Law's Restraining Medical Negligence and an Overview of the Clinical Establishments Act, 2010

Prashant Kumar Srivastava
Asst. Prof. Dept. of Law, Nims School of Law, Nims University Rajasthan, Jaipur

***Abstract*- Though medical profession is one of the noblest professions, is not immune to negligence which at times results in death of patient or complete / partial impairment of limbs, or culminates into another misery. Thus, nowadays medical negligence has become one of the serious issues in India. In many cases incompetent or negligence by medical professionals puts in trouble to the innocent patients, which many times led to litigation. In the last few months of the year 2017, there were few sensational cases. In a shocking incident, premature twins were allegedly declared dead by doctors of Max Hospital in Shalimar Bagh and handed over to their parents who realised that one of them was alive only when they were on their way to perform the last rites.**

Thus in the light of these problems the present paper aims to analyze the concept of negligence in medical profession in the light of case laws and some statutory provisions (specially the Clinical Establishments Act, 2010) .

I. INTRODUCTION

Medical profession is recognised as the one of the noblest profession and a doctor is like a God for a patient and the God is infallible. But as the doctors are human beings and to err is human, the doctors may commit a mistake sometimes, it may be by a doctor himself or by supporting staff, the act of negligence causes bigger problem, many times. In such condition, it is very difficult to determine who was negligent and under which circumstances.

Recently, a couple month before, premature twins were allegedly declared dead by doctors of Max Hospital in Shalimar Bagh and handed over to their parents who realised that one of them was alive only when they were on their way to perform the last rites. The police registered a case on Friday on the basis of a complaint filed by the family. This is not a single incident of medical negligence there are many cases can be seen in the daily news.

Indian legal system provides many provisions to protect the doctors from the criminal liability. For example, the Indian Penal Code (IPC), under Sections 88 to 92 presumes that a doctor always acts in good faith for the wellbeing of his patient. However, the concept of good faith assumes a complicated role in a medical malpractice suit. The term "Good Faith" is explained in Section 52 of the IPC as "Nothing is said to be done or believed in 'good faith' which is done or believed without due care and attention".

The IPC under section 304 – A, holds a doctor criminally liable for his negligent act; which states that: "Whoever causes 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 two years, or with fine, or with both". A rash and negligent act is one where the person is responsible for the consequences foreseen as the certain or highly probable outcome of his act. The liability under this section is created on the assumption of foreseeability of consequences which could result from a wrongful act. Thus if a medical practitioner does an act which he did not intend or even foresee but which a reasonable medical practitioner would have foreseen under similar circumstances as likely to cause death, he would be held guilty of the wrongful act.

It is important for a medical practitioner to remember that there can be no civil action for negligence if the negligent act or omission has not been attended by an injury to any person; but bare negligence involving the risk of injury is punishable criminally. For example, a patient is operated upon in an operation theatre without oxygen being available. The medical practitioner would be liable under criminal law even though oxygen may not have been needed by the patient. The mere act of exposing the patient to the risk of personal safety or life is enough to bring

criminal negligence into play as per Section 336 of IPC.

NEGLIGENCE AND MEDICAL NEGLIGENCE

In Roman law, negligence is traced from the terms "culpa" and "negligentia"; as contrasted with "dolus" or wrongful intention. Care or absence of "negligentia" is "deligentia".

Winfield[4] has defined negligence as a tort which is the breach of a legal duty to take care which results in damage, undesired by the defendant to the plaintiff. An act involving the above ingredients is a negligent act. The use of the word diligence in this sense is obsolete in modern English, though it is still retained as an archaism of legal diction.

Negligence is defined as the omission to do something which a reasonable man guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do. In the case of Btyth v. Birmingham Water Works Company, Baron Alderson defines negligence, as omission to do something which a reasonable man guided upon by those consideration which ordinarily regulate human affairs, would do, or doing something which prudent and reasonable man would not do. In common law, negligence is a complex relationship, a space, more than a "thing" a shifting, malleable, interaction between time and place and, to varying degrees, society, law, ethics, and professionals.

The elements of a cause of action in tort of negligence are:

(1) a duty to use ordinary care;

(2) breach of that duty;

(3) approximate causal connection between the negligent conduct and the resulting injury and

(4) resulting damage.

As a tort, negligence is the breach of a legal duty to take care, which results in damage undesired by the defendant, to the plaintiff. Negligence excludes wrongful intention since they are mutually exclusive. Carelessness is not culpable or a ground for legal liability except in those cases in which the law has imposed the duty of carefulness. Negligence may be in action or in omission.

Thus the term 'medical negligence' refers to an act or omission by a medical professionals or health care provider which deviates from accepted standards of practice in the medical community and which causes injury to the patient.

The perception about Medical negligence has shifted from crime to Tort approach. In earlier civilization (code of Hammurabi developed by Babylon's King some 20 Centuries before Christian era) doctor's hands were cut off if the patient died during operation; similar issue of Medical negligence could be found in Islamic law, Mosaic law, charaka samhita, sushnttha samhita, Manusmriti, Katrtirya's Arthashastre, yajnavllg',s smriti.) Medical negligence was considered more as a crime than as a tort. With the progress of civilization, medical negligence was increasingly treated as a tort by the judiciary so that the victim can be provided with damages. As common law evolved in England, the earliest recorded action against a medical man was mounted in 1374 when a surgeon, J Mort, was brought before the King's Bench considering his treatment of an injured hand. He was in fact held not liable, but the court said that if such a patient proved negligence, the court would provide a remedy.

Medical Negligence: Medical negligence is the failure of a medical practitioner to provide proper care and attention and exercise those skills which a prudent, qualified person would do under similar circumstances. It is a commission or omission of an act by a medical professional which deviates from the accepted standards of practice of the medical community, leading to an injury to the patient. It may be defined as a lack of reasonable care and skill on the part of a medical professional with respect to the patient, be it his history taking, clinical examination, investigation, diagnosis, and treatment that has resulted in injury, death, or an unfavourable outcome. Failure to act in accordance with the medical standards in vogue and failure to exercise due care and diligence are generally deemed to constitute medical negligence.

In legal sense, medical negligence is a subset of professional negligence which is a branch of the general concept of negligence that applies to the situation in which physician who represented himself or herself having special knowledge and art, breach's his or her duty to take care about his or her patient. The general rules apply in establishing that the physician who owed the duty of care is in breach of

that duty. Once the physician has accepted to treat the patient, the legal relationship between physician and patient is created, this means a medical relationship is established and this relationship resulted in duty to take care. The base of this legal relationship is the rule of "reasonable reliance" by the claimant on the skills of the defendant. Dealing with the question of duty to take care, the court observed:

Where a person is so placed that others could reasonably rely upon his judgment or his skill or upon his ability to make careful inquiry, and a person takes it upon himself to give information or advice to, or allows his information or advice to be passed on to, another person who, as he knows or should know, will place reliance upon it, then a duty of care will arise.

According to common law system of negligence, the medical practitioner has discretion in choosing the treatment which he proposes to give to the patient and such discretion is wider in cases of emergency, but, he must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care according to the circumstances of each case. A medical professional who holds himself out ready to give medical advice and treatment impliedly holds out that he is possessed of skill and knowledge for such purpose. Then, when he is consulted by a patient, owes certain duties, namely, a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give, and a duty of care in the administration of that treatment.

LEGAL PROVISIONS TO OVERCOME MEDICAL NEGLIGENCE IN INDIA

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

- *The Constitution of India*

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

  → *Article 21:*Protection of life and personal liberty':

  → *Article 32:* Remedies for enforcement of rights. The right to constitutional remedies therefore allows Indian citizens to stand up for their rights against anybody even the Government of India.

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

- *The Indian Penal Code, 1860:*

  The general condition of the penal liability is indicated by the Latin maxim - Actus non facit reum, nisi mens sit rea - the act alone does not amount to guilt; it must be accompanied by a guilty mind. Thus two conditions need to be fulfilled before penal responsibility can be rightly imposed. To attribute mens rea to a wrongful act, it is necessary that the act be done either wilfully or recklessly. Where the act is wilful, mens rea is obvious.

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

- Good faith ;
- Accident in doing a lawful act ;
- Act likely to cause harm, but done without criminal intent, and to prevent other harm ;
- Act not intended to cause death, done by consent in good faith for person's benefit ;
- Consent known to be given under fear or misconception ;
- Act done in good faith for benefit of a person without consent ;
- Causing death by negligence ;
- Causing grievous hurt by act endangering life or personal safety of others , and
- Causing hurt by act endangering life or personal liberty of others .

Up till 2005, medical practitioners could be held liable under civil and criminal negligence both. A land mark verdict in this regard was that of Dr Suresh Gupta v. Government of NCT of Delhi . It was felt by the jury that between civil and criminal liability of a doctor causing death of his patient, the court has a

difficult task of weighing the degree of carelessness and negligence alleged on the part of the doctor. For conviction of a doctor for alleged criminal offence, the standard should be a proof of recklessness and deliberate wrong doing. To convict, a doctor, therefore the prosecution has to come out with a case of high degree of negligence on the part of the doctor. Mere lack of proper care, precaution and attention or inadvertence might create civil liability but not a criminal one. Supreme Court thus ruled that doctors should not be held criminally responsible unless there is prime facie evidence before the Court in the form of a credible opinion from another competent doctor, preferably a Government doctor in the same field of medicine supporting the charges of a rash and negligent act.

Such a decision is expected to increase the quality of service in emergency cases, which the doctors feared to attend because of the chances of being charged under Section 304 and 304-A of IPC for criminal negligence. A doctor may be held liable for negligence on one of the two reasons:

(a) either he was not possessed of the requisite skill which he professed to have possessed, or, (b) he did not exercise, with reasonable competence in the given case, the skill which he did possess. The standard to be applied for judging, whether the person charged has been negligent or not, would be that of an ordinary competent person exercising - ordinary skill in the medical profession. The limited application of criminal prosecution against a medical practitioner therefore rests on the credible opinion from another competent doctor. In reality, however it is often claimed that physicians usually hesitate to testify against each other giving rise to a situation which is judicially labelled as the 'conspiracy of the silence'. Thus, under the existing law, it will be extremely difficult to hold a doctor criminally negligent.

- *The Indian Medical Council Act, 1956:*

The IMC Act came into force in 1956, which confers powers to the Medical Council of India to discipline erring members of the medical profession. However, this act does not have any provision for the award of damages to the complainant, though it has enough powers to punish the medical practitioners.

Section 24 of the IMC Act, empowers the Council to remove the name of any person enrolled on a state medical register on the grounds of professional misconduct. The council, in addition prescribes standards of professional conduct, etiquette and code of ethics for medical practitioners. The medical councils are supposed to self regulate the medical profession by monitoring their skills, conduct and to provide for continuous education.

- *The Consumer Protection Act:*

Since the year 1996, cases of medical negligence have been brought under the purview of the Consumer Protection Act, 1986 (CPA). This was the result of the landmark judgment in the case of Indian Medical Association v. V.P Shantha and Others . This judgment resolved the questions regarding the definition of terms such as 'Deficiency', 'Consumer' and 'Service' with respect to the CPA's application to cases of medical negligence. The Supreme Court order did not accept the claim of medical professionals who argued that the doctor-patient relationship is similar to a master-servant relationship, which is a 'contract of personal service' and should be exempted from CPA. The court in fact decreed that the doctor-patient relationship is a 'contract for personal service' and it is not a master-servant relationship. It is also said that the doctor is an independent contractor and the doctor, like the servant, is hired to perform a specific task. However, the master or principal (the patient) is allowed to direct only what is to be done, and when. The 'how' is left up to the specific discretion of the independent contractor (doctor). So, the doctor- patient relationship is a 'contract for personal service' and as such, cannot be excluded from CPA. The Supreme Court however held that 'A determination about the deficiency in service under the CPA is to be made by applying the same test as is applied in an action for damages for negligence'. The CPA however leaves outside its ambit services rendered free of charge by a medical practitioner attached to a hospital or nursing home. A payment of token amount for registration purpose only does not alter the position.

- *Public Interest Litigation (PIL):*

Any person can directly approach the High Court or the Supreme Court by filing a PIL when any grievances affecting the public at large are not properly redressed. PILs are usually resorted to when public health programmes are not implemented

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

BRIEF OVERVIEW OF THE CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2010

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

The Salient Features of the Act:

The Act came into force in four states of India, namely Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim and all Union Territories through vide notification dated 28 January, 2010. Later, it was adopted by Uttar Pradesh, Rajasthan and Jharkhand under clause (1) of article 252 of the Constitution. In 2013, the State of Maharashtra planed a multi-stakeholder committee to formulate the Maharashtra Clinical Establishment Act to an important step towards standardization of quality and costs in the private medical sector. Further, the Kerala Clinical Establishments (Registration, Accreditation and Regulation) Bill, 2009 is awaiting a go-ahead from the Government to be enforced.

Objective of the Act:

The objective of the Act is to make mandatory for registration of all clinical establishments, including diagnostic centres and single-doctor clinics across all recognized systems of medicine both in the public and private sector except those run by the defence forces. The registering authority facilitates policy formulation, resource allocation and determines standards of treatment. It can impose fines for non-compliance of the provision of the Act. The Act lays down Standard Treatment Guidelines for common disease conditions, for which a core committee of experts has been formed. Further, the Act makes all clinical establishments to provide medical care and treatment necessary to stabilize any individual who comes or is brought to the clinical establishment in an emergency medical condition, particularly women who come for deliveries and accident cases.

The National Council for Clinical Establishment:

The Act lays down establishment for the a Council Body called the National Council for Clinical Establishment which is responsible primarily for setting up standards for ensuring proper healthcare by the clinical establishment and develop the minimum standards and their periodic review.

Clinical Establishments and procedure for registration of the Clinical Establishment: The Act mandates that, no person shall run a clinical establishment, unless it has been duly registered in accordance with the provisions of the Act.

In September 2014, the Government of India, the Ministry of Health and Family Welfare issued the Application format for Permanent Registration of Clinical Establishments which requires the applicant to provide information such as, among others, establishment details, types of service, system of medicine, etc.

Minimum Standards to be followed by Clinical Establishments: Further, under the provision of the Section 12 it has been laid down that for the registration and continuation of a Clinical

Establishment, such clinical establishment shall fulfil the following conditions:

a) the minimum standards of facilities and services,
b) the minimum requirement of personnel,
c) provisions for maintenance of records and reporting, and
d) such other conditions as may be prescribed.

The minimum standards for hospitals are implemented on the basis of level of care provided by such hospitals.

In September 2014, the National Council for Clinical Establishments under the Chairmanship of Director General of Health Services, Government of India in consultation with various stakeholders has prepared following draft Documents with the objective of implementation of the Clinical Establishments Act :

a) Application format for Permanent Registration of Clinical Establishments,
b) Minimum Standards,
c) Formats for Collection of information and Statistics,
d) Template for Display of Rates, and Standard Treatment Guidelines of Ayurveda.

Accordingly, the draft document issued by the Government divided hospitals into four levels of hospitals as given below:

Hospital Level 1- The primary healthcare services provided by qualified doctors are categorised as the Hospital Level 1. It have a bed strength of not more than 30 which can be provided through trained and qualified manpower with support/supervision of registered medical practitioners with the required support systems for this level of care. Such hospitals provides services such as General Medicine, Pediatrics, First aid to emergency patient and Out Patient Services, Obstetrics & Gynecology, Non-surgical and Minor Surgery.

Hospital Level 2- Despites of the services provided at level 1 hospitals, level 2 provides services of Surgery and Anesthesia, through registered medical practitioner under supervision and with support of specialists. It will also have other support systems required for these services like pharmacy, laboratory, diagnostic facility, etc.

Hospital Level 3- In addition to the services provided at level 1 and 2, this level hospital will provide the facilities as well such as Multispecialty clinical care with distinct departments, General Dentistry, Intensive Care Unit. Tertiary healthcare services can be provided through specialists. It will also have other support systems required for these services like pharmacy, Laboratory, and Imaging facility.

Hospital Level 4 – Level 4 hospitals will include all the services provided at level 3. It will however have the distinction of being teaching/ training institution and it will have multiple super-specialties. It shall have other support systems required for these services. It shall also include the requirements of MCI/other registering body.

Template for Display of Rates:
The Hospitals are required to follow a particular template for display of the various rates related to PD, Investigation /diagnostic, emergencies, etc which is detailed in the draft documents issued by the Ministry.

CONCLUSION

To conclude with, India is already outshining itself in the global strata of pharmaceutical market. Though there are many cases in last years of medical negligence, it is apparently a boon above that for the fact that India is expected to witness a tremendous improvement in its public health as the Government is showing enthusiastic approach towards striving at the objective of the Clinical Establishments (Registration and Regulation) Act, 2010 to reduce medical negligence cases. With the implementation of the diligently drafted standards through this Act, it is expected that in the coming years each and every clinical establishment in India will be systematized and stringently compelled equipped with all the basic minimum standard of medical care and hence, the scenario of healthcare section in India is expected to grow through a tremendously appreciable revolution. Now, it is demand of time that, medical professionals will seriously follow the ethics of the profession to cure the patients carefully and bring the profession at top level.

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