A Medicolegal Aspect Of Breach Of Duty To Take Care Among Medical Practitioners -Based On A Cross Sectional Analytical Survey On The Level Of Awareness Regarding Medical Negligence Among Spinal Surgeons In Kerala.

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DECLARATION

I hereby declare that the report entitled "**A Medicolegal Aspect Of Breach Of Duty To Take Care Among Medical Practitioners --Based On A Cross Sectional Analytical Survey On The Level Of Awareness Regarding Medical Negligence Among Spinal Surgeons In Kerala**." submitted to the National University of Advanced Legal Studies, Kalamassery, Cochin for the partial fulfillment of the requirement of Post Graduate Diploma in Medical Law and Ethics is a bonafide work done by me and that to best of my knowledge no part of this project has been submitted earlier or elsewhere for any similar purpose.

Dr. VINU.V.GOPAL

CERTIFICATE

This is to certify that this project work titled **"A Medicolegal Aspect Of Breach Of Duty To Take Care Among Medical Practitioners --Based On A Cross Sectional Analytical Survey On The Level Of Awareness Regarding Medical Negligence Among Spinal Surgeons In Kerala."** submitted by Dr. VINU. V. GOPAL, for the award of the degree of Post Graduate Diploma in Medical Law and Ethics is to the best of my knowledge, a bona fide record of research work carried out at the National University of Advanced Legal Studies under my supervision. This project, or any part thereof, has not been submitted elsewhere for any degree

Place: Kochi

Date: 29-01-2022

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INTRODUCTION

1.1 BACK GROUND OF THE PROBLEM

Doctor patient relationship has deteriorated very much nowadays that the age old sanctity of doctors being considered healers or saviours has ended. It is now considered that doctors are there because the patient needs them and the livelihood of doctors depends on patients .This has become a great concern to the medical profession. Medical professionals are nowadays greatly frustrated as the services rendered by them are covered under the Consumer Protection Act.

The reason behind all these are probably the small percentage of failures despite due care and caution. Patient consider these as lack of adequate care and negligence on the part of doctors leading to a plethora of cases against a hospital and doctor taking a toll of his time and hard earned reputation.

Now a days consumer case can be filed easily in consumer courts and this usually encourage speculative complaints intended to defame a doctor or hospital. The court has recognized this fact and made ruling against criminal prosecution of doctors unless there is gross negligence prima facie.

The practice of spinal neurosurgery involves a high inherent risk of litigation due to the fact that it often involves instrumentation in close proximity to critical neurovascular structures and lack of ability of regeneration of spinal cord and nerve roots once injured leading to permanent disability

further adding to burden and distress among patients. There is evidence that neurosurgery, and spinal neurosurgery in particular, is among the highest-risk specialties with regard to risk of malpractice claims.

The successful practice of spinal neurosurgery is founded not only on the principle of technical excellence, knowledge, and clinical acumen, but also on commitment of surgeon to high ethical standards. Medical ethics is a foundational principle in medicine and rest on the principles of Hippocratic Oath to "First do no harm."

In the context of spine surgery, ethical behavior involves respecting the wishes and dignity of patients as well as surgeons, setting appropriate limitations on their scope of practice and prompt disclosure of errors or complications to patients and their families. The prompt disclosure of errors or complications to patients and their relatives is now universally advised by patient safety organizations and physician groups. Since then, there has been increased attention on the need for transparency between providers and patients regarding medical errors. There is sufficient evidence that lack of transparency about errors and complications increases the risk of litigation.

Globally in an analysis of 40,916 physicians from 1991 to 2005, 7.4% of physicians received a malpractice claim. Of the 25 medical and surgical specialties listed, neurosurgeons had the highest percentage of practitioners receiving a claim each year at 19.1%[1]. Historically, neurosurgeons have faced

[1] Jena AB, Seabury S, Lakdawalla D, Chandra A: Malpractice risk according to physician specialty. 365 NEJM 629–636 (2011)

high rates of malpractice lawsuits; Jena et al. noted that not only nearly 20% of neurosurgeons faced at least one malpractice claim annually between 1991 and 2005, but also median annual payments to plaintiffs were the highest in neurosurgery at more than $200,000 per year.

In this scenario, the main aim is to discuss the concept of ethical aspect of duty to take care by spinal surgeons, the constitutional perspective on the right to quality medical care, legal consequence following medical negligence suits and the present trends of malpractice claims related to spine surgery. The triad of clinical competence, effective communication skills and requisite knowledge of legal liabilities, on the part of the treating physician/surgeon, has been recognized as the key to reduce the number of litigations against medical practitioners.

Medical curriculum of India emphasizes training mainly in clinical competence but is largely silent especially with aspects of communication skills and legal liabilities. These deficiency have been brought out in “Vision 2015” document of MCI and they reiterated the need to include training in legal awarenss to the graduating doctors. A claim that “I did not know,” does not hold any respect in a court of law it is mandatory that doctors become familiar with legal terminology and duties, so that they are not caught entangled in the difficult web of legal proceedings.

Thus through this project, we will be aiming to touch upon what are the mitigation methods that can be adopted for preventing filing of such malpractise claims against medical professionals especially spinal surgeons.

1.2 ORIGIN OF MEDICAL NEGLIGENCE: IN ANCIENT INDIA

The concept of medicine and medical practices was prevalent in ancient India with a well-developed system of medicine called science of Ayurveda[2]. The Holy Ramayana gives the instances illustrating the advancement of surgical skill and medical treatment in those days. Dhanvantri has been regarded as an expounder deity of Ayurveda. Lord Dhanvantri appeared as an authority of Ayurveda possessing the stick (Danda) and water pot (Kamandal)[3]. One of the classical Vedic documents (comprising Rigveda, Yajurveda, Samaveda and Adharvaveda), Rigveda Samhita is the only primary collection, the other two being mainly derived from it. It contains a fairly elaborate account of the condition of medicine that prevailed in those days (about 700 B.C.)[3]. It provided the essentials for medical practice like administration of herbal drugs, surgical operations, cure of skin ailment by sunshine, hydotherapy, etc… According to Rigveda, Rudra was the best of physicians (Bhisktamobhisajam) and Indra as protector and guarantor of life[4]. The holy book referred above contains prayers to Indra for good health and protection from illness. Soma was the God who "healed whoever was sick."[4]

Notable works on medical science in ancient India are Charak Samhita, Sushruta Samhita and Vagbhata. [5] Sushruta Samhita, a work comprehending the surgical tradition of Indian medicine, ascribed to the Sage Susruta, the original of which have been composed around 600 B.C. (G.N.

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2 Charaka Samhita (3.8).

3 Charaka Samhita (4.6).

4 Rigveda

5 Bhishagratna, Kunja Lal; Sushruta Samhita, (1-2) ed., Culcutta (1907).

Mukhopadhyaya)[5]. It was one of the four treatises regarded as the source book for all the later surgical works in India[5].Later Manusmriti laid down comprehensive measures for the protection of the layman from irresponsible Physicians.[6] The penalties provided by the king in the cases of negligence of the physicians varied as per the severity of the lapse on the part of the physician and taking into account all other accompanying circumstances[6].

In both the Yajnavalkya Smriti and the Vihsnu Smriti, fines were prescribed for the improper treatment by the physicians[6]. The penalties imposed depended on whether a human or non-human suffered, class of the victim (higher the social class, higher the penalty). But Manu was never concerned with the class of the victim in inflicting punishment[6]. Sushrutsamhita states that the physician should obtain the permission of the king before commencing the treatment[6].

The practical training was to be carried on various objects for the purpose of learning so that the scholar did not experiment on human bodies. According to Charak Samhita, physician must have mastery over scriptures, experience, purity and cleverness[7]. After undergoing a specified period of training and studying the science of medicine and its practical application, a scholar would become the physician; but before starting his practice he was required to get permission of the king.[8] In ancient Indian Society, there were certain principles of law, which regulated this profession by delimiting the

6 Manusmriti, IX.284

7 Sushruta Samhita 1-9

8 Charaka Samhita (3.8)

Please see reference footnote 5 on page 4

freedom of practice and imposing certain restrictions as to qualifications, on scholars devoted to the science of medicine, teachers of medicine and physicians.[9,10]

The Arthasastra also provided a code of ethics for physicians. If a physician while treating a person found that the disease is dangerous to the life, the matter should be informed to the authorities.[9,10] If the person died, the physician had to pay a lowest fine; if death occurred due to any mistake on the part of the physician, and a medium rate fine will be prescribed by the King[10] If he died due to the negligence of the physician, the highest punishment would be inflicted. It was considered that the person treating a patient whether human or non human, was bestowed with a divine duty of care towards the patient. Apart from that, duties of physician were pre- fixed by the ancient documents.[9-10.]

a. Duties of Physicians

Apart from the qualifications of physicians, ancient literature speaks of professional ethics and physicians duties and their liabilities for causing harm to the patients.[11] Thus, the foremost duty of the Physician was to diagnose the disease very carefully and only after ascertaining the disease he could start the treatment with his ability and good sense[11].Physician (Vaidyas) was not free to treat any person. There were restrictions on them to treat hunters, fowlers, out

9 Charaka Samhita (3-8).
10 Id.
11 Supra note.4.

castes or sinners.[12] Duties of physician were again confirmed through the relevant ancient documents[11-12]

b. Concept of Punishment

Concept of punishment was specified in several literatures. The word "Mithya" has several meanings. It was applied according to the various situations. It means 'false', 'wrong' improper, error, illusive or incorrect. Charak Samhita used this word in the sense of wrong treatment.[13] Sushruta Samhita uses the word "Mithyopachara" in the sense of improper conduct. It is stated that the physicians who act improperly are liable to punishment.[14] As Yajnavalkya Smriti says, physician who acts improperly should, pay the first fine in the case of animals, the second highest in the case of man and highest in the case of kingsmen[15]. Manusmriti did not discriminate persons in this respect. It prescribed some penalty on the physician for improper treatment irrespective of the varna or category of victim[15]. Sushruta Samhita stated that "If the death of patient under treatment is due to carelessness, the physician shall be punished with severe punishment, growth of disease due to negligence or indifference of a physician should be regarded as assault or violence"[16]. These are the clear specifications in ancient literatures which relate to the specific enforcement of medical practice.

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12 Sushruta Samhita (1-2).

13 Supra note .4. Bhishgratna p. 370 314.

14 Manav Dharmashashtra, 9 284.

15 Shastri V.L, Yajnavalkyasmrithi , 4th ed., Bombay (1936). Yajnavalkyasmrithi (2- 242) reads:-Bhisanmithyacharan dandyastiryaksu prathamain damam, manuse madhyamam rajupurusesutamain daman (2-242)

16 Supra note. 7

c. Concept of Fine as Specific Form of Punishment

Ancient Indian law relating to practice of medicine furnishes examples of penalties for injuries due to negligent treatment. Pecuniary penalty was based on the social status of victim, i.e., whether the victim of maltreatment was animal (horse, cow, elephant and so forth) or a person of the middle class or king's retinue. Physician's duty to care varied with the social status of the person under treatment, but degree of pecuniary penalty was not dependent on the degree of guilt.[17] It was an absolute discretion of the judge to impose penalty, taking into account all factors.

From the above brief historical analysis it can be concluded that the legal order in ancient India was clearly supportive of the rights of patients against the negligence of physicians and improper medical treatments.

Now let us refer to the concept of medical negligence as it evolved under the common law.

1.3 ORIGIN OF MEDICAL NEGLIGENCE: IN ANCIENT EUROPE

Origin of modern medicine was in ancient Greece. Greeks developed specialised categories of doctors by the fifth century B.C and had established medical schools[18].

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[17] Code of Hammurabi (perhaps the oldest code) prescribed the law relating to the practice of surgery, it fixed the fee and penalties for improper treatment(These are the abstracts from J.M.M. Datta & H.K. Sahray., "Law relating to surgeons in ancient world". Your health, vol.17 (1968) pp. 15, 20

[18] John Heavly, Medical Negligence: Common Law Perspectives, Sweet $ Maxwell, London, 1999.p.112

Though this period marked a move towards a more secular approach to cures, it also laid the basis for the divinity of healing.[18] In the myth of Aesculapius, the Greeks invented different methods of treatment.[19] According to legend, Aesculapius was the offspring of a God (Apollo, God of truth) and a mortal.[20] Throughout Greece, temples and statues were erected in Aesculapiu's honour, to which healers would come for inspiration and the ill for a cure[21]. Like so many other myths cultivated by man, Aesculapius unwittingly performed a valuable social function. Through its "identification with a deity," this myth equipped the early physicians with the status to treat and to innovate. The writings of Hippocrates typified an emerging culture of paternalism and secrecy[21]. The notion of Hippocartic oath highlighted the dignity and decorum of medical profession[21].

The codification of medical ethics was crucial to its eventual professionalisation. Later the medical profession was institutionalized. The various codes promulgated throughout the centuries consistently emphasized the need of university practitioners to maintain a honorable facade to counter public apprehension of the degeneracy and inconsistency of health care practitioners.[22] The process towards professionalisation of health care in Greece suffered irreversible set back after the Roman conquest of the Mediterranean and later the education and practice of medicine came under the

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19 K P S Mahalwar, Medical Negligence and the Concept, Liabilities and Remedies 124 (Deeep & Deep Pub., 1991).

20 Id

21 Mondeville, Law and Medical Negligence, Yale University Press, (1993), pp. 145, 153.

22 See Webb- people, Medical profession, Scorer & Wing Publication, (1979), pp.13-124

influence of the Christian church.[23] Priests were urged to visit the sick and to cure, encouraged by the example of Jesus Christ's missionary healing work[23]. The early medieval monasteries made no obvious technical contribution to medicine, though they were responsible for humanizing and Christianising it as a healing and compassionate art.[23]

Later institutionalization of medicine began with the establishment of universities throughout the twelfth and thirteenth centuries, which encouraged the codification of past customs. In Europe, the university was central to the eventual professionalization of medicine and by the end of the medieval period, a process that was endorsed by the papacy and complemented by advances in printing.[24] Stressing the dangers caused by the quacks and charlatans, the university doctors petitioned the state to delegate control over medical licenses and practice. In 1518, Thomas Linacre successfully obtained from Henry VIII letter of patent for a body of regular physicians which in 1551 became the Royal College of Physicians of London.[25]

These laws, under which the Bishop of London retained ultimate jurisdiction, decided who could practice in the city and within a seven-mile radius thereof, forbidding unlicensed or domestic practice.[25]

Apart from that, the negative repercussion of scientific rationalization of health care are arguably and most keenly felt in the exclusion of the patient

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23 Id.

24 Supra note. 19.

25 Marcia Mobila Boumil & Cliffford E. Elias, The Law of Medical Liability in a Nutshell, West Publishing Co, London, 1995, p.115

from the discourse of health care.[25] The bid for public and State endorsement of the exclusive right of university doctors to practice was mirrored in Britan, though without the structured rivalry that existed in America.

Largely as a result of the British Medical Association's persistent campaigning the Medical Act of 1858 finally granted General Medical Council the power to control medical practice in Britain, limiting it to those enrolled on the Medical Register. Many developed nations such as Britain shifted from fee-for service to "implicit rationing" through centralized budgetary procedures.[26]

Medical defence bodies developed an attempt to protect licensed doctors and physicians from legal claims. Though there were a very few medical negligence actions, it "hit the headlines and were discussed prominently in daily news papers and medical journals".[27] The Medical Defense Union ("MDU"), founded by two solicitors and five "Gentlemen" was registered in Britain, under Companies Act, 1862 for preventing medical malpractices.[28] But the concept and meaning of medical negligence in its modern sense is a later development.

1.4 DEFINITION AND MEANING OF MEDICAL NEGLIGENCE

The prime object of the medical profession is to render service to humanity with full respect for the dignity of man. A doctor has a duty to use necessary skill, care, judgment and attention in the treatment of his patient.

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[26] John Hearly, Medical Negligence: Common Law Perspectives, Sweet $ Maxwell, London, 1999. p.30.

[27] Id.

[28] Supra note.21.

Any failure to exercise the above mentioned duty would lead to action for medical negligence. Regarding the definition of Medical Negligence, "Medical negligence is the breach of duty owed by a doctor to his patient to exercise reasonable care and skill, which results in some physical, mental or a financial disability." [29] Medical negligence law is generated chiefly by civil actions. Any crime of 'gross negligence manslaughter' has survived but is rarely prosecuted in the Health Care Context[30], and it would otherwise appear that instance of gross negligence are swiftly settled by the profession in private to minimize bad publicity. Later the concept of negligence changed accordingly.

'Negligence' was added to the common law in the seventeenth century with the increase of road traffic accidents. The beginning of the seventeenth century noticed a slow but steady transformation from an action of trespass on the case to an action for negligence.[31] The concept of negligence in its present form is not of Indian origin but is patterned on English law, where negligence is a separate tort. Hence it is important to know the English position relating to the same.[31]

Carelessness is actionable only when there is a duty to take care and when failure in that duty has resulted in damage. At the same time carelessness assumes the legal quality of negligence and entails the consequence in law of

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29 H.M.V. Cox, Medical Jurisprudence and Toxicology, Eastern Publication, New Delhi, 2001, p.16.

30 R. V. Bateman (1925) 94 L.J.K.B. 791.

31 Dr.Gourdas Chakrabarti., The law of Negligence, Calcutta,. Cambray & Co, Private Ltd Publication, 8th editon, 1996, p.4.

negligence.[32] Every profession requires some specialized skill and learning. Persons involved in the exercise of the requisite skill could be liable for negligence if they failed to take that special care[32]. In English law, the rule is imperitia culpa annumerature (want of skill is reckoned as a fault).[33] According to Winfield, in one form or another, a fair amount of negligence in the sense of doing what a responsible man could not do, or not doing what he would do was covered by medieval law[34].

In R.V. Bateman, the liability of physician and their duties was discussed.[35] The court stated that if a medical practitioner holds himself out to be a skilled practitioner, he is under an obligation to use the due caution, diligence, care, knowledge and skill in the treatment .The law requires a fair and reasonable standard of care and competence; irrespective of the fact that he is qualified or unqualified practitioner by a lower standard[35]. While adjudicating upon the standard of care to be observed by medical man, one should also have regard to some other relevant factors such as professional position, specialization, state of medical knowledge, development, availability of facilities, locality etc.[36] This was the stand adopted by English Court system.

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32 Donoghue V. Stevenson, (1923) A.C. 562 per Lord Mc Millian.

33 Id.

34 Malcolmkhan and Michelle Robson, Medical Negligence, London, Canvedish Publication, 1997 edition, 34. p.23.

35 1925 94 L. J .KB 791

36 Supra note.18.

1.5 INDIAN SCENARIO NOW

Indian courts usually rely upon English decisions. Justice Tendolkar observed in 1947, that action for negligence in India are to be determined according the principles of English common Law.[37] The said judgment was confirmed by Bombay High Court in appeal by Chagla C.J. and Bhagawati J. They observed that law on the subject in reality was not in dispute. The plaintiff has to establish first that there had been a want of complete care and skill on the part of defendant to such extent as to establish the necessary connection between the negligence of defendant and the ultimate death of plaintiff's son[38].

These observations make it clear that negligent act must be the proximate cause of the injury sustained by the plaintiff. It is noticed that very few victims complained against negligence of medical men and even if they sue for damages the case is decided in subordinate or district level court and it seldom goes in appeal before the High courts. Number of cases decided in higher courts is negligible and that too without laying down any new principle or theory with regard to liability in torts. The highest court of the country has affirmed the law laid down in Halsbury's Laws of England.

A person, who holds himself out as ready to give medical advice or treatment, impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person whether he is a registered medical practitioner or

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[37] Justice Tendulkar referred to principles laid down by Hale C.J. in Rich v. Rierpont, (1862) F$F 36, 176, Er 16.

[38] Amelia Floundurs V. Dr. Clement pereria, A.I.R. 1950 Bom

not, if he is consulted by a patient, he owes the patient certain duties namely a duty of care in administration of the treatment.[39] A breach of any of these duties will support an action for negligence by the patient. This principle has also been followed by the Hon'ble Supreme Court in Phillips India Ltd v. Kunjupunnu[40] and others, relying on English decisions.[41] Similar is the view of Madhya Pradesh High court[41] in J.N Shrivastava v Rambiharilal and others[42].

So the essential ingredients of actionable negligence in medical profession is (1) Existence of duty to take care whether it is so or not depends on the question of proximity[43] (2) Breach of duty to take care (3) The breach of duty must cause the injury or loss to the defendant. For the analysis of these three components, comprehensive information regarding duty of care, breach of duty of care and injury arising out of breach of duty of care is needed.

1.6 RATIONALE

The main rationale of this project is to understand the legal issues in spinal surgery and to find out the solutions for preventing the situations leading to malpractise litigations against spinal surgeons The data from this study would definitely guide future experimental operational research on these unexplored areas which will be relevant in the making of a competency based medical curriculum in Kerala. This study will also be an eye opener for the

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39 Supra note. 24.

40 AIR 1975 Bom.306.

41 Supra note.36.

42 AIR (1982) M.P.132.

43 Donoghue v. Stevenson, (1932) A.C. 31.H.L. proximate cause of the harm What is proximate is "that because of convenience of public policy or a rough sense of justice the law arbitrarily declines to trace a series of events beyond certain point quoted in Fleming, John G., " Law of Torts" 5th Edn, Sydney p.190.

health sector in Kerala where there are no unbiased management protocols for safe conductance of spinal surgery. The results of this study will also help to motivate the higher authorities regarding the need to re frame the legal and administrative policies and to restructure undergraduate medical curriculum with special emphasis on basic legal education. The findings of this study will definitely motivate the medical professional in taking up career in medical law and ethics also. This will definetly motivate formation of legal cell in all professional bodies and thus support the medical practioners to deal with medical negligence suits with confidence.

1.7 GAP IN KNOWLEDGE TO BE ADDRESSED

When a legal notice is received against a doctor, it creates a lot of emotional disturbance as the reputation of medical professionals is affected. They have to take care of the legal requirements and face the situation. This is a neglected field and not many studies are there regarding the issue especially in Kerala.

Spinal surgeons need to face litigation for breach of duty of care while treating patients. The results from the project and subsequent mitigation skills proposed will definetly improve the communication skills of treating physician while dealing with patients. This review based on an analytical survey will also give awareness on maintaining the ethical aspects and enhances the capability of handling such malpractice claims. It also involves checking of the effectiveness of law and its administration in a critical way. The mitigation methods recommended will help in avoiding such difficult scenarios providing

a better doctor patient relationship in future and thus make this study a highly relevant one.

Thus the secondary aim will be to assess the current the level of awareness regarding negligence suits among spinal surgeons based on Cross Sectional Analytical Survey among spinal surgeons in Kerala

This study also will try to propose solutions and mitigation methods to handle or avoid litigation based on a cross sectional analytical experience survey among spinal surgeons in Kerala.

1.8 RESEARCH OBJECTIVE

- To make a literature review of the extent of duty of the medical practitioner to take care his patients in conducting the spinal surgery
- To make a thorough literature review about the medical negligence and its legal consequence
- To find out the possible mitigation methods based on survey and literature review to improve the conduct of spinal surgery in Kerala and to propose practical solutions to avoid legal issues following medical negligence suits
- To assess awareness and knowledge about medical negligence among spinal surgeons

1.9 RESEARCH DESIGN

- **Type of Study:** Cross sectional analytical survey and critical review of literature

- **Population**

  Neurospinal surgeons working in Kerala both private and govt institution

- **Study tools:**

  Profoma to assess the demography, types of litigation and to analyse the mitigation methods to prevent litigation among neurospinal surgeons using a questionnaire.

Funding agency: no funding agency involved

Survey

Survey questionnaire was prepared and entered in in Google forms and send by e mail to spine surgeons.

Questionnaire was prepared based on previous studies. As a pilot study, survey questionnaire was initially sent to four senior neurospinalsurgeons working in various parts of Kerala. Upon expert review panel, corrections were made as per suggestions which we felt improved the readability and validity of the questionnaire. Only those consenting was able to fill the form A proper consent is also taken online from participants. Final form was sent to 150 spinal surgeons by email. The participant mail ID was collected from data base of Kerala neuroscience society. Majority of questions could be answered by selecting from the multiple choices given in the e-mail or in the web inter phase and few required the participant to write a short sentence. At four weeks, and 6 weeks re email was done for non responders. The questionnaire used is given in appendix. Investigator will be blindfolded.

We closed the study at 12 weeks. Data recorded in Google spread sheet was entered in SPSS version 16. (SPSS Inc., Chicago, IL, USA) Most of the statistics done were descriptive in nature.

1.10 LIMITATIONS

Response rate and informer bias is an issue. Hence, it is not known, how much the analysis with the obtained data reflects the practice trends among spine surgeons nationwide. Data were collected from surgeon's experience which are dependent on personal preference and may have a recall bias. Though with these deficiencies, we hope that our survey and literature review will act as a reference for future studies and formation of Indian guidelines.

1.11 CHAPTERISATION

The introduction chapter deals with the research problem including the background of the issue of medical negligence from a global perspective as well as the origin of medical negligence suit in India starting from the vedic period to the present situation in India now. The research objectives, research design, methodology including the limitations of the study were mentioned.

Chapter 2 describes the concept of medical negligence from the angle of spinal surgeons and the relevant issues were highlighted.

Chapter 3 deals with the concepts behind ethical medical practise with a specific reference to spinal surgery with inclusion of subchapters on duty of care and breach of duty of care ,confidentiality and informed consent, the ethics behind maintanence of medical records ,special issues like disclosure of errors, discharge against medical advise and ethics behind tort reforms.

In Chapter 4, the laws relating to medical negligence with special reference to Consumer Protection Act, role of professional bodies, criminal liability as per IPC and CRPC and the role of Human Rights Commission and its provisons were touched upon.

In chapter 5, based on an Empirical study on "The Level Of Awareness Regarding Medical Negligence Among Spinal Surgeons In Kerala" the issue of lack of awareness among medical professionals were analysed based on a cross sectional analytical survey and results were thoroughly analysed.

In Chapter 6, based on the critical review of literature and the results of analytical survey the recommendations and practical solution in avoiding the litigation suits against medical practitioners were addressed and the need for restructuring of medical curriculum for empowering medical professionals especially spinal surgeons were emphasized.

CHAPTER 2

THE ISSUES AND MALPRACTICES IN SPINAL SURGERY

Malpractice claims were particularly common following spine surgery compared to other neurosurgical subspecialties, with estimates suggesting that nearly 60% of cases involve spine surgeons. This skew is further exemplified by surveying the most frequent medical conditions among plaintiffs. Of the malpractice claims served to neurosurgeons between 2003 and 2012, the three most common conditions (intervertebral disc disease, back disorders/pain, and spinal stenosis) together comprised over 40% of all malpractice suits and payments totaled nearly $105 million[1]. The vast majority (79%) were elective procedures, in which the predominantly cited reasons included “lack of informed consent” (29.9%), “failure to treat” (20.8%), and “failure to diagnose” (19.5)[1]. Procedural error was more frequently cited as a reason for litigation of elective procedures (71.4%) than for emergent procedures (14.3%)[1]. Nearly 5% of spinal cord injuries result from medical or surgical procedures.[1]

It is well established that neurosurgery carries a high risk of malpractice litigation.

Please see reference footnote 1 on page 1

2.1 REASONS FOR LITIGATION IN SPINAL SURGERY

a. Delay in diagnosis and unnecessary radiological investigation

Law suits resulting from errors or delays in diagnosis of spinal cord injury are particularly challenging. A reasonable hypothesis can be drawn that early and frequent neuroimaging may obviate the possibility of future litigation.

Mody et al. identified a high rate of imaging use in "clinically unnecessary" situations and cites a tendency of providers to avoid cases perceived to carry elevated litigation risk. Specifically, among neurosurgeons surveyed, nearly 60% cited utilizing CT, MRI, and radiography as assurance practices, even when "clinically unnecessary."[44] These practice patterns present an important dichotomy juxtaposing clinical guidelines and prior literature, which remains divided regarding the use of early advanced imaging in patients presenting with acute-onset back pain.

Furthermore, plain-film radiographs may miss a subset of spinal cord injury cases with structural anomalies detectable only by MRI.

b. Wrong level surgery

Wrong-site surgeries are surgical procedures performed on the wrong patient or side. Designated as sentinel events by the Joint Commission on Accreditation of Healthcare Organizations (JC), they have been the second most commonly reported event from 1995 to 2005, involving 455 (12.8%) of

[44] Mody MG, Nourbakhsh A, Stahl DL, et al. The prevalence of wrong level surgery among spine surgeons. Spine (Phila Pa 1976). 2008;33(2):194–198.

3548 events[45]. With regard to spine surgery, wrong-level surgery is a particular subcategory of wrong-site surgery, defined as the correct procedure and site but incorrect level or portion of the operative field.

Intraoperative imaging is a major key to determining the correct spinal level. Site marking alone has proven to be insufficient. Mody et al. determined needle localization during anterior cervical surgery incorrectly marked the spinal level at a 17% rate[44]. With newer techniques and technologies, various localization modalities have been developed that utilize fluoroscopy or plain radiography in conjunction with fiducial marking of an anatomical landmark. Still, the continued prevalence of wrong-level surgery underscores its limitations. While intraoperative imaging has mostly become common practice, its use is not universal among providers. Only 80% of respondents strictly follow guidelines for intraoperative radiography[44]. Furthermore, intraoperative imaging is no panacea to wrong-level prevention. Miscounting or misinterpretation of spinal anatomy, patient obesity, operating room limitations leading to poor radiograph quality are all potential factors that negate the usefulness of imaging. In addition, there is also notable heterogeneity in the specific imaging methods and other preventative measures adopted. From the perspective of litigation, utilization of intraoperative imaging does not prevent liability.

Please see reference footnote 44 on page 22

[45] Goodkin R, Laska LL. Wrong disc space level surgery: medicolegal implications. Surg Neurol. 2004;61(4):323–341.

c. Death

In the context of spine surgery, intraoperative or perioperative death may occur from acute blood loss, cardiac arrest, anaphylaxis, massive pulmonary embolism, septic shock, pneumonia, acute respiratory distress disorder, or massive stroke. These outcomes may be a direct cause of the disease or injury being treated, due to technical aspects of the operation being performed, administration of anesthesia, preexisting medical conditions, incidents occurring in the postoperative period, or some combination of the above. Administration of a general anesthetic, required to perform most spine surgeries, carries a small risk of death itself. The risk of death from anesthesia was estimated to be 1 in 5500 cases in 1960 to 1 in 26,000 in 1984.[46] Reaction to drugs used for general anesthesia may cause anaphylaxis, cardiac arrythmias, liver necrosis, or malignant hyperthermia.

Unsurprisingly, patient death is a major aspect of litigation brought against neurosurgeons. In a recent analysis by Algie et al, 17.4% of claims brought against neurosurgeons involved patient death. Of all claims against neurosurgeons involving patient death, displacement of intervertebral disc was the most common associated medical condition, with an average payment of $457,222[47]. In these cases, improper performance of the procedure resulted in

[46] Vachhani JA, Klopfenstein JD. Incidence of neurosurgical wrong-site surgery before and after implementation of the universal protocol. Neurosurgery. 2013;72(4):590–595.

[47] Algie CM, Mahar RK, Wasiak J, et al. Interventions for reducing wrong-site surgery and invasive clinical procedures. Cochrane Database Syst Rev. 2015;(3):CD009404.

the highest total payments ($330,500 average payout per claim) in cases involving patient death[48].

d. "Ghost Surgery": When the Primary Surgeon Does Not Perform the Surgery

Increasingly, spine surgeons are allowing operations to be performed by other surgeons (e.g. ghost surgeon-partners, other co-surgeons, residents, or mid-level providers (Physician Assistants, Nurse Practitioners)) without the patient's informed consent

e. Denial, Abandonment, and Spoliation

Denial, abandonment, and spoliation are three additional factors contributing to malpractice suits. Denial comes in the form of ignoring new post-operative neurologic deficits; another means for obfuscation of malpractice. [49]

Examples of this include postoperative hemorrhagic shock, or other new surgical complications where those involved attempt to blame preexisting conditions. Abandonment occurs when a new postoperative deficit occurs, and the operating physician not only fails to acknowledge the problem but provides little or no postoperative follow-up. Here, postoperative care is, left almost entirely to mid-level providers. In such cases, patients begin to sense "their surgeon" may not have performed the surgery (ghost surgery) or does not care about the complications that occurred.

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[48] Devine JG, Chutkan N, Gloystein D, Jackson K. An update on wrong-site spine surgery. Global Spine J. 2020;10(1 suppl):41S–44S.

[49] Groff MW, Heller JE, Potts EA, et al. A survey-based study of wrong-level lumbar spine surgery: the scope of the problem and current practices in place to help avoid these errors. World Neurosurg. 2013;79(3-4):585–592.

Spoliation is the legal term of art for destruction of evidence. Spoliation of medical evidence (alteration, falsification, or destruction of medical records) occurs when physician/surgeon is acting with actual malice toward the patient, and is grounds for punitive damages in a medical negligence case.[48]

f. Neurologic Compression of the Limbs

Peripheral nerve injuries have been described in the literature for nearly a century and has been a frequent cause for claims.

Prognosis is usually favorable. Recovery takes several weeks to months and requires lengthy hospital stays also.

g. Ocular

A prolonged prone position during spinal surgery can cause external compression of the eye, causing serious and irreversible injury to the orbital structures.

h. Neurologic Risk

There is always a risk of medullary and radicular lesion to the spine and spinal contents during the surgical approach. These may result from direct instrumental trauma, faulty implant.[49]

i. Neurologic Risk and Spinal Implants

Whatever material is used (screws, hooks or inter bodycages implanted via a posterior, trans-foramen, trans-psoas or anterior approach), the cord or roots may be damaged by poor implant.

Please see reference footnote 48, 49 on page 25

j. Bleeding

Abnormal bleeding during discectomy should orient toward breach of a major vessel during the manoeuver. In such a case, immediate intervention by vascular surgeon is always mandatory.

k. Dural Tear

Incidental durotomy is an event during spinal surgery. McMahon et al, reported 7.7% rate of neurological damage with dural tear, versus 1.5% without. The risk of dural tear is three-fold higher in revision surgery[48].

2.2 LITIGATIONS AND MALPRACTISE

Medical negligence in spine surgery, as with any medical treatment, involves breach of standard of care. Although any surgical treatment is a endeavour, both the patient and the surgeon should naturally agree to achieve their common goal of improving the health condition but adverse events can occur. As surgery is a joint venture, requiring both the compliance and the surgeon's skills, medical error is a failure of a planned procedure to be completed as intended or the use of a wrong plan to achieve an aim.

The successful practice of spinal neurosurgery is founded not only on technical excellence, knowledge, and clinical acumen, but also on an unwavering commitment to high ethical standards. Ethics is a foundational principle in medicine, highlighted by the recitation of the Hippocratic Oath by medical students to "First do no harm."[48] In the context of spine surgery, ethical behavior involves avoiding any intentional wrongdoing or harm to patients, respecting the w ishes and dignity of patients, prompt disclosure of errors or

Please see reference footnote 48 on page 25

complications to patients and their families. The prompt disclosure of errors or complications to patients and their families is now universally advocated by patient safety organizations, experts, and physician groups. Since the publication of "To Err Is Human" by the Institute of Medicine in 1999[49], there has been increased attention on the need for transparency between providers and patients regarding medical errors. Although the risk of malpractice may be invoked as an obstacle of physician disclosure of errors, there is evidence that lack of transparency about errors and complications increases the risk of litigation. In a review of malpractice claims, 10% of claims cited failure to provide an explanation as motivation for pursuing litigation. Conversely, there is evidence that clear communication of errors to patients does not increase the risk of litigation. In 2002, an act was passed in Pennsylvania mandating the written and verbal disclosure of serious events to patients.

Spinal neurosurgery is among the highest litigated specialties due to the possibility of permanent disability from the natural history of the conditions being treated, the need for instrumentation placed in close proximity to vital neurovascular structures, and the unforgiving nature of the spinal cord and nerve roots to traumatic or iatrogenic injury. Tort reform is an important geographic determinant on the rate of malpractice claims levied against neurosurgeons and the average amount awarded per claim[50-51]

Please see reference footnote 49 on page 25

50 Hsiang J. Wrong-level surgery: a unique problem in spine surgery. Surg Neurol Int. 2011; 2:47.

51 Nassr A, Lee JY, Bashir RS, et al. Does incorrect level needle localization during anterior cervical discectomy and fusion

Overall, the rate of malpractice claims appears to be trending downward, but the amount awarded per claim has increased. Like other surgical subspecialties, wrong-sided surgery is considered a sentinel event with high risk for litigation, but the complex segmental anatomy of the human spinal column creates the possibility of wrong-level surgery, which is also highly litigated. In addition, spine surgeons treat conditions requiring prompt diagnosis and neurosurgical intervention to mitigate long-term disability, such as CES (Cauda Equina Syndrome) or incomplete spinal cord injury, which are also at increased risk for litigation. Prompt disclosure of medical errors and complications to patients has been associated with reduced rates of litigation. Above all, maintaining high ethical standards in the face of complications is critical in spine surgery

Medical negligence occurs when a physician fails to act as any reasonable physician would have acted under the same circumstances. A physician must exercise the same level of skill, diligence and judgment that any reasonable physician would have exercised under the same or similar circumstances. While a doctor's failure to meet this standard 'negligence', the mere fact that the doctor was negligent does not necessarily result in liability. Technically unsuccessful surgery does not mean a breach standard of care. All should be weighed in determining outcomes of litigation suits against medical negligence.

CHAPTER 3

ETHICAL MEDICAL PRACTISE WITH A SPECIFIC REFERENCE TO SPINAL SURGERY

3.1 ORIGIN OF MEDICAL ETHICS

Medical practitioners under "Hippocrates oath" who follow medical ethics must understand the word "Ethics" and derivation of its principles in medical practice over a period of time. "Ethics" refers to moral principles that control or influence a person's behavior whereas "ethical" means connected with beliefs and principles about what is right and wrong.[52] Origin of the word "Ethics" is from the Greek word "ethos" meaning custom or character. It exudes from within a person, imparts a value system distinguishing rights from the wrongs and build after imbibing values achieved from parents, religion, culture, society, faith and other influences. The principles of medical ethics have been penned down by many great physicians that affect every aspect of the medical professionals including their role as a physician as a private individual and as a clinical investigator.

3.2 DOCTORS AS A PHYSICIAN

It is quite obvious that out of these principles Hippocratic Oath[53] is the most revered one. That is an old (460-377 BC), honored and living "ethical code" for physicians and a binding document for their conduct.[52] Its relevance has been increasing over the time especially in conflict areas of the world. The

[52] Translation by North M. (US) National Library of Medicine. 2002. [Last accessed on 2012 Dec 4]. Available from: http://www.nlm.nih.gov/hmd/greek/greek_Oath.html .

aftermath of the biggest conflict of the present century, i.e., World War II (WW2), revealed the reciprocal vulnerability of the doctors in a changing socio-administrative milieu. Moreover, the most famous trial of the physicians of the Nazi era for their atrocities on the minority was not held on the basis of then existing rules and laws of the Germany, but on the basis of Hippocratic Oath[53] That implies that the professional ethical duties of doctors stand above the ruling powers and laws of the land. Most of the time oath takers are victimized for pursuing their duties as per their binding document.

3.3 ETHICAL DOCUMENTS

The physicians maintain their conduct to the highest standards from the time of antiquity on the basis of dynamic changes in the Hippocratic Oath wherein modern time has seen huge scientific and social changes. The original version of the oath was lacking many newer issues such as different professional aspect of medical specialization, privacy of the patients and doctors' societal and legal responsibilities. The World Medical Association in its 2nd general assembly modernized the oath in Declaration of Geneva in 1948 and the latest version was modified in 2006 in its 57th General Assembly in South Africa to incorporate the changing aspects of medicine.[54-56]

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53 Ghooi RB. The Nuremberg code-A critique. Perspect Clin Res. 2011;2:72–6. [PMC free article] [PubMed] [Google Scholar]

54 Ghooi RB. The Nuremberg code-A critique. Perspect Clin Res. 2011;2:72–6. [PMC free article] [PubMed] [Google Scholar]

55 ICCPR, 1966 article 7

56 ICESCR(International Covenant on Economic, Social and Cultural Rights), 1966

The "Nuremberg code" was another milestone in Ethical documents for physicians after the conviction of Nazi doctors and it was built as regulatory guidelines for all the physicians of the world. Furthermore, it never got the acceptance for ethical conduct in the western world. The "declaration of Helsinki" was adopted in 1964 as the extension of Nuremberg code[53-56]. Many new aspects were added in the Declaration where concept of legal guardianship was added for the consent for participation in clinical research in cases of legal incapacity. It also brought the concept of reviewing the research protocols by the independent committees.

Although Declaration of Helsinki became the most important milestone for the ethical conduct of the physician, it was ignored in major developed countries like USA where Tuskegee Syphilis Study compelled the parliament to pass an Act in 1974, creating a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission produced a report called "Belmont report" on the basis of principles of medical ethics introduced by Beauchamp and Childress in 1979 for the ethical treatment of human subjects that includes three major concepts. One is "respect for person," second "beneficence" and third was the "justice."[54] The Belmont report became the reference document for IEC/IRB.

Please see reference footnote 53-56 on page 31

3.4 INTERNATIONAL INSTRUMENTS FOR THE PROTECTION OF THE PATIENTS

As per Article 7 of International Covenant on Economic, Social and Cultural Rights 1966, "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."[54-56] Internationally, it was first articulated in the 1946 Constitution of the World Health Organization (WHO), whose preamble defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". The preamble further states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."

The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

3.5 DUTY OF CARE

The starting point for determining liability of the health care provider is the duty of care. A legally recognized obligation of health service provider to the patient is duty to take reasonable care. The duty has many different aspects and it means effectively that the doctor must take reasonable care for the well being of the patient in all aspects of the medical care .This includes the

consultation (or visit) itself, giving advice, maintaining confidentiality, making a diagnosis, referring the patent to a specialist or other doctor and giving or prescribing any treatment.

3.6 STANDARD REQUIRED FOR DUTY TO TAKE CARE

Din Mohammad J, quoting Bevan on Negligence, observed if the medical practitioner has the ordinary degree of skill accepted and practiced in his profession, he is entitled to his remuneration although his treatment has failed". This point recognizes that medical treatment is neither exact science, nor favorable outcomes can be anticipated.[57]

Every surgical operation involves risks and it would be wrong to say that simply because a misadventure or mishap occurred, the hospital and doctors are thereby liable. So "you should only find him guilty of negligence when he falls short of the standard of a reasonably skilful medical man."[58] Equally pertinent are the observations of Lord Denning in Roe Vs. The Ministry of Health to the following effect:[59] It is so easy to be wise after the event and to condemn as negligence that which was only a misfortune. We ought always to be our guard against it, especially in cases against hospitals and doctors. Medical science has conferred great benefits on mankind, but these benefits are attended by considerable risk. Every advance in technique is

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57 V.N. Whitmore Vs RN Rao AIR 1935 Lah 247.

58 WMA guidelines 1997
Supra note 37 p.34.

59 Jones vs. Manchester Corporation (1952) 2 All Ed 125, where Lord Denning observed: error due to inexperience or lack of supervision are no defence as against the injured person.

also attended by risk. Doctors like rest of us, have to learn by experience and experience often teaches in a hardway. Therefore, we must not look at a 1947 accident with 1954 spectacles."[60]

3.7 BREACH OF DUTY OF CARE

Lack of clinical competence can be construed as negligence and Indian courts judge cases of medical negligence on basis of Bolam Test (Bolam V. Friern Hospital Management Committee 1957, IWLR 582)[61]. This test defines negligence as failure to act in accordance with "standards of reasonably competent medical men of that time, which may not be the as it can be considered both a civil or criminal wrong, depending on its gravity. However for criminal negligence a gross negligence needs to be proved. A patient approaching a doctor / hospital expects medical treatment to be in accordance to requisite knowledge and skill. This relationship thus assumes the form of a contract retaining essential elements of a tort and failure to discharge this obligation on part of doctor or hospital, a tortious liability[60].

Tort is name given to a civil wrong which has harmed a person and this breach could attract judicial intervention. The person who commits the tortious act, is called atortfeasor and owes a legal liability towards the victim. The victim or plaintiff can sue for damages by a lawsuit, but must prove that the act / or lack of it caused the harm/injury. The onus to prove negligence thus lies

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[60] 1954 Times 2nd July

[61] Bolam V. Friern Hospital Management Committee 1957, IWLR 582 (Page no 37)

with the patient. Error in diagnosis or failure to cure a patient does not necessarily imply negligence[60].

Negligence is labelled as a tort, it can be collateral, comparative continued, criminal, hazardous, active or passive, wilful, reckless or "negligence per se[60]. Black's Law Dictionary defines negligence per se as "conduct, of action or omission, which may be declared as negligence without any argument or proof as it violates dictates of common prudence". The three cardinal elements in negligence are- duty of care, failure to exercise it (dereliction) and consequent damages.

Failure to exercise duty of care (Dereliction): This is defined as failure of a doctor to honour his duty owed to a patient. Such breach of duty may be an act of commission or an act of omission, with the latter carrying more punitive action.

Acts of omission: It occurs due to failure, oversight, lapse or forgetting to perform an action, eg failure to get blood pressure tested prior to spinal surgery, failure to get second opinion in writing prior to performing a orbitiomy with ophthalmology assistance etc. This failure to perform an act, called Actus reus (Latin for guilty act) in legal parlance, results in harm.

Acts of commission: This implies consciously performing an act which is wrong eg removing a lens which was not cataractous, giving anti VEGF injection in wrong eye. Such acts should not have been performed as per standard accepted protocols and would not be undertaken by a prudent doctor.

Please see reference footnote 60 on page 35

Causation of damage to the patient on account of dereliction: This occurs if it is proved that breach of duty was the real cause of damage. Example: a local chemotherapy in tumour bed caused meningitis following brain tumour treatment. Defective treatment cannot be counted as negligence unless supportive positive evidence including expert opinion is brought on record[62].

A doctor cannot be held negligent because a complication eg nerve injury following spinal tumour surgery occurred if she/ he has followed the standard operating protocol of managing such complications.[61]

A case by Supreme Court of India, Kusum Sharma Vs. Batra Hospital & Medical Research Centre" reported as 2010 AIR (SC) 1050, laid down 11 principles for medical negligence , of which a few are detailed , to understand the courts' mind set[61].

3.8 DUTY OF MEDICAL PRACTITIONERS AND ETHICS TO FOLLOW

- Breach of duty exercised by omission to do something which a reasonable, prudent man, guided by considerations which ordinarily regulate the conduct of human affairs, would do.[61]
- Negligence must be culpable/gross and not merely based upon an error of judgment or diagnosis.

Please see reference footnote 61 on page 35

[62] Kusum Sharma Vs. Batra Hospital & Medical Research Centre" reported as 2010 AIR (SC) 1050

- In the realm of diagnosis and treatment there is scope for genuine difference of opinion and one professional doctor is not negligent merely because his conclusion differs from that of other professional doctor.
- Often the doctor adopts a procedure which involves higher element of risk, but which he honestly believes as providing greater chances of success for the patient. In such cases result may not amount to negligence.
- It is our bounden duty and obligation of civil society to ensure that doctors are not unnecessary harassed or humiliated so that they can perform their professional duties without fear and apprehension.
- 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.
- Under normal circumstances, the onus or burden of proof lies heavily on the patient to prove negligence.

3.9 LOSS OR DAMAGE

Where a claim is brought for tort, damage is a necessary element of the cause of action. Where the plaintiff proves that the doctor was negligent but fails to show any injury or damage caused thereby, he will not be entitled to damages and the claim will be dismissed.[63]

Requirements to prove causation

The plaintiff in order to succeed in his action, he must show that:

[63] Sidhraj Dhadda vs. State of Rajasthan AIR 1994 Raj 68

a) The damage would not have occurred but for the defendant's negligence; or

b) The defendant's negligence materially contributed to or materially increased the risk of injury; or

c) If the claim is for negligent non-disclosure, had he been adequately informed he would not have accepted the treatment.

In Bolitho's case, a child was ill in hospital, no doctor attended the child in spite of frequent request made by the night sister. It had been agreed that it was negligent, if a doctor had visited and incubated the child, the cardiac arrest and brain damage that he suffered would have been avoided. But the defendants argued successfully that the plaintiff had failed to prove that if a doctor had come, she would have probably intubated. Facing with the conflict of medical opinion, the court held that the plaintiff had failed to prove that the outcome would have been different if the defendant had responded to the nurse's call.[64]

3.10 MATERIAL CONTRIBUTION TO DAMAGE

In Bonnington Castings Limited Vs. Wardlaw, the House of Lords held that the claimant does not have to establish that the defendant's breach of duty was the main cause of the damage unless it maternally contributed to the damage[65].

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64 Bolitho vs. City and Hackney Health Authority (1993) 4 Med. LR 381; CA; affd (1997) 4 All ER771, (HL).

65 1956 AC 613

In this case, employers were sued by an employee who had contracted pneumoconiosis (an industrial disease of the long due to inhalation of dust particles) from inhaling air which contained silica dust at his work place. The main source of the dust was from pneumatic hammers for which the employers were not negligent (the innocent dust). The crucial issue in the case was some of the dust ("guilty dust") came from swing grinders for which they failed to maintain dust extraction equipment. There was no evidence as to the proportion of innocent dust and guilty dust inhaled by the claimant. Nonetheless, the House of Lords drawing an inference of fact that the guilty dust was contributory cause, held that the employers were liable for the full extent of the loss.

3.11 MATERIAL CONTRIBUTION TO THE RISK

Following the House of Lords decision in Bonnington Castings case, the House of Lords in McGhee Vs. National Coal Board emphasized the list of material contribution to the risk[66]. In this case, the claimant who was working at the defendant's brick factory contracted dermatitis as a result of exposure to brick dust. The employers were not at fault for the exposure during working hours, but they were in breach of duty by failing to provide adequate washing facilities. It was agreed that brick dust had caused the dermatitis. Therefore, it was held that the failure to provide washing facilities materially increased the risk of the claimant contracting dermatitis.[67-68]

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66 1956 AC 613.

67 1983 All ER 41 (per se Pain J.)

3.12 REMOTENESS AND FORESEEABILITY

It is not sufficient to establish a duty of care, a breach of that duty and loss of a type recognized by law and caused by the breach, in addition to these what is equally important to hold the defendant liable for the loss or damage is that the loss was reasonably foreseeable at the time of breach that it could arise[68]. In other words if the loss caused is too remote and as a reasonable man cannot foresee as likely to occur, the tortfeasor is not liable to compensate the loss or injury.[69]

A recent medical case provides good example of the operation of the principles of remotes and foreseeability. In R Vs Croydon Health Authority, the claimant, a trained nurse, married and of child-bearing age, underwent a medical check up with a view to taking employment with the defendants. The radiologist who interpreted her X rays did not refer her for specialist opinion but simply opined she would not conceive and take up the employment. However, contrary to this, the claimant became pregnant who contended that she was entitled to damages she suffered trauma of pregnancy and had to bear the cost of upkeep of her daughter. The court said that the claimant's domestic life does not fall within the scope of the radiologist's duty.[70]

In conclusion, the concept of the standard of care has evolved over the years and will continue to change as legal theory in this area develops.[70-72]

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68 Per se Lord Mustill J in Wilsher vs. Essex Area Health Authority (1987) QB. 730 at 752

69 Charles J. Lewis; Clinical Negligence – A Practical Guide p. 212.

70 1978 Lloyd's Rep Med. 44 CA

71 American Medical Association Center for Health Policy Research . The Cost of Professional Liability in the 1980's. Chicago, IL: 1990. [Google Scholar]

72 Anderson GF. Billions for defense: The pervasive nature of defensive medicine. Arch Intern Med. 1999;159:2399–402. [PubMed] [Google Scholar]

Finally, clinical practice guidelines are being used more frequently in court cases as support for the standard of care; however, their acceptance and uses are continually changing and decided on a case-by-case basis.[73]

Emergency physicians should be aware of these landmark casesthat define the standard of care. Medical practiitoners should be familiar with the content of various clinical practice guidelines.[74-77] They should review the relevant laws based on the state they practice in. By practicing with these law concepts in mind, a physician can feel more confident and when faced with a malpractice action.

3.13 MEDICAL RECORDS

Documentation of medical records in a proper way is of utmost importance in preventing litigations against medical practitioners.

a Confidentiality Of Patient Records

Confidentiality is important as far as the rights of the patient is considered. The hospital authorities are legally bound to maintain

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73 The Kaiser Family Foundation. State Health Facts. Available at www.statehealthfacts.org. Accessed May 15, 2009. [Google Scholar]

74 Restatement of Torts, Second. Section 283.

75 Garthe v. Ruppert, 264 N.Y. 290, 296, 190 N.E. 643.

76 The T. Helling v. Carey, 83 Wash. 2d 514, 519 P.2d 981 (1974)J. Hooper, 60 F:2d 737 (2d Cir.), cert. denied, 287 U.S. 662 (1932)

77 Jones vs. Manchester Corporation (1952) 2 All Ed 125, where Lord Denning observed: error due to inexperience or lack of supervision are no defence as against the injured person.

confidentiality of personal medical records. The patient can claim negligence suit against the hospital or the doctor for a breach of confidentiality[78].

However, there are certain situations where it is legal for the authorities to give patient personal information. They are:

1) Referral.
2) Demanded by the court or by the police on a written requisition.
3) Demanded by insurance companies as provided by the Insurance Act.
4) Required for specific provisions of Workmen's Compensation cases, Consumer Protection cases, or for Income tax authorities.

Documents are also used for research purposes as the identity of the patient is not revealed. Such research has been exempt from an ethics review and researchers usually will not obtain informed consent from patients before using their records. Recently such records are all widely scrutinised by some instituitional review boards though not practised widely. These are raising some concerns.

b. Categories Of Medical Records

The different types of medical records are as follows: [79]

Certain records must be given to the patient as a matter of right.

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[78] Agrawal A, Kakani A, Baisakhiya N, Galwankar S, Dwivedi S, Pal R. Developing traumatic brain injury data bank: Prospective study to understand the pattern of documentation and presentation. Indian J Neurotrauma 2012;9:87-92

[79] Behere SB. Doctor & law. Dr People. 2010;2(7):11–14. [Google Scholar]

These are

- Discharge summary
- Referral notes
- Death summary in case of natural death.

These records need to be given without charge for all including patients who leave against medical advice. The hospital bill should not be tied up with these documents. The above documents cannot be refused even when the hospital bill is not paid.

Certain records like

- Copies of inpatient files
- Records of diagnostic tests
- Operation notes
- Videos
- Medical certificates
- Duplicate copies for lost documents

This requires a formal application to the hospital requesting for the records. It is necessary that the hospital bills are cleared and the necessary processing fee has been paid.

Certain records

- The outpatient file

- Inpatient file
- Files of medico-legal cases including autopsy reports

cannot be given to patients without any direction of the Court.

c. Medical Council Of India Guidelines On Medical Records

The issue of medical record keeping has been addressed in the Medical Council of India Regulations 2002 guidelines as follows: [80]

- Maintain indoor records in a standard proforma for 3 years from commencement of treatment (Section 1.3.1 and Appendix 3)
- Request for medical records by patient or authorized attendant should be acknowledged and documents issued within 72 hours (Section 1.3.2).
- Maintain a register of certificates with the full details of medical certificates issued with at least one identification mark of the patient and his signature (Section 1.3.3).
- Efforts should be made to computerize medical records for quick retrieval (Section 1.3.4).

d. Retaining of Medical Records

There are no definite guidelines in India regarding how long to retain medical records. Provisions of the Limitation Act 1963 and Section 24A of the Consumer Protection Act 1986, which dictates that it is advisable to maintain

[80] Singh S, Sinha US, Sharma NK. Preservation of medical records—an essential part of health care delivery. IIJFMT. 2005;3(4):1–8. [Google Scholar]

records for 2 years for outpatient records and 3 years for inpatient and surgical cases. [79]

The Medical Council of India guidelines also insist on preserving the inpatient records in a standard proforma for 3 years from the commencement of treatment. The records that are the subject of medico-legal cases should be maintained until the final disposal of the case even though only a complaint or notice is received.

It is necessary that the Government frames guidelines for the duration for which medical records are preserved by the hospitals so that hospitals are protected from unnecessary litigation in issues of medical records.

e. The Owner of Medical Records

It is the primary responsibility of the hospital to maintain and produce patient records on demand by the patient or court[81]. However, it is the primary duty of the treating physician to make sure that that all the documents are written properly and signed. An unsigned medical record has no legal validity. Failure to provide medical records to patients on proper demand will amount to deficiency in service and negligence.

f. Provisions for Summoning Medical Records

Medical records are acceptable as per Section 3 of the Indian Evidence Act, 1872 amended in 1961 in a court of law. Erasing of entries is illegal and

[81] Thomas J. Medical records and issues in negligence. Indian J Urol. 2009;25(3):384–388. doi: 10.4103/0970-1591.56208. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

questionable in Court of law. In the event of correction, the entire line should be scored and rewritten with the date and time. [82,83]

Medical records are usually summoned in a court of law in the following cases:

- Criminal cases.
- It is considered important evidence to corroborate the nature of the weapon used and the cause of death.
- Road traffic accident cases under the MACT (Motor Accident Claim Tribunal) Act for deciding on the amount of compensation.
- Labor courts in relation to the Workmen's Compensation Act.
- Insurance claims to prove the duration of illness and the cause of death.
- Medical negligence cases.

When the court issues summons for medical records, it has to be respected as it is a constitutional obligation. If the doctor is required to be present for giving evidence based on the medical records, he has to be present in the court.

g. Electronic Documentation of Medical Records In Neurosurgical Trauma

Head injury is one of the most important public health problem today so much so that it is being referred to as a 'silent epidemic' globally. Studies

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82 Baldwa M. Practical definition of medical negligence. Dr People. 2010;2(7):5–10. [Google Scholar]

83 Basu RN, Bose TK. Medico-legal aspect of clinical and hospital practice. Mumbai: English Edition Publishers; 2005. pp. 86–89. [Google Scholar]

regarding epidemiology of head injury are injury are very few especially in Kerala and most have conflicting reports.

Unlike developed countries, there is no well-established system for collecting and managing information on traumatic brain injury (TBI) in India especially in Kerala. Inadequate case definition, lack of centralized electronic reporting mechanisms, lack of population based studies, absence of standardized survey protocols and inadequate mortality statistics and registry are some of the major obstacles.

h. Problems with Paper Based Records

Lack of electronic documentation and dependence on printed records makes the task of documentation and consolidation of existing data on TBI from various hospitals and registries cumbersome.[84] Paper based records are also prone to duplication and human errors, which can be significantly reduced by electronic documentation. In addition, paper based documentation does not allow quick retrieval and analysis of data. Thus need for trauma registry is the need of hour and it is high time to start.

The design of a trauma database should correctly identify the defined population based on ICD (10) as the standard to identify the TBI cases. Once the cases are identified the next step is to design a valid, reliable and efficient data set to collect required information. Standardized proforma not only can act as an educational tool for doctors not to miss any injuries but it also can help in improved medical documentation of TBI patients. Careful selection and

[84] Navarange JR. Medical negligence. Dr People. 2009;2(4):4–7. [Google Scholar]

definition of each data point is essential and it is important to understand that too little data will be of limited value and too much data will be time-consuming and expensive to collect.

i. Need for Electronic Data Base

Development of an electronic head injury data registry needs a step wise systematic planning. The register needs to be short, user friendly electronic database proforma but covers all information so that each health personnel can fill it so easily. There should be separate data entry personnel's and a team to perform data analysis reporting. The availability of trained personal, adequate funding and institutional support is a must. The personnels should be properly trained for .A well-designed database can be used to pool multi-center trauma data for epidemiologic reports, to compare effectiveness of care among centers and to evaluate the performance improvement indicators.

Commercial available data collection programs are expensive which needs training, updates and maintenance which make these commercial products inaccessible for many low and middle income countries. It has created a need to locally develop electronic trauma registry software which can be used in our hospital settings. It is of utmost importance to understand the step to develop such a data collection system which needs a suitable and concise data entry form, a database and secure online electronic form, well trained personals to extract and enter data and most importantly personals to analyze and interpret data.

j. Recommendations

(1) Follow a standard case definition, (2) link multiple hospital-based registries, (3) initiate a state or country wide population-based registry, (4) conduct unbiased population based studies, and (5) introduce centralized and standard reporting systems

k. Case scenarios on criminal responsibility with respect to medical records

In the case of Dr. Shyam Kumar vs. Rameshbhai Harmanbhai Kachhiya, I(2006)CPJ16(NC) the National Commission held that an following surgery for glaucoma and cataract retina in the posterior chamber was weakened and eye sight was lost, it was held by the court that conducting the operation without obtaining informed consent was improper. [85-86] A patient can not be deprived of sufficient information and complication of surgery and hence the patient is entitled to claim compensation.

In a case where medical records and consent obtained from a patient were not produced, medical negligence was established based on the principle of res ipsa loquitur.

In the case of Meenakshi Mission Hospital and Research Centre vs. Samuraj and Anr., I(2005) CPJ 33 (NC), the National Commission held the hospital guilty of negligence on the grounds that the name of the anesthetist

[85] Modi CD. Organisation and management. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2001. pp. 348–361. [Google Scholar]

[86] Agarwal OP, Barkeshli M. Conservation of books, manuscript and paper documents. Lucknow: INTACT; 1997. pp. 25–48. [Google Scholar]

was not mentioned in the operation notes though anesthesia was administered by two anesthetists at 10 a.m and 10.30 a.m.

The child died and doctor who administered anesthesia was not produced before the Commission. Two progress cards about the same patient on two separate papers were produced. Activity of two anaesthetists inside the operation theatre was not explained.

The hospital is accountable for whatever happens in the hospital and was held liable to pay the compensation and cost. It is relevant to note that in this case the District Forum found the hospital negligent and awarded a compensation of Rs. 3 lacs and cost of Rs. 2000/-. Thereafter, the State Commission had dismissed the appeal with a cost of Rs. 500.

Transparency in dealings will always be defence in litigation. As the medical fraternity is not used to detailed record keeping, doubts do arise in the course of legal proceedings.

3.14 INFORMED CONSENT AND MEDICAL ETHICS

Medical practice today is not simple because of various factors impinging on the doctor-patient relationship. Mutual trust forms the foundation for good relationship between doctor and patient. Today, patients tend to be well- or ill-informed about the disease and health. With the hype created in the print and visual media regarding ‘beauty’, ‘shape, size and appearance of body parts’, ‘quality and quantity of hair’, etc., patients tend to come to dermatologists with unreasonable demands and unrealistic expectations.

Therefore, providing adequate information and educating the patient about realities and obtaining informed consent before subjecting a patient to any test/procedure/surgery is very essential[87].

a. Ethical Angle

The concept of consent arises from the ethical principle of patient autonomy and basic human rights. Patient's has all the freedom to decide what should or should not happen to his/her body and to gather information before undergoing a test/procedure/surgery. No one else has the right to coerce the patient to act in a particular way. Even a doctor can only act as a facilitator in patient's decision making[87].

There is also a legal angle to this concept. No one has the right to even touch, let alone treat another person. Any such act, done without permission, is classified as "battery" physical assault and is punishable. Hence, obtaining consent is a must for anything other than a routine physical examination.

b. Consent

In simple terms, it can be defined as an instrument of mutual communication between doctor and patient with an expression of authorization/ permission/ choice by the latter for the doctor to act in a particular way.

c. Implied Vs. Expressed Consent

The very act of a patient entering a doctor's chamber and expressing his problem is taken as an implied (or implicit) consent for general physical

[87] Drane JF. Competency to give informed consent. JAMA 1984;252(7):925–7.

examination and routine investigations.[88] But, intimate examination, especially in a female, invasive tests and risky procedures require specific expressed consent. Expressed (explicit) consent can be oral or written.

Written consents are preferable in situations involving long-term follow-up, high-risk interventions and cosmetic procedures and surgeries. It is also needed for skin biopsy, psoralen with ultraviolet A (PUVA) therapy, intralesional injection, immunosuppressive therapy, electrocautery etc.

Consent is necessary for photographing a patient for scientific/ educational/ research purpose or for follow up. Specific consent must be taken if the identity of the patient is likely to be revealed while publishing.

Consent is a must for participation in clinical trials and research projects.

d. Informed written Consent

Informed consent must be preceded by disclosure of sufficient information. Consent can be challenged on the ground that adequate information has not been revealed to enable the patient to take a proper and knowledgeable decision. Therefore, accurate, adequate and relevant information must be provided truthfully in a form (using non-scientific terms) and language that the patient can understand. It cannot be a patient's signature on a dotted line obtained routinely by a staff member[89].

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88 Capron A. Informed consent in catastrophic disease and treatment. University of Pennsylvania Law Review; 123:364–76.

89 Modern status of views as to general measure of physician's duty to inform patient of risks of proposed treatment. American Law Reports 3d, 88 (1978):1008.

Patient should be given opportunity to ask questions and clarify all doubts. There must not be any kind of coercion. Consent must be voluntary and patient should have the freedom to revoke the consent. Consent given under fear of injury/intimidation, misconception or misrepresentation of facts can be held invalid.

e. Pre-Requisites

Patient should be competent to give consent; must be an adult and of sound mind. In case of children, consent must be obtained from a parent.[89] In case of incapacitated persons, close family members or legal guardians can give consent. Adequate information should be provided to a prudent patient during informed consent.

Prudent patient means a reasonable or average patient. To decide whether adequate information has been given, courts rely on this "Prudent Patient Test". It is not easy to answer the question, How much information is "adequate"? A netizen may expect and demand detailed information. On the other hand, an illiterate may say that "I do not understand anything, doctor, you decide what is best for me!" If a patient knowingly prefers not to get full information that attitude also needs to be respected as a part of patient's right to autonomy.

Please see reference footnote 89 on page 53

Patients' perception of risk of a medical intervention is also highly individualistic, variable and unpredictable. The information provided to a patient should include all material risks. But, the list of risks and side effects cannot be exhaustive to the level of absurdity and impracticality. For example, hardly any patient can go through the product information leaflet included in any drug pack and if some body does, it is unlikely that the drug is consumed. So, what is expected is that the doctor should provide information that a prudent or reasonable patient would expect to make a knowledgeable decision about the course of action to be taken in the presence of alternatives.

f. Therapeutic privilege

If a doctor is of the opinion that certain information can seriously harm a patient's health - physical, mental or emotional - he has the privilege to withhold such information[90]. But, it should be shared with close relatives. This situation usually does not occur in cutaneous aesthetic surgical procedures.

g. Placebo

Use of placebos in certain self-limiting conditions or in patients with high psychological overlay or in those who insist for some form of medication is justified as there are high chances of benefit to the patient with negligible risk. Revealing the truth to the patient takes away the very purpose of administration of placebo.

[90] Physician’s duty to inform of risks. American Law Reports 3d, 88 (1986):1010–25

h. Blanket Consent

An all-encompassing consent to the effect "I authorize so and so to carry out any test/procedure/surgery in the course of my treatment" is not valid.[80] It should be specific for a particular event. If, consent is taken for microdermabrasion, it cannot be valid for any other procedure like acid peel. Additional consent will have to be obtained before proceeding with the latter.

If a consent form says that patient has consented to undergo laser resurfacing by Dr. X, the procedure cannot be done by Dr. Y, even if Dr. Y is Dr. X's assistant, unless it is specifically mentioned in the consent that the procedure may be carried out by Dr. X or Dr. Y (or his authorized assistants).

i. Documentation

It is important to document the process of consent taking. It should be prepared in duplicate and a copy handed over to the patient. It should be dated and signed by the patient or guardian, the doctor and an independent witness. Assisting nurse preferably should not be a witness. Like all other medical records, it should be preserved for at least 3 years.

j. Informed Refusal

Patient has got the right of self-determination[89]. If, a doctor diagnoses varicella in a child, the parent may choose to avail no treatment because of religious belief. Doctor's duty is to explain the possible consequences of non-

Please see reference footnote 80 on page 45
Please see reference footnote 89 on page 53

treatment and benefits of treatment and leave the decision to the parent. Such informed refusals must be documented clearly. But, a patient's freedom cannot impinge on the rights of others or cause harm to a third party or community. Therefore, the said parent's freedom of choice cannot extend to sending the child to school, as the infection can spread to other children.

Discharge against medical advice also falls into this category and needs to be properly recorded in the case sheet with signature of the patient/guardian.

In an emergency situation, for example intestinal perforation, a doctor may have to operate even in the absence of consent, to save the life of the patient. It is possible that even with such an intervention, the patient may not survive. Assuming that the doctor is competent and has exercised due care and diligence, doctor cannot be held responsible for patient's death, as he has acted in good faith and in the best interest of the patient. This protection is given under Section 88 of Indian Penal Code.

It is fairly common for the issue of informed consent to arise in medical malpractice cases. The question may arise as

- whether the physician had a duty to warn the patient of this particular risk?
- whether the patient was told of the risk?
- whether the patient actually understood the information being conveyed?

Informed consent is based on the ethical “principle of autonomy”

Thus, the patient must be presented with accurate and reliable information. Informed consent serves the functions of protecting patients from harm and encouraging medical professionals to act responsibly.

Historically, the two approaches to the question of when informed consent should be obtained are the professional practice standard and the reasonable person standard.

Under the professional practice standard, appropriate disclosure of information is based on the traditional practices of the professional community, relying on the belief that physicians, acting in the best interests, establish the amount and kinds of information to be disclosed. The primary objection to the professional practice standard is, of course, that it is inconsistent with the principle of patient autonomy[86-89]. The reasonable person standard, as the phrase suggests, is based on what a reasonable person would need (or want) to know. Thus, the determination of informational needs is shifted from physician to patient, based on the underlying belief that informed consent in law is a doctrine fashioned to permit patients to be the agents of decision making[89] .

k. Failure to perform emergency operation on the pretext of consent:

In the case of Dr. T.T. Thomas vs. Elisa[91] the plaintiff's husband was suffering from severe abdominal pain and pain had been diagnosed as a case of acute appendicitis, but the surgeon delayed in performing operation for two days on the ground that the patient refused the consent for treatment.

Please see reference footnote 86-89 on page 50

91 AIR 1987 Ker 52; 1987 (1) ACJ 192

The patient died due to perforated appendicitis. The court awarded a decree against the defendant for a sum of Rs. 37,000/- and ruled that the burden is on the surgeon to prove that non performance of the surgery or non administration of the treatment was on account of the refusal of the patient to give consent thereto. A surgeon, who fails to perform an emergency operation, must prove with satisfactory evidence that the patient refused to undergo the operation, not only at the initial stage but even after he was informed of the dangerous consequences of not undergoing the operation.

The Rajmal VS. State of Rajasthan[92] the plaintiff's wife died while she was being operated for laparoscopic tubectomy at primary health center. The hospital did not have compulsory medical equipments such as endotracheal anaesthesia, defibrillator and cardiac monitoring equipments side providing necessary trained staff. The court held the state of Rajasthan vicariously liable to pay Rs.1,00,000/- by way of compensation to the plaintiff along with the 12% p.a. from the due date to till the actual date of payment. The amount of Rs. 10,000/- which was paid by the collector on the spot. as interim relief excluded from the amount of compensation.

L. Pain and suffering due to foreign body in abdomen:

In Shanta Vs. State of Andhra Pradesh[93] the patient who underwent caesarian operation in a government hospital developed pain and other complications after the operation. The testing report disclosed that foreign body

[92] (1996) ACJ, 1966

[93] (1997) III CPJ 481, (HC of AP)

(mop) was left in para spinal region the course of operation. By operation the foreign body was removed but required another operation for complete recovery. The High Court which invoked its jurisdiction under article 226 of the constitution directed the state to pay compensation of Rs.3,00,000/- to the petitioner for negligent treatment given by the doctors in a Government Hospital.

3.15 OTHER ETHICAL ISSUES

a. Quality improvement

Medical negligence cases are on the rise due to variety of causes. Medical practiitoners hold the key to reducing the incidence of medical malpractice, and the cornerstone of their efforts is quality improvement.

Successful quality improvement relies on a system where the physicians can engage in frank discussions and disclosures or errors and focus on errors that could have been avoided. The desired quality outcome is that both patient and physician learn from each other's mistakes and those who exhibit a pattern of substandard care can be monitored closely, required to obtain remedial education and advise.

In exceptional cases they may be referred for possible disciplinary action according to the process prescribed by medical staff bylaws. [94-97]

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[94] Code Of Medical Ethics Regulations, 2002 Amended Upto 8th October 2016))(Published In Part Iii, Section 4 Of The Gazette Of India, Dated 6th April,2002)Medical Council Of India Notification

[95] Witman A, Park D, Hardin S. How do patients want physicians to handle mistakes? A survey of internal medicine patients in an academic setting. Arch Intern Med 1996;156:2565–

b. Obstacles for quality improvement program

Physicians are often hesitant to be critical of their colleagues because of fear that their discussions and conclusions could be subject to discovery of the adverse outcome and becomes the subject of a malpractice claim. Thus, the professional and ethical obligation to improve the quality of patient care make medical practitioner more hesitant due to fear of legal systems.

c. Disclosure of errors

The question of disclosing medical errors to patients and families engenders a greater anxietyon the physician. Experience in medical negligence has shown that if a patient's care has gone wrong, then a full and frank explanation to defuse the anger, upset, and resentment of the patient and may reduce substantially the risk that the patient will file suit in court. The American College of Emergency Physicians has adopted a policy on disclosure of medical errors[98]Failing to disclose errors to patients undermines public trust in medicine because it potentially involves deception and preservation of narrow professional interests rather than the well-being of patients.

d. Discharge Against Medical Advice

Patients who wish to leave against medical advice (AMA) often cause the emergency physician anxiety about the possibility of an adverse

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96 Kraman S, Hamm G. Risk management: extreme honesty may be the best policy. Ann Intern Med 1999;131:963–7.

97 American College of Emergency Physicians. Disclosure of medical errors. Available at: http://www.acep.org/webportal/PracticeResources/PolicyStatementsByCategory/Ethics/DisclosureMedicalErrors.htm. Accessed June 25, 2005.

98 Jeremiah J, et al. Who leaves against medical advice? J Gen Intern Med 1995;10(7): 403–5.

outcome.[98-99] This anxiety reflects not only due to concern for the patient's well-being but also an awareness of the possibility of a malpractice claim in case patient undergoes some damage following discharge.

Finally, the physician must be aware that the ethical obligation to do what is in the patient's best interest is not terminated by the patient's refusal to follow the physician's best advice. Thus, if the patient cannot be dissuaded from leaving AMA, it is important to provide appropriate discharge instructions. The emergency physician should make a referral for further evaluation and treatment on an outpatient basis and strongly encourage follow-up if patient wishes to.

e. Good Samaritan laws

Few situations present such potential for conflict between ethical principles and legal concerns as when the emergency physician is in the position of the Good Samaritan. One's impulse, based on the ethical principle of beneficence, is to come to the aid of a person in distress.

f. Futile (nonbeneficial) care

The concept of medical futility has existed at least since the time of Hippocrates, whose writings suggested three major goals for the practitioner of

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99 Jefer EK. Against medical advice: part I, a review of the literature. Mil Med 1993;158(2): 69–73.

100 Schuster DP. Everything that should be done – not everything that can be done. Am Rev Re- spir Dis 1992;145:508–9.

101 Ardagh M. Futility has no utility in resuscitation medicine. J Med Ethics 2000;26:396–9.

medicine: cure, relief of suffering, and withholding treatment when the patient's condition cannot be expected to respond. [99-102.]

g. Defensive medicine versus stewardship

The ethical principle of stewardship holds that physicians have a duty not only to the individual patient but also to society as a whole. The physician should pursue the best interests of the patient and, at the same time, bear in mind the responsibility to use health care resources wisely.[103-109]

h.The role of the expert witness

Medical malpractice litigation is conducted by trial attorneys who typically have limited knowledge of the medical science underlying their clients' claims. Furthermore, their efforts to persuade a jury depend on the professional authority of physicians acting in the role of expert witness. When cases go to trial, the process of educating a lay jury about the medical issues involved, so that they are informed sufficiently to render a verdict, becomes a battle of the experts.

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[102] Golin CE, Wenger NS, Liu H, et al. A prospective study of patient-physician communication about resuscitation. J Am Geriatr Soc 2000;48:S52–60.

[103] Anderson RE. Billions for defense: the pervasive nature of defensive medicine. Arch Intern Med 1999;159:2399.

[104] ibid

[105] American College of Emergency Physicians. Code of ethics for emergency physicians. Avail- able at: http://www.acep.org/1,1118,0.html. Accessed February 14, 2005.

[106] Office of the Assistant Secretary for Planning and Evaluation, US Department of Health & Human Services. Addressing the new health care crisis: reforming the medical litigation sys- tem to improve the quality of health care 11(2003).

[107] Larkin GL, Weber JE, Moskop JC. Resource utilization in the emergency department: the duty of stewardship. J Emerg Med 1998;16:499–503.

[108] American College of Emergency Physicians. Expert witness guidelines for the specialty of emergency medicine. Available at: http//www.acep.org/1,560,0.html. Accessed February 14, 2005.

[109] Donald C. Austin, MD vs. American Association of Neurological Surgeons, 253 F.3d 967, 972–73 (7th Cir. 2001).

The responsibility of serving in the capacity of expert witness in a medical malpractice case brings with it a number of ethical demands[103].

- The expert witness should possess current experience and ongoing knowledge in the area in which he or she is asked to testify.
- The expert witness should be willing to submit the transcripts of depositions and testimony to peer review.
- It is unethical for an expert witness to accept compensation that is contingent on the outcome of litigation.
- The expert witness should not provide expert medical testimony that is false, misleading, or without medical foundation.

The key to this process is a thorough review of available and appropriate medical records and contemporaneous literature concerning the case being examined. After this process is completed, the expert's opinion should reflect the state of medical knowledge at the time of the incident. The expert witness should review the medical facts in a thorough, fair, and objective manner and should not exclude any relevant information to create a view favoring the plaintiff or the defendant[104-107].

Expert witnesses should be chosen on the basis of their experience in the area in which they are providing testimony and not solely on the basis of offices or positions held in medical specialty societies, unless such positions are material to the witness' expertise. An emergency physician should not engage in advertising or solicit employment as an expert witness where such

advertising or solicitation contains representations about the physician's qualifications, experience, or background that are false or deceptive[107-108].

i. Tort reform: getting it right

Most of the medical profession's efforts in the realm of tort reform have been directed toward reducing the number of medical malpractice claims lacking in merit and limiting payments for claims that are pressed successfully. However, it is clear that, from an ethical standpoint, reform should be directed toward getting it right, not simply reducing losses[109]. A fundamental requirement of the application of justice to the harms caused by medical malpractice is that all victims of medical malpractice should be compensated fairly, and those who have not truly been harmed or whose harm was not the result of negligence should be excluded.

A system is needed in which physicians and health care workers are encouraged to report medical errors; such errors are disclosed to patients and families; claims, whether resulting from such disclosure or arising independently, are evaluated by impartial panels of experts; and all patients harmed by medical negligence are compensated fairly.[109.] It is impossible to predict with any certainty how the cost of such a system, designed to achieve justice for all victims of medical negligence, would compare with that of the current system[110]. Thus, it would appear that the amount of money currently

[110] Encinosa WE, Hellinger FJ. Have state caps on malpractice awards increased the supply of physicians? Health A airs 2005 May 31.

being wasted could fairly compensate many more deserving patients[110-113]. Justice, quite arguably, is within our reach.

[111] Brennan TA, et al. Relation between negligent adverse events and the outcomes of medical malpractice litigation. N Engl J Med 1996;335(26):1963.

[112] Anderson RA. Defending the practice of medicine. Arch Intern Med 2004;164:1173–8.

[113] Tillinghast-Towers Perrin. US tort costs: 2003 update: trends and findings on the cost of the US tort system. Available at: http://www.towersperrin.com/ TILLINGHAST/ publications/ reports/2004_Tort_Costs_Update/Tort_Costs. Accessed February 13, 2005.

CHAPTER 4

LAW RELATING TO MEDICAL NEGLIGENCE

4.1 CONSTIUITIONAL ASPECTS

The Constitution of India not only provides for the health care of the people but also directs the State to take stringent measures to improve the condition of health care of the people. The Constitution provides a framework for the achievement of the objective laid down in the preamble and secure all its citizens equitable justice for all in the field of health.

The right to health has not been integrated directly into the Constitution of India. Only right to life which is related to right to health is guaranteed under the Constitution. The Supreme Court has interpreted the right to life as embracing the right to live with human dignity, which included the quality of life along with all the basic human needs such as food, clothing, shelter, safe drinking water, education and health care.[114-115]

In State of Punjab v. Mohinder Singh Chawla[116] it was declared that since the right to health was an integral part of the right to life the Govt has a constitutional obligation to provide health facilities[116]. Similarly in Mr: 'X' v. Hospital 'Z' the Supreme Court held that the right to life includes the right to

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[114] Article 21 of the Constitution, which declares, " No person shall be deprived of his life or personal liberty except according to the procedure established by low".

[115] Francis coralie Mullin v. The administration Union Territory of Delhi A.I.R. 1981 SC 746 at p.753.

[116] (1997) 2 SCC 8371.

lead a healthy life so as to enjoy all facilities of human body in their prime condition.[117]

In a similar view, in Chameli Singh v. State of U.P it was held that the right to life implies the right to food, water, decent environment, education, medical care and shelter. These are basic human rights known to any civilized society. The civil, political; social and cultural rights enshrined in the Constitution cannot be exercised without these basic rights.[118]

Part IV of the Indian Constitution deals with certain principles known as Directive Principles of State Policy. Although the Directive Principles are asserted to be "fundamental in the governance of the country", they are not legally enforceable. They are guidelines for creating a social order characterized by social, economic, and political justice, liberty, equality, and fraternity as enunciated in the Preamble. These principles are fundamental in the governance of the country and the State is under the duty to apply these principles while exercising its law making power. The following directives are of relevance to the concept of Right to Health.

Article 39: Certain principles of policy to be followed by the State:

This Article secures Health of the workers, men and women. It also mandates that children be given the opportunities and facilities to live in a Healthy manner with freedom and dignity and that childhood and youth are protected against exploitation. It proposes that the working class is important in

[117] A.I.R. 1999 SC 495
[118] A.I.R. 1996 SC 1051

nation building and therefore state government shall provide protection to their Health.

The court observed that:

"It is obvious that in civilised society the importance of child welfare cannot be overemphasised because the welfare of the entire community, its growth and development depends upon the Health and well being of its children. Children are a supremely important national asset and the future well being of the nation depends on how its children grow and develop."[119]

Further, In Sheela Barse V. Union of India, Supreme Court has held that "A child is a national asset and therefore, it is the duty of the State to look after the child with a view to ensuring full development of its Personality."[119]

Clause (f) was modified by the Constitution 42nd Amendment Act, 1976 with a view to emphasising the constructive role of the State with regard to children.

Article 42: Provision for just and humane conditions of work and maternity relief:

This Article states that the State shall make provision for securing just and humane conditions of work and maternity relief. In U.P.S.C. Board V. Harishankar[119], Supreme Court has held that Article 42 provides the basis of the larger body of labour law in India. Further referring to Article 42 and 43, the Supreme Court has emphasised that the Constitution expresses a deep

[119] Sheela Barse v. Union of India (1986) 3 SCC 596.

concern for the welfare of the workers. The Court may not enforce the Directive Principles as such, but they must interpret law to set goal out in the Directive Principles. In Bandhua Mukti Morcha V. Union of India[120], Bhagwati, J. observed: "This right to live with human dignity enshrined in Article 21 derives its life breath from the Directive Principles of State Policy and Particularly clauses (e) and (f) of Article 39 and Article 41 and 42." Since the Directive Principles of State Policy are not enforceable in a Court of law, it may not be possible to compel the State through judicial process to make provision by statutory enactment or executive fiat for ensuring these basic essentials which go on to ensure a life of human dignity".[120]

Article 47: Duty of the State to raise the level of nutrition and the standard of living and to improve public Health:

Article 47 enumerates that 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 medical purposes of intoxicating drinks and of drugs which are injurious to Health[121].

Article 47 is helpful for imposing stringent conditions on liquor trade with reference to Article 19(6). In Vincent Panikurlangara V. Union of India the Court stated that "maintenance and improvement of public Health have to rank high as these are indispensable to the very physical existence of the

[120] Bandhua Mukti Morcha v. Union of India (AIR 1984 SC 802).
[121] Vincent v. Union of India (AIR 1987 SC 990).

community and on the betterment of these depends, the building of the society of which the Constitution makers envisaged. Attending to public Health, in our opinion, therefore is of high priority perhaps the one at the top".[121]

Article 48-A: Protection and improvement of environment and safeguarding of forests and wildlife.

Article 48-A requires that, the State shall endeavour to protect and improve the environment and to safeguard the forests and wildlife of the country.

This article was inserted by the 42nd amendment Act 1976. It obligates the State to endeavour to protect and improve the environment and to safeguard the forest and wild life of the country. In M.C. Mehta V. Union of India, it was held that, "Art 39 (a), 47 and 48-A by themselves and collectively cast a duty on the State to secure the Health of the people, improve public Health and protect and improve the environment."[122]

The Supreme Court, in Paschim Banghakhet Mazdoor Samity and others v. State of West Bengal and another[122], while widening the scope of Art: 21 and dealing with the government responsibility to provide medical aid to every person in the country, held that in a welfare State, the primary duty of the government is to secure the welfare of the people. The Paschim Banga reiterates the position that the right to medical services is part of the right to life

[122] Mehta V. Union of India (1987) 4 SCC 463; MC Mehta v. Union of India (regarding emission standards for vehicles) (1999) 6 SCC 12.

and the State has a duty to provide it either through the State machinery or through the private sector.[123,124]

Later in Paramand Kattara V. Union of India the court made only a declaration that legal or procedural technicalities cannot stand in the way of the doctor providing emergency medical care to accident victims. Eventhough this decision does not impose any positive obligation on doctors of private hospital to provide medical treatment to accident victims; it was an effective decision for the enforcement of the right of patient[125].

In welfare State, it is the obligation of the State to ensure the creation and the sustenance of conditions (1996) 4 SCC Art 21 imposes an obligation on the state to safeguard the right to life of every person. Preservation of human life is thus of paramount importance.[125-129] The effective enforcement of right to health through writ jurisdiction is not at all accessible to common man because of expensive cost of litigation. At the same time it could not be implemented through the court as merely a Directive Principle of State Policy.[130] Right to life, which includes protection of the health and quality

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123 Paschim Banga Khet Mazdoor Samity v. State of West Bengal (AIR 1996 SC 2426 at 2429 para

124 State of Punjab v. Ram Lubhaya Bagga (1998) 4 SCC 117.

125 ESC Ltd V. Subhash Chandra Bose (1992) 1 SCC 441 at 462.

126 Death of 25 Chained Inmates in Asylum Fire in TN In re v. Union of India (2002) 3 SCC 31.

127 Supra note.75.

128 Vikram v. State of Bihar (AIR 1988 SC 1782).

129 (1995) 3 SCC 42

130 A.I.R. 1989 SC. 2039

medical aid, is a minimum requirement to enable a person to live with human dignity."[130-133]

Art: 47 of Indian Constitution "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. The Supreme court, while examining the issue of the Constitutional right to medical aid under Art: 21,41, and 47 of the Constitution of India in State of Punjab V. Ram Lubhaya Bagga[127], observed that the right of one person correlates with a duty upon another individual, employer, government or authority. Hence, the right of a citizen to live under Art: 21 is an obligation on the State. This obligation has been reinforced through Art: 47, as its primary duty. No doubt, the government is rendering this obligation through health centers, but to be more meaningful they must be within the reach the people.[127-133]

Every citizen of this welfare State looks towards the State to perform this obligation effectively in a number of ways, including by way of allocation of sufficient funds. State should evolve the necessary legal machinery for handling the issue relating to the matter of negligence or intentional negligence from the part of hospital authorities, doctors and accessory staff. These in turn will not only secure the rights of its citizen to their satisfaction but will benefit the State in achieving its social, political and economic goals.

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131 A.I.R. 1987 SC. 994

132 1989 AIR 2039, 1989 SCR (3) 997

133 People's Union for Civil Liberties v. Union of India (1997) 1 SCC 301

In addition to the Constitutional developments the international conventions and other obligations have a direct impact on the Indian health conditions, in view of India's commitments to abide by and implement the Treaty obligations and the ratifications made by it under Article 51 of the Constitution.[126-129]

4.2 FUNDAMENTAL DUTIES

PART- IV-A of Indian Constitution deals with fundamental duties of citizens.

Article 51- A: Fundamental duties:

It shall be the duty of every citizen of India-

To protect and improve the natural environment including forests, lakes, rivers and wild life, and to have compassion for living creatures. It shows that every citizen is under the fundamental duty to protect and improve natural environment since it is closely related to public Health.

4.3 CRIMINAL AND CIVIL LIABILITY IN MEDICAL NEGLIGENCE

Medical malpractise occurs when a physician fails to act as any reasonable physician would have acted under the same circumstances. While a doctor's failure to meet this standard 'negligence', the mere fact that the doctor was negligent does not necessarily result in liability. Technically unsuccessful surgery does not mean a breach of standard of care[134].

[134] Mello MM, Chandra A, Gawande AA, Studdert DM. National costs of the medical liability system. Health Aff (Millwood).2010;29:1569-1577

The term "medical negligence" refer to wrongful actions or omissions of professionals in the field of medicine, in pursuit of their profession, while dealing with patients. It is not a term defined or referred to anywhere in any of the enacted Indian laws[135].

The consequences of legally cognizable medical negligence can broadly be put into three categories: (i) Criminal liability, (ii) monetary liability, and (iii) disciplinary action

Criminal liability can be fastened pursuant to the provisions of the Indian Penal Code, ("IPC"), which are general in nature and do not provide specifically for "medical negligence." For instance, Section 304A of IPC (which deals with the death of a person by any rash or negligent act and leads to imprisonment up to 2 years) is used to deal with both cases of accidents caused due to rash and negligent motor vehicle driving and also medical negligence leading to the death of a patient. Similarly, other general provisions of IPC, such as Section 3374 (causing hurt) and 3385 (causing grievous hurt), are also often deployed in relation to medical negligence cases[135].

Civil liability, i.e., monetary compensation can be fastened under the general law by pursuing a remedy before appropriate civil court or consumer forums. An action seeking imposition of the civil liability on the erring medical professional is initiated by dependents of the deceased patient or by the patient himself (if alive) to seek compensation[135].

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[135] Jena AB, Seabury S, Lakdawalla D, Chandra A. Malpractice risk according to physician specialty. N Engl J Med. 2011;365:629-636. (Page No 136)

Another consequence of medical negligence could be in the form of imposition of penalties pursuant to disciplinary action. Professional misconduct by medical practitioners is governed by the Indian Medical Council (IMC) (Professional Conduct, Etiquette, and Ethics) Regulations, 2002, made under IMC Act, 1956[135].

Medical Council of India (MCI) and the appropriate State Medical Councils are empowered to take disciplinary action whereby the name of the practitioner could be removed forever or be suspended. Professional misconduct is, however, a broad term which may or may not include medical negligence within its fold.

The line between civil liability and criminal liability is thin, and no sufficiently good criteria have yet been devised by the Supreme Court providing any clear and lucid guidance. The Supreme Court in Dr. Suresh Gupta v. Govt. of NCT Delhi put the standard for fastening criminal liability on a high pedestal and required the medical negligence to be "gross" or "reckless."[133-135]

Mere lack of necessary care, attention, or skill was observed to be insufficient to hold one criminally liable for negligence. It was observed in Dr. Suresh Gupta that mere inadvertence or simply a want of a certain degree of

care might create civil liability but will not be sufficient to attract criminal liability[136].

In this case, a young man was stated to have died during the simple procedure for nasal deformity for "not introducing a cuffed endotracheal tube of proper size as to prevent aspiration of blood from the wound in the respiratory passage," and the prosecution under Section 304A IPC was quashed by the Supreme Court setting aside the order of the High Court which had declined to quash the prosecution. The soundness of the view of the Supreme Court was subsequently doubted considering that word "gross" is absent in Section 304A IPC and that different standards cannot be applied for actions of the negligence of doctors and others.

Consequently, the matter was placed for reconsideration before a bench of higher strength Three judge bench (bench strength in Dr. Suresh Gupta was two) in Jacob Mathew v. State of Punjab on a reconsideration endorsed the approach of high degree of negligence being the prerequisite for fastening criminal liability as adopted in Dr. Suresh Gupta, and it was observed that "In order to hold the existence of criminal rashness or criminal negligence, it shall have to be found out that the rashness was of such a degree as to amount to taking a hazard knowing that the hazard was of such a degree that injury was most likely imminent." Supreme Court observed that the subject of negligence in the context of medical profession necessarily calls for a treatment with a

[136] Rovit RL, Simon AS, Drew J, Murali R, Robb J. Neurosurgical experience with malpractice litigation: an analysis of closed claims against neurosurgeons in New York State, 1999 through 2003. J Neurosurg. 2007;106:1108-1114.

difference. In this case, an aged patient in an advanced stage of terminal cancer was experiencing breathing difficulties and the oxygen cylinder connected to the mouth of the patient was found to be empty. By the time replacement could be made, the patient had died. Supreme Court set aside the judgment of the High Court and held that the doctors could not be criminally prosecuted.[136-139]

It would not be surprising if different benches of the Supreme Court in the above facts were to arrive at different conclusions. High Courts in both of the above cases, i.e., Dr. Suresh Gupta and Jacob Mathew surely held views different from that of the Supreme Court. The abstract principles sometimes do pose difficulty in their application to facts, much like in the practice of medicine[136-139].

The criminal liability and civil liability are not exclusive remedies and for the same negligence, both actions may be available. "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," as the standard of care from a doctor. It has been held by the courts that in the cases of medical negligence, Bolam test is to be applied, i.e., "standard of the ordinary skilled man exercising and professing to have that special skill," and not of "the highest expert skill." This is applicable to both "diagnosis" and "treatment." It

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137 Jacob Mathew vs State Of Punjab & Anr on 5 August, 2005

138 (2004) 6 SCC 422

139 Epstein NE. It is easier to confuse a jury than convince a judge:the crisis in medical malpractice. Spine (Phila Pa 1976). 2002;27:2425-2430.

is noted that the Supreme Court has now observed the need to reconsider the parameters set down in Bolam test.[139-144]

Every hospital cannot be expected to have state of the art facilities and be fully equipped with the latest inventions and techniques. Sometimes, it becomes difficult to prove that certain equipment was generally available or not considering that there is no central or regional record of equipment used by medical professionals or hospitals.[126-127]

4.4 LIABILITY OF HEALTH PROFESSIONALS

a. Structure of Liability:

The legal principles which we have considered including the duty, standard of care and causation, in general apply to all health professionals irrespective of whether they work in private hospital or government run hospital or practice privately and independently.

The general practitioners, who are not employed by the state, are independent contractors. They render or provide primary health care for consideration or free of charge in case of charitable hospital. Yet, the general

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140 Epstein NE. A review of medicolegal malpractice suits involving cervical spine: what can we learn or change? J Spinal DisordTech. 2011;24:15-19.

141 Daniels AH, Ruttiman R, Eltorai AEM, DePasse JM, Brea BA,Palumbo MA. Malpractice litigation following spine surgery.J Neurosurg Spine. 2017;27:470-475.

142 Daniels EW, Gordon Z, French K, Ahn UM, Ahn NU. Review of medicolegal cases for cauda equina syndrome: what factors lead to an adverse outcome for the provider? Orthopedics. 2012;35:e414-e419.

143 Agarwal N, Gupta R, Agarwal P, et al. Descriptive analysis of state and federal spine surgery malpractice litigation in the UnitedStates. Spine (Phila Pa 1976). 2018;43:984-990.

144 Elsamadicy AA, Sergesketter AR, Frakes MD, Lad SP. Review of neurosurgery medical professional liability claims in the UnitedStates. Neurosurgery. 2018;83:997-1006.

principles of law governing the tortious liability apply to all the health carer. In other words, the Bolam test applies to health career.

The following tortuous liabilities can be classified into two categories, namely

(a) Individual liability and (b) Institutional or hospital liability.

Individual liability of the medical practitioner arises where the injury or damage is caused by the negligent conduct. The medical man is bound to compensate the victim or the family of the victim or the patient whose death is caused by his wrongful, neglect or default[145]. Even the executors, administrators, heirs or representatives of any diseased medical practitioners are liable to pay compensation for any wrong committed by the deceased in his life time and for which he would have been subjected to an action.

For the negligent acts like a medical professional, a hospital/health care centre or nursing home can also be made liable. It is called health 'corporate liability' or 'institutional' liability.

This kind of liability is of two folds namely, i) primary/direct liability and ii) vicarious liability.

b. Primary liability

Where the negligence claim is targeted at the organization or administration of the hospital, such claims are canvassed as direct liability claims against the hospitals.[146]

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[145] Section 14 of the Fatal Accidents Act 1855

[146] Supra note 37 at p. 47

Vicarious liability is an exception to normal legal principles under which individuals are usually liable only for their own actions and not for those of others. Where a health carer is held liable for the acts of another because of some relationship like employer and employee is called 'vicarious liability.'

c. Personal Liability of Doctors

Liability of doctor for negligence in failing to exercise proper care and diagnosis:[147]

In Wood Vs. Thurston a drunken man was brought to the casualty ward of a hospital with a history of having been run over by a motor lorry. The surgeon did not examine him as closely as the case required and even failed to use his stethoscope which could have enabled him to discover the patient's true condition. In addition to this, he permitted the patient to return home who after a few hours died. The surgeon was held guilty of negligence in failing to make a proper diagnosis. Edler vs. Greenwich vs. Deptford Hospital (1951) The Times March 7, the court observed that the doctor was liable for failure to diagnose appendicitis.

d. Liability of doctor for error of judgments:

The courts have adopted on approach of extreme caution in determining liability of a doctor for medical malfeasance. Mere ever of judgment does not necessarily impose civil liability on the practitioner unless it is shown that he has fallen short of reasonable medical care. It is argued that it will be doing

[147] 1953 C.L.C. 6871.

disservice to the community at large if the court were to impose liability on doctors and hospitals for everything that happens to go wrong[148,149]

In Dr. Ravindra Gupta and others vs. Ganga Devi and others (1993) 3 CPR 255 it was observed that a mistaken diagnosis is not necessarily a negligent diagnosis.[150]

Liability of a doctor for not advising the patient to approach a better equipped hospital:

In Ram Biharilal vs. Shrivastava the operation theatre was under repair. There were no facilities for oxygen and blood transfusions, there was no anaesthetist and some life saving drugs was not available. Pipettes (tubes) for testing blood were broken, the saline apparatus was not in order and there were only two staff nurses for a 28 bed hospital.

In these circumstances, the court observed that the doctor should not have undertaken such a major operation in a hospital, which was lacking basic facilities. He should have advised the petitioner to approach another hospital which had all the facilities including specialists. The doctor, therefore, failed in his duty of care in undertaking the operation without taking necessary precautions.[151]

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148 Lord Denning, in Roe vs. Ministry of Health 1954 All ER 131.
149 AIR 1969 SC 128.
150 1976 78 D.L.R. (3d) 588
151 AIR 1985 MP 150

4.5 INSTITUTIONAL LIABILITY

In Hillyer Vs. Governors of St. Bartholomew's Hospital the question arose for the consideration of the court was whether the hospital was liable primarily for the injury caused to the patient by the surgeons and anaesthetist during the course of operation. It was held that the surgeons and anaesthetists were not servants as they are professionals and not bound by the directions as to the manner of performance of their work, therefore, as regards these professionals, hospital does not undertake to treat the patients through the agency of the surgeon or anaesthetist, but to procure the services of the surgeon and the anaesthetist.

Only the duty undertaken by the hospital is to exercise due care and skill in selecting them and not to ensure that they would not be negligent in treatment. This case makes it clear that the hospital owes a duty to exercise due care in the selection and appointment of its staff including the consulting doctors/surgeons. It shows the primary liability of the hospital cannot be linked with the persons exercising professional skill and care, rather primary liability is limited to secure the services of the health professionals, and provide provisions of proper facilities and appliances.[152]

[152] (2004) 6 SCC 422

4.6 VICARIOUS LIABILITY

A hospital can be held vicariously liable on numerous grounds on different occasions. Several High Court Judgments have held hospitals vicariously liable for damages caused to the patients by negligent act of their staff. [153-162]

In one judgment of the Kerala High Court in Joseph @ Pappachan V. Dr. George Moonjerly [1994 (1) KLJ 782 (Ker. HC)], in support of the following effect stated that "persons who run hospital are in law under the same duty as the humblest doctor: whenever they accept a patient for treatment, they must use reasonable care and skill to ease him of his ailment". The hospital authorities cannot, of course, do it by themselves; they have no ears to listen to the stethoscope, and no hands to hold the surgeon's scalpel. They must do it by the staff which they employ; and if their staffs are negligent in giving treatment, they are just as liable for that negligence as anyone else who employs other to do his duties for him.

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153 (1909) 2 KB 820, cited in Bournhill, Mobilia and Clifford E. Elias, "The Law of Medical Liability", the West Publishing Company, Minn, 1995, p. 192

154 Ramaswamy Iyer's Law of Torts 8th edition P. 521

155 (1942) 2 KD 293; (1942) 2 All ER 237.

156 1951 All ER 574.

157 (Trehan S.P. and Debashish Sankhari, Medical Professional Patient and the Law, TILEM, NLSIU (2nd edition, 2002) p. 45).

158 (1954) 2 QB 66.

159 AIR 1998 SC 189; (1998) 4 SCC 39

160 (1998) 1 CPR 39 (Ker).

161 (1998) 1 CPR 165 (Cal)

162 In Sharifabi I. Syed Vs Bombay Hospital and Medical Research Centre 1998 CCJ 1106 (Mah) the hospital was vicariously held liable to pay compensation for suffering of the patient due to wrong report of MRI.

In another judgment by the Madras High Court in Aparna Dutta v. Apollo Hospitals Enterprises Ltd. [2002 ACJ 954 (Mad. HC)], it was held that it was the hospital that was offering the medical services. The terms under which the hospital employs the doctors and surgeons are between them but because of this it cannot be stated that the hospital cannot be held liable so far as third party patients are concerned. It is expected from the hospital, to provide such a medical service and in case where there is deficiency of service or in cases, where the operation has been done negligently without bestowing normal care and caution, the hospital also must be held liable and it cannot be allowed to escape from the liability by stating that there is no master-servant relationship between the hospital, and the surgeon who performed the operation.

The hospital is liable in case of established negligence and it is no more a defense to say that the surgeon is not a servant employed by the hospital, etc. In another judgment by the National Consumer Redressal Commission in case of Smt. Rekha Gupta V. Bombay Hospital Trust & Anr.[2003 (2) CPJ 160 (NCDRC)], related to negligence of a consultant doctor, the Commission observed that the hospital who employed all of them whatever the rules were, has to own up for the conduct of its employees. It cannot escape liability by mere statement that it only provided infrastructural facilities, services of nursing staff, supporting staff and technicians and that it cannot suo moto perform or recommend any operation/ amputation. Any bill including consultant doctor's consultation fees are raised by the hospital on the patient

and it deducts 20% commission while remitting fees to the consultant. Whatever be the outcome of the case, hospital cannot disown their responsibility on these superficial grounds.

The hospital authorities are not only responsible for their nursing and other staff, doctors, etc. but also for the anesthetists and surgeons, who practice independently but admit/ operate a case. It does not matter whether they are permanent or temporary, resident or visiting consultants, whole or part time. The hospital authorities are usually held liable for the negligence occurring at the level of any of such personnel. Where an operation is being performed in a hospital by a consultant surgeon who was not in employment of the hospital and negligence occurred, it has been held that it was the hospital that was offering medical services. The terms under which the defendant hospital employs the doctors and surgeons are between them but because of this it cannot be stated that the hospital cannot be held liable so far as third party patients are concerned. The patients go and get themselves admitted in the hospital relying on the hospital to give them medical services for which they pay the necessary fee. It is expected from the hospital, to provide such medical service and in case where there is deficiency of service or in cases like this where the operation has been done negligently without bestowing normal care and caution, the hospital must also be held liable.

In State of Rajasthan Vs. Vidyavati, the Supreme Court observed that the State is vicariously liable for the tortious acts of its servants or agents which are not committed in the exercise of its sovereign functions. The issue is,

whether providing or undertaking medical care through the primary health centre constitutes sovereign function of the state[163]. The Supreme Court in Achutrao Haribhau Khodwa Vs. State of Maharashtra[164] While overruling the judgment of the High Court makes it clear that the high court has erred in arriving at conclusion that maintaining and running a hospital was an exercise of the state's sovereign function. Disapproving this line of thought, the Supreme Court pointed out that running a hospital is a welfare activity undertaken by the government, but is not exclusive function or activity of the government so as to be classified as one which could be regarded as being sovereign power of the state. The state would be vicariously liable for the damages payable on accounts of negligence of its doctors and other employees. Applying this principle, the Supreme Court held the state of Haryana liable for negligence of the doctor in a Government Hospital in performance of sterilization operation resulting in birth of an unwanted child.

Like a private employer, the state is liable to pay compensation for negligence of its medical practitioners who have committed the wrong in the course of their employment as a public servant. However, the state is not vicariously liable for negligence committed by Medical Practitioners of Government hospitals in course of their private practice or beyond the course of their employment as public officers.

The court referred its earlier decision in Kasturilal's case (AIR 1965 SC 1039) wherein it was noticed that in pursuit of the welfare ideal, the

[163] AIR 1962 SC 933.

[164] (1996) 2 SCC 634; (1996) 4 CTJ 950 (SC)

government may enter into many commercial and other activities which have no relation to the traditional concept of government activity in exercise of its sovereign function, similarly, running of a hospital, where the members of the general public can come for treatment, cannot be regarded as being an activity having a sovereign character.[165-166]

4.7 LIABILITY OF DOCTORS / HOSPITALS IN LAW OF CONTRACT

Actions of medical malpractice are primarily actions based on the tort of negligence. This is because for majority patients there is weak factual basis in contract. Most patients receive treatment in the state run hospitals and as such there is no direct contract between the government hospital patient and his treating doctor. Whereas, when a patient approaches a private health professional for medical care, the relationship between the hospital and the patient is one of contractual in nature. The private patient is entitled to sue his medical practitioner concurrently in tort and contract, although has not entered into a strictly defined contract with expressly written terms governing the agreement for medical case. It has been suggested that there is a contract between a patient and his practitioner even when the medical care is availed of the state run hospital.[167]

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165 Id

166 AIR 1965 SC 1039

167 Rodney Nelson-Jones and Frank Burton, Medical Negligence, Case Law, (2nd Edition 1995) Butterworths, p. 26).

Unlike the Constitutional law and law of Torts, the law of Contract is based upon rules of agreement between the parties for consideration.[168-171]

The scope of liability of the health professional for the breach contractual is very limited in comparing with law of torts.

The suit is not maintainable unless the plaintiff proves that he availed of service of the defendant health carer for consideration. No suit can be brought in the civil court for remedies under the law of contract without hiring the service for consideration. Any patient or his legal representative is competent to sue the professional. The procedure followed in Karnataka shows that the suit value of which less than 25,000/- shall be filed in the court of small causes within whose local limit the cause of has arisen. Where the value of the suit exceeds Rs.25,000 but does not exceed Rs.50,000 falls within the jurisdiction of the civil court (junior division). If the value exceeds Rs.50,000/- the suit should be filed in the civil court senior division. Appeal lies to the District Court from the order passed by the trial court. The Supreme Court is the highest appellate tribunal in the hierarchy of the civil court under the law of contract.

4.8 ACTION TAKEN AGAINST HEALTH CARE PROFESSIONALS IN MEDICAL NEGLIGENCE CASES

Health care professionals have a chance to face the below mentioned actions if such a case is filed against medical negligence.

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168 Id.

169 (1994) 112 D.C.R. (4th) 257 (Out. Ct., Gen. Div.)

170 Reynolds vs The Health First Medical Group (2000) Llyod's Rep. Med.240.

171 Consumer Unity Trust Society vs State of Rajastan CPR 241 1991 (NCDRC).

a) **Compensatory action:** seeking monetary compensation before the Civil Courts, High Court or the Consumer Dispute Redressal Forum under the Constitutional Law, Law of Torts/Law of Contract and the Consumer Protection Act.

b) **Punitive action:** filing a criminal complaint against the doctor under the Indian Penal Code.

c) **Disciplinary action:** moving the professional bodies like Indian Medical Council/State Medical Council seeking disciplinary action against the health care provider concerned.

d) **Recommendatory action:** lodging complaint before the National/State Human Rights Commission seeking compensation.

4.9 PATIENT RIGHT TO MOVE THE APEX COURT AND HIGH COURTS

Any person whose rights have been infringed can move the Supreme Court under article 32 of the Constitution.[172-178] The court has liberalized traditional rule that "only a person who has suffered injury by reason of his legal right or interest is entitled to seek judicial redress.

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[172] Adopted from Legal frame work for health care in India, edited by Prof. S.K. Varma, ILI, 2002, Lexis New Butterworths, New Delhi, P. 13

[173] Adopted from Legal frame work for health care in India, edited by Prof. S.K. Varma, ILI, 2002, Lexis New Butterworths, New Delhi, P. 13

[174] It was in Rudul Shah V State of Bihar (AIR 1983 SC 1086) in which the Supreme Court for the first time set up an important landmark in Indian Human Rights Jurisprudence by articulating compensatory relief for infraction of Article 21. Since then the court started awarding monetary compensation as and when the conscience of the court was shocked.

[175] AIR 1998 Journal 154

[176] D.K. Basu V State of Best Bengal AIR SC 610 at 625

[177] Article 32 (2) of the Constitution of India.

[178] Article 226 of the Constitution.

The Supreme Court has enlarged the rights of citizens under which any person or group of person or public spiritual individual may move the Supreme Court or High Court for the enforcement of fundamental rights of people who are unable to approach the court due to their illiteracy or social or economic condition.

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

Similarly, one can move the High Court by appropriate proceedings for the enforcement of the rights conferred and guaranteed under the constitution and other laws.

4.10 GUIDELINES FOR DOCTORS, WHEN AN INJURED PERSON APPROACHES HIM

i) Duty of a doctor when an injured person approaches him:

Whenever, a medical man is approached by an injured person, and if he finds that whatever assistance he could give is not really sufficient to save the life of the person, but some better assistance is necessary, it is the duty of the man in the medical profession to see that the person reaches the proper expert as early as possible.[179]

[179] AIR 1989 SC 2039

ii) Legal protection to Medical practitioners:

Where a doctor proceeds with treatment to an injured who appears or is brought before him, does not amount to breach of the law of the land. The court has attempted to resolve conflict of duties of doctors and police officers pertaining to investigation of the case. Investigation agency cannot supercede the professional obligation of doctors[179].

iii) No obstacle on medical practitioners from attending injured persons:

There is no legal bar or impediment on the part of medical professional, when he is called upon to attend an injured person needing his medical assistance immediately. The sincere attempt to protect the life of person is the top priority of not only medical professional but also of the police, or any other citizen who happens to be connected with the matter, or who happens to notice such an incident[178].

iv) Prevent harassment of doctors:

Unnecessary harassment of the members of the medical professional should be avoided. They should not be called to the police station to unnecessarily interrogation or for the sake of formalities. The trial courts should not summon medical men unless the evidence is necessary, even if he is summoned, attempt should be made to see that the men in this profession are not made to wait and waste time unnecessarily, the law courts have to respect for the men in the medical profession. The Supreme Court attempts to remove apprehension that prevents medical men from discharging their duty to a suffering person.

4.11 DAMAGES AND AWARD OF COMPENSATION

Once the plaintiff has proved that breach of duty and has shown that damage has resulted from that breach, the court will proceed with examining the award of damages. However, not every type of loss and expense will be recoverable. If the court arrives at the conclusion that the risk of damage which has occurred was too remote and it can not reasonably foreseeable, such damages are not recoverable. The assessment of damages is based upon the principles and methods of calculation evolved in the laws of contract and tort. However, there is vital difference in the principles applied to the assessment of damages in actions for tortious or contractual liability.

Types of damages[180,181]

In a case for personal injuries, damages are divided into two categories:

i) Special damages and

ii) General damages

Where inexact or unliquidated losses are compensated by an award of damages what is known as 'general damages.' This includes the non-pecuniary losses which are compensated under the heads of pain and suffering, loss

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[180] In Ballantine vs Newalls Company Limited (2001)1 ICR 25, it was held that a person who suffers mental anguish can recover compensation. Similarly, a person who is physically or mentally incapacitated by his injuries is entitled to be compensated for the anguish (H West vs Shephard (1964) AC 326).

[181] In assessing damage for the loss of amenities, the court generally take into the consideration: dependence of the injured on the help of other in his daily life (Heaps vs Perrite Limited (1937)2 All ER 60), the inability to lookafter (Rourke vs Bouton, The Times, 23rd June 1982), sexual impotency (Cook vs JL Kier (1970)1 WLR 774), inability to lead life which injured used to lead (Owen vs Sykes (1936)1 KB 192) and loss of prospects of marriage (Harris vs Harris (1973)1 Llyod's Rep 445).

amenity, future losses of income or profits and future expenses such as care and accommodation[182-183].

Whereas, 'Special damages' are those losses and expenses that have actually been incurred and which can be calculated with reasonable precision at the date of trial, they normally comprises specific losses of income such as loss of earnings or profits which arise as a result of the plaintiff being unable to work because of the injury and also specific expenses that have been incurred because of the tort or breach such as medical expenses, travel expenses, the cost of nursing care and attention. It has been suggested that classification of damages are important for pleading and procedural purposes and for the purpose of determining the appropriate rate of interest only.

iii) <u>Aggravated and exemplary damages:</u> Often a question which arises in the issue of medical negligence is, whether the court can award aggravated and exemplary damages for the injuries caused by the doctor's conduct. Where the conduct of the defendant is so outrageous and motivated by malice, additional compensation of what is known as aggravated damages can be awarded.[184]

After the emergence of the consumer protection act, 1986, the consumer can seek remedy by filing a simple complaint against the professional for monetary compensation in the consumer forum. Therefore, it is appropriate to

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182 In Nutbrown vs Sheffield Health Authroity (1993)4 Med. LR 187, the court awarded damaged on basis of the age and future prospects of the plaintiff.

183 In British Transport Commission vs Gourley (1956) A.C. 185, it was viewed that the injured claimant is entitled to recover damages in respect of loss of wages, salaries and fees as result of incident.

184 In Cutter vs Vauxhall Motors Limited (1971)1 QB 418, it was observed that the plaintiff was entitled to recover his medical and other expenses such as traveling costs, accommodation charges etc., Rialas vs Mitchell, The Times, July 17, 1984, the court held that medical and other expenses is part of the special damages.

examine the accountability of the medical professional under the Consumer Protect Act 1986.

4.12 CONSUMER PROTECTION ACT 1986

Patient as consumer[185-197]

In order to comply with the definition of 'consumer,' a person should have hired or availed of any services for a consideration. The element of consideration serves as a test to determine whether a patient is a consumer or not. Although the question of consideration constitutes an important criterion, nowhere in the Act, the term has been defined.

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185 See section 4 (1) of the CPA 1986.

186 Dr. Baidyanath Chaudhary, Medical Negligence- Tortious liability and the recent trends in India, CILI 2002, Vol. XV, p. 149)

187 Sudharani Srivastava, Consumer Protection and Medical Profession, AIR 1995, Journal p. 155

188 In Dr. A.S. Chandra vs. Union of India, a Division Bench of the High Court held that the persons availing of medical services for consideration in private practitioners, private hospitals and nursing homes are 'consumers'. However, a Division Bench of the Madras High Court has taken a different view in Dr. Subramanian vs. Kumaraswamy where it had been held that the services rendered to a patient by a medical practitioner or by a hospital by way of diagnosis and treatment, both medicinal and surgical, cannot be considered to be a 'consumer' within the meaning of Section 2(1)(d) of the Act.

189 (1992) 1 Andhra Law Time 713.

190 B. Shekar Hedge vs. Dr. Sudharshan Bhattacharya & another, (Dr. Neeraj Nagpal, Compendium of CPA Medical judgment (1st edition 1996) Vol. 1, p. 93); Consumer Education and Research Society vs. Dr. Ratila B. Patel (Ibid), the State Commission of Gujarat has taken the view that the surgeon and the Anaesthetist having been rendering "personal service," Commission has no jurisdiction to entertain any complaint against the category of such persons

Saraf D.N, Law of Consumer Protection in India, 1990 p.136.

191 Sowbhagya Prasad vs. State of Karnataka (1994) (1) CPR 140) the State Commission dismissed complaint filed against the governmental and doctor on the ground that service rendered in the government hospital free of charge was not a service

192 1992 (1) CPR 44.

193 (1992) 11 CRR 155

194 B.S. Heggade vs. Sudhansu Bhattacharya (1993) 111 CPJ 388 (NC).

195 AIR 1992 Journal 151

196 1996 JILI, Vol. 3 P. 384.

197 1996 SCJ Vol. 1, p. 16.

The absence of definition give rises an occasion to argue whether or not the consideration so vital for invoking the jurisdiction of the consumer forum. The literal interpretation of the definition shows that a person who wants to fall within the definition must satisfy three conditions.

A) The service must be hired by him;

B) The service should have been rendered to him;

C) For hiring service, he must have paid or promised to pay consideration

If services are rendered free of charge, it cannot be hire. If a patient gets free medical treatment in a governmental hospital or in any charitable hospital, without payment, is not a 'consumer.'

On the other hand if he obtains services or avails of medical facilities on payment basis in a private hospital or nursing home or clinic whether run by the Government or charitable institute, he is a 'consumer,' and therefore can invoke remedies provided in the Act by lodging a complaint before the appropriate forum. [198]

The implication of the National Commission emerges as medical services are of two folds namely,[198]

a) Services rendered by government hospitals, doctors, nursing home and dispensaries and

[198] B.C. Joshi vs. Dr. Sandeep Kumar & others (2002) 2 CPJ 125 where the state commission dismissed the complaint alleging negligence in treatment of a child in a government hospital free of charge; Smt. Vinod Kumari Srinivastava vs. Hindustan Aeronautics Ltd and another (1 (2003) CPJ 246), the State Commission observed that as no consideration is charged from patient for the medical services by the government dispensary, the complainant could not be a consumer in the CP Act.

b) Services rendered by private hospitals, practitioners and nursing homes.

Services rendered by government hospitals

The decision of the National Commission was vehemently criticized by the consumer activists who pointed out that in a socialist state, services are rendered by the state out of the resources collected from the people, if according to the constitution India is a socialist state, the people availing of services provided by the state be considered as services hiring for consideration and not the free of charge under the CP Act or else, it would be denial of the very foundation of the constitutional philosophy.[198-199] If a patient approaches a government hospital and gets wrong treatment or sustain injury due to the negligence of the doctor, no complaint can be made, because service is provided free of charge.

Services rendered by private medical practitioners and hospitals

Where a doctor makes available his services to potential users for a consideration, the service will come under the purview of the Act; it is not a contract of personal service. In Arvind Kumar Himatlal Shah Vs. Bombay Hospital Trust a complaint was lodged against the Hospital regarding carelessness and negligence while treating a patient. It was alleged that after the operation, the wound was continually bleeding; no senior doctor attended upon him, as a result of continuance bleeding the patient had died. The Commission that accepted the complaint directed the opposition party to pay

[199] Sowbhagya Prasad vs. State of Karnataka (1994) (1) CPR 140) the State Commission dismissed complaint filed against the governmental and doctor on the ground that service rendered in the government hospital free of charge was not a service

compensation for deficiency in rendering service. However, the question is whether the fee paid to a medical practitioner for operation includes post-operative care also? It has been held that "in fact fees paid to a medical practitioner for operation included post-operative care"[182-184].

It is now crystal clear that, according to the consumer forums, the services rendered by the private medical practitioners, hospitals and nursing homes are services within the meaning of the service under section 2(1)(o) of the Act and they are not services rendered under the contact of personal service but are services of professional nature.

Service for consideration:

Service rendered to a patient by a medical practitioner (except where the doctor render service free of charge to every patient or under a contract of personal service) by way of consultation, diagnosis or treatment, with medicinal and surgical, would fall within the ambit of 'service' as defined in section 2(1) (o) of the Act. [200,201]

Contract of personal service and contract for personal service. [202]

A 'contact of personal service' has to be distinguished from a 'contract for personal service.' 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

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200 Pravin Sharma vs. State of Punjab, Dr. Thirtha Goyal, 11 (1997) CPJ 571

201 Shashikala vs. Command Hospital (Air Force) and Others (2005)2 CPJ

202 Frankline CA, Modi's Medical Jurisprudence and Toxicology, (ed.) Tripathi (p) Ltd. 1988, p. 503.

'contract of personal service.[186-189] Such service is service rendered under a 'contract for personal service' and is not covered by exclusionary clause of the definition of 'service' contained in section 2(1)(c)of the Act.[189-193]

Service rendered free of charge:

Service rendered free of charge by a medical practitioner attached to 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[189-193].

Free service rendered at Non-government hospital:

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 taken amount for registration purpose only at the hospital favoring home would not alter the position.[189]

Service for charge at Non-government hospital

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.[190]

Service rendered free of charge and for charge at Non-governmental hospital:

Service rendered at a non-government hospital/nursing home where charges are required to be paid by persons who are in a position to pay and persons who cannot afford to pay are rendered service free of charge would fall within the ambit of the expression 'service' as defined in section 2(1) (o) of the Act irrespective of the fact that the service is rendered free of charge to persons who are not in a position to pay for such services. Free service would also be "service" and the recipient a "consumer" under the Act.[191]

Free service at Government hospital:

Service rendered at a Government hospital / health centre / dispensing 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 would not alter the position.

Free service and service for charges at Government hospital:

Service rendered at a government hospital/health centre/dispensary where services are rendered on payment of charges and also rendered free of charge to other persons availing such services would fall within the ambit of the expression 'service' as defined in section 2(1)(o) of the Act irrespective of the fact that the service is rendered free of charge to persons who do not pay for such service. Free service would also be "service" and the recipient a "consumer" under the Act.[192]

Free service upon insurance policy:

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 on 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' on defined in section 2(1) (o) of the Act.

Implications of the ruling

For the purpose of applicability of the Act, medical practitioners, government hospitals/nursing homes and private hospitals/nursing homes can be broadly classified into three categories:[185-199]

a) Where services are rendered free of charge to everybody availing the said services.

b) Where charges are required to be paid by everyone availing the services and

c) Where charges are required to be paid by persons availing services but some persons who cannot afford to pay are rendered service free of charges.

No difficulty exist in respect of first two categories, because, doctors and hospitals who render service without any charge whatsoever to every person availing service would not fall within the ambit of the 'service' u/s 2(1)(o) of the Act. So far as second category concerned, wherein the service is rendered on payment basis to all the persons, they would clearly fall within the ambit of section 2(1)(o) of the Act. The third category of doctors and hospitals

do provide free service to some of the patients but the bulk of the service is rendered to the patients on payment basis.

So far as patients are concerned, the ruling implies/aims at classification of patients into (a) paying patients, (b) non-paying patients.

The patients of the first category are consumers, in the event of any deficiency in the performance of medical service, the aggrieved party can invoke the remedies provided under the Act by filing a complaint before the consumer forum having jurisdiction to grant relief. Whereas, the patients of second category (except the patient of the third category of hospitals) are not consumers, for the obvious reason of availing services free of charge. It has been criticized that if a patient goes to a government hospital or charitable hospital or even a private hospital where no fee is charged and sustains injury due to the wrong treatment or negligence of the hospital/doctor no complaint can be made. The consumer forum cannot entertain a complaint against the government hospital and the hospital which provides free service to the people.

Does it mean where there is charity, there can be no negligence or no accountability for negligence under the CPA 1986, are the lives of crores of people who cannot afford expensive treatment at the mercy of charitable or government hospitals or dispensaries have no meaning?

The SC observation goes to show that a service is not a service if it is given free of cost. This is against the general notion that medical services are whether money is paid or not. All doctors, including those in government or charitable hospitals must be sued for compensation for injury caused by

negligence. In the Law of Torts, the hospitals run by state are vicariously liable for the act of doctors, in the same way; hospitals should be made amenable to the consumer forum irrespective of the element consideration. It would be a violation of the right to life if law gives licence to doctors to indulge in negligence with no liability for injuries caused while discharging free services.[203-205]

Immunity of Government Doctors from the judicial scrutiny

Army doctors and hospital:

It was argued that the complainant's wife died on account of negligence in the treatment of his wife who suffered burn injuries. The opposite parties who are army officers employed in the Military hospital as doctors contended that their service was not service as they did not charges fee on the patient, the National Commission held that the complainant was not a consumer and the hospital where the deceased patient got treatment rendering service free of charge would not mean service within the meaning of clause (c) of section 2(1) of the Act. No consideration paid by the petitioner-complainant for the treatment rendered to his wife in the military hospital. Hence the CP Act is not applicable.[206]

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[203] AIR 1992 Journal 151

[204] 1996 JILI, Vol. 3 P. 384.

[205] 1996 SCJ Vol. 1, p. 16.

[206] B.C. Joshi vs. Dr. Sandeep Kumar & others (2002) 2 CPJ 125 where the state commission dismissed the complaint alleging negligence in treatment of a child in a government hospital free of charge; Smt. Vinod Kumari Srinivastava vs. Hindustan Aeronautics Ltd and another (1 (2003) CPJ 246), the State Commission observed that as no consideration is charged from patient for the medical services by the government dispensary, the complainant could not be a consumer in the CP Act.

No action against Government doctor in certain specific circumstances

The patient was operated by a doctor in government service in a private nursing home run by him developed complications. The complainant lodged a complaint requesting departmental action against the doctor. The commission dismissed the complainant on the ground that action against the government doctor not within the jurisdiction of the consumer court and advised the complainant to seek remedy before a civil court.[207-208]

Civil Vs Criminal Negligence And Consumer Protection Act

Hospitals in India may be held liable for their services individually or vicariously. They can be charged with negligence and sued either in criminal/ civil courts or Consumer Courts. As litigations usually take a long time to reach their logical end in civil courts, medical services have been brought under the purview of Consumer Protection Act,1986 wherein the complainant can be granted compensation for deficiency in services within a stipulated time of 90 - 150 days. Cases, which do not come under the purview of Consumer Protection Act, 1986 (e.g., cases where treatment is routinely provided free of cost at non-government or government hospitals, health centers, dispensaries or nursing homes, etc.) can be taken up with criminal courts where the health care provider can be charged under Section 304-A IPC 4 for causing damages amounting to rash and negligent act or in Civil Courts where compensation is sought in lieu of the damage suffered, as the case may be.

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[207] Pravin Sharma vs. State of Punjab, Dr. Thirtha Goyal, 11 (1997) CPJ 571

[208] Shashikala vs. Command Hospital (Air Force) and Others (2005)2 CPJ

However, in some case the courts use the principle of "ipsa loquitur" which means things speak for itself. In such a scenario, it is presumed that the medical professional has acted beneath the set standard of care causing negligence. Under this principle it is presumed that the injury could not have been caused from anything but the negligence on part of the medical professional. In practice, the use of this principle by the judge would mean that the negligence has already ensued. Here the burden shifts onto the doctor to prove the case otherwise. Few examples are leaving an object inside the patient's body or operating the wrong patient.

Civil liability under Consumer Forum

An aggrieved person can approach the consumer courts to file a case against the accused person and the hospital. In Indian Medical Association vs. V.P. Santha6 the Hon'ble Supreme Court observed that the medical practitioners are covered under the Consumer Protection Act, 1986 and the medical services rendered by them should be treated as services under section 2(1) (o) of the Consumer Protection Act, 1986. Similarly under the new Consumer Protection Act, 2019, the medical services shall fall under the ambit of services as mentioned in section 2(42) of the new Act. Any matter in medical negligence on the part of the service provider will be considered as deficiency under section 42(11) of the new Consumer Protection Act, 2019.

Any aggrieved person can claim damages for medical negligence against a doctor or a hospital. Section 69(1) of the Consumer Protection Act,

2019 lays down the time limit within which a complaint for medical negligence must be filed as 2 years from the date of injury.

4.13 ACCOUNTABILITY OF MEDICAL PRACTITIONERS THROUGH PROFESSIONAL SUPREME BODIES

Medical practitioner includes practitioner of allopathic, Ayurveda and Unani, Dental, Physiotherapy, etc, medicine. Each branch of medical system is regulated by its own legislative enactment, for e.g. Allopathic practitioners are governed by the Indian Medical council Act 1956, similarly, dentists are by the Dental Council Act 1948, Homeopathic practitioners are by the Homeopathic Central Council Act 1973. These statutes provide for the establishment of medical councils at the national and states levels and confer them the authority to regulate medical education, registration of doctors and behavior of the members through the formulation of code of medical ethics.

4.14 THE INDIAN MEDICAL COUNCIL ACT 1956

In India owing to the prevalent ayurvedic and Unani systems, no medical act had been passed to control or restrict the medical practices. In 1916, the Government of India passed the Indian Medical Degrees Act to regulate the grant of titles implying qualification in Western Medical Science and to restrain the assumption and use by unqualified persons. [209-213] Within few years, the State Governments created medical councils in Maharashtra,

[209] Frankline CA, Modi's Medical Jurisprudence and Toxicology, (ed.) Tripathi (p) Ltd. 1988, p. 503.

[210] Id

[211] Section 12 of IMCA 1956.

[212] Section 19A, IMCA 1956

[213] Section 20A of IMCA 1956.

Gujarat, Madras, Bihar, Punjab and few other states by passing the Medical Act for registration of medical practitioners and supervision of medical education in their own states. However, registration was not compulsory under different state medical council acts except Bombay Medical Practitioners Act, 1936.

In the year 1933, the Indian Legislative Assembly passed an Act to be known as the Indian Medical Council Act which was repealed by the present Act of 1956. The Act of 1956 provides for reconstitution of the Medical Council of India, the maintenance of a medical register for India and matters incidental thereto. The Act empowers the Central Government to constitute a medical council, the membership of which is inter-alia, of persons to be selected by the agencies specified in Section 3 of the Act and the manner specified therein. It empowers the Medical Council to grant recognition to medical degrees granted by universities or medical institutions in India and such other qualifications granted by medical institutions in foreign countries. The Council prescribes the minimum standards of medical education required for granting recognition to the degrees awarded by Universities in India, prescribesstandards of professional conduct, etiquette and a code of ethics for medical practitioners and prescribes eligibility requirements to be a medical practitioner[209].

Disciplinary Action

Medical councils have the disciplinary control over the medical practitioners.[214-217] They have the power to remove the names of medical practitioners permanently or for a specific period from the medical registers when after due inquiry they are found to have been guilty of serious professional misconduct. There are two grounds on which the council may initiate disciplinary against any medical practitioner namely(a) conviction of any offence by a court of law and (b) guilty of professional misconduct. Any conduct of the practitioner which brings in disgraceful to the professional status what is known as "serious professional misconduct," for e.g. adultery or improper conduct or association with a patient, conviction by a court of law for offences involving moral turpitude, issuing false certificates, reports and other documents; issuing certificate of efficiency in modern medicine to unqualified person or non-medical person; performing an abortion or illegal operation for which there is no medical, surgical or psychological indication; contravening the provisions of the Drugs Act and regulation made thereunder; using touts or agents for procuring patients; publication of identity of a patient without his permission; performing an operation which results in sterility, without obtaining the written consent of patient/relative and refusing on religious grounds alone to extend medical assistance etc. If any one is found guilty of

[214] Section 14, 15 and 16 of IMCA 1956.

[215] Narayana Reddy KS, Essentials of Forensic Medicine and Toxicology, (15th Ed) 1995, Suguna Devi Publication p.20.

[216] D.K. Joshi vs. State of U.P. & others (2000) 5 SCC 80

[217] Avtavr Singh vs. Dr. Swaran Prakash Garg (2000) 1 CPR 44, the State Commission directed the Secretary, Ministry of Health and Welfare and the Chief Medical Officer to take necessary action against quack practitioner.(1991) 2 CPJ 553

offences mentioned in the warning notice issued by the appropriate medical council constitutes serious "professional misconduct".

Judicial procedure:

Generally, the council by itself does not start proceedings. The proceedings are started: (i) when a medical practitioner has been convicted by a court of law, and(ii) on a complaint lodged by any person or body against the practitioner. On receipt of the complaint, the same will be placed before the sub-committee or the Executive Committee which considers the complaint, causes, further investigation and takes legal advise. If no prima facie case is made out the complainant is communicated accordingly. On contrary, a prima facie case is established, a notice is issued to the practitioner specifying the nature and particulars of the charge and directing him to answer the charge in writing and to appear before the committee on the appointed day. After the conclusion of the case, the issue put to the voting. If the majority vote confirms that the charge has been proved, the council must vote again and decide whether the name of the practitioner should be removed from the register or he should be warned, not to repeat the offence.

Grievance Redressal Mechanisms Mechanisms at the national level

As it has already been observed, the Government of India has enacted various legislations for the purpose of regulate medical professional education, practitioners and their code of conduct, viz, the Medical Council of India, 1956, the Dentist Act 1948, the Nursing Council 1947, Indian Medicine Central Council Act 1970, State Medical Council Acts.[216-217] Any person who feels

aggrieved by the act of the practitioner may lodge a complaint before the concerned medical council in which register, the practitioner has been enrolled as qualified professional. Beside this, the similar complaint can be referred to the Secretary, Ministry of Health and Family Welfare, with a request to take appropriate action against the concerned practitioner for contravening the code of ethics and the provisions of the statute. The Council and Ministry of Health and Family Welfare are empowered to regulate the conduct of health professionals.

Mechanism at the state level:

Under the state legislation, any aggrieved person can make a complaint to the State Council or to the secretary, Ministry of Health and Family Welfare. The disciplinary committee constituted by the State Council looks into the complaint and recommends the necessary action to be taken against the accused-practitioner. The Council in collaboration with the Secretary, Ministry of Health and Family Welfare may launch prosecution against those persons who are practicing medicine without possessing recognized medical qualifications.

Mechanism at the district level

Although a complaint can be filed before the Chief Medical Officer of the concerned district, it is always beneficial to approach the state council for legal action. It is the primary responsibility of the District Magistrate and Chief Medical Officer to trace and initiate criminal action against the quake medical practitioners.

4.15 PROFESSIONALS LIABILITY UNDER THE INDIAN PENAL CODE

Under criminal law, the injured person or legal representative of victim of medical malpractice does not get remedy in terms of money or compensation. The main object of the law is not to award damages but to ensure that the doctor is put behind bars for his negligent act. However, under the Criminal Procedure Code, the court may award compensation to the aggrieved party out of the fine amount collected from accused.[218-227] In Mari Singh and State of Haryana vs. Sukhbir Singh the Supreme Court directed all criminal courts to exercise the power of awarding compensation to victims of offence in liberal way that the victims or their legal representatives may not have to rush to the civil courts for compensation. It may be argued that incidentally Indian Penal Code does not specify the crime of medical negligence, nonetheless, negligent act of the doctor causing hurt, grievous hurt or death has been brought within the ambit of the provisions of Indian Penal Code. A doctor may be punished for causing death by rash and negligent act, causing hurt by act endangering life or personal safety of others[218] and causing grievous hurt by act endangering life or personal safety of others.

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218 Section 304-A of IPC.
219 Section 337 of IPC.
220 Section 338 of IPC.
221 See Section 6 of Cr.P.C.
222 Section 28(1) of Cr.P.C
223 Section 28(2) CR.P.C.
224 Section 28(3) Cr.P.C.
225 Section 829 (2) Cr.P.C.
226 Section 29(3) Cr.P.C.
227 Section 151-152 of Cr.P.C.

Criminal liability

Under various provisions of Indian Penal Code, 1860 any person who acts negligently or rashly that results in threat to human life or personal safety or; results in death of a person then the person shall be punished with imprisonment and/or fine. However the court have observed that in a matter of negligence where a criminal case is being perused, the element of "mens rea" must be shown to exist. To check for criminal liability, it must be clearly shown that the accused did something or failed to do something which in the given circumstances no other medical professional in his ordinary senses and prudence would have done or failed to do.

The aggrieved party will first file a complaint with the local police authority against the concerned person/persons. If no action is taken, the aggrieved party can file a criminal complaint under Criminal Procedure Code,1973.

4.16 NATIONAL HUMAN RIGHTS COMMISSION

Beside different mechanisms of protecting patients from medical malpractice by the health care provider, there are other mechanisms whose institutions will enhance the existing mechanisms.[228-230] The present part focuses on the National Human Rights Commission as an alternative means of

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[228] Benjamin MS and C.B. Raju, "Criminal Clinical Negligence: who watches the life saviour- A critical appraisal, Kar.L.J. 2007(1) p. 26.

[229] Chulani, HL, "Professional Negligence under the Indian Penal Code" Cr. L.J. 1996, p. 133.

[230] Mihir Desai and Kamayani Bali Mahabal, Health Care Case Law in India, CEHAT, 2007, p. 139.http://nhrc.nic.in/dispArchive.asp?fno=1035Case No. 7122/24/98-99.

protecting patients' rights. NHRC/SHRC can hold the state accountable for violation of human rights of patients. NHRC can play vital role in fulfillment of national and international human rights norms. It accepts complaints regarding violation of human rights and asks for explanations from the government. It is not satisfied with the reply, it starts as independent investigation, in the course of which, the commission among other things can summon and witnesses to appear before it and then examine the under oath. It can also call for relevant documents. In its proceedings; the NHRC is endowed with all the powers of a civil court. Sometimes the NHRC initiates a general public inquiry also. Following investigation, the NHRC can award compensation or can issue directions. It has been successful sometimes, in persuading the state to pay compensation to victims of human rights violation. It can also recommend the granting of 'immediate interim relief' to a victim of human rights abuse or to his or her relative.

4.17 CORPORATE LIABILITY IN MEDICAL NEGLIGENCE

In 1991, corporate negligence was recognized as a cause of action by the Pennsylvania Supreme Court in the case of Thompson V. Nason Hospital.[231,237] Corporate negligence is a doctrine under which a hospital is liable if it fails to

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231 (2010) 3 SCC 480
232 AIR2019SC1143
233 Achutrao Haribhau khodwa and Ors v. the State of Maharashtra: 1996 SCC (2) 634
234 1969 AIR 128
235 IV (2007) CPJ 157 NC
236 1995 SCC (6) 651
237 Malay Kumar Ganguly vs. Sukumar Mukherjee and Ors: AIR2010SC1162

uphold the proper standard of care owed a patient. This "standard of care" ensures a patient's safety and well-being while hospitalized.

The theory of a hospital's liability is to create a non-delegable duty with which the hospital owes directly to a patient. In other words, an injured party does not have to establish the negligence of a healthcare professional in the employ of the hospital in order to bring forth a claim of corporate negligence. Vicarious liability is the cause of action for a claim wherein the injured party alleges negligence on the part of the hospital's employee or agent, such as a physician, nurse, therapist, etc.

The hospital's non-delegable duties, in the context of a corporate negligence claim, are classified into four general areas: a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; a duty to select and retain only competent physicians; a duty to oversee all persons who practice medicine in the hospital; and a duty to formulate, adopt, and enforce adequate and appropriate rules, policies, and procedures to ensure quality care for the patients.

The complex legal relationship between hospitals, doctors and paramedical staff leads to issues, which the courts find difficult to resolve. However, certain trends have emerged in modern medicine:

1. There is a need to provide competent care based on a national standard.

2. Competent care is no longer predicated on 'locality rules'. The state has to intervene with statutes and regulations to ensure that a 'standard' of practice is established in hospitals.

3. The hospital has both a vicarious as well as an inherent duty of care (corporate obligation) toits patients.

4. The statutory regulations result in doctors being involved directly in setting of standards. This brings a separate liability upon the doctors independent of their professional liability.

5. There is a demand not only for establishing initial standards of care, but for continuous monitoring of these standards and proactive measures to ensure that they are updated.

CHAPTER 5

EMPIRICAL STUDY ON THE LEVEL OF AWARENESS REGARDING MEDICAL NEGLIGENCE AMONG SPINAL SURGEONS IN KERALA BASED ON A CROSS SECTIONAL ANALYTICAL SURVEY

5.1 INTRODUCTION

It is essential for an expert medical witness to have a fare knowledge of all the branches of medical and ancillary science taught to a medical student in a course of studies[227]. The trainee period is a critical time for foresting ethical reasoning.[228,229] Good medical practice requires that medical graduates can demonstrate in practice knowledge and understanding of the law[230].

Global trends in medico legal issues are gradually catching the attention of the public and complaints against physicians seem to be escalating in developing countries. This has brought to the fore need for a high sense of professionalism among health care practitioners. This professionalism relies heavily on the depth of knowledge and application of medical ethics in the everyday practice of the health care practitioners [231].

The knowledge of Medico Legal issues are essential for maintaining the patient doctor relationship and prevent the commercialisation of the profession[232-233]. Lack of knowledge of legal medicine and legal aspects of practice of medicine is important issue that needs to be addressed promptly[234].

However, medical schools may not be able to give enough time to teaching of ethics, confidentiality and medico legal issues. The curriculum on

medico legal issues may not be adequate or practical enough to enable the medical student reliably address all ethical dilemmas likely to be faced in practice .Students and practising doctors reported widespread deficiencies in knowledge and understanding of legal rules.

Training period is the crucial time for developing the ethical views and awareness in young doctors. Doctors should familiarize themselves with the regulations and laws that concern their practice. Doctors have several ethical moral and legal obligations in their duties for faculty empowerment.

It is therefore very important that every doctor understands the nature of these obligations and then fulfils these obligations to the best of their ability[235,236]. They should improve the quality of patient care by identifying, analyzing and attempting to resolve the ethical problems that arise in practice.

Medical practitioners must be aware of legal and ethical implications of clinical practice[237]. Law and Medicine go hand in hand. The recent trends towards codifying the individual rights and freedom has filtered down to the relationship between physicians and patients[238]. If future doctors are to uphold and advocate effectively for the legal rights of patients they must have a sound grasp of the law and the confidence to apply the understanding.

By keeping these things in mind we carried out our present study to assess awareness and knowledge about Medico Legal issues among Interns and Post Graduate Students (PG Students) and to make the future medical practitioners aware about their medico legal responsibilities in their practice so that they can effectively handle medico legal cases.

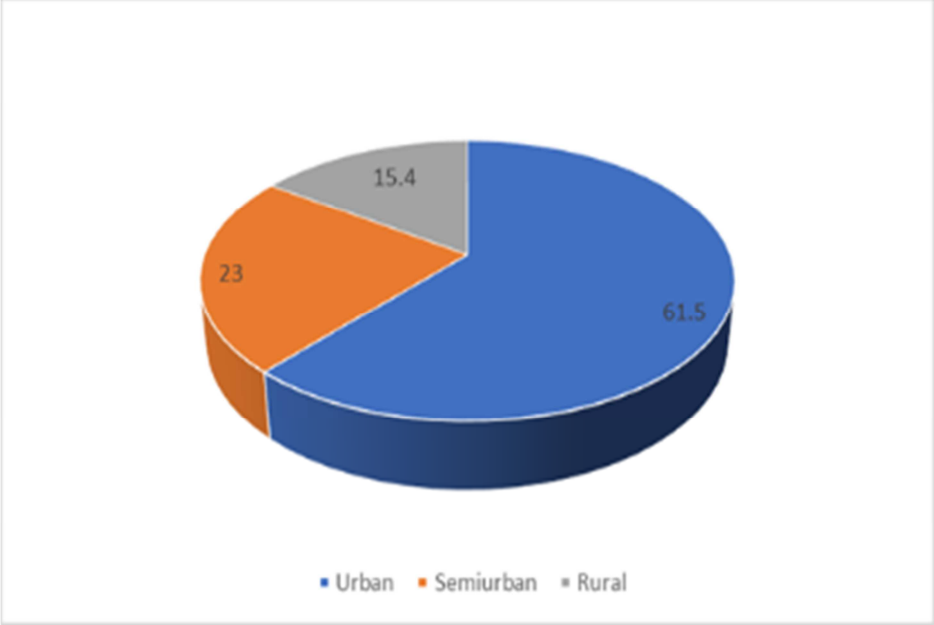
Methodology is discussed in introduction section of chapter 1

5.2 RESULTS

Of the 150 surveys sent, 82 were returned and response rate was 52%. But four surveys were highly incomplete and were discarded from the analysis. So, the study content is from the analysis of practices of 78 spinal surgeons working in different parts of the country. Majority of the spine surgeons (n = 70) were neurosurgeons, while 8 were orthopaedic surgeons.

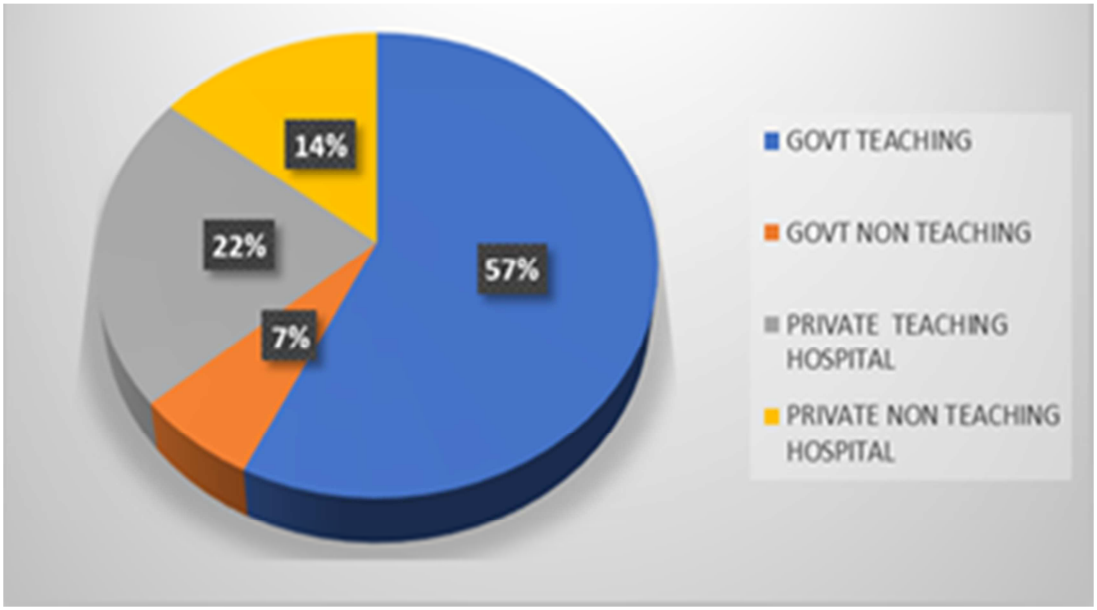
Majority (N=77, 98.7%) were male surgeons and 54 were from urban area, 18 from semiurban area, and 12 from rural area [Figure 1]

Figure 1: Distribution of respondents in the survey based on their location of hospital



N=46 (59.31) spine surgeons practiced in a Govt teaching hospital and 12 (14.8%) from private non teaching hospital and the rest were from govt. non teaching institutes 6(7.4%) and 14 (18.5%) were from private teaching institutes [Figure 2]

Figure 2: Distribution of respondents in the survey based on their instituitional background



Majority of surgeons were seeing more than 20 surgical cases per day and thus majority were from hospital which are having heavy case loads and probability of them facing litigation seems also very high. The details are given in Table 1

Table 1: Demographics of Respondents Who Participated In Survey

Variables		Frequency	Percentage
Gender	Male	77	98.7
	Female	1	1.3
Location of hospital			
	Urban	54	61.5
	Semiurban	18	23
	Rural	12	15.5
No of patients examined by practitioner per day			
	<5	0	0
	5-10	14	18.5
	10-20	9	11.1
	>20	55	70.4
Instituition			
	Govt teaching	46	59.3
	Govt non teaching	6	7.4
	Private teaching	14	18.5
	Private non teaching	12	14.8

Level of awareness

Table 2: Response frequency of questions pertaining to legal awareness

QUESTION	RESPONSE	N	%
1)What according to you are the action usually taken against doctors in breach of duty of care ?			
	Right answer	60	76.4
	Wrong answer	15	20
	I don't know	3	3.6
2)Who sanction monetary compensation for medical negligence ?			
	Right answer	67	85.7
	Wrong answer	3	3.6
	I don't know	8	10.7
3)Punitive action is initiated under which act?			
	Right answer	26	33.3
	Wrong answer	26	33.3
	I don't know	26	33.3
4)Is patient a consumer if treated free of charge ?			
	Right answer	28	35.7
	Wrong answer	42	53.6
	I don't know	8	10.7
5)Are Govt doctors who treat free of charge liable for compensation?			
	Right answer	20	25
	Wrong answer	50	64.3
	I don't know	8	10.7
6)In your opinion is there a duty of care from the side of medical practitioners to maintan a proper hospital record ?			
	Right answer	70	89.7

	Wrong answer	3	3.8
	I don't know	5	6.9
7)What is the first step of appraisal before consumer court			
	Right answer	39	50
	Wrong answer	39	50
8)Disciplinary action against medical practitioner is taken by			
	Right answer	48	62.1
	Wrong answer	22	27.6
	I don't know	8	10.2
9)Confidentiality of records rest with			
	Right answer	38	48.3
	Wrong answer	35	44.4
	I don't know	5	6.9
10)All documents are given a s matter of right except			
	Right answer	50	64.3
	Wrong answer	20	25
	I don't know	8	10.7
11)How long we have to retain medical records			
	Right answer	22	27.6
	Wrong answer	46	58.6
	I don't know	11	13.8
12)Are you capable of dealing with the litigation filed against doctors			
	Yes	28	35.7
	No	33	42.9
	I don't know	17	21.4

76.4%(N=60) gave the right answer to the question: “What according to you are the action usually taken against doctors in breach of duty of care”?

(N=3,3.6%) gave the response as I don’t know.

(N=67 and 85.7%) and (N=26, 33.3.%%) respective gave the right answer to the question. “Who sanction monetary compensation for medical negligence? and Punitive action is initiated under which act/rule?”. N=26 (33.3.%) gave the answer to question on punitive action as the terminology was not known to them.

The answer to the question; “Right to life is implicated in which article of constitution” was not known to anybody. None of the respondent were aware of their fundamental duties in relation to health care in India.

(N=28, 35.7%) were aware about the statement: “Is patient a consumer even if treated free of charge”?, and only (N-20,25%) were aware about the question “Are Govt doctors who treat free of charge liable for compensation?” while majority (N=50 ,64.3%) gave the wrong answer to this question.

It is good that N=70 (89.7%) were aware of the fact that there a duty of care from the side of medical practitioners to maintan a proper hospital record and only 3 gave a wrong answer to the question .

N=39 (50%) know about Consumers protection act and know that the first step in responding to litigation is to give a good reply after consulting a legal advise.

Only N=48, (62.1%) gave right answer an medical council of India responded by giving a right answer to the question who takes disciplinary action. Only N=38(48.3%) were aware of the fact that confidentiality of records rest with doctor itself and very few(N=22,27.6%) knew that the hospital records need to be maintained for a minimum period of 3 years and N=50,64.3% knew that it is a right of the patient to have all documents pertaining to their treatment records except IP register and that it is the duty of the hospital to provide the same if requested .

All these were demonstrated in Table 2

Capability Of Handling Medicolegal Cases:

35.7% respondent stated that they were capable[Figure 3] and confident of handling medicolegal litigation and the level of awareness in such cases amounts to an average of 5 on a 10 point leikert scale[Figure 4]. Only (N=39) have 25-50% capability of handling the medicolegal suits when such a distressing situation arises. [Figure5]

Figure 3: showing percentage of respondents capable of handling medicolegal suits as per the questionnaire survey

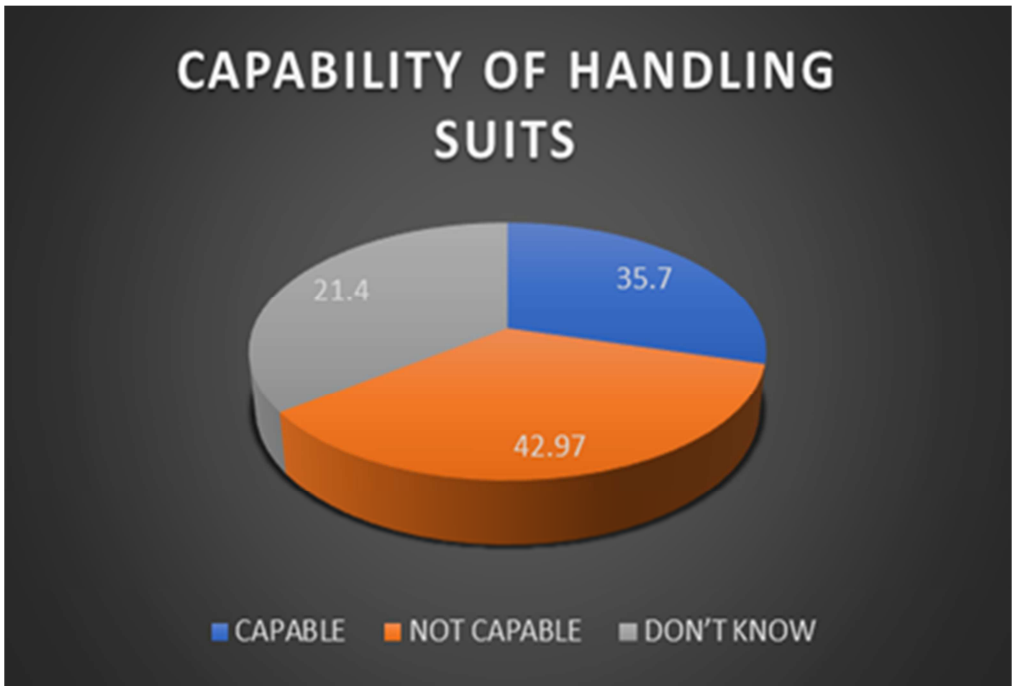


Figure 4: showing percentage of respondents and their level of awareness on a ten point leikert scale

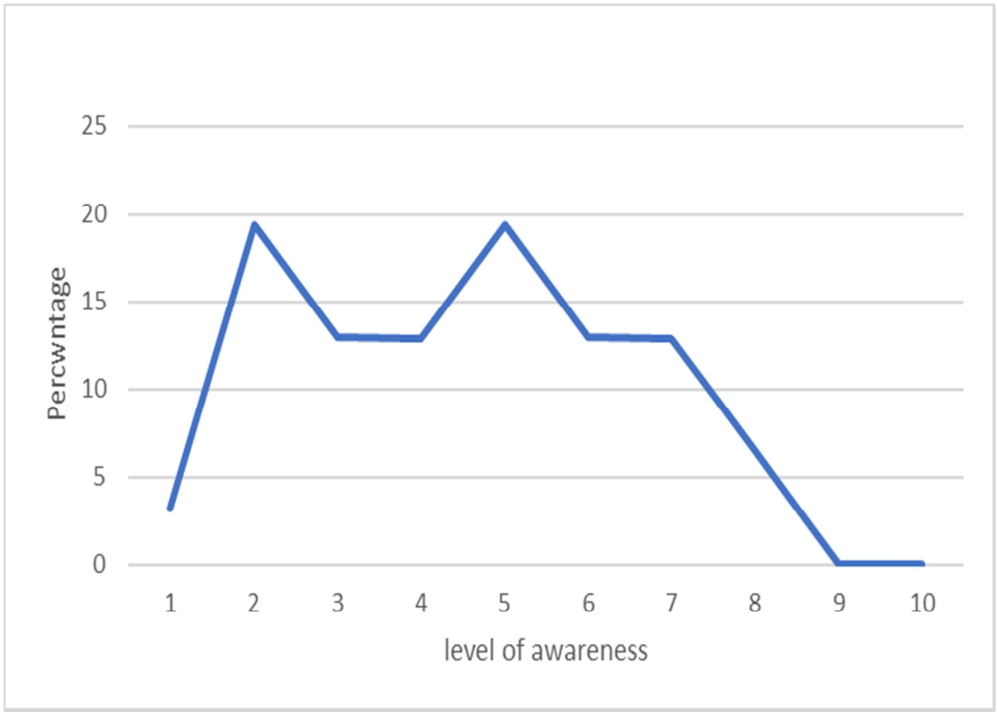
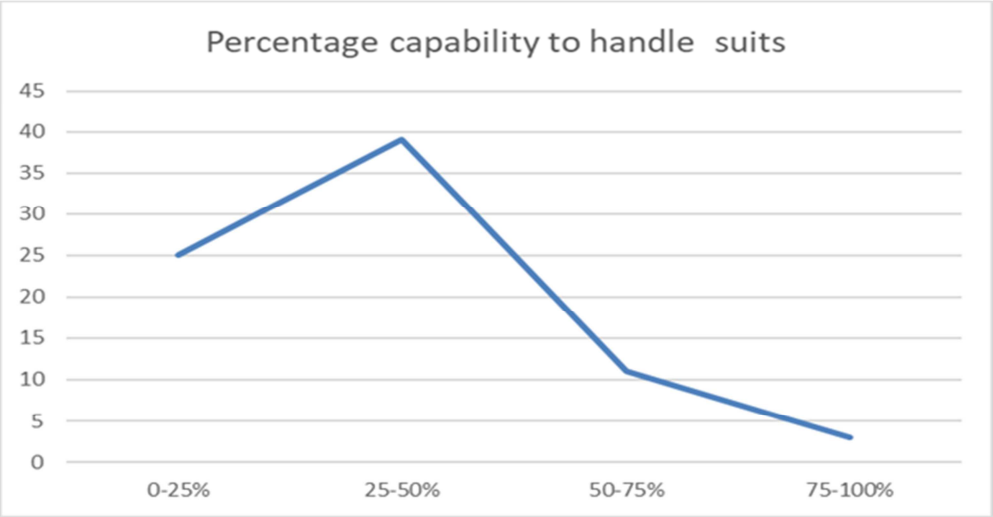


Figure 5: Percentage capability of respondents in handling medicolegal suits as per survey ?



5.3 DISCUSSION

Medical negligence suits are a devastating and stressful situation as far as a medical practitioner is concerned. When a legal notice is received against a doctor, it creates a lot of emotional disturbance as the reputation of medical professionals is affected. They have to take care of the legal requirements and face the situation. Many doctors are apprehensive in handling such cases may be because of fear, unwarranted laws and regulations, attending the court, harassment by the lawyers and questions by police personnel.[238]

With the increase in use of internet and social media, there is an increase in awareness among public on subject of ethical conduct of medical practitioners. Hence there are more cases against doctors. This issue is of immediate concern to medical fraternity. Hence all medical practitioners must be aware of legal and ethical implications of clinical practice. It should be included in curriculum also.

[238] Modi's Medical jurisprudence and toxicology.

The practice of spinal neurosurgery involves a high inherent risk of litigation due to the fact that it often involves instrumentation in close proximity to critical neurovascular structures and lack of ability of regeneration of spinal cord and nerve roots once injured leading to permanent disability further adds to burden and distress among patients. There is evidence that neurosurgery, and spinal neurosurgery in particular, is among the highest-risk specialties with regard to risk of malpractice claims. We carried out this survey to determine the knowledge and awareness of medical practitioners especially spinal surgeons working in the state of Kerala.

Most of the spinal surgeons were aware that medical records need to be maintained but are less was aware about medico legal record keeping in hospital. As per survey only very few knows that only after a specified time limit Medico Legal reports can be destroyed and hence, they have to be preserved. In view of the multitude of cases against the doctors under the Consumer Protection Act, it is advisable to preserve all the inpatient records for a period of at least 3 years and outpatient department records for 3 years. This was known to very few participants. This finding was similar to study conducted by Rai JJ, et al[239] among interns and postgraduates about medical law and negligence in Vadodara in 2016.

[239] Rai J. J., Rajesh V. Acharya, Dave D. Knowlege and awreness among interns and residents about medical law and negligence in a medical college in Vadodara- A Questionnaire Study. IOSR J Dental and Med. Sci. 2013; 3(4):32-38.

Legal Awareness among Doctors

Are doctors capable of handling litigation? Is there a need to have a knowledge regarding legal proceedings. When a legal notice is received against a doctor, it creates a lot of emotional disturbance as the reputation of medical professionals is affected. They have to take care of the legal requirements and face the situation.

They need to reply to a legal notice immediately and they should know how to appraise consumer forum and should maintain good relations with the complainant and should have a thorough legal knowledge to handle this situation .Needless to mention, medical professionals need to maintain a good relationship with their brothers in the profession. In case a hospital or a doctor finds itself or himself in a situation where it is very likely such an act falls under the category of medical negligence, say *res ipsa loquitur* or negligent per se, e.g., a case in which a wrong limb or organ was treated, operated, amputated, or infected, blood was given or qualification was wrongly written etc., such a case does not need any special evidence to establish and it is advisable that such a claim is compromised after taking the insurer into confidence. Furthermore, the doctor and/or hospital are entitled to engage the services of a lawyer to represent them in the matter.

Curricular Restructuring

Study findings are in agreement with study to assess the need of Medico legal Education by Pratibha Mardikar and Arti Kasulkar in 2015[240]. Medical council of India (MCI) has recommended that for MBBS graduates it is desirable and compulsory to know about IPC, Consumer Protection Acts, IMC acts, Human rights commission etc. Medical curriculum of India emphasizes training in clinical competence but is largely silent and fragmentary in aspect of communication skills and legal liabilities. These lacunae have been realized and the "Vision 2015" document of MCI reaffirms need to include training in communication skills to the graduating doctors. The neglected aspect "requisite legal knowledge", is still being overlooked and ignorance regarding legal liabilities often lands the physician in an unenviable position of being charged as a defendant, subjected to ignominy of a trial in either a consumer or criminal court. A claim that "I did not know," does not hold any water in a court of law and since a charge of professional negligence has economic, social and legal consequences.

5.4 LIMITATIONS

Response rate of our survey was only 52% which is a poor response. Hence, it is not known how much the analysis with the obtained data reflects the practice trends among spine surgeons nationwide. Data are collected from surgeon's experience which are dependent on personal preference and may

[240] Mayeda M, Takase K. Need for enforcement of ethical education- an analysis of the survey of postgraduate clinical trainee, BMC Medical ethics , 2005; 6(8).01-05.

have a recall bias. Though with these deficiencies, we hope that our survey will act as a reference for future studies and formation of Indian guidelines.

5.5 CONCLUSION

This study was an endeavor to assess the legal awareness among spinal surgeons of Kerala. Even though we have clear cut provisions and rules for medical negligence and breach of duy of care, majority of spine surgeons lacks the knowledge and awareness and are finding it difficult to can handle them independently. The data from this study would definitely guide future experimental operational research on these unexplored areas which will be relevant in the making of a competency based medical curriculum in Kerala. This study will also be an eye opener for the health sector in Kerala where there are no unbiased management protocols for safe conductance of spinal surgery. The results of this study will also help to motivate the higher authorities regarding the need to restructure undergraduate medical curriculum with special emphasis on basic legal education. The findings of this study will definitely motivate the medical professional in taking up career in medical law and ethics also.

All medical practiioners in their training period must undergo a compulsory legal learning program from a legal institute. Also medical associations should try to organise seminars, case discussions and CME's for interns and post graduates and faculty for empowerment in the legal field so that they can handle the litigations confidently and can improve patient care by

following proper mitigation methods there by avoiding litigation against medical practitioners.[241]

[241] Michael preston shoot ,Judy McKimm, Wing May Kong, Sue Smith.Readiness for legally literate medical practice? Student perceptions of their undergraduate medico-legal

CHAPTER 6

SOLUTIONS AND RECOMMEDATIONS TO AVOID LEGAL ISSUES FOLLOWING MEDICAL NEGLIGENCE SUITS

After critically analysing the literature, it is concluded that from the critical analysis of literature, we found that medical negligence cases had its origin from vedic period itself. The constitituional provisions mentioned closely resembles British rules. There are definite rules and regulation within the purview of IMC in terms of disciplinary action act; monetary compensationin in terms of Consumer Protection Act; punitive actions and criminal responsibilities in terms of IPC, recommendary action based on provisons of human rights commision rules. Also the doctors and hospital has definite role in maintaining the medical records and liable for negligence if not properly maintained.

The triad of clinical competence, effective communication skills and requisite knowledge of legal liabilities / responsibilities, on the part of the treating physician, has been recognized as the key to reduce litigation.

Medical curriculum of India emphasizes training in clinical competence but is largely silent and fragmentary in aspect of communication skills and legal liabilities. These lacunae have been realized and the “Vision 2015” document of MCI reaffirms need to include training in communication skills to the graduating doctors. The aspect of “requisite legal knowledge”, is still being

overlooked and ignorance regarding legal liabilities often lands the physician in an unenviable position of being charged as a defendant, subjected to ignominy of a trial in either a consumer or criminal court. A claim that "I did not know," does not hold any water in a court of law and since a charge of professional negligence has economic, social and legal consequences.

Is there a need to have a knowledge regarding legal proceedings?

When a legal notice is received against a doctor, it creates a lot of emotional disturbance as the reputation of medical professionals is affected. They have to take care of the legal requirements and face the situation.

One should not forget that it is very important to reply to a legal notice in a very thorough manner. A well prepared reply will serve as the basis of a Written Statement to be filed when case of Consumer Complaint is instituted against the doctor and/or hospital. Our personal experience is that in a good number of cases a well prepared notice reply achieves the desired result. In case when an unjustified, false, or speculative consumer case is filed alleging deficiency in service rendered by a hospital or a doctor, they have to take care of the requirements of the law such as the timely filing of a written statement, affidavit etc., and put up a good defense at the time of the hearing. Most importantly, case history, clinical records, report of investigation if any, affidavit of dealing doctors, X-rays, test results etc., will be of immense help.

The defending doctor or hospital has to apprise the Consumer Forum about the accepted practice in treatment, negligence on the part of patient in availing treatment promptly, or following medical advice etc.

Needless to mention medical professionals need to maintain a good relationship with their brothers in the profession.

Attention has to be given to corroborative medical literature on the subject. Lastly, relevant case law on the subject will also be helpful. In case a hospital or a doctor finds itself or himself in a situation where it is very likely such an act falls under the category of medical negligence, say res ipsa loquitur or negligent per se, e.g., a case in which a wrong limb or organ was treated, operated, amputated, or infected blood was given or qualification was wrongly written etc., such a case does not need any special evidence to establish and it is advisable that such a claim is compromised after taking the insurer into confidence. Furthermore, the doctor and/or hospital are entitled to engage the services of a lawyer to represent them in the matter.

There is no denying the fact that prolonged litigation adversely affects the reputation of a doctor or hospital even though he/it eventually wins the case. The medical fraternity is concerned with safeguards against speculative and vexatious claims. While one can not deny the fact that there are genuine cases involving medical negligence, the issue that bothers the medical fraternity is that quite often irreparable damage is caused to a doctor or a hospital on account of a large number of speculative complaints.

To summarize, a good defense that has to be put up by the doctor which includes the following:

- Avail the services of a good lawyer. The doctor and /or hospital are entitled to engage the services of a lawyer to represent them in the matter.
- Timely filing of a written statement, affidavit, and all other documents as required.
- It is important to properly maintain case history, clinical records, affidavit of all the treating doctors, X-rays, laboratory test results, etc. which will be of immense help in supporting the doctor's claim.
- Special attention has to be given to bring in the expert evidence of a qualified and independent medical professional. It is advisable to file an affidavit of the expert as well.
- Corroborative medical literature on the subject should be submitted.
- Relevant case law on the subject will also be helpful.
- Put up a good defense at the time of the hearing.

Current climate in our country is witnessing a degradation of doctor patient relationship, erosion of mutual trust leading to recurring conflict situations. Media, administrative set ups and governmental agencies are increasingly targeting health care facilities for perceived wrongs committed by physicians. Although conflict is both understandable and inevitable in all human dealings, its dramatic increase in the past decade is a cause of concern and introspection for the medical fraternity. Conflict if allowed to escalate, becomes destructive with the dissatisfied or trouble seeking patient, resorting to legal action seeking monetary compensation for “alleged /perceived

maltreatment practices." Research into doctor patient "difficult encounters" have identified some contributory factors to be - unreasonable / unscrupulous patients, yellow journalism, un -professionalism in doctors, lack of rapport due to poor communication skills.

While no generalized advice can eliminate the risk of litigation, examining common causes may prove helpful. A reported 24.4% to 56.4% of malpractice cases involve allegations that the spine surgeon did not obtain proper informed consent before surgery[242].

In most instances, a lack of informed consent reflects a communication failure of the important elements of the case, its risks and alternatives to surgery rather than the absence of a physical signed document. In a review of spine cases involving informed consent, Grauberger et al noted that failure to explain the risk of surgery (30.4%) or alternative treatment options (9.9%) represented the most common allegations [243]. Bhattacharyya et al examined 28 cases alleging a lack of informed consent against orthopedic surgeons. In this study, the authors noted that documentation of the informed consent process in the medical record and obtaining informed consent in the surgeon's office significantly lowered the rate of indemnity. Conversely, obtaining the informed consent on the hospital ward or preoperative holding area was associated with a significantly higher risk of indemnity. This data highlights the importance of

[242] Mello MM, Studdert DM, Brennan TA. The new medical malpractice crisis. N Engl J Med. 2003;348(23):2281–2284.

[243] Boutin PR. The medical malpractice crisis: is the medical review committee a viable and legal alternative? Santa Clara Law Rev. 1975;15:405.

both documentation and creating an environment that promotes physician-patient communication prior to surgery.[243]

Informed consent should include a complete discussion of risks, benefits, and alternatives to a proposed surgical procedure. Suits based on the lack of informed consent often center around the patient having felt rushed and/or brushed off during the office visit or visits, the failure to allow for sufficient time for preoperative education/questions (e.g. using models and illustrations, or other means), and in some instances, the total absence of any attempt whatsoever to have the patient intrinsically involved in operative decision-making.

Developing and adhering to protocols to minimize the risk of wrong-level surgery or retained foreign body represents another strategy that surgeons can employ to minimize litigation.

6.1 MITIGATION METHODS IN SPINAL SURGERY

a. Careful Patient Selection for Spine Surgery

Spine surgeons need to carefully select patients for spine surgery. Stringent preoperative clearance should be performed to determine whether patients are "safe" candidates for the recommended spinal procedures; (e.g. those with recent myocardial infarctions (e.g. < 6 months duration), coronary stents, and/or stroke strokes on Aspirin).[244]

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[244] US Department of Health, Education, and Welfare. Medical Malpractice: Report of the Secretary's Commission on Medical Malpractice. US Department of Health, Education, and Welfare; 1973.

b. Indications for Spine Surgery

Pain Alone: Pain alone is an insufficient indication for spine surgery. Patients should exhibit objectively identifiable neurological deficits that correlate with radiographic findings (e.g. MR/CT). Patients with secondary gain or complex regional pain syndromes too often do very poorly.

c. Neurological Deficits: Should be Sufficient to Warrant Surgery

Boden's seminal 1990 articles documented that both in the cervical and lumbar spine, there are ubiquitous asymptomatic normal age-related degenerative changes.[245] Boden cautioned, "the finding of substantial abnormalities of the lumbar spine in about 28 per cent of asymptomatic subjects emphasizes the dangers of predicating a decision to operate on the basis of diagnostic tests - even when a state-of-the art modality is used -without precise correlation with clinical signs and symptoms."[246]

Increasingly patients are not adequately neurologically examined, and their neurological examinations are not carefully correlated with radiographic studies to determine if spine surgery is necessary. Further, spinal surgeons need to independently interpret MR/CT studies and not rely on radiologists who may "over-interpret" findings, thus leading to unnecessary surgery. Unfortunately, presently too many surgical plans are generated in reverse; spine surgeons start

[245] Posner JR. Trends in medical malpractice insurance, 1970–1985. Law Contemp Probl. 1986;49(2):37–56.

[246] Nelson LJ III, Morrisey MA, Kilgore ML. Damages caps in medical malpractice cases. Milbank Q. 2007;85(2):259–286.

with an MRI, often without identifying any neurological deficits, perform high risk spinal procedures.

d. Failure to Perform Postoperative Neurological Exam to Pick Up New Deficits

Missed new neurological deficits are variously attributed to failure to properly examine the patient postoperatively. Too often, both the spinal surgeon and anesthesiologist allow the patient to leave the operating room and go to the intensive care units without being examined, only to realize hours later that the patient has sustained a devastating neurological injury, or great vessel injury. If that patient undergoes additional surgery, further subsequent MR/CT studies should be repeated.[246]

e. Administering Postoperative Narcotics Without Examination or Informed Analysis

Pain is the body's alarm system, and is still one of the most common reasons people seek medical attention. Recently, pain was re-characterized as a "vital-sign" and treated as an emergency, but often without any reasoned analysis of its etiology. This is especially true in the recovery room, where the first symptom of a developing epidural hematoma is severe/extreme wound pain. Without examination for leg weakness and without any reasoned informed analysis, the patient is often reflexively heavily sedated with opioid drugs. The diagnosis of paraparesis is, therefore, frequently missed, the wound is not re-explored, and patients are left with permanent paralysis.

f. Failures Related to Intraoperative Neural Monitoring (IONM)

Spine surgeons too often do not monitor or inadequately monitor spine surgery. A typical example is where somatosensory evoked potentials (SEP's) without motor evoked potentials (MEP's) are used to monitor cervical/thoracic surgery, thus missing early warnings of impending anterior spinal cord damage and ending up with irreversible neurological deficits (e.g. quadriplegia/ paraplegia.[247] Further, although IONM may clearly document when the spinal cord or nerve were injured, these findings are frequently ignored, and the monitoring records are falsified, destroyed, or "lost".

Additionally, postoperative neurological deficits are ignored or not recognized until days later by which times deficits are permanent/irreversible. This "blind eye" approach gives plenty of room for shuffle-and-jive, and smoke-and-mirrors obfuscation, leaving the defense to proffer: it was an "Act of God, a known risk of spine surgery"[248]. In short, IONM does not make a rough, rushed, or clumsy surgeon a gifted safe surgeon, nor a dishonest surgeon an honest surgeon.

g. Failures Related to Spoliation: Alteration, Falsification

This leads to destruction/falsifying evidence and/or operative notes; this problem is further exacerbated by "templated notes". When an adverse event occurs, it should be accurately recorded in the chart/operative note, but it rarely is. In fact, where major deficits occur, and everyone in the operating room

[247] Olsen RN. The reform of medical malpractice law: historical perspectives. Am J Econ Sociol. 1996;55(3):257–275.

knows what happened, they are too often involved in the cover-up; this results in false operative notes, false records, and amnesia on the part of adjunctive operative personnel. In these circumstances, defense attorneys are quick to coach witness: e.g. "If you remember…," to which the witness then responds, "I don't remember".[248]

h. Failure to Use Arterial Line Monitoring

Routine arterial line placement for most spine operations should be strongly considered to avoid intraoperative hypotension (e.g. cord ischemia, blindness in the prone position, anemia, other)., and better ensure patient safety, thereby avoiding the multiple complications attributed to hypotension. Spine surgeons should develop a consistent system to label, mark and identify operative levels that uses the assistance of intraoperative imaging. Additionally, intraoperative radiographs immediately prior to closure can help assess for retained foreign bodies particularly in cases involving multiple levels, high blood loss or where discrepancies exist in the surgical count.

Finally, surgeons should strive to provide a timely diagnosis and treatment of issues requiring urgent or emergent care. Delays in both diagnosis and treatment represent of the most consistent allegations in all studies reviewing litigation following spine surgery.

[248] National Practitioner Data Bank. Public use data file. U.S. Department of Health and Human Services. Accessed September 15, 2020. https://www.npdb.hrsa.gov/resources/publicData.jsp

6.2 PRACTICAL SOLUTION AND SUGGESTIONS TO REDUCE BURDEN OF PROOF WHILE FACING THE LEGAL PROVISIONS OF MEDICAL NEGLIGENCE

A doctor can be held liable for negligence only if one can prove that she/he is guilty of a failure that no doctor with ordinary skills would be guilty of if acting with reasonable care. The burden of proof of negligence, carelessness, or insufficiency generally lies with the complainant. The law requires a higher standard of evidence than otherwise to support an allegation of negligence against a doctor.

A Upholding of ethics by medical practitioners

1. Humanitarian touch

If a hospitalized patient has a bad outcome, some physicians may avoid making rounds in the presence of relatives. It is a good practice to maintain eye contact while addressing the patient and put a comforting touch on the patient .

2. Avoiding defensive medicine

It is better to avoid practicing defensive medicine. Particularly when affordability is an issue, victim is very likely to complain.

3. Good patient communication

Communicate clearly and effectively. Take time to ensure your patient understands their diagnosis, treatment, and medication plans, and then check their understanding by asking them to explain it back. This ensures instructions are properly followed and demonstrates your care toward patient.

4. Patient time

The longer the quality time a physician spends with the patient, the less likely will that physician be sued.

5. Accountability of doctors and hospitals

Accountability of medical professionals and hospitals needs to be addressed effectively by organisation and professional bodies .Professional committee should monitor whether this is done on a regular basis .Compassionate gestures count and need proper addressal.

6. Asset protection and indemnity

It is vital to the survival of physicians to develop an asset protection plan, in addition to professional medical liability insurance. Not only does a malpractice lawsuit reduce the physician's ability to make a living in medicine but also it can adversely impact or devastate both earned and invested assets.

7. Clinical guidelines

Adherence to clinical guidelines is an effective way to improve quality care and reduce variation in care. Clinical guidelines have been systematically developed nationally and globally to assist clinical decision-making (practice of evidence-based medicine). In medical negligence claims and in court, these guidelines may act as a source of information, provided they are the product of a recognized body and are deemed reliable. They can be seen as normative standards and are used as explicit standards of care at the time of the index

clinical event and also to assess the degree to which a questionable practice was in line with accepted standards.

8. Documentation

If the treating doctor does not document something happened, it is difficult to prove it occurred. Charting accurately and thoroughly can help to understand what happened to the patient. In addition, it will help in answering the questions raised about duty of care when called for a deposition months or years after an event has occurred. One cannot rely on their memory for the facts. Regardless of the system used, the purpose of documentation, from a legal perspective, is always to accurately and completely record the care given to patients, as well as their response to that care. Documentation has legal credibility when it is contemporaneous, accurate, truthful, and appropriate.

9. Hospital policies

If the physician follows hospital policy regarding treatments and protocols, they are less likely to get into trouble. If the physician diverts from regulations and hospital rules in managing the patient, the facility is less likely to defend.

10. Keeping updated

While most physicians stay up to date with the latest continued medical education programs/conferences/workshops/symposia, increasing advances in healthcare make it important to know what is happening in the world of medical news. Often medical news is reported in consumer publications and the

Internet. Often patient may discuss what is in the social media, the ability to discuss about those news with your patients will reinforce their confidence even though they may not be practiced by the treating doctor.

11. Potential litigant

A reasonable doctor should consider every patient as a potential litigant. It is to keep a doctor in constant awareness to stick to a prescribed standard of care and avoid any adventurous attempt. A doctor should not ignore any allegation in any form (oral or written) and should be able to handle allegations with clear and firmness in an intelligent and sympathetic manner.

12. Risk management

When a doctor is working for a hospital, the defendant doctor should notify risk management department of the hospital whenever a notice is served. Risk management employs lawyers who specialize in medical malpractice. The lawyer will help the defendant doctor through the process. Moreover, becoming educated and understanding (preparedness) what will happen help reduce anxiety.

13. Contributory negligence

When a patient by his/her own want of care, contributes to the damage caused in the process of treatment then they are said to be guilty of contributory negligence. For example, if the patient refusing to carry out the remedial treatment recommended by the doctor or indulging in activities forbidden by the doctor further exacerbates the damage. When there is negligence of two or

more persons toward the patient resulting in a particular damage, it is called composite negligence. They are jointly or severally held liable for the damages.

14. Informed consent

Informed consent means that the patient specifically consents to the proposed medical procedure. Informed consent is more than just consent. For a patient to give informed consent to a medical procedure, the health-care provider must inform the patient about all of the risks and complications that may reasonably occur during that procedure, however, minor they may be. Furthermore, the treating doctor should mention about alternatives treatments available and what happens if no treatment is done. Only after a patient is truly informed about the potential risks of a medical procedure can a patient give informed consent to the procedure. The treating doctor should understand that the patient has given consent to the procedure and not to all medical errors while on treatment. The failure to obtain informed consent can be a form of medical negligence or may give rise to a cause of action for medical battery.

6.3 UPHOLDING THE DEFENCES AGAINST MEDICAL NEGLIGENCE

No human being is perfect and even the most renowned specialist could make a mistake in detecting or diagnosing the true nature of a disease. It has been held in different judgments by the National Commission and by the Honorable Supreme Court that a charge of professional negligence against a doctor stood on a different footing from a charge of negligence. The IPC describes in following sections below regarding this difference:

IPC 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. Good faith implies genuine belief on the part of the doctor that his/her act of omission or commission would be in the best interest of the patient. The onus lies on the defendant (doctor) to prove that not only the good intentions but also a reasonable skill and care are exercised for the discharge of duty.

IPC Section 80: (Accident in doing a lawful act). Nothing is an offense 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. Accident implies without the prior knowledge or intention of causing the evil effect.

IPC 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 offense 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 express or implied, to suffer that harm, or to take the risk of that harm. The section highlights the importance of acting on good faith and with informed consent of the patient.

IPC Section 92: (Act done in good faith for benefit of a person without consent). Nothing is an offense 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/her from whom it is possible to obtain consent in time for the thing to be done with benefit. In all such cases, it is prudent to involve another senior colleague in making the decision and recording in detail the justification or circumstances under which the decision was taken.

IPC Section 93: (Communication made in good faith) No communication made in good faith is an offense by reason of any harm to the person to whom it is made if it is made for the benefit of that person. However, the doctor would be prudent enough to ensure that the communication is based on verifiable facts of the case, in a good faith for the benefit of the person it was made and in view of the delicacy of the matter, conveyed appropriately in the presence of spouse/relative/guardian.

Criminal Procedure Code Section 174: This section does not preclude the right of aggrieved relatives of a deceased patient to prosecute the doctor for criminal liabilities under IPC Section 304A (whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide shall be punished with imprisonment of either description for a term, which may extend to 2 years, or with fine, or with both), it prevents doctors from being arrested immediately after the unfortunate death of a patient. It also offers doctors an opportunity for being assessed by their peers for any of the alleged professional lapses.

6.4 OTHER SUGGESTIONS

a. Immunity of Government Doctors

The National Commission by its judgment and order has held that persons who avail themselves of the facility of medical treatment in government hospitals are not "consumers" and the said facility offered in the government hospitals cannot be regarded as service "hired" for "consideration." It has been held that the payment of direct or indirect taxes by the public does not constitute "consideration" paid for hiring the services rendered in the government hospitals. It has also been held that contribution made by a government employee in the Central Government Health Scheme or such other similar scheme does not make him a "consumer" within the meaning of the act.

b. Media trials

In the current situation, media is often referred as the fourth pillar of the democracy. However, it has no right to present the facts of a case in an unfair and prejudicial manner. A doctor cannot become a victim of malicious or defamatory reporting. A doctor should not be silent and should rebut the allegations. The doctor can take help of their professional association to convey the facts and support to resist a trail by media.

c. Prevention of harassment of doctors

The Supreme Court has warned the police officials not to arrest or harass doctors unless the facts clearly come within the parameters laid down in

Jacob Mathew's case. Even a threat was given to the police officers that if they did not follow these orders they themselves have to face legal action. The Supreme Court went on to say "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." The Supreme Court has attempted to remove apprehension that prevents medical people from discharging their duty to a suffering person.

Taking the judicial notice of incidents where the doctors are being harassed by the police in the guise of investigation and unnecessary delay in the medical evidence by way of frequent adjournments or by cross-examination, the court held that unnecessary harassment of the members of the medical professional should be avoided. They should not be called to the police station to unnecessarily interrogation or for the sake of formalities. The trial courts should not summon medical person unless the evidence is necessary, even if he/she is summoned, an attempt should be made to see that the people in this profession are not made to wait and waste time unnecessarily, the law courts have to respect for the people in the medical profession.

d. Hospital based committee

Is to be reconstituted and is essential to check the observance of medical ethics from the part of the medical practitioners.

e. Curricular restructuring

Medical council of India (MCI) has recommended that for MBBS graduates it is desirable and compulsory to know about IPC, consumer protection acts, IMC acts, Human rights commisiion etc .Medical curriculum of India emphasizes training in clinical competence but is largely silent and fragmentary in aspect of communication skills and legal liabilities. These lacunae have been realized and the "Vision 2015" document of MCI reaffirms need to include training in communication skills to the graduating doctors. The neglected aspect "requisite legal knowledge", is still being overlooked and ignorance regarding legal liabilities often lands the physician in an unenviable position of being charged as a defendant, subjected to ignominy of a trial in either a consumer or criminal court. A claim that "I did not know," does not hold any water in a court of law and since a charge of professional negligence has economic, social and legal consequences.

This study was an endeavor to critically review the literature on legal provisions of medico legal suits and to assess the legal awareness among spinal surgeons of Kerala. Even though we have clear cut provisions and rules for medical negligence and breach of duy of care, majority of spine surgeons lacks the knowledge and awareness and are finding it difficult to can handle them independently. The data from this study would definitely guide future experimental operational research on these unexplored areas which will be relevant in the making of a competency based medical curriculum in Kerala. This study will also be an eye opener for the health sector in Kerala where

there are no unbiased management protocols for safe conductance of spinal surgery. The results of this study will also help to motivate the higher authorities regarding the need to restructure undergraduate medical curriculum with special emphasis on basic legal education. The findings of this study will definitely motivate the medical professional in taking up career in medical law and ethics also.

Based on results of this study it is recommended that all medical practiioners in their training period must undergo a compulsory legal learning program from a legal institute Also Medical associations should try to organise seminars, case discussions and CME's for interns and post graduates and faculty for empowerment in the legal field so that they can handle the litigations confidently and can improve patient care by following proper mitigation methods thereby avoiding litigation against medical practitioners.[249]

[249] R. Jacob Mathew And Ors. vs The State Of Kerala And Ors. on 23 August, 1963

Appendix

Survey Proforma

- The questions in the survey are arranged concerning the subject sequentially to assess awareness regarding suits on medical negligence. How do you feel the intiative?
- Please mention whether you are a neurosurgeon or orthopaedic surgeon
- Don’t need to mention the name and address as it is a double blinded survey. Please mention gender

1)	What according to you are the action usually taken against doctors in breach of duty of care ?
	• Compensatory action • Punitive action • Disciplinary action • Recommendary action • All of above • None of above
2)	Who sanction monetary compensation for medical negligence ?
	• Consumer redressal forum • Indian medical council • National human righs commission • Police
3)	Punitive action is initiated under which act
	• IPC • CrPC • Medical council act • Human rights act
4)	Right to life is implicated in which article of constitution ?

5)	Is patient a consumer if treated free of charge ?
	• Yes • No
6)	Are Govt doctors who treat free of charge liable for compensation?
	• Yes • No
7)	Are you capable of dealing with the litigation filed against doctors
	• Yes • No
8)	In your opinion how much capable are you in facing litigation suits for breach of duty of care ?
	• 0-25 • 25-50 • 50-75 • 75-100
9)	In your opinion is there a duty of care from the side of medical practitioners to maintan a proper hospital record ?
	• Yes • No
10)	What is the first step of appraisal before consumer court
	• Reply to legal notice • Contact advocate • Maintain good relation to patients • Do nothing
11)	Disciplinary action against medical practitioner is taken by
	• IMC • Consumer redressal forum • Human rights commissioner • Police

12)	Fundamental duties of medical professional is mentioned in which article of constitution?
13)	Confidentiality of records rest with
	• Doctors • Hospital • Government • Medical director
14)	All documents are given a s matter of right except
	• Discharge • Referral • Death certificate • IP register
15)	How long we have to retain medical records?
	• 1yr • 2yr • 3yr • 4yr
16)	How much do you think is your legal awareness?
	• <25 • 25-50 • 50-75 • 75-100

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Abbreviations

CES	-	Cauda Equina Syndrome
CME	-	Continuing Medical Education
CRPC	-	Criminal procedure Code
CT	-	Computerisd Tomography
IMC	-	Indian Medical Council
IONM	-	Intraoperative Nerve Monitoring
IPC	-	Indian Penal Code
JC	-	Joint Commission
MACT	-	Motor Accident Claim Tribunal
MBBS	-	Bachelor of Medicine and Bachelor of Surgery
MCI	-	Medical Council of India
MDU	-	Medical Defense Union
MEP	-	Motor Evoked Potential
MRI	-	Magnetic Resonance Imaging
NHRC	-	National Human rights commisiion
O T	-	Operation Theatre
PUVA	-	Psoralen and ultraviolet A (UVA) therapy