctors with varying experience in medicine and the other questionnaire was sent to patients of varying age groups to help carry out research work.

On an oath of confidentiality questionnaires were filled to reveal information, which have thrown startling results.

This chapter begins with the survey conducted as regards the Doctors⁴⁷. To bring in clarity the answers has been put down in the form of pie charts.

The questionnaires were answered by a group of ten doctors in total. They were segregated on the basis of their years of practice in the medical field and classification was 1 year, 1-3 years and 3-10 years of experience.

The other set of questionnaires were sent out to a group of thirty patients⁴⁸. They were segregated on the basis of their age and classification was 20-30 years, 30-50 years and 50 years above.

ANALYSIS: DOCTORS

⁴⁷ Annexure-II/1.

⁴⁸ Annexure-II/2.

Chart 1

Ques -Did you ever have any contact with a legal institution in relation to your practice as a doctor ?

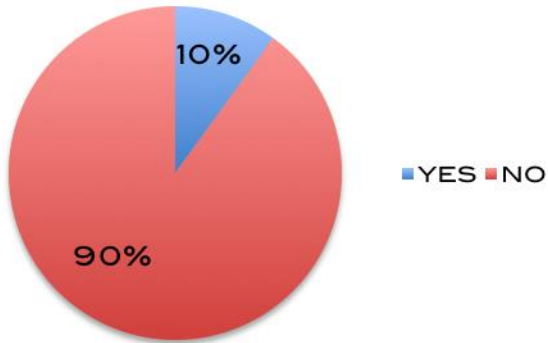


Chart 2

Ques -Are you aware about the framework regarding medico legal (MLC) cases ?

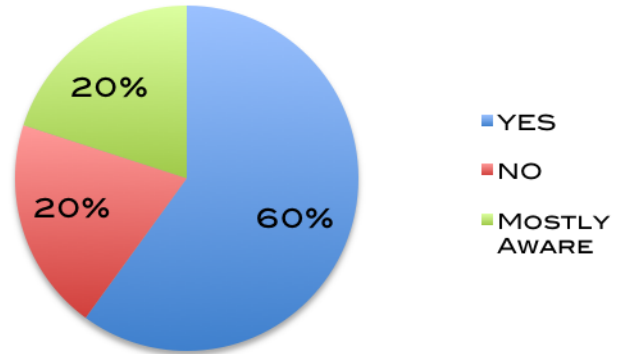


Chart 1 depicts that most of the doctors have not had any contact with a legal institution during their practice except one doctor with an experience of 7 years.

Chart 2 depicts that doctors with less years of experience (<3 years) were either not aware or mostly aware about the framework regarding medico legal cases.

Chart 3

Ques -Do you take special precautions during handling of medico legal cases ?

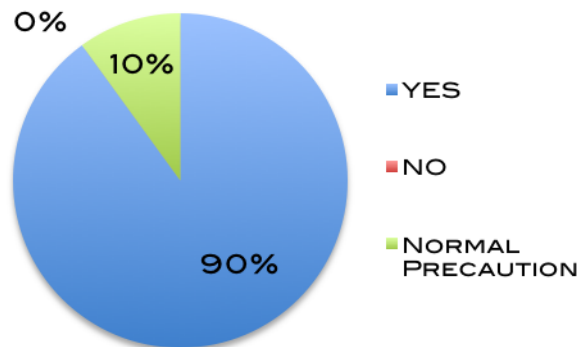


Chart 3 depicts that most of the doctors do take special precautions when it comes to MLC cases and only one doctor with an experience of ten years was taking normal precaution just like other cases.

Chart 4

Ques -Are you in favour of an ethical practice ?

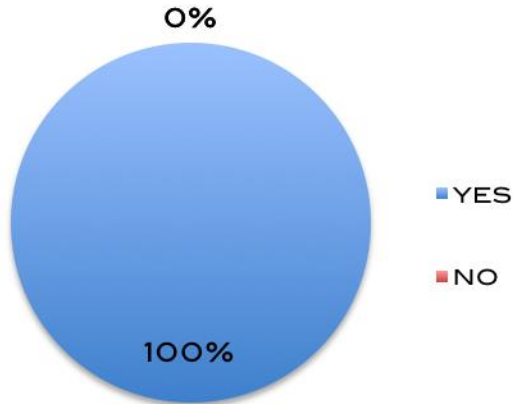


Chart 4 depicts that all the doctors irrespective of their experience are in favor of an ethical practice.

Chart 5

Ques -Are you in favour of ignoring ethics in order to save/help the patient ?

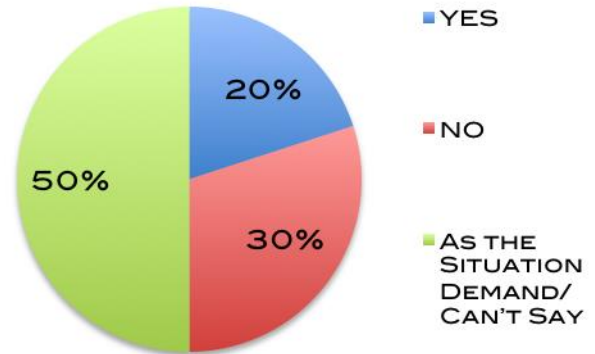


Chart 5 depicts that half of the doctors said as per the situation in hand they might ignore ethics of practice in order to save the patient. Whereas most of the doctors with an experience of over 7 years were not in favor of ignoring ethics. The results indicate that those with 1-3 years of experience will not have any problems in ignoring ethics if it were to help the patients.

Chart 6

Ques -Are you practising as per straightjacket ethics as provided by Indian Medical Council act ?

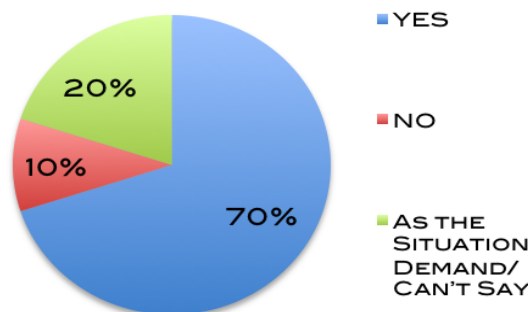


Chart 6 depicts that most of the doctors are practicing as per the ethical norms whereas one doctor with an experience of one year said he is not.

Chart 7

Ques -According to you is dichotomy useful for medical practise ?

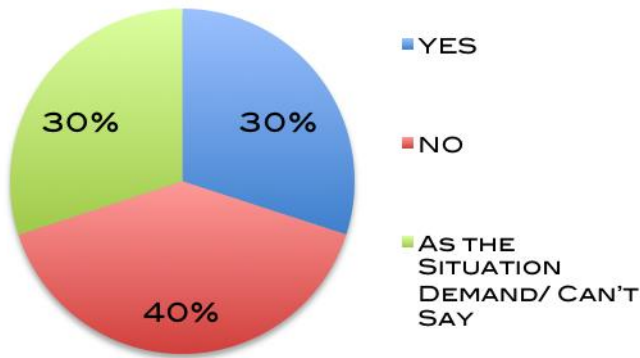


Chart 8

Ques -Are you aware of Medical Council of India's Code of Ethics ?

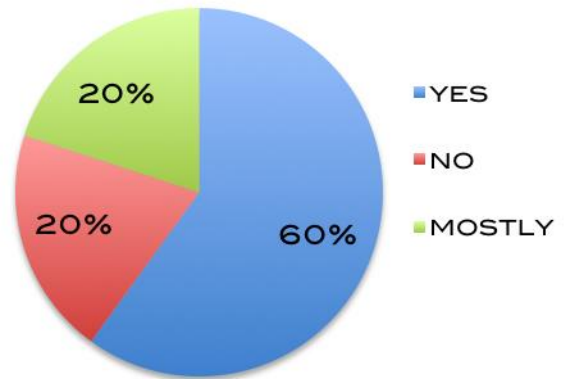


Chart 7 depicts that the doctors were of varied opinion on whether the dichotomy between saving lives and practicing as per ethics is useful for medical practice. Doctors with experience of over 7 years were of united opinion that it does not effect the practice.

Chart 8 depicts the awareness among doctors about the Indian Medical Councils code of ethics and to the utmost shock forty percent of the doctors (experience of upto 3 years) were either not aware or had an incomplete knowledge of the same.

Chart 9

Ques -Do you have a ethical committee in your institution ?

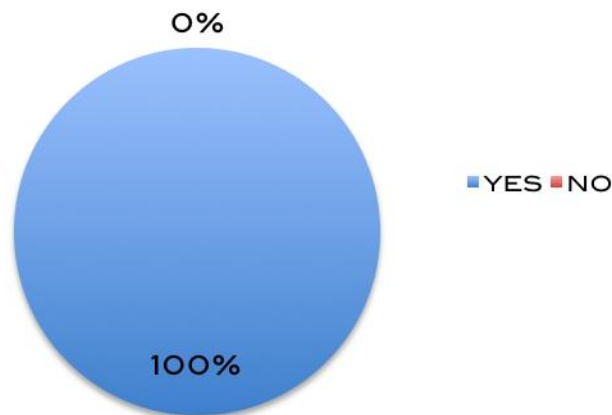


Chart 9 depicts that in all the medical institution there is an ethical committee.

Chart 10

Are you aware about other laws that affect the Medical Practice ?

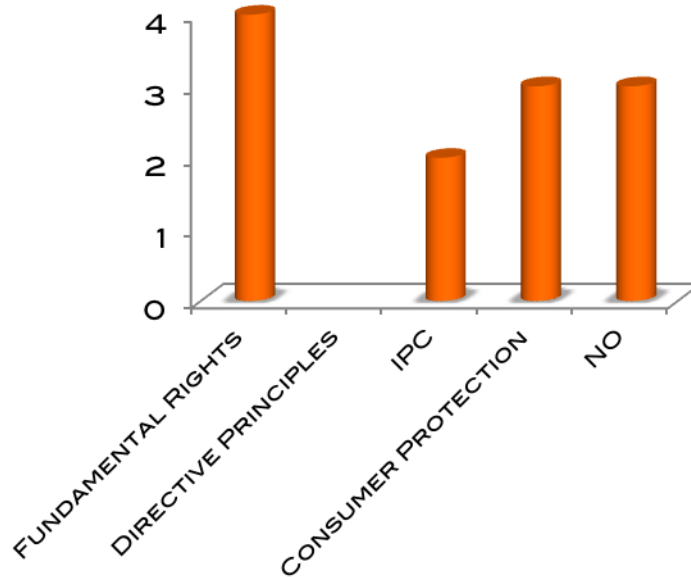


Chart 10 depicts the knowledge of the doctors about various laws that affect their practice. Thirty percent were not aware of any laws and a very few had knowledge about applicability of Fundamental Rights, Indian Penal Code, Consumer Protection Act or the Directive Principles of State Policy.

Chart 11

Ques -Are you in favour of a modification in Medical Ethics ?

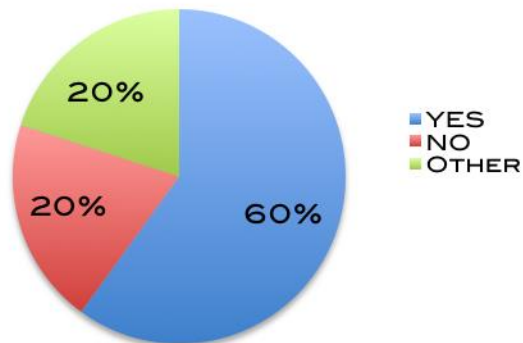


Chart 11 depicts that more than half of the doctors feel there is a need to modify the current ethics in the medical field and only a few were in acceptance of it in the present form.

Chart 12

Ques -Do you know what makes a practitioner negligent ?

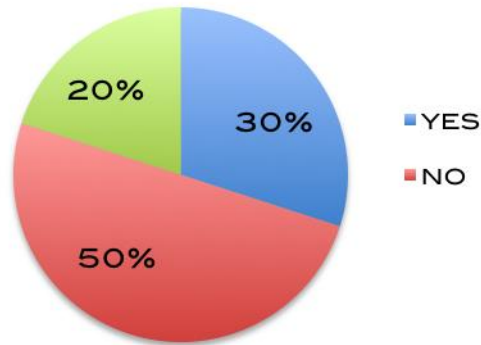


Chart 12 to a surprise depicts that half of the doctors are not aware as to what makes them negligent (mostly 1-3 years experience) and only the doctors with experience 7 years or more were fully aware about the same.

Chart 13

Ques -Are you taking precautions to prevent charge of negligence ?

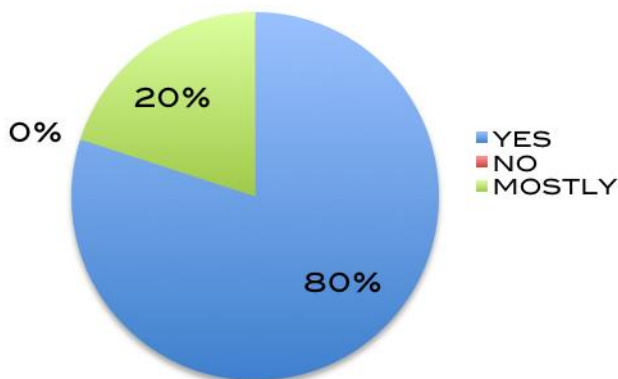


Chart 14

Ques -Do you think these precautions become a hindrance to your practice ?

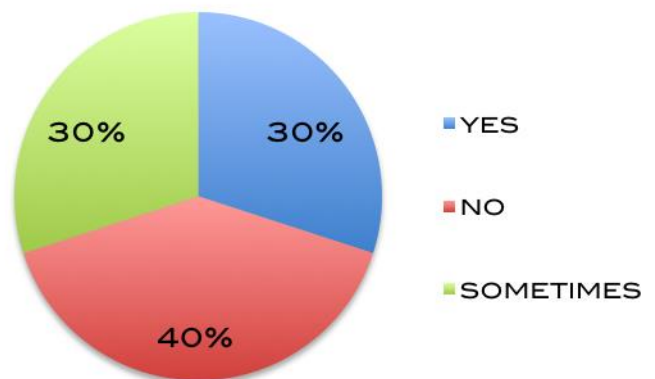


Chart 13 depicts most of the doctors are taking some steps or the other to prevent a charge of negligence.

Chart 14 depicts that the doctors had a varied response to the question on whether steps taken to prevent a negligence charge are a hindrance to your practice. The doctors with experience of more than 7 years were of the view that it does not have an impact whereas the experience bracket of 1-3 years found it to interfere with their practice.

Chart 15

Ques -Are you taking a proper consent before any examination or procedure and is it an informed consent ?

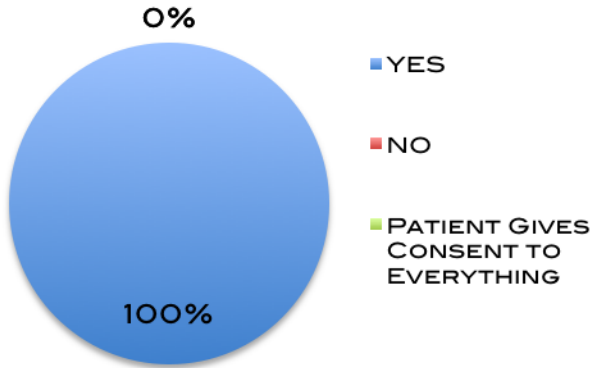


Chart 15 depicts that all the doctors are taking an informed consent from their patients before any procedure.

Chart 16

Ques -Do you think consent and documentation can prevent a charge of negligence ?

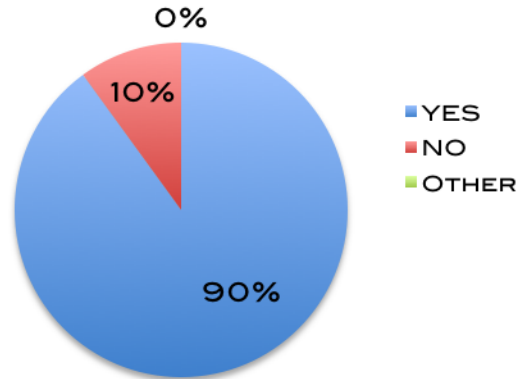


Chart 16 depicts that most of the doctors are of the opinion that consent and proper documentation can help prevent a charge of negligence.

Chart 17

Ques -Have you insured yourself against medical liabilities ?

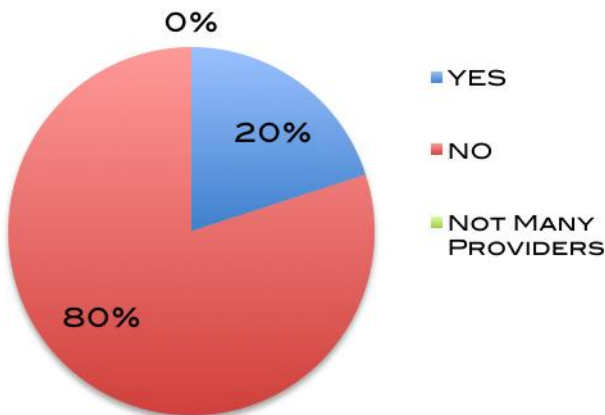


Chart 17 depicts that only two doctors with an experience of over 7 years have insured themselves against medical liabilities whereas all others have simply chosen not to.

Chart 18

Ques -The inclusion of Medical practice in Consumer Protection Act has made the practice defensive ?

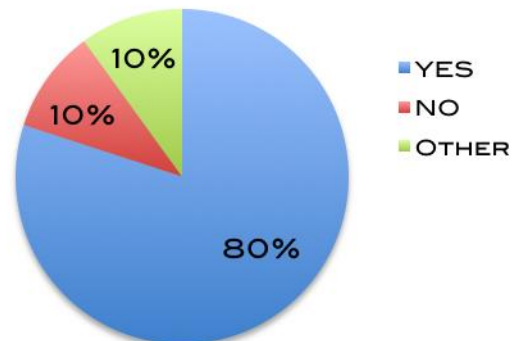


Chart 18 depicts eighty percent of the doctors are of the opinion that inclusion of medical practice in Consumer Protection Act has made their practice defensive.

Chart 19

Ques -Do you think Continuing Medical Education in relation to MLC and medical ethics at regular intervals is necessary ?

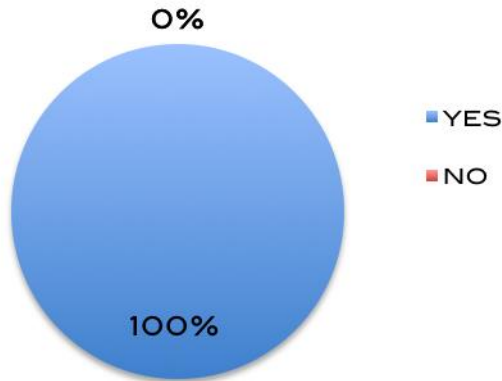


Chart 20

According to you what could help in eliminating medical malpractice in India ?

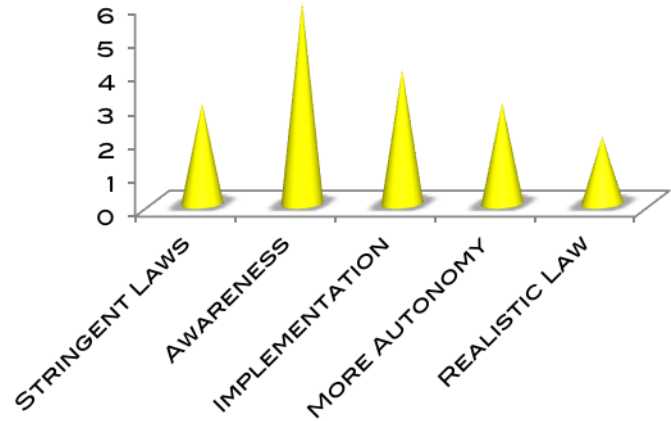


Chart 19 depicts that all the doctors think that continuing medical education at regular intervals is necessary.

Chart 20 depicts that spreading awareness and implementation of already established laws could help in elimination of medical malpractice in India as per the doctors.

The last question for the doctors was to give any suggestions regarding the prevalence of medical malpractice in India, the suggestions are summed up below:

1. Better working environment will help eliminate negligence, as the doctors would be able to pay their cent percent attention to patients.
2. Better pay to doctors will prove to be an incentive to create that urge of giving their best.
3. Non-Interference and Freedom to doctors in exercising their duties.
4. More time should be devoted to the subject of Laws and Ethics in the medical curriculum.

ANALYSIS: PATIENT

Chart 21

Ques - Do you have a health insurance?

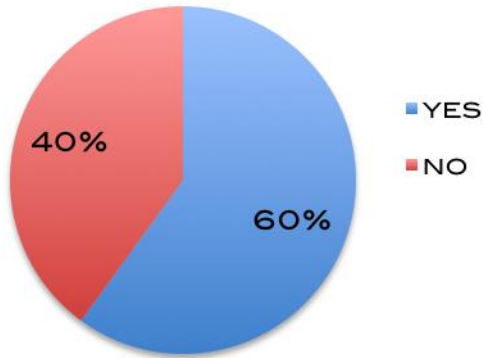


Chart 21 depicts that only sixty percent of the patients have health insurance.

Chart 22

Ques - Are you aware about the framework and special precautions regarding medico legal i.e cases where legal system would be involved?

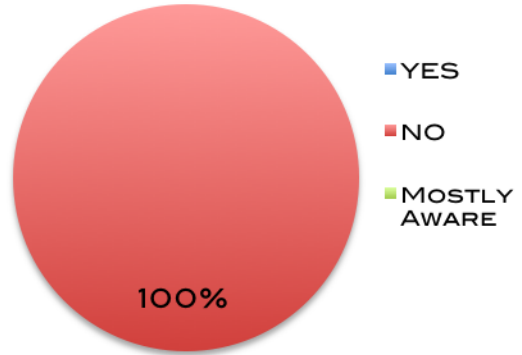


Chart 22 depicts that none of the patients had any knowledge about the framework regarding medico legal cases.

Chart 23

Ques - Have you ever been admitted to a hospital for your treatment?

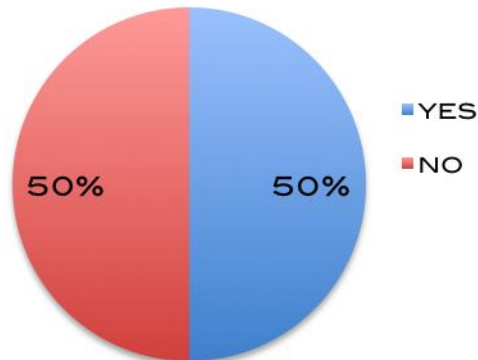


Chart 23 depicts that from our sample, half of the patients have been admitted to the hospital for treatment besides regular check-ups.

Chart 24

Ques - Are you in favour of ignoring medical ethics in order to save/help the patient?

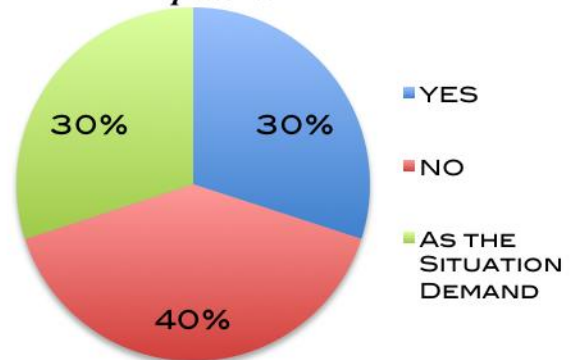


Chart 24 depicts that patients above the age of 29 years were not in favor of ignoring ethics, whereas patients below the age of 29 were inclined towards helping and saving the patient.

Chart 25

Ques - Do you prefer ethics being followed or saving lives even if it involves unethical practice?

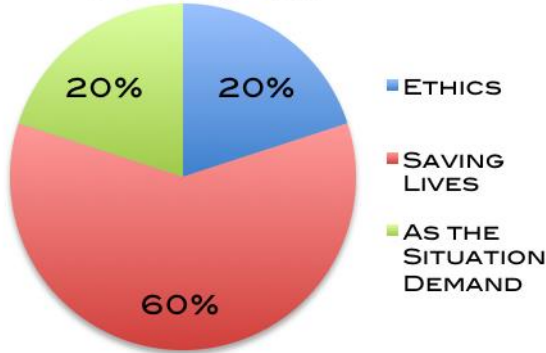


Chart 25 depicts that most of the patients think that saving lives is of utmost priority. However patients above the age of 50 years prefer ethics.

Chart 26

Ques - Will you force your doctor to adhere to ethical practice at the time of treatment?

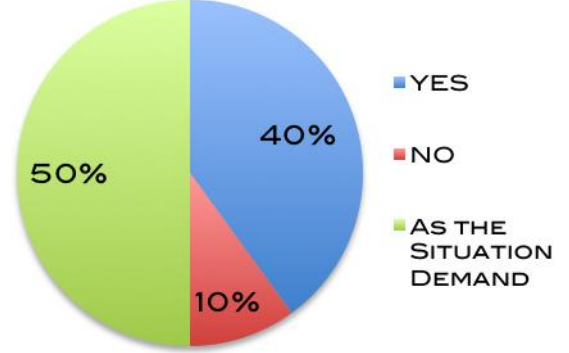


Chart 26 depicts that half of the patients were not clear whether they would force their doctor to adhere to ethical practice when their treatment is going on. Patients above the age of 29 years were still confident on ethical practice.

Chart 27

Ques - Does ethical practice mean charging fair money from patients or following proper procedures?

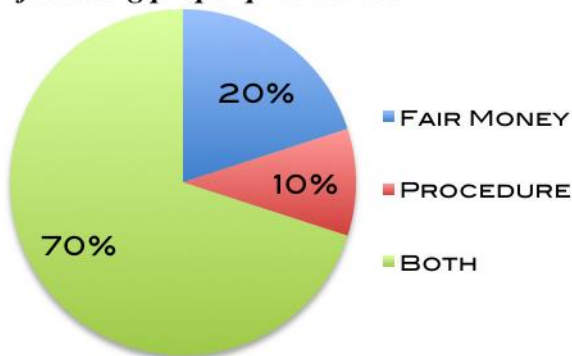


Chart 27 depicts that seventy percent of the patients think that ethical practice means charging fair money and following proper procedures. Twenty percent of the patients who think that ethical practice is charging fair money are of 20-29 years of age.

Chart 27

Chart 28

Ques - Are you aware about informed consent?

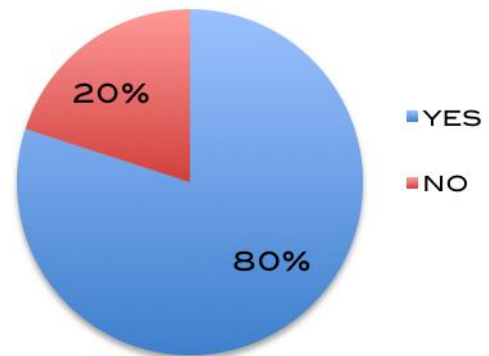


Chart 28 depicts that eighty percent of the patients are aware about what is an informed consent.

Chart 29

Ques - Did your doctor take an informed consent from you or your family?

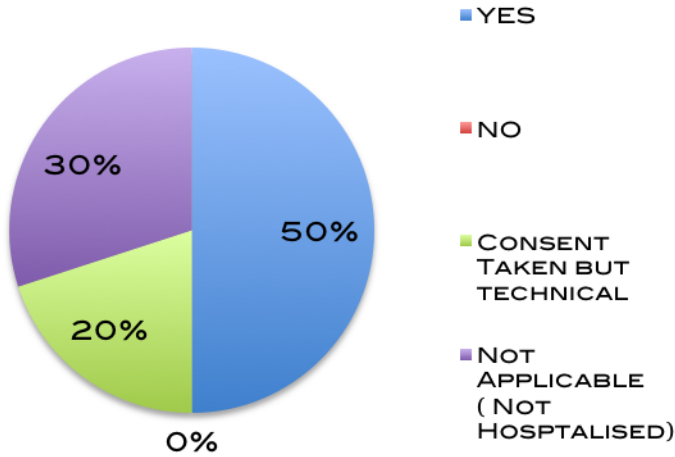


Chart 30

Ques - Are you aware about the Medical Council of India's Code of Ethics that a doctor needs to follow?

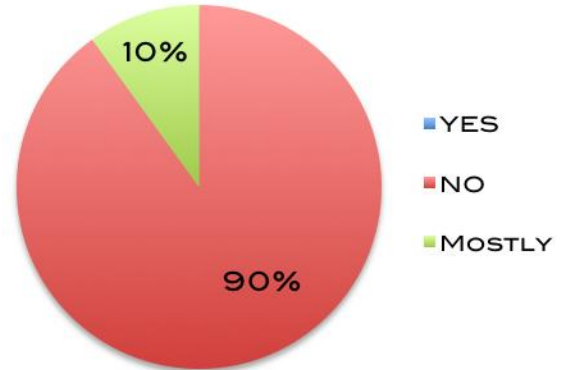


Chart 29 depicts that half of the patients who were hospitalized for treatment were informed properly about the procedures. Twenty percent of the patients said where an informed consent was taken it was so technical that they did not understand the pros & cons of the same.

Chart 30 depicts that surprisingly ninety percent of the patients are not aware of the code of ethics.

Chart 31

Ques - Are you aware that there is a Ethical Committee in every hospital?

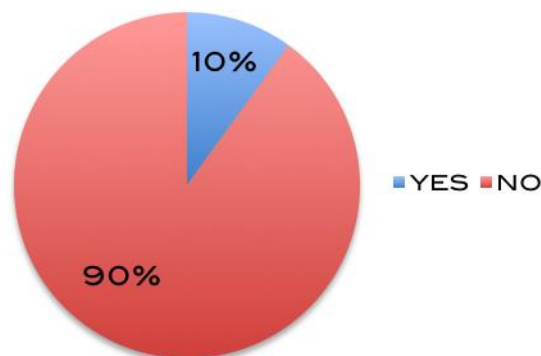


Chart 31 depicts the low level of information amongst patients, with ninety percent of them not being aware about presence of an ethical committee.

Chart 32

Ques - Will you complaint against your doctor for unethical practice in middle of your treatment or wait till something goes wrong?

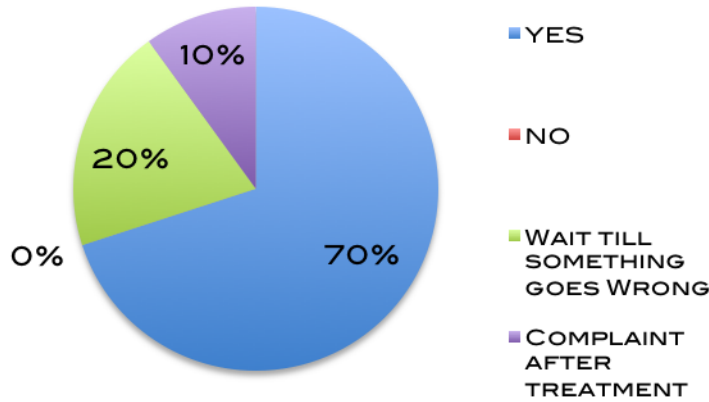


Chart 32 depicts that seventy percent of the patients will complaint against their doctor irrespective whether their treatment is going on or not. Another twenty percent said they would wait till something goes wrong.

Chart 33

Ques - Do you know what makes a medical practitioner negligent?

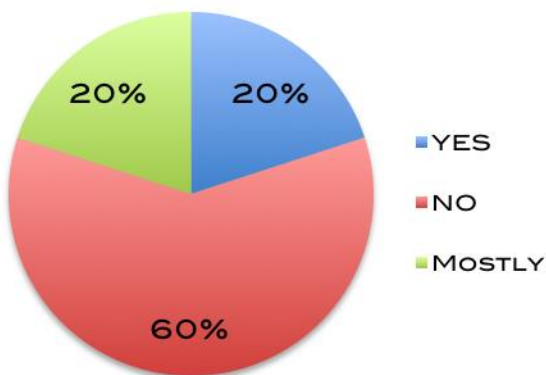


Chart 33 depicts that sixty percent of the patients are not aware of what makes a doctor negligent. Only those above the age of fifty years were aware of the same.

Chart 34

Ques - Will you give your consent to everything that seems useful till the time it does not involve huge money?

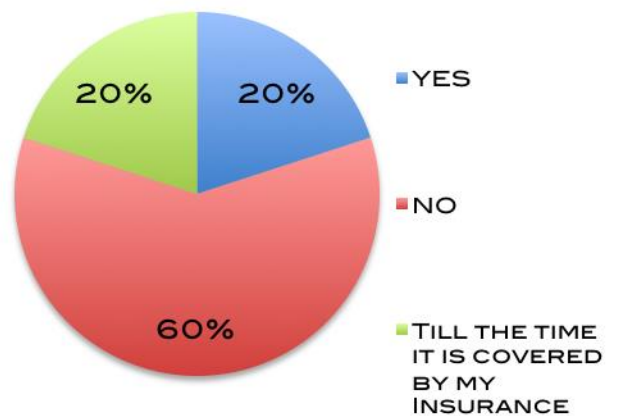


Chart 34 depicts that sixty percent of the patients will not give their consent even if it doesn't involve huge money. However, twenty percent were of the view that doctor knows the best and the remaining twenty percent indicated that they will give their consent if it is covered in their insurance.

Chart 35

Ques - Do you think consent and documentation are necessary or the doctor knows the best?

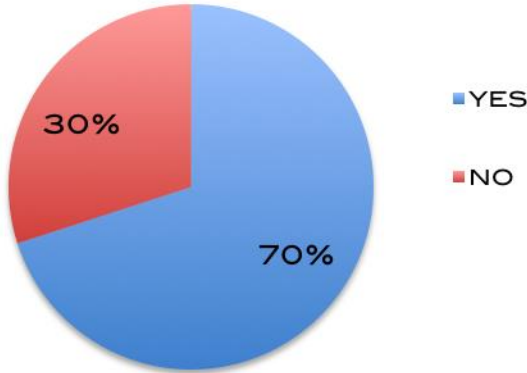


Chart 36

Ques - Are you aware that the Medical practice is covered under the Consumer Protection Act ?

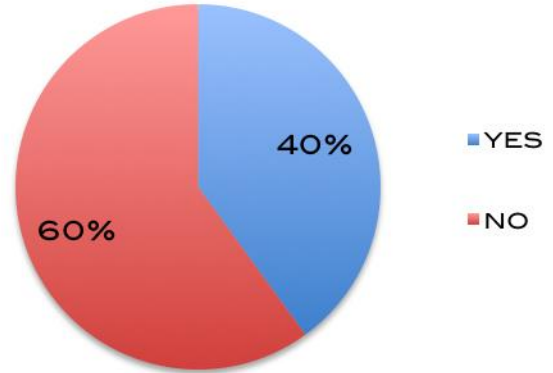


Chart 35 depicts that seventy percent of the patients think that consent and documentation are necessary in a medical treatment whereas thirty percent (mostly above the age of 50) rely on what the doctor says.

Chart 36 depicts that the awareness among patients about the medical field being covered under the Consumer Protection Act is poor. To the utmost shock sixty percent of the patients do not have any information regarding the same.

Chart 37

Ques - If answer to previous question is YES, are you aware about the procedure to file a complaint in Consumer Protection Forum?

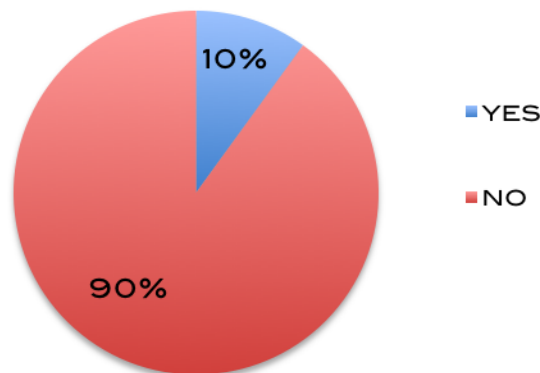


Chart 37 depicts that of the forty percent patients aware of the inclusion of medical services under the consumer protection act, only ten percent are aware of the procedure to file a complaint. It should be pointed out that a simple letter is sufficient to lodge a complaint in a consumer forum.

Chart 38

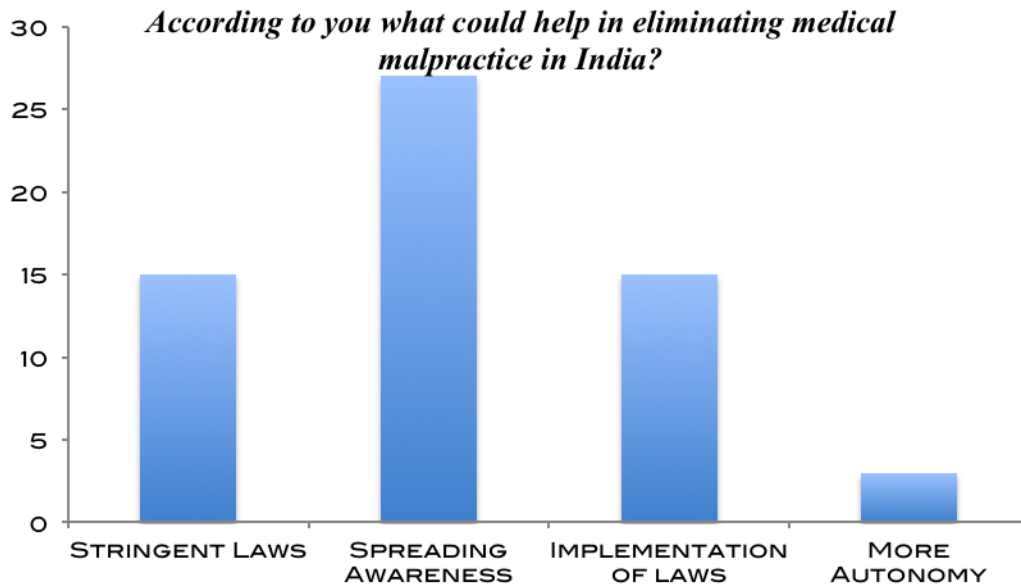


Chart 38 depicts that spreading awareness is considered to be the most effective way of eliminating medical malpractice in India according to the patients. Stringent laws and its implementation is also seen as a positive step. It is good to note that the doctors expressed a similar view when asked the same question.

The last question for the patients was to give any suggestions regarding the prevalence of medical malpractice in India, the suggestions are summed up below:

1. More Transparency to be introduced in the medical institutions regarding reports, procedures, billing and other related matters.
2. More Communication should be there between the Doctors and Patients.
3. Creating general awareness among masses regarding medical laws and ethics to build an informed class of patients.

OUTCOME OF THE ANALYSIS

From the information that has been collected out of this survey, we conclude that in India Doctors with less experience are not fully aware about various laws and guidelines related to medical practice.

This state of affair is very alarming as the freshly designated medical practitioners are not in sync with the knowledge that might affect their whole career. This can also be seen by the fact that all the doctors were in favor of continuing medical education regarding laws and ethics.

The other point that comes out of this survey is that very few doctors have insurance for medical liabilities. Of the others who do not possess such insurance it is because of their own choice. Also, they do not point out the lack of insurance providers

Further, the doctors are trying to avoid medical liabilities by taking special precautions. These precautions are over and above their normal practice that is an extra burden and appears to affect their practice.

It is for the authorities to realize that the Indian Medical Council should take some steps and ensure that every doctor has complete knowledge on the laws & code of ethics. This in my understanding would be the first step towards attaining a medical malpractice free India.

From the Patients perspective we come to find that in India a lot of people do not even have a health insurance. This is true not for the elderly but the younger strata of society. This situation is alarming as the young would not have a regular source of income and savings to support themselves in case of any emergency.

It was observed that the patients do not have knowledge about medico legal cases, the inclusion of medical services in consumer protection act, presence of an ethical committee in every hospital nor do they have any knowledge about the code of ethics as promulgated by Indian Medical Council. In such a scenario the patients are not aware on what makes the doctor negligent neither do they know about their legal rights and the remedies available to them.

Further, it is observed that the patients trust their doctors a lot and do not want to interfere with their decisions about the treatment. There is also a fear to institute a complaint against the doctors as it is believed that it might lead to jeopardizing the treatment. The patients will only be willing to lodge a complaint if something goes wrong.

With the patients, given that money plays an important factor for giving consent for various procedures and treatment, Insurance seems to be a very good option to counter this.

Similarly to the need of spreading awareness about the laws by Indian Medical Council among doctors, there is also a need to create mass knowledge among the patients. They should be imparted with education about their legal rights and the remedies available to them. This will further help them to make informed decisions, ensure that the doctors follow the right procedure, keep them in the ambit of ethics and not be duped for money.

CHAPTER IV - ECONOMIC RATIONALE FOR THE LAW

The primary function of tort law in the sphere of medical malpractice is to create incentives for efficient levels of care and hence to reduce the rate of inappropriate accidents to the number of accidents. Thus, all patient compensation systems aim towards two objectives:

The doctor can be given an incentive to take special care and avoid making mistakes which may harm their patients and their reputation (the “deterrence” objective); and the cost of the harm can be transferred away from the patient (the “compensation” objective).

All patient compensation systems attempt to deliver these objectives jointly with varying degrees of success, and with varying administration costs.

PREVENTION AND DETERRENCE

Deterrence concerns the allocation of resources to reduce the probability of accidents occurring and to reduce the loss in the event of an accident. Specific deterrence involves the direct prohibition or regulation of dangerous conduct or activities (e.g. by means of statutes or regulations) in order to reduce the number of injuries and injury-causing incidents, whereas general deterrence involves the use of compensation rules to provide indirect incentives to people to behave safely. Thus, tort law and medical malpractice law are supposed to provide general deterrence by inducing physicians and hospital organizations to prevent injuries.

Optimal Incentives

It is well known that beneficial activities can lead to costly outcomes (‘harm’, ‘injury’). Such costly outcomes can be reduced if the beneficial activities themselves are cut down, or if those involved take care to avoid them. However, to the extent that care is also costly, people may need to be given incentives to provide it. One natural incentive is to make the person causing the harm liable for the costs involved, if he fails to supply care beyond a sufficient threshold (i.e. behaves ‘negligently’). This potential attribution of fault provides a deterrent against insufficient care levels. As a consequence, tort rules will efficiently deter accident-causing behaviour if responsibility for the costs of injuries is imposed on those who can avoid or prevent accidents most cheaply.

A physician and a hospital organization have several ways to prevent accidents, e.g. apply new technology, invest in a hygienic surrounding and in training of doctors and assistants and so on. As long as the patient follows the directions of the doctor, e.g. eat diet food, take pills regularly, in most of the cases he has no influence on the accident apart from the fact that he became ill and consulted the doctor. As a consequence, medical malpractice law should hold the physician responsible because he can avoid costs of injury at cheapest cost by investing in precaution. To induce him to invest in precaution he needs to receive the optimal incentives from the liability system.

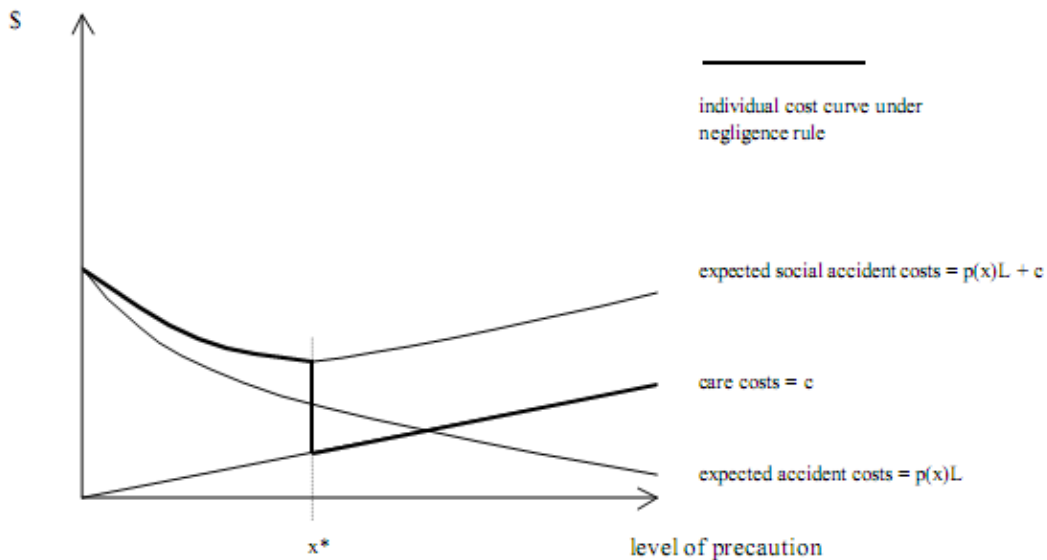
Efficient Level of Care

In theory, the appropriate level of care should maximize the net gains to society from the beneficial activities involved: this means that the marginal social benefit from an extra care should equal its marginal cost. In other words, the extra benefit to society (in terms of reduction in injury rates and their associated costs) from an extra care should just equal the extra resource cost to society of the extra care itself. The notions of benefit and cost referred here are broader than simple monetary amounts.

Minimizing Social Accident Costs

To demonstrate the minimization of the accident cost, the basic model of minimizing social accident costs can be applied. First, the physician's care costs (c) are constantly increasing with undertaking more precaution. Second, the probability of a medical malpractice (p) decreases with a higher level of precaution. Thus, $p=p(x)$ is a decreasing function of x . The expected cost of an accident depends on the probability that an accident occurs (p) and the loss (L), therefore the expected cost of accident equals p multiplied by L and is also a decreasing function of precaution ($p(x)L$). Third, the expected social cost of accident is the sum of the expected cost of accident and the cost of care, therefore it equals $p(x)L + c$. Finally, x^* represents the efficient level of precaution the physician should take, because the expected social cost of accident curve has its minimum here.

Figure 1⁴⁹



For a negligence rule, the courts have to define a legal standard of care (= due care level). If the injurer takes less than due care, he is liable. If the injurer takes due care or more, he

⁴⁹ Basic Model.

is not liable anymore. Therefore, according to the basic model, if the physician is liable his individual cost curve equals the expected social cost of accident, whereas if he is not liable his individual cost curve equals his cost of care. Thus, his expected individual cost reaches its minimum exactly at the due care level where his care cost are the lowest and where the due care level equals the efficient level of care.

Consequently, a negligence rule provides the optimal incentives to take the efficient level of care and to minimize social accident cost, assuming that courts are well informed and that they apply a clear and precise legal standard of care requiring a fixed amount of precaution. This is important, since uncertainty about the due care level does not induce the physician to take optimal levels of precaution. However, it is difficult for the courts to set the due care level equal to the efficient level of care, since they are in practice not fully informed. If the due care level is set below the efficient level of care, the injurer will minimize his cost by taking the due care level. However, the injurer does not take the efficient level of care. On the other hand, if the due care level is set a little bit above the efficient level of care, the injurer minimizes his cost by taking due care which is not the efficient level of care either. If the level of care is set far too high, the injurer minimizes his cost by taking the efficient level of care. *Thus, the efficient level of precaution which minimizes the social accident cost is only reached under a negligence rule if the level of due care is set equal to the efficient level of care or is set far too high.*

Optimal Compensation

Compensation, as a purpose of medical malpractice law, involves the allocation of losses resulting from accidents that occur. For the malpractice system to work as an efficient deterrent to negligent behavior, physicians must encounter an expected loss sufficient to make them fully aware of their deficiencies, but not substantially above that level. Apart from material losses that are, at least in principle, measurable in terms of money, damages are awarded for certain immaterial losses. Damages for mental distress such as pain, suffering, discomfort, humiliation, indignity, and embarrassment, are awarded under the head of “Immaterial losses or pain and suffering”. If awards do, in cases where immensely high sums for pain and suffering are granted, exceed the losses suffered by claimants, and if there are too many successful claims then we have a problem of *excessive liability*. This means, damage paid by the physician must not exceed the damage suffered by the patient. At the same time, a tort system should at least provide full compensation for material losses as well as for immaterial losses, not more and not less, since the victim should be in the same position of wealth he was in before the accident happened. Therefore the theoretical aim of the tort system is to set the value of an award equal to the loss suffered (*full compensation*).

Problems with Compensation for ‘Immaterial Losses’

The legal purpose of such compensation is on the one hand to redress for the non-pecuniary losses suffered and on the other hand satisfaction in the sense that the injurer is made to pay for his negligent action. However, these purposes of compensation are in some medical cases difficult to justify. For instance, medical science can keep people alive in a state of complete coma for many months or even years, with no hope of

recovery. No substitute pleasures need to be provided for those forgone, because the injured party is unable to enjoy any pleasures. Nevertheless, courts say that a person who is deprived of all the pleasures of life gets compensation for the fact of that deprivation. Thus, from an economic point of view, on the one hand the victim gets no utility from an award of damages in these cases and therefore would not need compensation. But on the other hand only full compensation has the deterrent effect on the injurer. Therefore, it is necessary to make the injurer pay full compensation to the victim.

Another problem with perfect compensation for pain and suffering is that, it is very difficult to calculate, because the relationship between the value of money - what it will buy - and damages awarded for pain and suffering cannot be measured like in financial losses.

Punitive Damages

Punitive damages are sometimes awarded to plaintiffs in addition to compensatory damages, i.e. over and above compensation for material and immaterial losses. These are only awarded in cases where injurers might escape liability or where harm is underestimated or where the injurers' gains are socially prohibited, because punishment and deterrence are supposed to lead to only full compensation. Thus, they also involve the danger of overcompensation and over deterrence, since the damage paid by the injurer exceeds the damage suffered by the victim. Although the term punitive damage implies punishment, the purpose of these damages is only partly punishment, but mainly deterrence.

STRICT LIABILITY VERSUS NEGLIGENCE RULE

The law, which currently applies to medical liability, sets negligence standard and is based on the principle of torts.

As pointed out earlier, mostly the cases of medical negligence are of unilateral accidents where only the injurer (i.e the medical practitioner) may reduce the risk for accident by taking precautions.

In this situation, if the applicable rule is strict liability, the injurer pays the damage in each case of accident. Therefore, the injurer, guided by his private considerations, takes all relevant social costs into account, internalizes the risk for damage and conducts himself professionally at socially optimal care and activity levels.

When the applicable rule is negligence, however, if the court determines a negligence standard based on social optimum, the potential injurer should adopt precisely this level of care. *He will not adopt a higher standard of care since exemption from liability has already been granted at an optimal level of investment, while any higher level of investment in precautions will necessarily entail higher costs.* Conversely, the potential injurer will not adopt a lower level of care since he will be made to compensate any potential victim for any damage caused while the benefit of saving in precautions will be lower.

In theory, the optimal level of care is achieved through the application of both rules but

the two liability rules differ in terms of behavior directing differential effects on potential injurer and victim's payoffs and risks allocated between the two.

The negligence system operates in practice very differently from this theoretical ideal, primarily because the decision-makers - courts, doctors, and patients lack the perfect information that is assumed by the models. It is because of this that the negligence rule has come under severe criticism. Because courts lack perfect information about appropriate care, the standards applied in practice are unpredictable and possibly systematically biased. With uncertain legal standards, a negligence rule may create non-optimal deterrence incentives or may not be able to convey to doctors the appropriate signals about the optimal level of care. A rule of strict liability in theory eliminates the need for courts to define due care.

Thus, in the context of judicial errors⁵⁰, the negligence regime is relatively more sensitive to judicial errors concerning the level of care adopted by the injurer and the appropriate level of care. The strict liability regime, on the other hand, does not suffer from such errors. It is, however, more sensitive to judicial errors concerning causality and damage assessment i.e determining whether an injury was caused by medical care or by the underlying disease and the extent of damage.

An important advantage of strict liability is seen in its decentralisation or self-selection effect. If different doctors have different costs of care, the optimal level of care, which minimizes the sum of the costs of care and the expected damages, is different for each doctor and it decreases with increasing per unit costs of care. Under strict liability regime, every tortfeasor doctor has an incentive to minimize these costs as these are the costs of the society as well as their private costs. *Such an efficient result is not reached under negligence rule, in which courts fix a due level of care according to the 'reasonable man' standard.* If this due level of care is somewhere in the middle between the optimal standard of a high and a low cost tortfeasor doctor, both of them get wrong incentives. Imperfect information further leads to longer periods of litigation accompanied by escalating litigation costs, inappropriate compensation, mismatch between claims and injuries as a result of which the negligence rule fails to achieve its central goals of compensation and deterrence.

Nevertheless, despite its flaws, it can be argued that it is better to select negligence rule over strict liability in the area of medical liability. As pointed out earlier, medical treatment always involves a basic risk that something might go wrong, since the human body of each patient can react differently to a certain treatment because of prior medical conditions. *A contract over a medical treatment is not comparable to a contract over the purchase of a good or a service, where the seller guarantees that he will deliver a perfect good and otherwise the buyer can claim compensation.* By contrast, a physician cannot guarantee the success of his treatment. Therefore the physician should not be held strictly liable without the possibility of exculpation, because he cannot bear the risk for every injury resulting from the basic risk of a medical treatment and which might happen although he took a high level of care. Thus, under a rule of strict liability he would be

⁵⁰ Errors in deciding the appropriate level of care and correctness of doctor's decision.

over deterred. However, in malpractice cases which do involve negligence, he should be held liable and thereby receive the correct deterrent signal to give him the optimal incentive to take more precaution.

A negligence rule requires the difficult decision of the court whether the behavior of the defendant is considered negligent or not. Thus, compared to a rule of strict liability, a negligence rule leads to higher administrative or litigation costs. On the other hand, strict liability does not allow the defendants exculpation and will therefore result in more claims, since the rule gives every victim who suffers harm caused by the injurer's activity the right to recover. Taking this into account, a negligence rule may lead to lower total administrative costs. To put it simply, a negligence rule results in fewer claims that are more complicated to settle, whereas a rule of strict liability results in more claims that are simpler to settle.

The superiority of the negligence rule over strict liability in the context of medical liability can also be argued on the basis that the former generates more information about the due and the efficient level of care. It requires the court to look into issues relevant for conveying the information needed by the market through the way of investigations: Has the doctor acted optimally, including appropriate professional up-to-datedness? Has the hospital acted optimally, for example, in purchasing the appropriate medical gear? The negligence mechanism thus ensures that the courts provide the market invaluable information focused on exposing the hidden actions and qualities of the doctor. On the other hand, a strict liability rule dispenses with such investigations, thus conveying much less information to the market. Negligence rule indirectly motivates the doctors and hospitals to adjust the appropriate medical procedures through time.

A similar argument can be put forward for medical cases of vicarious liability. Vicarious liability is the liability of a principal for a damage caused by its agent. If the agent causes damage to a third party, the third party may file a damage claim against the principal. In cases of medical negligence, the doctor serves as the principal; a medical student, nurse or any other staff may serve as an agent, while the third party is the patient who incurs damage. Alternatively, the hospital may serve as the principal, the doctor as the agent and the patient as the third party. An agent may hide her type from the principal, which might lead to a higher probability of damages post hiring (hidden information) or it might choose a low level of care for personal benefits at the expense of the principal (hidden action). If the cases of medical liability are governed by the negligence rule, then the doctor or the hospital obtains information about the negligent behavior of its employee. The principal can possibly write a contingency contract under which the agent is made to face the consequences if it has caused damage. In contrast, for the principal agent problem under a strict liability rule, any causation of damage by the agent triggers the liability of the principal. Thus this rule generates no information about the agents' negligence in court proceedings.

In the cases of medical negligence often the terminology of 'multiple tortfeasor' gains relevance. This is due to the fact that often doctors act together in a team or at least more than one health care professional is involved in a case of medical diagnosis and treatment. Under the rule of negligence, the injurers will act optimally together only if due level of

care is optimally determined. This is because, if one doctor fails to take the due level of care, then he will be held liable for the total amount of the accident loss. A rational doctor will assume that the other rational colleague has decided to exercise efficient precaution, and that being true; it is optimal for him to also exercise the optimal care level. Thus negligence rule ensures optimal incentives being generated for a group of doctors acting collectively.

While a comparison of the two liability rules over various issues may not produce a clear winner in general, but in the area of medical liability it would not be wrong to conclude that the negligence rule is the appropriate liability regime, which can be justified by sound economic rationale.

MEDICAL MALPRACTICE INSURANCE

Although not compulsory in India, usually every medical practitioner should have a liability insurance known as 'Professional Liability/Indemnity Insurance', which covers negligent malpractice resulting in an injury of a patient. Malpractice insurance has an important social value because it spreads risks and thereby protects the physician against the financial catastrophe that could result from even a single large finding against him. In this way, insurance supports the well functioning of the health system. Another benefit of such insurance is that, it creates certainty for risk-averse physicians. When people are risk averse, they prefer lower certain income rather than higher uncertain income. Hence, physicians prefer spending on these insurance premiums rather than bearing the risk of having to pay incalculable damages in case of an injury to the patient.

But, medical malpractice insurance has a disadvantage too. With an insurance cover, since a physician does not suffer a monetary loss from having to pay compensation (apart from the insurance premium); he simply passes on his liability to the insurance company. Thus, even if the liability system has a deterrent effect on the physician, it could be neutralized by the insurance system. The physicians thus may not take appropriate care, which they would have taken if they had to face any unforeseen liability themselves. In particular, the problems of moral hazard and adverse selection emerge which need to be considered in this context.

The Problems of Moral Hazard

Moral hazard means when the behavior of the insuree changes after the purchase of insurance so that the probability of loss or size of the loss increases. This occurs as a consequence of unequal information between the insurer and the insuree. In the context of medical negligence, this means that after getting insurance a doctor would have no incentive to undertake the efficient level of care. This would lead to higher chances of negligence or greater loss to the patient. The root cause of such a problem is the fact that the insurer does not know the exact riskiness of the doctor and hence his insurance premiums are too not tied to the expected liability of the doctor.

High-risk insurees try to hide information to get a premium lower than their actual risk requires, whereas low-risk insurees mostly do not have the possibility to signal that their actual risk requires a lower premium. Since, premiums are usually set for an entire

specialty group in a given region; the premiums are set according to an average risk level of the entire group. Thus, the high-risk insurees end up paying lower premiums and the low-risk insurees pay a higher premium than what their actual risk requires. Also, because a physician with a record of frequent negligence bears no larger share of the burden than his colleagues with excellent records, a physician might get the incentive to take fewer precautions, because he gets no benefit out of taking care.

The Problems of Adverse Selection

Adverse selection occurs when in ignorance of differences among policyholders; an insurer attracts those of above-average risk. This may occur if low-risk insurees drop out of the market rather than paying premiums designed to cover average risk. An insurer who raises rates may attract the worst risks and end up with higher claim costs and lower profits.

A physician might not take the efficient level of care, because he does not have to pay the damages himself. When he takes fewer precautions, damages might be more frequent or larger than without the insurance. As a consequence, to cover his costs, the insurer will raise premiums. The low risk insurees will leave the insurance, because they pay too high a premium compared to their actual risk. Finally, only the high risk insurees will stay in the insurance pool.

The consequences of moral hazard and adverse selection can be illustrated by a simple example. For instance, a physician could avoid an unexpected loss of Rs 1000 by spending Rs 100 for the insurance. If the premiums are set for a group of 100 physicians, his own premium will rise, as a result of the mishap, by only Rs 10 (and so will that of 99 other physicians). The individual physician is thus assessed only one tenth of what it would have cost him to prevent the injury. Therefore, the physician might not take the efficient level of care, because he does not have to pay the damages himself. Further suppose, after ten mishaps, the premiums double to Rs 200 for all the physicians. As a result, the low-risk physicians who haven't committed any of the ten mishaps but are compelled to pay higher insurance premiums may prefer to drop out of the market. This leaves only the high risk physicians in the market, and hence gives rise to the problem of adverse selection.

Overcoming these Problems

In particular, malpractice insurance rarely requires co-payment in the form of deductibles or coinsurance, and premiums are not generally experience-rated i.e based on prior claims experience. *If the physician had to pay an own contribution for each case of malpractice in the form of a deductible or co-insurance, he would face the monetary loss and thereby get an incentive to take a higher level of care to prevent future accidents.* Furthermore, he would also get the incentive to take more care, if the premium for the next period might be higher when it is based on the bad claims experience of the last period. Some insurance companies may respond to a persistent record of adverse claims by imposing restrictions on coverage or ultimately by nonrenewal of the contract for the next period. However, this strict policy could also lead to defensive responses, like a refusal to take high risk patients.

Although being sued does not seem to affect the physician, since the insurance policy covers negligent malpractice, the doctor nevertheless bears uninsurable costs of time (opportunity cost), in addition to anxiety and threat to reputation (medical service as an experience good). These costs might be equivalent to a high sum per claim and thus, could act as a per claim deductible. Thus, especially the risk of reputational loss lessens the moral hazard and adverse selection problems to some extent.

Therefore, the tort liability system and medical malpractice insurance should work as complements; the insurance system should support the deterrent objective of law, instead of neutralizing the incentives given by law.

ANALYSIS OF THE LEGAL FRAMEWORK FROM THE POINT OF ECONOMIC EFFICIENCY

Defensive Medicine

In a world where the efficient level of care is observable and known to everyone, i.e. individuals and courts, it is straightforward that negligence liability would produce socially optimal levels of care and hence would serve its purpose of deterrence efficiently. However, common sense that many physicians in the world buy malpractice liability insurance, tells us that these conditions are far fetched and that, in practice, problems of information disproportionateness prevent such a result. For example, courts cannot determine precisely what care a doctor has taken, while it is often the case that opinions differ as to what constitutes an appropriate standard of care. This can have numerous implications for the successful operation of a negligence tort law system. One of the most important implications here is that if the care-threshold and courts' abilities to apply it are unpredictable or physicians are extremely risk-averse (i.e. they are worried about mistakenly being found liable), they may over-invest in care. In the medical context, this is what is known as 'defensive medicine'.

The term defensive medicine has been used differently in various literatures. Some subdivide it into 'positive' and 'negative' defensive medicine. Positive defensive medicine means including extra tests or procedures conducted primarily to reduce liability. On the other hand negative defensive medicine includes procedures or patients avoided by a physician out of fear of liability. However, more recent literature generally uses defensive medicine only to refer to those extra tests and procedures undertaken out of fear of liability.

The study by Localio⁵¹ et al tries to link the incidence of caesarian deliveries in New York State in 1984 to physician malpractice premiums, on the grounds that caesarians are a lower risk method of delivery than vaginal birth. Having controlled for the clinical risk of caesarian delivery, patient socioeconomic status and physician/hospital characteristics, they find that the odds of a caesarian are three times more likely in high premium areas.

⁵¹ Troyen A. Brennan, "Identification of Adverse Events Occurring during Hospitalization: A Cross-Sectional Study of Litigation, Quality Assurance, and Medical Records at Two Teaching Hospitals" in *Annals of Internal Medicine* established by American College of Physicians, Volume 112, No.3, 1st February 1990 available at <http://annals.org/article.aspx?articleid=703656>.

They interpret this as evidence of defensive practices. In a series of three papers, Kessler and McClennan, using data on heart treatments in 1984, 1987 and 1990, estimated that reforms aimed at relaxing tort decreased expenditure on heart treatments by between 5% and 9% over the period. Given that the authors control for the outcomes of treatments, this can be interpreted as evidence of defensive medicine under tort: the ‘same’ cases, with the ‘same’ results, received less treatment expenditure under the reformed torts.⁵²

The above examples make it clear that over compensation and over deterrence can lead to the problem of defensive medicine. Where non-negligent physicians are held liable or where they have to pay more than full compensation, they will increase their level of precaution. In order to reduce the probability of liability, a physician may use superfluous tests and treatments. These payments which are not necessary from an efficiency point of view, represent a cost to the society. Thus, a physician tends to demonstrate a level of care so painstaking that neither a patient nor a jury would be likely to make the error of calling him negligent. But this immunity is bought at a cost to the society far in excess of its anticipated benefits. Thus, it is not efficient if physicians are over deterred and are induced to apply defensive medicine.

Hence, when assessing a negligence rule for medical negligence we should ideally be able to compare the deterrence benefits of such a rule, with the defensive costs that it may induce in practice. Therefore, a necessary condition for the adoption of negligence-based compensation is that it should provide net deterrence benefits.

Impact of Malpractice Tort Laws on Health Care Spending

Broadly speaking, medical malpractice laws affect the overall health care spending in two ways: by disturbing the prevailing malpractice insurance premiums and by affecting the extent of ‘defensive medicine’ used by physicians. Some analysts argue that tort laws which result in easier and higher compensation paid to the injured would lead to higher overall spending for health care. Firstly, it would increase the number and size of average award paid by malpractice insurers to claimant and, thus, increases premiums for malpractice insurance. Further, the rise in insurance premiums leads to insurers and individuals paying higher for health care services. Secondly, such tort laws would increase health care spending by escalating the intensity and volume of health care services provided. This effect is based on the premise that if laws are molded in favor of patients, then the perceived threat among physicians would rise and hence, drive them to deliver additional medical services in the form of higher ‘defensive medicine’.

Understanding such impacts of tort laws on health care spending has gained even more importance recently, since malpractice cases and insurance premiums for the physician’s liability insurance are increasing, especially in the U.S. where specialists tend to speak of a ‘malpractice crises’ or a ‘liability crises’.

⁵² Fenn, Paul, Alastair Gray, Neil Rickman and Robert Young, “Deterrence and Liability for Medical Negligence: Theory and Evidence”, *19th Annual Conference of the European Association of Law and Economics, Athens, 2002* available at <http://eale2002.phs.uoa.gr/papers/Fenn,%20Grey,%20Rickman%20&%20Young.pdf>.

In the US from the late 1960s to the mid-1980s malpractice claim frequency (number of claims per 100 physicians) increased at more than 10 percent a year; claim severity (average payment per claim) increased at roughly twice the rate of general inflation. According to this development, insurers increased their premiums for the liability insurance, e.g. from 1982 to 1984 premiums increased as much as 45 percent. In some states, malpractice insurance was temporarily not available at any price as insurance carriers left the states (Olsen 1999). Consequently, such a 'crisis' involves the danger that some physicians might leave the market and that the whole health system might be affected.

The main reasons behind such a development are the fact that in the US, increasing levels of compensation was paid for 'immaterial losses' and 'punitive damages'. This is also evident from the increased number of damages and by a higher litigation rate. This led to the problem of overcompensation and over deterrence, adding further to the 'crises'. This so-called 'crises' not only acts as a drain on the resources of the economy (in the form of unduly high health care spending), but also endangers the mere existence of the health care system.

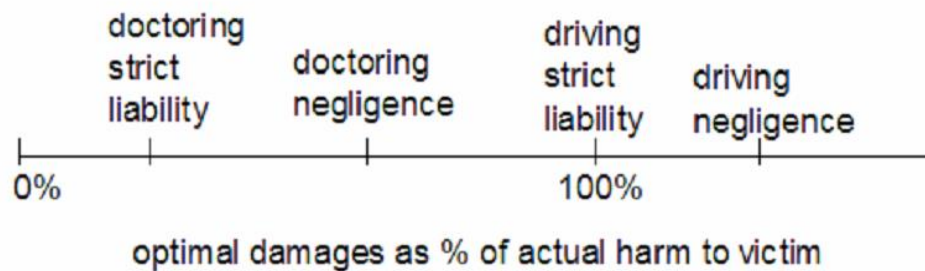
Thus, taking cues from the problems faced by the US health care system, the Indian malpractice laws must be applied so that the aim of providing justice to the injured patient does not lead to the problem of 'liability crises'.

*Positive Externalities - Should A Doctor Be Liable To Pay Less?*⁵³

According to legal principles, a doctor who negligently breaks a patient's leg should pay the same damages as a driver who negligently breaks a pedestrian's leg. According to economic principles, however, the driver should pay more than the doctor. Non-negligent drivers impose risk on others without being liable for it. When liability externalities are negative such as in the case of driving, liability should increase beyond full compensation to discourage the activity. Unlike pedestrians, patients contract with doctors for treatment and willingly submit to the risk of harm. Imperfections in medical markets cause some kinds of doctors to convey more positive than negative externalities on their patients. Doctors often create benefits for patients that exceed their fees in total and at the margin. Increasing liability for these doctors would discourage an activity that needs encouragement. Higher damages for doctors will cause them to perform fewer treatments that risk liability and discourage them from specializing in fields with high risk of liability. Lowering damages will decrease these undesirable effects and benefit patients.

Figure 2: Optimal Damages for Drivers and Doctors

⁵³ Cooter, Robert D. and Ariel Porat, "Liability Externalities and Mandatory Choices: Should Doctors Pay Less?", *Journal of Tort Law (University of Chicago Law & Economics, Olin Working Paper No. 313)*, Vol. 1, 2006 available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=946489.



The figure above depicts this idea. The line in the above figure represents optimal damages as a percentage of full compensation. For activities like driving, incentives are optimal under a rule of strict liability when damages equal 100% of the victim's harm. For a negligence rule, however, incentives for drivers' activity are optimal when damages exceed 100% of the victim's actual harm. For activities with positive externalities like medical care, incentives are optimal when damages are less than 100% of the victim's actual harm. For these activities, optimal damages fall as the rule of liability shifts from negligence to strict liability.

Unlike drivers, doctors usually have a contractual relationship with an injured patient. The contract may include a price that encompasses some, but not all, of the benefits to the patient, in which case we have price greater than benefit.

Thus, economic efficiency requires reducing the doctor's liability below the victim's actual harm, which current legal rules do not incorporate. This analysis may however be criticized as undermining one of the major goals of tort law, which is compensation. However, excessive liabilities discourage doctors from undertaking risky treatment and encourage them to engage in defensive medicine, the price of which is ultimately borne by the patient. It may be in the best interest of the potential victim i.e. the patients here, to provide for a part of the compensation by themselves.

EXTENSION OF THE CONSUMER PROTECTION ACT⁵⁴ TO MEDICAL PROFESSION

The Consumer Protection Act was enacted by the Indian parliament in the year 1986. This Act created Consumer Councils and other forums to settle consumer disputes. At present, there are 604 District Forums, 35 State Commissions with apex body as a National Consumer Disputes Redressal Commission (NCDRC) in the country. The Act seeks to promote and protect the various rights of consumer. Under Consumer Protection Act the definition of a consumer is extremely wide. Any person purchasing goods or indulging in the use of these goods is termed a consumer. Service under CPA means service of any description which is made available to potential users, but does not include rendering of any service free of cost or under 'contract of a personal service'.

It was only in year 1996 that the Supreme Court of India⁵⁵ held that the services rendered

⁵⁴ Act 68 of 1986.

⁵⁵ *Indian Medical Association v. V.P. Shantha and Ors.* (1995) 6 SCC 651.

by a medical practitioner are to be included and covered under the definition of services as per section 2(1)(0) of the Consumer Protection Act. It is true in theory, that this provision under the Consumer Protection Act has enlarged the scope of the subject. But what essentially remains to be analyzed is whether the inclusion of medical services in the ambit of the Consumer Protection Act has enhanced or limited economic efficiency in the system, in reality.

The inclusion of the medical services under the Consumer Protection Act is justified on several grounds. Firstly, a patient seeks a doctor's service for professional reasons. In this relationship a patient cannot control or dominate the relationship. In case of master-servant relationship a servant can be hired or fired at the master's will. Is a patient in a position to do such hiring and firing? To claim that this is true would mean ignoring the socio-economic realities of society. So, the doctor-patient relationship is a 'Contract for personal service'. Hence, it is not a 'contract of personal service' or 'master-servant relationship', how the proponents who are against the inclusion of medical malpractice cases in the CPA claim it to be. Secondly, the consumer of the health care industry cannot be excluded from the Act for it is not only doctors who are involved in the health care delivery but, the pharmaceutical industry, the medical equipment companies and other ancillary industries who are also equally involved. If the patient is not taken as a consumer then these other sectors involved in health care can also escape the provisions of Consumer Protection Act. Thirdly, Consumer Protection Act aims at simplification of procedures for seeking redressal of grievances of patients. The process can be initiated without any cost or without any court fee. It is thus aimed at securing speedy and inexpensive redressal of grievances. Lastly, it marks the growth of 'consumerism' in the country.

On the other hand, bringing medical services under the cover of CPA has generated an element of suspicion and mistrust which has marred the age-old doctor-patient relationship. While the consumer seems to be of the view that doctors have become over-cautious, doctors appear to be afraid of frivolous and vexatious litigation. It is claimed that this has resulted in situation where treatment costs have gone up due to defensive medicine practices and doctors are afraid of taking risky cases for fear of litigation. This has been named the "Doctor-Patient Mistrust Syndrome".

In principle, a district consumer forum⁵⁶ consists of: a person who is, or has been or is qualified to be a District Judge, who shall be its President, two other members who shall be persons of ability, integrity and standing and have adequate knowledge or experience of or shown capacity in dealing with problems relating to economics, law, commerce, accountancy, industry, public affairs or administration, one of whom shall be a woman. It is evident from the experience of the members of the district consumer courts, that they need not have background knowledge of medicine/medical practice. The interpretation and decisions regarding the closely related terms such as negligence, rashness, malpractice, misjudgement and misadventure in medical practice may pose severe problems in consumer forums constituting non-medical members. Often, a creation of a system of statutory advisory panel is suggested, which is largely impractical given the

⁵⁶ Composition of District Forum - Section 10 of The Consumer Protection Act, 1986.

large number district, state and national level courts that exist under the Consumer Protection Act. Thus, the highly technical orientation of medical field reflects a weakness in the efficient application the act.

It is often voiced by the medical community that bringing them in the ambit of CPA has labeled them as 'traders' and Patients as 'clients'. The Medical Council of India in principle does not allow doctors to be traders. The traders can advertise, solicit, can employ commission agents, put up large sign boards and bargain the price for selling the goods. Medical council of India prohibits doctors from doing any such act.

The rights of patients as consumers of health care industry have been practically non-existent in our country for a long period of time. Most of the basic rights of a patient such as right to know about his condition, right to participate in treatment decisions, right to have discussion with the doctor(s) which are recognised all over the world are alien to patients in India even today. The Consumer Protection Act serves not only the purpose of enlightening the patients but it also ensures effective implementation of patients' rights. At the same time, it also cannot be accepted that the application of the act is devoid of any limitations and is economically efficient. It is riddled with weaknesses which restrain the system from achieving efficiency. This is attested by an exercise I undertook of analyzing CPA which is explained below.

An analysis of the application of the Consumer Protection Act to cases of medical negligence was attempted, by analyzing relevant cases on which verdict was announced by the apex consumer body of NCDRC during the years of 2001-08. The total number of cases that reached a verdict during the period was 184. After a thorough study of all cases, the cases were quantified on various parameters such as-

- (i) Plaintiff in the case - doctor or patient
- (ii) Reason for filing of case
- (iii) Date of filing
- (iv) Date of verdict
- (v) Whether negligence of doctor was proved or not
- (vi) Compensation paid
- (vii) Party paying the compensation – Doctor, Hospital or Both
- (viii) Impact of medical treatment on patient- Hurt, Disabled or Death
- (ix) First appealed in which court (district, state or NCDRC) and the verdict and compensation announced
- (x) Compensation Claimed
- (xi) Medical specialty
- (xii) State in which the lapse in treatment occurred
- (xiii) Over-ruling of decisions (regarding liability of doctor and compensation) of state commission and district forum by NCDRC

It is important to mention here certain facts which facilitated my quantification of cases-

(a) An exhaustive list of cases pertaining to medical negligence was created. The two sources of information were the NCDRC office at Janpath, New Delhi and the legal site manupatra.com

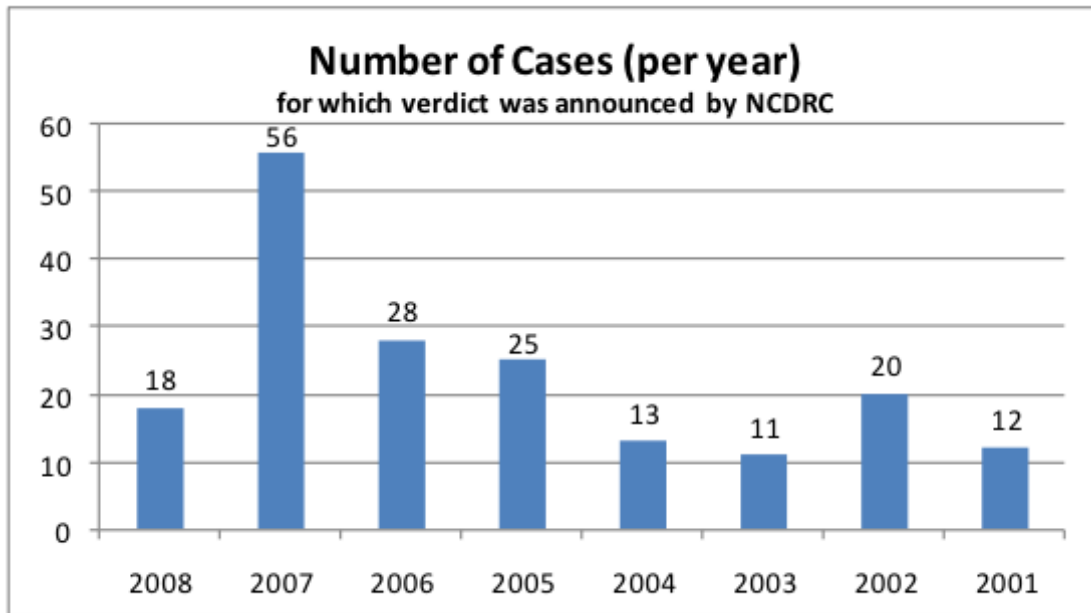
(b) A search for the exact phrase of “Medical Negligence” and words “Doctors+Hospital+Medical+Negligence” enabled me to build an exhaustive list of cases.

(c) There were 9 cases on which verdict had not been given, since these were sent back to the lower court for re-consideration. Precisely, they were not counted in the total number of cases.

(d) At present, in accordance with the Consumer Protection (Amendment) Act, 2002, a case can be filed before the District Consumer Forum for claims up to Rs 20 lakhs, State Commission up to Rs 1 crore, and National Commission above Rs 1 crore.

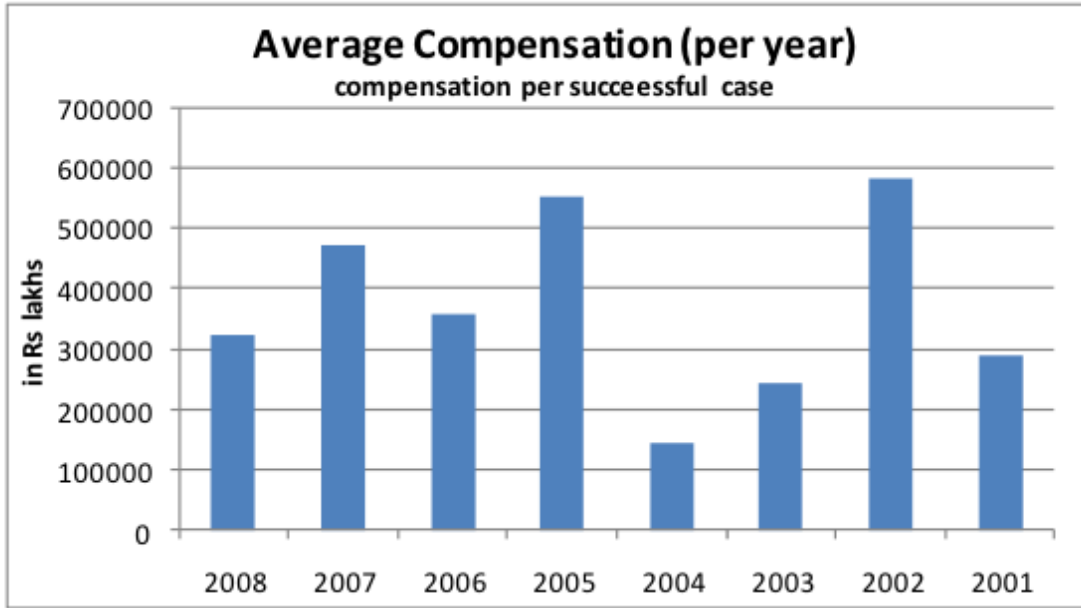
(e) Since the date of filing for every case was unavailable, the date of injury was used a proxy. Since the Consumer Protection Act defines a statute of limitation of two years, this is a reasonable proxy.

The results obtained are summarized in the graphs⁵⁷ below-

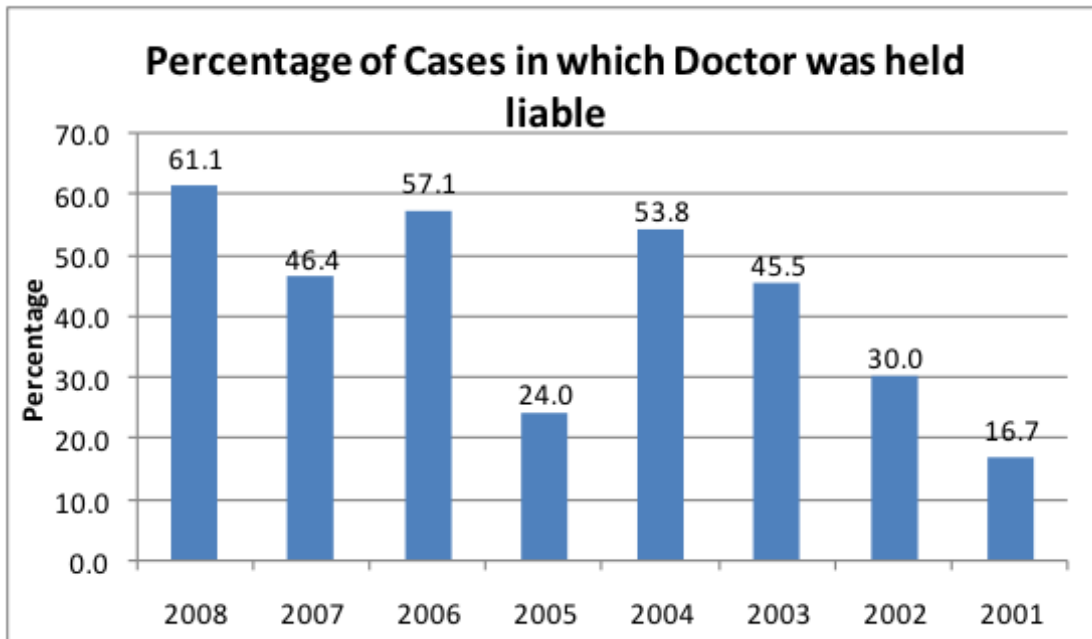


As depicted by the graph 1, there is no evident trend in the number of cases. The number of cases which reached a verdict in the year 2007 far exceeds those in any previous year. The number of cases for the year 2008 are however an underestimation, since the last case was available till the eight month of the year. But, incorporating this consideration may not affect our conclusion of no evident trend in the above statistics.

⁵⁷ Graph 1 – Number of Cases for which verdict was announced by the National Consumer Dispute Redressal Commission.

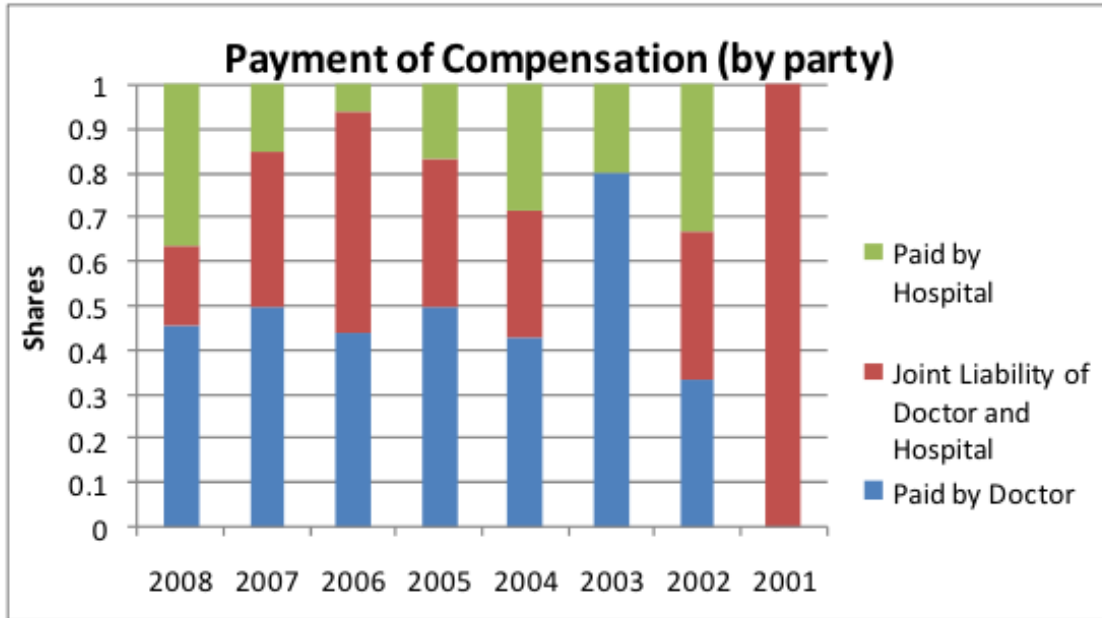


Graph⁵⁸ above depicts the average compensation per year was calculated for the cases which did prove the liability of doctor for a given year. As in the earlier graph 1, the average compensation per year also fails to indicate a trend. There is a wide held belief that the compensation being paid by the Consumer Forum in the cases of medical negligence has risen in the last few years. Such a belief is however not attested by our data.

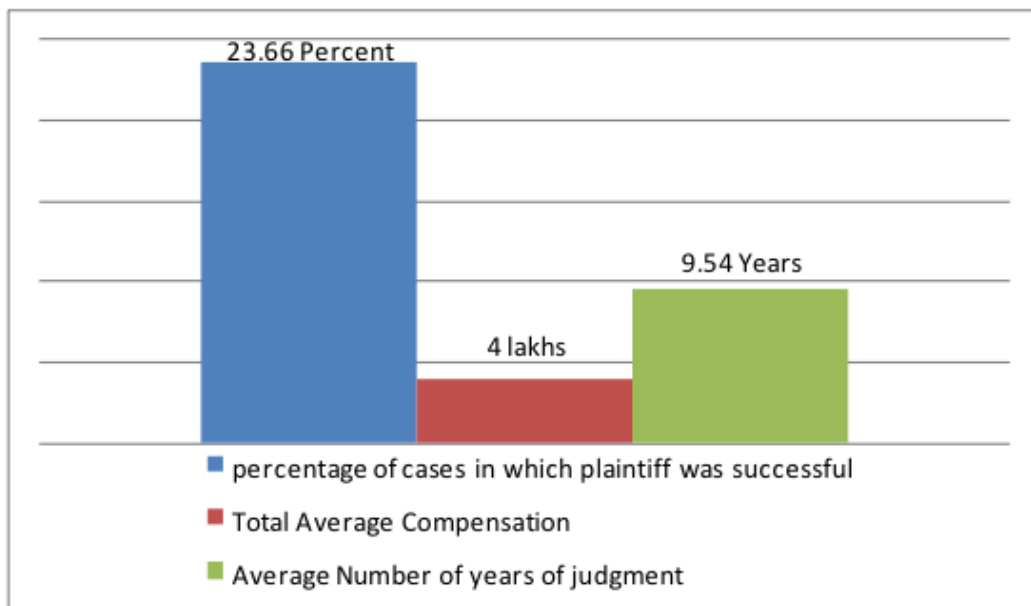


⁵⁸ Graph 2 – Average Compensation per successful case yearly.

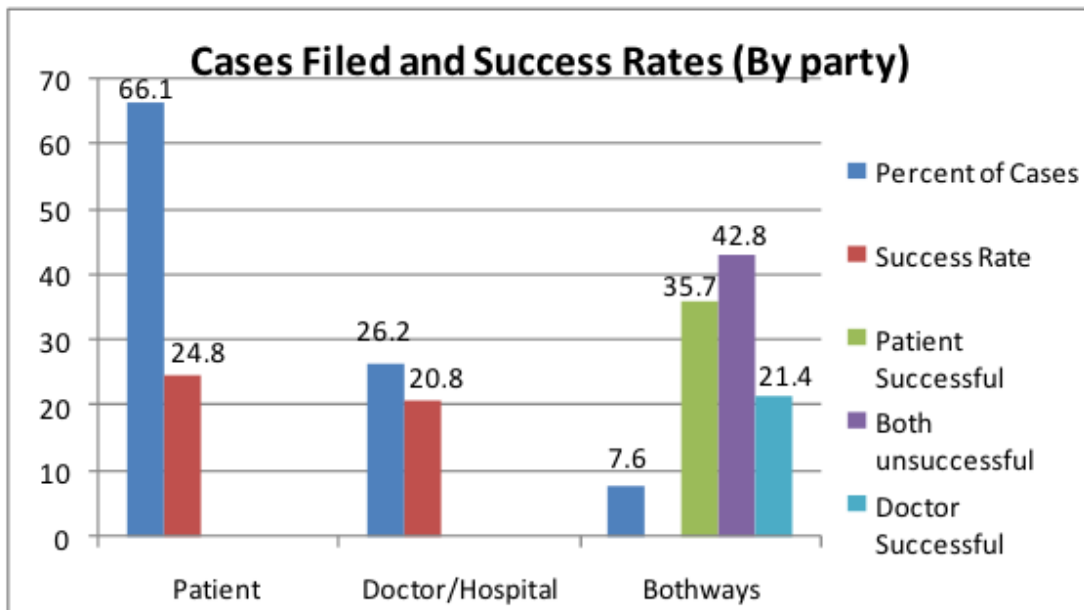
It is often claimed that the Consumer Forums are pro-consumers or patients, and hence over the years the courts have adopted a stricter outlook towards doctors. From the graph above⁵⁹ it is evident that the percentage of cases for which the doctor was held liable has risen since 2001 but the years 2005 and 2007 are significant departures from this trend. Thus, an increasing trend of doctors being held negligible does not go through our analysis.



The damages when negligence in a case is established could be dictated to be paid by the doctor, hospital or by both parties jointly. The graph above⁶⁰ indicates that for all years the share paid out by the doctor and doctor-hospital combined is above 60%. The hospitals alone are held responsible for medical negligence to a smaller extent.



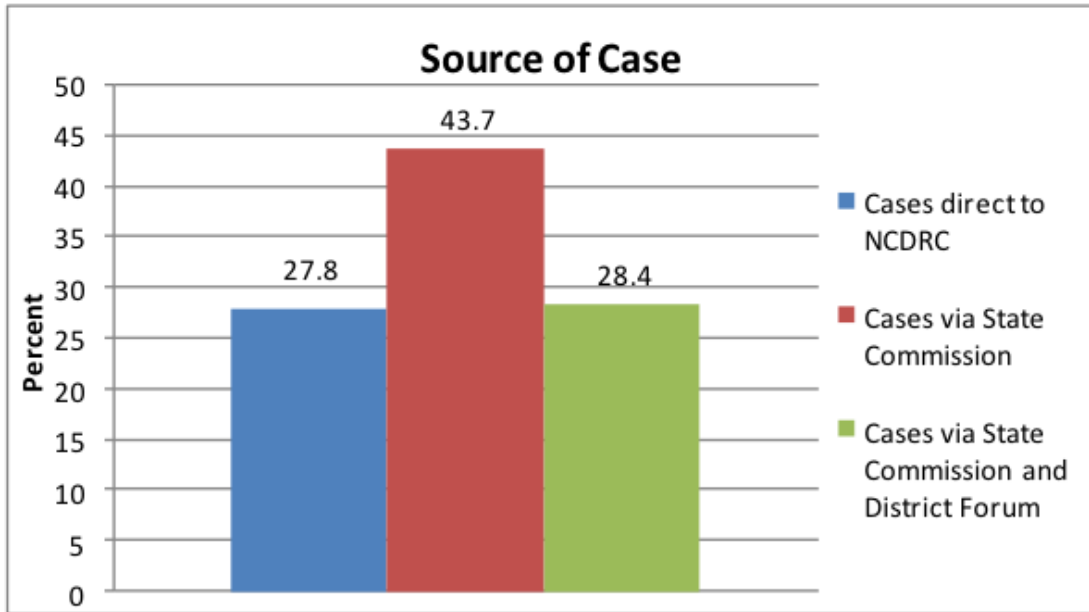
For all the cases together over the period examined, I find that the success rate for the plaintiff – which could either be the doctor or the patient, is a mere 23.66 percent as depicted in the graph⁶¹ above. Thus, it would not be wrong to conclude that most cases appearing before NCDRC are disposed in the favour of the opposite party and not the plaintiff. The average compensation paid out was Rs 4 lakhs. In addition, the average number of years of the judicial process is close to 9.54 years. The basic reason for extending medical service to Consumer Protection Act of guaranteeing speedy judgments does not seem to be fulfilled.



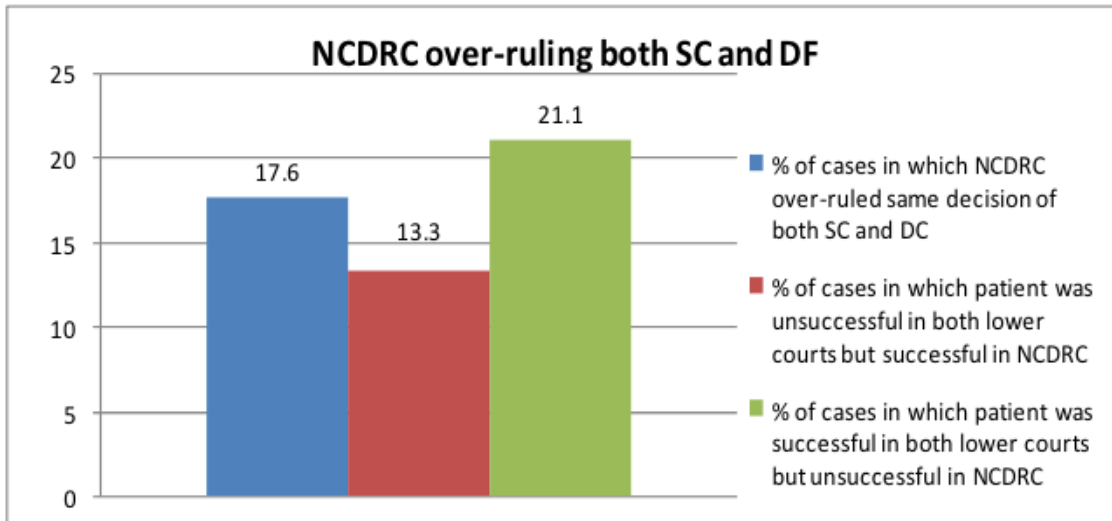
If we disaggregate the cases on the basis of the plaintiffs, as depicted in graph⁶² above, we find that 66 percent of the cases appearing before NCDRC were filed by patients, while 26 percent were filed by doctors or medical institutions. The remaining 8 percent of cases were filed both ways, i.e both the doctors and patients filed the case. The doctor filed to prove themselves non- negligent and patients for enhancement of compensation. Despite the higher number of cases being filed by the patients, the success rates of the two parties are quite close. While the success rate for patients is 24.8 percent, the success rate of the doctors is 20.8 percent. When the cases are filed both ways, in 35.7 percent of the cases the patient is successful in enhancing the compensation, while in 42.8 percent of the cases both the parties were unsuccessful. In the remaining, 21.4 percent of the cases the doctor is successful to prove that he was not negligent. Hence, this graph reiterates the conclusion of the previous graph that the success rate of plaintiff (whether it may be the doctor or the patient) is low.

⁶¹ Graph 5 – Success Rate, Average Compensation and Average number of years for judgment.

⁶² Graph 6 – Party by which cases filed and success rates.



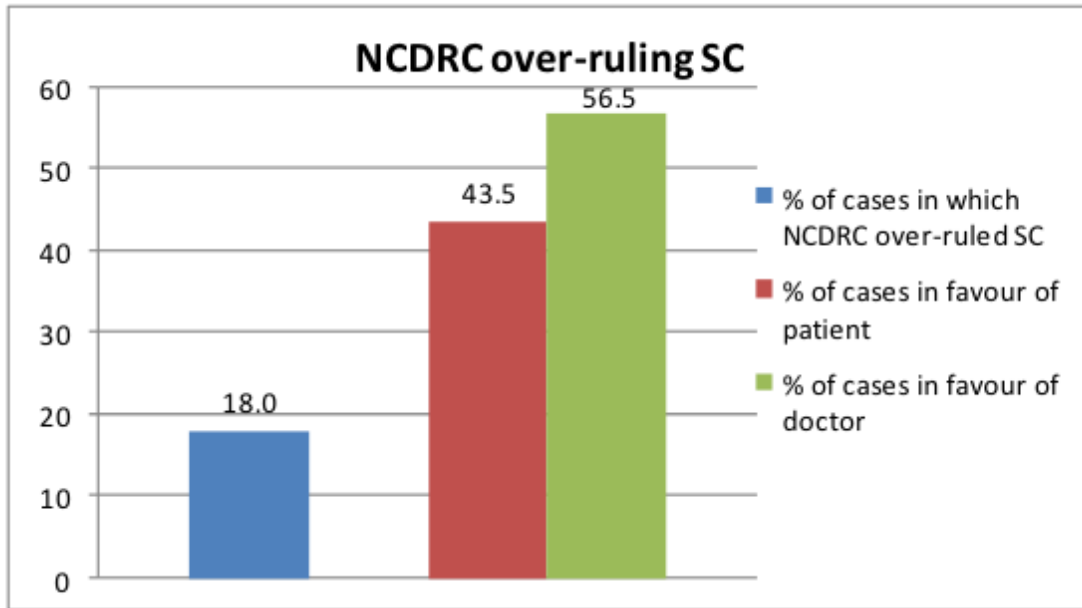
Moving to the origin of the cases, it is found that maximum numbers of cases that come before NCDRC are those which were first filed before the state commission. The number of cases coming via the district court and state commission is close to 28 percent and those coming directly to the apex body are also almost an equal percent as depicted by graph⁶³ above.



We are trying to analyze in how many cases the NCDRC reverses the same decision that was passed by the two lower courts. This will be indicative of the individual standing of

⁶³ Graph 7 – Source of Case.

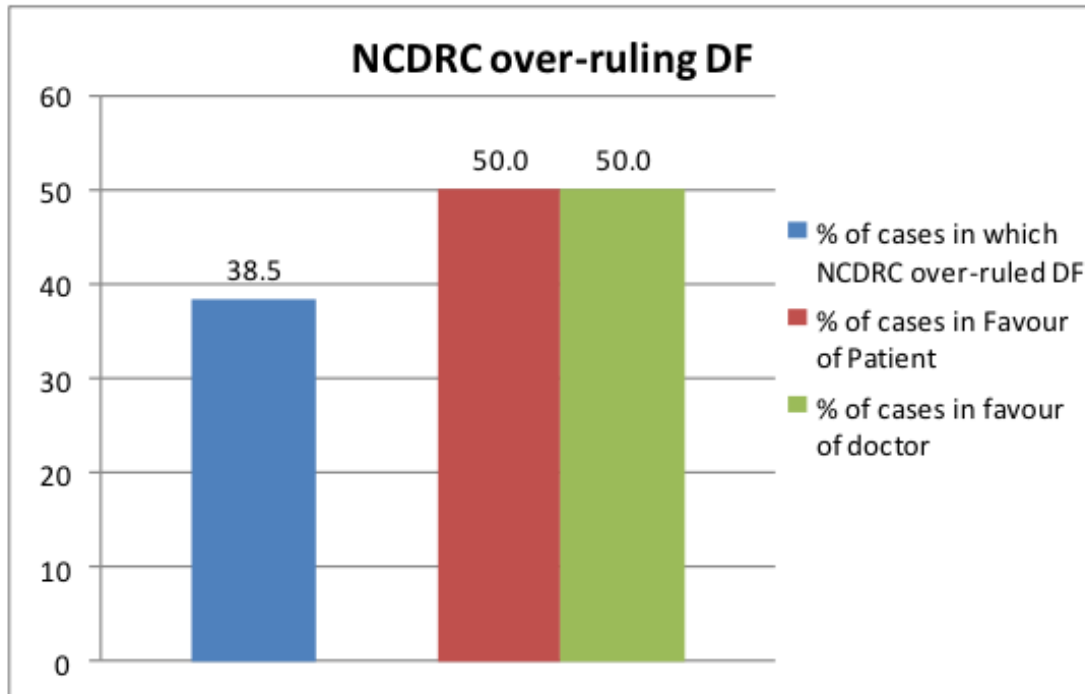
the decisions of NCDRC. It is found that in 17.6 percent of the cases the NCDRC over-ruled the same decision that was given by both the district and state commission. Further, in 13.3 percent of the cases were such that the patient was unsuccessful in both the lower courts but was granted compensation with the doctor being held negligent by NCDRC. In 21.1 percent of the cases the doctor who was held negligent by the lower courts was abstained from negligence by the NCDRC. This tells me that the probability of NCDRC overruling similar decisions of the lower courts is small.⁶⁴



Looking at specifically the cases in which the NCDRC over-ruled the decision of the State Commission, it is found that in only 18 percent of the cases the decision was reversed. Among the cases in which the decision was over-ruled, 43.5 percent of the cases now went in favour of the patient while 56.5 percent of the cases went in favour of the doctor. Hence, a patient is comparatively less probable to prove the doctor negligent if he has not been able to do so in front of the state commission. Also, there is a very small probability for the decision of the state commission to be reversed by NCDRC.⁶⁵

⁶⁴ Graph 8 – NCDRC overruling both state commission and district forum.

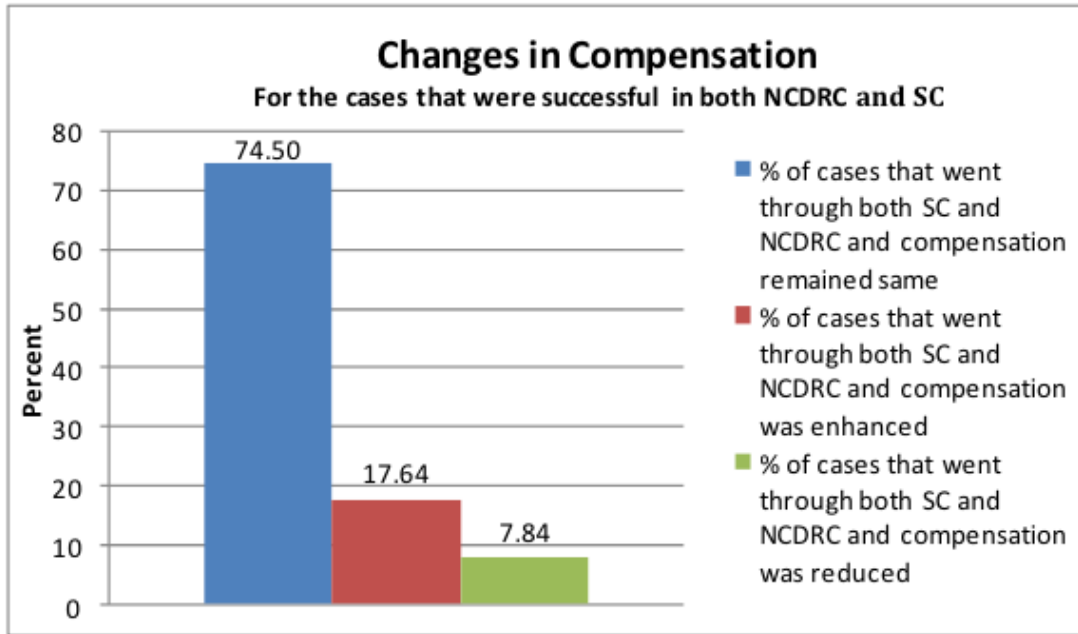
⁶⁵ Graph 9 – NCDRC overruling state commission.



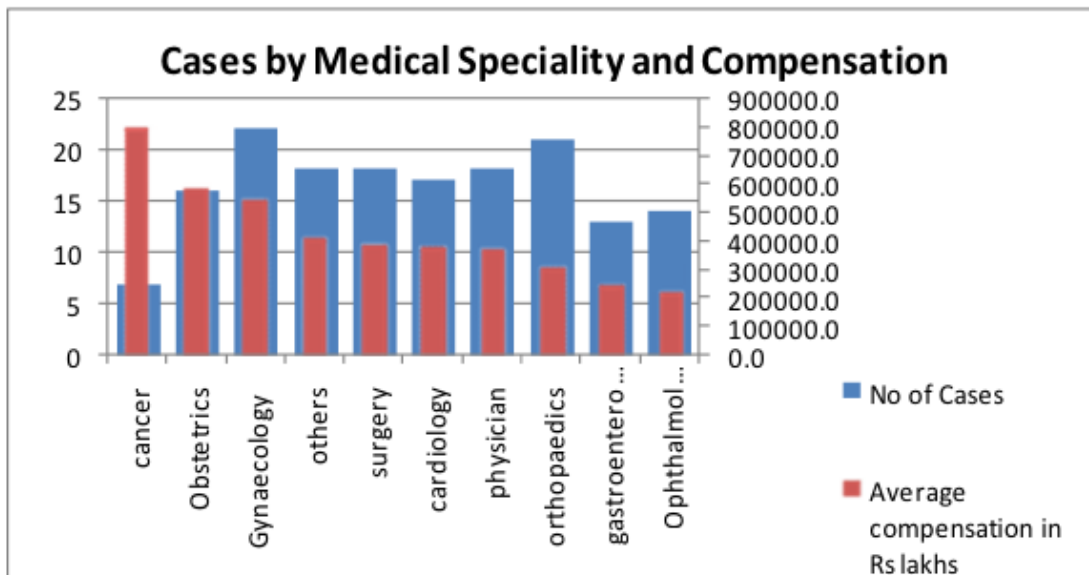
In contrast, NCDRC over-ruled the decision of the district forum in almost 38.5 percent of the cases that approached it. Out of these, the probability of the case going in favour of the doctor or the patient is the same. Nevertheless, there is indeed a greater likelihood of decision of the district forum being reversed by the NCDRC.⁶⁶

In totality, taking all the verdicts of the district forum and state commission, I find that in 28.9 percent of the cases NCDRC over-ruled either DF or SC.

⁶⁶ Graph 10 – NCDRC overruling district forum.

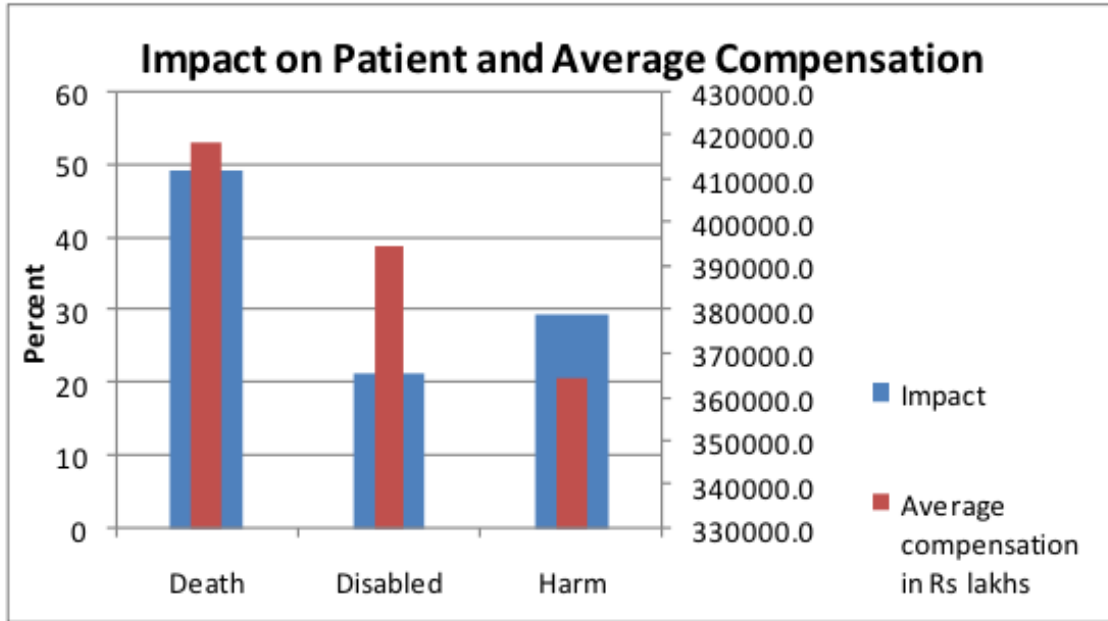


For changes in compensation, it was found that out of total cases that were successful (i.e patient being compensated) in both state commission and NCDRC, in close to three-fourth of the cases the compensation remained same. In 17.64 percent of the cases, compensation was enhanced while in only 7.84 percent of the cases were compensation reduced.⁶⁷



⁶⁷ Graph 11 – Changes in compensation for cases, which were successful in NCDRC and the State Commission.

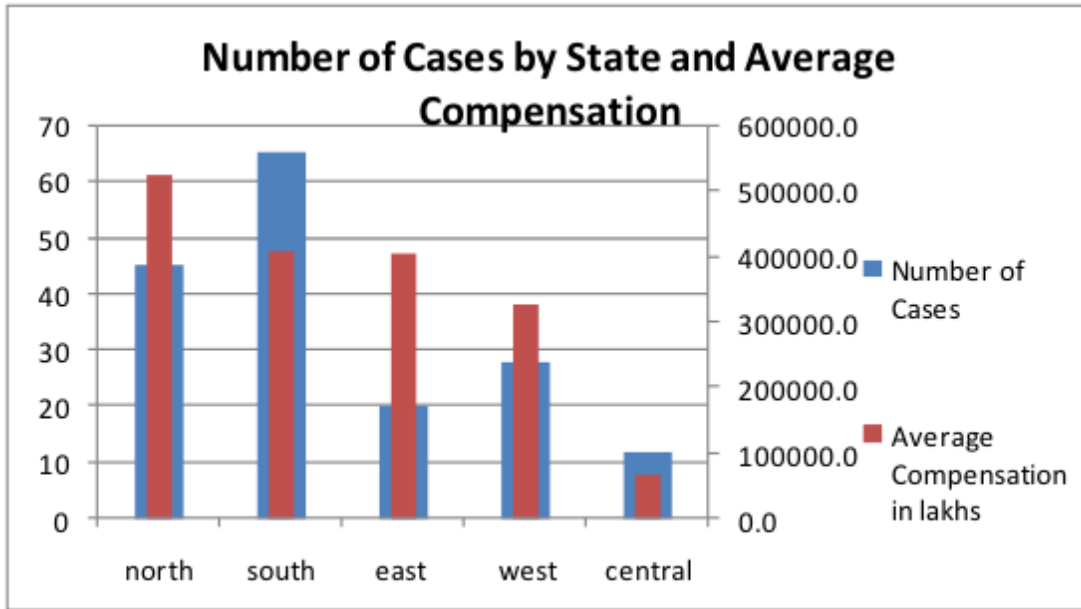
Moving now to the medical specialty, it is found that the specialties of orthopaedics, gynaecology, obstetrics, cardiology have the most number of cases. This is true since these are the relatively more risky medical specialties. In term of average compensation paid out cancer leads all other medical specialties, followed by obstetrics, gynaecology, surgery etc. This is indicative of the fact that the medical fields which can lead to death or permanent damage are more likely to face higher liabilities in terms of compensation paid.⁶⁸



Disaggregating cases on the basis of the impact of the medical treatment, it is found that in 50 percent of the cases of medical negligence filed, the patient had lost his life. In 20 percent of the cases the patient became disabled and in the remaining 30 percent he suffered some harm or loss, either of mental or physical agony. The average compensation paid out, is in line with the strength of the degree of impact. Maximum compensation is given in the case of death which is close to Rs 4.1 lakhs, followed by Rs 4 lakhs for disability and the least of Rs 3.6 lakhs for sustaining any harm.⁶⁹

⁶⁸ Graph 12 – Cases by Medical Specialty and Compensation.

⁶⁹ Graph 13 – Impact on patient and average compensation.



On the basis of the state in which the case of medical negligence occurred, a region based analysis has been undertaken. The maximum numbers of cases were for South India followed by North, West, East and Central regions. But the highest average compensation was paid for the cases of North India. The average compensation of the South, East and West region is almost at par, while that if the Central region is distinctly lower.⁷⁰

⁷⁰ Graph 14 – Number of cases and average compensation state wise.

CHAPTER V - JUDICIAL PRONOUNCEMENTS ON MEDICAL MALPRACTICE & NEGLIGENCE IN INDIA

The Indian judiciary has been pro-active when it comes to such a sensitive topic of medical malpractice and negligence. Over the years the judiciary has provided for different laws and procedures to deal with such cases and made an effort to protect the patients alongside safeguarding the doctors against vicious claims. Beginning with the efforts of the judiciary to include medical services within the ambit of consumer protection act to providing directions regarding doctor's liability and quantum of compensation, the judiciary has tried to fill for all the shortcomings of the legislations.

1. Indian Medical Association v. V.P. Shantha and Ors.⁷¹

Issue:

On issue whether a medical practitioner can be regarded as rendering 'service' under Section 2 (1)(o) of the Consumer Protection Act⁷², 1986 - This case can be held to be good law and an authority on this point of law.

Held:

Section 2 (1) (o) of Consumer Protection Act, 1986, Constitution of India and Indian Medical Council Act. The amenability of services rendered by medical professionals and hospitals under the Act of 1986. All kinds of services rendered by medical practitioner except where such services are rendered free of charges to all and under contract of personal service comes within term service under the Act. A contract of personal service cannot be assumed in absence of relationship of master and servant and service rendered by hospitals and doctors working therein where services are rendered free of cost to all does not come within purview of Act. Payment of token charges will not alter the nature of services rendered by such hospitals, also the services rendered by non-governmental hospital where charges are required to be paid for availing services comes within Act. Hospital where charges are collected from persons who are in a position to pay for service comes within the purview of the Act notwithstanding free services rendered to persons who are not in position to pay, so services rendered to both category are covered under the Act. Act is not applicable to Government hospitals where services are rendered absolutely free of cost to everyone. But in government hospitals where services are rendered free of cost and also on payment of fee comes under Act. Cases where payment of cost for medical services are paid by insurance company on behalf of insured patient does not change nature of service availed by persons to be free service. Even the services availed by dependents of any persons and charges of such service paid by employer as part of conditions of service will not make such service as free service.

⁷¹ (1995) 6 SCC 651.

⁷² Act 68 of 1986.

Important excerpts from the judgment:

On April 9, 1985, the General Assembly of the United Nations, by Consumer Protection Resolution No. 39/248, adopted the guidelines to provide a framework for Governments, particularly those of developing countries, to use in elaborating and strengthening consumer protection policies and legislation. The objectives of the said guidelines include assisting countries in achieving or maintaining adequate protection for their population as consumers and encouraging high levels of ethical conduct for those engaged in the production and distribution of goods and services to the consumers. The legitimate needs which the guidelines are intended to meet include the protection of consumers from hazards to their health and safety and availability of effective consumer redress. Keeping in view the said guidelines, the Act was enacted by Parliament to provide for the better protection of the interests of consumers and for that purpose to make provision for the establishment of consumer councils and other authorities for the settlement of consumers' disputes and for matters connected therewith. The Act sets up a three-tier structure for the redressal of consumer grievances. At the lowest level, i.e., the District level, is the Consumer Disputes Redressal Forum known as 'the District Forum'; at the next higher level, i.e., the State level, is the Consumer Disputes Redressal Commission known as 'the State Commission' and at the highest level is the National Commission.⁷³ The jurisdiction of these three Consumer Disputes Redressal Agencies is based on the pecuniary limit of the claim made by the complainant. An appeal lies to the State Commission against an order made by the District Forum⁷⁴ and an appeal lies to the National Commission against an order made by the State Commission on a complaint filed before it or in an appeal against the order passed by the District Forum.⁷⁵ The State Commission can exercise revisional powers on grounds similar to those contained in Section 115 CPC in relation to a consumer dispute pending before or decided by a District Forum⁷⁶ and the National Commission has similar revisional jurisdiction in respect of a consumer dispute pending before or decided by a State Commission.⁷⁷ Further, there is a provision for appeal to this Court from an order made by the National Commission on a complaint or on an appeal against the order of a State Commission.⁷⁸ By virtue of the definition of complainant in Section 2(1)(c), the Act affords protection to the consumer against unfair trade practice or a restrictive trade practice adopted by any trader, defect in the goods bought or agreed to be bought by the consumer, deficiency in the service hired or availed of or agreed to be hired or availed of by the consumer, charging by a trader price in excess of the price fixed by or under any law for the time being in force or displayed on the goods or any package containing such goods and offering for sale to public, goods which will be hazardous to life and safety when used, in contravention of the provisions of any law for the time being in force requiring traders to display information in regard to the contents, manner and effect of use of such goods. The expression "complainant", as defined in Section 2(1)(b), is comprehensive to enable

⁷³ Consumer Protection Act, 1986 - Section 9.

⁷⁴ Ibid., Section 15.

⁷⁵ Ibid., Section 19.

⁷⁶ Ibid., Section 17b.

⁷⁷ Ibid., Section 21b.

⁷⁸ Ibid., Section 23.

the consumer as well as any voluntary consumer association registered under the Companies Act, 1956 or under any other law for the time being in force, or the Central Government or any State Government or one or more consumers where there are numerous consumers having the same interest, to file a complaint before the appropriate Consumer Disputes Redressal Agency and the consumer dispute raised in such complaint is settled by the said agency in accordance with the procedure laid down in Section 13 of the Act which prescribes that the District Forum (as well as the State Commission and the National Commission) shall have the same power as are vested in a Civil Court under the CPC in respect of summoning and enforcing attendance of any defendant or witness and examining the witness on oath; discovery and production of any document or other material object producible as evidence; the reception of evidence on affidavits; the requisitioning of the report of the concerned analysis or test from the appropriate laboratory or from any other relevant source; issuing of any commission for the examination of any witness; and any other matter which may be prescribed. Section 14 makes provisions for the nature of reliefs that can be granted to the complainant on such a complaint. The provisions of the Act are in addition to and not in derogation of the provisions of any other law for the time being in force. (Section 3).⁷⁹

The definition of 'service' 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 service.⁸⁰

The definition of 'service' as contained in Section 2(1)(o) of the Act has been construed by this Court in Lucknow Development Authority v. M.K. Gupta⁸¹. After pointing out that the said definition is in three parts, the Court has observed:

The main clause itself is very wide. It applies to any service made available to potential users. The words 'any' and 'potential' are significant. Both are of wide amplitude. The word 'any' dictionary means; one or some or all'. In Black's Law Dictionary it is explained thus, "word 'any' has a diversity of meaning and may be employed to indicate 'all' or 'every' as well as 'some' or 'one' and its meaning in a given statute depends upon the context and the subject-matter of the statute". The use of the word 'any' in the context it has been used in Clause (o) indicates that it has been used in wider sense extending from one to all. The other word 'potential' is again very wide. In Oxford Dictionary it is defined as 'capable of coming into being, possibility'. In Black's Law Dictionary it is defined "existing in possibility but not in act. Naturally and probably expected to come into existence at some future time, though not now existing; for example, the future

⁷⁹ Para 10.

⁸⁰ Para 13.

⁸¹ AIR 1994 SC 787.

product of grain or trees already planted, or the successive future installments or payments on a contract or engagement already made." In other words service which is not only extended to actual users but those who are capable of using it are covered in the definition. The clause is thus very wide and extends to any or all actual or potential users.⁸²

Referring to the inclusive part of the definition it was said: The inclusive clause succeeded in widening its scope but not exhausting the services which could be covered in earlier part. So any service except when it is free of charge or under a constraint of personal service is included in it.⁸³

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 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 the right of such person to seek redress is not affected.⁸⁴

Referring to the changing position with regard to the relationship between the medical practitioners and the patients in the United Kingdom, it has been said: Where, then, does the doctor stand today in relation to society? To some extent, he is a servant of the public, a public which is widely (though not always well) informed on medical matters. Society is conditioned to distrust paternalism and the modern medical practitioner has little wish to be paternalistic. The new talk is of 'producers and consumers' and the concept that 'he who pays the piper calls the tune' is established both within the profession and in its relationships with patients. The competent patient's inalienable rights to understand his treatment and to accept or refuse it are now well established.⁸⁵

Consumerism is now firmly established in medical practice and this has been encouraged on a wide scale by government in the United Kingdom through the introduction of 'charters'. Complaint is central to this ethos - and the notion that blame must be attributed, and compensated, has a high priority.⁸⁶

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(1)(o) of the Act.⁸⁷

⁸² Para 14 at Page 255.

⁸³ Para 16 at Page 257.

⁸⁴ Para 24.

⁸⁵ Para 25.

⁸⁶ J.K. Mason and G.T.Laurie, *Law and Medical Ethics of Mason & McCall Smith*, IVth Edn, Oxford Publishing, 2011.

⁸⁷ Para 27.

On the basis of the above discussion we arrive at the following conclusions:⁸⁸

(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 Act⁸⁹.

(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 "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

⁸⁸ Para 56.

⁸⁹ The Consumer Protection Act, 1986.

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 center/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 center/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.

2. Jacob Mathew v. State of Punjab and Anr.⁹⁰

Brief Facts:

The FIR states (as per the translation in English as filed by the complainant):- "...the death of my father was occurred due to the carelessness of doctors and nurses and non availability of oxygen cylinder and the empty cylinder was fixed on the mouth of my father and his breathing was totally stopped hence my father died. I sent the dead body of my father to my village for last cremation and for information I have come to you. As per statement of imitator the death of Jiwan Lal Sharma has occurred due to carelessness of doctors and nurses concerned and to fit empty gas cylinder."

On the abovesaid report, an offence under Section 304A/34 IPC⁹¹ was registered and investigated. Challan was filed against the two doctors.

⁹⁰ (2005) 6 SCC 1.

⁹¹ The Indian Penal Code, 1860.

This judgment laid down broad general principles of medical negligence, which have to be considered by Courts in deciding matters since medical profession was placed within the purview of the Consumer Protection Act.

Conclusions arrived at by the Supreme Court are as under:⁹²

(1) Negligence is the breach of a duty caused by 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 definition of negligence as given in Law of Torts, Ratanlal and Dhirajlal (edited by Justice G. P. Singh), holds good. Negligence becomes actionable on account of injury resulting from the act or omission amounting to negligence attributable to the person sued. The essential components of negligence are three : 'duty', 'breach' and 'resulting damage'.

(2) Negligence in the context of medical profession necessarily calls for a treatment with a difference. To infer rashness or negligence on the part of a professional, in particular a doctor, additional considerations apply. A case of occupational negligence is different from one of professional negligence. A simple lack of care, an error of judgment or an accident, is not proof of negligence on the part of a medical professional. So long as a doctor follows a practice acceptable to the medical profession of that day, he cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply because a more skilled doctor would not have chosen to follow or resort to that practice or procedure which the accused followed. When it comes to the failure of taking precautions what has to be seen is whether those precautions were taken which the ordinary experience of men has found to be sufficient; a failure to use special or extraordinary precautions which might have prevented the particular happening cannot be the standard for judging the alleged negligence. So also, the standard of care, while assessing the practice as adopted, is judged in the light of knowledge available at the time of the incident, and not at the date of trial. Similarly, when the charge of negligence arises out of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that particular time (that is, the time of the incident) at which it is suggested it should have been used.

(3) A professional may be held liable for negligence on one of the two findings: either he was not possessed of the requisite skill which he professed to have possessed, or, he did not exercise, with reasonable competence in the given case, the skill which he did possess. The standard to be applied for judging, whether the person charged has been negligent or not, would be that of an ordinary competent person exercising ordinary skill in that profession. It is not possible for every professional to possess the highest level of expertise or skills in that branch which he practices. A highly skilled professional may be possessed of better qualities, but that cannot be made the basis or the yardstick for judging the performance of the professional proceeded against on indictment of negligence.

⁹² Para 49.

(4) The test for determining medical negligence as laid down in Bolam's case,⁹³ holds good in its applicability in India.

(5) The jurisprudential concept of negligence differs in civil and criminal law. What may be negligence in civil law may not necessarily be negligence in criminal law. For negligence to amount to an offence, the element of mens rea must be shown to exist. For an act to amount to criminal negligence, the degree of negligence should be much higher, i.e., gross or of a very high degree. Negligence which is neither gross nor of a higher degree may provide a ground for action in civil law but cannot form the basis for prosecution.

(6) The word 'gross' has not been used in Section 304A of I.P.C., yet it is settled that in criminal law, negligence or recklessness, to be so held, must be of such a high degree as to be 'gross'. The expression 'rash or negligent act', as occurring in Section 304A of the I.P.C., has to be read as qualified by the word 'grossly'.

(7) To prosecute a medical professional for negligence under criminal law, it must be shown that the accused did something or failed to do something which, in the given facts and circumstances, no medical professional in his ordinary senses and prudence would have done or failed to do. The hazard taken by the accused doctor should be of such a nature that the injury which resulted was most likely imminent.

(8) Res ipsa loquitur is only a rule of evidence and operates in the domain of civil law specially in cases of torts and helps in determining the onus of proof in actions relating to negligence. It cannot be pressed in service for determining per se the liability for negligence within the domain of criminal law. Res ipsa loquitur has, if at all, a limited application in trial on a charge of criminal negligence.

Passage defining negligence by professionals, generally and not necessarily confined to doctors, is to be found in the opinion of McNair J. in Bolam v. Friern Hospital Management Committee,⁹⁴ in the following words:

"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 the man on the top of a Clapham omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that 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 particular art." After a review of various authorities Bingham L.J. in his speech in Eckersley v. Binnie,⁹⁵ summarised the Bolam test in the following words:

"From these general statements it follows that a professional man should command the corpus of knowledge which forms part of the professional equipment of the ordinary member of his profession. He should not lag behind other ordinary assiduous and

⁹³ (1957) 1 WLR 582, 586.

⁹⁴ (1957) 1 WLR 582, 586.

⁹⁵ (1988) 18 Con LR 1, 79.

intelligent members of his profession in knowledge of the new advances, discoveries and developments in his field. He should have such an awareness as an ordinarily competent practitioner would have of the deficiencies in his knowledge and the limitations on his skill. He should be alert to the hazards and risks in any professional task he undertakes to the extent that other ordinarily competent members of the profession would be alert. He must bring to any professional task he undertakes no less expertise, skill and care than other ordinarily competent members of his profession would bring, but need bring no more. The standard is that of the reasonable average. The law does not require of a professional man that he be a paragon combining the qualities of polymath and prophet."

The classical statement of law in Bolam's case has been widely accepted as decisive of the standard of care required both of professional men generally and medical practitioners in particular. It has been invariably cited with approval before Courts in India and applied to as touchstone to test the pleas of medical negligence.

The cases of doctors (surgeons and physicians) being subjected to criminal prosecution are on an increase. Sometimes, such prosecutions are filed by private complainants and sometimes by police on an F.I.R. being lodged and cognizance taken. The Investigating Officer and the private complainant cannot always be supposed to have knowledge of medical science so as to determine whether the act of the accused medical professional amounts to rash or negligent act within the domain of criminal law under Section 304A of I.P.C. The criminal process, once initiated, subjects the medical professional to serious embarrassment and sometimes harassment. He has to seek bail to escape arrest, which may or may not be granted to him. At the end, he may be exonerated by acquittal or discharge but the loss which he has suffered in his reputation cannot be compensated by any standards. Statutory rules or Executive Instructions incorporating certain guidelines need to be framed and issued by the Government of India and/or the State Governments in consultation with the Medical Council of India. So long as it is not done, the Supreme Court proposes to lay down certain guidelines for the future which should govern the prosecution of doctors for offences of which criminal rashness or criminal negligence is an ingredient. A private complaint may not be entertained unless the complainant had produced prima facie evidence before the Court in the form of a credible opinion given by another competent doctor to support the charge of rashness or negligence on the part of the accused doctor. The Investigating Officer should, before proceeding against the doctor accused of rash or negligent act or omission, obtain an independent and competent medical opinion preferably from a doctor in Government service qualified in that branch of medical practice who can normally be expected to give an impartial and unbiased opinion applying Bolam's test to the facts collected in the investigation. A doctor accused of rashness or negligence, may not be arrested in a routine manner (simply because a charge has been levelled against him). Unless his arrest is necessary for furthering the investigation or for collecting evidence or unless the Investigation Officer feels satisfied that the doctor proceeded against would not make himself available to face the prosecution unless arrested, the arrest may be withheld.

The Legal principles laid down in Dr. Suresh Gupta v. Government of N.C.T. of Delhi,⁹⁶

⁹⁶ (2004) 6 SCC 422.

were also affirmed. The Legal maxim of Res ipsa loquitur's applicability was also discussed:

Res ipsa loquitur is a rule of evidence which, in reality, belongs to the law of torts. Inference as to negligence may be drawn from proved circumstances by applying the rule if the cause of the accident is unknown and no reasonable explanation as to the cause is coming forth from the defendant. In criminal proceedings, the burden of proving negligence, as an essential ingredient of the offence, lies on the prosecution. Such ingredient cannot be said to have been proved or made out by resorting to the said rule.

Important excerpts from the judgment:

A medical practitioner faced with an emergency ordinarily tries his best to redeem the patient out of his suffering. He does not gain anything by acting with negligence or by omitting to do an act. Obviously, therefore, it will be for the complainant to clearly make out a case of negligence before a medical practitioner is charged with or proceeded against criminally. A surgeon with shaky hands under fear of legal action cannot perform a successful operation and a quivering physician cannot administer the end-dose of medicine to his patient.⁹⁷

If the hands be trembling with the dangling fear of facing a criminal prosecution in the event of failure for whatever reason--whether attributable to himself or not, neither a surgeon can successfully wield his life-saving scalper to perform an essential surgery, nor can a physician successfully administer the life-saving dose of medicine. Discretion being better part of valour, a medical professional would feel better advised to leave a terminal patient to his own fate in the case of emergency where the chance of success may be 10% (or so), rather than taking the risk of making a last ditch effort towards saving the subject and facing a criminal prosecution if his effort fails. Such timidity forced upon a doctor would be a disservice to the society.⁹⁸

The purpose of holding a professional liable for his act or omission, if negligent, is to make the life safer and to eliminate the possibility of recurrence of negligence in future. Human body and medical science both are too complex to be easily understood. To hold in favour of existence of negligence, associated with the action or inaction of a medical professional, requires an in-depth understanding of the working of a professional as also the nature of the job and of errors committed by chance, which do not necessarily involve the element of culpability.⁹⁹

The subject of negligence in the context of medical profession necessarily calls for treatment with a difference. Several relevant considerations in this regard are found mentioned by Alan Merry and Alexander McCall Smith in their work¹⁰⁰. There is a

⁹⁷ Para 29.

⁹⁸ Para 30.

⁹⁹ Para 31.

¹⁰⁰ Alan Merry and Alexander McCall Smith, *Errors, Medicine and the Law*, Cambridge University Press, 2001.

marked tendency to look for a human actor to blame for an untoward event - a tendency which is closely linked with the desire to punish. Things have gone wrong and, therefore, somebody must be found to answer for it. To draw a distinction between the blameworthy and the blameless, the notion of mens rea has to be elaborately understood. An empirical study would reveal that the background to a mishap is frequently far more complex than may generally be assumed. It can be demonstrated that actual blame for the outcome has to be attributed with great caution. For a medical accident or failure, the responsibility may lie with the medical practitioner and equally it may not. The inadequacies of the system, the specific circumstances of the case, the nature of human psychology itself and sheer chance may have combined to produce a result in which the doctor's contribution is either relatively or completely blameless. Human body and its working is nothing less than a highly complex machine. Coupled with the complexities of medical science, the scope for misimpressions, misgivings and misplaced allegations against the operator i.e. the doctor, cannot be ruled out. One may have notions of best or ideal practice which are different from the reality of how medical practice is carried on or how in real life the doctor functions. The factors of pressing need and limited resources cannot be ruled out from consideration. Dealing with a case of medical negligence needs a deeper understanding of the practical side of medicine.¹⁰¹

At least three weighty considerations can be pointed out which any forum trying the issue of medical negligence in any jurisdiction must keep in mind. These are:

- (i) That legal and disciplinary procedures should be properly founded on firm, moral and scientific grounds;
- (ii) That patients will be better served if the real causes of harm are properly identified and appropriately acted upon; and
- (iii) That many incidents involve a contribution from more than one person, and the tendency is to blame the last identifiable element in the chain of causation - the person holding the 'smoking gun'.¹⁰²

Accident during the course of medical or surgical treatment has a wider meaning. Ordinarily, an accident means an unintended and unforeseen injurious occurrence; something that does not occur in the usual course of events or that could not be reasonably anticipated.¹⁰³ Care has to be taken to see that the result of an accident which is exculpatory may not persuade the human mind to confuse it with the consequence of negligence.¹⁰⁴

The Indian Penal Code enacted as far back as in the year 1860 sets out a few vocal examples. Section 88 in the Chapter on General Exceptions provides exemption for acts not intended to cause death, done by consent in good faith for person's benefit. Section 92 provides for exemption for acts done in good faith for the benefit of a person without his consent though the acts cause harm to a person and that person has not consented to suffer such harm. There are four exceptions listed in the Section which is not necessary in

¹⁰¹ Para 32.

¹⁰² Para 33.

¹⁰³ See, Black's Law Dictionary, 7th Edition.

¹⁰⁴ Para 34.

this context to deal with. Section 93 saves from criminality certain communications made in good faith. To these provisions are appended the following illustrations:-

Section 88: A, a surgeon, knowing that a particular operation is likely to cause the death of Z, who suffers under a painful complaint, but not intending to cause Z's death and intending in good faith, Z's benefit, performs that operation on Z, with Z's consent. A has committed no offence.

Section 92: A, a surgeon, sees a child suffer an accident which is likely to prove fatal unless an operation be immediately performed. There is no time to apply to the child's guardian. A performs the operation in spite of the entreaties of the child, intending, in good faith, the child's benefit. A has committed no offence.

Section 93: A, a surgeon, in good faith, communicates to a patient his opinion that he cannot live. The patient dies in consequence of the shock. A has committed no offence, though he knew it to be likely that the communication might cause the patient's death.¹⁰⁵

Sometimes prosecutions against doctor's are filed by private complainants and sometimes by police on an FIR being lodged and cognizance taken. The investigating officer and the private complainant cannot always be supposed to have knowledge of medical science so as to determine whether the act of the accused medical professional amounts to rash or negligent act within the domain of criminal law under Section 304A of IPC. The criminal process once initiated subjects the medical professional to serious embarrassment and sometimes harassment. He has to seek bail to escape arrest, which may or may not be granted to him. At the end he may be exonerated by acquittal or discharge but the loss which he has suffered in his reputation cannot be compensated by any standards.

We may not be understood as holding that doctors can never be prosecuted for an offence of which rashness or negligence is an essential ingredient. All that we are doing is to emphasize the need for care and caution in the interest of society; for, the service which the medical profession renders to human beings is probably the noblest of all, and hence there is a need for protecting doctors from frivolous or unjust prosecutions. Many a complainant prefers recourse to criminal process as a tool for pressurizing the medical professional for extracting uncalled for or unjust compensation. Such malicious proceedings have to be guarded against.

Statutory Rules or Executive Instructions incorporating certain guidelines need to be framed and issued by the Government of India and/or the State Governments in consultation with the Medical Council of India. So long as it is not done, we propose to lay down certain guidelines for the future which should govern the prosecution of doctors for offences of which criminal rashness or criminal negligence is an ingredient. A private complaint may not be entertained unless the complainant has produced prima facie evidence before the Court in the form of a credible opinion given by another competent doctor to support the charge of rashness or negligence on the part of the accused doctor. The investigating officer should, before proceeding against the doctor accused of rash or

¹⁰⁵ Para 35.

negligent act or omission, obtain an independent and competent medical opinion preferably from a doctor in government service qualified in that branch of medical practice who can normally be expected to give an impartial and unbiased opinion applying Bolam's test to the facts collected in the investigation. A doctor accused of rashness or negligence, may not be arrested in a routine manner (simply because a charge has been leveled against him). Unless his arrest is necessary for furthering the investigation or for collecting evidence or unless the investigation officer feels satisfied that the doctor proceeded against would not make himself available to face the prosecution unless arrested, the arrest may be withheld.¹⁰⁶

3. State of Punjab v. Shiv Ram and Ors.¹⁰⁷

Held:

The claim in tort can be sustained only if there was negligence on the part of the surgeon in performing the surgery. The proof of negligence shall have to satisfy Bolam's test. So also, the surgeon cannot be held liable in contract unless the plaintiff alleges and proves that the surgeon had assured 100 % guarantee of success.

Important excerpts from the judgment:

Slade L J, stated in his opinion that "in the absence of any express warranty, the court should be slow to imply against a medical man an unqualified warranty as to the results of an intended operation, for the very simple reason that, objectively speaking, it is most unlikely that a responsible medical man would intend to give a warranty of this nature. Of course, objectively speaking, it is likely that he would give a guarantee that he would do what he had undertaken to do with reasonable care and skill; but it is quite another matter to say that he has committed himself to the extent suggested in the present case."¹⁰⁸

Purchas LJ, stated in his opinion that "it is true that as a matter of deliberate election the defendant did not, in the course of describing the operation which he was recommending, disclose that there was a very small risk, one might almost say an insignificant risk, that the plaintiff might become pregnant. In withholding this information it must be borne in mind, first that the defendant must have believed that the plaintiff would be sterile, second that the chances were extremely remote that the operation would be unsuccessful, third that in withholding this information the defendant was following a practice acceptable to current professional standards and was acting in the best interest of the plaintiff, and fourth that no allegation of negligence in failing to give this information to the plaintiff is pursued any longer in this case. There are, therefore, in my judgment, no grounds for asserting that the result would necessarily be 100% successful."

In *Thake v Morris*,¹⁰⁹ the claim for damages was founded on contract and not in torts.

¹⁰⁶ Para 51-53.

¹⁰⁷ (2005) 7 SCC 1.

¹⁰⁸ Para 14.

¹⁰⁹ [1986] 1 All ER 497 (CA).

The Court of Appeal firmly rejected the possibility of an enforceable warranty. Neill L J said: "a reasonable man would have expected the defendant to exercise all the proper skill and care of a surgeon in that speciality: he would not have expected the defendant to give a guarantee of 100% success."

Nourse L J said: "of all sciences medicine is one of the least exact. In my view, a doctor cannot be objectively regarded as guaranteeing the success of any operation or treatment unless he says as much in clear and unequivocal terms."

We are, therefore, clearly of the opinion that merely because a woman having undergone a sterilization operation became pregnant and delivered a child, the operating surgeon or his employer cannot be held liable for compensation on account of unwanted pregnancy or unwanted child. The claim in tort can be sustained only if there was negligence on the part of the surgeon in performing the surgery. The proof of negligence shall have to satisfy Bolam's test. So also, the surgeon cannot be held liable in contract unless the plaintiff alleges and proves that the surgeon had assured 100 % exclusion of pregnancy after the surgery and was only on the basis of such assurance that the plaintiff was persuaded to undergo surgery. As noted in various decisions which we have referred to hereinabove, ordinarily a surgeon does not offer such guarantee.¹¹⁰

Medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. The oldest expression of this basic principle comes from Hippocrates,¹¹¹ who came to be known as the "Father of Medicine" and had devoted his entire life to the advancement of medical science. He formulated a code of conduct in the form of the Hippocratic Oath, as he realized that knowledge and skill were not enough for a physician without a code of standards and ideals. He coined an oath of integrity for physicians, a code of standards and ideals to which they must swear to adhere in the practice of their profession.

To consider dear to me as my parents him who taught me this art; to live in common with him and if necessary to share my goods with him; to look upon his children as my own brothers, to teach them this art if they so desire without fee or written promise; to impart to my sons and the sons of the master who taught me and the disciples who have enrolled themselves and have agreed to the rules of the profession, but to these alone the precepts and the instruction. I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone. To please no one will I prescribe a deadly drug nor give advice, which may cause his death. Nor will I give a woman a peccary to procure abortion. But I will preserve the purity of my life and my art. I will not cut for stone, even for patients in whom the disease is manifest; I will leave this operation to be performed by practitioners, specialists in this art. In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and all seduction and especially from the pleasures of love with women or with men, be they free or slaves. All that may come to my knowledge in the exercise of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret

¹¹⁰ Para 15-17.

¹¹¹ An early Greek Physician, born in 460 B.C.

and will never reveal. If I keep this oath faithfully, may I enjoy my life and practice my art, respected by all men and in all times; but if I swerve from it or violate it, may the reverse be my lot."

Many versions of Hippocratic Oath are prevalent. "Light From Many Lamps" a book edited by Lilian Eichler Watson contains a little different phraseology of that oath but certainly a beautiful commentary on the significance of the Hippocratic Oath. We would like to reproduce the oath and the commentary hereunder:¹¹² :

"I do solemnly swear by that which I hold most sacred: That I will be loyal to the profession of medicine and just and generous to its members; That I will lead my life and practice my art in uprightness and honor;

That into whatsoever house I shall enter, it shall be for the good of the sick to the utmost of my power, I holding myself aloof from wrong, from corruption, and from the temptation of others to vice; That I will exercise my art solely for the cure of my patients, and will give no drug, perform no operation for a criminal purpose, even if solicited, far less suggest it;

That whatsoever I shall see or hear of the lives of men which is not fitting to be spoken, I will keep inviolably secret. These things I do promise, and in proportion as I am faithful to this my oath may happiness and good repute be ever mine - the opposite if I shall be forsworn."

[F.N.: The Hippocratic Collection, containing the best of the ancient Greek medical writings, was put together by Aristotle and has survived through the centuries. The "Hippocratic Oath" is one of the last and most inspiring passages in this Collection. There are a number of versions of the famous Oath; but the form given here is the one commonly used today; and is an adaptation of a translation from the original Greek.]

"The medical profession is and always has been one of the most ethical of all professions; and this is due at least in part to the centuries-old influence of the Hippocratic Oath. This famous Oath has kept alive the high standards and ideals set by Hippocrates, and forms the basis of modern medical ethics.

Written more than twenty centuries ago, the Hippocratic Oath has inspired generations of doctors... and continues to do so even now. The Oath is still administered by medical schools to graduating classes; and thousands of physicians have framed copies on their walls along with their diplomas. Conscientious practitioners continue to live up to the principles and ideals set down for their profession so long ago by the "Father of Medicine."

Though it was written specifically for physicians, the Hippocratic Oath sets an enduring pattern of honor, integrity, and devotion to duty for all people, in all professions." And certainly to surgeons."

¹¹² Lilian Eichler Watson, *Light From Many Lamps*, Simon and Schuster, 1951, p. 181-182.

Many people argue that the original Hippocratic Oath is inappropriate in a society that has seen drastic socio-economic, political and moral changes, since the time of Hippocrates. Certain parts of the original oath such as teaching the master's sons the secrets of medicine without fees and the promise not to bring a knife to another's body but to leave it to 'practitioners of the craft' have been rendered obsolete as the modernisation of education has led to the teaching of medical science in institutions of higher learning, and specialisation in medicine has led to physicians who specialize in a variety of fields including surgery. Similarly, the legalisation on abortion and physician-assisted suicide in certain parts of the world, has made it awkward for some medical practitioners there to carry on in the tradition of the original oath.

This has led to the modification of the oath to something better suited for our times. One of the most widely used versions is The Declaration of Geneva which was adopted by the General Assembly of the World Medical Association at Geneva in 1948. Written with the medical crimes committed in Nazi Germany in view, it is a 'declaration of physicians' dedication to the humanitarian goals of medicine.' It is also perhaps the only one to mention treating people equally, without regard as to race, religion, social standing and political affiliations:

"I solemnly pledge myself to the service of humanity. I will give to my teachers the respect and gratitude which is their due. I will practice my profession with conscience and dignity. The health of my patient will be my first consideration. I will respect the secrets which are confided in me. I will maintain by all means in my power the honour and noble traditions of the medical profession. My colleagues will be my brothers and sisters. I will not permit consideration of religion, nationality, race or social standing to intervene between my duty and my patient. I will maintain the utmost respect for human life even under threat. I will not use my medical knowledge contrary to the laws of humanity. I make these promises solemnly, freely and upon my honour."

In recent times the self regulatory standards in the profession have shown a decline and this can be attributed to the overwhelming impact of commercialization of the sector. There are reports against doctors of exploitative medical practices, misuse of diagnostic procedures, brokering deals for sale of human organs, etc. It cannot be denied that black sheep have entered the profession and that the profession has been unable to isolate them effectively. The need for external regulation to supplement professional self-regulation is constantly growing. The high costs and investments involved in the delivery of medical care have made it an entrepreneurial activity wherein the professionals look to reaping maximum returns on such investment. Medical practice has always had a place of honour in society; currently the balance between service and business is shifting disturbingly towards business and this calls for improved and effective regulation, whether internal or external. There is need for introspection by doctors - individually and collectively.¹¹³

¹¹³ Para 26-30.

4. Dr. C.P. Sreekumar, M.S. (Ortho) v. S. Ramanujam¹¹⁴

Brief Facts:

Sections 2 (1) (g), 17 and 21 of Consumer Protection Act, 1986 were invoked for deficiency in service i.e Medical negligence. The respondent had suffered a hairline fracture in the neck of right femur in leg. During treatment by appellant, simple hairline fracture Garden type 1 developed into more serious Garden type III fracture . The Pre-operative evaluations were made and the appellant decided to perform hemiarthroplasty instead of going in for internal fixation procedure.

Issue:

Whether the surgery was justified as respondent was aged 42 years? Whether serious Garden III fracture developed on account of negligence of appellant doctor? The Appellant explained that fracture displaced on account of muscular spasm and this point was un-rebutted as no contrary evidence was produced.

Held:

Some divergence of opinion as to proper procedure has to be adopted. Hence, it cannot be said with certainty that appellant doctor grossly remiss in going in for hemiarthroplasty. The Appellant's decision in choosing it for patient of 42 years of age was not palpably erroneous or unacceptable as to dub it as case of professional or medical negligence.

Important excerpts from the judgment:

This Court observed that the judgment of Jacob Mathew had been followed repeatedly not only in India but in other jurisdictions as well and that it was the statement of law as commonly understood today. In paragraphs 24 and 32 of Jacob Mathew's case it has been observed thus:

The classical statement of law in Bolam's case has been widely accepted as decisive of the standard of care required both of professional men generally and medical practitioners in particular. It has been invariably cited with approval before the courts in India and applied as a touchstone to test the pleas of medical negligence. In tort, it is enough for the defendant to show that the standard of care and the skill attained was that of the ordinary competent medical practitioner exercising an ordinary degree of professional skill. The fact that a defendant charged with negligence acted in accord with the general and approved practice is enough to clear him of the charge. Two things are pertinent to be noted. Firstly, the standard of care, when assessing the practice as adopted, is judged in the light of knowledge available at the time (of the incident), and not at the date of trial. Secondly, when the charge of negligence arises out of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that

¹¹⁴ (2009) 7 SCC 130.

point of time on which it is suggested as should have been used.

At least three weighty considerations can be pointed out which any forum trying the issue of medical negligence in any jurisdiction must keep in mind. These are:

- (i) That legal and disciplinary procedures should be properly founded on firm, moral and scientific grounds;
- (ii) That patients will be better served if the real causes of harm are properly identified and appropriately acted upon; and
- (iii) That many incidents involve a contribution from more than one person, and the tendency is to blame the last identifiable element in the chain of causation, the person holding the "smoking gun."

These observations postulate the underlying principle that too much suspicion about the negligence of attending Doctors and frequent interference by Courts would be a very dangerous proposition as it would prevent Doctors from taking decisions which could result in complications and in this situation the patient would be the ultimate sufferer. Jacob Mathew's case was followed in *State of Punjab v. Shiv Ram and Ors.*¹¹⁵ which was a case of a failed tubectomy leading to a plea of medical negligence. This is what this Court had to say:

A Doctor, in essence, needs to be inventive and has to take snap decisions especially in the course of performing surgery when some unexpected problems crop up or complication sets in. If the medical profession, as a whole, is hemmed in by threat of action, criminal and civil, the consequence will be loss to the patients. No doctor would take a risk, a justifiable risk in the circumstances of a given case, and try to save his patient from a complicated disease or in the face of an unexpected problem that confronts him during the treatment or the surgery. It is in this background that this Court has cautioned that the setting in motion of the criminal law against the medical profession should be done cautiously and on the basis of reasonably sure grounds. In criminal prosecutions or claims in tort, the burden always rests with the prosecution or the claimant. No doubt, in a given case, a doctor may be obliged to explain his conduct depending on the evidence adduced by the prosecution or by the claimant. That position does not change merely because of the caution advocated in *Jacob Mathew* in fixing liability for negligence, on doctors.¹¹⁶

In *Samira Kohli v. Dr. Prabha Manchanda and Anr.*¹¹⁷ the basic issue was as to the principle governing "consent" to be taken from a patient prior to any invasive procedure. We find, however, that in the present case, the question of consent has not been raised by the respondent and on the contrary the case seems to be that the consent had, in fact, been taken. Even in his arguments the respondent did not deny lack of consent and on the contrary (as Mr. Ranjit Kumar has pointed out) in the Advocate's notice issued to Dr. C.P. Sreekumar appellant, on 19 November 1992, the fact that the respondent had agreed to

¹¹⁵ AIR 2005 SC 3280.

¹¹⁶ *State of Punjab v. Shiv Ram and Ors.*, (2005) 7 SCC 1 -Para 33.

¹¹⁷ AIR 2008 SC 1385.

the operation, has been admitted.¹¹⁸

In the light of the fact that there is some divergence of opinion as to the proper procedure to be adopted, it cannot be said with certainty that the appellant, Dr. Sreekumar was grossly remiss in going in for hemiarthroplasty. In Jacob Mathew case it has observed as under:

Negligence is the breach of a duty caused by 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 definition of negligence as given in Law of Torts, Ratanlal & Dhirajlal (edited by Justice G.P. Singh), referred to hereinabove, holds good. Negligence becomes actionable on account of injury resulting from the act or omission amounting to negligence attributable to the person sued. The essential components of negligence are three: "duty", "breach" and "resulting damage".

Negligence in the context of the medical profession necessarily calls for a treatment with a difference. To infer rashness or negligence on the part of a professional, in particular a doctor, additional considerations apply. A case of occupational negligence is different from one of professional negligence. A simple lack of care, an error of judgment or an accident, is not proof of negligence on the part of a medical professional. So long as a doctor follows a practice acceptable to the medical profession of that day, he cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply because a more skilled doctor would not have chosen to follow or resort to that practice or procedure which the accused followed.¹¹⁹

5. Martin F. D'Souza v. Mohd. Ishfaq¹²⁰

Brief Facts:

Sections 2 (1) (g), 21 and 23 of Consumer Protection Act, 1986 was invoked for deficiency in service i.e Medical negligence. The Judicial law was examined exhaustively as revolving around Bolams Rule. The Respondent was suffering from chronic renal failure and severe urinary tract infection only to be treated by Amikacin or Methenamine Mandelate (MM)-. Since MM cannot be used for patients suffering from renal failure, the Amikacin injection was administered to him. The Respondent complained to appellant doctor of slight tinnitus or ringing in ear and the Appellant immediately asked the respondent and his attendant (wife) to stop injection Amikacin and cap. Augmentine. But respondent on his own kept on taking Amikacin injections. Thus, appellant was not to be blamed in any way. It was the non-co-operative attitude of respondent and his continuing with Amikacin injection which was the cause of his ailment, i.e., impairment of his hearing.

¹¹⁸ Para 11-13.

¹¹⁹ Para 20.

¹²⁰ (2009) 3 SCC 1.

Held:

Nothing on evidence to show that appellant was negligent in any way. Rather he did his best to give good treatment to respondent to save his life, but respondent himself did not co-operate. In view of opinion of expert doctor from A.I.I.M.S¹²¹. the appellant doctor not guilty of medical negligence.

A medical practitioner is not liable to be held negligent simply because things went wrong from mischance or misadventure or through an error of judgment in choosing one reasonable course of treatment in preference to another. He would be liable only where his conduct fell below that of the standards of a reasonably competent practitioner in his field. For instance, he would be liable if he leaves a surgical gauze inside the patient after an operation vide *Achutrao Haribhau Khodwa and others v. State of Maharashtra and others*,¹²² or operates on the wrong part of the body, and he would be also criminally liable if he operates on someone for removing an organ for illegitimate trade.

The professional is one who professes to have some special skill. A professional impliedly assures the person dealing with him

- (i) That he has the skill which he professes to possess,
- (ii) That skill shall be exercised with reasonable care and caution.

Judged by this standard, the professional may be held liable for negligence on the ground that he was not possessed of the requisite skill which he professes to have. Thus a doctor who has a qualification in Ayurvedic or Homeopathic medicine will be liable if he prescribes Allopathic treatment which causes some harm.

Ratio Decidendi:

"Whenever a complaint is received against a doctor or hospital by the Consumer Forum, then it should first refer the matter to a competent doctor or committee of doctors, specialized in the field and only on their report a prima facie case of medical negligence can be made out and a notice can be issued to the concerned doctor/hospital."

Important excerpts from the judgment:

The law, like medicine, is an inexact science. One cannot predict with certainty an outcome of many cases. It depends on the particular facts and circumstances of the case, and also the personal notions of the Judge concerned who is hearing the case. However, the broad and general legal principles relating to medical negligence need to be understood.

Before dealing with these principles two things have to be kept in mind :

- (1) Judges are not experts in medical science, rather they are lay men. This itself often

¹²¹ All India Institute of Medical Sciences.

¹²² AIR 1996 SC 2377.

makes it somewhat difficult for them to decide cases relating to medical negligence. Moreover, Judges have usually to rely on testimonies of other doctors which may not necessarily in all cases be objective, since like in all professions and services, doctors too sometimes have a tendency to support their own colleagues who are charged with medical negligence. The testimony may also be difficult to understand, particularly in complicated medical matters, for a layman in medical matters like a Judge; and

(2) A balance has to be struck in such cases. While doctors who cause death or agony due to medical negligence should certainly be penalized, it must also be remembered that like all professionals doctors too can make errors of judgment but if they are punished for this no doctor can practice his vocation with equanimity. Indiscriminate proceedings and decisions against doctors are counter productive and serve society no good. They inhibit the free exercise of judgment by a professional in a particular situation.¹²³

The basic principle relating to medical negligence is known as the BOLAM Rule. This was laid down in the judgment of Justice McNair in Bolam v. Friern Hospital Management Committee¹²⁴ as follows:

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 the man on the top of a Clapham omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that 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 particular Article

Bolam's test has been approved by the Supreme Court in Jacob Mathew's case.¹²⁵

The standard of care has to be judged in the light of knowledge available at the time of the incident and not at the date of the trial. Also, where the charge of negligence is of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that point of time.

The higher the acuteness in an emergency and the higher the complication, the more are the chances of error of judgment. At times, the professional is confronted with making a choice between the devil and the deep sea and has to choose the lesser evil. The doctor is often called upon to adopt a procedure which involves higher element of risk, but which he honestly believes as providing greater chances of success for the patient rather than a procedure involving lesser risk but higher chances of failure. Which course is more appropriate to follow, would depend on the facts and circumstances of a given case but a doctor cannot be penalized if he adopts the former procedure, even if it results in a failure. The usual practice prevalent nowadays is to obtain the consent of the patient or of the person in-charge of the patient if the patient is not in a position to give consent before adopting a given procedure.

¹²³ Para 34-35.

¹²⁴ (1957) 1 WLR 582.

¹²⁵ Para 38.

There may be a few cases where an exceptionally brilliant doctor performs an operation or prescribes a treatment which has never been tried before to save the life of a patient when no known method of treatment is available. If the patient dies or suffers some serious harm, should the doctor be held liable? In our opinion he should not. Science advances by experimentation, but experiments sometime end in failure e.g. the operation on the Iranian twin sisters who were joined at the head since birth, or the first heart transplant by Dr. Barnard in South Africa. However, in such cases it is advisable for the doctor to explain the situation to the patient and take his written consent.

Simply because a patient has not favourably responded to a treatment given by a doctor or a surgery has failed, the doctor cannot be held straightway liable for medical negligence by applying the doctrine of *res ipsa loquitur*. No sensible professional would intentionally commit an act or omission which would result in harm or injury to the patient since the professional reputation of the professional would be at stake. A single failure may cost him dear in his lapse.¹²⁶

When a patient dies or suffers some mishap, there is a tendency to blame the doctor for this. Things have gone wrong and, therefore, somebody must be punished for it. However, it is well known that even the best professionals, what to say of the average professional, sometimes have failures. A lawyer cannot win every case in his professional career but surely he cannot be penalized for losing a case provided he appeared in it and made his submissions.

To fasten liability in criminal proceedings e.g. under Section 304A IPC¹²⁷ the degree of negligence has to be higher than the negligence which is enough to fasten liability in civil proceedings. Thus for civil liability it may be enough for the complainant to prove that the doctor did not exercise reasonable care in accordance with the principles mentioned above, but for convicting a doctor in a criminal case, it must also be proved that this negligence was gross amounting to recklessness.

The difference between simple negligence and gross negligence has broadly been explained in paragraphs 12 to 16 of Jacob Mathew's case, though difficulties may arise in the application of the principle in particular cases. For instance, if a mop is left behind in the stomach of a patient while doing an operation, would it be simple negligence or gross negligence? If a scissors or sharp edged medical instrument is left in the patient's body while doing the operation would that make a difference from merely leaving a mop?

The professional is one who professes to have some special skill. A professional impliedly assures the person dealing with him

- (i) That he has the skill which he professes to possess,
- (ii) That skill shall be exercised with reasonable care and caution.

Judged by this standard, the professional may be held liable for negligence on the ground that he was not possessed of the requisite skill which he professes to have. Thus a doctor

¹²⁶ Para 44-47.

¹²⁷ The Indian Penal Code, 1860.

who has a qualification in Ayurvedic or Homeopathic medicine will be liable if he prescribes Allopathic treatment which causes some harm vide Poonam Verma v. Ashwin Patel and Ors.¹²⁸ In Dr. Shiv Kumar Gautam v. Alima,¹²⁹ the National Consumer Commission held a homeopath liable for negligence for prescribing allopathic medicines and administering glucose drip and giving injections.¹³⁰

We, therefore, direct that whenever a complaint is received against a doctor or hospital by the Consumer Forum (whether District, State or National) or by the Criminal Court then before issuing notice to the doctor or hospital against whom the complaint was made the Consumer Forum or Criminal Court should first refer the matter to a competent doctor or committee of doctors, specialized in the field relating to which the medical negligence is attributed, and only after that doctor or committee reports that there is a prima facie case of medical negligence should notice be then issued to the concerned doctor/hospital. This is necessary to avoid harassment to doctors who may not be ultimately found to be negligent. We further warn the police officials not to arrest or harass doctors unless the facts clearly come within the parameters laid down in Jacob Mathew's case, otherwise the policemen will themselves have to face legal action.¹³¹

6. Kusum Sharma and Ors. v. Batra Hospital and Medical Research Centre and Ors.¹³²

Brief Facts:

Sections 2 (1) (g) and 21 of Consumer Protection Act, 1986 was invoked for Deficiency in service i.e Medical negligence. The husband of appellant No. 1 died of pyrogenic meningitis in respondent hospital and a complaint for medical negligence was instituted.

Principles stated:

Appellants have failed to make out any case of medical negligence against respondents and the National Commission was justified in dismissing complaint of appellants.

While deciding whether the medical professional is guilty of medical negligence following well known principles must be kept in view:

(I) Negligence is the breach of a duty exercised by 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.

(II) Negligence is an essential ingredient of the offence. The negligence to be established by the prosecution must be culpable or gross and not the negligence merely based upon

¹²⁸ AIR 1996 SC 2111.

¹²⁹ National Consumer Dispute Redressal Commission, Revision Petition No. 586 of 1999 decided on 10.10.2006.

¹³⁰ Para 49-53.

¹³¹ Para 116.

¹³² (2010) 3 SCC 480.

an error of judgment.

(III) The medical professional is expected to bring a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence judged in the light of the particular circumstances of each case is what the law requires.

(IV) A medical practitioner would be liable only where his conduct fell below that of the standards of a reasonably competent practitioner in his field.

(V) In the realm of diagnosis and treatment there is scope for genuine difference of opinion and one professional doctor is clearly not negligent merely because his conclusion differs from that of other professional doctor.

(VI) The medical professional is often called upon to adopt a procedure which involves higher element of risk, but which he honestly believes as providing greater chances of success for the patient rather than a procedure involving lesser risk but higher chances of failure. Just because a professional looking to the gravity of illness has taken higher element of risk to redeem the patient out of his/her suffering which did not yield the desired result may not amount to negligence.

(VII) Negligence cannot be attributed to a doctor so long as he performs his duties with reasonable skill and competence. Merely because the doctor chooses one course of action in preference to the other one available, he would not be liable if the course of action chosen by him was acceptable to the medical profession.

(VIII) It would not be conducive to the efficiency of the medical profession if no Doctor could administer medicine without a halter round his neck.

(IX) It is our bounden duty and obligation of the civil society to ensure that the medical professionals are not unnecessarily harassed or humiliated so that they can perform their professional duties without fear and apprehension.

(X) The medical practitioners at times also have to be saved from such a class of complainants who use criminal process as a tool for pressurizing the medical professionals / hospitals particularly private hospitals or clinics for extracting uncalled for compensation. Such malicious proceedings deserve to be discarded against the medical practitioners.

(XI) The medical professionals are entitled to get protection so long as they perform their duties with reasonable skill and competence and in the interest of the patients. The interest and welfare of the patients have to be paramount for the medical professionals.¹³³

As long as the doctors have performed their duties and exercised an ordinary degree of professional skill and competence, they cannot be held guilty of medical negligence. It is imperative that the doctors must be able to perform their professional duties with free

¹³³ Para 94.

mind.

Ratio Decidendi:

"Doctors performing their duties and exercising an ordinary degree of professional skill and competence cannot be held guilty of negligence."

7. V. Kishan Rao v. Nikhil Super Speciality Hospital and Anr.¹³⁴

Brief Facts:

Appellant was the complainant before the Consumer Disputes Redressal Forum and had filed the complaint seeking compensation for medical negligence. Complainant alleged that his wife was suffering from Malaria but she was treated for Typhoid as a result of which she succumbed to the disease. The District Forum held that there was negligence and directed payment of compensation. Appeals filed by the Hospital and Insurer were allowed on the ground that negligence of the doctor is not proved and that there was no expert evidence to prove negligence. Appeal filed by the complainant which was dismissed by the National Commission and the Complainant approached the Hon'ble Supreme Court.

Held:

The Apex Court held that it is for the Consumer Forum to decide whether any expert evidence is required to prove the medical negligence alleged by the complainant and it may not be necessary in many cases where the negligence is apparent and the principle of 'res ipsa loquitur' applies to such cases. It was further held that before forming an opinion that expert evidence is required, the Forum must reach a conclusion that the case is complicated enough to require the opinion of an expert or that the facts of the case are such that it cannot be resolved by members of the Forum without assistance of experts. The Bench held that decision in *Martin F. D'souza v. Moh'd Ishfaque*,¹³⁵ cannot be treated as a binding precedent and the direction in the said Judgment that the Consumer Forum and Criminal Courts should get the opinion of a competent Doctor or Committee of Doctors and notice should be issued to Respondent Doctor only if a competent Doctor or Committee opines that there is prima facie proof of medical negligence, is contrary to decisions of larger Bench of the Supreme Court.

Explaining the same it was observed:

In the opinion of this Court, before forming an opinion that expert evidence is necessary, the Forum under the Act must come to a conclusion that the case is complicated enough to require the opinion of an expert or that the facts of the case are such that it cannot be resolved by the members of the forum without the assistance of expert opinion. This Court makes it clear that in these matters no mechanical approach can be followed by

¹³⁴ (2010) 5 SCC 513.

¹³⁵ (2009) 3 SCC 1.

these forum. Each case has to be judged on its own facts. If a decision is taken that in all cases medical negligence has to be proved on the basis of expert evidence, in that event the efficacy of the remedy provided under this Act will be unnecessarily burdened and in many cases such remedy would be illusory.¹³⁶ This Court however made it clear that before the consumer forum if any of the parties wants to adduce expert evidence, the members of the forum by applying their mind to the facts and circumstances of the case and the materials on record can allow the parties to adduce such evidence if it is appropriate to do so in the facts of the case. The discretion in this matter is left to the members of forum especially when retired Judges of Supreme Court and High Court are appointed to Head National Commission and the State Commission respectively. Therefore, these questions are to be judged on the facts of each case and there cannot be a mechanical or strait-jacket approach that each and every case must be referred to experts for evidence. When the forum finds that expert evidence is required, the forum must keep in mind that an expert witness in a given case normally discharges two functions. The first duty of the expert is to explain the technical issues as clearly as possible so that it can be understood by a common man. The other function is to assist the forum in deciding whether the acts or omissions of the medical practitioners or the hospital constitute negligence. In doing so, the expert can throw considerable light on the current state of knowledge in medical science at the time when the patient was treated. In most of the cases the question whether a medical practitioner or the hospital is negligent or not is a mixed question of fact and law and the forum is not bound in every case to accept the opinion of the expert witness. Although, in many cases the opinion of the expert witness may assist the forum to decide the controversy one-way or the other.¹³⁷

In accordance with the Evidence Act, 1872 the legal maxim of 'Res ipsa loquitur' can be explained as: In a case where negligence is apparent, principle of 'res ipsa loquitur' applies and complainant does not have to prove any thing further. It is a principle of evidence intended to assist a claimant in a claim for damages who, for no fault of his, is unable to adduce evidence as to how the accident occurred.

In the treaties on Medical Negligence by Michael Jones, the learned author has explained the principle of res ipsa loquitur as essentially an evidential principle and the learned author opined that the said principle is intended to assist a claimant who, for no fault of his own, is unable to adduce evidence as to how the accident occurred. The principle has been explained in the case of Scott v. London & St Katherine Docks Co.,¹³⁸ by Chief Justice Erle in the following manner: "where the thing is shown to be under the management of the Defendant or his servants, and the accident is such as in the ordinary course of things does not happen if those who have the management use proper care, it affords reasonable evidence, in the absence of explanation by the Defendants, that the accident arose from want of care."¹³⁹

In a case where negligence is evident, the principle of res ipsa loquitur operates and the

¹³⁶ Para 13.

¹³⁷ Para 54.

¹³⁸ (1865) 3 H & C 596.

¹³⁹ Para 45.

complainant does not have to prove anything as the thing (res) proves itself. In such a case it is for the Respondent to prove that he has taken care and done his duty to repel the charge of negligence.

The decision of the Supreme Court in *Martin F. D'souza v. Moh'd Ishfaque*,¹⁴⁰ is per incuriam and cannot be treated as a binding precedent. Opinion of the Doctor or Committee of Doctors is not necessary before taking cognizance of case of medical negligence.

If the general directions in paragraph 106 in D'souza's case are to be followed then the doctrine of *res ipsa loquitur* which is applied in cases of medical negligence by this Court and also by Courts in England would be redundant. In view of the discussions aforesaid, this Court is constrained to take the view that the general direction given in paragraph 106 in D'souza's case cannot be treated as a binding precedent and those directions must be confined to the particular facts of that case. With great respect to the Bench which decided D'souza's case this Court is of the opinion that the directions in D'souza's case are contrary to -

- (a) the law laid down in paragraph 37 of Indian Medical Association's case¹⁴¹
- (b) and paragraph 19 in *Dr. J J. Merchant's case*¹⁴²
- (c) those directions in paragraph 106 of D'souza's case equate medical negligence in criminal trial and negligence fastening civil liability whereas the earlier larger bench in *Mathew's case* elaborately differentiated between the two concepts,
- (d) those directions in D'souza's case are contrary to the said Act which is the governing statute,
- (e) those directions are also contrary to the avowed purpose of the Act, which is to provide a speedy and efficacious remedy to the consumer. If those general directions are followed then in many cases the remedy under the said Act will become illusory,
- (f) those directions run contrary to principle of '*Res ipsa loquitur*' which has matured into a rule of law in some cases of medical negligence where negligence is evident and obvious.¹⁴³

8. Dr. Balram Prasad v. Dr. Kunal Saha and Ors.¹⁴⁴

Brief facts:

The claimant filed petition in 1999 before the National Commission claiming compensation for Rs. 77,07,45,000/- and later the same was amended by claiming another sum of Rs. 20,00,00,000/-. After the case of *Malay Kumar Ganguly v. Dr.*

¹⁴⁰ (2009) 3 SCC 1.

¹⁴¹ (1995) 6 SCC 651.

¹⁴² (2002) 6 SCC 635 .

¹⁴³ Para 48-50.

¹⁴⁴ (2014) 1 SCC 384.

Sukumar Mukherjee¹⁴⁵ was remanded by this Court to the National Commission to award just and reasonable compensation to the claimant by answering the points framed in the said case, the National Commission held the doctors and the AMRI Hospital negligent in treating the wife of the claimant on account of which she died. Therefore, this Court directed the National Commission to determine just and reasonable compensation payable to the claimant. However, the claimant, the Appellant-Hospital and the doctors were aggrieved by the amount of compensation awarded by the National Commission and also the manner in which liability was apportioned amongst each of them. While the claimant was aggrieved by the inadequate amount of compensation, the Appellant-doctors and the Hospital found the amount to be excessive and too harsh. They further claimed that the proportion of liability ascertained on each of them is unreasonable.

Held:

In Medical Negligence cases “Just compensation” should be assessed. Awarding meagre compensation under different heads is unsustainable in law and it is the duty of Tribunal/Commission/Court to consider relevant facts and circumstances of each and every case. While ascertaining compensation the scope of future prospects of income is to be decided by economic expert. The scope of "multiplier Method" in assessing compensation, the court may choose to deviate from standard multiplier method to avoid over compensation and rely upon quantum of multiplicand to choose appropriate multiplier.

Important excerpts from the judgment:

Before parting with the judgment we are inclined to mention that the number of medical negligence cases against doctors, Hospitals and Nursing Homes in the consumer forum are increasing day by day. In the case of Paschim Banga Khet Mazdoor Samity v. State of West Bengal,¹⁴⁶ this Court has already pronounced that right to health of a citizen is a fundamental right guaranteed under Article 21¹⁴⁷ of the Constitution of India. It was held in that case that all the government Hospitals, Nursing Homes and Poly-clinics are liable to provide treatment to the best of their capacity to all the patients.

The doctors, Hospitals, the Nursing Homes and other connected establishments are to be dealt with strictly if they are found to be negligent with the patients who come to them pawning all their money with the hope to live a better life with dignity. The patients irrespective of their social, cultural and economic background are entitled to be treated with dignity which not only forms their fundamental right but also their human right. We, therefore, hope and trust that this decision acts as a deterrent and a reminder to those doctors, Hospitals, the Nursing Homes and other connected establishments who do not take their responsibility seriously.

The central and the state governments may consider enacting laws wherever there is absence of one for effective functioning of the private Hospitals and Nursing Homes.

¹⁴⁵ (2009) 9 SCC 221.

¹⁴⁶ (1996) 4 SCC 37.

¹⁴⁷ Article 21 – Protection of Life & Personal Liberty.

Since the conduct of doctors is already regulated by the Medical Council of India, we hope and trust for impartial and strict scrutiny from the body. Finally, we hope and believe that the institutions and individuals providing medical services to the public at large educate and update themselves about any new medical discipline and rare diseases so as to avoid tragedies such as the instant case where a valuable life could have been saved with a little more awareness and wisdom from the part of the doctors and the Hospital.¹⁴⁸

¹⁴⁸ Para 148-150.

CHAPTER VI - CURRENT TRENDS RELATED TO MEDICAL MALPRACTICE IN INDIA

THE BOTCHED CAMPS

In November 2014, fifteen women died after undergoing botched sterilisation operations performed in the state of Chhattisgarh. In addition to those dead, seventy women were hospitalized in critical condition and twenty of them were put on mechanical ventilation.

With more than four million Indians sterilised every year, a system of quotas encourages officials and doctors to cut corners. India's sterilisation programme is coercive because ill-educated women are often offered money to accept surgery without knowing the full risks. State government officials who run the programme are pressed to meet quotas. In the Chhattisgarh case each of the women was paid to undergo the procedure. Reports have differed on how much each one was paid with some saying the amount was 1,400 rupees, while others have said it was 600. The government of India sometimes pays women under the family planning policy to be sterilised in order to curb population growth in the country.¹⁴⁹

Dr. R. K. Gupta carried out tubectomies on around 140 women in two different camps on November 8 2014 in Pendari, Bilaspur district and another on November 10, 2014. He was then awarded by the Chhattisgarh government for carrying out the record number of sterilisations. However, the women fell ill on November 10, 2014, two days after the surgery. By that night, eight of them had died, and their deaths were announced the following day. By November 13, 2014, thirteen deaths were reported with seventy hospitalised and some admitted in AIIMS.

S.K. Mandal, the chief medical officer in Chhattisgarh, suggested that the doctor who performed the operations was under pressure to meet government-set targets for a number of sterilisations that had to be performed. According to an unnamed medical official, by performing 83 sterilisations in six hours, the doctor who performed the sterilisations breached guidelines requiring surgeons to perform no more than 30 sterilisations per day.

The exact cause of the deaths the preliminary stage remained unclear. According to Amar Singh, the deputy health director of Chhattisgarh, the women appeared to have died from either blood poisoning or hemorrhagic shock. The leader of the investigation, police inspector S.N. Shukla, said that preliminary investigations suggested that the deaths were caused by either contaminated equipment or adulterated medicines. According to district medical officer M.A. Jeemani, results of post-mortems performed on some of the women who died suggested that the administration of tainted medicines might have caused the women's deaths.

On November 15, two senior Chhattisgarh officials stated that tablets of ciprocin that had been linked to the deaths contained zinc phosphide. This chemical is often used in rat poison. This conclusion arose from a preliminary report, and samples of the tablets were sent to other laboratories for verification. The company responded to this finding by

¹⁴⁹ www.firstpost.com last visited on April, 1 2015.

releasing a statement which said that information about the incident had been exaggerated, and denying that the pills they produced were contaminated.¹⁵⁰

After being condemned by Chief Minister Raman Singh, on 12 November, Dr. Gupta was arrested and thus suspended. He said, "*It was not my fault - the administration pressured me to meet targets. The surgeries went well but the problem was with the medicines given to the women.*"

On November 14, 2014, The director of the drug company, which allegedly supplied sub-standard medicines that were administered to the victims of sterilisation surgeries in Chhattisgarh, and his son were arrested. "Mahawar Pharma Pvt Ltd's director Ramesh Mahwar and his son Sumit have been arrested under section 420 for cheating, based on a complaint lodged by Food and Drug Administration (FDA) authorities".

The state government has also banned all medicines manufactured by the pharmaceutical company. The FDA also conducted raid and sealed a manufacturing unit of the company.

Chief Minister Raman Singh had blamed negligence for the incident and four health officials were suspended by the state, including the district's chief medical officer. The government promised to pay the equivalent of about four lac rupees to each of the affected families. Local health officials denied any responsibility for the deaths, with some suggesting added pressure from the government to perform many operations in a short space of time.

The Bilaspur high court on December 4, 2014 granted bail to Dr R K Gupta, the accused doctor but fate of the directors of the pharma company is still under consideration.¹⁵¹

For three months in the year 2015, the inquiry into the case seemed to have stopped with not even any newspaper reporting anything. It looked as if by arresting a few persons they had shown their consideration towards the death and forgot about finding the exact reason behind such a mis-happening or prevent any future negligence matter.

The Supreme Court on March 20, 2015 pulled up the Chhattisgarh government for filing "incomplete" affidavit over alleged botched up sterilisation surgeries at Bilaspur district. The social justice bench of Justices Madan B Lokur and U U Lalit observed "In view of our earlier order, Chhattisgarh has filed an affidavit. However, certain details like the number of FIRs filed, progress made in their investigation etc are not submitted. We expect the state to file complete affidavit," they also sought information about present status of the the judicial inquiry of a panel, headed by retired District Judge Anita Jha, formed to look into the sterilisation deaths.

¹⁵⁰ www.reuters.com last visited on March, 31 2015.

¹⁵¹ www.ndtv.com last visited on April, 1 2015.

THE UNIVERSAL HEALTH-CARE PLAN

The Draft National Health Policy 2015 by Ministry of Health & Family Welfare¹⁵²

This National Health Policy addresses the urgent need to improve the performance of health systems. It is being formulated at the last year of the Millennium Declaration and its Goals, in the global context of all nations committed to moving towards universal health coverage. Given the two-way linkage between economic growth and health status, this National Health Policy is a declaration of the determination of the Government to leverage economic growth to achieve health outcomes and an explicit acknowledgement that better health contributes immensely to improved productivity as well as to equity.

The primary aim of the National Health Policy, 2015, is to inform, clarify, strengthen and prioritize the role of the Government in shaping health systems in all its dimensions- investment in health, organization and financing of healthcare services, prevention of diseases and promotion of good health through cross sectoral action, access to technologies, developing human resources, encouraging medical pluralism, building the knowledge base required for better health, financial protection strategies and regulation and legislation for health.

The situation in quality of care is also a matter of serious concern and this seriously compromises the effectiveness of care. For example though over 90% of pregnant women receive one antenatal check up and 87 % received full TT immunization, only about 68.7 % of women have received the mandatory three antenatal check-ups. Again whereas most women had received iron and folic acid tablets, only 31% of pregnant women had consumed more than 100 IFA tablets. For institutional delivery standard protocols are often not followed during labour and the postpartum period. Sterilization related deaths a preventable tragedy, are often a direct consequence of poor quality of care. Only 61% of children (12 -23 months) have been fully immunized. There are gaps in access to safe abortion services too, and in care for the sick neonate.

Some hospitals, insurance companies and administrators have also resorted to various fraudulent measures, including charging informal payments. Schemes that are governed and managed by independent bodies have performed better than other schemes that are located in informal cells within existing departments or when managed by insurance companies. The insurance schemes vary widely in terms of benefit packages and have resulted in fragmentation of funds available for health care; especially selective allocation to secondary and tertiary care over primary care services. All National and State health insurance schemes need to be aligned into a single insurance scheme and a single fund pool reducing fragmentation. The RSBY scheme has now been shifted to the Ministry of Health & Family Welfare, helping the State and Central Ministry move to a tax financed single payer system approach. The Ministry could now compare the relative costs per patient for alternative routes of financing viz. purchase through insurance, or direct purchase from private sector and from public sector or free care by public sector as a form of tax based financing, and take the best decision for a given context.

¹⁵² Available at <http://www.mohfw.nic.in/showfile.php?lid=3014>.

Goal: The attainment of the highest possible level of good health and well-being, through a preventive and promotive health care orientation in all developmental policies, and universal access to good quality health care services without anyone having to face financial hardship as a consequence.

Key Policy Principles:

Equity: Public expenditure in health care, prioritizing the needs of the most vulnerable, who suffer the largest burden of disease, would imply greater investment in access and financial protection measures for the poor. Reducing inequity would also mean affirmative action to reach the poorest and minimizing disparity on account of gender, poverty, caste, disability, other forms of social exclusion and geographical barriers.

Universality: Systems and services are designed to cater to the entire population- not only a targeted sub-group. Care to be taken to prevent exclusions on social or economic grounds.

Patient Centered & Quality of Care: Health Care services would be effective, safe, and convenient, provided with dignity and confidentiality with all facilities across all sectors being assessed, certified and incentivized to maintain quality of care.

Inclusive Partnerships: The task of providing health care for all cannot be undertaken by Government, acting alone. It would also require the participation of communities – who view this participation as a means and a goal, as a right and as a duty. It would also require the widest level of partnerships with academic institutions, not for profit agencies and with the commercial private sector and health care industry to achieve these goals.

Pluralism: Patients who so choose and when appropriate, would have access to AYUSH care providers based on validated local health traditions. These systems would also have Government support and supervision to develop and enrich their contribution to meeting the national health goals and objectives. Research, development of models of integrative practice, efforts at documentation, validation of traditional practices and engagement with such practitioners would form important elements of enabling medical pluralism.

Subsidiarity: For ensuring responsiveness and greater participation, increasing transfer of decision making to as decentralized a level as is consistent with practical considerations and institutional capacity would be promoted. (Nothing should be done by a larger and more complex organization which can be done as well by a smaller and simpler organization.)

Accountability: Financial and performance accountability, transparency in decision making, and elimination of corruption in health care systems, both in the public systems and in the private health care industry, would be essential.

Professionalism, Integrity and Ethics: Health workers and managers shall perform their work with the highest level of professionalism, integrity and trust and be supported by a systems and regulatory environment that enables this.

Learning and Adaptive System: constantly improving dynamic organization of health care which is knowledge and evidence based, reflective and learning from the communities they serve, the experience of implementation itself, and from national and international knowledge partners.

Affordability: As costs of care rise, affordability, as distinct from equity, requires emphasis. Health care costs of a household exceeding 10% of its total monthly consumption expenditures or 40% of its non-food consumption expenditure- is designated catastrophic health expenditures- and is declared as an unacceptable level of health care costs. Impoverishment due to health care costs is of course, even more unacceptable.

Objectives:

Improve population health status through concerted policy action in all sectors and expand preventive, promotive, curative, palliative and rehabilitative services provided by the public health sector.

Achieve a significant reduction in out of pocket expenditure due to health care costs and reduction in proportion of households experiencing catastrophic health expenditures and consequent impoverishment.

Assure universal availability of free, comprehensive primary health care services, as an entitlement, for all aspects of reproductive, maternal, child and adolescent health and for the most prevalent communicable and non-communicable diseases in the population.

Enable universal access to free essential drugs, diagnostics, emergency ambulance services, and emergency medical and surgical care services in public health facilities, so as to enhance the financial protection role of public facilities for all sections of the population.

Ensure improved access and affordability of secondary and tertiary care services through a combination of public hospitals and strategic purchasing of services from the private health sector.

Influence the growth of the private health care industry and medical technologies to ensure alignment with public health goals, and enable contribution to making health care systems more effective, efficient, rational, safe, affordable and ethical.

Under the National Health Assurance Mission, the government would provide all citizens with free drugs and diagnostic treatment, as well as insurance cover to treat serious ailments. The proposed plan had to be rolled out in phases from April 2015 and to cover

the entire population by March 2019. It was estimated that to cover the entire population, it would cost an estimated \$11.4 billion annually.¹⁵³

This policy was announced in October 2014 as India's universal health plan that aims to offer guaranteed benefits to a sixth of the world's population. Healthcare experts cautioned that it could take decades before India's 1.2 billion people are adequately covered and that the costs of provision could face significant upward pressure. The Plan if approved, the government would need to drastically raise its healthcare spending. But despite rapid economic growth in the last 20 years, the government spends only about 1 percent of gross domestic product on healthcare. That compares to 3 percent in China and 8.3 percent in the United States.

But in March 2015, the Prime Minister has asked for a drastic cutback to this ambitious health care plan after cost estimates came in at \$18.5 billion over five years. The government has to make difficult choices to boost economic growth. The first full annual budget ramped up infrastructure spending, leaving less federal funding immediately available for social sectors.

The health ministry proposed rolling out the system from April 2015, and in October projected its cost as \$11.4 billion over four years. By the time the project was presented to the prime minister's office in January the costs had been pared to 1.16 trillion rupees (\$18.5 billion) over five years.¹⁵⁴

TRACKING THE MEDICAL NEGLIGENCE IN INDIA VIA NEWSPAPER REPORTS

The Horrifying camps of Sterilization

On November 12, 2014 in The Times of India it was reported that Botched tubectomy at government camp kills 11. A total of 83 women underwent tubectomies out of which nearly 60 were hospitalized. These surgeries were performed at the Nemi Chand Jain Cancer research center in Takhatpur, Chhattisgarh. The government suspended four senior doctors. It was also reported that the surgeries were literally performed within minutes and in this race to complete numbers it was the women who bear the brunt. The striking fact was that 37 percent of the total tubectomies in the world are done in India, and it is the only country in the world where female sterilizations predominates among various birth control measures. In a comparative chart the number of deaths and complications in sterilization surgery in India is shown to be increasing, with a total of 315 such cases in 2010-11 the number increased to 420 in 2012-13.

On November 14, 2014 in The Times of India it was reported that in the botched operations the pharma companies who are suspected manufacturers of drugs administered on victims in anticipation of raids burned down their stocks. The officials were still able to retrieve some samples from the burned stock. Other warehouses and stock at various places in India was also seized. The Chief Minister of Chhattisgarh ordered a probe into

¹⁵³ www.indianexpress.com last visited on April 3, 2015.

¹⁵⁴ www.economicstimes.indiatimes.com last visited on April 3, 2015.

the deaths but the doctor claims that bad quality drugs were responsible for such a situation and not the operations.

On November 15, 2014 in The Times of India it was reported that the drugs administered on the victims during the sterilization surgeries were contaminated with zinc phosphide, a rodent killing chemical. The government appointed retired district and sessions judge to probe into the incident. These tablets were manufactured by Mahavar Pharmaceutical Pvt. Ltd. The Police arrested directors of the pharma company and it was said that their company was buying medicines from other sources and packaged under their own names.

On November 16, 2014 in The Times of India there was a report regarding the statistics of sterilization camps in India. It was reported that despite the shocking statistics regarding females being subjected to sterilization surgeries more than any other contraceptive method the Indian women are still being herded to camps for these surgeries instead of being offered a mix of contraceptive methods. There is a health system prevailing in India which allowed a camp in an unused hospital when laparoscopic sterilizations are supposed to be done only in community health center-level hospitals. Then there was a doctor who performed 83 surgeries in few hours without sterilizing the surgical instruments. The union ministries over a dozen how-to manuals on quality control for sterilizations were bluntly ignored. Even the guidelines under supreme court decision *Ramakant Rai v. Government of India*,¹⁵⁵ 2005 and *Devika Biswas v. Government of India*¹⁵⁶ 2012 were not followed.

On November 20, 2014 in The Times of India it was reported that in Chhattisgarh alone a total of around 1.25 Lac sterilizations take place in a year. It is a fertile ground for doctors where they pocket around 93 Lac rupees annually for these surgeries. A marathon of surgeries i.e. a surgery every two minutes took place in Takhatpur which resulted in several deaths. The government gives attractive incentives to doctors and promoters to bring patients to camps and conduct sterilizations making it a lucrative business.

On November 24, 2014 in The Times of India a statement of Chhattisgarh health minister confirmed that medicines used during the botched sterilization surgeries were laced with zinc phosphide or rat killer poison. Various laboratories were given the work of analyzing the contents of the drugs seized from various companies and the finding jolted the promoters of these pharma companies who are already under arrest.

On November 29, 2014 in The Times of India it was reported that in a tubectomy camp held in Faridabad a 25 year old woman died during the surgery. The doctor like the Chhattisgarh case was a state government awardee, it was surprising to see that such a situation can soon arise after so many women died recently at another such camp.

On November 30, 2014 in The Times of India it was reported that cycle pumps were used to dilate the women's cervixes in a sterilization operations held in Odisha. The district medical authorities and the surgeon on duty defended such an act by saying that it was a

¹⁵⁵ Supreme Court Writ Petition (Civil) No. 209/ 2003 available at <http://www.hrln.org/hrln/images/stories/pdf/ramakant-rai-order.pdf>.

¹⁵⁶ Supreme Court Writ Petition(s) (Civil) No(s). 95/2012 available at <http://www.hrln.org/hrln/reproductive-rights/pils-a-cases.html>.

routine procedure. This comes close to the incident in Chhattisgarh where the lacunae's in following health standards during such operations were not followed resulting into a huge mis-happening. The cycle pumps were said to be a substitute of the expensive equipment's which were not affordable. Surgeries was performed on 56 women and an inquiry into the use of cycle pumps was ordered.

On December 2, 2014 in The Times of India it was reported that Infection and not just the fake medicines were behind the deaths of women at the Chhattisgarh sterilization camp. It was said that septicemia could have been responsible. It was urged that the reports of the fake medicines should be made public and even the post mortem examinations be provided. It looks as if the blame for the death is being passed on different reasons every now and then to overshadow the government's fault. It was also put to light that 85 percent of the Chhattisgarh family planning budget was spent on incentives and compensation for women to get the tubectomy. A demand for setting up of an independent inquiry committee into the matter as the inquiry set up by the state government does not seem to go beyond the medicines.

On December 3, 2014 in The Times of India it was reported that sterilization camps were banned in Odisha after the incident of using cycle pump on 56 women during tubectomies at a camp came to light. To ensure quality care such a decision was taken by the state government.

Overcharging to make Simple Medical Devices Fancy

On September 15, 2014 in The Times of India¹⁵⁷ it was reports that the patients pay three times the import price for stents. In a Maharashtra FDA report it was provided that the drug eluting stents were imported into India by a healthcare company for forty thousand which was sold to the distributor at a price of seventy three thousand. This was not the end as the distributor sold the same stents to a hospital for one lac rupees and the hospital charged ten thousand more. So in this series ultimately the patient had to give three times the actual landing cost of the stents. This overcharging rife is in the absence of any regulation to control or regulate the prices of medical devices.

Further, it was questioned whether the profits from these medical devices are used to bribe doctors by the pharma companies. A detailed investigation by the Maharashtra food and drug administration put light to many medical devices, prices for which increase three to four fold till it is actually used by a patient. The problem seems to be that these medical devices are notified under the Drugs and Cosmetics Act, 1940 but not included under the Drug Price Control Order, so the prices are neither monitored nor controlled.

On November 18, 2014 in The Times of India it was reported that an anonymous letter claims bribes by pharma companies to doctor which put around 300 doctors under the Medical Council of India for graft charges. The MCI summoned these doctors to answer the queries. According to this complaint a company based in Ahmedabad has been paying doctors lakhs of rupees as well as gifts for prescribing the firm's medicines even when cheaper alternatives are available. This company even after being priced 15-30 percent higher than other alternatives the sales of the company rose 400 percent.

¹⁵⁷ Annexure-III/Report 11.

On March 14, 2014 in The Times of India there was a report about G.B.Pant hospital where a rip-off for costly stents was going on in a nexus of doctors and pharma companies. The approved rate for drug eluting stents in all government facilities was twenty three thousand rupees. The hospital is only supposed to stock stents which are priced according to approved rate. It was reported that the doctors at the hospital prescribed high quality stents which were not available in the hospital and were supposed to be bought from outside. It was portrayed to the patients that due to the government notification they have to stock a mediocre level of stents which were cheaper. The doctors were working late into night and the cath labs use to stay open beyond regular times. It was shocking to see that in an affidavit submitted by the pharma company to Maharashtra FDA the stents priced double from the stock stents were actually of the same quality as the cheaper one, the only difference between them was the labeling and branding. The doctors were actually being paid a cut to prescribe the expensive stent which they would not have got if the stents stocked in the hospital were prescribed.

CONCLUSION

This dissertation has analyzed the issue of medical malpractice from a Law and Social perspective.

From the perspective of law, the medical malpractice law in India has evolved overtime from being governed by the law of torts to being a part of the Consumer Protection Act since 1995¹⁵⁸. The legal framework and the objective it is designed to serve are complicated not only by differences between the idealized theoretical arguments and reality but also by the peculiarities possessed by the medical market. The economic rationale of the law dictates an optimal level of compensation exactly equal to the loss suffered by the patient, neither more nor less. Further, given the inherent riskiness of medical treatments, a negligence rule of liability scores over strict liability since it avoids over deterrence of doctors, by not holding the doctor liable for every injury in theory. But, the real world is characterized by the lack of perfect information on the part of courts and individuals regarding the optimal level of care. This creates more problems than the legal framework attempts to address. In the absence of correct signals to the agents involved, the system becomes riddled with the problems of defensive medicine and rising health care costs.

Also, the implementation of laws possesses deficiencies that are attested by our analysis of medical cases under the purview of the NCDRC¹⁵⁹. We find evidence of excessively long period of judicial process while in principle the Consumer Protection Act is aimed at speedy redressal of consumer grievances. The possibility of the reversal of the decisions of the lower courts by the apex body contributes to this judgment delay. My findings suggest that NCDRC over-rules the decision of the state commission and district forum in approximately 18 and 39 percent of the cases. The low success rate of plaintiffs, at 24 percent, hints towards allowing for prior scrutiny of complaints and inclusion of a medical specialist on jury which may make jury decisions more credible and lead to higher success rates. It is crucial that the loopholes in the system must be plugged to ensure greater efficiency. Further, according to the findings of questionnaires filled by doctors and patients it was observed that awareness regarding current laws was very minimalist. A need to change the laws with regard to medical ethics was felt across board.

The economic rationale for the law is also rendered inefficient by the presence of medical insurance. Though medical insurance serves the purpose of spreading risks, it also negates the deterrence effect of tort law on doctors. But, looking at the current situation where most of the doctors and young patient have not availed for insurance services, there is a definite need to establish a stronger market of insurance in the medical field.

The dissertation also explores possible avenues to enhance economic efficiency of the system. Decoupling of liability, reversing the burden of proof and contracting over medical malpractice liability are some channels that may improve the system but do not

¹⁵⁸ *Indian Medical Association v. V.P. Shantha and Ors* (1995) 6 SCC 651.

¹⁵⁹ National Consumer Dispute Redressal Commission.

definitely guarantee success. Each of these has equally strong pros and cons that need to be weighed against each other. But nevertheless, the weakness in the system, as a result of absence of effective monitoring of health care facilities or health care practitioners is one thing that can be corrected definitely. Accreditation of health care institutions in the ambit of the Clinical Establishments Bill across the board is an effective step in the right direction.

Another thing that deserves to be mentioned is that, the incidence of medical negligence is quite distinct from the filing of claims. A defining feature of the medical liability system is that most events of medical negligence do not result in a legal claim, and most claims of malpractice are not tied to any act of negligence. Possible reasons for this could be that the injury was too minor to warrant a lawsuit, or that lawyers are only willing to take on claims for “attractive” clients. Alternatively, some people are simply not litigious in nature, or do not wish to damage a long-standing relationship with their doctor, especially. Yet another explanation is that patients simply do not recognize that they have suffered an injury due to negligence.

All the concerned authorities whether it is the Hospital, Government, Medical Council or any other institution working towards betterment of healthcare facilities should work together and take steps to provide:

- Quality healthcare
- Adequate healthcare
- Accessibility to basic healthcare.

The Indian government must display its’ commitment towards improving health care facilities by passing the National Health Bill, The Universal Health Care Plan and passing the Indian Medical Council amendment Ordinance into an Act, which I deem to be important means of enhancing efficiency in the system which will help curb medical negligence. As quoted by Mahatma Gandhi *“It is Health that is a persons real wealth and not pieces of gold and silver”*

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PRIMARY RESEARCH SOURCE

- Doctors practicing at Maharaja Agrasein Hospital, New Delhi.
- Patients from all over India.

ANNEXURE – I

I/1: THE INDIAN MEDICAL COUNCIL (AMENDMENT) ORDINANCE, 2013

An Ordinance further to amend the Indian Medical Council Act, 1956.

BE it enacted by Parliament in the Sixty-fourth Year of the Republic of India as follows:

(1) This Act may be called the Indian Medical Council (Amendment) Act, 2013.

(2) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

2. In the Indian Medical Council Act, 1956 (hereinafter referred to as the principal Act), for the long title, the following shall be substituted, namely:—

“An Act to provide for the reconstitution of the Medical Council of India and for the determination, coordination, maintenance, and regulation of standards of medical education, to regulate the practice of medicine, ensure adequate availability of doctors in all States and maintain the Indian Medical Register and for matters connected therewith or incidental thereto.”.

2 3. In section 3 of the principal Act,—

(a) in sub-section(1) (i) after clause (a), the following clause shall be inserted, namely:—

(aa) one member, to represent the Union territories by rotation, to be nominated by the Central Government;”;

(ii) in clause (b), the following proviso shall be inserted, namely:—

Provided further that a Health University with less than ten medical colleges affiliated to it, shall also be eligible to elect one representative to represent such medical colleges:

Provided also that such number of representatives shall be reviewed by the Central Government after every five years

(b) in sub-section (2), the following proviso shall be inserted, namely:—

“Provided that no person shall hold office as the President or the Vice-President for more than two terms.”;

(c) after sub-section (3), the following sub-section shall be inserted, namely:— 20 “

(4) The term of the Council shall be for a period of four years from the date of notification issued under sub-section (1).”.

4. After section 3A of the principal Act, the following section shall be inserted,

“3AA. The Central Government shall, as soon as possible, after the commencement of the Indian Medical Council (Amendment) Act, 2013, by notification in the Official Gazette, reconstitute the Council:

Provided that the Board of Governors constituted under sub-section (4) of section 3A shall continue to exercise the powers and perform the functions of the Council till the new Council is reconstituted.”.

6. In section 7 of the principal Act,—

(a) in sub-section (1), for the words “five years”, the words “four years” shall be

(b) for sub-section (2), the following sub-section shall be substituted, namely:—

“(2) Subject to the provisions of the Act, a member, whether nominated or elected, shall hold office for a term of four years.”;

“Provided that where there is a Health University in a State, that University shall elect, in such manner as may be provided by the rules made by the Central Government, one representative for every ten medical colleges affiliated to it to represent such medical colleges:

Provided further that a Health University with less than ten medical colleges affiliated to it, shall also be eligible to elect one representative to represent such medical colleges:

(c) in sub-section (6), for the words “five years”, the words “four years” shall be substituted.

7. After section 9 of the principal Act, the following section shall be inserted, namely:—

“9A. (1) The Council shall, subject to the provisions of the Act and rules made thereunder, take measures to determine, coordinate and maintain the standards of medical education and practice in medicine, and ensure adequate availability of doctors to all States.

(2) Without prejudice to the generality of the foregoing provisions, the measures referred to in sub-section (1), may, inter alia, provide for all or any of the following matters, namely: —

(a) lay down the standards of professional ethics in the practice of medicine;

(b) grant or withdraw permission for establishment of medical college and course of study in medical education and ensure compliance of its terms and conditions for such permission;

- (c) maintain the Indian Medical Register;
- (d) render advice to the Central Government or the State Government on matters relating to the medical education and practice in medicine;
- (e) facilitate medical education in the institutions situated outside the country;
- (f) undertake and recommend to the Central Government or the State Government such measures as may be necessary to regulate medical education in or outside the country;
- (g) organise seminars, symposiums and workshops in order to promote continuous medical education and practice in medicine; and
- (h) perform such other functions as may be provided by the rules made by the Central Government.”.

8. In section 13 of the principal Act, —

- (a) in sub-section (2), for the words “a citizen of India”, the words “a citizen of India or an overseas citizen of India” shall be substituted;
- (b) in sub-section (3), for the words “a citizen of India”, the words “a citizen of India or an overseas citizen of India” shall be substituted;
- (c) in sub-section(4A),for the words “a citizen of India” the words “a citizen of India or an overseas citizen of India” shall be substituted;
- (d) after sub-section (5), the following Explanation shall be inserted, namely:—

Explanation.— For the purposes of this section, the expression “overseas citizen of India” shall have the meaning assigned to it in clause (ee) of sub- section (1) of section 2 of the Citizenship Act, 1955.

9. In section 14 of the principal Act, in the proviso to sub-section (1), the words “for the time being for the purposes of teaching, research or charitable work” shall be omitted.

“23A. The enrolment of a person as a medical practitioner on the Indian Medical Register or the State Medical Register shall be valid for a period of ten years from the date of such enrolment:

Provided that a medical practitioner who has completed ten years of enrolment, may apply to the Council for renewal of his enrolment immediately after the 15 commencement of the Indian Medical Council (Amendment) Act, 2013, within a period of twelve months in such form, in such manner and with such fees, as may be prescribed:

Provided further that the Council may extend the period of twelve months, if applicant shows that he was prevented by sufficient cause from preferring the application within time.” 20

12. After section 30 of the principal Act, the following section shall be inserted,

“30A. (1) The President, Vice-President or any member of the Council may, by notice in writing under his hand addressed to the Central Government, resign from office: 25

Provided that the President, Vice-President or any member of the Council shall, unless he is permitted by the Central Government to relinquish his office sooner, continue to hold office until the expiry of three months from the date of receipt of such notice or until a person duly appointed as his successor enters upon his office or until the expiry of his term of office, whichever is the earliest. 30

(2) Notwithstanding anything contained in sub-section (1), the Central Government may remove from office the President, Vice-President, or any member of the Council, who—

(a) has been adjudged an insolvent; or

(b) has become physically or mentally incapable of acting as such President, Vice-President, or other member; or

(c) is of unsound mind and stands so declared by a competent court; or

(d) has been convicted of an offence which, in the opinion of the Central Government, involves moral turpitude; or

(e) has acquired such financial or other interest as is likely to affect 40 prejudicially the exercise of his functions as such President, Vice-President, or other member; or

(f) in the opinion of the Central Government, has so abused his position as to render his continuance in office detrimental to the overall public interest; or

(g) has been guilty of proved mis-behaviour.

(3) No person shall be removed from his office on the grounds specified in clause (e) or clause (f) or clause (g) of sub-section (2) unless he has been given a reasonable opportunity of being heard in the matter.”

13. In section 32 of the principal Act, for sub-section (2), the following sub-section shall be substituted, namely: —

“(2) In particular, and without prejudice to the foregoing power, such rules may provide for all or any of the following matters, namely: —

(a) the manner of electing the representative of the medical colleges under the first proviso to clause (b) of sub-section (1) of section 3;

(b) the mode of election of the Council under sub-section (1) of section 4; (c) the other functions of the Council under clause (h) of sub-section (2) of section 9A;

(d) the conditions relating to the payment of a fee for filing an appeal before the Central Government under sub-section (2) of section 24;

(e) any other matter which is required to be, or may be, provided by rules or in respect of which provision is to be made by rules.”

15. After section 33 of the principal Act, the following sections shall be inserted, namely: —

33A. (1) Without prejudice to the foregoing provisions of this Act, the Authority shall, in the discharge of its functions and duties under this Act, be bound by such directions on questions of policy as the Central Government may give in writing to it from time to time:

Provided that the Council shall, as far as practicable, be given opportunity to express its views before any direction is given under this sub-section.

(2) The decision of the Central Government whether a question is one of policy or not shall be final.

33B. (1) Where the Central Government considers it expedient so to do, it may, by order in writing, direct the Council to make any regulations or to amend or revoke any regulations already made within such period as it may specify in this behalf.

(2) If the Council fails or neglects to comply with such order within the specified period, the Central Government may make the regulations or amend or revoke the regulations made by the Council, as the case may be, either in the form specified in the order or with such modifications thereof as the Central Government thinks fit.

33C. Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule, regulation or both Houses agree that the rule and regulation should not be made, the rule and regulation shall, thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.

I/2: THE NATIONAL HEALTH BILL, 2009

MoHFW, GoI Working Draft: Version January '09 (PENDING)

A Bill to provide for protection and fulfillment of rights in relation to health and well-being, health equity and justice, including those related to all the underlying determinants of health as well as health care; and for achieving the goal of health for all; and for matters connected therewith or incidental thereto.

Whereas every human being is entitled to enjoyment of the highest attainable standard of health and well-being, conducive to living a life in dignity;

And whereas health is a fundamental human right indispensable for, and intricately linked with, the exercise of all other human rights;

And whereas right to health is an inclusive right extending not only to timely and appropriate health care but also to the underlying socio-economic, cultural and environmental determinants of health;

And whereas the persisting inequities, denials and violations in the matter of health in the country are cause for concern to all;

And whereas there is hence the need to mandate, enable, authorize, guide, and where necessary, limit, health policies and actions by all the relevant stake-holders, including the communities/ civil society, within a rights based approach, so as to lead to actualization of right to health for all;

And whereas there is also the need to set a broad legal framework for providing essential public health services and functions, including powers to respond to public health emergencies, principally through the State and local public health agencies, in collaboration with others in the public health system, including through the co- operation and formal collaborations between the Center and State;

And whereas there is need to have an overarching legal framework and a common set of standards, norms and values to facilitate the Governments stewardship of private health sector as a partner as well as for more effective operation of other existing and future public health related laws enacted at the Central and State levels and to unite them under;

And whereas the Constitution of India places obligations on the Government to ensure protection and fulfilment of right to health for all, without any discrimination, as a Fundamental Right under Articles 14, 15 and 21 (rights to life, equality and non-discrimination), along with some relevant fundamental rights under Article 17 (abolition of untouchability); Article 23 (prohibition of traffic in human beings and forced labour); and Article 24 (prohibition of employment of children in factories, etc.); and also urges the State, under the Directive Principles of State Policy, to eliminate inequalities in status, facilities and opportunities (Article 38); to strive to provide to everyone certain vital public health conditions such as health of workers, men, women and children (Article 39); right to work, education and public assistance in certain cases (Article 41); just and

humane conditions of work and maternity relief (Article 42); raised level of nutrition and the standard of living and improvement of public health (Article 47); and protect and improve environment (Article 48A); and identifies certain concomitant Fundamental Duties like obligating every citizen to denounce practices derogatory to the dignity of women; and to protect and improve the natural environment (Article 51);¹⁶⁰

And whereas the Union of India has signed various international treaties, agreements and declarations specifically undertaking to provide right to health including but not limited to: Universal Declaration of Human Rights (UDHR): Article 25 (1); International Covenant on Economic, Social and Cultural Rights (ICESCR): Article 12; Convention on the Rights of the Child (CRC): Article 24; Convention on the Elimination of All Forms of Discrimination against Women (CEDAW): Article 12; UN Convention on Rights of persons with disabilities (UNCRPD): Article 25; Declaration of Alma Ata (1978); Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care (1991); Declaration on the Elimination of Violence against Women (1993), Programme for Action of the International Conference on Population and Development, Cairo (1994); Platform of Action for the Fourth World Women's Conference, Beijing (1995) and the Millennium Development Goals (2000); Declaration of Commitment on HIV/AIDS, Global Crisis-Global Action (2001), WTO Doha Declaration on TRIPS Agreement & Public Health (2001), International Health Regulations, World Health Assembly (2005); WHO Framework Convention on Tobacco Control (WHO FCTC 2005), and several other declarations and conventions on underlying determinants of health;

And whereas it is necessary to give effect to these international treaties and declarations under Article 253 of the Constitution of India;

And whereas it is within the constitutional powers of Government of India under Item 14 in List I (Union List) in Schedule VII of the Indian Constitution, to legislate on matters that require to be legislated upon for implementing its international obligations under the international treaties and declarations, that are the principal subject matter of this Act;

And whereas the Hon'ble Supreme Court of India has, in several judgments, exhorted the Government of India to accord legal recognition to the health rights as vital component of the fundamental right to life; and the National Human Rights Commission has also directed the Government of India to enact a health law;

And whereas the Union of India is also mandated to legislate on: population stabilization and family planning; mental health; drugs; food safety; labour safety and welfare, including maternity benefits; social security and social insurance; employment; education; legal and medical professions; prevention and control of communicable diseases; registration of births and deaths and other vital statistics for health; port quarantine, seamen's and marine hospitals; and all the other health related social and economic planning

¹⁶⁰ Constitution of India

And whereas the Union of India has already enacted several laws in recent times, including, the Environment Protection Act, 1986; Mental Health Act, 1987; Constitution (73th and 74th) Amendment) Act, 1992, setting up Panchayats and urban local bodies, Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995; Constitution (86th Amendment Act), 2002 establishing fundamental right to education; Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003; Protection of Women from Domestic Violence Act, 2005; National Rural Employments Guarantee Act, 2005; Disaster Management Act., 2005; Food Safety and Standards Act, 2006, which have created favourable conditions for the achievement of goal of health for all.

CHAPTER II Obligations of Government in relation to Health:

- General obligations towards progressive realization of health and well being
- Core obligations towards determinants of health
- Obligations to provide access to quality health care services
- Specific public health obligations: Obligations of Central Government , Obligations of State Governments
- Obligations to respect, protect and fulfil

CHAPTER III Collective and Individual Rights in relation to Health:

- Right to health
- Right to access, use and enjoy
- Right against discrimination
- Right to dignity
- Right of participation, information
- Right to justice
- Rights specifically related to health care (Users Rights): Survival, integrity and security
- Right to seek health care and treatment
- Right to receive, use and enjoy health care and treatment
- Right to emergency treatment and care
- Right to reproductive and sexual health care
- Right to quality of care
- Right to rational health care
- Right to choice
- Right to be treated by a named health care provider
- Referral rights
- Right to continuity of care
- Right to fair selection
- Right to benefits of scientific progress and technology assessment
- Right to terminal care
- Right to information
- Right to medical records and data

- Right to autonomy/ self determination and prior voluntary informed consent
- Right to confidentiality, information disclosure, privacy
- Rights towards the application of users' rights
- Duties of users
- Rights of health care providers vis-à-vis users

CHAPTER IV Implementation & Monitoring Mechanism:

- National Public Health Board: constitution and composition; functions
- State Public Health Board constitution and composition; functions
- Decentralization and convergence in District, Block and Village level planning and implementation authorities
- Health Information Systems
- Government Monitoring
- Community based monitoring framework

CHAPTER V Redressal Mechanism for Health Rights:

- Disputes Resolution through Public Dialogues and Public Hearings (*Swasthya Jan Sunwais*); issues, outcome and follow-up
- Grievance redressal through In-house Complaints Forums at the institutional level
- Cause of action for complaints related to health, before designated district courts
- Remedies
- Orders of designated district courts
- Reasoned order
- Costs
- Binding effect
- Consequences of Breach of designated court's Temporary Orders
- Appeals
- Timeframe for designation of courts
- Dispensing of lawyers appearance and waiver of court fee
- Information on website
- Enforcement of monetary orders:

CHAPTER VI Residuary offences, penalties & immunities

- Criminal penalties
- Immunities

ANNEXURE - II

II/1: SAMPLE QUESTIONNAIRE FOR DOCTORS

Study on Medical Malpractice Law as part of Dissertation of Aditya Singhal for B.A.LL.B



MEDICAL LAWS

A Survey about awareness of Medical Malpractice Law in India

1. How long have you been practicing Medicine ?
2. What is the field of your practice ?
3. Did you ever have any contact with a legal institution in relation to your practice as a doctor ?
4. Are you Aware about the framework regarding medico legal (MLC) cases ? *Check all that apply.* YES NO MOSTLY AWARE
5. Do you take special precautions during handling medico legal cases ? *Check all that apply.* YES NO NORMAL PRECAUTION
6. Are you in favour of an ethical practice ? *Check all that apply.* YES NO AS THE SITUATION DEMAND / CAN'T SAY
7. Are you in favour of ignoring ethics in order to save/help the patient ? *Check all that apply.* YES NO AS THE SITUATION DEMAND / CAN'T SAY
8. Are you practising as per the straightjacket Ethics as provided by Indian Medical Council Act ? *Check all that apply.* YES NO AS THE SITUATION DEMAND / CAN'T SAY
9. According to you is dichotomy useful in medical practice ? Dichotomy of ethics on one hand and saving lives on the other *Check all that apply.* YES NO AS THE SITUATION DEMAND / CAN'T SAY

10. **Are you aware of Medical Council of India's Code of Ethics ?** *Check all that apply.* YES NO MOSTLY
11. **Are you aware about other Laws that affect the Medical Practice ?** Please tick the ones that are applicable on you *Check all that apply.* Fundamental Rights under the Constitution of India Directive Principles of State Policy under the Constitution of India Indian Penal Code Consumer Protection Act
12. **Do you have a ethical committee in your institution ?** *Check all that apply.* YES NO
13. **Are you in favour of a modification in Medical Ethics ?** *Check all that apply.* YES NO Other:
14. **Do you know what makes a practitioner negligent ?** In accordance with laws and medical ethics *Check all that apply.* YES NO MOSTLY
15. **Are you taking precautions to prevent charge of negligence ?** *Check all that apply.* YES NO MOSTLY
16. **Do you think these precautions become a hindrance to your practice ?** *Check all that apply.* YES NO SOMETIMES
17. **Are you taking proper consent before any examination or procedure , and is it an informed consent ?** *Check all that apply.* YES NO PATIENT GIVES CONSENT TO EVERYTHING AS LONG AS IT DOES NOT INVOLVE HUGE MONEY
18. **Do you think consent and documentation can prevent a charge of negligence ?** *Check all that apply.* YES NO Other:
19. **Have you Insured yourself against medical liabilities ?** *Check all that apply.* YES NO NOT MANY PROVIDERS
20. **The Inclusion of Medical practice in Consumer Protection Act has made the practice defensive ?** Considering the Defensive practice is not good for patients *Check all that apply.* YES NO Other:
21. **Do you think Continuing Medical Education in relation to MLC and medical ethics in regular interval is necessary ?** *Check all that apply.* YES NO DONT KNOW
22. **According to you what could help in eliminating medical malpractice in India ?** Stringent Laws , Spreading Awareness , Implementation of already established Laws , More autonomy in practice
23. **Any other Suggestions ?**

II/2: SAMPLE QUESTIONNAIRE FOR PATIENTS

Study on Medical Malpractice Law as part of Dissertation of Aditya Singhal for B.A.LL.B

Patient Questionnaire



MEDICAL LAWS

A Survey about awareness of Medical Malpractice Law in India

1. **What is your Age ?**
2. **Do you have a Health Insurance ?**
3. **Have you ever been admitted to a hospital for your treatment ?** Apart from regular medical check up
4. **Are you aware about the framework and special precautions regarding medico legal (MLC) i.e cases where legal system would be involved?** *Check all that apply.* YES NO MOSTLY AWARE
5. **Are you in favour of ignoring medical ethics in order to save/help the patient ?** *Check all that apply.* YES NO AS THE SITUATION DEMAND / CAN'T SAY
6. **Do you prefer ethics being followed or Saving Lives even if it involves unethical practice ?** *Check all that apply.* Ethics Saving Lives AS THE SITUATION DEMAND / CAN'T SAY
7. **Will you force your doctor to adhere to ethical practice at the time of treatment ?** *Check all that apply.* YES NO AS THE SITUATION DEMAND / CAN'T SAY
8. **Does ethical practice mean charging fair money from patients or following proper procedures ?** *Check all that apply.* Fair Money Procedure BOTH
9. **Are you aware about Informed Consent ?** *Check all that apply.* YES NO

10. **Did your doctor take an Informed Consent from you or your family ?**
Informed Consent is taking permission after explaining the pros and cons of a procedure before doing it *Check all that apply.* YES NO Consent was taken but we did not understand it completely as it was technical
11. **Are you aware about the Medical Council of India's Code of Ethics that a doctor needs to follow ?** *Check all that apply.* YES NO MOSTLY
12. **Are you aware that there is a Ethical committee in every hospital ?** *Check all that apply.* YES NO
13. **Will you complain against your doctor for unethical practice in middle of your treatment or wait till something goes wrong ?** *Check all that apply.*
YES NO Will Wait till something goes wrong Other:
14. **Do you know what makes a medical practitioner negligent ?** In accordance with laws and medical ethics *Check all that apply.* YES NO MOSTLY
15. **Will you give your consent to everything that seems useful till the time it does not involve huge money ?** *Check all that apply.* YES NO Till the time it is covered by my Insurance
16. **Do you think consent and documentation are necessary or the doctor knows the best ?** *Check all that apply.* YES NO Other:
17. **Are you aware that Medical practice is covered under the Consumer Protection Act ?** *Check all that apply.* YES NO Other:
18. **IF Answer to your previous question is YES , Are you aware about the procedure to file a complaint in Consumer Protection Forum ?** *Check all that apply.* YES NO Other:
19. **According to you what could help in eliminating medical malpractice in India ?** Stringent Laws , Spreading Awareness , Implementation of already established Laws , More autonomy in practice
20. **Any other Suggestions ?**