

CHAPTER-II
REVIEW OF
LITERATURE

REVIEW OF LITERATURE

The topic includes two terms: **Medical Malpractice** and **Consumer Protection Law**. Medical Negligence/Malpractice may be defined as “want of reasonable degree of care and skill or wilful negligence, on part of a medical practitioner in the treatment of a patient with whom a relationship of professional attendant is established, so as to lead to his bodily injury or to the loss of his life.” (Modi, 1920)

It is important here to note that medical profession was covered within the ambit of Consumer Protection Law in the year 1995 by Supreme Court of India in the landmark judgement of *Indian Medical Association v. V P Shantha and ors (1995)*, although the Act was enacted in 1986. When it was observed that the internal regulatory body ‘Medical Council of India’ could not confer disciplinary actions against wrong does, civil society organisations started approaching court for the rescue of victims of medical negligence and malpractices. Eventually, the judiciary acted as an external regulatory body for the medical profession.

Just as the topic of the doctoral research work finalised, its importance further enhanced with the passing of The Consumer Protection Act, 2019 and is now implemented that replaced The Consumer Protection Act, 1986. The Consumer Protection Act, 2019 (COPRA) was enacted with an objective to provide protection of the interests of consumers and for that, to establish authorities for timely and effective administration and settlement of consumers’ disputes and for matters connected thereto or incidental thereto. It is considered as ‘Deficiency’ in service as per Section 2(11) of the Consumer Protection Act, 2019 which explicitly states in its definition ‘(i) any act of negligence or omission or commission by such a person which causes loss or injury to the consumer; and (ii) deliberate withholding of relevant information by such a person to the consumer’. As mentioned earlier, the victims of medical malpractice/negligence find some relief under COPRA.

In the previous chapter, concepts related to doctoral research topic has been elaborately explained. This chapter focuses on ‘Review of Literature’ related to subject that enabled the researcher gain in-depth understanding about the subject.

The literature reviewed in this paper consists of various macro and micro studies conducted at international, national and local level about the subject. The chronological arrangement will help the reader understand a trend and minute details about the subject.

The research topic talks about medico-legal aspects as it involves both Medical Malpractice and the Consumer Protection Law. The objective of the research is also to prepare a module for Social Work intervention while dealing with medico-legal subjects. With this background, the related literature i.e. books, thesis, empirical papers and conceptual articles has been arranged in three themes: Literature with Medical perspective, legal perspective and social work perspective.

The thematic presentation also consists of the sub-themes as explained below.

Themes	Sub-themes
Medical	<ul style="list-style-type: none"> • Medical Malpractice • Medical Jurisprudence • Malpractice and Adverse Events • Based on certain Medical Speciality • Awareness about Medical Negligence and Consumer Protection Law • Components of Medical Negligence (informed consent, medical records, standard of care) • Malpractice as an indicator of Healthcare quality • Technological Advancements and Medical Malpractice
Legal	Descriptive Papers and Thesis
Social Work	<ul style="list-style-type: none"> • Medical Malpractice and involvement of social workers into interdisciplinary teams • Ethical Decision Making, Malpractice and Misconduct among social work profession • Human Rights and Social Determinants of Health

	<ul style="list-style-type: none"> • Impact of Medical Malpractice Lawsuits on the Healthcare workforce
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Review of Literature

Medical

Medical Malpractice:

Regan (1943) in his book ‘**Medical Malpractice**’, coined comparatively newer term ‘Malpractice’. He explains that it goes beyond negligence (failure to use proper skill and care) to wrongs that come in quite different categories such as assault by intervention without consent and breach of confidence, not respecting the ‘right of privacy’. The international author also developed self-test for ‘malpractice vulnerability’.

Sloan and Chepke (2002) in their international book titled ‘**Medical Malpractice**’, tried to examine the process of Medical Malpractice in US from legal, medical, economic and insurance perspectives, analyse past reforms and offer, realistic and achievable policy recommendations. The author argues that the complexity involved in the medical malpractice claims largely depend upon interaction of the four discrete markets that determine the outcomes- legal, medical malpractice insurance, medical care and government activity.

Hogan (2003) in his book ‘**Unhealed Wounds: Medical Malpractice in the Twentieth Century**’ has written internationally about the structural reforms that took place in medicine and law and to improve the healthcare quality of America. Earlier in USA, since the term medical malpractice was newer phenomena, the court found it difficult to determine what constituted error which was then ruled out with the case of *Pike v. Honsinger* in the New York State Court of Appeals in 1989. The court determined that the error for which physicians would be liable would have one of these characters: (1) The physician’s ‘departure from approved methods in general use’ (2) The physician’s ‘want of ordinary and reasonable care’ (3) Failure of the physician to give ‘proper instructions in relation to conduct, exercise and use of injured limb’ (4) Failure of Physician to ‘exert his best judgement’.

Medical Jurisprudence:

Subramanyam and Modi (2001)- Authors of Indian Origin. In the chapter titled '**Law Relation to Medical Man**', the description about The Consumer Protection Act 1986 has been added in the twenty-second edition of the Book '**Modi's Medical Jurisprudence and Toxicology**'. The chapter in detail covers the chronology of efforts, three tier structures of Consumer Forums, time-period for filing the case and its adjudication, coverage of medical services, comments on quackery. The author also provided various types of negligence i.e. active negligence, collateral negligence, criminal negligence, continued negligence, gross negligence, hazardous negligence, wilful or reckless negligence or negligence per se. The book has been referred widely for many years for medico-legal issues by doctors, lawyers, students, judiciary etc and can also be considered as 'bible of medico-legal issues in India'.

Malpractice and Adverse Events:

A global study was conducted by **Localio, Lawthers, Bernnan, Liard, Hebert, Peterson, Newhouse, Weiler and Hiatt (1991)** on the topic '**Relation between Malpractice Claims and Adverse Events due to Negligence-Results of Harvard Medical Practice Study III**'. The empirical study Matched individual case records with malpractice claims to assess fraction of instances of negligence that lead to claims. It was found that Ratio of Medical Negligence to Claims was 7.6: 1 (only 13% injuries result into malpractice claims). It concluded that there is limited usefulness of comparing medical malpractice claims and quality of healthcare.

Indicator of Healthcare Quality

Wang, Niyong, Jiang, Dear and Hsieh (2017) wrote an international paper on '**Records of Medical Negligence Litigation: A Potential Indicator of Health-care Quality in China**'. The paper starts with the basic idea of quality of healthcare which is difficult to measure. Empirical study design observed that it is not always necessary that the adverse outcomes are the result of medical malpractice or the healthcare delivery of poor quality. At the same time, the efforts to improve the quality of health care do not always result in the better health outcome. Researchers found that 80% of the cases were relating to internal medicine, general surgery, orthopaedics and obstetrics and gynaecology. The most frequent allegation in the medical malpractice suits were lack of consent or notification (25.1%) followed by

misdiagnosis (21.7%), delay in treatment (21.2%) and alteration or forgery of medical records (18%).

Negligence in Medical Subspecialty

Gidwani, Zaidi, Bircher (2009)- international authors have focused on the ‘**Medical Negligence in the Orthopaedic Surgery**’. The researchers found it important to focus on subspecialty orthopaedic since orthopaedic surgeons comprise 1/3rd of surgical community of UK. The reasons of medical negligence claims were categorised into substandard quality of surgery; undue delay in diagnosis or treatment; substandard peri-operative care; operation was not indicated; adequate patient consent not obtained or patient not warned of specific risks and finally that defective products/prostheses had been used. 55% cases were abandoned, and rest were settled out of courts for £4500 to £2.7 million (Median £45000 and Mean £163000). The duration from injury/incident to disposal/settlement varied from 9 months to 8 years.

Based on Components of Medical Care:

Brown (2009) in his paper has explained about **Medical Malpractice in the Endovascular Era by emphasizing on the ‘Standard of Care’** and the changes in its interpretations. The author goes on to explain the changing practices in the endovascular surgeries with the help of technological advancements and improvements in the medical practices. The international paper explains that the standard of care for the malpractice cases can be determined by several ways: (1) Defendant medical professional admits about breach of standard of care; (2) Plaintiff who is a medical practitioner establish standard of care; (3) *Res Ipsa Loquitur* which means “it speaks for itself”; (4) If even a lay person would know that standard of care has been violated, no expert testimony is required; and (5) Use of expert Medical Witness. Earlier, the standard of care was determined by the location in which physician practiced, i.e. Locality Rule. Hence, the physician practicing in rural area or small hospitals were not held to the same standards as the physician practicing in urban area. However, with the standardisation of medical education, the standardisation became a national standard. With the advancement, court also suggests that the generally accepted principles must be based on ‘scientific validity’. The paper stressed on that the standard of care is not what an average physician would do, or what most physician do, but what an ordinary physician would do in like or similar circumstances. To conclude the

paper talks about different modalities of 'Standard of Care' with various case laws and scientific and medical knowledge about endovascular surgery.

Thomas (2009) mentions in his international paper titled '**Medical Records and Issues in Negligence**' mentions the maintenance of medical records are important for two reasons: (1) Scientific evaluation of patient's profile (2) Issues of alleged negligence.

Proper record keeping is in nascent stage in India. It explained in detail different types of medical records to be maintained and what should it be consisting of. The paper further explains about confidentiality of medical records and the breach of confidentiality is negligence. The two types of medical records are (1) Personal Document (confidential information that should not be revealed without patient's permission); and (2) Impersonal Document (record loses its identity and patient's permission is not required).

Gogos, Clark, Bismark, Gruen and Studdert [2011] published their research work internationally on '**When informed consent goes poorly: a descriptive study of medical negligence claims and patient complaints**'. The empirical research was conducted with an objective to describe frequency, characteristics, and outcomes of medico-legal disputes over informed consent. Total 3.4% of medical negligence claims and 11.5% of complaints involved allegations of deficiencies in consent process. More than half i.e. 57% cases were against surgeons and four surgical subspecialties-Plastic, general, orthopaedic, and ophthalmic surgery accounted for 81% of cases against surgeons. In 71% cases, primary allegation concerned a complication of treatment that had not been mentioned or fully understood, followed by the scope of consent had been exceeded (10%), the risk that the procedure would confer no benefit (as opposed to harm) was not mentioned (6%), and the process through which the consent was obtained was unsatisfactory (6%). No case involved the primary allegations that there were problems with consent to experimental treatments or research protocols.

Filograna et al (2021) wrote a paper on "**Claimed medical malpractice in fatal SARS-CoV-2 infections: the importance of combining ante-and post-mortem radiological data and autopsy findings of correct forensic analysis**". COVID-19 Pandemic has several medico-legal implications, due to lack of preparedness and failure to promptly adopt effective

prevention and control measures. In Italy, during the first COVID-19 wave, the lack of hospital/intensive care unit (ICU) beds required the government to reallocate COVID-19 patients to long-term care facilities (LTCF) which is the facility majorly for elderly patients with physical and/or psychiatric impairment. The LTCF became the hotspots since the beginning of Pandemic. The paper describes the case of an elderly woman died from COVID-19 during first wave. The physicians were later accused of malpractice resulting in death of patient. The paper reviews the important and comprehensive medico-legal investigations into the case. It consists of analysis of the medical history, clinical imaging, post-mortem imaging, autopsy, histopathology, and micro-biology as well as assessment of medical knowledge about transmission of virus and management of COVID-19. Highlighting the importance of clinical and post-mortem imaging as well as challenges of medico-legal investigations of COVID-19 related deaths. At the end of investigation, the physicians were not found guilty.

Awareness and Knowledge of Medical Negligence and the Consumer Protection Act:

Shenoy, Ravuri, Harshavardhan, Rajalakshmi, Acharya and Sadual (2009) in their paper based on study conducted in India ‘**Be Aware or Beware! Awareness of COPRA (Consumer Protection Act)**’ aimed to assess the awareness regarding the Consumer Protection Act among Dentists consisting of Dental Teaching Staff and Interns of Mangalore. Total sample size was 146 professionals which included 37 staff, 44 post-graduates and 63 interns. It was found out that 50% of the staff, 42.9% postgraduates and 43.5% interns were unaware about the aims and objectives of Consumer Protection Act. 94.5% of the respondents agreed that the consent form filled by patient or caregiver must be preserved by dentists after the treatment is over. Around 72% of the respondents felt that they can be sued for rejecting the emergency case. The percentage of respondents who take written consent from their patients after explaining treatment procedures was highest among Interns (64.5%) followed by Postgraduates (40.50%) followed by Staff (24.30%) which indicates that interns take the informed consent more seriously than staff, however, as per the vicarious liability, the staff are at more risk to face malpractice suit than the interns.

Singh, Shetty, Bhat, Sharda, Agrawal and Chaudhary (2010) conducted a study ‘**Awareness of Consumer Protection Act among Doctors in Udaipur City, India**’ to evaluate awareness of Consumer Protection Act among dental and medical doctors in Udaipur

City, India. The number of respondents were total 448 professionals belonging to dental (222 professionals) and medical (226 professionals) categories. The awareness found was: Dental profession < Medical Profession, Female doctors < Male doctors, UG students < PG students, academic professionals < Private and combined professionals.

Rai, Acharya and Dave (2013), together conducted a study to assess ‘**The Knowledge and awareness among interns and resident about Medical Law and Negligence in Medical College in Vadodara- A Questionnaire Study**’. Knowledge about Medical Laws and ethics is very important and fundamental to the practice of medicine and the training period is very crucial in fostering ethical reasoning among medical students. Total 300 medical students participated in the study and they were given a questionnaire to fill including 30 questions related to knowledge on medical laws, record keeping, ethics, informed consent and medical negligence. Awareness among Interns related to Medico-legal Issues (70%) was found to be more than the other groups. (R1-44.9%, R2-56%, R3-60.4%) 94% of the respondents were able to answer to the questions related to record keeping. 56% of the interns were not aware about MCI Code of Ethics 2002. In this, the students at senior level had better awareness (R3-85%, R2-73% and R1- 62%). Almost 90% of the participants were aware about **informed consent**, 73% of them were aware about burden of proof, 86% were aware about the facts that make physician negligent, 55% of the respondents had no idea about Vicarious Liability and Res Ipsa Loquitor. One positive result found in this study was that 52% of the respondents i.e. more than half of the respondents agreed that **patient should approach consumer court**.

Singh, Bery, Biswas and Aggarwal (2014) conducted micro study titled ‘**Awareness about Consumer Protection Act and Medical Negligence among Private and Government Medical College and Hospital Faculty Members**’. A comparative analysis too was undertaken of the awareness level of medical and surgical specialists of private and government institution. Out of all faculties, 75% of the medical specialists from private institution scored very poor to poor and 25% moderate to good. Against this, 80% of the medical specialists from government hospitals scored very poor to poor and 20% of them scored moderate. However, among surgical specialists working in Private Institution, 60% scored very poor to poor and 25% scored moderate to good. And out of surgical specialists working in Government Medical College, 50% scored very poor to poor and 50% scored Moderate to Excellent.

Haripriya and Haripriya (2014) wrote a paper titled ‘**Knowledge about Medical Law and its Negligence among Doctors: A Cross-Sectional study**’ with the objective of assessing the knowledge of the healthcare professionals regarding medico-legal aspects and its negligence in India. Majority of participants (79.2%) were aware about the code of medical ethics 77% of the respondents had the knowledge about recordkeeping of the patients. Half of the respondents were aware about the objectives of Consumer Protection Act. 68% of the respondents were having exact knowledge about mercy killing. Around 44% were exactly aware about level of compensation for claiming at different centres as District, State and National Commissions. It was found that male doctors had more knowledge than the female doctors about medical negligence. Speciality General Surgeons were slightly more aware than Gynaecologists.

Varghese, Vaswani, Kumar and Shenoy (2016) conducted a study to evaluate ‘**the awareness and attitude about Medical Negligence and Medical Ethics among the Interns and Resident Doctors**’ in Mangalore. The knowledge about medical negligence and medical ethics are important among the medical practitioners to maintain doctor-patient relationship and prevent commercialisation of profession. (Haripriya 2014). This Indian study was empirical in nature. The scores were categories into good, average and poor knowledge. It was found out from the study that 61.3% of interns had poor knowledge, 38.7% of them had average knowledge, while none of the interns had good knowledge about medical negligence and medical ethics. However, 47.1% of the resident doctors had poor knowledge, 48.1% had average knowledge and 4.8% of resident doctors had good knowledge. The authors found out that the participants were not much aware about the questions related to euthanasia, vicarious liability and minimum age for giving consent.

Parmar and Rathod (2016) undertaken an empirical study to assess the ‘**Knowledge and awareness among the general population towards Medical Negligence**’ at Valsad, Gujarat among 100 respondents. It was found out that general population agreed more on clearly visible examples and were unsure about questions involving law related knowledge e.g. more awareness on failure to maintain records (55%), performing operations without written consent (71%), carelessly leaving instrument in patient’s body after operation (94%) and death due to negligence (72%).

Descriptive:

Kukreja, Godhi and Basavaraj (2011) wrote an Indian paper titled '**Consumer Protection Act and Medical Negligence – A Brief Insight**' provide an insight into Consumer Protection Act and Medical Negligence. The paper states that the enactment of law was not to punish all health professionals, but to expect medical practitioner to be reasonably skilful adopting ordinary skills and practices profession with ordinary care. It describes the meaning of 'service' as per COPRA, several Do's and Don'ts for medical professional and about types of consent such as implied consent, express consent, informed consent and proxy/substitute consent.

Legal

Mahalwar (1985) conducted doctoral research on '**Tortious Liability for Medical Negligence in India**'. The scholar from India used doctrinal method to study the phenomena. Every system of medicine, be it allopathy, homeopathy or ayurveda suffer from shortcomings. Since, the profession is handled by human agency, it is prone to imperfection, but at the same time, does not exonerate the human agencies from their share of liability for causing the harm. In India, around 70% of the medicine was practiced by quacks who make money from innocent rural population and causing health hazards. Reluctance of qualified doctors to go and serve in rural and remote areas have encouraged unqualified people to cheat. Tortious liability for medical negligence arises as a result of failure on doctor's part to comply with the reasonable standard in discharge of duties inherent in treatment of the patients. For medical negligence to be proven, the condition that the patient sustaining the injury is essential, only breach of duty cannot hold a medical practitioner liable. In the medical research institutions, volunteers taking risk of exposing themselves in medical experimentation must get the damages on the basis of strict liability. In the interest of justice, mere inability of proving the negligence shall not deprive a patient or volunteer of the remedy.

Bal [1996] wrote a paper on '**Protecting the Health Care Consumers: Is CPA Effective?**'. It is very essential to go through the paper as it has been published immediately after the inclusion of Medical services within the ambit of The Consumer Protection Act, 1986 after the landmark judgement in the case Indian Medical Association v. V.P. Shantha and others (1995). It starts with mentioning few of the advantages of the Consumer Protection Act, 1986 such as duration for justice and cost involved reduced dramatically. The consumer organisation

working in the field of healthcare welcomed the Consumer Protection Act, however, their enthusiasm reduced after the resistance by the medical professionals. The verdict of Supreme Court of India for the Writ petition of Indian Medical Council in November, 1995 set at rest the objections of medical professions and tried to eliminate discrimination by bringing the Government and Semi-government hospitals which offer paid services along with free services within the ambit of CPA. Association of Consumer Action on Safety and Health (ACASH), a forum established by the doctors was receiving and handling the complaints of consumers of healthcare even when it was not included in the CPA (Although earlier the complaints were channelized through other medical legislation).

Sahoo (2005) conducted his doctoral research work on '**A jurial analysis of medical negligence and consumer protection with special reference to Private Healthcare services in State of Orissa**'. The study has adopted empirical (for knowing the awareness level and reaction of consumer and medical professionals toward legal measures) as well as analytical (socio-legal approach) methods. The researcher mentions the reasons for the differences between actual number of medical negligence and the number of cases filed such as fatalistic attitude of the people, poverty, ignorance of healthcare consumers and low rate of success. The researcher found that 4% rural and 15% of urban patients mentioned that they have been victims of medical negligence in some or other form. Large number of doctors (79%-Rural and 69%-Urban) expressed that they do not want to be covered under COPRA and 83% Rural and 91% Urban medical practitioners had apprehension that false and frivolous cases will be filed. Majority of doctors (83%- Rural and 77%-Urban) expressed that consumer forums do not have expertise to adjudicate medical negligence cases.

Mathiharan (2006) wrote a paper '**Supreme Court on Medical Negligence**' mentions that International Covenants, the Constitution of India and Supreme Court of India in many of the cases have considered health as a fundamental right. When the Medical Council of India with their power conferred by Indian Medical Council Act, 1956 failed to enforce discipline among the members of professional association. Hence, the civil society organisation found a way for meeting the need by suing doctors under civil and consumers law. In the case of *State of Punjab v. Shiv Ram* sent a caveat to medical professionals to check on their unscrupulous and erring, business-minded colleagues. It was held further that self-regulatory standards in the medical

profession have shown a decline and can be attributed to impact of commercialisation of the sector. The reports against doctors for misusing diagnostic procedures, exploitative medical practice, brokering deals for sale of human organs etc are evident. The fact that black sheep have entered the profession and they are not able to isolate them effectively. The need for external regulations in place of self-regulation was constantly growing. The self-introspection by doctors individually and collectively is required to enforce discipline and high standards of profession by assuming active role.

Murthy (2007) in his conceptual paper ‘**Medical Negligence and Law**’ has elaborated on the legal decisions related to Medical Negligence as to what constitutes negligence in both civil and criminal law and what is required to prove the same. In addition, the Indian explained concept of implied undertaking, vicarious liability, reasonable skill, *res ipsa loquitur*, criminal negligence, difference between negligence, rashness and recklessness, burden of proof etc. with landmark judgements.

Pandit M S and Pandit S. (2009) in their paper ‘**Medical Negligence: Coverage of Profession, duties, ethics, case law and enlightened defense- A Legal Perspective**’ described about the doctor-patient relationship, duties of doctor, provisions of Consumer Protection Act, 1986 and the case laws that are important source of law in adjudicating various issues of negligence arising out of medical treatment. The author mentioned two major expectations of patient while approaching any doctor or hospitals: (1) Doctor/Hospital will provide treatment with all the knowledge and skills (2) they would not harm either because of negligence, carelessness or reckless attitude of doctor or any other staff members.

The paper also mentioned the duties of doctors: (1) Duty of care in deciding whether to undertake the case, (2) in deciding what treatment to give, (3) in administering treatment. Failure in exercising any of these duties can be considered as ‘Negligence’. (*Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Babu Godbole, Anr. and A. S. Mittal vs. State of UP*). Mere error in judgement in diagnosis or failure to cure a disease does not mean medical negligence.

Gigi (2011) conducted a study on ‘**Law and Negligence**’ with an objective of highlighting main drawback of the existing medico-legal system. The author mentions that the legal system

is passive and meaningless in many senses such as absence of competent court system, delay in processing the case, compliance of faulty procedures and absence of patient centred approaches are main drawbacks of the existing medico-legal system. The PIL was filed to question the functioning of consumer court and the Supreme Court commented that “after the enactment of the Act, the appropriate steps have not been taken by the Government for ensuring that the National Commission or the State Forums can function properly. Also the Consumer Dispute Redressal Agencies have not been fast enough in disposing cases. Several bottle-necks and shortcomings have also come to light in the implementation of the various provisions of the Act.” In addition to this, there shall be constitution of Medical Malpractice Tribunal System at District, State and National level.

Agrawal (2011) in his paper ‘**Medical Negligence: Law and its Interpretation**’ observes that there can be subjectivity in the decision making by the court since judges are not trained in medical science and high reliance is given to expert opinion and basic principle of prudence. Efforts shall be provided for objective decision making by emphasising on the concepts that may be involving an area of subjectivity.

Irene and Yadav (2014), has written a paper on ‘**Medical Negligence and Consumer Rights: An Analysis**’ from Legal point of view. The paper states in the beginning that although Health sector in India is the primary responsibility of Central, State and Local government. However, majority of the service is provided by private sector and has led to commercialisation. There can be two reasons of likelihood of professional negligence: (1) either the medical practitioner did not possess the requisite skills he/she was expected to have (2) he/she did not exercise with reasonable competence the skills possessed. The vital elements in medical negligence are: (a) a duty was owed (b) the duty is breached (c) the breach caused an injury and (d) damage. The author mentions that the Consumer Protection Act, 1986 has been considered unique and progressive piece of Social Welfare Legislation as it provides safeguard to the consumers against exploitation and unfair trade practices.

Dharam (2014) in his paper ‘**Medical Negligence Liability under the Consumer Protection Act: A Judicial Approach**’ described historically that earlier, medical negligence was

considered more as a crime than tort. In India, the concept has roots in *Sushruta Samhita* states that the physicians who act improperly are liable to punishment and quantum of penalty varies according to status of victims. The paper further talks about Negligence under Law of Tort and describes essential components of the same. McNair J. first provided a test for determining the negligence of a medical profession in Bolam's case to be 'standard of the ordinary skilled man exercising and professing to have special skills'. As per English view, if the practice is in accordance with the standards, the doctor cannot be held guilty for negligence.

Varam (2016) carried out a research work on '**the Liability of Doctors for Medical Negligence-A study with special reference to the Consumer Protection Act 1986**'. Methodology adopted was doctrinal and non-doctrinal. The researcher concluded from in-depth review of sources that there are three exciting revolutions in the healthcare delivery system in India: (1) Establishment of health institutions and provision of medical services (2) consumer awareness, right to seek quality care and right to seek justice (3) Government efforts in enacting laws, strengthening legal machinery and consumer redressal system to ensure professionalization and quality of patient care. Researcher further mentions that public awareness must be created regarding medical negligence through seminars, media, press and other audio-visual platforms to be conducted by lawyers and Indian Medical Council.

Sunitha (2016) conducted a doctoral research work on '**Civil Liability for deficiency in medical services with special reference to Surgical Treatments: A Critique of Consumer Protection Act, 1986**'. The method involved was doctrinal research that involved documental analysis, textual analysis and policy analysis. There is a need for revisiting the Consumer Protection Act, 1986 because the health sector is booming industry in India and medical terminology and technology is beyond the understanding of an average patient. Furthermore, the innovative marketing strategies complicates the situation and makes him more powerless. The number of medical negligence cases reported especially in surgical treatments increasing abysmally. The courts in India follow Bolam principle for fixing liability for medical negligence which has been watered down, if not abandoned by Bolitho, Chester and Montgomery decisions. There are no clear standards for computing compensation in COPRA. The time limit of 60 to 120 days for adjudication is hardly observed to be followed. The adjudicative body remain poorly manned and inadequately equipped. Majority of population

have no accessibility to protection as the government hospital is out of purview of CPA. The researcher also suggested legislation ‘The Protection from Deficiency in Medical Services Act’ that focus only on the issue of negligence and establishment of separate tribunals for analysing the cases involving medical profession.

Prakash (2016) conducted a study ‘**Medical Negligence-An Analytical Study focusing on Legal, Ethical and Clinical Perspectives**’. He focused on the aspect of medical negligence through three-dimensional perspectives i.e. legal, ethical and clinical perspectives. In India, 4.9% death occur due to unintentional injuries and the same is 1.4% among the death of infants. Researcher adopted theoretical and empirical methods. He observed the reasons for negligence can be improper records, improper consent, short –comings in explaining treatment modalities, missing to inform varying patient conditions, deficiency in incorporating proficiency, non-participation in External Quality Assessment Scheme, inadequate continued quality improvement, unawareness about existing laws regulating medical care, no or delayed referral to patients in case of complications, improper emergency handling, wrong laboratory report etc. 86.66% respondents were aware about the Consumer Protection Act, 1986. Researcher observed that the clinical changes are occurring with the progress of medical sciences, changes in the social milieu lead to ethical changes and law acts as a safeguard for population.

Kakade (2017) in his doctoral research work ‘**Changing Trends in the Law of Medical Negligence under the Consumer Protection Act**’ has tried to synthesise various aspects of reasoning which led to postulations of legal principles that are applied to medical negligence under the Consumer Protection Act. For studying the trends in Law of Medical Negligence, the researcher used mixed method wherein multiple methods were used to collect data and triangulate the data. Researcher found gradual increase in the number of cases in 3 decades from 1981 to 2011. 97.5% cases reaching Supreme Court were appeals and in National Commission, 20% were original petitions, 31% revision petitions and 49% were appeals. It was observed that the awareness of medico-legal concepts were 4 times higher in urban community than in rural community. Around 50% patients died and rest were disabled due to negligence. 80% of doctors were aware majorly about CPA, but only 17.6% of doctors were aware about various details of practice and procedure for claiming relief under the Act. The Supreme Court of India provided orders more in favour of complainant which was contrary in

orders passed by National Commission. Awareness of medical negligence and Consumer Protection Act was more among hospital administrators than the doctors.

Shinde (2017) in a paper published titled '**Medical Negligence Liability under Consumer Protection Act: Judicial Approaches in India**' from Legal Perspective. The paper elaborated the concept of 'Consumer' and 'Service'. Apart from mentioning the steps that the aggrieved party need to prove, they also should prove that the doctor's conduct was direct and approximate cause of the damage. Further, the paper suggests medical practitioners to avoid litigation that includes awareness among medical fraternity through continuous learning programs; ensure noting reading failure to take prescribed medicines, failure to follow instruction by patients; maintaining proper documentation and medical records; enhancing communication with patients and their relatives; keeping adequate precautions; taking insurance; medical practitioners to take initiative to establish platform where patients, other members of society and doctors to come together and discuss about relevant issues.

Murugavel (2018) conducted a doctoral study on '**Medical Negligence and Consumer Rights in India: A Critical Study**'. Doctrinal and Analytical methods were used by the researcher. He mentions that lack of consumer education is the root of the problem of unawareness among the people in India. The extrapolated figures are 400,000 deaths due to adverse drug reactions and 720,000 adverse events per annum in India. Failure on state to provide healthcare services and comply constitutional directives do not account for 'medical negligence' or 'medical malpractice'. It is stated that the doctors in the charitable and government hospitals are overworked, understaffed, with little or no diagnostic or surgical facilities and limited to choice of medicines and treatment procedures. The reasons of victims not approaching legal remedy everytime incidence of negligence occur can be attributed to lack of legal literacy, economic backwardness, problem of evidence to prove medical negligence, expensive and dilatory court system.

Rawal (2018) conducted a study on '**Enormity of Medical Negligence in India: Need for Review of Consumer Protection Laws**'. The researcher used purely doctrinal method. Further mentions that there is no legislation directly bearing on the Medical Negligence. In addition, the researcher elaborated on method used while computing compensation. In case of death of

patient, the assessment is done using multiplier method and in case of physical injury or disability, the compensation is ascertained depending upon the circumstances of cause. Suggestions included the need to have special medical tribunals for justice to victims.

Khatri (2018) conducted a doctoral research work on ‘**Unethical Medical Malpractices and Law: An Analytical and Critical Study of Malpractices in India**’ wherein she uses doctrinal and non-doctrinal methods and mentions that the cancer of corruption has entered into medical sector too. The supremely higher rates of treatment, not prescribing generic medicine rather prescribing medicines with high rate, unnecessary pathological test for the commission, intentional or wanton admitting of patients, taking out organ from patient’s body and selling it for money and seeking protection from powerful lobby for furthering malpractice are some of the examples of medical malpractice. It occurs due to irresponsibility, carelessness, illiteracy and above all hunger for making money. Discrimination of the patients based on caste, creed, economic factors, priority to VIP culture on all levels such as education, selection, treatment is rampant. Medical Council of India is influenced by politics and has to work as independent body. The research suggests need for creating awareness.

Yoga and Dhivya (2018) in their paper ‘**Study on Medical Negligence and Implications with Special Reference to Consumer Protection Act**’ emphasised that it is important to understand that the standard of care shall be at par as possessed by reasonably competent person and not necessarily by any specialist. Person would not require the most noteworthy master aptitude, but an ability to practice the conventional expertise of customary able man practising that specific craftsmanship. It also describes thoroughly criminal, civil liability and under Consumer Protection Law.

George (2019) conducted ‘**A critical study on the efficacy of the Consumer Protection Act, 1986 in case of Medical Negligence and Malpractice**’ as a part of doctoral research work. The research mentions the reason for worsening doctor-patient relationship such as level of corruption and dishonesty in the medical profession and health care industry, large scale inequality in health care industry, lack of facilities in government hospitals and nursing homes, technological advancements, adverse doctor-patient ratio in the country, expansion of health

insurance business, desire of patients to have more information about their treatment, increase in literacy and growing awareness on consumer rights, commercialization of medical profession and constitutional safeguards to right to health. Various statutes, PIL, Consumer Associations, Voluntary Organisations, Legal Aid authorities, judicial activism and role of NGOs have led to enactment of Consumer Protection Act, 1986. It also mentions that the Medical Council of India has been in most cases proven ineffective in checking incidents of malpractice and corruption in medical practice.

Bahl (2019) conducted doctoral research on the subject ‘**Critical Analysis of various Indian Legislations for Medical Negligence**’ using doctrinal methods. It mentions that in the field of public health, India as a country does not have comprehensive National Health Law which deals with the preparation of epidemics and natural disasters, surveillance of communicable and non-communicable diseases, safe water and sanitation and environmental sanitation. The courts while computing compensation, are still depending upon the mathematical formula for calculation of compensation which is not accurate in case of medical negligence. The compensation must be adequate and fair taking into consideration the fact that the victim who has lost complete control over the body, there is a feeling of helplessness and resignation for a person in the entire family and hence, it is very difficult to understand the plight and multiplier method cannot do justice in providing compensation. The research suggested to make new legislation, establish Medical Negligence Tribunal System, adopt ‘no-fault’ compensation program, fixing cost of treatment within affordable limit, patient centered approach, improvement in quality of healthcare, moral education for healthcare provider, provide adequate compensation in case of Gross Medical Negligence and establishment of in-house committee for redressal of complaint of medical negligence.

Social Work

Mullis (1995) published a journal article titled ‘**Medical Malpractice, Social Structure, and Social Control**’. Empirical study of medical malpractice litigations was conducted by applying Donald Black’s theory of social control. The structural variable of social control explains patterns in American Malpractice experiences such as increase in claim rates over 4 decades, persistence of tolerance as a model response to medical injury, why poor patients are less prone to file lawsuits, why claims are greater against surgical specialists than other medical

practitioners, why individual practitioners are sued more than hospitals and high frequency of prodefendant judgements.

Reamer (1995) published an international paper titled '**Malpractice Claims Against Social Workers: First Facts**' wherein he attempted to summarise the malpractice claims from the records of National Association of Social Workers Insurance Trust for the period 1969-1990. It explained in detail the meaning of *Misfeasance* (doing of proper act in wrongful or injurious manner or the improper performance of an act that might have been lawfully done), *malfeasance* (doing of a wrongful or unlawful act) and *Nonfeasance* (total omission or failure of an individual to carry out the performance of some distinct duty or undertaking that he or she agreed to do). It was found that the largest claims against Social Workers are for 'incorrect treatment' and 'sexual impropriety' i.e. 2/5th of all claims. Following which there were Breach of confidence or privacy (8.7%), incorrect diagnosis or failure to diagnosis (5.7%), suicide of patients (5.1%). Highest compensations in claims related to 'Sexual Impropriety' (2/5th of total compensation).

Landau (1999) published an international paper on '**Ethical Dilemmas in General Hospitals- Social Worker's Contribution to Ethical Decision Making**'. An empirical study was conducted by the researchers wherein 32 hospital social workers (14- directors of social work service and 18- direct practitioners) were interviewed about the perception of the factors including social workers' contribution to the resolution of ethical dilemma in general hospital in Israel. The findings that the researcher obtained were that although the ethical decision making in the health sector is inter-disciplinary process, the decisions are often affected by rivalry between social workers and other members of the health team, personality differences, type of ward and nature of ethical dilemma.

Barker and Branson (2000) an international authors wrote a book titled '**Forensic Social Work- Legal Aspects of Professional Practice (2nd Edition)**'. Forensic is a professional specialty that focuses on interface between society's legal and human service systems and includes activities such as providing expert testimony, investigating cases of possible criminal conduct and assisting legal systems in legal-psychological processes of adoption, terminal of parental rights, eldercare, disability rights, mandated treatment, juvenile and family courts, criminal justice, probation and parole etc and by that contribute for attainment of social justice. Legal regulation of social work profession is essential to maintain credibility. There has been

an increase in malpractice suits against social workers. There is a need to rise new credentials, tighter code of ethics and strict licensing laws among social workers. For this purpose, it is important to have knowledge of what constitutes malpractice, causes and behaviours that can lead to malpractice suits.

Csikai and Bass (2001) in their international paper titled **‘Health Care Social Workers’ Views of Ethical Issues, Practice and Policy in End-of-Life Care’** mentions that end-of-life care is the most difficult aspect faced by healthcare social workers. NASW has formulated the policy to help the healthcare social workers dealing with end-of-life care decisions and preservation of clients’ self-determination in these situations. It was found that 57% of respondents were not aware about policy. There are complex ethical issues arise from decisions regarding use of advancing medical technologies and/or other artificial treatments that may prolong life and/or compromise the quality.

James, McCullough and Richman (2006) wrote a paper titled **“A helping hand bitten: An ethical response to medical malpractice suits”**. The international paper beautifully explains the importance of communication between the physicians and patients substantiated by various other studies and both the parties’ reactions to the medical malpractice and lawsuits. Whenever, any medical practitioner is accused of malpractice, rightly or wrongly, is going to be rough ride of thoughts of discontinuing treatment to section or society, refusing to volunteer or looking at the difficulties in current functioning and make adjustment accordingly. The patients that file against doctors believe that the physicians have caused them to suffer by performing injudiciously, ineptly or negligently. Injured patients at times make emotional judgement about the cause of their misery and some respond by seeking legal redress. Severity of injury is closed related to the likelihood of responding legally. A survey of physicians who had been sued and patients who sued them found that, **the physicians were really unaware of their patients’ unmet emotional needs, the patients’ level of dependence, and their thirst for expressions of sympathy and compassion from their doctors**. Both the sets of responds agreed that the improvement in communication could be instrumental in averting malpractice suit. Resolving to file a suit against one’s physician seems a way to satisfy the angry feelings or frustration. Beckman and associates in their study found that the perceived feelings by patients included feelings of abandonment (32%), disrespect of patient and/or family views (29%), poorly delivered information (26%) or failure to understand the patient and/or family perspective

(13%). In another study, it was found that “Controlling for content, rating for higher dominance and lower concern/anxiety in their voice tones significantly identified surgeons with previous malpractice claims, compared to those who had no claims.” Study of 14,700 medical records found that 97% people who were negligently injured did not sue the responsible physicians. Burstin and Associates examined 31000 medical records and found that poor and uninsured patients who sustained injury were actually significantly less likely to sue than middle-class insured patients. The paper concludes that the physicians must be more sensitive to the emotional needs of the patients, particularly because their invasive and usually painful therapies almost always mobilize more patient anxiety than the treatment offered by nonsurgical specialists.

Kit Sum Syrine Yeung, Amy Po Ying Ho, Man Chun Hui Lo, Engle Angela Chan (2009) published an international paper titled ‘**Social Work Ethical Decision Making in an Inter-Disciplinary Context**’. It was written based on three interdisciplinary seminars organised with group of final year students from social work and nursing. Students of both the disciplines emphasised the important of ethical decision making and respected clients’ right of choice and decisions. Social Work students regarded principle of self-determination as primary priority. Nursing students gave more importance to duty of care than autonomy.

Reamer (2015) wrote an international paper titled ‘**Ethical Misconduct and Negligence in Social Work**’.

The paper mentions that there are four types of formal complaints can be filed against social workers with: (1) a state licensing board (2) the NASW (if Social Worker is member) (3) a civil court of law (4) Criminal Court of Law. Ethics complaints and lawsuits arise out of practitioner impairment that may be caused due to Environmental Stress and Personal Stress.

Tan and Chen (2018) in their international publication titled “**Second Victim: Malpractice Disputes and Quality of Life among primary care physicians**” emphasise on association between malpractice dispute experiences and well-being of physicians. A cross-sectional survey was conducted with 1206 primary care physicians. Out of all the participants, 25.2% reported having experienced a malpractice dispute. The physicians who had experienced malpractice dispute had significantly worsen health-related quality of life regard to general health, mental health and vitality. More effects were observed among the physicians

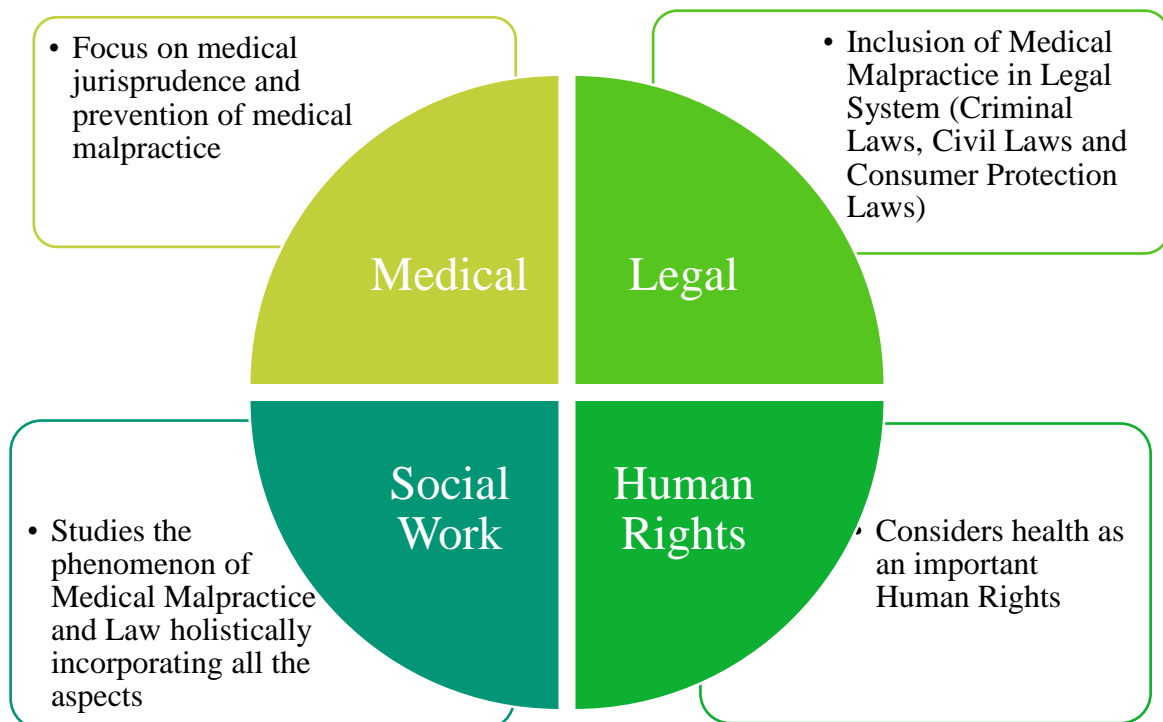
specializing in surgery or obstetrics and gynaecology. Hence, it can be observed that the malpractice dispute can have a long-term negative effect on the health of physicians.

Haigh, Kemp, Bazeley and Haigh (2019) published an international paper on subject **“Developing a critical realist informed framework to explain how the human rights and social determinants of Health relationship works.** The relationship between human rights and social determinants of health has not been considered and there is a lack of clarity and ambiguity how these two factors interact with each other and affect one another. WHO Commission on Social Determinants of Health, the 2011 Rio Declaration and 2015 Sustainable Development Goals consider human right as a key to address inequities in social determinants of health. Critical Realism believes that there exists a reality independent of our thoughts and stratified into three domains: Empirical, Actual and Real. The world is made of entities that provide powers or liabilities; the entities are not observable but their activated powers can be observable. Knowledge is transitive and social world is layered, complex and open system. The key to human rights relational structure is between right holders and duty bearers. The authors used Vermont Case Study to describe phenomena of how campaign for including health as human rights worked. Human Rights infringements are result of repressive power relationship that enables some agents to take destructive, coercive and oppressive advantages over others’ interest. It is related to structures and beliefs about class, gender, age and ethnicity. At the same time, it can trigger creative, reformatory and emancipatory mechanisms that enable and empower agents.

Till, Arendt and Niederkrotenthaler (2021) wrote a paper on **“Effects of Media Portrayals of alleged malpractice in Psychiatry and response strategies to mitigate reputational damage: Randomised controlled Trial”.** This is an empirical study with an objective to assess the effects of negative portrayals of a psychiatric ward in a television documentary on indicators of reputation, and to explore whether different public response strategies from clinic management are effective in mitigation of reputational damage. The participants were divided into 4 groups and one control group. The participants of intervention group watched 7 minutes footage of Günter Wallraff’s documentary Behind Closed Doors – Undercover in Psychiatry and Youth Welfare, depicting accusations of clinical malpractice in one German psychiatric clinic, which was subsequently discussed as partially inaccurate and misleading. After the footage, participants read one of four fictitious public responses of psychiatric clinic

management: Group 1 about denying the accusations, group 2 about attacking the accuser, group 3 about apology by chief psychiatrist and group 4 that the clinical management did not issue a response. The individuals that watched the footage expressed favourable attitudes not only toward a specific clinic but also psychiatry in general. The reputational parameters of the clinics responding to allegations were significantly better than those choosing not to respond. The controversial media reports not only affected a fear to approach psychiatric clinics but also created reputational threat to the psychiatry as discipline.

Research Gap:



The phenomenon of Medical Malpractice and Medical Negligence has been studied differently in different fields. Medical Field takes into consideration the aspects of medical jurisprudence and prevention of medical malpractice. There are multiple studies that focus on defensive medicine practice, knowledge of medico-legal issues and the components of medical malpractice. Many empirical studies have been carried out to find the awareness of medical practitioners but, very few from the medical care users’ perspective.

Legal field studies medical malpractice as a part of legal system. The studies reviewed majorly comprised of conceptual, doctrinal studies with lesser empirical base on inclusion of medical malpractice in the Legal System i.e. in criminal laws, civil laws and Consumer Protection Law.

Human right considers health as one of the integral human rights and talks on the protection of this vital right. It also studies the topic through the lens of different paradigms involving social determinants of health, progressive laws etc.

Social work studies this phenomenon of medical malpractice and law holistically incorporating all the aspects. It considers the medical malpractice as the violation of human rights and emphasis on the protection of the same. It also takes into account the impact of medical malpractice allegations on the medical practitioners. Social Worker with their unique expertise can mediate between the medical service providers, medical service users and the legal systems.

While reviewing the literature, it was observed that although the phenomenon has been studied from medical and legal aspects, there is a need to study the subject independently from social work perspective for holistic understanding about the subject and interventions at micro, mezzo and macro levels with a major focus on preventive aspects. The topic conceived here studies the Medical Malpractice as an Ethical Deviation from the professional practice. Further, it throws light on the legal protection of victims i.e., restoration. The study will not only revisit the order passed by the Consumer Grievance Redressal Machinery for Medical Malpractice, but also analyse it holistically. The study not only talks about a mere case on a paper but will try to relook into the entire experience (bio-psycho-social aspects) the medical service users and their caregivers underwent. In addition, it will also assess the present level of awareness about the phenomenon under study and the stakeholders' views briefly. With this background, social work intervention on prevention, promotion and restoration will be carved out as the outcome of this research.

The detailed methodology adopted while conducting the research is provided in the subsequent chapter.